

Two years survival rate of Class II ART restorations in primary molars using two ways to avoid saliva contamination

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Aim. To compare the survival rates of Class II Atraumatic Restorative Treatment (ART) restorations placed in primary molars using cotton rolls or rubber dam as isolation methods.

Methods. A total of 232 children, 6–7 years old, both genders, were selected having one primary molar with proximal dentine lesion. The children were randomly assigned into two groups: control group with Class II ART restoration made using cotton rolls and experimental group using rubber dam. The restorations were evaluated by eight calibrated evaluators (Kappa > 0.8) after 6, 12, 18 and 24 months.

Results. A total of 48 (20.7%) children were considered dropout, after 24 months. The cumulative survival rate after 6, 12, 18 and 24 months was 61.4%, 39.0%, 29.1% and 18.0%, respectively for the control group, and 64.1%, 55.1%, 40.1% and 32.1%, respectively for the rubber dam group. The log rank test for censored data showed no statistical significant difference between the groups ($P = 0.07$). The univariate Cox Regression showed no statistical significant difference after adjusting for independent variables ($P > 0.05$).

Conclusion. Both groups had similar survival rates, and after 2 years, the use of rubber dam does not increase the success of Class II ART restorations significantly.

Introduction

The Atraumatic Restorative Treatment (ART) approach was originally promoted as a means of oral health treatment for people living in remote areas, where there is lack of electricity, or in places where there are no oral health units, such as public schools and community centers^{1,2}. Due to the use of hand instruments to carry out the restorations, ART may promote a less traumatic technique towards patients and possibly produce smaller cavities in comparison to conventional preparations made with the conventional rotatory equipment³.

Single surface Class I ART restorations in primary teeth can have high success rates of almost 80% after 30 months⁴. Class II restorations, on the other hand, have lower success rates, varying in the range of 12–75% even after 3 years^{5–8}. Several researches have been carried out to find the reasons for these lower success rates.

It has been stated that survival rates of single surface ART restorations using high viscosity glass ionomer cements (GIC) as restoration material were high, and similar to those filled with amalgam^{9–11}. However, Class II restoration failure could be due to the restoration material or even the technique itself. Some studies have shown that restorations made using the conventional rotary instruments had greater success rates than those carried out with the ART approach^{8, 12, 13}. Operator inexperience^{5, 14, 15} and inadequate caries removal^{16, 17} have been suggested to contribute to Class II ART restoration failures. Among other factors, moisture contaminating

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the cavity before placing the restorative material could also cause higher failure rates in Class II ART restorations¹⁸. Therefore, the aim of this randomized clinical trial is to compare to compare the survival rates of Class II ART restorations placed in primary molars using cotton rolls or rubber dam as isolation methods. The null hypothesis is that no difference is to be found between these methods.

Material and methods

This study was approved by the Committee of Ethics in Research from the Federal University of Paraíba, under protocol number 134/04.

Sampling

Children were selected from two medium sized cities, João Pessoa and Campina Grande, from the Northeast region of Brazil where water is not fluoridated. The children were selected from schools located in the central areas of João Pessoa and Campina Grande. All schools in these areas were visited.

A total of 42 public schools were visited, from which 2316 children, aged between 6 and 7 years old, both genders, were examined for proximal caries lesions in primary molars, after the signed consent was obtained.

The proximal lesions should have had access to ART hand instruments, have a mesio-distal maximum dimension of 1 mm and a buccal-lingual maximum dimension of 2 mm length, measured on the occlusal surface using a periodontal probe. Cavitated carious lesions having pulpal involvement, swelling, fistula or pain were not included in the study, and these patients were referred to the university's paediatric dental clinic. The proximal surface of the adjacent tooth should be unimpaired, without visible lesions.

Only one cavitated carious lesion per child was selected. If more than one cavity was suitable in a child, one cavity was selected at random by drawing a piece of paper containing which molar should be included in the study. The other lesions were treated, but not within the framework of the present study. Out of the 2316 children examined, only 232 children participated in the study.

When all children had been selected, they were randomly assigned into one of two study arms, consisting of a control group ($n = 117$) of Class II ART restorations made using cotton rolls and an experimental group ($n = 115$) in which the restorations were made using rubber dam. Each child was individually allocated into a group by the use of generated random numbers, and no restrictions were considered. The group in charge of making the restorations or those who assessed the restorations did not have access to the randomization procedure. All children were allocated into the respective group before the restorations were made.

Restorations

Four final year dental students were thoroughly trained on the ART technique, especially on the glass ionomer manipulation. These students carried out all manipulation of the glass ionomers and restorations.

After supervised tooth brushing, the restorations made out on the school grounds. The child laid in supine position on a school table, according to Frencken et al.², and hand instruments were used throughout the treatment, under natural light.

