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Clinical evaluation of three caries removal approaches in primary teeth: A randomised controlled trial

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Objective: To evaluate the clinical performance and radiographic outcome of glass ionomer cement (GIC) restoration in primary molars using three caries removal techniques. ***Basic research design***: Randomised clinical controlled trial. ***Clinical setting***: Two standard dental clinics in 2 hospitals near Bangkok. ***Participants***: A total of 276 children, aged 6-11, having dentinal caries on the occlusal and/or proximal surface extending at least one-third of dentine without signs and/or symptoms of irreversible pulpitis. ***Intervention*:** Children were randomly allocated into 3 study groups with different caries removal techniques: Group 1, partial soft caries removal at enamel-dentine junction (EDJ) by spoon excavation; Group 2, complete soft caries removal by spoon excavation; and Group 3, conventional caries removal by steel burs. All cavity preparations were restored with GIC (Fuji IX, GC Corp., Japan). ***Main outcome measures:*** Clinical and radiographic evaluations were carried out at 6 and 12 months after restoration. ***Results:*** After 12 months, 89, 89, and 88 restorations in Groups 1, 2 and 3 were evaluated. The cumulative survival rates of GIC restorations in Groups 1, 2 and 3 were 83%, 83%, and 89% while the cumulative survival rates of pulp were 99%, 100% and 98% respectively. There were no statistically significant differences in the survival of GIC restorations or pulp in the three groups ($p>0.05$). ***Conclusion:*** The clinical and radiographic evaluations after 12 months indicated that partial soft caries removal at EDJ followed by GIC restoration was comparable to that of ART and conventional approaches.

Key words: *partial caries removal, minimal intervention, ART, survival*

Introduction

Although dental caries has declined considerably in the developed countries, it remains a public health problem in many developing countries. The major reasons are the low number of dental practitioners in underprivileged communities and lack of concern for oral health. Thailand's 2007 National Oral Health Survey showed 80.6% of 5 year-olds had caries experience with an average dmft score of 5.4 with the filled component being only 0.2 indicating a very high caries rate and low level of restorative care. Of those with dental caries, 6% received treatment in the rural area compared to 8% in urban areas (Prasertsom and Ratanarangsima, 2008). Oral health services should be developed and adjusted to match the needs of the population. Outreach services may be needed to increase restorative care to prevent caries progression, especially in a deprived community with limited personnel and facilities (Petersen, 2008).

Dental researchers have been concerned to preserve sound tooth structure as well as carious tissue on the cavity floor with partial caries removal (Mertz-Fairhurst *et al*., 1998; Ricketts *et al*., 2006). Atraumatic restorative treatment (ART) is a minimal intervention practice in managing dentinal caries. This approach is to remove only soft and infected dentine with hand instrumentation before restoring the cavity with glass ionomer cement (GIC). The success rates of single-surface ART restorations in permanent teeth in Thailand were 93% and 71% after 1 and 3 years though the success rate was lower in primary teeth (Phantumvanit *et al*., 1996). Lately, the 3-year cumulative survival rate of single-surface ART in primary teeth was significantly higher than the conventional approach using amalgam: 86% cf 80% (Taifour *et al*., 2002).

Researchers have also reported that soft carious dentine can be left under sealed restoration without prejudicing pulpal health and that such dentine is able to be repaired and remineralised due to change in the ecosystem (Fusayama and Terachima, 1972; Mertz-Fairhurst *et al.*, 1998). Kidd *et al*. (1996) reported that the microorganisms of soft and wet dentine at the enamel-dentine junction (EDJ) were more abundant than soft and dry dentine and that all soft dentine at EDJ must be removed before restoration to ensure minimal infection of the underlying dentine and arrest the carious process. Due to the potential of inner carious dentine to be repaired under sealed restoration, GIC, an adhesive material, is a prime restorative material for adhesion to tooth, remineralisation and to foster inhibition of secondary caries (Tantbirojn *et al.*, 2006). Besides, GIC is a frequently used alternative to amalgam for restoring primary teeth due to some concerns regarding environmental contamination from mercury and a demand for better esthetics. Recently, GIC and resin modified glass ionomer cement (RMGI) have been suggested as suitable alternatives to amalgam in Class I and Class II restorations in primary teeth (Daou *et al.*, 2009).

