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Research Article

Randomized Clinical Trial for Class II ART Restorations in Primary Molars: 24 Months Results

Zelada D[1*], Cosme T[1], Huanqui M[1], Pesaressi E[1], Diaz J[1], Medina J[2], Navarro MFL[3], Villena RS[1]

[1]Department of Pediatric Dentistry, School of Dentistry, San Martin de Porres University, Lima, Peru

[2]School of Medicine. San Martin de Porres University, Lima, Perú

[3]Department of Dental Materials, Endodontics and Operative Dentistry, Bauru School of Dentistry, Bauru, Brazil

***Correspondence author:** Diana Zelada López, Deparment of Pediatric Dentistry, San Martin de Porres University, Lima -Peru; Email: lzeladal@usmp.pe

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Abstract

Untreated dental caries in primary teeth is a public health issue worldwide and its management is based on Minimal Intervention Dentistry guidelines: Selective carious tissue removal, preservation of dental tissues and the use of biocompatible materials.

Objective: To evaluate the survival rate adapting the Atraumatic Restoration Technique (ART) through mechanical retentions in Class II cavities in primary molars.

Methods: This study enrolled 187 children with good general health aged 3 to 7 years (mean 5.53) from two public schools located in a low socio-economical community in Lima, Peru. Children with good general health, whose parents signed the informed consent form, were included in the study. Three trained operators performed 293 Class II restorations in primary molars using the ART hand instruments (SSWhite/Duflex; Rio de Janeiro, Brazil) and encapsulated high viscosity glass ionomer cement EQUIA Fil (GC Corporation; Tokyo, Japan). The children were referred to the San Martin de Porres University - Dental School Clinic for additional restorative care. Two calibrated examiners evaluated the restorations after 6, 12 and 24 months (Kappa intra- and inter-evaluators > 0.80). Data were analyzed by Mann-Whitney, Chi-square and Fisher's Exact tests.

Results: The mean dmfs (decayed, missing, filled surfaces) of the participants was 21.5 (SD= 10.1). The mean time for cleaning the cavity was 5.4 minutes and the restorative time, 6.6 minutes; no local anesthesia was needed for any case and the cooperation of children was mostly acceptable (94%). Success rates after 6, 12 and 24 months were: 90.3%, 77.2% and 67.7%, respectively for restorations without retention; and: 95.9%, 91.8% and 87.8%, respectively with retention. No statistically significant differences were observed for 6 months (p=0.08), but clearly detected for 12 and 24 months (p<0.001)

Conclusion: Proximal retentive grooves appear to be very promising for improving ART Class II restorations on primary teeth. Good cooperation rates and short treatment time are important aspects to consider for public health interventions, as well as the feasibility for working with ART in schools.

Keywords: Dental Caries; Glass Ionomer Cements; Pediatric Dentistry; Atraumatic Restorative Treatment; Children; Restorations

Introduction

Dental caries is ranked as the 10th most prevalent condition worldwide, affecting approximately 621 million children globally, it occurs in a high percentage of children presenting with untreated cavitated dentine lesions remaining as a major challenge to public health [1,2]. In Peru, limited oral health education, coupled with low cultural and socioeconomic levels in vulnerable areas, leads to higher caries rates. Parents seek dental treatments on advanced stages of the disease, when the child is experiencing pain or other acute symptoms. Given that caries is a dynamic and multifactorial disease, it is essential to manage risk factors to prevent the onset and/or progression of lesions [3]. Current dentistry recommends the application of minimally

invasive treatments to preserve tissue with remineralization potential, thereby maintaining functional teeth as long as possible [4].

