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Clinical evaluation of four different dental restorative materials: one-year results

Key words: Amalgam, glass ionomer cement, compomer, USPHS criteria, primary molars

Summary The purpose of the present study conducted in a school in Lebanon was to evaluate the one-year clinical performance of a polyacid-modified resin composite (PMC), a resin-modified glass ionomer cement (RMGIC), a high viscosity GIC (HVGIC) and an amalgam (Amlg). Hundred and forty-nine class I and class II cavities in 45 patients aged 6 to 8 years, with a high caries risk activity, were restored with these materials. Restorations were evaluated by two examiners at baseline, 6 and 12 months, according to USPHS criteria. Evaluation at 12 months showed that the retention of materials in class I and class II restorations in primary teeth was good. The recall rate was 97.4%. None of the restorations were clinically unacceptable, except for those with

secondary caries (9/138). RMGIC gave the best results. At one year, RMGIC had the highest percentage of intact marginal integrity. Marginal discoloration in PMC restorations compared to Amlg restorations was statistically more important ($p=0.013$). Secondary caries in HVGIC restorations, compared to Amlg restorations, were higher ($p=0.013$). Clinical performance of the 3 restorative materials compared to Amlg in class I and class II cavities at one-year recall is not uniform. The results suggest that RMGIC is a suitable alternative to Amlg for restorations in primary teeth. Restrictions should be considered for the materials with more secondary caries (HVGIC) and higher marginal discoloration (PMC).

Introduction

There is a strong demand for proper alternatives to amalgam, especially for restorations in the primary dentition. This has resulted from various causes: concern about toxicity of amalgam, importance of aesthetics, development of new restorative materials, and demand for materials with adhesive and caries protective characteristics combined with simple clinical application. Paediatric dentistry requires straightforward adhesive techniques and fluoride releasing aesthetic materials.

Alternatives to amalgam restorations for the primary dentition include conventional glass ionomer cements (GIC), resin-modified glass ionomer cements (RMGIC), and polyacid-modified composites (PMC, compomers) (CROLL 1998, QVIST ET AL. 1997, MARKS ET AL. 1999).

The fluoride release and the ion exchange adhesion of GIC with tooth structure is the main advantage of this particular group of materials (WILSON & KENT 1972). Low wear resistance, susceptibility to moisture and inferior flexural strength of GIC have led to the development of several modifications of the

original material (ESPELID ET AL. 1999). Light cured resin modified glass ionomer cements have been developed to improve the mechanical properties of conventional GIC. These materials have better wear resistance, higher fracture toughness and a longer working time, and like glass ionomer cements, they are able to release fluoride (CREANOR ET AL. 1994). HUBEL & MEJARE (2003) demonstrated that RMGIC has a better clinical performance when compared to GIC for restoration of proximal cavities in primary teeth.

Polyacid-modified composite resins known as compomers have been developed to overcome the technique sensitive mixing and handling properties of resin-modified glass ionomer cements (WELBURY ET AL. 2000). Compomers contain no water in their formulation and are one component, no mix materials in contrast to glass ionomer cements. Following the light curing phase, an acid-base reaction occurs only after absorption when fluoride can then be released (BERG 1998, TYAS 1998).

The PMC Dyract AP has been recommended as a restorative material in primary teeth because of its ease of application and

its handling characteristics (MASS ET AL. 1999); it provided satisfactory results and low failure rates after three years (MARKS ET AL. 1999).

Further development of glass ionomer cements focused on a higher powder to liquid ratio, a lower water content, and smaller glass particles, leading to higher viscosity glass ionomer cements (HVGIC) like Ketac Molar or Fuji IX. They have enhanced flexural strength characteristics (GUGGENBERGER ET AL. 1998). KUNZELMANN ET AL. (2003) showed that increasing the powder to liquid ratio of glass ionomer cements and incorporating more glass particles into the matrix improved their wear resistance. Based on their results, they recommended the new high viscosity glass ionomer cements in paediatric dentistry to improve the durability of restorations.

