Clinical Oral Investigations (2019) 23:3623–3635
https://doi.org/10.1007/s00784-018-2787-1

ORIGINAL ARTICLE

Randomized clinical trial of class II restoration in permanent teeth comparing ART with composite resin after 12 months

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Received: 13 September 2018 / Accepted: 18 December 2018 / Published online: 6 January 2019

Abstract

Objective This study evaluated the effectiveness of class II restorations, in permanent teeth, through the ART technique in comparison to composite resin.

Materials and methods Participants (154), aged 8 to 19 years, with good general health, with class II cavities in permanent teeth, and without pulp involvement and tooth pain were included in this parallel and randomized clinical trial. The Ethics Committee approval number was CAAE: 24012913.0.1001.5417. Seventy-seven restorations were made with each restorative material (Equia Fil-GC Corporation and Z350-3M). Evaluations occurred at 6 and 12 months by the criteria of ART and the USPHS modified. Data were analyzed by Mann-Whitney, chi-square, Fisher's exact, chi-square tests with linear trend and logistic regression by enter method ($p < 0.050$). The Kaplan-Meier test evaluated the survival rates of the restorations. The log-rank test compared the survival curves.

Results Regardless of the evaluation criteria used, the success rates of ART restorations were 98.7% (6 months) and 95.8% (12 months) and for composite resins were 100% (6 months) and 98.7% (12 months), with no statistical difference of restoration groups ($p > 0.050$). Survival rates for restorations, regardless of the evaluation criteria used, are the same as the success rates, with the exception of ART restorations at 12 months of follow-up (94.8%).

Conclusion No differences in the success rates of class II restorations of ART compared to resin composite, in permanent teeth, were observed after 12 months.

Clinic significant HVGIC can safely be used to restore proximal cavities in permanent teeth up to 12 months.

Keywords Glass ionomer cement · Composite resin · Posterior teeth · Permanent dentition · Atraumatic restorative treatment · Clinical trial

Introduction

The Minamata Treaty states that clinically effective and cost-effective mercury-free dental restorations need to be made available and promotes research and development of quality mercury-free dental materials [1]. Currently, the two main directly placed dental materials available as possible alternatives for amalgam are composite resins and glass-ionomer cements (GICs) [2].

Composite resin has excellent mechanical properties and a pleasant esthetic appearance [3, 4]. However, the material does not remineralize affected dentine, and it shows a low integrity of the restoration-tooth interface over time, which increases the changes for the development of secondary carious lesions [5]. In addition, composite resin is difficult to use in places without electricity and are

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considered technically more sensitive than dental amalgam and glass-ionomer cement [6, 7].

The GICs, in particular the high-viscosity (HVGICs), restorative type, is biocompatible, bioactive, releases fluoride, and has an excellent coefficient of linear thermal expansion and of modulus of elasticity which is similar to that of the tooth. It is the only "true" adhesive dental material because of its direct chemically bonding to dental tissues [8]. HVGICs can be used outside the dental surgery, increasing access to dental care and it is, therefore, the most suitable dental material within the Atraumatic Restorative Treatment (ART) concept.

A meta-analysis of the longevity of ART restorations concluded that the survival percentage of single-surface restorations in primary and permanent posterior teeth is high, that of multiple-surfaces in primary posterior teeth is low, and that the outcome for multiple-surface ART restorations in posterior permanent teeth is inconclusive because of the low numbers of studies available [9].

In order to increase the longevity of multiple-surface restorations of HVGIC in permanent teeth, encapsulated HVGICs have been developed. Compared to conventional HVGICs, the former showed an increase in flexural strength in multiple-surface restored cavities in a laboratory setting [10].

Another measure that may increase the longevity of multiple-surface HVGIC restorations is the creation of retention niches, near the dentin-enamel junction, using a rotating instrument in cases of conventional restorations [11] or hand instruments in case of the ART method [12].

In their systematic review, Mickenautsch and Yengopal [13] concluded that it is impossible to assert the superiority of composite resin restorations over high-viscosity glass-ionomer cement restorations in single- and multiple-surface cavities in both primary and permanent teeth. They also affirm that there is a shortage of randomized clinical trials with high internal validity to indicate the superiority of one material or another. The authors also pointed out the lack of head-to-head comparisons. The present study seeks, therefore, to improve the longevity of multiple-surface ART/HVGIC restorations by creating retention niches and using a capsulated HVGIC and therefore contribute to diminish the lack of data in this important clinical field. The results of this research will be of great value for clinicians who work in public services as well as those who work in private practice.

This study investigates the effectiveness of restorations produced through the ART method with application of proximal retention grooves in class II cavities in permanent teeth using an encapsulated HVGIC. The null-hypothesis tested is that there is no difference in the 12-month effectiveness of these ART/HVGIC multiple-surface restorations compared to conventional multiple-surface composite resin restorations.

Materials and methods

Sampling procedure

This randomized controlled clinical trial used a parallel-group design carried out in 17 public primary schools in the interior of the state of São Paulo, Brazil.

The sample size was determined using the proportional comparison formula for two-tailed test. Significance level and statistical power were adopted at 5% and 80%, respectively. The non-effectiveness proportions of the tested materials obtained from the literature were 18% for ART/HVGIC multiple-surface restorations of Ketac Molar [14] and 3% for multiple-surface composite resin restorations [15]. To compensate for the expected number of drop-outs over 36 months, the sample size was increased with 20% resulting in 77 restorations for each restorative group (http://www.lee.dante.br/esearch/amostragem/amostra.html). The experimental unit was the restored tooth and only one tooth per patient was included in the study. The inclusion criteria were the following: (1) participants in good general health and cooperatives for undergoing a dental exam, (2) a signed consent form, (3) one or two class II cavities in posterior permanent teeth without pulp involvement or toothache, (4) presence of an occluding tooth, (5) shown good oral hygiene. Exclusion criteria were the following: (a) subjects presenting mobile teeth, (b) those having more than two multiple-surface cavities in permanent teeth, having paranormal occlusion, wearing orthodontic appliance, and (c) shown poor oral hygiene.

