

# Durability of a polyacid-modified composite resin (compomer) in primary molars

## A multicenter study

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A polyacid-modified composite resin (compomer) restorative material was evaluated in primary molars in a multicenter study. One hundred and fifty-nine class-II restorations were placed by 6 dentists in 79 children. The restorations were evaluated during a 2-year period, using slightly modified USPHS criteria. After 1 year 151 restorations were evaluated and, after 2 years, 104. The cumulative failure rate after 1 year was 8% and after 2 years, 22%. The main reasons for failure were loss of retention (12%) and secondary caries (5%). The compomer material showed a high failure rate, comparable to that of other adhesive restorative materials currently used in primary molars. A large operator variation in failure rate indicates the technique sensitivity of the material. □ *Clinical study; deciduous dentition; dental materials; resin composite*

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Conventional glass ionomer cements (GIC) show potentials that make them very attractive as dental restorative materials. They adhere to enamel and dentin, enabling minimal removal of sound tooth substance. The cements act as a fluoride reservoir, releasing and absorbing fluoride, and show high biocompatibility. Disadvantages are sensitivity to technical handling and progressive degradation in an acidic environment. Their poor mechanical properties have restricted their use in loaded areas (1).

Because of the limited functional time of primary teeth, GIC has been used for some years in class-II restorations in this dentition. Large variations in survival times have been reported—in most cases shorter than for amalgams or resin composite restorations (2). A previously reported clinical evaluation of conventional GIC restorations showed a failure rate of 25% after 3 years. The main reasons for failures were isthmus fractures, loss of restoration, and progressive proximal dissolution (3).

Mathis & Ferrance (4) reported in 1989 on an experimental resin-modified GIC with improved properties. The first commercial resin-modified GICs were introduced as lining and base materials but were later modified to be used as restoratives. They are marketed in liquid-powder form, and the maximum light-curing depth of the mixed material is limited to 2-mm layers. Consequently, renewed mixing is necessary when the material is used in deeper cavities. To avoid this, one manufacturer introduced in 1991 a new one-paste restorative material as a compomer. It contained a radiopaque fluoro-silicate glass in a matrix of acidic polymerizable monomers but in insufficient amounts to

promote an acid-base reaction (5). Subsequently, McLean et al. (6) proposed that it be classified as a polyacid-modified composite resin. The material has good handling characteristics and color matching (7). The restorative system contains a self-etching primer, which is used as coupling agent. This primer contains PENTA, an ester of phosphoric acid, and adhesion-promoting monomers in acetone solvent. According to the manufacturer, the self-etching primer conditions the tooth tissues and penetrates the enamel and dentin. The decalcified smear layer is not rinsed away as in other bonding systems. A hybrid layer is formed, creating a micromechanical bond to the tooth tissue (8). Adhesion of the restorative material to the tooth is also claimed by the manufacturer to be obtained through ionic bonds between the hydrophilic phosphate groups of the PENTA and the calcium of the hydroxyapatite. Further adhesion is thought to be achieved through the hydrophilic TCB monomer (a reaction product between butane tetracarboxylic acid and 2-hydroxyethyl methacrylate (HEMA)) present in the restorative.

Attin et al. (9) reported physical properties for the compomer similar to those of resin composites. In vitro evaluations have shown high enamel and dentin bond strengths (10, 11). These findings were confirmed by results of a short-time clinical class-V abrasion/erosion study (12). The reported characteristics of the compomer and the simplified bonding system suggest that it should be used as an alternative material in primary molars.

The aim of this study was to evaluate, in a multicenter study, the clinical durability of a polyacid-modified composite resin (compomer) in class-II restorations in primary molars.

## Materials and methods

Seventy-nine children with a mean age of 8 years (range, 5–12 years), attending five Public Dental Health Clinics in or in the vicinity of the city of Umeå, Sweden, participated in the study. All children needing proximal restorations in primary molars and attending the clinics during the time of the study were invited to participate. Teeth that were judged to be close to exfoliation were excluded. After information about the study and parental consent, the restorations were made with a new compomer material, K71, later marketed under the name of Dyract (DeTrey/Dentsply, Konstanz, Germany). The term Dyract will be used hereafter. A total of 159 proximal restorations in deciduous molars were placed, 114 (72%) because of primary caries and 45 (28%) as replacements, in most cases of failed GIC restorations. Six experienced dentists who had been instructed about the operative procedure before the start of the study performed the treatments.

