

## Original Article

# A comparative survival analysis of high viscosity glass ionomer restorations using conventional cavity preparation and atraumatic restorative treatment technique in primary molars: A randomized clinical trial

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## ABSTRACT

**Background:** This randomized clinical trial (RCT) aimed to compare the 3-year survival rates of high viscosity glass ionomer restorations (HVGIC) using conventional cavity preparation and atraumatic restorative technique (ART) in primary molars.

**Materials and Methods:** In this RCT, 139 schoolchildren aged 6–9 years with dentinal caries in primary molars were randomly allocated to groups, i.e. the ART group and the conventional group, utilizing a random number generator. Adequate allocation concealment was done. Intervention was delivered using standard procedure and GC Fuji IX ART HVGIC was used as restorations in both the groups. Analysis was carried in 92 participants, and survival rates in both the groups were compared at 12, 24, and 36-month intervals. IBM SPSS software was utilized to analyze the time taken for the procedure and the Kaplan–Meier estimate was used to assess the survival rates. *P* value of 0.05 was considered statistically significant.

**Results:** The ART took longer to complete ( $16.48 \pm 2.02$  min) versus conventional rotary instrumentation ( $13.15 \pm 1.32$  min). The conventional method was slightly superior as compared to ART; excellent survival rates (i.e. >90%) were achieved in both groups at the end of 12-month follow-up with no significant differences at the end of 24 and 36 months as evident from Kaplan–Meier estimate ( $P = 0.255$ ).

**Conclusion:** Three-year follow-up showed that GIC restorations with ART and conventional method carried out using GC Fuji IX ART HVGIC were acceptably successful, substantiating the use of ART for the primary dentition in areas with high caries prevalence and limited access to dental care.

**Key Words:** Dental atraumatic restorative treatment, dental care for children, glass ionomer cements, molar, survival analysis

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## INTRODUCTION

Over the last few decades, the increase in dental caries in developing countries due to the consumption of

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processed food has led to the invention of atraumatic restorative technique (ART) as a means of delivering basic restorative procedures for underserved communities. Not only does this procedure save functional teeth from extraction, but it has also proven to be easy to execute with minimal equipment and monetary resources, which reduces the burden of oral health expenditure in underdeveloped and developing countries.<sup>[1]</sup>

Eventually, ART became the most researched technique to search for novel restorative material and minimal intervention approach strategies.<sup>[2]</sup> ART not only proved to be easy to perform compared to conventional restorative methods, but it also proved to be less sensitive, less painful, and economical, while producing comparable beneficial results in the maintenance of viable teeth.<sup>[3-5]</sup>

Glass ionomer cement is the only material that binds both enamel and dentin through chemical bonding; it also has had a similar thermal expansion to that of the tooth structure, induces absorption, and releases fluoride. They are also biocompatible and had established themselves as the material of choice for single surface restorations and decay limited to a dentinal extent.<sup>[6,7]</sup>

The advancement of these new-generation glass ionomer formulations has resulted in the development of better properties, such as improved handling characteristics, decreased set time, increased strength, and increased wear resistance, making glass ionomer cements the material of choice for ART.<sup>[8]</sup>

Although ART approaches using GIC are not recommended for proximal restoration due to loss of material by fracture and loss of bulk restoration related to material properties, the ART approach is still considered comparable to conventional amalgam restoration in single-surface restorations which can be carried out at economical cost with ease.<sup>[9-12]</sup>

Most ART procedures are performed on children in clinical and hospital settings, considering the costs of the treatment and the caries activity of the child; the most significant use of ART still exists in outreach and rural areas in underdeveloped and developing nations. Within these outreach initiatives and rural oral health services, the ART approach offers a viable approach to preserving functional teeth using minimal tools.<sup>[13-16]</sup>

Therefore, this randomized clinical trial (RCT) was performed to compare the time required for cavity