The size of the cavity was divided into small, medium, or large (see Fig. 1 for the explanation). Included subjects were examined using the Caries Assessment Spectrum and Treatment (CAST) instrument [16] from which a mean DMFT-score was retrieved.

Cavity size and mean DMFT-score were stratified variables in the randomization process which was carried out as follows. The tooth was considered the sample unit. Given the great difficulty in obtaining the required sample size, eligible teeth were recorded in an Excel spreadsheet according to cavity size and DMFT-score. In order to have a homogeneous distribution of these two factors over the two study groups, teeth were ordered by the DMFT-score and divided into two conglomerates; one containing the lower DMFT-scores and the other the higher DMFT-scores. These two conglomerates were further divided according to smaller/larger cavity size, totalizing four conglomerates: (a) lower DMFT-scores and smaller cavity sizes, (b) lower DMFT-scores and larger cavity sizes, (c) higher DMFT-scores and smaller cavity sizes, and () higher DMFT-scores and larger cavity sizes.

Using the "random" function in Excel, teeth were drawn for each of the two study groups within each of these four conglomerates, guaranteeing total impartiality. After completion of the randomization process, statistical tests were

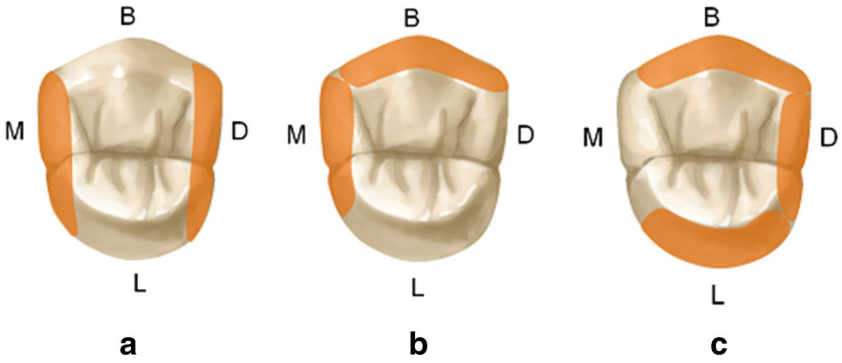

Fig. 1 Cavity size. Small: caries lesion restricted to proximal-lingual and proximal-buccal borders (**a**); medium: caries lesion involving more than proximal-lingual or proximal-buccal borders (**b**); and large: caries lesion involving more than proximal-lingual and proximal-buccal borders (**c**)

performed certifying that the two stratified variables, used in the randomization process, were equally divided between the study groups. Equality for the DMFT-score between the two study groups was tested using the *t* test and the Mann-Whitney *U* test for that of cavity size. Statistical significance was set at the 5% level.

Below is the flowchart indicated by the Consolidated Standards of Reporting Trials (CONSORT) (Fig. 2).

The present trial was approved by Human Ethics in Clinical Research Committees of the Bauru School of Dentistry and registered at the "Registro Brasileiro de Ensaios Clínicos – REBEC website under the registration number RBR-2jmbvt. The report followed the CONSORT (Consolidated Standards of Reporting Trials) and the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines.

Study subjects were presented a consent form that explained the nature of the study. Parents or legal guardians of children and adolescents/adults were requested to sign that form. Included subjects received instructions on oral health, particularly regarding oral hygiene and sugar consumption. In addition to the study restoration, all other oral health problems were taken care off.

Implementation

Training of examiners, operators, assistants, and evaluators

The training was carried out in the Clinical Research Center of the Bauru School of Dentistry, Brazil. The one operator (RMS) was trained in the application of ART method, creation of additional niches, and conventional restoration of composite resin under the supervision of two experienced dentists in ART (MFLN and JEF), through theoretical, laboratory, and clinical exercises before the start of the study.

The examiners (SRVM and RSB) and assistants were trained in the use of CAST and the annotation of the data at the Clinical Research Center of the Bauru School of Dentistry. The restoration evaluators were trained in using the ART [17] and the modified USPHS criteria [18] 1 month before each evaluation by means of theoretical and clinical training.

Examination

According to the study protocol, study participants would need to be recruited from public schools and from those attending dental services of health posts in the municipality of Bauru. Due to the enormous difficulty in finding eligible subjects, the search needed to be extended to public schools outside Bauru. This required approval by the competent local authorities. Eventually, the municipalities of Dois Córregos (80 km from Bauru) and Agudos (10 km from Bauru) were visited to complete the sample. A total of 24,000 individuals were examined to achieve the desired sample size.

The oral examination included the assessment of dental caries through the use of the CAST instrument, that of plaque through the Visible Plaque Index, and the presence of gingival bleeding through the Gingival Bleeding Index [19] as well as data on the cavity size and proximal contact and occlusion of the teeth selected for the study.

The examinations were performed with good lighting with an operating light, with those examined lying on table. The examiners were seated in the 12 o'clock position to the head of the subject and the recorders sat in the 9 o'clock position. Mouth mirrors, wooden spatulas, and the CPI (Community Periodontal Index) probe were the dental instruments used.

Treatment procedure

There was no possibility of masking the subjects from the treatment they received, as, according to protocol, all were informed about the available types of restoration.

In order to make composite resin restorations, the participants were attended at the Clinical Research Center (CRC) in Bauru, at a Private Dental Office in Dois Córregos and at the Integrated Health Center (IHC) in Agudos. The ART restorations were inserted at the municipal or state school in the three cities.

