

# Clinical evaluation of a polyacid-modified resin composite (compomer) in Class II restorations of primary teeth: a two-year follow-up study

L. Papagiannoulis, DDS, MSc, DO A. Kakaboura, DDS, DO F. Pantaleon, DDS K. Kavvadia, DDS, MDentSc, DO

*Dr. Papagiannoulis is Professor, Department of Pediatric Dentistry, Dr. Kakaboura is assistant professor, Department of Restorative Dentistry, Dr. Pantaleon is private practitioner, and Dr. Kavvadia is lecturer, Department of Pediatric Dentistry; they are all at the University of Athens-Greece.*

## Abstract

**Purpose:** The aim of the study was to assess the clinical performance of a compomer restorative material (Dyract, DeTrey/Dentsply) for the restoration of Class II cavities, extended into dentin in primary teeth.

**Methods:** The sample of the study consisted of 25 patients with 68 restored cavities. The restorations were evaluated with the modified Ryge criteria at baseline and after 6, 12 and 24 months. Examination was clinical, radiographic, and observation of cast replicas under scanning electron microscope (SEM).

**Results:** After 24 months, 100% of the restorations were retained, 3% presented bulk fractures, and 6% developed secondary caries at cervical margins. After 24 months, there was a significant reduction in marginal integrity while there was only slight change in anatomic form. Proximal contact was defective in 6% of the restorations and 8% showed marginal discoloration. SEM evaluation revealed a generalized occlusal and scattered marginal wear with no marginal gaps.

**Conclusion:** The compomer presented acceptable clinical performance in Class II restorations of primary teeth after 24 months in service. (*Pediatr Dent* 21:232-235, 1999)

Recent developments in dental materials technology offers a new category of light cured resinous restoratives, the polyacid-modified resin composites, known as compomers. These are resin composites containing acid-modified monomers and basic glass filler particles<sup>1</sup> which in an aqueous environment absorb water and undergo a slow rate diffusion-driven acid-base reaction, leading to a salt formation gradient at the uppermost material surface.<sup>2</sup> Compomers demonstrate improved physical, chemical and mechanical properties, and better wear resistance than traditional, reinforced and resin-modified glass ionomers<sup>3,4</sup>, but are still inferior in these properties compared to conventional resin composites.<sup>5</sup> Nevertheless, compomers were introduced for the treatment of Class I and Class II lesions in the primary dentition due to the fluoride releasing potential, the bonding capacity with enamel and dentin, without the need of acid etching, and the simple handling properties.

A limited number of clinical studies of the efficiency of compomers in restoring Class I and II carious lesions in primary teeth has been published with contradictory findings.<sup>6-8</sup>

The aim of the present study was to evaluate the performance of a compomer restorative material in Class II restorations in primary molars, based on clinical assessment, radiographic examination and indirect evaluation criteria.

## Methods

Twenty five children six to nine years old (7.5 years mean age), in a private pediatric dentistry practice participated in this clinical study. The purpose and the clinical procedure of the study were explained and parental consent forms were completed. The children were under a preventive program including diet consultation, oral hygiene instructions, topical fluoride applications, and recall every six months. The children selected for the study had primary carious lesions extending into dentin, in vital first or second primary molars, requiring Class II restoration. A total number of 68 lesions, 46 in first and 22 in second molars, were treated. No more than four compomer restorations were placed per patient, divided one per quadrant with the antagonist teeth being intact or restored with amalgam.

The compomer restorations were placed by two experienced pediatric dentists under a strict protocol. A pilot study was performed for inter-operator calibration regarding case selection, cavity preparation and filling procedure of the material. All restorations were placed under rubber dam isolation. Carious dentin was removed and a conventional Class II cavity design according to Black's principles was used. The buccolingual width of the cavities was one third to one half of the inter-cuspal distance and the gingival wall was placed above the cemento-enamel junction. Enamel margins were not beveled. Contoured stainless steel matrix bands and wooden wedges were used. In a few deep cavities, a small amount of a calcium hydroxide liner (Dycal, DeTrey/Dentsply, Konstanz, FRG) was applied at the axial and/or pulpal cavity walls. Dyract PSA Primer/Adhesive and Dyract restorative (DeTrey/Dentsply, Konstanz, FRG) were used to restore the cavities.

