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## ABSTRACT

Untreated dental caries in Chinese pre-school children is common. This prospective controlled clinical trial investigated the effectiveness of topical fluoride applications in arresting dentin caries. Three hundred seventy-five children, aged 3-5 years, with carious upper anterior teeth were divided into five groups. Children in the first and second groups received annual applications of silver diamine fluoride solution (44,800 ppm F). Sodium fluoride varnish (22,600 ppm F) was applied every three months to the lesions of children in the third and fourth groups. For children in the first and third groups, soft carious tissues were removed prior to fluoride application. The fifth group was the control. Three hundred eight children were followed for 30 months. The respective mean numbers of arrested carious tooth surfaces in the five groups were 2.5, 2.8, 1.5, 1.5, and 1.3 ( $p < 0.001$ ). Silver diamine fluoride was found to be effective in arresting dentin caries in primary anterior teeth in pre-school children.

**KEY WORDS:** clinical trial, fluorides, dental caries, caries arrest, preventive dentistry.

# Effectiveness of Silver Diamine Fluoride and Sodium Fluoride Varnish in Arresting Dentin Caries in Chinese Pre-school Children

## INTRODUCTION

Caries prevalence in young children in China is very high, and most of the decayed teeth are left untreated (Wong *et al.*, 2001). Innovative approaches are needed to improve this situation. It has been reported that arresting dentin caries in primary teeth is possible without restorative intervention (Mäkinen *et al.*, 1995; Lo *et al.*, 1998). The aim of this study was to investigate the use of topical application of fluoride to arrest dentin caries in upper primary anterior teeth in Chinese pre-school children. The first null hypothesis to be tested was that there were no differences in the effectiveness of silver diamine fluoride (SDF) solution, sodium fluoride (NaF) varnish, and water in arresting dentin caries. The second null hypothesis was that caries removal prior to fluoride application had no impact on its effectiveness in arresting caries. Intermediate 18-month results of this study have been reported (Lo *et al.*, 2001). The present paper reports on the final 30-month results of this study.

## MATERIALS & METHODS

This study was a prospective controlled clinical trial on a cohort of pre-school Chinese children. Approval from the Ethics Committee of the Faculty of Dentistry, University of Hong Kong, was obtained prior to the implementation of this study. The study site was Guangzhou in southern China. Fluoride concentration in the drinking water in Guangzhou is below 0.2 ppm. Fluoridated toothpaste is available in shops but is more expensive than non-fluoridated brands. Fluoride supplements are not available, and the dentists there rarely use topical fluoride.

A total of 375 children from 8 kindergartens and having dentin caries in the upper primary anterior teeth participated in this study. A letter was sent to the parents of these children explaining the purpose and procedures of this study. Written consent was received from the parents of all children. Oral health education was provided to all participants at the beginning of the study and reinforced regularly by the kindergarten teachers. At baseline, one trained dentist examined the children's upper incisors and canines in the kindergartens. The children's parents completed a short questionnaire at baseline and again after 24 months. The questions asked were the child's toothbrushing behavior and use of fluoride toothpaste, and parental satisfaction with the child's dental appearance and dental health.

Follow-up examinations were carried out every 6 mos after baseline by the same examiner without knowing the subjects' treatment group assignments. Caries was diagnosed at the cavitation level and explored with a sharp sickle-shaped probe at the center of the cavity. A tooth surface could be recorded as sound, caries-active, caries-arrested and black, caries-arrested but not black, filled, or missing. Active caries was recorded when the probe, applied with light force, could easily penetrate the dentin. Arrested caries was recorded if the dentin could not be penetrated. A lesion involving more than one tooth surface was recorded as a single-surface lesion if the width of the extension was less

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**Table 1.** The Caries Experience and Number of Active Carious Tooth Surfaces in Upper Primary Anterior Teeth of the Study Children at the Baseline Examination (SE in parentheses)

