

**JHANDIRA DAIBELIS YAMPA VARGAS**

**Clinical performance of adhesive restorations in anterior primary teeth and its impact on economic aspects and children's oral health-related quality of life**

São Paulo

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**Clinical performance of adhesive restorations in anterior primary teeth and its impact on economic aspects and children's oral health-related quality of life**

**Corrected Version**

Dissertation presented to the Dental School, University of São Paulo, by the Graduate Program in Dental Sciences to obtain the degree of Master of Science.

Concentration Area: Pediatric Dentistry

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***I would like to dedicate this work to my beloved family***

*“To my Mom, who inspires me every day.” There is nothing in this world that is quite as strong and enduring as my love for you!*

*“To my Dad, who always encouraged me to pursue my dreams, thank you for your endless support.*

*“To Paola and Pablo, my siblings, as a sign that we can open our wings and fly as far as our dreams lead us, it only depends on ourselves*

***Dedico este trabajo, a mi querida familia, con todo cariño,  
para ustedes.***

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*Cuidado!... Alerta de portunhol, daqui para frente....*



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*“Todo parece imposible hasta que se hace” –  
Nelson Mandela.*



## ABSTRACT

Yampa-Vargas JD. Clinical performance of adhesive restorations in anterior primary teeth and its impact on economic aspects and children's oral health-related quality of life. [Dissertation]. São Paulo: University of São Paulo, Dental School; 2018. Corrected Version.

The soundness of anterior primary teeth can be affected by several factors. Consequently, aspects such as pain, sensitivity, chewing impairment, malocclusions, systemic complications and low self-esteem (due to aesthetic impairment) can aggravate the situation of children with these lesions. Restorative procedures emerge to restore the functionality and aesthetics of these teeth. However, the available literature does not provide sufficient information about the effectiveness, durability or cost-effectiveness of techniques and materials used to restore anterior primary teeth. The aim of this dissertation is to explore some of the aspects related to currently restorative approaches performed in anterior primary teeth. This is a retrospective study (historical cohorts), based on data from dental records of children (from 3 to 6 years old) with anterior teeth restored as part of complete dental care, received in some clinical trials for investigating other purposes. Data related to the restorative procedures, socioeconomic characteristics and quality of life (related to oral health) were collected from these records, from the baseline and follow-ups. The present study will be divided in three chapters. In the first chapter we describe the real prevalence of restorative needs for primary anterior teeth in a sample of children looking for treatment and the impact of these needs on children's quality of life. In the second chapter, the success rate of restorations performed on anterior teeth, under relative Isolation technique, both with Composite Resin (CR) and resin modified glass ionomer cement (RMGIC) was evaluated and risk factors for the occurrence of failures were investigated. In the third chapter, an economic analysis was performed in order to verify if the RMGIC could be an economically feasible alternative to the CR, under the described circumstances. Our findings suggest the need of restorations in primary anterior teeth is not very high; however, it is associated with a negative impact on the children's quality of life. Children whose anterior teeth, need to be restored, are those with higher caries experience. Restorations involving proximal surfaces required more

reinterventions. When adhesive restorations are performed on anterior teeth, under relative isolation, those restorations performed with CR present a greater need for reinterventions (failures). Due to that, in a long-term analysis, CR restorations become as expensive as RMGIC restorations. The children`s quality of life is improved when anterior teeth are restored despite the restorative material used, but the need of reinterventions worsened children`s quality of life. Besides, the incremental cost of placing RMGIC is low and is compensated by its superiority compared to CR. In conclusion, to restore primary anterior teeth under relative isolation, the RMGIC represents a more efficacious and efficient alternative to the CR.

Keywords: Tooth, Deciduous. Dental Restoration, Permanent. Cost-Benefit Analysis  
Quality of life.

## RESUMO

Yampa-Vargas JD. Comportamento clínico das restaurações adesivas em dentes decíduos anteriores e seu impacto em aspectos econômicos e na qualidade de vida relacionada a saúde bucal das crianças [dissertação]. São Paulo: Universidade de São Paulo, Faculdade de Odontologia; 2018. Versão Corrigida.

A integridade dos dentes anteriores decíduos pode ser afetada por vários fatores. Em consequência, aspectos como dor, sensibilidade, dificuldade para mastigar, más oclusões, complicações sistêmicas e baixa autoestima (devido ao comprometimento estético), podem agravar a situação das crianças que apresentam essas lesões. Na tentativa de devolver a funcionalidade e estética desses dentes, surge a necessidade de realização de procedimentos restauradores. No entanto, a literatura disponível não oferece informações suficientes sobre a efetividade, empregabilidade, durabilidade ou custo-efetividade das técnicas e materiais utilizados para dentes anteriores decíduos. O objetivo deste trabalho é investigar alguns desses aspectos relacionados às abordagens restauradoras executadas atualmente para dentes anteriores decíduos. Trata-se de um estudo retrospectivo, de coortes históricas, baseado em dados de prontuários de crianças de 3 a 6 anos de idade com dentes anteriores restaurados, alocadas em estudos clínicos com outros propósitos. Dados relacionados aos procedimentos restauradores, socioeconômicos, de qualidade de vida associada à saúde bucal foram coletados dos prontuários, do início do estudo e dos 24 meses de acompanhamento. O estudo será descrito em três partes. No primeiro capítulo narramos a real prevalência de necessidade restauradora para dentes anteriores decíduos dentro de uma amostra de crianças que busca por tratamento odontológico, bem como o impacto dessa necessidade na qualidade de vida das crianças. No segundo capítulo foi avaliado o índice de sucesso das restaurações realizadas em dentes anteriores, sob isolamento relativo, com Resina Composta (CR) e com Ionômero de vidro modificado por resina (RMGIC), identificando os fatores de risco para a ocorrência de falhas. No terceiro capítulo, foi realizada uma análise econômica para verificar se o RMGIC seria uma alternativa viável, nas referidas circunstâncias. Nossos achados sugerem que a necessidade de procedimentos restauradores em dentes anteriores não é muito alta, porém essa necessidade tem um impacto negativo

na qualidade de vida das crianças envolvidas. Quem geralmente precisa desse tipo de restauração são as crianças com maior experiência de cárie. Quando são realizadas restaurações adesivas em este tipo de dentes, sob isolamento relativo, aquelas realizadas com CR apresentam maior necessidade de reintervenções (falhas), e isto faz que o custo se equivalesse ao RMGIC a longo prazo. As falhas aconteceram mais quando a restauração envolvia superfícies proximais. A qualidade de vida das crianças que receberam restaurações foi melhorada, independentemente do material usado, mas a ocorrência de falhas contribuiu para a piora. Além disso, o custo adicional de se utilizar o RMGIC é baixo e compensa sua superioridade comparado à CR. Assim, para restaurar dentes anteriores decíduos, sob isolamento relativo, o RMGIC é uma alternativa mais eficaz e eficiente comparada à RC.

Palavras-chave: Dente Anterior Decíduo. Restauração Dentária Permanente. Custo-Efetividade. Qualidade de vida.

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## 1 INTRODUCTION

The main motivation to perform research is the desire to better comprehend an unknown process. Do research represent an opportunity to learn and expand the knowledge about a relevant topic, and the possibility to explore our insights to really get to know what something is about. Research inspiration comes from a lot of elements, and usually emerges from researcher's particularly needs, during a determined time of his or her life. Thus, the present study arose from lived experiences from pediatric dental clinical practice, joined with a continuing concern of being offering the best possible treatment for children.

In our daily practice, it is common to perform restorative procedures in primary teeth, due to caries, developmental enamel defects (DED), dental fractures or dental wear. Nevertheless, when is about restoring anterior primary teeth, clinicians frequently report some difficulties (1–6). Besides, specific patterns are observed for dental procedures performed in these teeth. Clinically, we noticed the occurrence of dissimilar and constant failures, that leads to a consequent uncertainty from pediatric dentists at the time of choosing and executing one specific approach(7).

Professional uncertainty could be aggravated by the “excessive” variety of materials available nowadays, even more when these materials had been developed primarily to be applied in permanent teeth. Actually, most approaches for primary anterior teeth are simple extrapolations of therapies tested and used for permanent ones (8), despite the known differences between primary and permanent teeth.

Restorative procedures indicated to anterior primary teeth demands a broadly understanding of their particularities. Anterior teeth are important due to children's masticatory function, space maintenance, prevention of malocclusion, phonetics and also aesthetics (3,4,9–11). These features are very relevant and must be considered in dental care to avoid any complications that could affect directly the children' systemic health and the quality of life (12).

Since there is a lack of research about needs for restorative procedures in anterior primary teeth and their impact, and also reduced literature available about the performance of the restorations placed in these teeth, the present dissertation is an

attempt to improving the current knowledge about these issues, providing newfangled evidences about restorative approaches and contributing for defining important aspects of the design of other researches in the future. In order to better understand the factors related to children and to the need to performing restorative procedures in their anterior primary teeth, this dissertation is going to be divided in three chapters.

On Chapter I, we describe how frequent is the need to perform restorations in anterior primary teeth of children, identifying factors related to such type of need and its impact on Oral Health-Related Quality of Life (OHRQoL). On Chapter II, we evaluate retrospectively, how the clinical performance (survival) of restorations on anterior primary teeth is, comparing two different adhesive materials: Composite Resin (CR) and Resin Modified Glass Ionomer Cement (RMGIC) and detecting the possible associated factors with the occurrence of failures. Besides, in this chapter, we also pioneered in implementing a complex analysis of multiple ordered restoration failures. Finally, on Chapter III, we estimate the costs to perform restorations on anterior primary teeth of children when using different restorative materials, considering all cumulative costs from eventual reinterventions performed. We also assessed the impact of restoring procedures, both economically and also on children`s OHRQoL.

## 2 PROPOSITION

The aim of this study was to explore the clinical performance of adhesive restorations placed on anterior primary teeth and how they can interfere on costs and children's quality of life.

In view of this, the following specific objectives were outlined:

1. To evaluate the actual need for restorative procedures on primary anterior teeth affected by caries and how it can impact on children's quality of life.
2. To analyze the survival of anterior teeth restorations performed with two different adhesive materials (CR and RMGIC) used in clinical settings.
3. To investigate the impact of failures in restorations of anterior teeth on children's quality of life.
4. To perform an economic evaluation of restoring anterior primary teeth considering these two restorative materials as alternatives and including possible expected failures.



### 3 CHAPTER I

*Restoring anterior primary teeth: a real problem? – exploring children's needs and their impact on oral health-related quality of life.*

#### **Abstract**

This study aimed to verify the actual demand for restoration of anterior primary teeth due to caries among children who seek for dental treatment and explore the impact this condition on their oral health-related quality of life (OHRQoL). Preschool children who sought for dental care were selected for a clinical trial designed for other purposes (CARDEC-02 / NCT02473107). 206 children were examined by a calibrated examiner and all dental surfaces were classified according to caries severity using ICDAS. The same examiner proposed a treatment plan including all needs. Children presented Proximal surfaces classified with scores 4 to 6 were considered for operative treatment (restorative needs) and selected for this study. ECOHIS (Early Childhood Oral Health Impact Scale) scale was used to assess the impact of dental caries on the children's OHRQoL previous to treatment. Variables related to socioeconomic conditions, caries experience, and oral hygiene index were also collected. Poisson multilevel regression models were used to test the association between the outcomes (treatment needs and children's OHRQoL) and independent factors (PR, 95% CI). 2,472 anterior teeth were examined in the trial. 45% of these teeth (n=1,104) had at least one surface with caries lesions (ICDAS 1 to 6). From these, approximately 10% (n=105) required restorative treatment. The need for restorative treatment was associated with the child's caries experience (PR = 1.03, 1.02-1.05). Upper teeth presented 3 times more need of restorative treatment than the inferior ones (RP = 2.99, 1.55-5.79). Proximal surfaces showed more operative need when compared to smooth surfaces (RP = 32.03, 19.76-51.93). No association with type of teeth or number of surfaces affected was observed. Children with need of restorative treatment on their anterior primary teeth showed higher scores of ECOHIS (PR=1.28, 1.08-1.51). **CONCLUSION:** The need for restorative treatment due to caries in anterior teeth of preschool children who seek for dental treatment is often related to proximal cavities, but quite low. However; this condition is associated with a negative impact on their OHRQoL, demanding special attention.

Keywords: Dental Care; Tooth, Deciduous; Health Related Quality of Life

### 3.1 INTRODUCTION

Restorations have been pointed out as one of the commonest causes for children's entry into the dental care system (13). Dental caries is the most common condition that will require restorative treatment in anterior primary teeth (4,14) and it is usually related to the indication of performing operative procedures.

Anterior teeth are strongly linked to the oral and facial beauty (15,16). In this sense, the esthetic impairment due caries in anterior teeth leads parents or caregivers to seek for treatment. Due to that, it is crucial to understand a whole dental caries as a process and how it can affect every dimension of children and their parents, including their oral health-related quality of life (OHRQoL).

Although some surveys show the prevalence of caries in anterior teeth in different populations (17,18), a lack of information is known about how frequent the need of operative treatment is required in primary anterior teeth of those children who seek for regular dental care and its repercussion on children's life and well-being. Identifying the need for this kind of treatment and its actual relevance when offering dental care will be important to plan strategies, guide the improvement in therapies offered in such conditions and also define important aspects for being considered when designing further protocols.

Therefore, the aim of this study was to investigate the need for restorative treatment in anterior primary teeth among children who are seeking for dental care and its associated factors as well as to explore how this type of need can impact on children's OHRQoL.

## 3.2 MATERIAL AND METHODS

### **Study Description**

This is a cross-sectional, exploratory study, based on data collected from dental records of patients previously enrolled in a clinical trial focused on testing caries diagnosis strategies (CARDEC-2; NCT02473107 – Ethical Approval 944.742). The present research protocol was also approved by the Local Research Ethics Committee (2.585.006)

### **Study participants**

The above mentioned trial has been conducted on a mobile dental unit located in Barueri, São Paulo, Brazil. This municipality has approximately 240 thousand inhabitants and a human development index of 0.786 (19,20). The mean dmf-t at 5 years, for this Brazilian region, is 1.79 (20). The water is supplied with 0.7ppm of fluoride. The unit is a reference for children's dental care in the municipality.

The first 260 children, who sought for dental care at mobile dental unit, enrolled in the trial, were eligible to this study, whose purpose was to investigate the needs for restorative treatment. No eligible child was excluded from the sample.

### **Data collection**

The records from children enrolled in the trial, from March 2014 to November 2016, were assessed. Those children who presented restorative needs were identified, as one of the outcomes, in the present study. For the main trial, all children had been examined by a calibrated examiner. As a protocol, the clinical examination occurred after the teeth had been cleaned with rotating bristle brush and pumice/water slurry, using a dental mirror and a ballpoint-ended probe. Children were clinically examined by using the "International Caries Detection and Assessment System" – ICDAS (21) to classify the teeth surfaces according to the caries severity. The severest condition at each surface was recorded. After examination, the same dentist defined the complete plan for dental treatment for all included participants.

For anterior teeth, those surfaces classified with ICDAS score 4 (underlying dentin shadow), 5 (distinct cavity whit visible dentine) or 6 (extensive cavity whit visible dentin) were scheduled to be restored. Therefore, children presenting these ICDAS codes, in their records, were set as having present restorative needs. Since our purpose was to investigate the need of treatment due to caries, in this study, it was not considered teeth with trauma or teeth previously restored.

Besides caries codes for anterior teeth, data related to oral hygiene index (OHI-S) (Greene and Vermillion, 1964), caries experience – decayed, missed and filled – tooth (dmft) (20) and files containing the Brazilian version of the ECOHIS (Early Childhood Oral Health Impact Scale) questionnaire (22–24) were also collected.

A digital database containing baseline information from the trial was created based on data extracted from participants' files.

