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Composite restorations for primary molars: results after four years

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Abstract

Two composite resins (Ful-Fil® and X-55®) were placed in the primary molars of 50 children aged 4 to 8 years. A total of 357 restorations were placed in 3 different cavity preparations. The restorations were evaluated by 2 investigators at 0, 6, 12, 24, and 36 months using the USPHS evaluation criteria.

At 48 months 130 restorations were available for evaluation. This represents a recall rate of 36.4%; however, discounting the 169 restorations that were in teeth that exfoliated, the recall rate was 83.3%.

Statistically significant changes occurred in the color match category for both materials as well as the marginal integrity of the X-55 material. All other category changes were not statistically significant.

At 48 months a total of 39 failures had occurred for an overall failure rate of 10.9% (39/357). Seven restorations failed between 36 and 48 months. The failure rate for conventional preparations was 8.2% (9/110), for conventional bevel 6.7% (8/119), and for modified preparations 17.8% (22/128).

Because amalgam exhibits undesirable esthetic qualities and serves as a possible reservoir for the systemic absorption of undesirable mercury (Abraham et al. 1984; Vimy and Lorscheider 1985), investigators have focused their research on the use of composite resin for the restoration of posterior teeth. In 1982 the Council on Dental Materials, Instruments, and Equipment of the American Dental Association accepted revised guidelines for the use of composite resin for Class I and Class II restorations (ADA Council on Dental Materials, Instruments and Equipment 1982). Since then, several clinical studies have been submitted for approval by the ADA. As of May, 1986, 4 composites had been accepted for provisional approval for use in posterior teeth (ADA Council on Dental Materials Instruments and Equipment 1986). In 1986, Ful-Fil® was granted full acceptance for use in primary molar teeth. This study presents the 4-year results of a clinical trial examining the use of Ful-Fil in primary molars. Another experimental resin (X-55®) also was examined in this study.

Literature Review

Mack (1970) was the first to report on the use of composite resin for the restoration of primary molars. He described successful restoration of 2700 tooth surfaces with Adaptic®.[a] Mack did not use accepted criteria for evaluating the restorations but rather stated his impressions of how well the material performed in his practice.

Using USPHS criteria, Nelson et al. (1980) compared the clinical performance of two composites[a,b] and amalgam[c] in primary molars. After 3 years they reported that in 50 pairs of conventional Class II restorations in primary teeth, no significant differences were found in color matching, cavosurface marginal staining, or marginal adaptation. They found amalgam to be superior in anatomic form (wear) but recommended that composite could be used when primary molars would be expected to be functional for 3 years or less. Similar results were reported by Tonn et al. (1980). They placed a composite[d] and amalgam[e] in 137 conventional Class II restorations and found that the restorations compared favorably in all categories except anatomic form where amalgam appeared to be superior.

A 3-year report by Derkson et al. (1984) compared 90 Dispersalloy[c] and 94 Profile[f] restorations. These investigators concluded that 46% of the composite restorations and 80% of the amalgam restorations were

[a] Adaptic—Johnson & Johnson; East Windsor, NJ.
[b] Radio-opaque Adaptic—Johnson & Johnson; East Windsor, NJ.
[c] Dispersalloy—Lee Pharmaceuticals Corp; South Elmonte, CA.
[d] Epoxydent—Lee Pharmaceuticals Corp; South Elmonte, CA.
[e] Optaloy—LD Caulk Co; Milford, DE.
[f] Profile—SS White Dental Health Products; King of Prussia, PA.

clinically acceptable. The primary failure mode of the composite was a result of occlusal wear.

Using the USPHS system for evaluation of 76 Class II Ful-Fil[g] restorations in primary molars, Tonn and Ryge (1985) found that after 24 months the restorations all showed excellent ratings for color match, marginal discoloration, anatomic form, and marginal adaptation. In comparing these results with a previous study on amalgam,[e] they concluded that amalgam exhibited less occlusal wear but poorer marginal adaptation than the composite.