The primer was placed according to the manufacturer's instructions. The restorative material was applied in two incremental layers; the first layer filled the proximal box, while the second layer filled the rest of the cavity. Each layer was photopolymerized for 40 seconds with Elipar Visio II unit

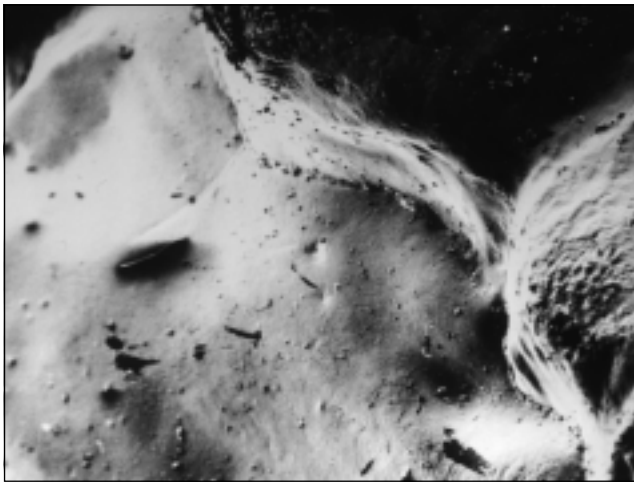


Fig 1. Occlusal surface of a restoration demonstrating marginal wear (six-month examination, secondary electron image (SEI), 100x).

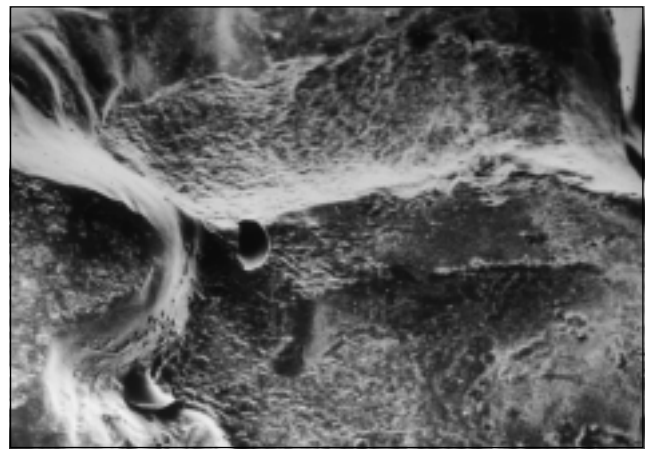


Fig 2. Occlusal wear of a restoration and micro-fractures on the surface (12-month examination, SEI, 40x).

(ESPE GmbH, Seefeld, FRG) emitting 650 mW/cm<sup>2</sup> light intensity as measured with a curing radiometer (Model 100, Demetron Research Corp., Danbury, CT). Following removal of the matrix band and wedge, the buccal and lingual margins of the proximal box received 40 seconds additional photopolymerization. The restorations were finished using 12-fluted carbide finishing burs (Jet Beavers, Morrisburg, Ontario, Canada) under water-spray and polished with the Enhance System (L.D. Caulk/Dentsply Int., Milford, DE, USA).

Evaluation of the restorations was performed at baseline (one week post insertion) and after 6, 12, and 24 months by two independent calibrated evaluators. When disagreement between the two evaluators occurred, a consensus was obtained. Evaluation included clinical assessment, bitewing radiographic examination, and indirect evaluation of representative cast replicas, randomly chosen at each recall.

The clinical assessment was based on modified Ryge criteria<sup>9</sup> to assess retention, bulk fracture of the restorative material, anatomic form, marginal integrity, proximal contact, marginal discoloration, secondary caries, and post-operative sensitivity. The radiographic examination was performed at baseline, 12 months, and 24 months, to evaluate the presence of secondary caries. For anatomic form, marginal integrity, proxi-

mal contact, and marginal discoloration the restorations were rated as A=indicating a clinically ideal condition, B=indicating an acceptable condition, and C=indicating an unacceptable condition considered as failure. Retention, bulk fracture post-operative sensitivity and secondary caries were ranked as A or C corresponding to the absence or presence of these criteria.

For the indirect investigation of the cast replicas, impressions were taken from representative restorations at baseline, 6, 12, and 24 months with a polyvinylsiloxane impression material (Reposil HF, DeTrey/Dentsply, Kostanz, FRG) and epoxy replicas (Araldit, Ciba-Geigy, Basel, Switzerland) were produced. The replicas were gold coated and the occlusal surfaces were subjected to qualitative examination regarding wear and marginal integrity, under a scanning electron microscope (SEM, 515 Phillips, Eindhoven, The Netherlands).

The results of the clinical assessment of the restorations were subjected to statistical analysis by  $\chi^2$ -test at a 95% level of significance.