Atraumatic Restorative Treatment (ART) is recognized as a minimally invasive approach for the prevention and control of dental caries, as well as for the restoration of affected tissues using adhesive materials. [5]. This approach can be performed without the need of sophisticated dental equipment, using only manual instruments and results in a child-friendly approach [6]. The restorative material mostly used for the ART is High-Viscosity Glass Ionomer Cement (HVGIC), which offers multiple benefits such as chemical adhesion to dental tissues and high biocompatibility, but limited flexural strength compared to composites [7]. High survival rates for single-surface ART restorations have been reported for both primary and permanent dentitions [8]; however, reports on two or more surfaces in an ART restoration are scarce and show lower success rates in primary teeth compared to permanent teeth, especially in Class II cavities where the restoration is often completely lost [9, 10]. With the advent of high-viscosity encapsulated glass ionomer cements combined with a resin coating, the risks of moisture contamination and salivary interference are reduced, resulting in improved outcomes for multi-surface ART restorations.

Furthermore, it provides a standardized powder-to-liquid ratio and the automated mixing process minimizes the potential for errors during this phase. The prepared material is subsequently delivered into the cavity using an application tip. Moreover, the incorporation of retentive grooves along the buccal and lingual walls of the proximal box has been suggested to enhance the contact surface area and improve the mechanical retention of the restoration. [11].

The purpose of this study was to evaluate the survival of Class II ART restorations performed with encapsulated glass ionomer using two cavity preparation techniques: with and without mechanical retentions, in children from public schools in Lima - Peru, after 24 months of follow-up.

Aim and Objectives

This research aimed to evaluate the effects of creating retentive grooves in the proximal boxes of Class II cavities using the ART technique.

Methodology

Study Design and Sampling

This was a randomized, longitudinal experimental study, part of an international multicenter study developed by the School of Dentistry of Bauru - University of São Paulo, Brazil, with the participation of the University of Brasília (Brazil) and the University of San Martín de Porres (Peru). The study received in Lima, Peru the ethical approval from the Ethics Committee at the University of San Martín de Porres (N° 116-2016-D-FO-USMP).

The Peruvian study was conducted in two public schools located in low peri-urban areas of Lima, both with similar socio-economic conditions. Children aged 3 to 7 years presenting with dentine interproximal carious lesions in primary molars with no pulpal involvement or signs of periapical pathology (e.g., fistula, abscess, pathological mobility) were selected between May 2015 and October 2017 to be enrolled in the study. Children with systemic conditions, whose parents did not sign the informed consent form to treatment, were excluded. Each patient was treated and re-evaluated at 6, 12, 24 and 36 months.

Once the eligible children and teeth were identified, the cavity preparation technique was randomized: Group 1 received the traditional ART technique [12]. Group 2 received ART with mechanical retentions. Randomization was conducted using the "RAND" function in Microsoft Excel and the study flowchart followed CONSORT guidelines (Fig. 1) [13]. Children who left the school or changed their place of residence during the follow-up periods were removed from the sample.

