Is it worth using low-cost glass ionomer cements for occlusal ART restorations in primary molars? 2-year survival and cost analysis of a Randomized clinical trial

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ABSTRACT

Objective: To evaluate the 2-year survival rate and the cost-effectiveness of Atraumatic Restorative Treatment (ART) using three different glass ionomer cements (GICs) for restoring occlusal dentin caries lesions in primary molars.

Methods: One hundred and fifty (150) 4-8-year-old children were selected, randomly allocated and treated in school tables according to the restorative material: Fuji IX Gold Label (GC Corp), Vitro Molar (nova DFL) and Maxxion R (FGM), the latter two being low-cost brands. Materials and professionals' costs were considered to analyse baseline total cost, and from this the cumulative cost of each treatment was calculated. Restoration assessments were performed after 2, 6, 12 and 24 months by an independent calibrated examiner. Restoration survival was estimated using Kaplan-Meier survival analysis and Cox regression was used to test association with clinical factors. Bootstrap regression (1,000 replications) compared material´s cost over time and Monte-Carlo simulation was used to build cost-effectiveness scatter plots.

Results: The overall survival rate of occlusal ART restorations after 2 years was 53% (Fuji IX = 72.7%; Vitro Molar = 46.5%; Maxxion R = 39.6%). Restorations performed with Vitro Molar and Maxxion R were more likely to fail when compared to Fuji IX. At baseline, Fuji IX was the more expensive option (p < 0.001), however, considering the simulation of accumulated cost caused by failures until 2-year evaluation, no difference was found between the groups.

Conclusions: After 2 years' follow up, restorations performed with Fuji IX proved to be superior in terms of survival, with a similar overall cost, when compared to low-cost glass ionomers cements (Vitro Molar and Maxxion R).

1. Introduction

Restorations in primary teeth are the most common procedures performed in paediatric dentistry [1] and the choice of the dental material and restorative technique are crucial to ensure restoration survival [2]. The need for an effective but low cost solution has increased demand for cost-effectiveness studies to evaluate the best economical intervention among those considered effective for the management of dental caries in children [3]. The cost-effectiveness analysis involves dividing the cost of an intervention in monetary units by the

expected health gain [4], which should be measured according to the variable of interest. The restorations' survival is the most frequently used outcome to describe the effectiveness of a dental restorative treatment [5].

The Atraumatic Restorative Treatment (ART) technique has been widely used for restoring primary and permanent teeth, becoming the treatment of choice in paediatric dentistry [6,7]. ART involves exclusive use of hand instruments, with reduced need for dental anaesthesia and no use of rotary instruments, allowing widespread implementation of the technique from dental offices to field conditions

[8]. However, the high costs of the recommended glass ionomer cements (GIC) for ART may be a barrier to its implementation. To overcome this problem, low cost GIC are commonly used [9].

A number of studies have been performed recently evaluating the cost-effectiveness on dental restorations [10,11], and some had demonstrated the economic advantage of ART over conventional treatment in both primary and permanent dentition [12–14]. However, none of them analysed the variability of GIC brands and powder-liquid ratio within these results in terms of their influence on the restorations' survival rate [9]. In addition, there is a lack of studies evaluating the long-term cost-effectiveness of GIC for ART restorations in primary teeth [15]. Thus, the aim of this study was to perform a survival rate evaluation and cost-analysis of ART restorations at 2 years, using three different GIC materials for occlusal dentin caries lesions in primary molars.

2. Materials and Methods

This manuscript was written following the guidelines recommended by the Consolidated Standards of Reporting Trials (CONSORT) and according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Statement. Both CONSORT and CHEERS checklists are available as supplementary materials.

2.1. Study Design and ethical consideration

This is a double-blind (participant and evaluator), randomized, three-arm (1:1:1 allocation) clinical trial. The preliminary 1 year survival results of this trial have already been published [9].

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This research was approved by local Research Ethics Committee (protocol number 464.863). The trial protocol was registered on the clinical-trials.gov platform (NCT02377297).

