SURVIVAL OF IONOMERIC RESTORATIONS WITH ATRAUMATIC RESTORATIVE TREATMENT IN CHILDREN UNDER 6 YEARS OF AGE

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ABSTRACT

Partial removal techniques and atraumatic restorative treatment are therapeutic options for the treatment of minimally invasive carious lesions in young children and socially disadvantaged populations. The purpose of this research is to determine the survival rate of Class I restorations performed in deciduous first molars with the atraumatic restorative technique. For this purpose, it was necessary to carry out a study through a clinical trial, split-mouth type. The variables evaluated were: survival of the restoration, restorative vitreous ionomer brand, restoration failures and evaluation time. The survival rate was 96%, 94% and 88% for Ketac Molar Easy Mix restorations and 86%, 76% and 68% for Riva Self Cure restorations after 2, 4 and 6 months of evaluation. The most frequent failures were: wear greater than 1mm and partial or total loss of the restoration, with the Riva Self Cure ionomer having the highest percentage of failures compared to Ketac Molar Easy Mix. A focus group was developed and the Pareto diagram was used to determine the actions needed to prevent caries.

Keywords: atraumatic restorative treatment; vitreous ionomer cements; pediatric dentistry.

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RESUMEN

Las técnicas de remoción parcial y el tratamiento restaurador atraumático son opciones terapéuticas para el tratamiento de lesiones cariosas mínimamente invasivas en niños pequeños y poblaciones con desventaja social. El propósito de esta investigación es determinar la tasa de supervivencia de las restauraciones Clase I realizadas en los primeros molares deciduas con la técnica de restauración atraumática. Para ello fue necesario realizar un estudio a través de un ensayo clínico, tipo split mouth. Las variables evaluadas fueron: supervivencia de la restauración, marca de ionómero vitreo restaurador, fallas en la restauración y tiempo de evaluación. La tasa de supervivencia fue 96%, 94% y 88% para las restauraciones con Ketac Molar Easy Mix y 86%, 76% y 68% para las restauraciones con Riva Self Cure después de 2, 4 y 6 meses de evaluación. Las fallas más frecuentes fueron: desgaste mayor a 1mm y la pérdida parcial o total de la restauración, siendo el ionómero Riva Self Cure el que presentó mayor porcentaje de fallas en comparación con el Ketac Molar Easy Mix. Se desarrolló un grupo focal y se empleó el diagrama de Pareto para determinar acciones necesarias para prevenir las caries.

Palabras claves: Tratamiento restaurador atraumático; cementos de ionómero vítreo; odontología pediátrica.

INTRODUCTION

Atraumatic Restorative Treatment (ART) focuses on the treatment of teeth affected by dental caries by removing the affected dentin with hand instruments, without the administration of local anesthesia. This is an alternative and low-cost procedure that dispenses with conventional technology and makes use of glass ionomer (Dorri *et al*., 2017; Faustino-Silva & Figueiredo, 2019)

According to Frencken (2017), this material is used in ART as part of the current paradigm of minimal invasion, minimal intervention, and minimal cavity preparation. Therefore, the World Health Organization recommends this treatment to provide restorative care for people who do not have access to dental care (Saber *et al*., 2019). In Peru, the Ministry of Health, according to data from the Clinical Practice Guide for the Prevention, Diagnosis and Treatment of Dental Caries in Children, states that the problematic oral health situation has not changed over time. Thus, the overall prevalence of dental caries in deciduous dentition in 2001-2002 was 60.5% and in 2012-2014 it was 59.1%. This would indicate that after 12 years, the preventive measures adopted in the country have not had an impact (Perú, Ministerio de Salud, 2017). Villena-Sarmiento *et al*. (2011) found that children under 6 years of age belonging to low-income areas do not attend dental services until 5 years of age, where the obturation component presents a very low value (von Feigenblatt, 2022; Macazana *et al.*, 2021; Huamán *et al*., 2021)

Faced with this situation, minimally invasive approaches have been adopted in the country in young children and socially disadvantaged populations, through partial removal techniques and atraumatic restorative treatment (ART), which show increasing evidence of better results compared to conventional complete caries removal (De Medeiros Serpa *et al*., 2017).

