

# Evaluation of Non-carious Cervical Lesions Restored with Resin-modified Glass Ionomer and Glass Carbomer: A Single-blind Randomized Controlled Clinical Trial

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## ABSTRACT

**Aims and objectives:** To compare and evaluate the clinical performance of glass carbomer cement over a period of 1 year, with that of resin-modified glass ionomer cement (RMGIC) in non-carious cervical lesions (NCCLs) in permanent teeth using the University of North Carolina (UNC)-modified United States Public Health Services (USPHS) criteria.

**Materials and methods:** Thirty-three subjects (30–60 years) with NCCLs of not >2 mm depth in premolars were recruited. Fifty-six NCCLs were restored with RMGIC (group I) and another 56 NCCLs with glass carbomer (group II). Single-blind evaluation of clinical parameters was performed at baseline, 3rd, 6th, and 12th month using modified USPHS criteria. Intragroup comparison at various intervals was evaluated using the McNemar test and the intergroup comparison using Fisher's exact tests.

**Results:** Recall rate was 73.2% for 1 year. Statistically significant decline was present after 12 months for marginal integrity ( $p = 0.008$ ), anatomic form (0.002), and color match ( $p = 0.0003$ ) for group II. Group I restorations showed better results in terms of retention, marginal integrity ( $p = 0.005$ ), color match ( $p < 0.0001$ ), wear ( $p = 0.0311$ ), recurrent caries ( $p = 0.0228$ ), marginal staining ( $p = 0.0086$ ), fracture ( $p = 0.0054$ ), and postoperative sensitivity ( $p = 0.0574$ ).

**Conclusion:** Glass carbomer, despite containing nano-sized powder particles and thermal setting, falls short of demonstrating acceptable clinical performance.

**Keywords:** Fuji II LC, Glass carbomer, Glass ionomer cement, Heat cure, Randomized controlled clinical trial, Resin modified glass ionomer cement, Single-blind, United States Public Health Services criteria.

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## INTRODUCTION

Resin-modified glass ionomer cement (RMGIC) introduced during 1989 overcame many inherent physical shortcomings of conventional GIC (cGIC). Adding light-cured resin particles to RMGIC ensued in increased early compressive plus flexural strength and improved resistance to initial moisture exchange and desiccation. Several clinical studies have demonstrated its longevity as a permanent restorative material.<sup>1,2</sup> Recently, a new restorative material that shares the essential chemistry of GIC was developed with prerogatives of improved physical characteristics. Glass carbomer GCP glass fill is a fluorapatite-containing cement with nano-sized powder particles which aid in remineralization and bonds to dentine and enamel.<sup>3</sup> It can set in an autopolymerization mode, i.e., the aqueous acid reacts with the basic glass in a neutralization reaction. Nevertheless, the manufacturers endorse using a high-octane dental polymerization light (1,400 mW/cm<sup>2</sup>) to accelerate this acid-base reaction. This is claimed to improve the marginal adaptation, increase bond strength, decrease porosity, increase compressive strength, and allow for shorter chair time.<sup>4-7</sup>

Few clinical trials have been done to equate the mechanical properties of glass carbomer cements with other restorative materials, but none compares the restorations in non-carious cervical lesions (NCCLs). Addressing this lacuna, we designed a study to compare the clinical working of glass carbomer cement with that of RMGIC (Fuji II LC) in NCCL restorations in permanent teeth over one year using the University of North Carolina

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(UNC)-modified United States Public Health Services (USPHS) criteria. The tested null hypothesis was that there would be no difference in the restorations done with Fuji II LC and those done with GCP carbomer techniques.

## MATERIALS AND METHODS

Following consent from the Institutional Review Board and the Institutional Ethical Committee, this study was chronicled with the Clinical Trials Registry of India (CTRI/2016/11/007497). All procedures executed were as per the ethical ideals of the national and institutional research committee and with the Helsinki declaration of 1975 and its subsequent amendments.

## Patient Selection

Patients amid the age group of 30–60 years were chosen based on the following inclusion conditions: good oral hygiene; the presence of at least two vital, non-mobile premolars having NCCLs not deeper than 2 mm. Patients unable to return for recall appointments and those having irreversible pulpitis, fracture, or periodontitis were excluded. Informed consent was obtained from the patients in their language, i.e., Tamil.

## Sample Size Calculation

The sample size was calculated as per results obtained from the study by Jyothi et al. where a similar comparison has been done between the clinical effects of using Giomer and RMGIC.<sup>8</sup> The current study tested RMGIC and glass carbomer in two groups with each patient receiving both the restorations, namely:

Group I: RMGIC (GC Fuji II LC, GC Co. Ltd., Tokyo, Japan).