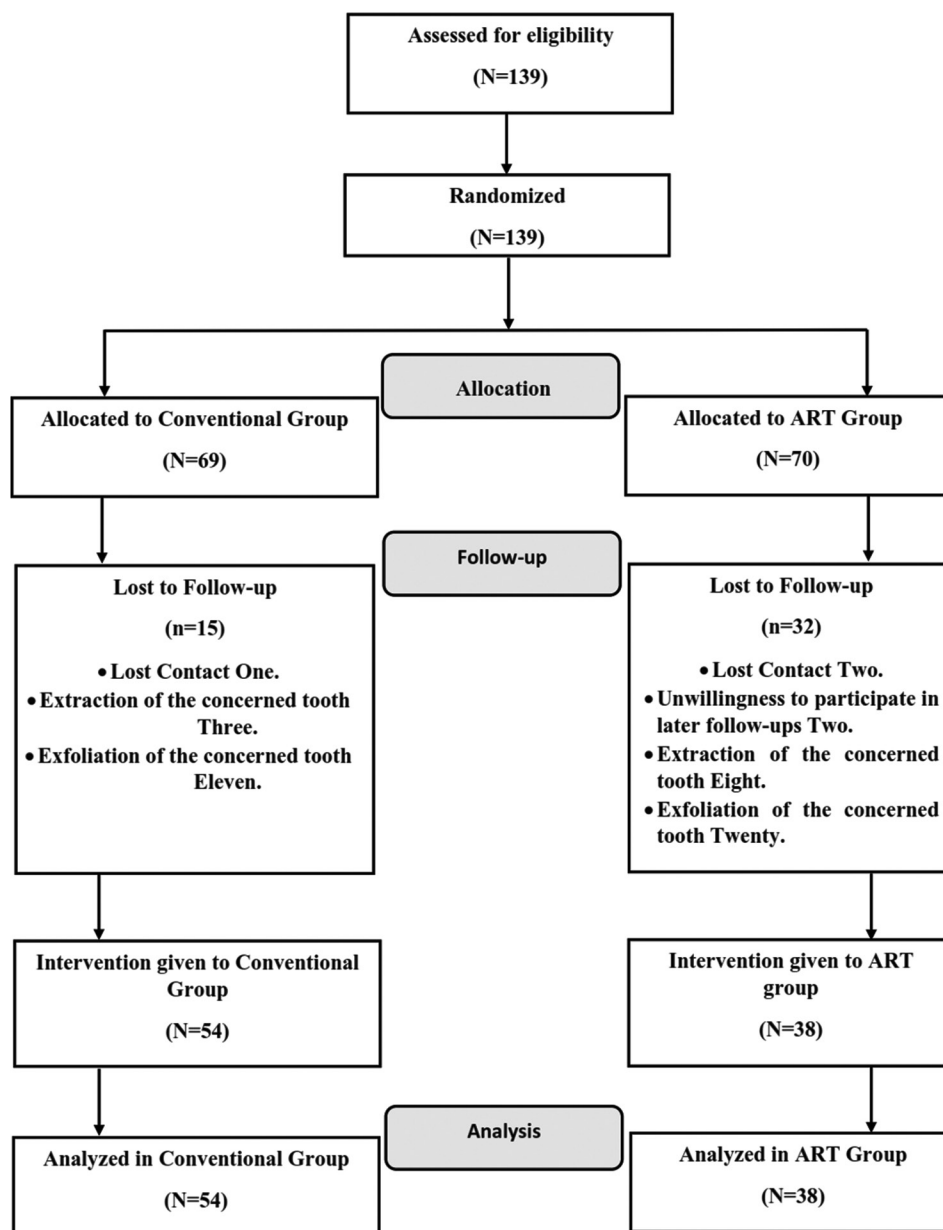
preparation, along with survival rates of high viscosity glass ionomer restorations using conventional cavity preparation and ART technique in primary molars over 3 years among children 6–9 years of age. The null hypothesis for this research was that there is no difference in cavity preparation time for these GIC restorations using traditional or ART approaches and survival rates over three years.

