# CARIES PREVENTION IN HIGH-RISK PRESCHOOL CHILDREN IN THE UNITED STATES

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#### Abstract

Dental caries is a common infectious disease affecting young children living in low-income families in the United States. Efficacious, safe, feasible and cost-effective caries prevention methods for these children are essential. Several studies have shown the efficacy of fluoride varnish and xylitol to improve the oral health of children.

The efficiency of caries prevention programs including the use of fluoride varnish or xylitol chewing gum in early childhood has not been well documented in communities with private dental services. The purpose of this study was to determine the caries prevalence and distribution in the primary dentition, and to evaluate the effectiveness of two prevention programs, including applications of fluoride varnish and the use of xylitol chewing gum in randomized groups of preschool children attending Head Start school programs in Northern Florida.

The caries preventive effect of fluoride varnish in the primary dentition was evaluated in a sample of 4-6 year-old Head Start schoolchildren in Alachua, Florida (n=142). Caries progression after nine months was analyzed using dmf(s/t) and ds values. A modified caries scoring system, which differentiates between active and inactive carious lesions, was used to evaluate the effect of fluoride on early noncavitated enamel lesions. The effect of xylitol gum was evaluated by measuring the levels of salivary mutans streptococci before and after a three week chewing period in 3-5 year-old children attending the Head Start school in Starke, Florida (n=61).

This study is in line with earlier reports that caries prevalence is high in Head Start preschool children. This study showed that active noncavitated enamel lesions were common in the primary dentition and that applications of fluoride varnish may offer an effective means of arresting these early enamel lesions. Chewing the xylitol gum reduced the levels of salivary mutans streptococci, thereby possibly reducing the risk for dental caries in these children.

While the detection and monitoring of early enamel lesions is critical in determining effectiveness of prevention therapy, this study suggests that fluoride varnish applications may offer an efficient, non-surgical treatment for decay in children. Also, the prevention program with xylitol may provide an additional method to be used in situations where other prevention methods are difficult to implement.

Keywords: fluoride, primary dentition, xylitol



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# **Abbreviations**

ADA American Dental Association a.m. ante meridiem, before noon

C celcius

CDC Center for Disease Control and Prevention

CFU colony forming unit

dmfs decayed, missing, filled primary teeth surfaces

dmft decayed, missing, filled primary teeth

ds decayed primary teeth surfaces

dfs decayed, filled primary teeth surfaces

dt decayed primary teeth
dft decayed, filled primary teeth
ECC early childhood caries

F fluoride

FDA Food and Drug Administration IRB Institutional Review Board

L liter

NHANES National Health and Nutrition Examination Surveys

NIH National Institute of Health

NS non significant

MEPS Medical Expenditures Panel Survey

ml milliliter

p.m. post meridiem, after noon
S. mutans Mutans streptococci
SEM standard error of the mean

SD standard deviation
USA United States of America

US DHHS United States Department of Health and Human Services

WHO World Health Organisation

# List of original publications

This thesis is based on the following publications, which are referred to in the text by their Roman numerals.

- I Autio-Gold J, Tomar SL (2005) Prevalence of noncavitated and cavitated carious lesions in five-year-old Head Start schoolchildren in Alachua County, Florida. Pediatr Dent 27:54-60.
- II Autio-Gold J, Courts F (2001) Assessing the effect of fluoride varnish on early enamel carious lesions in the primary dentition. J Am Dent Assoc 132:1247-1253.
- III Autio J (2002) Effect of xylitol chewing gum on salivary streptococcus mutans in preschool children. J Dent Child 69:81-86.
- IV Autio J, Courts F (2001) Acceptance of the xylitol chewing gum regimen by preschool children and teachers in Head Start program: a pilot study. Pediatr Dent 23:71-74.

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#### 1 Introduction

Dental caries is the single most common chronic disease of childhood in industrialized countries (Edelstein & Douglass 1995, US DDHS 2000). Despite the decline in the incidence, this disease is unequally distributed among the population in the United States, with caries incidence, prevalence, and severity being greater among minority and economically disadvantaged children than among other groups. Head Start is a national program providing comprehensive developmental services primarily to low-income preschool children and their families in the United States and these children have been shown to experience high levels of caries.

Prevention of dental caries in early childhood is important with respect to its future progression, to improve the quality of life, to reduce the costs of restorative treatment and to prevent operative-treatment-based dental anxiety. Different methods of prevention, such as topical applications of fluoride and use of xylitol products, have been studied mainly in older children and adopted for common use in Scandinavian countries in recent decades. These preventive measures are not widely in use in the United States, where dental care for children is mainly provided through private practice.

There is a need for implementation of effective caries preventive strategies for young high-risk children. The effectiveness of caries prevention could be improved by deploying treatment at targeted risk subjects or groups.

#### 2 Review of the literature

#### 2.1 Dental caries

Dental caries is an infectious and transmissible disease (Seow 1998). Current concept of dental caries center on the fermentation of carbohydrates by cariogenic plaque bacteria, producing organic acids, which dissolve the susceptible tooth minerals (Seow 1998). The carious lesion develops over a certain period, and is the result of dynamic, complex interactions of cariogenic bacteria and host defense mechanisms.

The caries process is initiated in the biofilm or dental plaque (Kidd & Fejerskov 2004). Dental caries is a localized, progressive demineralization of the hard tissues of the crown (coronal enamel, dentin), and root surfaces of teeth (cement, dentin), and is a dynamic process since periods of demineralization alternate with periods of remineralization through the action of fluoride, calcium and phosphorous contained in oral fluids (Fejerskov & Kidd 2003). Progressed lesions in dentin are characterized also by destruction of the organic matrix and are considered irreversible, and once destroyed, the tissues cannot be regenerated, requiring operative treatment.

# 2.1.1 Etiology of caries

The main factors in etiology of the dental caries are cariogenic bacteria, fermentable carbohydrates, a susceptible tooth and host (Keyes 1960). In young children, bacterial flora and host defense systems are still developing so they have unique risk factors, as well as unique behavioral patterns associated with feeding and oral hygiene (Seow 1998). Lack of enamel maturation or the presence of developmental structural defects in enamel may increase the risk for caries in preschool children (Tinanoff *et al.* 2002). 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 (Seow 1998). Poor diet and pre-term and low birth weight increased the development of dental caries in primary teeth in a group of 3-4 year-old children in London (Davenport *et* 

al. 2004). A number of behavioral, demographic, and clinically evident risk factors, which correlate with dental caries in young children have been identified; e.g., poor oral hygiene, feeding practices and the early colonization with mutans streptococci (Proceedings: Conference on early childhood caries 1998).

Mutans streptococci are significant determinants of the cariogenity of plaque (Seow 1998). Mutans streptococci have been associated mainly with the initial development of caries, and lactobacilli with the progression of carious lesions. Organisms are usually first detected when the first primary teeth emerge into the oral cavity (Seow 1998), which usually occurs at the age of about 6-10 months (Kreiborg *et al.* 1991). A window of infectivity by mutans streptococci from 19-31 months of age has been proposed (Caufield *et al.* 1993), though mutans streptococci have been detected in the predentate children also (Milgrom *et al.* 2000). Colonization of the oral cavity with mutans streptococci in children is generally the result of transmission of these organisms from the child's primary caregiver, usually the mother (Tinanoff *et al.* 2002).

Preschool children with high colonization of mutans streptococci have shown to have greater caries prevalence and greater risk for new lesions than children with lower levels (Thibodeau & O'Sullivan 1996). A highly significant correlation between the salivary numbers of mutans streptococci and their prevalence in the dentition, both in terms of the number of tooth surfaces colonized and the level of infection of tooth surfaces has been reported (Duchin & van Houte 1978, Lindquist 1991). The evidence points most consistently to young children being most likely to develop caries if they acquire mutans streptococci at a young age (Alaluusua & Renkonen 1983, Grindefjord 1995, Harris *et al.* 2004) and are likely to develop caries in their permanent dentition (Greenwell *et al.* 1990). Mutans streptococci are harboured by 33%-75% of 4-year-old children (Carlsson *et al.* 1975, Alaluusua & Renkonen 1983, Köhler *et al.* 1988, Caufield *et al.* 1993).

Dietary sugars are the major dietary factor affecting dental caries prevalence and progression. After ingestion of carbohydrate, fermentation acids cause a drop in plaque pH, which may lead to demineralization of enamel and tooth destruction. The intensity of caries in preschool children may be due to frequent sugar consumption (Tinanoff *et al.* 2002, Ruottinen *et al.* 2004). Dental caries at six years of age was associated with a higher daily sucrose intake that had started already at three years of age (Karjalainen *et al.* 2001). The sugar alcohols (e.g.; sorbitol and xylitol) are sweeteners that either are not metabolized by bacteria or are metabolized with lower rate. Reductions of levels of mutans streptococci have been achieved after the use of xylitol (Bánóczy *et al.* 1985, Mäkinen *et al.* 1989).

# 2.1.2 Caries experience and development in the primary dentition

Pit and fissure caries is the most common type of the caries in the primary teeth, the proportion being 80-88% (Ismail *et al.* 1992, Douglass *et al.* 2002) due to the narrow and inaccessible pits and fissures (Fejerskov & Kidd 2003). Therefore, the occlusal surfaces of the primary molars usually show the highest attack rates (Grindefjord 1995, Gizani *et al.* 1999) and the majority of new lesions are located on the occlusal surfaces of the second primary molars (Grindefjord 1995, Warren *et al.* 2002).

Studies have shown that decay in anterior primary teeth in young children is a risk factor for future caries progression (O'Sullivan & Tinanoff 1996, Greenwell *et al.* 1990, Johnsen *et al.* 1986). Children with early caries development exhibit high caries progression (Alaluusua & Renkonen 1983, Köhler *et al.* 1988), as well as high risk for further development of an extensive number of new carious lesions (O'Sullivan & Tinanoff 1996, Grindefjord 1995). They are also more likely to have caries in their permanent dentition (Greenwell *et al.* 1990, Kaste *et al.* 1996, Tinanoff *et al.* 2002).

Caries progression in the primary dentition is reportedly rapid, and within one year, enamel caries may progress into the dentin (Peyron *et al.* 1992). Additionally, enamel and dentin in primary teeth are thinner and proximal contacts broader than in permanent teeth, leading to increased caries susceptibility and more rapid progression of caries. Progression rates for lesions through the enamel are extremely variable between individuals and even between lesions in the same individual (Fejerskov & Kidd 2003).

#### 2.1.3 Early childhood caries

Early childhood caries (ECC) is a virulent form of caries that is associated with unusual dietary practices and usually affects toddlers and preschool children (Berkowitz 2003). Initially, ECC presents with smooth-surface carious lesions affecting the primary maxillary incisors and as the disease progresses, decay appears on the occlusal surfaces of the primary maxillary first molars, spreading to other primary teeth (Berkowitz 2003). According ADA (American Dental Association) statement, early childhood caries is defined 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 preschool-age child between birth and 71 months of age (ADA 2000). There is a great variety of definitions and diagnoses of ECC used worldwide, reflected in the variation in the prevalence data of ECC and a clear classification is still to be devised (De Grauwe *et al.* 2004). High-risk populations for ECC in the United States include Hispanic and Native American children, and children enrolled in Head Start programs (Berkowitz 2003).

# 2.2 Epidemiology of caries in young children

Epidemiology studies disease and its determinants in populations and groups. There are remarkably few epidemiological studies of caries in preschool children, but a wealth of data is available from studies of school-aged children (Fejerskov & Kidd 2003).

# 2.2.1 Global caries prevalence

Dental caries is still a major oral health problem in most industrialized countries, affecting 60-90% of schoolchildren and the vast majority of adults. It is also a most prevalent oral disease in several Asian and Latin-American countries, while it appears to

be less common and less severe in most African countries (WHO 2004). Table 1 presents prevalence of dental caries for 3 and 6 year-old children in Finland and Table 2 for 3 and 6 year-old children in the United States (WHO 2004).

Table 1. Caries prevalence for 3 and 6 year-old children in Finland

Age	% affected	dmft	Year	Source	
3 years	-	0.2	1997	1)	
6 years	48.2*	1.5	1991	2)	

<sup>\*</sup> Table represents both primary and permanent dentitions. 1) National Research and Development Center for Welfare and Health. 2) Nordblad A, Suominen-Taipale L, Rasilainen J. Suun terveys terveyskeskuksissa 1991 (WHO 2004).

