SIMILAR 1-YEAR CARIES INCREMENT AFTER USE OF FLUORIDE OR NON-FLUORIDE TOOTHPASTE IN INFANTS AND TODDLERS

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ABSTRACT: Although 1000 ppm fluoride (F) toothpaste is recommended for all age groups, many parents still choose 500 ppm F or non-F toothpaste for their toddlers to avoid the possibility of an excessive intake of F. As the comparison of the efficacy of F toothpastes has rarely been studied in infants and toddlers, the present study aimed to compare the caries increment with the use of 1000 ppm F, 500 ppm F, and non-F (xylitol with triple calcium phosphate) toothpastes in infants and toddlers. One hundred and seventy-three children aged 9–18 mo were randomly assigned into 3 groups according to the toothpaste used over a 12 mo period: group A: 1000 ppm F toothpaste; group B: 500 ppm F toothpaste; and group C: non-F toothpaste with xylitol and triple calcium phosphate. The children's caregivers received oral health education with hands-on tooth brushing practice several times during the study. Oral examinations were conducted at baseline and after 12 mo. The differences in the caries increment among the groups were analyzed with the Kruskal-Wallis test. There were no significant difference in the dmfs, both including and excluding white lesions, among three groups at baseline. After 12 mo, no significant difference was seen in the incremental dmfs, both including and excluding white lesions, among the three groups. Thus, the low dose F and the xylitol with triple calcium phosphate toothpastes might be suitable alternatives to high dose F toothpaste for use in the infants and toddlers age group in order to minimize the risk of an excessive intake of F and the development of dental fluorosis.

Keywords: Caries increment; Caries prevention; Fluoride; Infants and toddlers; Toothpaste; Xylitol

INTRODUCTION

The effectiveness of fluoride ion (F) containing toothpaste in caries prevention is generally known. A recent systematic review by Cochrane recommends the use of 1000 ppm F toothpaste for caries prevention in the general population,[1] while Ullah and Zafar's study recommends the use of <500 ppm F toothpaste for children under 6yr of age.[2] However, most studies of F toothpaste effectiveness among children included in the Cochrane review were carried out in 3- to 5-yr-old kindergarten students. Therefore, although there is a knowledge base on F effectiveness for the recommendations made for the use of F toothpaste in the 3- to 5-yr-olds and the general population, a gap of knowledge remains for the infant and toddler aged group. The Cochrane review also mentions that the evidence on the optimal concentration of F in toothpaste for caries prevention in the deciduous dentition is unclear.[1]

Another issue of interest with the use of F containing toothpaste, besides its effectiveness in caries prevention, is its role in contributing to dental fluorosis. This is of particular concern for children aged less than 3 yr which is a critical period for developing dental fluorosis if excessive F is swallowed.[3] Another

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Cochrane review suggests that higher levels of F (1000 ppm F or more) in toothpaste increase the risk of dental fluorosis in young children.[4] The severity of fluorosis depends on the amount and the duration of F exposure.[5] Therefore, the American Academy of Pediatric Dentistry (AAPD) recommends the use of a smear size of F toothpaste in moderate to high-risk children beginning at the time of eruption of the first tooth.[6] Meanwhile, Wong et al. revealed that the concentration of F contained in toothpaste was more closely related to the development of dental fluorosis than the frequency of tooth brushing or the amount of F toothpaste used.[3,4]

Although 1000 ppm F toothpaste is recommended for all age groups, many parents still choose 500 ppm F or non-F toothpaste for their toddlers to avoid the possibility of an excessive intake of F. Xylitol and/or other organics-containing toothpastes have become the alternatives to F toothpaste for those who are aware of dental fluorosis. Xylitol may have potential antibacterial activity against *Streptococcus mutans (S. mutans)* and enhance remineralization.[7-9] However, the efficacy of xylitol in reducing the incidence of caries and arresting the progression of caries remains unclear.[10-15] Other ingredients including triple calcium phosphate may help to enhance remineralization by supplying calcium and phosphate in the saliva. Although studies have indicated that calcium phosphate compounds have a remineralization effect,[15-17] the results of Vanichvatana et al.'s study did not show any additional effect from calcium phosphate compounds on the remineralization of artificial caries when used as a supplement to regular F toothpaste.[18]