Soft dentine was removed using only hand instruments, mainly spoon excavators, then the saliva barrier was placed. For the control group, new cotton rolls were placed on both sides of the molar, and for the experimental group, a rubber dam was used, fixed with a clamp on the adjacent distal tooth, without local anaesthesia.

Both groups had the same restoration procedure². The cavity was washed with cotton pellets dipped in water, and a matrix band was applied with wooden wedges. The cavity was conditioned with the liquid part of the GIC diluted with a wet cotton wool pellet for 15 s. It was then washed with three cotton pellets dipped in water, and dried with three cotton pellets. The glass ionomer Fuji™ IX (GC, Europe) was then hand mixed and placed into the cavity, and the press-finger technique was carried out with petroleum jelly. Excess was removed immediately using the hand instruments. After 5 min, the matrix was removed and the occlusion was checked with carbon paper.

After the restorations were made, no difference was visually observed between the restorations in the rubber dam group or those in the control group. This assured a successful blind evaluation system, so the examiners were blinded to the exposure categories.

Evaluation

The restorations were clinically assessed in six month intervals in a follow-up period of 2 years: at 6, 12, 18 and 24 months. A total of eight examiners were calibrated using 30 extracted teeth with Class II glass ionomer restorations. Their inter-examiner reliability was Kappa > 0.76 and their intra-examiner reliability was Kappa > 0.81. These examiners were blinded to the exposure categories. In other words, at the time of examination of the restoration, the examiners did not know to which group the child belonged to. These examiners used mouth mirrors and explorers, under natural light, to assess the restorations. The defects were measured using periodontal probes.

Restorations were assessed according to the following criteria: (i) *successful treatment*: when it was still present and correct or having only a slight wear or defect at the margin less than 0.5 mm in depth; (ii) *treatment failures*: when the restorations were either completely lost, or were fractured with defects 0.5 mm in depth or greater, had secondary caries or inflammation of the pulp; or (iii) *lost to follow-up*: when the children who were not found at the time of assessment, or when the teeth were lost to exfoliation or extraction. Also, the children who were not found at the time of assessment, or those who lost their teeth due to exfoliation or extraction, had their restorations censored for statistical analyses.

In case of need to repair, the restorations were re-done by the examiners, and were marked as failed. These failed restorations were excluded from further assessments. The more complex cases were referred to the university's pediatric dental clinic.

Statistical analysis

The results were analyzed using SPSS (v. 13.0). Survival analysis was carried out to determine

the survival rates and possible influences towards failure.

A Pearson's chi-square test was done in order to find out if there were differences between both groups in the number of children lost to follow-up or whose teeth shed.

Initially, bivariate survival analysis, using the Kaplan–Meier survival method and the log rank test, was carried out for the difference in the survival rates between the two groups. Then, univariate analyses using Cox regression were carried out testing the effect of independent covariates on the survival rate of both groups. The covariates tested were age, gender, upper or lower jaw, first or second molar and operators. The covariates would have been included in a multivariate model by a forward stepwise procedure with $P < 0.20$ as the cut-off point. As most P -values were above the cut-off point, the multivariate model was not realized. The confidence level for all analyses was previously established at 95%.

Results

Two hundred and thirty-two children participated in the study, 128 (55.2%) boys. The participant's mean age was 6.3 years. From the 232 restorations, 39.7% was in the upper jaw and 60.4% in the lower jaw, 81.9% were first molars and 18.1% second molars.

From the 232 children, 117 (50.4%) were randomly allocated in the control group and 115 (49.6%) in the rubber dam group. All these children received the restoration, according to the technique described beforehand. Throughout the study, a total of 48 (20.7%) children were considered as lost to follow-up. Others eventually lost their teeth due to exfoliation or extraction. Due to such reasons, a total of 77 restorations (33.2%) were censored (lost to follow-up), where 34 (14.7%) were from the control group and 43 (18.5%) from the rubber dam group ($\chi^2 = 1.82$; $df = 1$; $P = 0.18$).

The life table (Table 1) shows the number of restorations considered as success and failure during the 2 years of the study. The failures in the control were found to be from fractures greater than 0.5 mm or complete

Table 1. Survival table of Class II ART restorations in respect to the moments of evaluation, during 2 years.

