Randomised clinical trial of Class II ART restoration in primary teeth with and without retentive grooves after 12 months

E. Pesaressi[1], D. Zelada-Lopez[1], T. Cosme[1], J. Diaz[1], M. Huanqui[1], M. Fidela de Lima Navarro[2], R.S. Villena[1]

[1]*Department of Paediatric Dentistry, School of Dentistry, San Martin de Porres University, Lima, Peru.*
[2]*Department of Dental Materials, Endodontics and Operative Dentistry, Bauru School of Dentistry, Bauru, Brazil.*

DOI 10.23804/ejpd.2023.1968

Email: epesaressit@usmp.pe

Abstract

Aim The aim of the study was to evaluate the survival of Class II ART (Atraumatic Restorative Treatment) restorations in primary molars using encapsulated glass ionomer in cavities with and without retentive grooves. A total of 293 Class II restorations were performed on primary molars by three trained operators, using ART hand instruments (SS White/Duflex, Rio de Janeiro, Brazil) and restored with EQUIA Fil (GC Corporation, Tokyo, Japan). One hundred eighty-seven children aged 3 to 7 years (mean age = 5.5) from two public schools located in Lima, Peru, were included in the study. The restorations were performed following the ART protocol, randomising the presence or absence of proximal retentions. Cavity cleaning and restoration times were recorded by the assistant using a digital chronometer. After 6 and 12 months, evaluations occurred following the ART criteria. Data were analysed using the Mann-Whitney, Chi-square and Fisher's exact tests, Kaplan-Meier survival and logarithmic range. The mean dmf-s of the participants was 21.6 (S.D. = 10.2). The mean times to clean the cavity and apply the restorative material were 5.4 and 6.6 minutes, respectively. Success rates after 6 and 12 months for restorations without retentive grooves were 90.3% and 77.2%, respectively; and with retentive grooves 95.9% and 91.8%, respectively. Statistically significant differences were found at the 12-month follow-up ($p = 0.001$). The proximal retentive grooves increased the survival rate of ART Class II restorations in primary teeth after 12 months of follow-up.

KEYWORDS Dental caries, Glass ionomer cements, Paediatric dentistry, Atraumatic restorative treatment.

Introduction

Untreated dental caries in primary teeth is a public health issue worldwide and has been ranked 10th among the most prevalent diseases from 291 conditions affecting humankind [Kassebaum et al.,2015]. A modern management of cavitated lesions has been subject of a consensus that promotes the inactivation and control of the disease, by instilling healthy habits (hygiene and diet) and postponing invasive procedures in order to delay the repetitive restorative cycle [Banerjee et al., 2017]. Similarly, Minimal Intervention Dentistry for caries management prioritise the selective carious tissue removal of soft dentin from the peripheral substrate on which a restorative material can bond (ideally to enamel) to guarantee the preservation of the dentin-pulp complex health [Schwendicke et al., 2016]. This rationale aims to find restorative alternatives with better long-term survival, averting future costs related to re-interventions or more invasive options. This is especially relevant for countries with limited resources, acknowledging that untreated caries in severe stages is considered the fourth most expensive health condition to treat [Yee et al., 2002].

One of the most documented minimal intervention strategies has been the Atraumatic Restorative Treatment (ART), an approach that incorporates three pillars: preventive, therapeutical and restorative. The ART has evolved, from the initially proposed 'minimal intervention approach' in the mid-1980s, promoting the use of hand instruments together with an adhesive restorative material [Frencken et al., 1996]. ART aims to prevent the onset of dental caries lesions by sealing prone pits and fissures, impede the progression of early lesions with sealants/restorations and restoring cavitated lesions, preserving the structures with remineralization potential. Originally recommended for patients from underserved communities, ART is currently used around the world in both private clinics and public health settings, together with high-viscosity glass ionomer cement (HVGIC) as the most frequently reported restorative material associated to the technique [Frencken et al., 2017]. HVGIC is a bioactive material, releases fluoride during the first hours and has a similar thermal expansion coefficient and elastic modulus to dentine [Menezes-Silva et al., 2019]. Additionally, it develops chemical bonds with enamel forming links between calcium and carboxylic radicals from the HVGIC, together with molecular rearrangements resulting from the chemical interaction with the dentine substrate [Sidhu and Nicholson, 2016]. Since the HVGIC can be hand-mixed, it has been proposed to be used both in- and outside the dental clinic, turning it into a material of choice for outreach dental work. A