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Questions remain concerning the amount of carious dentine that should be removed and that should be left inactive and remineralised. The method of removing caries only at the EDJ level prior to restoring with RMGI or amalgam had been studied by Weerheijm *et al*. (1999). They found a substantial decrease in numbers of total viable count and Lactobacilli of the carious dentine after the 2-year period. The clinical study concerning a large number of restorations has not been published. This approach can preserve the vitality of the pulp in a manner more pleasing to uncooperative patients and can be provided for management of carious lesion for children in general. The hypothesis of the present study was that there is no difference in the survival of restorations and pulp among partial and complete soft caries removal and conventional caries removal techniques. Therefore, the objectives of this study were to evaluate the clinical and radiographic outcomes of three caries removal approaches in primary teeth: 1, partial soft caries removal only at EDJ by spoon excavation; 2, complete soft caries removal by spoon excavation; and 3, conventional caries removal by low speed handpiece and steel bur.

Material and methods

The study was a randomised clinical controlled trial study of three interventions for dentinal caries removal and restoration with highly viscous glass ionomer cement.

The study was carried out in Saraburi and Suphanburi provinces, which were randomly selected from 10 provinces near Bangkok. Using multi-stage cluster sampling, 6 primary schools were sampled with 450 schoolchildren aged from 6-11 years being invited to participate in the study. Approval was provided by the Thammasat University Ethics Committee and written informed consent was received from each parent. The participants were clinically screened from high risk children (dmft≥5) by one operator. The inclusion criterion was having a primary molar with dentinal caries without any sign and/or symptom of irreversible pulpitis (no gingival swelling or tooth mobility, no spontaneous pain). Radiographically, the dentinal caries involved at least one-third of the dentine without the pulp being exposed or radiolucency especially at furcations and/or periapical area or pathologic root resorption. Teeth were excluded if they were unrestorable such as having multi-surface caries or proximal caries extending beyond line angle involving more than half of buccal or lingual surface which need the stainless steel crown.

The calculation of the sample size was based on the survival of the class II conventional GIC (90%), ART restoration (70%) in primary teeth at 1 year (Lo *et al*., 2001; Yilmaz *et al*., 2006) at $\alpha = 0.05$, power = 90%. We expected the survival of class II GIC with partial caries removal was 70%. The calculated sample size was 84 plus 10% to account for anticipated dropouts, so the desirable sample size was estimated to be 92. The study was performed in standard-equipped dental clinics in two hospitals. Throughout the study, all restorations were accomplished by one operator familiar with all three caries removal techniques. Some 276 children (131 boys, 145 girls) were included. The cavity was opened with a high speed round bur to open access for caries removal. The children were randomly allocated to the 3 study groups by children picking the ball with a group number inside, without replacement.

For group 1 the soft carious dentine was removed by a spoon excavator with a circular motion. At the cavity wall, the soft carious tissues at EDJ were completely removed without further removal of the carious dentine. The cavity was wiped with wet cotton pellets and blown dried. Group 2 had all soft carious dentine was removed with a spoon excavator as atraumatic restorative treatment (ART). Spoon excavation was stopped when increased resistance was demonstrated. Group 3's intervention was excavation of carious dentine carried out by means of steel round burs in a low speed handpiece without water cooling. No local anesthesia was used in group 1 (EDJ) or 2 (ART). To avoid bias and over removal of carious dentine, local anesthesia was applied only in children having sensitivity during caries removal in group 3 (BUR).

After caries removal with each approach, the cavity and adjacent fissures were conditioned with dentine conditioner (10% polyacrylic acid, GC Corp., Tokyo, Japan) for 15 seconds and then washed with water and blown dried with a triple syringe. Glass ionomer cements (Fuji IX, GC Corp., Tokyo, Japan) were mixed by trained dental assistants according to the manufacturer's instructions and pressed into the depth of the cavity and the adjacent pits and fissures with the "press-finger" technique, coated with petroleum jelly.

Class II cavities were restored after placement of metal bands (T band) and wedges. Excess material was removed and checked for occlusal interference. The restoration was recoated with a layer of petroleum jelly.

