"Evaluation of Fluoride Release and Compressive Strength of a Bioactive Restorative Material and its Clinical Performance in Atraumatic Restorative Treatment in primary molars : an in vitro study & a randomized controlled trial"

Submitted by

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List of CONTENTS

INTRODUCTION

Although the prevalence of dental caries has been declined in industrialized countries, this disease continues to be widespread in the world especially in developing countries .Once it has become installed, it is of importance to use conservative procedures that simultaneously prevent caries progression and minimize healthy tooth structure wear . The most serious problem encountered during caries removal is anxiety, fear and pain. Pressure and heat during mechanical preparation and the annoying noise from the handpiece are to blame. Furthermore, Conventional caries removal involved the use of drilling often causes over preparation of sound healthy dentin because the drill remove infected and affected dentin, leading sometimes to pulp inflammation and even exposure.

This was perceived as unpleasant and painful by many patients, so local anesthesia had to be administered to control pain. System for caries removal and cavity preparation have been under strong pressure for development towards minimal invasive procedures and increased patient comfort.

During the last few decades, many alternative methods for cavity preparation and caries removal have been introduced, including atraumatic restorative treatment.

Atraumatic Restorative Treatment (ART) is a minimally intervention approach that concerned with preventive measures, sealing and filling cavities .The restorative technique needs the removal of the infected, softened and demineralized dentin by use of hand instruments, followed by the application of a chemical –adhesive material (1,2) for management of caries. This approach, that is an effective and economical method to prevent and control caries lesion progression, causes less dental anxiety and discomfort to the patients than conventional rotary instruments used in conventional restorative treatment.(3)

Initially, ART was recommended by the World Health Organization for escorting restorative care to people without access to dental services (2). ART was originally developed for economically underdeveloped populations with limited resources (4). It also has applications in industrial countries, however, especially for: very young children who are being introduced to oral care (5), patients who experience extreme fear or anxiety about dental Procedures(6,7), mentally and/or physically handicapped patients (7,8) ,home-bound elderly and nursing home resident patients (9,10) ,and patients from high-risk caries clinics who can benefit from ART as an intermediate treatment to stabilize conditions (5,11) .

ART has been proven to be a high quality and reliable approach in the management of dental caries, and became suitable for all patients, regardless of the economic and social situation (12,13)

ART has many advantages especially in pediatric dentistry as less anxiety, less pain and rarely requires local anesthesia (14).

A meta-analysis of ART showed that high-viscosity GICs presented higher clinical survival rates than conventional or medium-viscosity glass ionomers (15) so High-Viscosity Glass ionomer cements (GICs) is the most used material for the ART approach due to their biological, physical, and chemical properties (16). Notably, hand mixing of GICs might allow for an increased incidence of operator errors during material preparation, as the ratio of powder to liquid may vary according to manufacturer's recommendations(17). The quantity of powder dispensed varies according to powder packing density in the volumetric scoop. The volume of liquid dispensed from the manufacturer-supplied dropper bottle varies depending on the angle at which the bottle is held, the pressure applied to squeeze a drop, and the inclusion of air bubbles(17). With the purpose of decreasing these variables, encapsulated dental cements have been introduced in the market(18). These premade mixtures utilize mechanical mixing methods and allow standardization of the powder/liquid ratio in a sealed capsule, which is expected to reduce variation in clinical outcomes(18,19).

Resin modified GI are formulated by incorporating a small quantity of resin monomers and initiators into GI material in order to improve some of mechanical properties the clinical performance of RMGIs ,however, remain inferior to the resin composite material (20)

A novel restorative material has been developed as enhanced RMGIs (ACTIVA BIOACTIVE restorative).the resin monomer added to ACTIVA BIOACTIVE restorative are claimed to impart resilience to the material to improve its mechanical properties . this material are an esthetic fluorinated dental restorative material, with promising claims to be more bioactive and release more fluoride than glass ionomer cement (21) they are moisture friendly , transport water , and stimulate apatite formation at the material-tooth interface.in addition , these resins react to PH changes in the mouth by releasing and up-taking calcium ,phosphate and fluoride ions .

