CLINICAL EVALUATION OF TWO GLASS IONOMER CEMENT RESTORATIONS PLACED IN PRIMARY MOLARS WITH ATRAUMATIC RESTORATIVE TREATMENT TECHNIQUE: A RANDOMIZED CONTROLLED TRIAL.

Miss Manarin Boonyawong

A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Science in Pediatric Dentistry
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การศึกษาทางคลินิกของการบูรณะฟันน้ำนมด้วยวัสดุกลาสไอโอโนเมอร์ซีเมนต์ 2 ชนิด ด้วยเทคนิค Atraumatic Restorative Treatment: การศึกษาแบบสุ่มและมีกลุ่มควบคุม

น.ส.มนฤญช์ บุญญวงศ์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
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By	Miss Manarin Boonyawong
Field of Study	Pediatric Dentistry
Thesis Advisor	Associate Professor PRIM AUYCHAI, D.D.S., M.S.
Thesis Co Advisor	Assistant Professor DUANGPORN DUANGTHIP, D.D.S., Dr. med. dent., Ph.D., F.I.C.D.
	Dr. ARUNEE LAITEERAPONG, D.D.S., M.S., Ph.D.

Accepted by the FACULTY OF DENTISTRY, Chulalongkorn University in Partial Fulfillment of the Requirement for the Master of Science

..... Dean of the FACULTY OF DENTISTRY

(Assistant Professor SUCHIT POOLTHONG, D.D.S., M.S., Ph.D.)

THESIS COMMITTEE

..... Chairman

(Professor Chutima Trairatvorakul, D.D.S., M.S.)

..... Thesis Advisor

(Associate Professor PRIM AUYCHAI, D.D.S., M.S.)

..... Thesis Co-Advisor

(Assistant Professor DUANGPORN DUANGTHIP, D.D.S., Dr. med. dent., Ph.D., F.I.C.D.)

..... Thesis Co-Advisor

(Dr. ARUNEE LAITEERAPONG, D.D.S., M.S., Ph.D.)

..... External Examiner

(Assistant Professor Thanya Sitthisettapong, D.D.S., M.S., Ph.D.)

มนฤญช์ บุญญวงศ์ : การศึกษาทางคลินิกของการบูรณะฟันน้ำนมด้วยวัสดุกลาสไอโอโนเมอร์ซีเมนต์ 2 ชนิด ด้วยเทคนิค Atraumatic Restorative Treatment: การศึกษาแบบสุ่มและมีกลุ่มควบคุม. (CLINICAL EVALUATION OF TWO GLASS IONOMER CEMENT RESTORATIONS PLACED IN PRIMARY MOLARS WITH ATRAUMATIC RESTORATIVE TREATMENT TECHNIQUE: A RANDOMIZED CONTROLLED TRIAL.) อ.ที่ปรึกษาหลัก : รศ. ทพญ.ปริม อวยชัย, อ.ที่ปรึกษาร่วม : ผศ. ทพญ. ดร.ดวงพร ดวงทิพย์,ทพญ. ดร.อรุณี ลายธีระพงศ์

วัตถุประสงค์ การศึกษานี้มีวัตุประสงค์เพื่อศึกษาหาอัตราความสำเร็จของการบูรณะฟันกรามน้ำนม ทีมีรอยผุชนิดคลาสทู ด้วยเทคนิค Atraumatic Restorative Treatment (ART) ด้วยวัสดุกลาสไอโอโนเมอร์ซีเมนต์ชนิดความหนืดสูง (High-Viscosity Glass Ionomer Cement; GIC) และ กลาสไอโอโนเมอร์ซีเมนต์ชนิดความหนืดสูงที่มีส่วนผสมของสารซิลเวอร์ไดเอมีนฟลูออไรด์ (Silver Diamine Fluoride; SDF-GIC) ที่ระยะเวลา 6 และ 12 เดือน

วัสดุอุปกรณ์และวิธีการทดลอง การศึกษาทางคลินิกแบบสุ่มและมีกลุ่มควบคุม โดยคัดเลือกประชาการอายุ 3 ถึง 8 ปี จำนวน 150 คนทีมีฟันผุด้านประชิดตามเกณฑ์การคัดเข้า และสุ่มชี่ฟันเข้ากลุ่มควบคุม (Fuji IX GP) หรือ กลุ่มทดลอง SDF-GIC (Fuji IX GP+ Saforide) โดยทันตแพทย์สำหรับเด็กทำการบูรณะฟันกรามน้ำนมคลาสทู และทันตแพทย์ทันตกรรมบูรณะเป็นผู้ตรวจประเมินคุณภาพวัสดุที่ระยะเวลาติดตามผล 6 และ 12 เดือน โดยใช้สถิติทดสอบไคสแควร์ในการเปรียบเทียบอัตราความสำเร็จทางคลินิกระหว่างวัสดุอุด 2 ชนิด

ผลการศึกษา ณ เวลาการติดตามผล 6 เดือน พบว่า อัตราความสำเร็จทางคลินิกของการบูรณะฟันกรามน้ำนมชนิดคลาสทูด้วยวัสดุ SDF-GIC และ GIC เท่ากับร้อยละ 62.7 (ช่วงความเชื่อมั่นร้อยละ 95 เท่ากับ 50.7-73.6) และ ร้อยละ 73.3 (ช่วงความเชื่อมั่นร้อยละ 95 เท่ากับ 61.9-82.9) ตามลำดับ โดยไม่พบความแตกต่างของอัตราความสำเร็จของวัสดุบรณะทั้ง 2 ชนิดอย่างมีนัยสำคัญทางสถิติ (p=0.16) และเมื่อติดตามผลที่ระยะเวลา 12 เดือน อัตราความสำเร็จทางคลินิกของของการบูรณะฟันกรามน้ำนมชนิดคลาสทูด้วยวัสดุ SDF-GIC และ GIC เท่ากับร้อยละ 61.3 (ช่วงความเชื่อมั่นร้อยละ 95 เท่ากับ 49.4-72.4) และ ร้อยละ 58.7 (ช่วงความเชื่อมั่นร้อยละ 95 เท่ากับ 46.7-69.9) ตามลำดับ โดยไม่พบความแตกต่างของอัตราความสำเร็จของวัสดุบรณะทั้ง 2 ชนิดอย่างมีนัยสำคัญทางสถิติเช่นเดียวกัน (p=0.739)

สรุป การบูรณะฟันกรามน้ำนมที่มีรอยผุชนิดคลาสทูด้วยเทคนิค Atraumatic Restorative Treatment (ART) ด้วยวัสดุกลาสไอโอโนเมอร์ซีเมนต์ชนิดความหนืดสูง (High-Viscosity Glass Ionomer Cement; GIC) และ กลาสไอโอโนเมอร์ซีเมนต์ชนิดความหนืดสูงที่มีส่วนผสมของสารซิลเวอร์ไดอะมีนฟลูออไรด์ (Silver Diamine Fluoride; SDF-GIC) มีอัตราความสำเร็จที่ไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ เมื่อติดตามผลที่ระยะเวลา 6 และ 12 เดือน

สาขาวิชา	ทันตกรรมสำหรับเด็ก	ลายมือชื่อนิสิต .....
ปีการศึกษา	2562	ลายมือชื่อ อ.ที่ปรึกษาหลัก .....
		ลายมือชื่อ อ.ที่ปรึกษาร่วม .....
		ลายมือชื่อ อ.ที่ปรึกษาร่วม .....

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KEYWORD: CLINICAL STUDY, PRIMARY TEETH, SILVER DIAMINE FLUORIDE, GLASS IONOMER CEMENT, ATRAUMATIC RESTORATIVE TREATMENT

Manarin Boonyawong : CLINICAL EVALUATION OF TWO GLASS IONOMER CEMENT RESTORATIONS PLACED IN PRIMARY MOLARS WITH ATRAUMATIC RESTORATIVE TREATMENT TECHNIQUE: A RANDOMIZED CONTROLLED TRIAL.. Advisor: Assoc. Prof. PRIM AUYCHAI, D.D.S., M.S. Co-advisor: Asst. Prof. DUANGPORN DUANGTHIP, D.D.S., Dr. med. dent., Ph.D., F.I.C.D.,Dr. ARUNEE LAITEERAPONG, D.D.S., M.S., Ph.D.

Objective: The purpose of this study was to compare clinical success of a novel material (silver diamine fluoride incorporated with high-viscosity glass ionomer cement (SDF-GIC)) in Class II restoration in primary molars using atraumatic restorative treatment (ART) technique at 6- and 12- month follow-up.

Materials and Methods: A randomized controlled clinical trial using a parallel group design was carried out on 150 children aged 3-8 years old, from 5 public school in Samut Sakhon province, Thailand, with at least one class II cavities. They were randomly allocated to two treatment groups: ART restoration using either GIC (Fuji IX GP) or SDF-HVGIC (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 and 12 months.

Results: The overall clinical success (95 percent confidence interval) at the 6-month follow-up for the GIC and SDF-GIC were 73.3 percent (61.9-82.9) and 62.76 percent (50.7-73.6), respectively. At 12-month follow-up, the clinical success for SDF-GIC and GIC were 61.3 percent (49.4-72.4) and 58.7 percent (46.7-69.9), respectively. However, no significant difference was detected in clinical success between the study groups for both follow-up periods (Chi's square, p=0.161 for 6-month and p=0.739 for 12-month).

Conclusion: Class II ART restorations with the novel material (SDF-GIC) showed similar clinical success rate after 6 and 12 months compared to those with GIC.

Field of Study:	Pediatric Dentistry	Student's Signature .....
Academic Year:	2019	Advisor's Signature .....
		Co-advisor's Signature .....
		Co-advisor's Signature .....

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Introduction

Background and Rationale

Dental caries is one of the most common diseases globally (1). In Thailand, results of the National Oral Health Survey conducted in 2017 showed that over 52.9 % of 3-year-olds have experienced caries and the average dmft scores was 2.8 teeth/child, which most of them were left untreated (2). Untreated carious lesions can cause toothache, pain, and infection. The consequences will not only affect the children's oral health but also their general health, such as their growth, cognitive development, and also their quality of life (3).

Recently, the paradigm around the ideal management of carious lesions has been shifting. In order to prevent, or at least minimize, the serious complications of complete excavation of carious dentin close to the pulp, a minimally invasive, tooth-preserving method removal was developed (4). This can be performed selectively or partially. This approach is biological and less invasive, making it easier for the dentist to remove any remaining carious tissue without the risk of exposing the vital pulp (5). Minimally invasive approaches to managing caries, such as partial caries removal technique and atraumatic restorative technique (ART), both prevent dental caries and stop further progression. These techniques show improved outcomes over the conventional treatment which is complete caries removal (4).

ART is an alternative approach for managing dental decay, which involves the removal of decayed tissue using hand instruments alone, followed by the application of a chemical adhesive material (6). Therefore, patients who received ART have less painful experiences as well as less dental anxiety (7). The cost of ART is 50% less than amalgam and composite filling (8). The restorative material of choice for ART is a high-viscosity glass ionomer cement (GIC), which is also recognized as an appropriate material to be used in single surface cavities in both primary and also permanent teeth (6). GICs provide biocompatibility, fluoride release, chemical adhesion to the tooth surface and a coefficient of thermal expansion similar to that of natural teeth (8).

The longevity performance of ART restorations has been evaluated through clinical trials with the results of numerous studies showing the good performance of occlusal cavities in primary

and permanent teeth although there appears to be a much lower success rate for class II cavities (8-12). Secondary caries was observed as the main reason for failure (13, 14), resulting in the replacement of restorations in primary teeth(14, 15). One of the reasons is that primary teeth have higher tubule density and lower concentration of phosphate and calcium in peritubular dentin than do permanent teeth (16). Therefore, the characteristics of primary teeth is possibly interfering with the performance of restorative materials (16-18). Essentially, the major concern of ART is on the cariogenic bacteria that remain under the restorations (19). Hence, the improvement of the materials used for ART to overcome the concern on incomplete caries removal may lead to a higher success rate of ART (20).

In order to overcome this, a number of studies investigated the modified of GICs containing various antimicrobial agents (20-23) to improve antimicrobial property but the results remain controversial.

Silver diamine fluoride (SDF), a well-known antibacterial solution, was first introduced in 1969 by Nishino et al. (24) This colorless basic liquid has been used recently for halting down caries progression due to antimicrobial property and enhancement of fluoride remineralization. Multiple published systematic and updated reviews indicate that SDF application successfully arrests dental caries in children (3, 25, 26). Therefore, treating carious lesions with SDF solution application has been proposed for arresting dentin caries (27). Moreover, a recent study reported that SDF does not adversely affect the bond strength between glass ionomer cement and carious primary dentin (28). The unpublished 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 (29). 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 GIC (30). However, clinical trials

about the longevity of SDF-GIC restoration in primary teeth have not been reported in the literature yet. The novel material has a potential of being a restorative material for ART.

Therefore, the aim of this study is to evaluate the clinical success of a novel GIC (GIC containing SDF) of class II ART restorations in primary molars of preschool children compared to the standard material of ART (GIC).

Research Question

Is there any difference in the clinical success of class II ART restorations using GIC and SDF-GIC in primary molars of preschool children at 6- and 12-month follow-up?

Research Objective

To investigate and compare the clinical success of class II ART restorations using GIC and SDF-GIC in primary molars of preschool children at 6- and 12-month follow-ups.

Research Hypothesis

The null hypothesis tested is that there is no difference between the clinical success of class II ART restorations using GIC and SDF-GIC in primary molars of preschool children at 6- and 12-month follow-ups.

Research Design

The study is a randomized controlled clinical trial.

Conceptual Framework

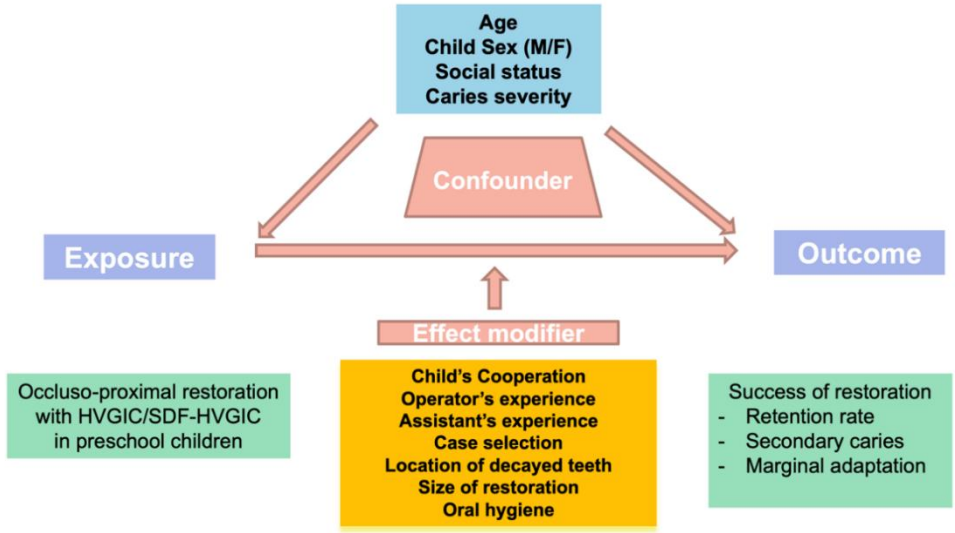

Figure 1. Conceptual Framework.

Operational Definitions

1. Atraumatic Restorative technique (ART)

Atraumatic Restorative Technique (ART) is defined as a minimal intervention care approach, to prevent or stop the development of carious and restore carious dentin lesion in a minimally invasive way (31). The procedure is done with hand instruments only, followed by the adhesive materials (6).

2. High Viscosity Glass Ionomer Cements (GIC)

High Viscosity Glass Ionomer Cement (GIC) is a modified glass ionomer cement with enhanced mechanical and physical properties by having a smaller particle size of glasses and higher proportion of glass. GIC is the material of choice for ART technique due antibacterial properties, fluoride release, rechargeability, and adhesion to tooth structure (32).

3. SDF-GIC

SDF-GIC is a GIC containing SDF with improved anti-bacterial and fluoride release properties without deteriorating the setting time or physical properties including bonding efficacy, microleakage, and shear bond strength.