Fuji IX is an encapsulated high viscosity GIC that hardens by a conventional acid-base neutralization reaction. Fuji IX (GC, Tokyo, Japan) showed a survival rate of 98.6%, 93.8%, and 88.3% after one, two and three years, respectively, of clinical evaluation (FRENCKEN ET AL. 1998). The successful use of high viscosity glass ionomer cements made them a promising alternative to amalgam in the primary dentition of very young or uncooperative children (MALLOW ET AL. 1995). In a study by RUTAR ET AL. (2002), Fuji IX showed excellent clinical performance in primary molar teeth over a three-years period.

A review of the dental literature from 1971 to 2003 related to the longevity and reasons for failure of restorations in stress-bearing cavities in primary molars has been published by HICKEL ET AL. (2005). It points out that compomer restorations have the lowest failure rate, as compared to amalgam, GIC and composite restorations.

The aim of the present study was to evaluate the clinical performance of four restorative dental materials in class I and class II cavities in primary molar teeth. The paediatric patients with a high caries risk activity (AAPD 2006a, b) were selected in a private school in Beirut, Lebanon. The polyacid-modified composite Dyract AP, the resin-modified glass ionomer cement Fuji II LC and the high viscosity glass ionomer cement Fuji IX were compared to amalgam restorations. The evaluation at baseline, after 6 months, and after 12 months included marginal adaptation, marginal discoloration, secondary caries, wear or loss of anatomical form, colour match, and surface texture.

Materials and Methods

Forty-five girls from a private school in Beirut, Lebanon (boarding and regular school) participated in this study. Patients were 6 to 8 years old +/-6 months. The children belonged to a social group of low socio-economic level and were considered as having a high caries risk activity (AAPD 2006a, b). They were selected by one clinician during a period of one month. A tooth brushing-program during class time was held twice per year.

Inclusion criteria for the study were: Patients to have a first and/or second primary molar in need of a class I or II restoration. Teeth were to be vital with normal appearance and morphology. Excluded were: Patients with a behavioural or health problem, and teeth in need of pulpotomy or pulpectomy. Parents of the selected children were informed about the study and signed an informed consent approved by the review board of Saint Joseph University in Beirut.

Restorative materials (Tab. I) were placed according to drawing lots and divided into four groups for restorations. Each patient received at least two restorations.

The children selected for this study received a total of 149 restorations: 38 amalgam restorations, 39 Dyract AP restorations, 37 Fuji II LC and 35 Fuji IX restorations. It happened that 83 of those restorations were class I and 66 class II, on the first and second primary molars. The two types of class were considered as a unique group for the evaluation of the restorations. The restorations were placed by five clinicians, all of them experienced with restorative procedures in paediatric dentistry.

Cavity preparations were performed under local anaesthesia using Scandicaïne 2% with noradrenalin (Septodont, St-Maur-des-Fossés, France). Carious enamel and dentin were removed. A conventional class I and class II cavity design according to Black's principles was used for the amalgam restorations. A high speed air rotor with ample water cooling was used for all the cavity preparations (KaVo, Biberach, Germany). For the amalgam restorations cavity preparation included removal of all carious tissue; cavity width was between a half and a third of the intercuspal dimension. For the Dyract AP, Fuji II LC, and Fuji IX, the cavity preparation was determined by the extent of the decay. Following cavity preparation the restorative materials were placed according to the manufacturers' instructions.

Cavities where remaining dentine was less than 2 mm thick were lined with calcium hydroxide (Dycal, DeTrey/Dentsply, Konstanz, Germany). For Dyract AP restorations, one coat of NRC was applied after cavity preparation, then two coats of Primer/Adhesive (Prime and Bond, DeTrey/Dentsply) were applied for 10 seconds. Surplus was trimmed and acetone dried with gentle air blow. A second layer of Prime and Bond was applied and light cured for 20 seconds. The cavity was then filled with Dyract AP, applied in 2 or 3 incremental layers. Each layer was polymerised for 60 seconds (Master Lite, Litema GSD, Baden-Baden, Germany) with an irradiation of 290 mW/cm². Irradiance performance has been checked with the Curing Radiometer 100 (Demetron Inc, Danbury, CT, USA).

