



Randomized Clinical Trial of ART Class II Restorations Using Two Glass Ionomer Cements: Six-month Follow-Up

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ABSTRACT

Objective: The purpose of this study was to compare success rates of ART (atraumatic restorative treatment) Class II restorations in primary teeth, performed with high-viscosity glass ionomer cement (HVGIC) and a Silver Diamine Fluoride (SDF)-incorporated with HVGIC (SDF-HVGIC) after 6 months.

Materials and Methods: A controlled clinical trial using a parallel group design was carried out on 150 children aged 4-8 years old, from 5 public kindergartens in Samut Sakhon province, Thailand, with at least one class II cavities. They were randomly allocated to two treatment groups: ART restoration using either HVGIC (GC Fuji IX GP[®]) or SDF-HVGIC (GC Fuji IX GP[®] + Saforide[®]). A total of 150 restorations were placed in vital primary molars by a pediatric dentist (HVGIC= 75, SDF-HVGIC= 75) and were evaluated by one calibrated examiner, blinded to the type of material and not involved in the placement after 6 months.

Results: After 6 months, 138 children (92 percent) remained in the study. The overall success rate (95 percent confidence interval) at the six-month follow-up for the HVGIC and SDF-HVGIC were 73.3 percent (61.9-82.9) and 62.7 percent (50.7-73.6), respectively. No significant difference was detected between the study groups (Chi's square test, P=0.16).

Conclusion: Class II ART restorations with HVGIC (high-viscosity glass ionomer cement) showed similar success rates after 6 months compared to those with SDF-HVGIC (SDF-incorporated high-viscosity glass ionomer cement).

Keywords: Clinical Study, Primary Teeth, Silver Diamine Fluoride, Glass Ionomer Cement, Atraumatic Restorative Treatment



1. Introduction

Atraumatic Restorative Treatment (ART) is a part of the contemporary caries management philosophy of minimal intervention dentistry concept (Frencken & Holmgren, 2004; Frencken & Leal, 2010). It is an alternative approach for managing dental caries which involves the removal of soft, decayed tissue using hand instruments, followed by the restoration of the cavity with a chemical adhesive material (Frencken, Leal, & Navarro, 2012). In addition, ART can be considered as an economical and effective method for preventing and controlling carious lesion development in vulnerable populations (Frencken & Leal, 2010). Recently, High-Viscosity Glass Ionomer Cement (HVGIC) has gained more acceptance in the treatment of primary molars (Bonifacio et al., 2013). It has been the material of choice for ART technique (van 't Hof, Frencken, van Palenstein Helderma, & Holmgren, 2006) because of excellent properties (Frencken, 2017) for restorative dentistry including capacity of fluoride release, high compressive strength, chemical bond to enamel and dentin, and thermal expansion coefficient similar to tooth structure (Mickenautsch, Yengopal, & Banerjee, 2010). Essentially, the major concern of ART is on the residual cariogenic bacteria that remain under the restorations (Weerheijm & Groen, 1999). Caries lesion in the margins of restorations remain the major reason for the replacement of restorative materials worldwide (Tyas, 2005). Therefore, a number of studies investigated modified GICs containing various antimicrobial agents to improve the antimicrobial property but the results remained controversial (de Castilho et al., 2013; Frencken et al., 2007; Hafshejani et al., 2017; Yesilyurt, Er, Tasdemir, Buruk, & Celik, 2009). The commonly used antimicrobial agents in modified GICs are chlorhexidine (Marti et al., 2014), antibiotics (metronidazole, minocycline, ciprofloxacin) (Yesilyurt et al., 2009), benzalkonium chloride and cetylpyridinium chloride (Botelho, 2004).

