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# Giomer composite compared to glass ionomer in occlusoproximal ART restorations of primary molars: 24-month RCT

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## ABSTRACT

***Background:*** Occlusoproximal restorations of primary molars usually fail, so it is necessary to investigate new materials that may overcome this challenge. Thus, this trial aimed to evaluate the longevity of occlusoproximal ART restorations in primary molars using a glass ionomer cement – GIC (Equia Forte® – GC Corp) and a Giomer resin composite – GCR (Beautifil Bulk Restorative® – Shofu Inc) after 24 months.
***Methods:*** One hundred and eighty-two (182) children aged from 4 to 8 years were selected and randomly assigned to GIC or GCR. A paediatric dentist treated them in the school setting in Cerquilho, Brazil, and the restorations were assessed after 3, 6, 12, 18 and 24 months. The primary outcome was the restoration survival, evaluated using the Kaplan–Meier and superiority Cox regression analyses. Intention to treat (ITT) was performed as a sensitivity analysis using superiority test *P* value and confidence interval (CI = 95%). Independent variables included gender, age, molar, jaw, cavity volume and caries experience.
***Results:*** The restoration survival after 24 months was GIC = 58.1% and GCR = 49.1% (HR = 1.24; CI = 0.97–1.59). ITT analysis showed a success of GIC = 61.1% and GCR = 52.2% (RR = 1.17; CI = 0.91–1.52). The superiority hypothesis was not proved in both analyses ($P > 0.05$).
***Conclusion:*** GCR does not have superior longevity than GIC in occlusoproximal ART restorations of primary molars.

***Keywords:*** Atraumatic Restorative Treatment, giomer, glass ionomer cement, paediatric dentistry, primary teeth.

***Abbreviations and acronyms:*** ART = atraumatic restorative treatment; DC = degree of conversion; DMFT = decayed, missing, filled teeth in permanent teeth; EAC = enamel access cutter; GIC = Glass Ionomer Cement; ICF = informed consent form; ITT = Intention to treat; RR = relative risk; WHO = World Health Organization.

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## INTRODUCTION

The atraumatic restorative treatment (ART) is part of the Minimal Intervention approach and includes preventive and restorative components.[1] Its restorative technique involves selective caries removal with hand instruments and restoration using an adhesive material, most frequently the high-viscosity glass ionomer.[2] ART was developed almost 40 years ago as an alternative to treat caries without conventional dental equipment (especially for underprivileged areas) and is an appropriate caries management for increasing dental treatment coverage in settings where it is often restricted.

The high-viscosity glass ionomer restorative material has many advantages, including chemical bonding to the tooth structure,[3] fluoride release and recharge[4] – which can prevent caries in the margins of restorations in primary teeth,[5] its bulk insertion – reducing the time for placing a restoration,[6] and its lower sensitivity to humidity compared to resin composite.[7,8] On the other hand, some mechanical properties of GICs are inferior compared to those of resin composites, such as mechanical strength and wear resistance.[9] Despite the improvement of GIC over time, occlusoproximal ART restorations using GICs in primary teeth still present higher failure rates compared to occlusal ones.[10–14] Evidence shows that the longevity of single-surface ART restorations can reach over 90% after 2 years, while multi-surface ART restorations demonstrate 60% longevity for the same period.[14,15] Thus, the search for any other adhesive

restorative material to improve the success rates in occlusoproximal restorations is still necessary.

A group of bioactive materials with new technology was introduced, entitled "giomer". Their composition is based on the surface pre-reacted glass ionomer (S-PRG) particle, which results from the pre-reaction of fluoroboroaluminosilicate glass with polyacid to form a glass–ionomer matrix structure and then blend it with the resin matrix. This particle allows the release of fluoride and other ions,[16] and its surface layer protects the structure's core from harmful moisture effects.[17] Moreover, laboratory studies demonstrate that this technology enables remineralization, prevents demineralization, inhibits cariogenic bacteria[18–20] and has promising clinical behaviour and good mechanical stability. Therefore, Giomers are not glass ionomers but rather materials that contain the S-PRG particle in their composition. Giomers are available as adhesive systems, standard resin composites, bulk-fill resin composites, injectable resin composites, sealants, among others. From the available Giomers, bulk-fill resin composites seem to be the most advantageous for use in paediatric dentistry because they reduce the session time needed for layering and adapting restorations in posterior teeth.[21]

Although Giomer restorative materials have been available for some years and present good behaviour and good mechanical stability,[22] the clinical evidence that supports their use is still scarce, primarily related to primary teeth.[23]

Thus, this trial aimed to evaluate the longevity of occlusoproximal ART restorations in primary molars using an encapsulated glass ionomer – GIC (Equia Forte® – GC Corp, Tokyo, Japan) and a Giomer resin composite with a one-step self-etch adhesive – GCR (Beautifil Bulk Restorative®/Beautibond® – Shofu Inc, Kyoto, Japan) – after 24 months.