For the Fuji II LC restorations, extensive mechanical retention was not necessary. GC cavity conditioner was applied for 10 seconds and the cement injected directly into the cavity using a GC applier. Two or three incremental layers were applied and polymerised for 60 seconds.

Tab. I Materials used in this study

Material	Manufacturer
Amalgam: Permite C	Southern Dental Industries GmbH, Cologne, Germany
Resin-modified glass ionomer cement, light-cured, in capsules: Fuji II LC	GC Corporation, Tokyo, Japan
High viscosity glass ionomer cement, in capsules: Fuji IX	GC Corporation, Tokyo, Japan
Polyacid-modified composite (compomer): Dyract AP	DeTrey Dentsply, Constance, Germany

For Fuji IX cavity preparations, GC cavity conditioner was also applied for 10 seconds.

Following removal of the matrix band and wedge, the palatal and buccal sides of the proximal box in class II restorations received an additional 20 seconds of photo-polymerisation. Occlusion was checked with articulating paper (DeTrey/Dentsply, Surrey, England). Dyract AP, Fuji II LC and Fuji IX were finished under water spray using finishing burs (Intensiv, Swiss Dental Products, Lugano, Switzerland).

The restorations were evaluated clinically according to USPHS (United States Public Health Services) criteria (RYGE 1980) at baseline, and after 6 and 12 months.

All evaluations were carried out by two evaluators (senior residents), scoring independently. If there was a disagreement on the rating, the clinicians re-examined the restoration and agreed on a joint final decision. Data were analysed using the binomial test, at a confidence level of 95%.

Results

At baseline, the 149 Class I and class II restorations in 45 patients were evaluated (38 amalgam, 39 Dyract AP, 37 Fuji II LC and 35 Fuji IX restorations). At 6 months recall, the entire material could be examined and evaluated. At 12 months recall, 138 restorations in 43 patients were evaluated (Tab. II) (two patients left school and were not available for examination; those patients had 5 restorations: 3 Fuji II LC, one amalgam and one Dyract AP restorations); and 6 restored teeth were naturally exfoliated after the second evaluation (the exfoliated teeth were 1 Fuji II LC restoration, 1 amalgam restoration, 2 Dyract AP restorations and 2 Fuji IX restorations). None of the restorations has been excluded by loss of retention over the evaluation period. The total number of restorations at the start of the study was 149, placed in 45 patients. At one year, the recall rate was 97.4%.

Results of clinical evaluation are shown in Table III.

Marginal adaptation

The one-year findings revealed marked differences in the extent of deterioration in marginal adaptation for the different material groups. The best results were seen with Fuji II LC which recorded the highest percentage of intact marginal integrity with 91% of Alpha score. Amalgam, Dyract AP and Fuji IX restorations showed respectively 86.2, 77.8 and 75% Alpha scores. The improved seal of the restorative systems was expressed in the absence of postoperative sensitivity.

Marginal discoloration

At one year, differences in marginal discoloration in Dyract AP restorations compared to amalgam restorations were statistically significant ($p=0.013$). No marginal discoloration was observed with Fuji II LC after one year.

Secondary caries

After one year, some secondary caries have been found (9/138). Differences in secondary caries in Fuji IX restorations, compared to amalgam restorations were statistically significant at $p = 0.013$. No tooth became non vital. The secondary caries detected in this study was exclusively located at the gingival and proximal margins of the restorations. After one year, only one restoration with Fuji II LC (3% of the evaluated restorations) had evidence of secondary caries. The scores for secondary caries obtained after one year with Dyract AP and Fuji IX (8.3 and 12% respectively) were the worst among the four tested materials.

Anatomic form

All materials tested performed well in regard to anatomic form. The scores for anatomic form for the four groups of restorations were similar.

None of the materials were clinically unacceptable in regard to wear or loss of anatomic form at one year (scores Alpha and Bravo only), with no statistical differences found.