Treatment Group	No. of Children	All Children		Children Available at 30 mos		
		dmfs	No. of Active Carious Surfaces	No. of Children	dmfs	No. of Active Carious Surfaces
SDF + excavation	76	4.83 (0.28)	4.13 (0.27)	61	4.61 (0.29)	3.82 (0.27)
SDF	77	5.01 (0.36)	4.26 (0.31)	62	5.35 (0.42)	4.32 (0.34)
NaF + excavation	76	4.74 (0.43)	3.92 (0.31)	62	4.77 (0.42)	3.82 (0.34)
NaF	73	4.71 (0.41)	3.82 (0.30)	61	4.33 (0.43)	3.54 (0.30)
Control	73	4.36 (0.33)	3.75 (0.29)	62	4.24 (0.36)	3.76 (0.34)
All groups	375	4.73 (0.16)	3.98 (0.13)	308	4.66 (0.17)	3.92 (0.14)

than one-third of the extended surface. A tooth with caries destroying more than two-thirds of the clinical crown was recorded as a retained root, and all surfaces of the tooth were recorded as missing due to caries. Pulp vitality of the teeth was also assessed. Pulpal exposure, presence of an abscess or a sinus, obvious discoloration, and premature hypermobility were taken as signs of a non-vital tooth. A 10% random sample of the children was re-examined for the assessment of intra-examiner reproducibility in all examinations.

After baseline examination, the children were sequentially allocated to one of five treatment groups, *i.e.*, the first child who came for the examination was allocated to the first group, the second child to the second group, the third to the third group, and so on. For children in the first group, the soft dentin in the caries lesions was carefully removed by means of hand instruments (excavators). Efforts were made to remove the caries along the dentin-enamel junction. Unsupported enamel was removed to render the cavity self-cleansing. Soft dentin judged to be close to pulp might be left behind. The cavities were then painted with a 38% silver diamine fluoride (SDF) solution (Safotide, Toyo Seiyaku Kasei Co. Ltd., Osaka, Japan). The fluoride application was repeated every 12 mos. Children in the second group had SDF applied to the caries lesions every 12 mos without prior removal of the carious tissues. For children in the third group, the soft dentin in the caries lesions was carefully removed, and then a 5% sodium fluoride (NaF) varnish (Duraphat, Inpharma GmbH, Cologne, Germany) was applied to the caries lesions. The fluoride varnish application was repeated every 3 mos. Children in the fourth group had fluoride varnish applied to the caries lesions every 3 mos without prior removal of the caries. Only water was painted onto the carious teeth in the last group of children. Dentists who were not involved in the examination of the children performed the treatments. No attempt was made to alter the children's access to dental care services or use of other fluoride agents, *e.g.*, fluoridated toothpaste.

### Statistical Analysis

We performed one-way analysis of variance (ANOVA) to assess the differences found among the five treatment groups regarding the children's mean age, dmfs scores and number of decayed tooth surfaces of the upper anterior teeth, and number of non-vital teeth at the baseline examination. Intra-examiner reproducibility at the tooth surface level in each examination was measured by the Kappa statistic. ANOVA was also used to assess the differences among the five treatment groups in the number of new and arrested carious tooth surfaces of the upper anterior teeth, and the increment of non-vital teeth at each follow-up examination. Scheffé's multiple-

comparison procedure was used to study the significant differences found among the five treatment groups. The level of statistical significance chosen was 0.05. Chi-square tests were used to assess the differences in the distribution of black and non-black arrested caries lesions in the five groups. Since ten pair-wise comparisons were performed, the statistical significance level was adjusted to 0.005. We performed analysis of co-variance (ANCOVA) to study the effects of selected independent variables on the number of arrested caries found at the 30-month examination. These variables included kindergarten, gender, receipt of other dental care during the study, baseline caries experience of upper anterior teeth, treatment group assignment, brushing habit at baseline and at 24 mos, use of fluoride toothpaste at baseline and at 24 mos, and caries experience of primary molars at 30 mos.

### RESULTS

A total of 375 children, 209 boys (56%) and 166 girls (44%), with a mean age of 4.0 yrs (SD = 0.8) attended the baseline examination. A total of 308 children attended the 30-month examination, giving an overall drop-out rate of 18%. The subject drop-out rates in the first to fifth treatment groups were 20%, 19%, 18%, 16%, and 15%, respectively ( $\chi^2$  test,  $p > 0.05$ ). Intra-examiner reproducibility was very good throughout the study. The values of the Kappa statistic for the duplicate examinations were at least 0.95 for the baseline and follow-up examinations.

The mean baseline dmfs score of the upper anterior teeth of the 308 children who were followed up for 30 mos was 4.66 (Table 1). Their mean number of tooth surfaces with active caries at baseline was 3.92. The differences in the above parameters between the initial group of 375 children and the 308 children who remained in the study were not statistically significant ( $p > 0.05$ ). There were also no statistically significant differences (ANOVA,  $p > 0.05$ ) among the five groups of children in any of the above parameters. Slightly more than half (55%) of the 308 children at baseline claimed that they brushed their teeth at least once a day. The majority of the parents, 73%, reported that their children used fluoridated toothpaste. There were no statistically significant differences among the five groups of children in their toothbrushing behavior ( $\chi^2$  test,  $p > 0.05$ ) or the use of fluoridated toothpaste ( $\chi^2$  test,  $p > 0.05$ ).

