

# Comparative Evaluation of Retention and Antibacterial Efficacy of Compomer and Glass Hybrid Bulk Fill Restorative Material as a Conservative Adhesive Restoration in Children with Mixed Dentition—An *In Vivo* Two-arm Parallel-group Double-blinded Randomized Controlled Study

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## ABSTRACT

**Aim and objective:** To compare and evaluate the retention along with antibacterial efficacy of colored compomer and glass hybrid bulk fill glass ionomer restorative material as a conservative adhesive restoration in children of age 6–12 years.

**Materials and methods:** Sixty children were selected fulfilling the inclusion and exclusion criteria falling in the age group of 6–12 years with mixed dentition and two groups were formed: group I—colored compomer and group II—glass hybrid bulk fill material. Initially, oral prophylaxis was carried out and baseline collection of saliva was completed. Then, the restorative treatment was completed. Retention of the material and antibacterial count [colony-forming units (CFU)/mL of saliva] was estimated at 1, 3, and 6 months after the restorative procedure.

**Results:** It was seen that retention rate with glass hybrid bulk fill group was 100%, whereas with colored compomer group it was 90% at end of 6 months. Although good antibacterial activity was shown by both the group at 1, 3, and 6 months follow-up but statistically significant drop was seen in the glass hybrid bulk fill group at 3-month intervals than the colored compomer group with a  $p$  value of 0.0001 ( $p < 0.05$ ).

**Conclusion:** Among both the materials, glass hybrid bulk fill restorative material showed good retention compared to Colored compomer material but it was not statistically very significant. Also, both the materials have shown good antimicrobial activity at 1, 3, and 6 months follow-up.

**Keywords:** Children, Compomer, Glass hybrid bulk fill, Retention, Saliva, *Streptococcus mutans*.

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## INTRODUCTION

The practice of dentistry for children is an essential component of children's overall health care. Although the dental fraternity has been successful in reducing the amount of dental disease in children with many aids like community water fluoridation, increased public awareness of dental disease prevention, a recent general report on oral health showed that there is still an immense ongoing need for pediatric dental health care.<sup>1</sup> For the same reason, various biomimetic materials are being used these days.

From the evolution in caries management of GV Black's "Extension for Prevention" to "Prevention of Extension"—minimally invasive dentistry, Simonsen outlined a minimally invasive tooth preparation and restoration, which he called as preventive resin restoration (PRR) or conservative adhesive restoration (CAR). Preventive resin restorations represent an evolution in the use of dental resins on posterior teeth.

Conventional glass ionomer cements (GICs) have the advantages of adhesion to tooth surface and release of fluoride and various other ions. Also, it performs well in low-stress areas, releases fluoride, calcium, and aluminum ions into the tooth and saliva. But at the same time, it has several drawbacks that limit their use for permanent teeth restoration because of its efficiency only in nonstress bearing areas to moderate stress-bearing areas. Also, GIC restorations have its own disadvantages like marginal deficiencies, wear, and secondary caries which jeopardize the long-term durability of GIC restorations.<sup>2</sup>

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Compomer has characteristic features of both composites and glass ionomers with claims of improved adhesiveness and fluoride-releasing properties.<sup>3</sup> Although compomer has been proved to have better clinical efficacy than conventional GICs, it has certain disadvantages like reduction in its strength because of the water uptake of up to 40%.<sup>4</sup> Also requires an additional etching and bonding step, thus resulting in technique sensitivity which makes it difficult in providing treatment to the children and causes behavior management problems.<sup>5</sup>

Recently, a glass hybrid bulk fill restorative material (a modification of GIC restorative material) has been introduced. EQUIA® Forte Fil is based on glass hybrid technology leading to superior physical properties and is a fast setting, esthetic restorative material. After mixing of cement the matrix formation gets stronger and properties are enhanced as there are new ultrafine, highly reactive glass dispersed within the glass ionomer fillers.<sup>3</sup>

Studies have shown a correlation between salivary levels of *Mutans streptococci* (MS) and restoration longevity.<sup>4</sup> There are no studies carried out in children in Indian scenario to evaluate and compare clinical properties of these two materials (colored compomer and glass hybrid bulk fill) for its use as CAR and also its correlation with *Streptococcus mutans*. So, an attempt was made to evaluate the retention and antibacterial efficacy of colored compomer and glass hybrid bulk fill restorative material.

## MATERIALS AND METHODS

### Study Design

This is an *in vivo*, two-arm, parallel-group, double-blinded, randomized controlled study with the treatment provided in

the Department of Pedodontics and Preventive Dentistry. The participants were allocated to one of the groups to evaluate its retention and antimicrobial properties of colored compomer and glass hybrid bulk fill restorative material (Flowchart 1).

