# Efficacy of GC Gold Label 9 and GC Miracle Mix® Restorations using Atraumatic Restorative Treatment (ART) in Rural Settings: A Randomized Controlled Trial

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***Objectives:*** *This study compared the longevity of high strength posterior glass ionomer and metal-reinforced glass ionomer using ART in rural settings within an 18-month observation period.* ***Study Design:*** *A non-blinded parallel design randomized controlled trial was conducted among children who attended dental outreach programs in a rural area of Southern India. Atraumatic Restorative Treatment (ART) was performed in 92 permanent posterior teeth with either high strength posterior glass ionomer or metal-reinforced glass ionomer restorations. The allocation ratio was 1:1. Restorations were evaluated at 1, 6, 12 and 18 months after placement.* ***Results:*** *The success rate of metal-reinforced glass ionomer restorations was 100%, 95.4%, 90.4% and 87.2% as compared to high strength posterior glass ionomer whose success rates were 100%, 93%, 85% and 61.8% at the four follow ups respectively. There was a statistically significant difference between the success rate of the two materials at the end of 18 months with the metal-reinforced glass ionomer restorations having a higher success rate (p=0.015). Conclusions : Although the clinical performance of both materials were largely similar, the metal-reinforced glass ionomer restorations had a higher success rate than the conventional GIC at the end of 18 months of follow-up.*

***Keywords:*** *Atraumatic Restorative Treatment, Glass ionomer cement, dental caries, Metal-reinforced.*

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## INTRODUCTION

Over the past decade, Atraumatic Restorative Treatment (ART), has been successfully used to control dental caries in developing regions of the world. ART involves excavating carious tooth structure with hand instruments only and restoring the cavity with an adhesive filling material. This treatment modality eliminates the prerequisite of rotary equipment and is in line with objectives of minimal intervention dentistry.[1] It is recommended by World Health Organisation (WHO) [2] as a vital constituent of its Basic Package of Oral Care (BPOC) for making restorative dental treatment more reachable to communities in developing nations such as India. The treatment is non-threatening, there is no noise, water cooling, or suction and does not require electricity. Most often, pain is absent or negligible so caries removal can be done without anaesthesia[3] making it a well-accepted treatment for children.[4-6] The ART approach has been field-tested since the mid-1980s. Since field conditions are often less than ideal, the biological and physical properties, availability, costs, ease of use, tolerance to operator variability, storage conditions and shelf-life of the materials chosen must be considered prior to use. Thus, one of the core requisites for the success of ART is the selection of appropriate restorative materials.[7]

The use of GIC is universally recommended for the same under field conditions. Preliminary investigations of ART restorations

were simple feasibility studies concentrating on retention of the glass ionomer material.[1,8] and placing a glass ionomer cement (GIC It was observed that owing to relatively poor physical properties, conventional GIC's exhibited much wear in stress-bearing occlusal cavities.[9-11] Recently, alternate materials with better handling and physical properties like high viscosity GICs have been promoted for the ART approach. Compared with conventional GIC, these have been found to have better properties.[12-14] Other alternatives to GICs include bonded and non-bonded amalgam alloys[15,16], composites[17] and hybrid resin-ionomers.[18] Expensive resin-based restorations needing special equipment and technique-sensitive dentin bonding systems are not appropriate for field use in rural settings.[19] but not limited to, developing countries. However, the requirement for the placement of the restorative materials under often less-than-ideal conditions imposes significant restrictions on their selection; and there have been very few randomized clinical trials or reports comparing different types of restorative materials and treatments. Although conventional glass-ionomer cements (GICs

One of the possible alternative materials is metal-reinforced glass ionomer. Studies have compared metal-reinforced glass ionomer restorative material to amalgam placed in conventionally prepared cavities and found that it is a promising alternative for Class I tooth cavities[20], has good fluoride release[21,22] and adequate mechanical properties including bonding to tooth structure. [23,24] The objective of this study was to compare the longevity of high strength posterior glass ionomer and metal-reinforced glass ionomer using ART in rural settings within an 18-month observation period.