## MATERIALS AND METHODS

The current RCT was performed on 139 school children from government schools among the 6–9-year age group from the southern urban division of Bangalore, in the state of Karnataka, India. Upon approval from the Ethical Review Board of A. E. C. S. Maaruti College of Dental Science and Research Centre (Letter No. AECS/MDS/404/2007-08), the research study also got clearance to conduct from the Deputy Director of Public Instruction Office (DDPI) of Bangalore south and the schools concerned. The minimum number of participants required for each group for two-tailed tests calculated using the Cochrane formula was 28. After accounting for possible loss to follow-up, an additional 10% of participants were planned to be included in the required sample in each group. However, the final sample consisted of a total of 139 participants enrolled for research as this study was a part of the school oral health program. These participants were randomly allocated to two groups utilizing a randomization sequence was created using Microsoft Excel 2007 (Microsoft office, USA) and allocation concealment was achieved through Sequential Numbered Opaque Sealed Envelopes created by an independent statistician blinded regarding the nature and outcome of the study [Figure 1].

Clinical trial registry was not sought as GIC restoration using conventional and ART method is a routinely employed procedure to restore carious tooth in pediatric dentistry, also this study was a part of school oral health program which was conducted following approval from the DDPI of Bangalore south and the schools concerned, along with parental consent.

The training and calibration of the two investigators were carried out in two phases, the first phase of which was the initial calibration phase, where investigators were trained to provide technical skills and operating efficiency required for complete operating control



**Figure 1:** Flow diagram of methodology.

while performing the clinical procedure. In the second phase of the study which was the final calibration phase, the investigator performed caries removal using both ART and conventional methods on ten subjects which were then assessed for their completeness in caries removal by experts in the field of conservative dentistry and endodontics followed by placement of GIC as per intervention in both groups, respectively. The kappa coefficient values were determined and were found to be 88% and reflected a high degree of conformity in observational judgment between the investigator and the research guide.

Participants were enrolled after receiving parental consent based on the following inclusion criteria: schoolchildren belonging to the 6–9-year age range and possessing open cavitated dentinal lesions and cavities (WHO TYPE III examination) that can be accessed with the smallest (0.9 mm tip) excavator.<sup>[17]</sup> Both the examiners examined the children for eligibility, and in case of controversy, a third independent examiner was consulted to break the ties. In the case of dental caries approximating pulp, an intraoral periapical radiograph was taken to assess the eligibility of the child for the allocation procedure. While those without parental consent and

with evidence of substantial caries (approximating dental pulp) in the radiograph and clinical review were exempted from being included in the research. During this stage, training of the nonblinded assistants and investigators was also carried out for recording details such as demographics, and study outcomes like the recording of time required for caries removal using stopwatch, the time required for placement of GIC restoration by both methods, evaluation criteria for GIC restorations. Blinding of the assistants and investigators was not feasible due to the nature of the procedure being carried out i.e. cavity preparation with high-speed airtor handpiece vs hand instruments. Hence, only the statistician analyzing the results was blinded.

The selected participants were divided into two groups, i.e. the ART group and the conventional restoration group, and intervention was carried out according to the groups.

#### Cavity preparation for conventional restoration group

For conventional methods of restoration, occlusal caries excavation was done using 0.8 mm × 0.8 mm (BR-49) and 1 mm × 0.8 mm (BR-45) round diamond burs (Dia Burs, Mani Inc.) using high-speed water-cooled airtor handpiece (i.e. N. S. K T112002 (speed 380,000–450,000 R. P. M) till sound dentin was reached.

