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Low-cost GICs reduce survival rate in occlusal ART restorations in primary molars after one year: A RCT

Isabel Cristina Olegário[a], Anna Luisa de Brito Pacheco[a], Mariana Pinheiro de Araújo[a], Nathalia de Miranda Ladewig[a], Clarissa Calil Bonifácio[b], José Carlos Pettorossi Imparato[a], Daniela Prócida Raggio[a,*]

[a] Orthodontics and Pediatric Dentistry Department, Dental School, University of São Paulo, São Paulo, Brazil
[b] Department of Cariology, Endodontology and Pedodontology, Academic Centre for Dentistry Amsterdam (ACTA), Amsterdam, The Netherlands

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ABSTRACT

Introduction: The high costs of the worldwide recommended GICs might be a barrier for the implementation of ART. To overcome this problem, low cost GIC are used even though there is a lack of evidence for the survival rate of restorations.
Objectives: To evaluate the performance of low-cost GICs used on occlusal ART restorations after one year.
Methods: A total of 150 primary molars in 150 children with occlusal caries lesions were selected in 4–8 year-old children. The patients were randomly allocated in three groups: G1–GC Gold Label 9 (GC Corp); G2–Vitro Molar (DFL) and G3–Maxxion R (FGM). All treatments were performed following the ART premises in school setting. Restorations were evaluated after 2, 6 and 12 months. Restoration survival was evaluated using Kaplan-Meier survival analysis and Log-rank test and Cox regression was used for testing association with clinical factors ($\alpha = 5\%$).
Results: GC Gold Label 9 had better performance compared to the low-cost GICs (HR = 1.47, CI = 1.04–2.08, $p = 0.027$). The overall SR of restorations was 65.33% and the SR per group was G1 = 77.55%; G2 = 61.11% and G3 = 42.55%.
Conclusions: The low-cost GICs have a poorer performance than GC Gold Label 9 in occlusal ART restoration in primary molars.

1. Introduction

Dental caries remains the most common oral condition, mainly in socioeconomic underprivileged populations [1]. In the primary dentition, untreated caries is the 10-most prevalent health condition, affecting 9% of the world population [2]. Concurrently, the WHO considers dental caries as the fourth most expensive chronic disease to treat [3]. In Brazil, the prevalence of untreated dental caries in primary teeth is high and, following a world pattern, it is mainly associated with low socioeconomic status [4].

A low-cost alternative to manage dental caries in deprived areas is the Atraumatic Restorative Treatment (ART) [5]. The high viscous glass ionomer cement is the material of choice for ART [6] since it has good biocompatibility, favorable setting time, as well as the release of fluoride and chemical bond with enamel and dentin [7–10]. Despite these characteristics, the relatively high cost of these materials compromise their use, either in public health or private practice in low-income populations.

In order to overcome this problem, low-cost Brazilian brands of glass ionomer cements were developed. Although these materials are not high viscous glass ionomer cements (powder:liquid ≤3.6:1) [11], they are recommended by manufacturers for ART. Brazilian brands such as Maxxion R (FGM, Joinville, BR) and Vitro Molar (DFL, Rio de Janeiro, BR) have the advantage of costing respectively 25% and 70% of the price of worldwide available brands, such as GC Gold Label 9 (GC Corp, Saint Paul, MN, USA) and Ketac Molar (3M/ESPE). Maxxion R was earlier investigated as a restorative material to be used with the ART approach in occluso-proximal cavities [12]. Vitro Molar, on the other hand, has some laboratory studies investigating its properties [12–16], but there are still no well designed clinical trials investigating its longevity as a restorative material. These materials are both commonly used in low-income communities, not only in Brazil, but also in the other

* Corresponding author at: Faculdade de Odontologia da Universidade de São Paulo, Av. Lineu Prestes, Zip Code 05508-000, 2227, São Paulo–SP, Brazil.
E-mail address: danielar@usp.br (D.P. Raggio).

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countries of Latin-America, and yet there is no evidence regarding their use for ART restorations in occlusal surfaces. Therefore, the aim of this study was to evaluate one year survival rate of occlusal ART restorations in primary molars using three different brands of glass ionomer cements (GC Gold Label 9 – GC Corp, Vitro Molar – DFL and Maxxion R – FGM).

2. Materials and methods

The present protocol was written following the guidelines of CONSORT (Consolidated Standards of Reporting Trials).

2.1. Trial design

This is a three-arm parallel randomized clinical trial which is registered at Clinical Trials website (NCT02377297).