2.2. Sample size calculation

The sample size was calculated based on the primary outcome of this trial (2-year survival of the restorations) using Stata 13.0 software (Stata Corp). The results reported by a metanalysis [6] of 93% survival rate of occlusal ART restorations using a high-viscosity glass ionomer cement, was used as reference for this sample size calculation. We considered a minimum difference of 20% between the tested materials, 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.

2.3. Eligibility criteria

All children were selected according to the following inclusion criteria: aged between 4 and 8 years old, and presence of at least one occlusal carious lesion in a primary molar without clinical signs or symptoms of pulp involvement. The exclusion criteria were I) children without good behaviour or good general health; II) for whom at least 2-year follow-up was not possible; III) whose parents or guardians had not read, accepted and/or signed the informed consent form.

If the child had more than one tooth that fit the inclusion criteria, a simple draw was made to know which tooth would be included. The selected occlusal cavities were then randomized according to the restorative material: Fuji IX Gold Label (GC Corp, Leuven, Belgium), Vitro Molar (Nova DFL, Rio de Janeiro, Brazil), or Maxxion R (FGM, Joinville, Brazil).

2.4. Randomization

The randomization list was generated through the website www. sealedenvelope.com in blocks of different sizes (3, 6 and 9) and stratified between two operators. To guarantee allocation concealment, the randomization was performed using opaque, sealed and sequentially numbered envelopes. In order to control selection bias, envelopes were opened by the Dental Assistant only once removal of carious dentin had been completed. Afterwards, the same Dental Assistant prepared the glass ionomer cement (GIC) in a different room from where the treatments were being performed. Only the ready-to-use material was delivered to the operator.

2.5. Restorative procedures

All procedures were performed in public schools of the municipality of Barueri (São Paulo, SP, Brazil) by two undergraduate dental students. Previously to the start of the study, the operators received a theoretical, laboratorial, and clinical training sections in how to perform selective caries removal using hand instruments and cavity restoration following the protocol proposed by Frencken and Holmgren [16].

Participants were placed on mattresses over school tables inside empty and previously sanitized classrooms to receive the restorative treatment. The operative field was backlit by portable lanterns and moisture control was obtained using cotton rolls. Selective caries removal was performed using hand instruments (ART cavity opener, enamel Hatchet and dentine excavators).

After cavity preparation, the cavity size (occlusal-cervical; buccal-lingual; mesial-distal) was measured using a periodontal probe. The cavity was then conditioned using the liquid from the respective material (10–15 s), followed by rinsing with water and drying with cotton pellets. The cavities were then restored with one of the three GIC brands: Fuji IX Gold Label (GC Europe, Leuven BE), Vitro Molar (Nova DFL, Rio de Janeiro, BR) 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 material was held under pressure for 20 seconds, followed by removal of excess material using a large excavator. After adjusting the occlusion, a new layer of petroleum jelly was applied to the GIC restoration.

For each participant, their information along with the clinical characteristics of the caries lesion were recorded in their clinical record. In order to calculate the cavity volume, we multiplied the measurements obtained and classified the results into two categories of cavity volume: $\leq 9.9 \, mm^3$ and $\geq 10 \, mm^3$ [17]. Other variables such as jaw (upper or lower), sex (male or female), and caries experience (WHO Criteria – DMFT/dmft) [18] were also collected. Caries experience were categorized based on the average caries index for 4 to 8-year-old children (DMFT + dmft $\leq$ 3 or > 3) as reported by the SB Brazil National Survey of 2010 [19].

The time spent in each restorative session was recorded by an assistant researcher from the moment the participant laid down on the school table until the restoration was finished (last layer of petroleum jelly applied), in order to calculate treatment duration and cost.

2.6. Evaluation of restorations

As all evaluations were conducted in the schools, in order to avoid loss to follow-up, all parents/caregivers were contacted by phone by the school´s principal one day before the clinical evaluation. The restorations were evaluated after 2, 6, 12 and 24 months by an independent, trained, calibrated and blind examiner using the criteria described by Roeleveld et al. [20]. The scores 00 or 10 were considered as success, while scores 11, 12, 13, 20, 21, 30, 40 or 50 were considered as failure of the restoration. The remaining scores 60, 70 or 90 were not

considered as success or failure (censored data for survival analysis). The width and depth of marginal defects, superficial wear and excess or lack of material were evaluated using a ballpoint probe and portable lantern.

