Atraumatic restorative treatment in Brazilian schoolchildren: 12 months preliminary clinical results

Patrícia Almada SACRAMENTO¹, Ana Flávia Sanches BORGES², Raphaela Farias RODRIGUES², Regina Maria PUPPIN-RONTANI¹

1 – Department of Children’s Dentistry – Division of Pediatric Dentistry – Piracicaba Dental School – University of Campinas – Piracicaba – SP – Brazil.

2 – Department of Operative Dentistry, Endodontics and Dental Materials – Bauru Dental School – University of São Paulo – Bauru – SP – Brazil.

ABSTRACT

Objective: To evaluate the clinical efficacy between two GICs, Fuji IX (GC Int. Corp.) and Ketac Molar (3M ESPE), used in Atraumatic Restorative Treatments (ART). Materials & Methods: A total of 82 children aged among 6-9 years old were included in this study. The materials employment criteria application followed the “split mouth” design, 71 restorations and 98 sealants were carried out with the Fuji IX in the left hemi arches and 70 restorations and 99 sealants were carried out with the Ketac Molar in the right hemi arches. The procedures were conducted in a school that did not have dental equipment. Previously to the restorative procedure, the children were supervised during tooth brushing. A trained dentist carried out all the restorations and sealants at the school playground with natural light and the teeth were isolated with cotton rolls. The performance of the restorations and sealants was evaluated by visual inspection in a 12 months preliminary follow up by one blinded trained examiner. Results: No significant difference was shown between the success rate of the GICs Fuji IX and Ketac Molar for the restorations (p > 0.05) and sealants (p > 0.05). Regardless of the material, the success rates were 82% for the sealants, 76% for the class I and 73% for the class II restorations. Conclusion: The GICs had a good performance and ART preliminary results provided curative and preventive treatments for patients who do not have access to conventional treatment.

RESUMO

Objetivo: Avaliar a eficácia clínica entre dois CIVs, Fuji IX (GC Int. Corp.) e Ketac Molar (3M ESPE), utilizados no Tratamento Restaurador Atraumático (TRA). Material e Métodos: 82 crianças com idade entre 6-9 anos foram incluídas no estudo. A utilização dos materiais seguiu o desenho de boca dividida, 71 restaurações e 98 selantes foram realizados com Fuji IX nas hemi arcadas esquerdas e 70 restaurações e 99 selantes foram realizados com Ketac Molar nas hemi arcadas direitas. Os procedimentos foram realizados em uma escola sem consultório odontológico. Previamente aos procedimentos, as crianças escovaram os dentes sob supervisão. Um dentista treinado realizou todas as restaurações e selantes no pátio da escola com luz natural e os dentes foram isolados com rolos de algodão. A performance das restaurações e selantes foram avaliadas por inspeção visual em 12 meses de acompanhamento por um examinador treinado e cego. Resultados: Não se observou diferença significante entre as taxas de sucesso do CIVs Fuji IX e Ketac Molar para restaurações (p > 0,05) e selantes (p > 0,05). Independentemente do material, a taxa de sucesso foi 82% para selantes, 76% para restaurações classe I e 73% para classe II. Conclusão: Os CIVs tiveram uma boa performance e os resultados preliminares do TRA promoveram tratamentos curativos e preventivos para pacientes que não tem acesso ao tratamento convencional.

KEYWORDS

Dental atraumatic restorative treatment; Glass ionomer cements; Pit and fissure sealants

PALAVRAS-CHAVE

Tratamento dentário Restaurador sem trauma; Cimentos de ionômero de vidro; Selantes de fossas e fissuras.
INTRODUCTION

Oral health prevention programs have been carried out in Brazil. However, a local study showed that even in the public health services the number of people not treated was 16 times higher with disadvantaged people and they had difficulty in obtaining dental treatment when deemed necessary [1]. According to Blinkhorn and Davies [2] the main reason for not providing dental care revolves around the need for expensive dental equipment and extensively trained people.

