

Comparative Evaluation of GC Gold Label IX with GC Gold Label IX Extra and GC Gold Label Hybrid in Cavitated Lesions Prepared by Hand Instrumentation Technique in Primary Molars: An *In Vivo* Study

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ABSTRACT

Aim: The purpose of the present study was to compare the clinical efficacy of GC Gold Label IX, GC Gold Label IX Extra, and GC Gold Label Hybrid in occlusal surface cavities in primary molars prepared by hand instrumentation technique.

Materials and methods: Ninety primary molars were selected from the children according to the inclusion and exclusion criteria. The selected teeth were randomly allocated into the following three groups, with 30 teeth in each group, according to the restorative material used: group I: GC Gold Label IX, group II: GC Gold Label IX Extra, and group III: GC Gold Label Hybrid. Occlusal cavities were prepared using hand instruments. Caries removal efficacy was verified using caries detector dye. The restorative materials were mixed and condensed into the prepared cavities. The restorations were assessed using modified United States Public Health Service (USPHS) evaluation criteria at 1, 3, and 6 months.

Results: The results were tabulated and statistically analyzed using the Chi-squared test. No significant difference was found in terms of color match, marginal discoloration, marginal integrity, surface roughness, and secondary caries, but a significant difference was observed in terms of retention and anatomic form between group I and group III.

Conclusion: GC Gold Label Hybrid exhibited better clinical performance with respect to GC Gold Label IX and comparable clinical performance with respect to GC Gold Label IX Extra.

Clinical significance: GC Gold Label Hybrid is a newly developed glass ionomer cement (GIC), and its clinical performance needs to be studied.

Keywords: Caries detector dye, GC Gold Label Hybrid, GC Gold Label IX Extra, GC Gold Label IX, United States Public Health Service evaluation criteria.

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INTRODUCTION

Pediatric restorative dentistry provides clinicians with guidance to form decisions about techniques and materials appropriate for pediatric patients. Restorative treatment of carious teeth is essential to stop disease progression. Different approaches are available for the excavation and restoration of carious lesions.¹

Caries removal using the air rotor is sometimes associated with patients' discomfort and pain.² An effective alternative would be to use simple hand instruments, seeking to make the environment more comfortable for the child patient. Hand excavation technique is one of the noninvasive methods, which is considered to be a patient-friendly treatment, especially for young children.³

During caries removal, caries-detecting dyes aid in the clinical differentiation of the infected dentin from the affected dentin.⁴ Caries detector dye (Kuraray International Limited) is composed of two components, that is, 1% acid red 52 dye (sulfurhodamine B) and propylene glycol.⁵ As the dye targets the demineralized collagen rather than bacteria, it provides a reliable method of preserving the remineralizable affected dentin and facilitates the removal of only infected dentin.⁴

Glass ionomer cements (GICs) are one of the most commonly used restorative materials in pediatric dental practices.⁶ High viscosity GICs (HVGIC) are claimed to have better mechanical properties. A novel self-adhesive material, GC Gold Label Hybrid GIC, is a recently introduced hand-mixed cement featuring glass hybrid technology.

The glass hybrid restorative system is reinforced with ultrafine, highly reactive glass particles. Additionally, it contains an additional

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high molecular weight polyacrylic acid along with the conventional polyacrylic acid, which has been claimed to show improved mechanical and handling properties. It has comparably high shear bond strength to dentin and shows acceptable marginal adaptation and reduced microleakage compared to conventional GICs.⁷ The fine size of fluoroaluminosilicate glass particles has also led to improved optical properties of the material. The small size of the glass particles minimizes collision against visible light waves, allowing light to penetrate through the restorative material. This improves the esthetic appeal as the material appears more translucent.⁶

Therefore, the present study was undertaken with the aim to compare the clinical efficacy of GC Gold Label IX, GC Gold

Label IX Extra, and GC Gold Label Hybrid in occlusal surface cavities prepared by hand instrumentation technique in primary molars.

MATERIALS AND METHODS

The study design was a randomized controlled trial. After obtaining clearance from the ethical committee of the institute, this study was conducted in the Department of Pediatric and Preventive Dentistry, Dasmesh Institute of Research and Dental Sciences, Faridkot. An informed written consent form was filled out by the parents/guardians of the children who fulfilled the selection criteria for the study.