The appropriate balance between the caries reduction benefit and harmful fluorosis effects should be a serious concern when recommending the use of F-containing toothpaste in very young children aged under 3 yr. Up to the present date, there has been no clear recommendation on the optimal concentration and amount of F toothpaste for use in reducing caries in children aged 9–18 mo, especially those with newly erupted teeth in which there is a sharp increase in both the prevalence and severity of caries. Previous studies in Thailand showed that the prevalence of early childhood caries (ECC) in 9–18-mo-old Thai children was high. ECC developed during the first year of life, with a prevalence of 2.0% in 9-mo-olds, and increased sharply afterwards, to 68.1% in 18-mo-old children.[19] The mean dmfs of Thai children, aged 9–18 months, was from 2.8 to 3.0,[19-21] which is considered severe ECC according to the definition of the AAPD.[22] Most studies on the effect of F toothpaste on ECC prevention compared the use of F toothpastes along with oral health education against controls with no intervention.[23-26] There are very few trials comparing the effects of low- and standard-F toothpastes on the reduction of caries in the primary teeth of infants and toddlers.[1,26,27] Therefore, the aim of the present study was to compare the caries increment in toddlers after using 500 ppm or 1000 ppm F toothpastes with a non-F (with xylitol and triple calcium phosphate) toothpaste as a control.

MATERIAL AND METHODS

Study design: This double-blinded field experimental study, in 13 villages of the U-Thong sub district, U-Thong district, Suphan Buri Province in Thailand, started in May 2013 and included follow up for 1 yr. The study was approved by the Ethics Committee of the Faculty of Dentistry, Chulalongkorn University in Bangkok (HREC-DCU 2013-018). The one-yr study involved primary caregivers and their 9- to 18-mo-old children (caregiver-infant dyads). Three different toothpastes in three different colored packages were randomly assigned to each group by one investigator: group A: toothpaste containing 1000 ppm F as sodium monofluorophosphate (Systema, Lion Corporation, Thailand) (1000 ppm); group B: toothpaste containing 500 ppm F as sodium monofluorophosphate (Kodomo, Lion Corporation, Thailand) (500 ppm); and group C: toothpaste containing 5% xylitol, 2.1% sarcosinate, triple calcium, and phosphate (Pureen, U.S. Summit company, USA) (xylitol). The drinking water in this area contains 0.1 to 0.5 mg F/L (ppm).

Sampling procedures: The sample size calculation was based on an earlier study of the effect of parental brushing on the caries increment in Thai children of the same age as the present study sample.[20] The difference in mean dmfs scores between the groups in the previous study was 15.3.[20] For the present study, 3 different toothpastes (1000 ppm, 500 ppm, and xylitol) were compared. As the control group in the previous study did not receive hand-on tooth brushing practice, we expected our mean scores difference to be less than that of the previous study.[20] A difference of approximately 5 between the mean incremental dmfs was expected. The size required for each group was 30 dyads, in order to detect such a small difference between groups over the 1-yr time period. It was assumed that the type 1 and 2 error rates would be 5% and 20%, respectively, and that the correlation coefficient between the repeated measurement scores would be 0.5.[28] A high dropout rate was expected.[20,29] Accordingly, the initially calculated size of 30 dyads for each group was increased to 60 dyads giving a total sample size for the study of 180 dyads. The subjects were divided into three clusters based on their village areas to eliminate the risk of the subjects sharing different toothpastes in the nearby village. The three clusters composed of 3 villages (60 dyads), 5 villages (61 dyads), and 5 villages (62 dyads).

Healthy children without systemic disease or enamel hypoplasia, born from December 2011 to September 2012 (aged 9- to 18-mo-old) and whose caregivers could read Thai, as indicated by having attended school for at least 4 yr, were recruited into the study. Written informed consent was obtained prior to the recruitment. Primary caregivers who planned to move out of the area within a yr and those with non-compliance (not using the assigned toothpaste and/or brushing their children's teeth less than 3 times a week) were excluded.