Table 2. Caries prevalence for 3 and 6 year-old children in the United States

Age	% affected	dft	Year	Source
3 years	11.5	0.4	1988-1991	1)
6 years	46.8	1.8	1988-1991	1)

<sup>1)</sup> NHANES III; Courtesy by Dr. L.M. Kaste (WHO 2004).

Caries in countries with good dental health is no longer evenly distributed (Vehkalahti *et al.* 1997). The increase of caries-free subjects has stabilized, accompanied by the continued presence of subjects with high caries experience, leading to a skewed distribution of caries prevalence in children (Vehkalahti *et al.* 1997). Eighty percent of dental caries identified in permanent teeth of children aged 5-17 years in the United States occur in 25% of children (Kaste *et al.* 1996, Brown *et al.* 2000). Among six year-old Finnish children, 75% were caries-free (dmft=0), and half of all the decayed teeth belonged to six percent of all six year-old children (Vehkalahti *et al.* 1997). Teeth of preschool-aged children are generally healthy, but the improvement in the dmft index has halted in industrialized countries. Those few children who have caries, now have more of it than before (Mattila *et al.* 2000). In Sweden and other European countries, a higher prevalence of caries has been reported in ethnic or minority immigrant population groups (Grindefjord 1995).

# 2.2.2 Caries prevalence of preschool children in the United States

In the United States, despite the decline in the incidence of dental caries over the past several years, the condition remains a significant problem for the nation's poor children (Litt *et al.* 1995). Based on the analyses of the data in the National Health and Nutrition Examination Surveys, or NHANES, which provides data from dental examinations of 4,300 children aged 2-5 years, the mean number of decayed or filled primary teeth (dft), decreased from 1.2 (NHANES I, 1971-1974) to 1.0 (NHANES III, 1988-1994) (Brown 2000). The percent affected with caries in 2-4 year-old children was 16.9 and at age of six it was 46.8 (NHANES III, Kaste *et al.* 1996). Surveys showed no reduction in untreated decay in children who were at or below the poverty level. In this data, mean dft value for

the poor and near poor five year-old children was 2.7 and for non-poor the mean dft was less than 1.0. For poor five year-old children with caries experience, the mean dft was 4.8, and for non-poor it was 3.2.

Data from the Medical Expenditures Panel Survey (MEPS) and the National Health and Nutrition Examination Survey (NHANES III) indicate that 20% of the children aged 2-5 years had a dental visit in the past year, suggesting that the mean age at first dental visit is more likely between three and five years of age (Edelstein *et al.* 2000). Unfortunately, groups at highest risk for disease – the poor and minorities – have lower rates than average of using dental care (Public Health reports 1993). On average, almost 20 percent of children aged 2-5 years have untreated dental caries (Bader *et al.* 2004). According to the Surgeon General's Report on Oral Health in America, caries in children living in low-income families is more likely to be untreated than caries in those living above the poverty level (US DHHS 2000). In 1988–1994, 36.8 percent of poor children aged 2-9 years had one or more untreated decayed primary teeth, compared to 17.3 percent of non-poor children (US DHHS 2000). The percentage of the population with untreated caries was smaller among persons with higher educational levels. Untreated dental decay can lead to severe tooth pain, infections, extensive and costly dental treatment or possible tooth loss (US DHHS 2000).

Most published studies of preschool children in the United States have looked at 3-5 year-old children enrolled in Head Start - A federally funded preschool education and child development program providing comprehensive developmental services primarily to low-income preschool children and their families in the country. These children suffer from higher caries experience compared to others (Berkowitz 2003) with high caries risk levels of at least a mean dft score of 2.0 (Tang et al. 1997). Studies in Head Start children have revealed different caries prevalence (Table 3). Louie et al. (1990) found a mean dft to range from 2.9 to 6.9 or a mean dfs from 4.8 to 16.6. The proportion of children affected with caries ranged from 16.9% to 76.4% (Table 3). The reasons for the wide variety of caries levels are several; overall decline of caries during the last decade, different diagnostic criteria and different geographic location of study population. When caries in these children was described as ECC, a survey of 1,230 children (3-5 years of age) in 37 Head Start programs, the prevalence of ECC was 18.5% for three year-old, 22.4% for four year-old and 27.9% for five year-old children (Barnes et al. 1992). The percentage of children affected with caries based on the survey was 50.6% for non-rural children and 70.5% for rural children (Barnes et al. 1992). Overall ECC prevalence based on multiple studies in U.S. preschool children have been reported to range from 11 % to 72% (Berkowitz 2003).

Table 3. Level of dental caries and proportion of children affected with caries in U.S. preschool children as reported in studies published from 1990-2004

Study	Location	Population	Age	N	Caries score	% children
Louie et al.	California,	Head Start	3-5	1,796	4.8-16.6 dfs/	76.4%
1990	Hawaii,				2.9-6.9 dft	
	Micronesia					
Barnes et al.	Southwestern	Head Start	3-5	1,230	6.4 dfs	50.6-70.5%
1992	states					
Kaste et al.	NHANES III	U.S. civilian	2-4	1,627	1.2 dfs/0.6 dft	16.9%
1996	USA	children				
Tang et al.	Arizona	Head Start	3	144	1.4 dmft	35%
1997						
Albert et al.	Manhattan	Head Start	4	668	2.4 dmft	49%
2002			3-4	1,605	1.1 dft/2.2 dfs	34%
Douglas et al.	Connecticut	Head Start	3-4	311	1.7 dmft	49%
2002						
Montero et al.	Connecticut	Head Start	3-4	517	3.0 dmfs	38%
2003						
Dye et al.	NHANES III	U.S. civilian	5	1,045	1.0 df	40.2 %
2004		children				
Siegal et al.	Ohio	Head Start	3-5	2,555	-	38%
2004						

# 2.3 Description of caries experience

Tooth surfaces and teeth cluster in individuals and individuals cluster in populations. The disease severity of the individual is usually described by counting the number of caries lesions in the individual, or the number of lesions exceeding a certain stage of lesion progression. The disease severity of the population is typically also described using the average number of caries lesions (e.g. the mean DMFT or DMFS) or frequency distribution of people according the number of caries lesions (Fejerskov & Kidd 2003).

Two commonly used indexes for describing dental caries include the DMFS index (Radike 1972) and the World Health Organization index (WHO 1997). Most caries data have been collected using the classical decayed, missing and filled teeth (DMFT) or tooth surfaces (DMFS) developed in the 1930s (Klein *et al.* 1938). Each method is based on the detection of untreated disease (D), even at various levels of measurement and scoring different manifestations of clinical symptoms. These methods also assess evidence of past disease, represented by restorations (F), or missing (M) teeth.

Occurrence of past caries and changes in it, both on the population and on the individual level, are commonly described by these indexes (DMFT/S), and occurrence of present caries is usually described by decayed teeth (DT) or decayed surfaces (DS). These indexes are recorded for primary teeth (dmft, dmfs, dt, ds) below the age of six years. Although DMFS index has proven useful over a number of decades for the

assessment of dental caries, recent changes in the epidemiology of the disease and increasing advancement of new diagnostic tools for its measurements have stimulated development of improved methods for assessing dental caries.

The world Health Organization index, which distinguishes four levels of active disease, allows for various levels of incipient decay as well. Both WHO and DMF indexes reflect the cumulative history of caries experience for the subject. WHO criteria include assessment of noncavitated lesions. Evidence of "carious involvement" of tooth structure before frank cavitation is noted as either initial caries (no clinically detectable loss of tooth substance) or enamel caries (demonstrable loss of tooth substance in pits, fissures, or smooth surfaces, but not softened floor or wall of undermined enamel). Caries of dentin is equivalent to frank cavitation traditionally scored with the DMFT index. A deep cavity with probable pulpal involvement is the final level. Caries experience of children has been described by using WHO criteria in several studies (Scheinin *et al.* 1985, Twetman & Petersson 1996, Alanen *et al.* 2000, de Sousa *et al.* 2002, Assaf *et al.* 2004, Klemme *et al.* 2004, Pieper & Schulte 2004).

#### 2.3.1 Caries diagnosis

Diagnosis process is a procedure during which observations are classified according to what is known about the etiology, pathology, therapy, prevention, and prognosis of each type of lesion observed (Fejerskov & Kidd 2003). As far as the caries lesion is concerned, diagnosis implies detecting a caries lesion, estimating its depth and degree of demineralization, and making a decision about its activity (Nyvad & Fejerskov 1997). In order to deliver effective prevention, accurate diagnosis and monitoring of lesions over time is required. Arresting dental caries depends entirely on early and accurate diagnosis.

# 2.3.2 Early enamel lesions

Dental caries develops where microbial deposits are allowed to form biofilms that are not frequently removed. Dental caries is a dynamic process, which leads to a change in the equilibrium between tooth substance and surrounding plaque fluid, resulting in a net loss of tooth mineral (demineralization). The typical initial active caries lesion in the enamel exhibits a whitish opaque, matt, or 'chalky' appearance with a rough surface (Nyvad *et al.* 1999, Fejerskov & Kidd 2003). This is due to increase in the internal enamel porosity, due to demineralization (Fejerskov & Kidd 2003). The classic description of the primary enamel lesion is the white-spot lesion, defined as the first macroscopic sign of caries-induced demineralization (Bjørndal & Mjör 2001). A well-mineralized surface zone is seen overlying a subsurface demineralization (Bjørndal & Mjör 2001).

Cycles of active disease and arrest of lesion progression in enamel are common (Fejerskov & Kidd 2003). The transition of an active lesion into arrested /inactive lesion is accompanied by characteristic changes of the surface features of the lesion. As lesion transforms into an inactive stage, they acquire a shiny, smooth/hard surface. During the redeposition of mineral (remineralization) through the surface layer into the internal

(subsurface) lesion, the surface layer itself forms a diffusion barrier against subsurface uptake of mineral (Larsen & Fejerskov 1989) and the arrested lesions with an intact surface layer remains as scars in the tissue (Fejerskov & Kidd 2003). The clinical distinction between active and arrested caries has been reported in several histological and histochemical studies (Nyvad and Fejerskov 1997). If an active lesion is subjected to efficacious preventive intervention, such as oral hygiene or topical fluorides, the activity of lesion is likely to change (Fejerskov & Kidd 2003).

According the NIH panel on Diagnosis and Management of Dental Caries (NIH Consensus Statement 2001), science of identifying early signs of caries is still a developing field, one which is also the next crucial era in dental care. The strategies proven most effective as primary interventions often are also effective in reversing or arresting early lesions (NIH 2001).

In the past it has been argued that enamel lesions could not be included in epidemiological assessments of caries as the reproducibility achieved would be inferior and insufficient (Burt 1997). However, it now appears that this is not the case as excellent reproducibility with kappa-values around 0.8 has been achieved by examiners using the D1 threshold (enamel lesions) in clinical studies (Deery *et al.* 2000, Forgie *et al.* 2000, Chesters *et al.* 2002). It has been demonstrated that the inter- and intra-examiner reliability is not necessarily reduced when noncavitated caries lesions are included in the recording system, provided that the examiners are thoroughly trained and calibrated before the study (Nyvad *et al.* 1999). Diagnostic criteria can be used to make distinctions in the activity status of lesions (Nyvad & Fejerskov 1997). Modified caries diagnostic criteria, which differentiate between active and inactive caries lesions at both cavitated and noncavitated sites, have been used with high reliability in the permanent dentition (Nyvad *et al.* 1999). However, differentiation of the activity of lesions has not been tested in the primary dentition (Nyvad & Fejerskov 1997).

#### 2.3.3 Dentinal lesions

Caries lesion, when developing on smooth surface enamel, is as a cone-shaped defect, wide at the tooth surface and becoming narrow towards the dentin-enamel junction. At this point, the lesion becomes wider again, and may extend to the pulp. Broadening of the lesion in the junction is the result of the early stages of demineralization not being seen in the enamel, but visible in dentin in terms of brownish discoloration. Dental caries affects enamel and dentin to significant depth while the outer surface may remain intact (Fejerskov & Kidd 2003).