### Source of Data

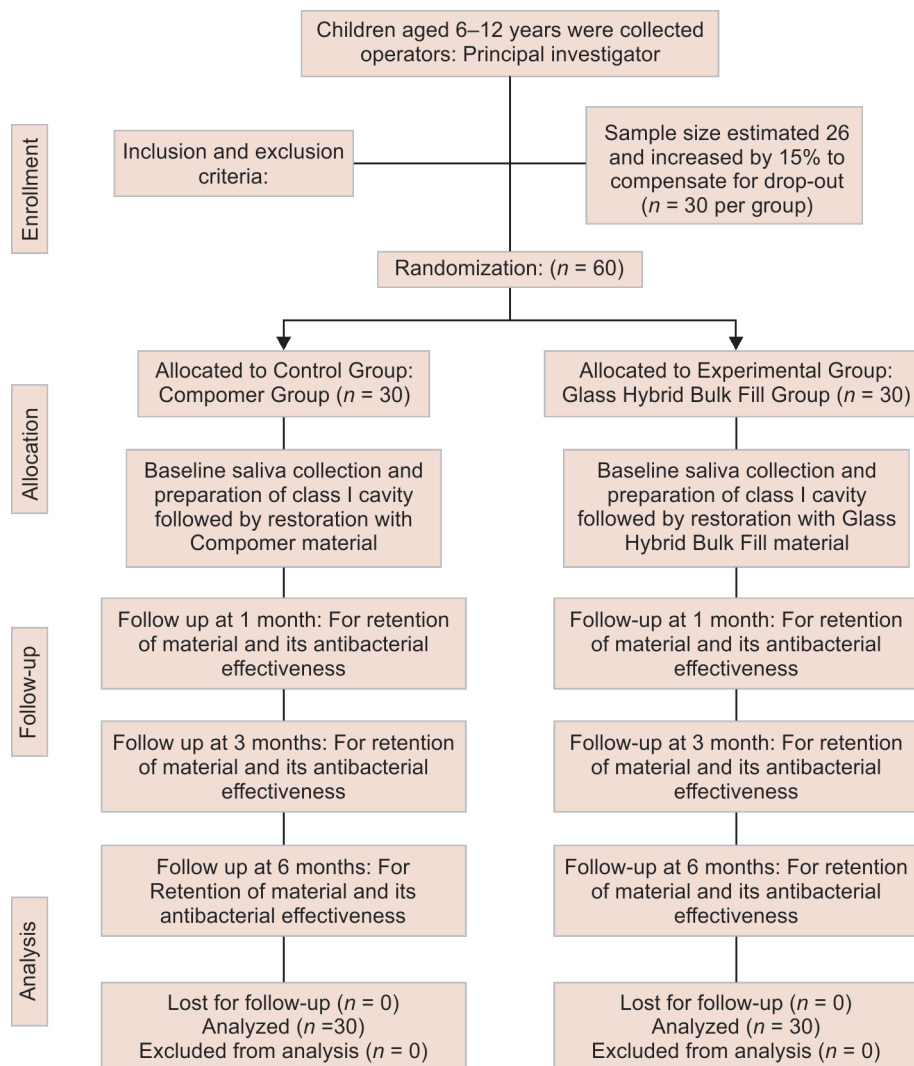
The study was conducted in the Department of Pedodontics and Preventive Dentistry with assistance from the Department of Oral Pathology and Microbiology, KLE Academy of Higher Education and Research, KLE VK Institute of Dental Sciences, Belagavi. Ethical clearance for the study was obtained from the Research and Ethics Committee (KLEVKIDS/2017/1125) of the KAHERs KLE VK Institute of Dental Sciences Belagavi.

### Sample Size Estimation

The sample size required for the study was calculated according to the formula:

$$n = \frac{2S^2}{d^2} (Z_{1-\alpha/2} + Z_{1-\beta})^2$$

Flowchart 1: Flow diagram of the methodology followed in the study



$n = 30$  in each group,  $d = 3.9897$ ,  $\alpha$  error = 5%,

$$Z_{\alpha} = 1.96, Z_{\beta} = 1.037, S_1 = 3.5454, S_2 = 5.654, S = \frac{S_1 + S_2}{2}$$

Based on the previous study having a confidence level of 85%, the probability is 0.05.<sup>6</sup> Therefore, the sample size obtained was 26 in each group. Including 15% dropout, the sample size chosen was 30 in each group. So, a total of 60 sample size was selected and divided into two equal study groups of 30 each.

### Selection of Subjects

Subjects for the study were selected according to the following inclusion criteria, i.e., children with mixed dentition, maxillary or mandibular first permanent molars with class I caries on occlusal surfaces involving enamel or dentin (type I or type II CAR), children having 2–3 decayed teeth. The exclusion criteria were proximal carious lesion, deep carious lesion, special child, children who are wearing any appliances, and inpatient who are on medication which affects salivary flow.

### Study Group and Randomization

All the 60 samples of the study group were equally divided into two groups by simple random sampling using computer allocation method to ensure standardization<sup>7</sup> namely group I (compomer group: Twinky star®, VOCO GmbH Germany) and group II (glass hybrid bulk fill group: Equia® Forte GC Europe).

The randomly generated sequence was sealed in a closed envelope. An independent pedodontist from the department who was not part of the study was designated in the allocation of the children to the two groups. The envelope was opened after obtaining informed consent once the patient was ready to receive the treatment.