Group II: Glass carbomer (GCP Dental, Netherlands).

The formula used for the calculation to find the number of subjects ( $N$ ) in each of the two groups, for a constant difference in proportions  $p_1$  and  $p_2$  between the two groups across  $n$  time points, was:<sup>9</sup>

$$N = \frac{\left[ z\alpha (2\bar{p}q)^{2.1} + z\beta (p_1q_1 + p_2q_2)^2 \right]^{1.2}}{n(p_1 - p_2)^2} (1 + (n-1)\rho)$$

Values used:

$p_1 = 0.8$  (for RMGIC–control);  $p_2 = 0.5$  (for glass carbomer–test);  $\rho = 0.6$   $n$  (time points) = 3 (patient follows-up 3 times).

$\alpha = 0.05$ ,  $Z 0.05 = 1.96$ ;  $\beta = 0.2$ ,  $Z 0.2 = 0.84$ ,  $\alpha$  (allowable type I error) 0.05 (5%),  $\beta$  (allowable type II error) 0.20 (20%) power of the study  $(1-\beta) = 80\%$ .

With these values, the sample size in each group was calculated as 56 (with an assumed 30% drop-out rate).

## Randomization

Each pair of selected premolars were randomly allocated to the two groups of RMGIC and glass carbomer using the lot system. Two lots were prepared. Each lot carried the side assigned to group I (RMGIC) or group II (glass carbomer). During the time of treatment, the patient could pick a lot manually in a random manner. Tooth to be intervened with RMGIC followed the tooth number mentioned in the lot. The other tooth was restored using glass carbomer. Hundred and twelve NCCLs were restored using the experimental design as shown in Flowchart 1. The flowchart proposed by CONSORT for clinical trials is depicted in Flowchart 2. Particulars of the materials used in the intervention are specified in Table 1.

## Restorative Procedure

Restorative treatments were performed by a single operator. All cavities were pumiced. To facilitate access and moisture control, a 212 Hu-Friedy cervical clamp and non-impregnated gingival retraction cord (#0) was used to retract the gingival tissues and place the rubber dam. No mechanical retention or beveled enamel margins were given as GIC bonds chemically to the tooth structure. Adhesion to dentin was enhanced by surface conditioning with an aqueous solution of 10% polyacrylic acid for 20 seconds.<sup>10</sup>

Fuji II LC capsule was amalgamated in a vibrator for 10 seconds at ~4,300 osc/minute. The material was immediately extruded into

the cavity and light-cured for 20 seconds using a visible light curing unit (Woodpecker Lux V Light Cure) at 1,200 mw/cm<sup>2</sup> according to the manufacturer's directives. Finishing, then polishing was done immediately after final setting with diamond polishing burs. A thin layer of nano-filled self-adhesive protective coating (G-Coat Plus) was light-cured onto the restoration. This liquid glaze prevents the initial sensitivity of GIC to water and ensures improved esthetics, surface smoothness, enhanced wear resistance, reduced risk of staining, and marginal protection.<sup>11</sup>

The glass carbomer capsule was mixed for 15 seconds at ~4,300 osc/minute. Soon after extruding the material directly into the cavity, a monomer-free silicone-based polysiloxane GCP gloss was applied onto the exterior of the restoration to protect against moisture and desiccation during curing. The restoration was heat-cured with a light cure device (GCP CarboLED CL-01) that has an output of 1,400 mw/cm<sup>2</sup> for 60 seconds (60°C).<sup>4</sup> Use of heat accelerates the matrix-forming reaction of glass carbomer and leads to a shorter setting time.<sup>12</sup> Finishing and polishing were done immediately after the final set with diamond polishing burs. GCP gloss was applied and cured again to provide an esthetic finish to the restoration.<sup>13</sup> Intraoral digital images were collected at baseline and each recall appointment using a Canon 1300 DSLR camera with an EFS 18–55 MM Canon lens having a 1.53 magnification (Canon Inc., Melville, NY, USA). Figure 1 shows the representative photographs of clinical evaluation at each evaluated time period.

## Evaluation of the Outcomes

Primary outcome measures were retention rate, marginal integrity, anatomic form, surface texture, color match, wear, marginal discoloration, recurrent caries, fracture, and postoperative sensitivity of the two materials.

