2-year survival and cost analysis of occlusoproximal ART restorations using encapsulated glass ionomer cement in primary molars: a randomized clinical trial

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Abstract

Background

Encapsulated glass ionomer cement is a promising option for atraumatic restorative treatment due to its potential to minimize the operator factor. This study aimed to compare two encapsulated glass ionomer cements, Equia Forte (GC Corp) and Riva Self Cure (SDI), in terms of their survival rates and costs for restoring occluso-proximal cavities in primary molars. The study was conducted in the city of Tietê, Brazil, and followed up with children over a period of 24 months.

Methods

Children aged 4–8 years with occlusal-proximal dentin carious lesions in primary molars were randomly assigned to receive either Equia Forte (EF) or Riva Self Cure (RSC). The primary outcome was 24-month restoration survival, analyzed using Kaplan-Meier survival analysis, Cox regression, and intention-to-treat (ITT) analysis. Secondary outcomes included a 24-month restoration cost analysis using Monte-Carlo simulation. Treatment was performed by two trained final-year students in a school setting, and one trained and calibrated examiner evaluated the restorations after 2, 6, 12, 18, and 24 months.

Results

A total of 152 children (76 in EF group and 76 in RSC group) were included in the study, and 135 (88.8%) were followed up at 24 months. There was no significant difference in the primary outcome between the two groups, with an overall restoration survival rate of 39% (45% in EF and 32% in RSC). However, there was a significant difference in the estimated incremental cost between the two groups, with RSC being more cost-effective from the Brazilian perspective (EF cost: $25.48, RSC cost: $19.30, incremental cost: US$6.18).

Conclusion

After two years of follow-up, Riva Self Cure showed comparable restoration survival to Equia Forte, while being more cost-effective from the Brazilian perspective. Encapsulated glass ionomer cements are a viable option for atraumatic restorative treatment, and their cost-effectiveness should be considered when selecting a material for such treatments.

Trial Registration

This randomized clinical trial was registered on ClinicalTrials.Gov - NCT02730000 (06/04/2016)

Introduction

Atraumatic Restorative Treatment (ART) is an innovative and minimally invasive approach for managing dental caries [1]. It is a patient-friendly treatment that requires no electricity, running water, or aerosol-

generating procedures, and can be provided outside of dental offices with similar effectiveness as in clinical settings [2, 3].

Glass ionomer cement (GIC) has become the most commonly used material for ART due to its chemical, biological, and physical properties [4]. However, dosing and hand mixing may increase the risk of error during material preparation, and operator skill is a significant factor in restoration survival rates [2].

To reduce this risk, encapsulated dental cement has been introduced as an option for ART and has gained popularity among dentists [5]. Encapsulated GICs are pre-proportioned in a powder/liquid ratio defined by the manufacturer and mechanically mixed, eliminating the operator's influence on the functional properties of the material, which is the primary advantage of this type of glass ionomer cement [5].

Randomized clinical studies have shown similar survival rates between encapsulated and hand-mixed GICs [6, 7], and laboratory studies have demonstrated that encapsulated GICs produce specimens with lower porosity and higher mechanical strength than hand-mixed specimens [8–11]. Despite the variety of encapsulated glass ionomer cements available, more evidence is needed to determine the best-suited material for ART restorations in dual-surface cavities, and cost-effectiveness data is currently lacking.

The cost-effectiveness of ART depends on the initial treatment cost, as well as the costs incurred during regular maintenance follow-up and the expenses associated with retreatment if the restoration fails [12]. Additionally, the restoration's effectiveness is reflected in the survival of the tooth [12]. In this study, we compare the cost-effectiveness of two types of encapsulated glass ionomer cements, Equia Forte and Riva Self Cure (which is cheaper in the Brazilian context), for the treatment of cavitated carious lesions in primary molars. We base our analysis on data from a 24-month follow-up randomized clinical trial to determine whether one material is non-inferior to the other.

Materials and Methods

This manuscrls (CONSORT) [13].

Study Design and ethical consideration

This is a double-blind (participant and outcome assessor), randomized, non-inferiority, two-arm (1:1 allocation) clinical trial. The study was registered on ClinicalTrials.gov (NCT02730000–06/04/2016) and ethically approved by the Research Ethics Committee of the University of São Paulo School of Dentistry (protocol number 1.608.416). Participants could only be included in the study after their parents/guardians gave written consent for their children to participate. Eligible children were asked to accept or decline participation using an assent form as their willingness to participate in the study.

