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Clinical Success of Compomer and Amalgam Restorations in Primary Molars

Follow up in 36 Months

Key words: Polyacid-modified composite, compomer, dental amalgam, deciduous dentition, clinical evaluation, scanning electron microscopy, fluoride

Summary The purpose of this study was to evaluate the three-year clinical performance of a compomer and an amalgam in primary molars and to determine fluoride content in the enamel of these teeth after exfoliation. Twenty patients aged six to eight years randomly received one compomer and one amalgam restoration. Restorations were evaluated at baseline, 12, 24 and 36 months according to modified USPHS criteria. In six pairs of exfoliated teeth fluoride content at 1 and 5 mm distance from the restorations was determined. Replicas were made to determine marginal adaptation (MA) by scanning electron microscopy (SEM). At occlusal margins compomer restorations had better MA than amalgam restorations ($p<0.01$). Compomer and amalgam restorations did not lead to different fluoride uptake in adjacent enamel and had an overall clinically satisfactory performance. The study confirmed that the assessed compomer is a suitable restorative material for class I and class II restorations in primary molar teeth.

Introduction

The use of substitutes for amalgam in pediatric dentistry has gradually increased due to a greater wish for tooth-colored restorations (Forss & Widström 2003, Peretz & Ram 2002), the debate over amalgam (Qvist et al. 1997) and the high failure rate reported for amalgam restorations in primary dentition (Qvist et al. 1986). Consequently a shift from amalgam to other materials such as composite resins and compomers was observed in recent years (Roshan et al. 2003). These materials are usually applied with adhesive systems, which might be demanding in pediatric dentistry. Thus, especially in pediatric dentistry simple adhesive techniques are required. Additionally, the restoration should act as a protective material with long-term secondary caries prevention for an average service time of three to five years in primary teeth. It is debated whether fluoride releasing materials are able to meet this criteria (Wiegand et al. 2007). Different materials have been considered as amalgam substitutes. Composites, even with simplified adhesive systems, are technique sensitive especially when an absolutely dry operation field cannot be guaranteed. Nevertheless, they have proven suitability even in primary molars (Attin et al. 2001). Other direct alternatives to amalgam restorations in primary dentition include glass-ionomer cements, polyacid-modified resin composite and compomers (Qvist et al. 1997, Marks et al. 1999). Compomers have been shown to release fluoride and therefore to have caries protective effect, although this effect is still controversially discussed (Eliades et al. 1998). They offer relatively good esthetics, together with improved physical, chemical and mechanical properties and acceptable wear resistance (Attin et al. 1996). These materials are easy to handle and are recommended in primary teeth for all classes of cavities (Papagiannoulis et al. 1999, Mass et al. 1999). With the use of a self-etching adhesive rather than acid etching prior to application of an adhesive, faster treatment can be achieved. Controlled clinical studies (Papagiannoulis et al. 1999, Mass et al. 1999, Roeters 1998) have shown low failure rates during observation periods between 1 to 3 years, with less than 3% failure rates after 3 years for class III restorations (Marks et al. 1999, Gross et al. 2001).

There is a lack of direct comparison between compomer and amalgam restorations in primary teeth. Moreover, as stated above, the impact of fluoride release from restorative materials on secondary caries is still questioned. In this sense it is of interest, if fluoride released from restorative materials could be absorbed by adjacent enamel. Thus, the aim of this study was to compare the clinical performance of compomer vs amalgam restorations in primary teeth and to determine the fluoride content of adjacent enamel.

Methods

A total of twenty children from a private school in Beirut (Lebanon) were included in the study. The population of this study had a low socio-economic background and represented a group with a high caries activity according to the caries risk assessment tool recommended by the American Association for Pediatric Dentistry (AAPD 2005–2006). The participants were selected out of 150 children by one clinician during routine dental examination according to inclusion criteria mentioned below. The children routinely received information and instructions to improve their oral hygiene, and had one oral examination per year. Before participating in the study, informed consent was obtained from the children's parent or guardian. The study was approved by the Ethics Committee of the University Saint-Joseph, Beirut, Lebanon. Inclusion criteria for the study were: patients aged 6 to 8 years old ± 6 months, with a first and/or second primary molar in need of a class I or II restoration. Teeth had to be vital with normal appearance and morphology. Excluded were: patients with a behavioral or health problem, patients with poor oral hygiene and teeth in need of pulpotomy or pulpectomy. Also excluded were teeth without adjacent neighboring teeth or teeth without an antagonist. Amalgam and compomer restorations were placed in a split mouth design in a prospective clinical study. Restorations were rated clinically according to modified USPHS criteria (Ryge 1980). Additionally, six pairs of exfoliated teeth were collected for analysis of fluoride content in the enamel adjacent to restorations and for determining marginal adaptation with scanning electron microscopy (SEM).