Dentin, on the contrary to enamel, is a vital tissue containing odontoblast processes and it is capable of defending against the caries process through the physiological mechanism of sclerosis (Bjørndahl & Mjör 2001). The first sign of dentin reactions to the enamel lesion is tubular sclerosis, which is the deposition of mineral within the dentinal tubules (Fejerskov & Kidd 2003).

Bacteria are rarely present within the lesion before cavitation of the enamel surface, although the dentin of noncavitated lesions may be soft and lightly infected (Ratledge *et al.* 2001). Once the cavity is directly exposed to the mass of bacteria, superficial tubular

invasion occurs. Now the most superficial part of the dentin becomes decomposed due to the action of acid on hydroxyapatite and proteolytic enzymes on the collagenous (type I) matrix, which results in the formation of the zone of destruction. Beneath this zone, tubular invasion of bacteria occur and with rapid lesion progression, the odontoblastic processes are first withdrawn and then destroyed without having produced tubular sclerosis. These empty tubules are invaded by bacteria, and the area is called the zone of bacterial penetration (Fejerskov & Kidd 2003).

# 2.3.4 Identifying caries with mutans streptococci

Salivary tests can be used to assess the presence of mutans streptococci colonization, caries activity and to identify individuals with caries disease. Assessment of microorganisms in saliva is based on the findings that there is an association between types and numbers of bacteria in dental plaque and those in saliva (Schaeken *et al.* 1987). Microbiological tests show close associations between odontopathogens and caries in subjects with high caries experience and conversely, low numbers or the absence of odontopathogens in low or caries-free subjects (Bowden 1997). The determination of salivary mutans streptococci has been found to be beneficial for evaluation of caries risk of an individual, for demonstration of highly cariogenic infection and for didactic purposes in health education (Larmas 1993, Vehkalahti *et al.* 1997).

# 2.4 Risk of caries on population and individual level

Risk is the probability that an event will occur. In epidemiology, it is most often used to express the probability that a particular outcome will occur following a particular exposure (Burt 2001). In dentistry, caries risk in a population level means the probability that new cases of caries will occur. Caries risk in an individual level means the probability that he or she will develop dental decay or experience a health-status change contributing to caries development over a specific period (Hausen *et al.* 1994). The term "risk factor" means an action or event that is related in some way to an outcome. A "risk factor" can be considered to play an essential role in producing an occurrence of the disease, while "risk indicators" are helpful in identifying groups at risk but give little information about the causes of the disease (Burt 2001).

Caries risk assessment predicts if new carious lesions will develop, or if early lesions will continue to grow. Caries risk assessment fosters the treatment of the caries process itself instead of surgical treatment of cavities (Tinanoff 1995, Powell 1998). Declining and skewed distribution of caries prevalence challenge us to accurately identify subjects particularly at risk for developing carious lesions, and thus to assess the risk for caries. Caries risk assessment is a clinical evaluation method with which dental professionals can target tailored preventive treatment to the individuals at high risk for caries. A necessary first step in preventing dental caries in preschool children is to understand the caries risk.

#### 2.4.1 Precavitated lesions in enamel

The detection of precavitated carious lesions is crucial in order to prevent the progression of dental caries before the occurrence of cavitation (Ismail 1997). In addition to nonsurgical management of dental caries, there are other reasons to detect incipient lesions early: Precavitated lesions are more prevalent than cavitated lesions (Anderson *et al.* 1993, Kingman 1997). Precavitated carious pits and fissures are three times more likely to be restored compared with sound tooth surfaces (Brown 1993). Previous caries experience and the presence of white spot lesions have been found to be the best indicators of future caries development (Wilson & Ashley 1989, Beck *et al.* 1992, Steiner *et al.* 1992, Hausen *et al.* 1994, Pienihäkkinen & Jokela 2002).

While a large proportion of precavitated lesions on smooth surfaces in children regress or progress slowly during a one-year period, the pattern of progression early in life may be different, 64% of such lesions in young children progressed to cavitation between ages of 2.5 and 3.5 years (Kaste *et al.* 1996). Hence, detection of precavitated lesions in infants and young children may predict high caries activity (Anusavice 1992). It has been reported that discolored pits and fissures and the number of white carious lesions are significant predictors of high caries activity (Bader & Shugars 1993, 1995).

### 2.4.2 Mutans streptococci

The most cariogenic bacteria are mutans streptococci, especially S. mutans and S. sobrinus (Fejerskov & Kidd 2003). Preschool children with high colonization levels of mutans streptococci have been shown to have greater caries prevalence and greater risk for new lesions than children with lower levels of mutans streptococci (Thibodeau & O'Sullivan 1996). Because mutans streptococci are considered to be the predominant pathogens of dental caries disease, individuals heavily colonized by them were thought to automatically be at high risk for caries. Indeed, in young children, early mutans streptococci colonization on tooth surfaces has been recognized as an indicator of later high scores of decayed, missing and filled surfaces in deciduous teeth (Alaluusua and Renkonen 1983, Köhler et al. 1988, Jokela 1997). It has been shown that salivary mutans streptococci levels correlate with caries in 3-5 year-old Head Start preschool children (Thibodeau & O'Sullivan 1996). Microbial tests can be effective in the assessment of caries activity and caries prediction in groups of persons with high or low caries experience (Bowden 1997). The combination of mutans streptococci counts, incipient caries lesions and use of candies were found to provide valuable information for assessment of caries risk (Pienihäkkinen et al. 2004).

The Dentocult-SM strip mutans—test was first introduced in 1989 (Jensen & Bratthall 1989). Evaluating mutans streptococci levels by means of Dentocult-SM strip mutans-test has been used in several studies (Mäkinen *et al.* 1996a, 1996b, Pienihäkkinen & Jokela 1995, 2002, Karjalainen *et al.* 2004). The practicability of the test in children has been evaluated and the test has been found to be accurate and the counts on the strip have been found to be a good indicator of colonization (Pienihäkkinen & Jokela 1995, 2002, Vehkalahti *et al.* 1996). Reductions in salivary levels of mutans streptococci (Mäkinen *et* 

*al.* 1996a, 1996b) and in levels of mutans streptococci in plaque and saliva (Isotupa *et al.* 1995) were found as determined by means of the Dentocult-tests.

Salivary tests are generally more usable than tests based on plaque, since the collection and handling of plaque tests are often more demanding (Mäkinen *et al.* 1996b). However, significantly better detection of mutans streptococci was achieved using plaque from the four approximal surfaces at two inter-dental spaces than with saliva with Dentocult-SM strip mutans-test (Seki *et al.* 2002). Also in terms of sensitivity, accuracy and kappa values, the site strip plaque test surpassed the salivary chair-side test when the Dentocult-test was used to evaluate the levels of mutans streptococci in plaque and saliva of 10 year-old children (Karjalainen *et al.* 2004). Screening of children by salivary or tongue-sampling methods is convenient, especially for field studies with dentally naive or fearful subjects for public health and population study purposes (Tanzer 1997). For validation of method, these chair-side techniques have been thoroughly compared with conventional selective agar plate culture. The comparison yields a good correlation between the methods with regard to detection of mutans streptococci, as well as counts on agar and score values (Alaluusua *et al.* 1984, Jensen & Bratthall 1989).

#### 2.4.3 Sociodemographic factors

There is consistent evidence for association between sociodemographic risk factors, such as low-income, and caries prevalence (Tinanoff *et al.* 2002). Preschool children from low-income families are more likely to have caries (Beck *et al.* 1992, Vargas *et al.* 2000). In addition to poverty level, it has been suggested that ethnic minorities show an increased risk of caries (Kaste *et al.* 1996, Shiboski *et al.* 2003). However, it has been difficult to separate the cultural influences of ethnicity from the effects of low socioeconomic status or poverty status on the prevalence of dental caries (Reisine & Douglass 1998). Montero *et al.* (2003) did not find any significant differences in dmfs scores when analyzed by ethnicity. Immigrant background has been reported to have a significant association with caries prevalence in children (Stecksen-Blicks *et al.* 2004).

# 2.4.4 Other risk factors

Sleeping with a bottle containing sweetened liquids (and/or prolonged use of bottle or sippy cup during the day) is considered a risk factor for caries in young children, especially when combined with other risk factors (Kanellis 2000). Prolonged pacifier sucking (longer than two years) and use of a nursing bottle at night have been reported to increase the occurrence of salivary lactobacilli and candida, which can be considered to be risk factors for dental caries in children (Ollila *et al.* 1998). Based on data from the third National Health and Nutrition Examination Survey on children aged two to five years, no association was found between breast-feeding and caries in primary teeth, but young children with poor eating habits were more likely to experience caries (Dye *et al.* 2004). The frequency of tooth brushing has been reported to have a significant association with caries prevalence (Stecksen-Blicks *et al.* 2004).

The presence of visible plaque on the teeth of young children can be used as an indicator of caries risk (Alaluusua & Malmivirta 1994, Kanellis 2000, Tinanoff *et al.* 2002). Several studies have shown the correlation between visible plaque on the primary teeth and caries risk (Beck *et al.* 1992, Alaluusua & Malmivirta 1994). However, more studies are needed to establish the best method to measure plaque for prediction of dental caries (Tinanoff *et al.* 2002). The potential for visible plaque to be an accurate predictor of caries risk in young children is encouraging, because screening could be done easily with this method.

In general, among children and adolescents, the most reliable predictor of future caries has been their caries experience (Downer 1978, Alaluusua *et al.* 1987, Demers *et al.* 1990, Gray *et al.* 1991, Holt 1995, Vehkalahti *et al.* 1996). However, previous caries experience is not a useful caries risk predictor for young children because there may not have been enough time for carious lesion development. Furthermore, the goal is to prevent caries initiation before the first signs of disease.

#### 2.5 Prevention

Preventive strategies are divided into two distinct groups: strategies aimed at the whole population and those aimed at groups or individuals at risk (Rose 2001). A population strategy, which focuses on health and the causes of the incidence of dental disease, is feasible in populations with high prevalence of oral diseases. Targeting individuals at risk attempts to protect susceptible individuals from developing further disease by changing their risk factors (Rose 2001). This approach is advocated in countries with decreased prevalence and skewed distribution of caries (Fejerskov & Kidd 2003).

A high-risk approach seeks to identify through screening and protect susceptible individuals or sections of the population, either as a group or as individuals. In this approach, groups living in particular areas with higher rates of caries can be identified, and principles of population strategy can be used. In population strategy, efforts are made to shift the risk distribution of the entire population to a more favorable level.

These concepts can be combined to use both the population approach, where measures are applied for everyone, and the individual risk approach, in which the groups of individuals are screened and targeted. Screening is used to detect those people at risk, for close monitoring and special preventive treatment.

Caries prevention measures aim to prevent the onset of caries, to arrest progression of caries lesions manifesting both subclinically and clinically, and even to repair them. Prevention can be successfully carried out both by eliminating causal factors of caries and by improving the resistance of teeth to caries attacks, even under conditions of heavy demineralization (Ten Cate & Duijsters 1982, Winston & Bhaskar 1998). Dentistry has several caries preventive measures to offer, some of which emphasize the patient's own responsibility in managing the disease, and the others rely on the dental professional for disease management. Patients at high risk for caries should be given the earliest opportunities for preventive treatment, either engaging the patient in managing the caries process or if not succeeding in this, providing intensified professional preventive measures (Tinanoff 1995, Winston and Bhaskar 1998).

From the beginning of the 1970s in Finland, all the children and adolescents under the age of 19 years have been entitled to free public dental care. During the 1970s and 1980s any preventive program was successful in preventing caries in Finland. Preventive dentistry in the United States has been poorly recognized (Tinanoff *et al.* 2002). There is a need in the United States to implement preventive strategies proven effective in Finland and other Nordic countries.

# 2.5.1 Fluorides in caries prevention

Although pit and fissure sealants, meticulous oral hygiene, and appropriate dietary practices contribute to caries prevention and control, the most effective and widely used approaches have included fluoride use (Bratthall *et al.* 1996). Fluoride's ability to inhibit or even reverse the initiation and progression of dental caries is well documented (Ten Cate 2004). However, if the bacterial challenge is too high, it is not possible for fluoride to overcome the challenge completely (Featherstone 2004).

