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A clinical evaluation of two glass ionomer cements in primary molars using atraumatic restorative treatment technique in India: 1 year follow up

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Aim. To compare the clinical performance of two glass ionomer cements, Amalgomer CR and Fuji IX in small and medium cavities prepared using Atraumatic restorative treatment approach in India.

Study design. One hundred school children in the age group of 4–9 years who had bilateral matched pair of carious lesions in primary posterior teeth were included. A split mouth design was used in which two materials were randomly placed in contralateral sides. The performance of the restorations was assessed after 1 year using Frenken's criteria (1996).Survival analysis of restoration was done using chi-square test.

Results. The survival rate of Amalgomer CR and Fuji IX class I restorations were 97.4% and 94.9%, respectively. In class II cavities 95.1% and 88.5% of Amalgomer CR and Fuji IX restorations were successful. Amalgomer CR and Fuji IX showed a success of 94.2% and 92.3% in small sized class II cavities. Amalgomer CR showed a 100% success for medium sized class I and II restorations. Whereas Fuji IX showed a 100% and 66.7% success in medium sized class I and II cavities.

Conclusion. The clinical performances of both materials were satisfactory at the end of 1 year and ART is suitable procedure to be done in a dental clinic for children.

Introduction

Dental caries is the most widely spread oral disease in the world, yet it tends to go untreated in underserved communities in both developing and industrialized countries as oral health is not a priority relative to the social, economic, political and other problems facing those countries[1]. According to Blinkhorn and Davies[2] the main reason for not providing dental care revolves around the need for expensive dental equipment and extensively trained personnel. Even in some developed countries children are deprived of adequate dental care because of fear and economic reasons. To overcome these difficulties Atraumatic restorative treatment (ART) technique has been introduced by WHO in 1994[3].

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Atraumatic restorative treatment (ART) is based on the principle of maximum preservation of sound tooth tissue and the concept of minimal intervention cavity design. This approach includes an innovative, largely pain free restorative treatment employing a material that does not predispose to bacterial recolonization. Glass ionomer cement has traditionally been the material of choice for ART because of its chemical bonding to enamel and dentin, fluoride release, and ease of use. Initially, conventional GIC were used in ART clinical trials[4].

Atraumatic restorative treatment (ART) is patient-friendly and less frightening than traditional techniques as there are no vibrating drills or noisy suction machines[5]. The investigations so far have shown that the ART approach is effective for the management of single-surface cavities in both permanent[6–8]and primary[7,9]. Honkala *et al.*[10] assessed the feasibility of the ART approach in primary teeth and all ART restorations were considered successful. Although

many short term clinical studies have shown high survivals for single surface ART restorations placed in primary molars, the findings have been less satisfactory for multiple surface restorations[7,9]. Thereby ART technique is highly recommended for the management of small occlusal carious lesions in primary and permanent teeth[11] and Arthur *et al.*[12] have found good success in medium sized proximal restorations using ART. In this regard, investigators have emphasized the need for accurate specifications of cavity sizes for the success of ART restorations[9,13].

It is accepted that most of the failures observed are material related, since glass ionomer has lower compressive strength and wear resistance than composite and Amalgam[14]. Nevertheless, success of ART restorations is dependent both on cavity sizes[13] and properties of restorative material[7].

Hence, there is a constant scientific work being done world-over for enhancing the properties of Glass ionomer cements to make it a near ideal restorative material for use under field conditions. One of the recent developments is Amalgomer CR, which offers the dental professionals the established benefits of glass ionomers (fluoride release, biocompatibility, natural adhesion to tooth structure and excellent aesthetics) combined with the strength of amalgam due to ceramic reinforcement in the glass ionomer cement. There has been no clinical study so far, however, to evaluate the clinical success of Amalgomer CR for use in ART. It would also be of interest to compare its performance with other material in the same patient. Fuji IX is one of glass ionomer cements marketed for ART and has shown a high success rate in primary teeth and therefore it was used for comparison of performance of restorative material[13,15].