The children selected for this study received one amalgam (Septalloy, Septodent, Saint Maur, France) and one compomer (Dyract, Dentsply, Konstanz, Germany) restoration – a total of 40 restorations – in a split mouth design on their first or second primary molars.

Restorations that were placed in the split mouth design were of the same tooth selection (i.e. contralateral teeth). Table I lists the materials used in the study.

All restorations were placed by one pediatric dentist with seven years working experience within a 60 day period. Cavity preparations were performed under local anesthesia (Scandicaïne 2% with Noradrenalin 1/100000, Septodent, Créteil, France). A high-speed air rotor with ample water cooling was used to open cavities (Kavo Magno 634 A, Biberach, Germany); round and cylindrical diamond bur for high speed were used (Intensiv, Swiss dental products, Lugano, Switzerland) (FG 316 M, 200SM, 219M, 200M, 212M, 218 M, 220M).

Cavities were completed using a high contra-angle handpiece with ample water cooling using round and cylindrical bur (010, 018) (Dentsply, Maillefer, CH-1338 Ballaigues, Switzerland). In the case of Class II cavities, the adjacent tooth was protected by means of Ivory matrix bands with a junior matrix holder during preparation (Hahnenkratt, Germany). External angles between axial walls and cavity floor were rounded. 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. For amalgam restorations a conventional cavity design according to Black's principles was prepared with a bucco-oral width between one third and one half of the intercuspal dimension. For compomer restorations, the cavity preparation was determined by the extent of the decay. For both amalgam and compomer restorations, rubber dam was placed after completion of the cavity preparation (Hygenic 14A, 203, Coltene Whaledent, Altstätten, Switzerland). Care was taken not to desiccate the cavities after preparation. Deep cavity areas were lined with calcium hydroxide (Dycal, Dentsply, Konstanz, Germany). For the compomer restorations, an adhesive system (Prime & Bond 2.1, Dentsply, Konstanz, Germany) was applied for 10 s. Excess adhesive was thinned with a gentle airflow. A second layer of adhesive was applied and light-cured for 20 s. The cavity was filled with the compomer (Dyract, Dentsply, Konstanz, Germany), with two incremental layers. Each layer was light-polymerized for 60 s (Master Lite, Litema, Baden, Germany) with an irradiation of 290 mW/cm^2. Irradiance performance was measured with a curing radiometer 100 (device No. 134099, Demetron Inc, Danburry, CT, USA). The operative procedure was performed according to manufacturer's recommendations. Occlusion was checked with marking paper (Dentsply, Surrey, England). At the end of the visit, restorations were finished and polished under liberal water spray with finishing burs (Intensiv) and finishing strips (Combifin, Vivadent, Schaan/Liechtenstein).

Twenty patients were assessed at baseline, fifteen at the first year recall, fourteen at the second year recall and twelve at the third year recall respectively. Five patients left school and moved out of Beirut after the first evaluation, and one patient left school after the second year assessment. One tooth with a compomer-restoration was exfoliated after the second year. Two teeth restored with amalgam were exfoliated after the second year evaluation.

Clinical evaluation

The restorations were assessed clinically according to USPHS criteria (Ryge 1980), at baseline (1 week after restoration), and after one, two and three years. Color match, anatomical form, marginal discolorations, caries, marginal adaptation and surface texture were evaluated.

Retention was defined as the restoration being present or absent at the recall visit. A fractured filling was ranked as Charlie.

Since all ratings at baseline were alpha, only one, two and three year data were statistically analyzed.