The restorative HVGIC was the encapsulated Equia system (GC Co., Tokyo, Japan), and Filtek Z350 XT Universal Restorative (3M ESPE, St. Paul, USA) was the composite resin (Table 1). Each of the clinical procedures followed a standardized protocol, detailed as follows:

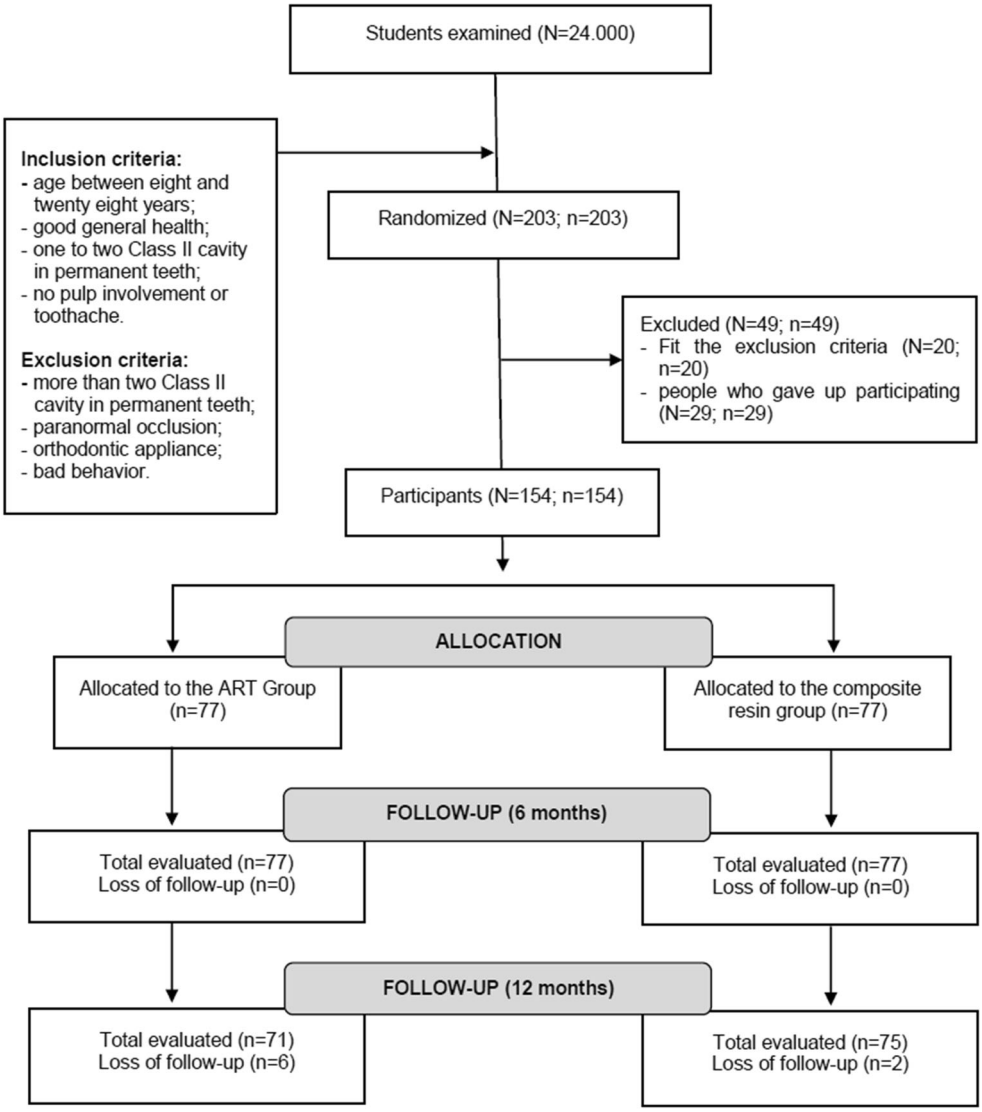

Fig. 2 CONSORT flowchart for clinical trials

N = individuals; **n** = cavities or restorations.

Note: Reasons for loss of follow-up: Participants who changed status or gave up participating in the survey.

ART/HVGIC protocol The ART guidelines as described by Frencken et al. [20] were followed. Isolation was achieved with cotton wool rolls. The cavity was opened with an ART opener and/or a dental hatchet when needed, and the soft and completely demineralized dentine was removed with hand excavators. The retentive grooves were then made using the modified 15L dentine spoon (SSWhite, Rio de Janeiro, Brazil), moving from gingival to occlusal direction, approximately 0.5 mm from the dentin-enamel junction. Then, the cavity was washed and dried with three wet and dry cotton wool pellets. The cavity was conditioned for 15 s using a cotton pellet with 20% polyacrylic acid during 15 s. The next step was the placing of a matrix band and a wooden wedge. The Equia Fil capsules (GC Corporation, Tokyo, Japan) were mechanically shaken for 10 s, placed in a syringe and squeezed empty from the bottom of the cavity until the material extended over the marginal ridge. Thereafter, digital pressure was held for 40 s creating a sealant-restoration in the occlusal surface. After initial set, excess material was removed with hand instruments. The matrix was carefully removed with buccal-lingual and occlusal movements, 5 min after the start of mixing. The occlusion was checked with carbon paper and the presence of a contact point with the neighboring tooth with dental floss. The entire surface of the restoration was cleaned and Equia Coat (GC Corporation, Tokyo, Japan) was applied followed by photo polymerization for 20 s. A drawing of the exact location of the restoration, differentiating the restoration from the adjacent sealant in the adjacent