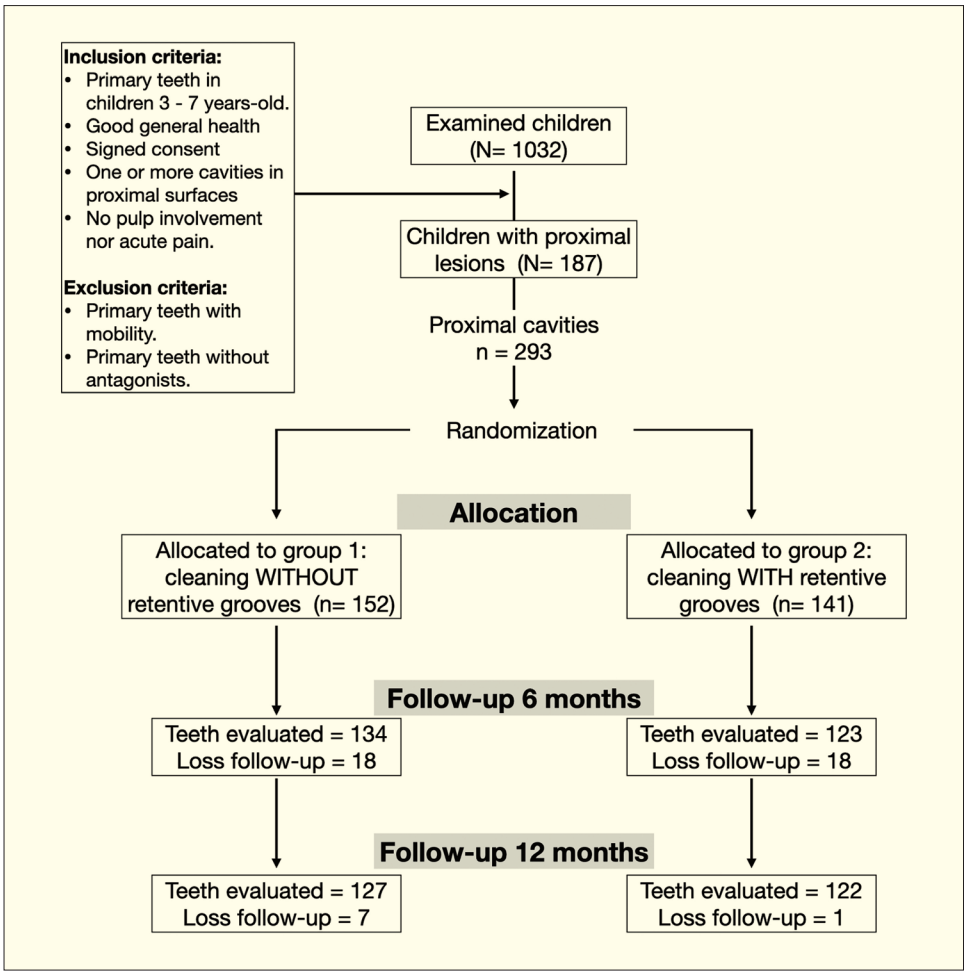

FIG. 1 CONSORT flowchart for clinical trials. N= number of children examined, n = number of proximal lesions included in the study. Drop-out was consequence of children moving to other city or school from the one they were examined and treated.

meta-analysis reported survival rates for ART restorations above 90% for Class I restorations in primary teeth, but a 65.4% survival for multiple surfaces restorations, after 2 years [de Amorim et al., 2019]. The deficiencies of multi-surface ART restorations have been attributed to limited mechanical properties from the material, operator factors, the size of the proximal cavity, working with an assistant, contact with a neighboring proximal HVGIC restoration or due to the patient's dietary habits [Hickel et al., 2005; Da Franca et al., 2016; Basso et al., 2015; Scholtanus and Huysmans, 2007]. The development of HVGIC on encapsulated version have shown improved mechanical properties [Molina et al., 2013]. One possible explanation relies on variability eradication during mixing, shorter time to obtain a viable mix together with the practicality of applying the material with a tip directly into the cavity. A proposed strategy that might increase the survival of multi-surface restorations is attributed to the creation of retentive grooves close to the enamel-dentine junction (EDJ), using rotary or hand instruments [Barata et al., 2008; Fernandes et al., 2019]. Using customised hand instruments to create additional vestibular and lingual retentions on proximal walls of class II cavities, showed in laboratory studies significantly increase in fracture resistance of HVGIC restorations. These findings need to be validated by randomised clinical trials. The aim of the present study was to evaluate the survival rates of ART Class II restorations performed in a public school in a suburban area of Lima -Peru, using an encapsulated high-viscosity glass ionomer system, with and without proximal retentive grooves after 6- and 12-month follow-ups.

Materials and Methods

Study design and sampling

The protocol of this longitudinal multi-center randomised clinical trial was jointly developed by the Bauru School of Dentistry - Sao Paulo University (Brazil), the University of Brasilia (Brazil), the University of Cordova (Argentina) and the San Martin de Porres University (Peru). The study established in Lima was carried out in two public schools located on suburban area of the city, close to the San Martin de Porres University Dental Clinic. The project followed the guidelines of the declaration of Helsinki (Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects) and was approved by the Ethics Committee from the Dental School - San Martin de Porres University. Sample size was determined using the proportional comparison formula for a two-tailed test. The level of significance was calculated at 5% and power at 80%. The non-effectiveness ratio of the evaluated material was 18% for multi-surface ART restorations using HVGIC [Cefaly et al., 2013]. To compensate for the expected loss rate during the projected follow-up period (36-months), the sample size increased by 30% resulting in 147 restorations per arm. The experimental analysis unit was the treated tooth, and each child could receive more than one restoration randomizing the type of cavity preparation to be performed. The cavity size and the caries experience (dmft/DMFT) were the stratification variables, in that order. The teeth were ordered in an Excel spreadsheet initially by the caries index and divided into two conglomerates,

the first with the lowest DMFT values and the second with the highest values. After this division, in each of these clusters the teeth were ordered by the size of the cavity and then each of these halves was divided into two parts, totaling four clusters namely: (a) lower dmf-t/DMFT-scores and smaller cavity size, (b) lower dmf-t/DMFT-scores and larger cavity size, (c) higher DMFT-scores and smaller cavity size and higher dmf-t/DMFT-scores and larger cavity size. After this division into four quarters, using the Excel random function, an experienced statistician divided the teeth drawn for each of the two experimental groups within each of these four quarters, ensuring total impartiality in the process of randomisation and allocation of units' samples (Group 1 without retention and Group 2 with retention) as shown by the flow chart following the CONSORT standards (Figure 1). Statistical tests were carried out to certify that the factors used in the randomisation were equally divided between the experimental groups, performing a t test for independent samples in the comparison between the caries index of the two experimental groups and a test Mann-Whitney U test to compare the cavity sizes of the two groups. For both cases, the p value could not be less than 5%, which would guarantee similarity between the groups in the baseline. The inclusion criteria were: (1) primary teeth in children aged 3 to 7 years; (2) children in good general health and cooperating during the diagnostic phase; (3) consent form signed by parents to participate in the study; (4) primary teeth with caries lesions in one or two proximal surfaces; (5) teeth without pulp involvement or acute symptoms. Exclusion criteria were: (1) primary teeth with mobility; (2) teeth without antagonists. The present manuscript is reporting the interim results after 6- and 12-months follow-ups, as the outcomes observed in this period was considered relevant for the clinicians.