### **Statistical Analysis**

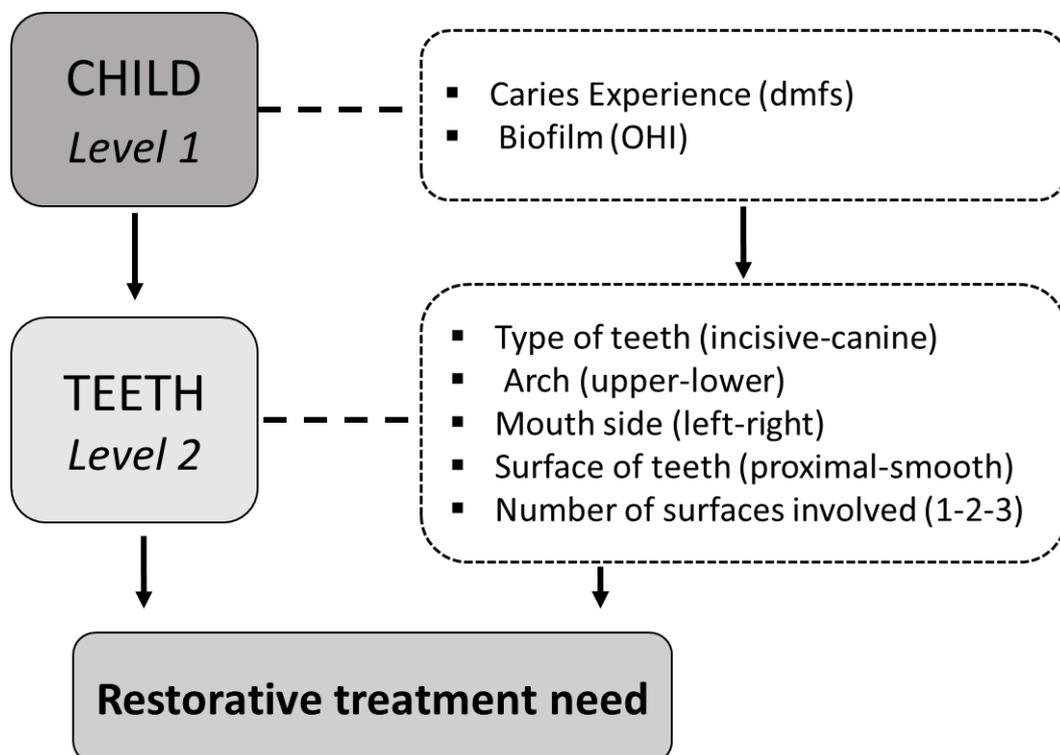
Statistical analyses were performed by using STATA 13.0 software (Stata Corp., College Station, Texas, USA). For the analyses, two outcomes were considered: the need of restorative treatment in anterior primary teeth and impact of the need of restorative treatment on the OHRQoL.

Multilevel Poisson regressions analyses with robust variance were used to identify possible associated factors with the mentioned outcomes. Initially, univariate analyses were performed for each independent variable. Subsequently, multiple regression analyses were performed using a forward stepwise approach. Variables were selected from using a hierarchical approach, in which the variables were ordered into levels to determine their inclusion in the statistical analysis. All associations were adjusted for covariates positioned in the same and upper levels of the model. In each level, the variable selection followed the forward stepwise method. In each level, those variables presenting p-values lower than 0.2 in the unadjusted model or those with a biological feasibility to be tested were selected for the multivariate analysis. The level of 5% was used to retain the variables in the multiple model.

For treatment needs, the tooth was considered as unity of analysis and the tooth and the child were set as levels. All teeth from included children were considered in this analysis. Tooth presenting at least one carious surface (ICDAS 4, 5 or 6) were considered as carious. Independent variables tested from both levels and the theoretical model were described in Figure 3.1. The analyses estimated the Prevalence Ratios (PR) and 95% of confidence interval (CI) related to tested variables.

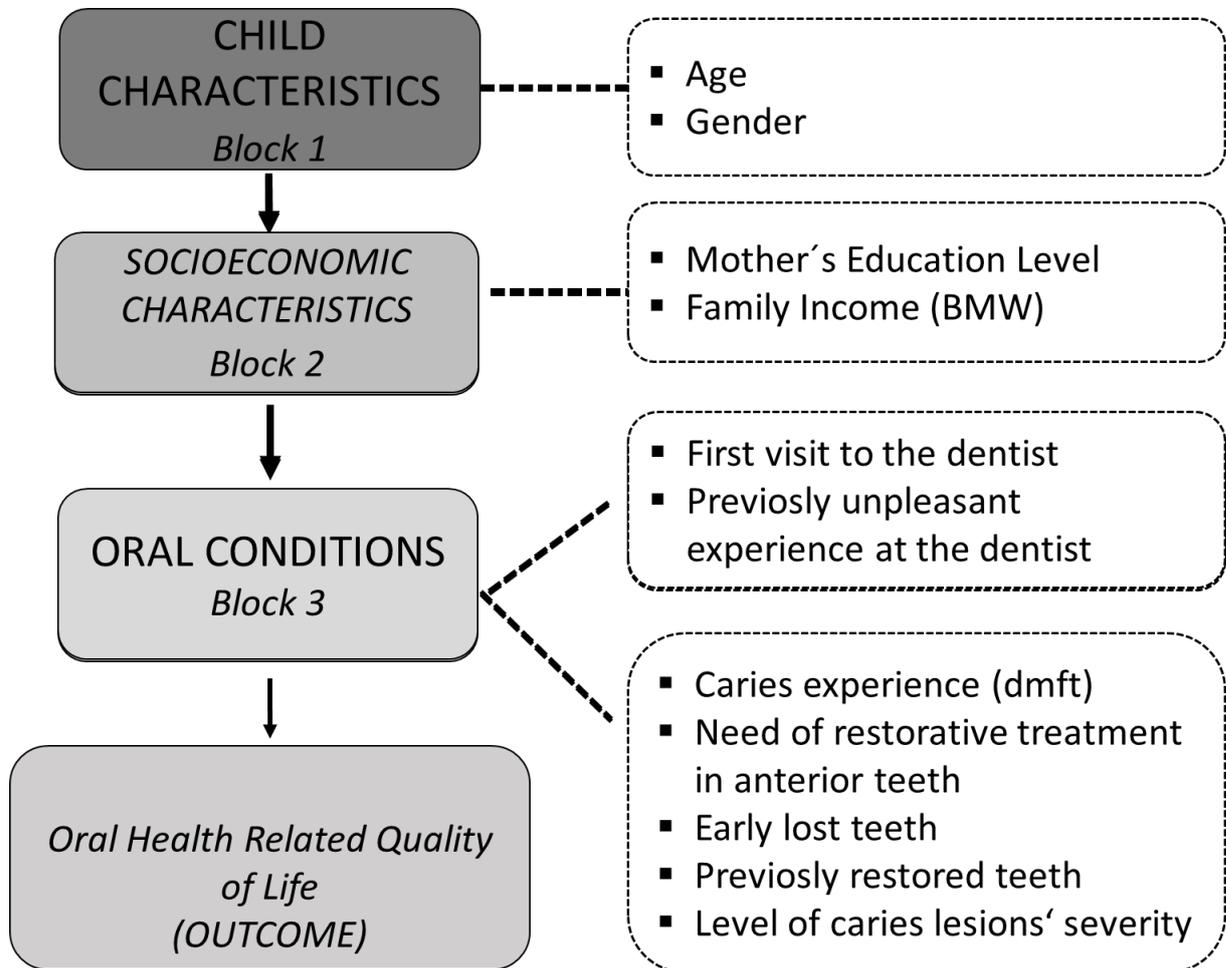
For the outcome OHRQoL related to caries, the unit of analysis was the child. All children selected for this study was included in this analysis. The ECOHIS scores were used as the outcome variable. The occurrence of untreated caries (need for restorative treatment) in anterior primary teeth was used as one of the independent variables of interest. The theoretical model for hierarchical analysis of OHRQoL related to caries is presented in Figure 3.2. The analyses using the hierarchical model estimated the Rate Ratios (RR) related to the tested variables with 95%CI.

Figure 3.1 – Theoretical model used to analyze the need for restorative treatment in anterior primary teeth



Source: Author

Figure 3.2 – Theoretical model used to analyze the OHRQoL related to caries in anterior primary teeth



Source: Author

### 3.3 RESULTS

The mean dmfs index of children included in the CARDEC-2 trial was  $3.8 \pm 3.8$  (Table 3.1). From all children included in the main trial ( $n=260$ ), 22% ( $n=58$ ) presented any anterior teeth with moderate or severe carious lesions, subsequently indicated for operative treatment (scores 4, 5 and 6 of ICDAS). For this exploratory study, 2,472 anterior primary teeth were considered. Approximately 45% of these teeth ( $n=1,104$ ) presented any type of caries lesions, classified with ICDAS scores 1 to 6. Restorative treatment was required in 4.3 % ( $n=105$ ) of the teeth (Table 3.2).

Proximal surfaces required much more operative treatment compared to smooth surfaces (Table 3.2). Upper teeth presented 3 times more need of restorative treatment, than the lower teeth ones (Table 3.2). The need for restorative treatment was also associated with the higher caries experience (Table 3.2).

Children who required restorative treatment in anterior primary teeth had higher ECOHIS scores reported (mean=6.91; SD=7.28), compared to those who did not present such type of need (Table 3.3). This result is independent of child's caries experience and age, that also were associated to children's OHRQoL, but for which the multiple model was also adjusted (Table 3.3).

Table 3.1 - Sample characteristics separated in individual, oral health and tooth levels

<b>Variables</b>	<b>Description</b>	<b>n</b>	<b>%</b>
<b>Individual Characteristics</b>			
<b>Sex</b>	Male	132	50.8%
	Female	128	49.2%
<b>Age</b>	2-3 years old	31	11.9%
	4-6 years old	229	88.1%
<b>Mother's Educational Level</b>	Secondary	202	77.7%
	College	48	18.5%
	Unanswered	10	3.8%
<b>Family Income (BMW) Brazilian minimum wage</b>	Up to 4 BMW	209	80.4%
	Up to 20 BMW	30	11.5%
	Unanswered	21	8.1%
<b>Oral Health Characteristics</b>			
<b>Caries Experience</b>	Low ( $\leq 3$ dmfs)	170	65.4%
	High ( $> 3$ dmfs)	90	34.6%
<b>Biofilm</b>	Mean	0.5846	SD= 1.0278
<b>Tooth Characteristics</b>			
<b>Type of teeth</b>	Central incisor	824	33.3%
	Lateral incisor	824	33.3%
	Canine	824	33.3%
<b>Arch</b>	Upper Arch	1236	50%
	Lower Arch	1236	50%
<b>Mouth Side</b>	Right Side	1236	50%
	Left Side	1236	50%

Source: Author

Table 3.2 - Association between the need of restorative treatment in anterior primary teeth and independent variables

<b>INDEPENDENT VARIABLE</b>	<b>Crude Prevalence Ratio (95%CI)</b>	<b>P value</b>	<b>Adjusted Prevalence Ratio (95%CI)</b>	<b>P value</b>
<b>AGE</b> (Ref. 2 –3 years old)				
5-6 years old	1.40 (0.63 a 3.10)	0.41	-	-
<b>TYPE OF TEETH</b> (Ref. Central Incisor)				
Lateral Incisor	0.54 (0.35 a 0.83)	0.01	-	-
Cuspids (Canine)	0.31 (0.17 a 0.57)	0.00		
<b>ARCH</b> (Ref. Lower Arch)				
Upper Arch	7.12 (3.81 a 13.3)	<0.001	2.99 (1.55 a 5.80)	<0.001
<b>CARIES´ EXPERIENCE</b> (Ref. Low Experience (dfms ≤ 3 sup))				
High Experience (dfms > 3 sup)	1.17 (1.11 a 1.22)	<0.001	1.03 (1.02 a 1.05)	<0.001
<b>SURFACE OF TEETH</b> (Ref. Smooth surface)				
Proximal Surface	62.77 (41.84 a 94.18)	0.21	32.03 (19.76 a 51.93)	<0.001
<b>*BIOFILM</b> (continue variable)				
	2,32 (1.2 a 4.6)	0.018	-	-
* variable did not present association in the multiple regression model				

Source: Author

Table 3.3 - Association between children's OHRQoL and needs for restorative treatment in anterior primary teeth as well as other independent variables

INDEPENDENT VARIABLE		ECOHIS SCORES MEAN SD	UNIVARIATE CRUDE RATE RATIO (95% CI)	P VALU E	MULTIPLE ADJUSTED RATE RATIO (95% CI)	P VALUE
<b>CHILD</b>	<b>AGE</b> (Ref. 3 years old)	3 years' old	1.96 (2.92)	Ref.	Ref.	
		4 years' old	3.77 (6.17)	0.47 (0.28 a 0.78)	<b>&lt;0.001</b>	1.34 (1.02 a 1.76) <b>0.03</b>
		5 years' old	4.09 (5.83)	0.51 (0.31 a 0.84)	<b>&lt;0.001</b>	1.46 (1.12 a 1.91) <b>0.01</b>
		6 years' old	5.50 (7.18)	0.69 (0.41 a 1.15)	<b>0.01</b>	1.85 (1.38 a 2.49) <b>&lt;0.001</b>
<b>SOCIOECONOMIC</b>	<b>SEX</b> Ref. (Male)	Male	4.45 (6.14)	Ref.	Ref.	
		Female	3.47 (5.73)	0.78 (0.69 a 0.89)	<b>&lt;0.001</b>	0.93 (0.82 a 1.06) <b>0.29</b>
	<b>FAMILY INCOME (BMW)</b> Ref. ( up to 20 Brazilian minimum wage)	Up to 20 BMW	3.17 (5.52)	Ref.	-	-
		Up to 4 BMW	4.16 (6.16)	0.76 (0.62 a 0.95)	<b>0.01</b>	
<b>MOTHER'S EDUCATION LEVEL</b> Ref. (more than 12 years)	More than 12	2.34 (4.48)	Ref.	Ref.		
	Less than 12	4.34 (6.21)	0.53 (0.44 a 0.66)	<b>&lt;0.001</b>	0.71 (0.57 a 0.87) <b>&lt;0.001</b>	
<b>ORAL HEALTH (PAST EXPERIENCES)</b>	<b>FIRST VISIT TO THE DENTIST</b> Ref. (No)	No	5.79 (6.95)	Ref.	-	-
		Yes	3.08 (5.22)	0.53 (0.47 a 0.61)	<b>&lt;0.001</b>	
	<b>PREVIOUSLY UNPLEASANT EXPERIENCE AT THE DENTIST</b> Ref. (No)	No	3.70 (5.76)	Ref.	-	-
		Yes	9.14 (7.48)	2.47 (2.05 a 2.98)	<b>&lt;0.001</b>	
<b>CARIES EXPERIENCE (dmft)</b> Ref. ( <3 dmft)	<3 dmft	1.79 (3.27)	Ref.	Ref.		
	>3 dmft	8.01 (7.52)	1.16 (1.15 a 1.18)	<b>&lt;0.001</b>	1.13 (1.11 a 1.15) <b>&lt;0.001</b>	



### 3.4 DISCUSSION

Our findings raised up that, even among children who are seeking for dental care, the need for restorative treatment in anterior teeth is not definitely high. In a clinical-based study, as the present one, we expected to find worse conditions, since patients tend not to go to the dentist unless severe symptoms appear (25). Nevertheless, some population-based studies also performed in Brazil showed similar situations (18,26) and we should consider as dental caries is a cumulative process, restorative needs could be less frequent in preschool children since they had shorter time to be established. Despite the modest prevalence, we consider important to point out that children who demands for restorative treatment in anterior teeth (22%) presented negative impact on OHRQoL, and that is why special attention should be given to repair or revert this condition. To the best of our knowledge, this is the first study that assessed the relation between need of restorative treatment in anterior primary teeth and OHRQoL of children.

We believe one of the reasons for this finding is aesthetics consequences caused by cavities in anterior teeth. The oral region denotes a big impact when determining overall facial attractiveness (16). Furthermore, health and/or esthetic impairment on anterior teeth can affect the child's appearance (3,5), what is not only a parental, but also a children's concern (11), even for younger children, since it may be attributed to their self-image conscious(5). Additionally, dental caries in anterior teeth has been linked to consequences as speech impairment, effects on development/eruption of successive tooth, acquired and prolonged oral habits and biting or mastication problems (11) and these complications can directly affect the OHRQoL of children (12).

ECOHIS questionnaire reflects the parents' perception about child's oral health and needs, what could be a limitation. However, due to the limited cognitive ability of preschool children and their emotional and social development, especially for 3-to-4-year-old children, it was the option for evaluating this outcome. Despite some slight differences in the answers when assessing OHRQoL of children aged 5-6 years, mothers can be considered as proxies for their young children(27). On the other hand,

considering the age group and the parent's perception for aesthetics, we believe that such aesthetical consequences could have been the major responsible for parental reports on child's OHRQoL, despite other factors could be equally important in the real context.

Another limitation is we cannot provide an isolate report for the condition of anterior teeth, since the impairment related to oral health is evaluated. Indeed, children who had cavities in anterior teeth usually present poorest oral conditions (Drury et al., 1999) and these findings became well evidenced in our study. They also have higher negative impact on OHRQoL. Additionally, children from our sample who needed restorative treatment in their anterior primary teeth (22%) concentrated the most part of surfaces that needed to be restored throughout the study, in both anterior and posterior teeth, reflecting the polarization of dental caries (28) due to inequalities in access to effective public health measures (as fluoridated toothpaste) or conditions of social exclusion (29). On the other hand, even opting for adjusting the model for caries experience and socio-economic characteristics (e.g. level of mother education), the need for restorative treatment in anterior teeth could be still associated to higher EOCHIS scores. Therefore, we conclude the anterior teeth, even in children with higher caries experience, it is a real matter to be considered by pediatric dentists.

