

Survival analysis of ART restorations in primary molars of preschool children: 1 year follow-up

Análise de sobrevivência de restaurações ART em molares decíduos de crianças com idade pré-escolar: acompanhamento de 1 ano

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Resumo

Dentre as abordagens minimamente invasivas atualmente disponíveis, o tratamento restaurador atraumático (ART) demonstra resultados promissores tanto na dentadura decídua quanto permanente. **Objetivo:** Avaliar a sobrevivência de restaurações ART Classe I, em pré-escolares, com duas marcas brasileiras de cimentos de ionômeros de vidro (CIV) em comparação com um CIV de referência. **Material e método:** Cavidades de 49 crianças pré-escolares (três a cinco anos de idade) com lesões cáries nos dentes posteriores (N = 81) foram preenchidas por dois odontopediatras experientes, de acordo com a técnica ART. Os CIV brasileiros Maxxion-R (MR) e Vitro-Fil LC (VF) e o CIV de referência, Ketac-Molar (KM), foram inseridos em uma sequência pré-estabelecida aleatoriamente. As restaurações foram avaliadas após 6 e 12 meses por outro pesquisador. As pontuações 0 e 1 foram consideradas bem-sucedidas, enquanto as pontuações 3-9 foram classificadas como falhas. Foram aplicadas a análise de sobrevivência de Kaplan-Meier e o teste log-rank ($p < 0,05$). **Resultado:** Não foram observadas diferenças estatisticamente significativas nas taxas de sobrevivência dos CIV testados após 12 meses. **Conclusão:** O desempenho clínico dos CIV brasileiros MR e VF, observado após 12 meses, sugere que estes podem ser uma alternativa para restaurações ART Classe I para proteger a esfoliação natural dos dentes decíduos. No entanto, até que sejam realizados estudos adicionais envolvendo um maior número de restaurações e períodos de acompanhamento mais longos, os CIV de referência, como o KM, devem continuar sendo o material de escolha para as restaurações ART.

Descritores: Tratamento restaurador dental sem trauma; cimentos de ionômeros de vidro; ensaio clínico.

Abstract

Among the minimally invasive approaches available today, the atraumatic restorative treatment (ART) has demonstrated promising results both in the primary and permanent dentition. **Objective:** To evaluate the survival of Class I ART restorations in preschoolers with two Brazilian brands of glass ionomer cements (GIC) in comparison with a reference GIC. **Material and method:** The cavities of 49 preschool children (three to five years) with carious lesions in the posterior teeth (N=81) were filled by two experienced pediatric dentists according to the ART technique. The Brazilian GICs Maxxion-R (MR) and Vitro-Fil LC (VF), and the reference GIC Ketac-Molar (KM) were placed in a randomly pre-established sequence. Restorations were evaluated after 6 and 12 months by another investigator. Scores 0 and 1 were considered successful, while scores 3-9 were classified as failures. Kaplan-Meier survival analysis and the log-rank test were performed ($p < 0.05$). **Result:** No statistically significant differences in survival rates of the tested GIC were observed after 12 months. **Conclusion:** The clinical performance the low-cost Brazilian GICs MR and VF observed after 12 months suggests that they may be an alternative for Class I ART restorations to safeguard the natural exfoliation of primary teeth. However, until further studies involving a larger number of restorations and longer follow-up periods are conducted, reference GIC such as KM should continue to be the material of choice for ART restorations.

Descriptors: Dental atraumatic restorative treatment; glass ionomer cements; clinical trial.



INTRODUCTION

Tooth decay is one of the most prevalent chronic diseases in the world, and according to the latest epidemiological survey conducted in Brazil (Ministry of Health, 2010), children under five years old have a DMFT of 2.43, with the decayed component accounting for over 80% of the index. During the last decade, new approaches to the treatment of dental caries have been developed. The current knowledge on the progression of caries sustains its management with emphasis on the control of biofilm and sugar intake, and the use less invasive restorative techniques¹⁻³.

