CARIES INCREMENTAL RATES AFTER THE USE OF 1000 PPM, 500 PPM AND NON-FLUORIDE CONTAINING XYLITOL TOOTHPASTE IN INFANT AND TODDLER

Miss Palinee Detsomboonrat

A Dissertation Submitted in Partial Fulfillment of the Requirements
for the Degree of Doctor of Philosophy Program in Dental Public Health
Department of Community Dentistry
Faculty of Dentistry
Chulalongkorn University
Academic Year 2015

อัตราฟันผุเพิ่มภายหลังการใช้ยาสีฟันผสมฟลูออไรด์ที่ความเข้มข้น 1000 ppm, 500 ppm และยาสีฟันที่ไม่ผสมฟลูออไรด์ชนิดที่มีไซลิทอลในเด็กวัยทารกและวัยเตาะแตะ

นางสาวพลินี เดชสมบูรณ์รัตน์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรดุษฎีบัณฑิต
สาขาวิชาทันตสาธารณสุข ภาควิชาทันตกรรมชุมชน
คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
ปีการศึกษา 2558

Thesis Title	CARIES INCREMENTAL RATES AFTER THE USE OF 1000 PPM, 500 PPM AND NON-FLUORIDE CONTAINING XYLITOL TOOTHPASTE IN INFANT AND TODDLER
By	Miss Palinee Detsomboonrat
Field of Study	Dental Public Health
Thesis Advisor	Assistant Professor Pagaporn Pantuwadee Pisarnturakit, D.D.S., M.Sc., Dr.P.H.

Accepted by the Faculty of Dentistry, Chulalongkorn University in Partial Fulfillment of the Requirements for the Doctoral Degree

.....Dean of the Faculty of Dentistry
(Assistant Professor Suchit Poolthong, D.D.S., M.S., Ph.D.)

THESIS COMMITTEE

.....Chairman
(Associate Professor Patita Bhuridej, D.D.S., M.S., Ph.D.)

.....Thesis Advisor
(Assistant Professor Pagaporn Pantuwadee Pisarnturakit, D.D.S., M.Sc., Dr.P.H.)

.....Examiner
(Associate Professor Chanchai Hosanguan, D.D.S., M.Sc.)

.....Examiner
(Special Professor Chutima Trairatvorakul, D.D.S., M.S.)

.....External Examiner
(Assistant Professor Tippanart Vichayanrat, D.D.S., M.S.D., CAGS, Dr.P.H.)

พลินี เดชสมบูรณ์รัตน์ : อัตราฟันผุเพิ่มภายหลังการใช้ยาสีฟันผสมฟลูออไรด์ที่ความเข้มข้น 1000 ppm, 500 ppm และยาสีฟันที่ไม่ผสมฟลูออไรด์ชนิดที่มีไซลิทอลในเด็กวัยทารกและวัยเตาะแตะ (CARIES INCREMENTAL RATES AFTER THE USE OF 1000 PPM, 500 PPM AND NON-FLUORIDE CONTAINING XYLITOL TOOTHPASTE IN INFANT AND TODDLER) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: ผศ. ทญ. ดร.ผกาภรณ์ พันธุวดี พิศาลธุรกิจ , 169 หน้า.

แม้ว่ายาสีฟันผสมฟลูออไรด์ที่ความเข้มข้น 1000 ppm จะได้รับการแนะนำให้ใช้ในทุกกลุ่มอายุก็ตาม พ่อแม่หลายๆคนยังคงเลือกใช้ยาสีฟันผสมฟลูออไรด์ที่ความเข้มข้น 500 ppm หรือ ยาสีฟันที่ไม่ผสมฟลูออไรด์ในเด็กทารกและเด็กวัยเตาะแตะ เพื่อที่จะหลีกเลี่ยงการได้รับฟลูออไรด์ที่มากเกินไป การศึกษาที่เปรียบเทียบประสิทธิภาพการป้องกันฟันผุของยาสีฟันที่ผสมฟลูออไรด์ในเด็กทารกและเด็กวัยเตาะแตะยังพบได้น้อย ดังนั้น การศึกษานี้มีวัตถุประสงค์เพื่อเปรียบเทียบฟันผุที่เพิ่มขึ้นภายหลังการใช้ยาสีฟันผสมฟลูออไรด์ที่ความเข้มข้น 1000 ppm, 500 ppm และยาสีฟันที่ไม่ผสมฟลูออไรด์แต่มีส่วนประกอบของไซลิทอลและทริปเปิลแคลเซียมฟอสเฟตในกลุ่มเด็กทารกและเด็กวัยเตาะแตะ ผู้ดูแลหลักและเด็กที่มีเด็กอายุ 9-18 เดือน จำนวน 183 คู่ ถูกจัดกลุ่มเป็น 3 กลุ่ม และสุ่มเลือกใช้ยาสีฟันที่มีความเข้มข้นของฟลูออไรด์แตกต่างกัน เป็นเวลา 12 เดือน กลุ่ม A –ใช้ยาสีฟันผสมฟลูออไรด์ความเข้มข้น 1000 ppm (1000 ppm); กลุ่ม B –ใช้ยาสีฟันผสมฟลูออไรด์ความเข้มข้น 500 ppm (500 ppm); กลุ่ม C –ใช้ยาสีฟันที่ไม่ผสมฟลูออไรด์แต่มีส่วนประกอบของไซลิทอลและทริปเปิลแคลเซียมฟอสเฟต (ไซลิทอล) ผู้ดูแลหลักได้รับทันตสุขศึกษา และฝึกปฏิบัติการแปรงฟันหลายครั้งตลอดระยะเวลาของการศึกษา ตรวจสภาวะช่องปากของเด็กเมื่อเริ่มการศึกษา และหลังการศึกษา 12 เดือน วิเคราะห์ข้อมูลทางสถิติโดยเปรียบเทียบความแตกต่างของฟันผุที่เพิ่มขึ้นด้วยสถิติวิเคราะห์ความแปรปรวนร่วม ผลการศึกษาพบว่า มีความแตกต่างกันอย่างไม่มีนัยสำคัญทางสถิติเมื่อเริ่มการศึกษา ค่าเฉลี่ยฟันผุ อุด ถอน ต่อด้านที่เพิ่มขึ้น ของกลุ่ม 1000 ppm, 500 ppm และ ไซลิทอล ภายหลังการศึกษาที่ 12 มีค่าเท่ากับ 7.30±11.54, 3.87±6.02 and 4.68±6.89 ตามลำดับ โดยที่มีความแตกต่างกันอย่างไม่มีนัยสำคัญทางสถิติ ดังนั้น การใช้ยาสีฟันที่ผสมฟลูออไรด์ที่มีความเข้มข้นต่ำและยาสีฟันที่ไม่ผสมฟลูออไรด์ที่มีส่วนประกอบของไซลิทอล และทริปเปิลแคลเซียมฟอสเฟตอาจจะเป็นทางเลือกหนึ่งสำหรับการเลือกยาสีฟันผสมฟลูออไรด์ที่ความเข้มข้นสูงในเด็กทารกและเด็กวัยเตาะแตะ

ภาควิชา ทันตกรรมชุมชน ลายมือชื่อนิสิต .....

สาขาวิชา ทันตสาธารณสุข ลายมือชื่อ อ.ที่ปรึกษาหลัก .....

ปีการศึกษา 2558

5376453932 : MAJOR DENTAL PUBLIC HEALTH
KEYWORDS: CARIES PREVENTION / CARIES INCREMENT / FLUORIDE / INFANT AND TODDLER / TOOTHPASTE / XYLITOL

PALINEE DETSOMBOONRAT: CARIES INCREMENTAL RATES AFTER THE USE OF 1000 PPM, 500 PPM AND NON-FLUORIDE CONTAINING XYLITOL TOOTHPASTE IN INFANT AND TODDLER. ADVISOR: ASST. PROF. PAGAPORN PANTUWADEE PISARNTURAKIT, D.D.S., M.Sc., Dr.P.H., 169 pp.

Although the 1000 ppm fluoride (F) toothpaste is recommended for all age group, many parents choose 500 ppm fluoride (F) or non-F toothpaste for their toddlers to avoid the possibility of excessive intake of F. Comparison on the efficacy of F toothpastes has rarely been studied in infants and toddlers. This study aimed to compare the caries increment rates of 1000 ppm F, 500 ppm F and non-F (xylitol with triple calcium phosphate) toothpaste in infants and toddlers. One hundred and eighty-three children aged 9- to 18-month (mo) were clustered into 3 groups and randomly assigned according to the toothpaste used over a 12-mo period. Group A: 1000 ppm F toothpaste (1000ppm); group B: 500 ppm F toothpaste (500ppm); and group C: non-F toothpaste with xylitol and triple calcium phosphate (Xylitol). The children's caregivers received oral health education with hands-on tooth brushing practices several times during the study. Oral examinations were conducted at baseline and after 12 mo. The difference in caries increment among the groups was analyzed by Analysis of covariance (ANCOVA). There was no statistically significant difference in dmfs among three groups at baseline. After 12 mo, the incremental dmfs of the 1000 ppm, 500 ppm, and Xylitol groups were 7.30±11.54, 3.87±6.02 and 4.68±6.89, respectively with no statistically significant difference. Thus, low-dose F and xylitol with triple calcium phosphate toothpastes might be the alternatives to high-dose F toothpaste in infants and toddlers age group.

Department: Community Dentistry Student's Signature .....
Field of Study: Dental Public Health Advisor's Signature .....
Academic Year: 2015

ACKNOWLEDGEMENTS

The success of this thesis can be succeeded by the attentive support from my advisors- Assistant Professor Pagaporn Pisarnturakit, D.D.S., M.Sc., Dr.P.H. I am also extremely grateful to Associate Professor Chutima Trairatvorakul, D.D.S., M.S. for her valuable guidance, advice and suggestions. I would like to express my great admiration, gratitude and appreciation to them. This study would not have been possible without their valuable supervision, advice, guidance and immense knowledge.

Also, I would like to express my deep gratitude to Dr. Pimolphan Laungwechakan, the head of Dental Department of U-thong hospital for coordinating the study area, Miss Sututta Srihara for helping in oral examination of children and the primary caregivers who cooperated and participated in this study.

I also would like to give my special thanks to my thesis committee members: Associate Professor Patita Bhuridej, Associate Professor Chanchai Hosanguan, Associate Professor Chutima Trairatvorakul and Assistant Professor Tippanart Vichayanrat, D.D.S., M.S.D., CAGS, Dr.P.H. Furthermore, I also wish to thank the Dental Research Fund, Faculty of Dentistry, Chulalongkorn University for the financial support of this doctoral study.

Finally, I would like to express my appreciative thanks to my beloved husband and family for their endless love and support during my entire study. I also would like to thank my friends and classmates for sharing their experience, their discussion and the encouragement provided during my study.

CONTENTS

Page

Page

Page

Page

Page

LIST OF TABLES

LIST OF FIGURES

CHAPTER I
INTRODUCTION

1.1 Background and rationale

Early childhood caries (ECC) is a significant dental problem affecting young children in both developed and developing countries, especially in low socio-economic areas [1]. In Thailand, the prevalence of dental caries in young children stayed high in the past two decades (51.7%-66.5%) [2]. Dental caries can occur in young Thai children when the first tooth erupts at approximately 9 months of age [3, 4]. Studies from both rural and suburban Thailand have reported a high prevalence of ECC [3-7]. The caries prevalence among 3-year-old children slightly decreased from 66.5% to 56.7% during 1989-2012 [8]. The majority of Thai children living in rural areas have more dental caries than those in urban areas [9]. The results of untreated caries directly causes toothache, infection, tooth loss and can negatively affect to nutritional status, physical development and growth of the children [10-14]. Dental caries also affect children's speech development which influence to their self-esteem and quality of life [15]. The treatment of ECC is difficult and complex. Moreover, the cost of restorative treatment is higher than the cost of preventive program which can be met by the funds available for essential public health programs [16, 17]. Therefore, an effective prevention procedure is desired for handling dental caries in young children.

ECC is a multi-factorial disease, its possible cause includes microorganism attacking tooth surface, the impaired host resistance, infant feeding habits, dietary habits, consumption of sugary foods, oral hygiene procedure, use of fluoride (F), and socioeconomic factors [3-5, 10, 18-24]. Home-based strategy is one of the successful prevention programs for ECC. It involves the oral self-care at home such as appropriate dietary habits, maintain good oral hygiene, and using fluoride toothpaste and fluoride supplements [25]. According to the American Academy Pediatric Dentistry (AAPD) and Canadian Dental Association, providing the supervised use of fluoride toothpaste after the first tooth eruption is the highly recommended for the prevention of caries and it's superior to the other preventive procedure such as utilize motivational interviewing and anticipatory guidance for the parents and caregivers, or oral health screening by community health nurses/family physicians/ pediatricians [26] The effectiveness of fluoride-containing toothpaste in preventing dental caries is generally known. A recent systematic review by Cochrane recommends the use of 1000 ppm F toothpaste for preventing dental caries in general population including children age under 6 years [27]. However, most studies on children included in the Cochrane review were conducted in kindergarten students aged 3 to 5 years old. The Cochrane review also suggests that higher levels of fluoride (1000 ppm F or more) in toothpaste increase the risk of fluorosis in children under 6 years old [28] because the period before 3 years of age is critical to

the development of dental fluorosis caused by excessive intake of fluoride. A study suggested that the severity of fluorosis depends on the amount and duration of F exposure [29]. The American Academy of Pediatric Dentistry (AAPD) recommends the use of a smear size of fluoride toothpaste in moderate to high-risk children starting at the eruption of the first tooth[30]. Nevertheless, some studies showed that the concentration of fluoride 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 [27, 31].

In spite of the established knowledge on the effectiveness of fluoride toothpaste in preventing dental caries and subsequent recommendation for the use in general population, a gap of knowledge remains for the infant and toddler aged group. Unclear evidence on the optimal concentration of F in toothpaste for preventing dental caries in deciduous dentition is also mentioned in the Cochrane review [27]. For the very young children aged less than 3 years, the appropriate balance between the caries reduction benefit and harmful fluorosis effects should be in a serious concern. Up to this date, there is no clear recommendation on the optimal concentration and amount of F toothpaste for reducing caries in children aged 9-18 months, especially those with newly erupted teeth. Most studies on the effect of fluoride toothpaste on ECC prevention compared the use of fluoride toothpastes along with oral health education against controls with no intervention

[32-34]. There are very few trials comparing the effects of low- and standard-fluoridated toothpastes on the reduction of caries in the primary teeth of infants and toddlers [27, 35, 36]. Difficulties in conducting such study might relate to cooperation of very young children as well as an ethical consideration if non- fluoridated toothpaste is generally available. Therefore, the aim of the present study was to compare the caries increment in toddlers after using 500 ppm F or 1000 ppm F toothpastes with a non- fluoridated (with xylitol and triple calcium phosphate) toothpaste as control. If their caries prevention effect is not different, the use of lower levels of fluoride concentration toothpaste would be suggested in order to decrease the risk of over consumption of fluoride in young children.

1.2 Research Question

Are the caries increments of tooth brushing with 1000 ppm F, 500 ppm F and non-fluoride containing xylitol toothpaste among infant and toddler different?

1.3 Research Objectives

The aim of this study is to evaluate the outcome of tooth brushing program in infant and toddler with different concentrations of fluoride toothpaste. The objective is to evaluate caries increment of infants and toddlers who attended the tooth brushing program with 1000 ppm fluoride toothpaste compare to 500 ppm fluoride toothpaste and non-fluoride containing xylitol toothpaste.

1.4 Research Hypothesis

After attending the tooth brushing program with different concentrations of fluoride toothpaste, children in 1000 ppmF and 500 ppmF group had lower caries increment than xylitol group.

1.5 Operational Definition

Early Childhood Caries (ECC) refer to the presence of one or more decayed (cavitated and non-cavitated lesions), missing (due to caries), or filled tooth surface on any primary teeth.

Primary Caregivers refer to mothers, grandparents, or any relatives who routinely take care of the children including the bringing of the child for vaccination, feeding, cleaning, and putting them to sleep.

Child oral health practice include four behaviors: toothbrushing, bottle feeding, sugared snack controlling, and use of fluoride supplement

Feeding practices refer to breast/bottle feeding and allowing the child to fall asleep with the nipple/bottle in the mouth.

Tooth cleaning refers to tooth brushing or tooth wiping

Incremental caries refers to the increasing amount of decayed tooth from previous examination.

1.6 Research Conceptual Framework

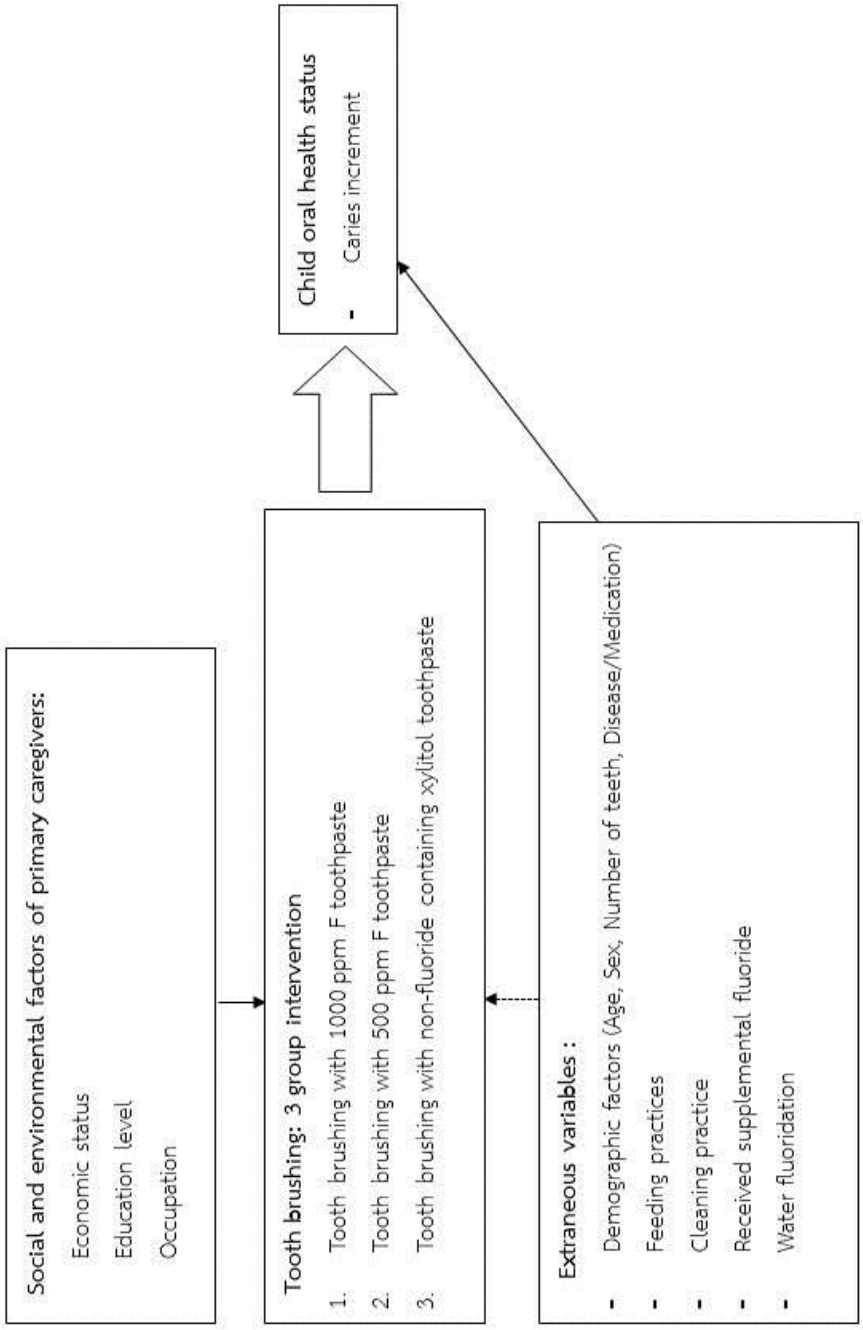


Figure 1 Research conceptual framework

CHAPTER II
LITERATURE REVIEW

2.1 Process of caries

Dental caries is a multifactorial, chronic and transmissible disease [37]. Caries occurs as a result of an unbalance process of demineralization and remineralization of tooth surface by microbial biofilm which facilitates by the proliferation of acidogenic, aciduric, and cariogenic bacteria [37]. The proliferation of acidogenic bacteria consequently reduces salivary pH [37]. The low salivary pH enables the demineralization. Frequent consumption of dietary sugars and acidic drinks during the day further prolongs the period of low pH [38]. The demineralization process at the tooth surface lead to a loss of mineral content in the tooth [39]. If this process progresses for a long time, it will become deeper into the tooth surface and the end result is a cavity. Demineralization usually takes many months or years to progress to cavitation, the end-point of the disease process known as dental caries [37]. The microbial biofilm tends to form and mature in definite locations on the tooth, particularly the occlusal surface, the proximal surface cervical to the contact point, and along the gingival margin. Thus, these are the most frequent sites found with caries lesions [40].

Demineralization occurs in two phases [37]. First, the bacteria metabolize fermentable carbohydrates producing organic acids that diffuse into the

crystals of tooth. When the acid reaches on a crystal surface, calcium and phosphate are dissolved into the surrounding crystals. This is the first phase of demineralization which will occur before it can be seen visually as gross demineralization. The mineral loss becomes deeper into the enamel or exposed dentine until it can be detected visually or radiographically in demineralization progresses. The earliest clinical sign that dental caries is in progress is called “white spot lesion”. This is the first phase in the range of the dental caries process, which can eventually lead to cavitation that is the second phase. At the white spot lesion phase, therapeutic intervention can arrest or reverse the process by remineralization prior to cavitation. If fluoride ions are present in sufficient concentration before or during demineralization, these ions can absorb onto the surface of the crystals and markedly inhibit demineralization [41, 42]. The important point is that if a carious lesion is non-cavitated, and especially if it is in the enamel, it can be reversed or arrested [37].

2.2 Early childhood caries (ECC)

2.2.1 Definition

The American Academy of Pediatric Dentistry (AAPD) defined Early childhood caries (ECC) as “the presence of one or more decayed (noncavitated or cavitated lesions), missing (due to caries), or filled tooth surfaces” in any primary tooth in a child 71 months of age or younger. In children younger than 3 years of age, any sign of smooth-surface caries is indicative of severe early childhood caries (S-ECC) [43].

The recent studies found that child rearing behavior of bottle feeding is not the only factor in caries development in young children. It is a multifactorial disease including both personal and environmental factors such as poor oral hygiene, feeding habits, frequent intakes of fermentable sugars, enamel hypoplasia, less-than--optimal fluoride exposure, low socioeconomic status, ethnicity, and limited access to professional dental care. Therefore, the U.S. Center of Disease Control and Prevention (CDC) recommended using the term “early childhood caries” instead of the terms “nursing caries”, “baby bottle tooth decay” or “nursing bottle syndrome” when describing any form of caries in primary teeth [20].

2.2.2 Current situation

A review of the epidemiology of ECC revealed that prevalence of ECC varies from population to population, however, it is the main dental problem affecting young children in both developed and developing countries especially in areas of social deprivation [1]. In developing countries ECC is a critical problem as well, enlarged by socio-environmental factors such as low income or deprived area. The prevalence of ECC in these countries is reported to be as high as 70% [1].

In Thailand, dental caries in young children is still high during the past two decades. The recent national oral health survey in 2012 reported that 56.7% of 3 years old children experienced dental caries. The average decayed, missing, filled teeth (dmft) score of 2.7 indicated that these children have dental caries on average

of 3 teeth per person and most caries in children have never been treated [44]. Moreover, 50.6% of these dental caries in 3 years old children are unrestorable and 3.2% of them had experience in extraction [44]. The sixth and the seventh Thailand National Oral Health Survey indicated decreasing trend of dental caries status in both three- and five-year-old children. The decreasing trend was revealed in both prevalence and average number of affected teeth per child. In the three-year-old children, the prevalence of dental caries and dmft score decreased from 61.4 to 56.7 percent and 3.2 to 2.7 teeth per person, respectively. In the five-year-old children, the prevalence of dental caries and dmft score decreased from 80.6 to 78.5 percent and 5.4 to 4.4 teeth per person, respectively. Although the trend of caries prevalence in Thai children was slightly decreased, while the majority of the children in Thailand living in the rural areas still have high dental caries rate [1].

Dental caries can be seen as early as the first teeth eruption in the mouth at around 9 months of age [3, 4, 6, 45]. Several studies in rural and suburban area of Thailand have confirmed the high prevalence and high severity of ECC [3-7, 45]. The incidence and increment of ECC among 9-18 months old children in Songkhla province were substantially high. The crude dmfs caries increment between 9 and 12 months old children was 1.1 ± 2.6, whereas it was 4.2 ± 5.1 between 12 and 18 months old children [3]. The prevalence of ECC rose sharply from 2.0% at 9 months old to 68.1% at 18 months old [7]. A study of Thai children aged 15-19 months in the

Suphan Buri province revealed a high prevalence and severe ECC. The prevalence of ECC was 82.8% with mean dmft score of 4.18±3.19 [4]. In the same area, the study using the participatory dental health education in small group discussion model to control caries showed a very high score of cavitated carious increment over the one year period. The incremental dmft of cavitated carious in the test and control group were 7.80±4.99 and 7.78±5.22, respectively [45]. While the study of children aged 9-18 months in Khonkaen province showed that dental caries occur in very young children during the first tooth eruptions at approximately three surfaces (dmfs = 2.96 surfaces/person) [6].

Thus, this information emphasizes that ECC is a serious health problem affecting infants and toddlers as early as the first tooth eruption and is a significant public health problem in Thailand.

2.2.3 Pattern

The unique pattern of ECC relate to chronology of primary tooth eruption and subsequent acquiring of cariogenic bacteria, namely Mutans Streptococci (MS).

At an early age, the incisor teeth which are the first to erupt would be more susceptible due to inappropriate bottle feeding habits and become decayed. The dental caries at smooth surface of maxillary incisor and occlusal fissure of the

first molar teeth are usually affected in children before 2.5 years of age, and it can be developed to occlusal fissures of the second primary molar teeth at 3.5 years of age. While as the proximal surfaces of all primary molar teeth are usually involved at 5 years of age [46]. Moreover, ECC pattern and severity can be related objectively to behavioral and social factors. The anterior caries pattern was significantly higher in children who falled asleep with a bottle or were allowed to sip from a bottle during the day compared with those who did not feed in this behavior [47].

Characteristic of initial carious lesion can be seen as white bands along with gingival margin of upper anterior teeth and it can develop and may further progress to a frank cavity. The lesion at early stage is difficult to detect and does not appear alarming. It causes the caregivers to take their child to see the dentist after the irreversible defects has already developed. Therefore, a correct diagnosis of initial caries in infant and toddlers is a basis for introducing proper preventive measures [24].

2.2.4 Impact

The consequences of undetected or untreated ECC are severe and significant [48, 49]. Rampant decay may lead to the need of removing multiple primary teeth, and life-threatening infections [15, 48, 50]. Consequences of ECC can lead to more widespread health issues such as stunting the child growth and weight due to associated pain and reluctance to eat [49, 51]. The children with ECC demonstrated

the higher risk of future caries both primary and permanent teeth comparing to caries-free children [51], had more number of hospitalizations and emergency room visits [50], had more treatment cost and time [15]. Toothache from ECC can affect a child's ability to concentrate in learning and affect their educational performance [15]. The studies showed that children received comprehensive dental treatment, would have improvement in the child's quality of life (QoL). The improvements of QoL related to the child having less pain and improved abilities to eat and sleep [15, 48].

2.3 Determinants

ECC associate with multiple risk factors includes: 1) biological factors (microorganism, tooth structure and oral environment); 2) behavioral factors (infant feeding practice, tooth brushing with fluoride toothpaste, dietary habit, dental attendance); and 3) Social and environmental factors (socioeconomic status, oral health knowledge and attitude of parent, family and social norm, water fluoridation) [1, 3, 5, 10, 18, 21, 22, 47]. The details are as follows:

2.3.1 Biological Factors

2.3.1.1 Microorganism

Mutans Streptococci (MS) and Lactobacilli can be found 100 times higher in dental plaque of children with rampant caries as compared to caries-free children [52]. Colonization with Mutans Streptococci is an important factor for early caries

initiation. Several studies have shown that children who have the higher caries experience can detect these bacteria earlier [18, 53, 54]. MS colonization can occur since 6 months on predentate children [55] and are more likely with increasing age, increasing number of teeth, and children whose bottle contained sweetened beverages [56].

Factors influenced colonization were frequent sugar exposure in the infants and habits that allowed salivary transfer from mother to infants. MS may be transmitted vertically from caregiver to child through salivary contact and horizontal transmission such as between other members of a family or other children in day care also occurs. Eliminating saliva-sharing activities such as sharing of equipment or utensils, an oral cleanser and a pacifier may decrease an infant's or toddler's acquisition of cariogenic microbes [57].

