CHAPTER 5

DISCUSSION

Since the primary intention of this study was to assess the degree of retention of a recently developed local-made pit and fissure sealant (Chula Dent) by comparing it with a conventional imported product (Concise™), it was decided to carry out an equivalence trial. The result of the study showed that the success of Chula Dent at 6 months, as measured by complete retention rate, was not different, even slightly higher, from that of Concise™ (98.3 versus 97.4%). This implicates that the ability of the new experimental material to retain on the pit and fissure surfaces was not inferior to the imported product within the clinically acceptable limit.

When retention to different surfaces were compared (Table 4.3), Chula Dent retained well on both occlusal and buccal surfaces while Concise loss was more evident on the buccal surfaces. Though the difference was small, this observation should be emphasized and monitored in a longer follow-up period.

The six-month retention rate for Chula Dent was 0.9% different from that of Concise with the difference in retention rates of 5.5% as the upper limit of the 95% CI for and –3.8% as the lower limit, respectively. Therefore, there is a 95% probability that the true retention rate of Chula Dent is either 5.5% better, or not more than 3.8% worse than Concise.

In any equivalence trial, the boundaries must be set via an informed debate regarding the meaning of clinical equivalence in the context under investigation (64). In terms of pit and fissure caries prevention, a panel of experts in pediatric dentistry determined that a new agent should be an acceptable alternative to the standard agent if the retention rate of the new material is not more than 10% worse than the standard. In this study, it was shown that Chula Dent is at least equivalent to Concise.

The performance of the new local sealant was satisfactory. None of the sealant in both groups was completely lost from the sealed teeth and no carious lesion developed during the study period. This was not surprising since it is established that the efficacy of resin sealants in preventing caries has been associated with their retention (31, 35, 68).

The results of this study have been compared to other studies and are displayed in Table 5.1. Only studies with similar population selection (school based children) and criteria of measurement are included. In cases where many tooth types were used in the study, only the retention rates of permanent first molars are included in the Table. With respect to retention rate, the results of this study compared favorably with others. Most studies reported sealant retention rates of above 90% after 6 and 12 months. Both Concise and Chula Dent had the six-month success rates higher than 95%, which implies that these materials are excellent for the purpose when properly placed (20).

The results of this study are outstanding with respect to the high retention rates of the sealants. Previous studies were performed using Concise as the fissure sealing material (28, 69, 70). The explanation of the high retention rates in the present study is probably the combination of the two major factors: the operator was highly skilled and experienced in using pit and fissure sealants, and the teeth selected were fully erupted, providing good conditions for moisture control.

Table 5.1 Success of pit and fissure sealant presented by percentage of complete retention obtained from various studies

First Author	Year	Type of sealant	Tooth	N at start (teeth)	Age (years)	Follow up (months)	% Complete retention		
							occlusal	buccal	tooth
Brooks(71)	1976	Delton	M1	121	6-8	12	95.9	-	-
Barrie*(28)	1990	Concise	M1	239 sites	5-6	6 12	91 88	70 30	- -
Gandini*(72)	1991	Concise	M1	38	6-11	6 12	- -	- -	97.3 91.9
Raadal *(73)	1991	Delton	P, M1	117	6-14	6 12	- -	- -	97.8** 96.6
Raadal *(69)	1996	Concise	M1, M2	73 pairs	5-13	6 12	- -	- -	100** 97.1**
Kanellis(74)	1997	Helioseal	M1	300 sites	1^{st}-4^{th} grades	6	97	74	89**
Nakornchai(19)	2000	Delton Dent Guard	M1	108 pairs	7-9	6 12 6 12	98 90.5 97 76.8	- - - -	75.5 65.3 65.3 47.4
Prasongtunskul (70)	2001	Concise	M1	70 pairs	7-8	6 12	98.4 94.8	96.7 93.1	95.1 89.7
Poulsen*(75)	2001	Delton	M1	170 pairs	7	6 12	- -	- -	90.09 85.17

* Only 6 and 12 month results were presented in the table.

** Complete retention by tooth sites.

P = premolars, M1 = first permanent molars, M2 = second permanent molars

Special considerations should be made before directly extrapolating laboratory results to clinical performance. An example of irrelevant laboratory results and clinical performance can be clearly seen by adhesion tests versus clinical retention rates. Laboratory results of a local sealant material revealed excellent performances in both mechanical and physical properties including adhesion to enamel represented by a shear bond test (14-17), whereas in a clinical study, the retention of this same material was found to be lower than expected and significantly less than a conventional sealant after 12 months follow-up (19). This can be explained by the different test conditions. In vitro adhesion test uses flat tooth surfaces prepared from extracted teeth as a substrate for bonding whereas a tooth surface in a clinical situation has deep pits and fissures. In such case, the viscosity or flow of an acid conditioner or sealant material affect the clinical retention rate. In addition, oral environment with saliva and moisture can interfere with sealant adhesion under clinical condition. Therefore, long-term clinical performance is of great importance.