#### Cavity preparation for atraumatic restorative treatment group

While caries exaction for ART procedure was carried out using small (EXC153/4), medium (EXC131/2), and larger (EXC129/0) size spoon excavator corresponding to sizes 1, 1.4, and 1.7 mm respectively by (Hu-Friedy Mfg. Co., LLC, Chicago, Illinois, United States). Where occlusal caries lesions involving dentin were present but could not be approached with the smallest (1 mm tip) spoon excavator, the 14/14 Off-Angle Hatchet (CP14/14) also by (Hu-Friedy Mfg. Co., LLC, Chicago, Illinois, United States) was used to widen the opening to accommodate the excavator for proper caries removal.

#### Restoration of atraumatic restorative treatment group and conventional method group with GC Fuji IX atraumatic restorative treatment

GC Fuji IX ART is a specially formulated cement that was developed to restore posterior cavities. The kit is specially designed and consists of two separate powder and liquid for manual hand mixing of the cement and a postrestoration cocoa butter varnish

which serves as a means to protect the cement once manipulated and place in the cavity.

In the current study, both the cavities were restored with GC Fuji IX ART (GC Corporation, Tokyo Japan, Lot No. 1204051) to keep the evaluation criteria similar.<sup>[18]</sup> The study subjects of both the groups were periodically recalled every 2 months for 3 years for the assessment of the survival rate of restorations using CPI probe with a 0.5 mm ball end tip using standard criteria as shown in Table 1. A third independent examiner who was not a part of the study assessed the restoration on follow-up visits. All the procedures carried out were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2000.

Since it would have been unethical to devoid and child from the needed treatment. The children who were excluded from being a part of the study were referred to the hospital for advanced treatment.

The restoration was said to be “survived” when they achieved score scores 0, 1, and 7, in the case when they achieved scores like 2, 3, 4, 5, and 8 they were said to “fail to survive.”

#### Statistical analysis

Statistical analysis was carried out using IBM SPSS software versus 24 for windows (New York, USA). Since the data were continuous type and showed normal distribution hence an independent sample

**Table 1: Standard criteria for the assessment of the restorations at various time intervals<sup>[16]</sup>**

Score	Criteria
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 <1.0 mm; repair is needed
3	Present, gross defect of >1.0 mm in depth; repair is needed
4	Not present, restoration has (almost) completely disappeared; treatment is needed
5	Not present, another restorative treatment has been performed
6	Not present, the tooth has been extracted
7	Present, wear and tear gradually over larger parts of the restoration but are <0.5 mm at the deepest point; no repair is needed
8	Present, wear and tear gradually over larger parts of the restoration which are deeper than 0.5 mm; repair is needed
9	Unable to diagnose



test was used to compare the mean age of the participants and time taken to complete the procedure by both the methods. Chi-square test was also used to compare the gender and age-wise distribution of the participants, and the arch of teeth allotted in both the groups. Ultimately to check for survival of restorations carried out using both the methods was assessed using Kaplan–Meier Survival Curves and the Log-Rank Test. The probability level was set at  $P \leq 0.05$  for statistical significance of all the tests.

## RESULTS

This comparative clinical study involved 139 participants aged between 6 and 9 years. Researchers were able to follow 92 participants out of 139 up to the proposed 3-year timeframe, resulting in 47 participants dropping out, i.e. 33.81%. Considering the age of the participants, it was observed that the majority of dropouts were observed in the 9-year age group, i.e. 32, whereas the 6-year, 7-year, and 8-year-old children showed a drop of three, three, and nine participants, respectively. Reasons such as exfoliation of the concerned tooth i.e. 31, extraction of the affected tooth i.e. 11, loss of contact i.e. three, and unwillingness to participate in subsequent follow-ups i.e. two were the reasons for drop-outs respectively [Tables 2 and 3].

The final analysis of the study consisted of 92 participants which consisted of 32 males and 22 females in the ART group while 22 males and 16 females in the conventional group respectively ( $P = 0.896$ ). The mean age of the study participants in the ART group was  $8.31 \pm 0.93$  years and that in the conventional method group was  $8.52 \pm 0.80$  years ( $P = 0.257$ ) [Graph 1 and Table 4].