Restorations were assessed soon after insertion, at 3 months, 6 months, and 1 year based on UNC-Modified USPHS criteria by a trained and calibrated evaluator who was blinded to the study.<sup>1,14–16</sup>

## Statistical Analysis

Graph Pad Prism 6 computer software was used for statistical analysis. An intragroup comparison was done for all parameters at different time intervals with the McNemar test. Intergroup analysis for all parameters between the two groups was done using Fisher's exact test. With a confidence interval of 95%, the level of significance was set at  $p < 0.05$ .

## RESULTS

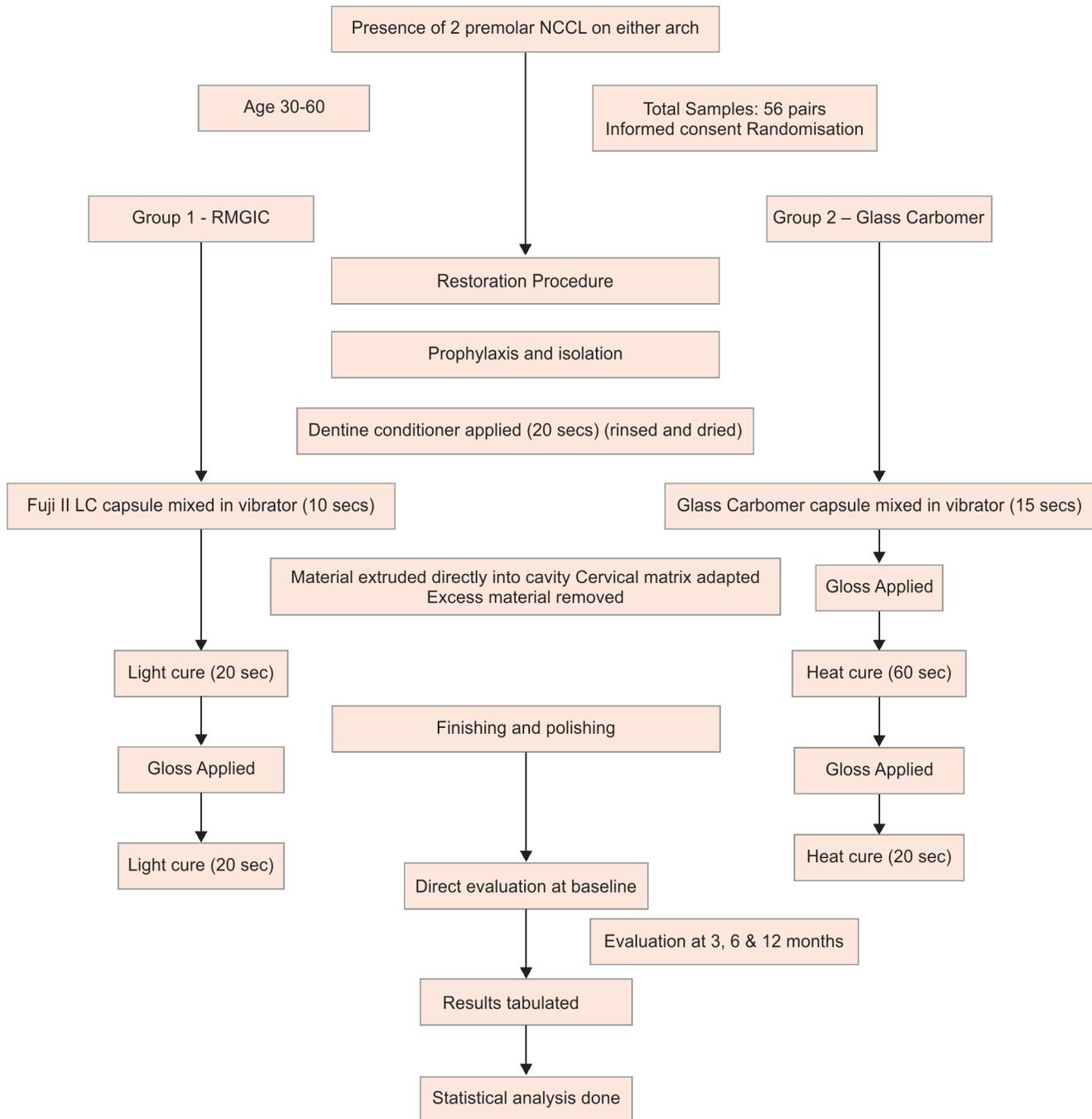
Fifty-six pairs of samples were recruited from 33 patients. The overall recall rate at 3 months was 80.4% and at 6 months and 1 year was 73.2%. For detailed comparative analysis, the data were statistically analyzed for only 37 samples from 21 patients who reported for all the timed evaluations.

