

# **PROTOCOL**

Approved on Dec 20, 2022

# **Atraumatic versus Silver-Modified Atraumatic Restorative Treatment in Primary Molars: A Randomized Trial on Minimally Invasive Caries Management and Oral Health-Related Quality of Life**

## **Introduction:**

Early childhood caries (ECC) is a term that describes the presence of one or more decayed (cavitated and non cavitated lesions), missed (due to caries), or filled teeth in a child's primary dentition before the age of six (American Academy of Pediatric Dentistry, 2016).

The American Academy of Pediatric Dentistry (AAPD) adopted the term ECC to better reflect its multi-factorial and complex etiology including biological, socioeconomic, and behavioral factors (Tinatof, et al 2017).

Although the initiating biological key factors including cariogenic bacteria, fermentable carbohydrates, and susceptible tooth surfaces are the same for both adults and children, some epidemiological studies have also documented some environmental factors as low socioeconomic status, minority status, in addition to feeding practices and vertical bacterial transmission from the mother to the child as risk factors for ECC (Anil & Anand, 2017).

According to WHO, ECC is one of the most common childhood diseases affecting 60-90% of children worldwide. (WHO, 2016). In developed countries, the ECC prevalence is estimated to range from 1 to 12%, whereas it rises to 70% among some disadvantaged groups in these countries (Anil & Anand, 2017).

In developing countries, ECC has been a significant problem in many areas and its prevalence varies from one population to another, where it has reached up to 85% in some developing areas in Far East Asia (Shrestha et al., 2021).

Reports on the prevalence of early childhood caries have been reported in many countries worldwide including the Middle East region: In Jordan for example, a study was done by Rajab and Abdullah (2020) on 1557 children, showed that the prevalence of ECC was 72.5%, and 77.2% among 4 and 5 years old respectively (Rajab & Abdullah, 2020). In the

United Arab Emirates, a study was conducted by Alkhayat (2018), reported that ECC prevalence in 3, 4 and 5-years old children was 25.6%, 36.8%, and 42.2%, respectively among 2957 participants (Alkhayat, 2018). In Lebanon, a study was done by (Chedid et al., 2011) on a small sample of Lebanese preschool children aged below 4 years, and found that 75% of 99 children suffered from ECC (Chedid et al., 2011).

Caries may have a negative impact on oral health-related quality of life in preschool children. Oral health-related quality of life (OHRQoL) is a multidimensional concept that consists of subjective evaluations of oral health, functional and emotional well-being, satisfaction with care, and sense of self (Ruff et al., 2022).

International Caries Detection and Assessment System (ICDAS) employs an evidence-based and preventively oriented approach, it is a detection and assessment system classifying stages of the caries process by using visual surface characteristics to measure surface changes and potential histologic depths of caries lesions. The classification criteria, and associated estimates of caries activity, are based on the histological extension of lesions into tooth structure. The scores are on a 7-point rating scale (Young et al., 2015).

Minimal intervention dentistry (MID) is a philosophy of dental care that aims to keep teeth healthy and functional throughout a person's life. It recommends preserving not only sound tooth tissues but also tissues with the potential to remineralize so as to maximize the healing potential of the tooth (Jiang et al., 2021).

Atraumatic restorative treatment (ART) is a minimally invasive approach for the management of cavitated lesions. The ART procedure involves removal of soft carious dental tissues using hand instruments without giving local anesthesia and placement of restoration using adhesive dental material, mostly high viscosity glass ionomer cement (GIC) which provides chemical adhesion to the tooth surface, fluoride release, and biocompatibility (Jiang et al., 2021).

Glass Ionomer Cement used in ART is considered as a satisfactory option for treatment of decayed primary teeth in young ages and a source of fluoride release which may help in arresting caries and preventing the development of new ones and it's acceptable from the child and parents due to its white color (Duangth et al., 2017).