Similar results were obtained in a 2-year report comparing the alloy Ease®[h] and Profile®[f] in Class II restorations in the primary molars of 37 children (Roberts et al. 1985). Marginal adaptation proved to be excellent in 92% of the composite restorations compared to 83% of the amalgam restorations, and wear occurred in only 17% of the composite restorations.

Modified cavity design for composites in primary molars has been addressed in several studies. Leifler and Varpio (1978) reported a high percentage (34%) of composite restoration failures in modified Class II preparations cut with a 0 round bur. Paquette et al. (1983) used a modified preparation wherein only carious enamel and dentin were removed with a round bur with no attempt to develop cavity retention or resistance form. They reported excellent results for this preparation in Class I restorations, but the Class II restoration had an unacceptable failure rate of 17–25%.

In a previous 2-year report evaluating 357 composite restorations in primary molars placed using 2 composites[g,i] and 3 cavity designs, Oldenburg et al. (1985) found that there were no significant statistical changes between materials or cavity preparations after 2 years except in the color match category. They did find an overall failure rate of 6.4% (23/357) with the highest percentage of failures occurring in the modified preparations (11.7%).

At present, there appears to be no standard approach to the conventional cavity preparation for the posterior composite restoration. For example, the clinical trials conducted by Paquette et al. (1983) and Nelson et al. (1980) employed different approaches to the cavosurface bevel. Nelson et al. (1980) did not use the bevel in their study and Paquette et al. (1983) beveled the cavosurface margins of their conventional preparations. Oldenburg et al. (1985) beveled some of their preparations and left others unbeveled. Because the modified cavity design may have implications for retention and marginal leakage and the ultimate success of the restoration, determination of its value is timely and relevant.

[g] Ful-Fil—LD Caulk Co; Milford, DE.
[h] Ease—LD Caulk Co; Milford, DE.
[i] X-55—LD Caulk Co; Milford, DE.

TABLE 1. Physical Properties and Composition of Ful-Fil and X-55

Product Description	*Ful-Fil*	*X-55*
Manufacturer	L.D. Caulk Co.	L.D. Caulk Co.
Particle size (microns)	0.04–10	0.04–10
Filler % (weight)	77.3	76.0
Filler composition	Ba glass SiO	Ba/Li glass SiO_2
Method of polymerization	Visible light	Visible light
Coefficient of thermal expansion (ppm/degree C)	28.1	——
Water sorption (mg/cm^2)	0.7	0.6
Condensable	Yes	Yes

A primary objective of this study was to compare the clinical advantages of beveling conventional preparations for primary molar resin restorations. A beveled modified restoration also was included in this study. Another objective was to examine 2 visible light-cured composite resin materials. Both materials were manufactured for the use in posterior restorations, and their physical properties suggested that the materials might have excellent potential as amalgam substitutes.

Methods and Materials

General Procedures

Children from the Chapel Hill, North Carolina, community participated in this study. In order to be eligible, it was necessary that each child: (1) be 4–8 years of age, (2) not be presently under the care of a dentist, (3) be available for recall appointments every 6 months for a minimum of 3 years, (4) have at least two Class II and/or Class I dental lesions present in primary molars, and (5) be mentally and physically healthy so that no unusual treatment procedures would be necessary. Approximately 225 children were screened and 50 were invited to participate in the study.

At the initial visit a complete health history questionnaire and parental consent form were completed. Hard and soft tissues were examined. A preventive program was initiated including oral hygiene instructions, a toothbrush prophylaxis, and the application of a topical fluoride. Bite-wing radiographs were obtained, as well as a panorex radiograph when appropriate. A treatment plan, including a list of all necessary restorations, was developed at this appointment. Using a table of random numbers, each posterior restoration was assigned 1 of 6 possible combinations of resin/cavity design. Two different resins and 3 cavity designs were used in the study.

Two visible light-cured experimental resins, F-70 and X-55, were used. F-70 has been marketed as Ful-Fil. They contained 0.04–10 μm filler particles and were filled approximately 75–80%. The only difference in the composites was that Ful-Fil contained

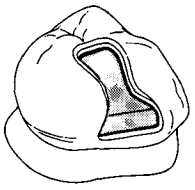
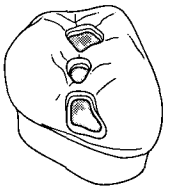




FIG 1 *(left)*. Conventional preparation. FIG 2 *(center)*. Conventional bevel preparation. FIG 3 *(right)*. Modified preparation.

barium glass particles and X-55 used barium-lithium glass particles (Table 1).