4. Clinical Success

Clinical success of restorations will be discussed based on the clinical assessment of clinical success rate, marginal defect, retention, and secondary caries.

Ethical Considerations

1. This study protocol was approved by the Ethics Committee of the Faculty of Dentistry, Chulalongkorn University (approval number: HREC-DCU 2019-17).

2. The study protocol was thoroughly explained to the parents of the study children. Written parental consent was obtained prior to participating in the study. The informed consent states the risks and benefits of entering the study, and the parents are free to withdraw their child from the study at any time without affecting the quality of care.

3. The parents were informed about the objectives of the study, study process, and the advantages and disadvantages of treatment prior to making the decision for their child to participate in the study.

4. Participants were recruited in the trial after their legal guardians signed an informed consent form containing detailed information about the research.

5. The proposed study procedure followed the guideline of ART technique, which is an effective, acceptable, and commonly adopted approach when managing dentin caries in field setting. Glass ionomer cements used in this study are commercially available. Also, the SDF product used in this study has been approved by the United State of America Food and Drug Administration (FDA).

6. All participants and primary caregivers received child oral health status report, and oral hygiene products (toothbrush and fluoride toothpaste). Participants with loss of restoration with secondary caries were informed and referred for appropriate care.

Chapter 2

Literature Review

International Caries Detection and Assessment System (ICDAS)

The visual and tactile examination of the teeth is enhanced when the clinician cleans and dries the pits and fissures while examining the teeth. The new criteria for detection and assessment of dental caries was first developed in 2002 and then in 2008 was revised following the validated accuracy as ICDAS II. ICDAS provides methods for classifying stages of the caries process and the activity status of lesions on the basis of their clinical visual appearance (33). The ICDAS detection codes on coronal caries range from 0 to 6 depending on the severity of the lesion (33). A description of each codes is given under the following table (**Table 1**) and showing on the figures below (**Figure2**).

Table 1. ICDAS caries detection code description.

Code	Description
0	Sound
1	First Visual Change in Enamel (seen only after prolonged air drying or restricted to within the confines of a pit or fissure.
2	Distinct Visual Change in Enamel
3	Localized Enamel Breakdown (without clinical visual signs of dentinal involvement)
4	Underlying Dark Shadow from Dentin
5	Distinct Cavity with Visible Dentin
6	Extensive Distinct Cavity with Visible Dentin

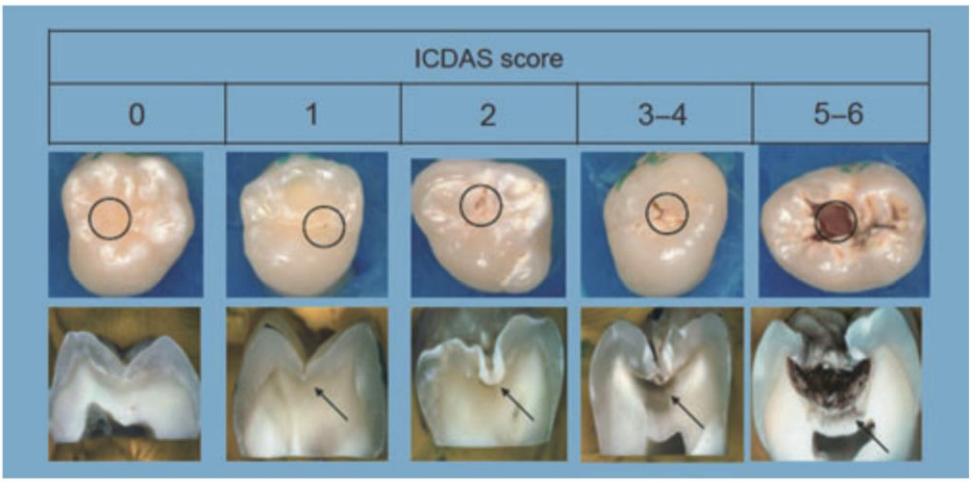

Figure 2. ICDAS clinical visual codes, based on evidence of the histological extent of lesion, stage the caries continuum.

Minimal invasive dentistry (MID)

Minimally invasive dentistry (MID) is an evidence-based intervention approach supported internationally that aims to do the least harm to affected and surrounding tissue (34). This intervention strategy employs individualized risk assessment and the early detection of carious lesions. Treatment includes efforts to remineralize non-cavitated lesions and conservative operative procedures that maintain tooth structure (35).

The philosophy of MID centers on early diagnosis, risk assessment, remineralization of early non-cavitated lesion and the preservation of tooth structure when restorations are absolutely necessary (36, 37). The example of MID is ART which concurs with the principles of carious lesion management and carious tissue removal as recommended by the International Caries Consensus Collaboration (ICCC) (31).

The 2012 review of Minimal Intervention Dentistry (MID) for managing dental caries, documented by the FDI task group, presented principle guidelines for treating dentin cavities (37). These are: Removing decomposed (previously labelled 'infected') dentin, because it is useless; Leaving demineralized (previously named 'affected') dentin behind, because it can be remineralized; and Restoring the cleaned cavity with a biocompatible material that has optimal physical properties, because it will ensure long-term integrity of the restored tooth.

Maximum tissue preservation along with maintaining pulp vitality (sensibility) is the main principle of minimally invasive dentistry, and the development of adhesive dentistry has promoted the MI philosophy into mainstream operative care. The rationale for this is that by this point, any residual bacteria will not have survived, the residual affected dentin will have remineralized and tertiary reparative dentin will have been deposited (38).

Selective Caries Removal

From the ICCC consensus on the terminology and recommendations (4) for the carious tissue removal and cavitated carious lesion management, support less invasive carious lesion management (**Figure 3**). For existing carious lesions, dentist should work with patient to manage the disease including control the lesion activity and arrest or inactivate to preserve dental hard tissue and avoiding the initiation of the restorative cycle. The disease in cavitated carious lesions either are noncleansable or no longer can be sealed are restorative interventions indicated.

When the restoration is indicated, the priorities are as follows: preserving healthy and remineralizable tissue, maintaining pulpal health, achieving a restorative seal, and maximizing restoration success (4). The aim of restorative management are to aid plaque control, protect pulp-dentin complex, restore the function, form, and aesthetics of the tooth (39).

Carious tissue is removed purely to create conditions for long-lasting restorations (4). Bacterially contaminated or demineralized tissue close to the pulp do not need to be removed. In deeper lesions in teeth with sensible (vital) pulps, preserving pulpal health should be prioritized, while in shallow or moderately deep lesions, restoration longevity becomes more important (4). The restoration longevity might be more important factor for teeth with shallow or moderately deep cavitated lesions, carious tissue removal is performed, according to selective removal to firm dentin. In deep cavitated lesion in primary or permanent teeth, preserving pulp should be prioritized, thus selective removal to soft dentin should be performed (4).

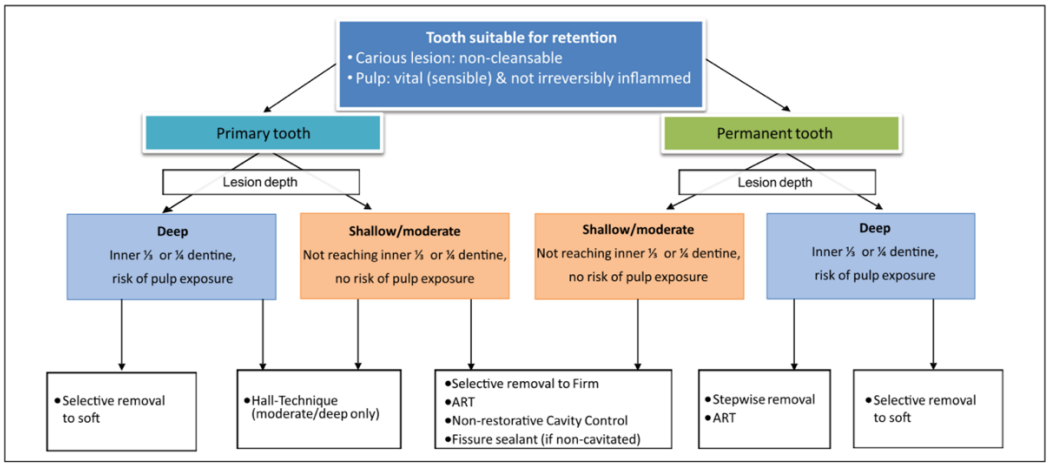

Figure 3. Diagram shows Decision making for noncleansable carious lesions in retainable teeth with vital pulps.

*ART, atraumatic restorative treatment.

Atraumatic Restorative treatment (ART)

The occurrence of cavitated caries lesion is still a problem in developed and developing countries (40), with an increasing prevalence. Therefore, the Atraumatic Restorative Treatment (ART) was developed by Frencken and Holmgren (41), and was first published in 1994 (42).

ART composes of two-part strategy for the management of caries: the restorative step, and the essential adjunctive educational-preventive strategies(6). Therefore, ART can be defined as a MID approach with the aim of preventing the development of carious lesion and stopping the progression into dentin (31). The performance of ART restorations for longevity has been evaluated through clinical trials with the results of numerous studies showing that ART performs well for occlusal cavities in primary and permanent teeth (8, 43) but there appear to be much lower success rates for occluso-proximal cavities in primary and permanent teeth (43). Thus, occluso-proximal or class II cavity is now the main focus for contemporary research (44).

ART was initially restricted to the treatment of cavitated teeth that would otherwise have been extracted in people from communities in developing countries (45). Overtime, ART has been proven to be a high quality and reliable approach in the management of dental caries, and therefore became suitable for all patients, regardless of the economic and social situation (46).

The ART approach was shown to be highly acceptable for its applications for providing restorative dental care to young children outside the traditional clinical setting (47). Since ART provides a much more acceptable introduction to dental restorative care than the traditional 'injection, drill and fill (45).

Therefore, ART restorations have been better accepted by children than the traditional restorative treatment (48). ART restorations are also the most cost-effective than conventional treatment (49, 50). In sum, the technique has been considered an innovative, painless and minimally invasive treatment for the management of caries. Other advantages (51) of ART compared with conventional restorative techniques using dental handpiece and burs include: provision of restorative dental treatment outside the dental surgery setting: a biologically friendly approach; minimal cavity preparations; low costs (52); reduced risk for subsequent endodontics and tooth extraction (53); and lower anxiety in children and adults (54).

The indicated material for ART is glass ionomer cement due to its physical and chemical properties, such as adhesion to tooth structure, biocompatibility, chemical setting reaction and the development and release of fluoride, which gives it preventive characteristics (55).

Later, the satisfactory behavior of ART was expected in the response to the introduction of High viscosity Glass Ionomer Cements (GIC) as a material of choice for this technique (56). This material was modified from the conventional glass ionomer cement with an alteration in power:liquid ratio to improve the mechanical properties and, consequently, the more longevity of the restorations (57). Despite the good restoration longevity for occlusal restoration using GIC, the survival rates of occluso-proximal restorations drop in approximately 30% in 2 to 3 years of follow-up (43).

The most recent meta-analyses (58) on the performance of ART restorations, including data up until February 2017, showed cumulative survival rates for single-surface and multiple surface ART restoration in primary teeth over the first 2 years at 94.3% (±1.5) and 65.4% (± 3.9), respectively (12) (**Table 2**).

Table 2. Overview of survival results (in %) and standard error (SE) of single- and multiple-surface ART restorations using high-viscosity glass-ionomer cement in primary posterior teeth by year survival.

Weighted mean score of ART restoration	1 Year of survival %survival (SE)	2 Year of survival %survival (SE)	3 Year of survival %survival (SE)
Single-surface	96.4 (1.1)	94.3 (1.5)	85 (5.7)
Multiple-surface	76.9 (3.8)	65.4 (3.9)	49 (12.4)

Systematic reviews have provided evidence of a high level of effectiveness for the use of high-viscosity glass-ionomer ART restoration in restoring single-surface cavities, both in primary and permanent posterior teeth, although its survival rates in restoring multiple surface cavities in primary molars needs to be improved (45).

Moreover, many studies (shows in Table 4) from systematic review (12) showed that the longevity of ART restorations using GIC in primary teeth is not different from those produced in the traditional way, using either amalgam (59) or resin composite (60).

In conclusion, ART is a reliable preventive and restorative approach to caries management in single-surface cavities, but its application in multiple-surface cavities still needs further research. There are many research papers that addressed the cause of associated with class II restoration failures in primary teeth. Some of them cited the isolation methods (61), the influence of the operator (62), and the carious lesion size (63). The reason for failure are usually the total or partial loss of the restoration and gross marginal defect (47, 64). These shortcomings may be related to the restorative material properties (65).

Protocol for producing ART restorations with GIC (45) are as follows:

1. Isolate the tooth with cotton wool rolls. Keep the area free from saliva.
2. Use an explorer, gently remove plaque and food debris from the deepest parts of the available pits and fissure.

3. Wash the pits and fissures, using wet cotton wool pellets.
4. Assess the extent of the carious lesion.
5. Enlarge the entrance of the cavity if it is found to be too small, using an Enamel Access Cutter or dental hatchet.
6. Break only very thin enamel that might fracture when the restoration is in place, using the hatchet.
7. Remove the carious dentin with hand excavators in a scooping movement, starting at the dentin-enamel junction and ending at the floor of the cavity. Leaving a little decomposed dentin behind is permitted if it is difficult to remove if the child becomes impatient.
8. Clean the cavity with a wet cotton pellet(s) followed by a dry cotton pellet.
9. Ensure that the fissures which run into the cavity are free from debris. Remove debris with a sharp probe.
10. Ensure that the enamel that forms the cavity opening is free from demineralization as far as possible).
11. Place 2 drops of liquid on the mixing pad. The first one, positioned in the corner of the pad, usually contains air bubbles and is, therefore, used for conditioning. Without releasing the pressure, move the bottle to the center of the pad and place a second drop there. This one should not contain air bubbles and will be used for mixing.
12. Condition the cavity and adjacent pits and fissures with diluted (15-20%) polyacrylic acid by passing the moist cotton pellet, dipped in the conditioner, around the dentin and enamel in the cavity for some 10-15 seconds. Bottled dentin conditioner is also available.
13. Ensure that the pellet touches the cavity walls. This is not always easy in small cavities. Use pellets appropriate to the size of the size of cavity. A disposable brush can also be used.
14. Wash with a wet cotton pellet(s) for some 5 seconds. Repeating this is necessary.
15. Dry with cotton pellet(s) for some (do not use an air syringe). The cavity will look shinny. Keep this situation uncontaminated by saliva and/or blood.
16. Ensure proper isolation. Perhaps replace cotton rolls.
17. Mix the GIC according to the manufacturer's instructions. Only accept a properly mixed GIC; no runny or dry mixture is acceptable. Encapsulated GIC can also be used.

18. Insert the GIC material into the cavity with the applier/carver instrument. Push the GIC into the corner(s) of the cavity (in case of enamel overhang) with the round end of the medium excavator. Insert a second portion of GIC and press it into place with the round end of the large excavator. Fill the adjacent pits and fissures but DO NOT overfill much, as the excess has to be removed.
19. Rub some petroleum jelly over your index finger (very thin layer), place the finger over the tooth surface and press for 20 seconds.
20. Remove the visible GIC excess with the carver end of the applier/carver instrument.
21. Check the occlusion with articulation paper.
22. Wait until the material has set and then adjust the bite with a medium-sized excavator and/or carver instrument.
23. Remove petroleum jelly-covered top layer of the GIC with a large excavator and/or carver instrument. Ensure a smooth GIC-onto-enamel junction. Use the round end of the small and/or large excavator to achieve this.
24. Protect the restoration with a thin layer of petroleum jelly again.
25. Remove the cotton wool rolls.
26. Ask the patient not to eat for at least one hour.

Clinical Success Rate

There are many criteria that has been used to evaluate clinical success of the restorations including United States Public Health Service (USPHS)/Ryge criteria, FDI criteria, ART criteria and the modified from the above criteria. In the case of restorative materials, restoration performance is often assessed via variable outcomes of longevity including retention, secondary caries, margin integrity, surface wear (66).

