



Clinical evaluation of class II high-viscosity glass ionomer cement and composite resin restorations in primary molars: one year result

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Abstract

Objective: To evaluate the clinical and radiographic performances of highly viscous glass ionomer cement (GIC) and composite resin (CR) class II restorations in primary molars at 12-month follow-up.

Materials and methods: Fifty-five pairs of primary molars with proximal dentin carious lesions in 37 children, aged 6-9 years, were studied. A split-mouth technique was designed. The teeth were randomly divided into 2 groups of restorative materials: highly viscous GIC (Fuji IX GP:GC Co., Tokyo, Japan) and CR (Filtek Z250:3M ESPE, St. Paul, U.S.A.). The restorations were evaluated clinically at 6 and 12 months following modified USPHS criteria. Bitewing radiographs were assessed at 12-month follow-up. All parameters of clinical and radiographic performances between the two groups were tested by Wilcoxon matched-pair signed-rank test.

Results: The cumulative failure rates of GIC and CR restorations at 12-month follow-up were 2.08% and 4.41% respectively. There was no statistically significant difference in the failure rate of both materials. There were no statistically significant differences in the clinical and radiographic performances between the two groups. All parameters both clinical and radiographical were similar between GIC and CR restorations.

Conclusion: Highly viscous glass ionomer cement and composite resin were highly effective materials for class II restoration in primary molars from 12-month results.

Key words: class II restoration, glass ionomer cement, composite resin, primary molar, cumulative failure, clinical evaluation

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Introduction

The restorative care for children in Thailand is still a Public Health's concern. Thailand's 2012 National Oral Health Survey showed that 76% of 5 year-old children needed tooth restorative care services. From those restorative care needed, Class II restoration had shown the highest percentage (60%) while class I restoration ranked second (43%)¹. Traditionally, amalgam has been preferred restoration for both class I and class II cavity due to its durability and low cost. Also, amalgam restoration is familiar technique used by dentists. However, amalgam restoration has many disadvantages. The safety of amalgam through its mercury toxicity and environmental pollution from its waste disposal are major concerns². Moreover, the principal of "extention for prevention" during cavity preparation using amalgam filling resulted in extensive loss of healthy enamel and dentin. In addition, filling with amalgam in large cavity extending beyond line angle is contraindicated and that stainless steel crown is recommended³.

With the development of adhesive materials, tooth preparation can be performed using minimal intervention. Alternative materials to amalgam which have been widely used include composite resin (CR) and glass ionomer cement (GIC). A meta-analysis showed overall success rate of CR in primary class II restorations was 83% while that of conventional GIC restorations was 75%⁴. The composite restorative procedure requires excellent moisture control which is very difficult to achieve when using for children and rubber dam placement is needed. The other drawback of composite resin is polymerization shrinkage which may result in marginal discoloration, poor marginal adaptation and secondary caries^{5,6}.

Glass ionomer cement has a number of advantageous properties to use in children such as tooth adhesion, fluoride releasing, pulpal

biocompatibility, and moisture tolerance^{3,7,8}. Despite their outstanding properties, the disadvantages of conventional GIC are brittleness and poor wear resistance⁹. Highly viscous GIC, with its finer glass particles, anhydrous polyacrylic acid of high molecular weight and high powder-to-liquid mixing ratio, had improved the surface abrasion and compressive strength which could be properly used for posterior teeth^{10,11}. Seven percentage cumulative failures had been reported for class II highly viscous GIC restoration in primary teeth over a 3-year period¹².

Until now, clinical research on highly viscous GIC in class II cavity in primary teeth has been limited. Most highly viscous GIC are related to application in ART technique¹³. Our study was aimed to evaluate one year clinical and radiographic performances of highly viscous GIC and the composite resin restoration of class II restoration in primary molars.

Materials and methods

The research protocol and informed consent form were reviewed and approved by The Mahidol University Institutional Review Board. The study was carried out at Pediatric Dental Clinic, Faculty of Dentistry, Mahidol University. The sample size was calculated under the assumption that type I error (alpha) and type II error were 0.05 and 0.1, respectively. The calculated sample size was 41 plus 25% accounted for anticipate dropouts, so the desirable sample size in each group was 52 teeth.