## MATERIALS AND METHODS

This manuscript was written according to the CONSORT Statement for randomised clinical trials, and the checklist is attached as a supplementary file.

### Study design and ethical aspects

This two parallel-arm, randomised, superiority trial with an equal allocation ratio was performed in a school setting. This study was approved by the Research Ethics Committee of the School of Dentistry, University of São Paulo (protocol 2.485.320), and it has been registered on ClinicalTrials.gov (NCT02962713). All children's caregivers included in this study signed an informed consent form (ICF) before the inclusion.

### Sample size and selection

A systematic review and meta-analysis reported the longevity of multiple-surface ART restorations in primary teeth after 2 years using high-viscosity GIC to be 62%.[15] The sample size was estimated using the website www.sealedenvelope.com. Considering an $\alpha$ of 5% and power of 80%, a superiority margin of 20% and adding 15% of potential loss to follow up, the total sample size resulted in 176 teeth.

Participants were selected after clinical screening at public schools. An examiner evaluated 1844 children aged between 4 and 8 years old at schools, searching for those who were eligible to the study, assessing the presence of at least one primary molar with occlusoproximal caries lesion (i.e. caries lesions that affected the occlusal surface and one of the proximal surfaces of the molar). We included only one tooth per child, and when the child had more than one tooth potentially eligible, a simple lottery was conducted on the day of the treatment to decide which one would be included in our trial. We used an opaque jar containing equal-sized pieces of paper with the number of eligible teeth for this lottery.

The inclusion criteria were children between 4 and 8 years old, with at least one occlusoproximal dentin caries lesion in a primary molar. There was no restriction on the cavity size, as long as it involved only the occlusal surface and one of the proximal surfaces of the molar.

The exclusion criteria were children with challenging behaviour at the initial examination, presenting signs or symptoms of pulp involvement, such as fistulae, pathological mobility, spontaneous pain and/or abscess near the selected tooth or children whose caregivers did not agree to participate through the ICF.

### Randomisation and blinding

The randomisation list was generated in blocks of different sizes (4, 6 and 8) on www.sealedenvelope.com. To ensure the allocation concealment, we used sealed opaque envelopes. An undergraduate student, who did not participate in the clinical phase of this study, prepared the envelopes. An independent dentist from the municipality was responsible for opening the envelopes only when the cavity was ready to receive the restorative material.

Due to the remarkable differences in the appearance of the restorative materials used in this study and the distinct clinical procedures involved in the use of each of them, blinding the operator, the participant and the evaluator was not possible.

### Operator

A paediatric dentist trained to execute ART restorations at the school setting was the only operator of the study and performed all the restorations. A dentist from the municipal department was responsible for handling the materials and assisting the operator.

### Clinical variables

The independent variables used in this study were gender, age, molar, jaw, cavity volume and caries experience.

The professional responsible for opening the randomisation envelopes was the same one who recorded the characteristics of each participant. When the child arrived to be treated, his/her name, gender and birth data were recorded. Then, the child lied on the table, and the operator checked whether one or more teeth were eligible (and requested the lottery when necessary). Thus, which arch (upper/lower) and molar (first/second) was registered. For caries experience assessment, we have used the World Health Organization (WHO) criteria.[24] The decayed, missing, filled teeth in permanent teeth (DMFT) and decayed, missing, filled teeth in primary teeth (dmft) were recorded.[25] Three measures were made with a probe to calculate the approximate cavity volume (distal-mesial, occlusal-cervical, buccal-lingual or buccal-palatal). As the cavities were not symmetrical, the volume achieved was not exact. The intention was to estimate the volume to assess if it would influence the restorations' longevity. The cavity measures were conducted after selective caries removal.

### Restorative procedures

The composition, instructions for use and other specifications of the materials used in the study are detailed in Table 1. The treatment phase occurred in November 2017, during school hours, in empty and prepared classrooms. As the restorations were done in the school setting, no suction or radiographs were available. The children lay down on a large table, and the operator positioned herself behind their heads to perform the treatment.

All children were treated according to the ART premises proposed by Frencken and Holmgren.[26] We performed selective caries removal to firm dentin[27] using hand instruments, without local anaesthesia. The moisture was controlled with cotton rolls for both groups. When lesions were not wide enough for spoon excavators to reach, the enamel was opened using an enamel hatchet or enamel access cutter (EAC). After cavity preparation, the operator measured the cavity to estimate the cavity volume ($mm^3$), and only then the randomisation envelope was opened, being the restorative material revealed. We have followed the manufacturers' instructions.

Control Group: Encapsulated high-viscosity Glass Ionomer Cement (GIC) – Equia Forte (GC Corporation, Japan).