Studies on the use of glass ionomer indicate that the fluoride it contains can be released for up to five years. In addition, the ionomer acts as a reservoir by absorbing fluoride ions from topical fluoride. This property would allow teeth treated with ART to be less susceptible to caries for a long time *(Saber et al*., 2019). According to the systematic review of Dorri *et al*. (2017), survival rates of restorative materials used with ART range from 90-100%, but success depends on several factors, including the brand of ionomer selected.

Among the different brands that have been used for TRA in the literature are mentioned: Fuji IX GC Int, Ketac Molar ESPE, Chemfil Dentsply, Chemflex Dentsply, and Fuji Plus GC Int. The latter three of low viscosity used less frequently (Araujo *et al*., 2020; Ersin *et al*., 2006; Pacheco *et al*., 2017; Saber *et al*., 2019). Ruengrungsom *et al*. (2018), mentioned that the success or failure of using ART will depend on several factors, among them: the experience and training of the professionals to achieve high success rates. This was seen by de Amorim *et al.* (2018), who found no significant differences between a dentist and dental therapists. It also states that almost half of the failures found are related to both the physical characteristics of the ionomer and the handling of the material by the operator.

The temporality of follow-up generally shows reports after 6, 12, 24 and 36 months or more years, however, there are no reports for shorter periods. This research aims to determine the survival of restorations with atraumatic restorative treatment (ART) by comparing two brands of restorative ionomers performed in Class I cavities of deciduous molars in a group of children 4 to 6 years of age, after 2, 4 and 6 months of follow-up, living in a low-income environment.

MATERIAL AND METHODS

A clinical experimental study was carried out. The Split mouth design was adopted (Pozos-Guillen *et al*., 2017), which consists of a simple division of the child's mouth into two parts (right and left), where one of the halves is randomly assigned a treatment modality to be compared after a follow-up period. The advantage of this design is its efficiency in sample size in which the participant is under his or her control, consequently, intersubject variability is controlled. This allows to allocate of few subjects in the sample compared to a parallel group trial. The population consisted of 100 deciduous molars of children aged 4 to 6 years, from a district classified as a low-income area. The sample was non-probabilistic (n=50 children) selected based on referential studies (Araujo *et al*., 2020; van Gemert-Schriks *et al*., 2007).

The inclusion criteria were children whose parents accepted their participation in the study and who signed the Informed Consent, from the San Genaro de Villa-Chorrillos Lima -Peru school. Children between 4 and 6 years old, who presented in the oral cavity at least two upper and/or lower deciduous molars with the following characteristics: Class I cavities that compromised dentin, qualified with codes 2 and 3 according to the criteria described by Frencken *et al*. (1996) and whose cavity opening diameter is less than 1.8mm (Menezes-Silva *et al*., 2019). Another criterion was that they were cooperative and receptive children.

The dependent variable was the survival of the restoration, the codes and criteria described by Frencken *et al*. (1996), and the independent variable, the brand of restorative glass ionomer (Ketac Molar Easy Mix (3M-ESPE) and Riva Self Cure (SDI)(De Lima-Navarro *et al*., 2007). Among the covariables, the types of failures in the restorations were analyzed and the other variable was evaluation time (2, 4 and 6 months). The researcher who diagnosed and applied the dental restorations was trained by a teacher with years of experience and a specialist in pediatric dentistry. The interexaminer and intraexaminer agreement was a Kappa value of 85% and 95% respectively for the diagnosis of dental caries, while for the follow-up evaluation of the restorations an interexaminer and intraexaminer Kappa value of 87% and 90% respectively was reached.

Randomization for the application of the ionomers Ketac Molar Easy Mix (3M ESPE) and Riva Self Cure (SDI) was performed by the support assistant. Two cavities (upper/lower molar, left/right) of equal score were selected according to the criteria for recording caries by Frencken *et al*. (1996) in each child. To select the brand of ionomer to be used in each selected tooth, a manual draw was performed (two pieces of paper with the names of each brand were used) after cavity preparation. Ketac Molar Easy Mix ionomer (3M ESPE) was applied in one cavity on one side (upper or lower) of the oral cavity, and Riva Self Cure ionomer (SDI) in the other contralateral molar (upper or lower). The operator did not know the brand of ionomer to be used, because the situation and mixing of the material were performed by another person (assistant) previously trained for this activity. The child was also not informed about the brand of ionomer used.

