Conventional versus resin-modified glass-ionomer cement for Class II restorations in primary molars. A 3-year clinical study

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Summary. Objective. To compare the clinical performance of two glass-ionomer cements (GICs) for Class II restorations in primary molars: a conventional cement (Fuji II®) and a resin-modified cement (Vitremer®).

Design. Split mouth and random assignment to the two materials were used for the majority of the molars.

Sample and methods. Forty consecutive 4–7-year-old children were included. One operator made 115 restorations: 53 with Vitremer and 62 with Fuji II. The restorations were evaluated clinically, radiographically and from colour photographs.

Results. The cumulative success rate of the Vitremer restorations was 94% and that of the Fuji II restorations 81%. The difference is statistically significant. The risk of a failed restoration was more than five times higher with Fuji II than with Vitremer as the restorative material. Of the 13 unsuccessful restorations, seven had lost their retention, four had secondary caries, and two were fractured.

Conclusions. The resin-modified GIC offered advantages over the conventional GIC for restoring approximal caries in primary molars.

Introduction

For many decades, amalgam has been the standard restorative material in paediatric dentistry. However, the detrimental environmental effects of mercury and debates on possible health effects of amalgam have resulted in a considerable reduction of its use in dentistry in the Nordic countries. Since 1995, the Swedish government has recommended restricted use of amalgam as a restorative material, particularly in children.

The most frequently used alternative to amalgam for restoring primary teeth has been glass-ionomer cements (GICs) [1]. The conventional GICs have many attractive features, such as adhesion to tooth structure enabling minimal removal of sound tooth substance, a slow release of fluoride which may produce a cariostatic action, good biocompatibility, and a shade similar to that of the tooth. The disadvantages are the slow rate of setting, susceptibility to moisture contamination or dehydration during the early stages of setting. Furthermore, GIC have low fracture toughness and poor resistance to wear [2,3].

Resin-modified GICs (RMGICs) have been developed to improve the mechanical properties. These materials have a better wear resistance, higher moisture resistance, higher fracture toughness and a longer working-time. The resin ratio of RMGICs ranges from 4·5 to 6% [4]. Unlike GICs, which set through slow acid–base reaction, RMGICs initially set through resin polymerization from exposure to visible light, followed by additional hardening through an acid–base reaction.

There are relatively few long-term studies on the clinical performance and longevity of GIC and RMGIC restorations in primary teeth. The clinical
results of GIC restorations are rather disappointing. Thus, after 3 years, Chem-Fil II® had a failure rate of 32% with a modified Black preparation and 25% with a saucer-shaped preparation [5], which is similar to the failure rate reported by Wendt et al. [6]. Östlund et al. [7] reported an even higher GIC failure rate of 60% after 3 years and in a 5-year trial, Welbury et al. [8] reported a lower survival time for GIC compared with amalgam restorations (33 vs. 41 months). Qvist et al. [1], reporting a failure rate of 37% after 3 years, concluded that GIC is not an appropriate restorative material for Class II restorations in primary molars.

In contrast, promising clinical results have been reported with RMGICs. After more than 5 years’ experience of RMGICs, Nicholson and Croll [9] reported the positive characteristics of Vitremer® and stated that RMGICs will become a mainstay restorative material for paediatric dentistry. Espelid et al. [10] compared a silver reinforced glass-ionomer material (Ketac-Silver®) with an RMGIC (Vitremer) in minimal Class II preparations in primary teeth and found that the RMGIC had the better performance.

Although clinical experience with RMGICs for Class II restorations in primary molars has been encouraging, there is still a need for long-term results on the material’s clinical behaviour. The aim of this study was to compare the clinical performance of two cements: a conventional cement (Fuji II®, GC Europe N.V. Leuven, Belgium) and a resin-modified cement (Vitremer, 3M Co, St Paul, MN, USA) for Class II restorations in primary molars.