## Results

All 68 original restorations (100%) were evaluated at six months, 64 restorations (94%) were examined at 12 months, and 55 (81%) were examined at 24 months. Five out of thirteen restorations not available for examination at 24-month recall, were on teeth naturally exfoliated and eight restorations

Table 1. Results From the Clinical Assessment of the Restorations

Criteria	Baseline			6-months			12-months			24-months		
	A	B	C	A	B	C	A	B	C	A	B	C
Retention	100%	0%	0%	100%	0%	0%	100%	0%	0%	100%	0%	0%
Bulk Fracture	100%	0%	0%	100%	0%	0%	100%	0%	0%	97%	0%	3%
Anatomic form	100%	0%	0%	81%	19%	0%	62%	38%	0%	61%	39%	0%
Marginal integrity	100%	0%	0%	80%	20%	0%	56%	44%	0%	56%	44%	0%
Approximal contact	100%	0%	0%	97%	3%	0%	94%	6%	0%	94%	6%	0%
Marginal discoloration	100%	0%	0%	100%	0%	0%	93%	7%	0%	93%	7%	0%
Secondary caries	100%	0%	0%	100%	0%	0%	94%	0%	6%	94%	0%	6%

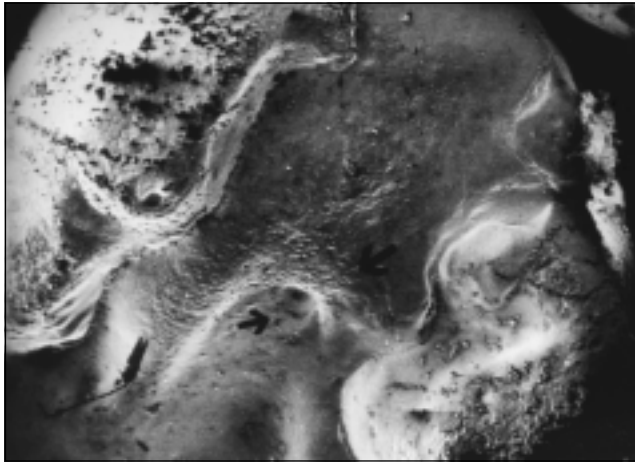


Fig 3a. Localized wear on occlusal surface at six-month examination (arrows) (SEI, 150x).

were on patients not available for examination. Results from the clinical assessment are summarized in Table 1.

All of the restorations were retained and were still in function after 24 months. Bulk fractures at the isthmus occurred in 3% of the restorations. Anatomic form showed slight evidence of change in 38% of the restorations and this occurred between the 6-month and 12-month periods. After 24 months there was a significant reduction in the marginal integrity with 44% of the restorations having some crevice formation.

Proximal contact was defective in six percent of the restorations, and 8% showed some marginal discoloration. Six percent of the restorations exhibited secondary caries at 24 months as determined by clinical and radiographic examination. In all cases, secondary caries developed adjacent to cervical margins. None of the patients complained of post-operative sensitivity.

The overall failure rate was calculated as the percentage of restorations requiring replacement due to secondary caries or bulk fracture relative to restorations evaluated at each recall. Failure rates were 0% after 6 and 12 months and 10% at 24. Failure rates were evenly distributed among operators and occurred similarly in first and second primary molars.

The indirect evaluation of restoration replicas by SEM revealed characteristic wear patterns at the time intervals tested. Some degree of scattered marginal wear of restorations was noted at six months (Fig 1). However, many restorations after 12 and 24 months in function were characterized by generalized occlusal wear and surface micro-fractures with no evidence of porosity (Fig 2). Localized wear at occlusal contact areas was presented in few restorations at the six-month examination but this finding was not observed at 12- or 24-month recalls (Fig 3a and 3b). Despite the pronounced marginal wear documented, no marginal gaps were found in the restoration replicas examined under the SEM.

## Discussion

Polyacid-modified resin composites (compomers) have been introduced as restorative materials for the conservative restoration of primary teeth based on the results of control clinical trials.<sup>1</sup> Although the results from clinical studies may not express the clinical performance of restorations placed by general practitioners, these studies show the potential of a restorative material for specific clinical applications and reveal the main causes of restoration failures.<sup>10</sup>