Silver diamine fluoride (SDF), a well-known antibacterial solution, colorless basic liquid has been used for halting down caries progression due to the antimicrobial properties of silver and the remineralizing of fluoride (Crystal & Niederman, 2019). The fluoride component strengthens the tooth structure under attack by the acid products of bacterial metabolism (Mei et al., 2017), decreasing its solubility, but in combination with silver, SDF may also interfere with biofilm, killing bacteria that cause the local environment imbalance that demineralizes dental tissue (Mei, Chu, Low, Che, & Lo, 2013). Therefore, SDF becomes one of the tools available to address caries by modifying the bacterial action on the tissue while also enhancing remineralization (Crystal & Niederman, 2019). The recent study reported that SDF does not adversely affect the bond strength between glass ionomer cement and carious primary dentin (Puwanawiroj, Trairatvorakul, Dasanayake, & Auychai, 2018). A study investigating the effect of incorporating 38% SDF at different concentrations to improve antibacterial activity of GIC found that physical properties of the GIC containing SDF at 5% (v/v GIC-liquid) which consist of 0.0152 g SDF provided the best esthetic profile and met the International Organization for Standardization (ISO) standards for setting time, compressive strength, microleakage, and shear bond strength without deteriorating the GIC fluoride releasing pattern (Jariyamana et al., 2017; Jintongart C., 2018). Moreover, the previous researchers



reported an *in vitro* result of incorporating SDF into GIC increased bonding efficacy and reduced microleakage at the dentin margin²¹.

Consequently, this novel GIC maximized the effect of fluoride release from GIC in carious lesion prevention which improved the antibacterial and remineralization properties of the materials. Recently, another unpublished *in vitro* test of this novel material also showed no difference in microleakage and shear bond strength compared to the standard HVGIC (Jitongart, Khumtrakoon, Daomanee, Auychai, & Laiteerapong). The novel material has a potential of being a restorative material for ART.

However, clinical trials about the longevity of SDF-HVGIC restoration in primary teeth have not been reported in the literature yet.

2. Objective of the study

The purpose of this clinical trial was to compare the success rates of ART Class II restorations in primary teeth, performed with high-viscosity glass ionomer cement (HVGIC) and an SDF-incorporated with HVGIC (SDF-HVGIC) after 6 months. The null hypothesis tested was that there would be no difference in the success rates of both materials at six-month follow-up.

3. Materials and methods

The study was approved by the Human Research Ethics Committee of the Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand under protocol number HREC-DCU 2019-017. It was also registered at the Thai Clinical Trials Registry (ClinicalTrials.co.th identifier: TCTR 20190731001). Written consents were obtained from parents/guardians of the participating children. This paper followed the protocol established by the Consolidated Standards of Reporting Trials Statement—CONSORT (Schulz, Altman, Moher, & Group, 2010).

This clinical trial was conducted in kindergartens in Ban Phaeo District in Samut Sakhon Province. The recruitment period started in July 2019 and ended in August 2019. The latest follow-up examination was in February 2020.

Study design.

This was a randomized, controlled clinical trial (the patient was blinded to the group assignment).

Eligibility criteria.

Children with Class II carious lesions on primary molars were recruited. Cavities should be scored 5 or 6 in the International Caries Detection and Assessment System (ICDAS) (Braga, Mendes, & Ekstrand, 2010) without involvement of buccal and lingual walls. The cavity should be assessed through an open occlusal enamel to allow insertion of hand instruments, according to the ART guidelines (Frencken, Pilot, Songpaisan, & Phantumvanit, 1996).



Children with primary teeth who had a history of pain or pulp involvement characterized by facial swelling or sinus tract, and children whose parents did not give written informed consent were excluded. We also excluded non-cooperative, those with special health care needs, and known sensitivities to silver or other heavy-metal ions or presence of any gingival or perioral ulceration or stomatitis. In such circumstances, parents were advised to bring children to receive dental treatment from local dental clinics. The final sample consisted of 150 children.

Sample-Size calculation.

Sample size calculation for this study was based on the article “Sample size requirements for pilot randomized controlled trials with binary outcomes: a simulation study”. The researchers concluded that the pilot RCT with a binary primary outcome should contain 60 subjects in each group to estimate the event rate with a reasonable degree of precision (Teare et al., 2013). Since one patient represented one cavity for the study, the number of samples in each group was 60 children. This was a prospective study with 6 months of follow up time. To compensate for sample drop-out, 20% of the calculated sample was added. As a result, the total sample size in the study was at least **75 teeth in each group** or **150 teeth in total**.