Methods

Subjects

Forty consecutive children, 24 boys and 16 girls, aged 4–7 years (mean = 6.2; SD = 0.88) were treated from 1995 to 98. Thirty-three of these children had at least two approximal dentin caries lesions in their primary molars; the rest had one dentin caries lesion each. All the children were regular patients at the Pedodontic Department of the Eastman Dental Institute in Stockholm. The parents gave informed consent and the Review Board of the Public Dental Health Service of Stockholm County Council gave ethical approval. The mean number of decayed, extracted and filled surfaces (defs) (03–05d), at the time of treatment was 4.7 (SD = 2.90).

In a majority of the cases, a split-mouth technique was used, in which each restorative material was randomly allocated to either side of the mouth by tossing a coin. In all, 115 restorations were performed: 53 with Vitremer and 62 with Fuji II. Radiographically, 17% of the lesions reached the enamel dentin border, 63% were in the outer half of the dentin and 20% in the inner half of the dentin. The number and distribution of first (n = 81) and second (n = 34) molars are shown in Fig. 1.

Restorative technique

One operator placed all the restorations under local anaesthesia. Rubber dam was not used. Using high-speed equipment and ample water-cooling, a saucer-shaped cavity was prepared, if necessary supplemented with a dovetail. Soft carious tissue was removed using low-speed equipment and round burs. The cavity preparation was finished with sharp excavators. Deep cavities were lined with Dycal® (De Trey/Dentsply, Konstanz, Germany). A thin steel matrix band was secured around the tooth with a matrix holder, Fig. 2. All the cavities were cleaned with 10% polyacrylic acid (Dentin Conditioner, GC, Europe N.V. Leuven, Belgium), and then irrigated and dried carefully to avoid desiccation.

Both the Fuji II and the Vitremer materials were manually mixed according to the manufacturer’s recommendations, and then squeezed into the cavity with a Hawe syringe (Centrix, Hawe Neos, Gentilino, Switzerland). After overfilling, the excess was burnished against the cavity margins and the occlusal surface was roughly modelled. Care was taken to prevent heavy occlusal contacts.

Fuji II After placement of the filling, the surface was protected with an unfilled light-cured resin to
prevent dehydration and moisture contamination. The restoration was allowed to set for 5 min (from the time of mixing) prior to removal of the matrix band. The filling was contoured with a petroleum-jelly coated round bur and slow speed equipment. A second coat of resin was then applied and cured.

**Vitremer** To wet the internal surfaces of the cavity, a primer was applied according to the manufacturer’s instructions. After insertion, the material was light-cured for at least 40 s. The matrix was then removed and necessary occlusal adjustments were made with a diamond bur and slow speed equipment with water-cooling.

**Assessment of restorations**

The restorations were assessed clinically, radiographically and from colour photographs at 6, 12, 24, 30 and 36 months after placement. (Fig. 3) During the course of the study, the assessors (one of which was the operator) were calibrated by evaluating the clinical and radiographic findings simultaneously. This procedure continued until agreement was obtained. At the end (after 36 months), the photos and the radiographs of the restorations were re-assessed independently by the examiners. The level of concordance of acceptable/not acceptable restorations was 96%. In five cases of questionable results, a joint decision was made.

A modification of the United States Public Health Service criteria was used [11]. Marginal and approximal adaptation, anatomic form and signs of caries were judged according to a four-grade scale: 1 and 2 were considered acceptable (successful), 3 and 4 not acceptable (unsuccessful):

**Marginal adaptation**

1. Restoration adapts closely to the tooth along margins
2. Clinically insignificant gap between restoration and cavity margins
3. Poor marginal adaptation with obvious gap with or without caries. Restoration needs replacement
4. Loss of restoration

**Anatomic form**

1. Good anatomic form with optimal approximal contact
2. Clinically acceptable shape with acceptable approximal contact
3. Insufficient approximal contact resulting in food impaction
4. No approximal contact

**Secondary caries**

1. Not observed (acceptable)
2. Present clinically and/or radiographically (not acceptable)

**Data analysis**

The data were analysed with two methods: the life table to assess the cumulative success rates and the failure incidence (number of new failures/100 restored tooth-years). The method for calculating incidence has been described in detail elsewhere [12]. To illustrate how the ratio ‘number of new failures divided by time-at-risk’ can be interpreted, take, for example, a failure incidence of six new failures/100 restored tooth-years. This means that if we follow 100 restorations for 1 year, we would expect six new failures. Similarly, six new failures would be expected if we follow 10 restorations for 10 years. The failures are assumed to have an equal distribution over time. The relative risk of a failure of the two types of restoration was also calculated.