While considering the percentage distribution of maxillary and mandibular teeth in both the groups, the ART group consisted of 24 (44.45%) teeth belonging to a maxillary arch and 30 (55.55%) belonging to the mandibular arch. Whereas the conventional group consisted of 24 (63.16%) teeth belonging to the maxillary arch and 14 (36.84%) teeth belonging to the mandibular arch [Table 5].

An estimation of the time taken to complete a GIC restoration using both methods suggested that completing a GIC restoration using a traditional method takes approximately  $13.15 \pm 1.32$  min, while completing the ART restoration takes  $16.48 \pm 2.02$  min. Application of Unpaired t-test

**Table 2: Age-wise distribution of dropped out study participants in atraumatic restorative treatment and conventional method group**

Age (years)	Technique	
	ART, n (%)	Conventional, n (%)
6	1 (0.72)	2 (1.44)
7	1 (0.72)	2 (1.44)
8	3 (2.16)	6 (4.32)
9	10 (7.19)	22 (15.83)

Drop-out participants=47 (33.81%). ART: Atraumatic restorative treatment

**Table 3: Reason for dropped out study participants in atraumatic restorative treatment and conventional method group**

Reason of drop-out	Technique	
	ART, n (%)	Conventional, n (%)
Lost contact	1 (0.72)	2 (1.44)
Unwillingness to participate in later follow-ups	0	2 (1.44)
Extraction of the concerned tooth	3 (2.16)	8 (5.75)
Exfoliation of the concerned tooth	11 (7.91)	20 (14.39)

Drop-out participants=47 (33.81%). ART: Atraumatic restorative treatment

between the time required by the two methods showed a highly statistically significant difference between both the methods ( $P \leq 0.001$ ) [Table 6].

The log-rank test shows that there is an overall statistically nonsignificant difference (i.e.  $\chi^2 = 1.295$ ,  $P = 0.255$ ) in the overall survival distributions between the two intervention groups, i.e. ART and conventional method [Table 7].

From our Kaplan–Meier survival curve, we can see that in the GIC restoration with conventional methods, the cumulative survival proportion tends to be higher than restorations performed using ART in all the three follow-up periods (i.e. 95% and 100% at 12 months, 74% and 61% at 24 months, and 48% and 39% at 36 months in conventional and ART group, respectively). Although it is evident that GIC restorations carried out using conventional methods seem to survive for a longer period, it still does not seem to survive significantly much longer compared to those restored with using the ART method ( $P = 0.255$ ) [Graph 2].

## DISCUSSION

Dental caries which is considered a preventable disease is among one of the most prevalent serious public health problems. Many times, the caries process

**Table 4: Age-wise distribution of study participants in atraumatic restorative treatment and conventional method group included in final analysis**

Age	Technique		Total $n_T$ (%)	P
	ART, $n$ (%)	Conventional, $n$ (%)		
6 years	3 (3.3)	1 (1.1)	4 (4.3)	0.718 (NS)
7 years	8 (8.7)	4 (4.3)	12 (13.0)	
8 years	12 (13.0)	7 (7.6)	19 (20.7)	
9 years	31 (33.7)	26 (28.3)	57 (62.0)	
Mean age	8.31±0.93	8.52±0.80	-	
Total	54 (58.7)	38 (41.3)	92 (100.0)	-

Test: Chi-square test and independent sample *t*-test; NS: Statistically not significant; level of significance= $P<0.05$ . ART: Atraumatic restorative treatment

**Table 5: Percentage distribution of the maxillary and mandibular teeth in both atraumatic restorative treatment and conventional group included in final analysis**

Technique	Quadrant	$n$ (%)	Total $n_T$ (%)
ART group	Maxillary	24 (44.45)	54 (100)
	Mandibular	30 (55.55)	
Conventional group	Maxillary	24 (63.16)	38 (100)
	Mandibular	14 (36.84)	