It is well documented that fluoride products, such as toothpaste, mouth rinse, and office topicals have been shown to reduce caries between 30% and 70% compared with no fluoride therapy (Jenkins 1985). Studies of two to three years in duration have reported that fluoride toothpaste reduces caries experience among children by a range of 15%-30% (CDC 2001). The caries inhibition of fluoride mouth rinses is low (10-20%) when applied as an adjunct to unsupervised use of fluoride toothpaste (Disney *et al.* 1989).

Fluoride in the drinking water has been shown to be effective in reducing the severity of dental decay in entire populations (Featherstone 2004). Initial studies of community water fluoridation demonstrated that reductions in childhood dental caries attributable to fluoridation were approximately 50% to 60% (CDC 2001). More recent estimates are lower from 18% to 40%, likely caused by the increasing use of fluoride from other sources, and the widespread use of fluoride toothpaste, probably being the most important factor (Newbrun 1989). CDC Work Group on the Fluoride Use in the United States recommended that continuation of community water fluoridation and regular use of fluoridated toothpaste are the foundation for sound caries prevention programs (CDC 2001). However, for persons at high risk for dental caries, additional fluoride measures might be needed. For children younger than six years of age, fluoride supplements should not be used in countries where fluoride toothpaste is widely available, due to increased risk of fluorosis (Fejerskov & Kidd 2003). Furthermore, since the primary mode of action of fluoride has been shown to be mainly topical and since there is little or no benefit of swallowing it, locally acting supplements are preferred (Fejerskov & Kidd 2003).

#### 2.5.2 Demineralisation - Remineralisation

Dental caries lesion progression is a highly dynamic process characterized by alternating periods of dissolution and redeposition of minerals in the dental hard tissue (Fejerskov & Kidd 2003). When the outcome of these processes over time is a net loss of tooth mineral,

a caries lesion develops or progresses i.e. demineralization occurs (Fejerskov & Kidd 2003). When redeposition of minerals predominates, the result may be an arrest of lesion progression or remineralization (Fejerskov & Kidd 2003). Clinical practice suggests that caries lesions can be arrested at any stage of lesion development – even at the cavitation level – provided that clinically plaque-free conditions are maintained (Nyvad *et al.* 1999).

Fluoride works to control early dental caries in several ways. Fluoride concentrated in plaque and saliva inhibits the demineralization of sound enamel and enhances the remineralization (i.e., recovery) of demineralized enamel (Featherstone 2004). As cariogenic bacteria metabolize carbohydrates and produce acid, fluoride is released from dental plaque in response to lowered pH at the tooth-plaque interface (Fejerskov & Kidd, 2003). The released fluoride and the fluoride present in saliva are taken up, along with calcium and phosphate, by demineralized enamel to establish an improved enamel crystal structure. This improved structure is more acid resistant and contains more fluoride and less carbonate (Fejerskov & Kidd, 2003). Fluoride is more readily taken up by demineralized enamel than by sound enamel (Fejerskov & Kidd, 2003). Cycles of demineralization and remineralization can continue throughout the lifetime of the tooth.

During the past decade, scientists have identified the importance of remineralization of noncavitated caries lesions (Anusavice 1997, Pitts & Lond 1993). This finding is partially associated with the ability of fluoride to remineralize and arrest lesions (Pitts & Lond 1993). Little attention has been focused on the identification and management of initial enamel lesions, because of the variability of the results in clinical studies reported in the literature (Anusavice 1997). Part of the variability in the caries increment reduction in clinical studies, may be associated with the diagnosis criteria used (Pitts & Lond 1993).

# 2.5.3 Fluoride varnishes in caries prevention

For over 30 years fluoride varnishes have been the standard of practice for the professional application of topical fluoride in Europe (Bawden 1998). In the United States, fluoride varnishes were introduced in 1991 (Tinanoff *et al.* 2002) and their use is increasing among the dental community. The primary reason for the wide acceptance of fluoride varnish is the easy, safe, convenient, and well-accepted application procedure (Øgaard *et al.* 1994), especially for young children. With fluoride varnishes, the amount of fluoride exposure to patients can be better controlled and less chair-time is required compared with conventional foams and gels (Øgaard *et al.* 1994). Fluoride varnish covers the teeth with an adherent film for a prolonged period of time, thereby enhancing the uptake of fluoride ions into the tooth structure. Fluoride is deposited as calcium fluoride, creating a reservoir of fluoride ions, which are slowly released (Ten Cate 1997). Thus the action of fluoride is related to its inhibition of the demineralization processes as well as its promotion of enamel remineralization.

In numerous studies, fluoride varnishes have proved to be clinically effective (Øgaard et al. 1994, Sköld et al. 1994, Seppä et al. 1995, Holm 1979, Zimmer et al. 1999; Peyron et al. 1992). Duraphat® has been the most extensively studied fluoride varnish (Sköld et al. 1994, Seppä et al. 1995, Holm 1979, Zimmer et al. 1999, Peyron et al. 1992; Helfenstein & Steiner 1994, Grodzka et al. 1982, Beltran-Aguilar et al. 2000). Studies

conducted between 1968 and 1985 reported caries reductions in permanent teeth ranging from 18 to 77 percent (De Bruyn & Arends 1987). A meta-analysis by Helfenstein and Steiner (1994) estimated a 38 percent reduction in DMFS value. A study conducted in India against a negative control showed caries reduction of 70 to 75 percent (Tewari *et al.* 1991). Children who received a minimum of two applications of fluoride varnish (Duraphat) per year in a community with a low socioeconomic status and generally high caries level showed a significantly lower caries increment in their permanent teeth when compared to the reference group, which received no professional fluoride application (Zimmer *et al.* 1999).

Recommendations regarding the appropriate frequency of fluoride varnish applications for high caries risk children and adolescents vary from one application every three to six months per year (Modéer *et al.* 1984, Axelsson *et al.* 1987, Seppä & Tolonen 1990, Petersson *et al.* 1991) to three applications during one week per year (Petersson & Westerberg 1994). The type and extent of preventive measures must be adjusted according to each subject's individual needs. For the high-caries patients with a heavy cariogenic challenge, topical application of fluorides as a sole preventive action might be insufficient, and thus could be supplemented with other preventive measures (Lindquist *et al.* 1989, Anusavice 1995, Krasse 1996, Burt 1998).

#### 2.5.4 Efficacy of fluoride varnish in the primary dentition

The efficiency of fluoride varnish in the primary dentition has not been well documented and/or the results are inconclusive. According the NIH Consensus Statement on the Diagnosis and Management of Dental Caries (2001) the evidence for effectiveness of fluoride varnish applied to primary teeth is still incomplete and inconsistent.

Grodzka *et al.* (1982) studied the efficacy of semiannual applications of Duraphat in 3.5 year-old children, but did not find significant differences in caries increments after a two-year period. Holm (1979) evaluated semiannual applications of Duraphat in three year-old children and found 44% caries reduction after two years. Peyron *et al.* (1992) studied the progression of approximal caries in the primary dentition and the effect of Duraphat varnish in caries progression in 3-6 year-old children. After one year, 51% of the enamel lesions in the varnish group showed progression and 83% progressed without fluoride treatment. Frostell *et al.* (1991) studied the effect of semiannual applications of Duraphat varnish on caries development in the primary dentition in four year-old children and found 30% caries reduction. A study by a Lo *et al.* (2001) reported that children with early childhood caries who were treated with 5% NaF (Natrium fluoride) varnish every three months had half the number of new carious surfaces on the maxillary anterior teeth and one third more arrested caries as a comparable group after 18 months.

# 2.5.5 Xylitol in caries prevention

Several clinical studies have shown that the consumption of xylitol reduces the incidence of dental caries (Scheinin et al. 1975a, 1975b, Kandelman & Gagnon 1990, Scheinin et

al. 1985, review by Mäkinen et al. 1996, Isokangas et al. 1988, 1991, 1993, Alanen et al. 2000). The first human trials were *Turku Sugar Studies*, which showed significant reductions in caries rates after consumption of xylitol chewing gum compared to sucrose gum (Scheinin et al. 1975). However, there is a lack of evidence of the effect of xylitol on caries reduction in the primary dentition. One of several xylitol studies conducted in Belize, children with high caries experience showed that consumption of xylitol gum was associated with arrest of carious lesions in the primary teeth and the highest dose of xylitol had the greatest effect (Mäkinen et al. 1996b).

There is a considerable amount of evidence that the use of gum or candy with xylitol prevents dental caries in the permanent teeth when used several times daily and the effectiveness varied between 30% and 60% when compared to controls without the gum use (van Loveren 2004). According the NIH Consensus Statement on the Diagnosis and Management of Dental Caries (2001) the evidence for xylitol is strong as the primary prevention of dental caries. The preventive effect of xylitol seems to derive from the remineralization of decalcified surfaces of teeth, replacement of fermentable dietary sugars and reduction of the amount of dental plaque or the amount of mutans streptococci in plaque and saliva (Trahan 1995).

### 2.5.6 Effect of xylitol on mutans streptococci and plaque

The most significant effect demonstrated so far in caries reduction is its ability to reduce the growth and acid production of mutans streptococci (Bánóczy et al. 1985, Mäkinen et al. 1989, Trahan 1995), the primary bacteria responsible for caries. Growth retardation of mutans streptococci is thought to result from an energy-spending "futile xylitol cycle" and impaired glucose uptake and metabolism (Söderling & Pihlanto-Leppälä 1989, Trahan 1995). Accumulation of xylitol intracellularly in mutans streptococci was found to inhibit its growth contribution to a reduction of mutans streptococci levels in plaque and saliva (Trahan 1995). Most natural mutans streptococci are able to ingest xylitol into the cell, which is then phosphorylated to xylitol-5-phosphate, but bacteria are not able to utilize this end product and it has to be expelled from the cell (Söderling & Pihlanto-Leppälä 1989).

With regard to dental plaque, several studies have shown xylitol to reduce the amount, adhesiveness and acidogenic potential of it (Isotupa *et al.* 1995, Trahan 1995, Söderling *et al.* 1989, 1991, 1997, Mäkinen *et al.* 1989, 1996, Isokangas *et al.* 1991). Xylitol has the ability to reduce the number of mutans streptococci in plaque (Isokangas *et al.* 1991, Loesche *et al.* 1984, Mäkinen *et al.* 1989, Söderling *et al.* 1989, 1991, 1997) and loosen the plaque and mutans streptococci binding to the tooth surfaces (Söderling *et al.* 1991). This effect was found to depend on the frequency of chewing and the initial level of mutans streptococci (Mäkinen *et al.* 1989), and seemed to persist after the habitual use of xylitol had stopped (Isokangas *et al.* 1991).

Long-term studies have shown xylitol gum to reduce mutans streptococci counts in saliva (Bánóczy *et al.* 1985, Loesche *et al.* 1984, Mäkinen *et al.* 1989, 1996, Isokangas *et al.* 1991). In a study by Mäkinen *et al.* (1996), the properties of whole saliva and dental plaque in relation to 40-month consumption of chewing gum containing xylitol, sorbitol

or sucrose were evaluated. At the endpoint, the groups that received 100% xylitol three or five times per day showed significantly lower plaque index and exhibited the lowest counts of salivary lactobacilli. All groups exhibited obviously an aging-related increase of salivary mutans streptococci scores, except the 100% xylitol groups, in which the mean scores did not change. Short-term studies have demonstrated a decrease in the levels of mutans streptococci in plaque or saliva (Söderling *et al.* 1997, Wennerholm *et al.* 1994, Söderling *et al.* 1989, Isotupa *et al.* 1995).

Xylitol has shown to reduce the probability of mother-child transmission of mutans streptococci, when mothers chewed xylitol gum regularly for two years (Söderling *et al.* 2000). Xylitol has also been shown to prevent acute otitis media, by growth retardation of *S. pneumoniae* and decreased adhesion of *S. pneumoniae* and *H. influenzae* (Kontiokari 1998).

#### 2.6 Compliance of prevention program

### 2.6.1 Compliance of children

Caries preventive measures emphasize the patient's own responsibility in managing the disease or the dental professional's role in disease management. Only minimal compliance in caries preventive measures at home or in practice is reached in high-risk patients compared with out-reaching group programs (Splieth *et al.* 2004). Thus, group programs are instrumental in providing effective and efficient caries prevention measures in children. Patients at high risk for caries should be engaged in managing the caries process or, if not succeeding in this, providing intensified professional preventive measures (Tinanoff 1995, Winston & Bhaskar 1998).