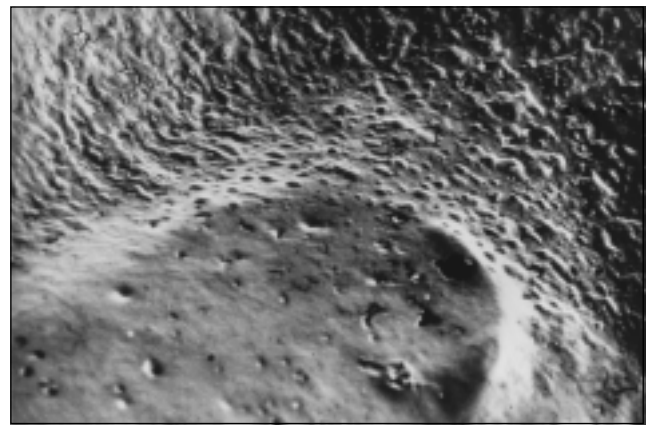


Fig 3b. Higher magnification of the region denoted by the arrows (SEI, 150x).

The 10% failure rate found in this study for compomer restorations compares well with the 9% overall failure rate reported for amalgam restorations in primary teeth, of children aged 6-9 years old.<sup>11,12</sup> A higher retention rate found in compomer restorations relative to conventional glass-ionomer (14-23%) and cermet-cements (32-41%),<sup>11,13-15</sup> is attributed possibly to a reduction in the fracture prevalence of compomers. For resin composite restorations in primary teeth, great variety in the failure rates have been reported (6-17%),<sup>10,12,16</sup> which do not allow for a reasonable comparison. Rate comparisons show that a relatively high retention rate was obtained with the compomer restorative.

The cavity design used in the present study followed Black's principles which may explain the high retention rates obtained. The influence of the cavity design on the survival rate of compomer restorations has not yet been evaluated. Peters et al.<sup>6</sup> reported failures only in compomer restorations placed in adhesive cavities after one year in service. However, in the study of Andersson-Wenckert et al.<sup>7</sup> a 22% failure is reported which may be associated with the minimal mechanical retention of the adhesive type of cavities prepared compared to cavities designed according to Black's principles.

The fractures of the restorations at the isthmus observed in the present study may be explained by the lower fracture toughness of compomers compared to resin composites and amalgam.<sup>17</sup> Therefore cavity design incorporating a shallow cavity with narrow isthmus should be avoided.

Although examination of restoration replicas revealed marginal wear leading to crevice formation and exposure of the cavity walls along occlusal margins, there was no evidence of secondary caries. The absence of secondary caries in restorations at 12-month recall, compares with the findings of Peters et al.<sup>6</sup> who reported only 1% recurrent caries incidence after one year. The absence of secondary caries at the occlusal margins may be related to the lack of marginal gaps. The secondary caries detected in this study was exclusively located at the gingival margins of the restorations. Thus, the marginal integrity at the cervical margins still remains a challenge with compomer restorations.

The compomer tested showed lower secondary caries incidence development than amalgams (9%) and cermet cements (9%), but higher than conventional glass-ionomers (4%).<sup>10,12</sup> For resin composites, a 6% recurrent caries rate has been reported in restorations with gingival margins placed on enamel.<sup>12</sup>

In another study,<sup>18</sup> 0.7% of secondary caries incidence has been reported for resin composite restorations but the location of the cervical margins was not defined.

The high frequency of recurrent caries in compomer restorations reported by Andersson-Wenckert et al.<sup>7</sup> may indicate operator and or technique problems since these restorations were performed by many operators without the use of a rubber dam.

The most common problems associated with the clinical performance of compomer restorations were loss of anatomic form and loss of marginal integrity. In both these criteria, compomers were found inferior compared to amalgam<sup>12,19,20</sup> and resin composite<sup>12,16</sup> for Class II restorations. This finding may reflect the influence of the lower wear resistance of compomers compared to amalgams and resin composites as documented in vitro.<sup>21</sup> Replica examination by SEM showed that loss of anatomic form and marginal integrity were attributed to occlusal surface wear. The lower rates in loss of anatomic form and marginal integrity found in compomer restorations in comparison with conventional glass-ionomer and glass cermet cements may be related to improved elasticity of compomers and less susceptibility to wear.<sup>4,5</sup>

A gradual reduction in the number of restorations with clinically excellent margins was noted within the evaluation period; while the loss of anatomic form was stabilized from 12 to 24 month period. This latter finding may be attributed to a functional wear occurring in the primary dentition that developed during the examination period of the study.

The results on marginal integrity at 12-month recall are consistent with the findings of Peters et al.<sup>6</sup> However in the present study only 38% of the restorations presented changes in anatomic form which is much lower than that reported in the aforementioned study. A possible explanation is the lower intensity (450 mW/cm<sup>2</sup>) of the light unit used in that study which may account for this difference.

