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Chapter 3

The effect of GIC brand on the survival rate of proximal-ART restorations

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Abstract

Background: Laboratory studies show diverse behaviour of several brands of glass-ionomer cements (GIC) design for the same indication.

Aim: This study investigated the clinical performance (survival rate: SR) of three GIC brands applied to proximal-ART restorations. Additionally, the SR of the tooth was evaluated.

Methods: Proximal cavities of 262 primary molars were restored. The patients had been randomly allocated to two operators and three GIC brands: Fuji IX, Hi Dense and Maxxion R. Restorations were evaluated after 1, 6, 12, 18, 24, 30 and 36 months. Failed restorations were, if possible, repaired or replaced. Linear regression analyses were used to evaluate the effect of GIC brand, operator and surface of restoration. Kaplan-Meier survival analysis and log-rank test were performed for both restoration survival and tooth survival ($\alpha=5\%$).

Results: After 3 years, 82.4% of the restorations were evaluated. The SR of the restorations was 24.4% and there was no difference among GIC brands (log-rank test, $p=0.6$). In the first 18 months, a significant operator effect and significantly more failures in distal surfaces were found. The SR of the tooth was 81.7%.

Conclusions: The SR of proximal-ART restorations was relatively low when compared to the SR of the teeth. There are no differences in the performance among the GIC brands used in the study.
Introduction

Atraumatic Restorative Treatment (ART) was developed for underserved communities to provide an alternative for preventing decayed teeth from being extracted (1). For the past twenty years ART has been one of the most researched minimal intervention approaches for caries management (2). When compared to traditional restorative procedures, ART is considered a less traumatic and friendlier approach for child populations (3, 4). The survival rates of single-surface or occlusal-ART restorations using high-viscosity glass-ionomer cements (GIC) in primary and permanent posterior teeth do not differ from the conventional restorations using amalgam (5-7). However, the survival rate of multi-surface or proximal-ART restorations does not meet with the ADA specifications for quality restorations (1). The most frequent failures found for proximal-ART restorations are loss of restoration and bulk fracture, generally attributed to the materials’ properties (8, 9, 10, 11).

GIC is the material of choice for ART mainly because of its properties, namely chemical bonding to enamel and dentin, fluoride release and uptake, as well as its chemical setting reaction (12, 13). Specially developed for ART, the high-viscosity GIC have the advantage of a relatively slow setting time and improved mechanical properties resulting in higher survival rate of the restorations (5). Testing the physical-mechanical properties of six high-viscosity GIC brands (Maxxion R, Vitro Molar, Hi Dense, Riva, Fuji IX and Ketac Molar Easymix), we found that two GIC brands (Maxxion R and Hi Dense) performed as good as the two most established GIC for ART (Fuji IX and Ketac Molar Easymix) in the majority of the tests (14). Besides presenting a good performance in laboratory studies, Maxxion R, a Brazilian GIC, has the benefit of costing less than 25% of the price of Fuji IX or Ketac Molar Easymix. Hi Dense, a metal-reinforced GIC, may have the advantage of both antibacterial and cariostatic properties, which are attributed to its silver content (15).

Although also serving as a treatment option in private dental practices (16, 17), the initial and most common applications for ART are still in outreach and rural areas in developing countries. In these areas, the costs of the treatment and the high-caries activity of the population must be considered when choosing both restorative approach and material. Another outcome to be considered is the survival of the tooth, even when without a perfect restoration, but preventing the tooth of being extracted. The present clinical trial was conducted in a field setting in Brazil and evaluated the survival rate of proximal-ART restorations (class II) in primary molars. The restorations were made using GIC of three different brands (Maxxion R, Hi Dense and Fuji IX). Additionally, a parallel evaluation on the survival rate of the tooth was conducted, considering the repaired restorations.

Material and Methods

Sampling procedure – This study was approved by the local Research Ethical Committee (USP, São Paulo, Brazil). A total of 2600 five-to-eight years old children, from 36 public schools in the city of Itatiba (State of São Paulo, Brazil) were examined and 265 of them fulfilled the inclusion criteria. Inclusion criteria consisted of children having at least one occluso-proximal carious lesion in a primary molar involving dentin, with dimensions not larger than 2 mm mesio-distal, 2.5 mm bucco-lingual and occluso-cervical. Exclusion criteria were: non-cooperative behaviour, pulp exposure, history of pain, presence of
swelling or fistula, tooth mobility and cavity not accessible to hand instruments. A written consent was obtained from the parents or legal guardians of the participating children.