The cavity form was determined by the extent of decay and/or the shape of an earlier failed restoration. External angles were rounded. A total of 144 (91%) cavities were classified as microcavities, and 15 (9%) as cavities with occlusal extension. The operation field was isolated with cotton rolls and a saliva ejector. A steel matrix band was applied around the tooth and wedged. The tooth was cleaned with liberal water spray. In the case of contamination with blood, a surface-active cavity cleanser containing 0.2% ethylenediaminetetraacetic acid (EDTA) (Tubulicid-blue, Dental Therapeutics Ltd, Ektorp, Sweden) was used for 10 sec to optimize the effect of the self-etching primer (13). In a few cavities, small amounts of calcium hydroxide cement (Dycal, DeTrey/Dentsply) were applied to the pulpal wall.

Dyract primer, PSA Prime/Adhesive, was applied to dentin and enamel for 10 sec; surplus was removed with gentle air flow, and the primer light-cured for 20 sec. A

second layer of primer was then applied and at once cured in the same manner. The cavity was immediately filled with the one component restorative—in large cavities in layers of 2 mm—and light-cured for 40 sec per layer. Occlusion was then checked. Finishing under liberal water spray was done at the same visit, and no surface protection was applied.

## Evaluation

The quality of the restorations was evaluated in accordance with slightly modified USPHS criteria (14, 15) (Table 1) at base line and after 1 year and 2 years or until exfoliation or failure. The six dentists were instructed in the criteria for evaluation before the start of the study. A calibration exercise was done before the 2-year evaluation. Most of the restorations were assessed at 2 years by two dentists independently, without knowledge of earlier assessments. In case of different scores, the restoration was re-evaluated, and a joint scoring agreed on. If a primary molar had exfoliated or been extracted between the first and second year, the assessments at the last examination were valid. Teeth exfoliated or extracted during the 1st year of the study were excluded.

The caries activity of the participants was estimated on radiographs. This was done by registration of new carious lesions on the proximal surfaces of primary and permanent molars between base line and 2 years (16).

## Statistical analysis

Descriptive statistics were used in describing the durability of the tested restorative material by cumulative failure rates. The correlation between the estimation of caries activity of the participants (number of new proximal lesions) and their secondary caries increment contiguous with the experimental restorations was tested with Pearson's correlation test.

Table 1. Criteria for clinical evaluation

Category	Score		Criteria
	Acceptable	Nonacceptable	
Retention	0		Restoration intact
	1		Restoration partly lost; fracture of the material
		2	Restoration totally lost
Anatomic form	0		The anatomic form of the restoration is intact
	1		Small loss of anatomic form; replacement is not necessary
		2	Gross change in anatomic form; replacement is necessary
Marginal adaptation	0		Restoration is continuous with existing anatomic form; explorer does not catch
	1		Explorer catches; no crevice is visible into which explorer will penetrate
	2		Crevice at margin; enamel exposed
		3	Obvious crevice at margin; dentin or base exposed
		4	Restoration mobile, fractured, or missing
Caries	0		No evidence of caries
	1		Superficial secondary caries of the enamel
		2	Secondary caries of the dentin

Table 2. Total number of evaluated restorations, restorations in exfoliated and extracted teeth, and dropouts for other reasons at the recalls

	Evaluated restorations, <i>n</i>	Exfoliated teeth, <i>n</i>	Extractions for orthodontic reason, <i>n</i>	Extractions for endodontic reason, <i>n</i>	Dropouts for other reason, <i>n</i>
Base line	159				
1 year	151	6		2	3
2 years	104*	27	3	2**	3***

\* All acceptable restorations at the 1-year evaluation minus dropouts.

\*\* One tooth with two very large restorations.

\*\*\* One patient moved. One patient with two restorations failed to turn up for evaluation.

## Results

Of the 159 restorations 151 were evaluated after 1 year and 104 after 2 years. Reasons for dropouts are shown in Table 2. A total of 40 restorations exfoliated or were extracted during the study. The assessment scores (percentages) at the recalls are shown in Table 3.

Twelve restorations failed during the 1st year and 20 between 1 and 2 years. Eighty-four per cent of the failures had been placed in proximal microcavities and 16% in cavities with occlusal extension. Sixteen (50%) of the failures were replacements of previously failed restorations. All teeth that were exfoliated or extracted between the 1- and 2-year evaluation had acceptable scorings at 1 year. Including these teeth with the same scores at the 2-year evaluation will result in a cumulative failure rate of 22%, with an operator variation of from 12% to 35% (Tables 4 and 5). Excluding these teeth will increase the percentage of cumulative failures to 28%.