The research data are available on *Mendeley Data* [<https://data.mendeley.com/datasets/3jm55gwcg4/1>].<sup>17</sup> A summary of direct evaluations presenting data for all clinical parameters at baseline, 3 months, 6 months, and 1 year is shown in Table 2. Figure 2 represents the percentage of restorations that recorded Alfa at baseline, 3, 6, and 12 months for each parameter.

## DISCUSSION

Clinical performance of restorations is best assessed in Class-V evaluations because NCCLs have an unretentive cavity form with

Flowchart 1: Experimental design



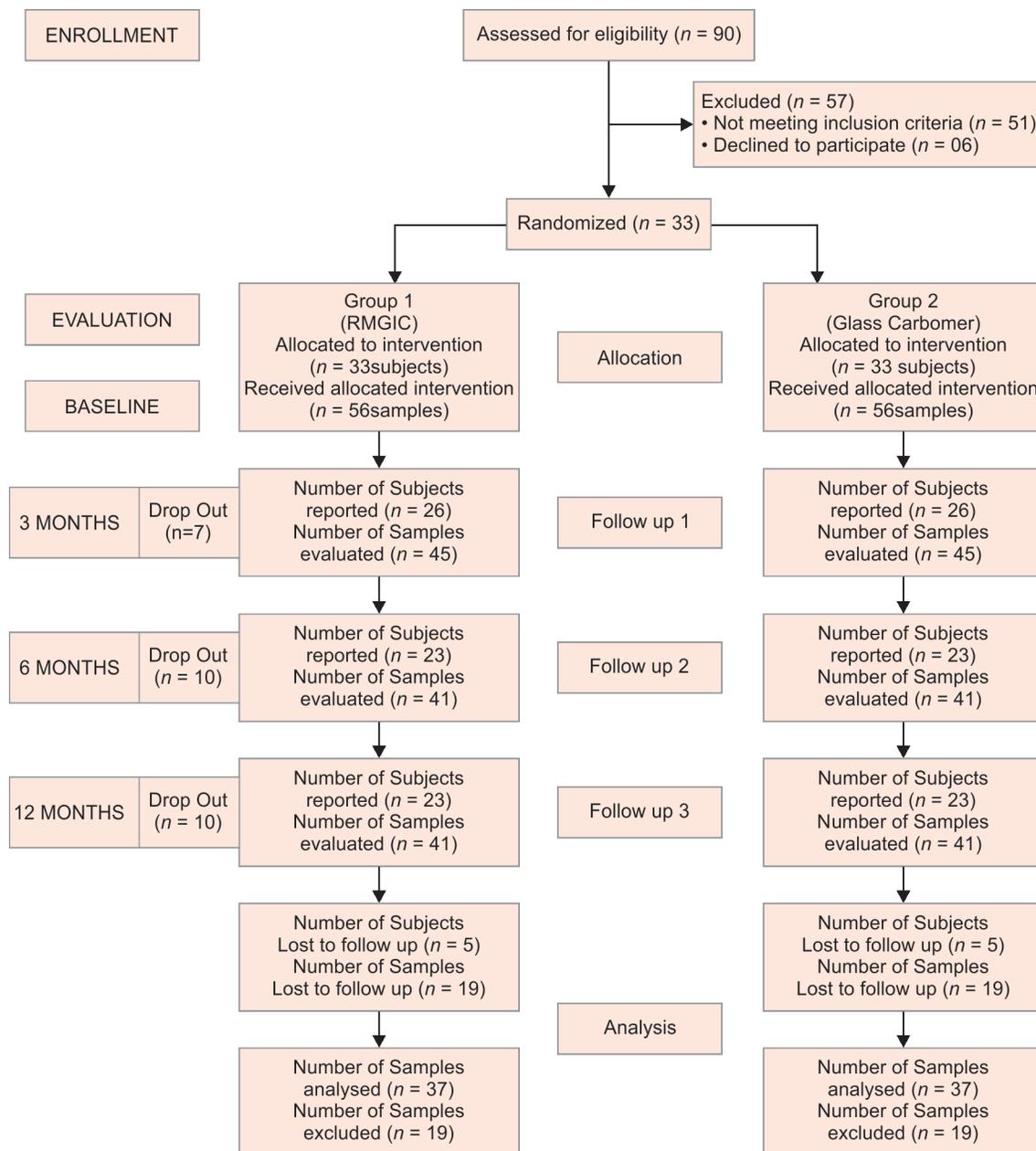
margins that lie on cementum or dentin, which is unfavorable for bonding. Age group and tooth selection were based on the prevalence of NCCLs.<sup>18,19</sup>