Sample size calculation

The sample size was based on the primary outcome - survival of encapsulated glass ionomer cement restoration in occlusoproximal cavities in primary molars. The sample size estimation was performed on the website https://www.sealedenvelope.com. A non-inferiority limit of 20% and a survival rate reported by Ersin et al., 2006 [14] for occlusoproximal ART restoration of 76% after 2 years was assumed for estimation. Considering a significance level of 5%, a power of 80%, and considering 20% for potential loss, we achieved a minimum sample size of 136 children. Only one tooth was included per child.

Randomization

The allocation sequence was generated electronically through a website (http://www.randomization.com/) with permuted block sizes (4, 6, and 8), and stratified by caries experience. The information was sealed in opaque envelopes and numbered sequentially.

Randomization was at the participant level, with children allocated to Equia Forte - Gc Corp (EF - Control Group) or Riva Self Cure (RSC - Experimental Group). An independent dentist generated the allocation sequence, and eligible children were randomly allocated to the treatment groups. The envelope containing the proposed treatment was sequentially selected by the dentist and opened only when the child was ready to undergo treatment by one of the operators.

Blinding

The blinding of the operators was not possible, because both capsules were different and it was possible to distinguish between them. However, the children, parents and outcome assessor were blinded by the appearance of the restoration with glass ionomer cement of both capsules being similar.

Eligibility criteria

Children aged 4 to 8 years attending public schools in the city of Tietê, Brazil, were screened and invited to participate in this study if they presented:

- at least one occluso-proximal caries lesion in dentin on a deciduous molar without signs or symptoms of pulpal involvement;
- generally cooperative behavior that could be managed by the operators in the school environment;
- no existing medical conditions.

Children who were considered eligible for the study were included only after the parents/guardians sent the signed informed consent form agreeing to their child's participation in the study, and the child's written consent. We included only one tooth per child, and all treatments were performed in public school classrooms. If the child needed additional treatment, they were referred to the nearest public oral health clinic.

Interventions

Children were seen during school hours in empty rooms, lying on a school table by two trained and calibrated dentists following the ART premises [15].

All restorations were performed with relative isolation of the operative field. The caries lesions were selectively removed with size-matched hand instruments. The cavity was then cleaned with a cotton-tipped ball soaked in water. The restorative protocol was the same for both materials:

- Conditioning the dentin with a drop of cavity conditioner (polyacrylic acid) and a microbrush for 10 seconds. following the guidelines of the manufacturer of their respective brand (Riva Conditioner and Equia Conditioner).
- Wash the cavity with three wet cotton balls, sequentially, and dry with three dry cotton balls, sequentially.
- Adaptation of the steel matrix strip to the proximal tooth cavity and kept in position with the aid of a wooden wedge.
- Mechanical manipulation of the glass ionomer cement with an amalgamator (Ultramat SDI).
- Application of the glass ionomer cement into the cavity with the aid of an applicator (SDI).
- Digital pressure with gloved and petroleum jelly finger.
- Removal of the excess with dental floss and manual instruments.
- Surface protection of the material with the appropriate brand-specific protector (Equia Forte - Equia Coat; Riva Self Cure - Riva Coat), light activation for 20 seconds.

Data such as the school the child belonged to, the period, full name, school history, date of birth, caries experience (DMFT), date of treatment, which operator treated the child, which material was used, the number of teeth treated as well as the tooth face, cavity size, plaque index, gingival health index, which materials were used for each restoration, and whether the treated tooth had an adjacent and an antagonist tooth were noted in the patient's file. All of this data was analyzed at each reevaluation.

The time spent on each restoration session was recorded by an assistant researcher from the time the participant lay on the school table until the restoration was completed in order to calculate the duration and cost of treatment.

All children were instructed not to consume solid foods for one hour after treatment.

Evaluation of restorations (primary outcome)

An independent, trained, calibrated, blinded examiner performed the reevaluation using the Roeleveld el al. [16] criterion after 2, 6, 12, and 24 months. Scores of 00 and 10 were considered success while scores of 11, 12, 13, 20, 21, 30 or 40 were considered failure. Scores of 50, 60, 70, or 90 were censored in the survival analysis. All recorded data were considered in individual clinical records for statistical analysis.

Cost Estimation (secondary outcome)

Costs for each group were estimated using a micro-cost approach, accounting for professional and material costs (payer perspective). All costs were measured in Real (R$) and converted into US dollars

(US$).