The survival of the restorations was evaluated at 6 and 12 months after placement by one independent evaluator, a public health dentist, unaware of the caries removal techniques. Frencken and colleagues' evaluation criteria (Phantumvanit *et al*., 1996) was used. The ball end of the CPI probe (0.5 mm in diameter) was used to measure the deficiency at the restoration margin. In analyzing the data, loss of restoration, marginal defect or wear of restoration deeper than 0.5 mm were considered as failure and needed to be repaired or retreated. Intra-examiner reliability performed before and during evaluation at 6 and 12 months as indicated by Kappa statistic was ranged from 0.79-0.86.

Clinical symptoms and discomforts during and after restoration were asked of the patient. Pulp was considered to have survived if no clinical or radiographic sign of irreversible pulpitis was noted. The pulp radiographic assessment was done blind by 2 pediatric dentists independently. When there was different opinion, discussion was taken until agreement was reached or, in 4 cases, a third opinion sought. The inter-examiner and intra-examiner reliability indicated by Kappa statistic was 0.82 and 0.86 respectively. Root canal treatment or extraction was performed if pulp failure was observed.

The survival of the restorations was calculated by means of Kaplan-Meier. The Logrank test was used to test differences among survival rates.

Results

The mean age of children in groups 1, 2, and 3 were 7.8 (sd 1.1), 7.5 (1.5) and 7.8 (1.6) and their mean dmft scores were 5.3 (sd 1.9), 5.4 (1.7) and 5.4 (2.2) respectively. During caries excavation, the pulp was exposed in 1 tooth in group 2 (ART) and 2 teeth in group 3 (BUR): these were excluded from the study. Therefore, the remaining 92, 91, and 90 GIC restorations were placed in groups 1, 2 and 3 respectively. In group 3, local anesthesia was used in 5 children.

After 6 and 12 months 90, 89 and 87 restorations and 89, 89 and 88 restorations in groups 1, 2 and 3 were analysed. The main reasons for dropouts were being absent from school on the day of evaluation or having moved to other communities (Figure 1).

The cumulative survival rates of GIC restorations after 12 months in groups 1, 2 and 3 were 83%, 83%, and 89% respectively. There were no significant difference in the survival of restorations among the three study groups after 12 months ($p>0.05$, Table 1). The main reason for the failure rate after 12 months in groups 1,2 and 3 was medium marginal defects (0.5 to 1.0 mm). Only 1 tooth (group 1) with gross marginal defect (>1.0 mm) showed secondary caries at the margin of GIC restoration. No wear of restorations was found in this study. Loss of restoration was seen in only 6 teeth and the appearance of the dentine after the restoration had been lost was typically hard and discolored.

There were no significant difference in the cumulative survival rates of class I and class II GIC restorations among the 3 groups (Table 2). Only in group 2 was the survival rate of class I restorations significantly higher than that of class II ($p=0.03$). All class I restorations in group 2 survived. However, all failed-class I restorations in groups 1 and 3 were due to medium marginal defects