To overcome these difficulties the Atraumatic Restorative Treatment (ART) technique was developed [3, 4]. The cost of an ART restoration is approximately half of the resin composite and amalgam restorations [5]. This consists of the removal of demineralized dental tissue by manual instrumentation (dental hatchet, sharp excavators and chisels). Only the infected dentin is removed. After that, the cavities are restored with conventional glass ionomer cements (GICs) [6, 7] due to their properties: adhesion to dental structures (enamel and dentin), biocompatibility to the dentinal pulp complex and fluoride release that re-mineralize the tooth mineral tissues [8-10]. In addition, GICs act against cariogenic microorganisms [11, 12], throughout the fluoride action, metallic ions presence and low initial pH level of the cure reaction [10, 13].

Many brands of GICs exist and many are inexpensive. They are, therefore, attractive to purchase for dentists and governments with a limited budget. Personal experiences have shown that many of the inexpensive brands lead to poor quality sealants and restorations [14]. A well-cleaned cavity can thus result in a poor restoration when substandard GICs are being inserted [14].

Compared to medium- and high-viscosity GICs, observed in the majority of in vitro studies, better results are found for high-viscosity GICs in relation to wear resistance, compressive strength and fracture toughness [15-17]. Therefore, it is correct to state that in order to obtain high survival rates of ART sealants and ART restorations, dental practitioners should use high-viscosity GICs and select those that have been tested favorably in clinical studies [4, 14].

This study was conducted to evaluate and compare the clinical efficacy between two high-viscosity GICs in ART restorations class I, class II and sealants in Brazilian schoolchildren with high caries activity and to evaluate the success rate of ART restorations and sealants after a 12 months preliminary follow up.

MATERIAL & METHODS

This study was approved by the Research Ethics Committee of FOP/UNICAMP (Approval No. 006/2003) according to the Resolution of the National Commission of Ethics in Research. Parents or guardians of the selected children signed informed consent forms.

Sample

A total of 637 children were examined from a public elementary school in Piracicaba, São Paulo, Brazil. A total of 82 children reached the inclusion criteria and were selected for this study. They were 53% female, 47% male, and aged 6-9 years.

Inclusion criteria for the subjects were the presence of at minimum one decayed cavity in the primary teeth on the right and left sides (classes I or II cavities) and a simultaneous need for occlusal sealing. The lesions should involve the dentin, and a cavity entrance should be large enough to be accessed with small excavators. The exclusion criteria were children with teeth with pulp exposure, a history of pain, or the presence of a swelling or fistula, and systemic health problems [18].

Restorative procedures

Initially, 100 restorations and 120 sealants with the Fuji IX (GC Co, Tokyo, Japan) and 98
restorations and 120 sealants with the Ketac Molar (3M ESPE, St. Paul, MN, USA) would be carried out. However, due to the absence of some parents or guardian consents, the total of 71 restorations and 98 sealants were carried out with the Fuji IX and 70 restorations and 99 sealants were carried out with the Ketac Molar.

The randomization was performed by raffle with paper after each child had received a number. The procedures were carried out in a school presenting no dental equipment. Previously to the restorative procedure the children brushed their teeth with the supervision of a dentist. For brushing they used toothbrushes and fluoride dentifrice, the reminiscent biofilm was removed with a moistened cotton pellet. The children were positioned horizontally on a table at the school playground.

A trained dentist carried out all the restorations and sealants following the ART manual instructions according recommendations of Frencken et al [19]. The dentist worked with natural light and the teeth were isolated with cotton rolls.

The materials employment criteria application followed the “split mouth” design, as follows: The Fuji IX and Ketac Molar were used to seal the permanent first molar and to restore the class I and II cavities in the primary teeth from the upper and lower left and right hemi arches, respectively. The materials description and manufacturers is described on Table I.

### Evaluations

ART sealants and ART restoration evaluations were carried out in the 12 months follow up. One blinded trained examiner conducted the evaluations.

The evaluation criteria were through visual inspection according to Frencken et al. [19]. The ART evaluation criteria were modified in this study; the 10th item concerning the tooth exfoliation was added because the 9th item is related to a tooth that cannot be evaluated, but not necessarily because of the primary tooth exfoliation (Table II).