The evaluation of the restorations with TRA was performed according to the criteria described by Frencken *et al*. (1996) with the use of a periodontal probe (CPI) with a 0.5 mm bead at the end and was recorded on a data collection form. The previously calibrated operator evaluated each restored tooth with TRA at 2, 4 and 6 months. The triple-blind design was guaranteed since the evaluator was unaware of the location of each mark of restorative ionomer placed in the cavities.

Regarding the analysis, the Mc Nemar test was used to compare the survival of the TRA restorations to the brand of restorative ionomer used at 2, 4 and 6 months.

A confidence level of 95% was accepted. In addition, the Cochrane Q test was applied to determine if there are significant differences in survival for each brand of ionomer through the evaluation time (2, 4 and 6 months) and the Wilcoxon test to determine significant differences in the types of failures according to the brand of ionomer in each control.

Survival analysis was performed through the actuarial method (life tables). Survival curves were plotted using the Kaplan Meier method and compared using the Log-Rank test.

In addition, a focus group was developed with the teaching staff at the primary level of the educational institution, to determine the main actions that should be developed to prevent the appearance of caries in the school's children. This method of data collection allows for interaction between 3-10 people, who discuss one or more topics in a relaxed and informal environment, under the guidance of a specialist in group dynamics (Hernández *et al*., 2006).

A Pareto Diagram is then made to determine the most important actions to be taken to prevent the appearance of caries. This technique is based on the analysis of the problem and is used to present data, drawing attention to the main causes or risk factors in the problem in question. It aims to determine 20% of the causes that cause 80% of the problems, “the vital few the trivial many” (Alteco, 2020). The research project was registered with SIDISI Code 52322 and approved by the International Ethics Committee of the Universidad Peruana Cayetano Heredia.

RESULTS AND DISCUSSION

The survival of the restorations at the end of the study was higher (88%) for the Ketac Molar Easy Mix glass ionomer brand (3M ESPE) compared to Riva Self Cure (SDI) with a value of 68%, with a statistically significant difference (Table 1).

Table 1. Survival of Class I restorations in deciduous molars with TRA when applying two brands of restorative ionomers.

Glass ionomer brand Restorer	**Survival of the restoration**			
	Survival		Failure	
	f	%	f	%
Ketac Molar Easy Mix (3M ESPE)	44	88	6	12
Riva Self Cure (SDI)	34	68	16	32

Mc Nemar p = 0,031

Figure 1 shows that across the evaluation time (2, 4 and 6 months) Ketac Molar Easy Mix (3M ESPE) brand glass ionomer had a higher percentage survival value (96%, 94% and 88%) over Riva Self Cure (SDI) brand ionomer (86%, 76% and 68%) respectively.

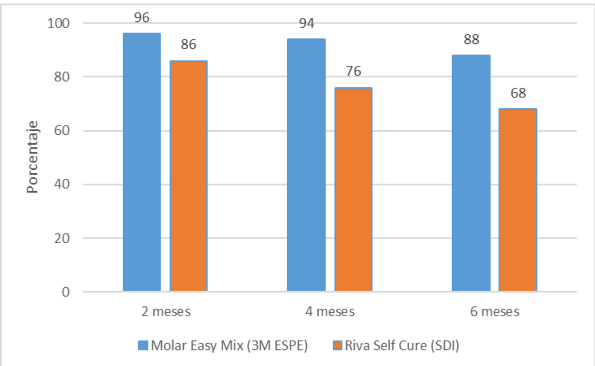

Figure 1. Evaluation time of Class I restorations in deciduous molars with TRA when applying two brands of restorative ionomers.

The estimated mean survival time was 5.8 months (standard error 0.128) for Ketac Molar Easy Mix (3M ESPE) and 5.24 months (standard error 0.21) for Riva Self Cure (SDI); with a statistically significant difference (p=0.014) according to Log Rank analysis (Table 2).