### Selection of Case and Recording of Case History

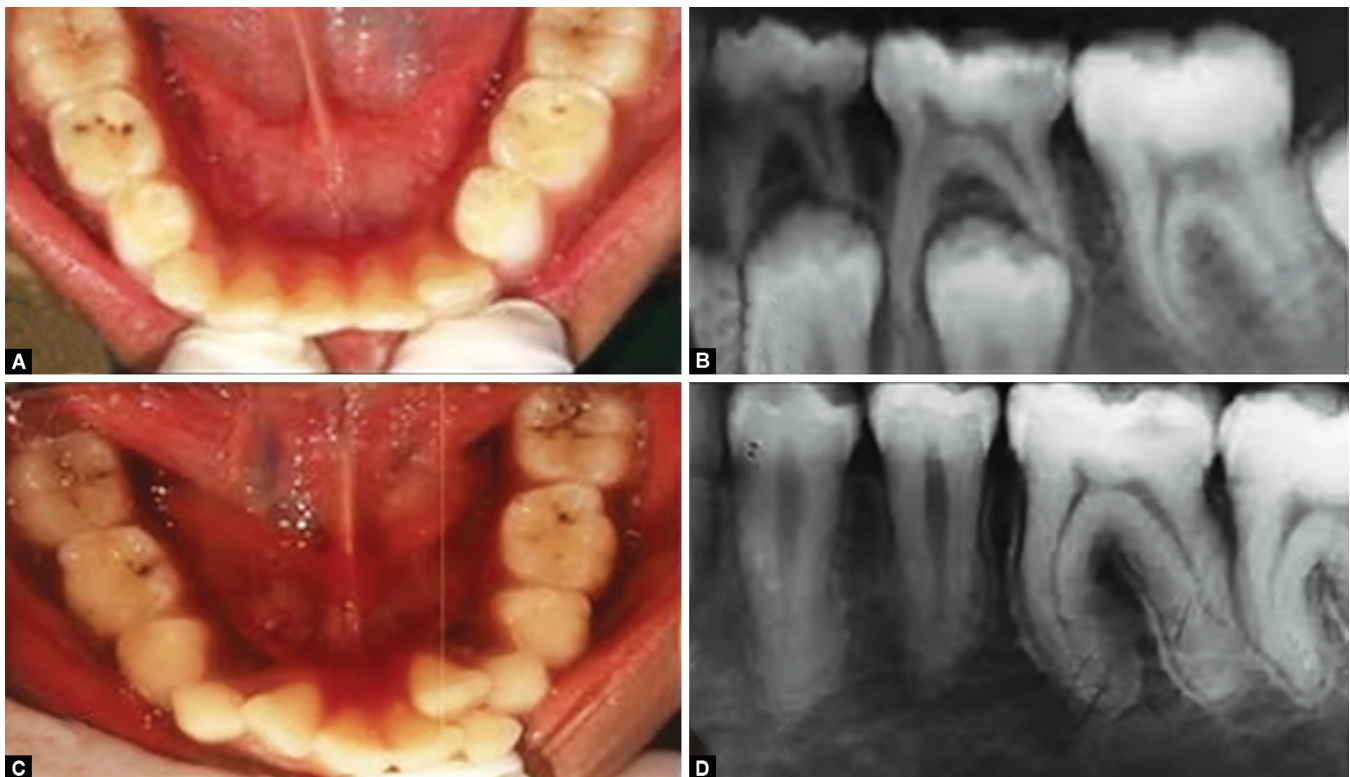
A case history was recorded in a special format prepared for this study. Caries status was recorded using deft/DMFT (WHO 1997).<sup>8</sup> The findings were recorded and preoperative intraoral photographs and intraoral periapical radiographs were taken to assess the depth of the carious lesion (Fig. 1). Oral prophylaxis was done and a saliva sample was collected to assess the baseline *S. mutans* count and necessary treatment was given. All the procedures of patient selection, saliva collection, restoration, and postoperative assessment were carried out by a single investigator to avoid any bias.

The saliva was collected between 9 am and 11 am only.<sup>9</sup> The collection of the saliva sample was completed using a suction method with sterile disposable syringes.<sup>10</sup> A saliva sample was collected from each patient for microbiological assessment of *S. mutans* count on four occasions: baseline, 1, 3, and 6 months and processed on the same day. The number of colony-forming units (CFU) of *S. mutans* in saliva was determined using a Stereomicroscope (Fig. 2).

### Procedure of Tooth Preparation for Receiving Restoration

The operator and the assistant were trained by the Pediatric Dentist from the Department of Pedodontics and Preventive Dentistry to perform CAR using the colored compomer and glass hybrid bulk fill as per the Standard Operating Protocol (SOP). After performing 10 restorations under the supervision of a Pediatric Dentist Principal investigator was allowed to start the research work.

Strict protocols of isolation were maintained by using a rubber dam after which fluoride-free pumice prophylaxis was performed on the concerned tooth. The tooth preparation for the class I cavity



**Figs 1A to D:** Photograph showing preoperative intraoral photograph and radiograph of a mandibular first permanent molar with caries involving enamel in a compomer group (group I) and glass hybrid bulk fill group (group II)



was done using high-speed round diamond points to receive the restorations according to minimally invasive dentistry.

In colored compomer group (group I) following the isolation of tooth and caries removal, the prepared tooth was etched for 15 seconds with 37.5% phosphoric acid etchant followed by rinsing for 20 seconds with an air-water spray and dried, leaving the dentin slightly moist. Then, bonding agent was applied and cured for 20 seconds using a curing light. Later restoration of the cavity was done using the manufacturer's instruction in horizontal layers with a thickness of only 2 mm at one time to allow polymerization of the material. Step-by-step polymerization was done for 40 seconds and any occlusal irregularities were removed using an articulating paper to maintain occlusion (Fig. 3).

In the glass hybrid bulk fill group (group II) after preparation of the cavity, glass hybrid restorative system was activated as indicated by the manufacturer for 10 seconds in the mixer. Immediately the ready-to-use capsules were loaded in the applicator and after the sound of 2 clicks material was inserted into the cavity. Once placed in the cavity, the material was pressed completely for 40 seconds using a finger which was coated with petroleum jelly and then excess material was then removed and irregularities were trimmed off (Fig. 4).

