

## Two-year clinical evaluation of a proprietary composite resin for the restoration of primary posterior teeth

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### Abstract

*The objective of this study was to compare the clinical performance of a strontium glass-filled composite resin (Profile®) and an amalgam alloy (Ease®) in primary molars. A total of 111 restorations (61 composite resin, 50 amalgam) were placed in 37 children. The PHS Clinical Rating System was used to evaluate color match, cavosurface marginal discoloration, anatomic form, marginal adaptation, and caries. Sixty per cent of the original composite resin and amalgam restorations were available for examination after 24 months. Ninety-two per cent of the resin restorations matched the surrounding tooth structure and no evidence of cavosurface marginal discoloration was observed in 81% at the conclusion of the study. No loss of anatomic form was seen in 83% of the resins or 87% of the amalgams. Excellent marginal adaptation was found in 92% of the resin restorations as compared to 83% of the amalgams. Only one restoration of each material experienced associated recurrent caries. Over a 24-month observation period, there was no significant difference between the composite resin Profile® and the amalgam alloy Ease in regard to their clinical performance as restorative materials for primary molars.*

An esthetic alternative to amalgam as a restorative material for posterior teeth has been sought for many years. In 1965 the successful introduction of composite resins for the restoration of anterior teeth initially appeared to hold promise for their use in posterior teeth as well.<sup>1,2</sup> However, subsequent long-term observations revealed a high rate of occlusal wear, marginal leakage, and an increase in recurrent caries.<sup>3,4</sup> Nevertheless, interest in the use of composite resins in the primary dentition continues to be intense for several reasons.

Restorations in primary molars do not require as

long a clinical life, and primary enamel wears at a rate which is similar to that of composite resin. In addition, amalgam restorations have been reported to fail much earlier in primary molars than in permanent posterior teeth (although the newer alloys have shown marked improvement).<sup>5,6</sup>

Recently, several investigators have evaluated the use of composite resin in primary molars.<sup>6,7</sup> Their findings have been contradictory and inconclusive. The differences observed probably were due to the physical properties of the particular composite resin being evaluated.

The objective of this study was to compare the clinical performance of a strontium glass-filled proprietary composite resin<sup>a</sup> and a proprietary amalgam alloy<sup>b</sup> in primary molars.

### Methods and Materials

The selection of children for participation in this study was based upon their need for Class I and Class II restorations in primary molars. A total of 111 restorations (61 composite resin, 50 amalgam) were placed in 37 patients. A rubber dam was used during the placement of all restorations. Standard Class I and II cavities were prepared using a #331 high-speed bur. The cavities were refined with slow-speed burs and the walls planed with hand instruments. The particular restorative material used in each cavity preparation was based on a table of random numbers.

A base of calcium hydroxide<sup>c</sup> was placed in all teeth to be restored with composite resin and when indi-

<sup>a</sup> Profile — S.S. White Dental Products International: Philadelphia, PA.

<sup>b</sup> Ease — L.D. Caulk Co.: Milford, DE.

<sup>c</sup> Improved Dycal — L.D. Caulk Co. Milford, DE.

cated in teeth to receive amalgam. Copal cavity varnish<sup>d</sup> was placed with a small cotton pellet and dried thoroughly prior to alloy insertion. The restorative materials were proportioned, triturated, placed, and finished according to the manufacturer's instructions. All amalgams were polished 48 or more hours after initial placement. The cavity margins of teeth to receive resin were etched with 50% phosphoric acid for 90 sec. After flushing with water for 20 sec, the enamel was dried well and a bonding agent applied to the etched surfaces and allowed to polymerize. A wedged, contoured matrix band was placed if the restoration was multisurfaced. Equal proportions of each paste (base-catalyst) composite resin were mixed and injected into the prepared tooth with a C-R syringe. The restoration was contoured with finishing strips and composite resin finishing burs once polymerization was complete. Final polish was obtained with a rubber cup and 1  $\mu$  diamond polishing compound.

The PHS Clinical Rating System<sup>8</sup> was used to evaluate color match, cavosurface marginal discoloration, anatomic form, marginal adaptation, and caries (Table 1).

The evaluations at the baseline and subsequent yearly intervals were performed independently by two examiners. The baseline evaluation was obtained two weeks after placement and the restorations were re-evaluated 12 and 24 months after insertion.

## Results

At the baseline evaluation, 79% of the composite resin and 78% of the amalgam restorations were judged Class II. The remainder were judged Class I. Eighty-five per cent (52/61) of the composite resin and 82% (41/50) of the amalgam restorations were evaluated at the end of 12 months. After 24 months 60% (37/61) of the composite resin and 60% (30/50) of the amalgam restorations were available for examination. Loss of primary teeth due to exfoliation was the primary reason for the decrease in the examination rate at 24 months (Table 2).