Table 2. Medians for survival time of Class I restorations in deciduous molars with TRA when applying two brands of restorative ionomers.

Ionomer brand	Means				p*
	Estimate	Standard error	Confidence interval of 95 %.		
			Lower limit	Upper limit	
Ketac Molar Easy Mix (3M ESPE)	5.80	0.128	5.550	6.050	0,014
Riva Self Cure (SDI)	5.24	0.210	4.829	5.651	
Global	5.52	0.123	5.278	5.762	

Note: the estimation is limited to the longest survival time, *Log Rank (Mantel-Cox).

The survival of Class I restorations in deciduous molars with TRA when applying the two brands of ionomer according to the evaluation time, found no differences after 2 months. At 4 months, the Ketac Molar Easy Mix (3M ESPE) glass ionomer showed a survival of 94% (n= 47 restorations) compared to 76% (n=38 restorations) of the Riva Self Cure (SDI) brand with a significant difference (p=0.035). At 6 months, Ketac Molar Easy Mix (3M ESPE) brand glass ionomer showed a survival of 88% (n=44 restorations) compared to 68% (n= 34 restorations) for Riva Self Cure (SDI) brand with significant difference (p=0.031). Without any brand discrimination, the survival of the restorations at 2, 4 and 6 months was 91%, 85% and 78% respectively (Table 3).

Table 3. Survival of Class I restorations in deciduous molars with TRA when applying two ionomer brands according to evaluation time.

Evaluation time	Survival of the restoration	Restorative Glass Ionomer Brand			Total	p
			RSC	KME		
2 months	Survival	f	43	48	91	0,18
		%	86%	96%	91%	
	Failure	f	7	2	9	
		%	14%	4%	9.0%	
4 months	Survival	f	38	47	85	0,035
		%	76%	94%	85%	

	Failure	f	12	3	15	
		%	24%	6%	15%	
6 months	Survival	f	34	44	78	0,031
		%	68%	88%	78%	
	Failure	f	16	6	22	
		%	32%	12%	22%	

Note: * Q test of Cochrane, RSC= Riva Self Cure (SDI), KME= Ketac Molar Easy Mix (3M ESPE).

When comparing the types of failures in Class I restorations in deciduous molars with TRA with the use of the two ionomer brands according to evaluation time, a significant difference was found after 2, 4 and 6 months respectively (Table 4), between the Riva Self Cure (SDI) brand and the Ketac Molar Easy Mix (3M ESPE).

Table 4. Types of failures in Class I restorations in deciduous molars with TRA when applying two brands of ionomer according to evaluation time.

Evaluation time	Survival of restoration / Failures			Restorative Glass Ionomer Brand		Total	p*
				RSC	KME		
2 months	Survival	Present	f	33	46	79	0,019
			%	66%	92%	79%	
		Present, Light Wear <0,5mm	f	10	2	12	
			%	20%	4%	12%	
	Failures	Present, Rough wear >1	f	1	1	2	
			%	2%	2%	2%	
		Absent	f	6	1	7	
			%	12%	2%	7%	
4 months	Survival	Present	f	23	44	67	0,001
			%	46%	88%	67%	
		Present, Light Wear <0,5mm	f	15	3	18	
			%	30%	6%	18%	
	Failures	Present, Rough wear >1	f	3	0	3	
			%	6%	0%	3%	
		Absent	f	9	3	12	
			%	18%	6%	12%	
6 months	Survival	Present	f	19	39	58	0,001
			%	38%	78%	58%	
		Present, Slight wear <0.5mm	f	15	5	20	
			%	30%	10%	20%	
	Failures	Present, Wear >0.5; <1	f	0	1	1	
			%	0%	2%	1%	
		Present, Coarse Wear >1	f	4	2	6	
			%	8%	4%	6%	
		Absent	f	12	3	15	
			%	24%	6%	15%	

Note: *Wilcoxon test for related samples, RSC= Riva Self Cure (SDI), KME= Ketac Molar Easy Mix (3M ESPE).