A total of 318 questionnaires was collected at the 24-month follow-up. Results showed that 80% of the children brushed their teeth at least once a day, and 91% used fluoridated toothpaste. There were no statistically significant differences among the five groups of children in the above behavior ( $\chi^2$  test,  $p > 0.05$ ). However, there was a significant improvement in brushing behavior (McNemar test,  $p < 0.001$ ) and in the use of fluoride toothpaste (McNemar test,  $p < 0.001$ ), compared with the baseline findings.

At the 30-month examination, there were statistically significant differences in the mean number of arrested carious

tooth surfaces among the five treatment groups (Table 2). Children who received an annual application of SDF had more arrested caries lesions in their upper anterior teeth than did the children in other groups (ANOVA,  $p < 0.001$ ). They also had a higher proportion of their arrested caries appearing black ( $\chi^2$  test,  $p < 0.001$ ) than did the other children. Children in the control group developed more new caries lesions in their upper anterior teeth (ANOVA,  $p < 0.001$ ) than did children receiving SDF and NaF varnish.

There were no statistically significant differences in the increment of non-vital teeth among the five groups of children. No adverse side-effects such as discoloration or damage to the gingival tissues were observed.

No significant changes in parental satisfaction with their child's dental appearance and dental health after 24 mos were found among the five groups of children (McNemar test,  $p < 0.05$ ). The presence of decayed anterior teeth was the main reason given by the parents as to why they were dissatisfied with their child's dental appearance or dental health. The presence of darkened teeth was mentioned by around 7% of the parents only. About two-fifths of the children had received other dental care during the study period. The vast majority of these treatments were performed on primary molars and were unrelated to the teeth involved in this study. In fact, only 12 out of the 308 children had received fillings in their upper anterior teeth. Results of the ANCOVA showed that children with a higher baseline caries experience in their upper anterior teeth, those having received SDF applications, and those who brushed their teeth more often had significantly more arrested carious tooth surfaces at the 30-month examination (Table 3).

## DISCUSSION

The first null hypothesis of this study is not supported by the 30-month results. It was found that an annual application of a 38% SDF solution was more effective in hardening or arresting dentin caries in upper anterior primary teeth than the application of a 5% NaF varnish at three-month intervals or a placebo. This is consistent with the earlier study findings after 18 mos (Lo *et al.*, 2001). This is also in agreement with the observations of other researchers in China (Li, 1984), Japan (Moritani *et al.*, 1970; Yamaga *et al.*, 1972), and Australia (Gotjamanos, 1996). A possible mechanism proposed by Yamaga *et al.* (1972) is the formation of silver phosphate on the tooth surface after

**Table 2.** Mean Number of New Caries Surfaces, Arrested Caries Surfaces, and Non-vital Teeth in the Upper Anterior Teeth of the Children at the 30-month Examination According to Treatment Group (SE in parentheses)

Treatment Group	No. of Children	New Caries Surfaces	Arrested Caries Surfaces	% Arrested Caries, Black	Non-vital Teeth
SDF + excavation	61	0.26 (0.09) <sup>b</sup>	2.49 (0.27) <sup>c</sup>	100 <sup>e</sup>	0.13 (0.05)
SDF	62	0.47 (0.11) <sup>b</sup>	2.82 (0.30) <sup>c</sup>	100 <sup>e</sup>	0.23 (0.06)
NaF + excavation	62	0.89 (0.20)	1.45 (0.19) <sup>d</sup>	26 <sup>g</sup>	0.26 (0.07)
NaF	61	0.70 (0.12) <sup>b</sup>	1.54 (0.27) <sup>d</sup>	66 <sup>f</sup>	0.21 (0.08)
Control	62	1.58 (0.25) <sup>a</sup>	1.27 (0.19) <sup>d</sup>	42 <sup>f</sup>	0.15 (0.02)
Significance		$p < 0.001$	$p < 0.001$	$p < 0.001$	$p = 0.56$

Multiple comparisons: a > b; c > d; e > f > g.