The immediate postoperative evaluation of all the restoration was conducted by an experienced examiner (Pediatric Dentist) who was completely blind to the procedure in the Department of Pedodontics and Preventive Dentistry and findings were recorded in a master chart.

### Postoperative Instructions

Patients were given postoperative instructions of not to drink or take water for 30 minutes and a soft diet for the next 24 hours and also to report to the dental clinic if any kind of pain, sensitivity, or fractured restoration was present.

### Follow-up and Evaluation

Patients were asked to come for follow-up at 1, 3, and 6 months. A new scale was used to check retention of the restorations which was restoration as per United State Public Health Service (USPHS) Ryge criteria<sup>11</sup> (Fig. 5).

### STATISTICAL ANALYSIS

All the collected data were systematized and entered on the excel sheet. Following which results were subjected to the statistical tests using IBM SPSS software (version 20.0, Chicago, IL, USA).

### RESULTS

Sixty patients were distributed according to age and gender among the two groups. The difference between the mean age for both the groups using the chi-square test was found to be statistically not significant (Table 1). Patients were equally distributed in both the groups as no statistically significant difference was present between genders in intergroup comparison (Table 2).

Comparison of retention was done using descriptive analysis. The difference between the percentages of retention of restorative material in both the groups was not statistically significant (Fig. 6) as only 3 patients out of 30 patients had partial loss of restorative material in compomer group (Table 3).

Comparison of the antibacterial property was done saliva using the independent "t" test. At 3-month follow-up maximum

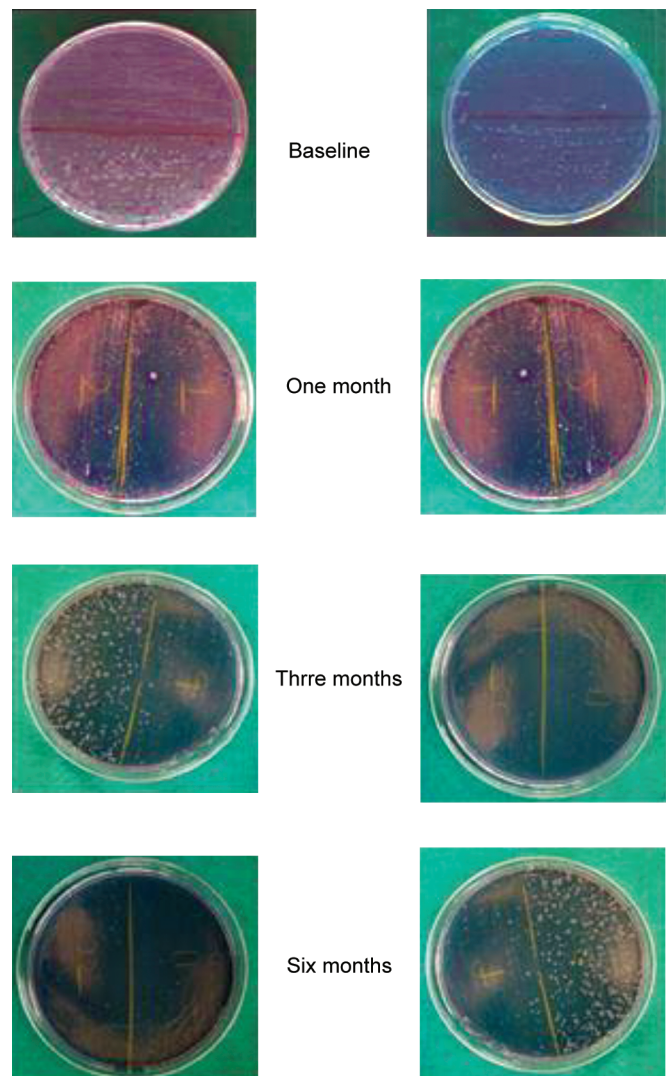


Fig. 2: Photographs showing microbiological evaluation at 1, 3, and 6 months follow-up for compomer group (group I) (Left) and glass hybrid bulk fill group (group II) (Right)

reduction was observed [mean *S. mutans* level of 190.00 ( $\pm 84.60$ )] in glass hybrid bulk fill group than colored compomer group [mean *S. mutans* level 655.00 ( $\pm 255.07$ )] with "t" value of  $-9.4775$  and a *p* value of 0.0001 ( $p < 0.05$ ) which was found to be highly significant at a 3-month time interval (Table 4).

At 1 and 6 months follow-up, both materials have shown good antibacterial effectiveness against *S. mutans* but there was no statistically noteworthy difference found between colored compomer and glass hybrid bulk fill GIC with "t" value of  $-0.6158$  and a *p* value of 0.5404 ( $p < 0.05$ ) (Fig. 7).