Long-term compliance of prevention programs is important for the treatment to be effective and to maintain the power in clinical studies. Treatment compliance needs to be evaluated since caries risk patients are often from socioeconomically disadvantaged families with low education level and poor self-efficacy. The acceptance and compliance of children in numerous xylitol studies have not been presented thoroughly. In two studies, a dietary questionnaire was used to follow the consumption of xylitol containing products to determine compliance of children, but the details were not described (Isokangas *et al.* 1988, Isotupa *et al.* 1995). In other studies, compliance has been assumed, since teachers and parents supervised the use of the gum (Kandelman *et al.* 1987, 1988, 1990, Mäkinen *et al.* 1995, 1996, Isokangas *et al.* 1993) or a dental nurse controlled and registered the compliance at schools (Isokangas *et al.* 1988). Kandelman & Gagnon (1987) used a questionnaire to evaluate the side effects of chewing the gum. Mäkinen *et al.* (1996) did not report the details of acceptance or compliance of chewing in a study, which evaluated the effect of polyol chewing gums in the primary dentition of 6 year-old preschool children.

In studies to evaluate the effect of xylitol on otitis media of children in Finnish day care centers, compliance was concluded to be mainly good (Kontiokari 1998). According this research team, even 3-5 year-old children in day care centers can chew the xylitol

gum at least for two to three months (Uhari *et al.* 1998) and the sweet taste of xylitol can be easily accepted by children (Kontiokari 1998).

Nordblad *et al.* (1995) organized a 'smart habit' campaign, which aimed to increase the consumption of xylitol chewing gum in 13 year-old schoolchildren in Finland. The xylitol campaign was conducted in elementary schools in the form of a quiz and a lesson related to xylitol. Almost half (41%) of the children used xylitol gum daily and the proportion increased during the campaign by 6% (Nordblad *et al.* 1995). An increase in the daily use of the xylitol gum and knowledge of the beneficial properties of xylitol was achieved by the campaign and oral health in children was positively promoted.

# 2.6.2 Compliance of care-givers, parents, teachers and health personnel

Most of the xylitol studies have been conducted within elementary schools, as they are well organized and may have existing prevention programs, such as fluoride rinsing (Kandelman *et al.* 1987, 1988, Kandelman & Gagnon 1990, Isokangas *et al.* 1988, 1993). However, the acceptance and compliance of teachers has not been presented thoroughly. Also studies analyzing the use of xylitol from a community perspective are lacking at present (Alanen *et al.* 2000).

Low compliance can lead to the high dropout rate, which can weaken the outcome of the study. Dropout rates reported in a few of the xylitol studies of two or three years' duration have been roughly 11-52 percent (Scheinin *et al.* 1985, Kandelman *et al.* 1988, Kandelman & Gagnon 1990, Mäkinen *et al.* 1996). In a study by Kandelman & Gagnon (1990) in 13 elementary schools in Montreal, Canada, the high dropout was due to very high mobility of the population in the low socioeconomic area and two schools withdrew from the project upon teachers' requests to reduce their daily workload.

Community intervention trials of chewing gum among schoolchildren can be subject to cluster effects (Machioulskiene *et al.* 2002). In a study by Machioulskiene *et al.* (2002), the high dropout rate was related to subclusters of classes within the school, which indicated that the intervention as such was not the reason to dropout, rather the norms within the local social network in the classes, which affected the behavior of a single individual. Also differences in the learning environment, such as teacher motivation and attitude may influence the children's engagement in the program (Machioulskiene *et al.* 2002).

Effective prevention programs can be achieved when schoolteachers are obligated to take an active role (Trummler & Weiss 2000). Positive results of a prevention program can be obtained in a situation where considerable efforts are made to maintain the interests of the subjects, school personnel, and parents (Mäkinen *et al.* 1996).

Since 1991, the use of xylitol gum has increased in Finland and more than half of all schoolchildren benefit from it (Honkala *et al.* 1999). Dental personnel in Finland have adopted xylitol rapidly as an additional preventive method, and daily use of xylitol gum has been included in routine dental health education information (Honkala *et al.* 1999). Currently, almost all dental health educators (94-100%) include xylitol as a separate topic in their dental health education (Laiho *et al.* 1995). Overall, countries with nationally supported prevention programs have adopted xylitol.

#### 2.7 Early oral health education

Motivation, support and education are the key factors in prevention programs that need to be emphasized in the future. Early oral health education can be a valuable tool to prevent caries in young children. Counseling with regular follow-up provided by a person of similar background and culture to the participants was shown to be an effective way to facilitate adoption of healthy behaviors and to improve the oral health of children (Harrison & Wong 2003). Regular home visits to mothers with infants, commencing at or soon after the time of the eruption of the first deciduous teeth, was shown to be effective in preventing the occurrence of nursing caries (Kowash *et al.* 2000).

Most educational messages are persuasive in nature and they attempt to persuade the listener to adopt healthy behaviors. Early health education can be difficult to implement in high-risk groups with sociodemographic risk factors. Educating parents of early childhood caries and the ways of preventing it has had minimal success in some programs (Berkowitz 2003, Kanellis 2000). Early health education may not be effective in altering inappropriate habits or improving preventive behaviors in some populations, but it remains an important component of preventive dental programs.

# 3 Purpose of the study

The purpose of this study was to determine the caries prevalence and to evaluate the effectiveness of two separate prevention programs, including applications of fluoride varnish and xylitol chewing gum on Head Start preschool children.

### Hypotheses

- 1. Caries prevalence is high in preschool children living in low-income families in Northern Florida.
- 2. Fluoride varnish applications and chewing the xylitol gum are feasible prevention methods for preschool children.
- 3. Applications of fluoride varnish arrest incipient lesions and reduce caries progression in the primary dentition during a nine-month study period.
- 4. Salivary level of mutans streptococci indicates caries risk.
- 5. Use of xylitol chewing gum three times a day for three weeks reduces levels of salivary mutans streptococci.

## 4 Materials and Methods

## 4.1 Subjects

Study subjects were selected to be 4-6 year-old Head Start schoolchildren in two separate counties in Northern Florida. Inclusion criteria were healthy children with guardian consent for participation. Exclusion criteria were medically compromised and uncooperative children. The research protocol and informed consent forms were reviewed and approved by the University of Florida Health Science Center Institutional Review Board (IRB) Involving Human Subjects.

For the fluoride varnish study, 221 children enrolled in the Head Start preschool program in Gainesville, Florida, were invited to participate. At baseline, 183 children with parental consent, in ten schools, were randomly assigned to the varnish (n=68) and the control (n=115) groups. The mean age of children at baseline was 5.5 years (min 4.0 yrs, max 6.0 yrs). Thirty-five subjects dropped out during the study and six were excluded due to extensive restorative treatment. The mean age of these children in the end of the study was 7.4 years (min 6.9 and max 7.8). The main reasons for the dropouts included family moves away from the area, withdrawal from the school program, or parental refusal to continue the study participation. After nine months, there were 59 children in the varnish group and 83 in the control group; 49.3% were females and 50.7% were males. The mean age of children was 6.3 years (min 4.7, max 6.7). The children represented a racial mixture of African-Americans (67.0%), Whites (23.5%), and 9.5% were of other or unknown race/ethnicity (I, II).

For the xylitol chewing gum study, 85 Head Start schoolchildren in Starke, Florida were invited to participate. Sixty-one healthy children (32 female, 29 male) with parental consent participated in the study. The mean age of the children was 4.3 years (min 3.3 yrs, max 4.3 yrs). The children represented a racial mixture of African-Americans (77.8%), Whites (18.5%) and Hispanic (3.7%) (III, IV).

### 4.2 Methods

In the fluoride varnish study, 142 randomly assigned children completed the study. In the varnish group (n=59), children received topical application of fluoride varnish (Duraphat®, 5%NaF, 22.6 mgF, Colgate-Palmolive) at baseline and after four months (two times). Children in the control group (n=83) received cleaning with fluoridated toothpaste by dental staff. The schools were located in areas where the fluoride in the drinking water was 0.80 mg F/L.

Alachua County Health Department and Pediatric Dental Clinic at the University of Florida provided dental examinations and dental care for these children. These children were transported by bus from the multiple different Head Start schools to the clinic on different days. Baseline fluoride varnish applications were performed at the University of Florida dental clinic after dental examinations and second applications after four months in the Head Start school classes. The control group did not receive any professionally applied fluoride treatments, since other topical applications of fluoride, such as gel or foam applications, require trays, suction and means of expectoration. Therefore, tooth brushing at baseline was the only fluoride application for the control group. Acceptance of the school visits by teachers and children was good.

Each fluoride application followed tooth brushing. After cotton roll isolation, teeth were dried and varnish was applied with a small brush to all surfaces of all teeth. In the school visits, each child placed his/her head in the investigator's lap. The teeth were dried using sterile cotton sponges and varnish was applied using the brush. Each child was advised not to drink for at least two hours or chew for at least four hours and to avoid rough, hard food for the next 24 hours. Children were told they should brush their teeth next morning (II).

In the xylitol study, children from five different Head Start classes were randomly assigned into the control or xylitol chewing gum group. Children in the xylitol group (n=33) chewed the gum sweetened only with xylitol (XyliFresh 100%, Hershey Food Corporation, USA) three times a day for three weeks during schooldays for approximately five minutes. Children in the control group (n=28) did not chew any gum. Detailed instructions for administering and monitoring the gum were distributed to teachers. Teachers delivered one pellet of gum to each study participant after breakfast (8 a.m.), lunch (11 a.m.) and snack (1 p.m.). The daily consumption level of xylitol was around 4.05 g (3 x 1.35g) (III, IV).

#### 4.2.1 Clinical evaluation

For the fluoride varnish study, dental examinations in supine position were carried out by two calibrated examiners in the dental clinic under the regular dental light. For visual examination, teeth were isolated with cotton rolls and the surfaces were dried with compressed air. The tip of the explorer was used gently to check for the loss of surface smoothness or the loss of tooth structure.

Surface-specific coronal caries, including enamel and dentinal caries lesions, were recorded using WHO criteria (WHO, 1997). Differentiation between active and inactive

enamel caries lesions was made on the basis of a combination of visual and tactile criteria. Scoring criteria for clinical caries assessments are included in Table 4 based on the criteria published by Nyvad *et al.* (1997).

Table 4. Description of the Caries Diagnostic Criteria

Sound	Sound, normal enamel translucency and texture.
Active noncavitated enamel	Active enamel caries, surface of enamel is
	whitish/yellowish opaque with loss of luster; feels soft
	or rough on probing. Presence of small porosity
	involving enamel only.
Inactive noncavitated enamel	Inactive enamel caries, surface of enamel is brownish
	or black. Enamel may be shiny and feels hard and
	smooth on probing. Small porosity involving enamel
	only.
Cavitated enamel	Enamel cavity easily visible with the naked eye;
	surface of cavity feels soft or leathery on probing.
Cavitated dentinal	Dentinal cavity easily visible with the naked eye;
	surface of cavity feels soft or leathery on probing.
Pulpal involvement	Dentinal cavity extending into the pulp.

Two calibrated dentists performed examinations at baseline and after nine months. They were unaware of the treatment group. Preliminary discussions and clinical rehearsals on caries diagnosis and calibration between the examiners and two other clinicians were completed before the initial examinations. Inter-examiner reliability of the caries diagnostic criteria was assessed by re-examination of 8%-10% of the subjects at each examination period. The results were expressed as percentage agreement and Cohen's Kappa. The percentage agreement for caries diagnoses was 79 % at baseline and 99 % after nine months. The Kappa values were 0.71 at baseline (substantial level of agreement) and 0.91 after nine months (excellent level of agreement) (I, II).

In the xylitol study, baseline examinations to determine caries were carried out by two calibrated examiners in the dental clinic prior to the study. To mask the examiners, all the other children from the same Head Start school were simultaneously examined. The salivary mutans streptococci levels were tested at baseline and after three weeks of chewing (III, IV).