The 3 cavity designs were: (1) a conventional conservative preparation, (2) a conventional preparation with a 45° 1 mm occlusal cavosurface bevel, and (3) a modified preparation in which the enamel was removed only for access to decay. The modified preparation also was beveled. The cavity designs are illustrated in Figs 1-3.

A total of 357 composite restorations (137 Class I, 188 Class II, and 32 Class V) were placed in primary molars by 3 experienced operators.

Clinical Technique

All restorations were placed with the aid of local anesthesia and a rubber dam. In most instances the child was treated by the same operator throughout the study to maintain consistent patient behavior. Prior to tooth preparation an interproximal wooden wedge was placed for maximum separation of the teeth; this displaced adjacent teeth and provided a guide for establishing the proper height of the gingival floor. Traditional Class I and Class II cavity preparations were prepared utilizing a #245 bur. For the beveled preparations, a D4P round diamond bur was used to create a 1.0-mm bevel in accessible enamel at approximately 45° to the cavosurface margin. The modified preparations were completed using a #2 round bur. An attempt was made to remove only carious enamel and dentin and no attempt was made to develop cavity resistance and retention form. For the modified preparation, all accessible enamel margins were beveled with the D4P round diamond bur.

Stainless steel matrix bands (0.002 in.) were adapted for all Class II cavity preparations and interproximal wedges were placed to seal gingival margins. A calcium hydroxide base[j] was placed over all exposed dentin. Enamel margins and bevels were etched for 90 sec with a solution of free phosphoric acid (50% by weight). The acid was removed by applying an air-water spray and the tooth was air dried. A bonding agent was distributed over the etched surfaces using a blast of air to prevent pooling in the proximal box area. The bonding agent was cured with the Prisma Lite®[k] prior to placement of the composite resin.

Amalgam condensers were used to adapt the composite to the cavity walls. The resin was placed in 1 increment and polymerized utilizing a Prisma Lite. Polymerization times varied from 20 to 60 sec according to the depth of cure required. Following removal of the wedge and matrix bands, the interproximal areas again were exposed to visible light for 20 sec.

All composite restorations were contoured and finished with fluted carbide finishing burs and finishing strips. Cups and discs[l] with petroleum jelly were used to smooth and polish the surfaces. After removal of the rubber dam, occlusal contact was checked and adjusted when needed.

Evaluation Procedures

Following completion of all restorative treatment, patients returned for a baseline evaluation of each restoration. Direct clinical evaluation of each restoration was completed independently by 2 evaluators using the criteria of the United States Public Health Service (USPHS) system as described by Cvar and Ryge (1970). However, the USPHS system was modified slightly to include a category for clinical evaluation of axial contour.

At baseline, 6, 12, 24, 36, and 48 months each restoration was evaluated in the following categories: color match, marginal integrity, wear, interfacial staining, axial contour, secondary caries, and postoperative sensitivity. Disagreements between evaluators were resolved immediately by consensus. In addition, clinical photographs were obtained at the recall intervals (Figs 4-7).

All evaluation data were recorded on evaluation forms and stored in a computer for tabulation and analysis. For purposes of this study, only the baseline and 48-month data will be presented and discussed. A McNemar's test was used to analyze changes over time from baseline to 48 months. For all other anal-

[j] Dycal—LD Caulk Co; Milford, DE.

[k] Prisma-Lite—LD Caulk Co; Milford, DE.

[l] Shofu Dental Corp; Menlo Park, CA.