2.7. Economical and Survival Analysis

For cost analysis, only direct costs were considered based on previous publication [21] adjusted to the Brazilian context, and under the payer perspective. The study adopted a public health program perspective and sought to provide information on the material choice and its effects on treatment survival and costs over time. The total cost comprised two components: professional and material costs. All costs were measured in Brazilian reais (R$) and converted to US Dollars (US$).

To calculate the professional cost, the procedure time was multiplied by the average income of a dentist (US$ 12.97/h) and a dental assistant (US$ 7.41/h) following the Brazilian Federal Law 3991/61. Material cost was determined using the average values obtained from three different providers of dental supplies (last updated in March 2019). For countable products, the average price was divided by the number of items in each package. For uncountable materials, an estimation was done based on their output which was further divided by the average value of each package. Accommodation costs and municipal taxes were not considered. No discount rates were applied.

If the dental restoration failed, we estimated the cost for repairs according to the type of failure (Table 1). Only one failure per restoration was considered for the analysis.

The data collected were tabulated in Excel. For descriptive and statistical analysis of the data, the STATA/SE 13.0 Software was used. The chi-square test was performed to evaluate whether the distribution among the variables analysed were equal among groups of restorative materials. The level of significance was set as 5%.

Kaplan-Meier survival analysis and log rank test were used to verify restoration survival rate after 2 years (primary outcome). In order to evaluate the association between outcome and participant characteristics, Cox Regression analysis was performed. All independent variables that reached a p value below 0.20 in the univariate Cox Regression were taken to the adjusted analysis.

In order to evaluate the secondary outcome (treatment cost), the mean professional and material costs were calculated to describe the cost components of each treatment. Due to the skewness of data distribution, the total cost of each strategy was compared using bootstrap regression analysis. This approach estimates the model with bootstrap errors under the assumption of independent errors which are analogous to the robust standard errors of linear regression [22]. Bootstrap replications were set as 1,000 and a fixed seed was determined.

In addition, a Bayesian approach was adopted to explore the uncertainties of the cost-effectiveness analysis. In this approach, health effects and costs are described by statistical distributions that better fits the data and their variability using XLSTAT 2018 (Addinsoft SARL, Paris, France). Based on the adjusted distributions, a Monte-Carlo simulation was performed to calculate the variables ΔT (incremental survival time) and ΔC (incremental cost), representing the difference, in months, between the survival time rate of restorations using Fuji IX and Vitro Molar ($T_{FUJI} - T_{VM}$) or Maxxion R ($T_{FUJI} - T_{MR}$), and the difference between the treatment costs (($C_{FUJI} - C_{VM}$) or ($C_{FUJI} - C_{MR}$)). The

number of simulations was set at 10,000. During each interaction, the variables ΔT and ΔC were computed using XLSTAT 2018. Summary descriptive statistics for both variables were evaluated to verify their quality. Finally, the values of ΔT and ΔC were plotted in two cost-effectiveness plans (scatter plots). To analyse the uncertainties about these variables, the percentage of dots in each quadrant of the plane was assessed visually.

3. Results

Patients were recruited in October 2014, and restorative treatments were performed between October and December of the same year. Follow-up evaluations started after 2 months of the restorations' placement, and it was finished after 24 months. The inter- and intra-examiner coefficients (Kappa) were 0.89 and 0.92, respectively.

Around 1,200 children aged 4 to 8 years old were evaluated throughout 27 public schools in the city of Barueri (São Paulo, Brazil). From those, 150 children fulfilled the inclusion criteria and were included in the study. The main reasons for non-inclusion were the absence of occlusal cavities eligible for the study, lack of signed informed consent form, and uncooperative child behaviour during the first clinical examination. The CONSORT flowchart for clinical trials is shown in Fig. 1, with detailed information regarding the number of participants at baseline and after 2, 6, 12 and 24 months of follow-up. Even if the child was evaluated only once (either at 2, 6, 12 or 24 months), it was included in the statistical analysis. This was possible because the Cox regression and the survival analyses take into account the time to evaluate the failure or success of the restoration within that specific period.

