Two-Year Clinical Evaluation of Three Restorative Materials in Primary Molars

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A variety of alternatives to amalgam are now available for use in Class I and Class II restorations in primary teeth, including glass ionomer cements, compomers and resin modified glass ionomer cements (RMGIC). ***Objectives:*** *This study evaluated the two-year clinical performance of three restorative dental materials: A resin modified glass ionomer cement (Fuji IILC), a compomer (Dyract AP) and a high viscosity glass ionomer cement (Fuji IX), in primary molars of pediatric patients with high caries risk activity and compared these results to those reported for amalgam restorations.* ***Study design:*** *One hundred and forty nine Class I and Class II cavities in 45 patients aged 6 to 8 years were restored with compomer, glass ionomer cements and amalgam. Restorations were evaluated according to modified Ryge criteria by two examiners at baseline, and after 6, 12, 18 and 24 months of oral function. The data was submitted to statistical analysis (binomial and hyper geometric tests, $p<0.05$).* ***Results:*** *Two-year recall rate was 62.42%. Class I performed better than class II restorations. The difference in marginal discoloration between compomer and amalgam restorations was statistically significant ($p=0.014$). No other significant differences were found between GIC, compomer and amalgam restorations. The clinical performance of the three restorative materials compared to amalgam in Class I and Class II cavities at two-year recall was acceptable.* ***Conclusions:*** *The results, even in a population with high caries risk activity, suggest that these materials are suitable alternatives to amalgam in Class I and Class II restorations in primary teeth.*

Keywords: *Amalgam, glass ionomer cement, compomer, USPHS criteria, primary molars, clinical evaluation, restorations.*

J Clin Pediatr Dent 34(1): 53–58, 2009

INTRODUCTION

Recent years witnessed changes in restorative dental materials. There is a strong demand to find and use proper alternatives to amalgam, especially for restorations in the primary dentition because of concerns regarding mercury toxicity and a demand for better esthetics.

Alternatives to amalgam restorations in primary dentition include conventional glass ionomer cements (GIC), resin-modified glass ionomer cements (RMGIC) and polyacid-modified composites (PMC) (compomers).[1,2,3] The fluoride ion release and uptake and the chemical adhesion to both enamel and dentin of GIC are the main advantages of this particular group of materials and have made them increasingly popular.[4]

Resin-modified glass ionomer cement (RMGIC)[5] and polyacid-modified composites (PMC) [3,6,7,8,9] restorative materials have been studied in clinical trials as alternatives to amalgam restorations in primary teeth. Furthermore, the high viscosity glass ionomer cements granted satisfactory clinical results.[10]

Annual failure rates in stress-bearing cavities of primary molars were determined to be: 0 to 35.5% for amalgam restorations, 0-25.8% for glass-ionomer restorations and 0-11% for compomer restorations.[11] Christensen observed in a 2001 paper that compomers and resin-modified glass ionomers had become the most popular restorative materials for posterior primary teeth[12] and while amalgam was the most common material used for Class II restorations, non-amalgam materials were significantly popular among California Pediatric Dentists.[13]

Glass ionomer cements have been recommended for Class I and Class II restorations in primary teeth in high-risk patients.[14] Performance of tooth-colored materials substi-

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tuted for amalgam in the primary dentition is often limited. The best scientific evidence is obtained by prospective clinical trials, despite that none of the cited materials (RMGIC, PMC, viscous glass ionomer and amalgam) were included in the same investigation or applied in the same oral environment.

Since the debate over the current material of choice for restoring Class I and Class II restorations remains unresolved, pediatric dentists must choose between amalgam, composite resin, glass ionomer cement, compomer and stainless steel crowns to restore primary teeth.

The aim of the present study was to evaluate the two-year clinical performance of three restorative dental materials in Class I and II cavities in primary molars in pediatric patients with high risk caries activity[15] and compare these results to those reported for amalgam restorations.

A compomer (Dyract AP, DeTrey Dentsply), a resin-modified glass ionomer cement (Fuji II LC, GC Corporation) and a high viscosity glass ionomer cement for posterior restorations (Fuji IX, GC Corporation), were compared to amalgam restorations (Non-gamma II Amalgam**,** Permite C (SDI), Southern Dental Industries).

MATERIALS AND METHOD

Forty five girls aged 6 to 8 years (+/- 6 months), from a private school (boarding and regular school) in Beirut, Lebanon, participated in this study. The children belonged to a low socio-economic level. The participants were selected by one specialist in pediatric dentistry during a period of 1 month.