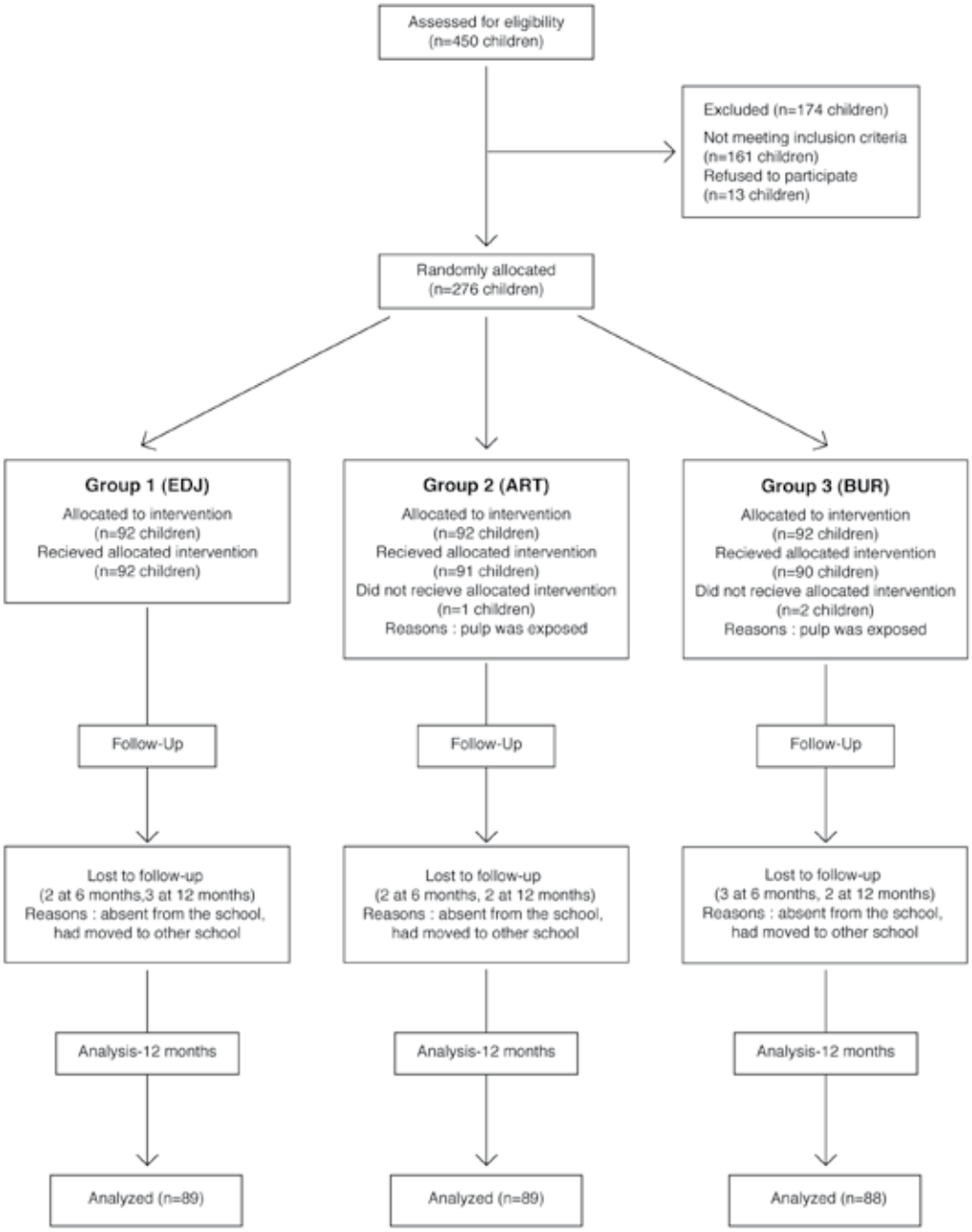


Figure 1. *Number of enrollment, allocation, follow-up, and analysis of restorations in Groups 1, 2 and 3*

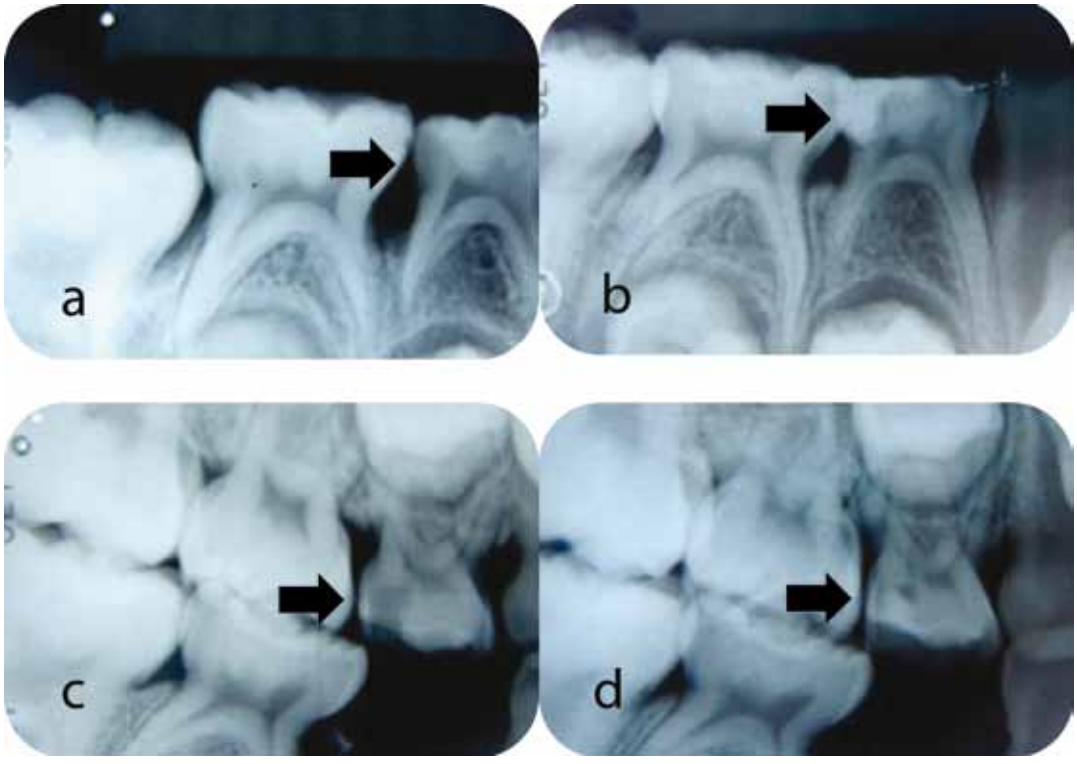
Table 1. Cumulative survival rates (%) for GIC restorations and pulp in groups 1, 2, and 3 after 6 and 12 months