# 4.2.2 Evaluation of the effect of fluoride varnish

The cross-sectional analysis of the effect of fluoride varnish on the caries progression was evaluated using dmf(s/t) and ds values, which are average measures of the past and present caries at the onset of the study and at the end. In this evaluation, two separate comparisons were performed between the groups. The first comparison was made without noncavitated enamel lesions (dmfs, dmft, ds) and the second comparison was made including active noncavitated enamel lesions (d<sub>E</sub>mfs, d<sub>E</sub>mf, d<sub>E</sub>s). Additionally, the

distribution of active noncavitated enamel lesions and status of the lesion at nine months was presented (II).

## 4.2.3 Evaluation of mutans streptococci in saliva

The number of salivary mutans streptococci was determined by using a simple chair-side method (Dentocult SM® Strip mutans, Vivacare/Vivadent, Orion Diagnostica, Finland). After one minute of chewing the paraffin wax, a plastic strip was rotated five times on the dorsum of the tongue and then it was withdrawn through softly closed lips to remove excess saliva. The procedure was successful with these children. The strip was transferred to a selective culture medium in glass tubes and was incubated at 37°C for 48 hours. After drying, the number of mutans streptococci bacteria/ml saliva was obtained by comparing the test strip with an evaluation chart provided by the manufacturer. Two calibrated examiners evaluated the coded strips, and they were unaware of grouping. In cases of the different interpretations of the strip, discussion between two examiners was conducted to decide the final score. The estimated levels described as equivalent by a level of mutans streptococci of score  $0 = <10^4$ ,  $1 = 10^4 - 10^5$ ,  $2 = 10^5 - 10^6$ ,  $3 = >10^6$  CFU of mutans streptococci/ml of saliva. The baseline measurements were done at the dental clinic and follow-up measurements after three weeks in a school classroom (III).

# 4.2.4 Identifying caries with mutans streptococci

In the xylitol study, the association between the levels of mutans streptococci and caries lesions was evaluated at baseline using sensitivity (Sn), specificity (Sp), positive (Pv+) and negative (Pv-) predictive values to assess the predictive value of mutans streptococci in identifying children with caries. "Sensitivity" in this case meant the ability to identify cases of disease and "specificity" was the proportion of correctly found healthy subjects. The sensitivity of a test was the number of true positive test results as a percentage of the total sick subjects examined, while specificity was its logical opposite. The predictive value of a positive test result was the number of true positives as a percentage of all the individuals with positive results and similarly the predictive value of a negative test result was the number of true negatives as a percentage of all individuals who gave negative results.

# 4.2.5 Evaluation of compliance and acceptance

Teachers' attitudes toward the xylitol study were measured using a questionnaire. The questionnaire consisted of six closed-ended questions regarding their attitude towards the chewing program and their opinion of children's acceptance. Teachers followed their delivery and guidance of gum chewing by using a daily checklist. They reported any events concerning the usage of gum, for example if a child refused or was not able to

chew the gum. Children's acceptance was measured in the end of the three-week chewing period by use of a picture selection test (IV).

#### 4.2.6 Statistical evaluation

Data for the xylitol study were evaluated using STATVIEW 4.0 software. Regression model analysis was used to evaluate the relationship between mutans streptococci and dsvalues. Chi-square analysis was used to evaluate differences between the groups at baseline and after three weeks for salivary levels of mutans streptococci (III).

For caries prevalence, data analyses were conducted at the person-level and the tooth-level. For person-level analyses, SAS version 9.0 statistical software (SAS Institute, Inc., Cary, NC) was used. Chi-square analysis was used to test differences in the prevalence of enamel and dentin lesions by sex and race. The GLM procedure (generalized linear modeling) was used for analysis of variance (ANOVA) modeling to test differences between children who had cavitated dentinal lesions and those who did not in the mean number of enamel lesions. Linear regression modeling was used to test the association between the number of enamel lesions and the number of dentinal lesions at baseline, before fluoride treatment. Tooth-level analyses were conducted by using SUDAAN 7.50 statistical software (Research Triangle Institute, Research Triangle Park, NC), which adjusts for the clustering effect of teeth within individuals when calculating standard errors. Tooth-level analysis tested differences in means and proportions by tooth type by using chi-square and t-tests based on standard errors that took into account the correlated nature of the data (I).

Fluoride varnish data were analyzed using STATVIEW 4.0 software. Differences in caries prevalence between the groups were evaluated using the Mann Whitney U-test and within the groups using the Wilcoxon Signed Rank Test (repeated-measures). Differences in the enamel caries distribution were analyzed using the Fisher's Exact Test (II).

## 5 Results

# 5.1 Prevalence and distribution of dental caries in the primary dentition

Prevalence of children who have experienced cavitated or noncavitated caries lesions in the primary dentition was 86.0%. Prevalence of cavitated dentinal lesions was 48.4% and for active noncavitated enamel lesion it was 70.6%.

Table 5 shows the mean number of decayed, missing, or filled primary teeth or tooth surfaces per child and prevalence of caries lesions, by lesion type for Whites and African-Americans. The mean number of active noncavitated enamel lesions  $(2.9\pm0.2)$  was slightly higher than the mean number of cavitated dentinal lesions  $(2.5\pm0.3)$ . The mean number of restored surfaces was  $1.2\pm0.4$  and only 8.1% of the children had one or more restored surfaces. When cavitated enamel or dentinal lesions and lesions with pulpal involvement and filled surfaces were combined, representing a traditional dfs score (decayed and filled surfaces), the mean number was  $4.3\pm0.5$ .

There were no significant differences between females and males in the prevalence of noncavitated or cavitated lesions. Some racial differences in the prevalence of noncavitated lesions were found. African-American children had a higher prevalence of active or inactive noncavitated lesions (80.4%) than Whites (69.2%) or others (33.3%); p<0.0001 (chi-square). The prevalence of cavitated lesions for African-American was 49.3%, for Whites 46.2%, and for others 47.6% with no statistically significant differences (I).

Table 5. Mean number of decayed, missing, or filled primary teeth or tooth surfaces per child and prevalence of caries lesions, by race and lesion type.

Race / Caries lesion type	Mean (SEM)	Median	Range	Prevalence of ≥1 lesion (%)
Total (n=221)				
Active noncavitated enamel surfaces	2.9 (0.2)	2.00	0-19	70.6
Inactive noncavitated enamel surfaces	0.2 (0.1)	0.00	0–5	7.7
Cavitated enamel surfaces	0.4 (0.1)	0.00	0-11	17.2
Cavitated dentinal surfaces	2.5 (0.3)	0.00	0-30	48.4
Pulpal involvement, surfaces	0.1 (0.0)	0.00	0–5	7.2
Filled surfaces	1.2 (0.4)	0.00	0–55	8.1
Missing surfaces	0.5 (0.2)	0.00	0–25	3.6
dft*	2.4 (0.2)	1.00	0–12	56.1
	` /			
dfs†	4.3 (0.5)	1.00	0–55	56.1
African American (n=148)				
Active noncavitated enamel surfaces	3.3 (0.3)	3.00	0-19	77.0
Inactive noncavitated enamel surfaces	0.2 (0.1)	0.00	0–4	10.8
Cavitated enamel surfaces	0.4 (0.1)	0.00	0-11	18.2
Cavitated dentinal surfaces	2.3 (0.3)	0.00	0-29	49.3
Pulpal involvement, surfaces	0.2 (0.1)	0.00	0-5	8.8
Filled surfaces	1.4 (0.6)	0.00	0-55	8.1
Missing surfaces	0.6 (0.3)	0.00	0-25	4.1
dft*	2.3 (0.2)	1.00	0-12	56.8
dfs†	4.23 (0.7)	1.00	0–55	56.8
White (n=52)				
Active noncavitated enamel surfaces	2.4 (0.4)	2.00	0-11	69.2
Inactive noncavitated enamel surfaces	0.0 (0.0)	0.00	N/A	0.0
Cavitated enamel surfaces	0.5 (0.2)	0.00	0–4	19.2
Cavitated dentinal surfaces	3.2 (0.8)	0.00	0-30	46.2
Pulpal involvement, surfaces	0.1 (0.1)	0.00	0-2	5.8
Filled surfaces	1.1 (0.7)	0.00	0-37	9.6
Missing surfaces	0.2 (0.2)	0.00	0-10	3.9
dft*	2.8 (0.5)	1.00	0-12	55.8
dfs†	4.8 (1.1)	1.00	0-40	55.8

SEM = standard error of the mean. \* Decayed or filled primary teeth. Includes teeth with cavitated enamel lesions, cavitated dentinal lesions, pulpal involvement, or restorations. <sup>†</sup> Decayed or filled primary tooth surfaces. Includes surfaces with cavitated enamel lesions, cavitated dentinal lesions, pulpal involvement, or restorations.

Most of the noncavitated lesions occurred on the occlusal surfaces of the first and second primary molars. Buccal surfaces of the second mandible molars and lingual surfaces of the maxillary second molars exhibited more noncavitated lesions than other surfaces. Cavitated lesions were more common than noncavitated lesions on the maxillary primary incisors, and the mesial surface was the most common cavitated surface. Occlusal surfaces of the second primary molars had a higher number of cavitated lesions than other surfaces (I).

Chi-square analysis tested the association between the presence of any noncavitated (active or inactive) enamel lesion and the presence of one or more cavitated enamel or dentinal lesions or lesions with pulpal involvement. There was a trend toward a significant association in this comparison (p<0.09).

In linear regression analysis, the number of cavitated enamel or dentinal lesions was not significantly associated with the number of noncavitated lesions affecting primary molars (R-squared=0.0038; p=0.36), but was significantly associated with the number of noncavitated lesions on anterior teeth (R-squared=0.13; P <0.0001) (I).

In the xylitol study, a mean dmfs value for the children was 5.7 (SD=10.4) and a mean ds value was 3.0 (SD=5.0) (III).

## 5.2 Evaluating the efficacy of fluoride varnish treatment

Distribution of active enamel lesions at the nine month study are presented in the Table 6. The percentage of active enamel lesions on the occlusal surfaces was 60.0~% in the varnish group and 78.6~% in the control group. In the varnish group, 81.2~% of the originally active enamel lesions were inactive or reversed after nine months (p<.001) compared to 37~% in the control group (Table 6). In the control group, 37.7~% of all surfaces were still active (p<.001) whereas only 8.1~% were active in the varnish group (Table 6). There were significantly more inactive lesions in the varnish group after nine months on all surfaces (P<.001). Clearly, remineralization in the control group was less evident. The probability of occlusal active enamel lesions to be reversed to inactive lesions was two times higher in the varnish group than in the control group (0.778/0.379) (II).

				original					

Tooth Surface	Group	No Change	Inactive	Progressed	Filled	Total
Occlusal	Varnish	10 (6.5)*	119 (77.8)*	6 (3.9)	18 (11.8)*	153 (60.0)
	Control	63 (35.6)	67 (37.9)	8 (4.5)	39 (22.0)	173 (78.6)
Buccal	Varnish	7 (9.9)	62 (87.3)*	0	2 (2.8)	71 (27.8)
	Control	10 (41.7)	9 (37.5)	0	5 (20.8)	24 (10.9)
Lingual	Varnish	4 (12.9)	26 (83.9)*	0	1 (3.2)	31 (12.2)
	Control	10 (41.7)	9 (37.5)	0	5 (20.8)	24 (10.9)
Total	Varnish	21 (8.1)	207 (81.2)*	6 (2.3)	21 (8.1)	255 (100)
	Control	83 (37.7)*	85 (38.6)	8 (3.3)	45 (19.9)	220 (100)

<sup>\*</sup> p<.001, percentages in parentheses

The efficacy in the fluoride study was reported by comparing the mean values of dmf(s/t) and ds for subjects in the study groups (Tables 7 and 8). Table 7 shows the mean values without noncavitated enamel lesions (dmfs, dmft, ds) and Table 8 including active noncavitated enamel lesions (d<sub>E</sub>mfs, d<sub>E</sub>mft, d<sub>E</sub>s).

No statistically significant differences in dmfs, dmft and ds values between the varnish and control groups could be seen at baseline. Mean values were higher in the control group when compared to the varnish group at nine months (p<.01 for dmft and p<.05 for dmfs and ds, Mann Whitney U-test) (Table 7). The mean dmfs value was significantly higher in the control group at nine months than at baseline (p<.001, Wilcoxon test) (Table 7). The mean ds value in the varnish group was significantly lower at nine months compared with the baseline value (p<.001, Wilcoxon test) (II).