The children routinely (before and during study) received information and instructions to improve their oral hygiene, and had two dental examinations *per* year.

Clinical requirements for restorations included: Patients aged 6 to 8 years +/- 6 months with their first and second primary molars requiring new Class I or Class II restorations. Specific criteria included vital teeth with normal appearance and morphology, and teeth with or without adjacent teeth.

Criteria for exclusion from the study: Patients having behavioral problems, patients with general health problems, patients with poor oral hygiene, molars requiring pulpotomy or pulpectomy.

Parents of children selected were informed about the study and signed an informed consent approved by the review board of Saint-Joseph University, Beirut, Lebanon.

The restorative materials selected for this study included a classical non-gamma II dental amalgam: Permite C (Southern Dental Industries GmbH 50859, Köln, Germany), a polyacid-modified composite (compomer): Dyract AP (DeTrey Dentsply, 78404 Konstanz, Germany), a resin-modified glass ionomer cement: Fuji II LC (GC Corporation, Itabashi-ku, Tokyo 174-8585, Japan), and a highly viscous glass ionomer cement for posterior restorations: Fuji IX (GC Corporation, Itabashi-ku, Tokyo 174-8585, Japan). The restorative material for each cavity was selected randomly by the investigator.

The children selected for this study received a total of 149 restorations (38 amalgam restorations, 39 Dyract restorations, 37 Fuji II LC and 35 Fuji IX restorations), of which 83 were Class I and 66 Class II, on their first and second primary molars (Table 1).

Table 1. Distribution of restorations according to materials and extension (Class)

	Class I	Class II	Total
Amalgam	25	13	38
Dyract AP	21	18	39
Fuji II LC	16	21	37
Fuji IX	21	14	35
Total	83	66	149

All restorations were placed by 5 selected clinicians (senior residents in Pediatric Dentistry), within a 6 months period after initial examination. The patients were never treated before the study. They were examined clinically and bite-wings radiographs were taken.

Cavity preparations were performed under local anesthesia using Scandicaïne 2% with Noradrenaline (Septodont, 94107 St-Maur des Fosses, France). Carious enamel and dentin were removed. A conventional Class II cavity design according to Black's principles was prepared for amalgam restorations. A high speed air rotor with ample water cooling was used for preparation (turbine KaVo Mango 634 A, KaVo, 88400 Biberach, Germany).

For amalgam restorations cavity preparation included removal of all carious tissue and cavity width was between 1/2 and 1/3 of the intercuspal dimension.

For Dyract II AP, Fuji II LC, and Fuji IX, the cavity preparation was determined by the extent of the decay.

For cavity preparation, round, cylindrical burs for high speed (Intensiv SA, Swiss Dental Products, 6916 Lugano Grancia, Switzerland) (FG 316M, 200 SM, 219M, 200M, 212M, 218M, 220M), and burs 010 and 018 for hand piece (Dentsply, Maillefer, 1338 Ballaigues, Switzerland) were used.

Ivory junior matrix holder and matrix bands (0.03-5mm, E. Hahnenkratt GmbH, 75203 Königsbach-Stein, Germany) were used to protect adjacent teeth during Class II preparation.

The pulpal axial walls of proximal boxes were prepared parallel to the pulp chamber and the isthmus was rounded. The gingival wall was placed above the cemento-enamel junction. After cavity preparation rubber dam was placed (Hygenic 14A, 203, Coltène-Whaledent Inc, Cuyahoga Falls, OH 44223, USA). Interproximal separation was achieved using wood-wedges (medium, Produits Dentaires SA, 1800 Vevey 1, Switzerland) placed before inserting the restoration. Air and water was used to wash, clean and dry the cavities. Following cavity preparation, the restorations were placed according to the manufacturer's instructions.

Deep cavities were lined with calcium hydroxide liner just against the pulp chamber (Dycal, DeTrey/Densply, 78404 Konstanz, Germany). For Dyract AP restorations, the cavity was treated with one coat of non-rinse conditioner NRC, and then two coats of Primer/Adhesive (DeTrey /

Dentsply, 78404 Konstanz, Germany) were applied for 10 seconds. Surplus was trimmed and acetone dried with a gentle air blow. A second layer of prime and bond was applied and light cured at a 2 mm distance for 20 seconds. The cavity was filled with Dyract AP, in 2 or 3 incremental layers. Each layer was polymerized for 60 seconds (Master Lite, Litema GSD, 7570 Baden-Baden, Germany) with an irradiation of 290 mW/cm^2. Irradiance performance was measured with a curing Radiometer 100 (Demetron, Inc, Danburry, CT 06810, USA) which was calibrated prior to use.