This is possible why, several options to restore and maintain the soundness of anterior teeth have surged among the past decades, between them, different kinds of restorations (4). The main objective of restorative procedures in primary teeth is their maintenance until natural exfoliation, justified from a functional, psychological, biological and aesthetic point of view (3). Special attention, however, should be given to those cases which often demands restorative treatment. The commonest teeth affected by caries and demanding restorative treatment are the upper incisors (30,31), probably due the lapse the teeth were left exposed to potential risk factors, what was also evidenced in our study. Besides, the proximal surfaces are strongly more affected by caries lesions, what could reflect the constant biofilm accumulation in approximal surfaces causing a local demineralization (white spot) and progressing rapidly until becoming cavitation (32). This progression is also attributed to a scarce of enamel and to a thinness characteristic of the approximal surface (33,34). Based on that, we can allege that anterior primary teeth certainly have different demands than posterior ones. Besides, the impact of non-restoring anterior primary teeth may be also different from the same for posterior ones.

Although the operative procedures (restorations) can be indicated in several cases like teeth with enamel defects (DED), dental fractures, dental pigmentations or bruxism (1), this study explored only those cases in which restorations had been indicated due to caries. Since the prevalence of other occurrences are even lower than caries, we opted for not including them to standardize our sample. Therefore, we cannot extrapolate our findings to all indications of restorations in anterior teeth, which could also have their special particularities, e.g. in traumatized teeth.

As this study was an attempt to identify the real need of restorative treatment in anterior primary teeth and to understand their patterns and actual impact, we can conclude that the need of restorative treatment in anterior primary teeth, due to caries, is not high, even in population seeking for dental care and mainly involve proximal surfaces. Nevertheless, children affected by this condition have a higher negative impairment on their OHRQoL. Facing such needs and their impact could be important to guide further actions.



## 4 CHAPTER II

*Clinical performance of adhesive restorations in anterior primary teeth, exploring multiple failures per restoration.*

### **ABSTRACT**

Restorative procedures on anterior primary teeth are challenging for Pediatric Dentistry due to the sensitive restoration technique and the difficulty to control moisture in young patients. This study aimed to evaluate the survival rate of adhesive restorations performed on anterior primary teeth and to identify possible factors associated to observed failures. This retrospective study was based on data from two cohorts of children (3 to 6 years old) previously enrolled in two clinical trials focused on caries detection (CARDEC-01/NCT02078453 and CARDEC-02/NCT02473107). Those children who received restorations on their anterior primary teeth had their records evaluated. These children had been followed by 24 months. Kaplan-Meier test was used to estimate restorations survival and Cox regression analysis were used to identify variables associated with the failures. Failures classified as major (replacement) and minor (repairment) were considered. An innovative statistical approach using conditioned risk set models permitted to analyze multiple cumulative failures per restoration, besides to conventional analyses in which only the 1<sup>st</sup> observed failure per restoration was considered. 144 children were included in this study, totalizing 380 primary restorations, and 456 restorations when including re-restorations or repaired restorations. On average, 35% (n=136) of the anterior restorations presented major failures and 10% presented minor failures. Primary restorations performed with CR presented higher failure rate (44%) than restorations performed with RMGIC (23%). When including repaired and replaced restorations, these figures slightly changed. While CR restorations failed earlier than RMGIC restorations in both situations analyzed. Primary restorations involving proximal surfaces failed more (HR=2.05; 95% CI:1.29-3.28) than those that included only non-proximal surfaces. The failures occurrence was also influenced by children caries experience both for primary restorations or considering re-interventions. We concluded that, for restorations placed

in anterior primary teeth, the performance of RMGIC was superior than CR. Besides the dental material, local and general characteristics as involvement of proximal surfaces and caries experience, are factors associated to failures observed in these restorations.

Keywords: Survival Rate; Tooth, Deciduous; Dental Restoration, Permanent; Restorative Dentistry.

## 4.1 INTRODUCTION

Restorative procedures in primary teeth aim to maintain them until natural exfoliation, that is justified from functional, psychological, biological and aesthetic beliefs (3). Research related to operative dentistry for children has been motivated around the world (35–39) and led to important changes in restorative approaches practiced in pediatric dentistry. Nevertheless, restoring primary anterior teeth has still been a challenging task for pediatric clinicians, due to the difficulty of handling patients with early childhood caries (ECC) (1,40), smaller dental dimensions, pulp proximity, reduced area for adhesion (2) and a hardship to perform a properly moisture control in young patients(41).

Nowadays, varieties of dental materials (amalgams, composites, glass ionomers, resin-modified glass ionomers, stainless steel, polycarbonate and zirconia crowns, among others) and related techniques are available for restoring primary teeth (42,43). To find out a perfect material is a difficult task (44–46), since each one has their advantages and disadvantages. Furthermore, to determine which material and/or which operative technique is more suitable for restoring anterior primary teeth could be confusing for pediatric dental practitioners.

Studies have assessed the longevity of restorations to understand the performance and the application of a specific restorative material. Conversely, few studies investigated the survival of adhesive restorations in anterior primary teeth (47–51). Moreover, these studies did not assess exclusively the clinical performance of restorations in anterior teeth because they have mainly focused on the longevity of restorations in posterior primary teeth (44,51–57). Due to that, the current practices used for these type of teeth are mostly extrapolations of approaches tested for permanent dentition (8). On the other hand, as described in Chapter I, situations which require this kind of restorative procedures significantly impact on children's OHRQoL. Then, this study was proposed to evaluate the survival of adhesive restorations performed on primary anterior teeth, using two cohorts of children enrolled in clinical trials in which complete dental care was offered and investigate factors associated with failures observed in these restorations.

Classically, studies investigating restoration survival have used conventional statistical analyses, in which the longevity of dental restorations is estimated based on the first failure experienced. However, in the real life, we observe that dental restorations may fail more than once, and that would make necessary repeated reinterventions. Therefore, to a properly understand of the pattern of failures and the overall survival of restorations it is necessary to perform new statistical methodologies that can fits in those circumstances, not because the traditional methods are wrong, but because they could imply an inefficient use of data. Consequently, it is important to highlight that, this study is also a new attempt to analyze survival of restorations, this study will presents an innovate approach for estimating longevity, where multiple and successive failures of restorations, placed in anterior teeth, were considered and analyzed (58,59).

## 4.2 MATERIAL AND METHODS

### **Study design, setting and ethical aspects**

After approval by the local Committee for Ethics in Research (Protocol 2.585.006, this cohort study was based on data collected from records of two groups of patients previously enrolled in clinical trials focused on caries diagnosis in primary teeth: CARDEC-01 (NCT02078453) designed to evaluate the impact of the radiographic examination on diagnosis and treatment decision of caries lesions in primary teeth, and CARDEC-02 (NCT02473107) aiming to assess the impact of detecting initial caries lesions. CARDEC-01 was composed by children who sought for dental care in the main clinic of Pediatric Dentistry, Dental School, University of São Paulo (FOUSP) and CARDEC-02 involved children who sought for dental treatment at the FOUSP mobile dental unit, located in the municipality of Barueri, São Paulo, Brazil. The dental units, despite different location, presented the same standards for dental care, including structure, materials and staff.

The CARDEC (CARies DEtection in Children) group is a collaborative group of people involved at these and other studies, formed by researchers, dentists,

graduate and undergraduate students and technicians with various and different independent roles (60). The children participation for both clinical trials was strictly voluntary, supported by a written informed consent signed for their parents and/or caregivers (containing detailed information about the studies and consenting the use of their data in future researches). For the present study, files related to those children were used for data collection. If, in the original written consents, parents or guardians rejected that data could be used in further studies, these files were not included for analyses.

## **Sample**

Our sample was comprised by records from children enrolled in the previously mentioned clinical trials. For these trials, all 3-to-6-year-old sought for dental care at the Dental Units of University of São Paulo (Figure 4.1) were eligible and did not exist any exclusion criteria, except for children who presented extremely inadequate behavioral problems during the initial appointment.

In the trials, children received the restorative treatment in two independent dental units, each one responsible for the enrollment of patients in the respective trial. After recruitment, participants of both cohorts, who presented ICDAS scores 4 to 6 in anterior primary teeth were treated. Each trial adopted specific protocols for conducting dental care for children. For anterior restorations, the main difference between cohorts was the type of material used to restore cavities located at anterior teeth (CR or RMGIC). These materials were scheduled to be used in each trial without a specific reason or purpose. The present study was designed after restorations had been placed and had no influence on the choices.

Children were recruited for trials from 2014 to 2015 and were followed up for 24 months. They were seen at every 6 months when they received preventive treatment and at every 12 month, when a detailed examination was performed (in their respective cohort) by a calibrated examiner using the “International Caries Detection and Assessment System” – ICDAS (61). The examiners classified the teeth surfaces according to caries lesion severity and Roeleveld criteria (62) for assessing restorations integrity. The severest condition at each surface was recorded. In the

intermediate appointments or urgency visits, restoration losses or new cavities were also registered.

Files from children who have had at least one adhesive restoration in their anterior primary teeth were included in our sample. We included both restorations placed in the baseline as well as in the follow-up visits. Thus, restorations placed from 2014 to 2017 could be included.

## **Restorative Procedures**

The restorative procedures for both groups of children were performed by trained and calibrated operators (dentist and assistant). They performed all anterior teeth restorations under relative isolation with cotton rolls and saliva ejector for moisture control. Firstly, removing dentinal caries tissue with drills (if necessary) and hand dentin excavators, then every trial followed their specific established protocol for restoring anterior primary teeth:

### *RMGIC group*

The material used in the anterior restorations was Vitremer™ (3M ESPE) following the manufacturer recommendations: the primer was applied to both enamel and dentinal surfaces for 30 seconds, after application, the primed surfaces were not rinsed, just dried using an air syringe and then light cured for 20 seconds. Subsequently the mixed ionomer was placed in bulk (mixture with equal number of level powder scoops and liquid drops) and a 40-second light exposure was used to cure the material. Finally, a light-cure finishing gloss (part of the Vitremer system) was applied after restoration had been finished and was light-cured for 20 seconds.

### *CR group*

Restorations were performed using a conventional adhesive system (Adper™ Scotchbond™ Multipurpose Plus - 3M ESPE) and composite resin (Filtek Z350 XT - 3M ESPE). After caries removal, the cavity was conditioned by phosphoric acid gel (35%) for 7 seconds in dentin and 15 in enamel. Then, abundant water was used for washing the acid (15 seconds). Subsequently, conditioned surfaces were smoothly dried with small cotton balls. The adhesive system was applied. First, enamel and dentin surfaces were covered with the primer, followed by a gently dry for 5 seconds.

Then, the adhesive was applied and light cured for 10 seconds. After that, composite resin increments were inserted into the cavity and each increment was light cured for 20 seconds, after that, restoration polishing was completed.

### **Research Staff**

Examiners and operators for both groups had vast experience on pediatric dental care and were previously trained and calibrated for the treatment protocols. At least 6 examiners and 10 different operators were involved in the two trials, performing the restorative procedures and reevaluating the children.

- *Examiners*

The initial exam was performed by one different examiner for each group, trained by a common team of experts. These examiners only executes that first examination and elaborate the treatment plan. Later, in the follow-up appointments, other four examiners (two for each group) performed the assessments as previously described.

- *Operators*

The operators (graduate students in Pediatric Dentistry) that performed the restorative procedures, in both units, were previously trained and calibrated. They followed the same philosophy in relation to minimal invasive dentistry, caries removal and restorative techniques. They followed standardized pre-established protocols (already described).

Figure 4.1 - The FOUSSP Mobile Dental Unit, located on a trailer parked at Carlos Osmarinho de Lima Educational Complex- Barueri-SP. The unit offered dental care as in the main unit and is reference for children in pediatric dental care



Source: Authors, Picture gently taken and donated by Rocha E.S. (2018, December)

## Data collection

A digital database containing participants' information collected from included files was created. As the main studies, for being clinical trials, had a standardized and very complete system to collect the data, we could extract all the information regarding the history of anterior deciduous teeth, from the baseline examination and following-up records, including dental charts for different examinations, treatment plans and description of performed procedures. We can also collect information about eventual urgency appointments and reinterventions performed. In these records, related variables to the treatment were also available, as tooth type, presence of endodontic treatment, arch, mouth side, number of restored surfaces, type of surfaces involved in the restoration, type of restorative material used. Other individual aspects possibly

associated with restoration failures were also explored, including age, gender and caries experience. Socioeconomic variables were not available at that time.

## **Outcomes**

The main outcome was the restored anterior teeth survival. For that, we considered as failures those situations in which any type of reintervention was demanded. The type of failure was derived from codes collected from patient's records as follows on Figure 4.2. As major failure, we classified those restorations that needed to be replaced or those that evolved to main complications as endodontic treatment or need of extraction needs. The need for other types of reintervention, such as repairs, contouring and polishing were considered as minor failures. Those restored teeth that never presented failures, or those that even with failures, the examiner judged that the reintervention was not needed (due to inactive carious tissue or for being close to the time of the natural exfoliation) were both considered as success.

## **Analysis**

The statistical analyses were performed using a computer program: Stata 13 (Texas, USA), version 13.1. Kaplan-Meier analysis (survival curves) was performed to assess the survival of restorations from the two cohorts using different materials. In an initial attempt, we considered both major and minor failures to estimate the survival. Then, in a second moment, all analyses were performed considering only major failures. The need for other types of reintervention, such as repairs, contouring and polishing (minor failures) were also considered to be analyzed, but, due to the low number of events such that, we opted for not performing a separate analysis for them. The mean time from failures was estimated using restricted means and, when necessary, extended means were estimated by exponential extrapolation of the Kaplan-Meier estimate (63).

To identify factors associated with the failures of restorations, we used two different statistical approaches in this study. Multivariate Cox regression analyses (or proportional hazards regressions) with shared fragility were performed when only the first failure observed in restorations was considered (single failure model), as in

conventional survival analyses(47,64,65). In this way, just failures in primary restorations were analyzed. To analyze ordered multiple failure events, mimicking real-life, an innovative method in Dentistry was applied in this study. For that, conditioned risk set models were used (58). In these models (multiple failure models), time to each event was measured from the entry time. For restorations which failed more than once, T0 was defined as the time when restoration was replaced or repaired and T1 the time when a new failure or survival were observed. This approach was used for each replacement or repair performed. In this marginal risk set model, it is created a variable (str) that identifies the failure rate group for each time span (59,66). This variable means the risk of first failure or at risk of each successive recurrence, when applicable.

The independent variables tested were: restorative material (RMGIC vs. CR), mouth side (right vs. left), arch (lower vs. upper), type of teeth restored (central incisor vs. lateral incisor or canines), number of surfaces involved in the restoration (discrete variable) and their type (smooth vs. approximal), previous endodontic treatment (no vs. yes), children gender (boys vs. girls), age (3-4 vs. 5-6 years-old) and caries experience (discrete variable). All them were tested in the analyses, however just the most pertinent will be presented in the results. The variables that presented values of  $p < 0.20$  in the unadjusted model analysis or those with a particular interest (biologically relevant) were selected for the multiple analysis final model. A significance level of 5% was set for this final model. For each model, the Hazard Ratio (HR) related to each independent variable was calculated with 95% of confidence interval (95%CI).