Among the minimally invasive approaches available today, the atraumatic restorative treatment (ART) has demonstrated promising results both in the primary^{4,5}, and permanent dentition^{6,7}. The ART has been more commonly applied in rural areas far from big cities in developing countries as part of public health programs⁸⁻¹⁰. The goal of ART is to stop the progression of the disease, with minimal intervention and maximum preservation of the dental tissues¹¹. Its application in pediatric dentistry could, therefore, represent an important step forward in controlling disease, particularly in small age children affected by early caries¹². The ART approach has the potential to prevent that decayed teeth are extracted and to safeguard the natural exfoliation of primary teeth without discomfort for the child. However, to ensure that the ART is successful, it is of fundamental importance that the restorative material used has an adequate performance.

High-viscosity glass ionomer cements (GICs) have been the materials of choice for ART restorations mainly because of its properties, such as chemical bond to enamel and dentin and the release and uptake of fluoride. Specially designed for ART, the high-viscosity GICs have a relatively slow curing and improved mechanical properties compared to low and medium viscosity cements, which has resulted in increased survival of restorations¹³. Recent systematic reviews have shown that the longevity of ART restorations with high-viscosity GICs is similar to the gold standard treatment with amalgam^{12,14-16}.

The cost/benefit of using a particular GIC in public dental services is an important factor to be considered in the decision making and planning of collective actions. The cost of the more resistant high-viscosity GICs recommended by literature¹⁶ is approximately three times higher than similar GICs manufactured in Brazil. This price difference has a large impact on the development and expansion of oral health to poorer populations at high risk of caries. However, choosing a lower cost GIC may also have an important impact on the long-term outcome of restorations, which must be carefully investigated¹³.

Therefore, the aim of this study was to evaluate the survival of Class I ART restorations in preschool children (three to five years) with two low-cost Brazilian brands of glass ionomer cements in comparison with a high-viscosity reference GIC over a period of 12 months.

MATERIAL AND METHOD

This prospective clinical study was approved by the Ethics Committee at Pontifical Catholic University of Curitiba, Brazil (CAAE: 06257212.8.1001.0100) in accordance with the recommendations of

the Brazilian National Health Council Resolution No. CNS 466/12. Signed informed consents were obtained from parents/guardians of each participating child. The study was conducted in two Early Learning Centers (ELCs) in the municipality of Sarandi, and in three ELCs in the municipality of Marialva, Paraná State, Brazil.

Participants

Healthy children aged three to five years who presented Class I carious lesions were selected to participate in the study. Children who presented teeth with pulp involvement, pain, and dental development defects affecting several teeth were excluded from the study.

Initial Evaluation

After supervised toothbrushing, clinical examinations were performed in all the children in the ELCs by a trained clinician in accordance with to the criteria established by the International Caries Detection and Assessment System (ICDAS)¹⁷. Teeth with scores four to six on the occlusal surface were selected to be included in the study, while those with values lower than four were treated non-invasively. Children who had very extensive and/or deep caries or pulp involvement were referred to the nearest basic dental health care unit.

Restorative Procedure

In a second moment, the children included in the study were scheduled for treatment in their own schools. Children were organized in alphabetical order and taken to a room offered by the CEMEI for the restorative procedure. A mattress was placed on a table, on which the child stayed in the supine position. All procedures were performed under ambient light.

The cavities were prepared and restored by two operators (one in each city) with experience in treating children, and trained according to the ART method¹¹. Removal of the carious dentin was performed only with sharp hand instruments. When the cavity was too small for the curette to remove the carious dentin, an ART Cavity Opener instrument (SSWhite, Rio de Janeiro, Brazil) was used in a circular motion to remove the unsupported enamel and increase access. Only the softened contaminated dentin was carefully removed from the cavity with a curette towards the dentin-enamel junction in a circular motion around the cavity, leaving the pulp chamber ceiling to the end. Moisture control was performed with relative isolation with cotton rolls. All cavities were pre-treated with polyacrylic acid for 10 seconds in an active manner, which were then cleaned with water and dried with cotton rolls.