To calculate the professional cost, the session time was timed by a researcher (other than the operator) including return visits. Thus, the time spent in each session was converted into hours and multiplied by the average income of the dentist per hour (US$ 12.97) and of a dental assistant (US$ 7.41), according to the Brazilian Federal Law 3991/61 [17]. For uncountable products, an estimate was made based on their production and divided by the average value of each package. For countable materials, the number of items in each package was divided by the total price of the product. Costs such as housing and municipal taxes were not considered. No discount rates were applied. Only one failure per restoration was considered for analysis. All data was tabulated in Excel.

Statistical analysis

Analysis of the primary outcome (restorative survival) between groups was compared using a non-inferiority two-sample test for survival data using Cox Regression (non-inferiority hypothesis/alternative HR > 0.80; CI = 90%). Considering the proportion of treatment success at 2-year follow-up, an intention-to-treat analysis (using multiple imputations considering baseline variables) was conducted as a sensitivity analysis using the p-value non-inferiority test and confidence interval (CI = 95%). These analyses were performed using NCSS statistical software (NCSS 2021, USA)..

As a secondary analysis, a Cox regression analysis was performed to investigate the association of other independent variables and restoration failure (two-tailed p values were reported). Treatment survival was assessed using Kaplan-Meier survival analysis and the Log-rank test (α = 5%). Baseline and total 2-year incremental cost between groups were compared using linear regression analysis considering the child level, and Bootstrap replications were set to 1000 using Stata 13.0 software.

For the cost-effectiveness analysis a Monte-Carlo simulation was performed according to the survival values of each material to calculate the variables ΔT (survival time) and ΔC (incremental cost), representing the difference in months between the survival time rate of restorations with Equia Forte and Riva Self Cure, and the difference between treatment costs. The number of simulations was set to 10,000, the variables ΔT and ΔC were computed using XLSTAT 2018. Finally, the values of ΔT and ΔC were plotted on two cost-effectiveness planes (scatter plots).

Results

A total of 1572 children between 4 and 8 years old were screened in 16 different public schools in the municipality of Tiete-SP in july 2018, and 152 were considered potentially eligible and invited to participate in the study. The children were randomly allocated with the help of a randomization list (76 to the Equia Forte group, and 76 to the Riva Self Cure group). Only one tooth was included per child. The CONSORT flow chart for clinical trials is shown in Fig. 1

Among the 152 children included in this study, the majority of the participants were boys (56%). In total, 65 molars were maxillary (43%) and 86 mandibular (57%). The main reason why children were not included was because they did not meet our eligibility criteria (n = 1420), while 43 children refused to

participate in the study. No children switched to the other group during the trial. More information about the basic characteristics of the participants is available in the additional file, and the descriptive analysis of the independent variables equivalent to the restorative material (Equia Forte and Riva Self Cure) are presented in Tables 1 and 2, respectively.

Table 1
Description of the restorative materials

Groups	Restorative Material	Composition	Expiry date / Batch
Experimental Capsule	**SDI** **Riva Self Cure®**	Fluoraluminosilicate glass (92 to 97%) Polyacrylic acid (3 a 8%)	2018-01 / B1510291F
Control Capsule	**GC CORP** **Equia Forte Fil®**	Fluoraluminosilicate glass (90 to 100%) Polyacrylic acid (5 a 10%)	2017-04 / 1504211

Table 2
– Descriptive analysis of the independent variables by restorative material (Equia Forte and Riva Self Cure).

Variables	Equia Forte n (%)	Riva Self Cure n (%)	p-value Chi-square	Stayed in n (%)	Dropped-out n (%)
Operator					
1	38 (50.67)	37 (49.33)		59 (78.67)	16 (21.33)
2	38 (49.35)	39 (50.65)	0.871	62 (80.52)	15 (19.48)
Caries Experience (DMFT/dmft)					
≤ 3	16 (38.10)	26 (61.90)		29 (69.05)	13 (30.95)
> 3	60 (54.55)	50 (45.45)	0.070	92 (83.64)	18 (16.36)
Jaw					
Upper	34 (52.31)	31 (47.69)		51 (78.46)	14 (21.54)
Lower	42 (48.28)	45 (51.72)	0.623	70 (80.46)	17 (19.54)
Age (years)					
3–5	18 (45.00)	22 (55.00)		28 (70)	12 (30)
> 5	58 (51.79)	54 (48.21)	0.461	93 (83.04)	19 (16.96)
Sex					
Female	37 (55.22)	30 (44.78)		50 (74.63)	17 (25.37)
Male	39 (45.88)	46 (54.12)	0.253	71 (83.53)	14 (16.47)
Volume					
≤ $10mm^3$	14 (46.67)	16 (53.33)		23 (76.67)	7 (23.33)
> $10mm^3$	62 (50.82)	60 (49.18)	0.684	98 (80.33)	24 (19.67)
Surface					
OM	28 (45.16)	34 (54.84)		48 (77.42)	14 (22.58)
OD	48 (53.33)	42 (46.67)	0.322	73 (81.11)	17 (18.89)
Total	76 (50)	76 (50)		121 (79.61)	31 (20.39)