### DISCUSSION

Dr GV Black the father of modern dentistry invented the principles of operative dentistry in the late 1800s. The foremost of his principle was the concept of "Extension for Prevention", i.e., remove the possibility of further decay on the surface of the tooth already afflicted with caries. So, it involved the removal of a substantial amount of tooth structure, more than the actual decay. Hence, a lot of healthy tooth structure was destroyed in the process.<sup>12</sup>



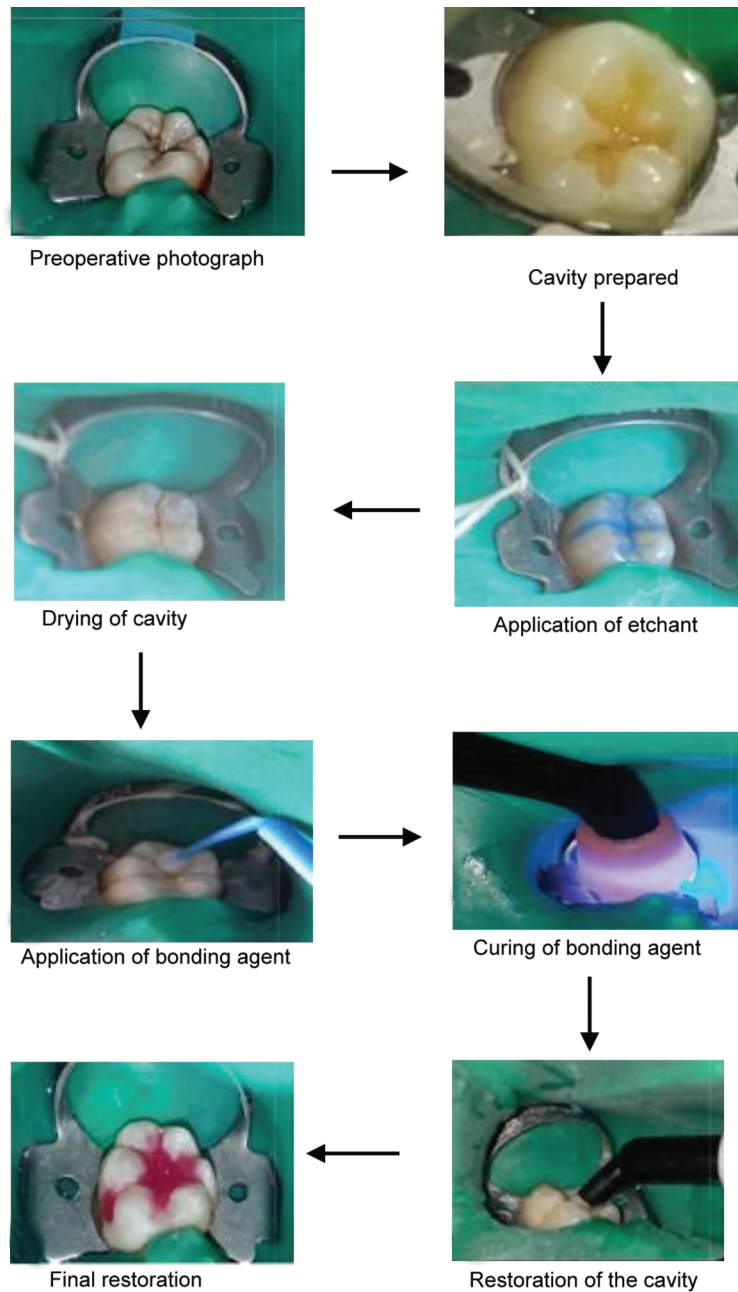


Fig. 3: Photograph showing a step-by-step procedure of restoration in a compomer group (group I)

Prevention of dental caries and minimal intervention dentistry (MID) plays a vital role in dentistry for children.<sup>13</sup> So in this minimally invasive dentistry approach, dental caries is treated as an infectious condition rather than an end product of it and therefore "Prevention of Extension" is practiced rather than radical "Extension for Prevention".<sup>12</sup>

The present study compared clinically and microbiologically the retention and antibacterial efficacy of colored compomer and glass hybrid bulk-fill restorative material. Children with mixed dentition were incorporated in the study with a mean age of  $10.82 \pm 1.05$  years as at this age group children are receptive to dental caries and are experiencing multiple permanent tooth eruption (Table 1). According to Caufield and Griffen, the second window of infectivity was seen between 6 years and 12 years coinciding

with the eruption of the first permanent molar, thus showing an increased risk of acquiring MS.<sup>14</sup>

The most persistent factor in caries risk assessment tool is the past caries experience according to AAPD guidelines. Therefore, in this study, the child at mild caries risk deft/DMFT score 2–3 was considered to maintain standardization in the inclusion criteria. The integrity of oral mucosa is maintained by saliva which is a multi-constituent fluid regulating the oral cavity. Saliva was used in the study because of its ease in sampling and processing for microbiological evaluation. As saliva has a buffering action bias can occur which was avoided by using unstimulated saliva which has a lower concentration of bicarbonate ions. The method used for the collection of saliva was the suction method in which sterile disposable syringes were used to draw saliva from the floor of the