Study group	*Time to follow-up (months)*	*Evaluated (n)*	*Restoration Failure (n)*	*Pulp Failure (n)*	*% Cumulative survival rate (SE) of*			
					Restoration	*(SE)*	*Pulp*	*(SE)*
Group 1	6	90	10	1	89	(3.3)	99	(1.2)
EDJ	12	89	15	0	83	(4.0)	99	(1.3)
Group 2	6	89	7	0	92	(2.9)	100	(0)
ART	12	89	15	0	83	(4.0)	100	(0)
Group 3	6	87	4	2	94	(2.5)	98	(1.6)
BUR	12	88	10	0	89	(3.4)	98	(1.6)

Table 2. Overall cumulative survival rates (%) for restoration class and age group in groups 1, 2, and 3 after 12 months

Study group	*% Cumulative survival rate (SE) of*							
	Restoration Class (SE)				*Age Group (SE)*			
	Class I	*(SE)*	*Class II*	*(SE)*	*6-8 years*	*(SE)*	*9-11 years*	*(SE)*
Group 1 EDJ	93 (n=27)	(5.0)	79 (n=62)	(5.2)	83 (n=76)	(4.3)	83 (n=13)	(10.8)
Group 2 ART	100 * (n=18)	(0)	79* (n=71)	(4.8)	84 (n=73)	(4.3)	81 (n=16)	(9.8)
Group 3 BUR	92 (n=24)	(5.6)	88 (n=64)	(4.1)	88 (n=68)	(3.9)	90 (n=20)	(6.7)

* significant difference between class I and class II restoration in Group 2 (p=0.03), Logrank test



a) Baseline radiograph showing deep dentinal caries on lower first primary molar.
b) Periapical radiograph 12 months after restoration.
c) Baseline radiograph showing deep dentinal caries on upper first primary molar.
d) Bitewing radiograph 12 months after restoration.
The dentinal caries under both restorations have not progressed over time.

Figure 2. *Radiographs before and after partial soft caries removal (Group 1) and 12 months after restoration with GIC*

(0.5 to 1.0 mm). In group 3, the success rate of class II restoration performed better than the other group, however, the difference was not significant ($p>0.05$). The survival rate for restorations in the younger (6-8 years old) and the older age groups (9-11 years old) did not differ (Table 2).

Clinical and radiographic signs of irreversible pulpitis were evaluated. Two teeth with fistulas were found in group 3 at the 6-month evaluation (BUR). Only 1 child in group 1 (EDJ) experienced pain during mastication, confirmed by radiographic sign of caries progression at the 6-month evaluation. The proximal part of the restoration was broken, therefore we decided to perform pulpotomy and no discontinuation of lamina dura at furcations or symptoms were presented at the 12-month evaluation. In group 2 (ART) no pulp failure was observed (Table 1). By measuring the width of dentine from radiographs, most of the dentine caries underneath the restorations revealed no progression in any group (Figure 2).