Group	Interval (months)	<i>N</i> _{start}	<i>N</i> _{failure}	<i>N</i> _{censored}	Failure rate (%)	Cumulative survival rate ± SE (%)
Control	0–6	117	43	11	38.6	61.4 ± 4.6
	6–12	63	21	11	36.5	39.0 ± 4.9
	12–18	31	7	7	25.5	29.1 ± 4.9
	18–24	17	4	5	38.1	18.0 ± 5.3*
Rubber dam	0–6	115	39	13	35.9	64.1 ± 4.6
	6–12	63	8	12	14.0	55.1 ± 4.9
	12–18	43	11	5	27.2	40.1 ± 5.3
	18–24	27	3	13	20.0	32.1 ± 5.9*

*N*_{start} = number of restorations at start of evaluation period; *N*_{failure} = number of restorations failed at end of the evaluation period; SE = standard error.

loss of the restoration (88.3%), due to secondary caries (6.7%) or inflammation of the pulp (5.0%); whereas in the rubber dam group, the failures were 83.8% due to fracture or loss of the restoration, 6.7% due to secondary caries and 9.5% due to inflammation of the pulp. No difference was found between both groups ($\chi^2 = 0.963$; *df* = 2; *P* = 0.62).

From the 232 Class II restorations, the overall cumulative survival rate was 34.4%. ART restorations made using the rubber dam had a median survival time of 20 months, and those in the control group had a median survival time of 15 months. Although the control group seems to have a shorter time to failure, the log rank and Kaplan–Meier analysis shows that these survival times are similar (*P* > 0.05) (Table 1).

Table 2 shows the univariate analysis done with each independent variable using the Cox Regression test. No influence of age, gender, tooth (first or second molar), jaw (upper or lower) or operator was found. Due to the high *P*-values in this analysis, the authors did not proceed to a multivariate analysis.

Discussion

Saliva contamination was thought to be one of the causes for the low success rate of Class II ART restorations. However, the use of rubber dam to avoid saliva contamination during

Table 2. Univariate analyses of the association of covariates on the survival rate of restorations from both study groups.

	Group, <i>n</i> (%)		Exp(B) (95% CI)	<i>P</i> *
Variables	Control	Rubber dam		
Age				
6 years	77 (33.2)	70 (30.2)		
7 years	40 (17.2)	45 (19.4)	0.87 (0.61–1.24)	0.23
Gender				
Male	58 (25.0)	70 (30.2)		
Female	59 (25.4)	45 (19.4)	0.81 (0.58–1.15)	0.15
Molar				
First molar	92 (39.7)	98 (42.2)		
Second molar	25 (10.8)	17 (7.3)	0.84 (0.54–1.31)	0.23
Jaw				
Lower	70 (30.2)	70 (30.2)		
Upper	47 (20.3)	45 (19.4)	0.91 (0.65–1.29)	0.27
Operator				
1	30 (12.9)	29 (12.5)		
2	29 (12.5)	29 (12.5)	0.69 (0.43–1.09)	
3	29 (12.5)	29 (12.5)	0.83 (0.53–1.32)	
4	29 (12.5)	28 (12.1)	0.64 (0.39–1.03)	0.23

*Overall significance calculated from chi-squared test.

Exp(B) = hazard ratio; 95% CI = 95% confidence interval.

the ART procedure does not significantly improve the survival rate of Class II restorations in primary teeth. This discussion section will be divided into subheadings for easier comprehension.

Sample size

No statistical difference was found between both methods of saliva control in this study, so we accepted the null hypothesis. However, no calculation of sample size was carried out prior to this study, and the sample size we have here may be small. If so, there is a possibility that we are making type II error from our results. On the other hand, a total of 2316 children were examined, and only 232 (10.0%) of them fit the inclusion criteria. This suggests that we practically included all possible subjects in our study, and a larger sample size would not have been possible within the scope of this study.

Censored data

The great number of restorations lost to follow-up in this study was mostly due to children transferred to other schools or other cities, which implies that the student's school

files and personal data are transferred to another sector of the public service and no record of the former student is kept at the original school. This caused the researchers to lose contact or track of the children. Although the number of children lost to follow-up is rather high, it is in accordance with other studies performed under similar conditions¹⁹. After having censored the data, no association was found between the number of restorations censored and the method used for saliva control ($P > 0.05$). Also, for the statistical analyses, the log rank test took the censored data into account²⁰. Moreover, the restorations that were not assessed due to exfoliation could have either survived or failed, but if the restoration stayed in the tooth until exfoliation, it could be considered as successful. Therefore, exfoliation of teeth may be regarded as a limitation for this type of study.

Variables affecting the success rate

Saliva contamination and moisture control. Success rates found with Class II ART restorations filled with GIC vary according to different GICs, dentists and study period. To our knowledge, no extended clinical trial was carried out comparing the influence of saliva contamination on the success rates of Class II ART restorations. Only one report was found which evaluated 59 restorations for 6 months and concluded that the rubber dam did not improve ART success rate¹⁸. Similarly, our study showed that ART restorations using rubber dam had a slightly higher success rate than the control group, but this difference was not statistically significant (Table 1). Therefore, one may suggest that possible saliva contamination is not the main cause for Class II ART restoration failures. The cause of such fractures may be due to other factors.