### Table I - Composition and manufacturers of materials used in the study

<table>
<thead>
<tr>
<th>Materials</th>
<th>Composition</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fuji IX</td>
<td>Powder: Aluminosilicate glass, polyacrylic acid</td>
<td>GC Co Tokyo, Japan</td>
</tr>
<tr>
<td></td>
<td>Liquid: Polycrylic acid, polybasic acid</td>
<td></td>
</tr>
<tr>
<td>Ketac Molar</td>
<td>Powder: Aluminium-calcium-lanthanum-fluorosilicate glass, 5% polycarbonate acid</td>
<td>3M ESPE St. Paul, MN USA</td>
</tr>
<tr>
<td></td>
<td>Liquid: Polycarbonic acid and tartaric acid</td>
<td></td>
</tr>
</tbody>
</table>

### Table II - Evaluation criteria for ART restorations and sealants

<table>
<thead>
<tr>
<th>Score</th>
<th>Criteria for restorations</th>
<th>Criteria for sealants</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Present, good</td>
<td>Present, good</td>
</tr>
<tr>
<td>1</td>
<td>Present, slight marginal defect for whatever reason, at any one place which is less than 0.5 mm in depth. No repair is needed</td>
<td>Partly present, visible pits and/or fissures are free of active caries. No sealant is needed</td>
</tr>
<tr>
<td>2</td>
<td>Present, marginal defect for whatever reason, at any one place which is deeper than 0.5 mm but less than 1.0 mm. Repair is needed</td>
<td>Partly present, visible pits and/or fissures show signs of active caries. Treatment is needed</td>
</tr>
<tr>
<td>3</td>
<td>Present, gross defect of more than 1.0 mm in depth. Repair is needed</td>
<td>Not present, pits and/or fissures show no signs of (active) caries. No treatment is needed</td>
</tr>
<tr>
<td>4</td>
<td>Not present, restoration has (almost) completely disappeared. Treatment is needed</td>
<td>Not present, pits and/or fissures show signs of active caries. Treatment is needed</td>
</tr>
<tr>
<td>5</td>
<td>Not present, other restorative treatments have been performed</td>
<td>-----</td>
</tr>
<tr>
<td>6</td>
<td>Not present, tooth has been extracted</td>
<td>-----</td>
</tr>
<tr>
<td>7</td>
<td>Present, wear and tear gradually over larger parts of the restoration but are less than 0.5 mm at the deepest point. No repair is needed</td>
<td>-----</td>
</tr>
<tr>
<td>8</td>
<td>Present, wear and tear gradually over larger parts of the restoration which are deeper than 0.5 mm. Repair is needed</td>
<td>-----</td>
</tr>
<tr>
<td>9</td>
<td>Unable to diagnose</td>
<td>Unable to diagnose</td>
</tr>
<tr>
<td>10</td>
<td>Tooth exfoliation</td>
<td>-----</td>
</tr>
</tbody>
</table>
The 0, 1 and 7 scores were considered a success and the 2, 3, 4 and 8 scores were considered failure of restorations. For sealants, scores 0, 1 and 3 were considered a success and scores 2 and 4 were failures. The 5, 6, 9 and 10 scores to the restorations and 9 score to the sealants were considered censured data. Restorations and sealants failures were not evaluated in future evaluations, but they were scored as failure.

Statistical analysis

The obtained data from the restoration and sealant evaluations were subjected to the Mann-Whitney Rank Sum Test (p < 0.05) statistical analysis for material comparisons during the 12 months follow-up and the Fisher Exact Test (p < 0.05) and the Chi-square Test (p < 0.05) to compare the rates of success and failure.

RESULTS

In relation the success of GICs (Table III) no significant difference was shown between the performance of GICs Fuji IX and Ketac Molar for class I (p = 1.0), class II (p = 0.299) and sealants (p = 0.357).

The Fuji IX presented a higher sealants success rate, followed by the class I and class II restorations. However, the GIC Ketac Molar class II restorations showed the highest rate of success. Observing all the restorations and sealants, the success rates observed were: sealants (82%), class I restorations (76%) and class II restorations groups (P > 0.05).

In general, seventy restorations were carried out with the Fuji IX and 71 restorations with the Ketac Molar in the primary molars; 98 sealants with the Fuji IX and 99 with the Ketac Molar in permanent first molars from 82 children (Table IV). Eighty-one children were collaborative and related that they would submit again to the treatment if needed. One child did not participate in the follow up and was removed from the sample. There was no related pain or pulp inflammation and no one presented fistula, edema or periodontal disease.