Placing ART restorations mostly are done on the field such as school playgrounds or in a classroom. The USPHS criteria have been criticized for their limited sensitivity in detecting improved clinical performances of restorative materials currently in use. Consequently, the FDI criteria, as well as the common ART criteria, were used to assess ART restorations (66). Since the ART criteria have less detailed and include fewer clinical restoration characteristics than the FDI criteria but are easier

and faster to use. Importantly, the modified ART criteria are a reliable measurement instrument for assessing ART restoration survival. Therefore, it is recommended as the ART criteria to use for restoration and tooth survival assessment in clinical oral health service studies (67). No significant difference is seen between USPHS and ART criteria when both were applied for same ART restorations and ART criteria are more stringent than USPHS criteria (68). Moreover, no significant differences between the FDI and ART criteria were detected regarding survival outcomes of ART restorations (9). In conclusion, ART criteria have reliable assessment of ART restorations.

In order to standardization and able to compare longevity of the restoration, the same definition of success, survival, and failure are prerequisites (69).

“Success” defines a restoration that is still functioning and no intervention (repair or replacement) is indicated, at the evaluation period. In this regard, refurbishment, recontouring and polishing is not considered to be an intervention (69).

“Survival” defines a restoration that requires repair. This category would also include teeth that require endodontic intervention, but with the restoration remaining in place, with the access opening restored following the endodontic therapy (69).

While “Failure” will be considered if cases where a restoration must be replaced, or the tooth has been removed for the reason related to the restorations, such as tooth fracture, but unrelated to periodontal health or trauma (69).

Interestingly, there is a research suggests that re-restoration of failed ART may not be necessary because of the remineralization effect of GIC restorations (70). Boon et al. in 2010 suggested redefining ART success as the number of teeth retained asymptomatically until natural exfoliation rather than focusing on restorative success or failure, an approach which moves evaluation of oral health away from a mechanistic view to a more functional, holistic frame of reference (70).

Glass-ionomer Cements (GICs)

Glass-ionomer cements (GICs) were invented by Wilson and Kent in 1969 at the Laboratory of the Government Chemist in London, UK (71). GICs have had a wide range of clinical uses in restorative, lining, luting and sealing application (32). GICs is an acid-base cement based on weak polymeric acids and basic powdered glass. Their setting take place within water and results in a complex polysalt matrix (32).

Glass

The original glass was based on the composition of SiO_2-AlO_3-$AlPO_4$-$NaAlF_6$. Essentially, all GIC glasses have been based on a similar formula of calcium or strontium fluoroaluminosilicate glass (72).

Liquid

The liquid is a polymeric acid having carboxylate group(s), with a lower molecular weight to prevent gelation. The inclusion of tartaric acid delays the setting reaction, improve working time and manipulation of the cement (73). Another important liquid component in setting the reaction of GICs is water, which influences the acid-base reaction (74).

Setting reaction

The filler portion is made up of a fluoroaluminosilicate glass which can range from 40 to 75% by weight in the cement mix. The proportion of filler relates to the qualities required for the cement, for example, low-viscosity luting cements on fissure protection materials have less powder compared with high-strength and high-viscosity cements used as restorative materials that bear occlusal loading (75). The set cement becomes a composite comprising unreacted glass fillers which are surrounded by a siliceous gel, embedding in a matrix made up of poly acid salts holding cement together. During setting,

GICs are sensitive to both moisture loss and uptake. Loss of water leads to dehydration of the cement that causes subsequent surface crazing and increased opacity and results in weakened cement in wear resistance and less esthetics. Recently, the high powder/liquid (P:L) ratio cements have improved water sensitivity and does not need to be protected during the first 24 hours but 2 to 7 minutes for the initial set (32).

GICs are versatile acid-base materials with a variety of uses in modern dentistry because of their bioactivity when set that causes them to develop an interfacial ion-exchange layer with the tooth and results in the high durability of tooth surface adhesion as well as recharging and releasing fluoride (76). The bond stability of GICs can be attributed to the bonding mechanism, which is based on a chemical interaction between the calcium from hydroxyapatite and the carboxylic groups from polyacrylic acid (76). Such interactions result in the formation of a relatively stable ion-exchange layer at the interface of tooth and the material; composing of the calcium and phosphate from the tooth structure and the calcium, fluorine, silicon, aluminum and/or strontium from the GIC (76).

The principle behind the adhesion of GICs to tooth structure can be explained by two inter-related mechanisms. First principle is the hybrid layer of micromechanical interlocking where the polyalkenoic acid component of the GIC acts on exposing the collagen fibers present in dentin allowing the ion components of the cement to diffuse into the collagen matrix and create micromechanical bonds. The Second principle is the true chemical bond of the ion between the carboxyl group of the polyalkenoic acid and the calcium ions of the hydroxyapatite (HA) crystal bonding to the collagen fiber (77). Overtime, an ion-exchange layer is formed between the GIC and the tooth structure as ions continue to diffuse in the interface zone, and the material adhere more strongly to tooth structure (76).

Later on, as with most other materials, GICs have been subjected to waves of improvements and developments. There has an innovation of the material which adjust the power to liquid ratio as an attempt to overcome the weakness of the physical properties. In essence, when compared to low-viscosity GIC, high-viscosity GIC restorations showed better physical/mechanical properties and higher survival rates (78).

GICs have been widely used for the restoration of primary teeth because of its several advantages including fluoride release, chemical bonding to enamel and dentin, tooth preparation with minimal removal of sound structure, biocompatibility and being user-friendliness (79). Moreover, GICs are one of the materials that is highly acceptable for use in children (32). For many children, it is not possible to achieve adequate moisture control due to inability to place a rubber dam clamp, often due to inability to seal operative area with rubber dam, or behavioral issues (32).

Even though, dental care of the pediatric patient involves the consideration of a number of factors, including age, caries risk, behavioral capabilities and compliance of the child and the parents (32). The longevity of the restorations relies on number of factors related to clinical variables, operator ability, patients' characteristics, and dental materials (80). Other factors including the side of the tooth (right/left), the restored surface (mesial or distal), and the presence or absence of the antagonist tooth had no influence on the longevity of restorations as described in other studies with primary teeth (64).

In the mid- to late- 1990s, high powder:liquid ratio conventional GICs were introduced, alternatively termed 'packable' or 'high viscosity' GICs(74). The examples of high viscosity GICs (GIC) are ChemFlex® (Dentsply DeTrey, Konstanz, Germany), Ketac Molar Aplicap® (3M ESPE, Seefeld, Germany), EQUIA® system (GC corporation, Tokyo, Japan), Fuji IX GP® EXTRA (GC corporation, Tokyo, Japan). Among many brands of restorative materials in this research we will choose Fuji IX GP® EXTRA (GC corporation, Tokyo, Japan) brand because of the outstanding performance(81) and the popularity usage in Thailand. (**Table 3**) From the study of Bonifacio et al.(64) showed no GIC brand effect on the survival rate of proximal ART restorations after 3 years. GICs have specially designed for ART with lower curing and improved mechanical properties compared to low and medium viscosity cement, which has results in increased survival of restorations (48).

Recent systematic reviews (12) have reported the longevity of GIC in ART restorations is similar to either amalgam (59) or resin composite (60) in children. Another systematic review on survival and reason for failure of restoration in primary teeth, it has been found that the main reason for failure observed was secondary caries followed by restoration loss and marginal adaptation (13). However, the rate of secondary caries and clinical performance of GIC in occluso-proximal restorations was significantly better compared to others materials, amalgam, composite resin, polyacid-modified resin and compomer (82).

Table 3. Restorative material: manufactures, characteristics, general composition, and manufacturers' instructions.

Material (manufacturer)	Material type	Composition	Manufacturer's instructions
GIC (GC Fuji IX GP® EXTRA, GC Corporations, Tokyo, Japan) 	High-viscosity glass ionomer cement (self-curing restorative material)	Powder: fluoroaluminosilicate glass; polyacrylic acid powder Liquid: polyacrylic acid, distilled water	1. Apply GC Dentin Conditioner for 10 s 2. Rinse with copious amount of water 3. Gentle air dry for 5 s, leaving a moist surface 4. Drop 1 drop of liquid and 1 powder scoop at a 3.6:1 powder:liquid ratio, mix for up to 45 s 5. Apply to tooth surface
Polyacrylic acid cavity conditioner (Cavity conditioner®, GC Corporations, Tokyo, Japan) 	A mild polyacrylic acid solution designed to remove the dentinal smear layer and to condition dentin, thus enhancing the bond between glass ionomer cement and dentin.	10% polyacrylic acid 90% distilled water	1. After tooth preparation, apply DENTIN CONDITIONER to the bonding surfaces for 20 seconds 2. Rinse thoroughly with water. Dry blotting with a cotton pellet. DO NOT DESICCATE. Best results are obtained when prepared surfaces appear moist (glistening).

Silver diamine fluoride (SDF)

Silver topical products, such as Silver Diamine Fluoride (SDF), have been used in Japan since 1969 to arrest caries and reduce tooth hypersensitivity in primary and permanent teeth (83). Recently, the United States Food and Drug Administration (USFDA) approved SDF as a device for reducing tooth sensitivity (84), and off label use for arresting dental caries is now permissible and appropriate for patients (85, 86).

Silver Diamine Fluoride (SDF) or $Ag(NH_3)_2F$ is a colorless ammonia solution containing silver and fluoride ions. As neutral silver fluoride is unstable, it is commonly dissolved in ammonia-water to form a more stable complex ion (87). At present, the mechanisms of SDF on caries arrest are not fully understood, although it is hypothesized to be a combined effect through inhibiting cariogenic biofilm (88), preserving collagen from degradation(87), and also increasing dentin hardness (89). Silver ions are assumed to be responsible for anti-microbial action of SDF, inhibiting the growth of all tested oral bacteria and denature enzymes that would breakdown collagenous dentin (90). In 2013, Mei et al. found that SDF has an antimicrobial activity against the cariogenic bacteria associated with dental caries, Streptococcus mutans and Lactobacillus acidophilus (91). While fluoride enhances the remineralization of dental hard tissue and promotes deposition of fluoroapatite, which is more resistant to acidic degradation than the normal tooth structure (92).

The most used concentration is 38% which contains high fluoride concentration as 44,800 ppm. Some clinicians were concerned about the use of SDF in young children because of the risk of causing dental fluorosis. However, since only a very small amount of SDF solution is applied onto carious lesion, researchers concluded that occasional application of SDF is well below toxic concentrations (93). Moreover, Fluoride exposure was below the United State Environmental Protection Agency (EPA) oral reference dose. Silver exposure exceeded the EPA oral reference dose for cumulative daily exposure over a lifetime, but for occasional use, the total using amount is below the toxic concentrations (94). Moreover, serum concentrations of fluoride and silver after topical application revealed no potential toxicity (94).

Laboratory studies of 38% SDF have shown that it has effect in inhibiting dentin demineralization and preserving collagen from degradation (87). Moreover, after being treated with SDF, a highly remineralized surface zone rich in calcium and phosphate can be found on the

arrested cavitated carious lesion. The dentin collagen is protected by the remineralized mineral materials (95). 38% SDF inhibited demineralization and preserved collagen from degradation in demineralized dentin. In conclusion, SDF application positively influences dentin remineralization.

Apart from staining the arrested lesion black, no other significant complication of SDF use among children was reported (3). SDF is effective in arresting dentin caries in primary teeth among preschool children '(96).

There are many studies reported clinical success with SDF in arresting dental caries (27, 85, 97), including Fung et al. who studied about the frequency and concentration of applying SDF in order to arrest the dental caries. Fung et al. found that applying 38% SDF every 6 months is more effective than applying 12% SDF (98).

The laboratory studies also found that an intense anti-bacterial effect on cariogenic biofilm and halting of caries progression (87). From the systematic review (3) of clinical trials of Silver diamine Fluoride in arresting caries among children, it was found the overall percentage of active caries that became arrested was 81% with 95% confidence interval, (68% to 89%); P <0.001.

Additionally, SDF has not been shown to reduce adhesion of resin or glass ionomer restorative materials (28). In contrast, the laboratory study showed that conditioning with 38% SDF increased the resistance of the GIC and composite restorations to secondary caries (89). Moreover, *ex vivo* studies demonstrated that SDF increased the microhardness and mineral density of the outer surface of caries lesions (89).

A review concluded that SDF is a safe, effective, efficient, and equitable caries preventive agent that appears to fit with the (WHO) World Health Organization's Millennium Goals and fulfil the United States Institute of Medicine's criteria for 21st century medical care (27). One significant limitation to note, as stated above, is that SDF treatment is that it will stain carious lesion black. This appearance may not be acceptable for some children and parents. Hence, it is necessary to inform patients and parents of this outcome of SDF treatment. Pretreatment discussion about the pros and cons of SDF treatment with the children and their parents is vital to patient satisfaction (97).

Figure 4. 38% SDF (Saforide®, Toyo Pharmaceutical Co., Ltd., Japan).

Related studies of antibacterial-GICs

GICs have become the most used material for ART approach due to their chemical, physical, and biological properties (48). As the use and acceptance of GICs increase, finding by scientific research groups have led to improved current limitations due to their poor mechanical properties, the main weakness of this material (32). Modifications and improvements of GICs have been continued to increase longevity and improve other physical and mechanical properties such as flexural strength, fracture toughness, wear properties, fluoride release properties, and also anti-microbial properties (99).

In consequence of the effectiveness of the antimicrobial effect of conventional GIC against S. mutans is still questionable (100). The antimicrobial mechanism of GICs is also not fully clear (99). In order to overcome the concern of remaining bacteria in the cavities using ART technique. Consequently, there are many researches studies the modifying GICs with various antimicrobial agents to improve the antimicrobial property (20-23). The antimicrobial agents commonly used for modifying GICs are chlorhexidine (101), antibiotics (20) (ciprofloxacin, metronidazole, minocycline), benzalkonium chloride and cetylpyridinium chloride (102) were added but exhibited controversial results for achieving expected physical and mechanical properties of GIC.

Recently, there are studies on improving antibacterial activity, fluoride release properties, and physical properties including compressive strength, bonding efficacy as microleakage, shear bond strength of a GIC Containing SDF (29, 30). Studies 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 (29, 30).

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. The novel material has been tested through *in vitro* laboratories and showed interesting impressive results Thus, it has a potential of being a restorative material for ART. However, clinical trials about the longevity of SDF-GIC restoration in primary teeth have not been reported in the literature yet.

Table 4 shows the success rate of longitudinal ART clinical studies of GIC restoration in primary molars.

Table 4. Longitudinal ART clinical studies of GIC restorations of primary molars.

Authors	Material*	Criteria	Age (Years)	Follow-up period	Success rate at 6 Months		Success rate at 1 Year		Success rate at 2 Year	
					Cl.I	Cl.II	Cl. I	Cl. II	Cl. I	Cl, II
Luo et al., 1999. (12m) and Lo et al., 2001(68). (24m)	Chem-Flex®	ART criteria	6-14	6m, 12m, 24m	-	-	96.6	46.2	96	41.7
	Fuji IX®				-	-	89.7	61.5	92	42.6
Taifour et al., 2012(103).	Fuji IX®	ART criteria	6-7	12m, 24m, 36m	-	-	95	72	91	60
Honkala et al., 2003(104). (In clinic setting)	Chem-Flex®	ART criteria and USPHS	2-9	8.3m, 22m	-	-	99	100	91	83
Ersin et al., 2006(105).	Fuji IX GP®	USPHS	6-10	6m, 12m, 24m	100	90.2	100	83.1	96.7	76.1
Deepa and Shobha, 2010(106).	Amalgomer	ART criteria	4-9	12m	-	-	97.4	95.1	-	-
	Fuji IX®				-	-	94.9	88.5	-	-
Hilgert et al., 2014(107).	Ketac™ Molar Easymix	ART criteria	6-7	6m, 12m, 24m, 36m	99.1	89.5	98.2	80.9	93.4	66.2
Molina et al., 2017(108).	EQUIA® fil or Chemfil® ROCK	ART criteria	5.8-21.4	6m, 12m	100	92.5	100	81.6	-	-
Lopes et al. 2018(58).	Glass carbomer®	ART criteria	6-10	6m, 12m	-	69	-	56	-	-
	EQUIA fil®				-	83	-	58	-	-

*Materials of interest are Glass Ionomer-based materials;

ChemFlex™ (a conventional glass ionomer cement, Dentsply, DeTrey GmbH, Germany)

Fuji IX®/Fuji IX GP® (a high-strength glass ionomer cement, GC Corporation, Tokyo, Japan)

Ketac™ Molar/Ketac™ Molar Easymix (3M ESPE, Seefeld, Germany)

EQUIA Fil® (a comprehensive, glass ionomer-based, bulk-fill, rapid restorative system, GC Corporation, Tokyo, Japan)

Chemfil® ROCK (an advanced glass ionomer restorative, Dentsply, DeTrey GmbH, Germany)

Glass carbomer® cement has been developed from glass ionomer.