Disscussion

In this study, we used the child as an analytical unit not the tooth since we evaluated the status of dmft and discomfort of each child. The study found that the survival of restorations among the 3 groups after 12 months did not differ, regardless of the amount of soft caries removal. Similarly, Foley *et al*. (2004) reported the comparable durability of restorations with GIC or amalgam in partial and complete caries removal over a 2-year period. A possible explanation might be that the adhesion of GIC to enamel or dentine in teeth prepared by hand excavation and the bur were comparable, as suggested by Czarnecka *et al*. (2006). They found that the quality of the interface between a GIC and either dentine or enamel observed by a light transmitting microscope were not influenced by the method of caries removal.

The survival of class II GIC restorations using hand and rotary instrument approaches in the present study did not differ. Contrary to our study, Yu *et al*. (2004) showed a significantly lower survival in class II restoration with the ART (hand instrument) approach compared to the rotary instrument approach. The success rates for class II ART restorations in primary teeth varied between studies, depending on the type of GIC and criteria for evaluation. The ART criteria we used for evaluation were considered more sensitive than the USPHS-Ryge criteria (Taifour *et al*., 2002). In our opinion, many restorations rated as failure with medium marginal defects (0.5 to 1.0 mm) according to the ART criteria may possibly survive without repair or replacement until the teeth exfoliate.

The survival of the restorations in the younger (6-8 years old) and the older age groups (9-11 years old) did not differ for each intervention. This implies that all 3 interventions can be accomplished successfully in children at the age of 6 to 11 years. Children with this age range are usually co-operative with the dental procedure and can communicate well with dentists. It would be interesting to study the survival rate of restoration using EDJ and ART approaches in children under 4 years old who are less communicable and more apprehensive for dental treatment. Also, the pulp response in newly erupted tooth may differ from the old pulp that was nearly exfoliating. It should be noted that the number of restorations in class I and in the 9-11 age group were lower than 30 in all groups which was insufficient sample size for analysis (power <30%). This is a concern in comparing the association between groups or within group and may influence the statistical significance.

In our study, no restoration rated successful in the partial soft caries removal group (group 1) showed clinical or radiographic signs of inflammation of pulp after 12 months, confirming findings elsewhere (Ribeiro *et al*., 1999). They found no sign of pulp degeneration in teeth with partially infected dentine removal and restoration with composite resin. In assessing radiographic outcomes after partial carious dentine removal in deep caries lesions by using digital subtraction of radiographic images, it was shown that lesion depth remained unchanged or decreased and tertiary dentine formation was observed at 10-year follow-up (Alves *et al*., 2010).

Few studies have reported the role of controlling caries in ART restoration in terms of pulpal infection after restoration. No failed restoration from irreversible pulpitis was found in any ART restorations in this study, while 0-2% of the ART restorations showed signs of irreversible pulpitis in the earlier studies (Ho *et al*., 1999; Menezes *et al*., 2006).

Two teeth with class II restorations in the conventional approach (group 3, BUR) showed pulp degeneration with fistulas at 6-month evaluation and were extracted. These 2 teeth were symptomless at the time of restoration placement as well as 6-month evaluation, one had a gross margin defect, while the other was in good condition. Possible explanations for the fistula might be incorrect diagnosis due to the difficulty in clinical diagnosis of pulp conditions especially in primary teeth or excessive removal of sound tooth tissue by the bur, which may have led to micro exposure of the pulp during caries removal and later pulp degeneration.

The partial removal of caries only at EDJ with hand instruments, without the use of airotor or air motor and without the need for local anesthesia, is a minimal intervention in caries and patient management. From observation, our patients were highly relaxed and co-operative throughout the treatment. Due to simpler and less invasive caries management, compared to the ART and conventional approaches, it could have applications for children and community.

It can be concluded that the partial caries removal approach only at EDJ and restoration with GIC was comparable to those of the ART and conventional approaches in managing dental caries, and is more likely to reduce the risk of caries exposure and avoid unnecessary pulp treatment without harm to the patients. However, since the follow-up of the study is only a year, a longer clinical observation period is required to confirm the outcomes.

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