It was found that the number of procedures censured was high. For class II restorations with the Fuji IX, the number of restorations censored was equal to the number of evaluated. In respect to the restorations with the Ketac Molar, the number of restorations censured was greater than the assessed for both class I (56%) and class II (57%).

### Table III - Success and failure percentages of the two GICs

<table>
<thead>
<tr>
<th></th>
<th>FUJI IX</th>
<th></th>
<th>KETAC</th>
<th></th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Success</td>
<td>Failure</td>
<td>Success</td>
<td>Failure</td>
<td>Success</td>
</tr>
<tr>
<td>Class I</td>
<td>77%</td>
<td>23%</td>
<td>75%</td>
<td>25%</td>
<td>76%</td>
</tr>
<tr>
<td>Class II</td>
<td>65%</td>
<td>35%</td>
<td>83%</td>
<td>17%</td>
<td>73%</td>
</tr>
<tr>
<td>Sealants</td>
<td>86%</td>
<td>14%</td>
<td>78%</td>
<td>22%</td>
<td>82%</td>
</tr>
</tbody>
</table>

Successful Scores: 0, 1, 7 (restorations) and 0, 1, 3 (sealants).

### Table IV - Sample distribution concerning the two GICs used in the 12 months preliminary follow up

<table>
<thead>
<tr>
<th></th>
<th>Fuji IX</th>
<th></th>
<th>Ketac Molar</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Class I (n = 18)</td>
<td>Class II (n = 52)</td>
<td>Sealsants (n = 98)</td>
<td>Class I (n = 18)</td>
</tr>
<tr>
<td>n %</td>
<td>n %</td>
<td>n %</td>
<td>n %</td>
<td>n %</td>
</tr>
<tr>
<td>Evaluated</td>
<td>13</td>
<td>72</td>
<td>26</td>
<td>50</td>
</tr>
<tr>
<td>Censured</td>
<td>5</td>
<td>28</td>
<td>26</td>
<td>50</td>
</tr>
<tr>
<td>Total</td>
<td>18</td>
<td>100</td>
<td>52</td>
<td>100</td>
</tr>
</tbody>
</table>

Censured scores: 5, 6, 9, 10 (Restorations) and 9 (Sealants).
DISCUSSION

The atraumatic restorative treatment approach is one of the existing minimal intervention approaches [4]. The use of this technique is justified by the fact that people who previously could not make use of primary care (prevention and limitation of damage) are met satisfactorily through the use of ART for dental treatment [20-22]. Furthermore, ART is an economic alternative and can be a strategic treatment to avoid tooth extractions as indicated by the World Health Organization [20]. A reduction in tooth extractions is a goal of the WHO for 2020 [23]. In addition, the ART promotes a less painful treatment, and friendly-patient treatment [24], which encourage people to treat their teeth, especially for afraid adults and children [25].

All procedures, ART restorations and ART sealants, were carried out by a trained dentist and without help, according to the technique recommended by the WHO for ART. ART restorations and ART sealants were evaluated by direct method and one blinded trained examiner conducted the evaluations according to the criteria in Table II. These criteria specifically designed for ART studies focuses on the presence of marginal defects and wear detected with the aid of a probe CPI-0.5 mm [26].

This study examined the performance of two high-viscosity GICs especially indicated for atraumatic restorations in the deciduous molar. It might be noted that both materials, the Fuji IX (GC Co) and Ketac Molar (3M ESPE), showed similar satisfactory performances for ART restorations and ART sealants according to others studies [27, 28, 29]. As a result, both materials may be indicated for these procedures. Fuji IX powder is Aluminosilicate glass and polyacrylic acid while Ketac Molar powder is Aluminium-calcium-lanthanum-fluosilicate glass and 5% polycarbonate acid. Calcium may be partially replaced by lanthanum, making the GIC more radiopaque [30]. Fluoride contributes to the strength and confers an anti-cariogenic property [30]. The liquid of the Fuji IX contains Polyacrylic polybasic acid and the Ketac Molar has instead Polycarboxylic acid and tartaric acid. The addition of tartaric acid reduces viscosity, increases the working time, decreases setting time and increases the strength of the cement [31].