Figure 4.2 - Criteria used for evaluate restorations at follow-ups and respective type of failures considered in the analyses

	<b>SCORE CODE</b>	<b>EVALUATION CHARACTERISTICS</b> (according to Roeleveld, 2006)
<b>Success</b>	<b>00</b>	Restoration present, correct
<b>Success</b>	<b>10</b>	Restoration present, slight marginal defect/wear of surface (<0.5 mm). No repair needed.
<b>Minor Failure</b>	<b>11</b>	Restoration present, gross marginal defect/wear of surface (>0.5 mm). Repair needed.
<b>Minor Failure</b>	<b>12</b>	Restoration present, underfilled (>0.5 mm). Repair needed.
<b>Minor Failure</b>	<b>13</b>	Restoration present, overfilled (>0.5 mm). Repair needed.
<b>Minor Failure</b>	<b>20</b>	Secondary caries, discoloration in depth, surface hard and intact, caries within dentin. Repair needed.
<b>Minor Failure</b>	<b>21</b>	Secondary caries, surface defect, caries within dentin. Repair needed.
<b>Major Failure</b>	<b>30</b>	Restoration not present, bulk fracture, moving or partial lost. Repair needed.
<b>Major Failure</b>	<b>40</b>	Inflammation of the pulp; signs of dentogenic infection (abscesses, fistulae, pain complaints). Restoration might still be in situ. Extraction needed.
<b>Major Failure</b>	<b>50</b>	Tooth not present because of extraction
	<b>60</b>	Tooth not present because of shedding
	<b>70</b>	Tooth not present because of extraction or shedding
	<b>90</b>	Patient not present

Source: Author

### 4.3 RESULTS

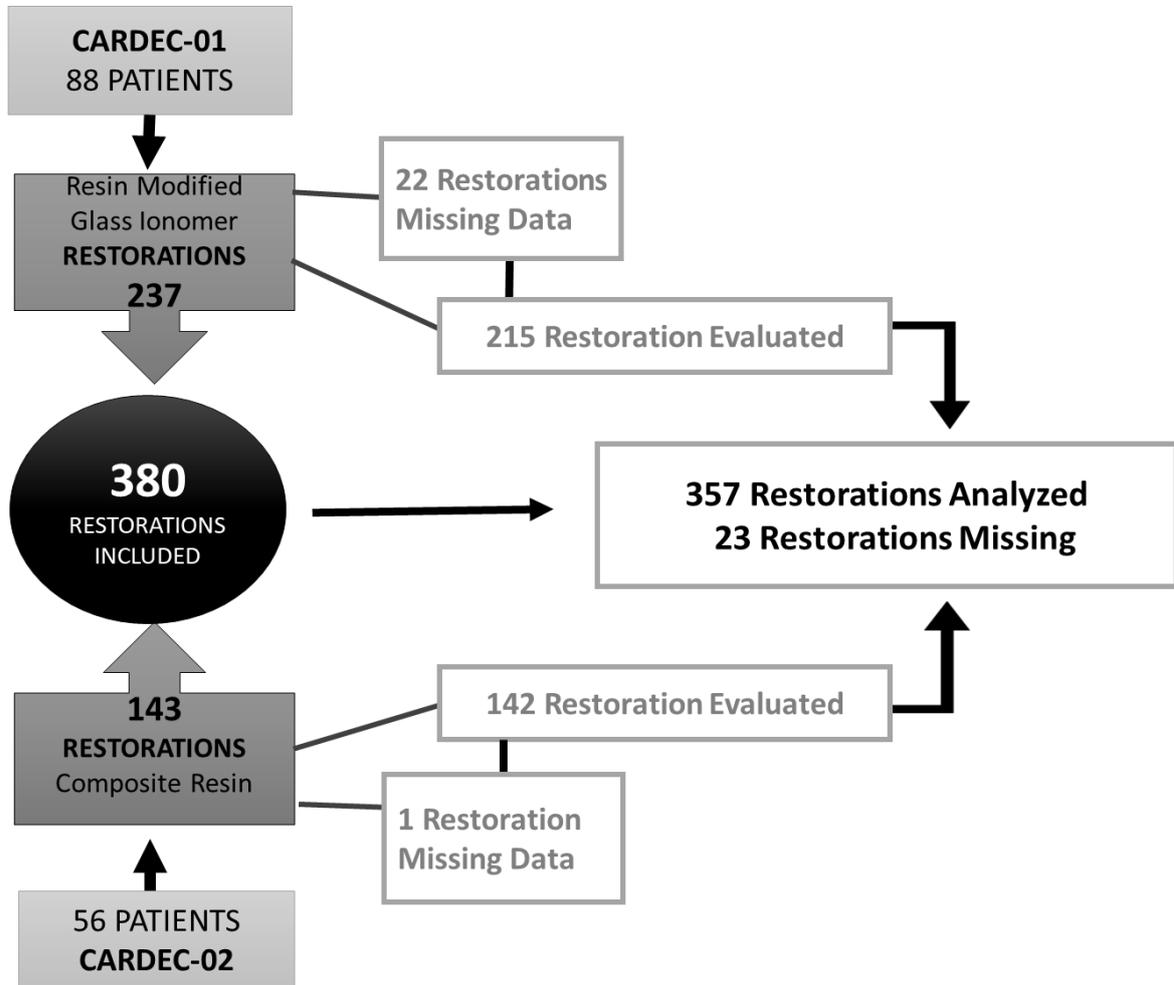
A total of 545 children were included in the two clinical trials (252 for CARDEC-01 and 293 for CARDEC-02), the records of all these participants were evaluated to select eligible participants and collect the information for this study. From them, 144 patients presented at least one anterior primary tooth restored, 53% (n=77) were male and 47% female (n=67). (table 4.1). In CARDEC-01 cohort, children presented a mean dmfs higher (15.01 SD=1.42) than CARDEC-02 cohort (8.78 SD=1.11). On average, each patient received two restorations (DP=1,8) on their anterior teeth (CARDEC-01 and CARDEC-02). From those, 237 restorations were performed with RMGIC and other 143 with CR. A total of 23 restorations (6%) from 8 patients could never be reevaluated during the follow-ups (figure 4.3), the mean of dmfs of those patients was 14.62 (SD= 13.73). Figure 4.3 shows our sample source and its distribution. There were no significant differences when analyzing separately all failures from just major failures, just a higher percentage.

Table 4.1 Characteristics and frequency of children included in the CARDEC trials

<b>SAMPLE CHARACTERISTICS</b>	<b>DESCRIPTION</b>	<b>CARDEC-01 N (%)</b>	<b>CARDEC-02 N (%)</b>	<b>TOTAL N (%)</b>
<b>Total Included Children</b>		<b>88 (61%)</b>	<b>56 (39%)</b>	<b>144 (100%)</b>
<b>Sex</b>	Male	45 (51%)	32 (57%)	77 (54%)
	Female	43 (49%)	24 (43%)	66 (46%)
<b>Age (dichotomized)</b>	3-4 years old	47 (53%)	28 (50%)	75 (52%)
	5-6 years old	41 (47%)	28 (50%)	69 (48%)
<b>Caries Experience (dichotomized)</b>	Low( ≤9 median)	36 (40%)	37 (66%)	73 (51%)
	High(>9 median)	52 (60%)	19 (34%)	71 (49%)

Source: Author

Figure 4.3 – Study sample composed by participants from two cohorts and who had anterior teeth restorations placed between 2014 and 2017



Source: Author

On table 4.2 is described the number of restorations that completed follow-up reexaminations. Similar proportions could be followed in both cohorts. The mean follow-up time was 28.7 months (CARDEC-01 and CARDEC-02).

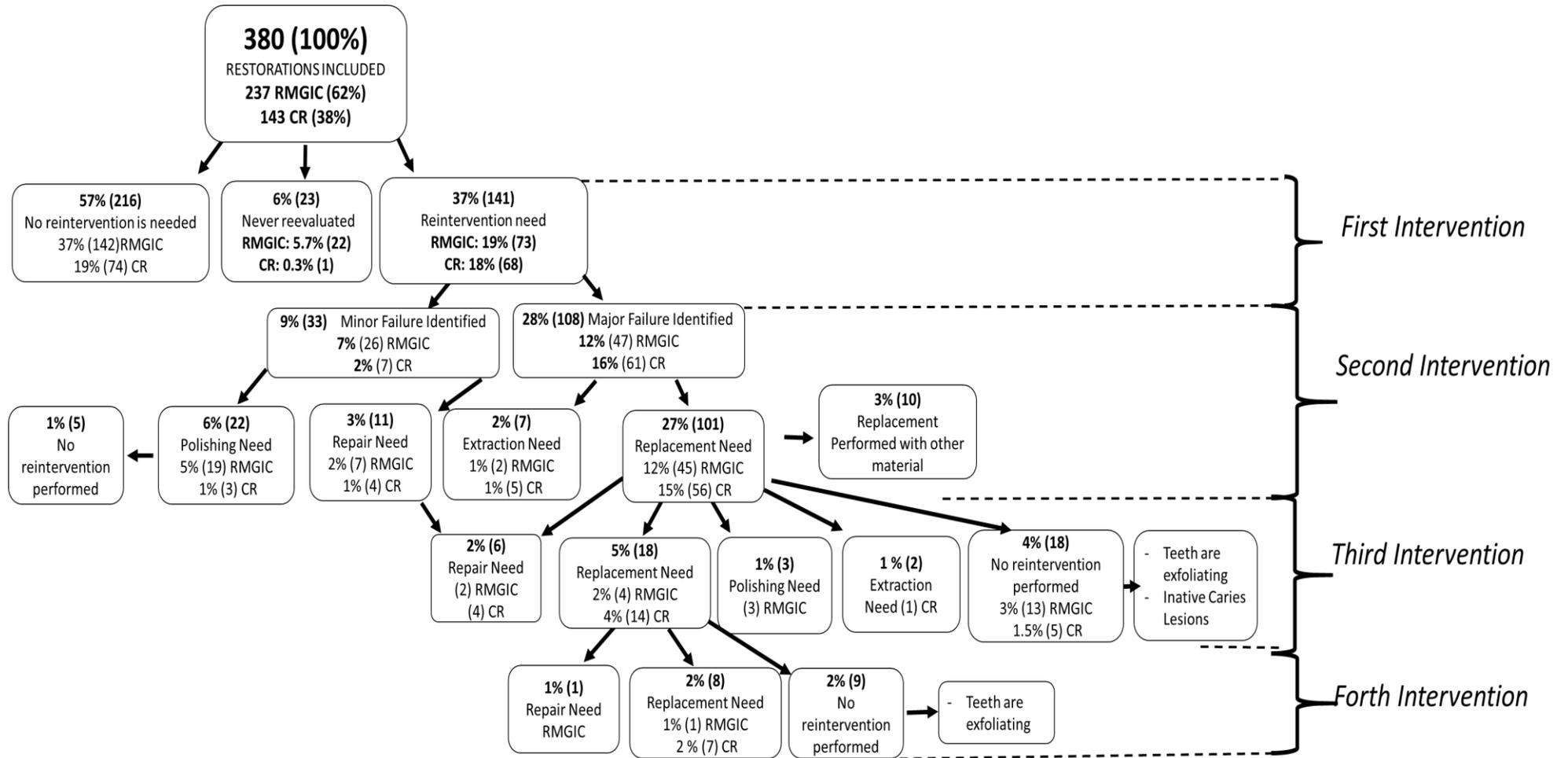
Table 4.2 - Anterior teeth restorations evaluated among 24 months of following-up.

<b>COHORT</b>	<b>RESTORATIVE MATERIAL</b>	<b>TOTAL INCLUDED RESTORATIONS N (%)</b>	<b>OF</b>	<b>12-months follow-up N (%)</b>	<b>24-months follow-up N (%)</b>
CARDEC-01	RMGIC	237 (62%)	Evaluated	211 (89%)	205 (86%)
			Not evaluated	26 (11%)	32 (14%)
CARDEC-02	CR	143 (38%)	Evaluated	127 (89%)	126 (33%)
			Not Evaluated	16 (11%)	17 (5%)
	<b>TOTAL</b>	<b>380 (100%)</b>		<b>380 (100%)</b>	<b>380 (100%)</b>

Source: Author

The flowchart below illustrates the natural history of restoration failures, replacements and repairments, observed in both cohorts (Figure 4.4).

Figure 4.4 – Flowchart, illustrating restorations and reinterventions performed on anterior primary teeth all over 24 month of following-up





Next results, related to the survival rate of restorations placed on anterior primary teeth, are going to be presented in two sections, the first section describes the survival obtained when we consider just a first single failure (showing the analysis for all failures and then, only for major failures). The second section describes the survival considering multiple failures occurred (considering all the reinterventions).

***All Failures (major failures + minor failures) – Single failure analysis (conventional survival)***

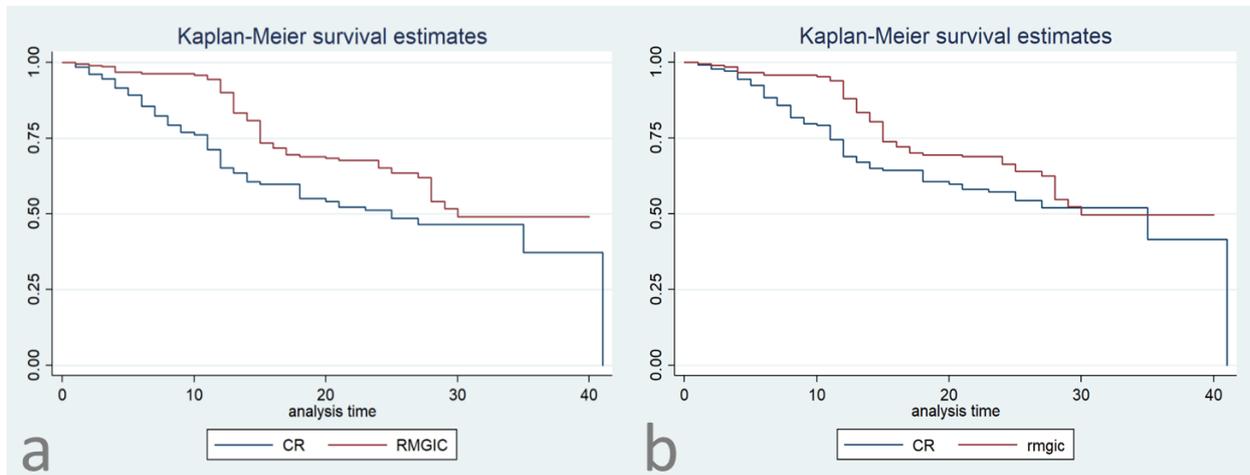
Only 8% of restorations had minor failures, the others presented failures considered as major (Figure 4.4). The restorations performed with CR presented higher failure rate (49%) than restorations performed with RMGIC (36%). The mean survival times for these materials were, respectively, 24.75 months (95%CI= 21.88 to 27.62) and 28.95 months (95%CI= 27.02 to 30.87) (Figure 4.5a). If we considered an extended mean for RMGIC would be 56.45 months.

Besides the restorative material used, the type of surface involved in the restoration (proximal) and restorations placed on the upper arch were considered risk factors to failure related to the teeth (Table 4.3). Additionally, those children with higher caries experience were those who presented more primary failures (Table 4.3).

***All Failures (major failures + minor failures) - Multiple Failures Survival***

When considering multiple failures, the restricted mean survival rates were slightly higher but similar between the restorative materials (RMGIC: 35% and CR: 39%) (Figure 4.5b). Additionally, survival times also slightly increased for both groups RMGIC (29.07 months; 95%CI=27.16 to 30.98) and CR (26.52 months; 95%CI=23.82 to 29.21).

Figure 4.5 - Kaplan-Meier curves for survival of restorations performed with different restorative materials, considering minor and major failures (a. Single First failure analysis and b. Multiple failures analysis)



Source: Author

On the other hand, considering the extended mean for RMGIC the mean survival time would be expected to be similar to those presented for single failures (57.38 months), maintaining the difference between restorative materials. Restorative material and caries experience were still associated with lower survival rates of the restorations. (Table 4.3). Repaired and contoured restorations had lower risk of failure than the primary restorations ( $HR=1.81^{e-14}$ ;  $95\%CI=3.70^{e-15}$  to  $8.91^{e-14}$ ); while replaced restorations had a higher risk of failure than the primary restoration ( $HR=61.61$ ;  $95\%CI=11.33$  to  $334.94$ ).

Table 4.3 – Cox regression models considering as outcome: all failures (including replacements and repairments) in restorations of primary anterior teeth

INDEPENDENT VARIABLE		SINGLE FIRST FAILURE				MULTIPLE FAILURES			
		Crude HR (95%CI)	P VALUE	Adjusted HR (95%CI)	P VALUE	Crude HR (95%CI)	P VALUE	Adjusted HR (95%CI)	P VALUE
<b>SEX</b>	Male	Ref.		-	-	Ref.		-	-
	Female	1.15 (0.71-1.87)	0.55			1.14 (0.55-2.36)	0.72		
<b>AGE (dichotomized)</b>	3-4 years old	Ref.		-	-	Ref.		-	-
	5-6 years old	1.35 (0.83-2.19)	0.23			0.70 (0.33-1.45)	0.33		
<b>CARIES EXPERIENCE</b>		1.01 (0.99-1.03)	0.39	1.02 (1.00-1.04)	0.03	1.03 (1.01-1.04)	<0.001	1.05 (1.03-1.07)	<0.001
<b>MOUTH SIDE</b>	Right	Ref.		-	-	Ref.		-	-
	Left Side	1.05 (0.74-1.49)	0.79			1.58 (0.75-3.37)	0.23		
<b>ARCH</b>	Inferior	Ref.				Ref.		-	-
	Superior	2.67 (1.40-5.11)	<0.001	2.23 (1.12-4.46)	0.02	0.80 (0.23-2.85)	0.74		
<b>TYPE OF TEETH</b>	Central Incisor	Ref.		-	-	Ref.		-	-
	Lateral Incisor	0.84 (0.56-1.28)	0.42			0.94 (0.32-2.72)	0.91		
	Canine	0.91 (0.55-1.51)	0.70			2.41 (1.08-5.39)	0.03		
<b>TYPE OF SURFACE INVOLVED</b>	Only smooth	Ref.		Ref.		Ref.		-	-
	Proximal	2.05 (1.29-3.28)	<0.001	1.72 (1.05-2.83)	0.03	1.74 (0.62-4.93)	0.29		
<b>ENDODONTIC TREATMENT</b>	No	Ref.		-	-	Ref.		-	-
	Yes	1.16 (0.49-2.71)	0.74			1.52 (0.57-4.06)	0.41		
<b>RESTORATIVE MATERIAL</b>									
Composite Resin		Ref.		Ref.		Ref.		Ref.	
RM Glass Ionomer		0.44 (0.27-0.73)	<0.001	0.38 (0.23-0.65)	<0.001	0.40 (0.20-0.83)	0.01	0.22 (0.09-0.52)	<0.001

Source: Author



***Major Failures (failures requiring replacement) – single failure analysis (conventional survival)***

When only major failures were considered, the differences between restorative materials became more evident. Thirty percent of restorations presented major failures (n=113). The restorations performed with CR presented higher failure rate (44%) than restorations performed with RMGIC (23%). The mean survival times for these materials were, respectively, 26.10 months (95%CI=23.32 to 28.87) and 32.69 months (95%CI= 30.86 to 34.52) (Figure 4.6 a). Considering the extended mean, survival time for the RMGIC would be 96.0 months.