As the study involved the use of a heat cure unit, the buccolingual depth of the selected NCCLs was kept  $\leq 2$  mm. This was measured with a calibrated probe. The use of heat increases the temperature within the cement which can lead to a rise in intra-pulpal temperature. Botsali et al. found that the use of GCP glass carbomer along with a CarboLED Lamp caused high intra-pulpal temperature variations ( $5.21 \pm 0.42^\circ\text{C}$ ) compared to Fuji II LC ( $3.84 \pm 0.47^\circ\text{C}$ ).<sup>20</sup> However, according to an *in vitro* study done by Zach and Cohen, only when the intrapulpal temperature

increased to  $11.1^\circ\text{C}$  did it result in irreversible pulpitis.<sup>21</sup> van Duinen et al. found that applying heat for 90 seconds using GC D-light Duo increases the surface temperature to  $50.2^\circ\text{C}$  but results in only  $2\text{--}3^\circ\text{C}$  increase in temperature in the pulp space.<sup>22</sup> This is because the thermal conductivity of glass-ionomers is low, and as found by Gavic et al., the pulpal temperature rise at 4 mm depths is much less than at 2 mm.<sup>23</sup> Despite this, they can conduct some heat into their bulk, and therefore can be heat-cured thus improving the rate at which they advance to their optimal physical characteristics.

Retention of glass ionomer to the tooth depends on the bond strength of the cement. In this study, a retention rate of 94.6% was

Flowchart 2: Consort flowchart



6 subjects were treated with 3 pairs of samples each, 11 subjects with 2 pairs and 16 subjects with 1 pair.

Reasons for complete dropout: Not responding to calls (4), out of town for long time interval (1)

Reasons of excluded analysis: Not present for all the evaluations due to their work-related issues; One patient could not come for 12 months evaluation because of a fractured leg. Some subjects did not come for 3/6 months evaluation but reported for the other evaluations

documented for RMGIC restorations, whereas 86.5% retention was attained for carbomer.

Clinical evidence suggests that restoration loss could be due to insufficient bonding of the cement to the enamel as cervical lesions present no macro-mechanical undercuts.<sup>24,25</sup> According to the manufacturer, glass carbomer has nano-sized powder particles that strengthen the material through an augmented particle surface in interaction with the glass-carbomer liquid resulting in stronger adhesion to the cavity wall.<sup>26</sup> Heating at low temperatures with light emitted from a high-powered polymerization unit also improves the mechanical properties and the shear bond strength to the enamel.<sup>27,28</sup> However, the outcomes of research done by

Olegário et al. showed a lower bond strength for carbomer than high viscosity GIC.<sup>5</sup> Research has shown that during the chemical reaction in the glass carbomer, hydroxyapatite gets partially consumed in the setting stage. This decreases the number of accessible ions required to bond with the mineral part of the tooth, resulting in inferior bond strength.<sup>26</sup> Dentinal water and intrinsic water of the cement also play a significant role in the bonding of glass ionomer cement to dental hard tissues because water acts as a medium in which acid-base reaction and ion exchange occur.<sup>29</sup> However, dehydration induced by the heat and light unit used to activate the material can be another possible explanation that may affect the interface between the dentine and carbomer resulting in



**Table 1:** Materials used in intervention

S. no.	Material	Company	Country	Lot no.
1	Dentin Conditioner; <i>Composition:</i> 10% polyacrylic acid	GC	Japan	1511111
2	RMGIC capsule (Fuji II LC); <i>Composition:</i> Aluminofluorosilicate glass, polyacrylic acid, 2-hydroxyethyl methacrylate, 2,2,4-trimethyl hexamethylene dicarbonate, triethylene glycol dimethacrylate	GC Corporation, Tokyo	Japan	1503101
3	Glass Carbomer capsule (GCP Glass Fill); <i>Composition:</i> Fluoroaluminosilicate glass, apatite, polyacids	GCP Dental	Netherlands	7501759
4	GCP gloss; <i>Composition:</i> modified polysiloxanes	GCP Dental	Netherlands	673924
5	RMGIC Gloss (G-Coat Plus); <i>Composition:</i> nanofilled resin	GC	Japan	1601061

**Fig. 1:** Representative photographs of clinical evaluation at each evaluated time-period

poor bond strength. Chen et al. recorded retention of 41.5% with glass carbomer at 1 year which is much less than the present study.<sup>30</sup>

Another reason for retention failure is the occurrence of sclerotic dentin in NCCL, which is more resilient to adhesion than normal dentin. Mjör et al. in their study on pulp-dentin biology found that owing to the wear on the cervical and occlusal surfaces of the tooth, defense mechanisms are stimulated leading to the development of reactionary and reparative dentin that obstructs the exposed dentinal tubules.<sup>31</sup> Thus, age becomes a component that alters the structure and composition of dentin resulting in retention failure of the restoration.