Differences between the findings at one, two and three years were statistically analyzed by means of a paired Wilcoxon Signed Rank Test (ranks: Alpha, Beta, Charlie), with the level of significance set at $p < 0.05$.

All evaluations were carried out by postgraduate dental students experienced in pediatric dentistry, who had not

Tab. I Restorative materials used in the study

Material	Manufacturer
Amalgam: Septalloy	Septodont, Saint-Maur, France
Compomer: Dyract	Dentsply, Konstanz, Germany
Adhesive System: Prime & Bond 2.1	Dentsply, Konstanz Germany

placed the restorations. Nine teeth restored with compomer, and seven teeth restored with amalgam could be collected after a clinical service of 3 to 3.5 years. The exfoliated teeth were collected as pairs (at least one with amalgam and one with compomer restoration) from six children. The teeth were stored in a thymol solution (0.1%) until further use.

SEM analysis

For the SEM analysis of the exfoliated teeth, all teeth were cleaned with fluoride-free pumice and water using rotating nylon brushes (Kerr Hawe, Bioggio, Switzerland) and dried with oil-free air.

Impressions were made with a polyvinyl siloxane (President light, Coltène Whaledent, Altstätten, Switzerland). Replicas were made with epoxy-resin (Stycast 1266, Emerson & Cuming, Westerlo, Belgium) and gold sputtered (Sputter SCD 030, Balzers Union, Balzers, Liechtenstein) for SEM evaluation. Marginal adaptation at the interfaces between tooth tissue and restorations was examined quantitatively with SEM (15 kV, WD approx. 20 mm, Amray 1810/T, Amray Inc, Bedford, MA, USA) at 200× magnification according to Lutz et al. (1991). All samples were examined for continuous "optimal margins" (no gap, no interruption of continuity) and non-continuous "imperfect" margins. Imperfect margins were divided into gaps due to adhesive or cohesive failure (NCM Pure), fracture of restorative material (NCM-FF) or fracture of enamel related to restoration margins (NCM-EF). For each restoration, the quality of the margin was determined and described as a percentage of the total length of the margins examined. Results from all groups were compared using ANOVA and the Scheffé F test. The level of significance was set at $p<0.05$.

Evaluation of fluoride content

For this evaluation, the exfoliated teeth that had been collected from the six children were prepared after replica manufacturing for SEM analysis according to Tepper et al. (2004). Two circular enamel windows – one at 1 mm distance from the restoration margin and one at least 5 mm distance – with a diameter of 3 mm were created using an acid-resistant adhesive tape (Puma Isolierband, Angst & Pfister AG, Zurich, Switzerland). The adhesive tapes were fixed to the specimen and its carrier with a low-viscosity polyvinyl siloxane (President light). To evaluate the amount of fluoride in the outer enamel surface, specimens were etched with 10 µl 2 M HCl for 5 s, 10 s, 15 s and for another 15 s. The acid together with the dissolved enamel components were collected using three blotting paper disks of standardized size, which were immediately transferred into 2 ml of TISAB solution (Total Ionic Strength Adjustment Buffer, DM Messtechnik, Seeon, Germany). To evaluate the fluoride concentration in these solutions, measurements were performed with an ion-selective electrode (Orion 960 Auto chemistry system, Orion Research AG Küsnacht, Switzerland) versus (double blind) measurements with paper disks only (Kissa 1983). Results were statistically analyzed using the Mann-Whitney U test. The level of significance was set at $p<0.05$.

Results

Seventy-five percent (n = 15), 70% (n = 14) and 60% (n = 12) of the children could be examined at recall assessment after one, two and three year recalls respectively.

Clinical evaluation

Clinical evaluation rates at baseline and at one, two and three year recalls are given in Table II. After three years comparable retention rates were observed for both compomer and amalgam restorations.

With the paired Wilcoxon Signed Rank Test (ranks: Alpha, Beta, Charlie) for two criteria significant differences were found:

- Amalgam exhibited less marginal discolorations than compomer (criteria 2) at one-year recall ($p = 0.0143$) and at two-year recall ($p = 0.05$).
- Compomer had better marginal adaptation than amalgam (criteria 5) at two-year recall ($p = 0.0455$).

For all other criteria, not even a clear tendency of difference was obvious between the two materials.