ACTIVA-BIOACTIVE restorative material claims to possesses characteristics of both composite and resin modified glass ionomer (RMGI) as strength, esthetics and physical properites of composites , Seals teeth against bacterial Leakage (22,23) and release and recharge more of calcium, phosphate and fluoride than glass ionomer (21) However, there is few studies evalute the clinical performance and mechanical properties of ACTIVA BIOACTIVE restorative material versus other restorative material .

AIM OF THE STUDY

The aim of this study is :

1- Evaluate the fluoride release capacity and compressive strength of a new bioactive restorative material .

2- Evaluate and compare the clinical performance and survival rates of bioactive restorative material with high viscosity glass ionomer in class I restoration performed using Atraumatic Restorative Treatment approach in primary molars.

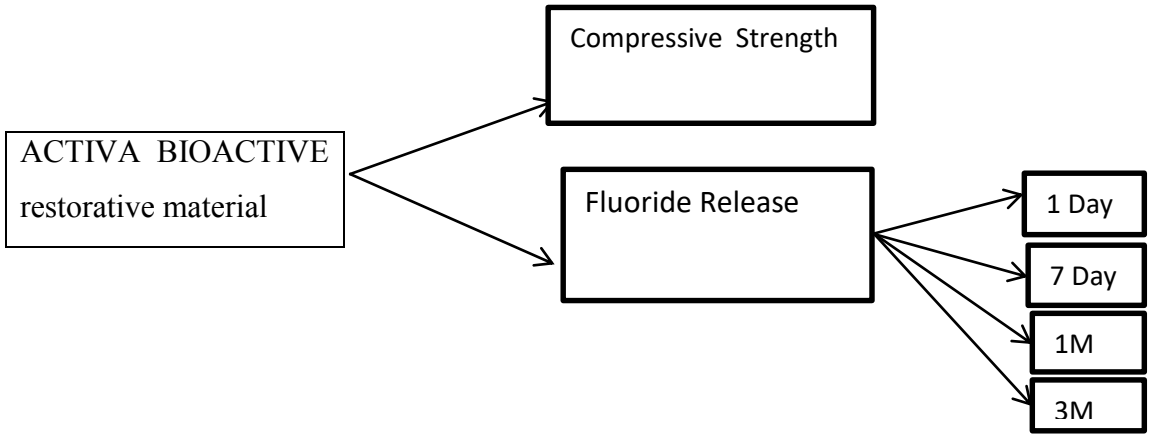
Materials and Methods

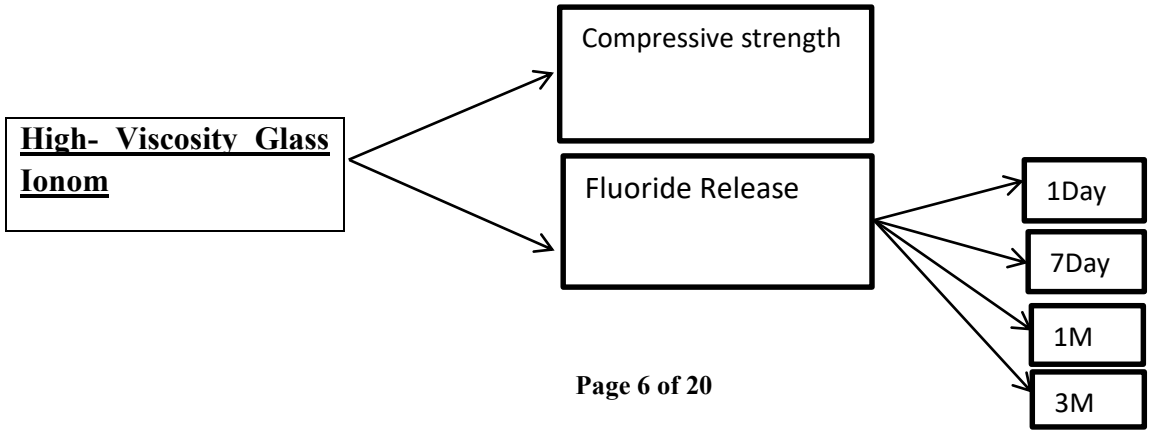
In Vitro Study

Materials

Material name:	ACTIVA BIOACTIVE restorative material	Fuji IX
Manufacture:	Pulpdent , Watertown, MA USA	GC America
Material type:	Enhanced resin modified glass ionomer	High-viscosity glass ionomer