Firstly, a micro applicator with a drop of the Cavity Conditioner (GC Corporation, Japan) was rubbed on the cavity walls for 15 s. Then the cavity was rinsed and dried using cotton pellets. In the presence of the adjacent tooth, a matrix band and a wooden wedge were placed. At this moment, the GIC capsule was activated, set in a mixer (Ultramat – SDI Limited, Australia) and mixed for 10 s. The GIC capsule was placed in an applicator, and the material was inserted into the cavity. This material is self-cured and allows a bulk application. Finally, a thin layer of the Equia Forte Coat® (GC Corp) was applied with a micro applicator and then light-cured (Emitter B – Schuster) for 20 s. An articulation paper was used to check if the restoration caused any occlusal interference. If the adjustment was necessary, we used an excavator, and the coating was re-applied. The child was instructed not to eat for 1 h.

Test Group: Giomer technology resin composite associated with a one-step self-etch adhesive – GCR – Beautibond and Beautifil Bulk Restorative (Shofu Inc).

After caries tissue removal, the cavity was washed by rubbing wet cotton pellets against its walls to remove debris and remnants of decayed tissue removal. In the presence of the adjacent tooth, a matrix band and a wooden wedge were placed to adapt the restoration. A thin layer of the one-step self-etch adhesive BeautiBond (Shofu Inc) was applied with a micro applicator and light for 10 s. The operator placed an appropriate amount of the Beautifil-Bulk Restorative in a disposable paper to prevent cross-contamination and inserted the material into the cavity, creating the desired shape with a spatula. The resin composite was light-cured for 20 s at each restoration surface. The composite was used in increments up to 4 mm. An articulation paper was used to check if there was any interference. In cases where the adjustment was necessary, it was done with a scalpel blade.

The operator restored all other teeth with caries lesions that could be performed at the school setting, showing no clinical signs of pulpal involvement. The restorative material used on these other teeth followed the group in which the child was allocated. Other treatment needs, such as endodontic treatment and extractions, were referred to a public health centre.

**Table 1. Detailed specification of materials used in the study**

| Product name | Manufacturer | Composition | Instructions for use |
|---|---|---|---|
| BEAUTIFIL-Bulk Restorative Batch: 081618 | SHOFU INC | Bis-GMA, UDMA, Bis-MPEPP, TEGDMA, S-PRG filler based on fluoroboroaluminosilicate glass, Polymerisation initiator, pigments and others | • Dispense an adequate amount of BEAUTIFIL-Bulk Restorative onto a paper pad from the syringe.<br>• Apply the dispensed material into the cavity using a suitable instrument and create the shape desired. In deeper preparations, place material in 4 mm increments.<br>• Light-curing: Light cure each layer (up to 4 mm increment) using a dental light-curing unit. In the case where the restored area is large, divide it into some parts to light-cure.<br>• Light-cure with a LED unit for 10 s (4 mm). |
| BeautiBond Batch: 101663 | SHOFU INC | Acetone, distilled water, Bis-GMA, carboxylic acid monomer, TEGDMA, phosphonic acid monomer and others | • Prepare the brush by attaching the disposable applicator tip to the handle.<br>• Dispense an adequate amount of BeautiBond on a dish and apply it to the entire inner surface of the cavity with the brush.<br>• After application, leave undisturbed for 10 s. Air dry with gentle air for about 3 s and then dry with stronger air until a thin and uniform bonding layer is obtained.<br>• Light-cure with a LED unit for 5 s |
| EQUIA Forte Fil Batch: 1708011 | GC Corporation | • Powder: 95% strontium fluoro alumino-silicate glass, 5% polyacrylic acid<br>• Liquid: 40% aqueous polyacrylic acid | • Before activation, shake the capsule or tap its side on a hard surface to loosen the powder.<br>• To activate the capsule, push the plunger until it is flush with the main body and hold it down for 2 s.<br>• Immediately set it into a mixer (or an amalgamator) and mix for 10 s<br>• Remove the mixed capsule from the mixer and load it into the applier. Make two clicks to prime the capsule then syringe.<br>• Within 10 s maximum after mixing, start to extrude the mixture directly into the preparation.<br>• Form the preliminary contour, and cover with a matrix if required. |
| EQUIA Forte Coat Batch: 1611091 | GC Corporation | 40%–50% methyl methacrylate, 10%–15% colloidal silica, 0.09% camphorquinone, 30%–40% urethane methacrylate, 1%–5% phosphoric ester monomer | • Dispense a few drops of EQUIA Forte Coat into a disposable dispensing dish. Replace bottle cap immediately after use.<br>• Immediately apply (within 1 min after dispensing) to the surfaces to be coated using the disposable micro-tip applicator. Use floss to apply to the approximal surface. Do not air blow. |
| Cavity Conditioner Batch: 1703031 | GC Corporation | 20% aqueous polyacrilic acid | • After tooth preparation, apply Cavity Conditioner to the bonding surfaces for 10 s using a cotton pellet or sponge.<br>• Rinse thoroughly with water and dry. Do not desiccate. |

Source: The above information was taken from the leaflet supplied by the manufacturers of each one of these materials.