2.3.1.2 Tooth structure and oral environment

Developmental defect of primary tooth may increase caries risk [22, 53, 58]. Such defect enhances plaque retention and increase MS colonization. For severe case, the loss of enamel enables greater susceptibility to tooth demineralization. Association between presence of enamel hypoplasia and high count of MS strong correlation is strongly found [59]. Enamel defects in the primary dentition are most associated with prenatal, perinatal or postnatal conditions such as low birth weight, and the child's or mother's malnutrition or illness. The prevalence of enamel

defects are common in primary dentition, with the overall prevalence ranging from 13%-39% in normal full-term infants to over 62% in those born preterm with very low birth weight [22, 58].

Saliva and its tooth-protective components show at least four important functions: (1) buffering ability, (2) antibacterial action, (3) a cleansing effect, and (4) maintenance of a saliva supersaturated in calcium phosphate. Fluoride is another important component of saliva that is discussed separately in other articles in this issue. The ability of saliva to deliver fluoride to the tooth surface persistently makes salivary fluoride an important player in caries protection by promoting remineralization and reducing demineralization [60].

2.3.2 Behavioral Factors

2.3.2.1 Infant feeding practice

Risk of developing ECC starts in the first year of life and is increased by poor child-rearing practices [3-5, 7, 18, 24, 61]. Studies confirmed that the frequency of milk intake is the most important determinant for ECC development, irrespective of whether the child was breast-fed or bottle-fed [3, 23, 61-63]. More frequency of breast or bottle feeding leads to the accumulation of milk on the child's tooth surfaces, especially on the upper incisors where there is low salivary flow. This might be a reason for the similar high caries level in the children exclusively breast-feed compared to the bottle-feed children [3]. On the other hand, children who feed on

supplementary foods will have lower tendencies of breast-feedings or bottle use. Rice and cereals are more difficult to digest than milk, and they take more time for the child to become hungry again. Therefore, the frequency of milk intake and acid exposure could be reduced and these children had lower levels of caries (Thitasomakul, Piwat et al. 2009).

Using a bottle at bedtime significantly affect caries risk (Reisine and Psoter, 2001; Subsandee et al., 2008). A study of bottle-using behavior in a group of Thai preschool children indicated that most caregivers used a nursing bottle before nap time to facilitate their child falling asleep because it was the easiest way to stop the child from crying and Thai children were weaned at 2.8±0.9 years old [64]. The most common reason for being unable to wean was the refusal of the child and the concerns of malnutrition and poor mental health among the early weaning child [64]. However, the study in longitudinal design indicated that duration of bottle use was not significantly related to caries risk, but the contents in the bottle such as juice, sugar-added milk were significantly associated with increasing caries risk in children [21].

Parents and caregivers often use fruit juice to put in the nursing bottle. Taking fruit juice is a concern because it is a cariogenic food due to its high sugar content and it is easily consumed from the nursing bottle [18, 65]. Sometimes caregivers provide sweet flavored milk or yogurt to stimulate their child's appetite [66].

Therefore, the provision of information on choosing non-sweetened milk or using a cup for fruit juice should be a concern in the dental caries prevention program.

2.3.2.2 Tooth brushing with fluoride toothpaste

The role of tooth brushing with fluoridated toothpaste is effective in caries prevention [67]. Several evidences indicated daily tooth-brushing with fluoride toothpaste in young children provides a statistically significant benefit [28, 31, 68-72] by reversing or arresting the demineralization process by the effect of fluoride enrichment [37]. Moreover, the regular tooth brushing with fluoride toothpaste may have a greater impact on caries in young children than restricting sugary foods. An advice on regular tooth brushing is more likely to be successful than the attempt to change dietary behaviors [73]. Considering the cost evaluation of tooth brushing programs, the effectiveness of fluoridated toothpaste is extremely good to caries prevention since the marginal cost for adding fluoride to the toothpaste is almost zero, and the utility of caries reduction from fluoride toothpaste has been well documented in randomized controlled trial studies [74]. Moreover, the American Academy of Pediatric Dentistry recommends the use of fluoridated toothpaste even from the first eruption of the teeth [75].

There is an evidence demonstrating that children who brushed their teeth themselves were more likely to have visible plaque [76] and brushing with parental supervision or assistance could also reduce ECC prevalence[77, 78]. Supervised tooth

brushing can be an effective target into socially deprived communities and a significant reduction in dental caries can thereby be achieved especially among caries-susceptible children [68, 71, 77]. Ideally, tooth brushing for young children should begin at home, under parental supervision even during the first tooth eruption. Children from socially deprived backgrounds are more likely to commence tooth brushing later in life and to brush less frequently than children from more affluent backgrounds [3, 79, 80].

Minimized rinsing after brushing with fluoride toothpaste will grant greater contact of fluoride on tooth surface and enhance cariostatic effect of fluoride in the mouth [81, 82]. Sjogren recommended a modified brushing technique that consists of : (1) spreading toothpaste on the teeth prior to brushing, (2) brushing for 2 minutes, (3) reducing the rinsing of the mouth and (4) refraining from eating or drinking for 2 hours after brushing. This technique has been found to reduce caries in preschool children by an average of 26% compared to a control group that also brushed with a fluoride toothpaste but received no instructions restricting rinsing [70].

2.3.2.3 Dietary Habit

The sugary foods are the major dietary factor affecting dental caries. Previous studies indicated that having sugary snacks and soft drinks at an early age significantly increased the incidence of ECC [3, 4, 83]. Most parents and caregivers use snacks or sweets as a reward due to their culture norm [19]. Moreover, fruit juice and fruit-

flavored drinks are frequently given to preschoolers as the popular child's diet because of their high taking by children, low cost, and the belief by parents that they are nutritious [53]. These sugary foods or drinks have a large cariogenic potential because of their high sugar content. The earliest consumption of cariogenic foods was by a child less than one year of age [3, 4, 79]. The results of the interview of caregivers in Thai young children also indicated that packaged carbohydrate snacks and cookies were popular among children with ECC and parents often used snacks or sweets as a reward or tool for controlling their child's behavior[79].

Because cariogenic foods and their advertisements are readily available even in remote areas, a child can be exposed earlier and more frequently to cariogenic foods than was previously possible. The easy access to convenience stores and the increase in the number of small grocery shops in villages also promote cariogenic food consumption among young children [84].

2.3.2.4 Dental Attendance

The American Academy of Pediatric Dentistry (AAPD) and the American Dental Association(ADA) recommends that a child should visit the dentist within six months from the eruption of the first primary tooth and no later than 12 months of age [75, 85] especially in children of low socioeconomic status, and certain selected high dental caries risk subgroups [86]. Early dental attendance provides the dentist an opportunity to reinforce parental child rearing practices related to oral health and

gives dental examination in children at the early stage. Early carious lesion can be found since the first eruption in children, for the reason that Mutan Streptococci colonization has been detected in predentate. Therefore AAPD advises parents to early take their children to see the dentist.

2.3.3 Social and Environmental Factors

2.3.3.1 Socioeconomic status

Socioeconomic status (SES) was measured by human capital indicators such as income, education, or occupational status that offer advantages to individuals and families [53]. There is a consistent evidence to support a strong association between socioeconomic factors and caries prevalence [21]. Preschool children from low-income families are more likely to have caries. The high caries risk children who have been shown to live in more significantly deprived neighborhoods, have a tendency to have parents with lower educational levels, have high sugary foods and drinks and brush their teeth less frequently [87-91].

2.3.3.2 Oral health knowledge, attitude and self-efficacy of parents

Parental factors play a key role in ECC, these includes knowledge, attitude and self-efficacy in children's oral health practice of the parents. Studies have also indicated that mothers or caregivers with low awareness of children's oral health showed presence of dental plaque and dental caries in their children [3, 23, 92-96].

Moreover, parental attitude and belief has a significant association with their practice. Most of parents expressed that the primary teeth have less value and care of the primary dentition was unnecessary, in which they do not need to restore carious primary teeth [92, 93]. Although some of the mothers said that dental decay in primary teeth was very important, but they allowed carious teeth left untreated or extracted [94]. Most of them also believed that primary teeth will just fall out whether decayed or not and permanent teeth will erupt in the same place.

Self-efficacy of the parents influences the child's oral health care. Studies indicated that parents or caregivers who have confidence in cleaning their child's teeth often do the child tooth brushing [96, 97].

2.4 Strategies for Prevention of ECC

Traditionally, three approaches have been used to prevent ECC [25]. The first is a community-based strategy, mainly organized and provided by public health authorities such as education program and fluoridating the water supply. This approach also includes training personnel and development of community preventive programs in high-risk communities. The community-based intervention which aims to provide dental home visit were found feasible and useful for addressing oral health concerns in the community. The oral health education program involving health visitors has shown the significant improvement on mothers recall of advice regarding feeding and oral care practice for their children [98]. It is

found that anticipatory guidance initiated during the mother's pregnancy was successful in reducing the incidence of S-ECC in very young children [99] and home visits to mothers with infants, commencing at or soon after the time of the eruption of the first primary teeth, was shown to be effective in preventing the occurrence of ECC [100]. Evidences indicated that the more structured health education accompanied with the dental gift bag, the more the positive oral health behaviors among parents [101, 102]. One intervention demonstrated that parent who received free distribution of a trainer cup, fluoride toothpaste, toothbrush, leaflet, and given dental advice by health visitors on the vaccination visit were more likely to report adopting three positive oral health behaviors [101]. This finding is supported by another previous finding that given oral health education together with fluoride toothpaste and toothbrush can significantly increase in infant tooth brushing, compared to no intervention, and only education or toothbrush and toothpaste given [102]. Although, the oral health program involving health visitors is a good approach, it revealed the initial barrier that dental home visit take a lot of man power and time. Some thoughtful recommendations have been made about the collaboration with existing public health programs such as well-baby clinics and involving other providers such as physicians are common threads [103]. A novel motivational interactive approach or community participatory approach by mothers on their children’s oral health, and the causes and prevention of ECC are more

effective than those using traditional counseling to promote preventive behaviors in mothers of young children [45, 101, 104]. However, as the effectiveness to prevent the development of ECC was not warranted [45].

The second approach, professional measures, are based on the provision of oral examination and early detection of ECC, diet counseling, and preventive care by dental professionals in the office. The provision of oral examination and early detection of ECC should occur in the first years of a child's life [105]. Preventive care by dental professionals such as fluoride gel, fluoride foam and fluoride varnish applications showed the anti-caries effect on both permanent and primary dentition [106]. The fissure sealing of first permanent molars also has a caries-preventive effect [107].

The third approach, home-based strategy, involves the oral self-care at home such as maintaining good oral hygiene, appropriate dietary habits, and using fluoride toothpaste and fluoride supplements. Oral self-care at home such as using daily fluoride toothpaste is the most cost-effective way to prevent caries in childhood [108, 109]. The fluoride-based interventions for ECC prevention are currently the best available evidence was also highlighted by the two recent systematic reviews on the topic [105, 110]. Effectiveness of supervised tooth brushing with fluoride toothpaste in kindergartens has been reinforced in various community-based demonstration trials during the recent years, all reporting a 20-30% caries reduction [34, 69, 111].

Currently used strategies for oral health promotion among preschool children in Thailand [112] are 1) oral health education for pregnant women visited antenatal clinic (ANC) in district hospital and the one-to-one counseling by dental professions in the prenatal period and early postnatal time period when mothers are receptive to health information, and possible to intervene the transmission of pathogenic bacteria; 2) service-based approach including screening and surveillance for dental caries in preschool children, oral health education in well baby clinic (WBC) and toothbrush distribution for 9-and 18-month-old children, preventive treatment using fluoride varnish in 9-12-, 18-, 24- and 30-month-old children; 3) family-based approach includes the improvement of child care skill activities for parents and caregiver network forming; and 4) community-based approach which includes community participation through Tambon Administration Organization (TAO).

Various kinds of oral health promotions among school-age children were also launched in Thailand [112] such as; 1) Surveillance and oral health promotion programs in elementary schools were launched in 1985 to 2001. In the 1992-2001 periods, the children under three years of age were added as a target of oral health promotion programs, which included dental health education; 2) Implementing a fluoridated milk project in Thailand through the primary schools were launched in 2000. Since 1992 the Office of the Basic Education Commission (OBEC) has allocated a budget for school fluoridated milk under the ‘food supplement’ category for pre-

schools and primary grade 1-4 students in public schools. It is appropriate to include fluoridated milk as part of the food supplement program to prevent cavities in Thai children, especially in those locations with low levels of fluoride in the drinking water (less than 0.3 parts per million) and which have a high prevalence of dental caries. In support of this strategy, the Department of Health integrated fluoridated milk with its oral health promotion and school disease prevention programs to maximize the impact on improving the oral health of Thai children; 3) In 2005 the Dental Health Division of the Department of Health launched the project named "Learning from Research: Food and Tooth Decay" under the collaboration and support of the Thailand Research Fund (TRF), the Thai Health Promotion Foundation (Thai Health), and the National Health Foundation (NHF). The purpose of the project was to support the emergence of a new generation of researchers from the population of students. Food and tooth decay was also an issue of relevance and concern for school-age youth. One way of helping youth gain a more profound understanding of the extent of the problem was to conduct a research study of the prevalence of tooth decay among students. And then, students can scientifically explore the factors related to dental disease by looking at associations with risk behavior such as eating patterns of the students, types of foods consumed, and the relationship between these foods and tooth decay; 4) Oral health promoting school network, aims to create an environment that is conducive to dental health by pressuring

schools to adopt a "no soda" policy. This policy was conducted in Thai schools; and 5) Service-based approach including fissure sealant; The Universal Health Insurance programs, which was launched by National Health Security Offices (NHSO) in 2001, provides comprehensive oral health care to the population who had any form of health insurance. The comprehensive oral health care comprised restorations, extractions, pulp treatment, scaling and prophylaxis, and preventive treatments such as fluoride application for high-risk groups, and sealants. This program also offers pit/fissure sealants for children up to 12 years old free of charge [80].

A review in Thailand showed that the young children received the few dental services. Oral health promotion activities in the Well Baby Clinic (WBC) are not widely practiced. Small numbers of under-five-year-old children attended dental check-ups [113]. Unfortunately, oral health promotion for 0-3-year old children activities in ANC and WBC were not sustainable because of the lack of supply and limited dental health personnel [114].

Lekswat and Promchai [115] have demonstrated the effectiveness of the oral health promotion program for preschool children by applying a community empowerment principle in Lumphun, Thailand. This 12-month study showed the beneficial effects on oral hygiene indices of children, and successfully empowered individuals and families to take responsibility for oral hygiene and eating healthy foods. The strategies included a 'bottom-up planning' by parents, village health

volunteers, Local Administration Organization (LAO) members, and community representatives to improve children's oral hygiene and snack consumption, and to improve the environment in day-care centers and villages. The results showed that oral hygiene of children under 3 years old in the experimental group dramatically improved more than those in the comparison group. Six LAOs allocated budgets to provide milk and to improve the environment and quality of lunches in 20 daycare centers. The program had a direct effect on nannies and cooks in preparing lunch, and controlling snack consumption at daycare center.

Although several oral health promotion in young children had launched for decades, they were not sustainable or did not take attention because the caregivers did not realize the importance of caries free in their children. Some activities of oral health promotion consumed high expense and more time which became barriers of attendance. Therefore, the activity with easy procedure, less expense and possible to regularly practice such as tooth brushing should be considered for a greater impact on caries prevention in young children.

2.5 Fluoride

2.5.1 Role of fluoride in caries prevention: Remineralization

Demineralization involves the loss of calcium, phosphate, and carbonate. These minerals can be taken by surrounding plaque and be available for reuptake into crystal voids in demineralized enamel to produce net mineral gain in

remineralization process [40, 59, 116]. The fluoride action in dental caries inhibition comprises three mechanisms: inhibition of demineralization, promotion of remineralization and interference with bacterial growth and metabolism [117]. Fluoride in plaque and saliva inhibits the demineralization of sound enamel and enhances the remineralization of demineralized enamel. When cariogenic bacteria metabolize carbohydrates and produce acid, fluoride is released from dental plaque in response to lowered pH at the tooth surface. The released fluoride and the fluoride present in the saliva are precipitated, along with calcium and phosphate, to create an improved enamel crystal structure. This improved structure is more stable, less acid soluble apatite. Fluoride is more readily taken up by demineralized enamel than sound enamel [118]. Fluoride also inhibits dental caries by disturbing the activity of cariogenic bacteria by inhibiting the carbohydrates metabolization and adhesive polysaccharides production [119]. In laboratory studies, Streptococcus mutans produces less acid in an environment with low fluoride concentration [120, 121].

In the past on fluoride research, investigators hypothesized that fluoride inhibited dental caries only at pre-eruptive phase, before the tooth erupts into the mouth [122-124]. Over the years, the laboratory and epidemiologic research indicated better understanding on dental caries prevention of fluoride. Post-eruptive effect of fluoride has gained greater popularity than pre-eruptive effect. Fluoride

works primarily after teeth have erupted, especially when small amounts are maintained constantly in the mouth [125].

There are strong evidences that the use of fluorides in several forms can prevent tooth caries in both children and adults [25, 27, 28, 68, 69, 71, 126-132]. The substantial reductions in dental caries in developed countries in the last few decades [133-135], attributed primarily to the widespread use of both systemic and topical fluoride.

Water fluoridation was introduced to use for caries prevention in the 1940s. The industry of systemic fluoridation, public campaigns and advertisements became popular mostly in western world in 1960s and 1970s [136]. It showed that water fluoridation was the important measures for the control of caries at the community level [137] and due to this the expense of dental restoration was reduced [138]. All infants and toddlers, regardless of their risk status, could benefit from water fluoridation. Water fluoridation is highly effective in preventing caries in primary teeth (40-60%), especially in children from low socioeconomic groups [25]. Water fluoridation provides the only mean of prevention that does not require a dental visit and parental motivation. Although children received fluoride from other source, studies (still) showed that water fluoridation was effective in reducing dental caries by 20-40% [139].

The Environmental Protection Agency/Department of Health and Human Services' recommendation for optimizing community water supplies to 0.7 ppm F is instituted [140]. The level of fluoride concentration varies and depends on the daily maximum temperature in each country which indicates the daily water consumption. The study in Thailand by Prateep et al (1984) showed that the optimal level of fluoride in drinking water for Thais is 0.5 ppm [141].

The fluoride toothpaste were established in 1980's [136]. Many publications confirmed that children should receive one form of systemic fluoride and appropriate forms of topical fluoride in 1990's [136]. Over the years, the topical use of fluorides (e.g., fluoride toothpastes, mouth rinses, gels, and varnishes) has gained greater popularity than the systemic use of fluorides (e.g., fluoride tablets and the addition of fluoride to drinking water), with fluoride toothpastes being the most widespread form of topical fluoride usage [142].

2.5.2 Benefit and risk of fluoridated toothpaste

The beneficial effects of topical fluoride agents have been examined in a series of Cochrane systematic reviews [31, 108, 143-148]. The maximum reduction in dental decay is achieved when fluoride is available pre-eruptive (systemically) to incorporate all the stages of tooth formation and post-eruptive (topically) at the tooth surface. Topically applied fluoride provides local protection on the tooth surface when teeth erupt into an environment with low concentrations of ionic

fluoride [31]. Therapeutic use of fluoride for children should focus on regimens that maximize topical contact, preferably in lower-dose but higher frequency approaches [31]. Fluoridated toothpaste is a good form to reach therapeutic regimens. Fluoride in toothpaste is taken up directly by dental plaque[149] and demineralized enamel [150]. Brushing with fluoride toothpaste increase the fluoride concentration in saliva 100- to 1,000-fold; this concentration returns to baseline levels within 1–2 hours [151]. Some of this salivary fluoride is taken up by dental plaque. The fluoride concentration in saliva and plaque can increase during regular use of fluoride toothpaste [149].

In *vitro* and in situ studies addressed the dose response between fluoride toothpastes and remineralization [152, 153]. The result showed that calcium uptake during remineralization was increased in the F groups compared to non-F group. In the F groups, it was shown that the high-fluoride groups were more prone to remineralization than low-fluoride groups [152]. While some studies evaluating the inhibition in demineralization in *vitro* showed no significant effect among 500 ppm sodiumfluoride (NaF) toothpaste with xylitol, 500 ppm NaF without xylitol and 1000 ppm monofluorophosphate (MFP), but 1000 ppm group had a tendency to inhibit demineralization more than other two groups [154, 155].

Modifying the low fluoride toothpaste composition could increase its cariogenic property. It has been shown that pH considerably influences F diffusion in

enamel. Researchers discovered that lowering the pH enhances the tendency for calcium fluoride (CaF2) formation on apatite substrates [152, 153]. Therefore, acidified toothpaste with low F concentration was developed and expected that it could maintain the caries prevention ability and reduce the amount of F ingested by preschool children. Evaluation on the effect of low fluoride toothpaste (412 and 550 ppm F) compare with 1,100 ppm in vitro study using a pH cycling model to determine the ability of these products to reduce enamel demineralization was examined. The 550 ppm F acidified toothpaste provided an equivalent mineral loss and had the same anticariogenic action as the 1,100 ppm F [156].

Studies have reported that fluoride toothpaste reduces caries experience among children by 15%–30% [27, 108, 109, 157]. Recommendations for the use of fluoride toothpaste in young children have been a controversial issue. Evidences from Cochrane systematic review, 66 studies in the permanent dentition and 6 studies assessed the effects of fluoride concentrations on the primary dentition which supports the international standard level of 1000 ppm fluoride for younger children and up to 1500 ppm for older children. The caries preventive effect of fluoride toothpaste increased significantly with higher fluoride concentrations. It was 23% (95% credible interval (CrI) 19% to 27%) for 1000/1055/1100/1250 ppm of fluoride concentrations and 36% (CrI 27% to 44%) for toothpastes with a fluoride concentration of 2400/2500/2800 ppm, but concentrations of 440/500/550 ppm

fluoride and below showed no statistically significant caries prevention effect comparing to placebo [27]. Comparing 1000 ppm and 250 ppm fluoride toothpaste, it revealed evidence of a statistically significant benefit for caries prevention 14% (CrI 1% to 26%)[27]. This significant benefit was also found in the two reviews comparing fluoride toothpastes at these concentrations [157, 158]. There was no statistically significant difference benefit of caries preventive effect of 1000 ppm fluoride toothpaste compared to 500 ppm fluoride toothpaste (8%, CrI -10% to 25%) or of 500 ppm fluoride toothpastes compared to 250 ppm fluoride toothpastes (6%, CrI -14% to 26%) [109].

A possible adverse effect associated with the use of fluoride toothpaste is the mottling of permanent teeth due to the swallowing of excessive fluoride by young children with developing teeth [159]. The dental fluorosis varies from typically mild white patches on the teeth to severe mottling of the teeth with brown staining. An evidence suggested that severity of fluorosis depends on the amount and duration of exposure [29]. During the first 4 years of life, children who were exposed to excessive fluoride will develop dental fluorosis in the maxillary permanent central incisor [160].

Although the mild forms of dental fluorosis do not establish a public health problem, it is important to balance the beneficial and harmful effects of topical fluoride therapies. The meta-analyses does not only showed that fluorosis did not have significant association with frequency of tooth brushing and the amount of

fluoride in toothpaste, but also showed the association between fluorosis and fluoride level of toothpaste used. There were evidences that a child who used fluoride toothpaste under 12 months of age was associated with an increased risk of fluorosis [28, 31].

Two randomized control trials compared the effect of giving children different levels of fluoride toothpaste. They found that the use of higher-concentration fluoride toothpaste (> 1000 ppm) was significantly associated with an increase risk/rate of fluorosis. One study compared 550 with 1000 ppm fluoride [161] , and the other compared 440 with 1450 ppm fluoride [162]. Both studies were in non-fluoridated areas and used Thylstrup and Fejerskov (TF) index score [31, 161, 162].

Because the high level of fluoride (1000 ppm or more) in toothpaste associates with an increased risk of fluorosis in children under 6 years of age, a risk-benefit decision needs to be discussed with parents/guardians [28]. Unfortunately, the study effect of ECC prevention of fluoride toothpaste among primary dentition has not been widely done and most of them compare fluoride toothpastes together with oral health education against no intervention [32-34]. There were only two studies that used placebo toothpaste [111, 163] and another two studies in China using non-F toothpaste in control group [34, 69]. Using no intervention instead of using placebo as control group may overestimate the caries prevention effect. Moreover, there were too few trials that compare the effect of low and standard

fluoride toothpastes on reduction of caries in the primary teeth of preschool children [35, 36].

2.6 Other substances contained in toothpaste

2.6.1 Xylitol

Xylitol is a five-carbon sugar polyol which known since a century ago. It is found naturally in vegetables, fruit and berries and is artificially manufactured from birch and beech wood [164]. Xylitol is used in foods, pharmaceuticals, and oral health products such as chewing gums, toothpastes.

Xylitol have potential antibacterial activity against mutans streptococci (MS) in plaque and saliva by disrupting their energy production processes and leading to cell death. Furthermore, a certain levels of xylitol reduces the adhesion of the MS to the tooth surface and also reduces their acid production potential [165].

There are numerous clinical studies evaluating the effectiveness of xylitol. Chewing gum has been the predominant modality for xylitol delivery in clinical studies[166]. Several studies of children who have consumed xylitol for three weeks or more have reported MS levels reduction in saliva and plaque [167-170]. However, few studies have not shown a long-term reduction of MS levels in saliva and plaque [171, 172]. Increasing salivary flow and pH by chewing a gum containing xylitol may be the mechanical action to reduce caries [173]. Moreover, chewing gum accelerates the processes of rinsing away acid and uptake of beneficial calcium phosphate

molecules to remineralize tooth enamel [174]. American Academy of Pediatrics (AAP) recommended dose for dental caries prevention is 3–8 grams/day of chewing xylitol gum in children more than four years of age[175].

Using toothpaste formulations with 10 percent xylitol (dose of 0.1 g/brushing) helps caries control in children by decreasing MS colonies in saliva and increasing pH value [176-178]. It has a positive effect on the quality of the oral environment. Synergistic use of small doses of xylitol in fluoride toothpaste might be useful to improve the cariostatic effects and enhance the remineralization [179]. Two studies revealed that combination of xylitol and fluoridated toothpaste might be more effective in enhancing remineralization than fluoride alone. They showed that fluoride toothpaste containing 10% xylitol resulted in a 13% reduction in caries increment for dmfs [177, 178]. In contrast, children who used fluoride plus 3% xylitol toothpaste or fluoride toothpaste without xylitol for 3 years revealed no difference in caries progression. [180]. Therefore, the efficacy of xylitol in reducing the incidence of caries and arresting the progression of caries remains unclear [181-183]. It is possible that xylitol-containing toothpaste may not contain the necessary therapeutic level. It is the only sweetener or adequate labeling [166].

In Thailand, there are many types of toothpaste for children that contain both xylitol in addition to 500 ppm fluoride and xylitol alone. Most toothpaste has

5% xylitol. There is no 10% xylitol in toothpaste for children. In addition, the effectiveness of 5% xylitol in the remineralization of early carious primary tooth lesions is still unresolved.

2.6.2 Calcium phosphate

Calcium and phosphate ions are one unit cell of the hydroxyapatite enamel structure. Hence, supplying adequate amount of available calcium and phosphate can enhance remineralization [184]. Two calcium phosphate compounds that can induce remineralization have been developed. First, casein phosphopeptide–amorphous calcium phosphate (CPP–ACP) consists of a product based on milk protein: casein phosphopeptide (CPP). This product stabilizes amorphous calcium phosphate (ACP) and forms CPP-ACP complexes, which increase the calcium and phosphate in dental plaque and lead to prevent demineralization and promote remineralization [185]. CPP–ACP is used as a professional dental product (GC Tooth Mousse). Moreover, CPP–ACP containing 900 ppm fluoride is available as CPP–ACPF paste (MI Paste Plus). Several in vitro studies, animal and human in situ experiments including clinical trial, on CPP–ACP indicated anticariogenic activity [186-189]. Second, functionalized tri-calcium phosphate (*f*TCP) is a modification of tri-calcium phosphate (TCP) which is produced from beta-tricalcium phosphate with sodium lauryl sulfate or fumaric acid by the ball milling[190]. *f*TCP, containing 5% sodium fluoride, calcium and phosphate, was introduced for professional use (Clinpro Tooth Cre`me; 3M ESPE,

Saint Paul, MN, USA). This compound can supply calcium and phosphate in saliva and deliver more fluoride and calcium ions to the enamel surface. However, the finding of Cochrane et al. showed that CPP released more calcium and fluoride than *f*TCP [191].

Although studies have indicated that calcium phosphate compounds has a remineralization effect in both in vitro, in situ and randomized clinical trial studies [192-197], few studies did not show any additional effect of calcium phosphate compounds on the remineralization of artificial caries when used as a supplement to regular fluoride toothpaste [198-200]. It is still unclear whether these products are better than fluoride toothpaste and there is no study of remineralization effect of the triple calcium phosphate compounds without fluoride.

CHAPTER III
RESEARCH METHODOLOGY

This chapter describes research design and setting, population and sample selection, research instruments, ethical consideration, intervention implementation, data collection and data analyses.