Outcome evaluations

One hundred and twenty-one children (79%) had the study tooth evaluated after 24 months and 31 children (21%) were lost to follow-up. The survival after 2 years was Equia Forte 45% and Riva Self Cure 32% (log-rank p = 0.020). The alternative hypothesis of non-inferiority was accepted by both the Cox regression analysis and the intention-to-treat analysis (Equia Forte = 33%; Riva Self Cure = 30%; p = 0.002). The Kaplan-Maier survival plot, the primary outcome analysis using Cox non-inferiority regression and the ITT analysis can be found in Fig. 2 and Table 3, respectively.

Table 3
Primary outcome analysis (restoration survival) using non-inferiority Cox Regression and Intention-to-treat analyses.

Outcomes	EQUIA	RIVA	p-value
Primary outcome – Non-Inferiority Cox Regression analysis*			
% Survival	32%	45%	0.020*
HR (90% C.L. of HR)	1.25 (0.88–1.79)		
Primary outcome – Intention-to-treat analysis (2 years) **			
N success/N total	25/76	23/76	0.002*
% Success	32.9%	30.2%	
Absolute difference (95%CI)	0.026 (-0.12 to 0.173)		

HR = Hazard Ratio

Ha = non-inferiority at α = 5%

* 100(1–2α)% Confidence Interval and p-value for non-inferiority survival data (Wald test)

** p-values and 95% CI were derived by Miettinen and Nurminen's method using non-inferiority test for two proportions

The reason for the failure of the evaluation of the restorations was mainly related to fracture of the restoration (score 30), followed by the absence of the patient on the day of reevaluation (score 90). According to the univariate cox regression analyses, it can be seen that there was no statistical relationship between the independent variables (operator, caries experience, arch, age, gender, restoration volume and restored surface) and the survival of the restorations (Table 4).

Table 4
– Univariate Cox Regression Analyses between Restoration Failures and Associated Factors.

Variable	2-year Survival%	SE	HR Univariate † 95% CI ‡	p-value
Restorative material				
Equia Forte (ref)	44.98	0.06	1.31 (0.85–2.01)	0.215
Riva Self Cure	32.06	0.06		
Operator				
1 (ref)	37.81	0.06	0.98 (0.63–1.51)	0.929
2	39.83	0.06		
Caries Experience (DMFT/dmft)				
1–3	34.86	0.08	0.88 (0.55–1.42)	0.616
> 3	40.24	0.05		
Jaw				
Superior (ref)	41.50	0.07	1.08 (0.70–1.68)	0.707
Inferior	36.56	0.06		
Age (years)				
3–5	34.52	0.08	0.78 (0.48–1.26)	0.319
> 5	40.11	0.05		
Sex				
Female (ref)	45.99	0.07	1.12 (0.72–1.74)	0.597
Male	34.75	0.06		
Volume				
0–10 mm^3 (ref)	43.27	0.11	1.29 (0.73–2.29)	0.388
> 10mm^3	37.55	0.05		
Surface				
OM	39.13	0.07	1.09 (0.70–1.69)	0.688
OD	38.22	0.05		
TOTAL	38.73	0.04	-	

Variable	2-year Survival%	SE	HR Univariate † 95% CI ‡	p-value
Restorative material				

HR = Hazard ratio; CI = confidence interval; SE = standard error 95% CI

The cost-effectiveness evaluations of the restorations were performed at 2, 6, 12, 18 and 24 months by measuring the time spent on each procedure, including costs such as consumables and professionals. Statistical analysis for the association of costs and treatment of the variables collected was performed using the Bootstrap Regression test. An incremental value for failure (score 11 and 12) or replacement (score 20, 21 and 30) of the restorations was added, stipulated at 50% and 100% of the total cost, respectively.

Initially the cost of Riva Self Cure ($12.73) was lower compared to Equia Forte ($17.25), after 24 months the cost of Equia Forte continued to show a significant difference compared to Riva Self Cure ($p < 0.05$). It is possible to see the difference in the final cost of $6.18 over time when comparing Equia Forte to Riva Self Cure. Other differences such as amounts spent on treatment as well as reevaluations can be found in the Table 5.