Silver diamine fluoride (SDF) consists of 25% silver, 5% fluoride, and 8% ammonia. SDF can arrest the caries progression and simultaneously prevent the formation of new lesions. This affordable topical solution's effectiveness is due to a combined action of remineralization aided by fluoride, potent germicidal effect by silver nitrate, and sclerotic dentine formation by silver salt. It requires minimal training, equipment, and personnel. SDF could be used for a broad range of situations, including, but not limited to, when local or general anesthesia is not preferred, when young children do not accept dental procedures, or when it is necessary to offer a less costly or less invasive alternative and recently as a non-aerosol releasing treatment during the pandemic (Wakhlo et al, 2021). Hence its use to arrest cavitated lesions in primary teeth is supported by the American Academy of Pediatric Dentistry (AAPD)(Crystal et al.,2017).

According to an umbrella review of systematic reviews (SR) done by BaniHani, et al in 2021, results from included SRs showed that 38% SDF has a statistically significant caries arrest effect in children and that its application is more effective than other preventive management strategies including GIC for arresting dentinal caries in the primary dentition ( $p < 0.5$ ). Moreover, caries arrest rate after single application of 38% SDF ranged between 31 and 79%, whereas biannual application has significantly increased the caries arrest rate to 53 and 91% (Duangthip et al., 2015; Jabin et al., 2020) (BaniHani et al., 2021).

However, occasionally, there may be a situation where the patient will not be able to return for subsequent dental treatment. In this case, the provider has an option of placing SDF and a glass ionomer cement (GIC) restoration during the same appointment to limit access of fermentable carbohydrates and improve the chances of SDF caries arrest. This technique is called Silver Modified Atraumatic Restorative Technique (SMART). By placing SMART restorations, the bacteria are eliminated and the nutrient source for any remaining bacteria is cut off by placing a chemically sealed restoration that will arrest and remineralize the caries lesion (Alvear Fa., 2016).

In an Egyptian study conducted by Radi et al. in 2021 on 60 primary molars, the mean survival rate of SMART restorations was 11.2 months higher than that restored with ART restorations, within a follow-up period of 12 months. Although there was a statistically significant decrease in all the tested clinical criteria success rate (spontaneous pain,

mobility, sensitivity to percussion and sinus or swelling) within both groups, with ( $P$ -value <0.001, effect size = 0.367) for the group treated with ART and ( $P$ -value <0.001, effect size = 0.187) for the group treated with SMART (Radi et al., 2021).

In China, a study was conducted by Jiang et al. in 2019 on 194 children, in which 101 children received SMART and 93 received ART. At 24-month follow-up, there was no significant difference between the ART restoration success rates of the two study groups ( $p > 0.05$ ). The success rate of these restorations was affected by the class of these restorations: Class I restorations had the highest success rate (~50 %), followed by Class V (~35 %), Class II (~15 %), and Class III (<10 %). Besides, the meantime used to place SMART restorations was shorter than that in ART restorations with 4.8 and 5.1 mins respectively ( $p = 0.006$ ).

In the same study, parents were asked to rate their satisfaction with their child's teeth using a 5-point scale (5=very satisfied, 1=very dissatisfied), and the Chinese version of the Early Childhood Oral Health Impact Scale (C-ECOHIS) was used to assess the children's OHRQoL before and 6 months after the restorative treatment. At the 6-month follow-up, the mean parental satisfaction score regarding their child's dental health status increased significantly ( $p<0.001$ ) from  $2.2 \pm 0.7$  to  $2.8 \pm 1.0$  in the SMART group and from  $2.3 \pm 0.8$  to  $2.7 \pm 0.9$  in the ART group. However, no significant changes ( $p>0.05$ ) in C-ECOHIS scores were found in either of the two groups after ART restoration placement (Jiang M et al., 2019).

There is a lack of clinical trials comparing ART and SMART restorations. Thus, it is suggested to compare the clinical outcome of both techniques and their impact on oral health related quality of life in preschool children.