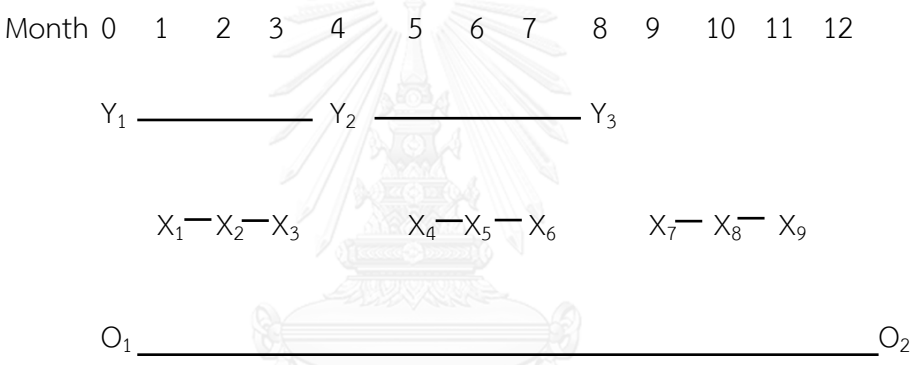
3.1 Research design and setting

3.1.1 Research design

This randomized, double blind field experimental study was conducted to evaluate the effectiveness of different concentration of fluoride toothpaste in preventing ECC in a group of Thai infant and toddler comparing to non-fluoride containing xylitol toothpaste. The program development was based on fundamental data from the feasibility study. All of the primary caregivers received an oral health education with hands-on tooth brushing practice for ECC prevention. The primary caregivers were divided into one comparison and two experimental groups. The experimental groups received different concentration of fluoride toothpaste (1000 ppm and 500 ppm). The comparison group received non-fluoridated toothpaste with xylitol and triple calcium phosphate for their child tooth brushing. Three different fluoride toothpastes with three different color packages were randomly assigned into each group. Subject assignment into three groups was done by one investigator: Group A: toothpaste containing 1000 ppm fluoride as Sodium monofluorophosphate

(Systema, Lion Corporation, Thailand) (1000ppm); Group B: toothpaste containing 500 ppm fluoride as Sodium monofluorophosphate (Kodomo, Lion Corporation, Thailand) (500ppm); and Group C: toothpaste containing 5% Xylitol, 2.1% sarcosinate, triple calcium, and phosphate (Pureen, U.S. Summit company, USA) (Xylitol). The data of dental caries were compared among three groups at baseline and after 12 months of the implementation of program.

The research design is presented in the following diagram.



Y_1 refers to the oral health education sessions provided to the primary caregiver and hands-on tooth brushing practice. Brushing kits were delivered to each caregiver (month 0, 4 and month 8).

X_1- X_9 refers to the caregivers who received home visits every month (conducted by Village Health Volunteer) to encourage the caregivers to perform child tooth brushing at a regular frequency.

O_1, O_2 refers to the data collection of child's oral health status, child feeding practices and child's oral cleaning practices by oral examination and questionnaire-guided interview, respectively.

3.1.2 Research setting

The site of this study was located in U-Thong sub district, U-thong district, Suphan Buri Province. U-thong is a district in the western part of Suphan Buri Province, central Thailand which is subdivided into 13 sub districts, 151 villages. U-thong sub district has 19,412 populations and the drinking water in this area contains 0.1 to 0.5 ppm F. Prevalence and severity of dental caries in this area is higher than the national level [44]. The caries prevalence of 3 years old children of U-Thong district in 2012 was 69.7 % and the average dmft (decayed, missing, filled teeth) score was 4.3. Preschool children in this group had a tendency to have parents with low educational levels, had high sugary foods and drinks and brush their teeth less frequently.

3.3 Research Instruments

Two types of instrument, intervention instruments and data collection instruments, were used in this study.

3.2 Population and sample

The study population comprised of primary caregivers and their 9- to 18-month-old child who lived in 13 villages of U-thong sub district, U-thong district. All of the primary caregivers who agree to participate were recruited into the study.

Random allocation

Considering the quality and validity of the study, minimizing the selection bias was prepared by random allocation. Concerning the contamination, the geographical cluster sampling was employed by village. Thirteen villages were clustered into three clusters. Labeling toothpaste A, B or C, was prepared in white opaque sealed envelope. Three toothpastes were randomly assigned to each by drawing lots in white opaque sealed envelope.

Inclusion criteria

Samples were recruited with the following criteria: 1) Being a primary caregiver of 9- to 18-month-old child (born from December 2011–September 2012); 2) Being capable to read Thai indicated by having attended school for at least four years; 3) Inform consent Obtained and 4) Having a healthy child without systemic disease or enamel hypoplasia .

Exclusion criteria

Subjects were excluded if 1) they planned to move out from the area within a year; 2) they did not use the assigned toothpaste and/or brushing their children's teeth for less than 3 times a week.

Sample size

This study compared the caries status before and after implementation among experimental and comparison groups. The minimum sample size for each group was estimated by the following formula [201] based on the effect of parental brushing on caries increment in Thai children at the same age in a previous study [6].

$$n = \frac{(Z_{(1-\alpha/2)} + Z_{(1-\beta)})^2 \sigma^2 (r+1)\,[1+(T-1)\rho]}{v^2 rT}$$

n = Sample size for each group

r = Ratio of experimental and comparison group

$Z_{(1-\alpha/2)}$ = Standard score at 95% confidence level ($1-\alpha$)

$Z_{(1-\beta)}$ = Standard score at 80% power ($1-\beta$)

σ = Standard deviation of score

T = Number of repeated measurement

ρ = Correlation coefficient among scores of repeated measurement

v = Difference of mean score among groups

In this study, there were two experimental groups and one comparison group, then the ratio of experimental and comparison group (r) = 2. This study was designed to collect data at Month 0 and Month 12, then number of repeated measurement = 1. From a previous study [6], the difference in mean dmfs scores between groups was 15.3. 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 received hands-on tooth brushing practice, we expected our mean scores difference to be less than that of the previous research [6]. The difference of 5 between the mean incremental dmfs was expected. Standard deviation in a previous study was 11.13. When α = 0.05; $Z_{(1-\alpha/2)}$ = 1.96 and β = 0.20; $Z_{(1-\beta)}$ = 0.84. The correlation coefficient among the repeated measured scores was 0.5. The formula for estimating minimum sample size was:

$$n = \frac{(1.96+ 0.84)^2(11.13)^2 (2+1) [1+(1-1)(0.5)]}{(5)^2(2)(2)}$$

$$= \frac{(2.8)^2 (11.13)^2 (3) (1)}{(5)^2(2)(2)}$$

$$n = 29.13$$

The minimum sample size for each group was 30. Compensating for an estimated 50% drop-out rate, the total number of subjects comprised of 60 primary caregivers for each group.

Sample recruitment was on a voluntary basis after being informed by the researcher from February to April 2013. All subjects from the six health care centers located in 13 villages were equally divided into three clusters based on their village areas to eliminate the risk of the subjects sharing different toothpastes in the nearby village. Then, the toothpaste was randomly assigned to each cluster. Each cluster composed of 3 villages (60 dyads using 1000 ppm F toothpaste), 5 villages (61 dyads using 500ppmF toothpaste) and 5 villages (62 dyads using non-fluoridated toothpaste with xylitol and triple calcium phosphate).

3.3.1 Intervention instruments

Intervention instruments composed of health education media, supporting instruments and a practice guideline. Details are given as follows:

3.3.1.1 Health education media: brochure

A brochure with information for performing proper child's oral cleaning with primary teeth was prepared. The brochure content composed of information as follows: 1) Role and importance of primary dentition; 2) Child's oral cleaning: importance of oral cleaning, how to brush the child's teeth, appropriate amount of toothpaste, appropriate frequency of oral cleaning, how to check the quality of the

child's teeth cleaning; 3) Cause of dental caries with easy-to-understand information and risk behavior specifications 4) Impact of dental caries: signs and symptoms of ECC.

3.3.1.2 Supporting instruments

Supporting instruments for increasing the expected outcome and eliminating the barriers were provided to each subject at the end of the first session. The supporting instrument includes 1) Clean cloth for wiping excessive toothpaste: muslin cloth which is three inches wide and four inches long; 2) Toothbrush: a small size toothbrush for children; 3) Plastic cups; 4) A round ended slant straw for plaque checking; 5) Small basket for keeping cloths, toothbrush and toothpaste; and 6) A leaflet for the method of tooth brushing.

3.3.1.3 Practice guidelines

The practice guideline developed in this study aimed to direct profession to perform the same procedure. The practice guideline consisted of three different parts (see Appendix A).

3.3.2 Data collection instruments

Questionnaire-guided interview, ECC recording form and oral hygiene recording form were developed for data collection and evaluating the intervention effectiveness. Details are as follows:

3.3.2.1 Questionnaire-guided interview

Newly developed questionnaire-guided interview for the primary caregiver consists of two sections (Appendix B and C).

Section 1: Baseline variables: The primary caregiver's data comprised of gender, age, relationship to the child, occupation, marital status, educational attainment, and family income. The child's data comprised of gender, age, birth order, and history of illness and medication.

Section 2: Child's oral health care practices: A series of questions ask to explore the behaviors related to the ECC including commencement of child's tooth cleaning, method of tooth cleaning, time of day and frequency of child's tooth cleaning, type and amount of toothpaste, type and frequency of milk feeding, type of sweetener in bottle, type and frequency of snack between meals, starting of supplementary food, type of drinking water, water sipping after milk feeding, and manner of putting the child to bed (with or without the bottle in his/her mouth).

3.3.2.2 ECC recording form

Dental caries of children were recorded in ECC recording form (see details in Appendix D). Number of erupted teeth and status of the teeth: sound teeth, non cavitated caries, cavitated caries, filling teeth and missing teeth were recorded using dmfs index (see details in Appendix E). To differentiate between plaque and white lesions/ fluorosis, tooth surfaces were cleaned with wet gauze pads before caries

examinations. Typical carious white lesions/non cavitated caries appear rough, opaque and arch, banana or kidney shaped on enamel surfaces, reflecting the retention of plaque along the curvature of gingival margin. By contrast, mild cases of dental fluorosis often appear smooth and shiny white horizontal lines running across the 'perikymata', a term referring to transverse ridge on the surface of the tooth, which correspond to the incremental lines in the enamel known as Striae of Retzius [202]. The intra-examiner reliability was measured using Cohen's kappa by examining twenty children twice in each survey. The kappa value for dmfs was 0.87.

3.3.2.3 Oral hygiene recording form

Information pertaining to teeth cleanliness was recorded in the Oral Hygiene Recording Form at 12 month. The oral hygiene recording form recorded the existence of the child's dental plaque for calculating the debris index (see details in Appendix F) and verified existence of the child's gingivitis (see details in Appendix G). 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 [203]. A blunt explorer was used to scrape the plaque from incisal third, middle third and lastly cervical third of labial of buccal and lingual surfaces to record the debris index accordingly. The kappa values for debris index, and gingival index were 0.61, and 0.89, respectively.

3.4. Ethical consideration

Both prior to and during the study implementation, ethical consideration was of major concern. Prior to the study implementation, the ethical approval from the Human Research Ethics Committee of the faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand was achieved: the ethical study No. HREC-DCU 2013-018 (see Appendix I). During the implementation, verbal persuasion to participate into the study voluntarily was explained along with the benefit of enrolling in this study. Additionally, the subjects were assured that their participation was strictly protected in terms of confidentiality and that there was no risk because the study results were anonymous and summarized descriptions. Informed consent was obtained from all participating parents or legal guardians (see Appendix H).

3.5 Research implementation steps and data collection

3.5.1 Preparation step

3.5.1.1 Obtain approval from the Ethical Committee;

3.5.1.2. Develop research instrument;

3.5.1.3. Seek villages as research setting to carry out the study;

3.5.1.4. Develop a practice guideline;

3.5.1.5. Meet and train of Village Health Volunteers (VHVs) for implementing the study following practice guidelines;

3.5.1.6. Set up a random assignment for the subjects into three groups according to type of fluoride toothpastes

3.5.2 Oral health education session and Hands-on tooth brushing practice

3.5.3 Intervention implementation

After obtaining approval from the Human Research Ethics Committee of the faculty of Dentistry, Chulalongkorn University, the program was implemented as follows:

a) At the first visit, six main activities were carried out by the dentist and/or research assistant as follows.

1. Each caregiver received information on the study design, and confidentiality protection was reassured from the researcher or the research assistant.

2. Then, the caregivers received a questionnaire-guided interview on the child's feeding and oral health care practices.

3. Then each child's oral examination was conducted in a knee-to-knee position by a pediatric dentist using a ball-ended probe and a mouth mirror under natural light. To acquire inter- and intra-examiner reliability assessment, using 20 subjects presenting with carious lesion covering all categories will be conducted.

4. A 30-minute session of oral health education were performed to the primary caregivers to emphasized the correlation between the growth and development of the child and the ECC, the identification of plaque, progression of white lesions/ non cavitated caries into cavitated lesions. They were informed that white lesions could be reversed by brushing with F toothpaste.

5. A 15-minute session of hands-on tooth brushing practice was provided to the primary caregivers by the researcher with assistance of the VHVs which were trained for tooth brushing technique by two dental personnel prior to the program commencement.

6. At the end of the first visit, 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 handed to each caregiver.

The monthly home visits were provided by the VHVs to encourage the caregiver to do the child's brushing at a regular frequency.

b) On the second and third visit, four main activities were carried out by the dentist and/or research assistant. These were the following:

1. After general greeting, tooth brushing exercise with a video and model was carried out for caregivers.

2. Meeting with the dentist and/or research assistant, caregivers demonstrated their child's tooth brushing, followed by dentist and/or research assistant's feedback.

3. A child's toothbrush and toothpaste were again given before leaving the second and third session.

4. An oral examination was performed to detect the cavitated lesions which require treatment.

c) At the last visit, two main activities were carried out by the dentist and/or research assistant, as follows:

1. After general greeting, each caregiver received the same questionnaire-guided interview on the child's feeding practices and oral health care practice for the second time.

2. Then each child's oral examination was again conducted by the same pediatric dentist for the second time.

3.5.3 Data collection

The tooth brushing program was implemented from May 2013 to May 2014 at 6 located settings. Data were collected twice; at baseline (Month 0; the first visit) and at one year (Month 12; the fourth visit) as follows:

A) Questionnaire-guided interview was used to collect data on:

a. Sociodemographic data

b. Child oral health care practices

c. Child fluoride usage

d. Child feeding practices

B) ECC recording form was completed by the pediatric dentist to collect data on:

a. Number of erupted teeth

b. Status of erupted teeth; dmfs index with modification [204].

C) Oral hygiene recording form was completed by the pediatric dentist to collect data on:

a. Clinical status of the child's gum

b. Child oral hygiene status

3.6 Data Analysis

Data was analyzed by using the SPSS statistical package version 17.0. Statistical analyses include the following:

3.6.1. Variable coding and scoring

A. Sociodemographic variables measured as categorical variables were coded as follow:

a) Gender was coded as 1 for male and 2 for female.

b) Relationship to child was coded as 1 for being the child's parents, 2 for being the child's grandparents and 3 for being the child's relatives. This variable was collapsed into 2 categories as 1 for parent and 2 for grandparents**/** relatives.

c) Child rearing experience was coded as 1 for having child rearing experience and 2 for never having child rearing experience.

d) Child's gender was scored as 1 for male and 2 for female.

e) Occupation was coded as 1 for unemployed, 2 for employed./ factory worker/ farmer, 3 for Government officer/ office worker and 4 for owner/ merchant. This variable was collapsed into 2 categories as code 1 for less stable occupation collapsed from code 1-2 and code 2 for more stable occupation collapsed from code 3-4.

f) Marital status was coded as 1 for married and 2 for single or divorce.

g) Highest education level was coded as 1 for primary school or less, 2 for high school or more.

h) Family income was coded as 1 for less than 10,000 baht per month, 2 for 10,000-14,999 baht per month, 3 for 15,000 baht or more.

B. Child oral care practices variables were coded and scored as follows.

a) People who usually or mostly takes care of the child was coded as 1 for being the child's parents, 2 for being the child's grandparents and 3 for being the child's relatives.

b) Commencement of brushing child's mouth during first tooth eruption was coded as 1 for commencement of brushing and 2 for never commencement of brushing.

c) Tooth brushing was coded as 1 for having tooth brushing and 2 for never having tooth brushing

d) Frequency of child's tooth brushing per week was coded as 1 for 1-2 days per week, 2 for 3-5 days per week, 3 for 3-5 days per week.

e) Frequency of child's tooth brushing per day was coded as 1 for less than twice per day, 2 for twice or more.

Frequency of child's tooth brushing per week and per day were collapsed into 4 categories follow as: code 1 for 0-2 days/ week, code 2 for 3-5 days/ week, code 3 for 6-7 days/ week and < 2 times/day, code 4 for 6-7 days / week and ≥2 times/day.

f) People who clean child's mouth was coded as 1 for being the child's parents, 2 for being the child's grandparents and 3 for being the child's relatives. This

variable was collapsed into 2 categories as 1 for parent and 2 for grandparents/ relatives.

C. Child fluoride using variables were coded and scored as follows:

a) Amount of toothpaste for tooth brushing was coded as 1 for not using toothpaste, 2 for smaller than a green pea, 3 for the size was that a green pea, 4 for half of a toothbrush and 5 for as long as a toothbrush.

b) Type of toothpaste was coded as 1 for toothpaste for children, 2 for toothpaste for adult.

c) Receiving fluoride tablet was coded as 1 for never receiving fluoride tablet, 2 for receiving fluoride tablet less than 3 days/week, 3 for receiving fluoride tablet 3-5 days/week and 4 for receiving fluoride tablet every day.

d) Water that children drink regularly was coded as 1 for bottled water, 2 for water contains in a gallon, 3 for rain water and 4 for tap water.

D. Child feeding practices variables were coded and scored as follows.

a) Type of milk feeding was coded as 0 for not being fed, 1 for breast feeding, 2 for breast milk in bottle, 3 for UHT pasteurized milk (flavorless), 4 for UHT pasteurized milk (sweetened), 5 for powdered milk (flavorless), 6 for powdered milk (sweetened), and 7 for sweetened condensed milk.

b) Frequency of breast feeding (per day) was coded as 0 for not breast feeding, 1 for less than 3 times/day, 2 for 3-5 times/day, 3 for 6-8 times/day, 4 for more than 8 times/day, 5 for other and filled specify.

c) Frequency of UHT pasteurized milk/powdered milk (sweet flavor) (per day) was coded as 0 for not drinking sweet flavored milk, 1 for less than 3 times/day, 2 for 3-5 times/day, 3 for 6-8 times/day, 4 for more than 8 times/day, 5 for other and filled specify.

d) Frequency of UHT pasteurized milk/powdered milk (flavorless) (per day) was coded as 0 for not drinking flavorless milk, 1 for less than 3 times/day, 2 for 3-5 times/day, 3 for 6-8 times/day, 4 for more than 8 times/day, 5 for other and filled specify.

e) Sipping water after milk feeding was coded as 0 for never sipping water after milk feeding, 1 for sometimes and 2 for every time.

f) Frequency of falling asleep with bottle/ at the breast was scored as 1 for not falling asleep with bottle, 2 for 3 times or less and 3 for 4 times or more.

g) Night-time bottle feeding was scored as 1 for having night-time bottle feeding and 2 for never having night-time bottle feeding.

h) Filling sweet substances in bottle of milk was coded as 0 for having filled sweet substances and 1 for not having.

i) Child get juice/soft drink/sweet liquid from sucking on the bottle was coded as 0 for sucking on the bottle and 1 for not sucking.

j) Frequency of snacking between meals was scored as 0 for never or one time, 1 for twice a day, 2 for 3 times/day or more.

k) Type of snack between meals was coded as 0 for Never, 1 for taking cake/cookies/bread, 2 for packaging snack/crisps/crackers, 3 for yogurt, 4 for toffee/candy, and 5 for soft drink.

E. Child oral hygiene was measured as a categorical variable from gingival index and debris index (clean or unclean status). Qualitative changes in the gingiva was scored as 0 for having normal gingiva and 1 for having mild inflammation (gingival index, see Appendix G); the cleanliness of tooth was measured by recording the existence of white plaque on the teeth (debris index, see Appendix F). Clean status was scored as 0 when no white plaque was observed on the teeth (debris index score = 0). Unclean status was scored as 1-3 when white plaque was observed on the teeth (debris index score)

3.6.2. Statistical tests

3.6.2.1. Sociodemographic characteristics were analyzed using descriptive statistics. Categorical variables such as gender, marital status, highest education level, occupation, family income, relationship to child, child rearing experience, child's gender, birth order of the child, feeding practice and oral cleaning of children were analyzed and reported in frequency and percentages. Continuous variables such as age of the primary caregiver, child's age, dmfs/dmft, incremental dmfs/dmft, gingival index, oral hygiene index were analyzed using mean and standard deviation.

3.6.2.2. Test of homogeneous characteristics of the dropout and remaining groups were analyzed by using the Chi-Square test or the Fisher's exact test for categorical variables (such as gender, marital status, highest education level, occupation, family income, relationship to child, child-rearing experience, child's sex and birth order of the child) and T-test for continuous variable such as age. While, the three sample groups were analyzed by using the Chi-Square test for categorical variables and Analysis of variance (ANOVA) for continuous variable such as age.

3.6.2.3. Outcome variables were analyzed using Chi-square test and Analysis of covariance (ANCOVA). The variables which were not part of the main experimental manipulation but might have an influence on the dependent variable were classified as covariates and they were included in the ANOVA analysis. One-way

ANCOVA was used to analyze the difference in average of erupted teeth, mean of dmfs/dmft, incremental dmfs/dmft, mean of gingival index, mean of oral hygiene index among three groups of children which using toothpaste with different fluoride concentration at baseline and after 12-month program implementation. The Chi-Square test was used to compare the oral health habits among three groups and compare the oral health habits before intervention and after 12-month.

CHAPTER IV
RESULTS

This chapter presents the evaluative results of the effectiveness of tooth brushing with 1000 ppmF, 500 ppmF and non-fluoride containing xylitol toothpaste among infant and toddler for ECC prevention. Presentation of the result composed of three main parts. The first part shows the description of the sample recruited in the study. The second part presents the difference in variables that includes dental caries status, oral hygiene status and oral health habit of children among three groups at baseline. The third part presents the difference in these variables among three groups at 12 months and the result of the hypothesis testing. The details are the followings:

4.1 Sociodemographic characteristic of sample

At baseline, there were 60, 61 and 62 primary caregivers and children in the 1000ppm group, 500ppm group and xylitol group, respectively. 41 primary caregivers and children (1000 ppm group: n=16; 500 ppm group: n=11, Xylitol group: n=14) lost to follow-up due to moving out (n=12), not attending appointments (n=27), and 2 subjects became seriously ill. Dropout rate was observed as 26.7%, 18.0% and 22.6% in 1000ppm group, 500ppm group and xylitol group, respectively. Details were illustrated in Table 1

Table 1 Number of participating primary caregivers at each visit by study group

Groups	1st visit, Month 0 (baseline)	2nd visit, Month 4 (after 1st session)	3rd visit, Month 8 (after 2nd session)	4th visit, Month 12 (after 3rd session)
1000 ppm	60	37	43	44
500 ppm	61	38	43	50
xylitol	62	38	38	48

11 primary caregivers and children were excluded from the analysis because the child's tooth brushing frequency was less than 3 times per week and/or the assigned toothpaste was not used in the child's tooth brushing (1000ppm group: n=7; 500ppm group: n=3; xylitol group: n=1). Therefore, a total of 131 primary caregivers and children (1000ppm group: n=37; 500ppm group: n=47, xylitol group: n=47) were included in the final analysis. As the numbers of remaining primary caregivers and children in the 1000ppm group, 500ppm group and xylitol group were more than the estimated minimum sample size, the numbers of sample size were adequate for analyzing by one-way ANOVA. The distribution of the dropouts is presented in Figure 2

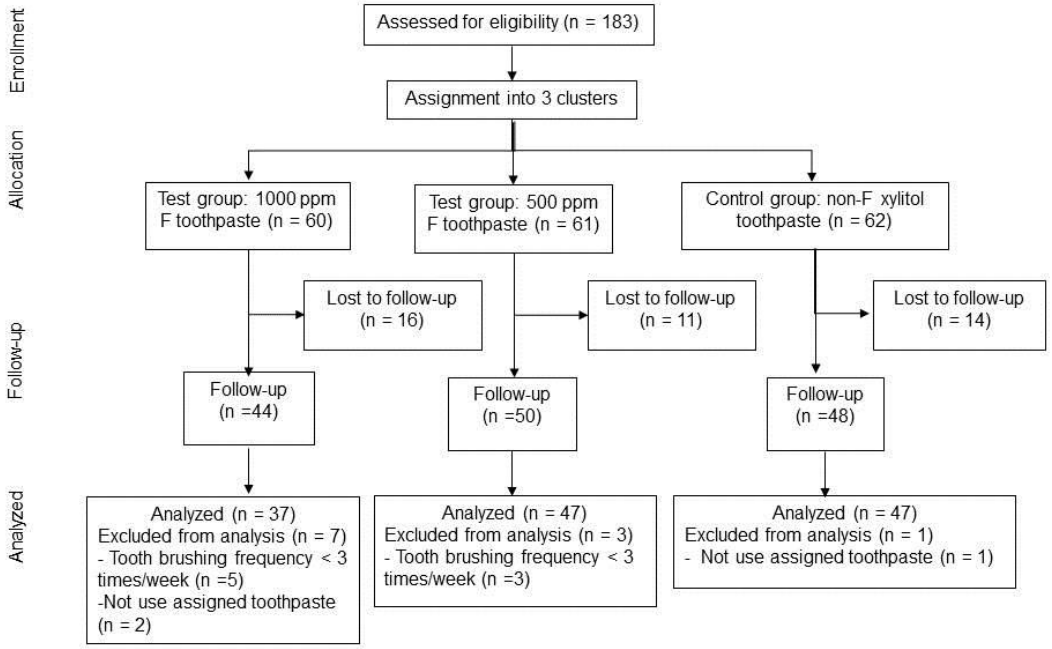


Figure 2 Flow chart of the three study groups subjects in the trial (n, number of subjects).

The difference in sociodemographic characteristics between the dropout and the remaining groups was tested to ensure their homogeneity. The results showed no statistically significant difference in all variables at α = 0.05, Details were illustrated in Table 2, Table 3 and Table 4.

Table 2 Sociodemographic characteristics of samples in the 1000ppm group by status of dropout / remaining

Sociodemographic characteristics	Remaining (n = 37)		Dropout (n = 23)		p-value[a]
	N	%	N	%	
Age of primary caregivers Mean (S.D.)	29.6 (12.9)		30.8 (10.8)		0.698[b]
Min, Max (years)	17, 64		17, 58		
Gender of primary caregivers					
Male	1	2.3	3	18.8	0.153
Female	36	97.7	20	87.0	
Age of child Mean (S.D.)	14.1 (5.2)		15.4 (4.8)		0.320[b]
Min, Max (months)	7, 29		7, 23		
Gender of children					
Boy	23	62.2	11	47.8	0.276
Girl	14	37.8	12	52.2	
Relationship to child (N=59)					
Parent	27	73.0	18	78.3	0.440
Grandparent/Relative	10	27	4	22.7	
Father's occupation (N=56)					
Less stable occupation	21	58.3	15	75.0	0.256
More stable occupation	15	41.7	5	25.0	
Marital status of caregiver					
Married	34	91.9	19	82.6	0.246
Single or divorced	3	8.1	4	17.4	
Mother's education level (N=54)					
Primary school or less	9	24.3	6	35.3	0.516
High school or more	28	75.7	11	64.7	
Stay-at-home mom					
Yes	19	51.4	8	34.8	0.210
No	18	48.6	15	65.2	
Family income/month					
9999 Baht (US $275) or under	14	37.8	8	34.8	0.970
10000 - 14999 Baht (US $275-413)	14	37.8	9	39.1	
15000 Baht (US $413) or over	9	24.3	6	26.1	

Sociodemographic characteristics	Remaining (n = 37)		Dropout (n = 23)		p-value[a]
Prior experience with children (N=53)					
Yes	30	85.7	15	83.3	0.557
No	5	14.3	3	16.7	

[a] Chi-square test or Fisher's Exact test, [b] T-test

Table 3 Sociodemographic characteristics of samples in the 500ppm group by status of dropout / remaining

Sociodemographic characteristics	Remaining (n = 47)		Dropout (n = 14)		p-value[a]
	N	**%**	**N**	**%**	
Age of primary caregivers Mean (S.D.)	35.7 (11.9)		31.3 (11.4)		0.226[b]
Min, Max (years)	15, 63		18, 60		
Gender of primary caregivers					
Male	1	2.1	1	7.1	0.409
Female	46	97.9	13	92.9	
Age of child Mean (S.D.)	15.2 (4.9)		17.4 (5.3)		0.140[b]
Min, Max (months)	7, 25		7, 25		
Gender of children					
Boy	24	51.1	8	57.1	0.689
Girl	23	48.9	6	42.9	
Relationship to child					
Parent	31	66.0	11	78.3	0.516
Grandparent/Relative	16	34	3	21.4	
Father's occupation (N=60)					
Less stable occupation	39	84.8	10	71.4	0.264
More stable occupation	7	15.2	4	28.6	
Marital status of caregiver					
Married	46	97.9	13	92.9	0.409
Single or divorced	1	2.1	1	7.1	
Mother's education level					
Primary school or less	23	48.9	3	21.4	0.068
High school or more	24	51.1	11	78.6	

Sociodemographic characteristics	Remaining (n = 47)		Dropout (n = 14)		p-value[a]
	N	%	N	%	
Stay-at-home mom					
Yes	21	44.7	5	35.7	0.552
No	26	55.3	9	64.3	
Family income/month					
9999 Baht (US $275) or under	17	36.2	4	28.6	0.811[†]
10000 - 14999 Baht (US $275-413)	16	34	6	42.9	
15000 Baht (US $413) or over	14	29.8	4	28.6	
Prior experience with children					
Yes	39	88.6	13	92.9	0.652
No	5	11.4	1	7.1	

[a] Chi-square test or Fisher's Exact test , [b] T-test,

[†] More than 20% have expected count less than 5.