The numbers and reasons for failure are shown in Table 4. Totally, 14 restorations failed because of secondary caries solely or in combination with a lost or fractured restoration. A total of 18 restorations were lost

during the study. None of the lost restorations had received calcium hydroxide cement as isolation. One restoration was replaced for unknown reasons by another dentist. The three restorations with a marginal adaptation score of 3 owing to marginal fracture were not replaced.

Caries activity could be evaluated on radiographs from 69 of the 79 children. Thirty-six developed two or more proximal lesions. Twelve of these patients developed three or more lesions. Nine of the 14 failed restorations with secondary caries had been placed in patients with two or more new proximal lesions during the study period. The measure of correlation between the caries activity and the individuals' secondary caries frequency was not statistically significant ( $r = 0.14$ ).

## Discussion

Compomers were recently introduced on the market and recommended for class-II cavities in primary teeth. They were presented as an improvement of glass ionomer cements, combining the good bonding proper-

Table 3. Distribution of scores in percentage at recalls for retention, anatomic form, marginal adaptation, and caries

	<i>n</i>	Score 0	Score 1	Score 2	Score 3	Score 4
<b>Retention</b>						
Base line	159	100				
1 year	150*	91	4	5		
2 years	103†	83	7	10		
<b>Anatomic form</b>						
Base line	159	93	7			
1 year	143‡	70	28	2		
2 years	93§	61	36	3		
<b>Marginal adaptation</b>						
Base line	159	95	5			
1 year	151	60	30	4		6
2 years	103†	27	48	10	5	10
<b>Caries</b>						
Base line	159	100				
1 year	151	94	3	3		
2 years	103†	89	2	9		

\* Information missing on one restoration failed because of caries.

† Information missing on one restoration replaced for unknown reason.

‡ Information missing on eight lost restorations.

§ Information missing on 10 lost restorations and 1 replaced for unknown reason.

Table 4. Numbers and cumulative frequencies (percentage) of failed restorations and reasons for failure

Reasons for failure	No. of failures			Cumulative failure rate (%)		
	0-1 year n = 151	1-2 years n = 104	Total	1 year n = 151	2 years n = 148*	2 years n = 116†
Caries	2	5	7	1	5	6
Loss of retention	5	7	12	4	8	10
Caries + loss of retention	3	3	6	2	4	5
Fracture	2	—	2	1	1	2
Fracture + caries	—	1	1	—	1	1
Poor marginal adaptation (score 3)	—	3	3	—	2	3
Unknown reason	—	1	1	—	1	1
Total	12	20	32	8	22	28

\* Including exfoliated and extracted teeth with acceptable scorings at the 1-year examination.

† Excluding exfoliated and extracted teeth.

Table 5. Number of restorations, failure rate after 2 years, and mean age of patients for each of the participating dentists

Dentist	No. of restorations	Cumulative failure rate (%)	Mean age of patients (years)
1	39	23	7.4
2	29	21	8.1
3	24	35	7.4
4	18	22	8.5
5	25	12	7.4
6	13	15	8.5
Total	148		

ties and fluoride release of the cements with the better mechanical and physical properties of the resin composites. Easier handling characteristics and good esthetics have led to an immediate high popularity and widespread use in spite of the lack of long-term evaluations. Only two longitudinal studies concerning primary teeth have been published. Peters et al. (17) reported a low failure rate of 3% after 1 year for Dyract restorations in primary molars. The same group evaluated 78 restorations after 2 years and reported 4 fractures (5%) and 2 superficial secondary caries lesions (18, 19). Krejci et al. (20) reported no failures after 6 months for 29 class-II restorations. As stated by Lambrechts et al. (21) and Roulet & Lösche (22), results from controlled clinical studies may not be generalized. In a multicenter study different background factors influence the results. The failure rate in this study of approximately 20% after 2 years was considerably higher than in the controlled studies. Several general practitioners were involved, reflecting better the everyday performance of the restorative. Working conditions were not always optimal. Patient groups, cavity forms, and technical handling of the restorative material may have varied to some extent in spite of careful instructions before the start of the study. Restorative materials like resin composites, compomers, and GIC require careful handling during application and rely on micromechanical bonding and/or adhesion to the tooth for retention. The materials are therefore more technique-sensitive than amalgams, which is reflected in the

large operator variation in the failure rate in this study, from 12% to 35%.