Amalgomer is a glass ionomer base with the strength of amalgam.

Chapter 3

Materials and Methods

Research Design

The study was a two-arm, parallel group, randomized controlled trial. The participants were allocated to one of the two arms to compare clinical evaluations between the novel GIC and the conventional GIC as ART restorative materials in terms of clinical performance in restoring and arresting carious lesions.

Population and Sample

1. Target Population

The population of this study was cavitated primary molars of children that were indicated for normal restoration without clinical characteristics of pulpal involvement (pain, swelling, fistula, abscess).

2. Study Population

The study population comprised cavitated primary molars of children aged 3-8 years old that were indicated for normal restorations without clinical characteristics of pulpal involvement (pain, swelling, fistula, abscess) in Ban Phaeo District in Samut Sakhon Province.

3. Sample Population

The sample population was cavitated primary molars of children aged 3-8 years old with class II cavities that were indicated for normal restorations without clinical characteristics of pulpal involvement (pain, swelling, fistula, abscess) in Ban Phaeo District in Samut Sakhon Province with the eligibility criteria as listed below:

Eligibility Criteria

The eligibility criteria were modified from the study of Lopes et al. 2018 (58) as follows:

1. Inclusion criteria

Children aged 3-8 years who have cavitated primary molars with the following characteristics:

- A class II lesion that can be accessed by using hand instruments (ICDAS 5 or 6) (33) according to the ART guidelines (6).
- No sign and symptoms of pulpal involvement (fistula, abscess, pulp exposure, or history of spontaneous dental pain and pathological mobility).
- No signs of tooth developmental defects or enamel defects such as hypomineralization, hypocalcification, hypoplasia.

Children whose parents or guardians filled in and signed the informed consent forms for their child to participate in the study.

2. Exclusion Criteria

Children with known sensitivities to silver or other heavy-metal ions, presence of any gingival or perioral ulceration or stomatitis.

Children with special health care needs.

Children whose cavitated primary molar has a deep carious lesion and a sign of pulpal exposure.

Sample Size

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 (109).

Since one patient represents one cavity for the study, the number of samples in each group was 60 children. This was a prospective study with 6- and 12-months of follow up time. To

compensate for sample patient who drop out, 20% of the calculated sample was added. Thus, the total sample size in the study was at least **75 teeth in each group** or **150 teeth in total**.

Sampling Method

All phases of this study were carried out in 5 schools in Ban Phaeo District of Samut Sakhon Province.

Children who fulfilled the eligibility criteria were recruited into the study. One primary molar per child was selected to prevent any cross-interaction of SDF through saliva which could affect the antibacterial activity of the restoration of interest. If there were more than one cavity meeting the inclusion criteria, one of them was randomly selected. In this circumstance, all the teeth that meet the inclusion criteria will be numbered and written on pieces of paper folded and placed inside an opaque box. A person who was not involved in the research was responsible for selecting one of the papers containing the tooth number to be selected and included in the research. The other cavitated carious lesions in the mouth of the selected children were referred to receive an appropriate treatment by dentists working in a public oral health center in the city.

Allocation

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

Simple randomization using a randomization program called sealed envelope™, https://www.sealedenvelope.com/simple-randomiser/v1/lists, was used to generate a scheme of random code of control and test group. Each child (representing one cavity) is considered as one sample. Therefore, each child had an equal chance of being assigned to either the control or the test group.

Interventions

The materials used in the ART technique in this study are:

1. Control group

   GIC (GC Fuji IX GP® EXTRA, GC Corporation, Tokyo, Japan)

2. Test group

   GIC (GC Fuji IX GP® EXTRA, GC Corporation, Tokyo, Japan)

   containing SDF solution (Saforide®, Toyo Pharmaceutical Co., Ltd., Japan)

Concealment

The randomization scheme was produced and a random code for each sample was placed in an opaque envelope. At the time of mixing the material, a dental assistant opened an envelope to get the assigned test and mixed the materials for the operator. However, the operator was not concealed due to the different characteristics of the materials. The patients were not informed as to which arm of the randomized groups they will were in.

Instruments

Instruments during different visits were as follows:

A. **During sample selection (Screening) Visit**

   1. Student tables
   2. Artificial clinical light
   3. Oral examination set (a tray, a mouth mirror, an explorers no.5, a cotton plier)
   4. Cotton rolls and gauze pads
   5. Surgical gloves
   6. Informed consent form (See in Appendix A)
   7. Screening record form (See in Appendix A)
   8. Consent forms (See in Appendix A)

B. **During Treatment Visit**

   1. Toothbrushing set (toothbrush and fluoridated (1000 ppm) toothpaste)
   2. Student tables
   3. Artificial clinical light
   4. Oral examination set (a tray, a mouth mirror, an explorers no.5, a cotton plier)

5. Cotton rolls and gauze pads
6. Surgical gloves
7. Data record forms (See in Appendix B)
8. Hand instruments for atraumatic restorative technique (spoon, carver, flat-ended instruments)
9. T-band matrix and wooden wedges
10. Dry and wet cotton pellets
11. Petroleum jelly (Vaseline®)
12. Polyacrylic acid cavity conditioner (Dentin conditioner®, GC Corporation, Tokyo, Japan)
13. Restorative materials; a GIC (GC Fuji IX GP® EXTRA, GC Corporation, Tokyo, Japan)
14. Silver diamine fluoride (Saforide®, Toyo Pharmaceutical Co., Ltd., Japan)
15. Mechanical pipette volume 0.1-3 μL (Proline® Plus, Sartorius, Germany.)
16. Randomization envelopes

C. During Evaluation Visit

1. Student tables
2. Artificial clinical light
3. World Health Organization (WHO) CPI probes
4. Oral examination set (a tray, a mouth mirror, an explorers no.5, a cotton plier)
5. Cotton rolls and gauze pads
6. Dry and wet cotton pellets
7. Surgical gloves
8. Case record forms (See in Appendix B)

Methods

The research study was registered in the website www.clinicaltrials.gov and www.clinicaltrials.in.th. This proposal was written following the guidelines of the Consolidated Standards of Reporting Trials Statement—CONSORT (110) and CONSORT participant flow chart of

the progress through the phase of a parallel randomized trial of two groups (110). The diagram of the study is shown in **Figure 5**.

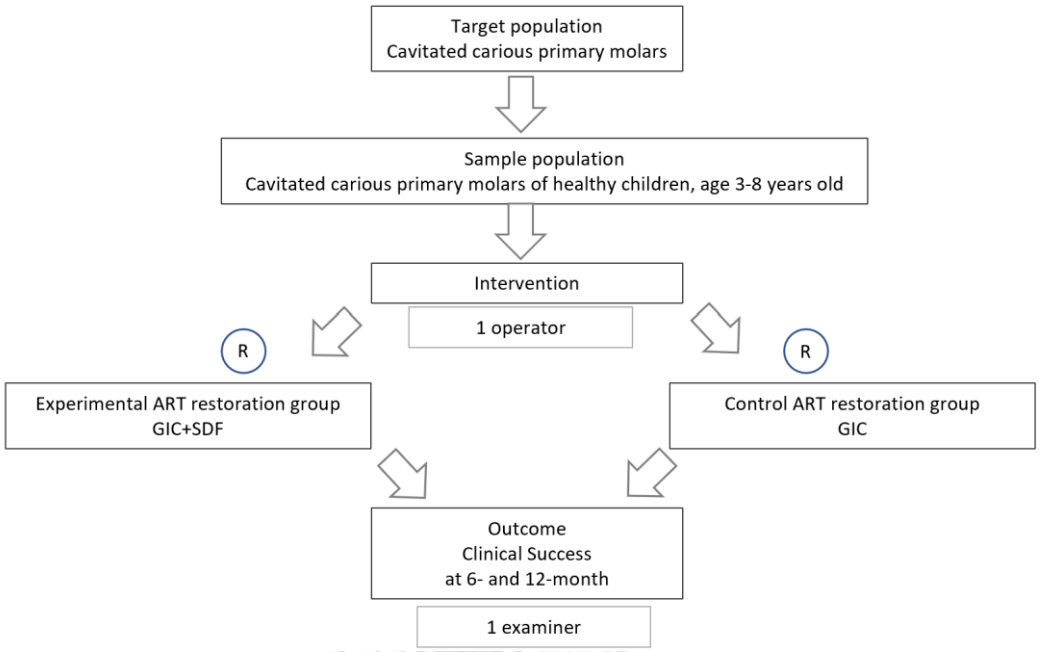

Figure 5. Diagram of the study.

A. Calibration and Training Session

All restorations were placed by one operator with the same assistant to keep the technique as uniform as possible. The examiner, another operative dentist who did not take part with restorations placement, evaluated the restoration at both 6- and 12-months follow-up. The procedures were standardized as described below:

a. Screening dentist

The screening dentist was calibrated by an experienced pediatric dentist. The training included diagnosing carious primary molars in accordance with the criteria established by the ICDAS (111) on photos and in children through clinical oral examination at a pediatric dentistry clinic.

b. Operator

Since the operator's skills and performance is a key factor affecting the success of ART restorations, a single trained operator performed all the restorations during the trial (112). The operator was trained by a specialist in pediatric/dental public health who has experience in placing ART restorations in a field setting. Training sessions included both the principle of ART and practices in laboratory and clinic. The ART procedures followed the approach outlined in the ART manual (6). Training and calibration was performed in the clinical setting in 10 patients.

c. Examiner

The dentist who is an independent examiner was an operative dentist. Training comprised of evaluating at least 10 ART restorations following the ART criteria in children. During the study period, the intra-examiner reliability was evaluated at baseline and follow up examinations.

d. Dental assistant

The dental assistant was responsible for mixing and manipulating the GIC in accordance with the manufacturers' instructions and transferring the mixture to the operator. During training session, the dental assistant practiced mixing the material following the manufactures' instruction until meeting the standardized mixing technique.

B. Screening

The treatment was performed using 3 student's tables as a portable bed and an operating light in a classroom.

1. Cleaning

The screening dentist cleaned and dried the teeth thoroughly with cotton pellets.

2. Screening

One dentist performed the clinical examination in a kindergarten classroom using a dental explorer, mouth mirror, and electric light bulb. Food debris was gently removed to avoid under recording of dental caries. The diagnostic criteria followed the recommendation of WHO (113) (**Table 5**) for dental caries experience and visible plaque index (VPI) for presence of dental plaque (114).

Table 5. WHO criteria

Code			Condition/Status
Primary teeth	Permanent teeth		
Crown	Crown	Root	
A	0	0	Sound
B	1	1	Caries
C	2	2	Filled, with caries
D	3	3	Filled, no caires
E	4	-	Missing due to caries
-	5	-	Missing for any other reason
F	6	-	Fissure sealant
G	7	7	Fixed dental prosthesis abutment, special crown or veneer/implant
-	8	8	Unerupted tooth (crown)/unexposed root
-	9	9	Not recorded

3. Collect the data

The dentist screened for the followings.

3.1 Visible plaque index (VPI)

The visible plaque of buccal and lingual surfaces of six index teeth (55, 51, 63, 75, 71 and 83) were recorded as presence of visible plaque (score 1) or absence of visible plaque (score 0). VPI scores were calculated as the percentage of the number of surfaces with visible plaque relative to the total number of surfaces examined (114).

3.2 Baseline caries experience (dmft)

Caries experience was measured by dmft index. A tooth was recorded as decayed (dt) when a lesion had an unmistakable cavity, undermined enamel, or detectably softened floor or wall. A tooth was recorded as missing (mt) when it was extracted due to caries. A tooth was recorded as filled (ft) when it was permanently filled without caries.

3.3 Class II lesions

The dentist examined for cavitated primary molars (ICDAS 5-6 (111)) which can be assessed by hand instruments following the eligibility criteria. The dental assistant noted down the cavity of interest as G2 (describe in Treatment Record forms in appendix A).

4. Inform teachers and parents/guardians

The informed consent forms were given to parents or guardians. Information about the patient's age (birthdate), gender, and their socio-economic status of patient as well as their medical and dental history was collected.

C. Treatment

The ART restorations were performed by one trained calibrated dentist, aided by one trained dental assistant, in a classroom where the child laid on connecting 3 student's tables as a dental chair, with portable artificial clinical light for illumination. The procedure was done according to the ART guidelines as described by Frencken et al (42).

1. Moisture control

Isolate the tooth with cotton wool rolls. The treatment area was kept free from saliva.

2. Plaque removal

With an explorer, plaque and food debris was gently removed from the deepest parts of the available pits and fissures.

3. Cleaning

The operator cleaned and dried the teeth thoroughly with cotton pellets.

4. Remove caries

Hand excavators compatible with the size of the carious cavity were used. Removing the infected dentin from the dentin-enamel junction (firm to tactile testing with a probe) to confirm a hard cavity margin of the cavity, while softened caries were left on the

pulpal floor if its removal was likely to endanger the dental pulp in keeping with the minimally invasive approach to caries management (115).

5. Clean the cavity

Cavity walls were cleaned with cotton pellets moistened with water.

6. Matrix and wedge

A matrix was applied and stabilized with a wooden wedge to define the proximal contour of the cavity.

7. Condition the dentin

A drop of polyacrylic acid cavity conditioner was applied with a micro-brush (Dentin conditioner®, GC Corporation, Tokyo, Japan) for 20 seconds. Then, the cavity was washed with three cotton pellets moistened with water and dried using three more pellets.

8. Prepare and Mix the materials

8.1 For the control group

A trained chairside assistant prepared the correct dosage (one spoon measure of the powder to one drop of polyacrylic acid) placed the polyacrylic acid bottle vertically and upside down, waited a few seconds until the bubbles rose and then dripped two drops. The second drop was used to mix with the powder because the initial drop may contain bubbles. The second drop of polyacrylic acid was spread over the paper pad with plastic spatula. Then, the powder was mixed in the acid in two stages— the first part for 10 seconds and the second part for 15-20 seconds, with moderate pressure applied. The material was used only when it was still glossy.

8.2 For the test group

A trained chairside assistant prepared the correct dosage (one spoon measure of the powder to one drop of polyacrylic acid): placed the polyacrylic acid bottle vertically and upside down, waited a few seconds until the bubbles rose and then dripped two drops. The second drop was used to mix with the powder because the initial drop may contain bubbles. The second drop of polyacrylic acid was spread over the paper pad of two μl of SDF (Saforide®, Toyo Pharmaceutical

Co., Ltd., Japan) was pipetted on the paper mixing pad, and the second drop of polyacrylic acid was mixed over the paper pad with plastic spatula. Then, the powder was mixed in the acid—the first part for 10 seconds and the second part for 15-20 seconds, with moderate pressure applied. The material was used only when it was still glossy.

9. Material insertion

The GIC material was inserted into the cavity with a #1 spatula followed by finger pressure using petroleum jelly for a few seconds. For occlusal-proximal cavities, an adapted matrix strip was used with a wooden wedge to maintain it in place, providing appropriate contour to the restoration. Protecting the restoration with petroleum jelly is necessary to inhibit syneresis and imbibition. The wooden wedge and matrix were removed.

10. Check the occlusion

After the initial set (approximately 5 minutes), the occlusion was checked with an articulating paper. If necessary, sharp instruments were used for adjustments. In that case, a new layer of petroleum jelly was then applied to the surface of the restoration.

11. Post-operative Instruction

The patient was instructed not to eat solid food for 1 hour. Also, school staff was asked to supervise the children to guarantee that patients followed this recommendation.

D. Evaluation

The treatment was performed using 3 student's tables as a portable bed and an operating light. The evaluation examination was held in the children's school.