Table 4 Sociodemographic characteristics of samples in the xylitol group by status of dropout / remaining

Sociodemographic characteristics	Remaining (n = 47)		Dropout (n = 15)		p-value[a]
	N	%	N	%	
Age of primary caregivers Mean (S.D.)	34.6 (14.6)		26.6 (9.0)		0.051[b]
Min, Max (years)	16, 73		15, 50		
Gender of primary caregivers					
Male	2	4.3	1	6.7	1.000
Female	45	97.9	14	93.3	
Age of child Mean (S.D.)	14.5 (4.0)		15.6 (3.2)		0.313[b]
Min, Max (months)	8, 24		9, 22		
Gender of children					
Boy	24	51.1	5	33.3	0.231
Girl	23	48.9	10	66.7	
Relationship to child					
Parent	33	70.2	11	73.3	1.000
Grandparent/Relative	14	29.8	4	26.7	

Sociodemographic characteristics	Remaining	Dropout	p-value[a]

	(n = 47)		(n = 15)		
	N	**%**	**N**	**%**	
Father's occupation (N=59)					
Less stable occupation	37	84.1	12	80.0	0.704
More stable occupation	7	15.9	3	20.0	
Marital status of caregiver					
Married	43	91.5	15	100	0.564
Single or divorced	4	8.5	0	0	
Mother's education level					
Primary school or less	19	40.4	4	26.7	0.337
High school or more	28	59.6	11	73.3	
Stay-at-home mom					
Yes	16	34.0	7	46.7	0.378
No	31	66.0	8	53.3	
Family income/month					
9999 Baht (US $275) or under	18	38.3	6	40	0.645
10000 - 14999 Baht (US $275-413)	11	23.4	5	33.3	
15000 Baht (US $413) or over	18	38.3	4	26.7	
Prior experience with children (N=51)					
Yes	30	75.0	10	100	0.179
No	10	25.0	1	0	

[a] Chi-square test or Fisher's Exact test, [b] T-test

Table 5 illustrated sociodemographic characteristics distribution of the samples by study groups. The one hundred and thirty-one children participating in this study comprised of 71 (54.2%) boys, and 60 (45.8%) girls. The average age at the commencement of the study was 14.6±4.7 months. The average age of primary caregivers were 33.6±13.4 years old. Most of them were female (90%), parents of the child (69.5%), married (93.9%); and having child rearing experience (83.2%). The majority of the fathers had less stable occupations (73.8% of fathers were

employee/factory worker/ farmer). Half of mothers (55%) were stay-at-home moms and only finished high school/vocational school (61.1%). A total of 49 families (37.4%) had a total family income of less than 10,000 Baht/month (~US $275), while 31.3% earned 10,000-15,000 Baht/month (~US $275-413) and 31.3% also earned 15,000 or over Baht/month (~US $413). Thailand's average monthly household income was 23,236 Baht/month (~US $640) in 2011. Comparison of characteristics of the samples among three groups showed statistically significant difference among three groups in father's occupation at $\alpha = 0.05$. Half of the fathers in the 1000 ppm had more stable occupations (30.6% of fathers were owners or merchants and 11.1% were government officers or office workers) compared to fathers in the 500ppm and non-F group. In contrast, the majority of other two groups had less stable occupational class (84.8% in 500ppm and 84.1% in non-F group were employee/factory worker/ farmer).

Table 5 Comparisons of sociodemographic characteristics between three groups at baseline

Sociodemographic characteristics	1000ppm (n = 37)		500 ppm (n = 47)		Xylitol (n = 47)		p-value[a]
	N	%	N	%	N	%	
Age of caregivers Mean (S.D.)	29.6(12.9)		35.7(11.9)		34.6(14.6)		0.093[b]
Min, Max (years)	17, 64		15, 63		16, 73		
Gender of primary caregivers							
Male	1	2.7	1	2.1	2	4.3	0.827[†]
Female	36	97.3	46	97.9	45	95.7	
Age of child Mean (S.D.)	14.1(5.2)		15.2(4.9)		14.5(4.0)		0.362[b]
Min, Max (months)	7, 29		7, 25		8, 24		
Gender of children							
Boy	23	62.2	24	51.1	24	51.1	0.518
Girl	14	37.8	23	48.9	23	48.9	
Relationship to child							
Parent	27	73.0	31	66.0	33	70.2	0.779
Grandparent/Relative	10	27.0	16	34.0	14	29.8	
Father's occupation (N=126)							
Less stable occupation	21	58.3	39	84.8	37	84.1	**0.014**
More stable occupation	15	41.7	7	15.2	7	15.9	
Marital status							
Married	34	91.9	46	97.9	43	91.5	0.362[†]
Single or divorced	3	8.1	1	2.1	4	8.6	
Mother's education level							
Primary school or less	9	24.3	23	48.9	19	40.4	0.069
High school or more	28	75.7	24	51.1	28	59.6	
Mother's occupation							
Stay-at-home mom	19	51.4	21	44.7	16	34.0	0.266
Working	18	48.6	26	55.3	31	66.0	
Family income/month							
9999 Baht (US $275) or under	14	37.8	17	36.2	18	38.3	0.570
10000 - 14999 Baht (US $275-413)	14	37.8	16	34.0	11	23.4	
15000 Baht (UD $413) or over	9	24.3	14	29.8	18	38.3	

Sociodemographic characteristics	1000ppm (n = 37)		500 ppm (n = 47)		Xylitol (n = 47)		p-value[a]
	N	%	N	%	N	%	
Prior experience with children (N=121)							
Yes	30	85.7	39	88.6	30	75.0	0.222
No	5	14.3	5	11.4	10	25.0	

[a] Chi-square test for comparing proportion between three groups ; α=0.05

[b] Analysis of variance (ANOVA) test for comparing mean between three groups ; α=0.05

[†] More than 20% have expected count less than 5.

4.2 Oral health status and health-related behaviors at baseline

4.2.1 Child oral health-related behaviors

4.2.1.1 Child oral health care practices

Tables 6 illustrated child's oral health care practice of the samples by study groups. Most of primary caregivers in 1000ppm, 500ppm and xylitol group commenced the child's mouth cleaning by wiping before tooth eruption (89.2%, 93.6% and 84.8%, respectively). They cleaned the child's teeth by clean cloth (89.2%, 78.3% and 82.2%, respectively) and toothbrush (56.8%, 71.7% and 55.6%, respectively). One third brushed their children's teeth in different frequency (almost every day or every day and ≥2 times per day). Most children's teeth were brushed by parent after waking up in the morning. Comparison of child's oral health care practices showed statistically significant difference among three groups in method of cleaning child's mouth by rinsing. There was only one group (500 ppm F) using rinsing their mouth.

Table 6 Comparisons of child's oral health care practice among three groups (N=131) at baseline.

Child's oral health care practice	1000 ppm		500 ppm		Xylitol		p-value[a]
	N	%	N	%	N	%	
Commencement of cleaning child's mouth*							
Wiping child's mouth before tooth eruption	33	89.2	44	93.6	39	84.8	0.389[†]
Wiping child's mouth during tooth eruption	26	70.3	35	74.5	25	54.3	0.101
Brushing child's teeth during first tooth eruption	14	37.8	23	48.9	20	43.5	0.595
Brushing child's teeth during many tooth eruption	7	18.9	8	17.0	3	6.5	0.196
Method for cleaning child's mouth*							
Wipe child's teeth with clean cloth	33	89.2	36	78.3	37	82.2	0.419
Rub child's teeth with finger	13	35.1	14	30.4	13	28.9	0.822
Rinse	0	0	4	8.7	0	0	**0.025**[†]
Tooth brushing	21	56.8	33	71.7	25	55.6	0.216
Frequency of child's tooth brushing (per week) (N=114)							
0–2 days / week	12	37.5	10	23.8	16	40	0.136
3–5 days / week	2	6.3	9	21.4	5	12.5	
6-7 days / week and < 2 times/day	4	12.5	6	14.3	10	25	
6-7 days / week and ≥2 times/day	14	43.8	17	40.5	9	22.5	
Time of day during which child's tooth brushing was performed*							
After waking up in the morning	17	53.1	31	72.1	25	62.5	0.238
After morning meal	2	6.3	0	0	0	0	0.071[†]
After evening meal	2	6.3	1	2.3	1	2.5	0.602[†]
After every meal	0	0	2	4.7	1	2.5	0.457[†]
Before going to bed	12	37.5	15	34.9	10	25.0	0.471
Person who clean child's mouth (N=124)							
Parent	29	80.9	34	75.6	35	77.3	0.770
Grandparent/Relative	7	19.4	11	24.4	8	18.1	

* Multiple responses allowed, [a] Chi-square test,

[†] More than 20% have expected count less than 5.

4.2.1.2 Fluoride exposure

In 1000 ppm and 500 ppm group, primary caregivers used toothpaste for child tooth brushing, while half of primary caregivers in xylitol group did not use. More than 70% of sample used small amount (smaller than green pea size) of toothpaste. Most of children did not have any experience of fluoride tablet. Half of children in 1000 ppm and 500 ppm group and one third of children in xylitol group drank water from tap water. Comparison of child's fluoride exposure showed statistically significant difference among three groups in receiving fluoride tablet. Most of 1000 ppm and xylitol group never receive fluoride tablet (94.1% and 95.2%, respectively), while 76.6% in 500 ppm group never receive it (Table 7).

Table 7 Comparisons of fluoride exposure among three groups (N=131) at baseline.

Child's fluoride using	1000 ppm		500 ppm		Xylitol		p-value[a]
	N	%	N	%	N	%	
Type of toothpaste for your child (N=81)							
No toothpaste	5	23.8	9	27.3	15	55.6	0.073[†]
Toothpaste for children	15	71.4	21	63.6	12	44.4	
Toothpaste for adult	1	4.8	3	9.1	0	0	
Amount of toothpaste for tooth brushing (N=51)							
Smaller than a green pea size	14	93.3	21	70	9	75	0.106
The size was that a green pea	1	6.7	3	30	3	25	
Half of a toothbrush	0	0	0	0	0	0	
As long as a toothbrush	0	0	0	0	0	0	
Receiving fluoride tablet (N=121)							
Never	32	94.1	36	76.6	40	95.2	**0.011**
Less than 3 days/week	2	5.9	9	19.1	2	4.8	
3-5 days/week	0	0	1	2.1	0	0	
Everyday	0	0	1	2.1	0	0	
The water that children drink regularly (N=130)							
Bottled water	6	16.2	11	23.4	11	23.9	0.409
Water contains in a gallon	6	16.2	10	21.3	2	4.3	
Rain water	4	10.8	6	12.8	4	8.7	
Tap water	19	51.4	18	38.3	25	54.3	
other	2	5.4	2	4.3	4	8.7	

[a] Chi-square test, [†] More than 20% have expected count less than 5.

4.2.1.3 Child feeding practices

Most children in the 1000ppm, 500ppm and xylitol groups had bottle feeding (58%, 66% and 69.5%, respectively) and about 20% of all children had mixed breast and bottle feeding. Breast-fed children had more frequent feeding than the bottle-fed one. Half of caregivers gave their child sipping water after milk feeding sometimes and one third of children fell asleep with bottles more than 3 times per week. Most of them had night-time bottle feeding and ate cake/cookies/bread between meals. Comparison of child feeding practices among three groups showed no statistically significant different in almost all variables except type of snack between meals. Xylitol group consumed cake/cookies/bread and packaging snack/crisps/crackers more than the other two groups as shown in Table 8.

Table 8 Child's feeding practices among three groups (N=131) at baseline.

Child's feeding practice	1000 ppm		500 ppm		Xylitol		p-value[a]
	N	%	N	%	N	%	
Type of milk feeding (N=129)							
Exclusive breast feeding	8	22	4	8.5	3	6.5	0.228
Bottle feeding	21	58	31	66	32	69.5	
Mixed breast and bottle feeding	7	19	12	25.5	11	23.9	
Frequency of breast feeding (per day) (N=38)							
Less than 3 times/day	0	0	0	0	1	10.0	0.260†
3-5 times/day	3	21.4	6	42.9	3	30.0	
6-8 times/day	4	28.6	6	42.9	4	40.0	
More than 8 times/day	7	50.0	2	14.2	2	20.0	
Frequency of UHT pasteurized milk/powdered milk (sweet flavor) (per day) (N=39)							
Less than 3 times/day	7	63.6	11	68.7	5	50.0	0.777†
3-5 times/day	2	18.2	1	6.3	2	20.0	
6-8 times/day	2	18.2	4	25.0	3	30.0	
More than 8 times/day	0	0	0	0	0	0	
Frequency of UHT pasteurized milk/powdered milk (flavorless) (per day) (N=90)							
Less than 3 times/day	5	25.0	12	34.3	9	25.7	0.358†
3-5 times/day	7	35.0	15	42.9	10	28.6	
6-8 times/day	6	30.0	6	17.1	15	42.9	
More than 8 times/day	2	10.0	2	5.7	1	2.8	
Sipping water after milk feeding (N=129)							
Never	1	2.8	1	2.1	1	2.2	0.997†
Sometimes	20	55.5	25	53.2	24	52.2	
Every times	15	41.7	21	44.7	21	45.6	
Frequency of child fell asleep with bottles (N=117)							
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(N=131)	32	86.5	39	83.0	42	91.3	0.490
Frequency of snacking between meals (N=126)							
Never or 1 time / day	25	69.4	30	66.7	26	57.8	0.624†
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	

Child's feeding practice	1000 ppm		500 ppm		Xylitol		p-value[a]
	N	%	N	%	N	%	
Type of snack between meals*							
Cake/cookies/bread	20	56	19	40.4	31	67.4	**0.033**
Packaging snack/crisps/crackers	21	58	24	51.1	35	76.1	**0.039**
Yogurt	18	50	18	38.3	21	45.7	0.550
Toffee/candy	5	14	6	12.8	5	10.9	0.915
Soft drink	8	22	14	29.8	9	19.6	0.492

* Multiple responses allowed, [a] Chi-square test, [†]More than 20% have expected count less than 5.

4.2.2 Child Caries Status

4.2.2.1 Caries Prevalence

The one hundred and thirty-one children, included in the final analysis, revealed that 106 children had erupted teeth. For those who had erupted teeth, the prevalence including white lesions caries of each group was 26.7%, 32.5% and 27.8% and prevalence excluding white lesions caries was 13.3%, 12.5% and 16.7% in 1000 ppm, 500 ppm, and xylitol group, respectively (Table 9 and Figure 3).

Table 9 Percentage of caries and caries-free children by study group at baseline

Group	N	No. of children with erupted teeth	including white lesion		excluding white lesion	
			Caries free N (%)	Caries present N (%)	Caries free N (%)	Caries present N (%)
1000 ppm	37	30	22 (73.3)	8 (26.7)	26 (86.7)	4 (13.3)
500 ppm	47	40	27 (67.5)	13 (32.5)	35 (87.5)	5 (12.5)
Xylitol	47	36	26 (72.2)	10 (27.8)	30 (83.3)	6 (16.7)
Total	131	106	75 (70.8)	31 (16.0)	91 (85.8)	15 (14.2)

Percentage value are given in parentheses

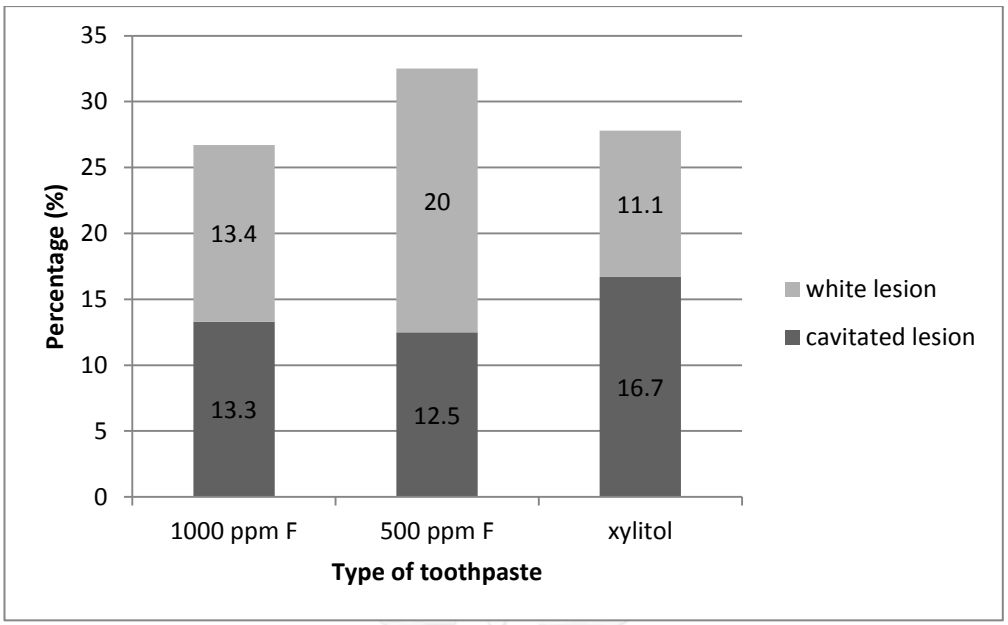


Figure 3 Caries prevalence by study group at baseline (N=106)

4.2.2.2 Means of dmft and dmfs

Children in 1000 ppm F, 500 ppm F and xylitol group had average erupted teeth 8.37±5.26, 8.93±4.41 and 8.28±4.73 teeth, respectively. There was no statistically significant difference in average number of erupted teeth in each child. After test of homogeneous characteristics of three groups using Chi-Square test and Analysis of variance (ANOVA), the variables which indicated heterogeneity among three groups were classified as covariates. These covariates such as; father's occupation, method of cleaning child's mouth by rinsing, receiving fluoride tablet and type of snack between meals had been identified and were entered into the analysis as covariates in ANCOVA analyses for comparing means of dmfs/dmft. There was no statistically significant difference in dmft/dmfs both excluding and including

white lesions among the three groups. Means of dmft/dmfs by study group at baseline are shown in Table 10.

Table 10 Means of dmft/dmfs by study group at baseline

Caries status	1000 ppm (n = 30)	500 ppm (n = 40)	Xylitol (n = 36)	p-value[a]
Average of erupted teeth *Mean±S.D.*	8.37±5.26	8.93±4.41	8.28±4.73	0.735
dmfs (including WL) *Mean±S.D.*	3.37±8.89	2.35±5.73	3.00±6.71	0.827
dmfs (including WL) *Min, Max (surfaces)*	0, 38	0, 30	0, 31	
dmfs (excluding WL) *Mean±S.D.*	2.07±6.64	1.18±3.88	1.22±4.33	0.696
dmfs (excluding WL) *Min, Max (surfaces)*	0, 30	0, 19	0, 24	
dmft (including WL) *Mean±S.D.*	1.43±3.04	1.28±2.39	1.83±3.56	0.715
dmft (including WL) *Min, Max (surfaces)*	0, 13	0, 9	0, 12	
dmft (excluding WL) *Mean±S.D.*	0.77±2.13	0.55±1.68	0.67±1.87	0.718
dmft (excluding WL) *Min, Max (surfaces)*	0, 9	0, 8	0, 8	

WL = white lesions, [a] Analysis of covariance (ANCOVA)

4.2.3 Child Oral Hygiene

The oral hygiene examinations revealed that 24 children (22.6%) had a slight change in gingival color and slight gingival edema and 31 children (29.2%) had debris present (debris Score 1-3). No significant difference in mean gingival index and debris index scores was detected among three groups at baseline (Table 11).

Table 11 Means and standard deviations of the gingival index and debris index by study group

Group Oral hygiene	1000 ppm (n = 30)	500 ppm (n = 40)	Xylitol (n = 36)	Total (n = 106)	p-value[a]
Gingival index	0.10±0.31	0.30±0.47	0.25±0.44	0.23±0.42	0.139
Debris index	0.17±0.48	0.35±0.63	0.36±0.57	0.30±0.57	0.306

[a] Analysis of covariance (ANCOVA)

4.3 Oral health status and health-related behaviors at 12 months

4.3.1 Child oral health-related behaviors

4.3.1.1 Child oral health care practices

Comparison of child's oral health care practices among three groups at 12 months showed no statistically significant difference in method for cleaning child's mouth, frequency of child's tooth brushing (per week), person who clean child's mouth, while there were difference in method for commencement of cleaning child's mouth and time of day during which child's tooth brushing (Table 12). Number of caregiver in 1000 ppm group starting brush child's teeth when first tooth eruption had more than other two groups, while the highest number of caregiver that starting brush child's teeth when first tooth eruption was xylitol group.

Almost of all primary caregivers in 1000ppm, 500ppm and xylitol group cleaned the child's teeth by tooth brushing (100%, 95.7% and 97.9%, respectively). Number of primary caregivers who brushed their child's teeth 6-7 days/week and ≥2 time/day in 1000 ppm group (75%) had more than in the other two group (55.3% in

500 ppm and 57.4% in xylitol group). Most children in 1000 ppm were brushed after waking up in the morning (54.1%) and before going to bed (32.4%), while most of the children in 500 ppm were brushed during taking a bath in the morning (68.1%) and in the evening (46.8%). Most children's teeth (>70%) were brushed by mother.

Table 12 Comparisons of child's oral health care practice among three groups (N=131) at 12 months

Child's oral health care practice	1000 ppm		500 ppm		Xylitol		p-value[a]
	N	%	N	%	N	%	
Commencement of cleaning child's mouth*							
Wiping child's mouth before tooth eruption	26	70.3	35	76.1	39	83	0.385
Wiping child's mouth when tooth eruption	8	21.6	11	23.9	5	10.6	0.216
Brushing child's teeth when first tooth eruption	10	27.0	6	13.0	2	4.3	**0.011**
Brushing child's teeth when many tooth eruption	25	67.6	32	69.6	42	89.4	**0.028**
Method for cleaning child's mouth*							
Wipe child's teeth with clean cloth	30	81.1	41	87.2	40	85.1	0.736
Rub child's teeth with finger	1	2.7	0	0	2	4.3	0.379†
Rinse	1	2.7	1	2.2	1	2.1	0.981†
Tooth brushing	37	100	45	95.7	46	97.9	0.431†
Frequency of child's tooth brushing (per week) (N=131)							
3–5 days / week	3	8.1	6	12.8	7	14.9	0.347
6-7 days / week and < 2 times/day	6	16.2	15	31.9	13	27.7	
6-7 days / week and ≥2 times/day	28	75.7	26	55.3	27	57.4	
Time of day during which child's tooth brushing was performed*							
After waking up in the morning	20	54.1	13	27.7	35	74.5	**<0.001**
After morning meal	2	5.4	1	2.1	1	2.1	0.618†
During taking a bath in the morning	13	35.1	32	68.1	9	19.1	**<0.001**
After lunch meal	2	5.4	0	0	3	6.4	0.227†
After dinner meal	3	8.1	2	4.3	6	12.8	0.330†
During taking a bath in the evening	12	32.4	22	46.8	14	29.8	0.190
Before going to bed	17	45.9	10	21.3	8	17.0	**0.007**
Person who clean child's mouth (N=100)							
Parent	30	81.1	37	78.7	36	76.6	0.883
Grandparent/Relative	7	18.9	10	21.3	11	23.5	

* Multiple responses allowed, [a] Chi-square test, † More than 20% have expected count less than 5.

4.3.1.2 Fluoride exposure

Comparison of child fluoride use among three groups after 12 months showed there were difference in amount of toothpaste for tooth brushing (p<0.05). Most of the caregivers used the green pea size toothpaste in 1000 ppm and xylitol groups (Table 13). Most children in 1000 ppm (51.4%), 500 ppm (42.6%) and xylitol (36.2%) group still drink from tap water.

Table 13 Comparisons of fluoride exposure among three groups (N=131) at 12 months

Child's fluoride using	1000 ppm		500 ppm		Xylitol		p-value[a]
	N	%	N	%	N	%	
Amount of toothpaste for tooth brushing (N=130)							
Smaller than a green pea	14	37.8	31	66	13	28.3	**0.014**[†]
The size of a green pea	22	59.5	15	31.9	31	67.4	
Half of a toothbrush	1	2.7	1	2.1	1	2.2	
As long as the toothbrush	0	0	0	0	1	2.2	
The water that children drink regularly (N=127)							
Bottled water	7	18.9	8	17	8	14.9	0.428
Water contains in a gallon	3	8.1	8	17	4	8.5	
Rain water	5	13.5	5	10.6	7	14.9	
Tap water	19	51.4	20	42.6	17	36.2	
other	3	8.1	6	12.8	15	25.5	

[a] Chi-square test, [†] More than 20% have expected count less than 5.

4.3.1.3 Child feeding practices

Table 14 illustrated comparison of child feeding practices among three groups at 12 months. There was statistical significant difference ($p<0.05$) in type of snack between meals. Children in Xylitol group consumed cake/cookies/bread and yogurt more than the other two groups.

Breast-fed children in 1000 ppm had more frequent feeding than the other two groups. Half of the child sipped water after milk feeding almost every time and one third of children fell asleep with bottles more than 3 times per week. Most of them did not have night-time bottle feeding (62.2-74.5%) and ate packaged snack/crisps/crackers (81.1-89.4%) between meals once a day (.83-86.5%).

Table 14 Comparisons of child's feeding practices among three groups (N=131) at 12 months.

Child's feeding practice	1000 ppm		500 ppm		Xylitol		p-value[a]
	N	%	N	%	N	%	
Frequency of breast feeding (per day) (N=21)							
Less than 3 times/day	2	20	5	62.5	3	75	0.182†
3-5 times/day	6	60	2	25	0	0	
6-8 times/day	2	20	1	12.5	1	25	
More than 8 times/day	0	0	0	0	0	0	
Frequency of UHT pasteurized milk/powdered milk (sweet flavor) (per day) (N=49)							
Less than 3 times/day	7	50	11	55	7	46.7	0.927†
3-5 times/day	5	35.7	4	20	4	26.7	
6-8 times/day	2	14.3	4	20	3	20	
More than 8 times/day	0	0	1	5	1	6.67	
Frequency of UHT pasteurized milk/powdered milk (flavorless) (per day) (N=100)							
Less than 3 times/day	7	26.9	15	41.7	14	36.8	0.315†
3-5 times/day	16	61.6	11	30.6	18	47.4	
6-8 times/day	3	11.5	9	25	5	13.2	
More than 8 times/day	0	0	1	2.7	1	2.63	
Sipping water after milk feeding) (N=131)							
Never	4	10.8	5	10.6	4	8.51	0.805
Sometimes	13	35.1	22	46.8	22	46.8	
Every time	20	54.1	20	42.6	21	44.7	
Frequency of child fell asleep with bottles (N=131)							
Never / week	21	56.8	27	57.4	28	59.6	0.999†
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	

Child's feeding practice	1000 ppm		500 ppm		Xylitol		p-value[a]
	N	%	N	%	N	%	
Night-time bottle feeding (N=131)							
Yes	23	62.2	33	70.2	35	74.5	0.473
No	14	37.8	14	29.8	12	25.5	
Frequency of snacking between meals (N=131)							
Never or 1 time / day	32	86.5	39	83	39	83	0.848[†]
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	
Type of snack between meals*							
Cake/cookies/bread	21	56.8	20	42.6	32	68.1	**0.044**
Packaged snack/crisps/crackers	30	81.1	42	89.4	40	85.1	0.562
Chocolate	11	29.7	14	29.8	19	40.4	0.464
Yogurt	21	56.8	24	51.1	41	87.2	**<0.001**
Toffee/candy	8	21.6	14	29.8	20	42.6	0.114
Soft drink	10	27	16	34	22	46.8	0.157
Thai desert	8	21.6	18	38.3	22	46.8	0.057

* Multiple responses allowed, [a] Chi-square test, [†] More than 20% have expected count less than 5.

4.3.2 Child caries status

4.3.2.1 Caries Prevalence

The one hundred and thirty-one children included in the final analysis. In 1000 ppm, 500 ppm, and xylitol group, the prevalence including white lesions caries of each group was 62.2%, 59.6% and 61.7% and the prevalence excluding white lesions caries was 40.5%, 42.6% and 53.2%, respectively (Table 15).