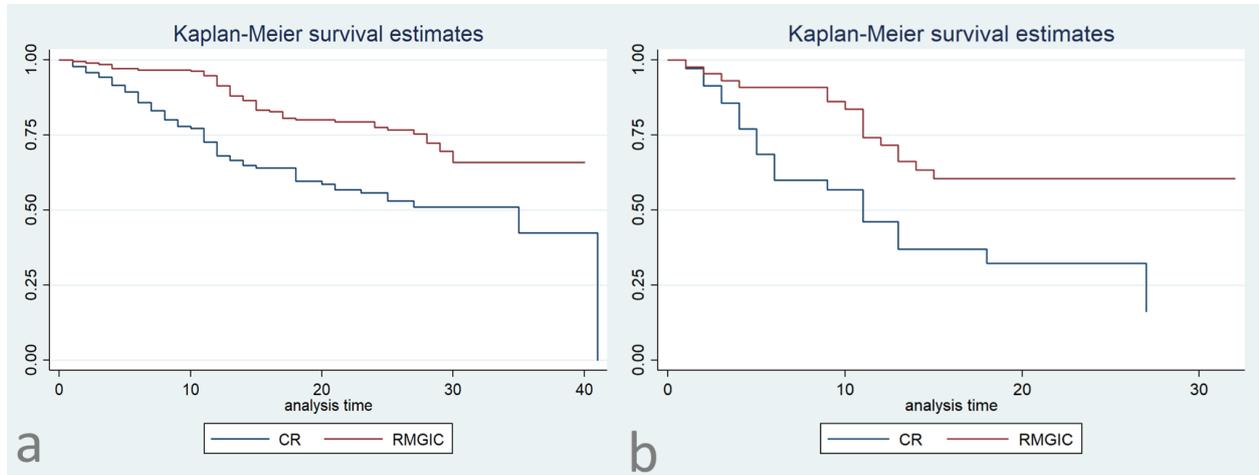
Trends observed in the regression analyses performed considering all failures were maintained when only major failures were considered (Table 4.4). Nevertheless, at this occasion, RMGIC restorations had an even lower risk of failure than CR restorations (Table 4.4). Moreover, restorations involving proximal surfaces still had more an increased risk of failure (Table 4.4).

***Major Failures (failures requiring replacement) – multiple failure analysis***

When we include multiple failures to the survival analysis, trends have not been changed, slight differences could be observed in survival curves plotted (Figure 4.6 b). The percentage of failures increased for both materials (RMGIC: 31%, CR: 59%) Survival time slightly increased for RMGIC reaching, on average, 30.62 months (95% CI: 28.79 to 32.45), while, for the CR decreased to 21.84 months (95%CI: 19.58 to 24.10).

Table 4.4 shows the Cox regression models for this outcome. As for single failures, caries experience and restorative material were similarly associated with the survival of restorations (Table 4.4). The reinterventions performed after the failures (repairments or replacements) did not fail more than the primary restoration (primary restoration vs. 1<sup>st</sup> reintervention - HR=0.35; 95%CI:0.30 to 1.52 / primary restoration vs. 2<sup>nd</sup> reintervention (HR=0.95; 95%CI=0.38 to 2.33).

Figure 4.6 – Kaplan-Meier curves for survival of restorations performed with different restorative materials, considering major failures (a. Single First failure analysis and b. Multiple failures analysis)



Source: Author

Table 4.4 – Cox regression models considering as outcome only major failures in restorations of primary anterior teeth

MAJOR FAILURES INDEPENDENT VARIABLE		SINGLE FIRST FAILURE				MULTIPLE FAILURES			
		Crude HR (95%CI)	P VALUE	Adjusted HR (95%CI)	P VALUE	Crude HR (95%CI)	P VALUE	Adjusted HR (95%CI)	P VALUE
SEX	Male	Ref.		-	-	Ref.		-	-
	Female	1.07 (0.59-1.93)	0.82			1.14 (0.61-2.12)	0.67		
AGE (dichotomized)	3-4 years old	Ref.		-	-	Ref.		-	-
	5-6 years old	1.20 (0.66-2.19)	0.54			0.97 (0.52-1.18)	0.92		
CARIES EXPERIENCE		1.01 (0.99-1.03)	0.41	1.03 (1.00-1.05)	0.03	1.03 (1.01-1.04)	0.00	1.05 (1.03-1.07)	<0.001
MOUTH SIDE	Ref.	Ref.		-	-	Ref.		-	-
	1.08 (0.72-1.61)	1.08 (0.72-1.61)	0.72			1.57 (0.77-3.21)	0.21		
ARCH	Ref.	Ref.		-	-	Ref.		-	-
	3.27 (1.55-6.89)	3.27 (1.55-6.89)	<0.001			1.16 (0.27-4.95)	0.84		
TYPE OF TEETH	Central Incisor	Ref.		-	-	Ref.		-	-
	Lateral Incisor	- 0.81 (0.50-1.33)	0.41			1.10 (0.47-2.59)	0.83		
	Canine	1.07 (0.60-1.88)	0.82			1.73 (0.79-3.78)	0.17		
TYPE OF SURFACE INVOLVED	Only smooth	Ref.		Ref.		Ref.		-	-
	Proximal	2.05 (1.29-3.28)	<0.001	2.03 (1.20-3.41)	0.01	1.81 (0.80-4.08)	0.15		
ENDODONTIC TREATMENT	No	Ref.		-	-			-	-
	Yes	1.94 (0.80-4.72)	0.14			1.38 (0.60-3.21)	0.45		
RESTORATIVE MATERIAL		Ref.							
Composite Resin		0.32 (0.81-0.57)	<0.001	Ref.		Ref.		Ref.	<0.001
RM Glass Ionomer				0.26 (0.14-0.48)	<0.001	0.40 (0.21-0.74)	0.00	0.22 (0.11-0.47)	

Source: Author



#### 4.4 DISCUSSION

Our main findings indicate that the occurrence of major failures on restorations, (replacement need), are linked to some specific aspects. The restorative material is one important variable influencing the replacement of restorations in anterior teeth. In the present study, we compare the performance of two of the adhesive restorative materials most commonly indicated and used. According to previous studies, CR and RMGIC are usually chosen to restore anterior teeth (35,38,40,48,67), even in permanent dentition, since they permit conservative preparations and fulfill patient's esthetics demands.

Glass ionomer cements have been widely used in Brazil to restore primary teeth due to the advantages of ease of the technique, which reduces chair time. In our study, RMGIC restorations had higher survival rate than CR restorations. The lower rates of failure achieved by RMGIC restorations is in line with literature, showing that RMGIC presented good survival rates for both anterior and posterior restorations (56,64,68–70). Properties such as chemically adhesion to enamel and dentin, lower sensitivity to moisture and lower shrinkage compared to CR may be associated to the better clinical performance achieved for RMGIC restorations in primary anterior teeth.

Differently from RMGIC, very few repairments were performed on CR restorations. Another retrospective study showed that most of the failed anterior CR restorations (83.3%) in primary teeth needed replacement (50), what was also evidenced in our study. That is why, the survival rates were less impacted when only major failures were considered. However, clinically, this difference could be an important pattern to be highlighted, especially considering costs and the entrance in the repetitive restorative cycle.

According to a recent systematic review, CR restorations placed on anterior permanent teeth presented a total annual failure rate of 24.1% (71). In contrast, we have found higher rates of failure for CR restorations performed in anterior primary teeth. This finding is independent of considering all failures or only major failures. This difference may be related to the differences on bond strength between primary and permanent

teeth (72), the sensitive technique of resins, to the hampered mission of controlling moisture in young children, the reduced amount of remaining tooth structure due extensive carious lesions (73) or also, the proximity of carious cavities to the gingival tissue, feature that aggravates the presence of humidity in our field from gingival fluids.

This supports our theory that the same material could behaves differently, when applied in anterior primary or permanent dentition, even when the expectancy was to get similar performances owing to the restorative protocols had being adjusted for primary dentition (e.g. etching time)(74). Actually, there is a lack of studies evaluating materials specifically for anterior primary teeth on the current scientific literature, reinforcing the present study as a manner of creating new and appropriate evidences for restorative dentistry in primary teeth. This observation might be explained due to the low prevalence of restorative needs reported for these type of teeth (compared to posterior ones) or also to an automatic extrapolation of results observed for permanent teeth. Besides its particular behavior in comparison with permanent teeth, primary anterior teeth are important to maintain child's good self-esteem, phonetics and oral functionality (75,76) and, consequently, oral health-related quality of life(77).

Some aspects about the protocol of use for the studied material should be raised up. CR restorations evaluated in this study were performed using a 3 step etch and rinse bonding strategy, according to the main trial pre-established protocol. By the time of its implementation, this approach was chosen based on the best current scientific evidences and such bonding system was appointed as the "gold standard"(78)We assumed that none or very slightly different results could be obtained by using, for example, a more recent self-etch bonding system. Regarding the manner for moisture control (relative isolation) during restorative procedures, we believe that it would not greatly change our findings. Although it is well known in the literature the CR is sensitive to moisture (41,79,80) and that could be easily solved by using the rubber dam, other alternatives, as relative isolation with saliva ejectors and cotton rolls, may be shown as efficient ways of moisture control (81).

We cannot simply assume the lower longevity in this study observed for CR is exclusively a matter of inadequate moisture control, since other factors are also present, as addressed before. Especially for the proximal surfaces, which presented approximately twice higher risk of failures than RMGIC, we should also consider that

we would also have additional technical difficulties in adapting the rubber dam and would probably need to use the local anesthesia when the option is to use the absolute isolation. Besides other characteristics could be added up as: the thinnest characteristic of the proximal surface, that contributes again to a limited bonding area; a shorter clinical crown height of anterior teeth, that requires a cavity preparation as conservative as possible, because the interproximal contact tends not to be easy to rebuild and usually it is going to be necessary the employment of matrices for that. Nevertheless, metal or polycarbonate band thickness could also hinder the insertion of the restorative material, resulting into an insufficient filling of cavity and a more shrinkage of the material, favoring the incidence of failures.

In a previous retrospective study, anterior two-surface CR restorations had 90.2% of success over three years and nearly half of failed multi-surfaces anterior CR restorations needed repairs (50). Although we have also tested the involvement of multiple surfaces as a risk factor for failure, the proximal involvement seemed to be a more important factor to be considered for anterior primary teeth. On the other hand, when failures on replaced restorations were included, this factor was not associated with the outcome. Usually, by the second or third restorative interventions, the cavity size tend to be increased (repetitive restorative cycle) and this condition could naturally minimize the deal caused by primary proximal cavities to be restored.

Given that our findings proceed from a population seeking for dental care, we assume that these results can be extrapolated to the reality of the dentists in their offices. Moreover by the fact of restorations had been placed under relative isolation methods, that makes these findings even closer to pediatric dentists` reality, since dentists are more likely to not choose rubber dam isolation technique to perform restorative treatments(41,80,82–84), even less for children.

The retrospective assessment of restoration longevity is common in dental research, because it offers information about restorations survival and characteristics possibly associated to the occurrence of failures. In this study, we could establish an explanatory relationship with some individual and dental features that are important to be considered from now on before performing restorations on anterior primary teeth. For finding that, we observed two cohorts, different between themselves due to the material used for restorations. Certainly, we must consider these cohorts could present

other possible differences besides that one, even trying to choose comparable cohorts. The CARDEC-01 presented, on average, children who had greater caries experience, what could influence on restorations survival (66,85,86), what it could have been minimized if we have opted for performing a randomized clinical trial (RCT) instead of a observational study. That is why, for this study, we adjusted the cox regression models for this variable to minimize this possible undesirable effect and permit a more reliable estimation of the effect of materials on restoration performance.

Although RCTs offer greater scientific support in the choice of treatment options, factors related to ethical, financial, time and human resources can difficult their execution. Another important aspect is that because the extremely controlled conditions that RCT are conducted, their results may not be completely inferred to clinical practice (71,87–89). Therefore, cohort studies seem to be important tools to precede this type of study and as well to identify possible factors associated with the success or the failure of these type of restorations. In the present study, research staff was trained to run defined protocols in each situation involving dental care in a RCT designed for other purposes. The level of experience and training (67,71,90) is certainly an aspect that approximate the cohorts in and reinforced their possibility of comparisons in terms of the restoration longevity. However, as restoration of anterior teeth were not the focus of such trials at that moment, we can assume a lower level of control was expected, compared to a classical RCT.

This study also comes into question the survival analyses in general and differently from previous studies, we have performed an innovative analysis, which includes the possibility of analyzing multiples failures events (58,59). In medical research is common to have an event of interest that can take place more than once in the same individual, in dentistry that is not different, especially when we think about dental restorations which from the moment that were placed are constantly in risk of failure. Considering that many features, related to the teeth, oral conditions, children and of course aspects related to the socioeconomically reality in which the patient is inhered can affect that restorations survival.

Unlike the conventional survival analyses where only a first failure is observed in the new analyses approaches there are considered all recurrent events (failures) and the patient continues to be observed even after the occurrence of the first event. (58,59)In

the first case from the moment that the subject presents the first failure, he is no longer monitored by the researchers and only part of the information is used, so important data obtained in the rest of the follow-up is wasted. Multiple failure analyses are very reasonable and applicable for this kind of outcome because they permit more approximate findings from the real world, when we observe that some restorations tend to failure multiple times, while others never fail.(57) Therefore, when there are non-standard situations, it is worth to apply innovative methods and looking for other alternatives that allow to analysis the complete data before discarding valuable information.

As available evidence normally presents models considering single failures, we opted for using both approaches in order to guarantee the comparability of our results. We used the conditional risk set model, a manner to incorporate robust variance-covariance estimators that are constructed to account for the intra-class correlation, since multiple events (different failure times within the same cluster) are correlated (59,66). The baseline hazard functions for the marginal models may be identical or different, but ignoring the intra-class correlation could yield rather misleading variance estimators (66). In the present study, the number of restorations under risk increased in 20% after including repairments and replacements. Even including these restorations, the restorative material was maintained as an importance source of variation when major failures were considered. Besides, the caries experience also influenced on the outcome tested. Nevertheless, when including these reinterventions, the RMGIC restorations survived, on average, for longer time, while CR decrease the survival time. Facing these changes, we can suggest the reinterventions can be even more critical for complicate for CR restorations and reinforcing the hypothesis that the RMGIC could be a better option to be chosen when restoring anterior teeth. This observation is loess expressive when only major failures were observed, reinforcing the observation that, differently from RMGIC, the CR tends not to require repairments, but replacements, what could impact on other outcomes, as costs and parent's and child's perceptions and preferences.

Undoubtedly, more controlled studies are needed to explore better the relationship of the survival of restorations in primary anterior teeth with the exposed risk factors. Our explanations can be important for clinicians and researchers to encourage a

development of new approaches and to improve the survival of these teeth restorations.

In conclusion, for restorations placed in anterior primary teeth, the performance of RMGIC was superior than CR. Besides the dental material, local and general characteristics as involvement of proximal surfaces and caries experience, are factors associated to failures observed in these restorations.