## MATERIALS AND METHOD

This study was a non-blinded parallel design randomized controlled trial conducted to evaluate the longevity of metal-reinforced glass ionomer restorative material and compare it with the gold standard posterior Glass-ionomer cement following caries excavation using the Atraumatic Restorative Treatment Technique. This study was conducted among children above 12 years of age from eight schools located in rural areas of Udupi District, Karnataka, India from December 2016 to March 2017 which was followed up for 18 months after restoring the teeth.

Those above 12 years of age with fully erupted permanent molars or premolars and whose parents gave written informed consent were included. Teeth with cavitated carious lesions in dentine, lesions accessible to caries excavation with hand instruments were criteria for inclusion. Presence of swelling /fistula near the carious tooth, extensive carious lesions, exposed pulp, pulpal pain and inflammation and absence of an opposing tooth were criteria for exclusion. Sample size of the study was calculated using G*Power®3.1.9.2 software. With success rate of 93% and 81% of RMGIC and GIC type IX one surface restorations[18] at power of 95% and alpha of 0.05 the sample size was calculated to be 84. Assuming 10% attrition rate, the final sample size was estimated to be 92 teeth. Ethical approval was obtained from the Institutional Ethics Committee of Kasturba Hospital and Kasturba Medical College, Manipal before commencement of the study. The school authorities granted permission to conduct screening and recruitment of the eligible children in the school premises. Verbal assent was obtained from the children prior to screening.

Data was recorded on a proforma regarding participant age, gender, class and subdivision, and school name. The tooth number as well as the type of restoration (metal-reinforced GIC or conventional GIC) for each tooth was noted. The follow-up scores for each tooth at one month, six months and 12 months and 18 months were also recorded on the same data sheet. In the month of December 2016, a total of 650 children above the age of 12 years were screened by two examiners in natural lighting; of these 152 were found eligible. The eligible children were given participant information sheets explaining the study procedure, its risks and benefits. Informed consent forms were given to both parents and children. A total of 55 children were excluded since the parents did not give written consent to participate. Eight children were further excluded on the day the restorations were placed as they did not co-operate during the procedure. Subsequently, 92 ART restorations were placed in permanent molars or premolars of 89 children from January to March 2017 (Figure 1). Following oral examination, the children were provided with oral health education in their respective classrooms for raising awareness on tooth brushing techniques and oral hygiene. Children who required treatment and were not included in the study were given referral cards and encouraged to avail free treatment at the university dental school.

Each patient received one of two restorations; GC Gold Label 9 (High Strength Radiopaque Posterior Glass Ionomer Restorative; Lot: 1707081, GC Corporation, Tokyo, Japan) or GC Miracle Mix® (Metal-Reinforced Crown & Core Build-Up; Lot: 1205091). Miracle Mix® (GC Corporation, Tokyo, Japan) consists of glass ionomer cement mixed with silver alloy powder. The allocation ratio was 1:1. For each tooth the restorative material to be placed was decided by flipping a coin. The next tooth would automatically receive the alternative restoration to ensure an equal number of teeth were allocated to study (GC Miracle Mix®) and control groups (GC Gold Label 9). Blinding was not possible in the study as the restorations differ in colour. The restorations were placed by two calibrated operators (SA, VGD) trained to perform ART in field settings. They treated the children in the dental chair of the mobile dental unit (Confident Dental Equipment Pt. Ltd., Bangalore,India) with the help of a dental surgery assistant. The carious tooth was isolated with cotton rolls and the surface was cleaned with cotton pellet to remove the debris. If needed, the opening of the cavity was enlarged with an enamel hatchet. Caries removal was carried out using small and medium sized sharp spoon excavators (#61/62 de excavator, Hu-Friedy Mfg. Co., LLC, Chicago, Illinois, USA). The clinicians used conventional optical and tactile criteria to determine the thoroughness of caries removal after cavity preparation.[25] Since the volume of calcium hydroxide lining and its extension could hinder performance of the restorations, [26] cavity preparations requiring calcium hydroxide lining were excluded from the study. A dental surgery assistant mixed the materials, in accordance with the manufacturers' instructions. Cements were placed into the cavity using a cement carrier. The restoration was inserted into the cavity corners using a ball burnisher and finger pressure was applied using a gloved finger coated with petroleum jelly.[27]