Grouping of the specimens:





Sample size:

The sample size estimation was done using Steven K. Thompson equation and assuming power 90% and effect size 0.05

$$n = \frac{N \times p(1-p)}{\left[\left[N-1 \times \left(d^2 \div z^2\right)\right] + p(1-p)\right]}$$

With:-

n (sample size)

N (population size) =90,000,000

p (probability value or p-value) =0.11

z (standard score or z-score)=1.96

d (difference between paired data or Effect Size) =0.5

So the resultant **n = 28.07**

Sample size analysis for compressive strength and fluoride release testing was calculated to be 28 specimens that will be distrubted as 7 in each experimental group (four groups) according to data collected from previous studies .

Methods:

I-Compressive strength

Preparation of the specimens: Specimens will be prepared in split Teflon mold according to ISO Guidelines specification No. 9917-1:2007(E) (24).

The material will be proportioned and mixed according to the manufacturer's instructions and then placed in special mold up to a slight excess. The mold will be closed and placed under pressure using a screw clamp. The whole assembly will be transferred to an incubator and maintained at a temperature of 37 °C. One hour after mixing, the specimens will be removed from the mold, finished using wet silicon carbide paper and stored in water in an incubator at a temperature of 37 °C until the time of testing.

*Testing procedures:

Compressive strength and for each material will be measured after 24 hours. Each specimen will be placed with the flat ends of the specimen between the platens of the universal testing machine and compressive load will be applied along the long axis of the specimen.

The load at fracture for each specimen, will be recorded and compressive strength will be calculated as follows (25) .

$CS = 4P/\pi d^2$

Where: p is the maximum load applied in Newtons.

d is the measured diameter of specimen, in millimeters.

II-Fluoride release :

*** Preparation of the specimens:**

Specimens will be prepared in split Teflon mold and then removed after one hour from mixing. The specimens will be finished and then coated with glass ionomer varnish and will be stored in water for 24 hours in an incubator at a temperature of 37 °C, then the specimens will be removed from the water and dried.

Each specimen will be immersed in deionized water in plastic bottles and will be stored in an incubator at 37°C till the time of testing. At the time of testing, each plastic bottle will be thoroughly shaken and then the specimen will be removed, dried and returned into a new bottle containing deionized water.

*Testing procedures:

The fluoride ion release will be measured after storage in deionized water for 1 day, 7 days, 1 month and 3 months using fluoride ion-selective electrode (ISE) attached to an ion meter.

In Vivo study

Study Population

Total of 60participants will be included in this study. 30 of them will be treated with (ACTIVA BIOACTIVE) restorative material in ART, 30 will be treated with (High-Viscosity glass ionomer) restorative material in ART.

Inclusion Criteria:

1-Children aged from 4 to 8 years old, in good general health

2-Children classified as class 3or 4 based on Frankle et al. classification. (26)

3-The children have at least one primary molar with class I carious lesion.

3- Asymptomatic teeth (without spontaneous pain)

Exclusion Criteria:

1. Medically compromised patient

2. Presence of pulp exposure, pain, mobility

3. Presence of swelling, abscess or fistula near the tooth

4. Not accessible carious lesion to hand instruments

Study design :

The study will be two parallel group, double blinded randomized controlled clinical trial that based on CONSORT (consolidated standars of reporting trials) guideline (27).The selected participant according to inclusion and exclusion criteria will be randomly allocated in two groups using (Research Randomizer Program) .

Blinding

All paticipant don't know the type of received restorative material (ACTIVA BIOATIVE or Heigh -viscosity GI restorative material) and the outcome will be evaluted by a examiner other than operator who doesn't know the type of received restorative material also.