Table 1 Materials used in the study

Material	Type	Manufacturer (batch no)	Composition
Cavity conditioner	Acid conditioner	GC Co., Tokyo, Japan (1210101)	20% polyacrylic acid
Equia Fil	Conventional glass-ionomer cement	GC Co., Tokyo, Japan (1212209)	Powder: 95% strontium fluoro-alumino-silicate glass, 5% polyacrylic acid liquid: 40% aqueous polyacrylic acid
Equia Coat	Low-viscosity nano-filled surface coating resin	GC Co., Tokyo, Japan (1210101)	50% methyl methacrylate, 0.09% camphorquinone
Phosphoric acid	Acid conditioner	FGM, Joinvile, Brasil (290515)	35% phosphoric acid
Single Bond Universal	Self-etching adhesive	3M ESPE, St. Paul, USA (565520)	Methacryloyloxydecyl dihydrogen phosphate, phosphate monomer, dimethacrylate resins, hydroxyethyl methacrylate, methacrylate-modified polyalkenoic acid copolymer, filler, ethanol, water, initiators, silane
Filtek Z350 XT Universal Restorative	Nanoparticulate composite	3M ESPE, St. Paul, USA (561946)	Organic resin: Bis-GMA/UDMA/TEGDMA, and Bis-EMA Fillers: combination of 20-nm silica fillers (non-agglomerated/non-aggregated), 4–11-nm zirconia fillers (non-agglomerated/non-aggregated), and aggregated zirconia/silica nanocluster comprised of 20-nm silica and 4–11-nm zirconia particles Filler loading (78.5 wt%), 58–60 vol%

Bis-GMA bisphenol A glycol dimethacrylate, *Bis-EMA* bisphenol A ethyl dimethacrylate, *DC* dual cured, *HEMA* hydroxyethyl methacrylate, *MDP* methacry-loxydecyl dihydrogen phosphate, *TEGDMA* Triethylene glycol dimethacrylate, *UDMA* Urethane dimethacrylate, *UEDMA* Urethane ethyl dimethacrylate

fissures was made on the clinical record. The operator gave instruction to the patient to not eat solid food for 1 h.

Conventional composite resin protocol The cavities were prepared according to the principals of minimal invasive dentistry with carbide burs no. 245 and no. 330 and spherical bur nos. 1, 2, and 3 (KG Sorensen, Cotia, Brazil) at high speed and the removal of the remaining carious dentine with spherical bur nos. 1, 2, and 3 (KG Sorensen, Cotia, Brazil) at low speed. The enamel margin in the proximal box was finished, and unsupported enamel from the preparation margins was removed using gingival marginal trimmers. Calcium hydroxide cement was applied in deep cavities, when needed, followed by the application of a resin-modified glass-ionomer cement (Vitrebond - 3M, Saint Paul, USA). For the preparation of the restorations, the recommendations of the manufacturer were followed. The enamel was etched with 35% phosphoric acid (FGM, Joinvile, Brazil) for 15 s, wash abundantly with air/water spray for 20 s, and dried with absorbent paper. Then Universal Single Bond (3M, Saint Paul, USA) was applied with a microbrush for 20 s, air sprayed gently for 5 s, and photo polymerized for 10 s. The installation of the steel matrix system and Palodent staple (TDV, Pomarode, Brazil) and wooden wedge for restoration of proximal contact and marginal crest were made. The insertion of composite resin from the Scotchbond Multipurpose and Filtek Z350 XT restorative system (3M ESPE, Saint Paul, USA) was made in oblique increments firstly in the proximal box(s), polymerization, insertion of composite resin in increments (2 mm thick) in the occlusal box and photo polymerization for 40 s with a LED light (Elipar FreeLight 2 LED light 3M ESPE, Saint Paul, USA), removal of coarse excess with scalpel blade, and occlusal adjustment with 12-blade multilayer drills FG 7803F (KG Sorensen, Cotia, Brazil) and T & F 7802 (Jet Carbide Burs, Kyoto, Japan). The finishing and polishing was performed immediately after the restorations were made with a 12 and 30-blade multilayer drills (FF9904 from Jet Carbide Burs), and for final gloss, the TDV felt discs were used together with the Poligloss paste.

The restorative procedure was timed for two periods: cleaning time: from the moment the dentist removed the instruments from the tray until he finished cavity cleaning and restoration time: from the placement of the matrix and wedge (ART) or adhesive system application (composite resin) until the instruments were returned on the tray. The need for administration of local anesthesia and the level of patient cooperation were recorded. The cooperation was measured by observing whether the patient met the operator's orders in performing the restorations such as opening and closing the mouth and tongue position

Evaluation

Photographic documentation with a Digital Canon EOS Rebel T5i 18.0 Megapixels, with EF 100MM F / 2.8 MACRO USM lens, with the aid of a photo mirror was performed before and after treatment and at the 6- and 12-month evaluation point. Masking the evaluators was not possible as they could easily differentiate the one restorative from the other.

The restorations were evaluated by SRVM and RSB using ART [17] and modified USPHS criteria, as described by Zanata et al. [18] (Tables 2 and 3, respectively). In class II

Table 2 Criteria for ART

Code	Description	Definition
1	Present, no change	Success
2	Present, slight defect at the margin and/or wear of the restoration of less than 0.5 mm; no repair is needed	Success
3	Present, marginal defect deeper than 0.5 mm. Repair is needed	Failed
4	Present, wear over larger parts of the restoration deeper than 0.5 mm. Repair is needed	Failed
5	Canes presence at the restoration margin. Repair is needed	Failed
6	Partially present, restoration and/or tooth breakdown. Repair is needed	Failed
7	Not present, restoration has completely disappeared. Treatment is needed	Failed
8	Not present, other restorative treatment has been performed	Excluded
9	Not present, tooth has been extracted	Excluded
10	Sensitivity or pulpal involvement	Failed

restorations, the width and depth of marginal defects, superficial wear, and excess or lack of material were measured with the aid of the CPI (Community Periodontal Index) or ballpoint periodontal probe.