The distribution between groups of materials among the variables analysed (sex, jaw, operator, cavity volume and caries experience) are described in Table 2. No statistically significant relationship between any of these variables was found in relation to the restorations' survival rate (p > 0.05).

After 24 months of evaluation, the survival rate per group was 72.7% for Fuji IX, 46.5% for Vitro Molar and 39.6% for Maxxion R (Table 3). The Kaplan-Meier survival analysis of all three restorative materials tested can be seen in Fig. 2, demonstrating the best performance for Fuji IX when compared to Vitro Molar (HR = 1.99; CI = 1.01-3.89) and Maxxion (HR = 2.24; CI = 1.15-4.39). Most of the restoration failures (n = 46, 58.7%) referred to score 30 of the evaluation criteria (absence of restorative material, restoration fracture or partial loss). The distribution of failure scores per restorative material is described in Table 4. Restorations performed with Vitro Molar and Maxxion R were more likely to fail after 24 months when compared to Fuji IX. There were no differences between the survival rates of Maxxion R and Vitro Molar (HR = 1.12, CI = 0.65-1.95, p = 0.668).

The mean time spent completing each occlusal restoration was 10.24 minutes (SD = 2.81). No difference was found among groups (Fuji IX: 11.10 minutes; Vitro Molar: 9.70 minutes; Maxxion R = 9.94 minutes).

Regarding restoration costs, the professional component was the most expressive proportion, representing more than 65% of the treatment cost in all three groups (Fig. 3). At baseline, Fuji IX was the more expensive option, requiring an investment of US$ 4.68 per restoration placed (Table 5). However, when considering the simulation of cost repairs after failures during the 2-years follow-up, no difference was found among groups (Table 5). The prospected mean and the bootstrap regression analysis evaluating the treatments cost over time is illustrated in Fig. 4.