With the above shown, the TRA technique offers an opportunity for restorative dental treatment in communities where electricity or means for the use of rotary instruments are not available. It is indicated in the prevention of oral health since it allows to promote better oral conditions, reduce the indication of exodontia and increase the number of teeth restored (Roshan & Sakeenabi, 2011; Saber *et al*., 2019).

The technique has demonstrated high success rates after one year of follow-up, with values ranging from 93-99% (Saber *et al*., 2019), mainly when restorations are placed in superficial lesions. For Saber *et al*. (2019), when reviewing studies with ART, in 2003 after 24 months of follow-up a success rate of 89.6% was found in single surface restorations in deciduous dentition. Likewise, a meta-analysis carried out up to 2006 reported a 95% survival rate with the use of high viscosity glass ionomers for these restorations. These values are close to the findings of this study, although it was evaluated within 6 months. De Medeiros Serpa *et al*. (2017) mention that there is a survival of 89.3% in single-surface TRA restorations in deciduous molars when evaluating Ketac Molar Easymix ionomer (3M ESPE) versus Filtek light-curing resin (3M ESPE). This value was very close to the 88% found in this study with the same brand of Ketac Molar Easy Mix ionomer (3M ESPE) and higher than the 68% shown by Riva Self Cure (SDI).

Roshan and Sakeenabi (2011) in a survival study of Class I restorations with the use of Fuji IX in deciduous dentition with the TRA technique, found that the survival of restorations placed in school was 82.2%, and those placed in a hospital clinical setting was 87.7%, after six months of evaluation. This value is close to the survival found in the present study (88%) with Ketac Molar Easy Mix ionomer (3M ESPE). Several studies mention that there would be very similar properties between Fuji IX and Ketac Molar Easy Mix (3M ESPE), which would explain this finding. Roshan and Sakeenabi (2011) add that after six months, the report of survival and failure of the restorations indicates 71.9% of restorations present in good condition in the school, a value close to 78% with the use of Ketac Molar Easy Mix (3M ESPE) recorded in the present investigation, in the same time. Likewise, 12.8% of restorations were found to be missing due to partial or complete loss of the material, while the present investigation found 6% of missing restorations with Ketac Molar Easy Mix (3M ESPE) while this value tripled (24%) when using Riva Self Cure (SDI). This was because the former would have better properties than the other ionomers.

However, Ersin *et al*. (2006), after six months of evaluation, using Fuji IX GP ionomer (GC) found 100% survival of single surface TRA restorations in deciduous dentition. As for failure reports, after two years, 3.3% corresponded to loss of the restoration compared to 15% obtained in the present investigation. This difference could be due to the clinical and physical characteristics of the ionomers used and/or the experience of the operators. In a review of the literature, de Lima *et al*. (2015) cite Silva's study conducted in 2009, with a double-blind randomized clinical trial and split-mouth evidenced that the survival of Ketac Molar Easy Mix (3M ESPE) with the technique gradually decreases after 12 months, 24 months and 48 months to values of 94.8%, 87.9% and 82.3% respectively. In the present study, despite being evaluated in the short term, this tendency to decrease from 2, 4 and 6 months was also found with 86%, 76% and 68% with Riva Self Cure (SDI), while with the Ketac Molar Easy Mix (3M ESPE) survival had higher values of 96%, 94% and 88% respectively.

van Gemert-Schriks *et al*. (2007) found 15.8% for gross marginal defects and 9.8% for total or partial loss after three years of evaluation with the use of Ketac Molar Easy Mix ionomer (3M ESPE). On the other hand, in the results of the present study in schoolchildren in Chorrillos, after six months of evaluation, 4% were found for gross wear and 6% for loss of the material for the Ketac Molar Easy Mix ionomer (3M ESPE). Some studies indicate that coarse ionomer wear could be induced by occlusal forces or insufficient wear resistance.

