CHAPTER 1

BACKGROUND AND RATIONALE

Significance of the Problem

Oral health remains one of the public health problems in Thailand as well as in several other countries. Dental caries is the most prevalent oral disease worldwide. Dental caries is a complex, multifactorial disease. In a simple term, the disease is an infectious disease caused by oral bacteria that results in localized destruction of tooth surfaces. When progress, dental caries leads to discomfort and pain, a restoration or a root canal therapy, and if severely decayed, extraction of the tooth. Many teeth loss will subsequently result in malocclusion.

The seriousness and societal costs of dental caries in children are enormous. The cost of dental caries can be considered in terms that include both financial and quality of life factors (1). Besides financial burden to the parents and family, possible sequelae of dental decay are malnutrition, infection, missing time from school, opportunity loss, psychological impact of the child, and compromise to future dentition. In addition, studies implicate early childhood caries as a contributing factor to other health problems. Children with early childhood caries were shown to weigh less than their age- and sex-matched caries-free children. It was hypothesized that the pain and infection associated with the disease may make it difficult for affected children to eat. Alternatively, poor nutritional practices may be responsible for both the reduced body weight and caries (2).

There is considerable evidence that children who develop caries at an early age continue to be at high risk for further caries development in the primary and permanent dentition (3-5). Perhaps the high level of infection by cariogenic microorganisms, or the establishment of poor nutritional practices, may be determinants of caries progression. In addition, dental treatment often requires comprehensive restorative regimes.

Thus, the consequences of early childhood caries are a significant problem not only in monetary terms to parents and government agencies paying for the care, but in potential risks to health and discomfort of the child with the disease (5).

Over the past few decades, a substantial reduction in dental caries experience has been observed among children and adolescents in the developed countries, particularly the smooth surface lesions. In Thailand, as reported in the 2000-2001 National Oral Health Survey in Thai schoolchildren, 12.5 % of children age 5-6 and 42.7% of age 12 were caries free, compared to 14.7 and 46.1% in 1994 (6). The mean decayed, missing, and filled tooth (DMFT) score for school children age 12 was 1.64. The majority of caries were single surface lesions on the occlusal surfaces of the first and second permanent molars, especially in the lower arch. The main reason of caries is occlusal anatomy which composes of deep pits and fissures. Such areas are difficult to clean.

Fortunately, dental caries is preventable when targets etiologic factors. The etiologic factors are multifactorial, which include bacteria, substrates, host factors and time. Proven effective methods to prevent dental caries among children and adolescents include daily oral hygiene practices, dietary control, optimal systemic and topical fluorides, pit and fissure sealants, and professional care on a scheduled basis.

Caries on pit and fissure surfaces of the teeth accounts for most of the present caries experience in childhood and adolescence as opposed to lesions on smooth surfaces. This attributes to the morphology of the occlusal surfaces, with the deep pits and fissures that are susceptible to decay. The development of pit and fissure caries occurs not only when the permanent teeth first erupt, i.e. in 6- to 14-year-old children, but also in adolescents and young adults (7). Although fluoride has been shown to be highly effective in prevention of caries on smooth surfaces, enamel surfaces with pits and fissures receive minimal caries protection form either systemic or topical fluoride agents. Hence the need to reduce or eliminate the carious process occurring in pits and fissures, primarily the occlusal or chewing surfaces of posterior teeth.

Dental sealant or pit and fissure sealant can be an effective preventive measure against pit and fissure caries (8). Sealing susceptible pits and fissures from the oral environment prevents bacteria from colonizing in the pit and fissure areas. Dental sealant also acts as a physical barrier against demineralization when the tooth surfaces contact with acid produced from the fermentation process of oral bacteria. Sealant application procedures are simple and can be done by auxiliary personnel. In addition, it is non-invasive thus avoids unnecessary loss of tooth structure, the risks associated with its use are minimal. Pit and fissure sealants are safe when properly placed using standard materials and procedures (9, 10). Pit and fissure sealants were introduced in 1967 (11) and their effectiveness was recognized by the American Dental Association in 1972 (12, 13). In Thailand, the Ministry of Public Health had adopted pit and fissure sealant as one of the measures in the Dental Prevention Plan during the year 1997-2001. All dental clinics under the Ministry of Health were encouraged to apply pit and fissure sealants on permanent first molars to reduce caries incidence.

In 2001, the Faculty of Dentistry, Chulalongkorn University alone purchased approximately 280,000 baht of imported pit and fissure sealants to service 3400 patients. When extrapolate this figure to the demand of the whole country, the expense for pit and fissure sealant can have significant economical impact. The development of a local-made pit and fissure sealant can reduce the demand for imported material and promote dental health of Thai children. Moreover, dental caries prevention will eliminate the exponential cost in restoration of carious teeth.

Basically, pit and fissure sealant is a mixture of monomers and appropriate initiators. The material does not require complicated technology in the production process. Considering the low investment and high demand, this material has potential to be commercialized.

The development of pit and fissure sealant starts with the selection of monomers and initiators to yield a desirable light-initiated resin mixture. Series of physical and mechanical property testings are carried out to find the composition with the optimal ratio. The next step is biocompatibility tests, both in vitro toxicity to cell lines

and animal study to ensure material safety. A well-controlled clinical study is a final step to assess the material effectiveness under service condition.

The first commercialized 'made in Thailand' pit and fissure sealant was developed by the National Metal and Material Technology Center (MTEC). Several studies have demonstrated the mechanical and physical properties of this material to be similar to imported materials. Such tests included hardness, diametral tensile strength, depth of cure, water sorption and solubility, and thickness of unpolymerized layer (14-17). In addition, biological and toxicity tests showed favorable results (18). However, a clinical study revealed that this material had inferior retention rate than the imported product after one year follow-up (19).

The Faculty of Dentistry, Chulalongkorn University supports research that leads to the development of dental materials for domestic use. Development of a pit and fissure sealant is conducted as a pilot project. During 2000-2002, the research group has developed a light-initiated sealant with optimal physical properties and safe for use in the clinical setting.

Thus, there is a need for a randomized clinical trial in order to investigate the effectiveness of this new local product. The primary intention was to assess whether the new material can retain successfully on the tooth surfaces and remain free of caries during the period of six months.