Training

Three operators (RV, DZ and JD) received training from a gold-standard trainer (MFLN) for the handling of ART instruments (SSWhite / Duflex; Rio de Janeiro, Brazil) and for the preparation of retentive grooves, as well as the management of the restorative encapsulated glass ionomer (EQUIA fil - GC Corporation, Tokyo, Japan). The operators had previously been trained and calibrated in the use of the CAST (Caries Assessment Spectrum and Treatment) by the author of the tool (JEF) [Mobarak et al., 2019]. Two independent examiners (EP and MH) also received training in the ART approach and evaluation criteria to determine the treatment status after 6 and 12 months using numerical values from 1 to 10.

Examination

A total of 1,032 schoolchildren aged 3 to 7 years were examined to reach the estimated sample size. The intra-oral examination included the visible plaque with the Visible Plaque Index, bleeding, the dental caries lesions with the CAST tool and the cavity size registration [Frencken et al., 2013; Ainamo and Bay, 1975]. The evaluations were carried out under artificial light (front-light LED Energizer - USA), with the child lying on a stretcher. The examiners were positioned at the 12 o'clock position at the level of the patient's head and the scorer at the 9 o'clock position. Mouth mirrors, wooden spatulas and a CPI (Community Periodontal Index) probe were used for the procedure. After registering the visible plaque and bleeding from surrounding soft tissues, children's teeth were brushed with a fluoride toothpaste and flossed to conduct the caries lesions detection and registration.

Treatment procedure

The treatment was carried out in an available school classroom with the patient lying on a specially equipped table, the operator worked with all the biosecurity measures and under artificial light (front-light), with the support of an assistant for material handling. It was not possible to mask the type of treatment that each child would receive from the operator, but they were masked for the patient and for the examiners during the follow-up controls after 6 and 12 months. The materials were handled following the manufacturer's recommendations (Table 1). The baseline caries status was registered in a clinical chart together with the oral hygiene index, the size of the cavity and cleaning/restoration time. Time was controlled by the assistant using a digital chronometer from the moment the operator touches the hand instruments until the wash/dry of the cavity with cotton pellets, after carious tissue removal was done (cavity cleaning time) and from the acid conditioning of the cavity to the end of light-curing of the coat after bite control (restoration time). To perform the treatments, the guidelines described in the ART manual were followed [Frencken et al, 1996]. The cavities were enlarged, when necessary, using an ART opener instrument and / or an ART hatchet (SSWhite / Duflex; Rio de Janeiro, Brazil), the decomposed dentin was removed using manual excavators. The cavity size was divided into small, medium, and large (Figure 2). Proximal retentions for randomised teeth in group 2 were created using the 15L dentin excavator (SSWhite / Duflex; Rio de Janeiro, Brazil), manipulating it from gingival to occlusal about 0.5 mm from the enamel-dentine junction (Figure 3). Then the cavity was washed and dried with cotton pellets. The cavity was conditioned with 20% polyacrylic acid (GC cavity conditioner - GC Corporation) for 15 seconds using a microbrush. A matrix tape and a wooden wedge were used to restore the interproximal anatomy. In the working sequence, the HVGIC capsule (EQUIA Fil, GC Corporation; Tokyo, Japan) was activated and mixed following the manufacturer instructions, and the 'press finger' technique was carried out, keeping the operator's finger in position for 40 seconds. After the initial setting of 2.5 minutes, excess material on the marginal ridge was removed carefully using a hand instrument, always moving the instrument from the restoration to tooth surface. After 5 minutes, the occlusion was checked and after removing the premature contacts, the surface protector was placed (GC Coat, GC Corporation; Tokyo, Japan) and light-cured for 20 seconds with an LED lamp (Figure 4). The size of the restoration was illustrated in the patient file. After the restoration was placed, the child and the teacher in charge were instructed so that the student would not eat for an hour. The application of different behavior management techniques according to the age of the patient was essential. No case required the application of local anesthesia. Uncooperative children and those who required more complex treatments were referred to the Dental Clinic of the San Martín de Porres University to receive specialised dental care.

Evaluation

Photographic documentation was made with a 20.2-megapixel Canon EOS 70D digital SLR camera, with an EF 100mm f / 2.8 MACRO lens, with the help of a mirror for photography after evaluations at 6 and 12 months.

The criterion used to assess the survival of the restorations was that of ART [Menezes-Silva et al., 2019]. For Class II restorations, the depth and caliber of the marginal defects were measured with the help of a CPI probe or periodontal probe with a round end. Each coordinating center trained its operators, assistants and evaluators. In addition to this, the inter-examiner coincidence Kappa values greater than 0.8.

