Effectiveness of atraumatic restorative treatment, Hall Technique and conventional restoration using resin or amalgam after 18 months of follow-up: a randomized controlled trial

Eficácia do tratamento restaurador atraumático, Hall Technique e restauração convencional usando resina ou amálgama após 18 meses de acompanhamento: um ensaio clínico randomizado

Eficacia del tratamiento restaurador atraumático, Hall Technique y la restauración convencional con resina o amalgama después de 18 meses de seguimiento: un ensayo controlado aleatorizado

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Rosário Maria Maciel Pessoa da Silva
ORCID: https://orcid.org/0000-0003-1501-6569
University of Pernambuco, Brazil
E-mail: rosariomacie24@hotmail.com

Gabriela Brito Vasconcelos
ORCID: https://orcid.org/0000-0002-5342-542X
University of Pernambuco, Brazil
E-mail: Gabriela.vasconcelos@upe.br

Rafaela Brito Vasconcelos
ORCID: https://orcid.org/0000-0002-1294-3300
University of Pernambuco, Brazil
E-mail: rafabvasconcelos@hotmail.com

Carolina da Franca Bandeira Ferreira Santos
ORCID: https://orcid.org/0000-0002-7365-2806
University of Pernambuco, Brazil
E-mail: carolina.franca@upe.br

Evert van Amerongem
ORCID: https://orcid.org/0000-0002-5260-993X
Academisch Centrum Tandheelkunde Amsterdam, Netherlands
E-mail: weamerong@gmail.com

Viviane Colares
ORCID: https://orcid.org/0000-0003-2912-2100
Abstract
There are different options for restorations of deciduous teeth. The aim of this study was to evaluate the success rate of conventional and atraumatic restorations, Class I and Class II lesions in primary molars. This is a randomized controlled trial in Olinda, Brazil. The control groups were the conventional restorations with resin (205) and amalgam (198), and the case groups were atraumatic approaches with the ART (211) and the Hall technique (117). A total of 731 restorations were performed in a dental office setting in 731 children (4- to 8-year-olds). All the restorations were evaluated after 6, 12 and 18 months. The survival rate of Class I restorations was higher (> 85% success) for all restorations compared to Class II (16.9%-99.1%, success/minor failure). The success rates of Class II restorations after 18 months were not satisfactory for conventional restorations with resin (16.9%, success/minor failure) and ART (31%, success/minor failure), while were satisfactory for conventional restorations with amalgam (70.3%, success), and outstanding for Hall technique (99.1%, success). The success rate for Class I was higher than II for all restorations. Considering Class II, the success rate was low for ART and conventional restorations with resin, satisfactory for amalgam, and excellent for Hall Technique.

Keywords: Dental caries; Child; Tooth deciduous; Dental atraumatic restorative treatment; Dental restoration permanent.

Resumo
Existem diferentes opções para o tratamento restaurador de dentes decíduos. O objetivo deste estudo foi avaliar a taxa de sucesso de restaurações convencionais e atraumáticas, lesões de Classe I e Classe II em molares decíduos. Este é um ensaio clínico randomizado que foi realizado em Olinda, Brasil. O grupo controle foi formado pelas restaurações convencionais com resina (205) e amálgama (198), e o grupo caso pelas restaurações atraumáticas (ART) (211) e pelos tratamentos com Hall Technique (117). Um total de 731 restaurações foram realizadas em consultório odontológico em 731 crianças (4 a 8 anos de idade). Todas as restaurações foram avaliadas após 6, 12 e 18 meses. A taxa de sucesso das restaurações Classe I foi maior (> 85% de sucesso) para todas as restaurações em comparação com a Classe II (16,9% -99,1%, sucesso / falha menor). As taxas de sucesso das restaurações Classe
II após 18 meses não foram satisfatórias para restaurações convencionais com resina (16,9%, sucesso / falha menor) e ART (31%, sucesso / falha menor), enquanto foram satisfatórias para restaurações convencionais com amálgama (70, 3%, sucesso), e excelente Hall Technique (99,1%, sucesso). A taxa de sucesso para Classe I foi maior que II para todas as restaurações. Considerando a Classe II, o índice de sucesso foi baixo para ART e restaurações convencionais com resina, satisfatório para amálgama e excelente para Hall Technique.