1. Cleaning

The examiner cleaned and dried the teeth thoroughly with cotton pellets.

2. Moisture control

The tooth was isolated with cotton rolls. The area was kept free from saliva.

3. Evaluation

The restorations were evaluated according to the modified ART evaluation criteria modified from ART criteria according to Lo and Holmgren, 2001 (47, 78) (**Table 6**) aided

with dental mouth-mirrors and CPI probe (diameter 0.5 mm) to measure the size of any marginal defect, the amount of wear, and secondary caries.

4. Data Collection

Dental assistant noted down the evaluation code and related data in the treatment recording form.

During the study period, restored teeth that caused pain and were not considered viable was extracted. For the most part, in the case of mechanical failure where parts of the restoration remained such the teeth was considered viable. Additionally, if the child was not experiencing pain, the restoration was left alone and the teeth exfoliated naturally (49).

Table 6. Evaluation criteria.

Code	Criteria
0	Present, in good condition
1	Present, slight marginal defect (≤0.5mm), **no repair** is needed
2	Present, slight wear (≤0.5mm), **no repair** is needed
3	Present, gross marginal defect (>0.5mm), repair is needed
4	Present, gross wear (>0.5mm), 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	Not present, restoration is repaired or replaced by another restoration
7	Tooth is missing, exfoliated or extracted
8	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 failure. Code 8 were considered as failure according to the intention-to-treat analysis.

Measurement

A. Variables

1. Independent variable

The independent variable is the intervention given, GIC and SDF-GIC.

2. Dependent variable

The dependent variable is the clinical success of the treatment at 6 and 12 months.

B. Outcome Measurement

1. Primary Outcome Measurement

- The primary objective of this trial is to determine whether the clinical success of a novel material (SDF-GIC) is comparable to of a standard material (GIC) following the modified ART criteria.

- Clinical success following the ART evaluation criteria in **Table 5.**

The ART restorations with scores 0, 1 and 2 were considered successful; those with scores 3-8 were considered as failures. Intention to treat (ITT) analysis was used in this study.

2. Secondary Outcome Measurements

2.1 Number of caries (active or inactive) in case of quotations partially or completely missing.

2.2 The relationship between the clinical success of restoration and type of ART restorative material according to other variables (type of surface, proximal contact, type of arch and type of molar).

2.3 Predictive model for clinical success of restoration by various independent variables (type of ART restorative material, type of surface, proximal contact, type of arch and type of molar).

C. Control Measure for Reliability of the Data

The examiner was assessed for the intra-examiner reliability with respect to the recording of clinical success based on the modified ART criteria (Table 5). At the recall

examination, the examiner examined 30 children (20% of sample population) with respect to clinical success of the restoration. Kappa at greater than 0.8 will be accepted for excellent agreement (116).

D. Data Collection

Demographic data was completed by a dental assistant who filled up the data record form (Appendix A). Outcomes for clinical success was assessed and compared after 6 and 12 months of the treatment by one independent calibrated examiner other than the operator.

The data collection form comprises the following information:

1. Demographic data
    a. Name
    b. Date of birth
    c. Sex
    d. School
2. Clinical success conclusion code (Primary outcome)
    a. Success = clinical characteristics shows all criteria of success
    b. Failure = clinical characteristics shows at least one criterion of failure or the restoration was not evaluated at follow-up.
3. Clinical data as noted as other variables affecting the restoration longevity
    a. Type of teeth (first molar, second molar)
    The scoring for Type of teeth will be defined as follows:
        1 = first molar
        2 = second molar
    b. Type of arch (maxilla, mandible)
        1 = maxilla
        2 = mandible
    c. Surface of cavity (mesial, distal)
        1 = mesial

2 = distal

d. Occluding tooth (presence, absence)

1 = presence

2 = absence

e. Proximal contact (presence, absence)

1 = presence

2 = absence

f. Baseline caries experience (dmft)

Data dmft was recorded as a total number of dmft.

(d = number of decayed teeth,

m = umber of missing teeth,

f = number of filling teeth)

g. Visible plaque index (VPI)

Data VPI was calculated as a percentage.

0 = absence

1 = presence

Statistical Analysis

The Data was entered and analyzed using the computer Statistical Package for the Social Science Plus version 22.0 (SPSS Inc., Chicago, Illinois, USA). The level of statistical significance was set at $p < 0.05$.

A. Demographic variables

1. **The baseline demographic data of the two groups** (age, sex, surface type, arch distribution, tooth distribution, presence of proximal contact, baseline caries experience (dmft), and percentage of dental plaque (VPI)) were presented by **descriptive statistics**, using the mean and standard deviation for continuous data and percentage for categorical data as shown in **Table 7**.

2. Compared **the difference of each categorical baseline demographic variables** between treatment groups. The data was analyzed using **Chi-square test**.

For the continuous baseline demographic variables, the data was tested for normality by using **Kolmogorov-Smirnov test**.

The differences between treatment groups was analyzed using **independent t-test** for normality distributed data and **Mann-Whitney U test** for skewed data.

Table 7. Baseline demographic variables and descriptive statistics use.

Variables	Type of Variable	Descriptive Statistics
Age	Continuous	Mean, S.D.
Sex	Categorical: dichotomous	Percentage, ratio
Type of tooth	Categorical: nominal (first molar, second molar)	Percentage
Type of Arch	Categorical: dichotomous (maxilla, mandible)	Percentage
Type of Surface	Categorical: dichotomous (mesial, distal)	Percentage
Proximal contact	Categorical: dichotomous (presence, absence)	Percentage
Baseline caries experience (dmft)	Continuous	Mean, S.D.
Visible Plaque Index (VPI)	Continuous	Percentage Mean, S.D.

B. Outcome variables

1. Primary outcome

- **The clinical success of both test and control** ART restorative materials was presented by **descriptive statistics** (number and percentage of tooth) **(Table 8)**.
- **The difference of success rates between test and control** ART restorative materials was compared by **chi-square test**.

Table 8. Primary outcome variables and descriptive statistics use.

Outcome Measurement	Variables	Type of Variable	Descriptive Statistics
Primary	Clinical success rate	Categorical: dichotomous (success, failure)	(Number, Percentage)

2. Secondary outcome

2.1 - **The number of partly or completely missing restorations (active and inactive)** between test and control ART restorative materials was presented by **descriptive statistic** (number and percentage of tooth) **(Table 9).**

- The difference of number of partly or completely missing restorations (active and inactive) between test and control ART restorative materials was compared by **Fisher's exact test.**

Table 9. Secondary outcome.

Outcome Measurement	Variables	Type of Variable	Descriptive Statistics
Secondary	Rate of partly or completely missing restoration	Categorical: dichotomous (inactive, active)	(Number, Percentage)

2.2 The difference of the clinical success rate of restoration between **test and control** ART restorative materials according to other variables (type of surface, proximal contact, type of arch and type of molar, baseline caries experience, visible plaque index, age)) was compared by **Chi-square test.**

2.3 Predictive model for clinical success of all restorations by various independent variables (type of ART restorative material, type of surface, proximal contact, type of arch and type of molar, baseline caries experience, visible plaque index, age) was calculated by **logistic regression.**

Chapter 4

Results

Baseline characteristics

A total of 653 children from 5 schools in Ban Phaeo district, Samut Sakhon Provinces was examined, 502 children were excluded because they did not meet the inclusion criteria, and one child whose parent declined to participate. Finally, there were 150 children enrolled in the study (75 children in each group). A CONSORT flow diagram showing the number of children and restorations present and absent at two evaluation times is presented in **Figure 6**.

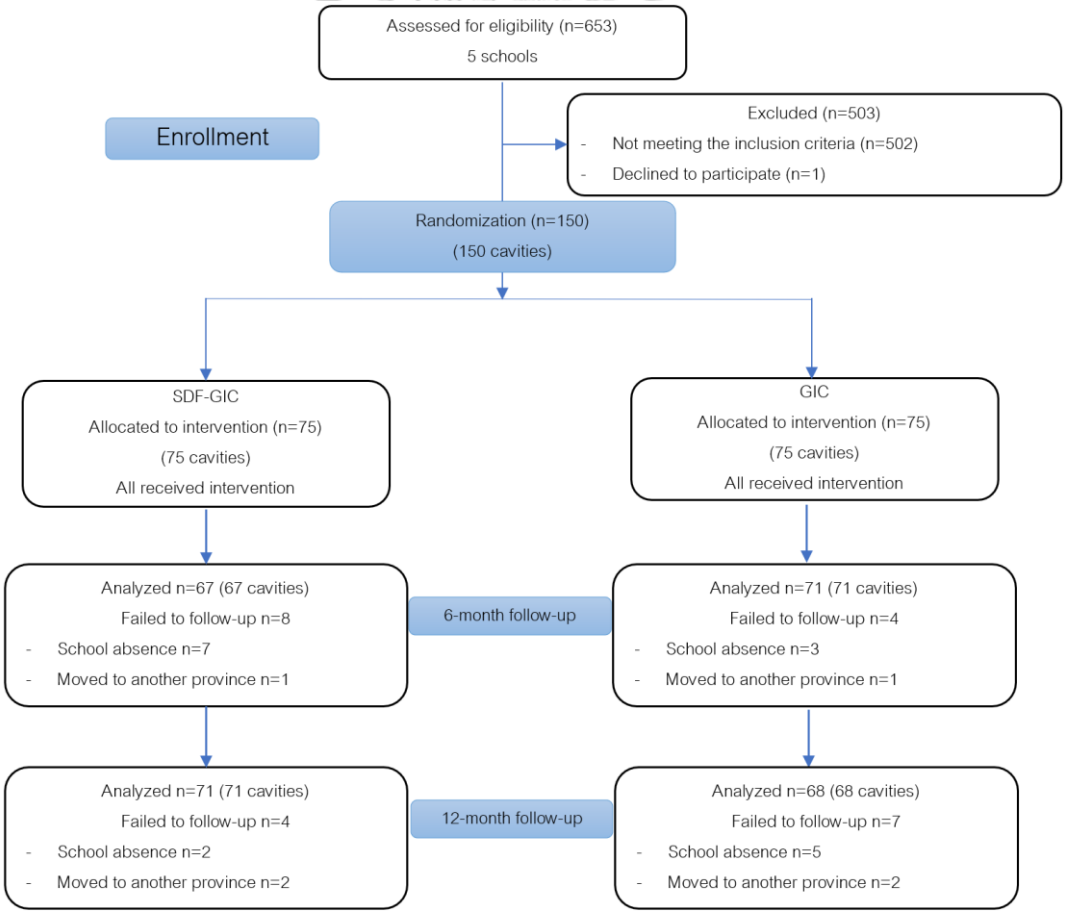

Figure 6. Flow diagram on the randomized trial.

The mean age of children was 6.3 (± 1.06) years, ranging from 3- to 8-years old. The mean dmft scores for 150 children were 6.93 ± 3.66 and mean visible plaque index (VPI) were 80.56%. Other baseline characteristics of the children and the restored cavities (sex, mean dmft score, surface type, arch distribution, and tooth distribution) can be seen in **Table 10**. Similar distribution was shown between the test and control study groups.

Table 10. Baseline characteristics of the children and the restored cavities.

(Independent t-test and Chi-square test)

	Test: SDF-GIC	Control: GIC	P-value*
Demographic background			
Sex: n (%)			
Male	38(50.7)	38(50.7)	1.000
Female	37(49.3)	37(49.3)	
Age: mean ± SD	6.26 ± 1.11	6.25 ± 1.01	0.958[a]
Oral health Status			
dmft: mean ± SD	6.91 ± 3.86	6.95 ± 3.48	0.947 [a]
%VPI: mean ± SD	81.08% ± 18.25	80.00% ± 18.75	0.714 [a]
Clinical characteristics			
Surface type: n (%)			
OM	37 (49.3%)	34 (45.3%)	0.624
OD	38 (50.7%)	41 (54.7%)	
Arch distribution: n (%)			
Maxilla	39 (52%)	38 (50.7%)	0.870
Mandibular	36 (48%)	37 (49.3%)	
Tooth distribution: n (%)			
First primary molar	46 (61.3%)	49 (65.3%)	0.611
Second primary molar	29 (38.7%)	26 (34.7%)	
Proximal Contact: n (%)			
No	13 (17.3%)	10 (13.3%)	0.497
Yes	62 (82.7%)	65 (86.7%)	

[a] Independent sample *t*-test

Children were evaluated after 6 months (n=138; 92%) and 12 months (n=139, 92.7%). The drop-out rate is 8 % and 7.3% at 6- and 12-month follow-ups, respectively. The reason for not being able to assess the restorations were mainly due to the children being absent from school on the day of examination and families moving to other provinces (Figure 6). Due to the covid-19 outbreak situation in February and March 2020, the examiner could not go to school to re-evaluate the children who were absent from school at 6 months.

Cohen's kappa coefficient or k values was used to determine the repeatability of the examiner (117). In our study, the examiner re-evaluating 20% of children (60 children). An intra-examiner kappa coefficient values for 6- and 12-month evaluation were 0.84 and 0.82 which showed an excellent agreement (116, 117).

Primary Outcome Analysis

Clinical Success

The status of restorations was determined at 6 and 12 months (**Table 11**). Fifty percent of restorations were assessed to be in good condition (code 0) or slight defects that did not require repair (code 1 and 2) while the principle reason for failure was that the restoration was missing either partly or completely (code 5). According to the intention-to-treat analysis, all teeth that were missing exfoliated, extracted, or not assessed were evaluated as failure.

Table 11. Number of restorations scored in the different evaluation codes for both groups at each assessment time.

Code	Criteria	Test (SDF-GIC)		Control (GIC)	
		6m	12m	6m	12m
0	Present, in good condition	37	35	46	36
1	Present, slight marginal defect (≤0.5mm), no repair is needed	8	10	8	7
2	Present, slight wear (≤0.5mm), no repair is needed	2	1	1	1
3	Present, gross marginal defect (>0.5mm), repair is needed	4	3	2	1
4	Present, gross wear (>0.5mm), repair is needed	2	2	3	0
5a	Restoration partly or completely missing with inactive caries, no repair is needed	3	6	0	4
5b	Restoration partly or completely missing with active caries, repair is needed	10	11	11	16
6	Restoration is repaired or replaced by another restoration	1	1	0	0
7	Tooth is missing, exfoliated, or extracted	0	2	0	3
8	Restoration is not assessed; child is not present	8	4	4	7
(0,1,2)	Success	47	46	55	44
(3-7)	Failure	20	25	16	24
(8)	Exclude	8	4	4	7

The overall success rates (95 percent confidence interval [95% CI]) at the 6-month follow-up for the SDF-GIC and GIC were 62.7% (50.7–73.6) and 73.3% (61.9 – 82.9), respectively, as shown in **Table 12**. No significant difference was detected between the study groups (Chi-square, p=0.161). At 12 months, the overall success rates of both materials were 61.3 percent (49.4-72.4) for the SDF-GIC group and 58.7 percent (46.7-69.9) for the GIC group. The difference was not significant (Chi-square, p= 0.739).

Table 12. Number of restorations as clinically successful for both study groups at 6- and 12-months, along with success rate, prevalence risk ratio, and p-value.