### Color Match (Composite resin only)

Ninety-eight per cent of the composite resin restorations were judged to match the adjacent tooth structure in regard to color (Alpha rating) at the baseline evaluation. Ninety-four per cent of the composite restorations matched at the end of 12 months, and 92% after 24 months. There would appear to be a tendency for the composite resin to change color gradually over time (Table 2).

TABLE 1. PHS Clinical Rating System

Category	Rating	Description
Color Match	Hotel	Metallic restorations- no rating
	Alpha	Restoration matches the adjacent tooth structure in color and/or translucency.
	Bravo	Mismatch in color and/or translucency is within the normal range of tooth color and/or translucency.
Cavosurface Marginal Discoloration	Charlie	Mismatch in color and/or translucency is outside normal range of tooth color and/or translucency.
	Hotel	Metallic restorations- no rating
	Alpha	No discoloration anywhere on margin between restoration and tooth structure
Anatomic Form	Bravo	Discoloration has not penetrated along margin in pulpal direction.
	Charlie	Discoloration has penetrated along margin in a pulpal direction.
	Alpha	Restoration is continuous with existing anatomic form.
Marginal Adaptation	Bravo	Restoration is discontinuous with existing anatomic form, but missing material is not sufficient to expose dentin or base.
	Charlie	Sufficient material lost to expose dentin or base
	Alpha	Restoration appears to adapt closely to tooth along periphery of restoration. Explorer does not catch when drawn across margins; if it does catch, it will only catch in one direction. No crevice is visible.
Caries	Bravo	Explorer catches, and there is visible evidence of crevice into which the explorer will penetrate; however, dentin or base is not visible.
	Charlie	Explorer penetrates into crevice and dentin or base is exposed.
	Delta	Restoration is fractured, mobile, or missing.
Caries	Alpha	No caries present
	Bravo	Caries present associated with restoration

<sup>d</sup> Copalite — Harry J. Bosworth Co. Skokie, IL.

TABLE 2. Distribution of Ratings

	Alpha	Bravo	Charlie	Delta	Hotel
<b>Color Match</b>					
Baseline					
Profile	60	1	0	0	0
Ease	-	-	-	-	50
12 Months					
Profile	49	3	0	0	0
Ease	-	-	-	-	41
24 Months					
Profile	34	3	0	0	0
Ease	-	-	-	-	30
<b>Cavosurface Marginal Discoloration</b>					
Baseline					
Profile	55	6	0	0	0
Ease	-	-	-	-	50
12 Months					
Profile	44	8	0	0	0
Ease	-	-	-	-	41
24 Months					
Profile	30	7	0	0	0
Ease	-	-	-	-	30
<b>Anatomic Form</b>					
Baseline					
Profile	60	1	0	0	0
Ease	49	1	0	0	0
12 Months					
Profile	44	8	0	0	0
Ease	39	2	0	0	0
24 Months					
Profile	31	6	0	0	0
Ease	26	3	1	0	0
<b>Marginal Adaptation</b>					
Baseline					
Profile	61	0	0	0	0
Ease	50	0	0	0	0
12 Months					
Profile	49	2	0	1	0
Ease	37	4	0	0	0
24 Months					
Profile	34	2	1	0	0
Ease	25	4	1	0	0
<b>Caries</b>					
Baseline					
Profile	61	0	0	0	0
Ease	50	0	0	0	0
12 Months					
Profile	51	1	0	0	0
Ease	41	0	0	0	0
24 Months					
Profile	37	0	0	0	0
Ease	29	1	0	0	0

**Cavosurface Marginal Discoloration** (*Composite resin only*)

Ninety per cent (55/61) of the composite resin restorations showed no evidence of marginal discoloration at baseline. At the 12-month evaluation this had decreased to 85% (44/52), and at 24 months it had further decreased to 81% (30/37). Although there was a gradual increase in the incidence of staining at the margins, there was no evidence that it was of the penetrating variety, Charlie rating (Table 2).

**Anatomic Form**

Eighty-five per cent (44/52) of the composite resin and 95% (39/41) of the amalgam restorations showed no clinical evidence of occlusal wear (Alpha rating) at the end of 12 months. At the 24-month evaluation 83% (31/37) of the resins and 87% of the amalgams were still in the Alpha category (Table 2).

There was no significant difference between the change in anatomic form between the two materials. The probability values were 0.342 and 0.961, respectively, at the 12- and 24-month periods (Chi square test where critical probability should be equal to or less than 0.05, Table 3).

**Marginal Adaptation**

At the 24-month evaluation period, 92% (34/37) of the composite resin restorations showed no deterioration in marginal adaptation (Alpha rating), as compared to 83% (25/30) of the amalgams (Table 2). These differences were not statistically significant ( $p = 0.283$ ). One composite resin was replaced because of fracture. In addition, one each of the resin and amalgam restorations also was scheduled to be replaced because of more severe marginal defects (Charlie ratings, Table 3).