At each evaluation point, subjects were guided in oral hygiene and received new brushing kits. The complementary treatments were offered to the participants.

In this study, which is part of a multicenter and international study, all the coordinators participated from the elaboration of the research protocol, the training of the CAST instrument, and calibration of the evaluators according to the ART and the modified USPHS criteria. Each center coordinator trained their operators, assistants, and evaluators. In addition, the training and calibration of the assessors of this study showed

Table 3 Modified USPHS criteria

Criterion	Code	Description	Definition
Color	Alpha (A)	The restoration appears to match the shade and translucency of adjacent tooth structure	Ideal success
	Bravo (B)	The restoration does not match the shade and translucency of adjacent tooth structure, but the mismatch is within the normal range of tooth shades	Satisfactory success
	Charlie (C)	The restoration does not match the shade and translucency of adjacent tooth structure, and the mismatch is outside the normal range of tooth shades and translucency	Unsatisfactory fail
Marginal discoloration	Alpha (A)	There is no visual evidence of marginal discoloration different from the color of the restorative material and from the color of the adjacent tooth structure	Ideal success
	Bravo (B)	There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration that has not penetrated along the restoration in a pulpal direction	Satisfactory success
	Charlie (C)	There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration, and the discoloration has penetrated along the restoration in a pulpal direction	Unsatisfactory fail
Relapse of caries	Alpha (A)	The restoration is a continuation of existing anatomic form adjacent to the restoration	Ideal success
	Charlie (C)	There is visual evidence of dark, deep discoloration adjacent to the restoration	Unsatisfactory fail
Anatomical shape	Alpha (A)	Restoration maintains continuity with dental surface	Ideal success
	Bravo (B)	Presence of sub-contour without dentin exposure	Satisfactory success
	Charlie (C)	Loss of material exposing dentin	Unsatisfactory fail
Marginal integrity	Alpha (A)	The explorer does not catch when drawn across the surface of the restoration toward tooth surface	Ideal success
	Bravo (B)	Visual evidence of crevice or discontinuity without exposure of dentin	Satisfactory success
	Charlie(C)	Evidence of crevice with dentin exposure	Unsatisfactory fail
	Delta (D)	Fracture or loss of restoration	Unsatisfactory fail
Surface texture	Alpha (A)	Texture similar to enamel, visually checked or by use of explorer	Ideal success
	Bravo (B)	Rough surface	Satisfactory success
	Charlie (C)	Surface rough enough to prevent sliding of the explorer, presence of cracks, bubbles	Unsatisfactory fail
		Absence of tooth or substitution by other treatment	Unsatisfactory fail

an excellent level of agreement represented by inter and intra-examiner Kappa higher than 0.80.

Statistical analysis

The results were analyzed using SPSS software (Statistical Package for Social Sciences, IBM Inc., USA), version 23.0.

To verify the association between restoration type and cavity size, sex, occlusion, proximal contact, dental group, anesthesia, and patient cooperation; the chi-square, Fisher's exact test, and chi-square test were used, where relevant ($p < 0.050$).

The association between restoration type and CPOD, plaque index, bleeding index, cleaning time, restoration time, and age were analyzed using the Mann-Whitney test ($p < 0.050$).

In order to analyze the distribution of the scores according to the ART and the modified USPHS criteria, as well as the percentage of success and failure for ART and composite resin restorations, the chi-square test, Fisher's exact, and chi-linear trend were used when relevant ($p < 0.050$).

The Kaplan-Meier test evaluated the survival percentages of the restorations in relation to the ART and modified USPHS criteria. The log-rank test compared the survival curves.

Results

Disposition of subjects

A total of 154 participants were selected from 19 municipal schools in the cities of Bauru, Dois Córregos, and Agudos from ages 8 to 19 years old.

Restoration type and independent variables

A statistically significant association was found between restorations for cavity size ($p = 0.029$), gender ($p = 0.041$), and use of anesthesia ($p < 0.001$) (Table 4).

No statistically significant difference was found between restorations with respect to DMFT, Visible Plaque Index (VPI), and Gingival Bleeding Index (GBI) ($p > 0.050$). A statistically significant difference was found between restorations and cavity cleaning time ($p < 0.001$) and restoration time ($p < 0.001$) (Table 5).

ART and modified USPHS criteria

According to ART criterion, success rates for ART restorations are 98.7% (6 months) and 95.8% (12 months), and for composite resin restorations success rates are 100% (6 months) and 98.7% (12 months). There was a statistically significant association between the restorations in the period of 6 and 12 months ($p = 0.033$, $p = 0.033$) (Table 6).

According to the modified USPHS criterion, success rates for ART restorations are 98.7% (6 months) and 95.8% (12 months), and for composite resin restorations, success rates are 100% (6 months) and 98.7% (12 months). There was a statistically significant differences between ART and composite restorations only at the 6-month evaluation ($p = 0.001$). However, this difference is not present after 12 months ($p = 0.310$) (Table 7).

At the 6-month evaluation, there was a statistically significant differences between ART and composite restorations and the following criteria are color ($p < 0.001$), anatomical shape ($p < 0.001$), and surface texture ($p < 0.001$). After 12 months, there was a significant association between the restorations and the anatomical criteria ($p < 0.001$) and superficial texture ($p < 0.001$) (Table 8).

The variables gender, location, age, DMF, VPI, GBI, toothache, occlusion, proximal contact, cavity size, anesthesia, and cooperation did not show statistical association with success rates of restorations of ART and composite resin after 12 months ($p > 0.05$).