Test: Descriptive statistics. ART: Atraumatic restorative treatment

**Table 6: Mean time taken to complete restoration between the conventional and atraumatic restorative treatment techniques**

Technique	Mean time±SD	SE	Unpaired <i>t</i> -test	P
Conventional	13.15±1.32	0.21	8.902	<0.001 (HS)
ART	16.48±2.02	0.29		

HS: Highly significant, level of significance =  $P<0.05$ . ART: Atraumatic restorative treatment; SD: Standard deviation; SE: Standard error

**Table 7: Mean time taken to complete restoration between the conventional and atraumatic restorative treatment techniques**

Overall comparisons			
	$\chi^2$	df	P
Log rank (Mantel-Cox)	1.295	1	0.255 (NS)

Test of equality of survival distributions for the different levels of treatment, NS: Statistically not significant, level of significance =  $P<0.05$

frequently progresses beyond the reversible stage and their impact on individuals and communities in terms of pain, suffering, impairment of function, and reduced quality of life, is considerable.<sup>[19,20]</sup> Although many countries run various programs to tackle this problem, still preventive programs are slow in reaching populations that need them the most. Even if the cost of many preventive programs is low, they

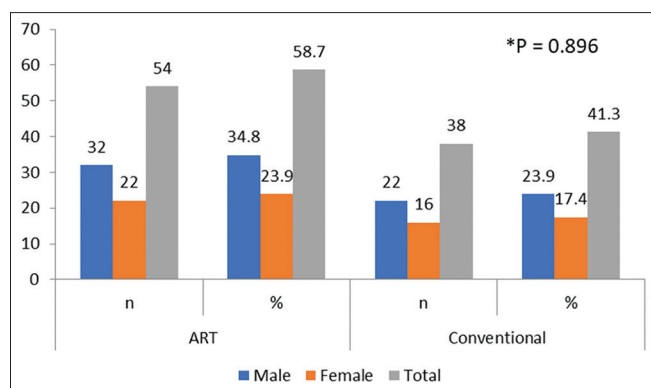
rarely reach the funded priority list of developing countries.<sup>[21]</sup>

Modern restorative care of carious lesions is based on monitoring early lesions to assess progression, accompanied by a minimal intervention approach, is costly, and requires extensive dental care setups, which might sometimes not be available in the case of outreach settings<sup>[22,23]</sup> While ART which was developed to provide solutions to restorative treatment needs in underprivileged and distant populations, is a simple and economical method that is different from routine operative treatment and significantly impacts restorative needs at community levels<sup>[24,25]</sup>

The current study is one of the few studies, which compare the survival of GIC restorations carried out using ART and conventional methods over a long period, i.e. 3 years. ART which has an additional benefit of a children-friendly technique over conventional technique as it has pain-free nature and has a greater level of acceptance than conventional treatment makes it worth assessing its survival rates.<sup>[3]</sup>

The study also demonstrated the excellent 1-year survival rate in both ART approach and conventional method using high viscosity GIC, i.e. above 95%, which is in accordance with Holmgren and Frencken 2000, and Yip *et al.* 2002.<sup>[26,27]</sup> However, the conventional method of restoring teeth exhibited a slightly higher survival rate as compared to the ART technique at the end of the 2<sup>nd</sup> and 3<sup>rd</sup> year, with clinically and statistically non-significant difference between these two-time intervals which is in accordance with the results obtained by Yu *et al.*, 2004, Hu *et al.* 2005.<sup>[28,29]</sup> This makes the ART treatment as beneficial as conventional technique in providing treatment to an individual with restorative need in the tooth with minimal decay, who are not able to access the dental care settings as the procedure involved in this study was similar to that used in outreach setups.