Colour match

At one year recall, none of the materials was clinically unacceptable in regard to colour match. No significant differences were found between materials evaluated. 94.4% of Dyract AP restorations, 97% of Fuji II LC and 94% of Fuji IX restorations were assigned Alpha scores in regard to colour match.

Surface texture

No statistical differences were found between the restorative materials tested in regard to surface texture. No significant differences were found for Fuji II LC restorations as compared with amalgam restorations.

More generally, none of the teeth were sensitive at any recall. None of the restorations were clinically unacceptable in regard to marginal adaptation, marginal discoloration, wear or loss of anatomical form, colour match, and surface texture. 9 out of 138 restorations showed secondary caries after one year and thus were considered as failed. The two best scores for secondary caries were obtained by amalgam and Fuji II LC, both with only one restoration failed.

Fuji II LC gave the best results in regard to all criteria when compared with the other materials.

Discussion

The design of the study was such that at least two restorative materials would be exposed to an identical oral environment (RIORDAN & FITZGERALD 1994). In most cases, the requirement for inclusion was the presence of at least two dentin lesions in need of restorative treatment and as a result the patients generally represented a group with a high caries activity (AAPD

Tab. II The cumulative number of restorations evaluated at baseline and at each recall

Material	Baseline	6 months recall	12 months recall
Amlg Permite C	38	38	36
PMC Dyract AP	39	39	36
RMGIC Fuji II LC	37	37	33
HVGIC Fuji IX	35	35	33
Total	149	149	138

Amlg = Amalgam, PMC = Polyacid-modified composite, RMGIC = Resin-modified glass ionomer cement, HVGIC = High viscosity glass ionomer cement

Tab. III Results of one-year clinical evaluation of amalgam, Dyract AP, Fuji II LC and Fuji IX restorations (results are in %) (a = Alpha, b = Beta, c = Charlie)

	Marginal adaptation			Marginal discoloration			Secondary caries		Anatomic form			Color match			Surface texture		
	a	b	c	a	b	c	a	b*)	a	b	c	a	b	c	a	b	c
Amalgam																	
Baseline n=38	100	-	-	100	-	-	100	-	97.4	2.6	-	100	-	-	100	-	-
6 months n=38	97.4	2.6	-	100	-	-	100	-	97.4	2.6	-	97.4	2.6	-	100	-	-
12 months n=36	86.2	13.8	-	94.4	5.6	-	97.2	2.8	94.4	5.6	-	97.2	2.8	-	88.9	11.1	-
Dyract AP																	
Baseline n=39	100	-	-	100	-	-	100	-	100	-	-	100	-	-	100	-	-
6 months n=39	94.9	5.1	-	97.4	2.6	-	97.4	2.6	97.4	2.6	-	97.4	2.6	-	97.4	2.6	-
12 months n=36	77.8	22.2	-	91.7	8.3	-	91.7	8.3	91.7	8.3	-	94.4	5.6	-	91.7	8.3	-
Fuji II LC																	
baseline n=37	100	-	-	100	-	-	100	-	100	-	-	100	-	-	100	-	-
6 months n=37	100	-	-	100	-	-	100	-	100	-	-	100	-	-	100	-	-
12 months n=33	91	9	-	100	-	-	97	3	91	9	-	97	3	-	94	6	-
Fuji IX																	
baseline n=35	100	-	-	100	-	-	100	-	100	-	-	100	-	-	100	-	-
6 months n=35	94.3	5.7	-	94.3	5.7	-	97	3	97	3	-	94.2	5.8	-	94.3	5.7	-
12 months n=33	75	25	-	94	6	-	88	12	94	6	-	94	6	-	91	9	-

*) According to USPHS criteria, «b» score means evidence of secondary caries

2006a, b). Preventive care was categorized as dietary advice and oral hygiene instruction.

The number of restorations examined varied because of loss of teeth and patient dropout. The recall rate was relatively high (97.4%) due to the possibility of following up the children at school.