The frequency of sealant partial loss in Chula Dent and Concise after 6 months in this study was 1.7% and 2.6% respectively. Again, it should be emphasized that no complete loss was found. The numbers correspond with findings from previous studies that reported the rate of sealant loss from permanent molars to be between 5 and 10% per year (8, 36, 76).

Current data shows that although primary sealant retention rates are high, gradual loss of sealant does occur (8). Partial loss is still an unresolved issue in sealant studies. The same appearance may be judged as 'partial loss' or 'partial retention'; some of these may seal the critical tooth surface successfully, while others seem to be obvious failures that may lead to total sealant loss and eventually carious lesions. It was suggested that partial sealant loss yields a surface with the same caries rate as a non-sealed surface (8). In the present study, partial loss was categorized as 'failure' according to conservative approach. Therefore the real success of both materials may be higher than the numbers reported in this study.

Regular maintenance and sealant addition when necessary is important in long-term caries protection after sealant placement. With appropriate clinical follow-up, sealant success rate is very high. Studies that incorporated routine recall and maintenance reported success at levels of 80% to 90% after the follow-up period of a decade or more (42, 43). The American Academy of Pediatric Dentistry stated in their clinical guidelines that the placement of pit and fissure sealants and their continued maintenance is a scientifically sound and cost effective technique (37). In this study, molars that had their sealant lost were repaired with the same material as the original application as soon as the sealant loss was detected.

It is speculated that factors affect the efficacy and retention of a pit and fissure sealant in different studies include type of tooth received sealant, age of the child and the location of measurement. Teeth that are located more posterior have less success rate than the anterior ones, in other words sealants on premolars usually retain better than molars due to ease of moisture control (33, 77). Older children cooperate better, resulting in greater success of pit and fissure sealants. In addition, in order to compare the findings to those from other studies, we have to consider the difference in locations of sealant measurement. There is no uniform method for reporting results of sealant studies (20). Most of the literature only reports the retention rates on occlusal surfaces (71, 72). Some studies reported sealant success by sites, dividing one tooth into different sites and using each tooth site rather than the tooth as a unit of analysis (40, 69, 78). Such reports result in higher retention rates due to the exclusion of pits and fissures on buccal or lingual surfaces which usually are less success. This is in agreement with the present study that found the occlusal retention rate to be higher than the total retention of the tooth (Table 5.2).

Table 5.2: Success of pit and fissure sealants by location of measurement

Location of measurement	Chula Dent success rate (%)	Concise success rate (%)
Occlusal	99.1	100.0
Buccal	99.1	97.4
Tooth	98.3	97.4

Few clinical sealant studies measured effectiveness on buccal surfaces of mandibular molars and lingual surfaces of maxillary molars (79). The success rate of pit and fissure sealants on occlusal surfaces is found to be significantly higher than that on the buccal surfaces (8, 28, 80). This may be due to the difficulty in controlling moisture contamination of these areas (8) or the effect of tooth flexure and stress-breaking during mastication process (79). Instead of 10% sealant loss per year, investigators often found 30% sealant loss from the buccal/lingual surfaces per year especially early after the application (8). This is in agreement with the present observation that sealant loss was predominantly from the buccal pit of mandibular molars. Since the caries protection provided by sealants is a function of their ability to remain firmly adhered to the tooth surface, a true measurement of sealant effectiveness should include every surface on a tooth. Since these pits are caries-prone and additional maintenance will be needed for the tooth in case of sealant loss from this area. It is therefore appropriate to consider both occlusal and buccal surfaces as one unit. However, in the present study, the locations of sealant loss were recorded.

Possible reasons for sealant failures include poor placement technique (inadequate moisture control, not sealing all pits/fissures, inadequate etching, rinsing and drying, insufficient curing time), material failure (poor adhesion, material wear), non-sealant failure (extraction of tooth, proximal caries development, tooth exfoliation). Sealant failure can also be a combination of these factors (81-83).