## **The Null Hypothesis**

There is no difference between SMART and ART in arresting caries, success, and retention rate as well as their impact on the oral health-related quality of life.

## Aim of the Study

### Primary Aim

This study aims to evaluate and compare the clinical outcomes of **Silver-Modified Atraumatic Restorative Treatment (SMART)** and conventional **Atraumatic Restorative Treatment (ART)** in the management of carious primary molars in preschool children. This comparison includes:

- **Success rate:** which include restoration integrity, marginal adaptation, absence of secondary caries, and tooth vitality.
- **Retention rate:** Determined by monitoring whether the restoration remains fully or partially retained over time
- **Caries arrest:** where arrested lesions present with hard, darkened surfaces and no progression in lesion size

### Secondary Aim

- To describe the change in oral health-related quality of life of preschool children before and after placement of ART and SMART restorations.

## **Materials and Methods**

### **Study design:**

Randomized clinical trial using split-mouth design technique.

### **Study setting:**

Inpatients at the clinics of Beirut Arab University.

### **Study Sampling:**

#### **• Size formula**

The sample size was specified by using the G power test, assuming a statistical level of significance of 5% and power 80% with normal distribution, and 0.367 effect size calculated from means and standard deviation of 2 groups obtained from a previous study (Jiang et al., 2021). The original sample size will be 64 molars, and will be increased up to 80 with a possible dropout.

#### **• Randomization**

Teeth will be randomly assigned to receive either SMART or ART technique, using a website (<https://randomization.com/>)

#### **• Grouping**

- **Group A** the teeth will be restored by ART using high viscosity glass ionomer cement (GC Fuji IX )
- **Group B** the teeth will be treated with silver diamine fluoride 38%, and then restored by high viscosity Glass Ionomer cement (Fuji IX), both according to manufacturer instructions.

- **Inclusion Criteria:**

- Generally healthy children of ages 3 to 6 years old, who have at least 2 bilateral decayed primary molars with occluso-proximal carious dentin lesions (scores 4 or 5) according to the International Caries Detection and Assessment System (ICDAS II)
- Children with negative (Rating 2) and positive (Rating 3) behavior, according to Frankel's behavior rating scale

- **Exclusion Criteria:**

- Children with systemic diseases/conditions
- Children with definitely positive and negative behavior
- Teeth with signs of pulpal pathology (abscess, fistula, mobility)
- Teeth with very deep cavities
- Teeth with signs of irreversible pulpitis

- **Ethical Approval:**

Written informed consent should be signed by patients' parents before participation in the study.

### **Materials:**

- **Silver Diamine Flouride 38%** (Advantage Arrest Silver Diamine Flouride 38%)
- **Glass Ionomer Cement**, Fujji IX GC (powder and liquid)

### **Methods:**

#### **I-Application of ART and SMART restorations:**

- a-Base line Periapical X-Rays when necessary
- b-Oral Prophylaxis
- c-Partial Isolation using saliva ejectors and cotton rolls
- d-Application.

**For Group A** the soft caries will be removed by sharp excavators and the cavity will be restored by Fuji IX GC (powder and liquid), according to the manufacturer's instructions.

**For Group B** the soft caries at the superficial walls will be removed and the teeth will be treated with silver diamine fluoride 38% for 1 minute, using micro-brushes, then dried and restored by Fuji IX GC. (Also in this group, soft caries at the superficial wall must be removed before placement of SDF and GIC)

## **II-Baseline and 6 months Assessment of ORQoL**

The Early Childhood Oral Health Impact Scale (ECOHIS) scales measures the Oral Health-Related Quality of Life (OHRQoL) of preschool children and their families. It consists of 13 items, covering six domains in two sections (Table 1). The child's impacts section contains 4 domains: symptom (1 item), function (4 items), psychology (2 items) and self-image and social interaction (2 items). The family's impacts section contains 2 domains: parental distress (2 items) and family function (2 items). The response categories for each question are rated on a 5-point Likert scale to record how often an event has occurred during the child's life: 0 = never, 1 = hardly ever, 2 = occasionally, 3 = often, 4 = very often, and 5 = don't know (Pahel et al.,2007).