Table 15 Percentage of caries and caries-free children by study group at 12 months

Group	N	including white lesion		excluding white lesion	
		Caries free	Caries present	Caries free	Caries present
		N (%)	N (%)	N (%)	N (%)
1000 ppm	37	14 (37.8)	23 (62.2)	22 (59.5)	15 (40.5)
500 ppm	47	19 (40.4)	28 (59.6)	27 (57.4)	20 (42.6)
Xylitol	47	18 (38.3)	29 (61.7)	22 (46.8)	25 (53.2)
Total	131	51 (38.9)	80 (61.1)	71 (54.2)	60 (45.8)

Percentage value are given in parentheses

Trend of prevalence rate (both including and excluding white lesion) showed in Figure 4. Prevalence rate including white lesion in 500 ppm group is the highest at baseline but it is the lowest at 12 months while prevalence rate excluding white lesion in xylitol group is the highest both baseline and at 12 months.

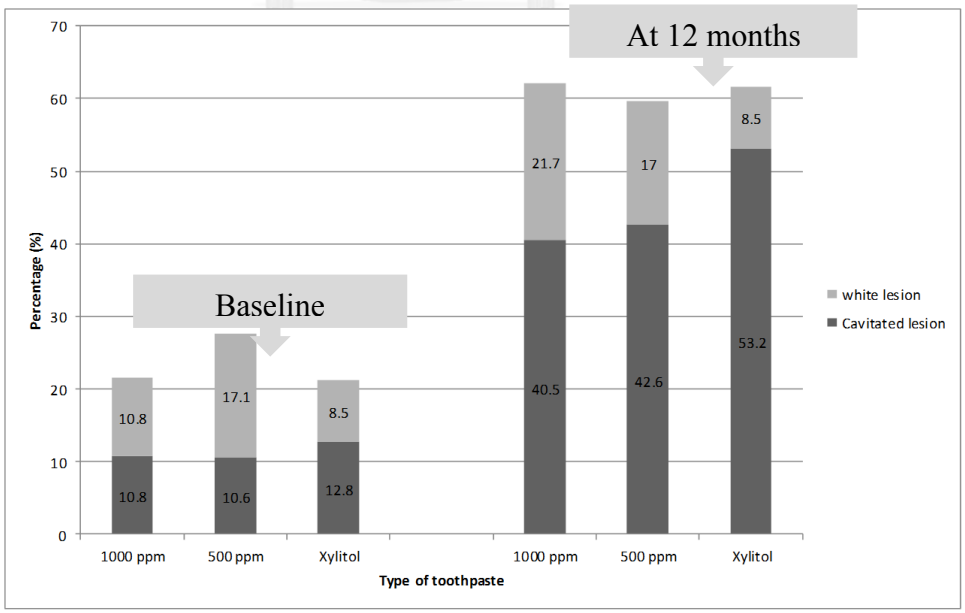


Figure 4 Prevalence rate by study group at baseline (N=106) and 12 months (N=131).

4.3.2.2 Caries Incidence

Table 16 shows caries incidence at 12 months, caries incidence including white lesions of each group were similar (43.2%, 31.9% and 40.4% in 1000 ppm, 500 ppm, and xylitol group, respectively). However, it was observed that caries incidence excluding white lesions of xylitol group was highest (34.0%) in comparison with 1000 ppm and 500 ppm groups (24.3% and 23.4%, respectively).

Table 16 Caries incidence by study group at 12 months

Group	N	including white lesion	excluding white lesion
		N (%)	N (%)
1000 ppm	37	16 (43.2)	9 (24.3)
500 ppm	47	15 (31.9)	11 (23.4)
Xylitol	47	19 (40.4)	16 (34.0)
Total	131	50 (38.2)	36 (27.5)

Percentage value are given in parentheses

4.3.2.3 Means and increment of dmft/dmfs

Average of erupted teeth was 15.30±4.43, 16.68±2.32, 15.94±3.29 teeth in 1000 ppm F, 500 ppm F and xylitol group. There was no statistically significant difference in average of erupted teeth at 12 months. The incremental dmfs both including and excluding white lesions were highest in 1000 ppm group, compared to those in the 500 ppm and xylitol groups (7.30±11.54, 3.87±6.02 and 4.68±6.89 for including white lesion and 4.78±12.03, 2.40±4.00, 3.68±7.27 for excluding white

lesion, respectively). In addition, large variation in caries status was observed in 1000 ppm group (Minimum caries = 0 surface, Maximum caries = 93 surfaces for including white lesions and Minimum caries = 0 surface, Maximum caries = 86 surfaces for excluding white lesions). In spite of the observed clinical differences, statistical analysis revealed the non-significant difference in dental caries among the three groups using ANCOVA analyses. After test of homogeneous characteristics of child oral health-related behaviors among three groups using Chi-Square test and Analysis of variance (ANOVA), the variables which showed statistically significant difference among three groups were classified as covariates. These covariates such as; method for commencement of cleaning child's mouth, brushing frequency/day, each time of day during which child's tooth brushing, amount of toothpaste used for brushing, type of snack between meals had been identified and were entered into the ANCOVA analyses as covariates analyses for comparing means of dmfs/dmft and incremental dmfs. There was no statistically significant difference in, dmft/dmfs, incremental dmfs both excluding and including white lesions among the three groups ($p>0.05$) (Table 17).

Table 17 Means and increment of dmft/dmfs by study group at 12 months

Caries status	1,000 ppm (n = 37)	500 ppm (n = 47)	Xylitol (n = 47)	p-value[a]
Average of erupted teeth *Mean±S.D.*	15.30±4.43	16.68±2.32	15.94±3.29	0.174
dmfs (including WL) *Mean±S.D.*	10.00±17.62	5.83±8.01	6.85±10.90	0.292
dmfs (including WL) *Min, Max (surfaces)*	0, 93	0, 31	0, 50	
dmfs (excluding WL) *Mean±S.D.*	6.97±16.10	3.55±6.10	4.79±9.31	0.356
dmfs (excluding WL) *Min, Max (surfaces)*	0, 86	0, 27	0, 39	
dmft (including WL) *Mean±S.D.*	4.38±5.29	3.34±4.11	3.51±4.33	0.551
dmft (including WL) *Min, Max (surfaces)*	0, 20	0, 15	0, 18	
dmft (excluding WL) *Mean±S.D.*	2.49±4.27	2.02±3.16	2.28±3.50	0.841
dmft (excluding WL) *Min, Max (surfaces)*	0, 20	0, 15	0, 14	
Increment dmfs (including WL) *Mean±S.D.*	7.30±11.54	3.87±6.02	4.68±6.89	0.153
Increment dmfs (excluding WL) *Mean±S.D.*	4.78±12.03	2.40±4.00	3.68±7.27	0.406
Increment dmft (including WL) Mean±S.D.	3.24±4.41	2.26±3.33	2.13±2.90	0.706
Increment dmft (excluding WL) Mean±S.D.	1.86±2.95	1.60±2.33	1.81±2.48	0.799

WL = white lesion, [a] Analysis of covariance (ANCOVA)

A case in the 1000 ppm group, revealed very high dmfs (dmfs = 93 and 86 surfaces for including and excluding white lesion, respectively), was indicated as an extreme case. This extreme value can deteriorate the group mean. If this extreme case was excluded from the analysis (Table 18), the mean dmfs and dmft including white lesion in 1000 ppm group would be 7.69±10.82 and 3.94±4. 65 respectively; the mean dmfs and dmft excluding white lesion would be 4.78±9.13 and 2.00±3.12, respectively. The incremental dmfs including white lesion were the highest

in 1000 ppm group, and excluding white lesions were the highest in xylitol groups. While 500 ppm group is the lowest increment both including and excluding white lesions.

Table 18 Means and increment of dmft/dmfs by study group at 12 months (excluding the extreme case)

Caries status	1,000 ppm (n = 37)	500 ppm (n = 47)	Xylitol (n = 47)
Average of erupted teeth *Mean±S.D.*	15.17±4.42	16.68±2.32	15.94±3.29
dmfs (including WL) *Mean±S.D.*	7.69±10.82	5.83±8.01	6.85±10.90
dmfs (including WL) *Min, Max (surfaces)*	0, 39	0, 31	0, 50
dmfs (excluding WL) *Mean±S.D.*	4.78±9.13	3.55±6.10	4.79±9.31
dmfs (excluding WL) *Min, Max (surfaces)*	0, 36	0, 27	0, 39
dmft (including WL) *Mean±S.D.*	3.94±4.65	3.34±4.11	3.51±4.33
dmft (including WL) *Min, Max (surfaces)*	0, 15	0, 15	0, 18
dmft (excluding WL) *Mean±S.D.*	2.00±3.12	2.02±3.16	2.28±3.50
dmft (excluding WL) *Min, Max (surfaces)*	0, 10	0, 15	0, 14
Increment dmfs (including WL) *Mean±S.D.*	5.97±8.38	3.87±6.02	4.68±6.89
Increment dmfs (excluding WL) *Mean±S.D.*	3.11±6.50	2.40±4.00	3.68±7.27
Increment dmft (including WL) Mean±S.D.	3.14±4.43	2.26±3.33	2.13±2.90
Increment dmft (excluding WL) Mean±S.D.	1.61±2.54	1.60±2.33	1.81±2.48

WL = white lesion, [a] Analysis of covariance (ANCOVA)

Trend of dmfs (both including and excluding white lesio three groups showed in Figure 5 and 6. Means of dmfs (both including and white lesion) were highest in 1000 ppm group compared to those in the and xylitol groups both at baseline and 12 months follow-up. . When th case was excluded from the analysis, xylitol group had higher increme

excluding white lesion than the other two fluoride groups. (Figure 7 and 8)

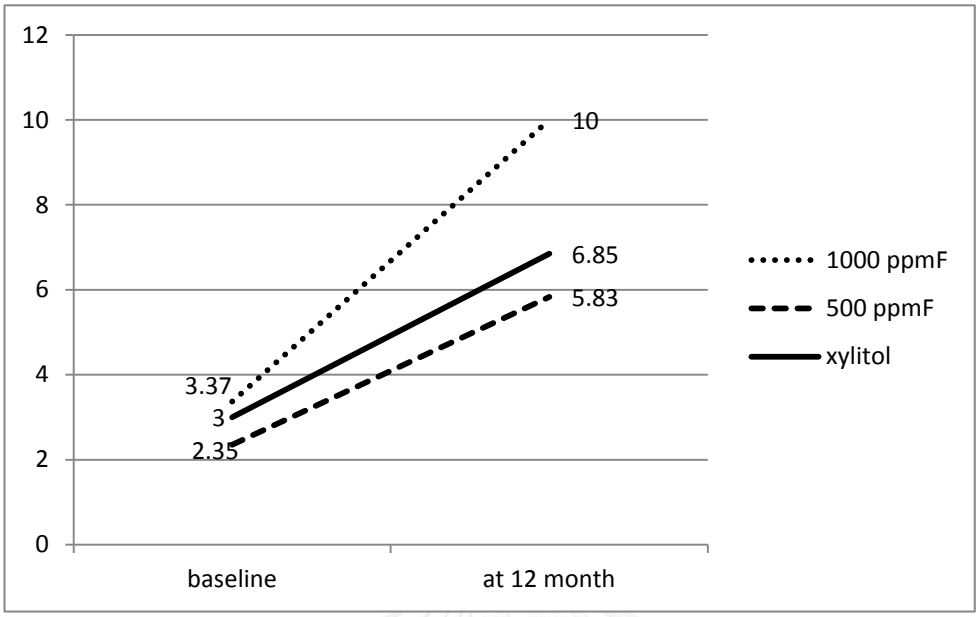


Figure 5 Means of dmfs (including white lesion) by study group

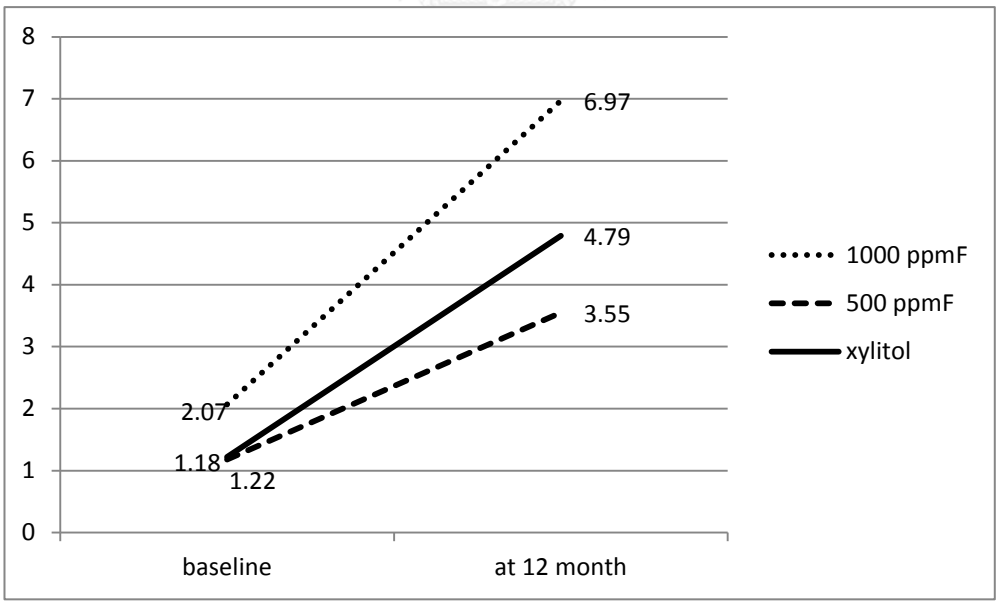


Figure 6 Means of dmfs (excluding white lesion) by study group

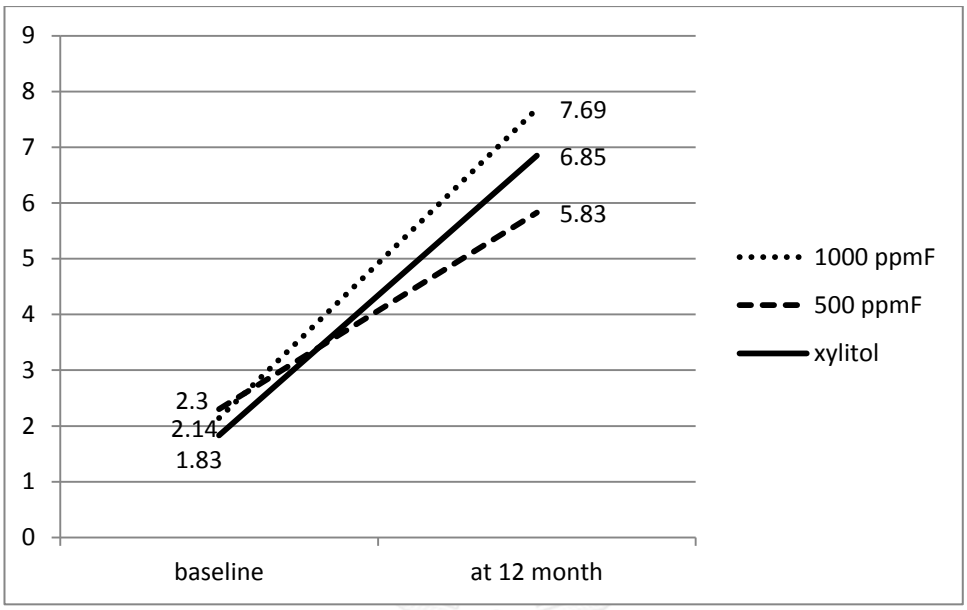


Figure 7 Means of dmfs (including white lesion) by study group (excluding the extreme case)

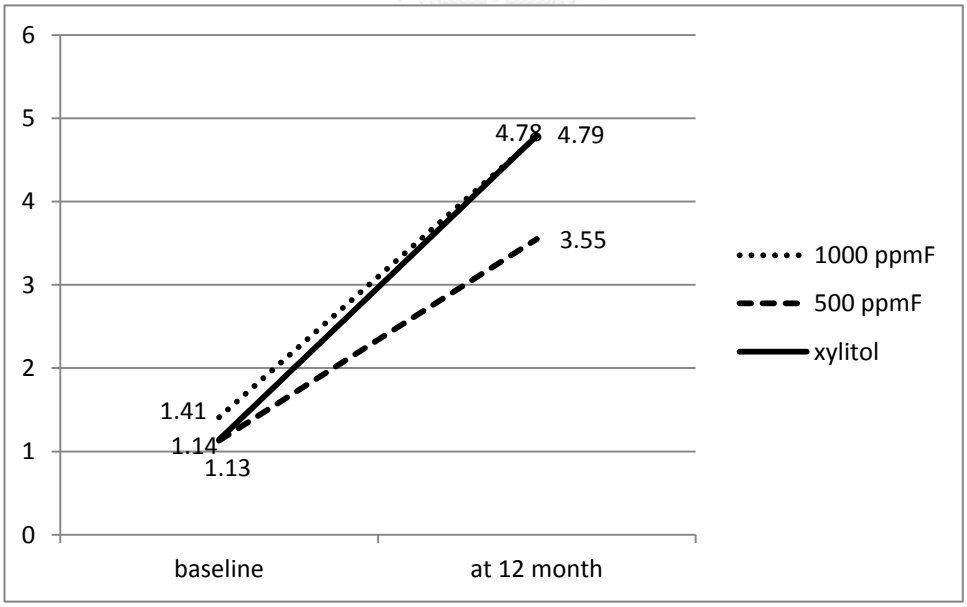


Figure 8 Means of dmfs (excluding white lesion) by study group (excluding the extreme case)

4.3.2.4 Caries Progression and New caries

Table 19 and Figure 9,10 shows the transitory changes in dental status over 12 month periods. The progression from sound surface or unerupted tooth to enamel lesion (d_1) or dentine lesions (d_2) was defined as new caries (code (U→d1,d2) or (S→d1,d2)). While the progression from enamel lesion (d1) to dentine lesions (d2) or missing teeth due to caries (m) and from dentine lesions (d2) progressed to missing teeth due to caries were defined as caries progression (code (d1→d2,m) or (d2→m)). The dental status in the majority of cases remained unchanged while the changing to new caries was the most transitional changes. Xylitol group had changed to new caries and progression caries more than 1000 ppm group and 500 ppm group (37.6% and 44.8%) whereas 500 ppm group had the highest regression caries (38.7%) for including white lesion. For excluding white lesion, the progression of caries was rarely found and it was the same trend with including white lesion which xylitol group had the highest new caries.

Table 19 Transitional probability of dental status of the whole mouth observed in the same children (N=131)

Transitional status	No. of transitional surfaces (%)			
	1000 ppm	500 ppm	Xylitol	Total
including white lesion				
New caries (U⟶d1,d2) or (S⟶d1,d2)	201 (32.2)	189 (30.2)	235 (37.6)	625
Progression (d1⟶d2,m) or (d2⟶m)	12 (20.7)	20 (34.5)	26 (44.8)	58
Regression (d2⟶d1)	8 (25.8)	12 (38.7)	11 (35.5)	31
excluding white lesion				
New caries (U⟶d2)	131 (29.7)	123 (27.9)	187 (42.4)	441
Progression (d2⟶m)	3 (75.0)	0 (0)	1 (25.0)	4

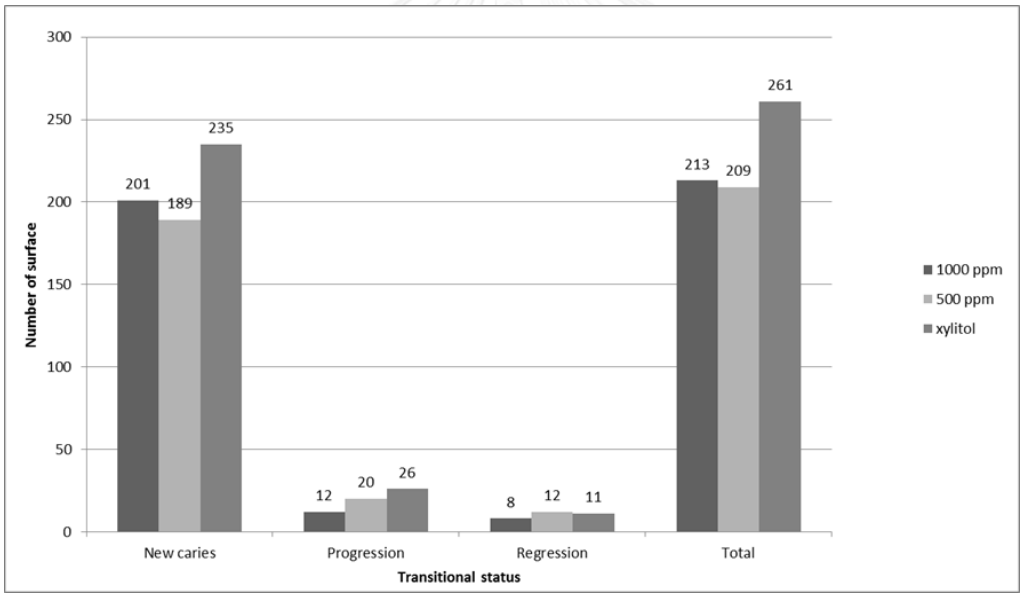


Figure 9 Total new caries and caries progression including white lesion by study group after 12 months

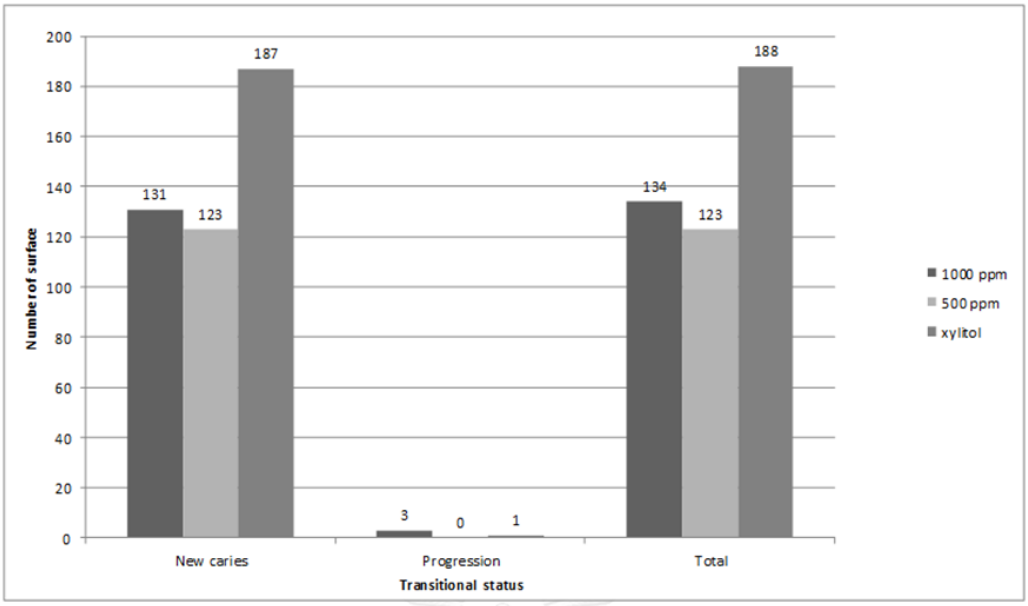


Figure 10 Total new caries and caries progression excluding white lesion by study group after 12 months

4.3.2.5 Prevented Fraction

Table 20 shows the treatment effect which was expressed as Prevented fraction (PF). The PF was the difference in mean incremental caries between toothpaste with 1,000 ppm and 500 ppm compare with xylitol group expressed as a percentage in incremental caries. The prevented fraction of 500 ppm group had better than 1000 ppm group.

Prevented fraction (PF) was calculated as follow;

$$PF = \frac{\text{Mean increment (control group) - Mean increment (test group)}}{\text{Mean increment (control group)}}$$

Table 20 Prevented fraction (PF) in mean incremental caries between 1,000 ppm and 500 ppm compare with xylitol group

Prevented fraction	1000 ppm	500 ppm
Increment dmfs (including white lesion)	-56%	17%
Increment dmfs (excluding white lesion)	-30%	35%
Increment dmft (including white lesion)	-50%	-6%
Increment dmft (excluding white lesion)	7%	17%

Table 21 Prevented fraction (PF) in mean incremental caries between 1,000 ppm and 500 ppm compare with xylitol group (excluding the extreme case)

Prevented fraction	1000 ppm	500 ppm
Increment dmfs (including white lesion)	-28%	17%
Increment dmfs (excluding white lesion)	15%	35%
Increment dmft (including white lesion)	-47%	-6%
Increment dmft (excluding white lesion)	11%	12%

4.3.3 Child oral hygiene

At the 12 months follow-up, 56 children (42.7%) had a slight change in gingival color and slight gingival edema and 85 children (64.9%) had debris present (debris Score 1-3). The mean gingival index and debris index scores are shown in Table 21. Oral hygiene status among the three groups does not have statistical difference (p>0.05).

Table 22 Means and standard deviations of the gingival index and debris index by study group at 12 months

Oral hygiene	1000 ppm (n = 37)	500 ppm (n = 47)	Xylitol (n = 47)	Total (n = 131)	p-value[a]
Gingival index	0.35±0.48	0.36±0.49	0.55±0.50	0.43±0.50	0.725
Debris index	0.59±0.59	0.74±0.69	1.08±0.77	0.82±0.72	0.185

[a] Analysis of covariance (ANCOVA)

4.4 Change in child oral health health-related behaviors

Comparing child oral health practices at baseline and after the intervention, no significant difference was found in person who clean the child's mouth and frequency of falling asleep with a bottle ($p>0.05$) (Table 22). However, the caregivers improved their child's tooth brushing practice (97.7%), the frequency of brushing (per week) was significantly increased after hands-on tooth brushing session ($p<0.05$). Nighttime bottle-feeding and snacking between meals were significantly decreased ($p<0.05$) after 12 month period.

Table 23 Comparisons of child's oral health practices at baseline and at 12 mos.

Factor	baseline		at 12 month		p-value[a]
	N	%	N	%	
Brushing	(N=131)		(N=131)		
yes	77	62.1	128	97.7	**<0.001**
no	47	37.9	3	2.3	
Frequency of brushing (per week)	(N=114)		(N=131)		
0–2 days / week	38	33.3	0	0	**<0.001**
3–5 days / week	16	14	16	12.2	
6-7 days / week and < 2 times/day	20	17.5	34	26	
6-7 days / week and ≥2 times/day	40	35.1	81	61.8	
Person who clean child's mouth	(N=51)		(N=130)		
Parent	98	79	103	78.6	0.862
Grandparent/Relative	26	21	28	21.4	
Sipping water after milk feeding	(N=129)		(N=131)		
Never	3	2.3	13	9.9	**0.023**
Sometimes	69	53.5	57	43.5	
Every times	57	44.2	61	46.6	
Frequency of child fell asleep with bottles	(N=131)		(N=131)		
Never / week	56	47.9	76	58	0.203
3 times or less / week	16	13.7	11	8.4	
4 times or more / week	45	38.5	44	33.6	
Night-time bottle feeding	(N=131)		(N=131)		
Yes	114	87.0	91	69.5	**<0.001**
No	17	13.0	40	30.5	
Snacking between meal (per day)	(N=126)		(N=131)		
Never or one time	81	64.3	110	84	**<0.001**
2 times	36	28.6	8	6.1	
3 times or more	9	7.1	13	9.9	

[a] Chi-square test or Fisher's Exact test

CHAPTER V
DISCUSSION

The present study investigated the caries prevention effect of toothpastes with different concentrations of fluoride (1000 ppmF, 500 ppmF, or non-fluoride containing xylitol and triple calcium phosphate) in a sample of 9- to 18-month-old Thai children over a 12-mo period. Results of the study were discussed and comments were given as follows:

5.1 Changes of variables

5.1.1 Child caries status

After the implementation, prevalence rate of cavitated lesion in this study (45.8%) is lower than 7th National Oral Health Survey in 3 year-old children (57%) [44]. This might be the consequence of the hands-on tooth brushing practice, thus the primary caregivers had more efficacy in cleaning their child's teeth.

The results indicated no statistically significant difference among the three groups in caries increment and caries status (dmfs) at the end of the study. It seems that anticaries potential among the three types of toothpaste used in this study do not differ, which is similar to previous studies showing no significant difference in caries prevention effect between 1000 ppm and 500 ppm fluoride toothpaste [36, 157, 158] and between the 440/500/550 ppmF group and placebo [27]. The Cochrane review indicated that there was an evidence of a dose response

relationship in that the prevented fraction (PF) increased as the fluoride concentration increased from the baseline although this was not always statistically significant [27]. Lima et al's study indicated the similar anticaries efficacies of 1100 ppm and 500ppm fluoride toothpaste in 2- to 4-year-old children for caries-inactive group [36]. Results of two studies in 6-9 months children also indicated no statistical significant different between 440/500 ppm F and control group [32, 45]. In contrast, studies on 3-year-old Chinese children reported significant reductions in caries after using of 1000-1100 ppm F comparing to control group [34, 69, 111]. The disagreement in results between the Chinese studies and this study may be due to dissimilar age groups; their studies were done in kindergarten students (3- to 5-year-old), while this study was conducted in infant and toddler. Moreover, their control group did not receive oral health education such as test group. This effect may show significant reductions when compare between two groups. Another study on the same age group, 9- to 18-month-old Thai children, indicated the significantly lower caries increment of hands-on tooth brushing program using 500 ppm fluoride toothpaste group comparing to the non-intervention group [205]. This difference may be due to the fact that their control group received regular oral health care in public health service while this comparison group received oral health education with hands-on tooth brushing practice. The study of Thanakanjanaphakdee and Triratvorakul 's study [205] showed the statistically significant differences of

incremental caries between test and control group. As the comparison group of this study received oral health education with hands-on tooth brushing practice, it is logically that the comparison group will have lower caries increment than the comparison group without hands-on tooth brushing practice in Thanakanjanaphakdee and Trairatvorakul's study.