Since most of the teeth examined were completely present, the sealant failures were probably technique failure rather than a defect in the sealant material, with

respect to the six-month results. The factor most likely contributing to sealant failure in the present study was inadequate moisture control, as most of the partial loss occurred on the buccal surfaces, which were the most difficult sites to prevent saliva contamination.

Another possible factor contributing to sealant failure was fracture of material due to masticatory force. Previous studies reported that sealant failure from early material loss was most likely to occur soon after placement (80, 84-86). Since most of pit and fissure sealant materials are unfilled resin, poor mechanical properties such as low wear resistance and lack of marginal toughness are not unexpected. This could cause clinical problems because the sealant is sometimes involved load-bearing sites. A thin margin can contribute to marginal fracture resulting in partial loss of the sealant (80).

The objective of the research design is to answer the research question with minimal possible biases. Several factors that can affect the outcome of the study were minimized and controlled so that the results of the study truly reflect the equivalence of Chula Dent to Concise.

The matched pair study design or 'half mouth design' used in the present study allowed the comparison of test and control sites in the same individual. Because the sites were subjected to almost identical oral environments, this method controlled for many potential confounding factors, particularly those due to physiological characteristics of the subjects, dietary, oral hygiene habits and preventive regimen (61). For the present study, the children were allowed to eat and brush their teeth normally, no specific instructions were given. Therefore, random allocation of test and control sides eliminated possible bias due to the side of dexterous of the children in chewing or brushing and side of dexterous of the operator during sealant application.

In addition, the allocation system used ensured that the distribution of the two sealant products between the right and left halves of the mouth was almost identical. The two etchants and sealants also had very similar appearances. Both echants were gel type with blue color and both sealants were opaque white with similar

consistency. Therefore, it was difficult to distinguish between them at both placement and recall examination. Since the recall visit was accomplished without access to the previous records, the examination was carried out on a blind basis. Opaque sealant material was chosen since it has been shown that the accuracy with which examiners are able to identify sealants is greater with opaque than clear sealants (29). Such approach also reduced the chances of bias. In addition, the tooth surfaces evaluated were air-dried before being examined for better vision to increase the measurement accuracy.

The subjects participated in this study were from elementary schools of Nongkae district, Saraburi province, who were already included in the dental preventive programs of the district hospital so that school teachers and parents were well compliant. Most of the children were from first and second grades. Analysis of the latest National survey of caries rate shows that the caries attack was more prevalent on occlusal surfaces, where caries also progressed more quickly (6). Therefore, molars are the most in need of caries prevention. From the investigator's personal observation, of all molars that fulfilled the selection criteria during screening examinations, some had become carious in the pits and fissures in only a few months' period while waiting for the commencement of the study. These teeth were not included in the study. The area of Nongkae district is non-fluoridated, thus increasing the caries risk of these children. This observation indicated that the criteria for inclusion of children selected to have sealants in the present study were appropriate. Some authors suggested that permanent first molars could be considered the relevant models for study of sealant because loss of these teeth at a young age leads to many dental problems in later years (87-89).

The inclusion criteria did not include bite-wing radiographs of the first permanent molars to detect proximal decay since those teeth were recently erupted, therefore had little chance of developing lesions on the proximal surfaces.

The methods currently used to evaluate clinical performance of pit and fissure sealants fall into two broad categories: qualitative and quantitative approaches. Each approach has advantages and shortcomings. The most widely accepted

evaluation technique is that adopted by the United States Public Health Services (USPHS) which utilizes a series of operationally defined rating scales for selected characteristics of dental restoration. The criteria are best suited to large-scale public health studies (85).

Clinical criteria used to assess the quality of sealants in the present study were modified from that of the USPHS. It was similar to those used in other sealant studies (83, 90). Although these criteria might appear somewhat coarse, they were simple and robust and thus appropriate for clinical evaluations carried out in a field setting. The ultimate goal of the clinical assessment was to assess whether further treatment was required for the tooth surfaces previously sealed. A dichotomous classification of success or failure would therefore be sufficed. Though sealant loss is a surrogate outcome, it will eventually lead to an end result of future dental caries.

The rationale for choosing an opaque over a clear sealant in this study is that there are obvious advantages to a color sealant than a clear one. It is easier to see (the sealant) during application, and much faster to assess retention over long time period (28, 39, 60). In addition, the colored sealant was extremely well accepted by both parents and children (91). Some have argued against use of an opaque sealant as it precludes continual examination of the sealed fissure. However, studies that examined the application of sealant over carious pits have not indicated any cause for concern when applying sealant over an incipient lesion or a stained fissure. In a study assessing the utility of clear versus colored (opaque) sealant (29), the combined identification error rate for opaque resin was only 1%, while for clear resin it was 23%. Significant differences were also found in the accuracy when three dentists carried out evaluation. The most common error was to identify the presence of clear resin on an untreated tooth. This study raises significant questions about the accuracy of studies done with clear sealant.