Palavras-chave: Cárie dentária; Criança; Dente decíduo; Tratamento dentário restaurador sem trauma; Restauração dentária permanente.

Resumen
Existen diferentes opciones para la restauración de dientes temporales.Comparar la tasa de éxito de cuatro tipos de restauraciones (ART, amalgama, resina y, Hall Technique), lesiones Clase I y Clase II en molares temporales.Este es un ensayo controlado aleatorio en Olinda, Brasil. Los grupos de control fueron las restauraciones convencionales con resina (205) y amalgama (198), y los grupos de casos fueron abordajes atraumáticos con la técnica ART (211) y la Hall Technique (117). Se realizaron un total de 731 restauraciones en un consultorio dental en 731 niños (de 4 a 8 años). Todas las restauraciones fueron evaluadas a los 6, 12 y 18 meses.La tasa de supervivencia de las restauraciones de Clase I fue mayor (> 85% de éxito) para todos los tipos de restauraciones en comparación con la Clase II (16,9% - 99,1%, éxito / fracaso menor). Las tasas de éxito de las restauraciones de Clase II después de 18 meses no fueron satisfactorias para las restauraciones de resina (16,9%, éxito / fracaso menor) y ART (31%, éxito / fracaso menor), mientras que fueron satisfactorias para las restauraciones de amálgama (70,3%, éxito ), y sobresaliente para la Hall Technique (99,1%, éxito). La tasa de éxito para la Clase I fue superior a la II para cualquier material. Teniendo en cuenta la Clase II, la tasa de éxito fue baja para ART y restauraciones de resina, satisfactoria para la amálgama y excelente la Hall Technique.

Palabras clave: Caries dental; Niño; Diente primario; Tratamiento restaurativo atraumático dental; Restauración dental permanente.

1. Introduction

Dental caries is one of the most common diseases in the world, affecting around 80% of people (Agnihotry, Fedorowicz & Nasser, 2016). Besides that, dental extraction is a common intervention for teeth with painful symptoms (Frencken, Leal & Navarro, 2012). The
Atraumatic restorative treatment (ART) approach emerged around 30 years ago in Tanzania, evolving from a form of caries management to improve quality and access to oral health care. The use of ART contributes to smaller cavity preparations and greater acceptance of dental treatment by children. ART has been implemented in the public oral health services of several countries (Frencken et al., 2012). The ART approach has characteristics that favor patient acceptance and cooperation, promoting an “atraumatic” treatment (Carvalho, Ribeiro, Bönecker, Pinheiro & Colares, 2009).

On the other hand, Amalgam is a restorative material used in conventional restorations, with the use of high speed and manual instruments for the removal of caries (Amorim, Leal, Mulder, Creugers & Frencken, 2014). Conventional restorations with the use of composite resin restorations have been widely used with children, because in addition to adopting a more conservative cavity preparation, preserving dental tissue structure, resin restorations present a better aesthetic result, similar to the deciduous tooth (Ersin et al., 2006).

Another option for the treatment of caries in primary teeth are steel crowns, manufactured in different sizes. These crowns can be placed on decayed teeth or teeth with developmental defects. Conventionally, the teeth are trimmed so that the crowns are placed under local anaesthetic. With the Hall technique, the crowns are pushed over the tooth without tooth preparation. Thus, in the Hall technique, the use of steel crowns is a simpler procedure and a broader indication (Innes et al., 2015). Then, the objective of this randomized controlled trial was to compare the success rate of atraumatic (ART and Hall technique) and conventional restorations (amalgam and resin), in Class I and Class II lesions in primary molars of children over 18 months.

2. Material and Methods

It was a randomized controlled trial, that evaluated the longevity of atraumatic and conventional restorations performed at dental offices in Olinda, state of Pernambuco-Brazil. Data collection occurred in 8 health units of the public system of health. The inclusion criteria were children between 4 and eight years old with occlusal and proximal caries in primary molars, without fistula, abscesses, mobility, and other pulp involvements. Seven hundred and thirty-one primary school children who had a primary molar with carious lesion of a similar size extending into the dentine with an entrance just large enough to allow access by hand instruments-were selected for treatment. A total of 731 restorations were placed being 211 ART (124 class I and 87 class II); 117 Hall technique class II; 198 with amalgam (104 class I
and 94 class II), and 205 with resin (103 class I and 102 class II) (Figure 1). The Hall technique was performed in a reduced number (only Class II) due to the difficulty of accessing the crowns in Brazil.