The prevented fraction of 1000 ppm F has shown negative value and there is no evidence of a dose response effect of the prevented fraction increase, it may be result from children in 1000 ppm group had severe caries more than xylitol groups.

Comparing the prevented fraction (PF) with other studies, the PF of 500 ppm F in this study (17%) is lower than Thanakanjanaphakdee and Trairatvorakul's study [205]. The overall prevented fraction beyond 1 years between 500 ppmF and control group was substantially reduced (84%) and was statistically significant ($p < 0.05$) [205]. It might be the consequence of not providing hands on tooth brushing with control group. The control group in their study had supervision by health care personnel defined by the public health department for well-baby clinic which brushing was taught in model only. However, the prevented fraction of this study is higher than Vachirarojpisan's study (8.8%) that used participatory group discussion [45].

Although this study found no statistical significant difference in caries increment, it might not be concluded that fluoride had no caries prevention effect in infants and toddlers. Potential caries prevention effect of xylitol and triple calcium phosphate in the comparison group might be the possible explanation for such non-difference between the three groups. For ethical reasons, the non-fluoride containing xylitol and triple calcium phosphate toothpastes was used as a comparison group instead of placebo toothpaste. These may somewhat limit the difference in findings between the fluoride and non-fluoride groups; this could have been more distinct if placebo toothpaste was used. Studies revealed that xylitol reduces the growth of MS and increase pH value [167-170, 173]. It provides a positive effect on the quality of the oral environment and enhance the remineralization [179]. In addition, findings indicated the similar incidence rates among the three groups when white lesions were included, but xylitol group revealed higher incidence rate if white lesions were excluded. This might be explained by fluoride's mechanism in impeding caries progression, and the non-fluoride toothpaste, in this study, contains 5 percent xylitol which do not reach the therapeutic level (10 percent xylitol or dose of 0.1 g/brushing). Moreover, the efficacy of xylitol in reducing the incidence of caries and arresting the progression of caries remains unclear [181-183]. Although many studies indicated that calcium phosphate compounds may help enhance remineralization by supplying calcium and phosphate in saliva, these studies was observed when used in

conjunction with the fluoride toothpaste. At present, there is no study of the triple calcium phosphate without fluoride toothpaste as used in this study, which xylitol group has only triple calcium phosphate ingredient without fluoride.

Although the result of Analysis of covariance (ANCOVA) showed that there was no statistically significant difference in dmfs and dmft both excluding and including white lesions among the three groups, there is some clinical observation that dmfs in 1000 ppm group is the highest at baseline. This might be explained that children in 1000 ppm group had severe caries more than other two groups. It might be due to their father's occupation which was more stable than other two groups. Moreover, the children in 1000 ppm group live in the municipality area which can be exposed to cariogenic foods earlier and more frequent than other two groups.

The extreme case was an 18-month-old child which her dmfs and dmft including white lesion at baseline were 38 surfaces and 13 teeth, respectively. She had debris present (score 3). She was frequently fed with bottle, both flavorless and sweet flavored milk frequently fall asleep with a bottle, frequently consumed carbohydrate snack and her caregiver started to brush her teeth at the time when many teeth have erupted. When the extreme case was excluded from the analysis, xylitol group had higher incremental dmfs excluding white lesion than the other two fluoride groups. It revealed the same trend with the incidence rate excluding white lesion. This might be explained that fluoride can impede caries progression when

comparing to non-fluoride group. However, the dmfs of three groups were not also statistically different.

5.1.2 Child oral health-related behaviors

At the end of the study, the three groups in this study demonstrated significantly improved brushing habits comparing to baseline. This result indicates that oral health education with hands-on tooth brushing practice and home visits enhanced the oral health care practices of the child's caregivers. Therefore, the effect of poor oral hygiene practice did not interfere the results of this study. Caregivers need to be educated because most infants and toddlers are not cooperative and may resist tooth brushing. A study [205] evaluating hands-on tooth brushing using fluoride toothpaste and home visits every 4 months in 9- to 18-month children found that the caries score of the intervention group was significantly lower than the control group. They also found that the intervention group had better oral cleaning behavior; however, other oral health behaviors were not modified in either group. This study, did not try to change other feeding habits other than brushing that may have an effect on caries progression. At 12 months, the results showed a higher percentage of caretakers reported brushing and increased frequency of brushing (per week). There were decreased nighttime bottle feeding and snacking between meals, while frequency of the child falling asleep with a bottle did not change. These changes may be due to the child development and/or the effect of hands-on

sessions. However, these factors have no contribution to our findings as they were included in the analysis as covariates and cofactors.

5.2 Implementation of program faced some limitation

This study attempts to fill the gap of knowledge in relation to the use of fluoride toothpaste in infants and toddlers where dental fluorosis is a particular concern. However, there were some unexpected limitations on methodological procedure that might affect the study's findings. The study was designed to compare the effectiveness of different fluoride concentrations (1000 ppm F, 500 ppm F, or non-fluoride containing xylitol and triple calcium phosphate). Firstly, at the follow-up stage, the researcher could not manage to have the same caregiver answering questionnaire and participating in every session. In Thai culture, usually the child is taken care by many caregivers in extended family such as parents, grandparents or relatives. This might lead to inconsistent responses but it reflected the real Thai situation. In addition, it was difficult for the examiners to detect non-cavitated caries in crying infants and toddlers using natural light. Because this study was conducted in a low socioeconomic group in a small rural area, the generalizability of the results should be concerned.

Secondly, for ethical reasons, it was necessary to provide the routine tooth brushing with toothpaste containing fluoride or other substances, which have the same anticariogenic properties twice a day. Using placebo toothpaste could be

impossible in this study. Toothpastes for children which were marketed in Thailand generally were fluoride toothpaste. Some of them were fluoride plus sugar polyol such as xylitol or sorbitol. Toothpaste with xylitol that was launched generally has 5% xylitol. There is no 10% xylitol in toothpaste for children. The non-fluoride containing xylitol and triple calcium phosphate toothpastes used as a comparison group in this study, instead of placebo toothpaste, were marketed for parents who are concern about fluorosis. Therefore, this study chose toothpaste containing 5% xylitol plus 2.1% sarcosinate, triple calcium, and phosphate without fluoride (Pureen, U.S. Summit company, USA) as a comparison group. This toothpaste was the best non-fluoride toothpaste available in the market at that time.

Thirdly, limitation of this study, the subjects who were grouped into three cluster based on village areas to eliminate the risk of toothpaste contamination among subjects in the nearby village. This population might be some differences of group characteristics. Children in some group lived in sub district municipality and they can be exposed to cariogenic foods earlier and more frequently than other group. However, this limitation can be adjusted by statistical analysis.

Lastly, the overall dropout rate after 1 year was 28.4% which was much lower than the expected rate of 50% used in sample size calculation. Although a short follow up period (12 mo) was used in the present study, 12 months period was adequate to detect change in incremental dmf rate in primary teeth. By reviewing

the previous studies in Thai toddlers living in rural areas where general population were considered high risk group, they found change in caries lesion for very young children [7, 45, 205]. Therefore, the present study decided to apply the 12 months follow up period. However, further studies with longer periods of follow up, would yield a more concrete result.

Moreover, calculation of the use of fluoride toothpastes and ingestion of toothpastes should be determined for each child in further study. It may be a question whether the total amount of fluoride ingested by children in each group is equal or not.

CHAPTER VI
CONCLUSION

6.1 Summary of the study

A clustered randomized, double blind field experimental study was conducted to evaluate the effectiveness of different concentrations of fluoride toothpaste in preventing ECC in a group of Thai infants and toddlers comparing to non-fluoride containing xylitol toothpaste.

The primary caregivers were divided into one comparison and two experimental groups. The experimental groups received different concentrations of fluoride toothpaste (1000 ppm F and 500 ppm F) and the comparison group received non-fluoridated toothpaste with xylitol and triple calcium phosphate for their child tooth brushing. Both experimental and comparison groups received oral health education with hands-on tooth brushing practice for ECC prevention.

The study population was the primary caregiver whose child lived in 13 villages of U-thong sub district, U-thong district, Supanburi province. Thirteen villages were clustered into three clusters for avoiding the contamination of sharing toothpaste. Three toothpastes were randomly assigned to each group by drawing lots in white opaque sealed envelope. Individuals who satisfied the inclusion criteria were enrolled in the study. They were excluded if they planned to move out from the area within a year and/or who had a limited ability to read Thai and/or did not

use the assigned toothpaste and/or brushing their children's teeth less than 3 times a week.

This study consisted of 2 parts: 1) preparation for implementation and 2) implementation of intervention. Details are as follows: 1) Getting approval for implementation from the Ethical Committee, developing the research instruments, and seeking for the setting. 2) Preparatory procedures for implementing the program included Village Health Volunteers (VHVs) meeting and tooth brushing technique training and developing practice guidelines for program implementation. 3) Children underwent an oral examination and their caregivers received a questionnaire-guided interview at baseline and at 12 month. 4) The caregiver received oral health education and hands-on tooth brushing practices. The hands-on tooth brushing practice was assisted by VHVs and reinforced for the second and third visits. Content of oral health education emphasized the correlation between growth and development and ECC, the identification of plaque, white lesions progressing into cavitated lesions. They were informed that white lesions could be reversed by brushing with F toothpaste. 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.

Data were collected at beginning of the study (baseline) and 12 months after enrolling to the study through individual clinical oral examination and interview. Data were collected from May 2013 to May 2014.

In summary, the results indicated that there were no statistically significant difference in caries increments using 1000 ppm, 500 ppm and non-F (xylitol with triple calcium phosphate) toothpaste in infants and toddlers. The incremental dmfs both including and excluding white lesions were 7.30±11.54, 3.87±6.02 and 4.68±6.89 for including white lesion and 4.78±12.03, 2.40±4.00, 3.68±7.27 for excluding white lesion in 1000 ppm, 500 ppm and xylitol, respectively. The results of the questionnaires showed no significant difference in the oral health habits of the children between the three groups at baseline or after 12 months. Comparing the oral health habits before and after the intervention, no significant difference was found in the habit of the child falling asleep with a bottle ($p>0.05$). However, nighttime bottle-feeding and snacking between meals were significantly decreased ($p<0.05$) after 12 months. The caregivers in each group improved their child's tooth brushing, the frequency of brushing (per week) was significantly increased after hands-on tooth brushing session ($p<0.05$).

6.2 Implication

Firstly, the implication of this study relates to the concern of fluorosis if high-dose F toothpaste is used in infants and toddlers age group. The results from this

study suggest that 500 ppm fluoride toothpastes could be the alternative toothpaste in infants and toddlers whose parents are concerned about fluorosis because there is no statistically significant difference between 500 and 1000 ppm in caries prevention effect. Xylitol toothpaste has a tendency for cavitated lesion to be observed and its cost is higher than other two groups. Therefore, xylitol is not an alternative choice.

Secondly, involving the caregivers in regular oral health education programs with hands-on tooth brushing practice and supervised daily tooth brushing improved the children's oral hygiene and caries increment. Caregivers need to be educated because most infants and toddlers are not cooperative and may resist tooth brushing.

REFERENCES

1. De Grauwe, A, Aps, JK, and Martens, LC, *Early Childhood Caries (ECC): what's in a name?* Eur J Paediatr Dent, 2004. **5**(2): p. 62-70.
2. Dental Health Division, DoH, Ministry of Public Health, *The 7th National Oral Health Survey 2012 Bangkok, Thailand*. 2012.
3. Thitasomakul, S, Piwat, S, Thearmontree, A, et al., *Risks for early childhood caries analyzed by negative binomial models.* J Dent Res, 2009. **88**(2): p. 137-41.
4. Vachirarojpisan, T, Shinada, K, Kawaguchi, Y, et al., *Early childhood caries in children aged 6-19 months.* Community Dent Oral Epidemiol, 2004. **32**(2): p. 133-42.
5. Sutthavong, S, Taebanpakul, S, Kuruchitkosol, C, et al., *Oral health status, dental caries risk factors of the children of public kindergarten and schools in Phranakornsriayudhya, Thailand.* J Med Assoc Thai, 2010. **93 Suppl 6**: p. S71-8.
6. Thanakanjanaphakdee W. and C, T, *Effectiveness of Parental Hands-on Toothbrushing Instruction toward The 1-Year Incremental dmf Rate of 9-18 Month Old Children.* J Dent Assoc Thai, 2010. **60**: p. 85-94.
7. Thitasomakul, S, Thearmontree, A, Piwat, S, et al., *A longitudinal study of early childhood caries in 9- to 18-month-old Thai infants.* Community Dent Oral Epidemiol, 2006. **34**(6): p. 429-36.
8. Dental Health Division. *Comparison of report on the2nd-7th national oral health survey of Thailand (2012).* 2013 [cited 2016 Jan 12]; Available from: http://www.anamai.ecgates.com/
9. Division, DH. *Comparison of the 2-7th National Oral Health Survey 1987-2012 Bangkok, Thailand.* . 2012 [cited 2014 October 10]; Available from: http://www.anamai.ecgates.com/userfiles/file/compare.pdf.

10. Brice, DM, Blum, JR, and Steinberg, BJ, *The etiology, treatment, and prevention of nursing caries.* Compend Contin Educ Dent, 1996. **17**(1): p. 92, 94, 96-8 passim.
11. Keulers, BJ, Roumen, RH, Keulers, MJ, Vandermeeren, L, and Bekke, JP, *Bilateral groin pain from a rotten molar.* Lancet, 2005. **366**(9479): p. 94.
12. Moschos, MM, Brouzas, D, Mezitis, M, and Zachariadis, N, *Visual loss due to a carious tooth.* Lancet, 2005. **366**(9495): p. 1504.
13. Psoter, WJ, Reid, BC, and Katz, RV, *Malnutrition and dental caries: a review of the literature.* Caries Res, 2005. **39**(6): p. 441-7.
14. Psoter, WJ, Spielman, AL, Gebrian, B, St Jean, R, and Katz, RV, *Effect of childhood malnutrition on salivary flow and pH.* Arch Oral Biol, 2008. **53**(3): p. 231-7.
15. Filstrup, SL, Briskie, D, da Fonseca, M, et al., *Early childhood caries and quality of life: child and parent perspectives.* Pediatr Dent, 2003. **25**(5): p. 431-40.
16. Meghashyam, B, Nagesh, L, and Ankola, A, *Dental caries status and treatment needs of children of fisher folk communities, residing in the coastal areas of Karnataka region, south India.* West Indian Med J, 2007. **56**(1): p. 96-8.
17. Yee, R and Sheiham, A, *The burden of restorative dental treatment for children in Third World countries.* Int Dent J, 2002. **52**(1): p. 1-9.
18. Harris, R, Nicoll, AD, Adair, PM, and Pine, CM, *Risk factors for dental caries in young children: a systematic review of the literature.* Community Dent Health, 2004. **21**(1 Suppl): p. 71-85.
19. Jose, B and King, NM, *Early childhood caries lesions in preschool children in Kerala, India.* Pediatr Dent, 2003. **25**(6): p. 594-600.
20. Milgrom, P, *Response to Reisine & Douglass: psychosocial and behavioral issues in early childhood caries.* Community Dent Oral Epidemiol, 1998. **26**(1 Suppl): p. 45-8.

21. Reisine, ST and Psoter, W, *Socioeconomic status and selected behavioral determinants as risk factors for dental caries.* J Dent Educ, 2001. **65**(10): p. 1009-16.
22. Seow, WK, *Biological mechanisms of early childhood caries.* Community Dent Oral Epidemiol, 1998. **26**(1 Suppl): p. 8-27.
23. Vanobbergen, J, Martens, L, Lesaffre, E, Bogaerts, K, and Declerck, D, *Assessing risk indicators for dental caries in the primary dentition.* Community Dent Oral Epidemiol, 2001. **29**(6): p. 424-34.
24. Veerkamp, JS and Weerheijm, KL, *Nursing-bottle caries: the importance of a development perspective.* ASDC J Dent Child, 1995. **62**(6): p. 381-6.
25. Ismail, AI, *Prevention of early childhood caries.* Community Dent Oral Epidemiol, 1998. **26**(1 Suppl): p. 49-61.
26. American Academy of Pediatrics and Oral Health Initiative. *Oral Health Risak Assessment: Training for Pediatricians and Other Child Health Professionals*. 2011 [cited 2011 April 15]; Available from: www.aap.org/commpeds/dochs/oralhealth/ohracme.cfm.
27. Walsh, T, Worthington, HV, Glenny, AM, et al., *Fluoride toothpastes of different concentrations for preventing dental caries in children and adolescents.* Cochrane Database Syst Rev, 2010(1): p. CD007868.
28. Wong, MC, Glenny, AM, Tsang, BW, et al., *Topical fluoride as a cause of dental fluorosis in children.* Cochrane Database Syst Rev, 2010(1): p. CD007693.
29. Ellwood, RP and Cury, JA, *How much toothpaste should a child under the age of 6 years use?* Eur Arch Paediatr Dent, 2009. **10**(3): p. 168-74.
30. American Academy of Pediatric Dentistry, *Guideline on fluoride therapy.* Pediatr Dent, 2012. **36(6); 162-165**.
31. Wong, MC, Clarkson, J, Glenny, AM, et al., *Cochrane reviews on the benefits/risks of fluoride toothpastes.* J Dent Res, 2011. **90**(5): p. 573-9.

32. Whittle, JG, Whitehead, HF, and Bishop, CM, *A randomised control trial of oral health education provided by a health visitor to parents of pre-school children.* Community Dent Health, 2008. **25**(1): p. 28-32.
33. Andruskeviciene, V, Milciuviene, S, Bendoraitiene, E, et al., *Oral health status and effectiveness of caries prevention programme in kindergartens in Kaunas city (Lithuania).* Oral Health Prev Dent, 2008. **6**(4): p. 343-8.
34. Rong, WS, Bian, JY, Wang, WJ, and Wang, JD, *Effectiveness of an oral health education and caries prevention program in kindergartens in China.* Community Dent Oral Epidemiol, 2003. **31**(6): p. 412-6.
35. Davies, GM, Worthington, HV, Ellwood, RP, et al., *A randomised controlled trial of the effectiveness of providing free fluoride toothpaste from the age of 12 months on reducing caries in 5-6 year old children.* Community Dent Health, 2002. **19**(3): p. 131-6.
36. Lima, TJ, Ribeiro, CC, Tenuta, LM, and Cury, JA, *Low-fluoride dentifrice and caries lesion control in children with different caries experience: a randomized clinical trial.* Caries Res, 2008. **42**(1): p. 46-50.
37. Featherstone, JD, *Dental caries: a dynamic disease process.* Aust Dent J, 2008. **53**(3): p. 286-91.
38. Stephan, RM, *pH and dental caries.* J Dent Res, 1947. **26**(4): p. 340.
39. Featherstone, JD, Nelson, DG, and McLean, JD, *An electron microscope study of modifications to defect regions in dental enamel and synthetic apatites.* Caries Res, 1981. **15**(4): p. 278-88.
40. Borges, BC, de Souza Borges, J, de Araujo, LS, et al., *Update on nonsurgical, ultraconservative approaches to treat effectively non-cavitated caries lesions in permanent teeth.* Eur J Dent, 2011. **5**(2): p. 229-36.
41. Featherstone, JD, Glena, R, Shariati, M, and Shields, CP, *Dependence of in vitro demineralization of apatite and remineralization of dental enamel on fluoride concentration.* J Dent Res, 1990. **69 Spec No**: p. 620-5; discussion 634-6.

42. ten Cate, JM and Featherstone, JD, *Mechanistic aspects of the interactions between fluoride and dental enamel.* Crit Rev Oral Biol Med, 1991. **2**(3): p. 283-96.

43. American Academy of Pediatric Dentistry, *Definition of early childhood caries (ECC).* Pediatr Dent, 2008.

44. Dental Health Division. *Report on the7th national oral health survey of Thailand (2012)*. 2013 [cited 2014 Feb 20]; Available from: http://www.anamai.ecgates.com/

45. Vachirarojpisan, T, Shinada, K, and Kawaguchi, Y, *The process and outcome of a programme for preventing early childhood caries in Thailand.* Community Dent Health, 2005. **22**(4): p. 253-9.

46. Johnsen, DC, Schechner, TG, and Gerstenmaier, JH, *Proportional changes in caries patterns from early to late primary dentition.* J Public Health Dent, 1987. **47**(1): p. 5-9.

47. Hallett, KB and O'Rourke, PK, *Pattern and severity of early childhood caries.* Community Dent Oral Epidemiol, 2006. **34**(1): p. 25-35.

48. Acs, G and Ng, MW, *Early childhood caries and well being.* Pediatr Dent, 2002. **24**(4): p. 288.

49. Acs, G, Pretzer, S, Foley, M, and Ng, MW, *Perceived outcomes and parental satisfaction following dental rehabilitation under general anesthesia.* Pediatr Dent, 2001. **23**(5): p. 419-23.

50. Wadhawan, S, Kumar, JV, Badner, VM, and Green, EL, *Early childhood caries-related visits to hospitals for ambulatory surgery in New York State.* J Public Health Dent, 2003. **63**(1): p. 47-51.

51. Peretz, B, Ram, D, Azo, E, and Efrat, Y, *Preschool caries as an indicator of future caries: a longitudinal study.* Pediatr Dent, 2003. **25**(2): p. 114-8.

52. Matee, MI, Mikx, FH, Maselle, SY, and Van Palenstein Helderman, WH, *Mutans streptococci and lactobacilli in breast-fed children with rampant caries.* Caries Res, 1992. **26**(3): p. 183-7.

53. Tinanoff, N, Kanellis, MJ, and Vargas, CM, *Current understanding of the epidemiology mechanisms, and prevention of dental caries in preschool children.* Pediatr Dent, 2002. **24**(6): p. 543-51.

54. Mattos-Graner, RO, Correa, MS, Latorre, MR, Peres, RC, and Mayer, MP, *Mutans streptococci oral colonization in 12-30-month-old Brazilian children over a one-year follow-up period.* J Public Health Dent, 2001. **61**(3): p. 161-7.

55. Wan, AK, Seow, WK, Purdie, DM, et al., *Oral colonization of Streptococcus mutans in six-month-old predentate infants.* J Dent Res, 2001. **80**(12): p. 2060-5.

56. Mohan, A, Morse, DE, O'Sullivan, DM, and Tinanoff, N, *The relationship between bottle usage/content, age, and number of teeth with mutans streptococci colonization in 6-24-month-old children.* Community Dent Oral Epidemiol, 1998. **26**(1): p. 12-20.

57. Berkowitz, RJ, *Mutans streptococci: acquisition and transmission.* Pediatr Dent, 2006. **28**(2): p. 106-9; discussion 192-8.

58. Seow, WK, *Enamel hypoplasia in the primary dentition: a review.* ASDC J Dent Child, 1991. **58**(6): p. 441-52.

59. Featherstone J. D., *Clinical Aspects of De/Remineralization of Teeth. Proceedings of Models Conference 1994.* Adv Dent Res, 1995. **9**(3): p. 169-340.

60. Dowd, FJ, *Saliva and dental caries.* Dent Clin North Am, 1999. **43**(4): p. 579-97.

61. Marino, RV, Bomze, K, Scholl, TO, and Anhalt, H, *Nursing bottle caries: characteristics of children at risk.* Clin Pediatr (Phila), 1989. **28**(3): p. 129-31.

62. Williams, SA and Hargreaves, JA, *An inquiry into the effects of health related behaviour on dental health among young Asian children resident in a fluoridated city in Canada.* Community Dent Health, 1990. **7**(4): p. 413-20.

63. Febres, C, Echeverri, EA, and Keene, HJ, *Parental awareness, habits, and social factors and their relationship to baby bottle tooth decay.* Pediatr Dent, 1997. **19**(1): p. 22-7.

64. Subsandee, K, Chongvisal, S, Kittitavornkul, N, and Wangprasertkul, N, *Bottle-using behaviors in a group of Bangkok preschool children.* CU Dent J, 2008(31): p. 273-82.

65. Dennison, BA, *Fruit juice consumption by infants and children: a review.* J Am Coll Nutr, 1996. **15**(5 Suppl): p. 4S-11S.

66. Wigen, TI and Wang, NJ, *Parental influences on dental caries development in preschool children. An overview with emphasis on recent Norwegian research.* Norsk Epidemiologi, 2012. **22**(1): p. 13-19.

67. Burt B. A., ESA, ed. *Dentistry, Dental Practice, and the Community. 5th ed*. 1999.

68. Holtta, P and Alaluusua, S, *Effect of supervised use of a fluoride toothpaste on caries incidence in pre-school children.* Int J Paediatr Dent, 1992. **2**(3): p. 145-9.

69. Schwarz, E, Lo, EC, and Wong, MC, *Prevention of early childhood caries--results of a fluoride toothpaste demonstration trial on Chinese preschool children after three years.* J Public Health Dent, 1998. **58**(1): p. 12-8.

70. Sjogren, K, Birkhed, D, and Rangmar, B, *Effect of a modified toothpaste technique on approximal caries in preschool children.* Caries Res, 1995. **29**(6): p. 435-41.

71. Curnow, MM, Pine, CM, Burnside, G, et al., *A randomised controlled trial of the efficacy of supervised toothbrushing in high-caries-risk children.* Caries Res, 2002. **36**(4): p. 294-300.

72. Frazao, P, *Effectiveness of the bucco-lingual technique within a school-based supervised toothbrushing program on preventing caries: a randomized controlled trial.* BMC Oral Health, 2011. **11**: p. 11.

73. Gibson, S and Williams, S, *Dental caries in pre-school children: associations with social class, toothbrushing habit and consumption of sugars and sugar-containing foods. Further analysis of data from the National Diet and Nutrition Survey of children aged 1.5-4.5 years.* Caries Res, 1999. **33**(2): p. 101-13.

74. Kallestal, C, Norlund, A, Soder, B, et al., *Economic evaluation of dental caries prevention: a systematic review.* Acta Odontol Scand, 2003. **61**(6): p. 341-6.

75. American Academy of Pediatric Dentistry, *Guildline on infant oral health care.* Pediatr Dent, 2012. **34 (6); 132-136**.

76. Habibian, M, Roberts, G, Lawson, M, Stevenson, R, and Harris, S, *Dietary habits and dental health over the first 18 months of life.* Community Dent Oral Epidemiol, 2001. **29**(4): p. 239-46.

77. Jackson, RJ, Newman, HN, Smart, GJ, et al., *The effects of a supervised toothbrushing programme on the caries increment of primary school children, initially aged 5-6 years.* Caries Res, 2005. **39**(2): p. 108-15.

78. Senesombath, S, Nakornchai, S, Banditsing, P, and Lexomboon, D, *Early childhood caries and related factors in Vientiane, Lao PDR.* Southeast Asian J Trop Med Public Health, 2010. **41**(3): p. 717-25.

79. Detsomboonrat, P and Pisarnturakit, PP, *Dental Caries and Related Oral Health Factors among 9 to 18 Month Old Thai Children.* Southeast Asian Journal of Tropical Medicine and Public Health, 2015. **46**(4): p. 786-797.

80. Trairatvorakul, C, *Early Childhood Caries Situation in Thailand*, in *4th Conference of Pediatric Dentistry Association of Asia*. 2004: Thailand.

81. Sjogren, K, Ekstrand, J, and Birkhed, D, *Effect of water rinsing after toothbrushing on fluoride ingestion and absorption.* Caries Res, 1994. **28**(6): p. 455-9.

82. Sjogren, K and Birkhed, D, *Factors related to fluoride retention after toothbrushing and possible connection to caries activity.* Caries Res, 1993. **27**(6): p. 474-7.

83. Touger-Decker, R and van Loveren, C, *Sugars and dental caries.* Am J Clin Nutr, 2003. **78**(4): p. 881S-892S.

84. Mobley, C, Marshall, TA, Milgrom, P, and Coldwell, SE, *The contribution of dietary factors to dental caries and disparities in caries.* Acad Pediatr, 2009. **9**(6): p. 410-4.

85. American Dental Association, *Your child's growing smile.* J Am Dent Assoc, 2012. **143**(1): p. 88.

86. Nainar, SM and Straffon, LH, *Targeting of the year one dental visit for United States children.* Int J Paediatr Dent, 2003. **13**(4): p. 258-63.

87. Moimaz, SA, Fadel, CB, Lolli, LF, et al., *Social aspects of dental caries in the context of mother-child pairs.* J Appl Oral Sci, 2014. **22**(1): p. 73-8.

88. Warren, JJ, Weber-Gasparoni, K, Marshall, TA, et al., *Factors associated with dental caries experience in 1-year-old children.* J Public Health Dent, 2008. **68**(2): p. 70-5.

89. Hallett, KB and O'Rourke, PK, *Social and behavioural determinants of early childhood caries.* Aust Dent J, 2003. **48**(1): p. 27-33.

90. Jigjid, B, Ueno, M, Shinada, K, and Kawaguchi, Y, *Early childhood caries and related risk factors in Mongolian children.* Community Dent Health, 2009. **26**(2): p. 121-8.