The restorations were carried out using three different commercially available brands of GICs, which were placed according a pre-established sequential randomization: 1- Maxxion-R/FGM (MR); 2- Ketac Molar/3M-ESPE (KM); 3- Vitro Fil-LC/Nova DFL (VF). In the case of children with more than one cavity to be restored, restorations started from the left to right of the mandible and then from left to right of the maxilla, successively.

An assistant was responsible for manipulating the GIC in accordance with the instructions of each manufacturer, and

transfer the mixture to the operator for its insertion. The GIC was inserted into the cavity with a conventional instrument followed by pressure with a finger lubricated with vaseline for 1 minute. In the case of the resin-modified Vitro Fil LC, the GIC was light cured for 20 seconds. The children were instructed to avoid solid food for at least an hour.

Survival Assessment

The restorations were assessed at 6 and 12 months by a third investigator, blind to the treatments, according to criteria for ART restorations proposed by Frencken et al.¹¹.

Statistical Analysis

The ART restorations with scores 0 and 1 were considered “successful”, while scores 2 to 9 were classified as “failure”. Kaplan-Meier survival analysis was conducted in the censored data to evaluate the rhythm in which the failures occurred in different materials studied¹⁸. In this study, data were analyzed in two moments, at 6 and 12 months. The difference between the survival curves was determined by the Mantel-Haenszel log-rank test. Analyses were performed using the R statistical software¹⁹.

RESULT

A total of 270 children between 3-5 years of age were examined, and 51 children (86 teeth) met the inclusion criteria for the study. Three children, two in the city of Marialva and one in the city of Sarandi, were not available for the final evaluation (12 months) and were excluded from the analysis. Thus, a total of 48 children (81 teeth) were evaluated, resulting in a recall rate of 94% in the final evaluation. Among the studied teeth, 28 were restored with KM, 28 with MR, and 25 with VF (Figure 1).

The vast majority of ART restorations presented scores 0 and 1, while those classified as failures obtained scores of 2 to 5. No restorations received score 6 or higher (Table 1). The survival rate of the materials used in the assessment performed at 12 months was 82.1% for KM, 72.0% for VF and 64.3% for MR (Table 2).

Figure 2 shows the survival curves with censored data for the three different materials. The survival of the materials decreased along the observation time. The GICs MR and VF had a lower survival rate as compared to KM, especially at the end of the observation period at 12 months. However, the log-rank test indicated no significant differences between the survival curves for the studied materials (P<0.05).