The English version of the ECOHIS was translated into Arabic using the well-recognized forward-backward translation technique. As with the English version, response options for Arabic Early Childhood Oral Health Scale (A-ECOHIS) (Table 2) are rated on a 5-point Likert scale as follows: 0 = never, 1 = hardly ever, 2 = occasionally, 3 = often, 4 = very often, and 5 = don't know (Farsi et al.,2017).

At baseline, parents will be asked to complete a questionnaire that consists of the Arabic version of Early Childhood Oral Health Scale (A-ECOHIS) (Table 2). After a 6- month follow-up period, parents will be assessed and asked to complete the same form of the baseline questionnaire.

**Table 1**

		Never 0	Hardly Ever 1	Occasionally 2	Often 3	Very Often 4	Don't Know 5
<b>Child impact</b>	<b>How often has your child, because of dental problems or the need for dental treatment:</b>						
	1) ...had pain in the teeth, mouth or jaws?						
	2) ...had difficulty drinking hot or cold beverages?						
	3) ...had difficulty to chew food?						
	4) ...had difficulty for pronouncing any words?						
	5) ...Missed pre-school or day-care?						
	6) ...had difficulty sleeping?						
	7) ...been annoyed or bad-tempered?						
	8) ...avoided laughing or smiling when around other children?						
	9) ...avoided talking?						
<b>Family impact</b>	<b>How often have you or another family member, due to dental problems or dental treatment of your child:</b>						
	10) ...felt upset?						
	11) ...felt guilty?						
	12) ...had to take hours or days off work?						
	13) ...had the family's economic situation affected?						

## **Outcome Measurements:**

The primary outcome measure in this clinical study is the success of the ART restorations placed. The children will be examined 6 months after placement of ART restorations (Jiang et al., 2016).

The same instruments used in the baseline examination will be used in the follow-up examinations. The status of the restorations and restored teeth will be assessed and recorded using codes and criteria commonly adopted in previous clinical studies of ART restorations (Lo et al., 2007).

0 = restoration present, no caries, no marginal defects, or wear

1 = restoration present, no active caries, slight defects or wear not greater than 0.5 mm

2 = restoration present, marginal defects greater than 0.5 mm

3 = restoration present, wear greater than 0.5 mm

4 = restoration present, active caries found associated with the filling

5 = restoration missing, no active caries, surface hard to gentle probing

6 = restoration missing, active caries found, surface soft to probing allowing penetration of the tip of a blunt probe

7 = tooth with signs of pulpal pathology

8 = tooth missing, extracted due to caries

9 = tooth naturally exfoliate

## **Statistical Analysis:**

Data analysis was carried out by using the statistical software SPSS (version 28, IBM SPSS statistics, USA. Based on the results of the Shapiro-Wilk test, most of the data were determined to follow a normal distribution. The significance level was set at  $p \leq 0.05$ . The qualitative data were presented as frequencies and percentages, whereas the quantitative data were presented as median, range, mean, and standard deviation values. Paired Samples

t-Test was used to compare the means of two related groups, it was used to assess changes in ECOHIS scores at baseline and after intervention. Fishers exact test was used to compare the outcomes between ART and SMART at a single time point. Categorical data like the relation between the success rate of both treatments and the type of the cavity was analyzed by using the Chi-Square Test of Independence. The significance level was set at  $p \leq 0.05$ .

