The ART of GIC proximal restorations in primary teeth

Bonifácio, C.C.

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Chapter 10

Survival rate of proximal-ART restorations using a two-layer technique for glass-ionomer insertion

Abstract

**Aim:** Good survival rates (SR) have been reported for occlusal-A RT restorations but not for proximal-A RT restorations. The high-viscosity consistency of the glass-ionomer cement (GIC) may lead to its incorrect adaptation to the cavity walls and thus to failure of the restoration. Because the use of a flowable GIC as a first layer seemed to improve its adaptation in proximal restorations in vitro, we evaluated whether the use of an intermediate flowable GIC layer would improve the SR of proximal-A RT restorations.

**Methods:** A total of 208 children (6-7 years old) with at least one occluso-proximal carious lesion in a primary molar were selected and randomly allocated to two groups: G1, conventional technique, one layer GIC (powder/liquid ratio 1:1); and G2, two-layer technique, consisting of a first layer of GIC with a flowable consistency (powder/liquid ratio 1:2) and a second layer of a regular consistency. Restorations were evaluated after 2, 6, 12 and 18 months. Restoration survival was evaluated using Kaplan-Meier survival and log-rank test. Poisson Regression Analyses (α=5) were used to verify the influence of factors such as insertion technique, restoration surface and operators.

**Results:** The overall SR of the restorations after 18 months was 68%. There was no difference in SR between the techniques. Neither did the other factors influence the SR.

**Conclusions:** Over 18 months, the use of an intermediate layer of flowable GIC in proximal-A RT restorations does not improve the restoration survival.
Introduction

The Atraumatic Restorative Treatment (ART) was developed in the mid-eighties to prevent the extraction of decayed teeth of patients in outreach areas, where resources such as electricity and rotary dental equipment were not easily accessible (1). Glass-ionomer cements (GICs) are chosen as the most suitable filling material for ART because of their biological, physical and chemical properties (2).

The high-viscosity GICs were specially developed for ART. They have a relatively slow setting time and better physical-mechanical properties, when compared to their predecessors (2-4), resulting in higher survival rates of the restorations (5). In a meta-analysis, Van’t Hof et al. (6) showed that ART restorations in single surface (occlusal) cavities using high-viscosity GIC have higher survival rates when compared to amalgam whereas the multi-surface (proximal) cavities in primary teeth required improvements.

Several clinical trials have investigated different causative factors associated to proximal-ART restoration failures, such as isolation methods, materials with different strengthened properties, influence of the operator, the post-restoration meal (time between restoration and loading) and the cavity size (7-13). Although in some cases the survival rate had increased, this type of restorations still does not meet the ADA specifications for quality of restorations (1).

The most reported reason for failure of proximal-ART restorations is loss of retention or bulk fracture (8, 14-16). These failures might be related to the material’s properties and also to an incorrect adaptation or cervical gap formation in proximal-ART restorations (17-19).

Recent laboratory studies show that the insertion of a thin layer of flowable GIC prior to the insertion of a regular high-viscosity GIC layer (two-layer technique) can improve the material adaptation within proximal cavities (20) and increase the bond strength to sound dentin (21). To investigate whether these findings are also clinically relevant we conducted a randomized-controlled clinical trial, in schools, applying this new insertion technique. The hypothesis tested was that there is no difference in survival rate of proximal-ART restorations made with one- or two-layer technique in primary molars.

Material and Methods

Sampling procedure – After approval for conducting the study was obtained from the local Research Ethical Committee (USP, São Paulo, Brazil), a total of 2000 children (6-7 years old) from public schools in the city of Barueri (State of São Paulo, Brazil) were examined. We selected 208 of them, who fulfilled all the inclusion criteria and had a written consent from parents or legal guardians. The inclusion criteria were: 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, cooperative behaviour, absence of fistula or abscess near the selected tooth and no mobility of the tooth. The dimensions of the cavity were measured using the graduations on the Michigan O with Williams’ markings periodontal probe (10).

Implementation - Only one cavity per child was included in the study. If a selected child had multiple cavities that met the inclusion criteria, one of them was randomly chosen. All the other cavities in the selected children were treated by other dentists who work in
oral health centers in the city. The operators were four final year dental students who were previously trained to perform ART, including the GIC mixing according to the manufacturer’s protocol and to the specific technique used in this study. A training week was included to give the operators the opportunity to familiarise themselves with the local conditions and the restorative technique prior to the start of the operative phase. The operators assisted each other and all treatments were performed on the school environment under less than optimal conditions. The children were randomly assigned to one of the operators and insertion technique.

Treatment procedure – No local anesthesia was applied during the treatments. Infected carious dentin was removed with hand instruments and all the cavities were restored with high-viscosity GIC Fuji IX (GC Europe, Leuven BE). After preparation, a metallic matrix band and a wedge were applied. All cavities received a conditioning with the diluted liquid from the respective material (10 s), followed by rinsing with water and drying with cotton pellets. The mixing and insertion of GIC was different for each group. In G1, the conventional restoration group, GIC was mixed according to the manufacturer’s instructions (powder/liquid ratio 1:1), and in G2, the experimental group (two-layer technique), a first layer of GIC with flowable consistency (powder/liquid ratio 1:2) was applied in the bottom of the cavity. The second layer was mixed according to the manufacturer’s instructions (powder/liquid ratio 1:1) and inserted in the cavity before the final setting of the first layer (20). After adjusting the occlusion, petroleum jelly was applied on the GIC. The presence or absence of adjacent and antagonist teeth was recorded.