SEM analysis of the occlusal aspects of the restorations

At the enamel-compomer interface "continuous-margin" (CM) was observed occlusally along 35.5 ± 16.0% of the total length of the margin (Fig. 1), which was significantly higher than at enamel-amalgam interface, where CM value was only 9.8 ± 8.1%.

The results showed more "non-continuous margins with filling fracture" (NCM-FF) occlusally for amalgam (8.6 ± 3.6%) than for compomer (3.2 ± 1.7%).

Significantly more "non-continuous margins pure" (NCM pure) were recorded for the amalgam restorations (77.8 ± 7.9%) than for the compomer restorations (56.7 ± 15.9%). The inter-

Tab. II USPHS criteria of amalgam and compomer restorations in primary teeth (observations are given in %).
A: Alpha B: Bravo C: Charlie

	Color Match			Marginal Discoloration			Secondary Caries		Loss of Anatomical Structure			Marginal Adaptation			Surface Texture		
Baseline	A	B	C	A	B	C	A	B	A	B	C	A	B	C	A	B	C
Amalgam (n = 20)	–	–	–	100	0	0	100	0	100	0	0	100	0	0	100	0	0
Compomer (n = 20)	100	0	0	100	0	0	100	0	100	0	0	100	0	0	100	0	0
1 Year																	
Amalgam (n = 15)	–	–	–	86.6	13.4	0	93.3	6.7	66.7	33.3	0	80	20	0	73.3	20	6.7
Compomer (n = 15)	93	6.7	0	46.6	53.4	0	93.3	6.7	53.4	46.6	0	93.3	6.7	0	93.3	6.7	0
2 Years																	
Amalgam (n = 12)	–	–	-	83.3	8.3	8.3	75	25	25	66.7	8.3	58.3	33.3	8.3	58.3	33.3	8.3
Compomer (n = 14)	85	14.3	0	35.7	63.3	0	78.5	21.5	35.7	64.3	0	85.7	14.3	0	71.4	28.6	0
3 years																	
Amalgam (n = 12)	–	–	–	41.6	50	8.4	50	50	16.7	75	8.3	25	66.7	8.3	41.6	41.6	16.7
Compomer (n = 12)	50	50	0	16.7	75	8.3	50	50	8.3	83.3	8.3	41.7	58.3	0	33.3	66.7	0