Study setting

The study will be performed at pediatric Department and Dental Puplic Health Department of Faculty of Dentistry, Ain Shams University, and at the institute of Graduate Studies and Research, Ain Shams University.

Sample size

The sample size estimation was done using Steven K. Thompson equation and assuming power 90% and effect size 0.05

$$n = \frac{N \times p(1-p)}{\left[\left[N-1 \times \left(d^2 \div z^2\right)\right] + p(1-p)\right]}$$

With:-

n (sample size)

N (population size)=90,000,000

p (probability value or p-value) =0.07

z (standard score or z-score)=1.96

d (difference between paired data or Effect Size)=0.05

So the resultant **n = 60**

Recruitment/Setting

The all participants of this study have been selected after compelet clinical examination has been done with full medical and dental history , history of medications and history of hospitalization. In patients who receive dental treatment as an usual care in clinics of Pediatric Dentistry and Dental Public Health Department at faculty of dentistry, Ain-Shams University.

Informed consent designed to include all data about dental procedures in this study and clear more details about time consuming in the procedure and follow up visits, used materials and adverse event of this procedure . All participants have the wright to withdraw from this study at any time .The consent will be assigned from each patient by the patient's parents or guardians after explanation of the study.

The full mouth rehabilitation will be performed by postgraduate student registered at the master Degree at the Pediatric Dentistry and Dental Public Health Department Faculty of Dentistry, Ain- Shams University

All subjects receive instructions on oral health, particularly in relation to oral hygiene and sugar consumption.

Material

Material name:	ACTIVA BIOACTIVE restorative material	Fuji IX
Manufacture:	PULPDENT	GC America
Material type:	Enhanced resin modified glass ionomer	High-viscosity glass ionomer

Sample Grouping

The 60 participant will be randomly divided into two group according to used material as follow:

Group I (control): will consist of 30 teeth that will be restored with conventional Atraumatic restorative treatment (ART) using by high-viscosity glass ionomer (Fuji IX)

Group II: will consist of 30 teeth that will be restored with Atraumatic Restorative Treatment (ART) using ACTIVA BIO ACTIVE restorative material

Steps of Procedure in group (control):

Atraumatic Restorative Treatment (ART) performed according to Frencken et al. guidelines (28)

►► Maintain relative isolation of the operatory field with cotton rolls.

►► Remove caries: using only hand excavators compatible with the size of the carious cavity. Both infected and affected dentin should be removed from the dentin–enamel junction.the affected dentin will be maintained in the remaining walls. Thin, unsupported

enamel was carefully removed using a hatchet placed on the enamel with slight pressure.

►► Clean the cavity: cavity walls should be cleaned with cotton balls moistened with water

►► Condition the dentin: apply a drop of 11.5% polyacrylic acid on a cotton ball for 15 s.

Then, wash the cavity with three cotton balls moistened with water and dry using three more cotton balls.

►►encapsulated GIC(Fuji IX), the plunger was placed on a hard surface and a mechanical mixer was used to mix the capsules for 10 seconds. The capsule was then placed into the

applicator to insert the GIC into the cavity.

►►After inserting the GIC, a gloved finger coated with petroleum jelly was used to apply pressure to the GIC for 1 minute.

►► Occlusion was checked and excess material was removed with a carver. Restorations were coated with a layer of petroleum jelly to prevent sorption during occlusal checking. ►►petroleum jelly was removed from the surface using at least two cotton wool pellets. GC Coat was applied to the surfaces of final restorations and light-cured for 20 seconds

►► Instruct the patient not to eat solid food for 1 hour.

Steps of Procedure in group :

►► Maintain relative isolation of the operatory field with cotton rolls.

►► Remove caries: using only hand excavators compatible with the size of the carious cavity. Both infected and affected dentin should be removed from the dentin–enamel junction.the affected dentin will be maintained in the remaining walls. Thin, unsupported

enamel was carefully removed using a hatchet placed on the enamel with slight pressure.