Restorative materials. One could argue that the GIC used in the present study could be the cause for the low survival rate found. However, in two different studies carried out in China, using Ketac Molar™ glass ionomer (3M ESPE, Seefeld, Germany), the success rates of Class II restorations were 54% and 57%, after

2 years and 2.5 years, respectively^{4, 21}. When Ketac Molar™ (3M ESPE) was compared to Fuji™ IX (GC), no significant difference was found between both cements after 3 years¹⁰. When Fuji™ IX GP (GC) was used as restoration material of proximal slot restorations in primary molars, success rates above 90% were found after 3 years^{22, 23}. The success rate found in this study, after an evaluation period of 2 years, for Class II restorations using Fuji™ IX (GC) was 34.4%. This value is in accordance with other studies, which showed success rates as low as 30% after a one year follow-up period⁵.

When comparing the GIC used to resin composite, it has been shown that when GIC is used in Class II restorations it has a slightly lower success rate than resin-based composite restoration after 2 years²⁴. However, such a difference was not statistically significant, and proximal slot restorations filled with GIC have demonstrated a high success rate of 94% after 3 years²³. So, one may suggest that the use of Fuji IX in this study may not have been the cause for the low survival rate of the restorations.

Dentists who carry out the restorations. Some studies have demonstrated that success rates of ART restorations can be operator-dependent. In other words, when experienced dentists make the restorations, it leads to greater success rates^{1, 14, 15}. This could be because dentists have some influence on the child's behaviour independently of the method used for the restoration²⁵. Also, the amount of infected dentine removed from the cavity, as well as the manipulation of the materials could influence the restoration's success rate. When the ART technique is carried out, there is a reduction, but not total removal, of microorganisms found in the carious lesion, such differences in the practitioners' cavity preparation may lead to failure of the restoration^{16, 17, 26, 27}. On the other hand, the use of a bur also may not remove all microorganisms from the lesion²⁸. Moreover, other defects caused by dentists differed, such as cervical gaps and residual caries in the cavity, have also been demonstrated to significantly influence the survival rate of Class II restorations⁵. In the

present study, four dental students made the ART restorations, but differences in success rates between them were not observed. Therefore, the main cause for the low success rates found in this study may not be operator-dependent, as the regression study showed no association between operators and the success rates of the control and rubber dam groups (Table 2). Nevertheless, it is difficult to compare the skills among different dentists and different study. Despite the fact that the dental students in the present study were considered similar, they could differ in skills to those who participated in other studies, thus possibly explaining the lower survival rate found.

Discomfort. One other cause for the restoration failure could be the discomfort felt by the child during the ART procedure. Nonetheless, no difference has been found in the discomfort felt by children whose restorations were made with or without local anesthesia (LA) during an ART restoration. The use of LA did not affect the survival rate of Class II ART restorations⁷. Therefore, children undergoing dental treatment with the ART approach are not more prone to discomfort or pain leading to crying and consequential hypersalivation. In consequence, this possibly did not affect the failure rate of the ART restorations.

The ART technique itself. The ART technique itself could be a cause of Class II restoration failure. Some studies have suggested that restorations made with the conventional method with the rotary motor have better survival rates than those made using the ART approach^{12, 13, 29}. However, ART restorations produce smaller cavities, and smaller cavity size produce higher survival rate for restorations³⁰. Still, the restorations in this study were made in the school grounds, as suggested by the ART approach guidelines², where there is no dental office and no possibility of using the drill.

Conclusion

The low success rate observed for restorations made using the rubber dam indicates that it is not worth the effort of using this procedure to enhance the success rate of Class II restora-

tions. Furthermore, it is worth mentioning that placing a rubber dam may compromise the 'atraumatic' aspect of ART, and possibly lead to greater discomfort in children. On the other hand, further investigations with the ART approach, especially in Class II cavities, are necessary in order to arrive at different strategies that may increase the success rate of such restorations in oral health programs.

What this paper adds

- This paper states that rubber dam used as saliva barrier during ART restorations does not improve the survival rate of Class II restorations;
- Also, these findings suggest that the ART approach may be carried out using cotton wool rolls, as suggested originally;
- Possible saliva contamination from using cotton rolls in ART restorations may not be responsible for the high number of Class II ART restoration failure.

Why this paper is important to paediatric dentists

- It is quite relevant to paediatric dentists, above all, those who carry out the ART approach. They may continue to make ART restorations in proximal cavities in primary molars using cotton rolls, as this will not affect the survival rate of the restoration.

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