Despite the little difference in ranking to ART restorations, the success rate was higher in the class I than the class II. Usually, the highest success of the class I restoration is more common [32, 33]. Class II restorations are still difficult to perform using the ART technique [28], it also owes itself to a greater complexity [29]. Rutar et al. [34] proposed a change in the restorative technique in order to improve the survival of multiple-surface glass ionomer restorations in the primary teeth. They suggested lowering the isthmus and keeping it out of occluding contact. According to the meta-analysis [35], cumulative survival rates for single-surface and multiple-surface ART restorations in the primary teeth over the first year were 95% and 71%, respectively. In the present study, the success rate for single-surface ART restoration showed a lower result (76%), whereas for multiple-surface ART restorations (73%) were similar. Compared with others studies that evaluated ART restorations in the primary molars after a 1-year follow-up, there was a wide variation in the survival rate results for both single-surface ART restorations; 95% [36], 82% [37], 80% [38], 74% [39]; and multiple-surface 89% [36], 73% [40], 31% [37].

One important factor involved in this study was the diameter of the cavities. It was not individualized, cavities were only divided between class I (single-surface) or class II (multiple-surface). The diameter of the cavities is directly related to the restorations success rate. Smaller cavities are related to higher failure rates due to the access difficulties for material insertion. Furthermore, if extra retention is required, especially in proximal restorations, retention niches can be made with special hand instruments, as described by Cefaly et al. [41]. Therefore, some authors recommend to choose the cavity sizes for ART treatments to ensure
the restoration’s success [6, 19, 42]. However, choosing cavity sizes is out of the ART philosophy that aims to increase the dental treatments for people that would not be usually treated.

The sealing of the pits and fissures by the “press-finger” technique accomplishes effective caries prevention [43]. Eighty sealed surfaces showed up caries free at the 12 months follow-up, even with fully or partially retention or absence of material. A possible reason for the high dentine lesion-preventive effect of glass-ionomer ART sealants in their clinically apparent absence have recently been reported [21]. SEM images of the pits and fissures apparently free of glass-ionomer sealant material revealed remnants of glass ionomer-like material left in the deepest parts of the pits and fissures [21, 35]. These remnants, most probably present because of the cohesive failure of the glass-ionomers [44], may continue to constitute a physical barrier against the acid produced in the plaque [35].

The ART occlusal sealants presented a highest success rate (82%) compared to the ART restorations. Others studies [45, 46] and a meta-analysis [35] showed a 100% success rate. The difference in the success rate may be related to the visual evaluation method performed in this study, because of the consideration of success only with the visible presence of material. However, we should consider that benefits such as the prevention of caries were achieved.

Some factors such as patient and operator positioning, illumination, operator comfort, accessibility for excavation of decay and cavities diameter can influence the efficacy of ART restorations [38]. In this study, an experience operator, in the school environment, performed the procedures with natural lighting following the ART manual instructions. The children were positioned horizontally on a table at the school playground, comfortably. No differences were observed concerning the success rate of ART restorations between the school environment and the hospital dental setup [38].

Over the preliminary 12 months follow-up, the GICs used in ART fulfilled their function. There were no cases of progression of carious lesions or appearance of new lesions. The treatment was well accepted by the community of the school and there were no pulpal exposure or significant painful sensitivity cases during the procedures.

These preliminary 12 months results showed that actions like this related to harm reduction, paralyzing caries progression, and prevention of tooth decay and extractions, are effective, cheaper and well accepted by the community.

CONCLUSIONS

According to the limitations of this study, the GICs had a good performance and ART preliminary results provided curative and preventive treatments for patients who do not have access to conventional treatment.

REFERENCES

Atraumatic restorative treatment in Brazilian schoolchildren: 12 months preliminary clinical results

Sacramento, PA et al.


<table>
<thead>
<tr>
<th>Number</th>
<th>Reference</th>
<th>Details</th>
</tr>
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**Regina Maria Puppin-Rontani**  
(Corresponding address)  
Address: Av. Limeira, 901. 13414-903, Piracicaba, SP, Brazil.  
E-mail address: rmpuppin@fop.unicamp.br  
Phone number: +55-19-2106-5286  
Fax number: +55-19-3421-0144  
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