Regardless of the evaluation criteria used, survival rates of ART restorations were 98.7% (6 months) and 94.8% (12 months), and for composite resins were 100% (6 months) and 98.7% (12 months). The mean survival time of ART restorations was 11.92 (0.08) months, and for composite resin restorations were 12 (0.00) months. There was no significant difference in the survival curves of restorations of ART and composite resin after 12 months ($p = 0.173$) (Fig. 3).

Discussion

One of the greatest concerns of both researchers and clinicians today is the indication of ART on multiple surfaces in permanent teeth. With the search for more effective restorative materials that require a minimally invasive technique, comparative studies using glass ionomer cement (GIC) and composite resin are necessary [21]. Besides that, given the very low quality of the evidence from studies on the subject, there is uncertainty about the restoration failure of ART compared with conventional treatment using composite [22].

Although Molina et al. [23] performed the only study comparing GIC through the ART technique with conventional composite resin restorations, for up to 3 years [24], the focus of the study was the care of patients with special needs. Thus, the literature still lacks randomized clinical trials with direct comparisons of these materials, which is the contribution of the present study.

The GIC of choice in this research was Equia Fil (GC Corporation, Japan), which in addition to bringing the advantages of an encapsulated GIC with the correct powder/liquid ratio, has superior physicochemical properties in laboratory studies and satisfactory results in studies [10].

Table 4 Association between restoration type and cavity size, sex, occlusion, proximal contact, dental group, anesthesia, and patient cooperation

Independent variables		ART *n* (%)	Composite resin *n* (%)	*p*
Cavity size	Small	45 (58.4)	61 (79.2)	0.029*
	Medium	23 (29.9)	12 (15.6)	
	Large	9 (11.7)	4 (5.2)	
Sex	Male	51 (66.2)	38 (49.4)	0.041
	Female	26 (33.8)	39 (50.6)	
Occlusion	No	2 (2.6)	0 (0.0)	0.152
	Yes	75 (97.4)	77 (100.0)	
Proximal contact	No	31 (40.3)	35 (45.5)	0.515
	Yes	46 (59.7)	42 (54.5)	
Dental group	Pre-molar	14 (18.2)	11 (14.3)	0.641
	Molar	63 (81.8)	66 (85.7)	
Anesthesia	No	71 (92.2)	0 (0.0)	< 0.001
	Yes	6 (7.8)	77 (100.0)	
Cooperation	No	5 (6.5)	10 (13.0)	0.183
	Yes	72 (93.5)	67 (87.0)	

*Chi-square test with linear trend

ART atraumatic restorative treatment

The composite resin chosen for the conventional restorations was the nanoparticulate Filtek Z350 XT (3M ESPE, Saint Paul, USA). An advantage of these resins would be the ability of mechanical resistance similar to the microhybrid composite resins reconciled to the high polishing advantage of microparticle composite resins [25]. Associated with the Filtek Z350 XT, the Single Bond Universal adhesive (3M ESPE, Saint Paul, USA) was chosen for its easy application in both wet and dry dentin. Its unique chemistry allows the rehydration of the collagen fibers and the formation of a hybrid layer even with the resected dentin, in addition to a lower postoperative sensitivity [26].

Standardization is a guiding principle of clinical trials with the aim of evaluating all participants in the same way, throughout the research. To this end, training, calibration, and certification of assessors, as performed in this study, are necessary throughout the process in order to correct possible errors in advance and ensure the highest quality data collection. Oral hygiene, protocol for contacting participants, and reporting and filling out specific forms should also be standardized [27–29]. In all the schools where the participants came from were given guidelines in oral hygiene and distribution of oral hygiene kits to students. In all, the information about caries prevention and periodontal disease and new distribution of oral hygiene kits were reinforced. Certainly, this was an important factor for the success of the restorations in this study.

According to the last large epidemiological survey carried out in Brazil, the need to restore two or more surfaces in posterior teeth at 12 years was 0.9% for the Southeast region and 1.2% for the country. From 15 to 19 years, this need was 1% for the Southeast region and 1.5% for the country [30]. This justifies the extreme difficulty encountered by the team in obtaining the desired sampling, being necessary to screen 24,000 subjects.

The dropout rate in this study was 5.19% after 12 months. All efforts were made to evaluate the restorations of the participants through an active search. The team worked very hard to find some of the participants who moved to farms or cities located far away from the original addresses. Fortunately, the evaluators were able to locate all study participants in the follow-ups, even those who changed their addresses, but

Table 5 Association between restoration type and DMFT, visible plaque index, gingival bleeding index, cleaning time, restoration time, and age

Independent variables	ART mean (SD)	Composite resin mean (SD)	*p**
DMFT	4.84 (3.51)	4.61 (3.40)	0.595
Visible plaque index	7.68 (9.81)	6.48 (9.00)	0.494
Gingival bleeding index	4.00 (6.10)	3.87 (5.47)	0.917
Cleaning time	957.77 (420.39)	1311.80 (367.80)	< 0.001
Restoration time	950.54 (133.53)	1297.59 (317.45)	< 0.001
Age	11.63 (2.96)	12.02 (3.37)	0.619

*Mann-Whitney test

ART atraumatic restorative treatment; *DMF* count of decayed (D), missing (M), and filled (F) teeth

Table 6 Distribution of the scores according to the ART criteria for composite resin restorations and ART

Criteria ART*	6 months			12 months		
	ART *n* (%)	Composite resin *n* (%)	*p***	ART *n* (%)	Composite resin *n* (%)	*p***
(1) Restoration present and correct	65 (84.4)	74 (96.1)	0.033	56 (78.9)	73 (97.4)	0.003
(2) Small marginal defect and/or wear with less than 0.5 mm; without need of repair	11 (14.3)	3 (3.9)		12 (16.9)	1 (1.3)	
(3) Marginal defect exceeding 0.5 mm. Need of repair	–	–		1 (1.4)	0 (0.0)	
(4) Wear exceeding 0.5 mm. Need of repair	–	–		1 (1.4)	0 (0.0)	
(6) Restore and/or fracture tooth. Need of repair	1 (1.3)	0 (0.0)		1 (1.4)	1 (1.3)	

*Scores 1 and 2 = success; 3, 4, and 6 = failure

**Chi-square test with linear trend

ART atraumatic restorative treatment; *n* = sample size

who remained in the state of São Paulo. Loss of follow-up in this study was due to moving to other states or quit to participate.