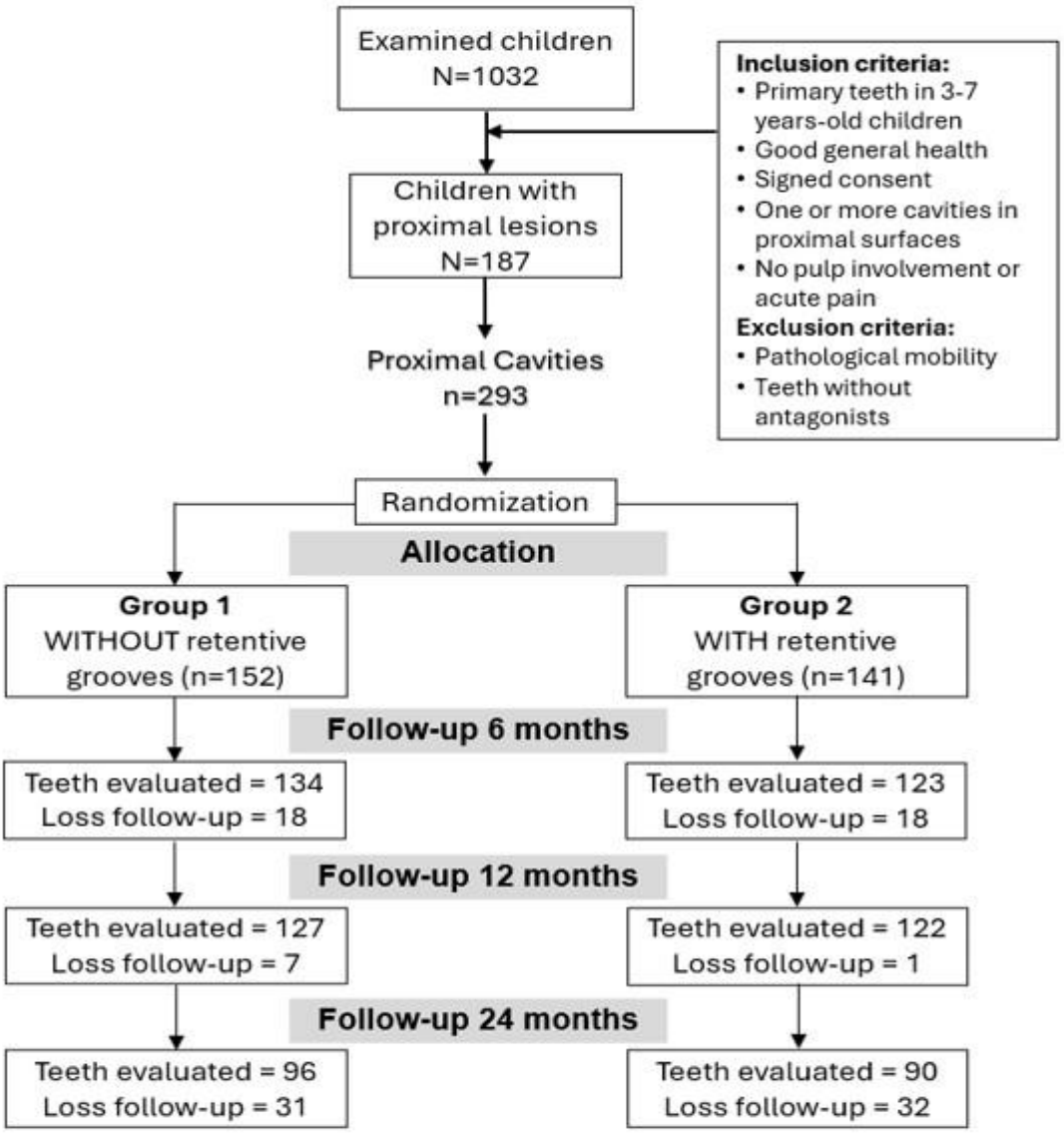

Figure 1: CONSORT flowchart for clinical trials. N= number of children examined, n = number of proximal lesions included in the study.

Operator Training

The operators received training in handling of ART instruments and in the preparation of retentive grooves by MFLN, as well as in the application of the glass ionomer material (Equia Fil, GC Corporation; Tokyo, Japan). Prior to this, the operators had already been trained and calibrated in caries detection using the Caries Assessment Spectrum and Treatment (CAST) system with Dr. Jo Frencken (The Netherlands). The inter and intra-examiner coefficients (Kappa) for both CAST and ART criteria were higher than 0.85.

Clinical Evaluation

After obtaining signed informed consent from the parents, data collection began by evaluating 1,032 children aged 3 to 7 years. Intraoral examination was performed at the school settings (without dental unit nor air pressure) with the child lying on a specially adapted table. The operator worked at the child's head level, following all biosafety protocols and using artificial light (LED front-light, Energizer - USA), a mouth mirror and a WHO periodontal probe. An assistant recorded patient data and indices including dmfs/DMFS, gingival bleeding and CAST [14]. Prior to examination, the operator performed oral hygiene using a toothbrush with fluoridated toothpaste (550 ppm F - Dentito) and dental floss for proximal areas. Custom-designed forms were used for recording data.

