

CHAPTER 4

RESULTS

Baseline Characteristics

A total of 120 children participated in this study. This comprised 56 females (46.7%) and 64 males (53.3%) recruited from 3 elementary schools in the district of Nongkae, Saraburi province. The mean \pm SD age at the start of the study was 87.49 ± 7.89 months (range 72-115 months). Table 4.1 shows the distribution of trial participants by gender, and age.

Table 4.1 Detail of participants: gender, and initial age (mean \pm SD, range)

Characteristics	Total
Gender	
Male/Female	64/56
(Percent)	(53.3/46.7)
Age (months)	
Mean \pm SD	87.49 ± 7.89
Range	72-115

The samples consisted of 240 (120 pairs) lower first permanent molars, equally distributed to the experimental and control groups or left and right sides. The total number of tooth surfaces was 480, with 240 being occlusal sealants and 240 buccal sealants.

At the end of the study, 111 children remained at the same schools. Of the 9 participants that changed schools, the investigator was able to find 5 children that moved nearby, hence 4 missing children, or 8 sample teeth (3.3%). Dropout was due to the family moving to remote areas where it was impractical to reach them for final

examination. Therefore the number of samples examined was 116 tooth pairs (232 teeth; 96.7%; Table 4.2).

Table 4.2 Number of children, samples (teeth), and tooth surfaces in the study

	At the start of trial N(%)	End N(%)	Missing N(%)
Number of children	120 (100)	116 (96.7)	4 (3.3)
Number of teeth	240 (100)	232 (96.7)	8 (3.3)
Number of surfaces	480 (100)	464 (96.7)	16 (3.3)

Primary Outcome Analysis

The status of the experimental and control sealants after the six-month observation period is given in Table 4.3. The table shows the retention of the two sealants according to the surfaces (occlusal, buccal) and tooth. When tooth was counted as one unit, the experimental sealant, Chula Dent, was fully retained on 98.3% of the teeth, while this was the case in 97.4% of the teeth sealed with Concise. The corresponding figures for partial retention were 1.7 and 2.6%, respectively. None of the sealant was totally lost from any of the teeth.

Table 4.3 Retention of sealant materials at 6 months, according to surfaces (occlusal, buccal) and tooth

Surface	N (pairs)	Chula Dent retention		Concise retention		p-value
		Complete (%)	Partial (%)	Complete (%)	Partial (%)	
Occlusal	116	115 (99.1)	1 (0.9)	116 (100)	0	1.00
Buccal	116	115 (99.1)	1 (0.9)	113 (97.4)	3 (2.6)	1.00
Tooth	116	114 (98.3)	2 (1.7)	113 (97.4)	3 (2.6)	1.00

Retention was excellent for both types of sealants: nearly all sealants retained on the tooth surfaces. When comparing the retention rates of the two groups, the results showed no statistical significant difference between Chula Dent and Concise (Table 4.3: McNemar's chi square, $p > 0.05$).

Details of the sealant retention by materials according to the type of sealant loss and by tooth pairs are presented in Table 4.4 and Table 4.5, respectively.

Table 4.4 Distribution of sealant retention outcomes by materials according to the type of sealant loss

Chula Dent Retention	Concise Retention			Total
	Complete retention	Partial loss	Complete loss	
Complete retention	111	3	0	114
Partial loss	2	0	0	2
Complete loss	0	0	0	0
Total	113	3	0	116

Table 4.5 Distribution of sealant retention outcomes by tooth pairs

Chula Dent Retention	Concise Retention	Tooth Pairs	
		N	%
Success	Failure	3	2.6
Failure	Success	2	1.7
Success	Success	111	95.7
Failure	Failure	0	0
Total		116	100