Follow-up Period	Material	Success rate (95% CI)	Prevalence Risk ratio (95% CI)	P-value
6-month	SDF-GIC	62.7 (50.7 - 73.6)	0.79 (0.57, 1.09)	0.161
	GIC	73.3 (61.9 - 82.9)		
12-month	SDF-GIC	61.3 (49.4 – 72.4)	1.06 (0.76, 1.47)	0.739
	GIC	58.7 (46.7 – 69.9)		

Secondary Outcome Analysis

2.1 The restorations that partly or completely missing with active caries

Figure 7. shows the number of restorations that were partly or completely missing with inactive and active caries of both materials at 6- and 12-month follow-up. There was no difference between test and control ART restorative materials at both 6 and 12 months. (Fisher's exact test (p=0.223 at 6 months, p=0.460 at 12 months))

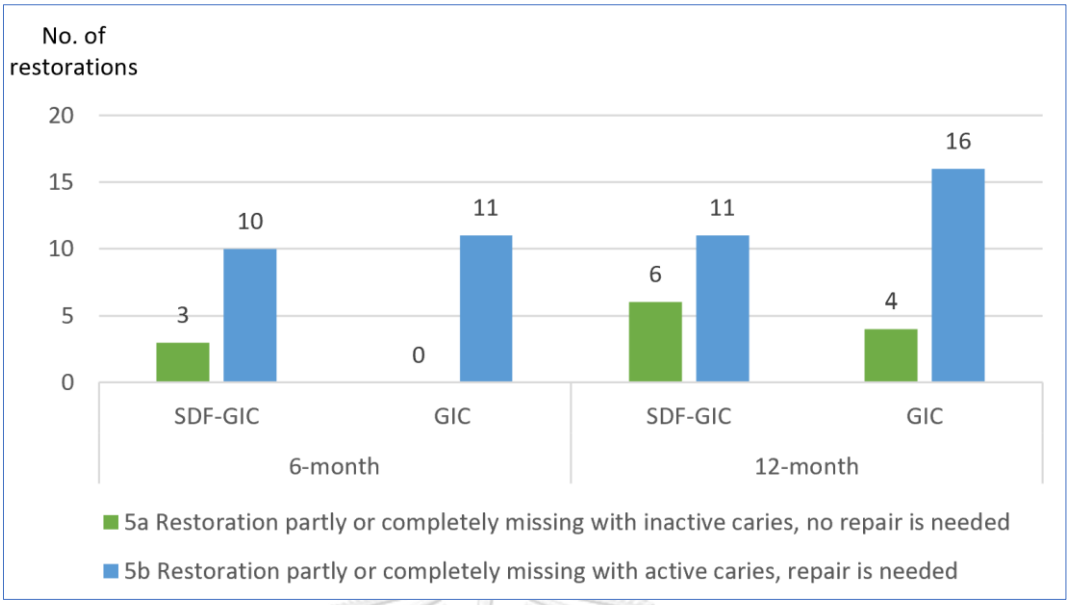

Figure 7. Number of restorations partly or completely missing with active caries.

2.2 The difference between the clinical success of restoration of **test and control** ART restorative materials and variables

There was no statistically significant difference between the clinical success rate and type of surface, presence proximal contact, type of arch, type of molar, and age group (**Table 13**).

Table 13. Success rate of restorations according to type of tooth surface, presence of proximal contact, type of arch, type of molar, and age group at 6- and 12-month follow-ups

	Group 1: SDF-GIC % (n/N)	Group 2: GIC % (n/N)	*p*-value
Overall			
6 months	62.7 (47/75)	73.3 (55/75)	0.161
12 months	61.3 (46/75)	58.7 (44/75)	0.739
Type of surface			
OM			
6 months	64.9 (24/37)	76.5 (26/34)	0.284
12 months	59.5 (22/37)	61.8 (21/34)	0.843

	Group 1: SDF-GIC % (n/N)	Group 2: GIC % (n/N)	*p*-value
OD			
6 months	60.5 (23/38)	70.7 (29/41)	0.339
12 months	63.2 (24/38)	56.1 (23/41)	0.523
Type of molar			
First molar			
6 months	60.9 (28/46)	77.6 (38/49)	0.078
12 months	63.0 (29/46)	63.3 (31/49)	0.982
Second molar			
6 months	65.5 (19/29)	65.4 (17/26)	0.992
12 months	58.6 (17/29)	50.0 (13/26)	0.522
Type of arch			
Maxilla			
6 months	64.1 (25/39)	78.9 (30/38)	0.149
12 months	66.7 (26/39)	60.5 (23/38)	0.576
Mandible			
6 months	61.1 (22/36)	67.6 (25/37)	0.565
12 months	55.6 (20/36)	56.8 (21/37)	0.918
Proximal contact			
presence			
6 months	61.3 (38/62)	72.3 (47/65)	0.187
12 months	59.7 (37/62)	60.0 (39/65)	0.970
absence			
6 months	69.2 (9/13)	80.0 (8/10)	0.560
12 months	69.2 (9/13)	50.0 (5/10)	0.349
Age			
3-5Y			
6 months	61.3 (19/31)	70.6 (24/34)	0.429
12 months	67.7 (21/31)	50.0 (17/34)	0.147

	Group 1: SDF-GIC % (n/N)	Group 2: GIC % (n/N)	*p*-value
6-8Y			
6 months	63.6 (28/44)	75.6 (31/41)	0.231
12 months	56.8 (25/44)	65.9 (27/41)	0.393

2.3 The relationship between the clinical success of all restorations and variables

The univariate logistic regression analysis showed that the success rate at 6 and 12 months was not significantly influenced by the type of restorations, type of surface, presence of proximal contact, type of arch, type of molar, visible plaque index, baseline caries experience, age, gender, primary caregiver, father's education, mother's education, family monthly income, age at start self-tooth brushing, assistance of tooth brushing, toothpaste usage, age at start using tooth paste, fluoride toothpaste, tooth brushing frequency, after toothbrushing behavior, and snack-intake frequency (**Table 14**). The results of the multilevel logistic regression analysis are presented in **Table 15.** Age at start tooth brushing significantly influenced the success rate of restorations ($p<0.05$).

Table 14. Logistic regression model of the success of restoration at 6- and 12-months follow-up.

Explanatory variables	6-month		12-month	
	Unadjusted Odds ratio	*p*-value	Unadjusted Odds ratio	*p*-value
Type of restorative				
SDF-GIC	0.61 (0.31, 1.22)	0.163	1.12 (0.58, 2.15)	0.739
GIC [a]	Ref	1	Ref	1
Type of surface				
Occluso-mesial (OM)	1.24 (0.62, 2.46)	0.547	1.05 (0.54, 2.01)	0.894
Occluso-distal (OD) [a]	Ref	1	Ref	1
Proximal contact				
None	1.4 (0.51, 3.81)	0.51	0.96 (0.39, 2.38)	0.926
Presence [a]	Ref	1	Ref	1
Type of arch				
Maxilla	1.38 (0.7, 2.75)	0.356	1.37 (0.71, 2.63)	0.351
Mandible [a]	Ref	1	Ref	1
Type of molar				
1st primary molars	1.2 (0.59, 2.44)	0.611	1.43 (0.73, 2.81)	0.3
2nd primary molars [a]	Ref	1	Ref	1
Visible plaque index	1 (0.15, 6.45)	1	1 (0.98, 1.02)	1
Baseline caries experience (dmft)	1.07 (0.97, 1.18)	0.16	1 (0.86, 1.16)	1
Age (mean)	1.08 (0.78, 1.5)	0.637	0.99 (0.73, 1.35)	0.938
Gender				
male	Ref	1	Ref	1
Female	0.85 (0.43, 1.69)	0.644	0.77 (0.4, 1.47)	0.424
Primary care giver				
Father and/or mother	1.25 (0.62, 2.53)	0.526	1.15 (0.59, 2.25)	0.68
Other relative	Ref	1	Ref	1

Explanatory variables	6-month		12-month	
	Unadjusted Odds ratio	*p*-value	Unadjusted Odds ratio	*p*-value
Father's education				
Mandatory education	Ref	1	Ref	1
Higher education	0.88 (0.44, 1.74)	0.705	1.36 (0.69, 2.67)	0.376
Mother's education				
Mandatory education	Ref	1	Ref	1
Higher education	1.12 (0.55, 2.27)	0.753	1.05 (0.54, 2.01)	0.894
Age at start tooth brushing				
0-24 months	2.53 (1.22, 5.25)	0.013*	2.86 (1.39, 5.87)	0.004*
Over 24 months	Ref	1	Ref	1
Age of start self-tooth brushing				
1-36 months	1.48 (0.63, 3.47)	0.364	1.17 (0.54, 2.55)	0.694
Over 36 months	Ref	1	Ref	1
Assistance of tooth brushing				
No	Ref	1	Ref	1
Yes	0.79 (0.37, 1.7)	0.545	1.09 (0.52, 2.31)	0.82
Toothpaste usage				
No	Ref	1	Ref	1
Yes	2.15 (0.13, 35.1)	0.591	1.51 (0.09, 24.59)	0.773
Age of start using toothpaste				
0-2 years	1.26 (0.61, 2.6)	0.539	1.43 (0.71, 2.86)	0.318
Over 2 years	Ref	1	Ref	1
Fluoride toothpaste				
No	Ref	1	Ref	1
Yes	1.31 (0.45, 3.85)	0.619	2.09 (0.73, 5.96)	0.167
Tooth brushing frequency				

Explanatory variables	6-month		12-month	
	Unadjusted Odds ratio	*p*-value	Unadjusted Odds ratio	*p*-value
Once daily	Ref	1	Ref	1
More than once daily	1.23 (0.52, 2.91)	0.641	0.96 (0.42, 2.23)	0.932
After tooth brushing behavior				
No snack/food intake	**Ref**	**1**	Ref	1
Have	**0.86 (0.42, 1.73)**	**0.668**	1 (0.51, 1.95)	1
Snack intake frequency				
≤ 2 times/day	Ref	1	Ref	1
> 2 times/day	1.09 (0.55, 2.16)	0.812	1.49 (0.77, 2.88)	0.231

[a] reference category

Table 15. Multivariate logistic regression model of the success rate of restorations at the 12-months follow-up.

Explanatory variables	Adjusted Odds ratio[b]	95% CI	*p*-value
Type of restorative material			
SDF-GIC	1.18	0.6 - 2.31	0.635
GIC	Ref	1	1
Age of start tooth brushing			
0-24 months	2.89	1.4 - 5.93	0.004*
Over 24 months4	Ref	1	1

[a] Reference category

[b] Excluded non-significant variables: type of surface, presence of proximal contact, type of arch, type of molar, visible plaque index, baseline caries experience, age, gender, primary caregiver, father's education, mother's education, family monthly income, age at start self-tooth brushing, assistance of tooth brushing, toothpaste usage, age at start using tooth paste, fluoride toothpaste, tooth brushing frequency, after toothbrushing behavior, and snack-intake frequency

Chapter 5

Discussion

Atraumatic Restorative Treatment (ART) is a part of the contemporary caries management philosophy of minimal intervention dentistry (118, 119). ART is an economical and effective method for preventing and controlling carious lesion development in vulnerable populations (119). GICs have increasingly gained more acceptance for treatment of primary molars. However, multiple surface GIC restorations have generally lower survival rates compared with single surface GIC restorations (12).

ART restorations in primary teeth were typically found to fail due to the total or partial loss of the restoration, gross marginal defects (120-122) and secondary caries (19, 123, 124). To overcome this, several studies investigated the use of modified GICs containing various antimicrobial agents. However, the results of these studies remain questionable (20-23).

The present clinical study was carried out to assess the clinical success of a novel material (SDF-GIC) in class II ART restorations in primary molars compared with a conventional GIC under field conditions. The novel material has shown promising results in prior *in vitro* studies, and therefore warranted further investigation via a clinical study. After performing the clinical study, we found that Class II ART restorations of the 2 materials have similar clinical success at both 6- and 12-month follow-up.

In our study, at 6-month follow-up, the success rate of Class II ART restoration of SDF-GIC and GIC were 62.7% (50.7 - 73.6) and 73.3% (61.9 – 82.9) respectively. At 12 months, the success rate were 61.3% (49.4 - 72.4) for SDF-GIC and 58.7% (46.7 – 69.9) for GIC. It should be noted that the success rate of Class II ART restorations in our study at 12-month follow-up was lower when compared to the recent systematic review reported the survival rate of Class II ART restoration which reported the survival percentage and standard errors of multiple-surface ART restorations in primary posterior teeth over the first year were 76.9% (± 3.8) (12). However, the systematic review included studies using both hand-mixed and capsule type, and from both clinical and school settings (12).

As it has been reported, the success rate of both GIC and SDF-GIC was lower than expected at 6- and 12-month follow-up period. Some issues, discussed below, may explain the inferior success of these restorations:

Addition of SDF: The addition of SDF may have affected the setting reaction of GICs, and by extension, the success rate. It was not surprising since the addition of antimicrobial agents into GICs mostly affects the physical and mechanical properties of the cement. This issue has also been reported in the review by Ching et al., where the addition of similar materials was shown reducing the physical properties of GICs (99). They have also been found to reduce compressive strength, and slightly increase the setting time when the concentration of antimicrobial agent increases (99).

The type of GIC: We used hand-mixed GIC because this was a preliminary clinical study. We needed to pipette SDF solution into the liquid part of GI. Pipette is more time consuming and using hand-mixed has less accuracy of powder: liquid ratio and more air void while hand-mixing leads to a lower success rate (125).

Oral hygiene: The success rate of restoration is lower in children with poor oral hygiene (124). Two recent studies demonstrated that patients with higher caries risk presented a decrease in the longevity of restorations (80, 126). The background of oral health status of the study samples was poor with dmft average 6.93 (± 3.66) and VPI average 81.1%. We hypothesize that this may have decreased the success rate of the restoration in this study group. However, we did not find the difference of success rate between groups of dmft score for the subgroup analysis (see in Appendix C).

Size of cavity: The size of cavity has been reported to affect the survival rate of its restorations (63, 106). The size of Class II cavities measuring less than 4 mm with involvement of proximal portion of tooth shows higher success rate when compared with the cavities involvement of proximal portion of tooth and extending up to central pit (106). Consistent with the study of Kemoli et al., the authors concluded that restorations with the highest survival rate were of sizes between 2 and 3 mm (mesio-distal, bucco-lingual, and depth) or volumes 10.0-19.9 mm^3 (63). In this study, the sizes of the included cavities varied and included all proximal cavities with no involvement of buccal or lingual surfaces, which may result in small to large size. Thus, the results of success rates in our study showed a wide range of success rates depending on the size of the cavity.

Use of intention-to-treat analysis: Most studies (47, 105, 106) usually exclude the dropped-out or missing sample (either tooth or child), but in our study, we used Intention-to-treat analysis, which includes all missing samples in the calculations, counted as a failure. Therefore, a lower success rate was expected. Nevertheless, with the evaluation criteria used in this study, restorations with minor failures were scored as failures.

Food consumption after treatment Even if the children were instructed to not eat or drink for 1 hour after receiving treatment, we cannot ensure that the children will follow the instruction. Additionally, Kemoli et al. found the survival rate of the proximal restorations was significantly influenced by the presence of hard consistency foods in the next meal consumed by each child (127).

However, we did not find a significant correlation between the success rate and type of surface, presence of proximal contact, type of arch and type of molar. This result is also observed in the studies of Ersin et al. (105), Deepa and Shoba (106) and Freitas et al (125). On the other hand, Saetiew et al. studied factors affecting the failure of Class II SMART restorations in mandibular primary molars using capsule-type GIC. They found that the factors of occluso-distal lesion in primary mandibular first molar, interproximal gingival inflammation and interproximal space were significantly associated with higher failure rate of simplified modified ART (SMART) at 6-month follow-up (128).

In addition to the issues raised above, the failure of restoration is multi-factorial and so, more factors should be considered. Moisture contamination, height of the restoration, temperature, mixing time, and powder liquid ratio might contribute to the failure of the restorations (123, 129). There are many studies that address the cause associated with Class II restoration failures in primary teeth. Some of the cite the isolation methods (61, 129), the influence of the operator (62, 121), and the carious lesion size (62, 106).

Caries lesions at the margins of restorations remain a major reason for the replacement of restorative materials worldwide (130). There is a higher risk of proximal surface developing caries lesions because of the presence of contact areas, which results in areas that are difficult to reach by toothbrush and are accessible only by flossing (131). This results in the higher failure rate of proximal

restoration when compared to occlusal restoration, also associated with poor oral hygiene (80). These shortcoming may be related to the restorative material properties (65), and there is still uncertainty regarding the optimal restorative material for primary dentition in Class II restoration (44, 126).

However, GIC restorations presented better performance than composite resin regarding the occurrence of secondary carious lesions, which seems to be related to the better physiochemical properties of GIC regarding biocompatibility, chemical bond to the tooth structure, similar thermal expansion coefficient compared to dentin, and mainly its ability to release and recharge fluoride (74, 132). In addition, SDF has been widely used to arrest and/or prevent caries progression (133, 134) (135). According to multiple published systematic and updated reviews, SDF has been widely used to arrest carious lesion in children due to its antimicrobial property and enhancement of fluoride remineralization (27, 136, 137). The mechanisms of SDF on carious tooth tissue, a series of chemical reactions take place that promote tooth desensitization and remineralization of demineralized tooth (138) by dentinal tubule blockage, inhibiting cariogenic biofilm (88), preserving collagen from degradation (87), and also increasing dentin hardness (89). Silver ions are assumed to be responsible for anti-microbial action of SDF, inhibiting the growth of all tested oral bacteria and denature enzymes that would breakdown collagenous dentin (90).