Along with the GIC restoration survival rates, our study also found that the operative time needed for the ART procedure is longer than the conventional method, similar to what Kikwilu *et al.*, 2001, and Honkala *et al.*, 2003 found.<sup>[30,31]</sup> This may be attributed to technique sensitiveness of the ART which requires the use of only hand instruments such as hatchets and spoon excavators of varying sizes for caries excavation and cavity preparation. The use of



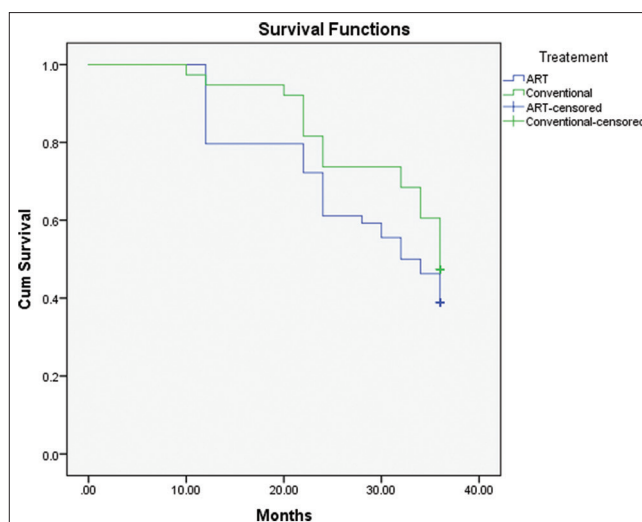
**Graph 1:** Gender-wise distribution of study participants in atraumatic restorative treatment and conventional method group included in final analysis. \*Chi-square test, level of significance =  $P \leq 0.05$ .

hand instruments requires the utmost technical skill and expertise to assess demineralized tooth structure on visual and tactile sensation. Care also has to be taken while using force for caries excavation to avoid unnecessary damage to the underlying structures. Hence, this kind of highly controlled excavation procedure requires more amount of time which also depends on the type of tooth being restored, i.e. primary or permanent, due to their structural and morphological differences.<sup>[32]</sup>

Although there were certain limitations of the study like the current study only involved single-surface restorations and did not control for participants' behavior, habit of bruxism, fluoride exposure, the size of the restoration, and oral hygiene practices which could influence the failure of restorations. Still, the study has a strong backbone of long-term assessment of survival rates of these restorations carried out by these methods.

The reason for choosing the 6–9 years of age group was that teeth will have been in the oral cavity for long enough to experience dental caries at this age, and would stay in the oral cavity for long enough before we complete the follow-up. High drop-out rates, i.e. 33.81 percent observed in our study, are mainly attributable to the loss of the affected teeth by exfoliation or extraction and mostly observed in children aged 8 and 9 years as they undergo a transition from primary molars to secondary molars. Apart from this, reluctance to participate in further follow-up and loss of contact was a minor cause for dropouts.

Success rates of ART which was almost similar as compared to conventional methods with statistically



**Graph 2:** Kaplan–Meier survival curves for glass ionomer restorations restorations carried out by atraumatic restorative treatment and conventional method over 3 years.

non-significant differences demonstrated the feasibility and ease of carrying out the ART technique even in very young children. This technique not only proved to be a method of high level of acceptance in children being less painful and a minimally invasive approach, but also proved itself to be a potential method to be used both in clinical and outreach settings irrespective of child's age.

The study also highlighted the finding that if appropriate care has been taken to limit the use of ART to only minimally decayed teeth and particularly to that for single surface restoration with good caries removal and restoration placement may result in a good clinical outcome as compared to that of modern restorative procedure with drill technique.

## CONCLUSION

The current study at the end of 1-year GIC restoration by both methods showed good survival rates. Even though the survival rate of high viscosity GIC restorations were slightly more for conventional methods as compared to those restored using ART after 3 years, the difference in survival by both methods was statistically not significant. Despite some limitations of the study, the study still proves that GIC restorations using ART can be carried out with ease and can give comparable survival results both in clinical and outreach settings.

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## Conflicts of interest

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or nonfinancial in this article.

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