**Figure 1** - Consolidated Standards of Reporting Trials (CONSORT) flow diagram of participants through each stage of the randomized trial.

Source: The authors.

Data collection was carried out in four months, one for each material used (amalgam, resin, glass ionomer cement -ART and steel crown - Hall technique). The order of the types of restorations per month was randomized, and all children who went to the health unit with decayed teeth and met the inclusion criteria, were treated with the same technique each month. For each child, one molar was selected for treatment. When the child had more than
one tooth with the criteria defined in this study, a tooth was included in the study at random. The children should be subscribed in the public health care system. Prior to treatment, signed written consent was obtained from parents or guardians of the children.

Fifteen dentists from the public health units did training composed of three phases: theoretical, laboratory, and clinical. Each dentist had to perform the different types of restorations during the clinical training phase. After the evaluations of the restorations performed during the training, eight dentists were selected to participate in the operative phase of the research. The evaluation of the restorations made by the dentists during the training period was performed to calibrate the evaluator for the operative phase. The codes and criteria for the restorations assessment is summarized in Table 1, according to Innes et al. (2015) and Roeleveld, Amerongen and Mandari (2006). The restorations made during the training were evaluated by a Ph.D. paediatric dentistry student, who did thereafter the evaluations during the entire clinical study.

Table 1 - Code and Criteria Used For the Assessment of Restorations.

| Score | Classification   | Criteria                                                                 |
|-------|------------------|--------------------------------------------------------------------------|
| 00    | Successful       | Restoration still present, correct                                        |
| 10    |                  | Restoration present, slight defect at the margin and/or wear of the surface; <0.5 mm in depth, no repair needed |
| 11    | Minor failure    | Restoration present, defect at the margin and/or wear of the surface; >0.5 mm in depth, repair needed |
| 12    |                  | Restoration present; underfilled>0.5 mm, no gap, repair needed            |
| 13    |                  | Restoration overfilled >0.5 mm, repair needed                             |
| 20    |                  | Secondary caries, discoloration in depth, surface hard and intact, caries within dentin; repair needed |
| 21    |                  | Secondary caries, surface defect, caries within dentine; repair needed    |
| 30    | Major failure    | Restoration not present, bulk fracture, moving (partly) lost; repair needed (if still possible without exposing the pulp) |
| 40    |                  | Inflammation of the pulp (restoration still in situ, not categorized in the former categories); fistula or severe pain complaints; extraction needed |
| 50    | Unable to evaluate | Tooth not present because of extraction                                  |
| 60    |                  | Tooth not present because of shedding                                      |
| 70    |                  | Tooth not present because of extraction or shedding; unable to diagnose   |

Source: According to Roeleveld et al., 2006 and Innes et al, (2015).

The Ph.D. student who was not involved in the placement of the restorations, evaluated the restorations after 6, 12 and 18 months using sharp sickle-shaped explorers, plane mirrors, and a portable light source (Kappa inter-examiner was 0.88). The ball end of the CPI probe (0.5-mm in diameter) was used to measure the size of any marginal defect and the amount of wear.
The data were analyzed using a software program (Epi info). All conclusions of the applied tests were taken considering the level of significance of 5%. Kaplan-Meier test was used to assess the significance of the success rates of the restorations. Also were used Log Rank, Breslow, Tarone Ware, and Wald tests to verify the longevity of the restorations according to the material used and the surface of the cavities.

This study was approved by the ethical committee of research of the University of Pernambuco (protocol no. 447.607). It was also approved by the Brazilian clinical trial registry through the number (RBR-8JQRW7).