Study regimen: The caregiver received an oral health education and hands-on tooth brushing practice. The session of oral health education emphasized the correlation between growth and development and ECC, and the identification of plaque with the white lesions which progressed into cavitated lesions. They were informed that the white lesions could be reversed by brushing with F toothpaste.

The hands-on tooth brushing practice was assisted by village health volunteers (VHVs) who were trained in tooth brushing technique by two dental personnel prior to the commencement of the program. Brushing kits consisting of a small-size toothbrush, the blinded respective toothpaste for each group, a clean cloth to wipe out toothpaste foam, a plastic cup, a small basket, a round ended slant straw for plaque checking, and a leaflet on the method of tooth brushing were delivered to each caregiver. No other behavior modification education was provided.

Due to the high expected dropout, rate as mentioned above, this study intended to follow the sample up to only 12 mo after the initial baseline oral health education and hands-on tooth brushing practice program was finished. The total process included 4 dental visits: baseline, 4 mo-, 8 mo-, and 12 mo-follow ups. The children underwent an oral examination and their caregivers received a questionnaire-guided interview at the baseline and at 12 mo. The hands-on tooth brushing practices were reinforced and the caregivers were again given toothpaste and a toothbrush at the second and third visits. The quality of tooth brushing was evaluated based on the presence of plaque accumulation and gingivitis on the child's upper anterior teeth. Each 4 mo recall examination was performed to detect cavitated lesions which required treatment. The caregivers received home visits every month by the VHVs for the purpose of encouraging the caregiver to perform brushing at a regular frequency.

Data collection: Data were collected at baseline and after 12 mo through an individual clinical oral examination and interview. The oral examination was conducted by one pediatric dentist who did not know which group the children were assigned to. The children were examined, in a knee-to-knee position, for dental caries and oral hygiene status using a ball-ended probe and a mouth mirror under natural light. The classification of dental findings was modified from Warren et al.[30] as follows: unerupted tooth (U), normal enamel surface (S), demineralization but no loss of enamel structure (d1), caries lesion with loss of tooth structure (d2), filled surface without evidence of secondary caries (f), missing tooth due to caries (m). The severity of ECC was determined using dmfs (including and excluding white lesions) and incremental dmfs (including and excluding white lesions). The child's oral hygiene was determined using the debris index (Greene and Vermillion)[31] and the gingival index (Loe and Silness)[32] The intra-examiner reliability was measured using Cohen's kappa by examining twenty children twice in each survey. The kappa values for dmfs, the debris index, and the gingival index were 0.87, 0.61, and 0.89, respectively.

Dental plaque or debris can be defined as the soft deposits, a white or pale yellow "slime layer," that is commonly found between the teeth and along the cervical margins.[33] We used a blunt explorer to scrape the plaque from the incisal third, then the middle third and lastly the cervical third of the labial or buccal and lingual surfaces to record the debris index accordingly. To differentiate between plaque with white lesions and dental fluorosis with white discolouration, the tooth surfaces were cleaned with wet gauze pads before the caries examination. Typical carious white lesions appear on the enamel surfaces as rough, opaque, and with an arched banana- or kidney-shape, reflecting the retention of plaque along the

curvature of the gingival margin. By contrast, the mild cases of dental fluorosis often appeared have smooth and shiny white horizontal lines running across the "perikymata," a term referring to a transverse ridge on the surface of the tooth, corresponding to the incremental lines in the enamel known as Striae of Retzius.[34]

The questionnaire-guided interview was done at the examination site. The primary caregiver's sociodemographic information and the child's oral health habits and care related to ECC were recorded.

Statistical analysis: Descriptive statistics including means, standard deviations, and frequency distributions of the dmfs of the three toothpaste groups were calculated using SPSS version 17.0. Comparison of the caries increment among the three groups was performed using the Kruskal Wallis test. The comparisons of the socio-demographic characteristics among the three groups and the oral health habits at the baseline and at the 12 mo follow-up were analyzed by the Chi-square test.