**Implementation** - Only one restoration per child was included in this study. All other cavities in the selected children were referred to the health centre of the municipality. The operators and the dentists in the municipality received a training course regarding the ART approach and preventive strategies to ensure that all of the children included in the study would be part of an oral-health program. The operators were two final year dental students who were previously trained to perform ART and to mix the GIC according to the manufacturers’ protocol. A try-out week was included to give the operators the opportunity to familiarise themselves with the local conditions prior to the start of the operative phase of the study. Both operators were assisted by the same local dentist and all treatments were performed on the school grounds. The children were randomly assigned into two groups, one for each operator. The GIC brand used in each child was assigned by a separate random list.

**Treatment procedure** – During treatment, in accordance with the ART approach (18), no local anesthesia was used. Infected carious dentin was removed with hand instruments and the cavities were restored with one of the three GIC brands: Maxxion R (FGM, Rio de Janeiro, BR), Hi Dense (Shofu, Ratingen, GE) or Fuji IX (GC Europe, Leuven BE). After cavity preparation its dimensions were measured using the graduations on the Michigan O with Williams’ markings periodontal probe (19) and a metallic matrix band and a wedge were applied. Moisture control was done with cotton wool rolls. All cavities received a pre treatment (conditioning) with the diluted liquid from the respective material (10 s), followed by rinsing with water and drying with cotton pellets. The GIC were mixed according to the manufacturers’ instructions (powder/liquid ratio 1:1) and inserted into the cavity with a conventional application instrument. After adjusting for the occlusion, petroleum jelly was applied to the GIC. The presence of adjacent and antagonist teeth was recorded. The moment of restoration (before or after the lunch break) was also recorded in order to evaluate the post-restoration meal consumption effect on the restorations’ survival rate. All children were instructed not to eat for one hour after the restoration was placed.

**Evaluation** - The survival rate of the restorations was evaluated after 1, 6, 12, 18, 24, 30 and 36 months according to the ART evaluation criteria adapted for proximal restorations (Table 1) (20). A restoration was considered as “failure” when codes 11-40 were registered. Codes 00 and 10 were considered as “success” and codes 50-91 were assigned when the tooth was unavailable for evaluation. All evaluations were carried out by one independent evaluator, trained and calibrated by a benchmark (Kappa = 0.89) (21).

The survival rate of the tooth was evaluated by classifying the restoration in minor and major failures [adapted from Innes et al., (22)]. The minor ones were restoration failure, which could be managed by repair or replacement of the restoration (codes 11-21) and major failures consisted of signs or symptoms of irreversible pulpal damage, such as dental abscesses or tooth fracture and unrestorable with ART (codes 30 and 40). The teeth with a restoration presenting minor or no failures were considered as “survived” and the major failures characterised as “failed”. When the tooth was unavailable for evaluation, it was censored. No distinction was made between extracted and shed teeth. For ethical reasons all the failed restorations were repaired or replaced when necessary and possible. The indicated extractions were referred to the health centre of the municipality.


*Statistical analysis* – Statistical analyses were carried out using Stata 11.2 software (StataCorp, Texas, USA). All significant differences were detected at 95% confidence level. The effect of GIC brand, operator, surface of the restoration, meal consumption, mouth-side, jaw, presence or absence of antagonist and adjacent tooth were evaluated in each evaluation time-frame using Linear regression analyses. The effect of cavity size on the survival rate of the restorations was evaluated using a chi-square test.

Kaplan-Meier survival analyses were performed on the censored data for both the survival of the restoration and the survival of the tooth. The difference between survival curves was determined with log-rank tests.

**Table 1:** Evaluation criteria for proximal-ART restorations (20).

<table>
<thead>
<tr>
<th>Score</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>00</td>
<td>Restoration still present, correct</td>
</tr>
<tr>
<td>10</td>
<td>Restoration present, slight defect at the margin and/or wear of the surface; &lt;0.5mm in depth, no reparation needed</td>
</tr>
<tr>
<td>11</td>
<td>Restoration present, defect at the margin and/or wear of the surface; &gt;0.5mm in depth, repair needed</td>
</tr>
<tr>
<td>12</td>
<td>Restoration present; under filled &gt;0.5mm, no gap, repair needed</td>
</tr>
<tr>
<td>13</td>
<td>Restoration overfilled &gt;0.5mm, repair needed</td>
</tr>
<tr>
<td>20</td>
<td>Secondary caries, discoloration in depth, surface hard and intact, caries within dentin; repair needed</td>
</tr>
<tr>
<td>21</td>
<td>Secondary caries, surface defect, caries within dentine; repair needed</td>
</tr>
<tr>
<td>30</td>
<td>Restoration not present, bulk fracture, moving, (partly) lost; repair needed (if still possible without exposing the pulp)</td>
</tr>
<tr>
<td>40</td>
<td>Inflammation of the pulp (restoration still in situ, not categorized in the former categories); fistula or severe pain complaints; extraction needed</td>
</tr>
<tr>
<td>50</td>
<td>Tooth not present because of extraction</td>
</tr>
<tr>
<td>60</td>
<td>Tooth not present because of shedding</td>
</tr>
<tr>
<td>70</td>
<td>Tooth not present because of extraction or shedding; unable to diagnose</td>
</tr>
<tr>
<td>90</td>
<td>Patient not present</td>
</tr>
<tr>
<td>91</td>
<td>Patient transferred</td>
</tr>
</tbody>
</table>