Randomization: sequence generation and allocation concealment.

The randomization scheme was produced using a randomization program called sealed envelope™, <https://www.sealedenvelope.com/simple-randomiser/v1/lists>, to generate a scheme of random code for each sample, placed in an opaque sealed envelope. At the time of mixing the material, a dental assistant opened an envelope to get the assigned intervention and prepared the materials for the operator. However, the operator was not blinded due to the different characteristics of the materials. The patients was not informed as to which arm of the randomized groups they were in.

Each child (representing one cavity) was considered as one sample. Therefore, each child had an equal chance of being assigned to either the control (HVGIC (GC Fuji IX GP® EXTRA, GC Corporation, Tokyo, Japan)) or the intervention group (HVGIC (GC Fuji IX GP® EXTRA, GC Corporation, Tokyo, Japan) containing 0.2 µl SDF solution (Saforide®, Toyo Pharmaceutical Co., Ltd., Japan)).

Interventions

HVGIC (GC Fuji IX GP® EXTRA, GC Corporation, Tokyo, Japan) as control and SDF-HVGIC (HVGIC (GC Fuji IX GP® EXTRA, GC Corporation, Tokyo, Japan) containing 0.2 µl SDF solution (Saforide®, Toyo Pharmaceutical Co., Ltd., Japan)) as test.

Methods

Medical history and oral examination were performed by one dentist. Oral examination consisted of assessing the presence of dental plaque according to the criteria Greene and Vermillion (1964) and recorded using of the visible plaque index (VPI) and caries experience according to the WHO criterion and recorded as mean decayed, missing, and filled teeth (dmft) scores (Organization, 2013).



Children who fulfilled the eligibility criteria and for whom the parents gave written informed consent allowing them to participate in the study were recruited into the study.

One primary molar per child was used to prevent any cross-interaction of SDF through saliva which may affect the antibacterial activity of the restoration of interest. If there is more than one cavity meeting the inclusion criteria, one of them will be randomly selected. The other cavitated carious lesions in the mouth of the selected children will be referred to receive an appropriate treatment by dentists working in a public oral health center in the city.

In summary, the 150 Class II ART restorations were performed by one trained pediatric dental resident, aided by a trained and calibrated dental assistant, in July 2019 at the school premises. Children were given oral hygiene kits of toothbrush and fluoridated toothpaste and received oral hygiene instructions.

The isolated tooth was isolated with cotton rolls, and the tooth surface was cleaned with a wet cotton pellet to removed debris and plaque. The infected tissue was removed from the surrounding walls and the enamel-dentin junction using sharp spoon excavators of appropriate size before proceeding to the floor of carious lesion, according to the ART approach guidelines/ protocol(Frencken et al., 1996).

Demineralized dentin was left on the cavity floor. The carious lesion was then cleaned with a small cotton pellet soaked in water and dried with a dry cotton pellet. No local anesthesia was used.

After the cavity preparation, a metal matrix was positioned, and stabilized with a wooden wedge to define the proximal contour of the restoration. The tooth surface was conditioned with GC Dentin Conditioner (GC Corporation, Tokyo, Japan) for 10 seconds, washed for 5 seconds and dried for 5 seconds with dry cotton wool pellets, according to the manufacturer's instructions.

The control or test restorative materials were inserted into the cavity using an applier/carver instrument, overfilled, and pressed down with a petroleum-jelly-coated finger. Bite check was performed and removed excess material. Petroleum jelly was then covered over the restoration surface.

Clinical Evaluation.

One calibrated examiner assessed the restorations using established modified ART restoration criteria (Table 1), on the school premise after 6 months. Debris and plaque from the tooth surface were removed before evaluation using a wet cotton pellet. The intra-examiner reliability was performed during clinical evaluations which expressed as kappa coefficient value of 0.84.