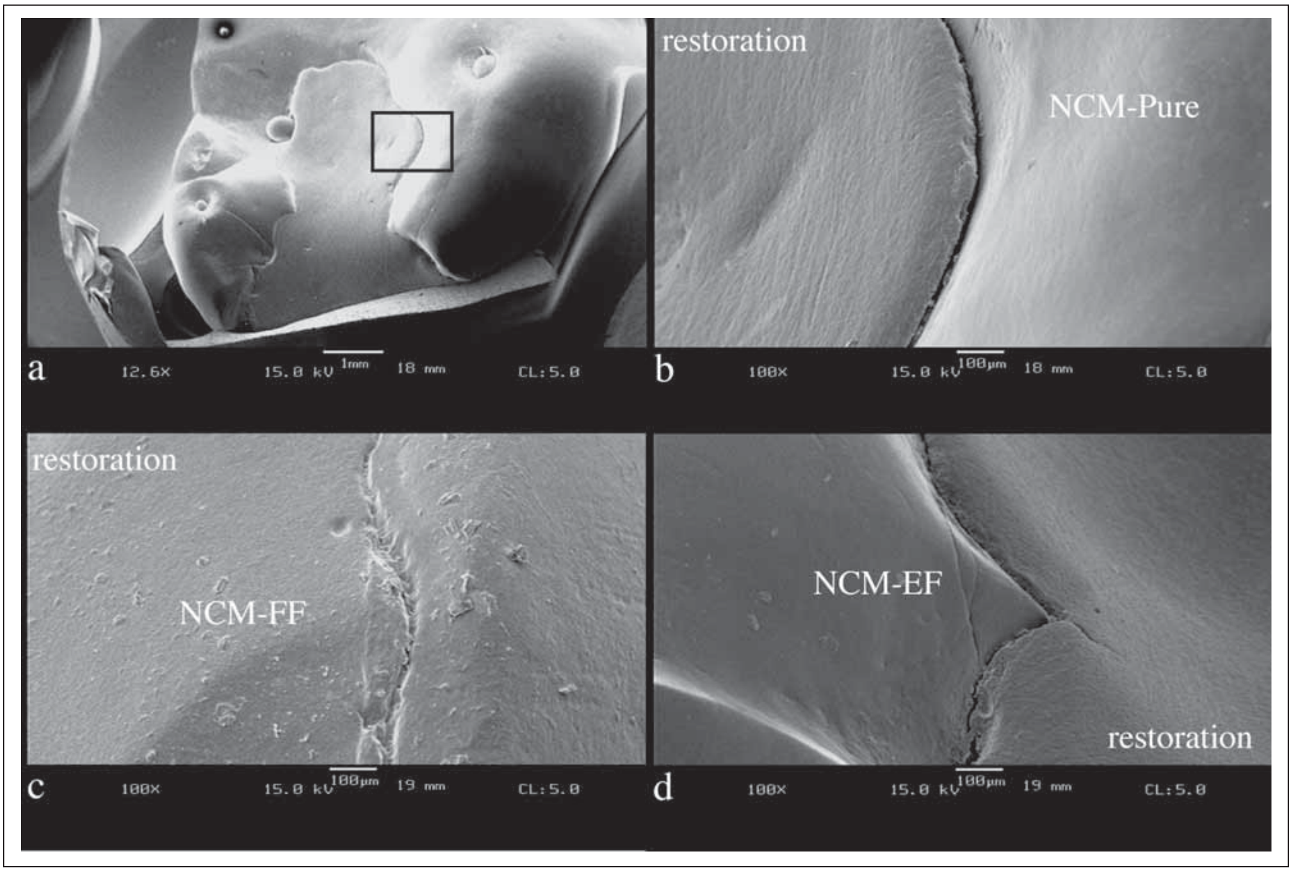

Fig. 1 SEM microphotographs of 3 three-year-old class II compomer restorations. Occlusal surface, original magnification, ×12.6 (a) and enlarged detail with a non-continuous margin (NCM-Pure) at ×200 (b). Approximal surface of another restoration with a non-continuous margin ant filling fracture (NCM-FF). Original magnification, ×100 (c). Occlusal surface with a non-continuous margin and an enamel fracture (NCM-EF). Original magnification, ×100 (d).

facial quality between enamel and restorative material was significantly better for the compomer restorations ($p<0.01$). No other significant differences were found between the two restoration types (Tab. III and IV).

Tab. III Percentage (mean ± SD) of continuous margin (CM) of amalgam and compomer restorations at different sites (axial, cervical and occlusal margins)

Site	Amalgam	Compomer
Axial Enamel	14.8±3.2	32.7±12.3
Cervical enamel	54.0±6.7	34.6±7.8
Occlusal	9.8±8.1	35.5±16.0
Axial	24.2±1.0	16.7±21.9
Cervical Dentin	n.a.	18.7±17.4

Tab. IV Percentages (mean ± SD) of continuous margin (CM), non-continuous margin filling fracture (NCM-FF), non-continuous margin pure (NCM Pure) of amalgam and compomer restorations at the occlusal margin.

Finish Line Localization	Amalgam	Compomer
CM Occlusal	9.8±8.1	35.5±16.0
NCM FF Occlusal	8.6±3.6	3.2±1.7
NCM Pure Occlusal	77.8±7.9	56.7±15.9

Enamel fluoride assessment

Table V shows a split mouth comparison of superficial enamel fluoride content in teeth restored with compomer and amalgam.

No significant differences were found between fluoride content close to amalgam (533 ± 403 ppm fluoride) and compomer restorations (514 ± 268 ppm fluoride). A significantly higher fluoride content was found in the enamel at 5 mm distance from the amalgam restorations (1111 ± 320 ppm fluoride) compared to enamel at the same distance from the compomer restorations (488 ± 147 ppm fluoride, Mann-Whitney U test; $p<0.01$).