Table 7. Mean dmfs, dmft, ds values in the varnish and control groups at baseline and at nine months.

Index	Mean (SD	) measure at b	aseline	Mean (SD) measure at nine months			
			Varnish vs.			Varnish vs.	
	Varnish Group	Control Group	Control	Varnish Group	Control Group	Control	
	(n=59)	(n=83)	P value	(n=59)	(n=83)	P value	
dmfs	2.5 (4.0)	2.6 (3.3)	NS	3.1 (4.3)*	4.1 (4.4)**	<.05	
dmft	1.6 (2.2)	2.1 (2.4)	NS	1.7 (2.3)	2.6 (2.3)**	<.01	
ds	2.0 (3.6)	2.0 (2.8)	NS	0.8 (1.6)**	1.4 (2.2)**	<.05	

dmfs = decayed, missing and filled surfaces; dmft = decayed, missing and filled teeth; ds = decayed surfaces. SD: Standard deviation. NS: non significant. \*p<.05, \*\*p<.001, when compared to the baseline values

When active noncavitated enamel lesions were included in the analyses, the mean  $d_E$ mfs,  $d_E$ mft and  $d_E$ s values were significantly lower in the varnish group after nine months than they were at baseline (p<.001, Wilcoxon test), while the mean  $d_E$ mfs and  $d_E$ mft values in the control group remained constant (Table 8). After nine months, the mean  $d_E$ mfs value (p<.01) the mean  $d_E$ mft value (p<.001) and the mean  $d_E$ s value (p<.001) were higher in the control group than they were in the varnish group (p<.001, Mann Whitney U-test) (Table 8). These differences are significant because of the decrease in the mean values in the varnish group (II).

Table 8. Mean  $d_E mfs$ ,  $d_E mft$ ,  $d_E s$  values including noncavitated enamel lesions, in the varnish and control groups at baseline and at nine months.

Index	Mean (SD) n	neasure at b	paseline	Mean (SD) measure at nine months			
			Varnish vs.			Varnish vs.	
	Varnish Group Co	ontrol Group	Control	Varnish Group	Control Group	Control	
	(n=59)	(n=83)	P value	(n=59)	(n=83)	P value	
$d_E mfs$	8.2 (7.2)	5.3 (4.0)	<.05	4.6 (6.5)**	5.7 (5.0)	<.01	
$d_{\rm E}mft$	5.2 (3.3)	4.2 (2.9)	NS	2.5 (2.7)**	4.0 (2.9)	<.001	
$d_{\rm E}s$	7.0 (5.7)	5.2 (4.0)	NS	1.2 (2.0)**	13.0 (3.0)**	<.001	

 $d_E$ mfs = decayed, missing and filled surfaces;  $d_E$ mft= decayed, missing and filled teeth;  $d_E$ s = decayed surfaces. SD: Standard deviation. NS: non significant. \*p<.05, \*\*p<.001, when compared to the baseline values

The race distribution was similar for the groups; in the varnish group 71.2% were African-American, 25.4% White, 1.7% Hispanic, 1.7% Asian, and in the control group 72.8% were African-American, 24.7% White, 1.2% Hispanic and 1.2% Asian. No significant differences in caries prevalence between races were found at baseline or at nine months based on the comparison of the mean dmfs values (Mann Whitney U-test) (II).

# 5.3 Evaluating the efficacy of xylitol on salivary mutans streptococci levels

Data for caries prevalence, age, and mutans streptococci levels at baseline and after three weeks are presented in Table 9. There were no differences in the age or caries prevalence between these two groups. There was a significant correlation at baseline between ds values and mutans streptococci levels (p<.001, Regression analysis) (III).

The overall change in mutans streptococci levels was evaluated. The shift to the lower levels in the xylitol group was greater than in the control group (p<.05, Chi-square). Most of the children (75%) in the control group kept the same level after three weeks, 22% had a decrease and only three percent had an increase in the level. In the xylitol group, 42% kept the same level, 10% had an increase and 48% decreased, in which 30% decreased only one level, but 15% decrease two levels and 3% decreased three levels (III).

Table 9. Distribution of salivary S. mutans scores and mean values for the ds-, dmfs-index and age.

Experimental	n	Age	S. mutans		Baseline		3 weeks
group			level	S. mutans	Mean	Mean	S. mutans
				distribution	ds(SD)	dmfs(SD)	distribution
Control group	28	4.2±0.6	0	3	0.0 (0.0)	0.0 (0.0)	3
			1	2	1.0 (1.4)	2.0 (2.8)	5
			2	8	1.3 (2.4)	2.0 (3.2)	8
			3	15	4.7 (5.8)	10.1 (12.2)	12
Xylitol group	33	$4.4 \pm 0.6$	0	4	0.5 (1.1)	0.8 (1.5)	10
			1	3	1.7 (2.9)	1.7 (2.9)	6
			2	12	1.1 (2.1)	3.1 (3.9)	7
			3	14	8.0 (6.4)	9.7 (6.6)	10

Mutans streptococci scores are determined as described in the manufacturer's (Orion Diagnostica) manual on paraffin-stimulated whole saliva of all subjects in experimental groups.

## 5.4 Identifying the presence of caries lesions with salivary tests

Sensitivity, specificity, positive and negative predictive values for mutans streptococci and ds are presented in Table 10. Sensitivity or ability to identify cases of disease, was high (90%) when the cut-off point for the mutans streptococci was level  $0 = 10^4$  CFU of mutans streptococci /ml of saliva) with caries-free children (ds=0), but specificity or ability to identify healthy subjects was low (33%). When the cut-off point for mutans streptococci was level  $2 = 10^{-5}$  CFU of mutans streptococci /ml of saliva), the sensitivity was low but the specificity i.e. the proportion of correctly found healthy subjects was higher (80%). The positive predictive value, the percentage of children diagnosed as having disease who actually did, was moderately high (77%) on children with high levels of mutans streptococci. The negative predictive value i.e. the percentage of those predicted not to have mutans streptococci infection who actually had disease was almost equal in all categories, the highest in level >0 (77%).

Table 10. Sensitivity (Sn), specificity (Sp), Positive (Pv+) and negative (Pv-) predictive values of ds and mutans streptococci scores.

Baseline S. mutans	Se (%)	Sp (%)	Pv+	Pv-
score				
>0	90	33	58	77
>1	84	43	60	72
>2	65	80	77	69

# 5.5 Compliance and acceptance of chewing the xylitol gum

## 5.5.1 Compliance of children

Children's acceptance and compliance for chewing was excellent. Positive ratings were given for xylitol gum chewing (94.3%) and for taste (85.7%). Children chewed the gum at designated times and none of the children swallowed the gum (IV).

# 5.5.2 Compliance of teachers

Teachers' acceptance of the chewing program was low. Three out of five participating teachers thought the gum chewing disturbed the classroom routine and four were not willing to participate in the program next year. Teachers' compliance was good and they followed the instructions during a three-week period (IV).

## 6 Discussion

#### 6.1 Materials and methods

## 6.1.1 Subjects

Head Start preschool children were selected to participate in this research due to their socioeconomic background and high level of caries. Head Start is a national program providing comprehensive developmental services primarily to low-income preschool children (birth through age five) and their families in the United States. Due to the structured Head Start program and school participation, these children can be provided prevention health programs in their early years.

## 6.1.2 Dropout rate

In the fluoride study, the dropout rate was high. The average age of dropouts was higher than the average age of participants in the end of the study. Age was found to be a significant individual predictor of dropout in a study by Machiulskiene *et al.* (2002), in which children dropped out since they moved to another school, which was the case also in this study. In fact, participating children were invited to the clinic for the dental examinations for the next nine month period, but due to the high dropout rate, the study was discontinued. The primary reasons for the high dropout rate were that children moved to different schools and the low motivation of parents to bring their children to the clinic. However, data from the first nine-month period was extensive enough to show the remineralizing effect of fluoride varnish on the noncavitated lesions in the primary teeth.

### 6.1.3 Caries measurements

In the fluoride varnish study, a modified scoring system, which differentiated between the active and inactive carious lesions, was used to evaluate the effect of fluoride on early noncavitated and cavitated lesions in the primary dentition. Differentiation between active and inactive enamel caries in the primary dentition has not been documented, and only a few studies have used it in the permanent dentition. It has been argued that the reproducibility achieved would be inferior and insufficient when differentiation of activity of early enamel lesions occur (Burt 1997). However, it has been reported that use of criteria based on an activity assessment could be performed with high reliability, even when noncavitated caries lesions are included in the scoring system (Nyvad *et al.* 1999, Pitts & Fyfee 1988). This study showed that differentiation of activity of lesions can be used for evaluating the effect of fluoride varnish on early noncavitated lesions.

In these studies, baseline caries measurements indicate that randomization was performed successfully. The Kappa-values indicate that calibration and standardization were performed successfully. The inter-examiner reliability has been assessed by examinations of approximately ten percent of the subjects in other studies as well (Warren *et al.* 2002, Ismail *et al.* 1992).

Caries progression in the primary dentition is reportedly rapid, and within one year, enamel caries may progress into the dentin (Peyron *et al.* 1992). Therefore, nine months was regarded as a sufficient time to study the progression rate of enamel caries lesions. Because traditional restorative treatment decisions are often based on the enamel lesions, it was important to show that active enamel lesions can be arrested.

#### 6.2 Caries occurrence

It has been shown that Head Start children suffer from high caries experience, which is also reported in this study. These children are susceptible to dental caries perhaps due to poorer nutrition, less emphasis on following good health practices, and insufficient access to dental care (Tinanoff *et al.* 2002). Since there are only few studies that have assessed the prevalence of noncavitated and cavitated caries lesions in the primary dentition, but none that specifically focused on children living in low-income families, the new information from this research was that active noncavitated lesions are common in the primary dentition in this underprivileged group. This study revealed that these children have a significant amount of untreated decay in their mouth, which is another common problem in this group (Albert *et al.* 2002, US DDHS 2000). There is a definite need for preventive measures including health education, promotion and treatment of decay in young children living in families of low economic status in the United States.

## 6.3 Effect of fluoride varnish on caries progression

During the past decade, scientists have identified the importance of remineralization of non-cavitated caries lesions. This finding is partially associated with the ability of fluoride to remineralize and arrest lesions. Therefore, monitoring of early noncavitated enamel lesions in this study was essential to evaluate the effect of fluoride varnish.

There are only few studies of the effect of fluoride varnish in the primary dentition and of which the results are inconclusive (Grodzka *et al.* 1982, Holm 1979, Peyron *et al.* 1992, Frostell *et al.* 1991, Lo *et al.* 2001). This study showed that fluoride varnish is effective in arresting early active enamel lesions in the primary dentition. This work is in line with the earlier study by Zimmer *et al.* (1999) which showed that applications of fluoride varnish is a feasible and effective method of preventing caries in economically deprived children who are at high risk for developing future caries. This study proposes that varnish applications can be performed in the school environment, allowing more children with high risk for caries to be reached. Since the goal of prevention is either to ensure that a disease process never starts or to reverse the disease in its early stages, health authorities should recommend performing on-site prevention for caries-risk children, i.e. in kindergartens and elementary schools.

## 6.4 Association of mutans streptococci and caries

Due to skewed distribution of dental caries i.e. a small proportion of children have the highest number of carious lesions; risk assessment is a necessary step for effective preventive treatment. In order to find these at risk children, risk indicators must be established. The present study found a significant association between caries and mutans streptococci levels as shown earlier (Thibodeau & O'Sullivan 1996) and that the association was significant, when subjects were carrying higher levels of mutans streptococci. In this study, the highest ds and dmfs values were found in children with the highest salivary mutans streptococci levels.

This study also assessed the sensitivity and specificity of saliva tests to identify children with caries. In cases with high levels of mutans streptococci, the sensitivity i.e. for saliva test to correctly identify diseased subjects was moderate, but the specificity i.e. the proportion of correctly identified healthy subjects was higher (80%). The positive predictive value, the percentage of children diagnosed as having disease who actually did, was moderately high (77%) on children with high levels of mutans streptococci, which indicates that testing mutans streptococci in saliva in young children at high risk for caries is a moderately good indicator of caries activity.