Inadequate bonding of restoration also results in marginal gaps, microleakage, and subsequently postoperative sensitivity.<sup>32</sup> This study showed decreased sensitivity for both materials from the preoperative to the postoperative phase, but the discrepancy was not statistically significant.

The marginal integrity of the restoration is associated with the viscoelastic property of the restorative material, water sorption at the tooth-restorative interface, and unique stress patterns at the cervical margin of the tooth.<sup>33</sup> In this study, marginal integrity significantly deteriorated for both materials after 6 months. Most marginal defects were small, either at the occlusal aspect or at the cervical margin. Resin-modified glass ionomer cement undergoes curing shrinkage due to the presence of resin resulting in volumetric changes that can create marginal gaps.<sup>34</sup> In contrast, glass carbomer does not shrink during the polymerization process as it does not contain any solvents or resin and is as such monomer free.<sup>13</sup> Also, since GICs are prone to water uptake and hygroscopic expansion over time it can result in lower marginal adaptation. Hence, the application of gloss provides effective surface protection and improved marginal sealing.<sup>12</sup> However, the marginal integrity of both materials was differentially affected even in the presence of

a gloss coating. This can be due to the lack of moistening effect of the surface gloss and in the case of glass carbomer combined with the dehydrating influence of the high-power light-curing unit it may have developed into a rapid decline of the tooth-material interface, leading to increased levels of leakage. Also, loss of the protective surface gloss over time can lead to defects in marginal integrity. Both Neo et al. and Gladys et al. noticed that margins that were ideal at restoration placement substantially worsened after 6 months.<sup>35,36</sup> Hence, with regard to marginal properties, it is fair to conclude that the enamel bonding efficacy of both materials is possible to deteriorate over time.

Fracture toughness is an intrinsic property of a material that resists the transmission of a surface crack through it. At 1 year, RMGIC showed one Charlie rating whereas carbomer had four, due to bulk restoration fracture. Five carbomer restorations had a small chip but were clinically acceptable and were rated as Bravo. Olegário et al. in a 3-year randomized clinical trial of ART restorations found that the main reason for carbomer restoration failure was bulk fracture/restoration loss because of the creation of internal cracks during the setting of the material, which can get disseminated leading to restoration breakdown.<sup>37</sup>

The fracture resistance of a material also depends on its composition which includes powder particle size and powder liquid ratio. Resin-modified glass ionomer cement with an average particle size of 5.9  $\mu\text{m}$  and a powder liquid ratio of 3.2 g/1.0 g have numerous small glass particles well-dispersed in the matrix which might be responsible for its high compressive strength.<sup>38</sup> Carbomer with its nano-size powder particles results in reduced fracture toughness. Cracks continually run across the matrix phase or next to the matrix/particle interface. Hence, tinier particles in the material cause minimal crack deflection, resulting in a decreased fracture toughness.<sup>39</sup>