3. Results

In general, for Class I restorations, the success rate was higher than 85%, after 18 months of follow-up (Table 2).

| Restorations | Evaluation % (n) | 6 months | 12 months | 18 months |
|--------------|-----------------|----------|-----------|-----------|
|              | success | Minor failure | Major failure | Unable |
|              |         |           |           |          |         |           |           |          |         |           |           |          |
| Atraumatic   | Glass    | 91.9      | 5.6       | 1.6      | 0.8      | 87.1     | 0.0       | 8.9       | 4.0      | 85.4     | 2.4       | 5.7       | 6.5       |
|              | Ionomer  | (114)     | (7)       | (2)      | (1)      | (108)    | (0)       | (11)      | (5)      | (105)    | (3)       | (7)       | (8)       |
| Amalgam      | Conventional | 96.2      | 1.0       | 1.8      | 1.0      | 96.2     | 0.0       | 1.9       | 1.9      | 96.2     | 0.0       | 0.0       | 3.8       |
|              | Resin    | (100)     | (1)       | (2)      | (1)      | (100)    | (0)       | (2)       | (2)      | (100)    | (0)       | (0)       | (4)       |
|              | (98)     | (0)       | (1)       | (0)      | (94)     | (4)       | (0)       | (1)       | (93)     | (4)       | (0)       | (2)       |
| P value      | 0.040    | 0.012     | 0.864     | -        | 0.019    | 0.009     | 0.001     | 0.320     | 0.009    | 0.134    | 0.003     | 0.258     |

Source: The authors.

Considering Class II restorations, after 6 months, better results were observed for atraumatic restorations (ART and HT). In the analysis of all restorations, considering "success" and "minor failure", after 6 months, results were obtained between 97.5% and 99.1%. After 18 months of follow-up, the success was higher among restorations with stainless steel crowns (HT) and amalgam, more than 70% success (Table 3).
Table 3 – Distribution of evaluation of the restorations Class II after 6, 12 and 18 months.

| Restorations       | Evaluation % (n)       | 6 months |              | 12 months |              | 18 months |              |
|--------------------|------------------------|----------|--------------|-----------|--------------|-----------|--------------|
|                    |                        |          | success      | Minor failure | Major failure | Unable    | success      | Minor failure | Major failure | Unable    |
| Atraumatic         | Crows                  | 99.1     | (116)        | 0.0        | (0)          | 0.0       | (0)          | 99.1         | (115)        | 0.0       | (0)        | 0.9       | (1)        |
|                    | Glass Ionomer          | 87.4     | (76)         | 9.2        | (8)          | 2.3       | (2)          | 1.1          | (1)          |          |           |          |           |
| Conventional       | Amalgam                | 78.0     | (71)         | 4.4        | (4)          | 3.3       | (3)          | 14.3         | (13)         |          |           |          |           |
|                    | Resin                  | 3.9      | (4)          | 74.5       | (76)         | 19.6      | (20)         | 2.0          | (2)          |          |           |          |           |
|                    |                        |          |              |            |              |           |              |              |              |           |           |           |           |
| P value            |                        | <0.001   | <0.001       | <0.001     | <0.001       | <0.001    | <0.001       | <0.001       | <0.001       | <0.001    | <0.001    | <0.001    | <0.001    |

Source: The authors.

The type of restoration is a determinant factor to alter the survival time of the material in the evaluated patients. The restoration with more prolonged survival was the crown (Hall technique), followed by conventional restoration using amalgam, and the shorter longevity was for the conventional restoration using resin. The average of time was 17.8 months (95% CI:17.6-18.1), 17.3 months (95% CI:16.9-17.7), 16 months (95% CI:15.5-16.5), and 12 months (95% CI:11.2-12.9) for crowns (Hall technique), amalgam, glass ionomer (ART) and, resin, respectively (Table 3 and Figure 2).
Figure 2 - Longevity of restorations according to the material.

Regarding the restoration Class (I or II), the comparison test of survival between groups was significant (p-value <0.001), indicating that the surface of the restoration is a determining factor for the material survival time. On the average, the Class I group had a survival of 17.4 months (95% CI:17.1-17.6) and the Class II group had a 14 month survival (95% CI:5.0-14.5) (Table 4 and Figure 3).