Therefore this study was done to evaluate and compare the clinical efficacy of Amalgomer CR and Fuji IX in a clinical setup simulating field conditions taking into consideration the cavity sizes. The null hypothesis to be tested was that there is no difference in the survival of restorations with both glass ionomer cements in the primary molars at end of 12 months.

Materials and methods

This split mouth design study was conducted in Peadiatric dental clinic of Manipal college of Dental Sciences, India from 2005 to 2007. The study received ethical approval from Ethical Committee of Kasturba Medical College, Manipal (KHEC No.10/2006).

For this cohort study, the target group consisted of children in the age group of 4–9 years. Six schools in Manipal were selected depending upon the children's accessibility to the dental hospital. The procedure of the study, the risk and benefits of the study were explained to the child and the parents. Written consent form which was according to the guidelines of 'The Ethical Committee' was obtained from both parents before proceeding with the study. The investigator was trained to perform the restorations in the dental setting under the supervision of expert professor.

Selection criteria

Each child had a record that included name, age, sex, class, school name, phone number, address, medical and dental history. A single investigator examined all the children with mouth mirror and probe under day light, along with a dental assistant to record the observations. A total of 1075 children were examined. Criteria for caries diagnosis was cavitation into dentin Inclusion criteria were that bilateral matched pair of dentinal carious teeth of either single or multiple surface teeth with opposing and adjacent caries free teeth and the opening wide enough for the smallest excavator (diameter = 0.9 mm) to enter. The exclusion criteria were that teeth should be free of any pathology like pain, sinus or swelling and cases judged to be unrestorable by ART guidelines and thereby 253 children were selected. Around 15 children were excluded from the study as their parents did not give written consent.

Radiographs were taken for the selected teeth and teeth assessed for the depth of cavity and root length, and if only they had no pulpal exposure, no osseous changes and two-third of root length present the teeth were selected for the study. Otherwise they

were treated accordingly after informing their parents. Subsequently only 100 children were included in the study to receive bilateral restorations with Amalgomer CR and Fuji IX using ART technique. The buccolingual, mesiodistal width was measured using dentarum divider and scale and depth of cavity was measured with markings on Williams probe. While measuring the size of a class II cavity, a matrix band was placed in between the teeth. The cavities were classified as small and medium depending on mesiodistal and buccolingual width. Depth of all cavities ranged between 3 and 4 mm. The following classification was done:

1. Small cavity: class I – cavities measuring 3–4 mm mesiodistally and buccolingually; class II – cavities measuring less than 4 mm with involvement of proximal portion of tooth.
2. Medium cavity: class I – cavities measuring more than 4 mm but less than 8 mm mesidistally and buccolingually; class II – involvement of proximal portion of tooth and extending up to central pit.

Clinical procedure

The selected tooth was isolated with cotton rolls and surface was cleaned with cotton pellet to remove the debris so as to improve the visibility. The entrance of the cavity was widened using the enamel hatchet and small or medium sized sharp excavators (S642017, GC Corporation, Tokyo, Japa) were used depending on size of the cavity to remove the caries. Caries was removed from the dentinoenamel junction using sharp spoon excavators of appropriate size before proceeding on to the floor of the cavity. The cavity and adjacent pits and fissures were conditioned for 10 s using the conditioner to increase the bond strength. Conditioners used were dentin conditioner (GC Corporation) for Fuji IX restorations and Amalgomer conditioner for Amalgomer CR restorations. The conditioned surfaces were then washed with water moistened cotton pellets and then blotted dry with fresh cotton pellets. If the cavity was contaminated with saliva then conditioning of cavity was done once again.