Statistical analysis

Patient information was registered (gingival bleeding index,

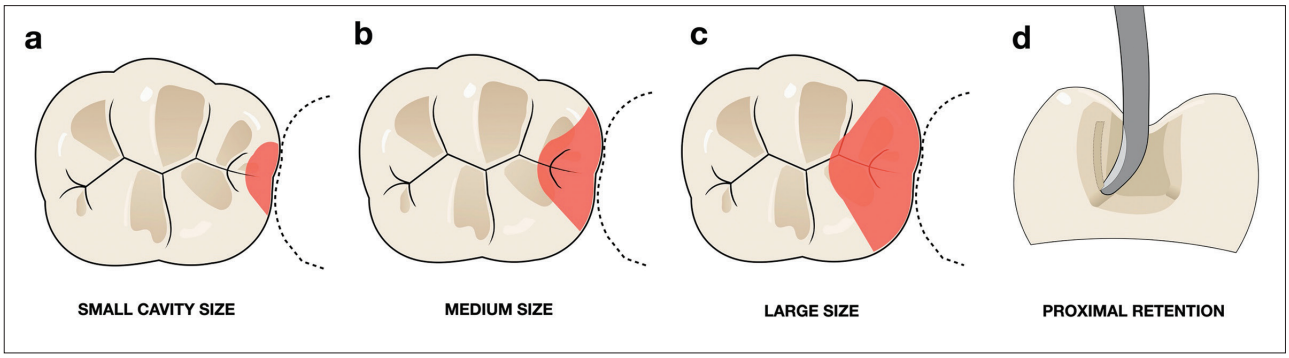

FIG. 2 Cavity size (a) Small: caries lesion limited to the interproximal surface; (b) Median: caries lesion extending 2 mm beyond one or both proximal buccal or lingual edges; (c) Large: caries lesion that extends beyond one or both proximal-buccal or proximal-lingual edges including the occlusal surface (d) Diagram proximal retentive grooves made with 15L dentin curette (SSWhite / Duflex; Rio de Janeiro, Brazil).

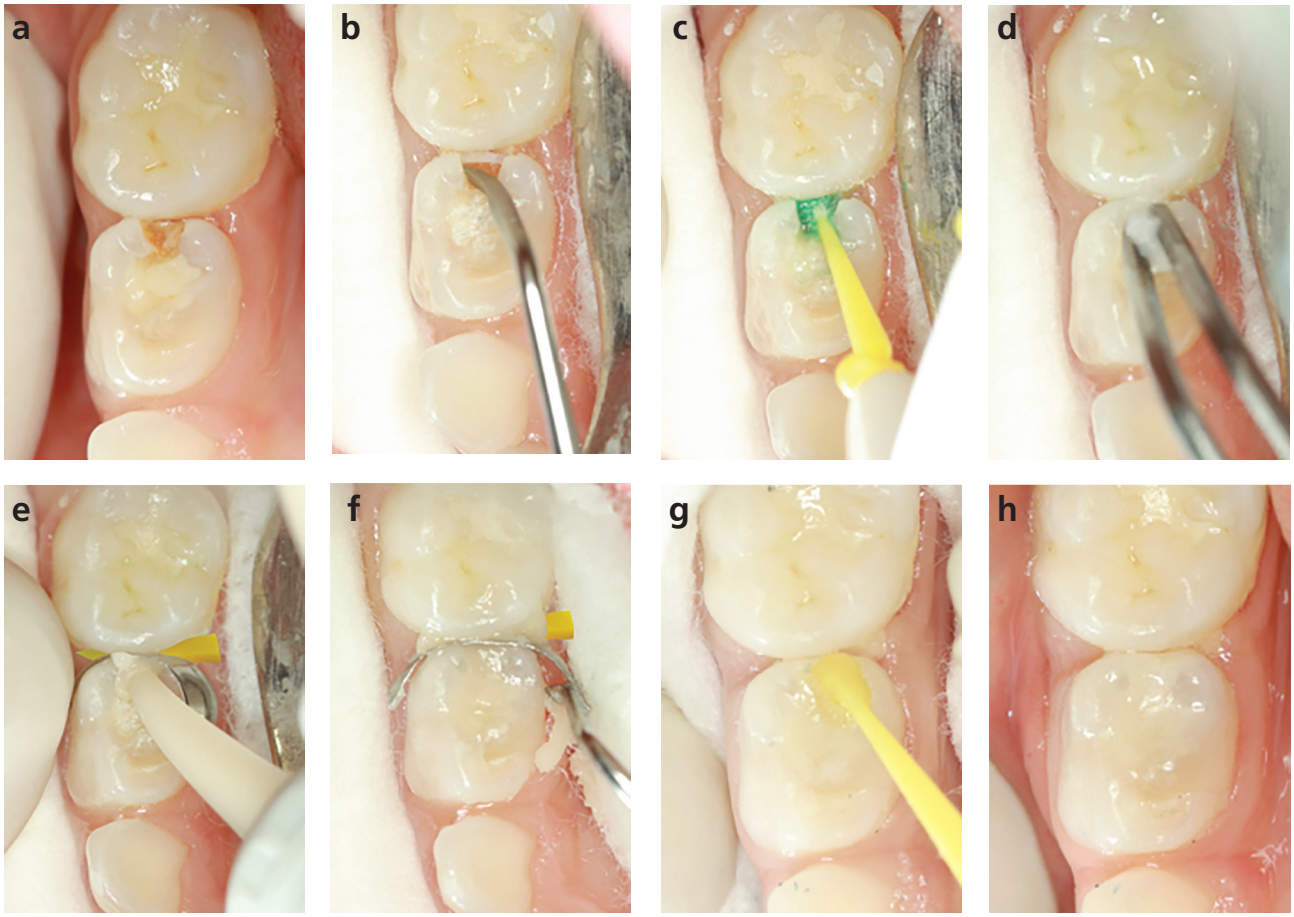

FIG. 3 Treatment protocol: (a) Small size 84 distal interproximal lesion, (b) removal of decomposed dentin and creation of proximal retentions, (c) conditioning with 10% polyacrylic acid for 15 seconds, (d) washing and drying with cotton pellets, (e) injection of encapsulated high-viscosity glass ionomer (EQUIA fil) after placement of metal matrix and wooden wedge, (f) removal of lateral excesses with hand instruments, (g) surface protection with GC Coat and posterior light curing with LED lamp, (h) final aspect of the restoration.

caries status using CAST tool, and size of the cavity), coded and entered into an Excel spreadsheet, the teeth to be treated were coded to avoid selection bias. The file was used to randomise the teeth into two arms: with or without proximal retentions (function "Random" of Microsoft Excel). The restorations were evaluated by two calibrated examiners (MH and EP) after 6 and 12 months (intra and inter-evaluator Kappa> 0.80). The examiners were blind, not being aware of the treatment that each tooth had received (with or without retentions) and used the evaluation criteria for ART restorations (Table 2). The data was analysed by Mann-Whitney, Chi square and Fisher's exact tests. The Kaplan-Meier test evaluated the survival percentages of the restorations in relation to the ART with or without retention grooves.