Table 2: Summary of direct evaluations

	Group I												Group II																							
	Baseline				3 Months				6 Months				12 Months				Baseline				3 Months				6 Months				12 Months							
	n	t	%	n	n	t	%	n	n	t	%	n	n	t	%	n	n	t	%	n	n	t	%	n	n	t	%	n	n	t	%	n				
Recall rate	56	56	100.0	45	56	56	100.0	45	56	56	100.0	45	56	56	100.0	45	56	56	100.0	45	56	56	100.0	45	56	56	100.0	45	56	56	100.0	45	56	56	100.0	45
Retention	56	56	100.0	45	56	56	100.0	45	56	56	100.0	45	56	56	100.0	45	56	56	100.0	45	56	56	100.0	45	56	56	100.0	45	56	56	100.0	45	56	56	100.0	45
Marginal integrity	56	56	100.0	43	56	56	100.0	43	56	56	100.0	43	56	56	100.0	43	56	56	100.0	43	56	56	100.0	43	56	56	100.0	43	56	56	100.0	43	56	56	100.0	43
Anatomic form	55	56	98.2	36	56	56	100.0	33	56	56	100.0	33	56	56	100.0	33	56	56	100.0	33	56	56	100.0	33	56	56	100.0	33	56	56	100.0	33	56	56	100.0	33
Surface texture	53	56	94.6	34	56	56	100.0	34	56	56	100.0	34	56	56	100.0	34	56	56	100.0	34	56	56	100.0	34	56	56	100.0	34	56	56	100.0	34	56	56	100.0	34
Color match	53	56	94.6	40	56	56	100.0	40	56	56	100.0	40	56	56	100.0	40	56	56	100.0	40	56	56	100.0	40	56	56	100.0	40	56	56	100.0	40	56	56	100.0	40
Wear				39	56	56	100.0	36	56	56	100.0	36	56	56	100.0	36	56	56	100.0	36	56	56	100.0	36	56	56	100.0	36	56	56	100.0	36	56	56	100.0	36
Recurrent caries				45	56	56	100.0	41	56	56	100.0	41	56	56	100.0	41	56	56	100.0	41	56	56	100.0	41	56	56	100.0	41	56	56	100.0	41	56	56	100.0	41
Marginal staining				45	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39
Fracture				44	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39
Postoperative sensitivity				43	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39	56	56	100.0	39

Number (n) and percentage (%) of total (t) restorations that scored Alfa at baseline, 3, 6, and 12 months for each parameter

The surface roughness of carbomer was much less when compared to RMGIC.<sup>40</sup> This can be because of the lower abrasion resistance of RMGIC. Resin-modified glass ionomer cement comprises glass particles in a resinous and hydrogel matrix. As the matrix degrades, the surrounding glass particles get separated from the matrix, producing a rough surface.<sup>41</sup>

On a similar note, RMGIC (78.4%) showed greater wear than carbomer at all periods: it was statistically significant at 6 months ( $p = 0.0211$ ) and 1 year ( $p = 0.0311$ ). Resin-modified glass ionomer cement with low wear resistance also resulted in subsequent loss of anatomic form.<sup>38</sup> On the other hand, carbomer having less surface roughness may be attributed to the nanoparticle size of the filler particles that result in a smoother exterior and are easier to finish and polish.<sup>42,43</sup>

The roughness on the surface of restorative materials also determines the materials' color stability. On a rough surface, light scatters, reducing restoration shine, and leading to easy deposition of stains.<sup>44</sup> Decreasing the size of powder particles also provides excellent clinical smoothness of the surface resulting in reduced marginal staining. In this study, for both materials, the percentage of restorations showing discoloration increased with time. A Bravo rating for carbomer at baseline was given as the marginal discoloration was seen at the distal margin of the restoration, where it was difficult to access during finishing and polishing.