The cost-effectiveness plan confirmed the lower effectiveness pattern of Vitro Molar (ΔC = -1.615, ΔT = -4.668) and Maxxion R (ΔC = -3.073, ΔT = -5.235) in occlusal restorations compared to Fuji IX (Figs. 4 and 5 respectively); around 80% of the dots were distributed between quadrants I and IV in both plots. On the other hand, it was not possible to confirm the cost advantages among GICs, since visually the
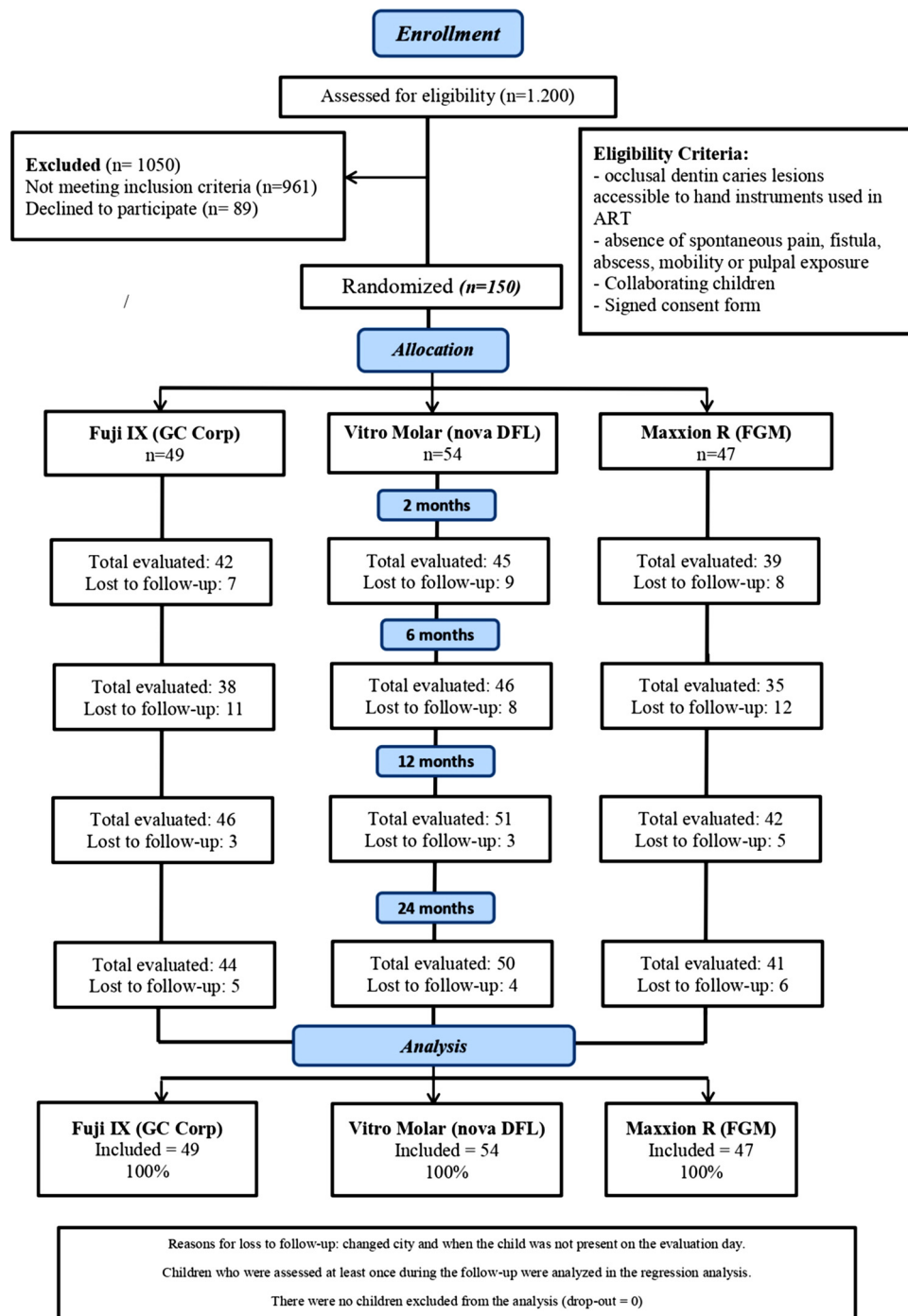
Table 1
Costs repairs according to the types of failure and initial cost (IC)

Clinical evaluation	Scores	Cost of repair	Final cost
Success	00 or 10	None	1 x IC
Minor failure	11, 12, 13, 20 or 21	Half of IC	1.5 x IC
Major failures	30	Full IC	2.0 x IC

Fig. 1. Consort Flow Diagram.

dots were equally distributed between upper and lower quadrants.

4. Discussion

The present study intended to investigate the survival rate of three brands of GIC as well as estimate the cost of a restoration over time, through a cost-effectiveness analysis of ART restorations in occlusal cavities of primary molars. Thus, we compared one of the most widely used GIC, Fuji IX, with two other low-cost GIC used in Brazil and Latin America – Vitro Molar and Maxxion R.

The most common problem in clinical trials is loss of follow-up. It may be noted that the drop-out rate of our study was extremely low. This is due to the environment in which this study was conducted

(schools), thus allowing the evaluator to seek information regarding children. Each school was notified by e-mail about each participant evaluation day in order to ensure that the child would not be absent on the day of the assessment. If the participant was absent at evaluation, a second day of evaluation was performed.

The cost-effectiveness of ART restorations has already been presented in the literature for restorations in elderly patients [13] and with a proposal to replace amalgam with ART in the primary teeth of a population at high risk of caries [14]. However, none of these studies considered the variability of GIC brands and powder-liquid ratio in either survival or cost analysis.