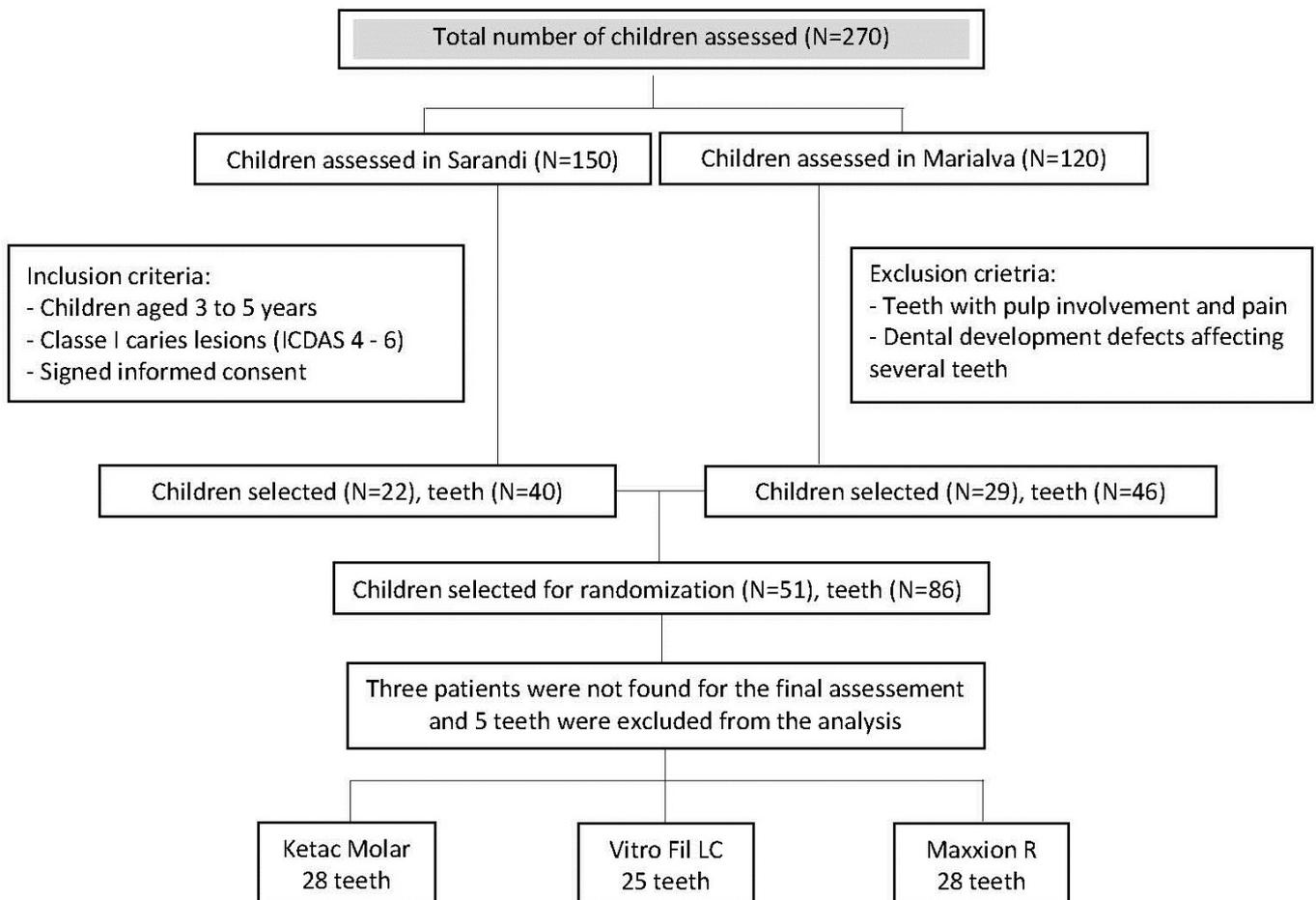


Figure 1. Flow chart illustrating the screening of participating children.

Table 1. Number (%) of ART restorations after 12 months, according to the scoring criteria by Frencken et al.¹¹

GIC*	Scores						Total
	0 (%)	1 (%)	2 (%)	3 (%)	4 (%)	5 (%)	
KM	20 (71.43)	4 (14.29)	1 (3.57)	2 (7.14)	1 (3.57)	0	28
VF	15 (60.00)	3 (12.00)	2 (8.00)	1 (4.00)	2 (8.00)	2 (8.00)	25
MR	15 (53.57)	3 (10.71)	1 (3.57)	3 (10.71)	4 (14.28)	2 (7.14)	28
Total	50 (61.72)	10 (12.34)	4 (4.93)	6 (7.41)	7 (8.64)	4 (4.93)	81

*GIC: Glass ionomer cement; KM: Ketac Molar; VF: VitroFil; MR: MaxxionR.

Table 2. Survival Analysis of the ART restorations

GIC*	Time (months)	At risk	Events	Survival	Standard deviation	IC (95%)	
						Inferior	Superior
KM	6	28	4	0.857	0.0661	0.737	0.997
	12	24	1	0.821	0.0724	0.691	0.976
MR	6	28	6	0.786	0.0775	0.648	0.953
	12	22	4	0.643	0.0906	0.488	0.847
VF	6	25	6	0.760	0.0854	0.610	0.947
	12	19	1	0.720	0.0898	0.564	0.919

*GIC: Glass ionomer cement; KM: Ketac Molar; VF: VitroFil; MR: MaxxionR.