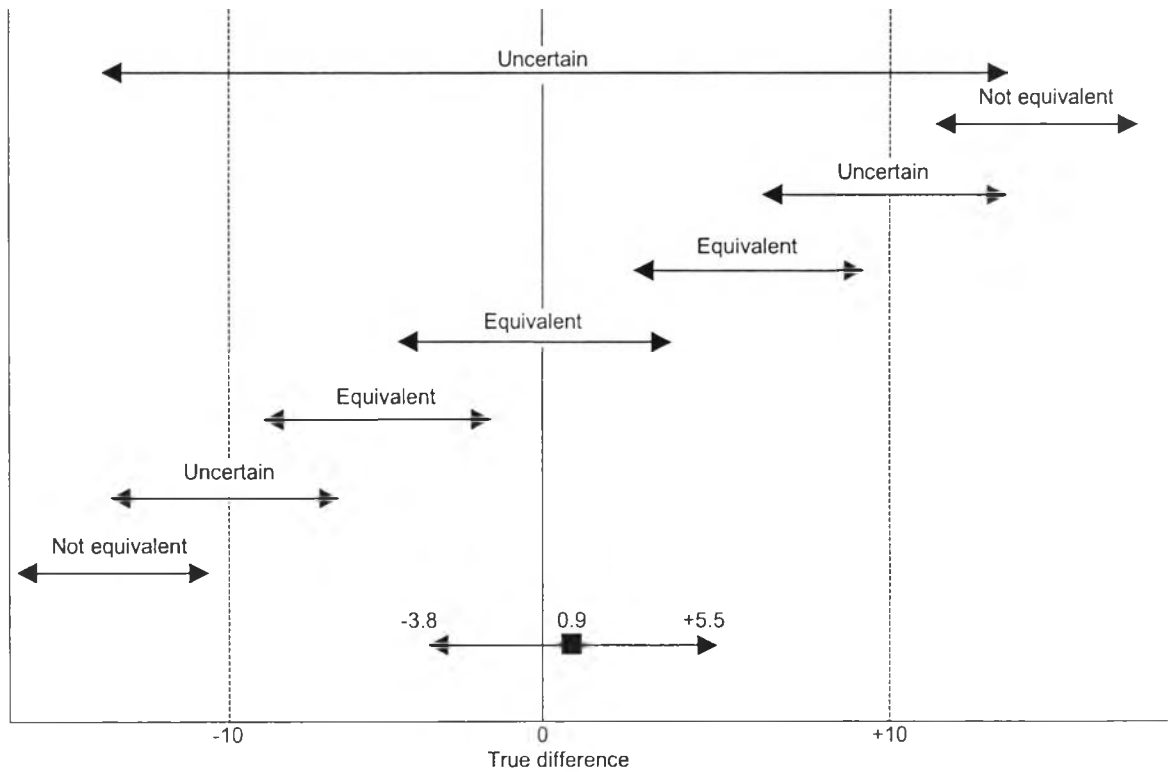
Table 4.6 shows the mean retention rates with 95% confidence interval of the two sealants. At six months, retention rate for Chula Dent group was 98.3% compared with 97.4% for Concise sealant group, a difference of 0.9% (95% CI -3.8%, 5.5%). As the CI includes 0 and the 95% CI lies within the acceptable range, this study

has demonstrated that the retention of Chula Dent is neither superior nor worse than Concise (Figure 4.1).

Table 4.6 Mean retention rates with 95% confidence interval of the two sealants at six months

Material	N	Mean (%)	95% Confidence interval
Chula Dent	116	98.3	95.9-100
Concise	116	97.4	94.5-100

Figure 4.1 Examples of possible results of using the confidence interval approach: -10 to +10 is the pre-specified range of equivalence; the horizontal lines correspond to possible trial outcomes expressed as confidence interval, above each line is the decision concerning equivalence. The difference in retention rates with 95% confidence interval between Chula Dent and Concise is displayed. (Modified from Jones et al. Br Med J 1996;313:37)



Secondary Outcomes Analysis

When tooth surface was the unit, the retention rates for the occlusal surfaces were 99.1% and 100% for Chula Dent and Concise. For the buccal surfaces, the numbers were 99.14% and 97.4% respectively (Table 4.3). Only 5 sites were incompletely covered, 2 with Chula Dent and 3 with Concise (Table 4.7). Of the 5 partial loss sites, the only occlusal surface failure was from the mesial pit of Chula Dent group.

None of the sealed teeth developed carious lesions in the treated sites, and none of them needed approximal restoration affecting the sealants.

Table 4.7 Location of partial loss, and caries according to type of sealants and tooth surfaces

	Chula Dent			Concise		
	Occlusal	Buccal	Total	Occlusal	Buccal	Total
No. of partial loss	1	1	2	0	3	3
Caries	0	0	0	0	0	0