Bivariate analysis was carried out with the Chi-square test and logistic regression was used for testing differences between the materials when adjusting for the background variables age, type of tooth and defs value, and radiographic score at the time of restoration. A *P*-value of < 0.05 was considered statistically significant. The data were processed in SPSS for Windows, version 11.0 (Chicago, IL, USA).

**Results**

The median follow-up time was 36 months (SD = 6.9). Overall, 96% (51/53) of the Vitremer and 82% (51/62) of the Fuji II restorations were judged successful after 36 months or until exfoliation (including two teeth lost to follow-up after 12 and 24 months), Fig. 3. The difference in success rate between the two materials was statistically significant and it remained after adjusting for the background variables. When tested separately against the success rates of the two materials, none of the background variables age,
Glass-ionomer restorations in primary molars

The cumulative success rates of the two materials after 12, 24 and 36 months with the life table method are given in Table 1. The success rate of the Vitremer restorations declined from 98 to 94% from 24 to 36 months of observation, while the success rate of the Fuji II restorations was 81% at both times.

The failure incidence of the Vitremer restorations was 1·3 new failures/100 restored tooth years and the corresponding value for Fuji II restorations was 6·2 (Table 2). Thus, the risk of a failed restoration for Fuji II was 5·2 (6·2/1·3) times higher than for Vitremer.

Twelve molars exfoliated during the study. They had been judged as successful at the preceding examination. The distribution of exfoliated teeth according to time after restoration is shown in Table 1. One tooth was lost to follow-up after 24 months and another was re-restored by mistake at the 12-month examination. Thirteen restorations failed and the most common type of failure was loss of retention (Table 3). Pulpal complications as a consequence of restoring the tooth were not recorded.

Discussion

The split-mouth design was chosen so that the two restorative materials would be exposed to a nearly

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**Table 1.** Cumulative success rates of Fuji II and Vitremer Class II restorations in primary molars.

<table>
<thead>
<tr>
<th>Start time (months)</th>
<th>Number at start of study</th>
<th>Withdrawn during study (n)</th>
<th>Failures (n)</th>
<th>Cumulative proportion of success at end (SE)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vitremer:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>53</td>
<td>0</td>
<td>0</td>
<td>1 (0·0)</td>
</tr>
<tr>
<td>12</td>
<td>53</td>
<td>0</td>
<td>0</td>
<td>1 (0·0)</td>
</tr>
<tr>
<td>24</td>
<td>53</td>
<td>5&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1</td>
<td>0·98 (0·02)</td>
</tr>
<tr>
<td>36</td>
<td>47</td>
<td>46</td>
<td>1</td>
<td>0·94 (0·02)</td>
</tr>
<tr>
<td><strong>Fuji II:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>62</td>
<td>0</td>
<td>1</td>
<td>0·98 (0·02)</td>
</tr>
<tr>
<td>12</td>
<td>61</td>
<td>1&lt;sup&gt;b&lt;/sup&gt;</td>
<td>3</td>
<td>0·94 (0·02)</td>
</tr>
<tr>
<td>24</td>
<td>57</td>
<td>8&lt;sup&gt;c&lt;/sup&gt;</td>
<td>7</td>
<td>0·81 (0·05)</td>
</tr>
<tr>
<td>36</td>
<td>42</td>
<td>42</td>
<td>0</td>
<td>0·81 (0·05)</td>
</tr>
</tbody>
</table>

<sup>a</sup>exfoliated.
<sup>b</sup>lost to follow-up.
<sup>c</sup>seven exfoliated and one lost to follow-up.

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**Table 2.** Failure incidences (number of new failures/100 restored tooth-years) of Fuji II and Vitremer restorations followed up to 42 months and the relative risk of a failed restoration.