The most frequent reason for dropout in this study was exfoliation of the restored teeth. Exfoliated teeth and teeth extracted for reasons not immediately related to the restorative material pose a particular problem in clinical evaluations in the mixed dentition. Including or excluding these teeth will under-/over-estimate, respectively, the failure rate in the calculation of the results. Both methods are used in the literature when evaluating restorations in primary teeth (23-26). The true failure rate in this study will probably be found closer to the lower failure rate.

The main reason for failure was loss of retention. The high frequency is not in agreement with earlier reports of bond strength and clinical retention of compomer restorations (10-12, 17-20). Clinical loss of restorations may be caused by factors like insufficient adhesion of the material to tooth substance, inadequate handling, moisture contamination, or caries.

There may be several reasons for insufficient adhesion. The bonding mechanism of the self-etching primer is not fully clear. The self-etching primer systems generally produce a shallower depth of demineralization, if any, than systems with a separate etching agent. Eick et al. (27) found that the dentin was wetted but not penetrated with this primer system, resulting in a low bond strength. It has therefore been proposed that etching of the enamel with phosphoric acid will improve the retention and sealing ability of the compomer (28). At the start of this study a primer application time of 10 sec for the first layer was recommended by the manufacturer. Today the recommended time is 30 sec. The shorter conditioning time may have resulted in insufficient hybrid layer formation and weak micro-mechanical retention. Insufficient adhesion will also occur if the carrier agent of the primer is allowed to evaporate before application in the preparation.

Not using rubber dam may increase the risk of moisture contamination, which results in a decreased adhesion. Rubber dam was not used in this study because it is not routinely used in daily practice by the

participating clinicians for restorations in primary teeth. However, Peters et al. (17), who showed a very low failure rate for Dyract restorations in their controlled clinical study, did not use rubber dam either.

A pressed working situation of the general dentists participating can also lead to inadequate adaptation due to imperfect handling of the material. Difficulties in inserting the material into narrow cavities can lead to inclusion of air. Inadequate curing time or layer thickness exceeding the recommended 2 mm leads to incompletely cured material at the bottom of the restoration, which results in decreased bond strength. According to Attin et al. (9), a continuous decrease in microhardness is seen at increasing layer thickness of compomer material.

Finally, in class-II restorations in primary molars with little mechanical retention, the bite force might exceed the adhesion. During in vivo wear a gradually decreasing bond strength may be caused by hydrolytic degeneration and bite forces. This is especially true in children with bruxism and a possible reason for loss of some restorations.

Loss of restoration was in this study often found in combination with recurrent caries. Whether caries was a reason for loss of retention or secondary to a partially loosened restoration could not be distinguished.

Recurrent caries is the main reason for failure of amalgam and composite restorations (29–31). Clinical experience and longitudinal evaluations of conventional and resin-modified GIC materials have shown a low frequency of secondary caries (32–38). Recurrent caries was the second reason for failure in this study. The low caries frequency contiguous with GIC materials is probably due to the relatively high fluoride leakage of these materials (39). The compomer shows considerably lower fluoride release than GIC and resin-modified GIC in vitro and in vivo (40–42). This low fluoride release in combination with the number of caries active participants can explain the high number of secondary caries contiguous with the test restorations in this study. In cases with high caries risk, a restorative material with higher fluoride release might, in combination with additional prophylaxis, aid in lowering the risk for secondary caries.

Other restorative materials used in primary teeth have also shown large variations in reported failure rates (2). The reported failure rate after 2 years for amalgam generally varies between 20% and 50% and for composite restorations from 16% to 50% (25, 29, 30, 43, 44). Conventional GIC materials have generally shown failure rates between 20% and 30% after 2 years (3, 26, 43, 45). In a preliminary report Qvist et al. (46), comparing a conventional GIC with a resin-modified GIC, reported failures rate of 27% and 12%, respectively, in class-II restorations in primary teeth after 1½ years. Lower failure rates are usually to be found in controlled prospective studies and higher ones in retrospective field studies.

In conclusion, this study showed a high failure rate of the compomer Dyract after 2 years, although it was comparable to that of most other restorative materials currently used for restorations in primary molars. The large operator variation in failure rate indicates the technique sensitivity of the material.

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