The cost of high viscosity GIC brands, such as Fuji IX, may influence dentists' or health care managers' choice in both private practice and

Table 2
Descriptive analysis of the independent variables by restorative material (Fuji IX, Vitro Molar and Maxxion R) in occlusal cavities.

Variables	Fuji IX n (%)	Vitro Molar n (%)	Maxxion R n (%)	Total n	p-value Chi-square
Operator					
1	28 (39.44)	18 (25.35)	25 (35.21)	71	
2	20 (25.64)	36 (46.15)	22 (28.21)	78	0.061
Caries Experience (DMFT/dmft)					
≤3	20 (37.74)	17 (32.08)	16 (30.19)	53	
>3	29 (29.90)	37 (38.14)	31 (31.96)	97	0.598
Jaw					
Upper	25 (34.25)	26 (35.62)	22 (30.14)	73	
Lower	24 (31.17)	28 (36.36)	25 (32.47)	77	0.914
Side					
Right	24 (29.63)	35 (43.21)	22 (27.16)	81	
Left	25 (36.23)	19 (27.54)	25 (36.23)	69	0.134
Sex					
Female	22 (28.95)	25 (32.89)	29 (38.16)	76	
Male	27 (36.49)	29 (39.19)	18 (24.32)	74	0.187
Volume					
≤ 9.9 mm^3	48 (34.29)	48 (34.29)	44 (31.43)	140	
≥10 mm^3	1 (10.00)	6 (60.00)	3 (30.00)	10	0.182
Total	**49 (32.67)**	**54 (36.00)**	**47 (31.33)**	**150**	

public health centres, since the price of the material is often the main criteria considered instead of long-term cost-effectiveness. The 2-year survival analysis followed the previously published results of 1 year follow up [23], showing a better performance of Fuji IX over both materials. The cost-effectiveness analysis should be considered, instead of just considering the initial price. When we say "low cost", we mean that the initial price is reduced compared to Fuji IX. In the end, it is important to emphasize that initial lower price does not mean an overall lower cost over time, as we could observe many restoration failures in 2 years. In addition, it is important to highlight that only one failure was considered per treatment. If a survival analysis with multiple events was performed, wider difference between treatments may be found.

As all treatments were made during school class period, we did not consider the indirect costs which are related to out-of-pocket expenses of patients by using the service. Although the payer perspective was used in this study, variable overhead costs (electricity, instruments, and
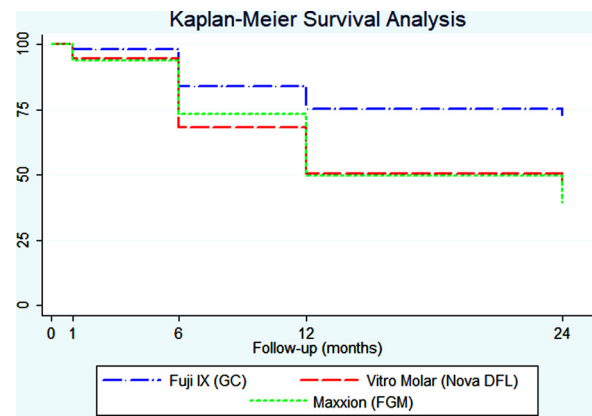

Fig. 2. Kaplan-Meier Survival Analysis graph (Log-rank p = 0.007).

Table 4
Descriptive analysis of the evaluation of the restorations after 2 years and distribution of the scores according to Roeleveld et al. (2006) by group of restorative material

Scores	Fuji IX n	Vitro Molar n	Maxxion R n	Total n	
00	31	20	15	66	**Success: 83**
10	5	6	6	17	
11	2	0	0	2	**Failure: 67**
12	4	6	4	14	
13	0	0	0	0	
20	0	0	0	0	
21	0	4	0	4	
30	7	18	21	46	
40	0	0	1	1	
50	0	0	0	0	
60	0	0	0	0	**Censored: 0**
70	0	0	0	0	
90	0	0	0	0	
Total	49	54	47	150	-