Occlusion was checked with an articulating paper and excess material was removed with a carver. For class II restorations, a mylar strip (Samit Straight Matrix/Mylar strip, Samit Industries,

New Delhi, India) was placed between the teeth to contour the proximal surface and maintain a contact through which a floss could be passed. A wedge was placed to support the strip under the contact point at the gum margin during restoration. After the material was condensed into the cavity the wedge was removed and the mylar strip was gently detached from the interproximal area using back and forth motion. After the procedure the children were asked not to rinse their mouth, drink fluids or eat food for 30 minutes. A single examiner (VGD) evaluated the restorations at one month, six months, 12 months and 18 months from the time of placement of the restoration. The patient was seated on a chair facing a window or door with the examiner in front of the patient. The tooth was wiped with a cotton pellet to remove debris prior to evaluation. Each tooth was examined using a mouth mirror and a CPITN probe under natural illumination. Failed restorations in either group were re-restored with High Strength Radiopaque Posterior GIC during the follow-up examinations.

The restorations of both groups were assessed for retention, marginal integrity and bulk fracture using the criteria given by Frencken *et al.,*1996 (Figure 2). [28] Assessment of intra-examiner variability was calculated by Cohen's Kappa using IBM SPSS software version 20. Kappa statistic for intra-examiner reliability after repeated examination of 10% of the study group was 0.89.

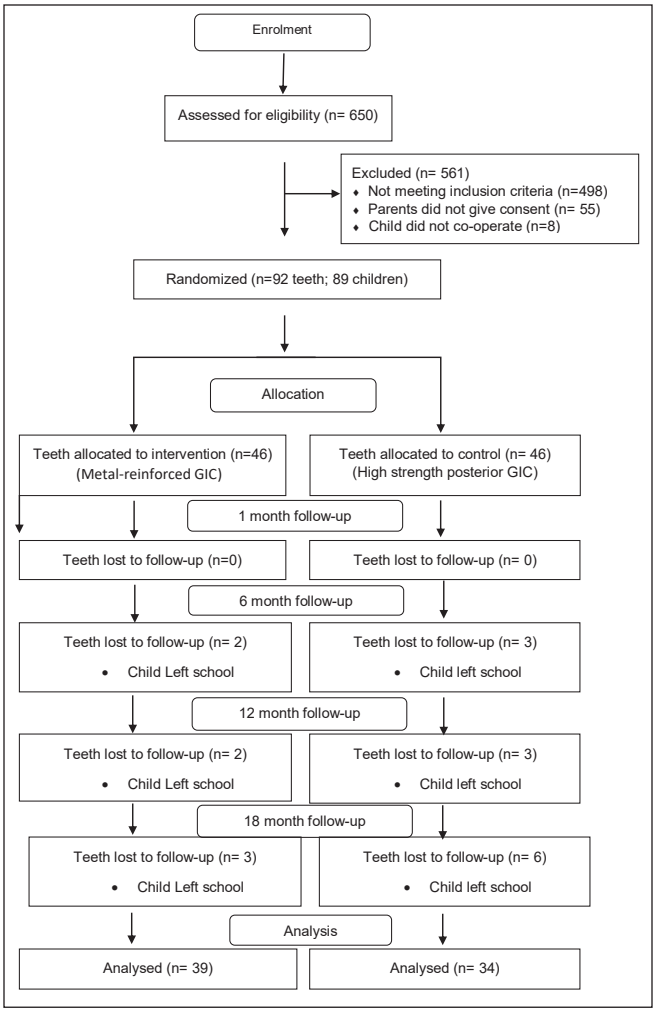


**Figure 1: Flowchart according to CONSORT 2010 guidelines**

Data analysis was carried out using IBM SPSS software version 20, SPSS Inc. Chicago, USA**.** For data analysis ART scores zero and one were considered as successful. Scores two, three and four were considered to be failures. Scores five to nine were not observed. Failed restorations that were re-restored during follow-up examination were considered as 'Failed' during data analysis. A new dichotomous variable was computed for each of the 4 follow up periods where restorations were assigned either "Success or Failure" according to the above categorization. Cochran Q test then was used to compare within group success rates at the 4 follow up periods. Chi- square test was used to compare the success rates of the two study groups. The Kaplan-Meier method and the Log Rank test was used to plot the survival distributions for both the materials. The probability level for the study was set at $p < 0.05$.