<table>
<thead>
<tr>
<th>Material</th>
<th>Number of restorations</th>
<th>Number of failures</th>
<th>Risk time (months)</th>
<th>Failure incidence</th>
<th>Relative risk</th>
<th>CI 95%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fuji II</td>
<td>62</td>
<td>11</td>
<td>2012</td>
<td>6·56</td>
<td>5·17</td>
<td>1·34–19·91</td>
</tr>
<tr>
<td>Vitremer</td>
<td>53</td>
<td>2</td>
<td>1888</td>
<td>1·27</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**Table 3.** Number of failed restorations according to type of failure and time after placement.

<table>
<thead>
<tr>
<th>Time (months) after placement</th>
<th>Type of failure</th>
<th>Secondary caries&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Fracture</th>
<th>Loss of retention&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 12</td>
<td>Fujii</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Vitremer</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12–23</td>
<td>Fujii</td>
<td>2</td>
<td></td>
<td></td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Vitremer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24–35</td>
<td>Fujii</td>
<td></td>
<td>1</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Vitremer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; 35</td>
<td>Fujii</td>
<td></td>
<td></td>
<td></td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Vitremer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>4</td>
<td>2</td>
<td>7</td>
<td>13</td>
</tr>
</tbody>
</table>

<sup>a</sup>judged clinically and/or radiographically.
<sup>b</sup>restoration mobile or lost.

The type of tooth, dfs value and radiographic score at the time of restoration gave any statistically significant difference.

The cumulative success rates of the two materials after 12, 24 and 36 months with the life table method are given in Table 1. The success rate of the Vitremer restorations declined from 98 to 94% from 24 to 36 months of observation, while the success rate of the Fuji II restorations was 81% at both times.

The failure incidence of the Vitremer restorations was 1·3 new failures/100 restored tooth years and the corresponding value for Fuji II restorations was 6·2 (Table 2). Thus, the risk of a failed restoration for Fuji II was 5·2 (6·2/1·3) times higher than for Vitremer.
identical oral environment. In most cases, the requirement for inclusion was the presence of at least two proximal dentin lesions in need of restorative treatment, and because of this, in general the patients represented a group with a relatively high caries activity (reflected by a high caries experience). The children were also relatively young at the time of restoration – 4–7 years. It might be expected that this would have an effect on the success rates. However, neither the age nor the caries experience of the child at the time of restoration significantly influenced the success rates.

Due to exfoliation of the primary teeth, follow-up times in clinical trials on the survival of restorations in primary molars are often short and include a number of censored teeth. For example, Andersson-Wenckert et al. [5] and Qvist et al. [1] reported that about 1/3 of the restorations were censored because of exfoliation during an observation period of 3 years. In contrast, the relatively low age of the children at the time of restoration in the present study meant that a majority of the successful restorations could be followed for 3 years. Hence, the number of censored teeth was relatively low.

In the literature, different methods have been used to assess the proportion of successful restorations in primary teeth. Although there is no ideal way to deal with exfoliated teeth, the failure incidence has advantages when comparing different restorative materials. Thus, all the restorations contribute with their individual follow-up time until the tooth exfoliates, is lost to further follow-up or until the end of the study. A disadvantage with failure incidence is the assumption that the failure rate is constant over time, which in the present material was not the case: the proportion of failures was higher after 24 months (Table 1).

The life table method is also useful for assessing the success rate. Notably, however, as exfoliated teeth are recorded as withdrawn, they tend to lower the proportion of successful restorations in each follow-up interval. More than half of the failures occurred after 24 months in the present study, emphasizing the importance of follow-up beyond this time. This circumstance was also pointed out by Espelid et al. [10], who found a substantial number of failures beyond 2 years of observation of Ketac-Silver and Vitremer restorations.

The number of restorations included in the present study is small and one operator had made them all. The results may not therefore be directly comparable with studies involving a large number of restorations and several operators. Nevertheless, the statistically significant higher success rate of Vitremer compared with Fuji II restorations (94 vs. 81%) is in agreement with previous results where conventional GIC materials showed failure rates of 20–60% after 2–3 years [1,5,7,13,14], whereas corresponding failure rates of RMGIC materials were 2–20% [10,15,16].