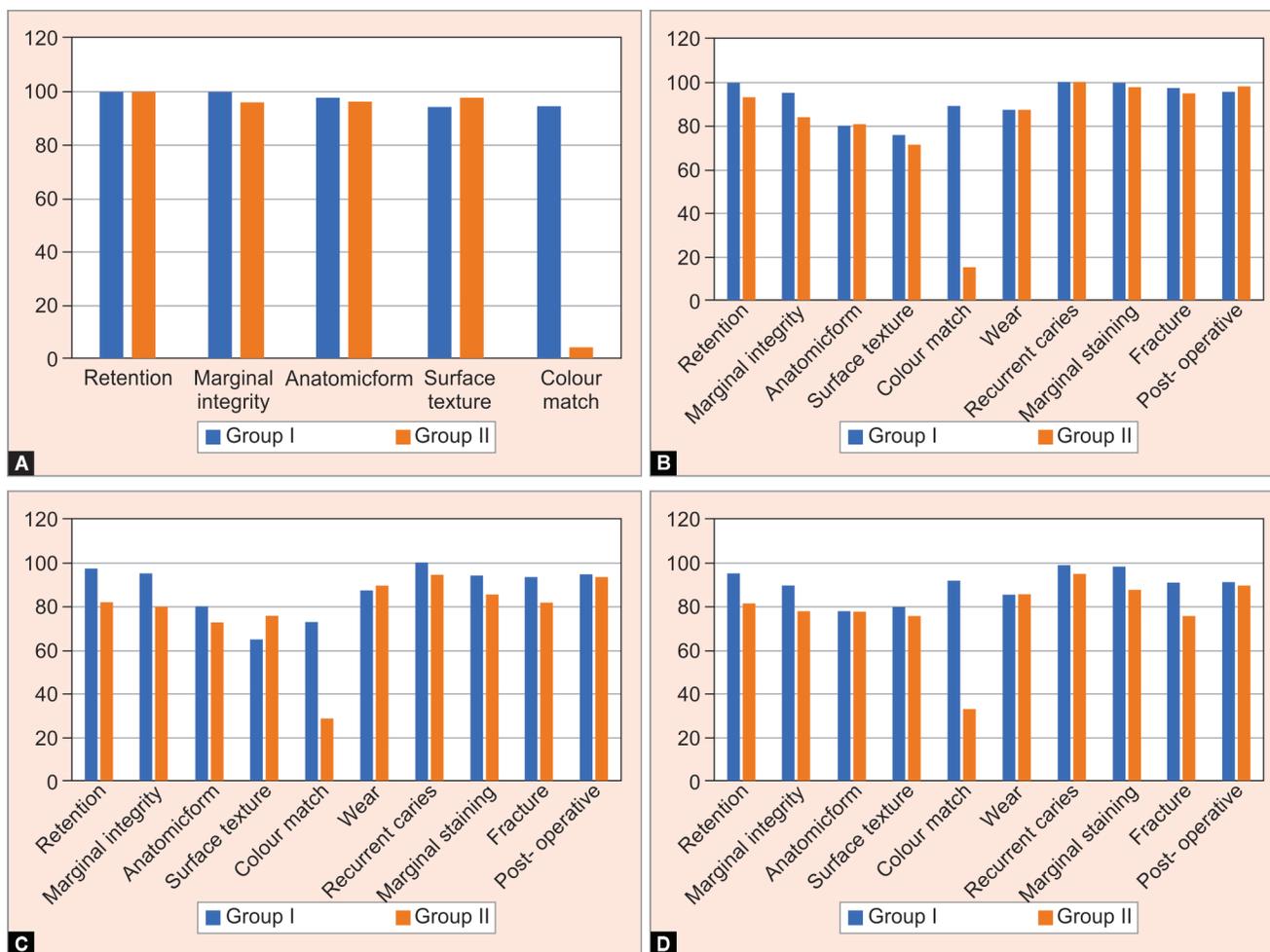
We also observed that upon placement 97.3% of RMGIC had an excellent color match with the surrounding tooth, which reduced to 86.5% in 1 year. This is similar to a study by Neo et al. who found the color match of RMGIC to be less than satisfactory after 18 months (48% Alfa rating).<sup>35</sup> This could be because of pigment absorption on the rough restorative surfaces from nutritional habits. In the case of carbomer, the color matching increased from none upon placement to 40.5% in 1 year. This suggests that even carbomer did not show color stability over time. Savas et al. found clinically unacceptable color changes in carbomer when placed in various beverages for 28 days.<sup>45</sup>

This study involved only NCCLs. Therefore, the presence of caries after placement of the restoration may be because of the oral environment, the cavity, the material, the operator's skill, or the procedure. In this study, only Carbomer showed the presence of caries (5.4%). This is slightly more than Chen et al. who reported the occurrence of caries as 2.6% following 12 months of glass carbomer material placement.<sup>46</sup> It may be speculated that the application of surface gloss along with its heat treatment would have possibly occluded the diffusion of fluoride which is required to inhibit caries.<sup>43</sup> However, none of the RMGIC restorations showed caries occurrence despite gloss application. This is similar to a study by Abdalla et al. who evaluated the clinical performance of RMGIC in NCCLs and found no secondary caries at the end of 1- and 2-year recalls.<sup>47</sup> Since the marginal integrity of both the materials was differentially affected, it is possible, that oral microorganisms gained entry via gaps at the tooth restoration interface.<sup>48</sup>

Considering the limitations of this study it can be said that a 1-year clinical assessment is truly a short time to assess the long-standing clinical behavior of restorative materials.

In conclusion, though RMGIC showed superior clinical performance compared to carbomer not much statistically significant difference was seen between them. Hence, the null hypothesis was accepted that there would be no difference in the restorations done with RMGIC and those done with GCP glass carbomer cement. Glass carbomer, despite containing nano-sized powder particles and thermal setting, falls short of demonstrating





**Figs 2A to D:** Percentage graph of restorations that scored Alfa at baseline, 3 months, 6 months and 12 months for each parameter

acceptable clinical performance. Conclusions of this study must be validated by a more extended phase of observation.

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