## 5 CHAPTER III

*Impact of failures on restoration in anterior primary teeth - exploring their influence in economic aspects and children's quality of life related to oral health*

### **ABSTRACT**

The use of economic analysis and patient-centered outcomes can be helpful in health care for determine a more suitable treatment. This study aimed to perform an economic evaluation of two different restorative materials for anterior primary teeth, considering the cumulative costs caused by the need of repairments and replacements due to failures. Besides, we investigated the impact of their failures on OHRQoL. Data from the same 144 patients (380 adhesive restorations) in Chapter II, were evaluated retrospectively for this study. Data related to direct and indirect costs of RMGIC and CR restorations were collected considering cumulative costs over 24 months. The ECOHIS scores reported before and after restorative procedures were also registered. Costs related to treatment using the two materials were compared using bootstrapping regression analyses. ECOHIS scores in each cohort were compared before and after treatment using Wilcoxon test and between the cohorts using the Mann Whitney test. Poisson regression analyses were performed to test the influence of materials and failures over 24 months on OHRQoL. Incremental cost-effectiveness ratio (ICER) was calculated using the RMGIC as an alternative to CR using different effects (survival rate, survival time and change in OHRQoL). Restoration of cavities on anterior primary teeth improved children's OHRQoL, but those children who presented failures on their restorations, despite the restorative material, reported having lower ECOHIS scores after 24 months. RMGIC restorations were more expensive (BR\$=45.18; 95%CI=41.88 to 48.47) than CR (BR\$=35.60; 95%CI=32.10 to 39.09) at baseline, but this difference was diluted after 24 months due to a higher number of reinterventions (RMGIC: BR\$=59.78; 95%CI=53.74 to 65.81; CR: BR\$=58.04; 95%CI=50.60 to 65.48). Costs of non-proximal restorations seemed to be less influenced than proximal ones. The ICERs, despite the effect considered, was not superior to BR\$=0.50 per unit of effect considered. Although failures on restorations can impact on OHRQoL, no direct

relationship was observed for any specific restorative material. Besides, the RMGIC is shown as a suitable alternative to CR, being considered economically feasible to be used as restorative material for caries in primary anterior teeth.

Keywords: Cost-Effectiveness; Anterior Teeth Primary; Quality of life

## 5.1 INTRODUCTION

Currently, the performance of restorative techniques and materials is investigated considering their survival rates and times (91). However, other outcomes have been showed as relevant when testing some intervention, before widely disseminate is use in clinical practice. Among these outcomes, we could state the costs (economic evaluations) and the patient-centered outcomes, e.g. patients' satisfaction and impact on OHRQoL.

The economic evaluations are increasing in health care, and especially in dental research, since the knowledge about costs (arising from diseases and from their alternatives forms of treatment) leads to a constantly improvement of health care protocols (92–94). One of the economic analysis used in dentistry is the Cost-effectiveness analysis (CEA). The main purpose of CEA is to evaluate treatment procedures costs and then, compare them to establish a relationship with the clinical benefits that they can provide.

Evaluate the cost-effectiveness of dental restorative approaches helps identify which interventions/materials actually works and how much they cost. In pediatric dentistry this analysis was widely used (95–97) and have been reported as an instrument that helps clinicians in the decision making process. However, thinking about primary anterior teeth, the literature does not offer any register of how much costs to perform restorations on these type of teeth, neither if there is a more cost-effective alternative treatment for them.

It was already demonstrated that the survival of restorations performed on anterior primary teeth is differently than those performed on posterior or permanent teeth. Consequently, it is also necessary to investigate if the current approaches used for anterior teeth are being effective, and also determine which of the available treatment modalities can be more suitable economically.

Both, economic and effectiveness aspects can influence the decision making, but mostly important, this decision have to consider the patient's needs, because dental restorative care and its long-term effects are directly related to children's OHRQoL(11,75,76,98,99). It is known that restorative treatment can impact on

children's OHRQoL(27,77,100,101), although we can expect such type of effect for adhesive restorations, few studies have tested this hypothesis systematically (102). As we showed in chapter II, CR restorations presented more failures requiring replacement than RMGIC. Nevertheless, the best of our knowledge, the impact of these failures has not been explored yet. Therefore, the aim of this study was to investigate the impact of failures in restorations of anterior teeth on children's OHRQoL and also, to perform an economic evaluation of restoring anterior primary teeth investigating if the RMGIC is a possible efficient alternative to CR when the relative isolation is chosen.

## 5.2 MATERIAL AND METHODS

### **Study Description**

The present study has a retrospective design and was elaborated following the guidelines of "The Consolidated Health Economic Evaluation Reporting Standards' (CHEERS) statement. It was based on the same sample from chapter II (two cohort of children from CARDEC trials). The ethical issues, characteristics of patients, inclusion methods, dental treatments and following-up information were already described.

### **Data Collection**

Information about the Brazilian version of the ECOHIS questionnaire (22–24) were collected from the children's files. The ECOHIS total scores were registered considering two moments: the baseline and the 24-month follow up.

The information regarding costs of restorative procedures performed on anterior primary teeth were collected from the patients' files (digital baseline). The files contained reports of every restorative treatment executed, specifying the quantity of materials, instruments, and time used during the session. Data was registered by trained and calibrated operators on predetermined sheets, that also contained information related to patients' out-of-pocket expenses (Annex 2). The costs of all

restorations performed among 24 months of following-up of patients from the two cohorts were evaluated.

### *Costs assessment*

For this study, we adopted a societal perspective approach (94,103) to calculate the cost of restorative procedures, which were measured in Brazilian Real (BRL). To determine a final total cost of an anterior teeth restoration, both of the direct and indirect costs were considered and summarized. On figure 5.1 are presented all the aspects for costs composition. Direct costs represented those expenses that are straightly associated with the restoration technique and indirect costs comprehended other expenses incurred by patients and caregivers to be receiving the restorative treatment. In case of missing data, due to incomplete registers or due to the absence of the cost sheet in patient's file, it was solved by imputing values corresponding to the mean cost of each specific restorative procedure (primary restoration, repairment, replacement or polishing). determined by the cohort or restorative group. Details related to the calculation was described below (Figure 5.1).

#### *Direct costs: Professional costs*

To calculate these costs, the time spent (in hours) by the operators (dentist and dental assistant) in each restorative session was multiplied by the average income of a dentist and the dental assistants per hour, according to the minimum wage for the state of São Paulo, as suggested by Brazilian Federal Law (16.665) (104).

### Material costs

To estimate the material cost, we consider every dental material used during the restorative sessions, each material's quantity registered on the file was multiplied by a mean value of the material price (previously assessed in three different dental stores).

### Equipment/ instrumental maintenance costs

Equipment and maintenance costs were calculated considering a total time (in hours) that patient stayed at the dental unit, during the restorative procedures. This time was multiplied by the average cost of equipment utilization. In addition to these costs, the depreciation of both instrumental and equipment was calculated and summarized, it was based on the estimation of the lifespan, calculated with 3 years for instruments and 5 years for equipment combined to a monthly use of 160 hours for our calculations.

### Accommodation cost

The cost for the mobile dental unit accommodation was estimated per hour of use, by applying the cost per m<sup>2</sup> to the space (area) occupied by the dental unit (13.5 mm<sup>2</sup>). The lodging cost was based on the current municipalities taxes and the average of previous local property market research. Summarized to this, the estimate of electricity was also measured following the same methodology.

### *Indirect costs*

Costs considered as indirect, for this study, were those costs (out-of-pocket) that the patients/caregivers expended with transportation to arrive to the dental appointments; or expenses due to salary discounts of the accompanier (in the case of work absenteeism). The time of children and parents was also valued and converted to a monetary value.

Transportations costs were calculated based on the distance from participants' homes to the dental unit. That distance was calculated by Google Maps routes. As the majority of children informed to show up using car as their type of transportation, this method was patronized for all of children and all of appointments. The distance obtained was multiply by an average price for fuel used by a car. A fixed ratio of 8.5 kilometres per litre of fuel was assumed.

### Time Value

The time of patients and their accompanying caregivers was also considered in this study, including the time related with transportation, waiting time and active treatment.

To value the accompanying person's and children time, an average of monthly Income for Brazilian population was estimated using the mean from 2012 to 2017. For the analysis the mean value referent to a working day was used (mean= 4,87 [IBGE surveys](#), Brazil). Then, the mean number of working days in the same period was considered. Assuming 8 hours for a working day. The same strategy was used for value children time.

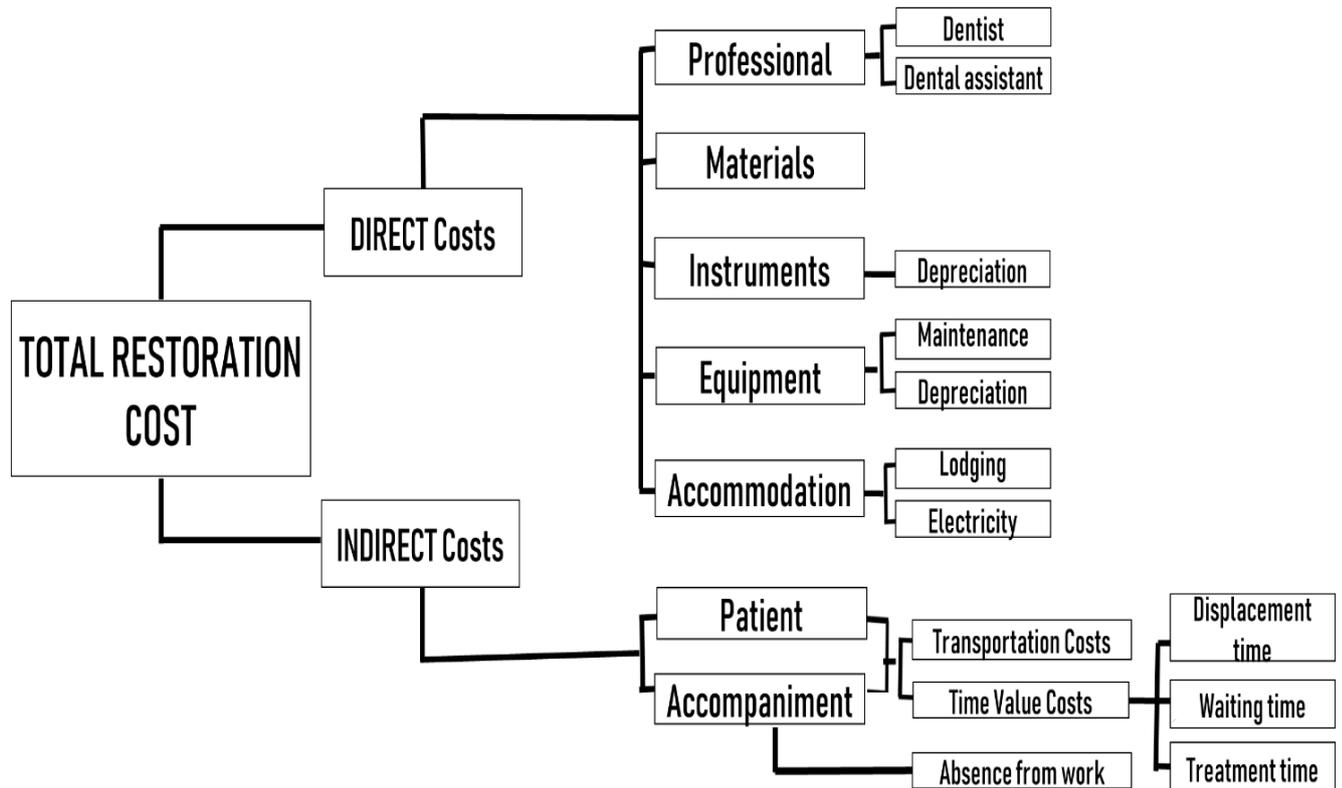
Displacement times were estimated, from the child's residence to the dental unit (round-trip) based on Google Maps routes given the type of transportation informed (car).

Waiting time was assumed as 15 minutes per session attended. These partial times were considered for all dental visits attended by each child.

### Absence from work

If accompanying person reported losing wages due to absenteeism during his/her child's dental visits, an additional cost was included, corresponding to a time that the accompanying children stayed in treatment multiplied by an average of costs of 8h-working day.

Figure 5.1 - Scheme showing all the items considered to calculate a costs of restorations performed on primary anterior teeth



Source: Author

## Statistical Analysis

### *Quality of life*

Prior to statistical comparison, to evaluate normality and homogeneity of variance, the variable ECOHIS scores were submitted to Kolmogorov-Smirnov and Levene's tests. As no measures were normally or homogeneously distributed, we used non-parametric tests. Then, we compared ECOHIS scores obtained at baseline and after 24 months using Wilcoxon tests. We conducted between restorative of ECOHIS scores at baseline and after treatment using Mann-Whitney tests. To interpret differences between scores before and after each treatment, we calculate the minimal important difference using the distribution approach. For that, we estimated the ES, dividing the mean of the differences by the SD of the baseline scores (105).

To evaluate the impact of anterior teeth's restorative failures we performed multilevel univariate and multiple Poisson regressions analyses with robust variance that was used to identify possible associated factors with the mentioned outcomes. Initially, univariate analyses were performed for each independent variable. We explored other independent variables, including: sex (male or female), age (3 to 4 years vs. 5 to 6 years), caries experience (i.e. the number of decayed, missing, and filled surfaces of primary teeth;  $dmf-s < 4$  vs  $dmfs \geq 4$ ), For these analyses, two outcome variables were considered. Subsequently, multiple regression analyses were performed using a forward stepwise approach. Variables were selected from using a hierarchical approach, in which the variables were ordered into levels to determine their inclusion in the statistical analysis. All associations were adjusted for covariates positioned in the same and upper levels of the model. In each level, the variable selection followed the forward stepwise method. In each level, those variables presenting p-values lower than 0.2 in the unadjusted model or those with a biological feasibility to be tested were selected for the multivariate analysis. relative risk (RR) values and 95% confidence intervals (95% CIs) were calculated. The level of 5% was used to retain the variables in the multiple model.

### *Economic analysis*

Based on the assumption that survival rates achieved by adhesive restorations on anterior primary teeth are not very high, we assume that this could have an impact on the cost of these procedures, considering that possibility, in this chapter, we outlined two main purposes:

- Estimate and compare the costs of two different restorative approaches (RMGIC and CR) used for restoring anterior primary teeth.
- Calculate the incremental cost-efficacy (ICER) of using the RMGIC as an alternative material to restorative treatments of primary anterior teeth. For that, all reinterventions (repair and replacement) for 24 months of following-up were considered.

For our analyses the software used was Stata13 (StataCorp LP, Texas), and the significance level set was set at 5%. According to an intention-to-treat analysis, the costs and the effect of the two restorative methods used for anterior primary teeth, were measured and explored in the present study. Variables tested for baseline costs analysis included: restorative material (RMGIC vs CR), type of teeth (central incisor, lateral incisor or canines), number of surfaces restored (one surface vs. two or more surfaces), type of surface involved in the restoration (smooth or approximal) and age (dichotomized: 3 to 4 years vs. 5 to 6 years). Retrospectively, the incremental costs registered at files for anterior teeth restorations, throughout 24 months, were measured, in Brazilian Real (BRL), and then compared using Student's test. A bootstrapping quantile regression analysis was also performed. The variables tested for incremental costs were: restorative material (RMGIC vs CR), number of surfaces restored (one surface vs. two or more surfaces), type of surface involved in the restoration (smooth or approximal), number of interventions performed (initial restoration vs. multiple reinterventions), age (3 to 4 years vs. 5 to 6 years), caries experience (dichotomized by the median: <9 vs.>9). These strategies were used for comparing separately direct and indirect costs.

Since the CR is a more widely used material than RMGIC, it was used as the reference for calculations of ICER. Then, the aim of this analysis was to verify if the RMGIC restorations of anterior primary teeth could be more efficient way of allocating resources compared to CR. Thus, the ICER was calculated dividing the incremental cost of performing RMGIC restorations instead of CR restorations by the incremental effect of making the above-mentioned choice. As effect, we set: the mean survival rates, the mean survival times and rate of change in ECOHIS scores (baseline vs. 24-month follow-up), considering the minimum important difference.

Analysis of the restorative approaches' cost-effectiveness were adopted to assess the more effective method for restoring anterior primary teeth. The total average of restorative procedures' costs will be

$$\text{ICER} = (\text{costRMGIC} - \text{costRC}) / (\text{effect RMGIC} - \text{effectRC})$$

### 5.3 RESULTS

#### *Impact of Restorative failures on OHRQoL*

One hundred twenty-two parents (84.7%) responded the ECOHIS questionnaires, both at the baseline and after 24 months from the treatment. As mentioned in Chapter II, children from CARDEC-01 cohort presented higher caries experience (mean dmfs=15.0, SD=1.4) than those from CARDEC-02 (mean dmfs=8.8, SD=1.1). ECOHIS scores at baseline were also higher in CARDEC-01 (RMGIC restorations) than in CARDEC-01 (CR restorations) (Table 5.1).

Despite the cohort, final ECOHIS scores were reduced after children received dental treatment (Table 5.1). At 24-month follow-up, no differences could be observed between groups (Table 5.1 and 5.2). Higher final ECOHIS scores were associated with children with higher caries experience and higher baseline ECOHIS scores (Table 5.2).