RESULTS

The 173 primary caregivers and children were allocated into the 3 groups (1000 ppm: n=53; 500 ppm: n=59, xylitol: n=61) at baseline. One-hundred and thirty-one dyads (1000 ppm: n=37; 500 ppm: n=47, xylitol: n=47) completed the trial (response rate = 75.7%). The 41 lost cases included 12 cases who moved out of the villages, 27 cases who did not attend appointments, and 2 cases who became seriously ill. Therefore, 131 dyads were included in the final analysis

For those who had erupted teeth, the prevalence including white lesions caries rose from 16.0% at baseline to 61.1% at 12 mo follow-up. Comparisons of the baseline characteristics of the members, who completed the trial, in the three groups are shown in Tables 1–5.

Table 1. Comparisons, between the three groups at baseline, of the sociodemographic characteristics of age of primary caregivers, age of child, child's sex, and relationship to the child (N=131)

		Toothpaste type						p value*
		1000 ppm of F (Mean±SD)		500 ppm of F (Mean±SD)		Non-F (Mean±SD)		
Age of primary caregivers (yr)		29.6±12.9		35.7±11.9		34.6±14.6		0.021*
Age of child (mo)		14.1±5.2		15.2±4.9		14.5±4.0		0.510
		1000 ppm of F		500 ppm of F		Non-F		
		N	%	N	%	N	%	
Child's sex	Boy	23	62.2	24	51.1	24	51.1	0.518
	Girl	14	37.8	23	48.9	23	48.9	
Relationship to the child	Parents	27	73.0	31	66.0	33	70.2	0.779
	Relative	10	27.0	16	34.0	14	29.8	

*The Chi-square test was used for comparing the proportion and the Kruskal-Wallis test for comparing the means between the three groups; $p \leq 0.05$ was considered to be statistically significant.

Table 2. Comparisons, between the three groups at baseline, of the sociodemographic characteristics of father's occupation, marital status of caregiver, mother's education level, stay-at-home mom, and child rearing experience (N=131)

		Toothpaste type						p value*
		1000 ppm of F		500 ppm of F		Non-F		
		N	%	N	%	N	%	
Father's occupation	Unemployed	2	5.6	1	2.2	1	2.2	N.A.
	Government official/ office worker	4	11.1	3	6.5	3	6.5	
	Business owner/ merchant	11	30.6	4	8.7	6	13.0	
	Employee/ factory worker / farmer	19	52.8	38	82.6	35	76.1	
Marital status of caregiver	Married	34	91.9	46	97.9	43	91.5	N.A.
	Single or divorced	3	8.1	1	2.1	4	8.6	
Mother's education level	Up to primary school	9	24.3	23	48.9	19	40.4	0.069
	High school or more	28	75.7	24	51.1	28	59.6	
Stay-at-home mom	Yes	19	51.4	21	44.7	16	34.0	0.266
	No	18	48.6	26	55.3	31	66.0	
Child-rearing experience	Yes	30	85.7	39	88.6	30	75.0	0.222
	No	5	14.3	5	11.4	10	25.0	

*The Chi-square test was used for comparing the proportion and the Kruskal-Wallis test for comparing the means between the three groups; $p \leq 0.05$ was considered to be statistically significant; N.A.=not applicable.

Table 3. Comparisons, between the three groups at baseline, of the oral health habits of children of falling asleep with a bottle, night time bottle feeding, frequency of brushing, and snacking between meals (N=131)

		Toothpaste type						p value*
		1000 ppm of F		500 ppm of F		Non-F		
		N	%	N	%	N	%	
Falling asleep with a bottle	Never/week	12	40.0	24	55.8	20	45.5	0.246
	3 times or less/week	2	6.7	7	16.3	7	15.9	
	4 times or more/week	16	53.3	12	27.9	17	38.6	
Night-time bottle feeding	Yes	32	86.5	39	83.0	42	91.3	0.49
	No	5	13.5	8	17.0	4	8.7	
Frequency of brushing	0–2 days/week	12	37.5	10	23.8	16	40.0	0.136
	3–5 days/week	2	6.3	9	21.4	5	12.5	
	Almost everyday or everyday and <2 times/day	4	12.5	6	14.3	10	25.0	
	Almost everyday or everyday and ≥2 times/day	14	43.8	17	40.5	9	22.5	
Snacking between meals	Never or 1 time/day	25	69.4	30	66.7	26	57.8	N.A.
	2 times /day	10	27.8	12	26.7	14	31.1	
	3 times or more/day	1	2.8	3	6.6	5	11.1	

*The Chi-square test was used for comparing the proportion and the Kruskal-Wallis test for comparing the means between the three groups; $p \leq 0.05$ was considered to be statistically significant; N.A.=not applicable.