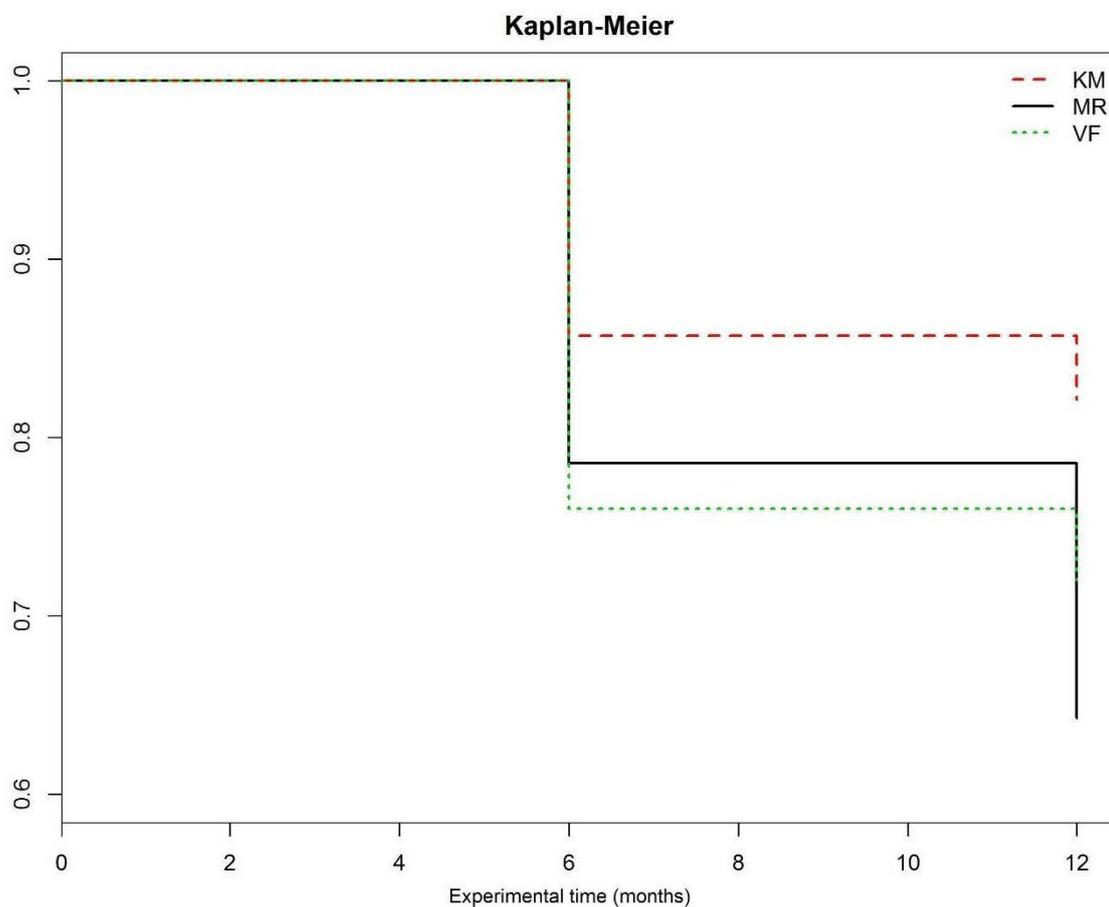


Figure 2. Survival curves for the three glass ionomer cements tested. Log-rank, $P < 0.05$.

DISCUSSION

This study evaluated the survival of class I ART restorations in the primary molars of young children (three to five years) with three different brands of GICs during a 12-month period.

No statistically significant differences in survival rates among the three GICs tested one year after placement of ART restorations were found. Our results corroborate those found by Bonifácio et al.²⁰, who also reported similar survival rates among the low-cost Brazilian GIC MR and another reference GIC (Fuji IX) after three years. However, unlike the present study, the authors evaluated proximal class II restorations in primary teeth of children between 5 and 8 years.