## Evaluation

The primary outcome of this study was the restorations' survival. Evaluations of restorations were performed by a trained and calibrated dentist using the criteria of Roeleveld *et al*.,[28] detailed in Table 2. The evaluator underwent a 3-day training of clinical and laboratory activities with an expert. After this training, the evaluator assessed restorations in 10 children who did not participate in the study and repeated the same evaluations 2 days after that for intra-examiner agreement calculation. A benchmark examiner also assessed the same 10 restorations to obtain inter-examiner reproducibility. The examiner was recalibrated before all assessments. Only restorations with no repair needed (classified in scores 00 and 10) were considered as a success.[28]

The clinical assessment was performed after 3, 6, 12, 18 and 24 months in a school setting inside empty classrooms selected for this purpose. The width and

**Table 2. Criteria of Roeleveld *et al.* for restorations assessment[28]**

| Score | Criteria |
|---|---|
| 00 | Restoration still present, correct |
| 10 | Restoration present, slight defect at the margin and/or wear of the surface; <0.5 mm in-depth, no reparation needed |
| 11 | Restoration present, defect at the margin and/or wear of the surface; >0.5 mm in depth, repair needed |
| 12 | Restoration present; underfilled >0.5 mm, no gap, repair needed |
| 13 | Restoration overfilled >0.5 mm, repair needed |
| 20 | Secondary caries, discolouration in depth, surface hard and intact, caries within dentin; repair needed |
| 21 | Secondary caries. Surface defect, caries within dentin; repair needed |
| 30 | Restoration not present, bulk fracture, loose, (partly) lost; repair needed (if still possible without exposing the pulp) |
| 40 | Inflammation of the pulp (restoration still *in situ*, not categorised in the former categories); fistula or severe pain complaints; extraction needed |
| 50 | Tooth not present because of extraction |
| 60 | Tooth not present because of shedding |
| 70 | Tooth not present because of extraction or shedding; unable to diagnose |
| 90 | Patient not present |

Restorations considered to have survived are scored by codes: 00 and 10, those considered to have failed by codes: 11, 12, 13, 20, 21, 30 or 40, while those considered to be unrelated to success and failure are coded: 50, 60, 70 or 90.

depth of marginal defects, surface wear, lack and excess of material were measured using a WHO probe.

### Statistical analysis

The analysis for the primary outcome (restoration survival) was tested using a two-sample superiority test for survival data using Cox regression (superiority/alternative hypothesis Hazard ratio <1.20; CI = 90%). The proportion of treatment success at 24 months of follow-up (intention to treat analysis using multiple imputation[29] considering baseline variables) was performed as a sensitivity analysis using superiority test *P* value and confidence interval (CI = 95%), derived by Miettinen and Nurminen's method.[30] These analyses were performed using NCSS Statistical software (NCSS 2021, USA).

As a secondary analysis, a two-tailed Cox regression analysis was performed to investigate the association of the prognostic factors for restoration failure. Variables that reached a *P* value of <0.20 in the univariate analysis were considered for the adjusted analysis. Treatment survival was evaluated using Kaplan–Meier survival analysis and Log-rank test ($\alpha = 5\%$). The latest analyses were performed using Stata 17.0 software (StataCorp LP, College Station, TX, USA).

The significance level for all the tests was set as 5%.

## RESULTS

One hundred and eighty-two (182) participants aged between 4 and 8 years old and enrolled in one of the 15 public schools were included in this trial (mean age 6.4 ± 2.5 years). The restorations were placed in November 2017, and the evaluations were performed between February 2018 and November 2019. The weighted Kappa value for inter-examiner reproducibility (between the evaluator and an expert) was 0.89, and the intra-examiner agreement was 0.94.

The participants' flow since the enrolment and the losses to follow-up in each evaluation are presented in Fig. 1. All children who were evaluated at least once during the follow-up period were included in the survival analysis. Thus, only five participants were never evaluated (dropout rate: 2.7%). For the intention to treat analysis, 21 children who were absent in the 24-month evaluation were included using multiple imputations.[29] All losses to follow-up occurred because the children moved to another state, and we lost contact with them and their families.

The baseline distribution of variables and chi-square analysis between groups are shown in Table 3. The chi-square test did not show a statistical difference in the distribution of the baseline characteristics evaluated (age, caries experience, jaw, molar, gender and volume) amongst the restorative materials tested.

Fig. 2 illustrates the curves of the Kaplan–Meier survival analysis. The survival rates of each group were GIC = 58.1% (SE = 0.06) and GCR = 49.1% (SE = 0.06) after 24 months. Log-rank test did not find a statistical difference between the restorative materials after 2 years ($P = 0.168$).