91. Uribe, S, *Early childhood caries--risk factors.* Evid Based Dent, 2009. **10**(2): p. 37-8.

92. Szatko, F, Wierzbicka, M, Dybizbanska, E, Struzycka, I, and Iwanicka-Frankowska, E, *Oral health of Polish three-year-olds and mothers' oral health-related knowledge.* Community Dent Health, 2004. **21**(2): p. 175-80.

93. Riedy, CA, Weinstein, P, Milgrom, P, and Bruss, M, *An ethnographic study for understanding children's oral health in a multicultural community.* Int Dent J, 2001. **51**(4): p. 305-12.

94. Blinkhorn, AS, Wainwright-Stringer, YM, and Holloway, PJ, *Dental health knowledge and attitudes of regularly attending mothers of high-risk, pre-school children.* Int Dent J, 2001. **51**(6): p. 435-8.

95. Chestnutt, IG, Murdoch, C, and Robson, KF, *Parents and carers' choice of drinks for infants and toddlers, in areas of social and economic disadvantage.* Community Dent Health, 2003. **20**(3): p. 139-45.

96. Gussy, MG, Waters, EB, Riggs, EM, Lo, SK, and Kilpatrick, NM, *Parental knowledge, beliefs and behaviours for oral health of toddlers residing in rural Victoria.* Aust Dent J, 2008. **53**(1): p. 52-60.

97. Finlayson, TL, Siefert, K, Ismail, AI, and Sohn, W, *Maternal self-efficacy and 1-5-year-old children's brushing habits.* Community Dent Oral Epidemiol, 2007. **35**(4): p. 272-81.

98. Hamilton, FA, Davis, KE, and Blinkhorn, AS, *An oral health promotion programme for nursing caries.* Int J Paediatr Dent, 1999. **9**(3): p. 195-200.

99. Plutzer, K and Spencer, AJ, *Efficacy of an oral health promotion intervention in the prevention of early childhood caries.* Community Dent Oral Epidemiol, 2008. **36**(4): p. 335-46.

100. Kowash, MB, Pinfield, A, Smith, J, and Curzon, ME, *Effectiveness on oral health of a long-term health education programme for mothers with young children.* Br Dent J, 2000. **188**(4): p. 201-5.

101. Davies, GM, Duxbury, JT, Boothman, NJ, Davies, RM, and Blinkhorn, AS, *A staged intervention dental health promotion programme to reduce early childhood caries.* Community Dent Health, 2005. **22**(2): p. 118-22.

102. Sgan-Cohen, HD, Mansbach, IK, Haver, D, and Gofin, R, *Community-oriented oral health promotion for infants in Jerusalem: evaluation of a program trial.* J Public Health Dent, 2001. **61**(2): p. 107-13.

103. Harrison, R, *Oral health promotion for high-risk children: case studies from British Columbia.* J Can Dent Assoc, 2003. **69**(5): p. 292-6.

104. Harrison, R, Benton, T, Everson-Stewart, S, and Weinstein, P, *Effect of motivational interviewing on rates of early childhood caries: a randomized trial.* Pediatr Dent, 2007. **29**(1): p. 16-22.

105. Gussy, MG, Waters, EG, Walsh, O, and Kilpatrick, NM, *Early childhood caries: current evidence for aetiology and prevention.* J Paediatr Child Health, 2006. **42**(1-2): p. 37-43.

106. Weintraub, JA, Ramos-Gomez, F, Jue, B, et al., *Fluoride varnish efficacy in preventing early childhood caries.* J Dent Res, 2006. **85**(2): p. 172-6.

107. Mejare, I, Lingstrom, P, Petersson, LG, et al., *Caries-preventive effect of fissure sealants: a systematic review.* Acta Odontol Scand, 2003. **61**(6): p. 321-30.

108. Marinho, VC, Higgins, JP, Sheiham, A, and Logan, S, *Fluoride toothpastes for preventing dental caries in children and adolescents.* Cochrane Database Syst Rev, 2003(1): p. CD002278.

109. Twetman, S, Axelsson, S, Dahlgren, H, et al., *Caries-preventive effect of fluoride toothpaste: a systematic review.* Acta Odontol Scand, 2003. **61**(6): p. 347-55.

110. Ammari, JB, Baqain, ZH, and Ashley, PF, *Effects of programs for prevention of early childhood caries. A systematic review.* Med Princ Pract, 2007. **16**(6): p. 437-42.

111. You, BJ, Jian, WW, Sheng, RW, et al., *Caries prevention in Chinese children with sodium fluoride dentifrice delivered through a kindergarten-based oral health program in China.* J Clin Dent, 2002. **13**(4): p. 179-84.

112. Department of Health , MoPH. *Dental Health*. [cited 2015 Nov17]; Available from: http://eng.anamai.moph.go.th/main.php?filename=index.

113. Ungchusak, C, Prasertsom, P., Nakornchai, S., Leelathaveewut, P., Taveeboon, S., & and Taveeboon, B, *Revised situation of problem and knowledge in primary tooth dental caries project*. 2004: Bangkok: TRF.

114. Wongkongkathep, S, *Review of dental health personnel and Thailand oral health services.* 2006, Bangkok: Ministry of Public Health.

115. Lekswat, P and Promchai, S. *The effectiveness of an Oral Health Promotion Program by Applying a Community Empowerment Principle in Preschool Children, in Lumphun, Thailand.* 2007; Available from: http://icoh.anamai.moph.fo.th/eng/.

116. Cochrane, NJ, Cai, F, Huq, NL, Burrow, MF, and Reynolds, EC, *New approaches to enhanced remineralization of tooth enamel.* J Dent Res, 2010. **89**(11): p. 1187-97.

117. Lynch, RJ, Navada, R, and Walia, R, *Low-levels of fluoride in plaque and saliva and their effects on the demineralisation and remineralisation of enamel; role of fluoride toothpastes.* Int Dent J, 2004. **54**(5 Suppl 1): p. 304-9.

118. White, DJ and Nancollas, GH, *Physical and chemical considerations of the role of firmly and loosely bound fluoride in caries prevention.* J Dent Res, 1990. **69 Spec No**: p. 587-94; discussion 634-6.

119. Hamilton, IR, *Biochemical effects of fluoride on oral bacteria.* J Dent Res, 1990. **69 Spec No**: p. 660-7; discussion 682-3.

120. Bowden, GH, *Effects of fluoride on the microbial ecology of dental plaque.* J Dent Res, 1990. **69 Spec No**: p. 653-9; discussion 682-3.

121. Marquis, RE, *Diminished acid tolerance of plaque bacteria caused by fluoride.* J Dent Res, 1990. **69 Spec No**: p. 672-5; discussion 682-3.

122. Mc, CF and Likins, RC, *Fluorine in human teeth studied in relation to fluorine in the drinking water.* J Dent Res, 1951. **30**(2): p. 172-6.

123. Murray, JJ, *Efficacy of preventive agents for dental caries. Systemic fluorides: water fluoridation.* Caries Res, 1993. **27 Suppl 1**: p. 2-8.

124. Groeneveld, A, Van Eck, AA, and Backer Dirks, O, *Fluoride in caries prevention: is the effect pre- or post-eruptive?* J Dent Res, 1990. **69 Spec No**: p. 751-5; discussion 820-3.

125. Clarkson, BH, Fejerskov, O, Ekstrand, J, and Burt, BA, *Rational use of fluorides in caries control*, in *Fluoride in dentistry*, O. Fejerskov, J. Ekstrand, and Burt B. A., Editors. 1996, Munksgaard: Copenhegen. p. 347-57.

126. Azarpazhooh, A and Main, PA, *Fluoride varnish in the prevention of dental caries in children and adolescents: a systematic review.* J Can Dent Assoc, 2008. **74**(1): p. 73-9.

127. Ciketic, S, Hayatbakhsh, MR, and Doran, CM, *Drinking water fluoridation in South East Queensland: a cost-effectiveness evaluation.* Health Promot J Austr, 2010. **21**(1): p. 51-6.

128. Guzman-Armstrong, S, Chalmers, J, and Warren, JJ, *Ask us. White spot lesions: prevention and treatment.* Am J Orthod Dentofacial Orthop, 2010. **138**(6): p. 690-6.

129. Pulido, MT, Wefel, JS, Hernandez, MM, et al., *The inhibitory effect of MI paste, fluoride and a combination of both on the progression of artificial caries-like lesions in enamel.* Oper Dent, 2008. **33**(5): p. 550-5.

130. Quinonez, RB, Stearns, SC, Talekar, BS, Rozier, RG, and Downs, SM, *Simulating cost-effectiveness of fluoride varnish during well-child visits for Medicaid-enrolled children.* Arch Pediatr Adolesc Med, 2006. **160**(2): p. 164-70.

131. Schirrmeister, JF, Gebrande, JP, Altenburger, MJ, Monting, JS, and Hellwig, E, *Effect of dentifrice containing 5000 ppm fluoride on non-cavitated fissure carious lesions in vivo after 2 weeks.* Am J Dent, 2007. **20**(4): p. 212-6.

132. Twetman, S, *Prevention of early childhood caries (ECC)--review of literature published 1998-2007.* Eur Arch Paediatr Dent, 2008. **9**(1): p. 12-8.

133. Menghini, G, Steiner, M, Thomet, E, et al., *Further caries decline in Swiss recruits from 1996 to 2006.* Schweiz Monatsschr Zahnmed, 2010. **120**(7): p. 590-600.

134. Reich, E, *Trends in caries and periodontal health epidemiology in Europe.* Int Dent J, 2001. **51**(6 Suppl 1): p. 392-8.

135. Steiner, M, Menghini, G, Marthaler, TM, and Imfeld, T, *Changes in dental caries in Zurich school-children over a period of 45 years.* Schweiz Monatsschr Zahnmed, 2010. **120**(12): p. 1084-1104.

136. Kargul, B, Caglar, E, and Tanboga, I, *History of water fluoridation.* J Clin Pediatr Dent, 2003. **27**(3): p. 213-7.

137. Lennon, MA, *A systematic review of public water fluoridation--a commentary.* Community Dent Health, 2000. **17**(3): p. 130-3.

138. Griffin, SO, Jones, K, and Tomar, SL, *An economic evaluation of community water fluoridation.* J Public Health Dent, 2001. **61**(2): p. 78-86.

139. Newbrun, E, *Effectiveness of water fluoridation.* J Public Health Dent, 1989. **49**(5 Spec No): p. 279-89.

140. Department of Health and Human Service. *Proposed HHS Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental Caries.* July 15,2012]; Available from: http://www'hhs.gov/news/press/2011pres/01/pre_pub_frn_fluoride.html.

141. Pantumvanich P., SY, Hansawat S., Leksawat P., R.G. Schamschula.,, *The relationship between fluoride level in drinking water and dental fluorosis in Chiangmai, Program and Abstracts of Science and* 1984.

142. Ripa, LW, *A critique of topical fluoride methods (dentifrices, mouthrinses, operator-, and self-applied gels) in an era of decreased caries and increased fluorosis prevalence.* J Public Health Dent, 1991. **51**(1): p. 23-41.

143. Marinho, VC, Higgins, JP, Logan, S, and Sheiham, A, *Fluoride mouthrinses for preventing dental caries in children and adolescents.* Cochrane Database Syst Rev, 2003(3): p. CD002284.

144. Marinho, VC, Higgins, JP, Logan, S, and Sheiham, A, *Topical fluoride (toothpastes, mouthrinses, gels or varnishes) for preventing dental caries in children and adolescents.* Cochrane Database Syst Rev, 2003(4): p. CD002782.

145. Marinho, VC, Higgins, JP, Sheiham, A, and Logan, S, *Combinations of topical fluoride (toothpastes, mouthrinses, gels, varnishes) versus single topical fluoride for preventing dental caries in children and adolescents.* Cochrane Database Syst Rev, 2004(1): p. CD002781.

146. Marinho, VC, Higgins, JP, Sheiham, A, and Logan, S, *One topical fluoride (toothpastes, or mouthrinses, or gels, or varnishes) versus another for preventing dental caries in children and adolescents.* Cochrane Database Syst Rev, 2004(1): p. CD002780.

147. Marinho, VC, Higgins, JP, Logan, S, and Sheiham, A, *Fluoride varnishes for preventing dental caries in children and adolescents.* Cochrane Database Syst Rev, 2002(3): p. CD002279.

148. Marinho, VC, Higgins, JP, Logan, S, and Sheiham, A, *Fluoride gels for preventing dental caries in children and adolescents.* Cochrane Database Syst Rev, 2002(2): p. CD002280.

149. Duckworth, RM and Morgan, SN, *Oral fluoride retention after use of fluoride dentifrices.* Caries Res, 1991. **25**(2): p. 123-9.

150. Stookey, GK, Schemehorn, BR, Cheetham, BL, Wood, GD, and Walton, GV, *In situ fluoride uptake from fluoride dentifrices by carious enamel.* J Dent Res, 1985. **64**(6): p. 900-3.

151. Bruun, C, Givskov, H, and Thylstrup, A, *Whole saliva fluoride after toothbrushing with NaF and MFP dentifrices with different F concentrations.* Caries Res, 1984. **18**(3): p. 282-8.

152. ten Cate, JM, Exterkate, RA, and Buijs, MJ, *The relative efficacy of fluoride toothpastes assessed with pH cycling.* Caries Res, 2006. **40**(2): p. 136-41.

153. Advani, S, Sogi, S, Hugar, S, et al., *Remineralization effects of two pediatric dentifrices and one regular dentifrice on artificial carious lesion in primary teeth: An in vitro study.* J Int Soc Prev Community Dent, 2014. **4**(2): p. 96-102.

154. Toda, S and Featherstone, JD, *Effects of fluoride dentifrices on enamel lesion formation.* J Dent Res, 2008. **87**(3): p. 224-7.

155. Tantasethi, K and T., T, *Effect of Dentifrices on Early Enamel Lesion in Primary Teeth: in vitro study*, in *Graduate Research Conference*. 2014: Khon Kaen University.

156. Brighenti, FL, Delbem, AC, Buzalaf, MA, et al., *In vitro evaluation of acidified toothpastes with low fluoride content.* Caries Res, 2006. **40**(3): p. 239-44.

157. Ammari, AB, Bloch-Zupan, A, and Ashley, PF, *Systematic review of studies comparing the anti-caries efficacy of children's toothpaste containing 600 ppm of fluoride or less with high fluoride toothpastes of 1,000 ppm or above.* Caries Res, 2003. **37**(2): p. 85-92.

158. Steiner, M, Helfenstein, U, and Menghini, G, *Effect of 1000 ppm relative to 250 ppm fluoride toothpaste. A meta-analysis.* Am J Dent, 2004. **17**(2): p. 85-8.

159. Haftenberger, M, Viergutz, G, Neumeister, V, and Hetzer, G, *Total fluoride intake and urinary excretion in German children aged 3-6 years.* Caries Res, 2001. **35**(6): p. 451-7.

160. Bardsen, A, *"Risk periods" associated with the development of dental fluorosis in maxillary permanent central incisors: a meta-analysis.* Acta Odontol Scand, 1999. **57**(5): p. 247-56.

161. Holt, RD, Morris, CE, Winter, GB, and Downer, MC, *Enamel opacities and dental caries in children who used a low fluoride toothpaste between 2 and 5 years of age.* Int Dent J, 1994. **44**(4): p. 331-41.

162. Tavener, JA, Davies, GM, Davies, RM, and Ellwood, RP, *The prevalence and severity of fluorosis in children who received toothpaste containing either 440 or 1,450 ppm F from the age of 12 months in deprived and less deprived communities.* Caries Res, 2006. **40**(1): p. 66-72.

163. Fan, X, Li, X, Wan, H, et al., *Clinical investigation of the anticaries efficacy of a 1.14% sodium monofluorophosphate (SMFP) calcium carbonate-based dentifrice: a two-year caries clinical trial on children in China.* J Clin Dent, 2008. **19**(4): p. 134-7.

164. Bar, A, *Caries prevention with xylitol. A review of the scientific evidence.* World Rev Nutr Diet, 1988. **55**: p. 183-209.

165. Roberts, MC, Riedy, CA, Coldwell, SE, et al., *How xylitol-containing products affect cariogenic bacteria.* J Am Dent Assoc, 2002. **133**(4): p. 435-41; quiz 492-3.

166. Nayak, PA, Ullal Anand Nayak, and Vishal Khandelwal, *The effect of xylitol on dental caries and oral flora.* Clinical, Cosmetic and Investigational Dentistry, 2014. **6**: p. 89–94.

167. Autio, JT, *Effect of xylitol chewing gum on salivary Streptococcus mutans in preschool children.* ASDC J Dent Child, 2002. **69**(1): p. 81-6, 13.

168. Thaweboon, S, Thaweboon, B, and Soo-Ampon, S, *The effect of xylitol chewing gum on mutans streptococci in saliva and dental plaque.* Southeast Asian J Trop Med Public Health, 2004. **35**(4): p. 1024-7.

169. Holgerson, PL, Sjostrom, I, Stecksen-Blicks, C, and Twetman, S, *Dental plaque formation and salivary mutans streptococci in schoolchildren after use of xylitol-containing chewing gum.* Int J Paediatr Dent, 2007. **17**(2): p. 79-85.

170. Makinen, KK, Alanen, P, Isokangas, P, et al., *Thirty-nine-month xylitol chewing-gum programme in initially 8-year-old school children: a feasibility study focusing on mutans streptococci and lactobacilli.* Int Dent J, 2008. **58**(1): p. 41-50.

171. Deshpande, A and Jadad, AR, *The impact of polyol-containing chewing gums on dental caries: a systematic review of original randomized controlled trials and observational studies.* J Am Dent Assoc, 2008. **139**(12): p. 1602-14.

172. Fontana, M, Catt, D, Eckert, GJ, et al., *Xylitol: effects on the acquisition of cariogenic species in infants.* Pediatr Dent, 2009. **31**(3): p. 257-66.

173. Machiulskiene, V, Nyvad, B, and Baelum, V, *Caries preventive effect of sugar-substituted chewing gum.* Community Dent Oral Epidemiol, 2001. **29**(4): p. 278-88.

174. Nayak, PA, Nayak, UA, and Khandelwal, V, *The effect of xylitol on dental caries and oral flora.* Clin Cosmet Investig Dent, 2014. **6**: p. 89-94.

175. Dentistry, AAoP, *Policy on the use of xylitol in caries prevention.* Pediatr Dent, 2010. **32**((special issue)): p. 36-38.

176. Jannesson, L, Renvert, S, Kjellsdotter, P, et al., *Effect of a triclosan-containing toothpaste supplemented with 10% xylitol on mutans streptococci in saliva and dental plaque. A 6-month clinical study.* Caries Res, 2002. **36**(1): p. 36-9.

177. Sintes, JL, Elias-Boneta, A, Stewart, B, Volpe, AR, and Lovett, J, *Anticaries efficacy of a sodium monofluorophosphate dentifrice containing xylitol in a dicalcium phosphate dihydrate base. A 30-month caries clinical study in Costa Rica.* Am J Dent, 2002. **15**(4): p. 215-9.

178. Sintes, JL, Escalante, C, Stewart, B, et al., *Enhanced anticaries efficacy of a 0.243% sodium fluoride/10% xylitol/silica dentifrice: 3-year clinical results.* Am J Dent, 1995. **8**(5): p. 231-5.

179. Sano, H, Nakashima, S, Songpaisan, Y, and Phantumvanit, P, *Effect of a xylitol and fluoride containing toothpaste on the remineralization of human enamel in vitro.* J Oral Sci, 2007. **49**(1): p. 67-73.

180. Petersson, LG, Birkhed, D, Gleerup, A, Johansson, M, and Jonsson, G, *Caries-preventive effect of dentifrices containing various types and concentrations of fluorides and sugar alcohols.* Caries Res, 1991. **25**(1): p. 74-9.

181. Ekambaram, M, Itthagarun, A, and King, NM, *Comparison of the remineralizing potential of child formula dentifrices.* Int J Paediatr Dent, 2011. **21**(2): p. 132-40.

182. Chi, DL, Tut, O, and Milgrom, P, *Cluster-randomized xylitol toothpaste trial for early childhood caries prevention.* J Dent Child (Chic), 2014. **81**(1): p. 27-32.

183. Evans, A, Leishman, SJ, Walsh, LJ, and Seow, WK, *Inhibitory effects of children's toothpastes on Streptococcus mutans, Streptococcus sanguinis and Lactobacillus acidophilus.* Eur Arch Paediatr Dent, 2015. **16**(2): p. 219-26.

184. Reynolds, EC and Walsh, LJ, *Additional aids to the remineralisation of tooth structure*. Preservation and restoration of tooth structure, ed. n. ed. 2005, Brisbane: Knowledge Books and Software,.

185. Reynolds, EC, Cai, F, Cochrane, NJ, et al., *Fluoride and casein phosphopeptide-amorphous calcium phosphate.* J Dent Res, 2008. **87**(4): p. 344-8.

186. Cochrane, NJ, Saranathan, S, Cai, F, Cross, KJ, and Reynolds, EC, *Enamel subsurface lesion remineralisation with casein phosphopeptide stabilised solutions of calcium, phosphate and fluoride.* Caries Res, 2008. **42**(2): p. 88-97.

187. Reema, SD, Lahiri, PK, and Roy, SS, *Review of casein phosphopeptides-amorphous calcium phosphate.* Chin J Dent Res, 2014. **17**(1): p. 7-14.

188. Reynolds, EC, *Casein phosphopeptide-amorphous calcium phosphate: the scientific evidence.* Adv Dent Res, 2009. **21**(1): p. 25-9.

189. Yimcharoen, V, Rirattanapong, P, and Kiatchallermwong, W, *The effect of casein phosphopeptide toothpaste versus fluoride toothpaste on remineralization of primary teeth enamel.* Southeast Asian J Trop Med Public Health, 2011. **42**(4): p. 1032-40.

190. Karlinsey, RL and Pfarrer, AM, *Fluoride plus functionalized beta-TCP: a promising combination for robust remineralization.* Adv Dent Res, 2012. **24**(2): p. 48-52.

191. Cochrane, NJ, Shen, P, Yuan, Y, and Reynolds, EC, *Ion release from calcium and fluoride containing dental varnishes.* Aust Dent J, 2014. **59**(1): p. 100-5.

192. Karlinsey, RL, Mackey, AC, and Stookey, GK, *In vitro remineralization efficacy of NaF systems containing unique forms of calcium.* Am J Dent, 2009. **22**(3): p. 185-8.

193. Karlinsey, RL, Mackey, AC, Stookey, GK, and Pfarrer, AM, *In vitro assessments of experimental NaF dentifrices containing a prospective calcium phosphate technology.* Am J Dent, 2009. **22**(3): p. 180-4.

194. Karlinsey, RL, Mackey, AC, Walker, ER, and Frederick, KE, *Preparation, characterization and in vitro efficacy of an acid-modified beta-TCP material for dental hard-tissue remineralization.* Acta Biomater, 2010. **6**(3): p. 969-78.

195. Mensinkai, PK, Ccahuana-Vasquez, RA, Chedjieu, I, et al., *In situ remineralization of white-spot enamel lesions by 500 and 1,100 ppm F dentifrices.* Clin Oral Investig, 2012. **16**(4): p. 1007-14.

196. Memarpour, M, Fakhraei, E, Dadaein, S, and Vossoughi, M, *Efficacy of fluoride varnish and casein phosphopeptide-amorphous calcium phosphate for remineralization of primary teeth: a randomized clinical trial.* Med Princ Pract, 2015. **24**(3): p. 231-7.

197. Memarpour, M, Soltanimehr, E, and Sattarahmady, N, *Efficacy of calcium- and fluoride-containing materials for the remineralization of primary teeth with early enamel lesion.* Microsc Res Tech, 2015. **78**(9): p. 801-6.

198. Brochner, A, Christensen, C, Kristensen, B, et al., *Treatment of post-orthodontic white spot lesions with casein phosphopeptide-stabilised amorphous calcium phosphate.* Clin Oral Investig, 2011. **15**(3): p. 369-73.

199. Vanichvatana, S and Auychai, P, *Efficacy of two calcium phosphate pastes on the remineralization of artificial caries: a randomized controlled double-blind in situ study.* Int J Oral Sci, 2013. **5**(4): p. 224-8.

200. Lata, S, Varghese, NO, and Varughese, JM, *Remineralization potential of fluoride and amorphous calcium phosphate-casein phospho peptide on enamel lesions: An in vitro comparative evaluation.* J Conserv Dent, 2010. **13**(1): p. 42-6.

201. Twisk, JWR, ed. *Applied longitudinal data analysis for epidemiology : a practical guide.* . 2003, Cambridge University.: Cambridge, UK

202. DenBesten, P and Li, W, *Chronic fluoride toxicity: Dental fluorosis*. Fluoride and the oral environment, ed. A. Lussi, Huysmans, and H.P. Weber. Vol. 22. 2011, Switzerland: Monogr Oral Sci. Basel, Karger.

203. Darby, ML and Walsh, MM, *Dental Hygiene: Theory and Practice*. 2010, Canada: Elsevier, St.Louis, Missouri

204. Warren, JJ, Levy, SM, and Kanellis, MJ, *Dental caries in the primary dentition: assessing prevalence of cavitated and noncavitated lesions.* J Public Health Dent, 2002. **62**(2): p. 109-14.

205. Thanakanjanaphakdee, W and Triratvorakul, C, *Effectiveness of Parental Hands-on Toothbrushing Instruction toward The 1-Year Incremental dmf Rate of 9-18 Month Old Children.* Journal of the Dental Association of Thailand, 2010. **60**(2): p. 85-94.

APPENDIX A

PRACTICE GUIDELINE FOR ECC PREVENTION

This practice guideline aimed to inform professionals to perform the same procedure throughout the study. The practice guideline consists of 3 different parts as follow:

Part I: At Month 0

Prior to meet the dentist, the primary caregiver will be approached for their participation in this study by the researcher or the research assistant. Oral explanation of the research purpose will be given, confidentiality of their responses assure by reporting findings as aggregates or themes. Questionnaire-guided interview will be performed prior to these following steps.

1. To create good dentist-patient relationship, dentist will make good greeting by asking general condition of the child and the primary caregiver.
2. To acquire child dental caries status, the children oral status will be examined by the dentist in knee-to-knee position under natural light.
3. To acquire inter- and intra-examiner reliability assessment, using 20 subjects presenting with carious lesion covering all categories will be conducted.
4. The primary caregivers of every child will be trained on tooth brushing technique to assure the quality of their tooth brushing. Tooth brushing

training will include demonstration of tooth brushing technique by dental personnel and the returned demonstration on their child's teeth will be performed by the caregivers. Then, caregivers will be instructed in assessing the tooth brushing quality by evaluating of the plaque accumulation on upper anterior teeth.

5. At the end of visit, brushing kit will be given to each primary caregiver.

Part II: At Month 4 and Month 8

1. After general greeting, primary caregivers will be asked about frequency of child's tooth brushing. If the frequency of tooth brushing is less than 3 days per week, that sample will be excluded from study.

2. The dentist will evaluate plaque accumulation on child's upper anterior teeth to assess the quality of tooth brushing and primary caregivers will obtain encouragement for cleanliness of tooth.

3. The dentist will examine cavitated caries on child's tooth to be referred for treatment.

4. Primary caregivers demonstrate tooth brushing with their children, followed by dentist's feedback and discussion on tooth brushing exercise for each case.

5. At the end of visit, another toothbrush will be given to each primary caregiver again.

Part III: At Month 12

1. Questionnaire-guided interview will be performed again by primary caregivers on their feeding and child's oral cleaning practices after program implementation for evaluating and changing of these behaviors.
2. To create good dentist-patient relationship, dentist will make good greetings by asking the general condition of the child and the primary caregiver.
3. The child's oral examination will be performed by dentist to obtain the child's dental caries status and the child's oral hygiene status.

APPENDIX B

QUESTIONNAIRES FOR THE PRIMARY CAREGIVERS (ENGLISH)

ID.....

Questionnaire guided interview for the primary caregiver (1st visit)

Section 1: Baseline variables

Please fill in the blank or check ✓ the box with the most appropriate answer.

1. Primary caregiver's name and last name.....
2. House No.....Village No.....Sub-district.....
   District....**U-Thong**.....Province.....**Suphan Buri**.....Tel.No. .....
3. Gender Male ☐ Female ☐
4. Age.....years
5. Relationship to the child
   Parent ☐ Grandparent ☐
   Uncle/aunt ☐ other (please specify).....
6. Previous experience in child's rearing Yes ☐ No ☐
7. Child's name and last name .....
8. Child's gender Male ☐ Female ☐
9. Child's age..... months
10. Birthdate.....month .....Year.....
11. Child's birth order.....
12. Chronic/Illness history
    No ☐ Yes ☐ (please specify).....
    Don't know/ don't remember ☐
13. Medication
    No ☐ Yes ☐ (please specify).....
    Don't know/ don't remember ☐

14. Who usually takes care of your child/children at home? (More than 1 answer)

Mother ☐ Father ☐ Grandparent ☐

Uncle/aunt ☐ other (please specify).....

15. Mother's occupation

Stay-at-home mom☐ Civil servant ☐ Employees ☐

Business owner ☐ Merchant ☐ Agriculturist/ gardener ☐

Factory workers ☐ other ☐ (please specify).....