In the descriptive analysis, a statistically significant association was found for cavity size, gender, and anesthesia (Table 4).

As most of the cavities were classified as small, both for ART restorations and for composite resin restorations, there was a statistically significant association. In addition to the difficulty of obtaining the sample, even with the randomization of the cavities selected for the study, many children who were drawn to the composite resin group gave up the research.

No doubt ART has the ability to be more comfortable for patients, since noise and vibrations related to the rotating apparatus are absent. This "atraumatic" effect is further reinforced by the fact that local anesthesia is rarely needed in the approach of the technique [31–33].

The statistical difference observed for anesthesia was expected, since ART restorations do not use anesthesia, unless it is more comfortable for the patient [34].

No statistically significant difference was found between restorations and DMFT, Visible Plaque Index (VPI) and Gingival Bleeding Index (GBI), which characterizes sample uniformity (Table 5).

Although the VPI and GBI were not used in the sample stratification, the restorations were homogeneous regarding these characteristics that could influence their performance [35, 36].

A statistically significant difference was found between restorations and cavity cleaning time and restoration time (Table 5). This was expected, since one of the advantages of the ART technique is the reduction of the office time [34, 37–39].

Taking into account success and failure of the restorations, according to ART criteria, there was a statistically significant association between the restorations in the 6- and 12-month period (Table 6). According to the modified USPHS criteria, there was a statistically significant association between the restorations only in the 6-month evaluation (Table 7). This difference occurred due to a greater variability in the distribution of the restorations by the ART criterion scores compared to the distribution of the same restorations by the modified USPHS criteria scores. The success rates over time for composite resin restorations were 100% (6 months) and 98.7% (12 months) for both restorations rating criteria. For ART restorations, using the two evaluation criteria, the success rates were the same for 6 months (98.7%) and 12 months (95.8%).

Table 7 Percentage of success and failure of ART restorations and composite resin according to the modified USPHS criteria

USPHS criteria*	6 months			12 months		
	ART *n* (%)	Composite resin *n* (%)	*p***	ART *n* (%)	Composite resin *n* (%)	*p***
Ideal	25 (32.5)	47 (61.0)	0.001	27 (38.0)	36 (48.0)	0.310
Satisfactory	51 (66.2)	30 (39.0)		41 (57.8)	38 (50.7)	
Unsatisfactory	1 (1.3)	0 (0.0)		3 (4.2)	1 (1.3)	

*The ideal and satisfactory scores = success; unsatisfactory = fail

**Chi-square test with linear trend

ART, atraumatic restorative treatment; *n*, sample size; *USPHS*, United States Public Health System (public health service of the USA)

Table 8 Distribution of scores according to the modified USPHS criteria for ART restorations and composite resin

Criteria	Score	6 months			12 months		
		ART *n* (%)	Composite resin *n* (%)	*p*	ART *n* (%)	Composite resin *n* (%)	*p*
Color	Alpha	33 (43.4)	55 (71.4)	< 0.001	32 (45.0)	38 (51.4)	0.609
	Bravo	43 (56.6)	22 (28.6)		39 (55.0)	36 (48.6)	
Marginal discoloration	Alpha	75 (98.7)	74 (96.1)	0.315	65 (91.5)	70 (94.6)	0.785
	Bravo	1 (1.3)	3 (3.9)		6 (8.5)	4 (5.4)	
Relapse of caries	Alpha	76 (100.0)	77 (100.0)	–	69 (97.2)	74 (100.0)	0.235
	Charlie	0 (0.0)	0 (0.0)		2 (2.8)	0 (0.0)	
Anatomical shape	Alpha	43 (56.6)	70 (90.9)	< 0.001*	45 (63.4)	66 (89.2)	< 0.001 *
	Bravo	33 (43.4)	7 (9.1)		23 (32.4)	8 (10.8)	
	Charlie	0 (0.0)	0 (0.0)		3 (4.2)	0 (0.0)	
Marginal integrity	Alpha	70 (90.9)	72 (93.5)	0.471*	56 (78.9)	69 (92.0)	0.072*
	Bravo	6 (7.8)	5 (6.5)		12 (16.9)	5 (6.7)	
	Charlie	0 (0.0)	0 (0.0)		2 (2.8)	0 (0.0)	
	Delta	1 (1.3)	0 (0.0)		1 (1.4)	1 (1.3)	
Surface texture	Alpha	42 (55.3)	63 (81.8)	< 0.001	32 (45.1)	56 (75.7)	< 0.001
	Bravo	34 (44.7)	14 (18.2)		39 (54.9)	18 (24.3)	

*Chi-square test with linear trend

ART, atraumatic restorative treatment; *n*, sample size

The ART criterion is used in most studies evaluating ART restorations, while the USPHS criterion is used to assess the longevity of restorations in general [40, 41].

We consider interesting to use the modified USPHS criterion in this study since this criterion can evaluate marginal discoloration, color, and surface texture, which are not taken into account in the ART criterion [42].