For the Fuji II LC restorations, an extensive mechanical retention was not necessary. GC cavity conditioner was applied for 10 seconds. Cement was injected directly into cavity with a GC capsule applier. Two or three incremental layers were applied and polymerized for 60 seconds in total.

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

Following removal of the matrix band and wedge, the palatal and buccal sides of the proximal box received additional 20 seconds of photopolymerization.

Occlusion was checked with articulating paper (DeTrey / Dentsply, Weybridge, Surrey KT15 2SE, England).

Dyract AP, Fuji II LC and Fuji IX were finished under cooling with a water spray using finishing burs (Intensiv, Swiss Dental Products, 6916 Lugano Grancia, Switzerland).

The restorations type was randomly selected by the investigator and each patient received at least 2 restorations.

The restorations were evaluated clinically according to USPHS (United States Public Health Services Criteria)[16] with regard to color match, wear or loss of anatomical form, marginal discoloration, secondary caries, marginal adaptation and surface texture at baseline, and at 6, 12, 18, and 24 months recalls.

For statistical analysis purposes, restorations receiving a score of "Charlie" in any category were classified as failed restorations.

Restorations were evaluated independently by two investigators, senior residents in Pediatric Dentistry. Upon a disagreement on the rating, the clinicians re-examined the restoration and arrived at a joint final decision. Data obtained by evaluating each criterion were analyzed using the binomial test at a confidence level of 95%.

The results between one-year and two-year recall were compared for each type of restoration. The data was analyzed statistically using hypergeometric distribution test ($p<0.05$).

Procedures that required a high visual accuracy and some visual evaluations were performed under magnification. A binocular stereoscopic microscope with a 6 x magnification was used for that purpose.

Impressions were made with a low viscosity polyvinyl siloxane material (Pierre Roland, Produits Dentaires Pierre Roland, BP 216, 33708 Merignac Cedex, France) at placement and at the two-year recall, as an additional documentation measure for intended future study. Replicas were manufactured using epoxy-resin (Stycast 1266, Emerson & Cuming, B-2260 Westerlo, Belgium) to later clarify the mechanism of *in vivo* marginal disintegration of restorative materials.

RESULTS

One-hundred-forty-nine Class I and Class II restorations (38 Permite C amalgams, 39 Dyract AP, 37 Fuji II L C and 35 Fuji IX restorations) in 45 patients were evaluated at baseline. At 6 months recall, the entire material could be examined and evaluated.

At one-year recall, 43 patients and 138 teeth were evaluated. 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. At the time of recall, 94% of the amalgam restorations, 92% of the Dyract AP, 89% of the Fuji II LC and 94% of the Fuji IX restorations were still available for evaluation.

At 2-year recall, 93 restorations in 31 patients (21 amalgams, 26 Dyract AP, 23 Fuji II LC and 23 Fuji IX restorations) were available for evaluation, which represents a recall rate of 62.42%. Specifically, restorations available for evaluation at this time were 55% for amalgam, 66% for Dyract AP, 62% for Fuji II LC and 65% Fuji IX restorations.

During the entire study whole, 6 patients (13.33%) left school and 41 restored teeth (27.5%) were naturally exfoliated. Between the one and 2 year evaluation 7 teeth were collected.

The drop outs at the end of the study were partially due to subjects moving to another school and becoming out of reach. This was a low-income population, most of whom did not have a contact phone number.

The number of restorations available at each recall is shown in Table 2, while the results of the clinical evaluation according to USPHS criteria are shown in Table 3. The clinically defective and unacceptable restorations with a "Charlie" score were all class II restorations: 2 Permite C (amalgam), 4 Dyract AP, 1 Fuji II LC and 2 Fuji IX restorations.

None of the teeth with retained restorations were sensitive at any recall.

Table 4 shows the results of the binomial tests used to evaluate the differences between amalgam restorations and restorations with the other materials after two-year recall.

Only the difference in marginal discoloration in Dyract AP restorations compared to amalgam restorations was statistically significant ($p=0.0104$). No other significant differences were found with Fuji II LC and Fuji IX restorations compared to amalgam restorations.

The hypergeometric test has been used to investigate the

Table 2. The cumulative number of restorations which have been evaluated.