In agreement with previous reports [10,13,16], the main reasons for failure were loss of retention and secondary caries. It is therefore recommended that the prepared cavity has mechanical retention. All four failures due to secondary caries occurred with
the Fuji II restorations. Three of them were observed radiographically as radiolucencies under the restorations and caries was confirmed after removal of the fillings. One failed restoration showed caries along the cavity margins. Loss of retention was less common with Vitremer than with Fuji II. This might be explained by the dual setting mechanism of Vitremer ensuring a more complete hardening of the material and a higher fracture toughness compared with Fuji II. In a recent study by Qvist et al. [15], longer survival times were reported for RMGIC materials with cavity conditioning than without. Another possible explanation could therefore be that the use of a primer with Vitremer secures a better adaptation to the cavity walls than the adaptation achieved with Fuji II. One of the major reasons for failure was endodontic complication in the study by Qvist et al. [15]. In this study, however, no case of endodontic complication was observed, possibly at least partly due to the use of lining in deep cavities and perhaps also due to the relatively frequent follow-up examinations.

Conclusions
The resin-modified GICs offered advantages over the conventional GICs for restoring approximal caries in primary molars. The risk of a failed restoration with Fuji II was more than five times higher than with Vitremer. For both types of GICs, loss of retention and secondary caries were the main reasons for failure.

Acknowledgements
The Stockholm County Public Dental Health Service supported the study.

Résumé. Objectif. Comparer les performances cliniques de deux ciments verre ionomètre pour restaurations de classe II des molaires temporaires : un ciment conventionnel (Fuji II®) et un ciment renforcé en résine (Vitremer®).

Mise en place. La répartition des deux matériaux a été faite au hasard en «split mouth» dans la majorité des cas.


Résultats. Le taux de succès des restaurations au Vitremer était de 94% et celui des restaurations au Fuji II de 81%. La différence est statistiquement significative. Le risque d’échec était cinq fois plus important avec Fuji II qu’avec Vitremer. Sept des treize restaurations avec échec avaient perdu leur rétention, quatre présentaient des caries secondaires et deux étaient fracturées.

Conclusions. Le ciment verre ionomère renforcé en résine a été plus efficace que le ciment verre ionomère conventionnel pour la restauration des caries proximales des molaires temporaires.


Design. Für die Mehrzahl der untersuchten Molaren war eine randomisierte Halbseitenstudie durchgeführt worden.


Ergebnisse. Die Überlebensrate betrug 94% für Vitremer-Füllungen und 81% für Fuji II Füllungen. Dieser Unterschied war statistisch signifikant. Das Risiko einer nicht erfolgreichen Füllung war bei Fuji II fünfmal höher als bei Vitremer. Von den 13 als nicht erfolgreich gewerteten Füllungen waren sieben Retentionsverluste, vier mit Sekundärkaries und zwei waren frakturiert.


Resumen. Objetivo. Comparar el funcionamiento clínico de dos cementos de ionómero de vidrio para restauraciones Clase II en molares temporales: Un cemento convencional (Fuji II) y un cemento modificado con resina (Vitremer).

Diseño. Se dividió la boca y se asignaron al azar los dos materiales usados en la mayoría de los molares.

Muestra y Métodos. Se incluyeron 40 niños entre 4 y 7 años. Un operador hizo 115 restauraciones: 53 con Vitremer y 62 con Fuji II. Las restauraciones
fueron evaluadas clínicamente, radiográficamente y usando fotografías a color.

Resultados. El porcentaje de éxito acumulado con las restauraciones de Vitremer fue del 94% y para las restauraciones con Fuji II un 81%. La diferencia es estadísticamente significativa. El riesgo de que una restauración fallase con el Fuji II fue más de 5 veces mayor que con Vitremer como material restaurador. De las 13 restauraciones fallidas, 7 perdieron su retención, 4 tenían caries de recidiva y 2 se fracturaron.

Conclusiones. El cemento de ionómero de vidrio modificado con resina ofrece ventajas sobre el cemento convencional de ionómero de vidrio para la restauración de caries proximales en molares temporales.

References