Evaluation - The restorations were evaluated after 2, 6, 12 and 18 months according to the ART criteria adapted for proximal restorations (17) (Table 1). A restoration was considered as a “failure” when codes 11-40 were registered. Codes 00 and 10 were considered as a “success” and codes 50-91 were assigned when the tooth was unavailable for evaluation. All evaluations were performed by two blinded and independent evaluators, who were trained and calibrated with a “gold standard” (11) regarding the evaluation criteria (Kappa = 0.94).

Statistical analysis – Statistical analysis were carried out using Stata 11.2 software (StataCorp, Texas, USA). All significant differences were detected at 95% confidence level. The influence of insertion technique, operator, presence or absence of antagonist and adjacent tooth, tooth surface involved in the restoration, mouth-side and jaw (upper or lower teeth) were evaluated in each assessment using Poisson regression analysis.

Kaplan-Meier survival analysis were performed on the censored data for the restoration survival. The difference between survival curves was determined with log-rank tests.

Results

After 18 months the drop out rate was 6% and was equally distributed among the groups. One child died, others moved from school or city, or lost the restored tooth by exfoliation or extraction. Of the 208 restored cavities, 110 (53%) were made with the conventional technique and 98 (47%) were made with the two-layer technique. The overall cumulative survival of the restorations was 68%; for the conventional group this was 67% and 68% for the two-layer group. The survival curves, with censored data, are presented in Figure 1. Log-rank test indicated no significant different between the groups (p=0.8).
The Poisson regression-analysis confirmed the absence of a significant difference between groups. The operator, presence or absence of antagonist and adjacent tooth, surface of restoration, mouth-side and jaw had no influence on the survival rate of the restorations. The majority of failure characteristics were total or partial loss of the restoration (82%).

Discussion

Glass-ionomer cements have been intensively investigated as restorative material for primary molars, and, in general, the results have been disappointing (22). Although high-viscosity GIC produced much better results than the early conventional materials (5, 23), their consistency may contribute to incorrect cervical adaptation (17-19). On the basis of promising results from recent laboratory studies (20, 21), we investigated whether inserting GIC with the two-layer technique would improve the survival rate of proximal-ART restorations in a school setting.

After 18 months, our results showed a survival rate of 68%. The null-hypothesis was not rejected, as the survival rates of proximal-ART restorations made with one- or two-layer technique in primary molars were similar.

<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>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>

The application of a GIC liner in proximal cavities was first described by McLean and Gasser in 1985 (24). Such layer was combined with either resin composite or amalgam as final restoration, in what is often called “open sandwich” restoration. Because the cervical area of proximal cavities is often difficult to clean and to isolate from saliva and gingival fluid, it is more sensitive to secondary caries formation (22). In an area of such high risk, the
use of an adhesive and fluoride releasing material, such as the GIC, might provide extra protection. With high-viscosity GIC, the cervical adaptation was reported to be poor (17-19). Laboratory studies testing flowable GIC as a liner suggested that material adaptation to the enamel and bond strength to sound dentin were both increased, and microleakage was reduced (20, 21). However, these findings did not result in a better clinical performance in our study.

Irrespective of the insertion technique, the main reason for failure was restoration fracture or loss (n = 38). As some remnant material was observed on the bottom of the cavity, most of the restorations failures (90%) were caused by restoration fractures. We therefore speculate that we did not find a better success for the two-layer group as whereas the adaptation to tooth structures may have improved, the fracture resistance of the material may have worsened, since the reduced powder content of the first layer contains fewer glass particles in the set material. However, Fonseca et al. (25) reported no difference in the diametral tensile strength of conventional GIC when the powder/liquid ratio was reduced by 50%.

A possible reason for the absence of difference between the insertion techniques is that the operators were well trained for the restorative technique. We found no operator effect and for both groups a reasonable survival rate was observed. Individual differences are expected between the different operators. To prevent that a more sensitive and laborious method, would accentuate differences in individual skills, the operators received a comprehensive training not only in ART preparation and restoration techniques but also in handling and insertion of the GIC for the two-layer technique. This training may have
improved their skills in performing proximal-ART restorations in general, making the insertion technique irrelevant.

Although previous studies have investigated the survival rate of proximal-ART preparations restored with composite resin (7), several cavity-preparation methods (8, 15) and isolation methods (13, 26), none of them significantly reduced the failure rate. Mickenautsch et al. (27) showed in a systematic review that proximal-ART restorations made with high-viscosity GIC or amalgam were equally successful. Nevertheless, they could also be classified as equally unsuccessful, as their survival rates were both very low.

Our study suggests that the two-layer technique does not increase proximal-ART restoration longevity. Several authors have reported that the failure of ART restorations may not be attributed to a specific variable but to a combination of factors such as cavity selection and preparation, salivary contamination, restorative material, and knowledge and clinical skills of the operator (12-14, 17, 28, 29). Despite the improved mechanical properties of the high-viscosity GIC, they are difficult to manipulate and to insert into the cavity. The strength of the restorative material or its adaptation to the cavity wall seems to make no difference when the operators are well trained to use the technique and to manipulate the material (7, 15). To minimize the cumulative effect of all causes of failure in proximal-ART restorations, we therefore recommend that particular attention be paid to operators’ training, and on developing alternative self-curing restorative materials with enhanced mechanical properties.

The standing question is whether it is possible to improve the success rate of proximal-ART restorations made under field conditions to the point that they would be as successful as the ones made under ideal conditions in private practices (30, 31). Although an 18-month assessment showed that the two-layer technique using a flowable GIC under another GIC layer did not improve the survival of proximal-ART restoration, the results of ongoing studies may provide more insight into one of the most popular minimal intervention techniques and the appropriate material for proximal restorations.

**Acknowledgments**

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References