The distribution of restorations failure scores for each group, according to the criteria of Roeleveld *et al.*[28] appears in Fig. 3. Both groups' main failure reasons were bulk fracture and absence of restorative material (score 30), followed by secondary caries (score 21). Fig. 3 includes all the failures observed during the study, regardless of the time they occurred.

The primary outcome analysis using superiority Cox regression and ITT analysis can be found in Table 4. The ITT analysis found that the success rates after 24 months were 61.1% and 52.2% for GIC and GCR groups respectively. An absolute difference of 0.089% was found, and the superiority was not shown (relative risk (RR) = 1.17, 0.91–1.52, $P = 0.573$).

The analysis of prognostic factors to the restoration's failure is presented in Table 5. None of the variables appraised (restorative material, age of the children, caries experience, jaw and cavity volume) has influenced the survival of the restorations ($P > 0.05$). Adjusted Cox regression was not performed because only the restorative material presented

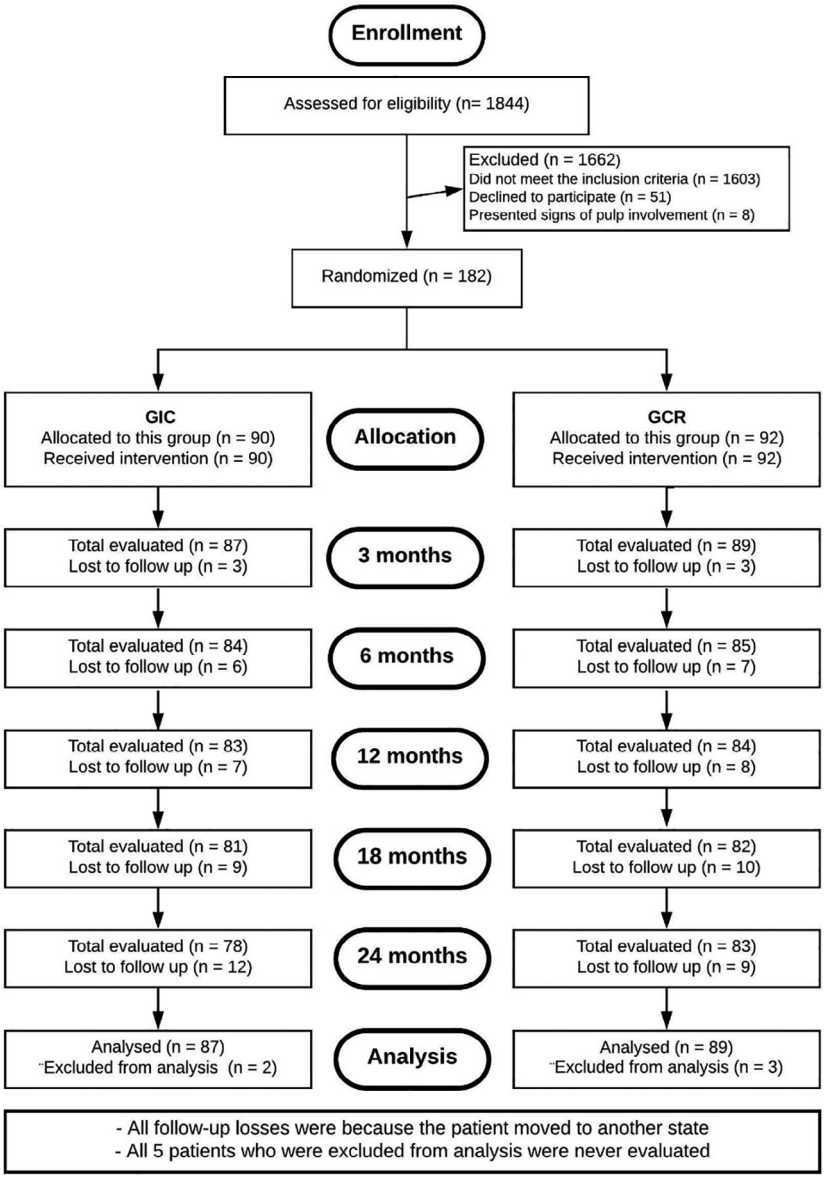


**Fig. 1** Flow diagram of the progress of the patients through the phases of this trial.

a *P value* lower than 0.2 in the univariate test. GCR performance was not superior to the GIC in occlusoproximal restorations of primary molars after 2 years.

The results of both ITT (ITT success and ITT failure) and the logistic regression analyses are shown in Table 5. When considering the dropouts at 24 months as success, GIC presented 66.3% success, whereas GCR had 55.4% successful restorations. However, when considering the dropout as failures, at least 50% of the restorations in both groups failed. Nevertheless, no difference was found between the groups and restoration success ($P > 0.05$), as also occurred in the survival analysis.