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

	Prospected mean U$ Dollar (SD)	Coefficient (SD)	p-value	95% Confidence Interval
Baseline Total Cost				
Equia Forte (ref)	17.25 (4.14)			
Riva Self Cure	12.73 (3.49)	-4.51	< 0.001*	-5.70 to -3.32
6-months Total Cost				
Equia Forte (ref)	21.24 (10.63)			
Riva Self Cure	15.26 (6.13)	-6.08	< 0.001*	-8.81 to -3.34
1-year Total Cost				
Equia Forte (ref)	23.11 (11.32)			
Riva Self Cure	16.74 (7.27)	-6.37	< 0.001*	-9.38 to -3.36
18-months Total Cost				
Equia Forte (ref)	25.17 (11.06)			
Riva Self Cure	18.57 (7.73)	-6.60	< 0.001*	-9.59 to -3.61
2 years Total Cost				
Equia Forte (ref)	25.48 (11.72)			
Riva Self Cure	19.30 (8.17)	-6.17	< 0.001*	-9.45 to -2.90
SD = Standard Deviation; *p < 0.05 95% CI				

All cases that required treatment due to restoration failure were referred to a health center, as explained previously by the Consent Form, these costs were stipulated and increased for the calculation of each reassessment. During the 24 month reassessment, the cumulative costs impacted by the material used were Riva Self Cure $19.30 and Equia Forte $25.48 when compared to the initial cost. The cost-effectiveness plan confirmed the lower standard of effectiveness of Equia Forte when compared to Riva Self Cure in occlusoproximal restorations in deciduous teeth, and can be visualized in the scatter plot (Fig. 3).

Discussion

This study aimed to investigate the survival rate of two brands of encapsulated GIC, as well as to estimate the cost of a restoration over time through a cost-effectiveness analysis of ART restorations in occlusoproximal cavities of primary molars, and this is the first randomized clinical trial comparing the survival and cost of two encapsulated materials for occlusoproximal cavities in primary teeth.

The literature (2) indicates that the type of cavity and the factor of the operator are two variables that can influence the success rate of the ART technique. Therefore, the operators in this study were trained and used materials that were not dependent on operator manipulation so that this factor would not influence the success rate of ART. In an attempt to evaluate if there were any variables that could influence the survival outcome of both materials, information such as caries experience, operator, arch, age, gender, restoration volume and restored surface were collected. However, using Cox regression it was possible to analyze that the variables did not influence the survival of the restorations, since there was no statistical difference when analyzed together. Similarly, the children who did not present at the 24-month reevaluation also did not influence the final analysis, since the Cox regression adjusted the data generating values from the parameters of this study.

A recent systematic review proved by a meta-analysis that there is no difference in the success rate of the ART technique when performed in the field and in the clinic. This reaffirms the results of this randomized clinical trial conducted in schools. In addition, as a way to decrease a common problem with clinical trials, schools were notified of when evaluations would be performed, thus decreasing the chances of participants being lost to follow-up. (3) Besides, it is important to emphasize that the literature has already proven that the ART technique has established itself in dentistry with a longevity similar to that of conventional restorative treatment (18)

A comparative study of occlusal and occlusoproximal restorations using the ART technique with high-viscosity glass ionomer cement found a 15% success rate for occlusoproximal restorations, unlike our study that found a 39% success rate after 24 months of follow-up (19). This may be due to the different materials used, as the authors used manually manipulated glass ionomers, and we used encapsulated ones. The literature points to high success rates when using encapsulated materials, such as the one we used in our manuscript. Miletić et al (2020)(20) points to 93% success in their restorations using Equia Forte, while Freitas et al (2018)(7) achieved 76% success in ART restorations using Riva Self Cure, both encapsulated materials.

The study was conducted in a school setting, so general variable costs such as electricity, depreciation of equipment and instruments were not included, only direct costs such as professional costs and materials were evaluated, which may overestimate our cost since restorations were not repeated even when necessary. Also, since we estimated the final cost statistically, the final result may not truly represent the actual final cost. Our conclusions can be transferred to other healthcare systems as long as it is done sparingly and considering the context of the healthcare system applied. We also do not account for the costs of experimentation and implementation. However, these are likely to be limited, since ART is easy to

apply without specific equipment or a large amount of training. However, future studies should consider these costs. And these may be a limitation for this trial and the data analyzed.

The Monte-Carlo simulation, which performed a projection for a statistical sample of 10,000 simulations, allowed us to evaluate the cost-effectiveness of the treatment. In countries where the budget for human resources and material purchase are limited for both public and private health practices, selecting the material that offers the best balance between financial resource and effectiveness becomes crucial (21).