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## Appendix 1

### The English Version of the Informed Consent

#### Parental Permission Form [Form H-VI(A)]

**Principal Investigator**

:

**Atraumatic versus Silver-Modified Atraumatic  
Restorative Treatment in Primary Molars: A  
Randomized Trial on Minimally Invasive Caries  
Management and Oral Health-Related Quality of Life**

**Date**

:

#### PURPOSE OF RESEARCH STUDY

The purpose of this research study is to compare the clinical outcomes of restoring primary molars using Atraumatic Restorative Treatment and Silver Modified Restorative Treatment and their effect on oral health-related quality of life. We anticipate that approximately 50 children will participate in this study.

#### PROCEDURES

- Every Child will receive a glass ionomer restoration on one side, and silver diamine fluoride with glass ionomer cement on the other side.
- The parents will complete a questionnaire at the beginning of the study and after 6 months.
- The check-up will be done after 3 and 6 months. The first session may last for about 30 mins, and the other visits will last for 15 minutes.

#### RISKS/DISCOMFORTS

Your child might feel a metallic taste that lasts no longer than 2 days. If your child accidentally shows black stains on the soft tissues, don't worry because these stains will disappear within few days.

#### BENEFITS

- The benefits include arresting caries in primary molars and thus preventing caries progression.
- This study may benefit society if the results lead to a better understanding of caries arresting using glass ionomer cement and Silver Diamine Fluoride with Glass Ionomer Cement.

### **VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW**

Your child's participation in this study is entirely voluntary: You choose whether to allow your child to participate, and we will also ask your child whether he or she agrees to take part in the study. If you decide not to allow your child to participate, or your child chooses not to participate there are no penalties, and neither you nor your child will lose any benefits to which you would otherwise be entitled. If you and your child choose to participate in the study, you or your child can stop participation at any time, without any penalty or loss of benefits. If you want to withdraw your child from the study, or your child wants to stop participating, let us know by calling Dr. Sana Solh: 76187209.

### **CIRCUMSTANCES THAT COULD LEAD US TO END YOUR PARTICIPATION**

Under certain circumstances we may decide to end your child's participation before he or she has completed the study.

### **CONFIDENTIALITY**

Any study records that identify you or your child will be kept confidential. The records from your child's participation may be reviewed by people responsible for making sure that research is done properly, including members of the BAU Institutional Review Board. All of these people are required to keep your identity and the identify of your child confidential. Otherwise, records that identify you or your child will be available only to people working on the study, unless you permit for other people to see the records]. Code numbers will be used rather than participants' names on data sheets, keeping records in a locked file cabinet.

### **COMPENSATION**

Your child will not receive any payment or other compensation for participating in this study.

### **IF YOU HAVE QUESTIONS OR CONCERNS**

You and your child can ask questions about this research study now or at any time during the study, by talking to the researcher(s) working with you and your child] or by calling Dr. Sana Solh at (76187209). If you or your child have questions about your child's rights as a research participant or feel that your child has not been treated fairly, please call the BAU Institutional Review Board at 00961 1 300110 ext. 2743 / 2689.

### **IF YOU ARE HARMED BY PARTICIPATING IN THE STUDY**

If you feel that your child has been harmed in any way by participating in this study, please call [Dr Sana Solh] at [76187209]. Please also notify the BAU Institutional Review Board at 00961 1 300110 ext. 2743 / 2689.

### **STATEMENT BY THE RESEARCHER / PERSON TAKING THE CONSENT**

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the information in this parental form. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving this parental form, and it has been given freely and voluntarily.

### **WHAT YOUR SIGNATURE MEANS**

Your signature below means that you understand the information in this consent form. Your signature also means that you agree to allow your child to participate in the study.

**Child's Name** : \_\_\_\_\_

**Contact (phone number)** : \_\_\_\_\_

**Signature of the Child (if applicable)** : \_\_\_\_\_

**Name of Participant's Legally Authorized Representative** : \_\_\_\_\_

**Signature of Participant's Legally Authorized Representative** : \_\_\_\_\_

**Date** : \_\_\_\_\_