SDF application, which is rather insoluble. In this study, only the upper primary incisors and canines were involved, because caries in the three- to four-year-old Chinese children was mainly found in these teeth (Wong *et al.*, 1997). Whether the same outcome will be found in other tooth types needs further investigation.

The second null hypothesis of this study is not rejected by the 30-month findings, because there is no evidence to show that removal of carious tissues prior to application of the fluoride agents has an effect on their ability to arrest dentin caries. No statistically significant differences in the mean number of arrested carious tooth surfaces after 30 mos were found between children who had their caries excavated prior to SDF application and those who had not (95% CI = 0.75 to -1.42). The finding for NaF varnish was similar (95% CI = 0.04 to -2.12). The present study findings do not support the assumption that caries removal prior to fluoride treatment is advantageous because the bacterial load in the caries lesion is reduced (Fusayama, 1979; Weerheijm and Groen, 1999). Despite this, caries removal prior to the application of sodium fluoride varnish in this study reduced the proportion of the arrested caries lesion that had become black. This may be a better outcome in terms of esthetics. However, excavating the

**Table 3.** Results of Analysis of Covariance (ANCOVA) on the Number of Arrested Carious Tooth Surfaces Found at the 30-month Examination (n = 308)

Independent Variable	Estimate	SE	P value	Multiple Comparison
Treatment group			< 0.001	
SDF+caries removal (1)	1.12	0.32		(2) > (3), (4), (5)
SDF (2)	1.38	0.33		(1) > (3), (5)
NaF+caries removal (3)	0.07	0.32		
NaF (4)	0.33	0.33		
Water (5) <sup>a</sup>				
Toothbrushing at 24 mos			0.003	
Twice daily (1)	3.70	1.30		(1), (3) > (4)
Once daily (2)	3.11	1.30		
Occasionally (3)	3.66	1.30		
No brushing (4) <sup>a</sup>				
Baseline dmfs of anterior teeth	0.24	0.03	< 0.001	
(Intercept)	-3.24	1.34	0.910	

F-value = 11.59;  $df = 8, 298$ ;  $p < 0.001$ ;  $R^2 = 0.24$ .

<sup>a</sup> Reference category.

carious tissues before SDF application had no significant beneficial effect. The use of SDF without caries removal in community-based programs has the advantage of being simple and easily obtaining good cooperation from young children. No significant change in parental satisfaction with their child's dental appearance was found among the children who received SDF treatment. The presence of black arrested caries lesions *per se* did not lead to an increase in parental dissatisfaction.

In this study, examiner blindness was not broken during the examinations. Blackening and hardening of dentin caries lesions occurred not only in children receiving SDF solution applications but also in children receiving NaF varnish and in the control group. Since all arrested caries lesions appeared similar, the examiner would not be able to guess a subject's group assignment.

The disadvantages and advantages of using SDF to arrest caries were discussed in detail in a preceding paper (Lo *et al.*, 2001). In summary, the main advantage of SDF is its effectiveness in arresting dentin caries. It is inexpensive and therefore affordable in most communities. The treatment procedure is simple and requires no expensive equipment or support infrastructure. It is non-invasive, and thus the risk of spreading infection is very low. One of the disadvantages of using SDF to arrest caries is that the lesions will be stained black. The SDF solution also has a metallic taste.

Results of an *in vitro* study in Australia (Gotjamanos, 1997) suggested that topical application of a 40% silver fluoride solution on a caries lesion may allow 3 to 4 mg of fluoride to reach the systemic circulation and have a potential to cause fluorosis when used in young children. In response, the Health Department of Western Australia reported that it had conducted an investigation and found no evidence to support that a single fluoride dose of any magnitude will cause fluorosis in man (Neesham, 1997) and doubted the validity of the study method used by Gotjamanos (1997).

No recommended frequency of application of SDF solution can be found in the dental literature. A low frequency of application, once a year, was used in this study to reduce any potential toxic effect of SDF. A higher frequency of application, once every 3 mos, was adopted for NaF varnish, because such a program is recommended for children with high caries risk (Newbrun, 2001; Pienihakkinen and Jokela, 2002).

The 30-month results of this study showed that the annual application of silver diamine fluoride solution is effective in arresting dentin caries in primary anterior teeth in Chinese preschool children. There is no evidence to support the hypothesis that caries removal prior to the fluoride treatments has an effect on their ability to arrest dentin caries. Further studies are needed to identify the caries-arresting effect of silver diamine fluoride on posterior teeth and on root surfaces.

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