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 9917-1:2007 is applicable to both hand-mixed and capsulated cements for mechanical mixing) standards for setting time and compressive strength without deteriorating the GIC fluoride release pattern (29). Consequently, this novel GIC maximized the effect of fluoride release from GIC in carious lesion prevention that 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 GIC (30). Consequently, the use of novel SDF-GIC in preventing caries lesion in the margins of class II surfaces will be beneficial due to the fluoride releasing and silver antimicrobial abilities of the SDF solution. Moreover, another study found higher mineral contents in the dentin of

carious lesions after treatment with SDF compared with normal dentin (89). Puwanawiroj et al. found that SDF does not adversely affect the bond strength between glass ionomer cement and carious primary dentin (28). Thus, the novel material has a potential of being a restorative material for ART.

The reasons for failure are usually the total or partial loss of the restoration (47, 55, 139) and gross marginal defects (64, 121, 140). In our study, with regard to the failure of Class II restorations for GIC observed, the predominant failure characteristic was the loss of the restoration, which accounted for around half of the failures observed.

The ART Criteria is used to evaluate the degree of marginal defects and wear and assessing the partial or complete loss of restoration. As the study aimed to investigate the antimicrobial activity in arresting caries, the ART Criteria was modified in order to allow for the observation of caries activity (active or inactive), The modification was made to score 5 (restoration partly or completely missing). Since we added SDF solution, we expected the outcome of arresting dentin carious lesion. Thus, to observe the effect of the cavity's surrounding carious dentin, we modified the criteria into 5a (with arrested caries and no repair is needed), if cavities showed dentin that appeared hard and darkened (considered to be a sign of caries arrest and remineralization), and 5b (with active caries and repair is needed), if cavities were filled with food impaction and active caries.

Of the missing restorations, there were active caries in 10 restoration of SDF-GIC group and 11 restorations of GIC group at 6 months. At 12 months, there were active caries in 11 restoration of SDF-GIC group and 16 restorations of GIC group.

Therefore, results show that SDF-GIC has a greater number of missing restorations with inactive surrounding and fewer active caries, compared with GIC. This observation is consistent with the previous *in vitro* studies of SDF-GIC, which found higher antimicrobial activity and enhanced bonding efficacy (29, 30).

Methodology

The randomization and allocation concealment: Allocation and concealment of children to the treatment groups was performed by computer randomization program called sealed envelope™ which is so accurate that there is no difference of baseline characteristics of children and teeth between two groups.

Selection of sample: We chose the children aged 3-8 years because the information from the previous national oral health survey by Ministry of Public Health in Thailand in 2018 reported dental caries of 3- and 5-years old were 52.9% and 75.6%, respectively, and almost 99% of children in both groups were still left untreated. Therefore, the children around these ages will be able to receive an oral examination and dental restorations as needed. Additionally, if we chose to place restorations in children at this age, to prevent the loss of dental arch space from an erupting first permanent molar.

Controlling reliability: Since there is a study that found that the operator can influence the success rate of the restoration (120), in our study, there was only one trained operator, one examiner, and one dental assistant who mixed the material. With regard to the examiner, intra-examiner kappa coefficient values were 0.84 and 0.82 for 6- and 12-month evaluation which is considered as almost perfect agreement (116).

Limitations of the current study.

Several limitations should be taken into consideration while interpreting the findings of the study. 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. Moreover, when using distinguishable restorative material such as GIC and SDF-GIC, it is not possible to blind operators and examiner regarding the treatment groups since SDF-GIC shows greyish color after mixing. This results in a single-blind trial. Split-mouth design could not be done since adding SDF may affect the oral environment. In order to avoid cross contamination of SDF in material, one child represented one tooth of the test or control group.

Furthermore, We also noticed that climatic characteristics might have affected the success rate of the restoration which also be reported earlier in the study of Hesse et al. (126). During the treatment period, there were a variety of environments such as outdoor rain, outdoor sun, and indoor air-conditioned room. A warmer climate may interfere with the GIC setting reacting prior to its insertion into cavity. This is because the chemical bonding of GIC with the tooth substrate is accomplished by an ionic interaction between carboxyl group from polyacids and calcium from hydroxyapatite (141), and that the setting rate of material can be accelerated by increasing the GIC temperature (142). If the gellification reaction is hastened by the warm weather, less polyacrylic acid

will be available to react with dentin, leading to fewer cross-links and lower wettability of material (126). This may reduce its adhesion, possibly contributing to a less long-lasting restoration.

For further study,

Encapsulated GIC promoted better ART performance than hand-mixed GIC (125). A study found that developing encapsulated GICs containing SDF solution reduced the incorporation of air bubbles during mixing procedure (143), reduced the presence of porosities (air voids) in the cement matrix (144), and created a more accurate proportion of powder and liquid ratio of the glass ionomer cement. Other benefits of encapsulated GIC over hand-mixed GIC include the ability to prepare a more precise SDF: GIC proportion and eliminating the time-consuming pipetting process. Therefore, future clinical trials may consider using encapsulated GIC instead of hand-mixed GIC. To fully observe the effect of antimicrobial activity from the restoration, a long-term follow-up is needed.

Chapter 6
Conclusion

This is the first study that evaluate the clinical success of the novel restorative material (SDF-GIC). Within the limitations and based on the results of this study, the following conclusions can be drawn: The clinical success of novel atraumatic restorative treatment (ART) Class II restorations in primary teeth was similar to the high viscosity glass ionomer (GIC) restorations after 6 and 12 months follow-up. Furthermore, the success rate of the restoration was not significantly influenced by type of restorative materials, type of surface, presence of proximal contact, type of arch, and type of molars.

However, of all partly or completely missing restorations, SDF-GIC restorations showed good trend in arresting caries of the cavity when compared to GIC. On the other hand, the missing GIC restorations were found with active caries. Therefore, more long-term follow-up is needed to evaluate further the effect of SDF to surrounding cavities.

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APPENDICES

Appendix A

Data Collection Forms

Oral Examination Form

แบบบันทึกการตรวจ screening

Date .... School .... Class …........

Case	Information	Teeth data									
	Name.										
	Tel.	55	54	53	52	51	61	62	63	64	65
	Birth date	85	84	83	82	81	71	72	73	74	75
	dmft=										
	Name.										
	Tel.	55	54	53	52	51	61	62	63	64	65
	Birth date	85	84	83	82	81	71	72	73	74	75
	dmft=										
	Name.										
	Tel.	55	54	53	52	51	61	62	63	64	65
	Birth date	85	84	83	82	81	71	72	73	74	75
	dmft=										
	Name.										
	Tel.	55	54	53	52	51	61	62	63	64	65
	Birth date	85	84	83	82	81	71	72	73	74	75
	dmft=										

Code: d คือ ฟันผุระดับ ICDAS3 เป็นต้นไป, m คือ ฟันที่ถูกถอนก่อนกำหนดเนื่องจากฟันผุ, f คือ ฟันผุที่ได้รับการบูรณะแล้ว

Participant General Information Forms

แบบบันทึกข้อมูลทั่วไปของผู้เข้าร่วมการวิจัย

Date ..... School ..... Class .....

case	Name Lastname	Gender	Birthdate (DD/MM/YY)	Age (Y/M)	Identification number	Telephone number	Baseline dmft	Inclusion tooth	Selected tooth
								E D D E E D D E	
								E D D E E D D E	
								E D D E E D D E	
								E D D E E D D E	
								E D D E E D D E	
								E D D E E D D E	
								E D D E E D D E	

Treatment Recording Forms

แบบบันทึกข้อมูลผู้เข้าร่วมการวิจัย ณ วันที่ทำการรักษา

Case	Material	Behavior	Baseline dmft	Selected tooth	Surface	Occluding tooth	Proximal contact
	A, B*	++,+,-,--		54,55,64,65 ,74,75,84,85	OM, OD	Yes, No	Yes, No
1	A	++		84	OM	/	X

Material: A = GIC, B = SDF-GIC

Frankl Behavior: +,+ = highly cooperative; + = cooperative; - = non-cooperative; -,- = definitely non-cooperative

Evaluation Recording Forms

แบบบันทึกข้อมูลผู้เข้าร่วมการวิจัย ณ วันที่ติดตามผล 6 เดือน

ลำดับ	Behavior	Selected tooth	Surface	Occluding tooth	Proximal contact	6-month Follow-up										
Example	++,+,-,--	54,55,64,65,74,75,84,85	OM, OD	Yes (/), No (X)	Yes (/), No (X)	0	1	2	3	4	5a	5b	6	7	8	Performance conclusion
1	++	84	OM	/	X		/									S

Code:

- Data will be filled following the Modified ART Criteria score (**Table5**).
- Performance conclusion Success (S), Failure (F), Excluded (E)

-

Appendix B

Consent Forms

School Consent Letter

บันทึกข้อความ

ส่วนงาน ภาควิชาทันตกรรมสำหรับเด็ก คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย **โทร**. 02-218-8906

วันที่ 6 **เดือน** ธันวาคม **พ.ศ**. 2561

เรื่อง ขออนุญาตใช้สถานที่เข้าทำการเก็บข้อมูลเพื่อทำวิจัยในนักเรียนชั้นอนุบาล 1 ถึง 3

เรียน ผู้อำนวยการโรงเรียนในเขตอำเภอบ้านแพ้ว จังหวัดสมุทรสาคร

สิ่งที่ส่งมาด้วย แนวทางการศึกษาวิจัย จำนวน 1 ชุด

เนื่องด้วย ข้าพเจ้า ทันตแพทย์หญิงมนฤญช์ จิตรวรรณภา นิสิตปริญญาโทของภาควิชาทันตกรรมสำหรับเด็ก คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย จะทำการวิจัยเรื่อง "การศึกษาทางคลินิกของการบูรณะฟันน้ำนมด้วยวัสดุกลาสไอโอโนเมอร์ซีเมนต์ 2 ชนิด ด้วยวิธี Atraumatic Restorative Treatment" โดยมี รองศาสตราจารย์ ทันตแพทย์หญิง ปริม อวยชัย เป็นอาจารย์ที่ปรึกษาวิทยานิพนธ์ การวิจัยนี้เป็นการวิจัยทางคลินิก โดยจะบูรณะฟันน้ำนมที่มีรอยผุด้วยวัสดุชนิดกลาสไอโอโนเมอร์ซีเมนต์ 2 ชนิดและติดตามความสำเร็จของวัสดุทั้ง 2 เป็นระยะๆ

ประโยชน์ที่ได้จากการวิจัยครั้งนี้คือ อาสาสมัครจะได้รับผลประโยชน์โดยตรง คือ ได้รับการตรวจฟัน และหากพบว่ามีรอยผุจะได้รับการบูรณะ รวมถึงส่งต่อเพื่อรับการรักษาอย่างเหมาะสมต่อไป ในระหว่างการศึกษาอาสาสมัครจะได้รับยาสีฟันผสมฟลูออไรด์ และแปรงสีฟันเพื่อใช้ในการทำความสะอาดฟัน และผลการวิจัยนี้สามารถใช้เป็นแนวทางในการเลือกชนิดของวัสดุอุดฟันที่เหมาะสมต่อไป

ในการนี้ผู้วิจัยจึงใคร่ขออนุเคราะห์ใช้นักเรียนเป็นกลุ่มตัวอย่างและใช้โรงเรียนเป็นสถานที่ดำเนินการวิจัย โดยจะขอเข้าไปตรวจฟันนักเรียนเพื่อคัดเลือกเป็นกลุ่มตัวอย่าง ทั้งนี้จะประสานกับทางโรงเรียน เพื่อกำหนดวันเวลาดำเนินการศึกษาวิจัยมิให้กระทบการเรียนการสอน เพื่อให้การศึกษาวิจัยครั้งนี้สำเร็จลุล่วงไปด้วยดี

จึงเรียนมาเพื่อโปรดพิจารณา และหวังเป็นอย่างยิ่งว่าจะได้รับความอนุเคราะห์จากท่าน

ขอกราบขอบพระคุณมา ณ โอกาสนี้

.....

(ทันตแพทย์หญิงมนฤญช์ จิตรวรรณภา)

.....

(รองศาสตราจารย์ ทันตแพทย์หญิง ปริม อวยชัย)

อาจารย์ที่ปรึกษาวิทยานิพนธ์

ผู้วิจัยหลัก โทร. 089-776-8554 (ทพญ.มนฤญช์ จิตรวรรณภา)

Parent/Guardian Consent Form

หนังสือขออนุญาตตรวจสุขภาพช่องปาก

เรียน ท่านผู้ปกครอง

เนื่องด้วยข้าพเจ้า ทพญ.มนฤญช์ จิตรวรรณภา นิสิตปริญญาโท ภาควิชาทันตกรรมสำหรับเด็ก คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย จะทำการวิจัยเรื่อง “การศึกษาทางคลินิกของการบูรณะฟันน้ำนมด้วยวัสดุกลาสไอโอโนเมอร์ซีเมนต์ 2 ชนิด ด้วยวิธี Atraumatic Restorative Treatment” โดยมี รองศาสตราจารย์ทันตแพทย์หญิง ปริม อวยชัย เป็นอาจารย์ที่ปรึกษางานวิจัย

การวิจัยนี้เป็นการวิจัยทางคลินิก โดยจะบูรณะฟันน้ำนมด้วยวัสดุชนิดกลาสไอโอโนเมอร์ซีเมนต์ 2 ชนิดและติดตามผลความสำเร็จของวัสดุทั้ง 2 เป็นระยะๆ เพื่อคัดเลือกกลุ่มตัวอย่างที่ตรงกับลักษณะที่ต้องการในงานวิจัย ทางผู้วิจัยจึงมีความประสงค์ที่จะขออนุญาตตรวจสุขภาพช่องปากนักเรียน ณ โรงเรียนที่บุตรหลานท่านศึกษาอยู่เป็นอันดับแรก

หากพบว่าเด็กนักเรียนคนใดได้รับการคัดเลือกและสามารถรับการรักษาฟันด้วยวิธีดังกล่าวได้ จะได้รับการบูรณะฟันด้วยวัสดุกลาสไอโอโนเมอร์ซีเมนต์ รวมถึงการติดตามผลการรักษาเป็นระยะๆ โดยไม่เสียค่าใช้จ่ายใดๆ ในทุกขั้นตอนที่กล่าวมา นอกจากนี้ฟันผุซี่ข้างเคียงอื่นๆ จะได้รับการส่งต่อไปรับการรักษาที่เหมาะสมต่อไป

จึงเรียนมาเพื่อขอความอนุเคราะห์จากท่านผู้ปกครองในการยินยอมให้บุตรหลานของท่าน เข้ารับการตรวจคัดเลือก เพื่อเข้าร่วมเป็นกลุ่มตัวอย่างในงานวิจัยครั้งนี้

ทพญ.มนฤญช์ จิตรวรรณภา
(ผู้วิจัย)

ข้าพเจ้านาย/นาง/นางสาว.....โทร.....

มีความสัมพันธ์เป็น.....เป็นผู้ปกครองของ ด.ช./ด.ญ.....

หมายเลขบัตรประจำประชาชนของบุตรหลานท่าน คือ .....