2.2. Sample size and selection

This research was approved by the Research Ethics Committee of the Faculty of Dentistry, University of São Paulo (number: 569123).

The sample size was calculated according to log-rank test in the survival analysis, considering a minimum difference of 20% between the tested materials. It was considered a probability of type I error of 5% and a power of 80%. Adding on 15% to predict possible loss-to-follow-up, we reached the number of 150 teeth. The experimental unit was the tooth, and only one tooth per patient was included in the study.

The selection was made after visual assessment of primary molars in public schools at the city of Barueri, São Paulo and, it was performed by 2 trained examiners in October 2014. To select the 150 children, dentists evaluated approximately 1200 children. All the children were instructed on oral health, particularly in relation to hygiene guidelines and sugar consumption.

2.3. Inclusion criteria

Children were selected according to the following criteria:

- Children aged between 4 and 8 years;
- Good behavior and good health conditions;
- With possibility of following-up for at least one year;
- Whose parents have accepted and signed the consent form;
- At least one primary molar with occlusal dentin caries lesion accessible to hand instruments;
- Absence of fistula or abscess near the tooth, no painful symptoms reported, no pulp exposure and no mobility.

2.4. Operators

The operators were two undergraduate students from the last semester of the dental school. The operators received first a theoretical approach regarding the ART precepts [5], followed by laboratory training in how to prepare, insert the material in to the cavity and finish the restoration. Additionally, two trial weeks were included to give the operators the opportunity to familiarize themselves with the local conditions before the start of the operative phase. During these try-out weeks the operators were supervised by ICO. The operators were assisted by a local dentist and an assistant, who were previously trained on how to mix the GICs according to the manufacturers' protocol.

2.5. Blinding (masking)

The children were randomly assigned into three groups: GC Gold Label 9, Vitro Molar or Maxxion R.

The randomization process was designed in blocks of different sizes generated by the website sealedenvelope.com. We used sealed, sequentially numbered, opaque envelopes stratified by operator. These were opened by the dental assistant, in a different room from which the treatment was being carried out. The GIC was then mixed and taken to the operator for the restoration of the cavity, to ensure the blinding of the operators and patients, and also assure allocation concealment.

As all the GIC used in this study have similar color, consistency and application form, it was possible to blind the operator, the patient and the evaluator.

2.6. Treatment procedure

The children were treated during the school period in public schools at the city of Barueri-SP. The treatments were performed on school tables, in empty classrooms at schools and without dental facilities.

The clinical approach followed the ART guidelines proposed by Frencken and Holmgren [5]. No local anesthesia was used during treatment. The plaque was removed and an enamel hatchet was used to access underlying softened dentine when necessary. Infected carious dentin was removed with hand instruments. Conditioning of the cavity was done with the liquid from the respective material (10–15 s), followed by rinsing with water and drying with cotton pellets. Moisture control was done with cotton rolls.

The cavities were restored with one of the three GIC brands: GC Gold Label 9 (GC Europe, Leuven BE), Vitro Molar (DFL) and Maxxion R (FGM, Joinville, BR). The GICs were hand mixed according to the manufacturers' instructions (powder/liquid ratio 1:1) by a dental assistant and inserted into the cavity with a #1 spatula. A thin layer of petroleum jelly was rubbed over the index finger and the restoration was pressed for 20 s.

After adjusting the occlusion, a new layer of petroleum jelly was applied to the GIC restoration. The amount of GIC used, treated tooth, cavity size, caries experience (dmft/DMFT), occlusal contact and possible contamination (saliva/blood) were recorded and noted in individual forms. The duration of the restorative procedure was also recorded. After the restoration procedure was finished, the children were instructed not to eat for at least one hour.

All the other treatments needs, that could not be performed inside the schools, such as endodontic treatment and extractions, were referred to public health centers and performed by the dentists from Barueri city.

2.7. Evaluation

The primary outcome of this study was the longevity of occlusal restorations, which were evaluated after 2, 6 and 12 months according to the Roeleveld et al. criteria [17]. The scores are described in Table 1. The width and depth of the marginal defects, and excessive surface wear or lack of material were measured with the aid of a periodontal probe which had a ball-shaped tip of 0.5 mm in diameter.

A restoration was considered as 'failure' when there was a defect in the filling greater than 0.5 mm, when secondary caries was observed, when the restoration was not present or when the pulp was inflamed or the tooth was extracted (scores 11–40). We considered as success when the restoration was still present or a