Cavity size was categorized before treatment based on the following criteria:

- Small: Caries lesion limited to the interproximal surface
- Medium: Caries lesion extending 2 mm beyond one or both proximal buccal or lingual edges
- Large: Caries lesion that extends beyond one or both proximal-buccal or proximal-lingual edges including the occlusal surface (Fig. 2)

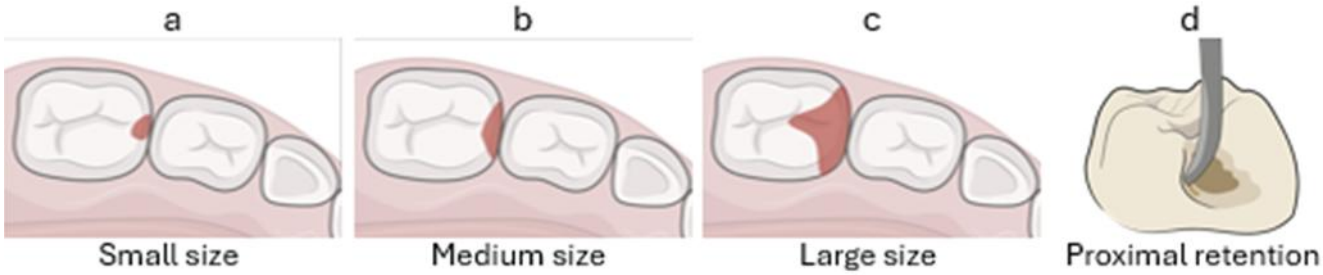

Figure 2: Cavity size: Small (a), Medium (b), Large (c) and proximal retentive grooves (d).

Clinical Procedure

The materials employed in this study included: Cavity conditioner (20% polyacrylic acid), EQUIA Fil high-viscosity glass ionomer and EQUIA Coat (GC Co., Tokyo, Japan). Clinical care provided at school; the child is positioned on a specially adapted table and the operator works with the aid of hand instruments and artificial light (Fig. 3). Given the preschool and school-age patient population, behavior management was consistently implemented to promote a positive attitude and enabling efficient care. Treatment followed ART protocol guidelines using only manual instruments (SSWhite / Duflex; Rio de Janeiro, Brazil) under relative isolation [12]. The details of restorative procedures can be seen on paper regarding 12 months follow up [15]. Cavity access was enlarged with an opener, unsupported enamel was removed with a hatchet, when necessary (Fig. 3) and decomposed dentin was removed using excavators, starting at the dentine-enamel junction. For Group 2 cavities, retentive grooves were created on buccal and lingual walls using a 15L excavator (SSWhite / Duflex) in a gingival-to-occlusal direction (Fig. 3). Cavities were cleaned with cotton pellets moistened with water, then with dry ones. The restoration process started with the application of polyacrylic acid (GC Cavity Conditioner) for 15 seconds using a microbrush (Fig. 3), followed by rinsing and drying with cotton pellets (Fig. 3). A metal matrix and wooden wedge were placed to re-establish proximal contact. The EQUIA Fil capsule was mixed for 10 seconds using a GC Capsule mixer CM-II, inserted into the applicator and dispensed to fill the cavity from the base to the margins (Fig. 3). Digital pressure was applied with a petroleum jelly-coated finger for 40 seconds, followed by removal of excess material using hand instruments. After 5 minutes, the matrix was carefully removed. Occlusion was checked after the initial setting reaction with articulating paper and premature contacts were adjusted. Finally, EQUIA Coat was applied with a microbrush (Fig. 3) and light-cured for 20 seconds using LED lamp Silverlight. Cavity cleaning and restoration times were recorded (in seconds). Children were advised not to eat for one-hour post-treatment. Those requiring additional care were referred to the Specialized Clinic of the Dental School of the San Martín de Porres University.