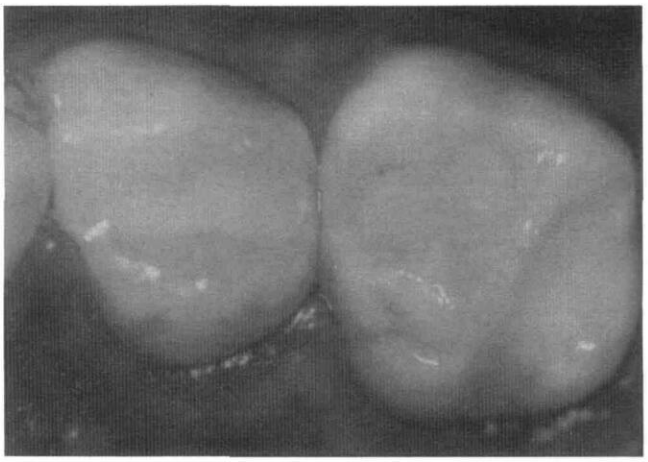


FIG 4. Conventional occlusal preparation restored with Ful-Fil on first primary molar. Conventional bevel preparations, mesio-occlusal and occlusal-lingual on second primary molar restored with Ful-Fil (taken at baseline).

FIG 6. Modified disto-occlusal preparation in first primary molar restored with Ful-Fil. Conventional bevel mesio-occlusal preparation in second primary molar restored with X-55 (taken at baseline).

yses, the Mantel-Haenszel chi-square test was used as the test statistic. An alpha of 0.05 was used as the level of significance for all tests (Fleiss 1981).

Results

Three evaluators participated in the study and all evaluations were conducted by a combination of 2 of those 3. The overall agreement at baseline for all evaluation categories was 99% with all disagreements occurring in the color matching category. At 48 months, the overall agreement for the evaluation categories was 94% with the most disagreements occurring in the color match category with 83% agreement. Color match disagreements were limited to differences between Alfa and Bravos. Agreement for the other categories was: marginal integrity 96%, wear 97%, interfacial staining 94%, and axial contour 100%.

Of the 50 patients treated at baseline, 48 were available at the 48-month recall. At baseline 357 restorations were evaluated and at the 48-month recall 130 restorations were evaluated, including 7 restorations which failed between 36 and 48 months. One hundred sixty-nine restorations were not evaluated because they were in teeth which had exfoliated naturally and 26 restorations were unavailable for recall. Thirty-two restorations had failed previously and were not available for evaluation at 48 months (Table 2). Thus, the 48-month recall rate (including failures) was 36.4% (130/357); however, discounting exfoliated teeth and failures 0–36 months, the recall rate was 83.3% (130/156). The successful restorations evalu-

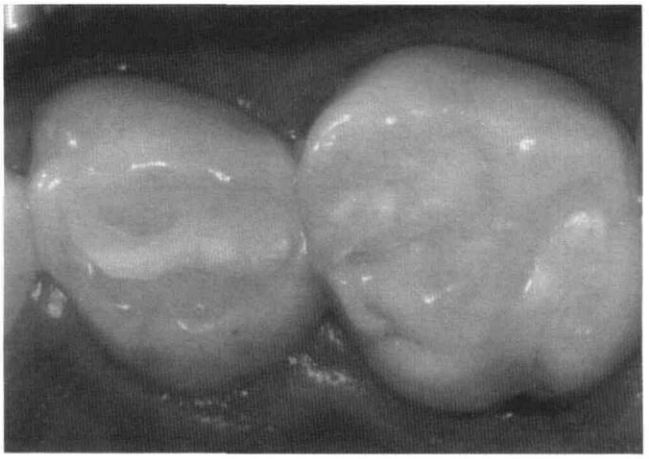


FIG 5. Same restoration as *Fig 4* (taken at 48 months).

FIG 7. Same restorations as *Fig 6* (taken at 48 months). Note failure of DO on 1st molar and wear and marginal stain on MO of second primary molar.

TABLE 2. Summary of All Restorations at 48 Months

Available at 48 months	123
Failures 0–36 months	32
Failures 36–48 months	7
Restorations in exfoliated teeth	169
Unavailable restorations	26
Total	357

ated at 48 months (123) and the failures will be presented and discussed separately.