Table 1. Evaluation criteria (modified from ART criteria according to Lo and Holmgren, 2001(E. Lo & C. Holmgren, 2001)

Code	Criteria
0	Present, in good condition
1	Present, slight marginal defect ($\leq 0.5\text{mm}$), no repair is needed
2	Present, slight wear ($\leq 0.5\text{mm}$), no repair is needed
3	Present, gross marginal defect ($> 0.5\text{mm}$), repair is needed
4	Present, gross wear ($> 0.5\text{mm}$), repair is needed
5a	Restoration partly or completely missing with inactive caries, no repair is needed
5b	Restoration partly or completely missing with active caries, repair is needed
6	Restoration is repaired or replaced by another restoration
7	Tooth is extracted because of restoration failure, dental caries
8	Tooth is missing, exfoliated or extracted
9	Restoration is not assessed; child is not present

Clinical evaluation was performed using a blunted explorer, a plane front-surface mirror, and an electric light bulb as a light source. Restorations coded 0-2 were considered success. Those coded 3-7 were considered defective as were those with a secondary carious lesion. Code 8-9 were considered censored observation and excluded from the analysis. /Code 8-9 were considered as failure according to the intention to treat analysis.

Statistical Analysis.

Descriptive statistics included the computation of the success rate of restorative materials at six months. Chi-squared and Fisher's exact tests were used to assess statistically significant differences between materials at 6-month evaluation period. A difference was considered statistically significant if $P < 0.05$. Intraexaminer agreement was assessed with kappa coefficient values.

4. Results

Baseline features. A total of 150 children were included in the study, 76 males (50.7%) and 74 females (49.3%), with a mean age of 6.3 (± 1.06) years, ranging from 4- to 8-years old. The baseline assessment showed a mean (\pm SD) decayed or filled primary teeth (dmft) index of 6.93 ± 3.66 . The children mean plaque score was 0.81 (± 0.19).

Success rate. Table 2 shows the evaluation score of the restorations at six months according to restorative material, surface type tooth position and presence of the proximal contact. The overall success rate (95 percent confidence interval [95% CI] at six-month follow-up for the HVGIC and SDF-HVGIC were 73.3 percent (61.9-82.9) and 62.7 percent (50.7-73.6), respectively. No significant difference was detected between the study groups (Fisher's exact test, $P=0.16$).

**Table 2.** Success rate of restoration at 6-month follow-up examinations (intention to treat analysis)

	Group 1: SDF-HVGIC	Group 2: HVGIC	P-value*
All surfaces	47/75 (62.7%)	55/75 (73.3%)	0.161
Surface type			
Surface of cavity (OM)	24/37 (64.9%)	26/34 (76.5%)	0.284
Surface of cavity (OD)	23/38 (60.5%)	29/41 (70.7%)	0.339
Tooth position			
Upper 1st Molar (54,64)	12/17 (70.6%)	19/20 (95%)	0.045
Upper 2nd Molar (55,65)	13/22 (59.1%)	11/18 (61.1%)	0.897
Lower 1st Molar (74,84)	16/29 (55.2%)	19/29 (65.5%)	0.421
Lower 2nd Molar (75,85)	6/7 (85.7%)	6/8 (75%)	0.605
Proximal Contact			
Yes	38/62 (61.3%)	47/65 (72.3%)	0.187
No	9/13 (69.2%)	8/10 (80%)	0.56

The drop-out rate of both groups was 8% (Twelve students). The reasons for participants' dropping out were irregular school attendance or migration to other provinces. (Figure 1)