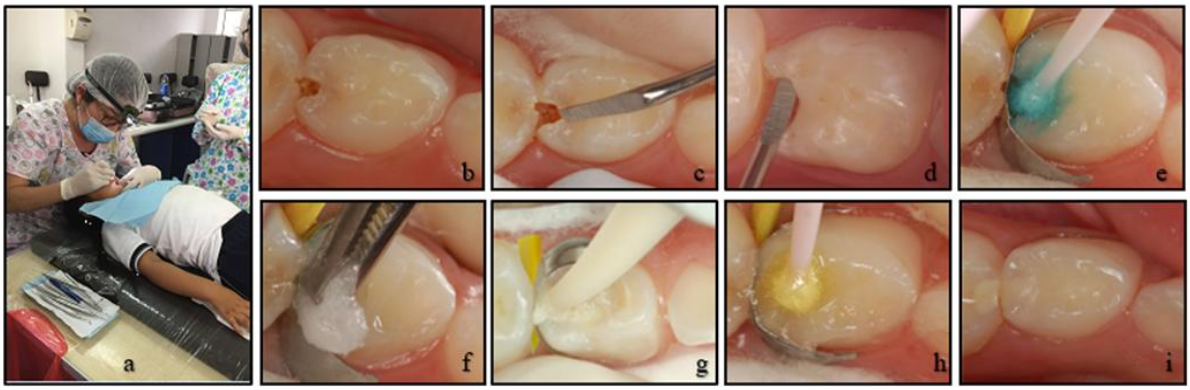

Figure 3: Restorative procedure sequence. (a) Clinical care provided at school. (b) Caries lesion on tooth 74. (c) Unsupported enamel removal. (d) Retentive grooves created on group 2. (e) Application of polyacrylic acid. (f) Rinsing and drying with cotton pellets. (g) EQUIA Fil inserted in the cavity. (h) EQUIA Coat application. (i) Final restoration.

Evaluation

At 24 months post-treatment, calibrated evaluators (MH and EP), with intra- and inter-examiner Kappa > 0.80, performed clinical and photographic assessments using a round-tipped periodontal probe to measure marginal defects. Evaluators were blind; they were unaware of the type of treatment each tooth received (with or without retentions). Examiners had received training in the ART adapted Frencken criteria [16], which determine success or failure by assigning scores from 1 to 10, as well as the modified USPHS (United States Public Health System) criteria.

Statistical Analysis

Data from the clinical forms were entered into a Microsoft Excel database and then analyzed using descriptive statistics with SPSS version 29. Comparative analysis between the ART restorations with and without retentions was conducted using Mann-Whitney, Chi-square and Fisher's Exact test.

This paper reports on the 24-month follow-up results.

Results

The mean age of the children enrolled in the study was 5.53 years. The unit of analysis was the cavity to be restored. A total of 293 Class II restorations were performed by three trained operators (DZ, JD and RV) on primary molars using ART hand instruments (SSWhite / Duflex; Rio de Janeiro, Brazil) and encapsulated glass ionomer cement (EQUIA Fil; GC Corporation, Tokyo, Japan). Most restorations were performed in girls (68%). Behavioral management techniques were essential to ensure effective treatment according to the child's age and overall cooperation was acceptable, with only 6% of children being uncooperative.

The mean dmfs (decayed, missing, filled teeth) of the participants was 21.6 (SD = 10.2) and the average number of teeth with plaque retention was 18.1 (SD = 4.3). The average time to clean the cavity using hand instruments was 5.4 minutes and the average restoration time was 6.6 minutes. None of the cases treated required local anesthesia.

The primary molars with the highest prevalence of proximal lesions were lower right second molars, upper right first molars, lower left first molars and upper left first molar, accounting for 15%, 14.3%, 13.3% and 9.2%, respectively. Medium-sized cavities were the most prevalent (42.3%). Tooth loss during follow-up occurred proportionally in both groups (Fig. 1). Cavity size did not influence the success rates of Class II ART restorations (Table 1).

Restoration survival was classified as successful when given a score of 1 ("present, no change") or 2 ("present, slight marginal defect or wear < 0.5 mm; no repair needed") as shown in Table 2.