The 123 successful restorations evaluated at 48 months included 42 conventional alloy preparations, 37 conventional bevel preparations, and 44 modified alloy preparations. The successful restorations included 62 restored with Ful-Fil and 61 restored with X-55. Sixty-one restorations were Class I, 44 were Class II, and 18 were Class V. The USPHS ratings for the successful restorations at 48 months is shown in Table 3.

Color Match

The per cent Alfa ratings for color match dropped substantially from baseline for both Ful-Fil and X-55. The color change for Ful-Fil dropped from 86% Alfa to 29% Alfa; X-55 dropped from 87% Alfa to 38% Alfa. A single Charlie rating (X-55) was given for color; all others were Alfas and Bravos. The change in color over time was statistically significant for both materials, but there was no significant difference in the color change between Ful-Fil and X-55 at 48 months.

Marginal Integrity

Marginal integrity deteriorated slowly over the evaluation period for both materials. Ful-Fil changed from 99% Alfa at baseline to 94% Alfa at 48 months. Changes were from Alfa to Bravo with no Charlie ratings. The X-55 changed from 100% Alfa at baseline to 85% at 48 months. One Charlie rating was recorded at 48 months. The change in Ful-Fil was not statistically significant but the change in X-55 was. Ful-Fil was superior to X-55 in this category at 48 months but this difference was not statistically significant.

TABLE 3. Ratings by Evaluation Categories at 48 Months for Cavity Designs and Materials

Material	*Ful-Fil*			*X-55*			*Total*		
USPHS Ratings	*A*	*B*	*C*	*A*	*B*	*C*	*A*	*B*	*C*
(Color Match N = 123)									
Conv	7	14	0	5	15	1	12 (29%)	29	1
Conv/B	4	15	0	7	11	0	11 (30%)	26	0
Mod	7	15	0	11	11	0	18 (41%)	26	0
Total	18 (29%)	44	0	23 (38%)	37	1	41 (33%)	81	1
(Marginal Integrity N = 123)									
Conv	20	1	0	16	5	0	36 (86%)	6	0
Conv/B	19	0	0	17	1	0	36 (97%)	1	0
Mod	19	3	0	19	2	1	38 (86%)	5	1
Total	58 (94%)	4	0	52 (85%)	8	1	110 (89%)	12	1
(Interfacial Staining N = 123)									
Conv	18	3	0	16	5	0	34 (81%)	8	0
Conv/B	16	3	0	13	5	0	29 (78%)	8	0
Mod	16	6	0	17	5	0	33 (75%)	11	0
Total	50 (81%)	12	0	46 (75%)	15	0	96 (78%)	27	0
(Wear N = 123)									
Conv	21	0	0	19	2	0	40 (95%)	2	0
Conv/B	19	0	0	15	3	0	34 (92%)	3	0
Mod	22	0	0	22	0	0	44 (100%)	0	0
Total	62 (100%)	0	0	56 (92%)	5	0	118 (96%)	5	0
(Axial Contour N = 123)									
Conv	8	0	0	10	0	0	18 (100%)	0	0
Conv/B	8	0	0	9	0	0	17 (100%)	0	0
Mod	5	0	0	4	1	0	9 (90%)	1	0
Total	21 (100%)	0	0	23 (96%)	1	0	44 (98%)	1	0

Interfacial Staining

After 48 months Ful-Fil had an 81% Alfa rating compared to 99% Alfa at baseline. X-55 showed a similar decrease, falling from 96% Alfa to 75% Alfa. These category changes were from Alfa to Bravo and each reached borderline statistical significance for both materials. The difference between the ratings of Ful-Fil and X-55 at 48 months was not significant.

Wear

For the wear category, Ful-Fil had dropped from 100% to 99% and 98% Alfa at 24 and 36 months, respectively, but this reversed to 100% Alfa at 48 months. This reversal either was due to exfoliations or to the difficulty in the clinical evaluation of wear using the USPHS criteria. The X-55 material dropped from 100% to 96% and exhibited a reversal also. None of these changes were statistically significant.