## DISCUSSION

The improved mechanical properties of resin composites over glass ionomers such as compressive strength wear-resistance[9] and the advantages that Giomer technology offered inspired us to perform this superiority trial. We also believed that the ions released from the S-PRG particle could reduce the failures related to caries around restorations. However, after 2 years, GCR performance was not superior to the GIC in occlusoproximal ART restorations of primary molars. Therefore, we must be careful about evaluating the evidence supporting Giomers, as the results are based mainly on lab studies.[18–20]

The survival rate of the GIC in this clinical trial after 2 years (58.1%) is consistent with the mean

**Table 3. Baseline distribution of variables between restorative materials and chi-square analysis**

| Variables | GIC n (%) | GCR n (%) | Total n | *P* value Chi-square |
|---|---|---|---|---|
| Age (years) | | | | |
| 4–6 | 40 (50) | 40 (50) | 80 | |
| 7–8 | 50 (49.1) | 52 (50.9) | 102 | 0.896 |
| Caries experience (DMFT/dmft) | | | | |
| ≤3 | 51 (51.5) | 48 (48.5) | 99 | |
| >3 | 39 (47) | 44 (53) | 83 | 0.543 |
| Jaw | | | | |
| Upper | 35 (50.7) | 34 (49.3) | 69 | |
| Lower | 55 (48.7) | 58 (51.3) | 113 | 0.788 |
| Molar | | | | |
| First | 62 (50.8) | 60 (49.2) | 122 | |
| Second | 28 (46.7) | 32 (53.3) | 60 | 0.598 |
| Gender | | | | |
| Female | 39 (46.43) | 45 (53.57) | 84 | |
| Male | 51 (52) | 47 (48) | 98 | 0.569 |
| Volume ($mm^3$) | | | | |
| ≤10 | 55 (50.5) | 54 (49.5) | 109 | |
| 10–20 | 20 (51.3) | 19 (48.7) | 39 | |
| >20 | 15 (44.1) | 19 (55.9) | 34 | 0.785 |
| Total | 90 (49.5) | 92 (50.5) | 182 | |

survival rate of multiple-surface restorations depicted in the systematic review used for our sample size estimation (62%).[15] As expected, the survival rates obtained for both groups in this trial are still low compared to single-surface ART survival rates after 1 year, also reported in the review (93%).[15] Evidence suggests that this high number of failures in occluso-proximal restorations are more related to the type of the cavity than the technique or restorative material itself.[13,14] Currently, stainless steel crowns have the highest success rates for restoring primary molars.[12] However, they are still not available in our country. Therefore, new clinical trials on adhesive materials are necessary to improve the survival rate in multi-surface cavities.

Initially, the ITT analysis was not planned in our study since the reassessments were made at school, so the non-attendance of participants would not be related to dental treatment. However, the ITT is generally proposed as the gold standard analysis strategy to report clinical trials because it includes non-compliant participants in the test, increasing the external validity of the results.[31,32] Therefore, an ITT analysis using multiple imputations was performed to establish the success ratio of restorations at 24 months, and Miettinen and Nurminen's method failed to demonstrate the superiority of GCR over GIC.

As seen in Fig. 3, both groups' most prevalent failure reason was a total loss or bulk fracture of the material (score 30), followed by secondary caries (score 21). This finding corroborates with a systematic review that addresses reasons for the failure of restorations in primary teeth.[12]

We chose to use a one-step self-etch adhesive and GCR restorations because the treatments were performed in a school setting, where the triple syringe and saliva suction were not available to rinse the phosphoric acid. However, studies indicate that one-step self-etch adhesives may not be suitable for use in primary teeth,[33] which may have contributed to failures in the GCR group. This is the first clinical study to use the Beautibond adhesive® on primary teeth. Only one *in vitro* study assessed the performance of Beautibond® and other self-etching adhesives for bonding to dentin of primary teeth, in which Beautibond® presented good results of microtensile bond strength to dentin of primary teeth.[34] Further studies using Beautibond need to be conducted to test its effectiveness in primary teeth.