**Results**

Considering 0.8 as observed effect size, we performed the *post hoc* power analysis of our sample, which revealed an observed power of 0.99. From the 265 selected children, three of them had non-cooperative behaviour and were excluded. Of the 262 children (mean age ± 6yrs) who participate in the study, 135 (51.5%) were female. The children were randomly allocated and 88 (33.6%) of them had their cavities restored with Maxxion R; 88 (33.6%) with Hi Dense and 86 (32.8%) with Fuji IX; 151 (58%) were placed in the upper jaw and 111 (42%) in the lower jaw; 127 (48%) were in the left side and 135 (52%) in the right side; 164 (63%) involved the distal surface and 97 (37%) the mesial surface of the elements; 128 (49%) were placed before and 134 (51%) after the lunch-break. The mean volume of the cavities was 13 mm$^3$ (SD± 11.8). All cavities were classified according to a relative-volume category proposed by Kemoli *et al.* (19). The intra observer reliability was performed within one week-interval, in 40 cavities (15% of the sample), and was 0.9
On a restoration-survival level, the lost to follow-up percentage after 3 years was 18% and it was equally divided over the three groups (GIC brands). The reasons for lost to follow-up of the restorations were patient moved school or city, followed by tooth not present. The cumulative survival of the restorations was 24% after 3 years. Once a restoration failed it continued to be considered as a failure, but for ethical reasons it was repaired or replaced if possible.

The survival of the tooth was calculated irrespective of whether restorations failed or not and were repaired or not. On a tooth-survival level, after 3 years, the lost to follow-up percentage was 56%. This percentage included the teeth that were re-restored by another dentist, which were considered as censored data. A cumulative survival of 82% was observed. The survival curves, with censored data, are presented in Figure 1. A log-rank test indicated a statistically significant difference between the survival curves \(p<0.001\), where the survival of the tooth was significantly higher than the survival of the restoration.

There was no difference in success rate of the restorations among the different brands of GIC (log-rank test, \(p=0.6\)). Figure 2 shows the survival curves of the restorations made with the three different materials. Different operators had significantly different cumulative survival curves for the restorations (log-rank test, \(p=0.004\), Figure 3). The disto-occlusal restorations presented a significantly higher rate of failures than the mesio-occlusal restorations (log-rank test, \(p<0.001\), Figure 4). The linear regression analyses confirmed the significant difference between operators and between disto-occlusal and mesio-occlusal surfaces for the first 18 months.

The cavity size, meal consumption, mouth-side, jaw, presence or absence of antagonist and adjacent showed no effect on the survival rate of the restorations. The main failure characteristics were total or partial loss of the restoration (68%), gross marginal defect (11%) and restoration underfilled or worn (10%).

Discussion

Experts recommend that only high-viscosity GIC that have been field-tested in long-term follow-up studies should be used with ART (23). With this in mind, clinical trials are generally performed with the strongest and the most expensive GIC brands (11, 24-26). Although ART might be more cost-effective than comparable amalgam restorations (27), the cost of the recommended GIC is still high for the public health system in developing countries. The Brazilian brand used in this study (Maxxion R) has the advantage of costing less than 25% of the price of the GIC used in the majority of the ART studies (Fuji IX and Ketac Molar Easymix), without compromising the mechanical and physical properties (14, 28). Another brand selected for this trial (Hi Dense) contains silver particles in its composition. These particles may give the material both antibacterial and cariostatic properties, which are perhaps due to its low early-term wear resistance (14). The third material, Fuji IX, was used as a control, as it is one of the most commonly used and well-established GIC for ART.
Figure 1: Survival curves of the restorations and the teeth. Log-rank, $p<0.001$.

Figure 2: Survival curves per GIC brand. Log-rank, $p=0.6$. 
The effect of GIC brand on the survival rate of proximal-ART restorations

Figure 3: Survival curves per operator. Log-rank, \( p=0.004 \).