Material	Baseline	12 months recall	24 months recall
Amalgam	38	36	21
Dyract AP	39	36	26
Fuji IILC	37	33	23
Fuji IX	35	33	23
Total	149	138	93

Table 3. The number of A, B and C scores obtained for the various USPHS criteria, arranged by types of restorations and by time of evaluation.

Criteria Materials	Time	USPHS1 Color match	USPHS 2 Marginal discoloration	USPHS 3 Caries	USPHS 4 Anatomical form	USPHS 5 Marginal adaptation	USPHS 6 Surface texture
Amalgam	Baseline nb=38	A=38	A=38	A=38	A=37 B=1	A=38	A=38
	12 months nb=36	A=35 B=1	A=34 B=2	A=35 B=1	A=35 B=2	A=31 B=5	A=32 B=4
	24 months nb=21	A=18 B=1 C=2	A=16 B=3 C=2	A=18 B=3	A=15 B=4 C=2	A=15 B=4 C=2	A=15 B=4 C=2
Dyract AP	Baseline nb=39	A=39	A=39	A=39	A=39	A=39	A=39
	12 months nb=36	A=34 B=2	A=29 B=6 C=1	A=33 B=3	A=34 B=2	A=27 B=8 C=1	A=33 B=3
	24 months nb=26	A=22 C=4	A=14 B=8 C=4	A=22 B=4	A=19 B=3 C=4	A=15 B=7 C=4	A=21 B=1 C=4
Fuji II LC	Baseline nb=37	A=37	A=37	A=37	A=37	A=37	A=37
	12 months nb=33	A=32 B=1	A=33	A=32 B=1	A=30 B=3	A=30 B=3	A=31 B=2
	24 months nb=23	A=22 C=1	A=18 B=4 C=1	A=19 B=4	A=15 B=7 C=1	A=16 B=6 C=1	A=20 B=2 C=1
Fuji IX	Baseline nb=35	A=35	A=35	A=35	A=35	A=35	A=35
	12 months nb=33	A=31 B=2	A=31 B=2	A=29 B=4	A=31 B=2	A=25 B=8	A=30 B=3
	24 months nb=23	A=21 C=2	A=19 B=2 C=2	A=20 B=3	A=17 B=4 C=2	A=14 B=7 C=2	A=18 B=3 C=2

differences of results between one and two-year recalls. This test revealed no significant differences between one and two- year recalls in color match, caries or surface texture for Dyract AP, Fuji II LC and Fuji IX restorations.

Differences between one and two-year recalls in Dyract AP restorations, in marginal discoloration, anatomic form and marginal adaptation were statistically significant with p-values of p=0.007, p=0.0226 and p=0.000057 respectively. Thus Dyract AP showed a significant degradation in marginal discoloration, anatomic form and marginal adaptation between one and two-year recalls.

Differences between one and two-year recalls in Fuji II LC restorations in marginal discoloration, anatomic form and marginal adaptation were statistically significant with p-values of p=0.0088, p=0.023 and p=0.04217 respectively, and so Fuji II LC showed also a significant degradation in marginal discoloration, anatomic form and marginal adaptation between one and two-year recalls.

Differences between one and two-year recalls in Fuji IX restorations in anatomic form and marginal adaptation were statistically significant with p-values of p=0.0429 and p =0.0035 respectively. Fuji IX showed degradation in anatomic form and marginal adaptation between one and two-year recalls.

Table 4. Results of the binomial test for difference between amalgam and the other restorative materials at two-year recall.

Criteria Materials	USPHS 1 Color match	USPHS 2 Marginal discoloration	USPHS 3 Caries	USPHS 4 Anatomical form	USPHS 5 Marginal adaptation	USPHS 6 Surface texture
Dyract AP	0.520	0.0104*	0.520	0.525	0.094	0.204
Fuji IILC	0.140	0.522	0.421	0.325	0.500	0.071
Fuji IX	0.342	0.329	0.579	0.185	0.185	0.320

* = significant difference (p<0.05)

DISCUSSION

The present study investigated differences in the clinical performance between an amalgam (Permite C), a resin modified glass ionomer cement (Fuji IILC), a compomer (Dyract AP) and a high viscosity glass ionomer cement (Fuji IX), in primary molars of pediatric patients with a high caries risk activity.

The design of the study was chosen so that at least two different restorative materials would be exposed to identical oral environment.[17]

Failing or clinically unsatisfactory restorations with

scores of "Charlie" after two years were always attributed to Class II cavities.