The lifetime of restorations in primary and young permanent teeth is shorter than in adult's teeth (QVIST ET AL. 1986; QVIST ET AL. 1990a, b; FORSS & WIDSTRÖM 2003). One-year clinical data, as reported here, is short term, but is still of value considering the intrinsically shorter service life of restorations in primary teeth. It is especially useful as it allows to detect early the major risks, like secondary caries. In this regard, two materials have had markedly higher scores: Dyract AP and Fuji IX, with 8.3 and 12% of Bravo scores respectively. Longer evaluation periods are needed to define the long-term clinical performance of the materials tested for use in permanent teeth.

At one year recall, 91% of the Fuji II LC restorations had a clinically ideal marginal adaptation: Alpha, the highest score. The greatest percentage of perfect marginal integrity was also recorded for Fuji II LC which is in agreement with a study by GLADYS ET AL. (1998). The resin-modified glass ionomer cement had an overall better performance with respect to marginal adaptation, and marginal defects; this is in accordance with the results given by ESPELID ET AL. (1999).

At the one year recall, marginal discolorations were 16.7% Bravo scores for the Dyract AP restorations, which is the highest level of Bravo scores seen among the different materials tested; this discoloration was located on the proximal part of the class II restorations specifically and did not progress towards the pulp. This however was still considered as a clinically acceptable situation, even if differences were statistically significant ($p=0.013$).

LUO ET AL. (2000) evaluated the clinical performance of Dyract AP in class I and class II cavities for one year, and reported that the marginal discoloration remained problematic and needed to be improved. The present results are in agreement with this previously published study.

In most studies, marginal discoloration is not a criterion for the evaluation of amalgam restorations. It was, however, included in this study because of the possibility, in some areas, to see the margin.

The clinical performance of Fuji II LC in this study is comparable to other studies (BRACKET ET AL. 2001, ABDALLA ET AL. 1997, GLADYS ET AL. 1998).

The secondary caries detected in this study was exclusively located at the gingival and proximal margins of the restorations. The absence of secondary caries at the occlusal margins may be related to the lack of marginal gaps. Thus the marginal integrity at the cervical margins still remains a challenge. The

present results are in accordance with a study by PAPAGIANNOULIS ET AL. (1999).

Encapsulated materials were used to reduce problems caused by hand mixing and to optimise the placement and mechanical properties of the materials. Perhaps the better results of Fuji II LC capsules can partly be attributed to the fact that an encapsulated system is more practical and gives a uniform mixture with more stability.

An important point in discussing results is the apparently different viscosities of the test materials. It is an obvious assumption that the higher viscosity of Fuji IX in comparison to the other materials possibly affected the adaptation to the internal cavity wall (VAN DIJKEN ET AL. 1997). In the present study, Fuji IX exhibited the worst result for marginal adaptation after one year: only 75% of Alpha scores.

It should be mentioned that the data recorded are based on qualitative evaluation of the restorations by two observers using clinical criteria. The subjective assessment may be a limitation of this study, as it occurs in all clinical trials. So far, the three restorative materials have not presented an identical clinical performance.

Conclusion

The clinical performance of the three restorative materials compared to amalgam in class I and class II cavities at one-year recall is not uniform. The clinical results, even in a population with a high caries risk activity, suggest that one of those materials (Fuji II LC) is a suitable alternative to amalgam when used as class I and class II restorations in primary teeth, whereas some restrictions should be considered for the materials which exhibited higher marginal discoloration: the polyacid-modified resin composite Dyract AP, and more secondary caries: the high viscosity glass ionomer cement Fuji IX.

The resin-modified glass ionomer cement (Fuji II LC) has obtained better scores than the polyacid-modified resin composite material (Dyract AP) and the high viscosity glass ionomer cement (Fuji IX) in restoration of class I and class II lesions in primary molars.

Résumé

L'objectif de cette étude effectuée dans une école au Liban, avec une population à risque carieux élevé, est d'évaluer les performances cliniques d'un compomère (PMC), d'un ciment verre ionomère renforcé par la résine (RMGIC), d'un ciment verre ionomère à haute densité de particules (HVGIC), et d'un amalgame dentaire (Amlg).

