CHAPTER 5

Discussion

5.1 Discussion

This study was designed as a randomized clinical trial. The operators could not be blinded because appearances and steps in applications of the two materials are totally different. However, all four operators in this study followed the same treatment protocol and all procedures were done under supervision of one instructor. All teeth were randomly allocated to each material group; consequently, the baseline variables were not different between two groups. For radiographic evaluations, two blinded examiners were calibrated with one standard examiner before evaluating the radiographs. However, for clinical evaluations, the examiners were not blinded but evaluated all treated teeth according to the same clinical criteria under supervision of one instructor. Moreover, signs and symptoms were directly obtained from the patients; thus, decreasing the evaluator's subjective bias.

In this study, at the follow-up period of 9.4±3.1 months, there was no statistically significant difference of the overall favorable outcomes between the Dycal® and Vitrebond™ (92.6%) and Biodentine™ (82.1%) groups. Noticeably, if negative cold test was not considered as unfavorable criteria, all treated teeth in this study presented favorable clinical and radiographic outcomes.At this relatively short follow-up, this study demonstrated that pulp protection with either Dycal® and Vitrebond™ or Biodentine™ has capability to protect the dentin-pulp complex to maintain its function.

The overall favorable outcomes were 92.6% in the Dycal® and Vitrebond™ group. If negative cold test was not considered as an unfavorable criterion, 100% of treated teeth in this group have favorable outcomes. Similarly, Memarpour et al.(76)used Dycal® and Vitrebond™ as a pulp protection material in deep carious lesion in young permanent molar of children with mean age of 8.2 years old and showed that all teeth remained vitality and no periapical lesion was observed at 3 and a half years

follow-up. Nevertheless, another previous study showed 73% success rate of pulp protection with CH and RMGI in deep carious lesion (72). The higher success rate of our study may be due to the difference of age between two studies. In our study, the mean age was 10.1±2.3 years old which younger than that in previous study, which was 23.4 ± 4.9 years old. The younger tooth has highly cellular pulp tissue, a wide-open apical foramen, and rich blood supply. So, the younger tooth may have much better healing potential than the older tooth(47). Another reason may be due to the different inclusion and success criteria, all selected teeth in previous study were reversible pulpitis teeth and the success criteria were the presence of dentin bridge formation, absence of furcation radiolucency, and absence of internal/external root resorptions. However, inclusion criteria of our study were teeth that diagnosed with normal pulp and reversible pulpitis, and dentin bridge formation was evaluated but was not considered as an unfavorable or favorable outcome.

The overall favorable outcomes were 82.1% in the Biodentine™ groups. If negative cold test was not considered as an unfavorable criterion, 100% of treated teeth in this group have favorable outcomes. To date, there are limited clinical studies that reported the success rate of Biodentine™ as a pulp protection material after complete caries removal. Recently, there was one clinical study in which Biodentine™ was used to restore deep cavities with no pulp exposure and the result showed that Biodentine™ restoration was well tolerated as all 80 teeth tested had a positive pulp vitality test at 1 year (100). Moreover, Biodentine™ was used as an indirect pulp capping agent following the incomplete caries removal, the result showed 83.3% clinical success rate at 12 months (103).However, more long-term study with Biodentine™ is still required.

In this study, 12.7% (7/55) of treated teeth had negative response to cold test. However, all teeth presented favorable radiographic outcomes. Hashem et al. (103) reported that teeth diagnosed with reversible pulpitis tended to have negative response to EPT and cold test. In contrast, all teeth that had negative cold test in our study were pre-diagnosed with normal pulp.

In the Dycal® and Vitrebond™ group, there were 7.4% (2/27) of treated teeth that had negative response to cold test. Previous studies showed wide range of negative cold test between 3.7% - 13.3% of teeth treated with CH and RMGI (72, 104).

In the Biodentine™ group, there were 17.8% (5/28) of treated teeth that had negative response to cold test. Similarly, Hashem et al. (103) showed that 16.7% (6/36) of teeth treated with indirect pulp capping with Biodentine™ (in patients mean age 28 years old) lost vitality (negative cold test and EPT) after 12 months. In contrast to previous study(100), 100%(80 teeth) in patients mean age 36 years old had positive pulp test after 1 year follow-up.