Table 4 - Longevity of the restoration according to the the material and surfaces of the cavities.

| Factor evaluated | Log Rank | Breslow | Tarone-ware |
|------------------|----------|---------|-------------|
| Restorations     | <0.001   | <0.001  | <0.001      |
| Class (I or II)  | <0.001   | <0.001  | <0.001      |

Source: The authors.
4. Discussion

For Class I restorations, in the sample evaluated in this study, good results were obtained for all types of restorations, with success above 85% after 18 months of follow-up. However, there was a difference between the types of restorations, with better results for amalgam and resin. Differences in results may be related to the complexity and quantity of the cavities involved, as well as, depending on the accuracy of the technique and other factors (Roshan & Sakeenabi, 2011). Good results observed for class I restorations have been reported in other studies. In a study carried out by Menezes, Rosenblatt and Medeiros (2006), where the teeth restored with ART in one surface lesions achieved a success rate of 95% at 6 months and 82% at 12 months, without recurrent caries or pulpal infection evidence. Similarly, Ersin et al. (2006) also observed a high success rate of 91% for Class I resin restorations.

For Class II restorations, the studies have demonstrated less satisfactory results than for Class I. In this study, the success rate of class II restorations made with glass ionomer by ART was 40.2% after 12 months, and even worse results were found by Franca, Colares and
van Amerogen (2011) that observed only 15.2% of success for class II restorations after 12 months of follow-up. Maybe the environment of restoration makes a difference since the present study occurred in the dental office while in Franca et al. (2011) study the restorations were performed in the school environment in a way less comfortable for the dentist than in the dental office.

For conventional resin restorations, only 2% success was observed after 12 months in this study. However, the inclusion of minor failures should be considered to assess longevity and the satisfactory outcome of restorations. The sensibility of the protocol might be taken into account, since the resin is much more sensitive to moisture than glass ionomer and, in general, a rubber dam is not available in public services in Olinda.

Following this theory, the atraumatic restorations with glass ionomer showed better results (success + minor failure) of 56.3% after 12 months of follow-up; and conventional resin restorations presented a result of 20.6% after the same period. The most critical survival of the resin restorations, and glass ionomer restorations is following Santamaría et al. (2017), who had worst longevity for compomer restorations.

The Hall technique was performed only for Class II due to the reduced number of steel crowns obtained for this study and because of the high failure rate for these cavities restorations according to the literature (Franca et al., 2011).

For Class II restorations, excellent results (success over 99%) were observed for crowns and good results (success over 70%) for conventional amalgam restorations after 18 months.

Crowns placed on primary molars teeth with carious lesions are likely to reduce the risk of major failure or pain in the long term compared to conventional fillings. Crowns fitted using the Hall Technique may reduce discomfort at the time of treatment compared to conventional fillings (Innes et al., 2015). In this study, using the Hall Technique, it was successful above 99% after 18 months for class II restorations, which was much higher than that observed for other types of restorations.

Stainless steel crowns have demonstrated better longevity compared with amalgam restorations for primary molars, although amalgam has shown a notable clinical success for Class II. It is necessary to keep in mind two points: the need to reduce the use of amalgam as a mercury-containing material when aiming to reduce environmental contamination (Fuks, 2015), and also that the HT is more cost-effective than conventional restorations (Schwendicke et al., 2019). Hall technique restorations are more favorable with respect to discomfort when compared to the conventional steel crown restorations (Ayedun et al., 2020).
Besides that, Hall technique is an intervention with high clinical success and shorter treatment time, aspects that make this technique indicated as an alternative for decayed deciduous teeth with multisurface lesions (Ebrahimi et al., 2020).

In this study, the best results were found for Hall technique restorations, followed by conventional restorations with amalgam. The worst results were seen for conventional restorations using resin and ART using glass ionomer.

This study revealed that the success rate of restorations in primary molars was higher for class I compared with Class II. In addition, the restorations Class II presented better results when restored using metal crowns through the Hall technique and conventional technique using amalgam.

5. Conclusion

The success rate for Class I was higher than II for all restorations. Considering Class II, the success rate was low for ART and conventional restorations with resin, satisfactory for amalgam, and excellent for Hall Technique.

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Conflict of interest

The authors declare that they have no conflicts of interest in the publication of this paper.

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**Percentage of contribution of each author in the manuscript**

Rosário Maria Maciel Pessoa da Silva – 30%
Gabriela Brito Vasconcelos – 10%
Rafaela Brito Vasconcelos – 10%
Carolina da Franca Bandeira Ferreira Santos – 10%
Evert van Amerongen – 20%
Viviane Colares – 20%