Discussion

This study indicates that an observation of one year was not sufficient to stress differences in clinical performance between the materials under investigation. Not until the three year period did the materials show significant differences in clinical behavior. We found a comparable retention rate for both amalgam and compomer during the observation period of 36 months, which is in agreement with Duggal et al. (2002) who observed comparable retention rates for both Dyract and amalgam over a 24-month period. Additionally to clinical observations, exfoliated teeth were collected in our study for analysis of fluoride content and marginal adaptation. Although the proportion of exfoliated teeth was relatively low, some interesting additional information could be gathered.

Tab. V Fluoride content (ppm) in superficial enamel at different distances (1 mm and 5 mm) from the margins of the amalgam and compomer restorations as recorded per individual child.

Child	1 mm distance		5 mm distance	
	Compomer	Amalgam	Compomer	Amalgam
1	385	273	539	861
2	233	443	382	866
3	*	473	432	929
4	734	405	653	**
5	358	1337	284	1560
6	859	268	636	1339
Mean ± SD	514 ± 268	533 ± 403	488 ± 147	1111 ± 320

* Restoration debonded before measurement
** The tooth was too extensively restored

The strength of our study is the direct comparison of both restorative techniques in a split mouth situation. One limitation is the small number of restorations at two- and three-year recall. Hence, the results should be interpreted with caution.

Clinical evaluation

Amalgam exhibited significantly less marginal discoloration at one- and at two-year recall respectively, as compared to compomer.

According to the manufacturer (Dentsply), the bond strength of the compomer using the respective adhesive system is higher to dentin than to enamel. This difference in bond strength may account for the higher discoloration observed at the enamel margins. In accordance with the manufacturer's instructions, no acid etching of the cavity margins was done prior to restoration with Dyract. In accordance with the results of the present study, several authors have reported marginal discoloration with Dyract (Tyas 2000, Demirci et al. 2002, Demirci & Sancakli 2006, van Dijken 1996). However, it might be easier to detect a slight marginal discoloration between two light-colored materials, (e.g. tooth hard tissue and compomer), than between a dark grey material (i.e. amalgam) and dental hard tissue.

Although some discoloration of the compomer was observed at three-year recall, none of the restorations were clinically unacceptable for this reason.

In accordance with our study, Marks et al. (1999) had shown that the color of Dyract restorations after 3 years of clinical service had markedly changed. Other researchers have also reported color change over time for this material (Roeters et al. 1998).

The secondary caries detected in the present study were mostly located at the gingival and proximal margins of the restorations. No significant difference regarding secondary caries was found between amalgam and compomer restorations, which is in accordance with a study by Papagiannoulis et al. (1999). The proposed fluoride release from the compomer was, therefore, not sufficient to prevent formation of secondary caries. Marginal integrity at the cervical margins still remains a challenge also with compomer restorations. A "forgiving effect" compensating for inadequate operative procedures or poor oral hygiene can not be expected through fluoride release.

SEM analysis

SEM evaluation of Class II restorations *in vivo* is uncommon, since the critical cervico-proximal part of the restoration is usually not available for assessment (Kreijci et al. 1994, Cardoy et al. 1997). In our study, replicas were made from exfoliated teeth, which allowed a quantitative SEM analysis of all restoration margins. Fuks et al. (2002) showed that SEM evaluation revealed the highest percentage of defects at the cervical margins, which is in accordance with the present study. In a study by Krämer & Frankenberger (2001) the SEM analysis of surfaces and marginal areas displayed an inferior adhesive performance primarily in proximal areas, which is in accordance with the present study. Differences in proximal and cervical areas were not significant, whereas a higher rate of continuous margins was observed for compomer restorations in the occlusal area compared to amalgam restorations. This effect might have been due to the use of an adhesive system, which has been shown to result in good marginal adaptation in previous studies also (Duggal et al. 2002). Amalgam was used without an adhesive system, thus purely relying on mechanical retention from retentive preparation and mercuroscopic expansion.

Enamel fluoride assessment

Previous studies have shown that compomers release only small amounts of fluoride as compared to fluoride-releasing materials, such as glass ionomer cements (van Dijken et al. 1997). It is well known that fluoride from compomers mostly leaches out within a few weeks after application, resulting in a very low level fluoride release afterwards. A recharging effect by local fluoride applications, as seen with glass ionomer cements, seems to be less probable (Wiegand et al. 2007).