►► Clean the cavity: cavity walls should be cleaned with cotton balls moistened with water and dry using three more cotton balls.

►► Insert a ACTIVA BIOACTIVE restorative material to the cavity without application of acid etching or bond

►► Occlusion was checked and excess material was removed with a carver.

►► Instruct the patient not to eat solid food for 1 hour.

Study procedure

In VIVO Study

Atraumatic Restorative Treatment will be formed by two different restorative materials (ACTIVA BIOACTIVE and High- viscosity Glass ionomer) and long term survival of restorative material will be evaluated at 3,6 and 9 months .

Outcomes

The outcome of this study is the longevity of ACTIVA BIOACTIVE restorative material versus high –viscosity glass ionomer in (ART) in Class I carious cavity of primary teeth

Longevity of the restoration

Treatment longevity will be evaluated clinically after 3, 6 and 9 months according to the Frencken and Holmgren criteria (29) in the class I restorations using sharp sickle shaped explorers, WHO CPI periodontal probes, which has a ball tip with 0.5 mm diameter,plane mirrors, and light source of dental unit.

The codes and criteria used to evaluate the ART restorations are found in the Table

Score	Criteria(17)
0	**Present, good**
1	**Present, slight marginal defect for whatever reason, at any one place which is less than 0.5 mm in depth.** ***No repair is needed.***
2	**Present, marginal defect for whatever reason, at any one place which is deeper than 0.5 mm but less than 1.0 mm.** ***Repair is needed.***
3	**Present, gross defect of more than 1.0 mm in depth.** ***Repair is needed.***
4	**Not present, restoration has (almost) completely disappeared.** ***Treatment is needed.***
5	**Not present, other restorative treatment has been performed.**

6	**Not present, tooth has been extracted.**
7	**Present wear and tear gradually over larger parts of the restoration but is less than 0.5 mm at the deepest point.** ***No repair is needed.***
8	**Present, wear and tear gradually over larger parts of the restoration which is deeper than 0.5 mm** ***Repair is needed.***
9	**Unable to diagnose**

Note : Restorations considered to have survived are scored by codes: 0,1,7; those considered to have failed by codes: 2,3,4,8; while those that are considered to be unrelated to success and failure are codes:5,6

Data Management:

All data will be entered electronically.

Participant's data will be stored in numerical order in secure place and limited access files. Soft copies of the files will be protected by password access.

The hard copy will be kept confidential and private with the investigator throughout the study.

Adverse Event Reporting

Adverse events in vivo part of study :

1-partial or compelet failure of restoration that will need to be repaired

2-recurrent caries around restorations

3-Inflammatory reactions of pulps of restored teeh that will need pulp therapy

4-Infection of pulp of restored teeth that may develop an abscess or facial celluitis which will need pulp therapy or extraction with or without space maintainer.

5-time consuming during dental perocedure and follow up visits

Adverse events in vitro part of study

There is no adverse events in this part.

Statistical analysis

Data will be collected, tabulated, and statistically analyzed using suitable statistical test to achieve the aim of this study .

References

1- Frencken JE, Pilot T, Songpaisan Y,مPhantumvanit P. Atraumatic restorative treatment(ART): rationale, technique, and development.J Public Health Dent. 1996;56(3 Spec No):135-40.
https://doi.org/10.1111/j.1752-7325.1996.tb02423.x

2- Frencken JE, Holmgrem CJ. Atraumatic Restorative treatment for dental caries. Nijmegen: STI Book; 1999.

3- Arrow P, Klobas E. Minimum intervention dentistry approach to managing early childhood caries: a randomized control trial. Community Dent Oral Epidemiol. 2015;43(6):511-20.

4. Frencken JE, Pilot T, Songpaisan Y, Phantumvanit P.Atraumatic restorative treatment (ART): Rationale,technique, and development. J Public Health Dent 1996;56(special issue):135-40.

5. American Academy of Pediatric Dentistry. Policy onalternative restorative treatment (ART). ReferenceManual 2007-08. Pediatr Dent 2007;29:38

6. Schriks MC, van Amerongen WE. Atraumatic perspectiveof ART: Psychological and physiologicalaspects of treatment with and without rotary instruments.Community Dent Oral Epidemiol 2003;31:15-20.