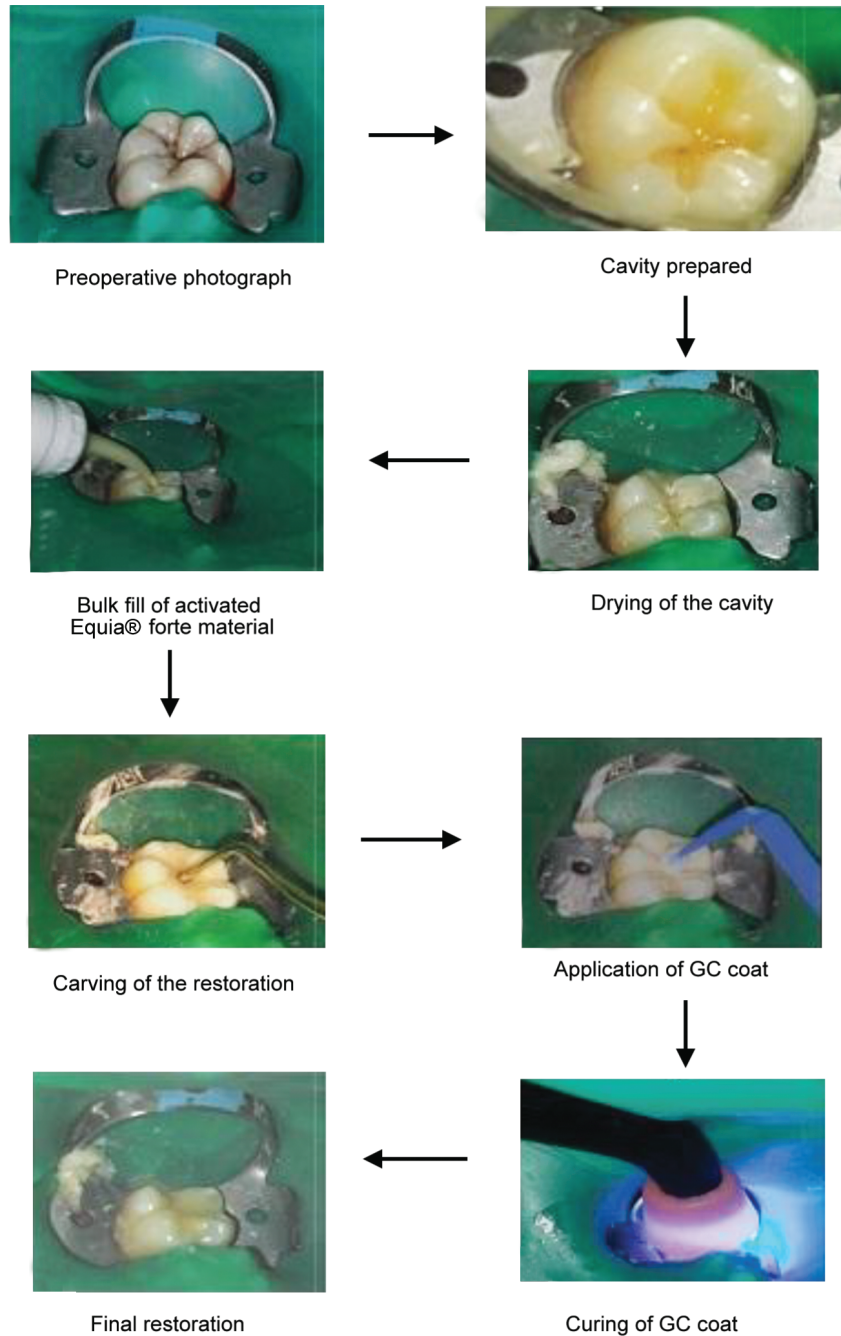


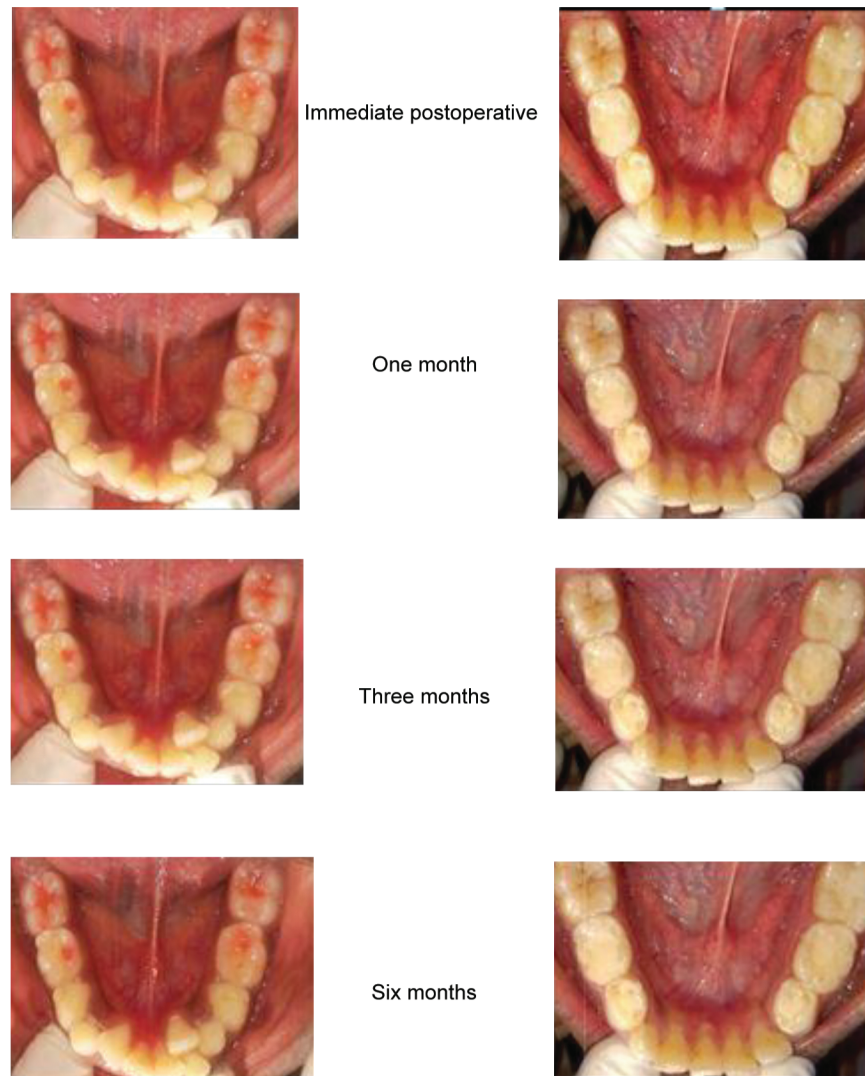
Fig. 4: Photograph showing a step-by-step procedure of restoration in glass hybrid bulk fill group (group II)

mouth because of its ease of use and to avoid any contamination, reducing any chance of error.<sup>9</sup> A saliva sample was taken between 9 am and 11 am only to maintain evenness and to minimize the effect of circadian rhythm on the samples.<sup>10</sup>