The main advantage of the Brazilian brands tested in this study over the reference GIC is their cost (<25%). However, in a recent review article, Frencken et al.¹³, warned on the risks involved in using low-cost GICs, which can, according to the authors, result in poor restorations even when the cavity is suitably cleaned and prepared according to ART standards. *In vitro* studies have shown that the Brazilian high-viscosity GIC MR presents, in general, inferior physical and mechanical properties in comparison with the reference GICs²¹⁻²³. In a study conducted by Bonifácio et al.²², MR performed well in tests of strength, with no statistically significant differences in flexural strength compared to KM²². Shintome et al.²¹, demonstrated the microhardness values obtained by a reference GIC (Fuji IX) were statistically superior to MR at all times tested, but the authors also demonstrated that the hardness of GICs increased over time. Another study demonstrated that adherence to both the enamel and dentin of the GIC KM was statistically superior to that of MR²². Therefore, care must be exercised before Brazilian high-viscosity GIC brands such as the MR may be considered.

The resin-modified GICs such as VF were developed to increase resistance and to enable the direct occlusal contact with the restorative material or on the edge or cavity, particularly when cavities are large. In this study, the survival rate found for the restorations with VF was 72% after 12 months. A similar result was found by Faccin et al.²⁴, who obtained a survival rate of 85% between 12 and 24 months. The authors concluded that ART restorations with a resin-modified cement is a suitable treatment option for the dental office²⁴. The difference in the survival rates found between the two studies may be explained by different reasons. In the study above, the authors used a reference resin-modified GIC (Vitremer 3M / ESPE), which cost considerably more than the Brazilian equivalent (VitroFil LC). Different operating environments may also have an influence on the results. The resin modified GICs require more controlled isolation, since the contamination by moisture can negatively influence its physical properties. Finally, resin-modified GICs do not permit digital pressure and thus flow and adhesion may have been compromised. Although ART has been developed for areas without access to electricity²⁵, battery-powered light curing equipment are now available, making VF a viable alternative in poor communities in developing countries.

The success of ART restorations is dependent on several factors such as material, operator and technique¹⁴. The most common failures resulting from these factors are related to material wear, complete loss of the material and the associated decay on the edge of the cavity¹². Thus, care was exercised in order to minimize any possible lack of control during the restorative treatment. The handling of materials was always conducted by one operator, different from the one

responsible for the restoration, who was trained in the preparation of each material according to the instructions of each manufacturer. All restorations were performed by two clinicians with extensive experience in dealing with young children, and properly trained in the ART technique. The clinician, in turn, had no control over the choice of the GIC, irrespective of the cavity to be restored, thereby avoiding possible selection bias.

An interesting observation related to this study was the number of failures observed. Despite the lack of statistical differences in survival rates of the materials, it was observed that for all materials studied, the higher number of failures occurred in the period between the restoration and the first 6 months, indicating that in this study the ART restorations tended to fail earlier after insertion of the restorations. It is known that the post-restoration consumption of food with "hard consistency" may negatively influence the longevity of ART treatments²⁶. The patients in our study were instructed not to eat for an hour after the procedure was performed, but there was no way we could supervise them, and given the young age of the patients enrolled in our investigation, we can not guarantee that the instructions were strictly followed. *In vitro* studies showed that the hardness of the high viscosity GICs tends to increase²¹, while wear tends to decrease over time²⁶. Thus, a more strict control of postoperative food ingestion could have influenced the results positively, increasing the survival rates.

One important limitation of this study concerns the relatively small number of cavities restored and the short-term follow-up. A larger number of children and longer follow-up periods might have resulted in significant differences between the GICs tested. By observing the survival curves (Figure 2), it would be expected that the restorations with GICs MR and VF might not adequately survive in the long-term, which could jeopardize the survival of the tooth. However, since the ultimate objective is to preserve the tooth until its exfoliation, many restorations considered "failures" in this study (scores 2 to 5) could be repaired, extending the longevity of the restoration. Thus, new studies involving a larger number of restorations, as well as longer follow-up periods, are required to demonstrate that the Brazilian brands of GIC are suitable to maintain the primary dentition in the long term.

CONCLUSION

Based on the survival rate results of ART restorations after 1 year, we can conclude that:

- There were no significant differences in survival between the reference GIC KM and the low-cost Brazilian GICs VF and MR;
- However, until further studies involving a larger number of restorations and longer follow-up periods are performed, reference GICs such as KM should continue to be the GICs of choice.

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CONFLICTS OF INTERESTS

The authors declare no conflicts of interest.

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