Healthy children aged between 4 and 8 years, with one or more primary molars with occlusal caries accessible for excavation with only hand instruments, were included if they did not show any signs or symptoms of reversible pulpitis or irreversible pulpitis. Exclusion criteria included extensive caries with pulpal pain, exposed pulp, or swelling/fistula related to the carious tooth, cavities requiring a base/liner under the restoration, and pit and fissure caries where hand instruments are not accessible.

Ninety primary molars were randomly allocated into three groups, with 30 teeth in each group, according to the restorative material used: group I—restoration with GC Gold Label IX (*n* = 30), group II—restoration with GC Gold Label IX Extra (*n* = 30), and group III—restoration with GC Gold Label Hybrid (*n* = 30).

After obtaining the complete medical and dental history of the patients, the children were seated comfortably in the dental chair and made familiar with the instruments to be used during the procedure. Sharp, sterile small and medium-sized spoon excavators (GDC Dental Pvt. Ltd., Hoshiarpur, India) were used for the excavation of caries. Unsupported enamel was removed with an enamel hatchet (GDC Dental Pvt. Ltd., Hoshiarpur, India). Caries

excavation was stopped when hard dentin was detected. The carious tooth was isolated with cotton rolls and saliva suction tips.

Caries removal efficacy was verified using caries detector dye (Kuraray Noritake Dental Inc., Okayama, Japan). A single drop of the dye was applied to the cavity using a microapplicator tip (SS White Dental Pvt. Ltd., New Delhi, India). After 10 seconds, the dye was rinsed with water. The area with a darker, intense pink stain was again excavated. The use of dye for detection of remaining carious dentin and its subsequent excavation was carried out to ensure complete removal. This process was repeated until lightly stained dentin was achieved.

Cotton rolls (Caprisons Dental Pvt. Ltd., Mumbai, India) were used to isolate the prepared cavity along with saliva suction tips (Waldent Innovations Pvt. Ltd., New Delhi, India). The cavity was conditioned with GC Dentin Conditioner using a cotton pellet, rinsed with water, and dried by gently blowing with an air syringe. The required amount of powder and liquid (according to the type of restorative material used in the respective groups) was dispensed on the mixing pad using an agate spatula. The mixed cement (GC Dental Corporation Limited, Tokyo, Japan) was carried and condensed into the cavity using a plastic filling instrument (GDC Dental Pvt. Ltd., Hoshiarpur, India). After initial contouring of the restoration, GC Fuji Varnish was applied over it. Instructions were given to the patient not to eat or drink anything for an hour.

A single examiner, who was blinded to the materials used in the patients, conducted the evaluation of the restorations at baseline, 1, 3, and 6 months from the time of placement. The examiner inspected the restorations using a mouth mirror and explorer (GDC Dental Pvt. Ltd., Hoshiarpur, India) under dental light illumination, using modified United States Public Health Service (USPHS) evaluation criteria. It included seven parameters: retention, marginal discoloration, anatomical form, marginal integrity, color match, surface roughness, and secondary caries,⁸ as shown below in Table 1.

Table 1: Scores—Alfa (A), Bravo (B), Charlie (C), Delta (D)

Category	Score		Criteria
	Acceptable	Unacceptable	
Retention	A		Retained
		B	Missing
Color match	A		Excellent color match
	B		Slight mismatch in color, shade, or translucency
		C	Obvious mismatch, outside the range
		D	Gross mismatch
Marginal discoloration	A		No discoloration evident
	B		Superficial staining (removable, usually localized)
		C	Deep staining (not removable, generalized)
Marginal integrity	A		Undetectable
	B		Explorer catches; no crevice is visible into which explorer will penetrate or crevice in enamel
		C	Obvious crevice at margin; dentin or base exposed
		D	Restoration is mobile or fractured
Surface roughness	A		Smooth surface
	B		Slightly rough or pitted
Anatomic form		C	Surface deeply pitted; irregular grooves present
	A		The restoration is continuous with the tooth
	B		Slight under-restoration or over-restoration
		C	Restoration is under contoured; dentin or base is exposed
Secondary caries		D	Restoration is missing, partially or totally
	A		None
		B	Present

Source: Oänal and Pamir⁸

RESULTS

The data were tabulated in Microsoft Excel 2007, and G*Power statistical software version 3.1 was used for the analysis. The sample size was calculated using 80% power, an effect size of 0.40, and a confidence level of 95%. The statistical analysis among the groups was performed using the Chi-squared test.