Table 4. Comparisons, between the three groups at baseline, for dentate children only, of the oral hygiene characteristics of the gingival and debris indices (N=131)

	Toothpaste type			p value*
	1000 ppm of F (Mean±SD)	500 ppm of F (Mean±SD)	Non-F (Mean±SD)	
Gingival index	0.10±0.31	0.30±0.47	0.25±0.44	0.132
Debris index	0.17±0.48	0.35±0.63	0.36±0.57	0.108

*The Chi-square test was used for comparing the proportion and the Kruskal-Wallis test for comparing the means between the three groups; $p \leq 0.05$ was considered to be statistically significant.

Table 5. Comparisons between the three groups at baseline, for dentate children only, of the dental caries characteristics of average number of teeth, caries prevalence including white lesions, caries prevalence excluding white lesions, dmfs including white lesions, and dmfs excluding white lesions (N=131)

	Toothpaste type			p value*
	1000 ppm of F (Mean±SD)	500 ppm of F (Mean±SD)	Non-F (Mean±SD)	
Average number of teeth	8.37±5.26	8.93±4.41	8.23±4.73	0.735
	1000 ppm of F (%)	500 ppm of F (%)	Non-F (%)	
Caries prevalence including white lesions	26.7	32.5	27.8	
Caries prevalence excluding white lesions	13.3	12.5	16.7	
	1000 ppm of F (Mean±SD, [minimum number of carious surfaces, maximum number of carious surfaces])	500 ppm of F (Mean±SD, [minimum number of carious surfaces, maximum number of carious surfaces])	Non-F (Mean±SD, [minimum number of carious surfaces, maximum number of carious surfaces])	
dmfs including white lesions	3.37±8.89 [0, 38]	2.35±5.73 [0, 28]	3.00±6.71 [0, 31]	0.905
dmfs excluding white lesions	2.07±6.64 [0, 30]	1.18±3.88 [0, 17]	1.22±4.33 [0, 24]	0.946

*The Chi-square test was used for comparing the proportion and the Kruskal-Wallis test for comparing the means between the three groups; $p \leq 0.05$ was considered to be statistically significant.

In terms of the socio-demographic characteristics, there was a statistically significant difference among three groups in the age of the primary caregivers. The primary caregivers in the 1000 ppm group were younger than those in the other two groups. For other variables, there was no difference between the three groups through statistical analysis. In the other aspects, including the oral health habits of children, the mean gingival index and the debris index score as well as the caries status, regardless of whether white lesions were included or not, there were no statistically significant differences among the three groups (Tables 1–5).

At the 12 mo follow-up, there continued to be no significant difference in the oral health habits, the oral hygiene, and the dental caries status between the three groups ($p>0.05$, Tables 6–8).

Table 6. Comparisons, between the three groups after 12 months, of the oral health habits of children of falling asleep with a bottle, night time bottle feeding, frequency of brushing, and snacking between meals (N=131)

		Toothpaste type						p value*
		1000 ppm of F		500 ppm of F		Non-F		
		N	%	N	%	N	%	
Falling asleep with a bottle	Never/week	21	56.8	27	57.4	28	59.6	N.A.
	3 times or less/week	3	8.1	4	8.5	4	8.5	
	4 times or more/week	13	35.1	16	31.9	15	31.9	
Night-time bottle feeding	Yes	23	62.2	33	70.2	35	74.5	0.473
	No	14	37.8	14	29.8	12	25.5	
Frequency of brushing	3–5 days/week	3	8.1	6	12.8	7	14.9	0.347
	Almost everyday or everyday and <2 times/day	6	16.2	15	31.9	13	27.7	
	Almost everyday or everyday and ≥2 times/day	28	75.7	26	55.3	27	57.4	
Snacking between meals	Never or 1 time/day	32	86.5	39	83	39	83	N.A.
	2 times/day	2	5.4	2	4.3	4	8.5	
	3 times or more/day	3	8.1	6	12.8	4	8.5	

*The Chi-square test was used for comparing the proportion and the Kruskal-Wallis test for comparing the means between the three groups; $p \leq 0.05$ was considered to be statistically significant; N.A.=not applicable.