7. Mjor lA, Gordan vv. A review of atraumatic restorativetreatment (ART). Int DentJ 1999;49:127-31.

8. Pilot T. Introduction: ART from a global perspective.Community Dent Oral Epidemoil 1999;27:421-2.

9. Lo EC, Luo Y, Tan Hp, Dyson JE, Corbet EF. ARTand conventional root restorations in elders after 12months. J Dent Res 2006;85:929-32.

10. Honkala S, Honkala E. Atraumatic dental treatmentamong Finnish elderly. J Oral Rehabil 2002;29:435-40.

11. Honkala E, Behbehani J, Ibricevic H, Kerosuo E, ALJameG. The atraumatic restorative treatment (ART) approach to restoring primary teeth in a standard dental clinic. IntJ Paediatr Dent 2003;13:172-9.

12- Ismail A. Minimal intervention techniques for dental caries. J Public Health Dent. 1996;56:155–60.

13- Phantumvanit P, Songpaisan Y, Pilot T, Frencken JE. Atraumatic restorative treatment (ART): a three-year community field trial in Thailand – survival of one-surface restorations in the permanent dentition. J Public Health Dent. 1996;56:141–5.

14-Frencken JE. The state-of-the-art of ART restorations. *Dent Update* 2014;41:218–20.

15.van't Hof MA, Frencken JE, van Palenstein Helderman WH, Holmgren CJ. The atraumatic restorative treatment (ART) approach for managing dental caries: a meta-analysis. Int Dent J. 2006;56(6):345-51

16. Pani SC, Abbassi MFA, Saffan AD, Sumait MAA, Shakir AN. Factors influencing Saudi dental students' preference of amalgam or composite for posterior dental restorations. S J Oral Sci. 2014;1(1):30–6.

17. Billington RW, Williams JA, Pearson GJ. Variation in powder/liquid ratio of a restorative glass-ionomer cement used in dental practice. Br Dent J. 1990;169(6):164-7.

18- Nomoto R, McCabe JF. Effect of mixing methods on the compressive strength of glass ionomer cements. J Dent. 2001;29(3):205-10.

19- Nomoto R, Komoriyama M, McCabe JF, Hirano S. Effect of mixing method on the porosity of encapsulated glass ionomer cement. Dent Mater. 2004;20(10):972-8.

20- Sidhu SK . Clinical evalution of resin-modified glass -ionomer restoration. Dent Matar 2010;26:7-12

21- Slowikowski L, et al. Fluoride ion release and recharge over time in three restoratives. J Dent Res 93 (Spec Iss A): 268, 2014 (www.iadr.org).

22.Zmener O, Pameijer CH, Hernandez S. Resistance against bacterial leakage of four luting agents used for cementation of complete cast crowns. Am J Dent 2014;27(1):51-55.

23. Zmener O, Pameijer CH, et al. Marginal bacterial leakage in class I cavities filled with a new resin-modified glass ionomer restorative material. 2013.

24- ISO (2007), ISO 9917. Water-Based cements.

25- Garcez RM, Buzalaf MA, de Araújo PA. Fluoride release of six restorative materials in water and ph-cycling solutions. J Appl Oral Sci 2007;15(5):406-11.

26- Frankl SN, Shiere FR, Fogels HR (1962) Should the parent remain with the child in the dental operatory? J Dent Child 29, 150-163.

27-Moher, D., Hopewell, S., Schulz, K. F., Montori, V., Gøtzsche, P. C., Devereaux, P. J., et al. (2010). CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trial. BMJ, 340, c869. for the CONSORT Group.PubMedCrossRefGoogle Scholar

28- Frencken JE, Holmgren CJ. How effective is ART in the management of dental caries? Community Dent Oral Epidemiol. 1999;27(6):423–30.

29-Frencken JE, Holmgren CF. Tratamento restaurador atraumático (ART) para a cárie dentária. São Paulo: Santos, 2001.