There were some possible reasons for negative response to cold test. The first reason may be from false negative in young permanent teeth with incomplete root formation. Fuss et al. (105) showed that cold test was more reliable than electrical pulp test in the young teeth whether they have open or closed apex. In this study, the pulpal response was tested only by cold test (Green Endo-Ice®). However, inaccuracy of the cold test in young patients may be the result of pulpal innervation that was not yet complete and younger patients may also be more anxious and less reliable. Other cause of negative response may be the result of large restoration and pulp calcification (106, 107). Caliskan (106) demonstrated that the tooth with large restoration placement showed false negative response and after removal of the restoration the tooth positively responded to stimulation. Biodentine™ was applied as a bulk into the cavity may act as an insulator for cold test. Noticeably, the pulp protection material may act as a barrier of cold thermal stimulation. However, there was no study confirming this assumption and more study is needed to confirm this assumption. Furthermore, early changes in the periapical hard tissue were not easily detected by using periapical radiographs (103, 108). More sensitive technique may easily detect the new lesions than periapical radiographs did. In addition, the teeth that negatively respond to cold test and have an absence of periapical lesion may be in the process of developing in pulp necrosis. It must be noticed that five out of seven teeth had negative response to cold test were maxillary teeth, in which it is difficult to detect periapical radiolucency due to the superimposition of anatomical structure. In further study, long-term follow up may confirm the outcomes of these teeth that negatively respond cold test.

Unemori et al. (45) reported that a combination of CH and GI or RMGI as pulp protection, frequently chosen for deep cavities, showed 11% of postoperative sensitivity. In this study, all teeth in both groups did not have postoperative sensitivity. Not only pulp protection material but several factors, such as individual profile, the shape and depth of the cavity, and occlusion of restoration, can also relate to the causes of postoperative sensitivity. Polymerization shrinkage of resin composite can usually provoke sensitivity (109). However, the incidence of postoperative sensitivity barely occurs when the restoration technique is carefully followed. For resin composite restorations in this study, we applied the incremental technique which may reduce polymerization shrinkage of resin composite. This careful treatment protocol may result in the absence of postoperative sensitivity in this study.

From the *in vitro* study of Hashem et al. (90), they suggested that the final restoration with resin composite placement covering Biodentine™ should be delayed for two weeks to allow sufficient intrinsic maturation of material to withstand contraction forces from the resin composite. However, the final restoration in this study was placed immediately after Biodentine™ was allowed to set, following the manufacturer's recommendation of approximately 12 minutes for an initial setting reaction (110). This immediate placement of final restoration is beneficial for pediatric patients because it reduces the number of treatment visits. However, it is unknown whether the immediate or delayed placement of restoration will have any clinical significant effect on the outcome of treatment. Additional follow-up and evaluation of restorations would be required.

Regarding the sealing ability, bacterial leakage through the final restoration material can affect the treatment outcome. RMGI, such asVitrebond™, has high sealing ability and also bond to dentin. So, the use of CH liner in combination with GI or RMGI base was one of the most common practices regarding pulp protection for deep cavities (7, 70). In this study, Dycal® and Vitrebond™ used as pulp protection material in deep carious lesions demonstrated good clinical and good radiographic outcomes. According to the literature review,Biodentine™ has sealing ability that is as good as that of RMGI (85-87). Biodentine™ can lead to formation of apatite deposits that may increase the sealing efficiency of the material (111). The outcomes of Biodentine™ used as pulp

protection material in this study also demonstrated good clinical and good radiographic outcomes.

For the handling properties, when Biodentine™ was used as a pulp protection material in this study; we found it easily to handle as a bulk into cavity.Moreover, it is easily cut back by dental burs, resulting in very satisfactory restoration performance.