Figure 4: Survival curves per surface restored. Log-rank, \( p<0.001 \).
Our results showed no GIC-brand effect on the survival rate of proximal-ART restorations after 3 years. Irrespective of the material, the main reason for failure was restoration fracture or loss. This finding indicates that the GIC may not be the suitable for the proximal-ART restorations, given the fact that they all lead to a high failure rate.

Previous studies used restorative materials with strengthened mechanical properties aiming to increase the survival rate of proximal-ART restorations in primary molars. Using GIC and composite resin, Ersin et al. (29), found no difference in survival rate of occlusal- and occluso-proximal-ART restorations, after 24 months, when the same type of cavity and different materials were compared. Accordingly, Eden et al. (8) observed that after one year proximal-ART restorations made with composite resin had low survival rates regardless of the preparation method. The survival rates were 56.8% for the ART prepared cavities and 56.9% for cavities prepared using conventional methods. Topaluglu-Ak et al. (9) also used resin composite to restore cavities prepared with different caries removal methods and found no significant difference in the cumulative survival after two years (54% for ART and 46% for chemomechanical caries removal). Comparing proximal-ART restorations made with high-viscosity GIC and with amalgam, Mickenautsch et al. (30) showed in a systematic review that both materials seemed to be equally successful. These studies suggest the use of composite resin or amalgam does not improve the success of proximal-ART restorations.

Multiple-surface restorations have generally lower survival rates when compared to singlesurface restorations (5-7, 10). Working in field conditions, the cumulative effect of variables influencing the success rate of the restorations occasionally increases. One of the evaluated variables in this study was the cavity size. Kemoli et al. (19) reported that cavities with volumes between 10 and 19.9 mm$^3$ had significantly higher survival rate when related to any of the other restoration volumes. In the present study, we did not find any cavity-size effect but the mean volume of the restorations was 13 mm$^3$, which classify them as the most prone to fail, according to a relative-volume category proposed by Kemoli et al. (19). Despite the fact that operators were trained, we found an operator effect, which is often reported in ART studies (3, 10, 21), though it was significant only in the first 18 months of evaluation. Within the same period a significantly higher failure was observed for the disto-occlusal restorations, which may be justified by the lack of proper illumination, access and other adverse conditions. The influence of these effects underlines the vulnerability of the method. After 18 months, more than 70% of the placed restorations had failed, which may explain the absence of significant differences in the subsequent evaluations.

Our discouraging results after 36 months (24% survival rate) raise the question of whether these restorations should have ever being placed. Although they perform poorly, the proximal-ART restoration might result in the retention of several teeth, which would otherwise have been extracted at an earlier stage (1, 10). The need for re-restoring the failed ART restorations in primary molars was investigated by Boon et al. (31) and their results indicated that a re-restoration may not be necessary in all cases. The authors recommended that new studies should focus on the survival of the restored teeth and not remain limited to the restoration survival, as in many previous studies.

With the evaluation criteria used in this study, restorations with minor failures were often scored as failures. We worked with the standard evaluation criteria applied by the majority of ART clinical studies (Table 1). Nevertheless, according to these criteria cases of overfilling (score 13) or underfilling without gap (score 12) were considered as failures and
in these cases the restorations were, most probably fulfilling their role of stopping caries progression and maintaining the function of the tooth.

The tooth survival rate was analysed including the survived, failed and repaired restorations. From the 191 failed restorations, 119 were repaired or replaced. In a 36-month follow-up evaluation, 70 of these repaired restorations were available for evaluation and 52 (74%) had survived. After three years, the overall cumulative tooth survival rate was 82%. This result encourages new studies to investigate not only the retention of the restoration but also the retention of the tooth, in view of the first objective of ART, which was to prevent decayed teeth from having to be extracted (1,2).

The scores 50-70 were all considered censored data and no distinction was made between extracted and shed teeth. Indeed, this was due to the fact that, in most cases, it was not possible to establish the reason why the tooth was absent. It may be that some of the major failures such as pulp damage or pain were missed as the teeth could have been extracted between the evaluations. The other censored data (scores 90-91) were mainly because of children who moved to another district during the course of the study or were sick and absent from school for a prolonged period.

The results of the present study indicate that less well-established GIC brands may be an option for ART restorations. The fact that restorations presenting minor failures can be repaired should be taken into account when ART is the treatment of choice, with a view to preserving the tooth. The field of dental materials should consider the fact that GIC, besides their innumerable advantages, do not appear suitable for long term restorations in proximal cavities in primary teeth.

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