Results

One hundred eighty-seven children were enrolled in the study (average age = 5.5 years). The average dmf-s was obtained from

Material	Type	Manufacturer	Composition
Cavity conditioner	Acid conditioner	GC Co., Tokyo, Japan	20% polyacrylic acid
EQUIA Fil	High viscosity glass-ionomer cement	GC Co., Tokyo, Japan	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	50% methyl methacrylate, 0.09% camphorquinone

TABLE 1 Brands and composition of materials used in the study.

the CAST codes, showing a 21.6 (SD = 10.2) (Table 3). A total of 293 Class II restorations were placed in primary molars using ART hand instruments (SSWhite / Duflex; Rio de Janeiro, Brazil) and restoring with the EQUIA Fil encapsulated glass ionomer cement (GC Corporation; Tokyo, Japan). One hundred forty-one restorations were placed in the research arm (with retention grooves) and 152 restorations were placed for the control arm (without retention grooves). Of these restorations, 68.6% were performed in female patients. The average time to clean the cavities with hand instruments was 5.4 minutes and the restoration time was 6.6 minutes, the time invested for cleaning or restoring the teeth show no statistical significative difference in the survival rates ($p > 0.05$). None of the cases required application of anesthesia and the cooperation of the children was acceptable, with only 6% of children not cooperating that were excluded from the study. 4.4% of the treated teeth presented post-operative pain that was carefully monitored by the researchers. A higher proportion of medium size cavities were treated in the study, cavity size did not influence the success rates of ART Class II restorations (Table 4). After 6 months and 12 months the loss to follow-up were 18 and 7 teeth for group 1 (without retention) and 18 and 1 for group 2 (with retention), respectively. The success rates (codes 1 and 2) after 6 and 12 months were: for restorations without retention of 90.3% and 77.2% respectively, and for restorations with retention 95.9% and 91.8%, respectively (Table 5). The observed data did not show statistically significant differences between groups after the 6-month control ($p = 0.08$) but were detected after the 12-month control ($p=0.001$). The statistical analysis shows no cluster effect for those children who received more than one restoration ($p > 0.05$), the comparison of means and medians was performed among children who received one, two or three restorations. The Kaplan-Meier survival analysis of both restorative approaches tested can be seen in Figure 5, demonstrating the best performance for Class II restorations with retentive grooves in comparison to the treatments without retentive grooves after the 12-month follow-up (HR=1.23; IC95% 0.94-1.62).

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	Caries 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

TABLE 2 Evaluation criteria for ART restorations.

Independent variables	Mean	S.D.	Min	Max
Age	5.5	1.2	3	7
Teeth with plaque	18.1	4.3	0	25
Bleeding	3.7	3.9	0	17
dmf-s	21.6	10.2	2	54

TABLE 3 Mean age, standard deviation, number of teeth with plaque, number of teeth with bleeding, dmf-s.

Discussion

In our study, the survival rate was significantly higher for the ART Class II restorations with retentions (91.8%) versus the group without them (77.2%) after 12 months. Interestingly, the failure types were easily repairable (marginal gaps or restorations lost), meaning that with regular monitoring the teeth survival could be ensured for young children. Randomised clinical trials on ART Class II restorations in deciduous teeth showed a wide spectrum of survival rates, from 18% to 81.6% after 3-year follow-ups [Ainamo and Bay, 1975; Carvalho et al., 2010]. For the present study important technical details certainly contributed to the survival of the restorations: waiting for 2,5 minutes to start excess removal from restoration to tooth surfaces and waiting 5 minutes to remove the matrix. In addition, the retentive grooves also contributed to maintaining the initial adhesion of HVGIC to dentine, that takes approximately 150 minutes to consolidate [Menezes-Silva et al., 2019]. No statistically significant difference was found between groups for the 6-month analysis, but statistically significant difference was observed at the 12-month. From all restorations 6.4% required marginal repairmen and 9.2% total replacement (3.6-fold higher for the group without retentive grooves). Considering the field conditions in which the treatments were performed this seems to be a true reflection of the potential of ART Class II restorations with retentive grooves. The 12-month survival mean values for ART Class II restorations with proximal retentions

Cavity size	Baseline	6 months						12 months			
		W/o ret		W/ ret				W/o ret		W/ ret	
	n	(%)	n	(%)	n	(%)		n	(%)	n	(%)
Small	98	(33.5)	53	(39.6)	26	(21.1)		48	(37.8)	26	(21.3)
Medium	124	(42.3)	54	(40.3)	62	(50.4)		53	(41.7)	62	(50.8)
Large	71	(24.2)	27	(20.1)	35	(28.5)		26	(20.5)	34	(27.9)
TOTAL	293	100	134	100	123	100		127	100	122	100

n= absolute number of teeth for each cavity size. W/o ret= without proximal grooves; W/ ret= with proximal grooves.

TABLE 4 Distribution of treated teeth according to cavity size and follow-up.