Regarding the bond strength of Biodentine™ with resin composite, different adhesive systems and CHX did not affect the bond strength of Biodentine™ to resin composite (53, 90, 91). From the present study, the cavity was irrigated with CHX and was etched with 37% phosphoric acid (Scotchbond™), followed by bonding (Adper™ Single Bond). There was no adverse complication observed in the Biodentine™ group. However, when compared to CH and RMGI, Biodentine™ has longer setting time. In addition,Biodentine™ has higher cost than CH liner in combination with GI or RMGI base.

No discoloration was observed in any tooth in both groups of material. This finding agreed with previous studies which reported that Biodentine™ maintained color stability after light radiation and when applied in absence of blood contamination (92, 94). In agreement with clinical study of Koubi et al. (100) who reported that Biodentine™ remained satisfactory clinical outcome when used as pulp protection in posterior restoration. Previous study showed that CHX can effect discoloration of Biodentine™(93). On the other hand, in this study, prepared cavities were irrigated with 2% CHX before placing pulp protection materials but no discoloration was observed in any treated tooth at follow-up period. However, evaluation of discoloration in this study was performed by comparing the immediate postoperative and follow-up photographs; thus subjective bias may affect the evaluation. Evaluation of discoloration with less subjective bias is needed to compare this effect of material.

Dentin bridge formation has been one of the factors commonly used to determine the success of treatment (72, 112). From previous study (72), the newly formed dentin under the pulp protection with CH and GI was measured radiographically at 3 and 6 months. Nevertheless, the authors of previous study reported that this indirect measurement still needs the histological investigations to support their findings. From

literature review, in the *in vitro* study, Biodentine™ has ability to modulate TGF-β1 secretion of the pulp cells, thus inducing reparative dentin synthesis (11). In swine teeth, Biodentine™ demonstrated dentinogenesis activity in deep cavities. Nevertheless, Biodentine™ occasionally related with an atypic formation of pulp calcification which was observed from light microscopy in young age of the animals (84). Dentin bridge formation and pulp calcification were not presented in both groups of material from radiographic examination in this study. This difference could be related to direct and indirect evaluations, our evaluations were made radiographically, whereas the evaluations of previous study were histologically evaluated by light microscopy. With the limited investigation of this study, further research with long-term follow up is still required to evaluate the pattern of dentin formation in both groups of pulp protection materials.

Regarding to their desired properties such as biocompatibility, excellent seal, and healing promotion, Dycal® and Vitrebond™ or Biodentine™ can be used as pulp protection material with appropriate properties. As shown in Table 5.1

Table 5.1 Desired properties of pulp protection material compared to Dycal® and Vitrebond™ and Biodentine™

Properties	**Dycal® and Vitrebond™**		**Biodentine™**
	Dycal ®	**Vitrebond™**	
Biocompatibility	Good	Good	Good
Sealing effect	Absence of post. op sensitivity		Absence of post. op sensitivity
Promote healing	Yes	Yes	Yes
Color stability	Yes		Yes
Handling properties	More difficult		Easier
Cost	Lower	Lower	Higher

The limitation of this study is that the true thickness of RDT in all treated teeth was not assessed. It was currently unclear of the optimal RDT that is able to protect the pulp from injury. RDT has an important role in pulpal repair responses. Currently, there

is no accurate practical method that can indirectly measure the remaining dentin thickness. In this study, the teeth were included following the inclusion criteria of ¾ of lesions in the bitewing radiographs and transparency of the pulp which RDT may be less than 1 mm. However, these inclusions may be too rough and subjective. However, alltreated teeth were randomly allocated into two groups; therefore, we expect the equal distribution of different RDT in two tested groups. Measurement the true thickness of RDT with reliable and affordable methods should be performed in the future study.

In conclusion, at the relatively short follow up of 9.4±3.1 months of this study, the favorable outcome of pulp protection with Biodentine™ in permanent teeth with deep caries of 6-18 years old patients is not higher than that with Dycal® and Vitrebond™.

5.2 Clinical application

Further study is still needed regarding pulp protection with Biodentine™ in deep carious lesions.

5.3 Further research suggestions

Due to limitation of the relatively short follow up of this study, further clinical studies with longer follow-up and a larger sample size are needed. Moreover, determination of the thickness of newly formed dentin is recommended in the future study.