The glass ionomer cements' specifications used in the study are summarized in Table 1. The tooth selection for the restorative material was done randomly and restorations were placed by a single operator to avoid any differences in the procedure. Thereby both glass ionomer cements were placed in a child in the opposite side of same arch. The cements were inserted into the cavity using a cement carrier and overfilled slightly. The restorative material was inserted into the corners using the excavator or ball burnisher and it was pressed with a vaseline coated gloved finger so as to push the material into deeper parts of the cavity and adjacent pits and fissures. Occlusion was checked with articulating paper (Accu Filn II, Farmingdale, NY, USA) and excess material was removed with the carver. The restorations were covered with vaseline to prevent moisture contamination. For class II cavities a mylar matrix strip was placed in between the teeth and a wedge was inserted so as to contour the matrix to the tooth surface. The restoration was left for 2–3 min to harden and then the wedge and mylar matrix strip were removed. Children were instructed not to eat for at least 1 h. Local anaesthesia was not given and no child reported of any discomfort during the procedure. Table 2 gives the distribution of cavities and restoration.

Table 1. Specifications of the glass ionomer cements tested.

Material	Manufacturer	LOT number	Composition
Amalgomer CR	Advanced Health Care, UK	110518-51	Powder: Fluoroaluminosilicate glass, polyacrylic acid powder, tartaric acid powder and ceramic reinforcing powder. Liquid: Polyacrylic acid, distilled water
Fuji IX	GC Corporation Tokyo, Japan	0603141	Powder: Fluroaluminosilicate glass powder, polyacrylic acid power Liquid: Polyacrylic acid, polybasic carboxylic acid, distilled water

Table 2. Distribution of restoration according to cavity type and size.

	Class I		Class II			
Restorative material	**Small**	**Large**	**Small**	**Large**	**Mesio-occlusal**	**Disto-occlusal**
Amalgomer CR	32	7	52	9	11	50
Fuji IX	32	7	52	9	11	50

Evaluation of restoration

A single examiner who was not involved in the placement of restorations and who was also blinded to the type of material evaluated the restorations at 12 months. Debris from the tooth surface was removed before evaluation using scaler and wet cotton. Evaluation of the clinical efficacy of Fuji IX and Amalgomer CR in 200 restorations of both class I and class II over a period of 12 months with regard to retention, marginal integrity and fracture was done by the evaluation criteria (Table 3) as given by Frencken *et al.* (1996) using a 0.5 mm ball ended CPITN probe[6]. Kappa value for intraexaminer variability after repeated examination of 10% study group was found to be 0.81. Around 10 post-operative radiographs in each type of cavities were taken randomly to check for any changes, but no obvious pathological changes were seen.

Table 3. Evaluation criteria for ART restorations.

Code	Criteria
0	Present, good
1	Present, slight marginal defect at any one place which is less than 0.5 mm, no repair needed.
2	Present, defect at any one place which is deeper than 0.5mm repair required
3	Present, gross defect of more then 1.00 mm in depth, repair required
4	Not present, restoration has 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 part, restoration but less than 0.5 mm, at deepest point, no treatment required
8	Present wear and tear gradually over larger parts of restoration which is deeper than 0.5 mm, repair needed
9	Unable to diagnose

Each restoration was given one of the above scores at the end of 12 months. Restorations were denoted successful when the scores were 0, 1 or 7.
Restorations were termed failed when scores were 2, 3, 4, 8 or 9.

Data analysis

The data was entered in SPSS v. 13 and survival rate of two restorative materials were compared using chi-square test. The probability level was set at $P < 0.05$ for statistical significance.

Results

Baseline statistics

A total of 100 children with bilateral comparable pair of carious lesions were selected for the study in the age group of 4–9 years and the mean age was 5.3 ± 2.3 years. Among the restorations 17 were placed in the upper and lower second primary molar, 46 in lower first primary molar and 20 in upper first primary molar. A total of 78 class I restorations and 122 class II restorations were done.

Evaluation of restorations

All the 200 restorations were evaluated at the end of 12 months. A survival rate of 96% and 91% of Amalgomer CR and Fuji IX was seen respectively (Table 4).

Class I restorations

Class I Amalgomer CR restorations were successful (97.4%) when compared with Fuji IX restorations (94.9%). Small class I restorations showed 96.9% and 93.8% success rate of Amalgomer CR and Fuji IX, respectively. Medium Class I restorations showed a 100% success for both Amlagomer CR and Fuji IX (Table 5).