According to the results of the present study, all three materials displayed good clinical performance. On intergroup comparison of the materials, no significant differences were obtained in terms of color match, marginal discoloration, marginal integrity, surface roughness, and secondary caries.

Significant results were observed only when comparing group I with group III in terms of retention and anatomical form at the 6-month interval, where GC Gold Label Hybrid showed better results. Therefore, GC Gold Label Hybrid exhibited the best clinical performance compared to the other materials. Additionally, the clinical performance of GC Gold Label IX Extra was found to be comparable to GC Gold Label Hybrid.

The null hypothesis tested was that all the materials displayed similar clinical performance. Since restorations using GC Gold Label Hybrid were found to be clinically superior in efficacy compared to the other two materials, the null hypothesis was rejected.

DISCUSSION

Hybrid technology was introduced by GC Corporation as GC Gold Label Hybrid. It consists of two parts: HVGIC along with the nano-filled coating material, which aims to improve the properties of this glass ionomer cement.

It has been well documented that glass ionomer cements confer the advantage of good adhesion to the surface of the tooth. Ions, both from the cement as well as the tooth surface, diffuse and create an ion-exchange layer, which helps GICs adhere strongly to the tooth structure. This strong adhesion aids in the retention of these restorative materials.⁹ This was reflected in the results of the present study in [Table 2](#) as all the restorations of three groups were retained at 1-month follow-up. No significant difference was observed at the 3-month follow-up. Although not significant, the restoration failure of group I and group II could be attributed to factors such as cavity size and variations in masticatory forces.¹⁰

At the 6-month follow-up, no significant result was obtained when comparing GC Gold Label IX (group I) and GC Gold Label IX Extra (group II), as well as GC Gold Label IX Extra (group II) and GC Gold Label Hybrid (group III). However, a significant difference in retention was observed when comparing GC Gold Label IX (group I) and GC Gold Label Hybrid (group III). This could be attributed to the fact that GC Gold Label Hybrid adapted well to the cavity walls and showed minimal shrinkage stress when used as a bulk material. The strong matrix of the cement provided improved chemical bonding and stability to the tooth structure.¹¹ Moshaverinia et al.¹² compared GC Gold Label IX and GC Gold Label Hybrid and concluded that GC Gold Label Hybrid showed better flexural strength compared to GC Gold Label IX. This improved flexural strength leads to better fracture resistance, thereby preventing loss of restoration.¹³

The intergroup comparison of retained restorations among the three groups was evaluated in terms of color match at regular time intervals of 1, 3, and 6 months of follow-up. Lack of translucency has always been one of the problems encountered with GICs compared to other esthetic restorative materials.¹⁴ In our study, three different glass ionomer materials were compared, and

therefore, any significant difference with respect to color match was not expected. For all three groups, the restorations showed excellent color match at the 1-month follow-up. No significant difference in color match was observed among the three groups at the 3- and 6-month follow-ups, as shown in [Table 2](#).

Although no significant difference was observed at the 6-month follow-up, a few cases of slight mismatch and obvious mismatch were found. This could be attributed to the dietary habits of the patient and the associated pigment absorption by the materials during mastication over time.¹⁵ Among the three materials, the best performance regarding color match was found with GC Gold Label Hybrid (group III) at the end of the 6-month follow-up. This could be attributed to the presence of small glass filler particles in GC Gold Label Hybrid, which provided better shade and a higher degree of translucency. This was in accordance with the study by Menezes-Silva et al.¹⁶ who also concluded that GC Gold Label Hybrid showed clinically acceptable color match at 6-month evaluation follow-up.

A good marginal seal is essential for the longevity of the restoration.¹⁷ Marginal discoloration can be defined as staining that occurs in the crevice between the cavity wall and the restoration, affecting the margins of the restoration. The intergroup comparison of marginal discoloration of restorations is shown in [Table 2](#) at intervals of 1, 3, and 6 months of follow-up. At the end of 1 month, no restoration in any of the three groups showed evident marginal discoloration. No significant differences were observed at 3 and 6 months of follow-up when comparing the three groups. It was also noted that out of all restorations, GC Gold Label IX (group I) showed the highest number of restorations with marginal discoloration (four restorations) at the end of 6 months, compared to one restoration each in GC Gold Label Extra (group II) and GC Gold Label Hybrid (group III).

The better results observed with GC Gold Label Hybrid (group III) could be attributed to the manufacturer's claim that it contains two types of polyacrylic acid with different molecular weights. The higher molecular weight polyacrylic acid, combined with ions released from the highly reactive glass fillers, forms a strong matrix. The lower molecular weight polyacrylic acid assists in adhesion, ensuring good cavity adaptation and a strong, durable bond with teeth.