Table 7. Comparisons, between the three groups after 12 months, for dentate children only, of the oral hygiene characteristics of the gingival and debris indices (N=131)

	Toothpaste type			p value*
	1000 ppm of F (Mean±SD)	500 ppm of F (Mean±SD)	Non-F (Mean±SD)	
Gingival index	0.35±0.48	0.36±0.49	0.55±0.50	0.244
Debris index	0.59±0.59	0.74±0.69	1.08±0.77	0.454

*The Chi-square test was used for comparing the proportion and the Kruskal-Wallis test for comparing the means between the three groups; $p \leq 0.05$ was considered to be statistically significant.

Table 8. Comparisons between the three groups after 12 months, for dentate children only, of the dental caries characteristics of average number of teeth, caries prevalence including white lesions, caries prevalence excluding white lesions, dmfs including white lesions, caries incidence including white lesions, caries incidence excluding white lesions, dmfs including white lesions, dmfs excluding white lesions, increment dmfs including white lesions, and increment dmfs excluding white lesions (N=131)

	Toothpaste type			p value*
	1000 ppm of F (Mean±SD)	500 ppm of F (Mean±SD)	Non-F (Mean±SD)	
Average number of teeth	15.30±4.43	16.68±2.32	15.94±3.29	0.174
	1000 ppm of F (%)	500 ppm of F (%)	Non-F (%)	
Caries prevalence including white lesions	62.2	59.6	61.7	
Caries prevalence excluding white lesions	40.5	42.6	53.2	
Caries incidence including white lesions	43.2	31.9	40.4	
Caries incidence excluding white lesions	24.3	23.4	34.0	
	1000 ppm of F (Mean±SD, [minimum number of carious surfaces, maximum number of carious surfaces])	500 ppm of F (Mean±SD, [minimum number of carious surfaces, maximum number of carious surfaces])	Non-F (Mean±SD, [minimum number of carious surfaces, maximum number of carious surfaces])	
dmfs including white lesions	10.00±17.62 [0, 93]	5.83±8.01 [0, 31]	6.85±10.90 [0, 50]	0.292
dmfs excluding white lesions	6.97±16.10 [0, 86]	3.55±6.10 [0, 27]	4.79±9.31 [0, 39]	0.356
	1000 ppm of F (Mean±SD)	500 ppm of F (Mean±SD)	Non-F (Mean±SD)	
Increment dmfs including white lesions	7.30±11.54	3.87±6.02	4.68±6.89	0.153
Increment dmfs excluding white lesions	4.78±12.03	2.40±4.00	3.68±7.27	0.406

*The Chi-square test was used for comparing the proportion and the Kruskal-Wallis test for comparing the means between the three groups; $p \leq 0.05$ was considered to be statistically significant.

For those who were caries free at baseline, including those with white lesions caries, the incidence rate for each group of caries including white lesions was similar (43.2%, 31.9%, and 40.4% in the 1000 ppm, 500 ppm, and xylitol groups, respectively). However, it was observed that caries incidence rate excluding white lesions of xylitol group was highest (34.0%) compared to the 1000 ppm and 500 ppm groups (24.3% and 23.4%, respectively). In term of the severity of dental caries, the incremental dmfs of the 1000 ppm group, both including and excluding white lesions, were the highest (7.30±11.54, 3.87±6.02 and 4.68±6.89 for including white lesions, and 4.78±12.03, 2.40±4.00, 3.68±7.27 for excluding white lesions, in the 1000 ppm, 500 ppm, and xylitol groups, respectively). In addition, a large variation in caries status was observed in the 1000 ppm group shown in Table 8. In spite of the observed clinical differences, the statistical analysis revealed no significant difference in dental caries between the three groups.