The opaque sealant used in this study provided good visibility that allowed reliable evaluation. It may be, however, difficult to detect caries under such sealant especially under field condition (25, 92).

With respect to the different sides of the mouth, the operator who performed all the sealant application procedure in this study started with the left molar of the patient, regardless of the type of material from the randomization. The results revealed that the retention rates of sealants according to sides were equivalent.

The number of samples at the end of the study was 96.7% of the number at the start, or 8 samples (3.3%) missing. Dropout was due to children dropping out from schools and the family moving to remote areas where it was impractical to reach them. Although bias due to loss of follow-up can be a major problem in prospective studies (93), it was not the case here. The outcomes were not affected since the dropout rate in the present study, less than 5% after 6 months, was minimal. In addition, there was no effect on the treatment and control arms of the trial since the study was done in the same individual.

Assuming that all samples lost from the treatment group (Chula Dent) did badly (sealant failure), and all lost from the control group (Concise) did well (sealant success), then the outcomes were recalculated under these assumptions. The retention of Chula Dent and Concise would be 95% (95%CI 91.0, 99.0) and 97.5% (95%CI 94.7, 100) respectively. The difference was +2.5 (95%CI +8.2, -3.2). In other words, in the worst case scenario, the success of Concise would be 2.5% better than Chula Dent. There is 95% chance that Concise would be 3.2 times less success than Chula Dent or 8.2 times more success, which is still within the 10% pre-specified acceptable boundary. Since the conclusion of the trial does not change, thus implicates the strength of the study results.

Using the Power and Precision statistical program for proportions equivalence (94), it was found that this study would have power of close to 100% to show that the event rate for Chula Dent would be at least as high as the event rate for Concise. The assumptions were that the event rates for Concise and Chula Dent populations were 97.4% and 98.3% respectively, that a difference of 10.0 points or less was unimportant, that the sample sizes in the two groups were113 and 114, and that

alpha (1 tailed) was set at 0.05. Therefore, the power of the present study was more than sufficient.

In order to increase the precision and accuracy of the study, the evaluator was blind to the type of treatment used and the intraexaminer reliability was excellent as shown by kappa of more than 0.9. The study was meticulously designed and conducted concerning the carefully selected population, material and methods, highly skilled operator and well-calibrated measurement. In addition, the very low rate of dropout increases the validity of the study.

The results of this study suggest that the retention rates achieved for Chula Dent and Concise placed on mandibular first permanent molars were satisfactory. This is of substantial benefit, since the caries protection achieved when the children were in the age group where the first permanent molars had erupted recently and are at high risk of developing caries (28).

In the present study, the investigator chose 6 months for the first reported examination since it was shown that the highest rate of sealant loss resulting from material failure occurred during the first six months (44, 45). Nevertheless, some researchers failed to detect the difference at six months' time (19). Thus, follow-ups of six-month intervals were planned as the period also corresponds to the regular dental recall examinations.

In the view of a public health program, the cost of placing sealants must be less than or have benefits that outweigh the replacement of a restoration. Nevertheless, there are many intangible benefits of pit and fissure sealants such as maintaining a tooth free of decay, reducing or eliminating pain and discomfort associated with a diseased tooth, preventing weakening of tooth structure by the excessive drilling of tooth tissue, and reducing the time lost from school and the workplace as parents accompany their children on dental appointments to treat the sequelae of dental decay (32).

Regarding the safety of pit and fissure sealant materials, some concerns were raised that the monomers, Bisphenol-A (BPA), leached out of these resin materials might be estrogenic. BPA is not a direct ingredient of dental sealants, but is a residual monomer leaching out of the cured resin when the curing process of a sealant is incomplete. Based on the presently available evidence, there was no potential concern on the estrogenicity of dental sealants (55, 60). No reports of adverse health effect has been attributed to the leached components of dental sealants.

It is important to remember that sealant protection is limited to the pit and fissures. In order to achieve the greatest possible caries reduction, sealants should be used in conjunction with other caries preventive methods, such as systemic and topical fluorides, noncariogenic dietary habits, and fluoride containing dentifrice. Since fluoride has its greatest effect on the smooth surfaces of the teeth and sealants protect the pits and fissures, a comprehensive prevention program should employ both regimes (32).