The intergroup comparison was conducted in terms of marginal integrity at 1, 3, and 6 months as shown in [Table 2](#). At the 1-month follow-up, no catch was found when probed with an explorer along the margin of the restoration with the tooth structure for all groups. No significant results were obtained at the 3- and 6-month follow-ups. Loss of marginal integrity usually results from defects present between the cavity margin and the restoration. Although nonsignificant results were observed, it was noted that at the end of 6 months, group I showed the highest number of cases of marginal integrity failure (four restorations), whereas group II and group III each showed only one restoration with marginal integrity failure. The failures in group I could be attributed to the high viscosity of this material, resulting from a high powder-to-liquid ratio and reduced glass particle size, which may have prevented proper wetting of the tooth surface and contributed to marginal integrity failure.¹⁸

The intergroup comparison of surface roughness at 1, 3, and 6 months of follow-up is shown in [Table 2](#). It was observed that for all three groups, all restorations showed a smooth surface at the 1-month follow-up. No significant results were found when comparing the three groups at the 3- and 6-month follow-ups. However, it was noted that at 6 months, three restorations in

Table 2: Results of the restorations in groups I, II, and III according to the parameters of modified USPHS criteria at the intervals of 1, 3, and 6 months from baseline

Evaluation criteria		Retention						Color match																				
		1 month		3 months		6 months		3 months		6 months		6 months																
Alfa	Bravo	p-value	Alfa	Bravo	p-value	Alfa	Bravo	p-value	Alfa	Bravo	p-value	Alfa	Bravo	Chi value	Chi p-value													
Group I	N 30	0	1	30	0	1	27	3	1.07	0.3	24	6	1.17	0.278	23	4	0	1.15	0.56	16	4	4	2.42	0.297				
Group II	N 30	0	1	30	0	1	29	1	3.18	0.078	24	6	4.41	0.044	23	4	0	2.34	0.126	16	4	4	4.41	0.109				
Group III	N 30	0	1	30	0	1	30	0	1.01	0.313	27	3	1.071	0.306	25	3	1	2.28	0.319	23	2	2	0.446	0.8				
Group III	N 30	0	1	30	0	1	30	0	2.15	0.34	23	3	1	0.31	0.85	25	2	2	2.15	0.34	23	3	1	0.31	0.85			
Marginal discoloration																												
Evaluation criteria		Marginal discoloration						Marginal integrity																				
		1 month		3 months		6 months		3 months		6 months		6 months																
Alfa	Bravo	p-value	Alfa	Bravo	p-value	Alfa	Bravo	p-value	Alfa	Bravo	p-value	Alfa	Bravo	Chi value	Chi p-value													
Group I	N 30	0	1	30	0	1	23	2	2	0.01	0.99	16	4	4	1.83	0.08	23	2	2	0.01	0.99	16	4	4	1.83	0.08		
Group II	N 30	0	1	30	0	1	25	2	2	2.33	0.31	16	4	4	4.41	0.01	23	2	2	2.33	0.31	16	4	4	4.41	0.109		
Group III	N 30	0	1	30	0	1	28	2	0	2.15	0.34	23	3	1	0.31	0.85	25	2	2	2.15	0.34	23	3	1	0.31	0.85		
Surface roughness																												
Evaluation criteria		Surface roughness						Anatomic form																				
		1 month		3 months		6 months		3 months		6 months		6 months																
Alfa	Bravo	p-value	Alfa	Bravo	p-value	Alfa	Bravo	p-value	Alfa	Bravo	p-value	Alfa	Bravo	Chi value	Chi p-value													
Group I	N 30	0	1	30	0	1	23	3	1	2.01	0.365	15	6	3	3.51	0.172	23	3	1	3	3.08	0.37	15	6	3	6	4.68	0.19
Group II	N 30	0	1	30	0	1	25	1	3	1.16	0.55	15	6	3	4.06	0.131	23	3	1	3	4.32	0.22	15	6	3	6	8.07	0.04
Group III	N 30	0	1	30	0	1	27	3	0	4.03	0.131	23	3	1	0.011	0.99	25	1	3	1	5.07	0.16	23	3	1	3	1.08	0.78
Group III	N 30	0	1	30	0	1	27	3	0	2.15	0.34	23	3	1	0.011	0.99	25	1	3	1	5.07	0.16	23	3	1	3	1.08	0.78
Secondary caries																												
Evaluation criteria		Secondary caries																										
		1 month		3 months		6 months																						
Alfa	Bravo	p-value	Alfa	Bravo	p-value	Alfa	Bravo	p-value																				
Group I	N 30	0	1	30	0	1	27	0	1.071	0.3	22	2	0.49	0.48														
Group II	N 30	0	1	30	0	1	29	0	3.15	0.07	22	2	2.51	0.11														
Group III	N 30	0	1	30	0	1	29	0	1.01	0.31	26	1	1.09	0.295														
Group III	N 30	0	1	30	0	1	30	0	2.15	0.34	23	3	1	0.011	0.99	25	1	3	1	5.07	0.16	23	3	1	3	1.08	0.78	