Code	6 months			12 months		
	W/o ret	W/ ret		W/o ret	W/ ret	
	n (%)	n (%)	p value	n (%)	n (%)	p value
1	104 (77.6)	111 (90.2)	0.018	80 (63.0)	102 (83.6)	0.009*
2	17 (12.7)	7 (5.7)		18 (14.2)	10 (8.2)	
3	4 (3.0)	4 (3.3)		9 (7.1)	3 (2.5)	
4	1 (0.7)	1 (0.8)		1 (0.8)	0 (0.0)	
5	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.8)	
6	0 (0.0)	0 (0.0)		1 (0.8)	1 (0.8)	
7	8 (6.0)	0 (0.0)		18 (14.2)	5 (4.1)	

*Chi-square test with linear trend, *statistically significant difference. Bold numbers are the codes considered success (survival ART codes 1 and 2). W/o ret = without proximal grooves, W ret = With proximal grooves.*

TABLE 5 Distribution of scores according to the ART criteria.

seems promising (91.8%), when compared with the systematic review mean score (76.9%) for multi-surface ART restorations in primary teeth [de Amorim et al., 2019]. ART Class II restorations have been a clinical challenge showing lower survival rates when compared with the single surface counterparts, especially when treating high caries risk populations such as the one included in the present study. Many efforts have been conducted searching for alternatives to prolong the survival of ART Class II restorations challenging different restorative adhesive materials (HVGIC, glass carbomer, zinc-reinforced, resin-modified GIC, compomers or composite resin)[Mobarak et al., 2019; Ersin et al., 2006], insertion techniques (i.e. bilayer) [Hesse et al., 2015], use of rubber dam or through the creation of mechanical retentions. A recent systematic review has stated that the operator and the type of restoration are the main factors influencing success of ART restorations [Diem et al., 2014]. All children from the two schools included in the study come from high-risk communities (early childhood caries, low socio-economic status, illiterate parents, bad oral hygiene and detrimental dietary habits). The oral examination was conducted for every child from 3 to 7 years of age from two public schools to reduce the risk of selection bias. There was no gender or dmf-t statistical difference of children from the two schools during the baseline evaluation, reason why all teeth were included in a unique list to proceed with the randomisation. Because of the nature of the investigation the operator could not be blinded during the cavity cleaning. On the other hand, patients and examiners were considered blind, not knowing the type of cavity preparation performed for each restoration. Internal and external validity could be maintained. Caries detection was done with the CAST instrument, but in order to facilitate comparability with other studies, the codes were converted to dmf-s. CAST codes 5 (distinct cavitation into dentine, the pulp chamber is intact) were the ones considered to be restored for the present study [Mobarak et al., 2019]. Even though the visible plaque and gingival bleeding were not used in the sample stratification, the restorations were homogeneous regarding these characteristics that could influence their clinical performance. The dropout rate in this study was 15.0% after 12 months. Much effort was made to avoid attrition bias, through an active search and numerous visits to the schools. Loss of follow-up in the study were mainly related to children moving to other cities or schools and changing home phone numbers, not being able to control their treatment status. This was the expected drop-out, similar to other studies, but the impact on the results is something researchers could not calculate. Closer attention is needed to track the patient's

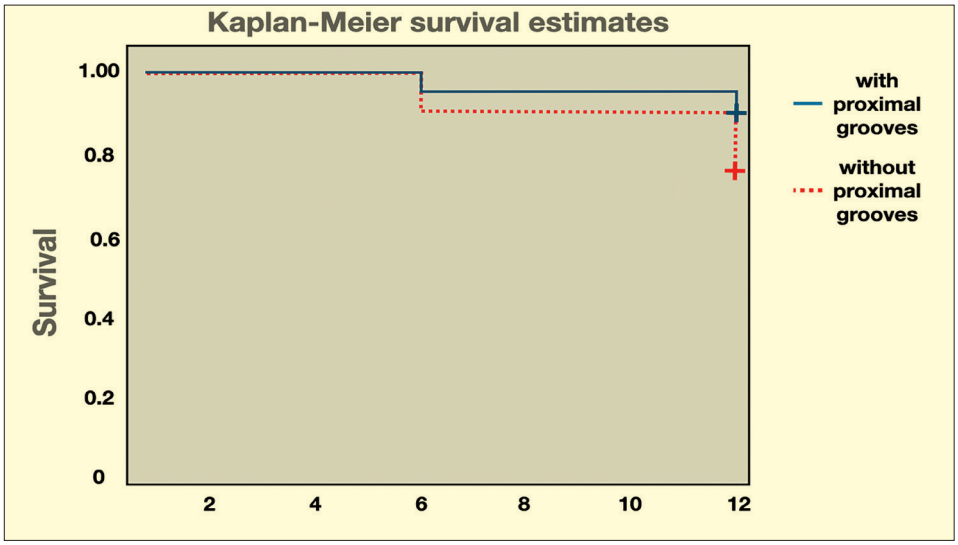

FIG. 4
Survival curves for ART restorations with and without proximal grooves using encapsulated glass ionomer (HR=1.23; IC95% 0.94-1.62).