Although the survival results are more external in scope, the cost analysis was based on a Brazilian reality regarding professional and material cost. Although Equia Forte showed a higher initial cost when compared to Riva Self Cure and both materials showed no significant difference regarding survival, after 24 months of evaluation it was found that the cost of Equia Forte remained higher than Riva Self Cure. The cost-effectiveness then confirms the conclusion that the Riva Self Cure restorative material shows a dominant pattern with respect to cost, although survival is similar for both groups.

Conclusion

After 2 years of follow-up, the survival of Riva Self Cure was found to be non-inferior to Equia Forte. However, in terms of overall cost, Riva Self Cure proved to have a lower overall cost, making it the most cost-effective option for the treatment of occlusoproximal restorations in deciduous molars using the ART technique.

Declarations

Ethics approval and consent to participate

This research was previously approved by the Research Ethics Committee of the University of São Paulo School of Dentistry under protocol number 1,608,416. An informed consent was obtained from all parents and/or legal guardian for the child to be included in the study, as well as a signed consent form from the child. All methods were performed in accordance with the relevant guidelines and regulations.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analyzed during the current study are available to the public upon reasonable request to the corresponding author.

Competing interests

The authors declare that they do not have competing interests.

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Contribuitions

JRG was responsible for results interpretation, and drafted the manuscript. CSS, ICO, and MPA were involved in the trials' phases and data acquisition. ICO, and MMB performed the statistical analysis and helped in the data interpretation. DH, CCB, MMB, ICO and DPR was part of the study's design. JRG, CSS, ICO, and DPR was part of the data interpretation. DPR was the PI, responsible for the study design, and corrected the text. All authors reviewed the manuscript's final version.