Fluoride enhances the rate of remineralization of dental hard tissues and multiple fluoride treatments on tooth structure with low fluoride concentrations are beneficial (Karantakis et al. 2000). In an *in vitro* investigation it was shown that compomers are less effective in inhibiting adjacent tooth demineralization than glass ionomer cements (Donly & Grandgenett 1998). The results of a study by van Dijken et al. (1997) indicate that the fluoride concentration released *in vivo* from a restoration after one year of clinical service is not high enough to affect the plaque levels adjacent to restorations.

In our study no significant difference was found between fluoride content close to amalgam or compomer restorations. However, a significantly higher fluoride content was found in the enamel at 5 mm distance from the amalgam restorations. A change in fuoride content of nutrition or oral health products could be a possible explanation for the significantly higher fluoride content measured in two teeth with amalgam restorations compared to their compomer counterparts, which both exfoliated about three month before the respective amalgam-filled teeth.

Compomer as well as amalgam restorations exhibited a high frequency of secondary caries at cervical and proximal margins. This might confirm the hypothesis that fluoride release from compomer restorations in service is not high enough to prevent formation of secondary caries.

Conclusions

The present results show that both compomers and amalgam restorations had an overall clinically satisfactory performance at three year recall. No difference in fluoride content of enamel adjacent to the respective restorations was detected. The study confirmed that the assessed compomer is a suitable restorative material for class I and class II restorations in primary molar teeth.

Résumé

L'objectif de cette étude est d'évaluer les performances cliniques après trois ans d'un compomère et d'un amalgame sur molaires lactéales, de déterminer la concentration en fluor au niveau de l'émail adjacent après exfoliation.

Vingt patients âgés de 6 à 8 ans ont reçu chacun arbitrairement une restauration au compomère et une restauration à l'amalgame dentaire. Les restaurations sont évaluées au temps 0, à 12, 24 et 36 mois, selon les critères USPHS. La concentration en fluor à 1 et 5 mm de distance des restaurations des 6 paires de dents exfoliées et collectées est déterminée. Des empreintes sont effectuées afin de déterminer l'adaptation marginale à l'aide d'un microscope électronique à balayage (MEB). Au niveau occlusal, les restaurations au compomère présentaient une meilleure adaptation marginale ($p<0{,}01$). Les restaurations au compomère et à l'amalgame ne présentaient pas des concentrations de fluor différentes au niveau de l'émail adjacent et leurs performances cliniques étaient satisfaisantes. Cette étude confirme que le compomère est un matériau de restauration convenable sur des cavités classe I et classe II sur molaires lactéales.

Zusammenfassung

Das Ziel der vorliegenden Studie war es, die klinische Bewährung von Amalgam- und Kompomerrestaurationen in Milchmolaren zu vergleichen. Neben klinischen Kriterien wurde die Randdichtigkeit der Füllungen und der Fluoridgehalt des Schmelzes der versorgten Zähne untersucht.

Bei 20 Kindern im Alter zwischen 6 und 8 Jahren wurde je eine Kompomer und eine Amalgamfüllung gelegt. Die Füllungen wurden direkt nach dem Legen, sowie nach 12, 24 und 36 Monaten mit Hilfe modifizierter USPHS Kriterien klinisch untersucht.

Nach Zahnverlust konnten sechs Paar restaurierter Zähne gesammelt werden. Deren Fluorid-Gehalt wurde im Abstand von 1 mm und 5 mm vom Restaurationsrand bestimmt. Replika wurden angefertigt und die Randdichtigkeit im Rasterelektronenmikroskop bei 200-facher Vergrösserung untersucht.

Die marginale Adaptation der okklusalen Füllungsränder war bei Kompomerrestaurationen signifikant besser als bei Amalgamfüllungen ($P<0{,}01$). Es wurden weder signifikante Unterschiede im Fluoridgehalt des Schmelzes noch in der klinischen Qualität zwischen Kompomer und Amalgamrestaurationen gefunden. Die klinischen Auswertungen zeigten eine akzeptable Qualität der untersuchten Restaurationen. Die Resultate der Studie bestätigen, dass Kompomere als Alternative zu Amalgamfüllungen in Milchmolaren empfohlen werden können.

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