The school children, aged 6-9 years, were recruited from two primary schools in Bangkok. A screening examination was performed in the primary schools by a trained dentist with the permission of their parents. A total of 689 children were received oral and bite-wing radiograph examination. In teeth with deep caries, periapical radiograph was performed to

determine periapical lesion. The inclusion criteria were: 1) Presence of two proximal caries in primary molars involved dentin but not exposed the pulp with similar size and shape in contralateral teeth, 2) The carious lesions involved small to large proximal surface but not extended beyond one-fourth of buccal or lingual surfaces. Teeth were excluded if the radiographic examination revealed pathologic finding or $\geq 1/2$ root resorption. Restorations were interpreted as failure if the marginal adaptation, cavosurface marginal discoloration, and anatomic form parameters were ranked as "Charlie" and the secondary caries parameter were ranked as "Bravo". The parameter of the radiographic examination were interpreted as failure if the cervical margin adaptation, void, and adaptation to vertical wall of the step parameters were ranked as "3" and the radiolucencies adjacent to the restoration parameter was ranked as "2". Those included restorations that were interpreted as failure at 6-month follow-up were excluded for the analysis at 12 months. One hundred and ten primary molars, in 37 children, were included. The procedures, possible discomforts, benefits, and possible risks were fully explained to all children and their parents. Informed consent were obtained from parents. A split mouth technique was applied. All teeth in either side of the arch were randomly allocated into two groups by a coin toss; Group 1) restoration with Glass ionomer cement (GIC: Fuji IX GP, GC Co., Japan), Group 2) restoration with composite resin (Filtek Z250, 3M ESPE, St. Paul, U.S.A.). The cavities were prepared as minimal intervention approach. The infected carious dentin was removed using bur and/or a spoon excavator and restored with GIC or composite resin according to the manufacturer's instructions. In GIC group, the prepared cavity was conditioned with 10% polyacrylic acid for 20 seconds. In CR group, GIC lining (Vitrebond

Light Cure Glass Ionomer Liner/Base: 3M ESPE, St. Paul, U.S.A.) was applied in deep cavity for pulp protection. After etching with 37% phosphoric acid, the adhesive (Adper Single Bond 2: 3M ESPE, St. Paul, U.S.A.) was applied. All restorations were performed by one pediatric dental resident who was familiar with the procedures. Local anesthesia and rubber dam was used in all children in CR group while in GIC group, local anesthesia or rubber dam was used as necessary, such as in children who felt discomfort or having gag reflex during procedures. All children received oral hygiene instruction and topical fluoride at the day of the operation.

The cumulative failure rate of the restoration was evaluated from the clinical performances at 6 and 12 months. The clinical performance of the restoration was assessed according to the modified U.S. Public Health Service methodological technique presented in Table 1¹⁴. At 12-month follow-up, bite-wing radiograph was performed. The radiograph was assessed according to the criteria described in Table 2¹⁵. The clinical and radiographic evaluations were assessed by a blinded examiner who did not place any restoration. If the restoration failed as explained in Table 1 and Table 2 or showed clinical and radiological pathologic findings, the appropriate treatment was performed. At each recall visit, children were received topical fluoride application. Intra-examiner reliability performed before and during evaluation at 6 and 12 months as indicated by Kappa statistic was 0.93.

The differences of the survival of the restorations and all parameters of clinical and radiographic performances between the two groups were tested by Wilcoxon matched pair signed-rank test. A p value of $\leq .05$ was considered to be a statistically significant different.

Table 1 Codes and clinical criteria used to evaluate restorations

Criteria	Code	Definition
Marginal adaptation	Alpha	Restoration closely adapted to the tooth. No crevice visible. No explorer catches the margins
	Bravo	Explorer catch. No visible evidence of the crevice into which the explorer could penetrate. No dentin or base visible.
	Charlie	Explorer penetrate into a crevice that is a depth expose dentin or base
Cavosurface marginal discoloration	Alpha	There is no discoloration anywhere on the margin between the restoration and the tooth structure.
	Bravo	Discoloration is present but has not penetrated along the margin in a pulpal direction.
	Charlie	Discoloration has penetrated along the margin in a pulpal direction.
Anatomic form	Alpha	The restoration is continuous with existing anatomic form.
	Bravo	The restoration is discontinuous with existing anatomic form, but missing materials are not sufficient to expose dentin or base.
	Charlie	Sufficient restorative material is missing to expose dentin or base.
Secondary caries	Alpha	No caries is present at margin of the restoration, as evidenced by softness, opacity, or etching at the margin.
	Bravo	There is evidence of caries at the margin of the restoration.

Marginal adaptation, Cavosurface marginal discoloration, Anatomic form ranked as “Charlie” was interpreted as failure. Secondary caries ranked as “Bravo” was interpreted as failure.