## RESULTS

The sample consisted of total 92 restorations placed in posterior permanent teeth of 89 participants. The mean (SD) age of the subjects was 13.8 (0.7). There were more females (55.1%) than males (44.9%) at baseline. The mean (SD) DMFT at baseline was 2.7 (1.5). Most participants had good (79.8%) or fair (20.2%) oral hygiene **(as per OHI-S index).** [29]

No tooth was extracted or lost during the entire period of follow-up. Table 1 describes the status of all the restorations placed (buccal, proximal and occlusal) and their condition at follow-up examination. At the end of 1 month, most of the GIC (95.6%) and all metal-reinforced glass ionomer (100.0%) restorations were present and in good condition (Score 0) according to the ART Assessment criteria as described in Figure 2. Two GIC restorations showed slight marginal defects of less than 0.5 mm in depth (Score 1). At the six months follow up, more metal-reinforced glass ionomer (93.2%) fillings were completely intact (Score 1) as compared to glass-ionomer cement (79.1%). Marginal defects i.e. score one and two were also more in GIC (13.9%) than in metal-reinforced glass

| Score | ART Assessment Criteria |
|---|---|
| 0 | Present, good |
| 1 | Present, slight marginal defect for whatever reason, at any one place which is less than 0.5mm in depth; no repair is needed |
| 2 | Present, marginal defect for whatever reason, at any one place which is deeper than 0.5mm but less than 1.0mm; 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 |

**Figure 2: Criteria for scoring ART restorations at follow-up examinations**

ionomer (4.4%). Gross defect needing repair (Score 3) was seen in only one GIC restoration. Three fillings were completely dislodged (Score 4) i.e. two GIC (4.6%) and one metal-reinforced glass ionomer (2.2%). At the end of one year, more metal-reinforced glass ionomer fillings were present and fully intact (85.7%), i.e., score 1. Five GIC and three metal-reinforced glass ionomer fillings showed marginal defects (**Score 1 and 2**). An equal number, three each of both restorations showed complete loss **(Score 4)**. At the end of 18 months, 82.1% of the metal-reinforced glass ionomer restorations were intact **(Score 1)** as compared to 55.9% for GIC restorations (Table 1).

The success rate of metal-reinforced glass ionomer was 100%, 95.4%, 90.4% and 87.2% when examined at one month, six months, 12 months and 18 months as compared to GIC whose success rates were 100%, 93%, 85% and 61.8% at the four follow ups respectively. There was a statistically significant difference between the success rates of the two materials at the end of 18 months with the metal-reinforced glass ionomer restorations having a higher success rate (p=0.015) (Table 2). The Kaplan Meier survival curves for both restorations showed the survival curves with censored data for both the materials. The survival of the materials decreased during follow up. The high strength posterior glass ionomer material had a lower survival rate as compared to metal-reinforced glass ionomer, especially at the end of the observation period at 18 months (Figure 3). The log-rank test too showed significant differences between the survival curves for the studied materials (P<0.05). A total of 48(occlusal), 18(buccal) and 7(proximal) restorations were placed for the two groups respectively. When compared against the type of cavity restored, we found no statistically significant difference between the performances of the two materials. However, Metal Reinforced GIC did seem to have a higher success percentage for occlusal and buccal surfaces as compared to GIC (Table 3).