Table 4. Status of restorative material in 12 months.

Score	Criteria	Amalgomer CR	Fuji IX
0	Present, good	49	25
1	Present, slight marginal defect at any one place which is less than 0.5 mm, no repair needed	47	65
2	Present, defect at any one place which is deeper than 0.5mm, repair required	3	5
3	Present, gross defect of more then 1.00 mm in depth, repair required	1	3
4	Not present, restoration has completely disappeared, treatment needed	0	0
5	Not present, other restorative treatment has been performed	0	0
6	Not present, tooth has been extracted	0	0
7	Present wear and tear gradually over larger part, restoration but less than 0.5mm, at deepest point, no treatment is required	0	1
8	Present wear and tear gradually over larger parts of restoration which is deeper than 0.5 mm, repair needed	0	1
9	Unable to diagnose	0	0

Table 5. Success rate of restorative materials according to cavity type.

Type of cavity		Material used for restoration: Amalgomer CR	Material used for restoration: Fuji IX	*P*
Class I	Small	31 (96.9%)	30 (93.8%)	0.554
	Medium	7 (100%)	7 (100%)	
Class II	Small	49 (94.2%)	48 (92.3%)	0.696
	Medium	10 (100%)	6 (66.7%)	0.058
Mesio-occlusal		11 (100%)	9 (81.8%)	0.138
Disto-occlusal		47 (94%)	45 (90.0%)	0.461

Class II restorations

A success rate of 95.1% of Amalgomer CR and 88.5% of Fuji IX were found in class II cavities. The survival rate of restorative material in small class II cavities were 94.2% and 92.3% for Amalgomer CR and Fuji IX restorations, respectively. Though there were no statistical significant difference in the retention of large class II cavities between two materials, Amalgomer CR performed clinically better than Fuji IX. ($P = 0.058$). Mesio oclusal cavities restored by Amalgomer CR showed a higher survival rate than disto-occlusal restorations unlike Fuji IX. The null hypothesis was accepted (Table 5).

Discussion

The atraumatic restorative treatment approach is one of the existing minimal intervention approaches and is based on removing demineralized tooth tissues using hand instruments and restoring the cleaned cavity and adjacent pits and fissures with an adhesive filling material, usually a glass ionomer[4]. This approach has been advocated not only for field use but also for the management of children in clinic settings[10].

In order to avoid any attrition of the sample size extreme care was taken to know the details of the children, i.e., the demographic data were recorded. Furthermore a good administration was kept during the study period so that pupils can be easily traced even if they had left school prematurely. Due to this all the 100 children were able to be followed up. Children in the age group of 4–9 years were selected keeping in mind that dental caries is more in the age group and that teeth will not exfoliate during the study period resulting in dropout like in previous studies[14,16].

The most common teeth affected in the primary dentition due to caries are the molars and their premature loss results in space loss. Therefore to prevent the loss of these teeth in effective manner primary molars were selected for the clinical evaluation of the two restorative materials. The split mouth design was followed so as to compare the two materials in the same child, in such a way so that all parameters and environment are kept constant. Generally restorations of teeth in children are more difficult than in adults. Lo *et al.*[13] in their study have found that 93% children treated with ART did not perceive pain and 83% were willing to receive ART restorations in future. Therefore it can be concluded that ART can be used in children. Radiographs taken as a part of study helped to accurately elucidate the true extent of the lesion.