The present study incorporated the use of first permanent molar teeth because it being the first permanent tooth to erupt in the oral cavity, it is the one that is most commonly affected with dental caries. From a functional and developmental point of view, they have a key role in balanced occlusion. It is the strongest tooth in the arch and helps in providing anchorage. Loss of first permanent molars can lead to severe problems in mastication and hampering the growth and development of

the child. Retention of the restoration is a function of bond strength.<sup>15</sup> The present study utilized the United State Public Health Service (USPHS) criteria for the assessment of the restorations.<sup>11</sup>

The use of attractive and glittering colors attracts the attention of children and results in their positive behavior during the dental treatment. Also allowing children to choose different colors of restorative material has a good effect in reducing fear and impatience and they would willingly maintain oral hygiene.<sup>16</sup> In our study, very good results have been found with the use of multi-colored compomer material with respect to retention which was in line with a study by Hugar et al.<sup>17</sup>



**Fig. 5:** Clinical evaluation of compomer restoration at 1, 3, and 6 months follow-up in a compomer group (group I) and glass hybrid bulk fill group (group II)

**Table 1:** Mean, standard deviation, and intergroup comparison of two groups namely compomer group (group I) and glass hybrid bulk fill group (group II) with respect to mean age using the Chi-square test

Age	Compomer	(%)	Glass hybrid bulk fill	(%)	Total	(%)
9 years	4	13.33	6	20.00	10	16.67
10 years	6	20.00	3	10.00	9	15.00
11 years	9	30.00	14	46.67	23	38.33
12 years	11	36.67	7	23.33	18	30.00
Total	30	100.00	30	100.00	60	100.00
Mean age	10.90	10.73	10.82			
SD age	1.06	1.05	1.05			

Chi-square = 3.3762  $p = 0.3371$

Due to recent breakthroughs in resin-based restorative materials, development of bulk-fill composite came into existence overcoming the need for incremental layering. It speeds up the restoration process by complete the restoration of the cavity in a single step. The various advantages of this bulk fill material being it increases curing depth, avoiding polymerization shrinkage, no

voids, and no contamination between consecutive layers. Also decreased number of steps required in the placement of the material. The splendid esthetics of this material widen many options for posterior restorations to fulfill patients' expectations. EQUIA system was clinically proven several years ago, based on which glass hybrid bulk fill offers a great alternative for routine use.<sup>3</sup> This

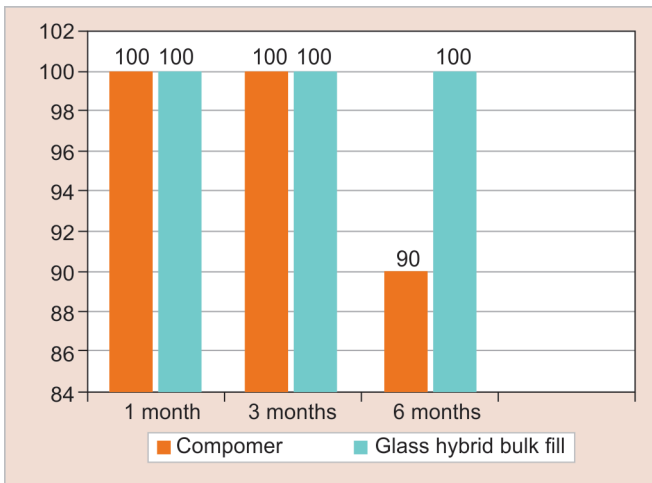


**Table 2:** Intergroup comparison of the gender distribution of subjects in both the groups namely compomer group (group I) and glass hybrid bulk fill group (group II) using a Chi-square test

Gender	Compomer		Glass Hybrid Bulk Fill		Total	(%)
		(%)		(%)		
Male	21	70.00	17	56.67	38	63.33
Female	9	30.00	13	43.33	22	36.67
Total	30	100.00	30	100.00	60	100.00

Chi-square = 1.1482  $p = 0.2841$ **Table 3:** Comparison of retention of the restorative material in compomer group (group I) and glass hybrid bulk fill restorative material (group II)

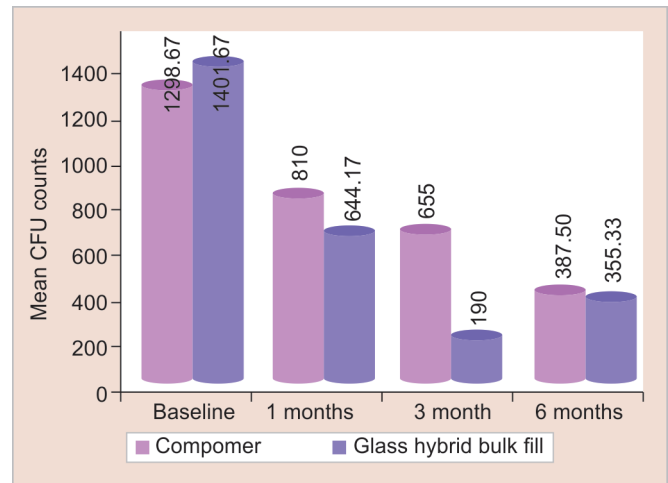
Visit	Material used	Total	Retention					
			Alpha	(%)	Bravo	(%)	Charlie	(%)
1 month	Compomer	30	30	100	-	-	-	-
	Glass hybrid bulk fill	30	30	100	-	-	-	-
3 months	Compomer	30	30	100	-	-	-	-
	Glass hybrid bulk fill	30	30	100	-	-	-	-
6 months	Compomer	30	27	90	3	10	-	-
	Glass hybrid bulk fill	30	30	100	-	-	-	-