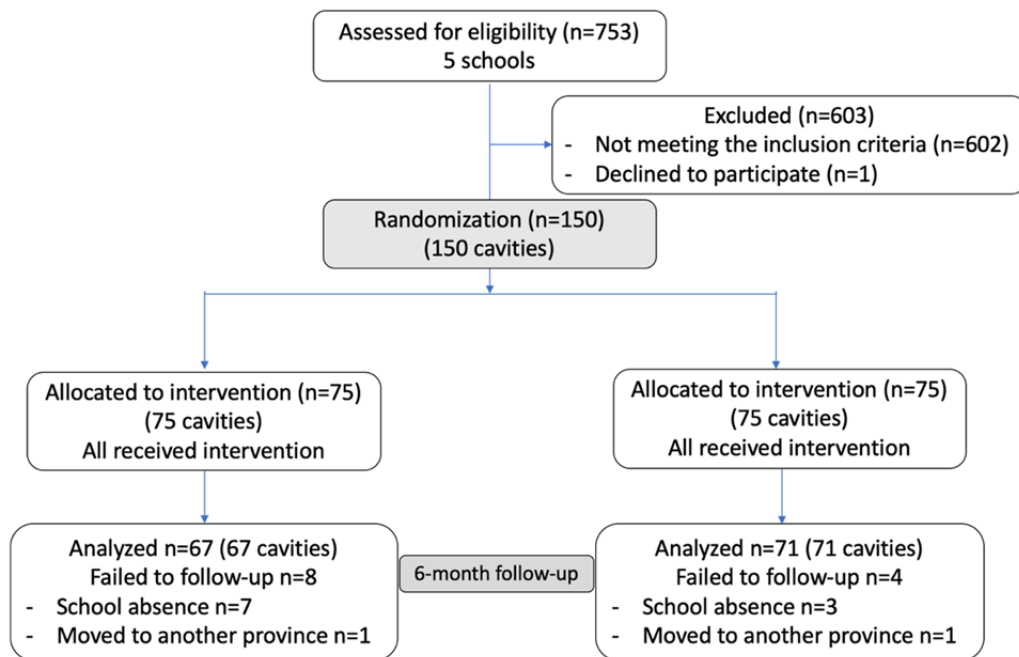


Figure 1. Flow of participants over the 6-month study period.

**Table 3.** Success rate of restoration at 6-month follow-up examinations

Code	Criteria	Group 1: SDF- HVGIC	Group 2: HVGIC	PRR (95% CI)	p-value
0	Present, in good condition	37	46	0.79 (0.57, 1.08)	0.139
1	Present, slight marginal defect (0.5mm), no repair is needed	8	8	1 (0.6, 1.68)	1
2	Present, slight wear (0.5mm), no repair is needed	2	1	1.34 (0.59, 3.04)	0.56
3	Present, gross marginal defect (>0.5mm), repair is needed	4	2	1.35 (0.75, 2.44)	0.405
4	Present, gross wear (>0.5mm), repair is needed	2	3	0.79 (0.27, 2.35)	0.649
5a	Restoration partly or completely missing with inactive caries, no repair is needed	3	0	2.04 (1.73, 2.41)	0.08
5b	Restoration partly or completely missing with active caries, repair is needed	10	11	0.95 (0.58, 1.53)	0.814
6	Restoration is repaired or replaced by another restoration	1	0	2.01 (1.71, 2.37)	0.316
7	Tooth is extracted because of restoration failure, dental caries	0	0	N/A	N/A
8	Tooth is missing, exfoliated or extracted	0	0	N/A	N/A
9	Restoration is not assessed, child is not present	8	4	1.37 (0.89, 2.12)	0.229
(0,1,2)	Success	47	55	0.79 (0.57, 1.09)	0.161
(3-7)	Failure	20	16	1.15 (0.81, 1.63)	0.444
(8,9)	Exclude	8	4	1.37 (0.89, 2.12)	0.229

Clinical evaluation of restorations at the 6-month follow-up is shown on **Table 3**. Of the 75 novel material (test, SDF-HVGIC) restorations placed, 47 restorations were assessed as success. Twenty restorations failed because restoration partially or totally dislodged with secondary caries (13 restorations; 17%), wear or gross marginal defect (6 restorations; 8%), and 1 restoration was replaced by another restoration (1%). Out of 75 control material restorations (HVGIC), 55 restorations were assessed as success. Sixteen restorations failed because of partly or completely missing with active caries (11 restorations; 14%), wear or gross marginal defect (5 restorations; 7%).

5. Discussion

The hypothesis of the benefit of this novel GIC in preventing caries lesion in the margins of occluso-proximal surfaces is related to the fluoride releasing and antimicrobial ability from silver in SDF solution. In our study the survival rate of Class II restorations in primary teeth using SDF-HVGIC and HVGIC at the 6-month recall examination was 62.7 and 73.3 percent, respectively. The survival rate of HVGIC was 10.6 percent higher than SDF-HVGIC, but this difference was not statistically significant. The possible explanations for inferior



performance were the addition of SDF may intervene with physical properties of GIC. Though we did not find that in the in vitro experiment (Jintongart C., 2018).