**Table 2: Comparison of the efficacy of GIC and Metal-reinforced GIC restorations over the follow-up period of 18 months**

| Follow-up time period | Restoration type | | | | | p-value |
|---|---|---|---|---|---|---|
| | | High strength posterior GIC | | Metal-reinforced GIC | | |
| | | N | (%) | N | (%) | |
| 1 month | Success | 34 | 100.0 | 39 | 100.0 | NA |
| | Failure | 0 | 0.0 | 0 | 0.0 | |
| 6 months | Success | 31 | 91.2 | 38 | 97.4 | 0.333 |
| | Failure | 3 | 8.8 | 1 | 2.6 | |
| 12 months | Success | 26 | 76.5 | 35 | 89.7 | 0.205 |
| | Failure | 8 | 23.5 | 4 | 10.3 | |
| 18 months | Success | 21 | 61.8 | 34 | 87.2 | 0.015 |
| | Failure | 13 | 38.2 | 5 | 12.8 | |

Chi-square test was the test of significance

p < 0.05 was considered statistically significant

**Table 3: Success rate after 18 months of the two restorative materials according to the type of cavity prepared.**

| Success based on type of cavity prepared | Restoration type | | | | | p-value |
|---|---|---|---|---|---|---|
| | | High strength posterior GIC (n=34) | | Metal-reinforced GIC (n=39) | | |
| | | N | (%) | N | (%) | |
| Occlusal (n=48) | Success | 12 | 54.5 | 21 | 80.8 | 0.067 |
| | Failure | 10 | 45.5 | 5 | 19.2 | |
| Buccal (n=18) | Success | 8 | 80 | 8 | 100 | 0.477 |
| | Failure | 2 | 20 | 0 | 0 | |
| Proximal (n=7) | Success | 1 | 50 | 5 | 100 | 0.286 |
| | Failure | 1 | 50 | 0 | 0 | |

Chi-square test was the test of significance

P < 0.05 was considered statistically significant

**Table 1: Follow up of GIC and Metal-reinforced GIC restorations according to ART Assessment criteria**

| Follow up | Restorative material | ART Assessment Scores | | | | |
|---|---|---|---|---|---|---|
| | | Score 0 N (%) | Score 1 N (%) | Score 2 N (%) | Score 3 N (%) | Score 4 N (%) |
| 1 month | High-strength posterior GIC | 44 (95.6) | 2 (4.4) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| | Metal-reinforced GIC | 46 (100.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| 6 months | High-strength posterior GIC | 34 (79.1) | 6 (13.9) | 0 (0.0) | 1 (2.3) | 2 (4.6) |
| | Metal-reinforced GIC | 41 (93.2) | 1 (2.2) | 1 (2.2) | 0 (0.0) | 1 (2.2) |
| 12 months | High-strength posterior GIC | 31 (77.5) | 3 (7.5) | 2 (5.0) | 1 (2.5) | 3 (7.5) |
| | Metal-reinforced GIC | 36 (85.7) | 2 (4.7) | 1 (2.3) | 0 (0.0) | 3 (7.1) |
| 18 months | High-strength posterior GIC | 19 (55.9) | 2(5.9) | 5(14.7) | 1(2.9) | 7(20.6) |
| | Metal-reinforced GIC | 32(82.1) | 2(5.1) | 2(5.1) | 0(0.0) | 3(7.7) |