DISCUSSION

The present study investigated the caries prevention effect of toothpastes with different concentrations of F (1000 ppm F, 500 ppm F, or 0 ppm F containing xylitol and triple calcium phosphate) in a sample of 9- to 18-mo-old Thai children over a 12-mo period. We found that there was no significant difference among the three groups in the caries increment and the caries status (dmfs) at the end of our study. It seems that the anticaries efficiency among the three types of toothpastes used in this study does not differ, which is similar to previous studies showing no significant difference in the caries prevention effect between 1000 ppm F and 500 ppm F toothpaste.[27,35,36] Lima et al.'s study indicated similar anticaries efficacies for 1100 ppm F toothpaste and 500ppm F toothpaste in 2- to 4-yr-old children for a caries-inactive group.[27] Moreover, the Cochrane review indicated a non-statistically significant difference between the 440/500/550 ppm F toothpaste groups and a placebo group.[1] In contrast, studies on 3-yr-old Chinese children reported significant reductions in caries after using 1000–1100 ppm F toothpaste compared to a control group.[37-39] The disagreement in the results between these Chinese studies and our study may be due to dissimilar age groups being involved. Their studies were done in kindergarten students (3- to 5-yr-olds), while our study was done in infants and toddlers (baseline age 9–18 mo). Another study on the same age group, 9- to 18-mo-old Thai children, found a significantly lower caries increment in the group with a hands-on tooth brushing program using 500 ppm F toothpaste group compared to the no intervention group.[20] This difference may be due to the fact that their control group received regular oral health care in the public health service while our comparison group received oral health education with hands-on tooth brushing practice.

Although this study found no statistical difference in caries increment, it should not be concluded that the topical use of F toothpaste had no caries prevention effect in infants and toddlers. A potential caries prevention effect of the xylitol and triple calcium phosphate toothpaste used in the comparison group might be a possible explanation for the lack of a significant difference between the three

groups. For ethical reasons, the non-F containing xylitol and triple calcium phosphate toothpaste was used in the comparison group instead of a placebo toothpaste. This may limit somewhat the differences in the findings between the groups with the F and non-F toothpastes, which could have been more distinct if placebo toothpaste had been used. In addition, the finding of similar caries incidence rates among the three groups when white lesions were included, but a higher rate for the non-F group if white lesions were excluded, might be explained by the action of F in impeding caries progression.

Even though the dmfs of the three groups were not statistically different, there were some variations among the groups. The diversity of the father's occupation (41.7% stable occupation [government official, office worker, business owner, merchant] and 52.8% unstable occupation [employee, factory worker, farmer], Table 2) in the 1000 ppm group may have contributed to the greater variation in the dmfs of this group (0 to 93 surfaces) compared to the 500 ppm and the xylitol groups (0 to 31 surfaces and 0 to 50 surfaces, respectively, Table 8), where the majority of fathers in the 500 ppm and the xylitol groups had a higher percentage of unstable occupation (82.6% and 76.1% unstable occupation [employee, factory worker, farmer], respectively, Table 2). The variations in the paternal occupational stability in the subjects were an unavoidable weakness in the community study.

This study attempts to fill the gap of knowledge in relation to the use of F toothpaste in infants and toddlers where dental fluorosis is a particular concern. The study was designed to compare the effectiveness of toothpastes with different F concentrations. Because our study was conducted using subjects of low socioeconomic status in a small rural area, the generalizability of the results may be limited. The overall dropout rate after 1 year was 24.3% which was much lower than the expected rate of 50% used in the sample size calculation. We are aware of the relatively short follow up period, 12 mo, used in the present study. By reviewing all previous studies in Thai toddlers living in rural areas where the general population are considered to be a high risk group for developing dental caries, a 12 mo period was considered to be adequate to detect a change in the incremental dmf rate in deciduous teeth.[19,20,29] Therefore, we decided to use a 12 mo follow up period for the present study. However, further studies with a longer period of follow up, may yield a more definitive result.

CONCLUSION

In summary, our results indicated that there were no statistically significant differences in the caries increments between toddlers using non-F toothpaste, low dose-F toothpaste, and the conventional 1000 ppm-F toothpaste. The implication of this study is thus that, in the infant and toddlers age group, the use of low dose-F toothpaste or xylitol with triple calcium phosphate toothpaste might be better alternatives to the use of the conventional high dose 1000 ppm-F toothpaste as they would carry a lower risk for the development of dental fluorosis.

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