Those children who presented failures had higher ECOHIS scores, independently of these other mentioned variables (Table 5.2).

Table 5.1 - Comparison of ECOHIS scores reported by parents at baseline and after 24 months of follow-up

	<b>Baseline ECOHIS</b> Mean (95%CI)	<b>Final ECOHIS (24 months)</b> Mean (95%CI)	<b>P value</b>	<b>MID*</b>
<b>CARDEC-01</b>	8.0 (5.0-11.0)	2.0 (1.0-5.0)	<0.001q	4.605 (~5)
<b>CARDEC-02</b>	4.0 (2.0-6.0)	2.5 (2.0-4.0)	0.03	3.095 (~4)
<b>P Value</b>	<0.001	0.85		

\* MID: Minimum importance difference – calculated as a half of standard deviation correspondent to the mean baseline ECOHIS score for the cohort (106).

Source: Author

Table 5.2 ECOHIS Regression Model, showing a statistical difference for quality of life outcome

INDEPENDENT VARIABLE	FINAL ECOHIS	UNIVARIATE		MULTIVARIATE	
	scores Mean (SD)	RR (95%CI)	P VALUE	RR (95%CI)	P VALUE
<b>RESTORATIVE MATERIAL</b>					
RMGIC (ref.)	4.66 (5.80)				
CR	3.84 (4.14)	0.91 (0.76 - 1.08)	0.29	1.07 (1.03 - 1.05)	0.47
<b>BASELINE ECOHIS</b>					
CARDEC-01 (ref.)	-				
CARDEC-02		1.04 (1.03 - 1.04)	<0.001	1.04 (1.03 - 1.06)	<0.001
<b>OCORRENCE OF FAILURES</b>					
No (ref.)	4.02 (5.71)				
Yes	4.66 (4.83)	1.20 (1.01 - 1.43)	0.04	1.20 (1.01 -1.43)	0.04
<b>FAILURES IDENTIFIED BY PARENTS</b>					
No (ref.)	3.89 (4.53)				
Yes	7.62 (8.01)	2.05 (1.68 - 2.51)	<0.001	-	-
<b>ENDODONTIC TREATMENT</b>					
No (ref.)	4.47 (5.34)				
Yes	3.54 (4.29)	0.81 (0.60 - 1.10)	0.18	-	-
<b>SEX</b>					
Male (ref.)	3.06 (4.93)				
Female	5.67 (5.13)	1.99 (1.68 - 2.38)	<0.001	1.96 (1.64 - 2.33)	<0.001
<b>AGE (dichotomized)</b>					
3-4 years old (ref.)	3.98 (4.46)				
5-6 years old	4.69 (5.86)	1.20 (1.01 - 1.42)	0.03	1.23 (1.04 - 1.46)	0.02

Source: Author



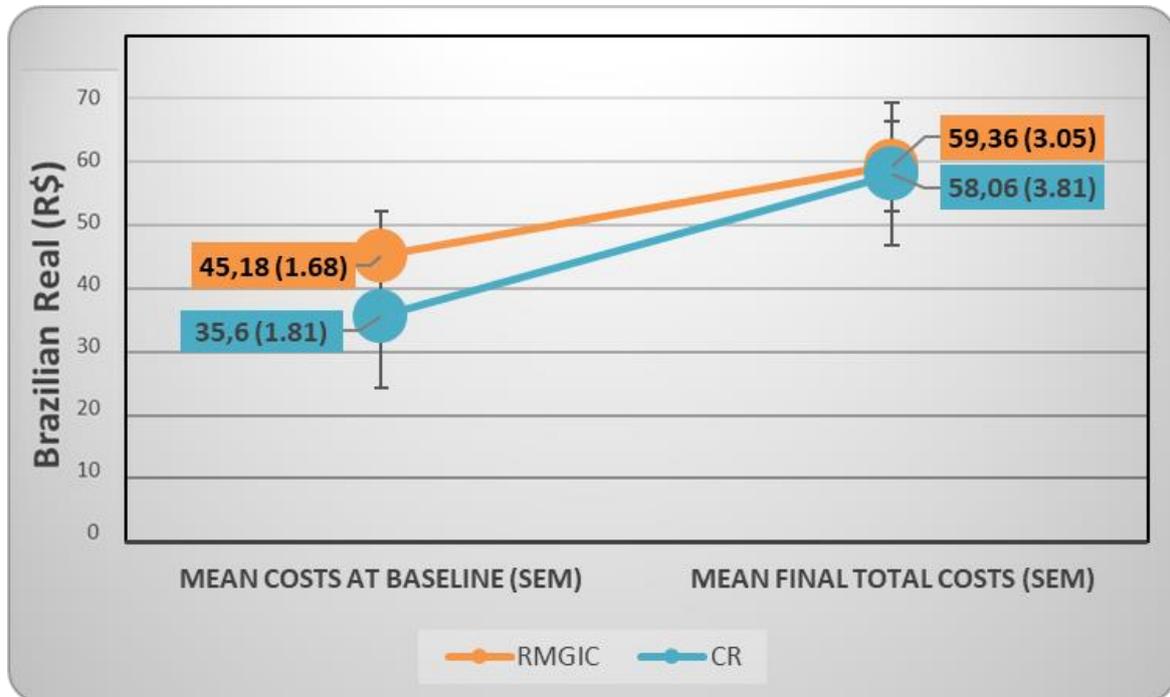
## Economic analysis

A total of 380 restorations placed on anterior primary teeth were considered for this study, 62% (n=237) performed with RMGIC and 38% (n=143) with CR. At baseline, the mean cost for RMGIC restorations in anterior primary teeth was higher than for CR restorations. Indeed, the baseline costs were influenced by the restorative material used (Table 5.3). Despite the child's group age, the proximal restorations were also related to higher costs.

The CR restorations requires a higher number of interventions (mean=1.24, 95%CI=1.15 to 1.32) than RMGIC (mean=1.65 95%CI=1.41 to 1.88) during the 24 months of following up. 15% of RC restorations and 12% of RMGIC restorations required replacement (Figure 4.4). From these, 4% (n=18) were not actually performed, but their costs were estimated and computed. 3% (n=10) were replaced but using different materials and the actual cost was considered. After 24 months, the cumulative cost, considering all reinterventions (Figure 4.4), resulted in an equivalence in costs between groups which used different restorative materials (Figure 5.2, Table 5.4). In a long-term analysis, proximal surfaces were still associated to higher costs, as well as those children with higher caries experience (Table 5.4).

When performing a subgroup analysis, RMGIC restorations not involving proximal surfaces tended to present higher costs than RC restorations, while proximal restorations tended to have, on average, similar costs despite the material used (Table 5.5).

Figure 5.2 - Comparison of anterior teeth's restorations costs at baseline and after 24 months of following-up



Source: Author

Table 5.3 – Baseline costs (Brazilian Real) of restorations performed in anterior primary teeth

VARIABLES		BASELINE COSTS Mean (SD)	UNIVARIATE		MULTIVARIATE	
			Coef. (95%CI)	P VALUE	Coef. (95%CI)	P VALUE
<b>RESTORATIVE MATERIAL</b>	Composite Resin	35.60 (1.78)	Ref.		Ref.	
	RM Glass Ionomer	45.18 (1.68)	-13.09 (-16.94- -9.23)	<0.001	-9.6 (-12.03- -7.16)	<0.001
<b>TYPE OF TEETH</b>	Central Incisor	-	Ref.		-	
	Lateral Incisor		-1.13 (-4.32-2.04)	0.48		
	Canine		1.33 (-5.04-7.70)	0.68		
<b>NUMBER OF RESTORED SURFACES</b>	One surface	-	Ref.		-	
	Two or more surfaces		2.30 (0.26-4.34)	0.03		
<b>TYPE OF SURFACE INVOLVED ON REST.</b>	Only smooth surface	-	Ref.		Ref.	
	Proximal surfaces involved		5.70 (2.27-9.14)	<0.001	6.01 (3.39-8.62)	<0.001
<b>AGE (dichotomized)</b>	3-4 years old	-	Ref.			
	5-6 years old		-2.58 (-5.19-0.38)	0.61	-0.98 (-3.30-1.34)	0.41

Source: Author



Table 5.4 Cumulative costs (Brazilian Real) of restorations performed in anterior primary teeth accounted for 24 months

<b>VARIABLES</b>		<b>CUMULATIVE FINAL COSTS</b>				
		<b>FINAL COSTS MEAN (SD)</b>	<b>UNIVARIATE</b>		<b>MULTIVARIATE</b>	
			<b>Coef. (95%CI)</b>	<b>P VALUE</b>	<b>Coef. (95%CI)</b>	<b>P VALUE</b>
<b>RESTORATIVE MATERIAL</b>	Composite Resin	58.06 (3.81)	Ref.		Ref.	
	RM Glass Ionomer	59.36 (3.05)	0.77 (-12.29-13.83)	0.91	0.79 (-8.17-9.75)	0.86
<b>NEED OF REINTERVATION</b>	Yes	-	Ref.			
	No		27.12 (23.51-30.72)	<0.001	-	-
<b>TYPE OF TEETH</b>	Central Incisor	-	Ref.		-	-
	Lateral Incisor		0.85 (-7.55-9.25)	0.20		
	Canine		1.33 (-8.57-15.85)	0.59		
<b>NUMBER OF RESTORED SURFACES</b>	One surface	-	Ref.		-	-
	Two or more surfaces		5.90 (2.37-9.44)	<0.001		
<b>TYPE OF SURFACE INVOLVED ON REST.</b>	Only smooth surface	-	Ref.		Ref.	
	Proximal surfaces involved		11.69 (2.89-20.48)	0.01	12.80 (5.19-20.41)	<0.001
<b>NUMBER OF INTERVENTIONS</b>	Initial restoration	-	Ref.		-	-
	Reinterventions performed		27.38 (23.79-30.97)	<0.001		
<b>AGE (dichotomized)</b>	3-4 years old	-	Ref.		-	-
	5-6 years old		-3.32 (-11.27-4.64)	0.41		
<b>CARIES EXPIERENCE (dichotomized)</b>	dmfs < 10	-	Ref.		Ref.	
	dmfs > 10		9.54 (2.64-16.46)	0.01	11.48 (3.44-19.52)	0.03

Source: Author



Table 5.5 – Subgroup analysis of mean cumulative costs (Brazilian Real) when considering or not proximal surfaces

	<b>RMGIC (95% CI)</b>	<b>CR (95% CI)</b>
Restorations involving proximal surfaces	BR\$ 61.49 (55.45 to 67.53)	BR\$ <b>65.00</b> (56.43 to 73.57)
Restorations not involving proximal surfaces	BR\$ <b>53.59</b> (43.97 to 63.20)	BR\$ <b>44.31</b> (35.42 to 53.21)

Source: Author

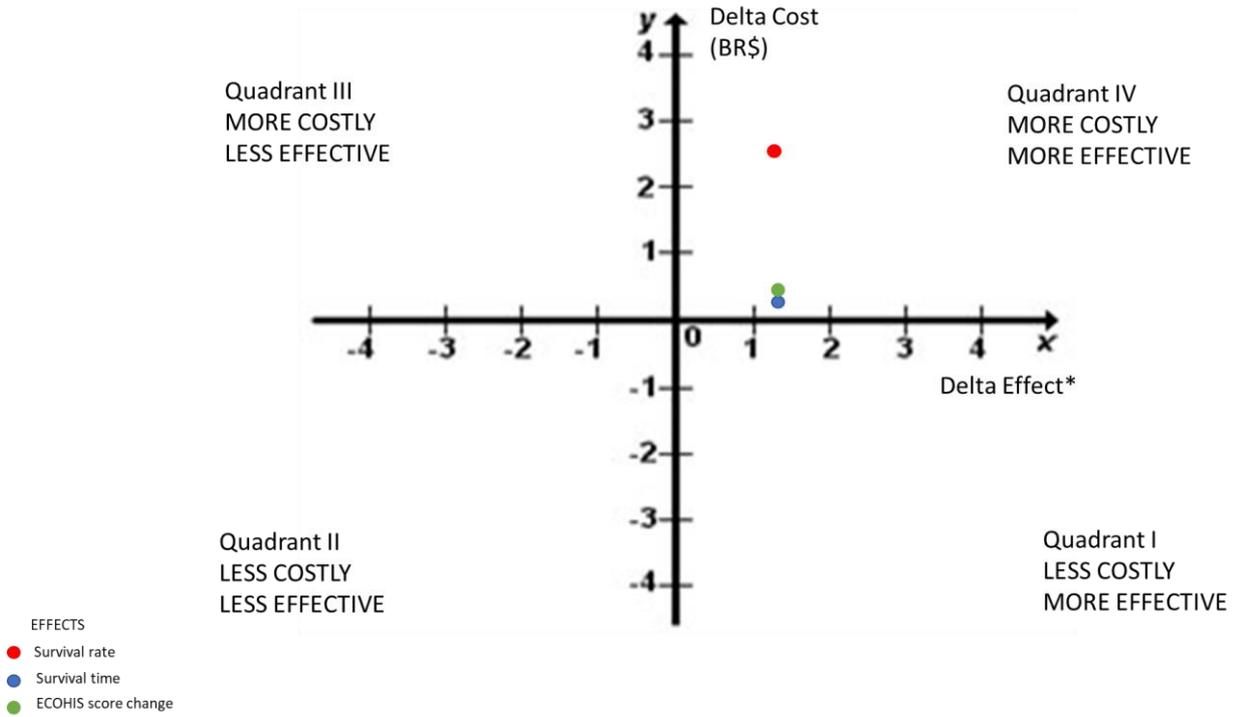
The ICERs, despite the effect and scenarios considered, were very low (less than BR\$ 1.00 per unit of effect (Table 5.6). Then, the RMGIC could be considered a cost-effective option to substitute CR when restoring anterior primary teeth, since they represent a more costly option but very close to 0 (Table 5.6) (Figure 5.3).

Table 5.6 - Economic analysis considering the costs and of using the RMGIC as an alternative to CR (summarizing figures for the worst scenario related to each effect)

<b>Restorative Material</b>	<b>COSTS</b>	<b>EFFECT</b>	<b>ICER</b>
<b>Survival rates*</b>			
RMGIC	BR\$ 59.36	0.65	-
CR	BR\$ 58.06	0.61	-
Delta	BR\$ 1.30	0.04	<b>BR\$ 0.33 per survived restoration</b>
<b>Survival times**</b>			
RMGIC	BR\$ 59.36	29.1	-
CR	R\$ 58.06	26.5	-
Delta	BR\$ 1.30	2.60	<b>R\$ 0.50 per year survived</b>
<b>ECOHIS score change***</b>			
RMGIC	BR\$ 59.36	0.43	-
CR	BR\$ 58.06	0.29	-
Delta	1.30	0.14	<b>R\$ 0.09 per child in whom impact on ORHQL was observed</b>

Source: Author.

Figure 5.3 - Cost-effectiveness plot - combinations of incremental costs and effects of RMGIC under CR for different effects (\*note the units of effects are different and the points were plotted in the same graphic just for illustration and interpretation of the trends in the economic analysis)



Source: Author

## 5.4 DISCUSSION

Our findings highlighted the restoration failures may influence on children's OHRQoL and also, on economic aspects. Besides, even not influencing on impact on directly on changes in OHRQoL, the RMGIC can be an efficient way to allocate the resources with a superior effect in terms of survival (both survival time and rates). Knowing these patterns could be helpful in choosing the most suitable treatment to be performed for that situation.

As discussed in the Chapter I, cavities in anterior teeth have a negative impact on OHRQoL. In this study, we confirmed that restoring these cavities really improved the parents' perception on their child's OHRQoL. Moreover, those children who needed reinterventions on their anterior restored teeth reported higher scores of ECOHIS when compared to those that did not presented restorative failures until the end of the study. OHRQoL seems to be more affected when major complications happen (100,107). Probably, carious anterior teeth, as well as failed restorations on these teeth represent one of these situations, since impact on aesthetics, phonetics and masticatory function.

Although the CR, on average, has had a shorter survival time and a higher failure rate than RMGIC, this difference seems not have impacted on the OHRQoL reported 24 months after treatment. A previous study which investigated the impact on different treatment for anterior teeth in children also showed no difference between treatments even when non-restorative approach was one of the options (77). This could be one possible explanation to our absence of association with OHRQoL. Another issue the child was the unit for this analysis of impact. Children who have higher caries usually have a higher number of restorations in anterior teeth and also experience more failures in their restorations, as showed in Chapter II. This pattern could be a more determinant aspect than the restorative materials by themselves, despite their differential failure rates. On the other hand, we should also considerate possible lower power for this analysis in proving such difference and the possible differences in cohorts as mentioned in other parts of this dissertation.