**Caries**

One restoration of each material was diagnosed as having recurrent caries associated with it during the 24-month study. Statistical analysis of the data revealed no significant differences between the two materials in regard to the incidence of caries ( $p = 0.263$ , Table 3).

**Discussion**

The findings in this study do not support previous observations of undesirable clinical properties associated with composite resins and amalgams.<sup>4,5</sup> Color stability and shade match achieved with the composite resin remained high throughout the observation period. The resin used in this investigation is available in four stock shades which enhanced the ability of the operator to match more nearly the surrounding tooth structure.

TABLE 3. Distribution of Changes

	Profile	Ease
<i>Color Match</i>		
Change from baseline to 12 months		
Change	2	Not evaluated
No change	50	Not evaluated
Change from baseline to 24 months		
Change	3	Not evaluated
No change	34	Not evaluated
<i>Cavosurface Marginal Discoloration</i>		
Change from baseline to 12 months		
Change	8	Not evaluated
No change	44	Not evaluated
Change from baseline to 24 months		
Change	4	Not evaluated
No change	33	Not evaluated
<i>Anatomic Form</i>		
Change from baseline to 12 months		
Change	7	3
No change	45	38
Change from baseline to 24 months		
Change	6	5
No change	31	25
Chi Square	p = 0.342 (baseline to 12 months)	
Critical probability $\leq 0.05$	p = 0.961 (baseline to 24 months)	
	No significant difference	
<i>Marginal Adaptation</i>		
Change from baseline to 12 months		
Change	3	4
No change	49	37
Change from baseline to 24 months		
Change	3	5
No change	34	25
Chi Square	p = 0.469 (baseline to 12 months)	
Critical probability $\leq 0.05$	p = 0.283 (baseline to 24 months)	
	No significant difference	
<i>Caries</i>		
Change from baseline to 12 months		
Change	1	0
No change	51	41
Change from baseline to 24 months		
Change	0	1
No change	37	29
Chi Square	p = 0.372 (baseline to 12 months)	
Critical probability $\leq 0.05$	p = 0.263 (baseline to 24 months)	
	No significant difference	

Cavosurface marginal discoloration is indicative of leakage between the resin-tooth interface. The staining observed was superficial and did not appear to penetrate deeply. However, it appeared to increase during the relatively brief 24-month observation period. It was also significant to note that although the primary teeth were acid etched and a bonding agent was employed, cavosurface staining continued to increase. Therefore, marginal percolation still may be a matter of concern with composite resin restorations.

The amalgam restorations exhibited slightly less occlusal wear than the composite resin. However, the incidence of loss of anatomic form was not high in either material. This observation supports the findings of Nelson et al.<sup>6</sup> who postulated that reduced wear was the result either of lighter occlusal forces in the primary dentition or because the adjacent primary tooth enamel wears at a rate similar to the resin material.

Although there was no statistical difference be-

tween the composite resin and the dental amalgam in regard to marginal deterioration, the authors' subjective impression was that the composite resin restorations were less susceptible to marginal breakdown. It would appear that since there was no significant difference in the incidence of caries, nor any difference in the replacement rates of the two materials, any real or apparent differences in the marginal adaptation have minimal clinical significance in the primary dentition.

The results of this study indicate that composite resin can be employed successfully in the restoration of primary molars, particularly in late mixed dentition. However, there are other considerations. The monomer in the composite resin has been suggested as a pulpal irritant which can cause postoperative sensitivity even if a calcium hydroxide base has been placed over the exposed dentin prior to completing the restoration.<sup>10</sup> Interestingly, this sensitivity has not been reported in primary teeth.

Obtaining proper interproximal contact is difficult when using resins because they cannot be packed under pressure and, to a lesser degree, because of polymerization contraction. Forceful prewedging helps minimize this limitation but it remains a concern for the clinician. It has been shown that the gingival response to a well-finished composite resin is satisfactory,<sup>11</sup> but this finish is more difficult to obtain in the gingival portion of a Class II restoration. The creation of occlusal anatomy and a functional occlusion requires the judicious use of carbide finishing burs, discs, and diamond points. Due to the similarity in color between the surrounding enamel and composite resin, it is extremely difficult to remove excess resin without inadvertently grinding away occlusal enamel. The composite resin restoration is also more time consuming to place and complete. Modified cavity designs have shown promise in reducing some of these difficulties.<sup>12</sup>

## Conclusions

There appeared to be no significant difference in the clinical performance of the composite resin Profile when coupled with acid etching and bonding, and the amalgam alloy Ease for the restoration of primary teeth in the two-year observation period of this study. However, the clinician should be aware of the limi-

tations of composite resins. Improved esthetics remains the only true advantage of composite resins over amalgam at this time. Resins with improved physical and mechanical properties are being developed and they may overcome many of the present operational limitations.

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