location to perform home evaluations as suggested by a previous study [van Gemert-Schriks et al., 2007]. Longitudinal studies in permanent dentition have shown that the encapsulated glass ionomer shows similar survival rates in single surfaces to those shown by resin composites for single surface restorations [Gurgan et al.,2020]. Conversely, survival rates for Class II restorations have been historically low. The literature is abundant regarding possible reasons of early loss of glass ionomer restorations: powder-liquid ratios, operator factor, an inexperienced assistant, bubble formation during mixing, marginal caries lesion, block fracture due to cohesive failure or marginal wear, the latter two resulting from material failure [Smales and Yip, 2020]. Numerous strategies have been proposed to increase the durability of ART Class II restorations without showing encouraging long-term results. Randomised controlled trials on ART have compared the survival rates of HVGIC with amalgam restorations for being considered the 'gold-standard' of restorative materials, resulting in similar success rates for permanent teeth after 6 years for single surface restorations but not for multiple surface restorations on primary or permanent teeth [Mickenautsch et al., 2010]. There is a need to find comparable, patient-friendly alternatives to amalgam for Class II restorations in the primary teeth due to the long-term clinical demand in very young children with untreated multi-surface cavitated lesions. Long-term monitoring is still needed to translate these findings into clinical recommendations, reason why these results are preliminary from an ongoing 3-year randomised clinical trial. The Minamata Convention on the use of mercury calls for restorative materials to seize the place of dental amalgam [United Nations Environment Programme, 2013]. The International Association for Dental Research (IADR), together with the International Dental Federation (FDI) and the World Dental Industry (WDI) defended the reduction in teaching and using dental amalgam, concomitantly with the promotion of oral health and prevention, demanding an increase in research and development of alternatives to dental amalgam. The signatory countries agreed to gradually decrease the use of dental restorations based on amalgam and consequently mercury, and there was a need to promote dental research on the subject, finding in the encapsulated glass ionomer a viable alternative both in outreached scenarios and in hospital service clinics, under the concept of minimal intervention. Our results, together with the findings from other studies, show that encapsulated glass ionomers and the use of proximal retentions could be considered a promising alternative for the management of small and medium cavitated lesions as a non-inferior alternative to resin composite or dental amalgam. Constant improvement of restorative materials allows us to observe better long-term survival of HVGIC restorations, both for primary and permanent dentition. An encapsulated high-viscosity glass ionomer chosen for this study have started to be widely commercialised showing in vitro and clinical promising results [Molina et al., 2013]. Probably in part this is due to the precise powder/liquid ratio, the automatization involved in the mixing process, which reduces the variability found for the hand-mixed versions together with shorter mixing times (10–12 seconds for capsules). These superior mechanical properties are attributed to the reduction of the particle size of the vitreous matrix and the use of a bis-GMA surface protector [Diem et al., 2014], which allows the material to mature and reach its maximum mechanical resistance hours after it was applied. The coat plays an important role also in the water dynamics during setting reaction, protecting the surface of the restoration from the saliva or liquid sorption during the first hours of the setting reaction, which might be translated into better mechanical properties for the HVGIC like minimal roughness and less micro-cracks. A combined strategy was proposed for this investigation, using the confirmed efficacy of creating retentive grooves, together with a superior HVGIC, providing a reproducible quality mix, protected by a light-cured cover (EQUIA coat) with potentially superior clinical performance. Since the early years, ART has been considered a patient-friendly procedure and very well accepted by paediatric patients, something the present study confirms. The use of hand excavators (mechanical method) has been advocated by the recent caries management consensus together with minimal intervention recommendation for pediatric patients, showing better suitability for selective caries tissue removal [Banerjee et al., 2017]. This minimally invasive approach has been shown to reduce dental anxiety due to the lack of noise, vibration and heat produced by a bur and handpiece [Frencken, 2017]. For community clinics or dental school programs, the ART approach still displays a great potential to serve patients, historically neglected by conventional dentistry.

Conclusion

This 12-month follow-up study evidenced that proximal

retentive grooves increased the survival rate of ART Class II restorations in primary teeth. Good cooperation rates and short working times should be considered for future public health interventions. More long-term studies are also needed to translate findings into clinical recommendations.

Acknowledgments

The authors thank the school authorities for opening their doors to the research team and the families who provide their consent trusting their children's health. We also extend our deepest gratitude to the support from the Department of Dental Materials, Endodontics and Operative Dentistry, from School of Dentistry in Bauru; the authorities from the San Martin de Porres University for the logistic support. Extending this acknowledgment to Dr. Jo E. Frencken for training the research team. Thanks to GC Corporation for providing the materials and equipment to make this research possible.

Conflict of Interest

Eraldo Pesaressi declares that he has no conflict of interest. Diana Zelada-Lopez declares that she has no conflict of interest. Tania Cosme declares that she has no conflict of interest. Julia Diaz declares that she has no conflict of interest. Marianela Huanqui declares that she has no conflict of interest. Maria Fidela de Lima Navarro declares that she has no conflict of interest. Rita S. Villena declares that she has no conflict of interest.

Funding

The work has been supported by the Dental School of San Martin de Porres University.

Ethical approval

The project followed the guidelines of the declaration of Helsinki (Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects), it was registered at the Registro Brasileiro de Ensaios Clínicos – REBEC website under the registration number RBR-2jmbvt and was approved by the Ethics Committee from the Dental School of the San Martin de Porres University (N° 116-2016-D-FO-USMP in Lima – Peru.