Success rates at 6, 12 and 24 months were as follows:

- Without retentive grooves: 90.0%, 77.1% and 68.0%, respectively
- With retentive grooves: 95.9%, 91.8% and 87.7%, respectively

No statistically significant difference was observed at 6 months (p = 0.08), but significant differences were found at 12 and 24 months (p = 0.001) (Table 3).

Cavity size	Baseline		6 months				12 months				24 months			
			Group 1		Group 2		Group 1		Group 2		Group 1		Group 2	
	N	%	n	(%)	n	(%)	n	(%)	n	(%)	N	(%)	n	(%)
Small	98	(33.4)	53	(39.6)	26	(21.1)	48	(37.8)	26	(21.3)	36	(37.5)	20	(22.2)
Medium	124	(42.3)	54	(40.3)	62	(50.4)	53	(41.7)	62	(50.8)	40	(41.7)	45	(50.0)
Large	71	(24.2)	27	(20.1)	35	(28.5)	26	(20.8)	34	(28.5)	20	(20.8)	25	(27.8)
TOTAL	293	100	134	100	123	100	127	100	122	100	96	100	90	100

Table 1: Prevalence of treated teeth and survival of restorations with and without retentive grooves at 6, 12 and 24 months.

Code	Description	6 months		12 months		24 months	
		Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
1	Present, no change	**104 (77.6)**	**111 (78.7)**	**80 (63.0)**	**102 (83.6)**	**50 (52.1)**	**67 (74.4)**
2	Present, slight defect at the margin and/or wear of the restoration of less than 0.5 mm; no repair is needed	**17 (12.7)**	**8 (5.7)**	**18 (14.2)**	**10 (8.2)**	**15 (15.6)**	**12 (13.3)**
3	Present, marginal defect deeper than 0.5 mm. Repair is needed	4 (3.0)	3 (2.1)	9 (7.1)	3 (2.5)	6 (6.3)	3 (3.3)
4	Present, wear over larger parts of the restoration deeper than 0.5 mm. Repair is needed	1 (0.7)	1 (0.7)	1 (0.8)	0 (0.0)	1 (0.7)	0 (0.0)
5	Caries presence at the restoration margin. Repair is needed	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	3 (3.1)	1 (1.1)
6	Partially present, restoration and/or tooth breakdown. Repair is needed	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	3 (3.1)	0 (0.0)
7	Not present, restoration has completely disappeared. Treatment is needed	0 (0.0)	0 (0.0)	18 (14.2)	5 (4.1)	18 (18.8)	7 (7.8)

Table 2: Distribution of ART restoration survival evaluation scores.

	6 months			12 months			24 months		
	Group 1	Group 2		Group 1	Group 2		Group 1	Group 2	
	n (%)	n (%)	p	n (%)	n (%)	p	n (%)	n (%)	p
Success	121 (90.0)	118 (95.9)	0.08	98 (77.1)	112 (91.8)	0.001	65 (68.0)	79 (87.7)	0.001
Failure	13 (10.0)	5 (4.1)		29 (22.9)	10 (8.2)		31 (32.0)	11 (12.3)	

Table 3: Success rates of ART restorations at 6, 12 and 24 months.

Discussion

Advances in prevention and minimally invasive dentistry represent new strategies for managing dental caries and preventing the consequences of untreated lesions in pediatric patients. These approaches also help address health inequalities in public health settings [17]. The use of hand excavators (selective carious tissue removal) for managing carious lesions has shown better acceptance and reduces the risk of more complex and expensive treatments later in life [18,19]. Additionally, this technique reduces patient anxiety by avoiding the need of anesthesia, together with the noise, vibration and heat generated by rotary instruments and high-speed dental equipment [6].