group I exhibited deeply pitted and irregular surfaces, while only one restoration each in group II and III showed a pitted, irregular surface.

This could be attributed to the fact that the addition of SmartGlass filler (GC Corporation Ltd.) in GC Gold Label IX Extra resulted in increased surface hardness compared to GC Gold Label IX, potentially leading to a decrease in surface roughness. Similarly, in the case of GC Gold Label Hybrid, it combines hybrid fillers where more voluminous glass fillers are supplemented with small, highly reactive fillers, as claimed by its manufacturer. Additionally, a unique protective composite coating on the filler particles contributes to its improved surface smoothness.

Anatomic form is a measure of the loss of substance and is useful in evaluating the clinical performance of restorative materials that are soluble or vulnerable to abrasion.¹⁹ Table 2 showed the intergroup comparison of anatomic form among the three groups at regular time intervals of 1, 3, and 6 months of follow-up. No significant findings were observed at 1 and 3 months of follow-up. At the 6-month follow-up, while comparing GC Gold Label (group I) with GC Gold Label IX Extra (group II) and GC Gold Label IX Extra (group II) with GC Gold Label Hybrid (group III), no significant differences were observed. However, a significant difference was observed when comparing GC Gold Label (group I) with GC Gold Label Hybrid (group III).

It could be due to the fact that the nano-filled resin-coated fillers incorporated in GC Gold Label Hybrid show reduced potential for moisture contamination during setting, thereby decreasing early failure from masticatory forces. The nano-filled resin coating on the filler particles can infiltrate the restorative surface to seal any defects, thus retarding crack propagation and occlusal wear of this restorative material.²⁰ This was in accordance with the study conducted by Moshaverinia et al.¹² who reported that GC Gold Label Hybrid performed better in terms of wear resistance compared to GC Gold Label IX.

The comparison of restorations among the three groups in terms of secondary caries from baseline at regular intervals of 1, 3, and 6 months of follow-up has been shown in Table 2. No significant differences were observed at 1, 3, and 6 months of follow-up. This was in accordance with the study by Gurgan et al.²¹ who reported no recurrent caries during their study. Fluoride release is considered one of the most important advantages of glass ionomer cements. They have the ability to release fluoride over time, which is clinically beneficial as it helps protect the tooth from further decay.⁹

Although no significant difference was observed at the 6-month follow-up when comparing the three groups, secondary caries was observed in only two cases of GC Gold Label IX (group I) and 1 case of GC Gold Label IX Extra (group II). This could be attributed to the loss of marginal adaptation, which led to microleakage and percolation of microorganisms along the margins of the restoration, resulting in secondary caries.²² Also, it was found that maintenance of oral hygiene measures was compromised in such cases.

Limitations of the Study

The implementation of oral hygiene measures varies from patient to patient and could have impacted the restoration outcomes. Additionally, the evaluation period of this study was short. It is recommended that further long-term studies be carried out to accurately assess and compare the clinical performance of these glass ionomer cements.

CONCLUSION

It was concluded that GC Gold Label Hybrid showed better clinical efficacy compared to GC Gold Label IX, while GC Gold Label IX Extra showed comparable clinical performance to GC Gold Label Hybrid in occlusal surface cavities in primary molars prepared using hand instrumentation techniques.

Clinical Significance

Dental caries is a global problem that can significantly impact the quality of life of children. If affected teeth are left unrestored, dental caries can progress to pain and infection. Therefore, every effort should be made to retain these teeth functionally for as long as possible. Young children often struggle with complicated and lengthy dental procedures. As a result, they are advised to receive restorative dental treatment before the condition becomes painful.

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