Ionomer restorations can be lost due to several reasons, such as insufficient cleaning or conditioning in the cavity, or improper mixing of the material. The present investigation controlled for the human factor, because there was a dentist and assistant who were both trained and followed the manufacturer's instructions. Other factors could explain the failures of TRA restorations, such as secondary caries, extensive cervical margins, material properties and environmental conditions (temperature changes, humidity, etc). It is recognized that in the TRA protocol it is recommended not to eat or drink within the first hour after completion of the restoration (Ersin *et al*., 2006; van Gemert-Schriks *et al*., 2007). In this study, the children were given post-treatment instructions with a poster, but they were not thoroughly supervised after receiving the treatment, which may have partly influenced their results. As explained by de Amorim *et al*. (2018), after analyzing the results of several investigations, many failures were due to the characteristics of the ionomer. However, Luengas-Quintero *et al*. (2013) and van Gemert-Schriks *et al*. (2007) add that environmental aspects such as temperature, atmospheric humidity and altitude, among others, would also contribute to material loss.

It should be remembered that the TRA technique does not replace conventional restorations, but it is an alternative for children, special patients or for the treatment of populations living in areas without access to dental services. Among the limitations of the study is the number of teeth evaluated for each brand of ionomer, although a minimum referenced by other authors. Among the advantages was that it was performed on the same subject, which implies control of subject variability, as pointed out by Pozos-Guillen *et al.* (2017), unlike other studies. Due to the short time frame of six months, there was the advantage of no loss of subjects, which is observed in other investigations of greater temporality of 12, 24 and 36 months of follow-up. Although we did not record or control variables that may have influenced the appearance of failures in the restorations, such as factors related to the material used (humidity, handling, environmental conditions), factors related to the operator (experience, academic degree, perception of comfort), it is important to identify them as critical factors for the success and comfort of the patient.

Applying the TRA technique or another is an element that the development of dentistry has allowed. Pediatric dentistry is improving every day. The education of the new generations is a distinctive element that can prevent different affectations, which saves resources for both dental clinics and families.

The research team also conducted a focus group with primary school teachers, led by an expert dentist facilitator, to determine the main actions that should be taken to prevent caries in children. The main responses are shown in Figure 2.

Figure 2. Actions derived from the focus group with primary school teachers.

Subsequently, a Pareto diagram was drawn up with the actions that should be prioritized to correctly educate children and their families to prevent the appearance of caries. Figure 3 shows the result of this diagram, in which educational sessions in educational institutions with the participation of children and their families, correct brushing of teeth after each meal, dialogue with families on oral hygiene for everyone and avoiding excessive consumption of sugar in beverages and food in infants are the most important actions to develop from the educational point of view.

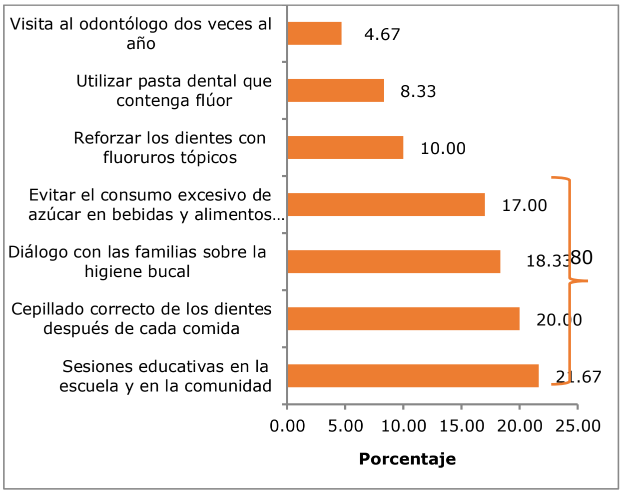

Figure 3. Pareto diagram.

These actions are approved by the participants and become part of the communication strategy with the educational community. From that moment on, parents are prepared by the specialists to guide both the children and the family on how to brush correctly, which foods to avoid and which ones to encourage.

CONCLUSIONS

It is concluded from the results that the TRA restorations should be monitored from the fourth month after the treatment, which will allow timely decisions to be made for the replacement of the material in the short term and also to control some factors such as dietary habits, hygiene habits, among others, for the benefit of the health of the child population. Caries prevention is an important task that should be developed starting with the care and control of oral hygiene in children. Class I restorations made with Ketac Molar Easy Mix glass ionomer showed better survival time compared to restorations with Riva Self Cure ionomer at 2, 4 and 6 months.

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