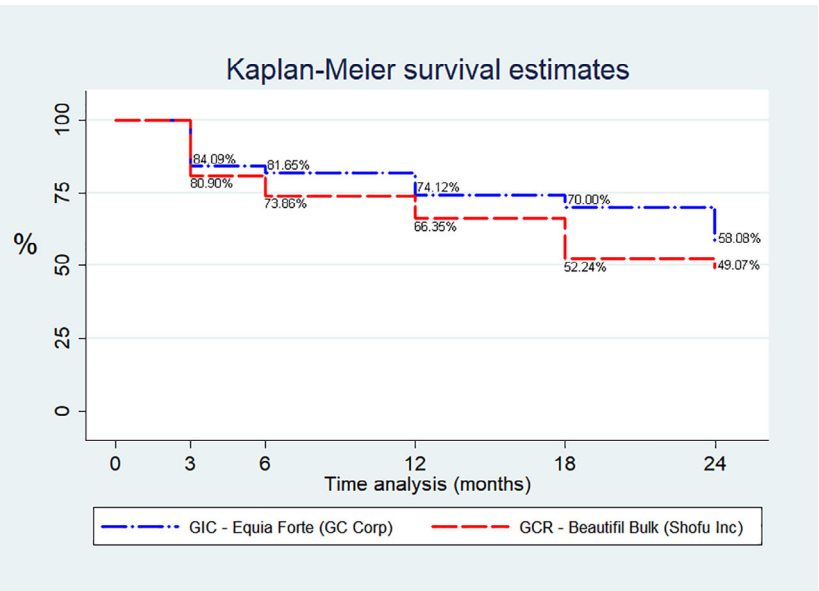


**Fig. 2** Kaplan-Meier survival estimates between groups over 24 months.

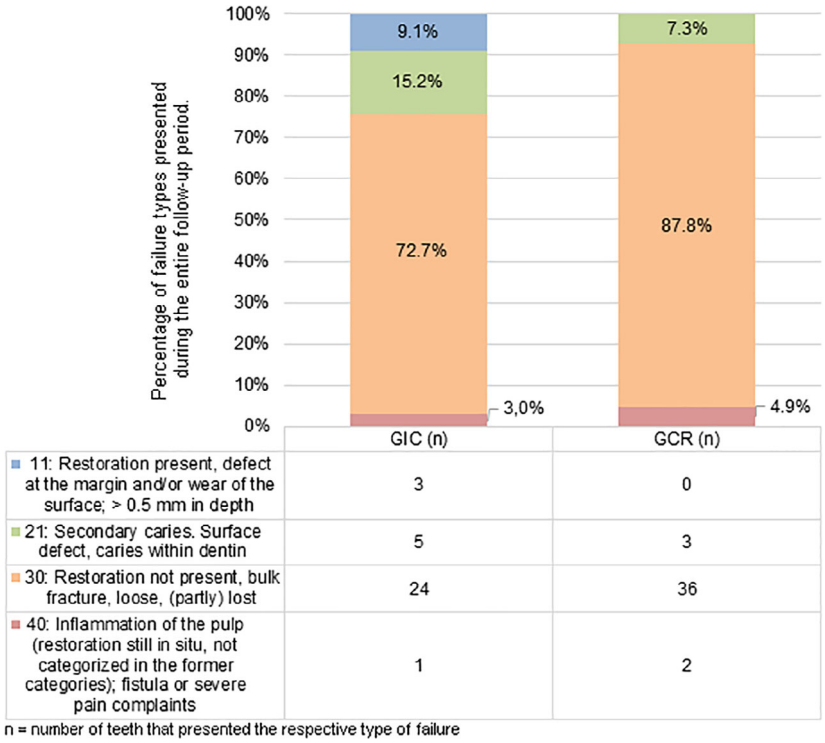


**Fig. 3** Prevalence of restoration failure scores over 24 months according to the criteria of Roleveld at al. (2006).[28]

**Table 4. Primary outcome analysis (restoration treatment survival) using superiority Cox regression and Intention-to-treat analyses**

| | GIC | GCR | *P* value |
|---|---|---|---|
| Primary outcome – Superiority Cox regression analysis* | | | |
| % Survival | 58.1% | 49.1% | 0.412 |
| HR (90% C.L. of HR) | 1.24 (0.97 to 1.59) | | |
| Primary outcome – Intention-to-treat analysis (24 months)** | | | |
| N success/N total | 55/90 | 48/92 | 0.937 |
| % Success | 61.1% | 52.2% | |
| Absolute difference (95% CI) | 0.089 (−0.05 to 0.23) | | |
| Relative Risk - RR (95% CI)** | 1.17 (0.91 to 1.52) | | 0.573 |

HR, hazard ratio; CI, confidence interval.
*100 (1−2α) % confidence interval and *P* value for superiority survival data (Wald).
***P* values and 95% CI were derived by Miettinen and Nurminen's method using superiority test for two proportions.

**Table 5. Univariate and adjusted Cox regression analysis (two-tailed) between treatment failure and prognostic factors after 24 months**