Many studies have shown that multiple surface restorations generally have lower survivals than single surface restorations.[18, 19] This was also seen in this study, where Class II restorations showed more degradations than Class I restorations.

It has been shown that cavity size does affect the survival of restorations; the larger the preparation the larger the risk for failure of the restoration.[20] Effectively, in the present study the satisfactory results were inversely proportional to the cavity size, indicating that there was a greater retention of the material in smaller cavities.

Studies showed that the use of a high filler glass ionomer cement to restore primary molars showed a two-year survival rate of 92% for Class I cavities and 66% for Class II cavities. None of the restorations appeared however to fail due to recurrent caries.[9,21] Our results are in accordance with these previously published studies.

The small number of restorations of different materials available for evaluation at the two-year recall may have masked differences that could have been seen if a higher percentage of the restorations were available at two-year recall or if the number of the restorations in the study had been greater

In the present study, observation of changes in the anatomic form seemed to indicate that the materials evaluated were not greatly affected by wear. This is the major limitation of the study; the evaluation of wear was subjective, as it relied on the examiner's assessment in determining whether the anatomic form had changed over time. Thus, caution should be exercized when interpreting these results. The method was qualitative and of course could not produce the precise quantification provided by other methods of wear analysis, such as the indirect cast comparison method.[22] Nevertheless, our subjective results were supported by the findings of other authors who used indirect evaluation.

No significant differences were found in regard to caries. This is in agreement with a study by Qvist *et al* 2004[23] who showed that RMGIC (like Fuji II LC evaluated in our study) and GIC (like Fuji IX) had similar cariostatic effects on restored teeth and adjacent tooth surfaces. Kavvadia *et al* 2004 also showed no statistical significant differences between amalgam and compomer restorations at two-year clinical evaluation.[24]

Caries contiguous with the margin can result from both the nature of the restorative material and the general oral health of the patient, while the marginal adaptation is chiefly dependent on the characteristics of the restorative material. Preventive programs possibly contributed to the low frequency of secondary caries as well as the experience of the pediatric dentist who placed the restorations.

From the data shown in Table 4 for marginal adaptation, some interesting facts can be observed. The four tested materials exhibit a continuous decrease in marginal adaptation over the length of the experiment, as shown by the proportion of scores A (non visible evidence of a crevice along the margin) after one and two years, as compared to the number of restorations available for evaluation at these two periods of time: Amalgam: 86.1% and 71.4% (at one and two years respectively).Dyract AP:75.0% and 57.7%. Fuji II LC: 90.9% and 69.6%. Fuji IX: 75.7% and 60.9%.

Clearly, the overall results are similar for amalgam and Fuji II LC, with a greater negative response for Dyract AP and Fuji IX.

Considering the worst outcome (score C, crevice along the margin and dentin or base exposed), the respective negative outcomes are: Amalgam: 0% and 9.5% (one and two years respectively). Dyract AP: 2.8% and 15.4%. Fuji II LC: 0% and 4.3% and Fuji IX: 0% and 8.7%.

In this respect, Dyract AP (PMC) appears as the least successful in terms of marginal adaptation, and Fuji II LC (RMGIC) has the best outcome. For that reason, this RMGIC should be preferred to the other evaluated materials for Class I and Class II restorations in the primary dentition.

The results of the present investigation showed that the compomer (Dyract AP), the resin modified glass ionomer cement (Fuji IILC), and the high viscosity glass ionomer cement (Fuji IX) in Class II restorations of primary molars do not differ significantly. Meanwhile, the compomer presents significant deterioration, shown by a marked increase in the number of "Charlie" rated restorations in both marginal discoloration and marginal adaptation over a period of two years.

CONCLUSIONS

After two years, the recall rate was 62.42 %. There were significantly lower survivals for high viscosity GIC (Fuji IX), resin-modified GIC (Fuji II LC) and polyacid-modified composite (Dyract AP) restorations placed in Class II cavities compared with Class I cavities.

The three restorative materials Dyract AP, Fuji II LC and Fuji IX showed a statistically significant increase in the degradation of their marginal adaptation and anatomic form between one and two-year recall.

The number of unsatisfactory restorations was greater in cavities with 2 surfaces at 12- and 24-month evaluations. The high percentage of unsatisfactory scores for multi-surface restorations requires proper long-term, cost-effective analysis to justify the routine use of those materials for more than one surface cavity preparation.

When considering all the criteria in this study, the resin-modified glass ionomer cement Fuji IILC combines the best scores for restoration of primary molars of Class I and Class II, in a population with a high caries risk activity.

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