Regarding the marginal integrity problems found in the present study, only a low percentage of restorations demonstrated marginal discoloration. The main contributing factor causing marginal discoloration is small fractures. Resin composite restorations in primary teeth demonstrated a higher rate of marginal discoloration<sup>16,19</sup> than the compomer examined except for the study by Barr-Agholme et al.<sup>12</sup> who reported a substantially higher percentage.

## Conclusions

1. The commercially available compomer tested performed very well in restorations of Class II cavities of posterior primary teeth, prepared according to Black's principles, after a two-year observation period.
2. The survival rate after 24 months in function was comparable with the results of clinical studies regarding the use of other materials for the restoration of primary teeth.

## References

1. Lutz F: State of the art of tooth-colored restorations. *Oper Dent* 21:237-248, 1996.
2. Eliades G, Kakaboura A, Palaghias G: Acid-base reaction and fluoride release in visible light-cured compomer restoratives. *Dent Mater* 14:57-63, 1998.
3. Blackwell G, Kase R: Technical characteristics of light curing glass ionomer and compomer. *Proceedings of Confer-*

ence on Clinically appropriate alternatives to amalgam. Biophysical factors in restorative decision making. *Trans Acad Dent Mater* 9:77-88, 1996.

4. Kuzelmann K: Glass ionomer cements, cermet cements, hybrid glass ionomer and compomers. Laboratory trials-wear resistance. *Proceedings of Conference on Clinically appropriate alternatives to amalgam. Biophysical factors in restorative decision making. Trans Acad Dent Mater* 9:89-104, 1996.
5. Powers J, and Burgess J: Performance standards for compative dental restorative material. *Proceedings of Conference on Clinically appropriate alternatives to amalgam. Biophysical factors in restorative decision making. Trans Acad Dent Mater* 9:68-76, 1996.
6. Peters T, Roeters J, Frankenmolen F: Clinical evaluation of Dyract in primary molars: 1-year results. *Am J Dent* 9:83-87, 1996.
7. Andersson-Wenckert, Folkesson UH van Dijken JW: Durability of a polyacid-modified composite resin (compomer) in primary molars. A multicenter study. *Acta Odont Scand* 55:255-260, 1997.
8. Vulicevic Z, Beloica D, Vulovic N: A clinical trial of the compomer system. *J.D.R.* 76:165, Abs 1211, 1997.
9. Ryge G: Clinical criteria. *Int Dent J* 30:347-358, 1980.
10. Kilpatrick NM: Durability of restorations in primary molars. *J Dent* 21:67-73, 1992.
11. Hickel R, Voss A: A comparison of glass cermet cement and amalgam restoration in primary molars. *J Dent Child* May-June:184-188, 1990.
12. Barr-Agholme M, Oden A, Dahllof G, Modeer T: A two-year clinical study of light-cured composite and amalgam restorations in primary molars. *Dent Mater* 7:230-233, 1991.
13. Walls AW, Murray JJ, McCabe JF: The use of glass polyalkonate (ionomer) cements in the deciduous dentition. *Br Dent J* 165:13-17, 1988.
14. Forsten L, Karjalainen S: Glass ionomers in proximal cavities of primary molars. *Scand J Dent Res* 98:70-73, 1990.
15. Kilpatrick NM, Murray JJ, McCabe JF: The use of reinforced glass ionomer cement for the restoration of primary molars: a clinical trial. *Br Dent Res* 179:175-179, 1995.
16. Oldenburg TR, Vann J, Dilley D: Composite restorations for primary molars: two year results. *Pediatr Dent* 7:96-103, 1985.
17. Kerby RE, Knobloch L, Berlin J, Lee J: Fracture toughness of glass ionomer and resin-based restorative materials. *J Dent Res* 76(SI):317 Abs 2425, 1997.
18. Roberts MW, Moffa JP, Broring CL: Two-year clinical evaluation of a proprietary composite resin for the restoration of primary posterior teeth. *Pediatr Dent* 7:14-18, 1985.
19. Tonn EM, Ryge G: Clinical evaluation of composite resin restorations in primary molars: a four year follow-up study. *JADA* 117:603-606, 1988.
20. Roberts JF, Sheriff M: The rate and survival of amalgam and performed restorations placed in a specialist paediatric dental practice. *Br Dent J* 169:237-244, 1990.
21. Attin T, Vataschki M, Hellwig E: Properties of resin-modified glass-ionomer restorative materials and two polyacid-modified resin composite materials. *Quintessence Int* 27:203-209, 1996.