At the 6-month evaluation, there was a statistically significant differences between ART and composite restorations and color, anatomical shape and surface texture criteria. After 12 months, there was a significant association between restorations and anatomical shape and surface texture criteria (Table 8). The difference found in the color of the restorations disappeared with the time of follow-up, remaining satisfactory

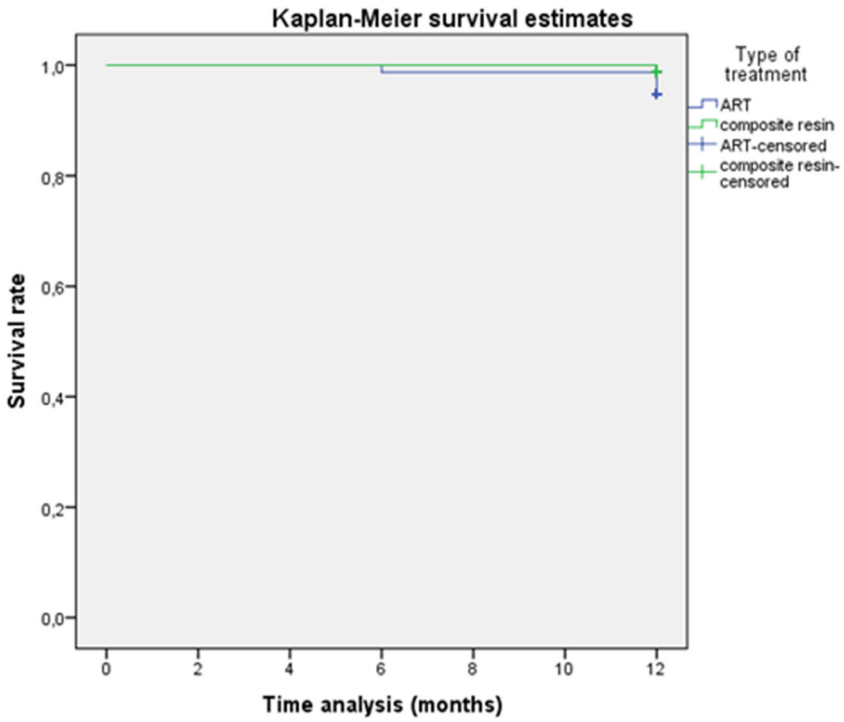

Fig. 3 Survival curves for restorations of ART and composite resin ($p = 0.173$)

since the first evaluation. This was probably due to the excellent quality of the high viscosity GIC used in this study. Although there were differences between the restorations and their anatomical forms and superficial textures, during the 12 months of follow-up, they did not compromise the quality of the restorations. The anatomical shape of ART restorations would be a disadvantage over composite resin restorations, since this anatomy is achieved by digital pressure. In addition to the composite resin being nanoparticulated, which guarantees a high surface smoothness, the polishing of the restorations carried out after their preparation also contributes to a smoother surface texture.

Although the independent variables do not present a statistically significant association with the success rates of the restorations, some important considerations are necessary.

Gingival inflammation has a negative impact on the quality of class II restorations, as it may result in contamination, especially during the placement of the metal matrix, which is a mechanical stimulus that can cause bleeding if the area is inflamed [35, 36]. For this reason, orientation in oral hygiene is of fundamental importance before beginning the placement of the restorations [43].

Although GICs are excellent biocompatible materials that release fluoride and biomimetics, their physical strength may not be sufficient enough to reliably restore large areas exposed to stress [44]. Thus, to ensure excellent success rates, ART restorations should ideally be restricted to relatively small cavities surrounded by sufficient dental structure and self-retentive [32]. This fact was evidenced by the excellent success rates of this study in which most of the cavities were considered small and medium, and were associated with the technique of making additional retentions in the proximal boxes.

This study showed that the ART technique, when executed in the correct way, associated with a material of excellent quality, can produce optimum results. In addition, the presence of a trained assistant during clinical procedures may have contributed to success rates, since the dentist could spend more time controlling the saliva after conditioning, while the assistant manipulates the restorative material [37, 40, 44, 45].

Despite the studies showing that absolute isolation favors the restorative success of ART [35, 36], in the present work even with relative isolation, the authors achieved high success rates. It is also important to highlight that the use of absolute isolation can lead to greater discomfort of the patient, since it may require the use of anesthesia and may compromise patient collaboration.

The results of the survival analysis when compared with those of restorative success rates are the same, except for the 12-month period for ART restorations, for both criteria. Although there was no statistically significant difference, the success rate of ART restoration was 95.8%, the survival rate was 94.8%. Thus, survival analyses underestimate the actual effectiveness of the restorations in non-inferiority studies, which could be better evidenced in longer follow-up periods.

The Atraumatic Restorative Treatment (ART) has been gaining a lot of space in modern dentistry due to several aspects: minimally invasive technique, with greater preservation of healthy dental structures; restoration with high viscosity GIC is considered the most biomimetic material in current dentistry; reduction in the number of pulp exposures; less stress and anxiety of the patient, since it rarely causes pain, not requiring anesthesia; as well as being an economical and efficient method for the prevention and control of carious lesions, since it presents high resolution, with shorter office time [21, 37, 38, 46]. It is considered, therefore, as a solid strategy based on health promotion and prevention of caries disease, allowing a great population reach in public health [47].

This 12-month follow-up study evidenced restorative success of ART similar to that of composite resin, but it needs to be monitored for a longer period to evidence the longevity of this restorative technique.

Funding The work was supported by the São Paulo Research Foundation (FAPESP, grant 2014/01626–3).

Compliance with ethical standards

Conflict of interest The authors declare that have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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