CHAPTER 4

Results

As shown in Figure 4.1, 120 teeth were initially recruited into the study. Total of 55 teeth were excluded because 33 teeth had irreversible pulpitis, 2 teeth were unrestorable, 3 teeth did not see pulp by transparency after caries was completely removed, and 17 teeth had pulp exposure, thus leaving 65 teeth that were randomized into two groups of materials (32 teeth in the DV group and 33 teeth in the B group).

At the follow-up period, 10 teeth (five teeth per group) were lost to follow-up due to inability to contact parents (3 patients) and no shows (7 patients). In this study, seven percent of the required sample size was added to compensate for follow-up loss; however, this data showed 15.4% follow-up loss which is higher than the expected loss. The total numbers of 55 teeth were available for analysis in this study (27 teeth in the DV group and 28 teeth in the B group)as shown in Figure 4.1. The final subjects in this study consisted of 24 females and 31 males, aged from 6.9 to 17.9 years old with the mean age of 10.1±2.3 years old. Forty percent (22/55 teeth) were at the G stage and 60% (33/55 teeth) were at the H stage of root development. Approximately 72.7% (40/55 teeth) were diagnosed as normal pulp and 27.3% (15/55 teeth) were diagnosed as reversible pulpitis. Approximately 45.5% (25/55 teeth) were maxillary teeth and 54.5% (30/55 teeth) were mandibulary teeth. Approximately 81.8% (45/55 teeth) were restored with resin composite and 18.2% (10/55 teeth) were restored with SSCs. The mean follow-up period was 9.4±3.1 months. Regarding operator, 1.8% (1/55 teeth) were treated by operator 1, 21.8% (12/55 teeth) were treated by operator 2, 49.1% (27/55 teeth) were treated by operator 3, and 27.3% (15/55 teeth) were treated by operator4.

The baseline variables including gender, age, stage of root development, diagnosis, tooth type, types of restoration, follow-up period, and operators are shown in Table 4.1 There were no significant differences of the baseline variables between the DV and the B groups.