L'étude porte sur 149 restaurations sur 45 patients, pour des cavités de classe I et classe II sur molaires lactéales. Les restaurations sont évaluées par deux examinateurs différents de

l'opérateur, au temps 0, à 6 et à 12 mois, selon les critères USPHS.

Après 12 mois il est démontré que les performances cliniques des différents matériaux ne sont pas uniformes. Le taux de rétention était de 97,4%. Aucune restauration n'a été cliniquement inacceptable, sauf pour les quelques cas de caries secondaires (9/138). RMGIC a présenté le pourcentage le plus élevé d'adaptation marginale parfaite, ainsi que les meilleurs résultats pour l'ensemble des critères évalués. La décoloration marginale des restaurations au PMC comparée aux restaurations à Amlg était statistiquement significative ($p=0,013$). La différence dans les caries secondaires avec HVGIC, comparées aux restaurations à Amlg, était statistiquement significative: $p=0,013$.

Les performances cliniques d'un PMC, d'un RMGIC et d'un HVGIC, comparées à celles d'un Amlg, dans des cavités classe I et classe II sur molaires lactéales après 12 mois, ne sont pas uniformes.

Les résultats cliniques sur une population à risque carieux élevé suggèrent que l'un de ces matériaux (RMGIC) est convenable et peut être utilisé comme alternative à Amlg. Des restrictions devront être considérées pour les deux autres matériaux avec un taux plus élevé de caries secondaires (HVGIC) et de décoloration marginale (PMC).

Zusammenfassung

Das Ziel der vorliegenden Untersuchung war die Überprüfung des Zustandes von Restaurationen im Milchgebiss nach einem Jahr. Es wurden vier verschiedene Materialien verwendet: ein Kompomer (Dyract AP), ein lighthärtender Glasionomerzement (Fuji II LC), ein chemisch härtender Glasionomerzement mit höherer Viskosität (Fuji IX) und ein Amalgam (Permite C).

Es wurden insgesamt 149 Präparationen der Klassen I und II an 45 Patienten im Alter von sechs bis acht Jahren vorgenommen. Die Füllungen erfolgten mit Dyract AP, Fuji II LC, Fuji IX und Amalgam. Die Restaurationen wurden jeweils nach der Fertigstellung, nach sechs und nach zwölf Monaten durch zwei Personen nach der USPHS-Norm überprüft.

Die Überprüfungen nach zwölf Monaten ergaben, dass die in Milchzahnläsionen verwendeten Materialien zu verschiedenen Ergebnissen führten. Alle Restaurationen waren klinisch erfolgreich in Bezug auf Farbe, Verlust von Material, anatomische Formgebung, Randverfärbung, Randadaptation und Oberflächenstruktur. Fuji II LC erreichte für alle Kriterien die besten Bewertungen. Dyract zeigte mehr Randverfärbung ($p=0,013$) und Fuji IX mehr Sekundärkaries ($p=0,013$) als Amalgam.

Nach einem Jahr Beobachtung lässt sich feststellen, dass der klinische Erfolg beim Einsatz der drei Füllungsmaterialien im Vergleich zu Amalgam für die Klassen I und II verschieden ist. Die besten Ergebnisse wurden mit dem lighthärtenden Glasionomerzement erreicht.

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Erratum

In dem Beitrag «Bruxismus – gesicherte und potentielle Risikofaktoren. Eine systematische Literaturübersicht» von ANDREJA KULIŠ und JENS CHRISTOPH TÜRP (Schweiz Monatsschr Zahnmed 2008; 118: 100–107) steht auf Seite 101 bei dem Hallenser Anatomen WELCKER versehentlich ein falscher Vorname; statt WILHELM WELCKER muss es korrekt HERMANN WELCKER heissen. Dementsprechend muss im Literaturverzeichnis das Initial «W» durch «H» ersetzt werden.

Die Redaktion bittet, diesen Fehler zu entschuldigen.