equipment depreciation) were not included in the cost analysis because treatments were performed in a field setting (schools). Discounts were also not applied, despite being a long-term study evaluation, because it
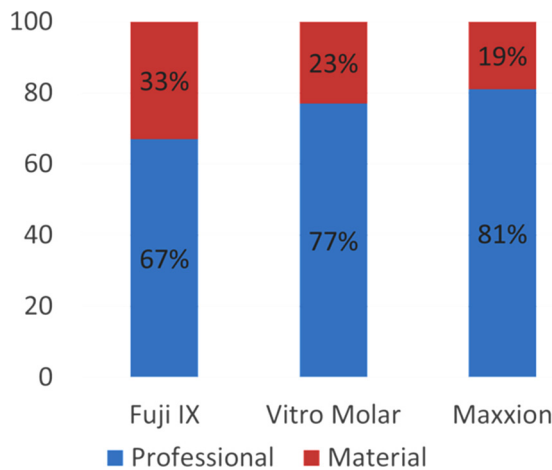
Table 3
Univariate and Adjusted Cox Regression Analyses between Occlusal Restoration Failures and Associated Factors

Variable	Survival %	SE	HR Univariated † 95% CI ‡	p-value	HR Adjusted† 95% CI ‡	p-value
Restorative material						
Fuji IX (ref)	72.74%	0.06				
Vitro Molar	46.47%	0.07	2.23 (1.15-4.31)	0.017*	1.99 (1.01-3.89)	0.045*
Maxxion R	39.60%	0.08	2.45 (1.26-4.78)	0.008*	2.24 (1.15-4.39)	0.018*
Operator						
1 (ref)	56.20%	0.06	1.28 (0.79-2.08)	0.314	-	-
2	49.33%	0.06				
Caries experience						
1-3	52.32%	0.07				
>3	53.47%	0.05	1.04 (0.63-1.71)	0.885	-	-
Jaw						
Superior (ref)	59.25%	0.06	1.41 (0.87-2.30)	0.162	1.35 (0.83-2.21)	0.226
Inferior	47.38%	0.06				
Side						
Right (ref)	47.50%	0.06	0.72 (0.44-1.18)	0.198	0.74 (0.45-1.21)	0.239
Left	59.90%	0.06				
Sex						
Female (ref)	42.09%	0.06	0.56 (0.33-0.91)	0.020*	0.62 (0.37-1.04)	0.069
Male	64.42%	0.05				
Volume						
≤ 9.9 mm^3 (ref)	55.10%	0.04				
≥10 mm^3	22.22%	0.13	2.15 (0.98-4.72)	0.057	1.46 (0.64-3.31)	0.365
TOTAL	**53.07%**	**0.04**				

HR = Hazard ratio; CI = confidence interval; SE = standard error * $p < 0.05$, 95% CI

Fig. 3. Graph of the distribution of the components of the total cost by material.

Table 5
Evaluation of the cost between materials over time using Bootstrap regression analysis (1000 repeats).

	Prospected mean U$ Dollar (SD)	Coefficient (SD)	p-value	95% Confidence Interval
Baseline Total Cost				
Fuji IX (ref)	4.66 (0.13)			
Vitro Molar	3.65 (0.11)	−0.69 (0.18)	< 0.001*	−1.07 to -0.32
Maxxion R	3.37 (0.08)	−0.92 (0.22)	< 0.001*	−1.37 to -0.46
6-months Total Cost				
Fuji IX (ref)	5.32 (0.28)			
Vitro Molar	4.63(0.29)	−1.2 (0.26)	< 0.001*	−1.72 to -0.68
Maxxion R	4.17 (0.26)	−0.69 (0.26)	0.011*	−1.22 to -0.16
1 year Total Cost				
Fuji IX (ref)	5.84 (0.38)			
Vitro Molar	5.18 (0.31)	−0.01 (0.62)	0.988	−1.23 to 1.21
Maxxion R	4.73 (0.26)	−0.34 (0.45)	0.456	−1.24 to 0.56
2 years Total Cost				
Fuji IX (ref)	5.88 (0.38)			
Vitro Molar	5.25 (0.30)	0.41(0.62)	0.490	−1.32 to 0.63
Maxxion R	4.84 (0.26)	−0.34 (0.49)	0.504	−0.81 to 1.63
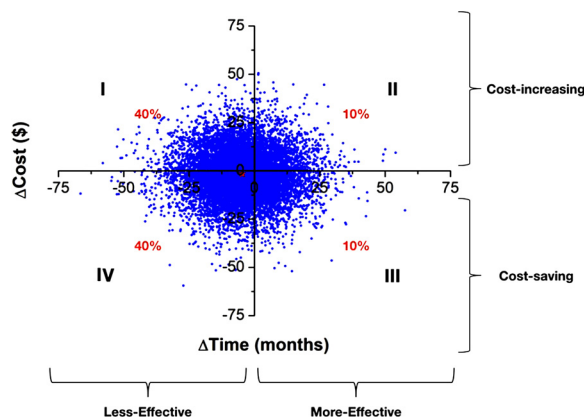
Fig. 4. Cost-effectiveness plan for Vitro Molar related to the reference material Fuji IX.