A recent meta-analysis (de Amorim et al., 2018) showed that one-year survival percentages and standard errors of multiple-surface ART restorations in primary posterior teeth was 76.9% (± 3.8). However, the mean survival rate was including both capsulated and hand-mixed type of material. After one year, the survival rate reported in the literature for Class II restorations in primary teeth using hand mixed HVGIC was 54 percent (E. C. Lo & C. J. Holmgren, 2001; Lo, Luo, Fan, & Wei, 2001); 61.5 percent (Fuji IX GP) and 46.2 (Chemflex).

Several limitations should be taken into consideration while interpreting the findings of the study. When using distinguishable restorative material such as HVGIC and SDF-HVGIC, it is not possible to blind operators and evaluator regarding the treatment groups. This is a single blind trial, in which the study participants were blind. Given the constraints of the field setting, no radiographs were taken for caries diagnosis. This might have led to a certain degree of underestimation of the caries increment, particularly proximal surfaces. The high failure rates of restorations done in field setting might be explained as follows. Firstly, operative technique such as using only hand instrument may not achieve the appropriate cavity outline form.

Apart from field setting, there are several aspects to the management of dental caries with ART technique that address the associated cause of Class II restoration failures in primary teeth. The consistency of the meal consumed by each child after the restoration placement significantly influenced the survival rate of proximal restorations (Kemoli, Opinya, van Amerongen, & Mwalili, 2011). Despite the fact that the operator was trained, there is still an operator effect is often reported in ART studies (Kemoli, van Amerongen, & Opinya, 2009). Although previous studies have investigated the survival rate of Class II ART restorations using different isolation methods, none of them significantly reduced the failure rate. The use of rubber dam does not increase the success of Class II ART restoration significantly (Carvalho, Sampaio, Diniz, Bonecker, & Van Amerongen, 2010). In consistent with a systematic review reported that the isolation technique does not influence the longevity of restorations (Cajazeira, De Saboia, & Maia, 2014). The use of encapsulated GICs reduces the incorporation of air bubbles during mixing procedure (de Franca Lopes et al., 2018). Encapsulated GIC promoted better ART performance than hand mixed GIC over one year (Freitas, Fagundes, Modena, Cardia, & Navarro, 2018). Due to the developing phase of this novel material, the process of pipetting the SDF solution into the liquid of HVGIC, resulting in using the hand mixed type HVGIC this research even it showed lower success rate when compared to capsule type HVGIC. Lower survival rate may be due to poor oral hygiene is observed from visible plaque as found in the study (Kemoli et al., 2011) by Kemoli et al. in 2011 found the survival rate of proximal ART restorations was significantly influenced by oral health status of child.

The predominant failure characteristic of Class II restorations for GIC was the loss of the restoration. This pattern failure for ART restorations was also reported by Lo (E. C. Lo & C. J. Holmgren, 2001) and colleagues after two years of clinical service. In addition, we rarely observed secondary caries at the margin which is a major



cause of restoration failure (E. C. Lo & C. J. Holmgren, 2001). The surface texture, anatomical form, marginal discoloration and integrity of all restorations placed in our study were satisfactory for both materials. With the evaluation criteria used in this study, restorations with minor failures were often scored as failures. We used the standard evaluation criteria used by the majority of ART clinical studies. Nevertheless, according to the intention to treat analysis, loss of follow-up cases were considered as failures.

However, there is no publish data, to our knowledge, regarding the clinical performance of the novel SDF-GIC restorative materials in primary molars. Further study of longer period of follow-up is needed to observe the effect of SDF-HVGIC to carious tooth.

The ART approach has the potential not only to improve patient experience of dental treatment but also to potentially reduce health costs and improve access to oral healthcare for sub-urban population. The latter aspect now needs to be investigated with capsule pre-mixed and in larger population.

6. Conclusion

Within the limitations and based on the results of this study, the following conclusion can be drawn: The clinical performance of novel ART Class II restorations in primary teeth was similar to the HVGIC restorations after 6 months follow-up.

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