Since the highest caries prevalence is seen in children with the highest mutans streptococci values, reducing mutans streptococci levels is important in high-risk groups (Zickert *et al.* 1983, Köhler *et al.* 1988). This study used a directed population strategy to evaluate the efficacy of prevention, in which the groups of individuals, i.e. Head Start schoolchildren, were identified as a high-risk group based on the high prevalence of dental caries. Mutans streptococci counts were used to assess the effect of xylitol, since in

high-risk groups the effect of reduction of cariogenic bacteria can be significant utilizing preventional measures.

## 6.5 Effect of xylitol on salivary levels of mutans streptococci

The reducing effect of chewing the xylitol gum on salivary mutans streptococci demonstrated in a number of earlier short-term studies (Trahan 1995, Isotupa *et al.* 1995, Wennerholm *et al.* 1994, Loesche *et al.* 1984, Söderling *et al.* 1989) was also noticed in this study. One of the reasons could be that mutans streptococci are not able to grow on xylitol (Mäkinen *et al.* 1996, Trahan 1995).

The significance of reduction in mutans streptococci levels is that it may also lead to the lower caries prevalence. Since the highest caries prevalence is seen in children with the highest mutans streptococci levels, reducing the levels is important in high-risk groups (Zickert *et al.* 1983, Köhler *et al.* 1988). It has been stated that clinical relevance of reductions of mutans streptococci remains still to be shown (van Loveren 2004). However, there is strong evidence that xylitol gum or candy prevent dental caries when used several times daily (reviews: van Loveren 2004, Hayes 2001, Lynch & Milgrom 2003).

A weakness of this study was the omission of "placebo gum". Chewing of any gum could have a mechanical cleaning effect. However, several studies have shown that placebo gum do not affect mutans streptococci levels and that polyols are active ingredients of chewing gums able to modulate the amount of plaque and its microbial composition (Söderling et al. 1997). Other studies have also shown that the gums containing sorbitol did not reduce mutans streptococci counts in saliva (Loesche et al. 1984, Wennerholm et al. 1994). It has been demonstrated that the effect of xylitol is not a response of differential stimulation of salivary flow either (Mäkinen et al. 1989, Aguirro-Zero et al. 1993, Söderling et al. 1989, Wennerholm et al. 1994, Hujoel et al. 1994, Hildebrandt & Sparks 2000, Isokangas et al. 1993). Xylitol's ability to prevent the transmission of mutans streptococci from mother to child cannot be explained by chewing effect (Isokangas et al. 2000, Söderling et al. 2000, 2001). The claim that the preventive effect of chewing sugar-free gum is related only to the chewing process has been proposed (Edgar 1998, Machiulskiene et al. 2001).

The other factor for omission of the placebo gum was that it is difficult to motivate very young children to chew the disagreeable gum base with the same frequency and duration as the sweetened gum, even in the short-term studies. The sorbitol gum was not accepted for the control group as chewing the gum was not widely accepted in this age group. The same beneficial effect on reducing the amount of germs in mouth could not been claimed with the sorbitol and that chewing gum containing sugar could induce harmful effect on teeth.

The duration of this xylitol chewing gum study was short. However, this was a pilot study to test gum chewing programs and feasibility in this special high-risk group. Even after four weeks of chewing, the saliva levels of mutans streptococci were significantly reduced in groups receiving xylitol, but did not change in the group receiving sorbitol

(Isotupa *et al.* 1995). A large-scale clinical trial would require a large number of subjects and considerable resources to implement.

## 6.5.1 Compliance of the xylitol program

The compliance and acceptance of the xylitol gum by children was excellent in this study, which has also been reported in other studies (Isokangas *et al.* 1988, Lam *et al.* 2000). In studies that evaluate the effect of xylitol on otitis media in children attending day care centers, compliance was good, because children accept the sweet taste of xylitol (Kontiokari 1998). Even 3-5 year-old children in day care centers can chew the xylitol gum at least for two to three months (Uhari *et al.* 1998). Although the results in the current study suggest that children would chew xylitol gum if given to them, it is possible that children would not like to chew the xylitol gum for a longer period. Many studies of self-reported compliance have found that adult subjects overestimate their compliance (Besch 1995), which is likely to apply to children, especially in the situation where the teachers constantly would reinforce and monitor the gum use (Machiulskiene *et al.* 2001). Compliance was reported to decrease over time in the chewing program, which lasted for 3 years (Machiulskiene *et al.* 2001). This is not surprising if the required daily dose is five pieces of gum.

Teachers' acceptance toward the gum program in this study was low, possibly because the chewing program may have required extra effort to control the class. In a study by Kandelman & Gagnon (1990), during the second year of the program 2 of 13 schools stopped their participation because some teachers had difficulties continuing to integrate this additional workload into their daily activities. Since chewing the gum is not accepted behavior in a school environment in the United States and teachers in this study were introducing the gum for the first time, it might have generated extra stress for the teachers. However, even three year-old children can quickly learn the technique of chewing and not to swallow the gum (Uhari *et al.* 1998). The chewing gum program was originally planned to include other schools, but the proposal was turned down due to the decision that chewing gum is not developmentally appropriate for 3-4 year-old children. This attitude prevailed in spite of introducing the literature on the success of xylitol programs in other studies. A teachers' role in preventive chewing gum program is essential and motivating them must be emphasized in future programs.

The use of xylitol chewing gum is recommended in Finland and many other countries as a "smart habit" on an individual level. Dental personnel in Finland have adopted xylitol rapidly as an additional preventive method, and daily use of xylitol gum has been included in routine dental health education information (Honkala *et al.* 1999). There are several reasons why the use of xylitol is high in Finland. Xylitol, for caries prevention, was initially tested in Finland. There have been commercial interests for several years since xylitol products were produced in Finland. Xylitol has the official endorsement of national dental organizations, and label statements that highlight the benefits of xylitol to boost consumer awareness. Advertizing has been active among manufacturers and Finnish dentists have been strong proponents of the use of xylitol. Currently, almost all dental health educators (94-100%) include xylitol as a separate topic in their dental health

education (Laiho *et al.* 1995). Overall, countries with nationally supported prevention programs have robustly adopted xylitol.

Despite the overwhelming evidence of superior dental benefits, commercial success of xylitol in the United States has developed sporadically. Gum chewing has been forbidden in schools in the United States and is generally culturally unacceptable among school administrators. Commercialization efforts in the United States have not yet received the kind of official recognition as in Finland. However, the Food and Drug Administration (FDA) has approved xylitol as a food additive for use in foods for special dietary uses and its use is increasing.

#### 6.6 General discussion

Despite great achievements in oral health, problems still remain in many areas all over the world - particularly among underprivileged groups. At present, the distribution and severity of oral diseases vary among different parts of the world and within the same country or region (WHO 2004). The significant role of sociobehavioral and environmental factors in oral disease and health is evidenced in an extensive number of surveys (WHO 2004).

There is insufficient emphasis on primary prevention of dental diseases in the United States, which poses a considerable challenge due to the privatized health system. Oral health care is not fully integrated into national, community or most private health programs. There are profound oral health disparities across regions. These may relate to socioeconomic status, ethnicity, age, gender or general health status.

However, some opportunities exist to expand oral disease prevention and health promotion knowledge and practices through community health programs and in private health care settings. Major future challenges will be to translate knowledge and experiences about disease prevention into feasible action programs. Social, economic and cultural factors impact the delivery of oral health services and how people care for themselves. Reducing disparities requires extensive approaches that target populations at highest risk for specific oral diseases and involves improving access to existing care.

Clinical and public health research has shown that a number of individual, professional and community preventive measures are effective in preventing dental caries (WHO 2004). Community water fluoridation, professional and individual measures, including the use of fluoride rinses, gels, varnishes, toothpastes and the application of dental sealants are common methods to prevent dental caries. With appropriate diet and nutrition, primary prevention of dental disease can be achieved. It is known, that children with a high risk for developing caries need extra protection and are often not compliant enough to undertake fluoride therapy themselves. Based on this research, fluoride varnish applications may be a practical prevention method that can be performed in the school environment, allowing more high-risk children to be reached.

Xylitol-based interventions for dentistry have not been readily adopted in the United States. Research has concentrated mainly on the preventive effect of fluorides and has not focused on xylitol as a potential preventive agent. The oral biologic effects of xylitol suggest that the use of the xylitol gum can be considered a valuable tool in caries

prevention. It has been suggested that xylitol candy may be as effective as chewing gum as a xylitol delivery vehicle toward caries prevention (Alanen *et al.* 2000). Other alternatives, such as xylitol lozenges, tablets and candies should be investigated as potential tools for long-term prevention in young children. Prevention programs using xylitol products in well-regulated institutional programs, such as preschools, are very attractive. Major limitations to extending the xylitol gum use in the United States is that chewing gum is not considered safe for small children and is actively discouraged in schools. Thus xylitol lozenges, mints and tablets could offer acceptable choices for xylitol based prevention for young children in the United States.

Chewing the xylitol gum should be promoted, as it may offer an efficacious and cost-effective caries prevention strategy, which may greatly improve the quality of oral health for young children. It has been shown that habitual chewing of xylitol gum appears to have a long-term preventive effect by reducing caries risk for several years after habitual chewing has ended (Hujoel *et al.* 1999). Habitual chewing should be started at least one year before permanent teeth erupt.

The prevention program with xylitol may provide an additional method to be used in situations where other prevention methods are difficult to implement. Also, it provides an easy and inexpensive distribution mechanism, since no specific equipment, health care facilities or personnel are needed. Furthermore, through the xylitol program, it is possible to educate and motivate children, parents and school personnel to promote oral health practices at schools. The systematic use of xylitol can help children to become conscious of their own health and of ways to actively improve it. Since the goal of prevention is either to ensure that a disease process never starts or to reverse the disease in its early stages, health authorities should recommend performing on-site prevention for caries-risk children, i.e. in kindergartens and elementary schools.

# 7 Summary

The purpose of this research work was to determine the caries prevalence and distribution in the primary dentition of preschool children in Northern Florida, USA and to evaluate the effect of fluoride varnish on caries progression and the effect of xylitol chewing gum on the salivary levels of mutans streptococci on two separate randomized studies.

The caries preventive effect of fluoride varnish in the primary dentition was evaluated in a sample of 4-6 year-old Head Start schoolchildren in Alachua, Florida (n=142). Caries progression after nine months was analyzed using dmf(s/t) and ds values. The effect of xylitol gum was evaluated by measuring the levels of salivary mutans streptococci before and after three weeks chewing period in 3-5 year-old Head Start schoolchildren in Starke, Florida (n=61).

This study is in line with earlier reports that caries prevalence is high in Head Start preschool children. This study showed that active noncavitated enamel lesions were common in the primary dentition and that applications of fluoride varnish reduced the progression of caries in these children. The use of xylitol gum reduced mutans streptococci levels in saliva thereby possibly reducing the risk for dental caries in these children. Acceptance of chewing by children was good, but by teachers low. Salivary mutans streptococci levels were found to be moderately good indicators of caries activity in these young children, which is in line with earlier studies.

Fluoride varnish applications may be a practical prevention method for high-risk children living in low-income families in the United States. Also the prevention program with xylitol may provide an additional method to be used in situations where other prevention methods are difficult to implement.

## **8 Conclusions**

There are few well-studied strategies available to prevent and control high rates of caries in young children in communities reliant on private dental care. Water fluoridation, fluoridated toothpaste and professionally applied fluoride gels and foams and sealants are the most common preventive methods for young children currently in the United States. This study showed the beneficial effect of fluoride varnish in preventing progression of dental caries and the effect of xylitol in reducing salivary mutans streptococci levels, thereby improving the oral health of young children.

Use of xylitol chewing gum should be promoted, as it may offer an efficacious and cost-effective caries prevention strategy, which may greatly improve the quality of oral health for young children. Fluoride varnish applications may offer an effective means of arresting early noncavitated lesions in the primary dentition. While the detection and monitoring of these lesions is critical in determining effectiveness, this study suggests that fluoride varnish therapy may offer an efficient, non-surgical alternative for the treatment of decay in children.

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