The standardization of the size of the cavity was important for effective comparison of retention of the two restorative materials, as the size of cavity has been reported to influence the survival rate of its restorations[12,17,18] and need for research regarding the cavity size and success of restoration have always been emphasized[9,13]. Moreover a good cavity choice enables the operator to adequately remove dental caries using hand instruments and to achieve adequate cavo material adhesion during the placement of restorative material[18]. Although patients were treated in a clinic environment rubber dam, local anaesthesia, three way syringe were not used. This helped to simulate the field conditions where these facilities are not available. The cavity preparation was carried out by one trained investigator to prevent as much as possible any variation in cavity designs. Cavities were prepared conservatively removing only the carious lesion leaving behind hard dentin as Mertz Fairhust *et al.*[19] have clearly shown after a 1 year clinical trial, sealed occlusal restorations survived longer and that dentinal caries left behind the occlusal lesions that were sealed over did not progress and neither did remaining tooth structure crumble under occlusal loading during trial period.

In this study particular care was taken to free the dentinoenamel junction from caries to enhance bonding to the restorations material and strong unsupported cusps were left intact where access for caries removal was deemed satisfactory. This is because removal of hard dry dentin, essentially demineralized with relatively few bacteria present appears to be unnecessary which may result in additional unwarranted removal of sound tooth tissue at DEJ and possible pulpal exposure[20]. It is also reported that any technique which effectively removes infected dentine should be adequate to halt the carious process, if the cavity is sealed and provides a firm foundation for restoration[21].

The cleaned cavity was conditioned using the conditioner given by the manufacturers since conditioning reduces microleakage[22]. Both restorative material were quite easy to mix to a smooth consistency, though Amalgomer CR had a certain sticky adhesive quality about it which is due to optimization of polyacrylic acid in the liquid and controlled particle size in powder components, which aided its placement into cavities especially those of maxillary arch. The material did not stick to the instruments, when the instruments were coated with spirit or powder of the cement. This greater adhesive property has helped in its retention in unprepared fissures. Firm finger pressure was applied as done by Frencken *et al.*[6] over restorative material which ensured good penetration of glass ionomer into pits and fissures as even if there is loss of restoration the remnants would confer protection against caries[23]. It is also reasonable to assume that the pressure applied reduced voids and improves the surface consistency thus contributing to reduced wear during hardening stages of glass ionomer. The restorations were assessed according to Frenken *et al.* criteria (1996)[6] at the end of 12th month as it has been applied in most other ART studies. No significant difference is seen between the USPHS and ART criteria when both were applied for same ART restorations and ART criteria are more stringent than USPHS criteria[7].

The majority of restorations in this study were assessed to be in good condition whereas failure of restorations was mainly due to gross marginal defect and same pattern of failure of restoration was seen in earlier studies[7,9,10]. No caries was found in the restored teeth, since pits and fissures adjacent to the restorations were sealed which is similar to a study in Syria which showed no caries development adjacent to cavity margins restored with glass ionomer[9].

Though this study was carried out in a dental set up the results can be compared with those of field studies because no facilities such as suction, three-way syringe or rubberdam was used which are unavailable in the field. Few investigators have tested the efficiency of ART in primary teeth and reported a success rate of approximately 50–93% in class I cavities after 1 year[11,13,24–26]. But higher success rate of restorations was expected as this study was conducted in a dental clinic. In this study the survival rate of class I restorations are

higher than the class II restorations in primary teeth which is in line with previous studies[7,24]. It is reasonable to assume that multiple surface restorations are more material, operator and environment dependent than single surface restorations.

At the end of 12 months 97.4% of class I Amalgomer CR restorations were successful when compared to 94.8% of Fuji IX restorations. These results are consistent with those achieved at the end of 12 months by Yip *et al.* using Fuji IX[24]. Mickenautsch *et al.*[25] reported a 1-year survival of one-surface ART restorations using Fuji IX and Ketac Molar as 93.6%. Elise Sasso Faccin *et al.*[26] in a dental set up in Brazil had shown a retention of 85% at the end of 1 year in class I cavities. Similarly, in a study done in a clinical set up in Kuwait, retention of 93.7% and 83.3% was seen for class I and II restorations at the end of 22 months respectively[10]. But this high success rate has reservations due to smaller sample size and higher drop out rate. A 100% success rate of class I restorations has been reported by Nazan Kocatas *et al.* (2006)[16] and could be attributed to application of the varnish over restorations.