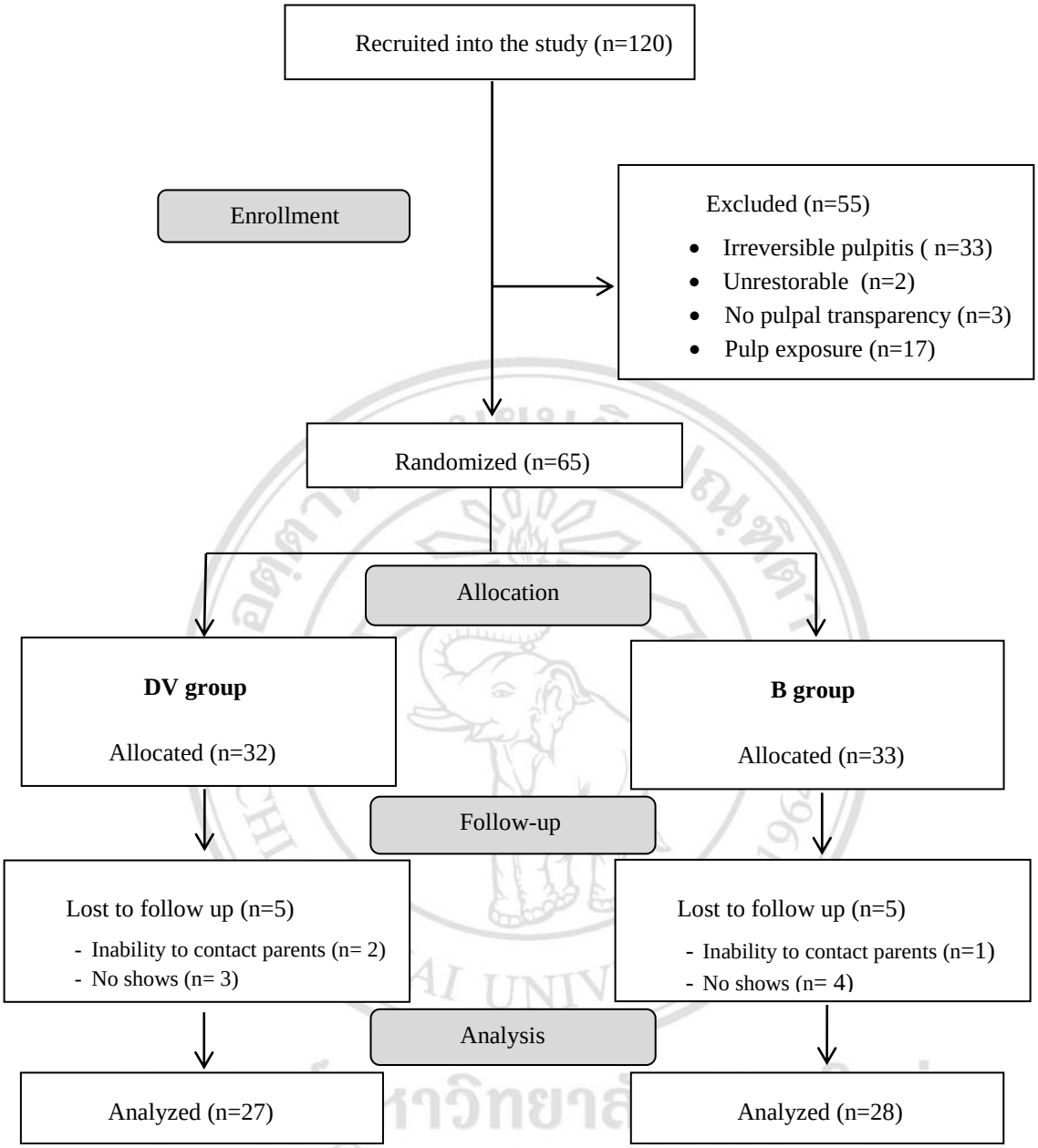

Figure 4.1 Consort 2010 flow diagram of the study

Table 4.1 Baseline variables of the Dycal®&Vitrebond™ and Biodentine™ groups

	Total	**DV group**	**B group**	***P* value**
Number of teeth	55	27	28	-
Gender % (n/N)				0.90*
Female	43.6 (24/55)	44.4 (12/27)	42.9 (12/28)	
Male	56.4 (31/55)	55.6 (15/27)	57.1 (16/28)	
Age				0.29ŧ
Range,Y	6.9-17.9	7.2-17.9	6.9-12.4	
Mean±SD,Y	10.1±2.3	10.5± 2.9	9.8±1.4	
Stage of root development % (n/N)				0.66*
G[a]	40.0 (22/55)	37.1 (10/27)	42.8 (12/28)	
H[b]	60.0 (33/55)	62.9 (17/27)	57.2 (16/28)	
Diagnosis % (n/N)				0.70*
Normal pulp	72.7 (40/55)	70.3 (19/27)	75.0 (21/28)	
Reversible pulpitis	27.3 (15/55)	29.7 (8/27)	25.0 (7/28)	
Tooth type % (n/N)				0.88*
Maxillary teeth	45.5 (25/55)	44.4 (12/27)	46.4 (13/28)	
Mandible teeth	54.5 (30/55)	55.6 (15/27)	53.6 (15/28)	
Restoration % (n/N)				0.50 ɣ
SSC	18.2 (10/55)	22.2 (6/27)	14.3 (4/28)	
Resin composite	81.1 (45/55)	77.8 (21/27)	85.7 (24/28)	
Follow-up period				0.17 ŧ
Range, M	6.1-18.1	6.1-17.1	6.2-18.1	
Mean±SD, M	9.4±3.1	8.8±2.7	10.1±3.3	
Operators % (n/N)				0.25ɣ
Operator 1	1.8 (1/55)	3.7 (1/27)	-	
Operator 2	21.8 (12/55)	18.5 (5/27)	25.0 (7/28)	
Operator 3	49.1 (27/55)	59.3 (16/27)	39.3 (11/28)	
Operator 4	27.3 (15/55)	18.5 (5/27)	35.7 (10/28)	

SD, standard deviation

*Values analyzed by $\chi 2$ test.