☐ ยินยอมให้บุตรหลานของท่านเข้าร่วมการวิจัยในครั้งนี้

☐ ไม่ยินยอมให้บุตรหลานของท่านเข้าร่วมการวิจัยในครั้งนี้

ลงชื่อ.....(ผู้ปกครอง)

Parental Information Sheet

หนังสือชี้แจงรายละเอียดการเข้าร่วมวิจัย

เรียน ท่านผู้ปกครอง

เนื่องด้วยข้าพเจ้า ทพญ.มนฤญช์ จิตรวรรณภา นิสิตปริญญาโท ภาควิชาทันตกรรมสำหรับเด็ก คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย จะทำการวิจัยเรื่อง “การศึกษาทางคลินิกของการบูรณะฟันน้ำนมด้วยวัสดุกลาสไอโอโนเมอร์ซีเมนต์ 2 ชนิด ด้วยวิธี Atraumatic Restorative Treatment” โดยมี รองศาสตราจารย์ทันตแพทย์หญิง ปริม อวยชัย เป็นอาจารย์ที่ปรึกษางานวิจัย

การวิจัยนี้เป็นการวิจัยทางคลินิก โดยจะบูรณะฟันน้ำนมด้วยวัสดุชนิดกลาสไอโอโนเมอร์ซีเมนต์ 2 ชนิด และติดตามผลความสำเร็จของวัสดุทั้ง 2 เป็นระยะๆ โดยวัสดุบูรณะที่เลือกใช้นั้นมีคุณสมบัติสามารถปลดปล่อยฟลูออไรด์ที่เป็นสารช่วยส่งเสริมการคืนกลับแร่ธาตุสู่ผิวฟันและยับยั้งการสูญเสียแร่ธาตุออกจากผิวฟัน และ/หรือมีส่วนประกอบของแร่ธาตุเงินที่จะช่วยยับยั้งการเจริญเติบโตของเชื้อโรคบริเวณรอยผุ โดยการให้การรักษาดังกล่าวจะเป็นการบูรณะฟันที่ผุกร่อนเป็นรู หรือ โพรงให้สามารถกลับมาใช้งานได้ใกล้เคียงฟันปกติมากที่สุด แต่อาจก่อให้เกิดสีของฟันที่เข้มขึ้น เช่น สีน้ำตาล สีดำ และสามารถเกิดการหลุดกร่อนตามการใช้งานได้

หลังจากที่ผู้วิจัยได้ขออนุญาตตรวจสุขภาพช่องปากนักเรียน ณ โรงเรียนที่บุตรหลานท่านศึกษาอยู่ไปแล้วนั้น พบว่าเด็กนักเรียนที่เป็นบุตรหลานของท่านได้รับการคัดเลือกให้รับการรักษาฟันด้วยวิธีดังกล่าว โดยจะได้รับการบูรณะฟันด้วยวัสดุกลาสไอโอโนเมอร์ซีเมนต์ รวมถึงการติดตามผลการรักษาเป็นระยะๆ โดยไม่เสียค่าใช้จ่ายใดๆ ในทุกขั้นตอนที่กล่าวมา นอกจากนี้ฟันผุซี่ข้างเคียงอื่นๆ จะได้รับการส่งต่อไปรับการรักษาที่เหมาะสมต่อไป

จึงเรียนมาเพื่อขอความอนุเคราะห์จากท่านผู้ปกครองในการยินยอมให้บุตรหลานของท่าน เข้าร่วมรับการรักษาในงานวิจัยครั้งนี้

ทพญ.มนฤญช์ จิตรวรรณภา

(ผู้วิจัย)

Parent/Guardian Consent Form

หนังสือยินยอมให้เข้าร่วมการวิจัย

ข้าพเจ้า ..... เบอร์โทรศัพท์.....

.ที่อยู่ .....

ผู้ปกครองของ ด.ช./ด.ญ. .....เกี่ยวข้องเป็น .....ได้รับทราบขั้นตอนและวิธีการวิจัย ผลดีและผลเสียของการเข้าร่วมการวิจัย เรื่อง “การศึกษาทางคลินิกของการบูรณะฟันน้ำนมด้วยวัสดุกลาสไอโอโนเมอร์ซีเมนต์ 2 ชนิด ด้วยเทคนิค Atraumatic Restorative Treatment”

ข้าพเจ้ายินดีอนุญาตให้ ด.ช./ด.ญ. ..... เข้าร่วมการวิจัยนี้

.....

(.....)

ผู้ปกครอง

กรุณาตอบคำถามเกี่ยวกับประวัติทางการแพทย์ของบุตรหลานท่านตามข้อมูลด้านล่างนี้

1. บุตรหลานของท่านมีโรคประจำตัวดังต่อไปนี้หรือไม่
   ☐ โรคหัวใจ ☐ โรคเลือด ☐ โรคปอด ☐ โรคตับ ☐ โรคไต
   ☐ โรคหอบหืด ☐ โรคชัก ☐ อื่นๆ (โปรดระบุ).....
   ☐ ไม่มีโรคประจำตัวใดๆ
2. บุตรหลานของท่านเคยเข้ารับการนอนพักรักษาตัวที่โรงพยาบาลหรือไม่ ☐ ใช่ ☐ ไม่ใช่
3. บุตรหลานของท่านมีประวัติแพ้ยา หรือไม่ ☐ แพ้ (โปรดระบุ)..... ☐ ไม่แพ้
4. บุตรหลานของท่านมีประวัติแพ้สารประกอบเงิน หรือไม่ ☐ แพ้ ☐ ไม่แพ้
5. บุตรหลานของท่านมีประวัติแพ้สารประกอบฟลูออไรด์ หรือไม่ ☐ แพ้ ☐ ไม่แพ้
6. ถ้าเคยได้รับการถอนฟัน หลังถอนฟัน แผลหายเป็นปกติและไม่มีอาการผิดปกติอื่นใด ☐ ใช่ ☐ ไม่ใช่ (โปรดระบุอาการผิดปกติ).....
7. บุตรหลานของท่านมีอาการแพ้ยาชาที่ใช้ในการทำฟันหรือไม่ ☐ แพ้ ☐ ไม่แพ้ ☐ ไม่ทราบ

Study Protocol and Consent Form Approval

No. 040/2019

Study Protocol and Consent Form Approval

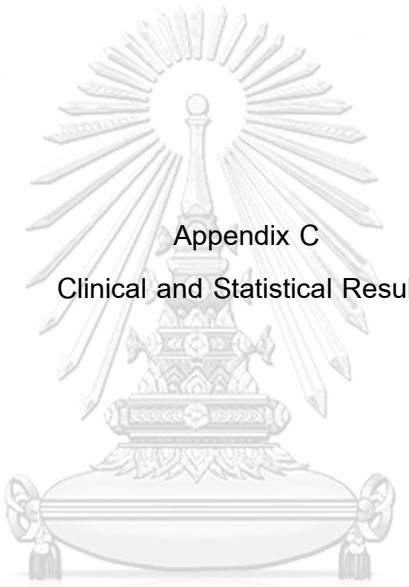
The Human Research Ethics Committee of the Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand has approved the following study to be carried out according to the protocol and patient/participant information sheet dated and/or amended as follows in compliance with the **ICH/GCP**

Study Title	: Clinical evaluation of two glass ionomer cement restorations placed in primary molars with atraumatic restorative treatment technique: a randomized controlled trial
Study Code	: HREC-DCU **2019-017**
Study Center	: Chulalongkorn University
Principle Investigator	: Miss Manarin Chitwannapa
Protocol Date	: March 25, 2019
Date of Approval	: May 3, 2019
Date of Expiration	: May 2, 2021

(Assistant Professor Dr. Kanokporn Bhalang)
Chairman of Ethics Committee
Associate Dean for Research

*A list of the Ethics Committee members (names and positions) present at the Ethics Committee meeting on the date of approval of this study has been attached (upon requested). This Study Protocol Approval Form will be forwarded to the Principal Investigator.

Approval is granted subject to the following conditions: (see back of the approval)



Appendix C

Clinical and Statistical Results

Related studies of ART restorations using Glass Ionomer Cement

No.	Year	Setting	Type of material	Brand of material	Author	Samples Age	Criteria	6m Single surface	6m Multiple surface	12m Single surface	12m Multiple surface	24m Single surface	24m Multiple surface
1	1999-2001	School	hand-mixed	ChemFlex	Luo et al. 1999 (12m), Lo et al. 2001 (24m)	6-14Y	ART criteria	-	-	96.6	46.2	96	41.7
	1999 -2001	School	hand-mixed	Fuji IX GP	Luo et al. 1999 (12m), Lo et al. 2001 (24m)		ART criteria	-	-	89.7	61.5	92	42.6
2	2004	clinic	capsule	Fuji IX GP	Yip et al. 2002 (12m), Yu et al. 2004 (24m)	7-9Y	USPHS	-	-	95	66	89	49
	2004	clinic	capsule	Ketac Molar	Yip et al. 2002 (12m), Yu et al. 2004 (24m)		USPHS	-	-	94	65	94	55
3	2002	Clinic	Hand-mixed	Fuji IX and KetacMolar	Taifour et al.	6-7Y	ART criteria	-	-	95	72	91	60
4	2003	Clinic	Hand-mixed	ChemFlex	Honkala et al.	2-9Y (mean 5.7)	ART criteria	-	-	92.3	88.9	91	83
5	2006	School	Hand-mixed	Fuji IX GP	Ersin et al.	6-10Y (mean8.7)	USPHS	100	90.2	100	83	96.7	76.1

No.	Year	Setting	Type of material	Brand of material	Author	Samples Age	Criteria	6m Single surface	6m Multiple surface	12m Single surface	12m Multiple surface	24m Single surface	24m Multiple surface
6	2006	Clinic	Hand-mixed	Ketac molar	Menezes et al.	4-6Y	Own satisfactory criteria	95	64	82	31	-	-
7	2010	School	Hand-mixed	Fuji IX	Deepa and Shobha	4-9Y (mean 5.3)	ART criteria	-	-	94.9	88.5	-	-
8	2014-2017	Mixed	Capsule	Ketac molar Easymix	Hilgert et al.	6-7Y (mean 6.8)	ART criteria	99.1	89.5	98.2	80.9	93.4	66.2
9	2017	Clinic	Capsule	EQUIA system/ Chemfil Rock	Molina et al.	SHCN	ART criteria	100	92.5	100	81.6	100	81.6
10	2018	School	Capsule	EQUIA Fil	Lopes et al.	6-10Y (mean8Y)	ART criteria	-	83	-	86	-	-
*	2018		SR & MA	GIC	DeAmorim et al.			-	-	96.4	76.9	94.3	65.4
11	2020	School	Hand-mixed	Ketac molar	Jiang et al.	3-4Y	ART criteria	85	65	75	44	50	14
	2020	School	Hand-mixed	PretreatSDF+GIC	Jiang et al.	3-4Y	ART criteria	85	64	74	44	49	14

No.	Year	Setting	Type of material	Brand of material	Author	Samples Age	Criteria	6m Single surface	6m Multiple surface	12m Single surface	12m Multiple surface	24m Single surface	24m Multiple surface
12	2020	School	Hand-mixed	Fuji IX GP	OUR STUDY	3-8Y	ART criteria	-	73.3	-	58.7	-	-
	2020	School	Hand-mixed	SDF-GIC	OUR STUDY	3-8Y	ART criteria	-	62.7	-	61.3	-	-

Success rate of restorations according to different success criteria

		6m				12m			
		Success Rate (95%CI)		success/all		Success rate (95%CI)		Success/all	
		SDF-GIC	GIC	SDF-GIC	GIC	SDF-GIC	GIC	SDF-GIC	GIC
Intention to treat	(0,1,2/0-8)	62.7% (50.7-73.6)	73.3% (61.9-82.9)	47/75	55/75	61.3% (49.4-72.4)	58.7% (46.7-69.9)	46/75	44/75
Per protocol	(0,1,2/0-7)	70.1% (57.7-80.7)	77.5% (66.0-86.5)	47/67	55/71	64.8% (52.5-75.8)	64.7% (52.2-75.9)	46/71	44/68
0,1,2,5a=success+ITT	(0,1,2,5a/0,1,2,3,4,5b,6,7,8)	66.7% (54.8-77.1)	73.3% (61.9-82.9)	50/75	55/75	69.3% (57.6-79.5)	64% (52.1-74.8)	52/75	48/75
0,1,2,5a=success+PP	(0,1,2,5a/0,1,2,3,4,5b,6,7)	74.6% (62.5-84.5)	77.5% (66.0-86.5)	50/67	55/71	73.2% (61.4-83.1)	70.6% (58.3-81.0)	52/71	48/68

Subgroup analysis according to

1. Baseline caries experience (dmft) score at 6 and 12 months

	6 months					12 months				
	SDFGI		GI			SDFGI		GI		
dmft	Success (n=47)	%	Success (n=55)	%	p-value	Success (n=46)	%	Success (n=44)	%	p-value
1	2	4.3%	1	1.8%	0.468	2	4.3%	1	2.3%	0.584
2	1	2.1%	4	7.3%	0.230	1	2.2%	4	9.1%	0.152
3	9	19.1%	3	5.5%	0.032*	7	15.2%	3	6.8%	0.205
4	4	8.5%	5	9.1%	0.918	4	8.7%	5	11.4%	0.673
5	3	6.4%	6	10.9%	0.422	5	10.9%	5	11.4%	0.941
6	2	4.3%	7	12.7%	0.133	2	4.3%	4	9.1%	0.367
7	5	10.6%	5	9.1%	0.793	5	10.9%	4	9.1%	0.779
8	6	12.8%	4	7.3%	0.352	6	13.0%	4	9.1%	0.551
9	3	6.4%	4	7.3%	0.859	4	8.7%	2	4.5%	0.430
10	2	4.3%	4	7.3%	0.519	2	4.3%	2	4.5%	0.964
11	4	8.5%	5	9.1%	0.918	5	10.9%	5	11.4%	0.941
12	3	6.4%	3	5.5%	0.843	1	2.2%	1	2.3%	0.975
14	1	2.1%	2	3.6%	0.653	0	0.0%	2	4.5%	0.144
15	0	0.0%	1	1.8%	0.353	0	0.0%	1	2.3%	0.304
16	1	2.1%	1	1.8%	0.911	1	2.2%	1	2.3%	0.975
19	1	2.1%	0	0.0%	0.277	1	2.2%	0	0.0%	0.325

2. Baseline caries experience group at 6 months

		Success 6 months				p-value
		SDFGI (n=47)		GI (n=55)		
		n	%	n	%	
dmft	≥ 3	44	93.6%	50	90.9%	0.612
	< 3	3	6.4%	5	9.1%	
dmft	≥ 4	35	74.5%	47	85.5%	0.164
	< 4	12	25.5%	8	14.5%	
dmft	≥ 5	31	66.0%	42	76.4%	0.246
	< 5	16	34.0%	13	23.6%	
dmft	≥ 6	28	59.6%	36	65.5%	0.540
	< 6	19	40.4%	19	34.5%	
dmft	≥ 7	26	55.3%	29	52.7%	0.794
	< 7	21	44.7%	26	47.3%	
dmft	≥ 8	21	44.7%	24	43.6%	0.916
	< 8	26	55.3%	31	56.4%	
dmft	≥ 9	15	31.9%	20	36.4%	0.637
	< 9	32	68.1%	35	63.6%	
dmft	≥ 10	12	25.5%	16	29.1%	0.688
	< 10	35	74.5%	39	70.9%	

3. Baseline caries experience group at 12 months

		Success 12 months				p-value
		SDFGI (n=46)		GI (n=44)		
		n	%	n	%	
dmft	≥ 3	43	93.5%	39	88.6%	0.420
	< 3	3	6.5%	5	11.4%	
dmft	≥ 4	36	78.3%	36	81.8%	0.673
	< 4	10	21.7%	8	18.2%	
dmft	≥ 5	32	69.6%	31	70.5%	0.927
	< 5	14	30.4%	13	29.5%	
dmft	≥ 6	27	58.7%	26	59.1%	0.970
	< 6	19	41.3%	18	40.9%	
dmft	≥ 7	25	54.3%	22	50.0%	0.680
	< 7	21	45.7%	22	50.0%	
dmft	≥ 8	20	43.5%	18	40.9%	0.805
	< 8	26	56.5%	26	59.1%	
dmft	≥ 9	14	30.4%	14	31.8%	0.887
	< 9	32	69.6%	30	68.2%	
dmft	≥ 10	10	21.7%	12	27.3%	0.541
	< 10	36	78.3%	32	72.7%	

VITA

NAME	Manarin Boonyawong
DATE OF BIRTH	10 July 1989
PLACE OF BIRTH	Bangkok
INSTITUTIONS ATTENDED	Chulalongkorn University
HOME ADDRESS	199/1 Soi Sribumpen Rama 4 road Thungmahamek Sathorn Bangkok 10120