16. Father's occupation

Stay-at-home mom☐ Civil servant ☐ Employees ☐

Business owner ☐ Merchant ☐ Agriculturist/ gardener ☐

Factory workers ☐ other ☐ (please specify).....

17. Marital status

Married ☐ Separated ☐ Single☐ Divorced☐

18. Highest level of education

Less than sixth grade ☐ Sixth grade ☐

High school/ Vocational school ☐ Bachelor degree or higher☐

19. Family income per month (Total income of father and mother)

Less than 10,000 Baht ☐ 10,000 -15,000 Baht ☐

15,001 -30,000 Baht ☐ More than 30,000 Baht ☐

Section 2: Child's oral health care practice

1.1 Commencement of cleaning child's mouth (More than 1 answer)

Wiping child's mouth before tooth eruption ☐

Wiping child's mouth during tooth eruption ☐

Brushing child's teeth during first tooth eruption ☐

Brushing child's teeth when many tooth eruption or complete eruption☐

Don't know/ don't remember ☐ No cleaning☐ (Go to Number 2)

1.2 Method for cleaning child's mouth (More than 1 answer)

Wipe child's teeth with clean cloth ☐ Rub child's teeth with finger ☐

Rinse ☐ Tooth brushing ☐ other (please specify).....

1.3 Frequency of child's tooth brushing (per week)

Less than 1 day/week ☐ 1-2 day/week ☐

3-5 day/week ☐ Everyday ☐

1.4 Frequency of child's tooth brushing (per day)

Not every day ☐ Once a day ☐

Twice a day ☐ More than twice a day ☐

1.5 Time of the day in which child's tooth brushing was performed (More than 1 answer)

After waking up in the morning☐ After morning meal☐

After evening meal ☐ After every meal☐

Before going to bed☐ other (please specify).....

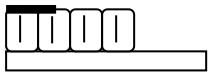
1.6 Usually, who clean child's mouth?

Mother ☐ Father ☐ Grandparent ☐

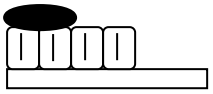
Uncle/aunt ☐ other (please specify).....

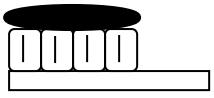
1.7 Amount of toothpaste for tooth brushing

No toothpaste☐

Smaller than a green pea ☐ 

The size was that a green pea ☐ 

Half of a toothbrush ☐ 

As long as a toothbrush☐ 

1.8 Type of toothpaste for your child

Toothpaste for children ☐ (please specify).....

Toothpaste for adult ☐ (please specify).....

2. Does the child receive fluoride tablet?

Never☐ Less than 3 day/week ☐

3-5 day/week ☐ Everyday☐

3. The water that the child drink regularly

Bottled water ☐ (please specify brands).....

Water contains in a gallon ☐ (please specify brands).....

Rain water ☐ Tap water ☐ other (please specify).....

4. Type of milk feeding (More than 1 answer)

Breast feeding ☐ (Go to Number 5)

Breast milk in bottle ☐ (Go to Number 5)

UHT pasteurized milk (flavorless) ☐ (Go to Number 7)

UHT pasteurized milk (sweetened) ☐ (Go to Number 6)

Powdered milk (flavorless) ☐ (Go to Number 7)

Powdered milk (sweetened) ☐ (Go to Number 6)

Sweetened condensed milk ☐ (Go to Number 6)

Stop to drink milk ☐ when.....months

5. Frequency of breast feeding (per day)

No breast feeding ☐ Less than 3 times/day ☐

3-5 times/day ☐ 6-8 times/day ☐

More than 8 times/day ☐ other (please specify).....

6. Frequency of UHT pasteurized milk/powdered milk **(sweet flavored)** (per day)

No drinking ☐ Less than 3 times/day ☐

3-5 times/day ☐ 6-8 times/day ☐

More than 8 times/day ☐ other (please specify).....

7. Frequency of UHT pasteurized milk/powdered milk **(flavorless)** (per day)

No drinking ☐ Less than 3 times/day ☐

3-5 times/day ☐ 6-8 times/day ☐

More than 8 times/day ☐ other (please specify).....

8. Does the child sip water after milk feeding?

Never ☐ Sometimes ☐ Every times ☐

9. Frequency of child falling asleep with bottles/at the breast in 1 month ago

Never ☐ Less than 4 times/week ☐ 4-6 times/week ☐

Every day ☐ other (please specify).....

10.In 1 month ago, does the child wake up to drink milk at night?

No ☐ Yes ☐ frequency of nighttime feeding.....times

11. Do you fill sweet substances e.g. sugar, honey in bottle of milk?

No ☐ Yes ☐ (please specify type and time).....

12. In addition to milk, does the child get juice/soft drink/sweet liquid with sweet taste from sucking on the bottle?

No ☐ Yes ☐ (please specify type and time).....

13. Starting time to eat rice, bread, noodle (Please identify.....years.....months)

14. Frequency of snacking between meals

Never ☐ Once a day ☐ Twice a day ☐

3 times/day ☐ More than 3 times/day ☐

15. Type of snack between meals (More than 1 answer)

No snack ☐ Cake/cookies/bread ☐ Packaging snack/crisps/crackers☐
Yogurt☐ Toffee/candy ☐ Soft drink ☐

Other (please specify).....

APPENDIX C

QUESTIONNAIRES FOR THE PRIMARY CAREGIVERS (THAI)

แบบสอบถาม สำหรับผู้ดูแลหลัก

แบบสอบถามเลขที่.....

อาสาสมัครได้รับทราบถึงขั้นตอน การทำวิจัยนี้แล้วและยินยอมที่จะร่วมการวิจัยโดยการตอบแบบสอบถามนี้

ส่วนที่1 : ข้อมูลพื้นฐาน

20. ชื่อ – นามสกุล ผู้ดูแลหลัก.....

21. บ้านเลขที่.....หมู่ที่.....ตำบล.....
อำเภอ อู่ทอง จังหวัด สุพรรณบุรี เบอร์โทรศัพท์.....

22. เพศ ชาย ☐ หญิง ☐

23. อายุ.....ปี

24. ความสัมพันธ์กับเด็ก
พ่อ แม่ ☐ ปู่ ย่า/ตา ยาย ☐
ลุง ป้า น้า อา ☐ อื่นๆ (โปรดระบุ).....

25. ท่านเคยมีประสบการณ์ในการเลี้ยงดูเด็กเล็กด้วยตนเอง ใช่☐ ไม่ใช่ ☐

26. ชื่อ – นามสกุล เด็ก.....

27. เพศของเด็ก ชาย ☐ หญิง ☐

28. อายุของเด็ก..... เดือน

29. เกิดเมื่อวันที่.....เดือน.....ปี.....

30. เด็กเป็นลูกคนที่.....ของครอบครัว

31. ประวัติการเจ็บป่วยเรื้อรังของเด็ก
ไม่มี ☐ มี ☐ ระบุ.....
ไม่รู้/จำไม่ได้☐

32. ยาที่เด็กได้รับเป็นประจำ

ไม่มี ☐ มี ☐ ระบุ.....

ไม่รู้/จำไม่ได้☐

33. เมื่อเด็กอยู่บ้าน ผู้ที่ดูแลเด็กมากที่สุดในครอบครัวของท่านคือใคร (ตอบได้มากกว่า 1 ข้อ)

แม่☐ พ่อ ☐ ปู่ ย่า/ตา ยาย ☐

ลุง ป้า น้า อา ☐ อื่นๆ โปรดระบุ.....

34. อาชีพของมารดา

เลี้ยงลูกและทำงานบ้านอยู่ที่บ้าน ☐ รับราชการ/รัฐวิสาหกิจ ☐

รับจ้าง ☐ เจ้าของธุรกิจ ☐ ค้าขาย ☐ ทำนา/ทำไร่/ทำสวน ☐

ลูกจ้างโรงงาน☐ อื่น ☐ (โปรดระบุ) .....

35. อาชีพของบิดา

เลี้ยงลูกและทำงานบ้านอยู่ที่บ้าน ☐ รับราชการ/รัฐวิสาหกิจ ☐ รับจ้าง ☐

เจ้าของธุรกิจ ☐ ค้าขาย ☐ ทำนา/ทำไร่/ทำสวน ☐ ลูกจ้าง

โรงงาน☐ อื่น☐ (โปรดระบุ) .....

36. สถานภาพสมรสของบิดา-มารดา

แต่งงานอยู่ด้วยกัน ☐ แต่งงานแยกกันอยู่ ☐ หย่า ☐

หม้าย ☐

37. ระดับการศึกษาสูงสุดของท่าน

ต่ำกว่า ป.6 ☐ ป.6 ☐

มัธยมศึกษา/อาชีวศึกษา ☐ ปริญญาตรี หรือสูงกว่า ☐

38. รายได้ต่อเดือนของครอบครัว (รายได้ของพ่อและแม่ของเด็กรวมกัน)

น้อยกว่า 10,000 บาท ☐ 10,000 -15,000 บาท ☐

15,001 -30,000 บาท ☐ 30,000 บาท ขึ้นไป ☐

ส่วนที่ 2 : การดูแลสุขภาพช่องปากของเด็ก

1.1 ท่านเริ่มทำความสะอาดช่องปากและฟันของเด็กเมื่อใด (ตอบได้มากกว่า 1 คำตอบ)

เริ่มเช็ดช่องปากก่อนฟันขึ้น ☐ เริ่มเช็ดช่องปากเมื่อฟันเริ่มขึ้น ☐

เริ่มแปรงฟันเมื่อฟันเริ่มขึ้น☐ เริ่มแปรงฟันเมื่อฟันขึ้นหลายซี่หรือขึ้นครบ☐

ไม่รู้/จำไม่ได้ ☐ ไม่ได้ทำ ☐ (ข้ามไปทำข้อ 2)

1.2 วิธีทำความสะอาดฟันเด็ก (ตอบได้มากกว่า 1 คำตอบ)

ใช้ผ้าสะอาดชุบน้ำเช็ดฟัน ☐ ใช้นิ้วถู ☐ ให้เด็กบ้วนปาก ☐

ใช้แปรงสีฟันแปรง☐ อื่นๆ (โปรดระบุ).....

1.3 ความถี่ในการแปรงฟันให้เด็ก (สัปดาห์)

น้อยกว่าสัปดาห์ละ 1 วัน ☐ สัปดาห์ละ 1-2 วัน☐

สัปดาห์ละ 3-5 วัน☐ แปรงทุกวัน ☐

1.4 ความถี่ในการแปรงฟันให้เด็ก (วัน)

บางวันก็ทำ บางวันก็ไม่ได้ทำ ☐ วันละ 1 ครั้ง ☐

วันละ 2 ครั้ง ☐ มากกว่า วันละ 2 ครั้ง☐

1.5 ช่วงเวลาที่แปรงฟันให้เด็ก (ตอบได้มากกว่า 1 คำตอบ)

หลังตื่นนอนในตอนเช้า ☐ หลังอาหารเช้า ☐ หลังอาหารเย็น ☐

ทุกครั้งหลังอาหาร ☐ ก่อนเข้านอน ☐ อื่นๆ (โปรดระบุ).....

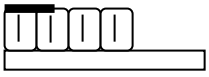
1.6 โดยปกติใครเป็นคนแปรงฟันหรือทำความสะอาดช่องปากให้เด็ก

แม่☐ พ่อ ☐ ปู่ ย่า/ตา ยาย ☐

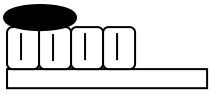
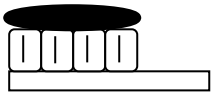
ลุง ป้า น้า อา ☐ อื่นๆ ☐ (โปรดระบุ).....

1.7 ปริมาณยาสีฟันที่ใช้ในการแปรงฟันให้เด็ก

ไม่ได้ใช้ยาสีฟัน ☐

ขนาดเล็กกว่าเมล็ดถั่วเขียว □ 

ขนาดเท่าเมล็ดถั่วเขียว□ 

ครึ่งแปรงสีฟัน□  ยาวเท่าแปรงสีฟัน□ 

1.8 ชนิดยาสีฟันที่ใช้แปรงให้เด็ก

ยาสีฟันสำหรับเด็ก□ (โปรดระบุ).....

ยาสีฟันสำหรับผู้ใหญ่ □ (โปรดระบุ).....

2. เด็กเคยได้รับยาน้ำหรือยาเม็ดฟลูออไรด์หรือไม่

ไม่เคย □ น้อยกว่า สัปดาห์ละ3 วัน □

สัปดาห์ละ 3-5 วัน □ ทุกวัน □

3.แหล่งน้ำที่เด็กดื่มเป็นประจำ

น้ำบรรจุขวด □ ยี่ห้อ..... น้ำบรรจุเป็นแกลลอน/ถัง □
ยี่ห้อ.....น้ำฝน□น้ำประปา □ อื่นๆ□ (โปรดระบุ).....

4.ปัจจุบันเด็กของท่านกินนมอะไร (ตอบได้มากกว่า 1 คำตอบ)

นมแม่จากเต้า □ (ข้ามไปทำข้อ 5) นมแม่ใส่ขวด□ (ข้ามไปทำข้อ 5)

นมกล่อง UHT ชนิดจืด □ (ข้ามไปทำข้อ 7) นมกล่อง UHT ชนิดหวาน □ (ข้ามไปทำข้อ 6)

นมผสมบรรจุในกระป๋องชนิดจืด□ (ข้ามไปทำข้อ 7)

นมผสมบรรจุในกระป๋องชนิดหวาน□ (ข้ามไปทำข้อ 6)

นมข้นหวานผสมน้ำ□ (ข้ามไปทำข้อ 6) เลิกกินนม □ เมื่ออายุ.....เดือน

5. ความถี่ที่ท่านให้เด็กกินนมแม่ ต่อวัน

ไม่ได้กินนมแม่แล้ว ☐ น้อยกว่าวันละ 3 ครั้ง ☐ วันละ 3-5 ครั้ง ☐
วันละ 6-8 ครั้ง☐ มากกว่า วันละ8 ครั้ง☐ อื่นๆ☐ (โปรดระบุ).....

6. ความถี่ที่ท่านให้เด็กกินนมขวด/นมกล่อง <u>รสหวาน</u> ต่อวัน

ไม่ได้กิน☐ น้อยกว่าวันละ 3 ครั้ง ☐ วันละ 3-5 ครั้ง ☐
วันละ 6-8 ครั้ง ☐ มากกว่า วันละ8 ครั้ง☐ อื่นๆ☐ (โปรดระบุ).....

7. ความถี่ที่ท่านให้เด็กกินนมขวด/นมกล่อง <u>รสจืด</u> ต่อวัน

ไม่ได้กิน☐ น้อยกว่าวันละ 3 ครั้ง ☐ วันละ 3-5 ครั้ง ☐
วันละ 6-8 ครั้ง☐ มากกว่า วันละ8 ครั้ง☐ อื่นๆ☐ (โปรดระบุ).....

8. ท่านให้เด็กจิบ/ดื่มน้ำ หลังจากกินนมหรือไม่

ไม่เคย ☐ บางครั้ง ☐ ทุกครั้ง ☐

9. ใน 1 เดือนที่ผ่านมาเด็กหลับคาขวดนม/นมแม่หรือไม่ บ่อยแค่ไหน

ไม่มี ☐ น้อยกว่า สัปดาห์ละ 4 ครั้ง ☐ สัปดาห์ละ 4-6 ครั้ง ☐
ทุกวัน ☐ อื่นๆ☐ (โปรดระบุ).....

10. ใน 1 เดือนที่ผ่านมาเด็กตื่นขึ้นมากินนมตอนกลางคืนหรือไม่

ไม่☐ ใช่ ☐ โดยตื่นมากินตอนกลางคืน จำนวน.....ครั้ง

10. ท่านเติมสารให้ความหวาน เช่น น้ำตาล น้ำผึ้ง ลงใน**<u>นม</u>**ที่เด็กดูดจากขวดหรือไม่

ไม่☐ ใช่ ☐ (โปรดระบุชนิด).....โดยให้ดูดช่วงเวลา.....

11. <u>นอกจากนม</u>ท่านให้เด็กได้รับ น้ำผลไม้ โอวัลติน น้ำอัดลม น้ำหวาน หรือ ของเหลวที่มีรสหวานใส่ในขวดนมให้เด็กดูดหรือไม่

ไม่☐ ใช่ ☐ (โปรดระบุชนิด).....โดยให้ดูดช่วงเวลา.....

12.ท่านให้เด็กเริ่มทานอาหาร เช่น ข้าว ขนมปัง ก๋วยเตี๋ยว ตั้งแต่อายุเท่าใด

ระบุ.....ปี.....เดือน

13. ท่านให้เด็กกินขนมระหว่างมื้ออาหารบ่อยแค่ไหน

ไม่ได้ให้ □ วันละ 1 ครั้ง □ วันละ 2 ครั้ง □
วันละ 3 ครั้ง □ มากกว่า วันละ 3 ครั้ง □

14.ขนมที่ท่านให้เด็กทานระหว่างมื้อเป็นขนมชนิดใด (ตอบได้มากกว่า 1 คำตอบ)

ไม่ให้ทานเลย □ ขนมเค้ก/คุกกี้/ขนมปังนิ่ม□ ขนมกรุบกรอบถุง/ขนมปังกรอบ□
ลูกกวาด/ท๊อฟฟี่ □ นมเปรี้ยว/โยเกิร์ต□ น้ำอัดลม □
อื่นๆ □ (โปรดระบุชนิด).....

APPENDIX D

ECC RECORDING FORM AND ORAL HYGIENE RECORDING FORM

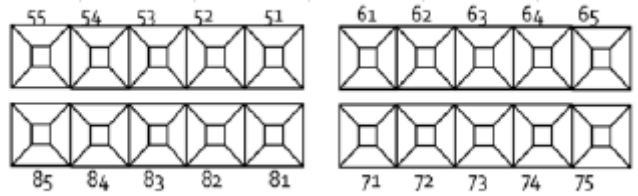
แบบบันทึกการตรวจฟัน

เลขที่.....

ชื่อ-นามสกุลของเด็ก.....

ที่อยู่..... อำเภออู่ทอง จังหวัดสุพรรณบุรี

อายุ.....เดือน เพศ ☐ชาย ☐หญิง



หมายเหตุ.....

ผู้ตรวจ.....วันที่ตรวจ..... ครั้งที่.....

score	criteria
s	ไม่ผุ
d1	ผุชนิดไม่เป็นรู (white spot)
d2	ผุชนิดเป็นรู
f	อุดเนื่องจากการผุ
m	ฟันถอน
5	ฟันหายไปที่ไม่ใช่จากการผุ
6	เคลือบหลุมร่องฟัน
U	ฟันยังไม่ขึ้นหรือขึ้นบางส่วน
9	ไม่บันทึก

Oral Hygiene Recording Form

Date _____ Idenfication Number _____

Name_____

Age _____ Boy [ ] Girl [ ] Examiner_____

Gingivitis Index [ ] Score 0

[ ] Score 1

OHI Plaque Index

	Labial			Lingual			Sum	Number	Index
	Rt	An	Lt	Rt	An	Lt			
U									
L									

Score	Criteria Gingivitis
0	Normal gingiva
1	Mild inflammation- slight hange in color, slight edema

Score	Criteria Oral Hygiene
0	No debris or stain present
1	Soft debris covering not more than one third of the tooth surface, or presence of extrinsic stains without other debris regardless of surface area covered
2	Soft debris covering more than one third, but not more than two thirds, of the exposed tooth surface
3	Soft debris covering more than two thirds of the exposed tooth surface

APPENDIX E

DMFS INDEX

The decayed, missing and filled caries surfaces (dmfs) index is used to describe the amount of dental decay in children per tooth surface. The index includes an individual number of surfaces with decayed, missing and filled primary teeth to quantify his amount of surface with dental decay. Molars and premolars are considered having 5 surfaces, front teeth 4 surfaces. Again, a surface with both caries and filling is scored as d. Maximum value for dmfs comes to 128 for 28 teeth.

Criteria for classifying dental caries per surface are as follow:

U = Unerupted tooth; tooth is not erupted at all, or erupted less than ½ of the tooth surface in anterior teeth, or the buccal contour is not visible in posterior teeth.

S = Sound tooth; normal enamel surface and no restoration.

d1= Initial caries/non cavitated caries; the lesion demonstrates whitish opaque or brown stain on pit and fissure surface without micro-cavity and no soften floor/wall.

d2 = Cavitated caries; the lesion certainly catches the probe with cavity and softened floor/wall of undermined enamel, and include a deep lesion with probable pulpal involvement.

f = Filled surface without evidence of secondary caries.

m = Missing teeth due to caries.

5 = Missing teeth due to another reason

6 = Sealant teeth

9 = Not recorded

APPENDIX F

DEBRIS INDEX

The debris index, one part of the Oral Hygiene index, measures the amount of plaque on tooth surfaces (Moslehzadeh, n.d.). This Index is in turn based on 12 numerical determinations representing the amount of debris found on the buccal and lingual surfaces of each of three segments of each dental arch (anterior teeth, left and right posterior teeth). The maxillary and the mandibular arches are each composed of three segments. Each segment is examined for debris. From each segment, one tooth is used for calculating the individual index, for that particular segment. The tooth used for the calculation must have the greatest area covered by debris.

Criteria for classifying debris are as follow: (Figure I)

0 = No debris or stains present

1 = Soft debris covering not more than one third of the tooth surface, or presence of extrinsic stains without other debris regardless of surface area covered.

2 = Soft debris covering more than one third, but not more than two thirds, of the exposed tooth surface.

3 = Soft debris covering more than two thirds of the exposed tooth surface.

After the scores for debris are recorded, the Index values are calculated. For each individual, the debris scores are totaled and divided by the number of surfaces

scored. At least two of the six possible surfaces must have been examined for an individual score to be calculated.

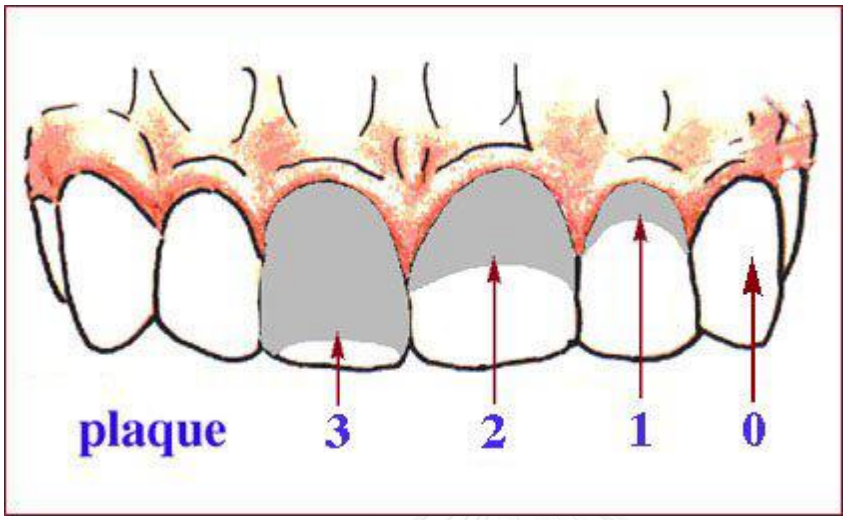


Figure 11 Criteria for classifying debris

APPENDIX G

GINGIVITIS INDEX

The Gingival Index (Loe and Silness,1963) was created for the assessment of the gingival condition and records qualitative changes in the gingiva. The criteria are:

0 = Normal gingival

1 = Mild inflammation to slight change in color and slight edema

Figure 12 Criteria for classifying gingivitis

APPENDIX H

CONSENT FORM

หนังสือแสดงเจตนายินยอมเข้าร่วมการวิจัย

วันที่.....เดือน.....ปี.....

ข้าพเจ้า.....อายุ.....ปี อาศัยอยู่บ้านเลขที่.....ถนน..... ตำบล..... อำเภอ.....จังหวัด..... รหัสไปรษณีย์..... โทรศัพท์ .....

ขอแสดงเจตนายินยอมเข้าร่วมโครงการวิจัย เรื่อง “ผลของการป้องกันฟันผุภายหลังการใช้ยาสีฟันผสมฟลูออไรด์ที่ความเข้มข้น 1000 ppm, 500 ppm และยาสีฟันที่ไม่ผสมฟลูออไรด์แต่มีส่วนประกอบของไซลิทอลในเด็กทารกและวัยหัดเดิน” โดยข้าพเจ้าได้รับทราบรายละเอียดเกี่ยวกับ ที่มา จุดมุ่งหมายในการทำวิจัย และรายละเอียดขั้นตอนต่างๆที่จะต้องปฏิบัติหรือได้รับการปฏิบัติ ประโยชน์ที่คาดว่าจะได้รับของการวิจัยและความเสี่ยงที่อาจจะเกิดขึ้นจากการเข้าร่วมการวิจัย รวมทั้งแนวทางป้องกันและแก้ไขหากเกิดอันตรายขึ้น ค่าตอบแทนที่จะได้รับ ค่าใช้จ่ายที่ข้าพเจ้าจะต้องรับผิดชอบจ่ายเอง โดยได้อ่านข้อความที่มีรายละเอียดอยู่ในเอกสารชี้แจงผู้เข้าร่วมการวิจัยโดยตลอด อีกทั้งยังได้รับคำอธิบายและตอบข้อสงสัยจากหัวหน้าโครงการวิจัยเป็นที่เรียบร้อยแล้ว

ข้าพเจ้าจึงสมัครใจเข้าร่วมในโครงการวิจัยนี้ หากข้าพเจ้ามีข้อข้องใจเกี่ยวกับขั้นตอนของการวิจัย หรือหากเกิดเหตุการณ์ที่ไม่พึงประสงค์จากการวิจัยขึ้นกับข้าพเจ้า ข้าพเจ้าจะสามารถติดต่อกับ นางสาวพลินี เดชสมบูรณ์รัตน์ 181/13-14 ต.ตลาดกระทุ่มแบน อ.กระทุ่มแบน จ.สมุทรสาคร 74110 โทร. 081-4226944

ข้าพเจ้าได้ทราบถึงสิทธิ์ที่ข้าพเจ้าจะได้รับข้อมูลเพิ่มเติมทั้งทางด้านประโยชน์และโทษจากการเข้าร่วมการวิจัย และสามารถถอนตัวหรืองดเข้าร่วมการวิจัยได้ทุกเมื่อ โดยจะไม่มีผลกระทบต่อการบริการและการรักษาพยาบาลที่ข้าพเจ้าจะได้รับต่อไปในอนาคต และยินยอมให้ผู้วิจัยใช้ข้อมูลส่วนตัวของข้าพเจ้าที่ได้รับจากการวิจัย แต่จะไม่เผยแพร่ต่อสาธารณะเป็นรายบุคคล โดยจะนำเสนอเป็นข้อมูลโดยรวมจากการวิจัยเท่านั้น

ข้าพเจ้าเข้าใจข้อความในเอกสารชี้แจงผู้เข้าร่วมการวิจัย และหนังสือแสดงเจตนายินยอมนี้โดยตลอดแล้ว จึงลงลายมือชื่อไว้

ลงชื่อ.....ผู้เข้าร่วมการวิจัย/ผู้แทนโดยชอบธรรม/ วันที่.....

(.....)

ลงชื่อ.....ผู้ให้ข้อมูลและขอความยินยอม/หัวหน้าโครงการวิจัย/ วันที่.....

(.....)

APPENDIX I

ETHICAL APPROVAL FORM

No. 049/2013

Study Protocol and Consent Form Approval

The Human Research Ethics Committee of the Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand has approved the following study to be carried out according to the protocol and patient/participant information sheet dated and/or amended as follows in compliance with the **ICH/GCP.**

Study Title	: Caries prevention effect of various concentrations of fluoride toothpaste in 9-18 month old children
Study Code	: HREC-DCU **2013-018**
Study Center	: Chulalongkorn University
Principle Investigator	: Dr. Palinee Detsomboonrat
Protocol Date	: March 15, 2013
Date of Approval	: May 14, 2013
Date of Expiration	: May 13, 2015

V. Lertchirakarn.

(Associate Professor Dr. Veera Lertchirakarn)
Chairman of Ethics Committee

K. Bhalang

(Assistant Professor Dr. Kanokporn Bhalang)
Associate Dean for Research

*A list of the Ethics Committee members (names and positions) present at the Ethics Committee meeting on the date of approval of this study has been attached (upon requested). This Study Protocol Approval Form will be forwarded to the Principal Investigator.

Approval is granted subject to the following conditions: (see back of the approval)

VITA

Miss. Palinee Detsomboonrat was born in Bangkok, Thailand on June 13, 1978. In 2001, she was conferred with an honorary the degree of Doctor of Dental Surgery (D.D.S.) from Faculty of Dentistry, Chulalongkorn University. After graduation, she worked as lecturer at the Department of Community Dentistry, Faculty of Dentistry, Chulalongkorn University, Thailand (2001-2004). In 2005, she started her post-graduate study for the Master of Science in Pediatric Dentistry at the Faculty of Dentistry, Chulalongkorn University (2005-2008). And she continued her education for the Degree of Doctor of Philosophy in Dental Public Health at the Faculty of Dentistry, Chulalongkorn University in 2010.