ŧValues analyzed by t-test.

ɣValues analyzed by fisher's exact test.

a =  b = 

(102)

At the follow-up period of 9.4±3.1 months, the clinical favorable outcomes were 92.6% (25/27) in the DV and 82.1 % (23/28) in the B groups. There was no statistically significant difference between the clinical outcomes in both groups (*P* = 0.42). Radiographic favorable outcomes were 100% (27/27) in the DV and 100 % (28/28) in the B groups. All teeth showed intact lamina dura and all teeth (22 teeth) with pre-operative open apex had continued their root formations.

To be considered to have overall favorable outcomes, the tooth evaluated must have both clinical and radiographic favorable outcomes. The overall favorable outcomes were 92.6% (25/27) in the DV and 82.1% (23/28) in the B groups. There was no statistically significant difference between the outcomes of both groups (RD, 10.5%; 95% CI, -8.4% to 29%; *P* = 0.22) as shown in Table 4.2

Table 4.2 The outcomes ofpulp protection with Dycal® and Vitrebond™ and Biodentine™

	DV group % (n/N)	**B group** % (n/N)	**RD**	**95% CI**	***P* value**
Clinical outcome Favorable outcome	92.6(25/27)	82.1(23/28)	10.5%	-8.4% to 29%	0.22[γ]
Radiographic outcome Favorable outcome	100(27/27)	100 (28/28)	-	-	-
Overall outcome Favorable outcome	92.6 (25/27)	82.1 (23/28)	10.5%	-8.4% to 29%	0.22[γ]

RD, risk difference

CI, confident interval

[γ] Values analyzed by fisher's exact test.

All unfavorable outcomes (7 teeth; 2 in the DV group and 5 in the B group) were due to negative response to the cold test. However, all of them had no clinical symptoms and had favorable radiographic outcomes. The percentages of teeth with negative cold test were 7.4% (2/27) in the DV and 17.8% (5/28) in the B group. Demographic data of 7 teeth with negative cold test were shown in Table 4.3 Clinical and radiographic evaluation of teeth with unfavorable outcomes was shown in Table 4.4. In addition, discoloration, pulp calcification, and dentin bridge formation were not observed in any tooth in this study.

Table 4.3 Demographic data of teeth with negative cold test

No.	Tooth	Material	Diagnosis	Stage of root development	Type of restoration
1	26	Dycal® + Vitrebond™	Normal pulp	Closed apex	Resin composite (Occlusal)
2	16	Dycal® + Vitrebond™	Normal pulp	Open apex	SSC
3	16	Biodentine™	Normal pulp	Closed apex	Resin composite (Occlusal)
4	37	Biodentine™	Normal pulp	Closed apex	Resin composite (Occlusal)
5	16	Biodentine™	Normal pulp	Closed apex	Resin composite (Occlusal)
6	25	Biodentine™	Normal pulp	Open apex	Resin composite (Occlusal)
7	36	Biodentine™	Normal pulp	Open apex	Resin composite (Occlusal)

Table 4.4 Clinical and radiographic evaluation of teeth with unfavorable outcomes

No.	Tooth	Material	Clinical evaluation				Radiographic evaluation		
			Cold test	Post-operative sensitivity	Pain on stimulation	Abnormal mobility	Continued root formation	Periapical radiolucency	Pulp calcification & dentin bridge formation
1	26	Dycal® + Vitrebond™	Neg	no	no	no	-	no	no
2	16	Dycal® + Vitrebond™	Neg	no	no	no	yes	no	no
3	16	Biodentine™	Neg	no	no	no	-	no	no
4	37	Biodentine™	Neg	no	no	no	-	no	no
5	16	Biodentine™	Neg	no	no	no	-	no	no
6	25	Biodentine™	Neg	no	no	no	yes	no	no
7	36	Biodentine™	Neg	no	no	no	yes	no	no