Scientific evidence had previously reported that the survival of Class II restorations using the ART technique was lower compared to single-surface restorations [20]. Therefore, continuous efforts to improve the longevity of these restorations have led to modifications in material components, including improvements in adhesion and molecular structure, as noted in previous studies [21-26]. Longitudinal studies in primary teeth have shown that glass ionomer cement, compared to other materials over a follow-up of up to five years, achieved survival rates of 97.42% at three years and 94% at four years, using the ART technique in deciduous molars with high-viscosity GIC [27,28]. Also, reduces the risk of secondary caries that has been recognized as the main reason restorative materials failed [29,30]. Other randomized clinical trials on Class II ART restorations in both primary and permanent teeth have reported a wide range of survival rates, from 56% to 74% [31]. However, survival was generally higher for single-surface restorations and for those performed with composite resin while Class II restorations consistently showed lower survival rates [25,32,33]. Multiple factors contribute to early failure of the restorative material, including powder-liquid mixing errors, operator skills, inexperience of the assistant, air bubbles in the mixture, marginal caries, marginal wear and fractures due to poor cohesion [9,34]. Therefore, long-term clinical reports (e.g., 24 months) were needed to test strategies that might contribute to long-term survival [35-38].

The combination of retentive grooves with an encapsulated high-viscosity glass ionomer cement allowed to obtain acceptable survival rates of Class II ART restorations with retentions (87.7%), significantly higher than in the group without retentions (68%). Moreover, the types of failures encountered were easily repairable (e.g., marginal gaps or restoration loss), suggesting that regular monitoring could ensure long-term survival of restorations in treated children. Nevertheless, longer follow-up is needed to translate these findings into clinical recommendations and the results of the ongoing 36-month follow-up are awaited. Amalgam has traditionally been used for pediatric restorations, but since the Minamata Convention in 2013, the use of mercury in dental restorations has been discouraged [39]. This agreement, supported by the International Association for Dental Research (IADR), the World Dental Federation (FDI), World Health Organization (WHO) and the World Dental Industry (WDI), to promote oral health to make restorative approaches less needed and find alternatives to dental amalgam due to mercury's toxicity and environmental impact [40].

As a result, dental education and research now emphasize health-promoting, preventive approaches to reduce the burden of oral diseases. High-viscosity glass ionomer cement has gained widespread acceptance as it aligns with the principles of minimally invasive dentistry and can be used in both private and public practice. Furthermore, this material exhibits mechanical, optical and fluoride-releasing properties that make it well-suited for such clinical applications [41-44]. In this study, the durability of HVGIC restorations in primary first and second molars with interproximal carious lesions represents the continuation of a clinical trial evaluating outcomes at 6, 12 and 24 months. [45]. To improve follow-up rates and evidence quality, it is suggested to track treated patients at their homes if they cannot be located at school.

Strength of Study

- Proximal retentive grooves appear to be a very promising option for the success of Class II restorations using the ART technique in primary teeth
- The encapsulated glass ionomer cement used in Class II ART restorations demonstrated high success rates, suggesting it is a viable treatment option for pediatric patients
- In terms of public health, the ART technique and encapsulated glass ionomer cement can be considered suitable due to their short working time and ease of application [11,46,47]

Conclusion

In conclusion, ART Class II restorations using encapsulated HVGIC with proximal retentions appear to be a promising option for managing dentine interproximal carious lesions, showing clinical performance and survival rates above the conventional ART approaches.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Financial Disclosure

None.

Ethical Statement

The project did not meet the definition of human subject research under the purview of the IRB according to federal regulations and therefore, was exempt.

Acknowledgment

None.

Author's Contribution

MFLN was the general coordinator of the multicenter study and gold standard clinical trainer of ART. Participated in generating the study protocol, wrote and reviewed the manuscript.
RSV coordinator of the study in Lima, Perú, wrote and reviewed the manuscript.
DZ main clinical operator, wrote and reviewed the manuscript

JD collaborate as second clinical operator
TC clinical assistant and collaborated to write the manuscript
EP and MH performed the control evaluations at 6, 12 and 24 months follow up.
JM did the statistical analysis.
All authors critically revised and approved the final manuscript.

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