Among all the available restorative materials, adhesive materials are those that are used mostly for anterior teeth. CR and RMGIC are conservative and aesthetics options for restorations (73,79). The CR, in a Brazilian societal perspective (93,108).

could represent a more efficient allocation of economic resources than RMGIC for restoring anterior primary teeth. Although both products are available in the Brazilian dental market, the cost per portion of CR is lower than that per portion of RMGIC. This may be one reason that justify the wider use of CR by Brazilian dentists in general. On the other hand, due to higher number of failures, costs over 24 months became similar between treatments, diminishing a possible advantage of CR, that would be the lower cost. Therefore, it seems to be inadmissible to compare treatments only by the cost they represent in the beginning since the repercussions related to these treatments can undermine important aspects among them.

It is also important to point out that the type of surface involved on anterior restorations seemed to be also determinant for variations on the mean final costs. Restorations involving approximal surfaces in anterior teeth, demanded more reinterventions by themselves, increasing the final costs, independently of the material, the type of teeth or the number of surfaces restored. On the other hand, in non-proximal cavities the use of RMGIC is evidently a costlier option to be considered.

The economic analysis permits that two different outcomes (costs and effects) are combined to guide decision making process. Nowadays, economic analysis are often used in pediatric dentistry (109–114), focusing in understanding the real expenses of specific dental procedures. Using these analyses, it is possible to find out if an alternative treatment is a more efficient manner of allocating resources than other, currently used. In this sense, this is the first attempt of evaluating the incremental cost-effectiveness of using RMGIC instead of CR on restorations for anterior primary teeth, bringing significant information to clinical decision-making in such circumstances.

To perform such kind of economic analyses, it is crucial to define the purpose (as mentioned above), but also the more appropriated perspective. The present study follows a societal perspective, because, since we intended to compute the impact of failures in these analyses, it is relevant to consider besides the direct costs, those indirect costs related to the need of successive appointments to repairments and replacements of restorations. In addition, different effects were considered for cost-effectiveness analyses. Besides the survival rates and times (related directly to failures on restorations), we decided to include the changes in OHRQoL as a possible effect derived from the restorative material. This choice was important, since it takes into account not only the costs, material and procedures characteristics, but also, the

patient's perspective, considering that anterior teeth are specially associated to children perception of beauty and self-esteem(75,115).

The restoration using RMGIC was shown to be a more efficacious treatment since its survival rates and times tended to be superior to CR. On the other hand, the additional cost to achieving one year of survived restoration or one survived restoration was considered minimum, on average less than BR\$1.00. The same is also valid for the patient-centered outcome used. Although we do not have a willingness to pay, it is a common sense that this additional cost per effect is reasonable and could be feasible if this treatment is implemented in regular dental care. Therefore, using RMGIC could lead to less failures in restorations in anterior primary teeth by an almost insignificant incremental cost.

In conclusion, although failures on restorations can impact on OHRQoL, no direct relationship was observed for any specific restorative material. Besides, the RMGIC is shown as a suitable alternative to CR, being considered economically feasible to be used as restorative material for caries in primary anterior teeth.



## 6 FINAL CONSIDERATIONS

The present study has emerged as an effort to elucidate a clinical need observed when concerns restoring children's anterior primary teeth. A perception that the occurrence of "failures" were constant and different for this type of teeth, encouraged us to carry out this methodology and try to find answers for the possible causes of these events. A retrospective study involves obtaining information and then analyzing and judging the facts. It exhibits different benefits than other studies and are especially helpful in addressing diseases of low incidence as in our case. So, even with all the limitations that a retrospective study design may present, our results are quite relevant and should be considered, since they offer a first view on a subject never assessed before.

Making a weighting of all the features observed in this dissertation, we can state that the need for restorative procedures in anterior primary teeth is low and it is definitely related to a high caries experience. Children who present this kind of need are normally those children that also have individual characteristics that make them more prone to develop caries lesions and consequently, to need restorative procedures. Nevertheless, despite the low frequent need, children who have cavities in anterior primary teeth present impact on their OHRQoL that is why, the restorative approaches for primary anterior teeth earns an extra importance and deserves special attention from clinicians.

There are basically three major aspects that have to be considered when restorations on these teeth are planned. The first one is to face that the differences between permanent and primary teeth (anatomical, chemical composition, morphology and physiology) may influence the bonding of dental materials and as a result of that, the clinical decision making must predict differences in the clinical behavior of adhesive materials. The second aspect concerning anterior primary teeth that are to be restored, is the restorative material. Pediatric dentists are often confronted with the decision of which material or technique is more suitable for each case. We observed that for anterior primary teeth, RMGIC offers better survival rates than CR and seems to be a better alternative, especially when it is going to be performed in young children and under relative isolation technique. The third aspect to be considered is the cost effectiveness of the restorative material used. Even having to invest initially more for

performing RMGIC restorations, over the time, RMGIC is a more efficacious and also, efficient way of allocating economical resources, since requires less reinterventions over time and represent a minimum extra investment of resources in a long-term analysis.

We found that one of the most critical factors impacting the increase of costs and the survival of restorations was the involvement of approximal surfaces. Hence, when we have anterior teeth that we know that approximal surfaces are going to be involved into restoration, we should be more careful at performing restorative procedures, giving extra attention to these teeth and becoming necessary as well closer follow-ups, in order to identify possible early failures and prevent major complications. This is especially important since failures have been associated with a negative impact in the children's OHRQoL, what reinforces the use of a material less susceptible to failures in daily clinical practice.

In this way, this dissertation has discussed some important features related to restoring anterior primary teeth, aiming to give to pediatric dentists the information to assist them in the decision-making process and to guide researchers in further studies. Still, there is necessary more exploration about this topic for a better understanding of the approaches, in order to achieve restorations in anterior primary teeth with clinical excellence and more predictability.

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<sup>1</sup> According to Vancouver style.

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## ANNEX 1- ETICHC'S COMMITTEE AUTHORIZATION



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### PARECER CONSUBSTANCIADO DO CEP

#### DADOS DO PROJETO DE PESQUISA

**Título da Pesquisa:** RESTAURAÇÕES ADESIVAS EM DENTES DECÍDUOS ANTERIORES: ESTUDOS DE COORTES INCLUINDO ANÁLISE ECONÔMICA

**Pesquisador:** Mariana Minatel Braga

**Área Temática:**

**Versão:** 1

**CAAE:** 84921518.8.0000.0075

**Instituição Proponente:** Faculdade de Odontologia da Universidade de São Paulo

**Patrocinador Principal:** Financiamento Próprio

#### DADOS DO PARECER

**Número do Parecer:** 2.585.006

#### Apresentação do Projeto:

O objetivo deste trabalho será avaliar o índice de sucesso de restaurações realizadas em dentes anteriores decíduos. Neste estudo também serão avaliados os fatores de risco associados com as falhas das restaurações, e a custo-eficácia desse tipo de tratamento (considerando possíveis necessidades de reintervenção a longo prazo). Serão realizados estudos de coortes históricas, divididos em duas etapas, utilizando dados de duas coortes de crianças atendidas em lugares e condições diferentes: G1(estudo clínico CARDEC-01) e G2(estudo clínico CARDEC-02). A primeira etapa do trabalho consistirá da revisão dos prontuários de crianças dos dois grupos. Os dados serão coletados com o objetivo de avaliar o desempenho de restaurações feitas em dentes anteriores decíduos de crianças atendidas nesses 2 centros desde 2014 até a atualidade, e com no mínimo algum período de acompanhamento pós-tratamento registrado. Será verificado o sucesso das restaurações para se estimar a sua sobrevida. Para compor o custo acumulado dos tratamentos, serão coletados os custos acumulados dos procedimentos realizados (incluindo tratamentos e eventuais retratamentos das crianças ao longo de 24 meses) registrados nos prontuários desses pacientes. Na segunda etapa do estudo, as crianças incluídas na fase anterior, serão convidadas a participarem de um novo exame. Essa etapa teria por finalidade avaliar todas as coortes seguindo um mesmo padrão e, ainda, avaliar possíveis características não padronizadas nas coortes descritas. Todas as restaurações serão avaliadas clinicamente por um examinador previamente treinado e calibrado, utilizando o critério FDI. O desfecho desta fase será a falha

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Continuação do Parecer: 2.585.006

restauradora (escores 4 ou 5 do critério FDI). Também serão avaliadas características clínicas como: índice de placa visível, sangramento gengival, extensão da restauração, oclusão e tipo de mordida. Assim, novas taxas de sobrevida serão calculadas de acordo com esse critério e fatores associados serão testados. Para ambas as etapas do estudo, a longevidade/sobrevida das restaurações será avaliada pelo teste de Kaplan-Meier.

Análise de regressão múltipla de Cox com fragilidade compartilhada será usada para avaliar as variáveis clínicas e individuais associadas com as falhas restauradoras. Para estimativa da custo-eficácia, serão consideradas como eficácia, a taxa de sobrevida nos diferentes estudos e computado o custo acumulado registrados nas coortes citadas. Eventuais análises de subgrupo serão exploradas para os possíveis fatores associados a falhas.

#### Objetivo da Pesquisa:

O objetivo primário do presente estudo será avaliar o comportamento clínico de restaurações realizadas em dentes anteriores decíduos. Como desfecho secundário, descrever a sobrevida das restaurações realizadas em dentes anteriores decíduos em diferentes contextos.- Analisar tipos de falhas e os possíveis fatores associados aos insucessos dos procedimentos restauradores.- Estimar a relação de custo-eficácia da realização de dentes decíduos anteriores, levando-se em conta o sucesso dessas restaurações.

#### Avaliação dos Riscos e Benefícios:

Os riscos em participar da pesquisa são mínimos. Para a etapa I, os prontuários já coletados em outras duas pesquisas serão utilizados. Para utilização desses dados, serão verificados os TCLE primários e no caso de os responsáveis terem solicitado autorização para nova utilização dos dados, isso será feito. Para a etapa 2, os riscos são inerentes a um exame Odontológico convencional e, para isso, um novo TCLE será apresentado aos pais e termo de assentimento apresentado às crianças alfabetizadas. No caso de crianças não alfabetizadas, o assentimento verbal será obtido previamente a realização do exame para fins da pesquisa.

Os benefícios desta pesquisa ajudará a encontrar informações para que o tratamento odontológico em crianças possa ser melhorado, contribuindo para o desenvolvimento da Odontologia. Além disso, se forem constatadas falhas ou se for necessário tratamento odontológico, este será realizado pela equipe de dentistas, onde a pesquisa está sendo desenvolvida.

#### Comentários e Considerações sobre a Pesquisa:

Esta pesquisa é relevante pois avaliará o índice de sucesso de restaurações realizadas em dentes anteriores decíduos. Neste estudo também serão avaliados os fatores de risco associados com as

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Continuação do Parecer: 2.585.006

falhas das restaurações, e a custo-eficácia desse tipo de tratamento (considerando possíveis necessidades de reintervenção a longo prazo). Serão realizados estudos de coortes históricas, divididos em duas etapas, utilizando dados de duas coortes de crianças atendidas em lugares e condições diferentes: G1(estudo clínico CARDEC-01) e G2(estudo clínico CARDEC-02).

**Considerações sobre os Termos de apresentação obrigatória:**

Foram apresentados:

Projeto detalhado, autorização da Clínica, Folha de rosto, termo de assentimento e TCLE.

**Recomendações:**

Tendo em vista a legislação vigente, devem ser encaminhados ao CEP-FOUSP relatórios parciais anuais referentes ao andamento da pesquisa e relatório final, utilizando-se da opção "Enviar Notificação" (descrita no Manual "Submeter Notificação", disponível na Central de Suporte - canto superior direito do site [www.saude.gov.br/plataformabrasil](http://www.saude.gov.br/plataformabrasil)).

Qualquer alteração no projeto original deve ser apresentada "emenda" a este CEP, de forma objetiva e com justificativas para nova apreciação.

**Conclusões ou Pendências e Lista de Inadequações:**

Não há pendências.

**Considerações Finais a critério do CEP:**

**Este parecer foi elaborado baseado nos documentos abaixo relacionados:**

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1070022.pdf	07/03/2018 16:20:34		Aceito
Projeto Detalhado / Brochura Investigador	ProjetoComite.docx	07/03/2018 16:12:34	Jhandira Daibelis Yampa Vargas	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TermodeAssentimento.docx	07/03/2018 16:05:09	Jhandira Daibelis Yampa Vargas	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Termodeconsentimento.docx	07/03/2018 16:04:45	Jhandira Daibelis Yampa Vargas	Aceito
Declaração de Instituição e Infraestrutura	AutclinicaComite.pdf	07/03/2018 15:59:03	Jhandira Daibelis Yampa Vargas	Aceito

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Continuação do Parecer: 2.585.008

Folha de Rosto	FolhaderostoComite.pdf	07/03/2018 15:57:57	Jhandira Daibelis Yampa Vargas	Aceito
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**Situação do Parecer:**

Aprovado

**Necessita Apreciação da CONEP:**

Não

SAO PAULO, 06 de Abril de 2018

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Assinado por:  
Maria Gabriela Haye Biazevic  
(Coordenador)

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**ANNEX 2- COSTS SHEETS USED IN THE CLINICAL TRIALS**



Nº \_\_\_\_\_

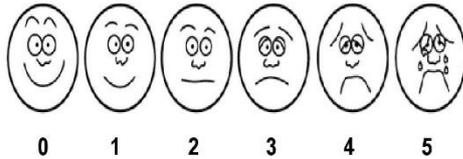
Sessão nº \_\_\_\_\_

**TEMPO E CUSTO DOS PROCEDIMENTOS – TRATAMENTO**

Data	Procedimento	Tempo (s)
Dentista / Auxiliar: _____		
Material		
Abridor de boca	Envelope 19 x 37 cm (unidade)	Paramonoclorofenol (gota)
Ácido fosfórico (1cm)	Envelope 9 x 26 cm (unidade)	Pasta profilática (1 cm)
Ácido poliacrílico (gota)	Escova para profilaxia (unidade)	Pedra pomes (1 porção)
Adesivo dentinário (porção)	Espátula de inserção nº1	Película raio-x adulto (unidade)
Afastador labial	Espátula de madeira (unidade)	Película raio-x infantil (unidade)
Água para autoclave (300 ml)	Espátula de manipulação de CIV	Pinça porta-grampo de Palmer
Agulha curta (unidade)	Espátula Hollembach	Porta agulha
Agulha extra curta (unidade)	Espátula nº7	Porta matriz
Alavancas – jogo	Evidenciador Replak (gota)	Posicionador radiográfico
Álcool 70 (50 ml*)	Filme PVC (30 cm)	Pote Dappen
Alicate perfurador de Ainsworth	Fio de sutura (unidade)	Régua endodôntica
Anestésico (tubete)	Fio dental (10 cm)	Resina composta (incremento)
Anestésico tópico (1 cm)	Fixador (50 ml)	Restaurador temporário (1 cm)
Arco de Young	Fôrceps	Revelador (50 ml)
Avental descartável (unidade)	Gaze (1 compressa)	Rifocort (1 cm)
Babador (unidade)	Grampo isolamento (unidade)	Roleta de algodão (unidade)
Banda matriz 5 mm (unidade)	Guta percha (1/5 bastão)	Saco de geladinho (unidade)
Banda matriz 7 mm (unidade)	Iodofórmio (1 cm)	Seringa carpule
Bandeja	Ionômero Fuji IX (porção)	Seringa descartável (unidade)
Bisturi (unidade)	Ionômero Riva (cápsula)	Sobreluva (unidade)
Bloco de espatulação (1 folha)	Jogo clínico	Soro fisiológico (50 ml)
Broca diamantada (unidade)	Lençol de borracha (unidade)	Sugador (unidade)
Cabo para bisturi	Lima endodôntica (1 jogo)	Sugador endodôntico (unidade)
Calçador de Ward	Líquido de Dakin (50 ml)	Tesoura reta
Canudo p/ triplice (1/3 unidade)	Luva descartável (1 par)	Tira de acabamento (unidade)
Cariostático (gota)	Mandril para CA (unidade)	Tira de lixa de aço (1/2 unidade)
Colgadura	Máscara descartável (unidade)	Tira de poliéster (1/2 unidade)
Colher de dentina	Microbrush (unidade)	Touca descartável (unidade)
Cunha de madeira (unidade)	Óculos de proteção	Vaselina (1 cm)
Descolador de Molt	Papel carbono (1/3 folha)	Verniz Duraphat (1 cm)
Disco de acabamento (unidade)	Papel para radiografia (unidade)	

**DESCONFORTO**

“Como você se sentiu ao tratar o(s) dentinho(s) agora?”



**Dentista**, como a criança reagiu nesta sessão?

- ( ) Criou muita dificuldade
- ( ) Criou alguma dificuldade
- ( ) Indiferente
- ( ) Cooperou razoavelmente
- ( ) Cooperou bem