Table 2 Codes and radiographic criteria used to evaluation restorations

Criteria	Code	Definition
Cervical margin adaptation	1	Cervical margin is good
	2	Cervical margin shows defects but no repair is needed.
	3	Cervical margin shows defects and repair is needed.
Void (indicated the homogeneity of restoration material)	1	No detectable voids
	2	Detectable voids but no repair is needed
	3	Void is shown and repair is needed.
Adaptation to the vertical wall of the step	1	The adaptation is good.
	2	The adaptation shows defect but no repair is needed.
	3	The adaptation shows defect and repair is needed
Radiolucencies adjacent to the restoration	1	No detectable radiolucencies
	2	Detectable radiolucencies

Cervical margin adaptation, Void, Adaptation to the vertical wall of the step ranked as “3” were interpreted as failure. Radiolucencies adjacent to the restoration ranked as “2” was interpreted as failure.

Results

A total of 55 pairs of carious dentin lesions were included for restoration. Of these, 55 carious dentin lesions were restored with composite resin and another 55 carious dentin lesions were restored with GIC. The restorations were placed in 29 pairs of upper molars and 26 pairs of lower molars. Forty eight pairs of molars, 26 first molars (mesial caries=6, distal

caries=20) and 22 second molars (mesial caries =12, distal caries=10), were left available for evaluation at 6-month follow-up due to 5 children moved to other schools. One GIC restoration and one CR restoration were changed to amalgam. According to the participated children, those two restorations were not dislodged and no symptom was noted. At 12-months, three pairs of molars had

normal exfoliation, restorations in two pairs of molars failed at 6 months, so there were 43 pairs of molars, 23 first molars (mesial caries = 5, distal caries = 18), 20 second molars (mesial caries=12, distal caries=10,) presenting for assessment.

Clinical performance evaluation

After 6 months, one GIC restoration and one CR restoration had failed due to poor marginal adaptation. At 12-month follow-up, one CR restoration had also failed due to poor marginal adaptation. The cumulative failure rate

of GIC restoration and CR restoration were 2.1% and 4.4% respectively. There were no statistically significant differences between groups ($p>0.05$) (Table 3).

The results of clinical performances of the GIC and CR restorations at 6- and 12-month follow ups were presented in Table 4. For marginal adaptation parameter, one GIC and two CR restorations were scored as “Charlie”. No statistically significant difference of the clinical outcomes in each parameter between of the two groups were found ($p>0.05$).

Table 3 Clinical performances evaluation at 6 months and 12 months

Criteria	Rating	Number of restorative materials(%)			
		6 months (n=48)		12 months (n=43)	
		GIC	CR	GIC	CR
Marginal adaptation	A	42(87.5)	45(93.7)	39(90.7)	38(88.4)
	B	5(10.4)	2(4.2)	4(9.3)	4(9.3)
	C	1(2.1)	1(2.1)	0	1(2.1)
Cavosurface marginal discoloration	A	48(100)	48(100)	43(100)	43(100)
	B	0	0	0	0
	C	0	0	0	0
Anatomic form	A	47(97.9)	48(100)	39(90.7)	42(97.7)
	B	1(2.1)	0	4(9.3)	1(2.3)
	C	0	0	0	0
Secondary caries	No	48(100)	48(100)	43(100)	43(100)
	Yes	0	0	0	0

No statistically significant difference between groups at each parameter at 6 and 12-month follow-ups

Table 4 The cumulative failure of clinical performances at 12-month follow-up

Materials/ months	Number of restoration					Cumulative Failure (%)
	Placed	Withdrawn	Evaluated	Success	Failure	
GIC						
0	55	0	55	55	0	0
6	55	7	48	47	1	2.08
12	48	5	43	43	0	2.08
CR						
0	55	0	55	55	0	0
6	55	7	48	47	1	2.08
12	48	5	43	42	1	4.41

Radiographic performances parameter

The results of radiographic performances of all restorations at 12-month follow-up were presented in Table 5. For cervical adaptation parameter, one CR restoration was rated as “3”.

Discussion

One GIC restoration and one CR restoration were changed to amalgam filling without any sign of dislodged filling and symptom. In my opinion, the restorations were changed to amalgam fillings by misdiagnosis or misbelief. Some dentists believed that GIC restoration is only a temporary restoration. The split- mouth design was selected so that the two restorative materials would be exposed to the same oral environment and the patient behavior’s effect was limited. We selected highly viscous GIC in our study due to its greater compressive strength than the resin-modified glass-ionomer cement¹¹. The compressive strength has been used as an indicator of a material’s ability to resist the force of mastication, which is suitable for posterior teeth.