Failure of class II restorations are higher than class I restorations which could be attributed to less adequate mechanical retention provided by ART instruments[14]. In this study the retention rate of class II restorations is between 95.1–88.5% which is higher than the previous studies where the success ranged from 45% to 70%[7,9,14,16].

Selection of small to medium cavity in this study may be a reason for higher success rate as the extension of cavity form to create a bulk of restorative material, is not of major importance for the durability of class II glass ionomer cement restorations in primary molars as long as outer and inner angles are well rounded[27]. Proper handling of the materials and adequate isolation could also be reasons for higher retention rates. On the other hand, with the use of retention niches Daniela *et al.* have shown a success of 100% and 93% for Fuji VIII and Ketac Molar multiple surface restorations, respectively in multiple surface cavities[28].

Small class II cavities restored with Amalgomer and Fuji IX showed a success rate above 80% in this study. Aruthur *et al.*[12] had reported a success of 62% after 1 year in class II cavities which measured 2–3 mm mesiodistally. It is reasonable to assume that in case of small cavities prepared by ART approach, it minimizes the contact of the restored surface with occluding cusps and thereby reducing the probability for excessive wear or fracture in the glass ionomer. In cavities lesser than 2mm in size restorations may fail because if the entrance of the cavity is small and the depth is more, then it is difficult to get the material into the depth of the preparation resulting in voids in the top layer which would fracture under pressure later.

Medium sized class I cavities exhibited a 100% success for both the restorative materials and this could be attributed to the large surface area which is available for the chemical adhesion of the glass ionomer cements. It may be due to higher compressive and tensile strength of Amalgomer CR medium sized class II cavities restored with Amalgomer CR showed a higher success rate than Fuji IX.

Mesio-occlusal Amalgomer CR restorations were more successful than the disto-occlusal restoration which can be due to limited visibility of the tooth surface to the operator and due to lack of moisture control. Whereas the success of Fuji IX was otherwise and no obvious reason can be attributed to it. But the results cannot be mooted as the number of mesio-occlusal restorations was smaller than that of disto-occlusal restorations. The use of rubberdam could have improved the retention rates of restorations[29] but the rubberdam was avoided to simulate field condition and cost factor.

The overall success rate of Amalgomer CR is marginally higher than that of Fuji IX restorations. Ceramic reinforcement of glass ionomer cement may be responsible for the higher strength of Amalgomer CR than that of Fuji IX which renders Amalgomer CR more resistant to wear and fracture. The physical and mechanical properties of Amalgomer CR are said to be in comparison with Amalgam

as claimed by manufacturer (Table 1). According to Williams, Billington and Pearson[30] reinforced materials are significantly stronger than other materials.

Though larger cavities were decided to be taken in the beginning of the study, availability of very few cases for analysis made it difficult to arrive at any definitive conclusion.

The higher success rate of restorations in this study may be attributed to proper cavity selection, efficient cavity preparation, proper handling of materials and improved physical properties of Amalgomer CR. An overall failure rate of 7% is very much lesser than the other studies and is substantially better than that found in all other studies on conventional selfcure glass ionomer. Taking into consideration the success of restorations, both restorative materials can be used for cavities prepared with ART and the technique is strongly recommended for management of small and medium occlusal and proximal carious lesions in primary teeth. Although the early 12 month findings are promising, evaluation of restorations for more periods is required.

Conclusion

In this clinical study at the end of 12 months, both Fuji IX and Amalgomer CR using ART technique in primary molars showed good survival rates. Survival rates of class I restorations were better than class II restorations for both restorative material. The survival of small cavities using ART technique was good. The restorations of medium cavities were also successful but conclusions cannot be arrived for medium cavities since sample size was small.

What this paper adds?

- Amalgomer CR and Fuji IX can be used for restoring primary molars using ART approach.
- A good cavity selection influences the retention of restorative material.

Why this paper is important for paediatric dentist?

- This paper reports on the effective preparation of cavity and restoration for the success of restorations in children with minimal facilities.

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