was possible to update all values throughout the study completion. Thus, only direct costs comprising professional and material costs were assessed.

The most significant cost component was the professional cost, which is directly related to the time spent completing each treatment. However, as the restorative technique used was the same for the three groups, there was no time difference among them and, consequently,
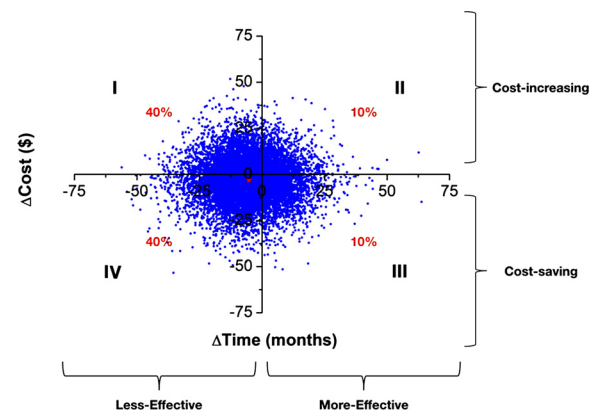

Fig. 5. Cost-effectiveness plan for Maxxion R related to the reference material Fuji IX.
Footnote Fig. 4 and 5:
Median value is represented as a red cross in the CE plan. The estimated percentage of sample distribution in each quadrant are described in red.

the material cost was determinant in the difference of baseline costs. When considering the failures and the cost of repairs, the difference between the groups lost significance from the 6 months of follow-up and lasted up to 24 months. It is important to note that the cost of the repairs was estimated (study limitation), since they were not performed as part of the present research. These values are probably underestimated, since only one repair was predicted for each failure.

The Monte-Carlo simulation, which made a projection for a larger statistical sample (10,000 simulations), allowed the evaluation of treatment cost-effectiveness even though it was designed as an efficacy study. In countries where the budget for purchasing material and human resources is restricted for either public health or private practice, selecting the material that offers the best balance between effectiveness and financial resources becomes crucial [3]. To better visualize the cost-effectiveness, CE plans were plotted. Although the survival results have a wider external validity, the cost analysis was based on a Brazilian reality (materials and professional costs).

Although Fuji IX presented higher initial cost when compared to Vitro Molar and Maxxion R, this difference was no longer perceived after 24 months' evaluation due to the expected repair needs among restorations placed with low-cost GIC materials. The cost-effectiveness plan confirms those findings by showing a dominant pattern of Fuji IX regarding effectiveness but a similar cost trend among groups.

5. Conclusion

After 2 years' follow up, restorations performed with Fuji IX proved to be superior in terms of survival, with a similar overall cost, when compared to low-cost glass ionomers cements (Vitro Molar and Maxxion R), being the most cost-effective option for treating occlusal restorations in primary molars using ART technique.

CRediT authorship contribution statement

Isabel Cristina Olegário: Conceptualization, Data curation, Formal

Declaration of Competing Interest

All authors declare that they have no conflict of interest.

Acknowledgments

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