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Figures

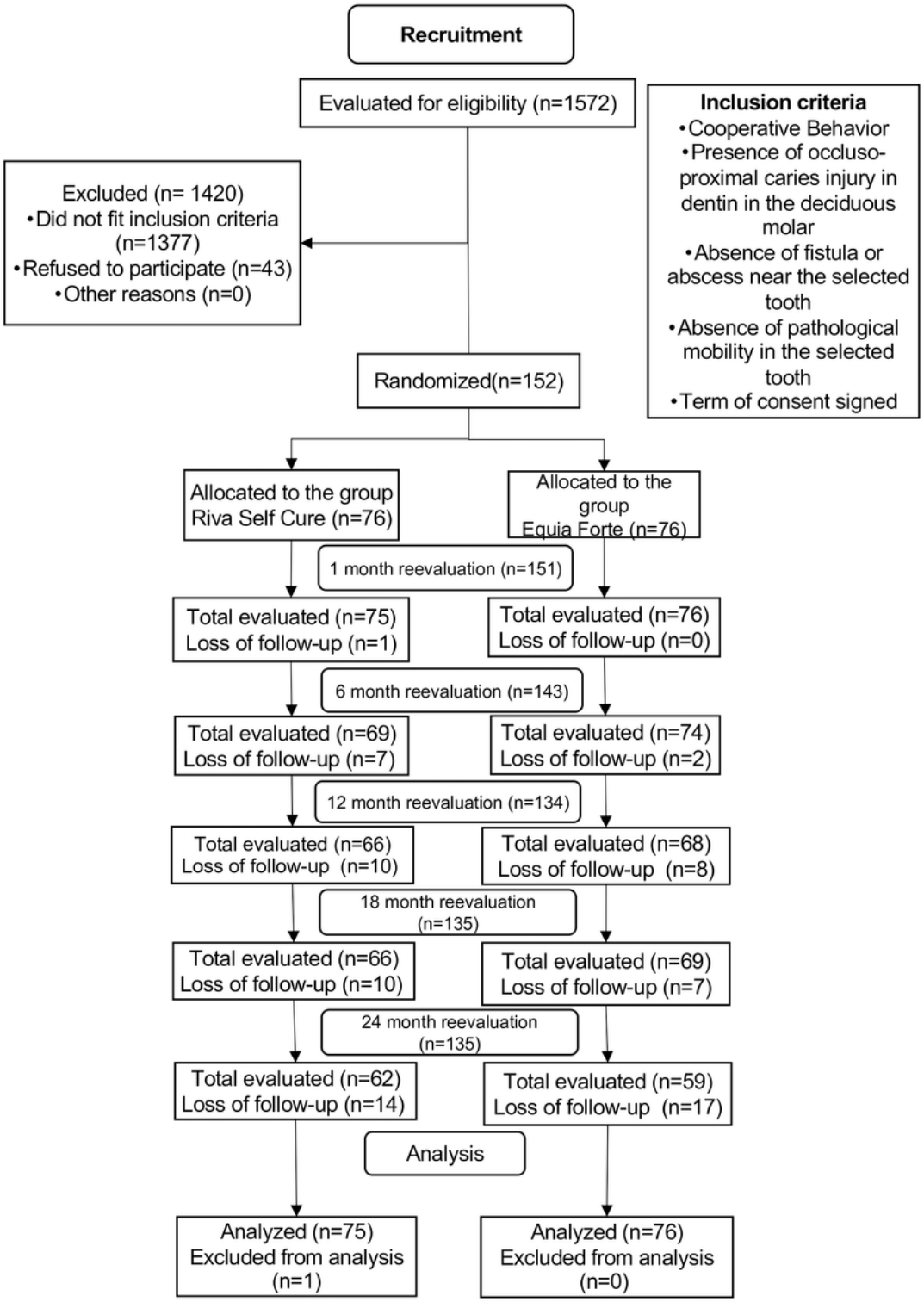

Figure 1

CONSORT flowchart for clinical trials

Reasons for loss of research follow-up: Transfer to another school in another state or city and/or absence on the day of reevaluation; *Inclusion in the analysis*: The research participant has come to at least one

evaluation; *Exclusion of the analysis*: The research participant is not present on the day of the reevaluation