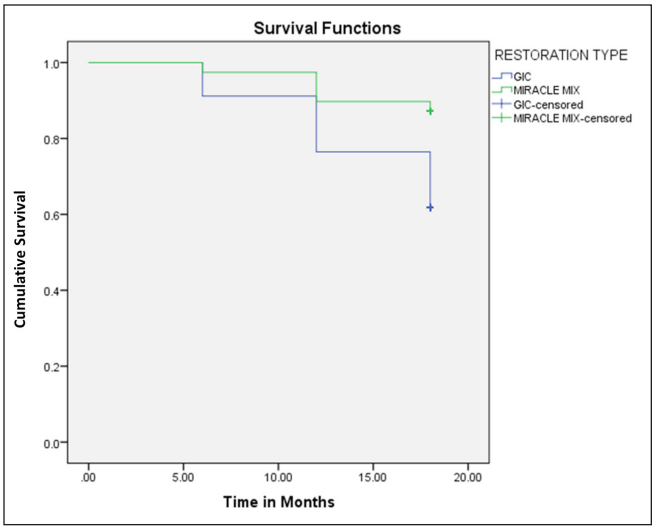


**Figure 3: Kaplan Meier Survival analysis curve for the two materials.**

## DISCUSSION

The success rate of metal-reinforced glass ionomer was 87.2% as compared to GIC whose success rates was 61.8% at the fourth follow-up. It was also observed that the percentage of completely intact restorations was much higher in the metal-reinforced GIC group (82.1%) than the other group (55.9%). When compared against the type of cavity restored, metal-reinforced glass ionomer had higher success rates than GIC for occlusal and buccal cavities although the differences observed were not statistically significant.

Although the success rate of the metal-reinforced glass ionomer was found to be better at every stage of follow up, statistically significant difference between the success rates was only found at the end of 18 months. At the end of 1 month, most of the GIC restorations were present and in good condition according to the ART Assessment Criteria. At the 6-months, 12 months and 18 months follow up, marginal defects were the reasons for failure. Gross defect needing repair and complete loss of the restoration was seen in few teeth restored with GIC. Although cumulative success rates in our study are slightly lower than previous studies using packable GICs[4,30] similar reasons for failure have been reported.[4,12,30]

Both materials were hand mixed, therefore, may be undermined by dissimilarities in temperature and relative humidity.[31] The hand-mixed technique is reported to produce an unbalanced dispersal of unreacted glass filler particles in the plastic mass. These can form agglomerates that contain voids prone to cracking when the material is under load.[32] A previous study stated that marginal degradation of glass ionomer materials may be explained in part by its tendency for dissolution at low pH.[33] For occluso-proximal lesions, a study reported that the absence of a proper proximal contact had a negative influence on the longevity of restorations.[34] This could possibly explain the gradual wear of both materials during the study. Of the 46 teeth in each group, only 39 teeth in the metal-reinforced GIC group and 34 teeth in the high strength posterior GIC group were available for examination at the end of 18 months. Change of school from high school level to pre-university level of some of the students was the cause for this attrition.

The limitations of the study include the attrition of the study sample over the follow up period of 18 months. Blinding of neither operator, participant nor examiner was possible as the materials were different in appearance. Though blinding of the operators could not be carried out, randomization was done to reduce selection bias as far as possible. Multiplicity of operators can interfere in restorations' longevity.[30,35] Since restorations were placed by two different operators, some operator effect could be expected although both had the same level of experience and training in the ART approach. Radiographic examination was not carried out to assess the extent and severity of the carious lesions or any secondary caries, if present, in relation to the restorations as this study was done in a field setting. Anterior carious lesions were not included in this study as metal-reinforced GIC is not aesthetic material and therefore, cannot be placed in anterior teeth.

Previous studies testing encapsulated GIC[36] and amalgam[15] with ART were not conducted in field settings. A few clinical studies have investigated the success of resin-modified glass-ionomers with ART.[18,37,38] Resin-modified glass-ionomers would be fit for use with the ART approach only when a light-curing device is available. The requirement of additional equipment for these materials would limit the usage in certain rural settings. Since metal-reinforced glass ionomer is dispensed as a powder-liquid, and can be hand mixed using readily available instruments, it can be used in any setting. It also binds to tooth structure by chemical bonding therefore, satisfies the ART criteria of being an 'adhesive' restorative material. Recent evidence on survival of ART restorations in permanent posterior teeth, using high strength posterior glass ionomer in single-surface restorations presented high survival rates over the first 3 years while multiple-surface restorations presented lower survival percentages over the first 5 years.[39] An increase in failure rate over time observed in our study is consistent with previous literature.

We observed that both materials showed a satisfactory clinical performance, with little difference between the materials with respect to wear after 12 months. However, at the 18 months follow up the metal-reinforced glass ionomer material had an overall better performance with fewer marginal defects for posterior restorations in permanent teeth performed in the field settings. These findings need to be validated by further research by other investigators.

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