The cumulative survival of high-viscosity GIC restoration after one year in our study was 98% which was comparable to the previous studies^{12,16}. The restorations that were interpreted as failure from radiographs were not

included in the cumulative failure rate because those defected restoration may also showed defects from radiographs. Yilmaz et al.¹⁶ reported that the success rate of high-viscosity GIC class II restorations at one year follow-up was 91%. The restoration failures were from the Charlie rating of cavosurface marginal discoloration and secondary caries while, in our study, the one failure restoration was from the Charlie rating of marginal adaptation. Rutar et al.¹² reported the cumulative survivals of highly viscous class II GIC restorations at one and three years were 99% and 93% respectively. The marginal adaptation of class II restoration after 3 years was 93% and the incidence of secondary caries was Zero.

Secondary caries at the margin of the restoration was rarely found in GIC restoration due to the demineralization inhibition effect of fluoride releasing restorative material¹⁷. Qvist et al.¹⁸ studied the longevity and cariostatic effects of conventional GIC and amalgam restoration. They found only 1 from 384 GIC class II restorations having secondary caries in primary teeth. They also found that less caries progression that required operative treatment on tooth surface adjacent to GIC restorations compared to amalgam restorations (16% versus 30%). This is important concerning the

Table 5 Radiographic performance evaluation at 12-month follow-up

Criteria	Rating	GIC(n=43)	CR(n=43)
Cervical margin adaptation	1	39(90.7)	41(95.4)
	2	4(9.3)	1(2.3)
	3	0	1(2.3)
Void	1	43(100)	43(100)
	2	0	0
	3	0	0
Adaptation to vertical wall of the step	1	43(100)	42(97.7)
	2	0	0
	3	0	1(2.3)
Radiolucencies adjacent to restoration	1	43(100)	43(100)
	2	0	0

No statistically significant difference between groups at each parameter at 12-month follow-up

prevention of caries in adjacent permanent tooth.

The cumulative survival of CR restoration after one year in our study was 96% which was comparable to the previous studies^{5,19}. Fuks et al.¹⁹ assessed the clinical performance of class II restoration using RMGIC and composite resin (Z 100). They found no Charlie rating score on any parameter in composite restoration but two Charlie rating scores (marginal adaptation and unfavorable contact point) in RMGIC restoration after two years. Rastelli et al.⁵ studied the performances of class II composite restoration in primary teeth with different techniques and types of composite resin after one year. They found three Charlie rating scores on discoloration of the margin. The highest failure rating score was secondary caries occurrence (10%).

We found that the radiographic performances of class II GIC restorations rated as "2" were higher than composite resin in the cervical margin adaptation but there were no statistically significant difference in both materials ($p > 0.05$). One class II composite resin restoration had a gross margin defect and slightly mobile which appeared defects in both cervical margin adaptation and adaptation to vertical wall and that replacement was needed. Fuks et al.¹⁹ showed that 47% of composite resin restorations presented radiographic defect that might require replacement while GIC restoration presented significantly less radiographic defects at 2-year follow-up. The cervical marginal defects that we found the most in GIC restoration were overextended margin or shorten margin. The inappropriate matrix and wedge placement may contribute to those overextended margin. The cervical marginal defect was also caused by imperfect insertion of material into the deepest part of the cavity, however, it appeared insignificant which replacement was not needed.

Our study was the only study that compared the failure rate, clinical and radiographic performances of GIC and CR restorations in primary teeth using split mouth design. The success rate of clinical performances of GIC and CR were 98% and 96% respectively and that all parameters were not statistically significant different. We selected small to large proximal carious lesions of primary teeth including those indicated for stainless steel crown. The favorable results of GIC and CR restorations indicated that both materials can be used for class II restoration in primary teeth. GIC restoration could be a treatment of choice for managing proximal caries in patient with high caries risk due to its fluoride releasing property. Also, GIC restoration may be properly used in young children as its procedure is less sensitive than CR restoration, and that using rubber dam is not necessary. Furthermore, lining material was not needed in deep cavity for GIC restoration due to its pulpal biocompatibility.

In conclusion, our findings demonstrated that highly viscous GIC and CR restorations gave excellent results on the marginal discoloration, anatomic form and secondary caries criteria. Two percentages of failures caused by poor marginal adaptation were observed in GIC restoration while four percentages of failures were observed in CR restoration after 12-month follow-up. The results showed that one year clinical and radiographic performances of class II highly viscous GIC and the composite resin restoration in primary teeth are comparable.

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