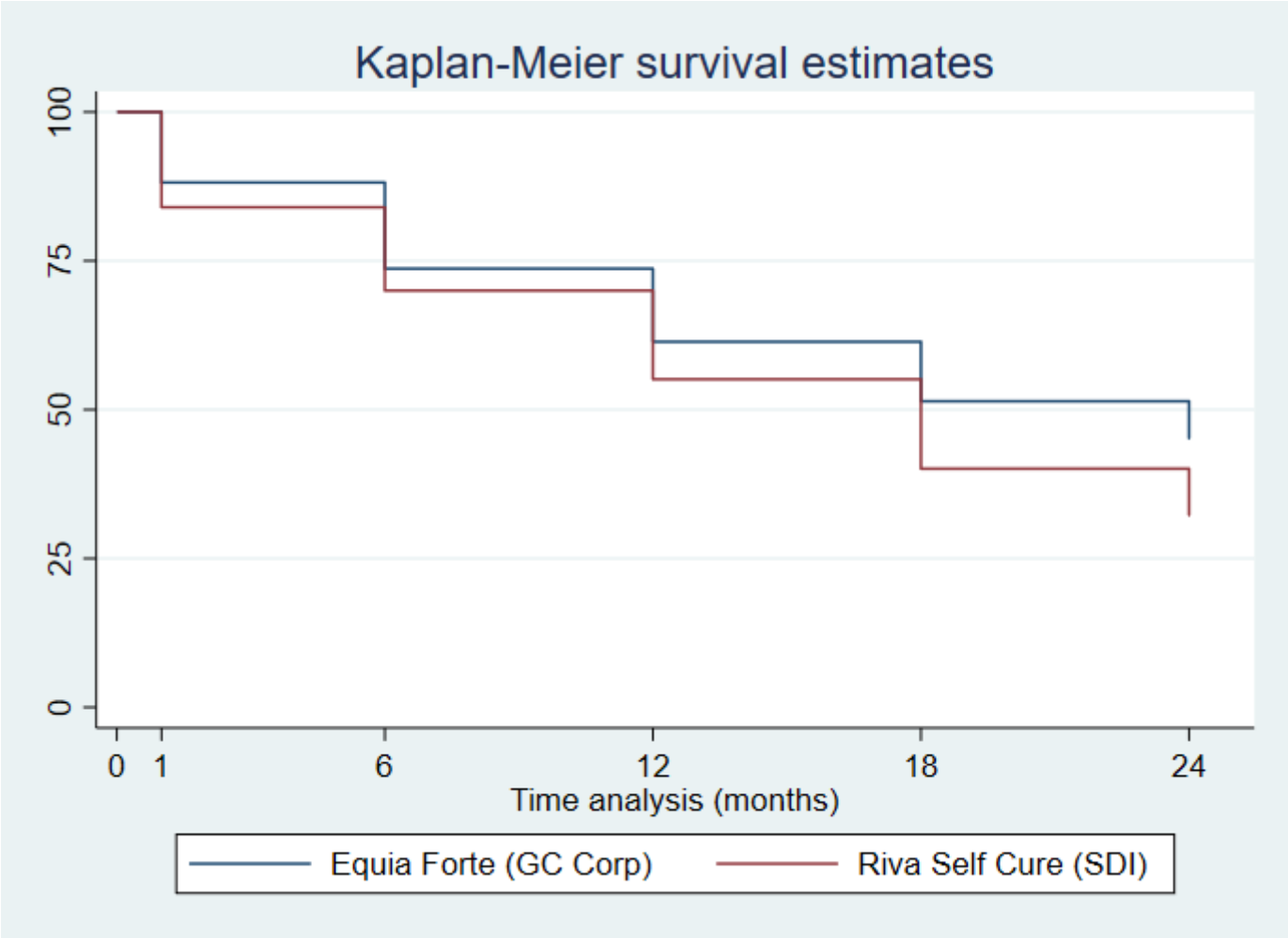

Figure 2

Kaplan-Maier Survival Analysis

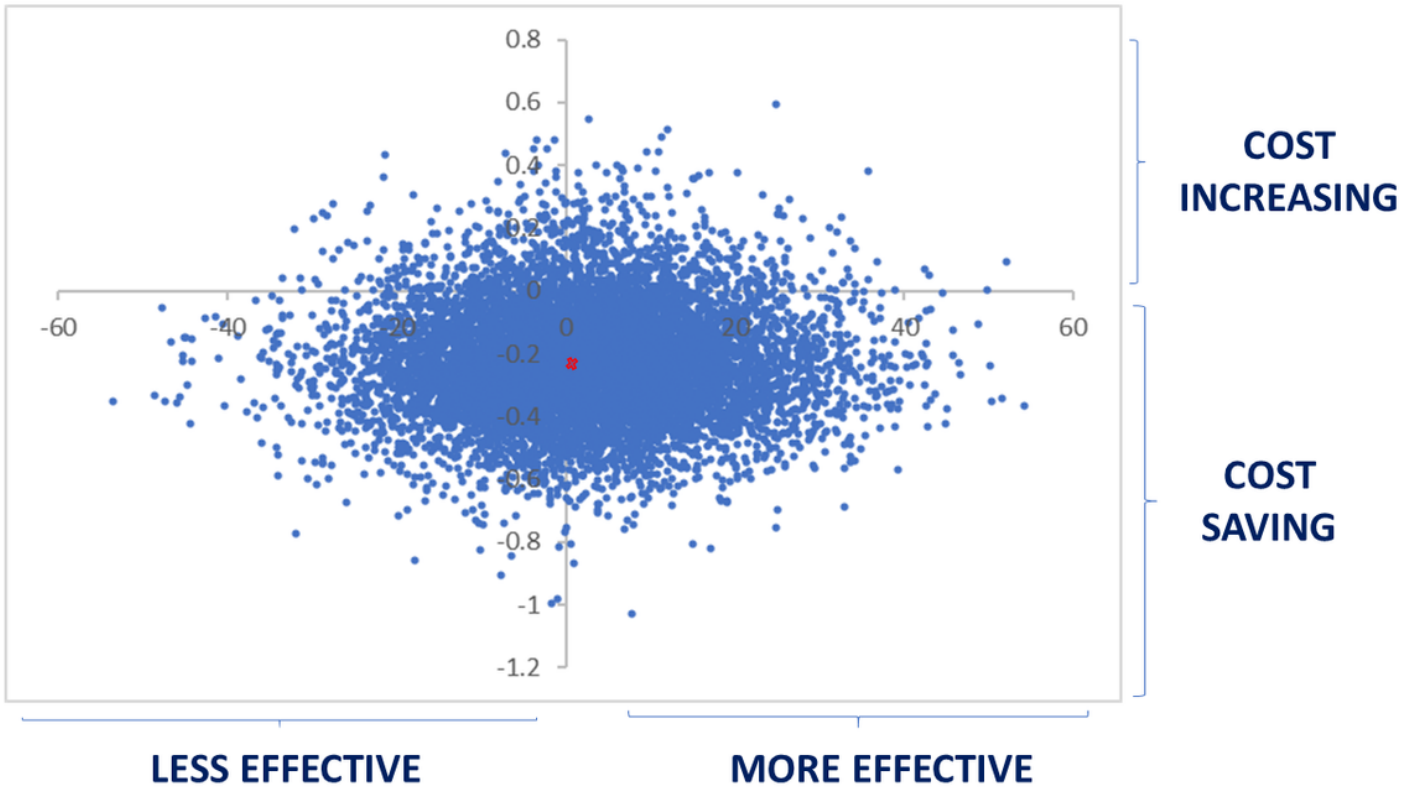

Figure 3

Riva Self Cure Cost Effectiveness Plan related to Equia Forte reference material