Informed consent

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

References

› Ainamo J, Bay I (1975) Problems and proposals for recording gingivitis and plaque. Int Dent J 25:229–235
› Banerjee A, Frencken JE, Schwendicke F, Innes NPT (2017) Contemporary operative caries management: consensus recommendations on minimally invasive caries removal. British Dental Journal 223:215–222
› Barata TJE, Bresciani E, Cestari Fagundes T, Gigo Cefaly DF, Pereira Lauris JR, Lima Navarro MFL (2008) Fracture resistance of Class II glass-ionomer cement restorations. Am J Dent 21:163–167
› Basso M, Brambilla E, Goñe-Benites M, Giovannardi M, Ionescu AC (2015) Glass ionomer cement for permanent dental restorations: A 48-months, multi-centre, prospective clinical trial. Stoma Edu J 2(1):25-35
› Carvalho TS, Sampaio FC, Diniz A, Bönecker M, Van Amerongen WE (2010) Two years survival rate of Class II ART restorations in primary molars using two ways to avoid saliva contamination. Int J Paediatr Dent 20(6):419-25.
› Cefaly DFG, Barata TJE, Bresciani E, Fagundes TC, NavarroMFL (2013) Clinical evaluation of multiple-surface ART restorations: three-year follow-up. Braz Dent Sci 16:33–40.
› Da Franca, C., Colares, V., & Amerongen, E. (2016). The operator as a factor of success in ART restorations. Brazilian Journal Of Oral Sciences, 60-64. Retrieved from https://www.fop.unicamp.br/bjos-new/index.php/bjos/article/view/852
› de Amorim RG, Frencken JE, Raggio DP, Chen X, Hu X, Leal SC (2018) Survival percentages of atraumatic restorative treatment (ART) sealants and restorations in permanent teeth: an updated systematic review and meta-analyses. Clin Oral Investig 22:2703–2725
› Diem VT, Tyas MJ, Ngo HC, Phuong LH, Khanh ND (2014) The effect of a nano-filled resin coating on the 3-year clinical performance of a conventional high-viscosity glass-ionomer cement. Clin Oral Investig 18(3):753–9.
› Ersin NK, Candan U, Aykut A, Onçağ O, Eronat C, Kose T (2006) A clinical evaluation of resin-based composite and glass ionomer cement restorations placed in primary teeth using the ART approach: results at 24 months. J Am Dent Assoc 137(11):1529-36
› Fernandes EP, Freitas MC, Oltramari-Navarro PV, Navarro RL, Menezes-Silva R, Wang L, Lauris JR, Navarro MFL (2019) Proximal retention grooves may increase early fracture strength of ART restorations. Braz Dent Sci. 2019; 22:111-117.
› Frencken JE (2017) Atraumatic restorative treatment and minimal intervention dentistry. Br Dent J 223:183–185.
› Frencken JE, de Souza AL, van der Sanden WJ, Bronkhorst EM, Leal SC (2013) The Caries Assessment and Treatment (CAST) instrument. Commun Dent Oral Epidemiol 41:71–77
› Frencken JE, Pilot T, Songpaisan Y, Phantumvanit P (1996) Atraumatic restorative treatment (ART): rationale, technique, and development. J Public Health Dent 56:135–140
› Gurgan S, Kutuk ZB, Yalcin Cakir F, Ergin E. A randomized controlled 10 years follow up of a glass ionomer restorative material in class I and class II cavities. J Dent. 2020; 94:103175
› Hesse D, Bonifacio CC, Bönecker M, Guglielmi CAB, da Franca C, van Amerongen WE, Colares V, Raggio DP (2015) Survival rate of atraumatic restorative treatment (ART) restorations using a glass ionomer bilayer technique with a nanofilled coating: a bi-center randomized clinical trial. Pediatr Dent 38(1):18-24.
› Hickel R, Kaaden C, Paschos E, Buerkle V, García-Godoy F, Manhart J (2005) Longevity of occlusally-stressed restorations in posterior primary teeth. Am J Dent 18(3):198–211
› Jiang M, Fan Y, Li KY, Lo ECM, Chu CH, Wong MCM. Factors affecting success rate of atraumatic restorative treatment (ART) restorations in children: A systematic review and meta-analysis. J Dent. 2021 Jan;104:103526.
› Kassebaum NJ, Bernabé E, Dahiya M, Bhandari B, Murray CJ, Marcenes W (2015) Global burden of untreated caries: a systematic review and metaregression. J Dent Res 94(5):650–658
› Menezes-Silva R, Cabral RN, Pascotto RC, Borges AFS, Martins CC, Navarro MFL, Sidhu SK, Leal SC (2019) Mechanical and optical properties of conventional restorative glass ionomer cements - a systematic review. J Appl Oral Sci 27:e2018357
› Mickenautsch S, Yengopal V, Banerjee A (2010) Atraumatic restorative treatment versus amalgam restoration longevity: a systematic review. Clin Oral Investig 14(3):233-40
› Mobarak E, El-Deeb H, Daifalla LE , Ghaly M, Mustafa M, Sabry D, Fatah H, Mulder J, Creugers NHJ, Frencken JE (2019) Survival of multiple-surface ART restorations using a zinc-reinforced glass-ionomer restorative after 2 years: A randomized triple-blind clinical trial. Dental Materials 35(9):e185-e192
› Molina GF, Cabral RJ,Mazzola I, Lascano LB, Frencken JE (2013) Mechanical performance of encapsulated restorative glass-ionomer cements for use with atraumatic restorative treatment (ART). J Appl Oral Sci 21:243–249
› Scholtanus JD, Huysmans MC (2007) Clinical failure of class-II restorations of a highly viscous glass-ionomer material over a 6-year period: a retrospective study. J Dent 35:156-62
› Schwendicke F, Frencken JE, Bjorndal L, Maltz M, Manton DJ, Ricketts D (2016) Managing carious lesions: consensus recommendations on carious tissue removal. Adv Dent Res 28:58–67
› Sidhu SK, Nicholson JW (2016) A review of glass-ionomer cements for clinical dentistry. J Funct Biomater 7: 16.
› Smales RJ, Yip HK (2000) The atraumatic restorative treatment (ART) approach for primary teeth: review of literature. Pediatr Dent. 22(4):294-8
› United Nations Environment Programme. Report of the intergovernmental negotiating committee to prepare a global legally binding instrument on mercury [Internet]. Geneva: The Organization; 2013 [cited 2013 March 14]. Available from: http://www.unep.org/hazardoussubstances/Mercury/Negotiations/INC5/tabid/3471/Defaut.aspx
› van Gemert-Schriks MCM, van Amerongen WE, ten Cate JM, Aartman IHA (2007) Three-year survival of single- and two-surface ART restorations in a high-caries child population. Clin Oral Invest 11:337–343
› Yee R, Sheiham A (2002) The burden of restorative dental treatment for children in Third World countries. Int Dent J 52(1):1-9.