| Variable | Survival % | Failure % | SE | Univariate HR 95% CI | *P* value |
|---|---|---|---|---|---|
| Restorative material | | | | | |
| GIC (ref) | 58.1 | 41.9 | 0.06 | | |
| GCR | 49.1 | 50.9 | 0.06 | 1.35 (0.85–2.14) | 0.901 |
| Age | | | | | |
| 4–6 (ref) | 50.3 | 49.7 | 0.06 | | 0.376 |
| 7–8 | 57.1 | 42.9 | 0.06 | 0.81 (0.51–1.29) | |
| Caries experience (DMFT/dmft) | | | | | |
| ≤3 | 52.2 | 47.8 | 0.06 | | |
| >3 | 55.1 | 44.9 | 0.06 | 0.90 (0.57–1.43) | 0.671 |
| Jaw | | | | | |
| Upper (ref) | 53.6 | 46.4 | 0.07 | | |
| Lower | 53.5 | 46.5 | 0.05 | 0.96 (0.60–1.53) | 0.863 |
| Cavity volume | | | | | |
| 10 $mm^3$ (ref) | 61.2 | 38.8 | 0.05 | | |
| 10–20 $mm^3$ | 38.8 | 61.2 | 0.09 | 1.33 (0.77–2.30) | 0.312 |
| >20 $mm^3$ | 45.1 | 54.9 | 0.09 | 1.14 (0.64–2.05) | 0.653 |
| Total | 53.5 | 46.5 | 0.04 | | |

Ref = reference category; HR = Hazard ratio; CI = Confidence Interval; SE = Standard Error.

To the best of our knowledge, this clinical trial is the first to assess the performance of a bulk-fill Giomer composite as a restorative material for ART restorations for primary teeth in school settings. Bulk-fill composites have the advantage of increased depth of cure and lower polymerisation shrinkage than conventional composites, which reduces the time needed for layering and adapting restorations in posterior teeth.[21] However, an *in vitro* study assessed the degree of conversion (DC) of monomers of different bulk-fill composites and found that the Beautifil Bulk Restorative presented poor DC.[35] This might have been an additional reason for failures in the GCR group.

It is essential to mention that the limited moisture control in the school setting may have influenced GCR's performance, which can be stated as a limitation of our study. We know that resin composites are more sensitive to humidity than glass ionomers, but our purpose was to treat children using ART premises; thus, using the rubber dam isolation was not an option. This reinforces the choice of high-viscosity glass ionomer as the most suitable restorative material for the ART restorative technique.

A common problem in longitudinal studies is the loss of follow-up. Although we did not have direct contact with the caregivers of the children included in this study, the loss to follow-up of this trial was low in all assessments (Fig. 1). The access given by the Education Secretariat for tracking the students might explain the low attrition rate. With the system, even if the child moves from one school to another, we could know exactly where this child was currently enrolled. The platform's limitation is that it only works for our state, losing contact with the participant if he moved from the state. In addition to the digital system, we have the support of the schools, which have files of students and provide us with their telephone numbers and addresses if they were absent from class on assessment days. Thus, when children missed school on the days of the reevaluation, the dentist performed the assessment at their homes.

The main limitation of this study is regarding blinding. We know that blinding participants, operators, and outcome assessors is a methodological precaution recommended to minimize performance and detection bias in a clinical trial, making results more reliable.[36] However, in our trial, the participants, operator and outcome evaluator were not blinded to the groups due to the visual aspect of the restorative materials tested and different restorative protocols. When blinding is not possible due to logistical factors, it is recommended that researchers must be transparent when reporting this limitation and that the allocation groups are, apart from the intervention, treated as equally as possible,[37] as we have done.

The allocation concealment was assured through opaque sealed envelopes, opened only when the cavity was ready to receive the restorative material. To prevent allocation bias, a research member who was not present during the treatment and evaluated the restorations performed the randomisation list and envelope arrangement. Table 3 shows the uniform distribution of the baseline characteristics between groups and a chi-square test showing no difference in the collected variables. This confirms the validity of the randomisation process and allows us to consider only the plausible variables for the regression model.

Therefore, our results suggest that there is no advantage of using GCR rather than GIC for improving the longevity of occlusoproximal ART restorations in primary molars. The present study is one of the first clinical studies to evaluate the performance of a Giomer resin on primary teeth. Therefore, further studies are needed to build robust evidence on this topic. Future clinical studies should use another type of adhesive system in their investigations and compare a Giomer material with a non-Giomer composite to find out if the presence of the S-PRG particle in the material would be clinically relevant.

## CONCLUSION

After 24 months, the survival of GCR is not superior to the GIC in occlusoproximal restorations of primary molars.

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## CONFLICT OF INTEREST

None of the authors has any conflicts of interest.

## AUTHORS' CONTRIBUTION

DPR conceived the ideas, designed, coordinated the research at all phases and proofread the manuscript. ALP designed, screened, evaluated the participants and drafted the manuscript. ICO delineated, treated the patients and analysed the data. CML was involved in the procedures that ensured allocation concealment and searched for the childrens' current school on each evaluation. RCO and TKT curated and collected the data. All authors critically revised the text and approved this final version.

## ETHICAL APPROVAL

This study was approved by the Research Ethics Committee of the School of Dentistry, University of São Paulo (protocol 2.485.320). All procedures performed in this study involving human participants were in accordance with the ethical standards of the National

Commission of Ethics in Research (CONEP – Brazil) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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## SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

**Data S1.** CONSORT checklist.

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