**Fig. 6:** Graphical representation of an intergroup comparison between two groups namely compomer group (group I) and glass hybrid bulk fill group (group II) with respect to the retention of the restorative material

was in line with a study done by Grossi et al. in which glass hybrid bulk fill showed promising results.<sup>18,19</sup>

When the intergroup comparison was done both the material have shown good antibacterial activity at 1, 3, and 6 months follow-up and a highly significant maximum reduction of *S. mutans* level was found at 3 months in glass hybrid, whereas the reduction in compomer group was gradual. Even though there was a rise in *S. mutans* count from 3 months onward in the glass hybrid bulk fill group, the rise was not very significant maintaining its antibacterial effectiveness (Table 4). Glass hybrid bulk fill group and colored compomer group have shown better retention at 6 months interval with complete retention of 100 and 90%, respectively, indicating good retention property due to their superior physical, chemical, and mechanical properties<sup>3</sup> (Table 3).

From the result mentioned above, it can be seen that in the intragroup analysis there was a marked reduction in *S. mutans*

**Fig. 7:** Graphical representation showing the difference between the mean *Streptococcus mutans* colony-forming units/mL of saliva ( $\times 10^5$  CFU/mL) in two groups namely compomer group (group I) and glass hybrid bulk fill group (group II) at baseline, 1, 3, and 6 months' time points

colony count at 3-month intervals compared to baseline but at the same time there was a slight increase in *S. mutans* colony count at 6 months interval. The active agent in the milieu is released relatively within a very short period of time causing a short-term effect. Initially, a phenomenal burst effect is seen. This shows that the antimicrobial property of this material showed the greatest effect at 3 months with a slight decrease in this antimicrobial property indicating that some intervention is required at a 3-month interval to enhance its antimicrobial effectiveness.

The bacterial reduction may have resulted from the removal of decayed tooth structure. This investigation also reported the re-establishment of *S. mutans* over the period of 6 months. One of the explanations for the resurgence of bacteria may be the organism's ability to readily colonize the restored surfaces. Also as teeth are bathed in saliva, saliva may serve as a source of a cariogenic organism at susceptible sites.<sup>20,21</sup>

**Table 4:** Difference between the mean *Streptococcus mutans* colony-forming units/mL of saliva ( $\times 10^5$  CFU/mL) in two groups namely compomer group (group I) and glass hybrid bulk fill group (group II) at baseline, 1, 3, and 6 months' time points using independent "t" test

Time points	Compomer [group I]			Glass hybrid bulk fill [group II]			"t" value	p value
	Mean	SD	SE	Mean	SD	SE		
Baseline	1298.67	420.83	76.83	1401.67	213.14	38.91	1.1959	0.2366
1 month	810.00	418.62	76.43	644.17	230.60	42.10	-1.9005	0.0623
3 months	655.00	255.07	46.57	190.00	84.60	15.45	-9.4775	0.0001*
6 months	387.50	239.50	43.73	355.33	156.48	28.57	-0.6158	0.5404
Changes								
Baseline-1 month	488.67	731.39	133.53	757.50	271.58	49.58	1.8873	0.0641
Baseline-3 months	643.67	486.19	88.77	1211.67	237.51	43.36	5.7495	0.00001*
Baseline-6 months	911.17	552.07	100.79	1046.33	249.11	45.48	1.2223	0.2265
1-3 months	155.00	531.97	97.12	454.17	252.41	46.08	2.7829	0.0073*
1-6 months	422.50	432.93	79.04	288.83	257.23	46.96	-1.4538	0.1514
3-6 months	267.50	344.74	62.94	-165.33	193.33	35.30	-5.9981	0.0001*

Even though our study showed that glass hybrid bulk fill restoration was better than compomer restoration at 1, 3, and 6 months intervals, there are a few limitations to our study like smaller sample size, and follow-up span is only till 6 months. So to justify its use to larger sample size and long follow-up should be carried out in larger geographical areas to corroborate the present results of the study.

In the future, it will be interesting to obtain corresponding data with the relationship between MS and the success of different minimal intervention techniques and biomimetic restorative materials in a larger population with the consideration of all possible parameters which are involved in the development of caries. Since the advent of caries starts from an early age, schoolchildren need to be targeted and the use of preventive therapies needs to be implemented at the earliest to avoid it from causing irreparable damage to the dental tissues. As rightly said by Bill Gates "Treatment without prevention is simply unsustainable".

## CONCLUSION

Among both the materials, glass hybrid bulk fill restorative material showed a superior retention rate as compared to colored compomer material but it was not statistically significant. And both the materials have shown good antimicrobial activity after 6 months follow-up. The conclusion drawn from the present study needs to be carried out with bigger sample size and continuing to follow-up for an extended time to implement at the national level for CARs in children.

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