Axial Contour

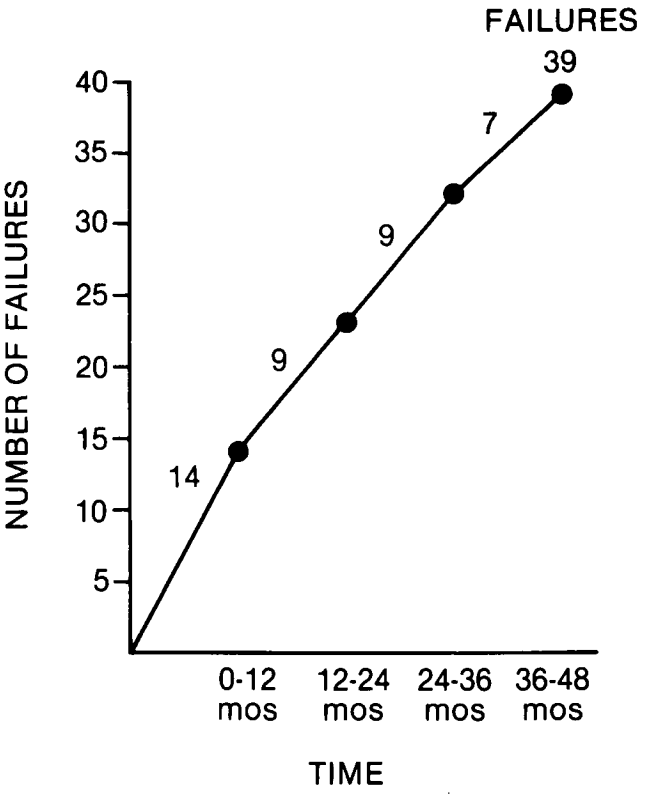
Both materials showed high Alfa ratings for axial contours at 48 months. Ful-Fil was rated 100% Alfa and X-55 was 92% Alfa. No Charlie ratings were recorded. Axial contour was examined only on Class II restorations.

Failures

At 48 months a total of 39 failures occurred for a failure rate of 10.9% (39/357). A restoration was considered a failure when it required replacement because it was missing, fractured, or recurrent caries was present. Fourteen failures occurred between baseline and 12 months, 9 between 12 and 24 months, 9 between 24 and 36 months, and 7 between 36 and 48 months (Table 4). To study the 39 failures more closely, failures were examined by cavity design, material, and preparation classification as illustrated in Table 5. The failure rate for conventional preparations was 8.2% (9/110), for conventional bevel preparations 6.7% (8/119), and for modified preparations 17.2% (22/128). When comparing materials, Ful-Fil had a failure rate of 9.2% (17/184) and X-55 had a failure rate of 12.2% (22/173). The failure rate for preparation classification was: Class I 3.6% (5/137); Class II 18% (34/188); and Class V 0% (0/32). More than half of all the failures (21) occurred in primary first molars. The disto-occlusal restoration of the lower first primary molar failed in 13 teeth.

Because 3 operators participated in this study, it was important to examine the operator effect on the performance of the materials in various cavity designs. In comparing ratings of restorations placed by different operators, there were no statistically significant operator differences. Failures were divided fairly evenly among operators: 1 operator had 15 failures, 1 had 13, and the other 11.

TABLE 4. Number of Failures Over Time



Discussion

Interexaminer reliability is important when reporting clinical trials using the USPHS criteria as the evaluation tool. In this study the overall agreement rating at 48 months was 94% compared with 99% at baseline. The color match category was the one that contained most disagreements (83% agreement) and it influenced negatively the overall agreement rating. Because all disagreements in the color match category were between Alfa and Bravo, this difference has little clinical significance. The difference between an Alfa and Bravo color is subtle and probably could not be distinguished by a nondentist.

The 48-month recall rate of 36% (130/357) of the restorations is disappointing. The major reason for this low rate is the loss of many restorations because of exfoliation of the primary teeth. This is a major problem in research design of clinical studies involving primary teeth. Discounting exfoliations, the recall rate was 83%, which is excellent for a 4-year follow up.

After 48 months there are sufficient findings to detect clear differences between the Ful-Fil and X-55 materials. Ful-Fil exhibits superior qualities for marginal integrity, interfacial staining, and wear. These differences are not significant but favor the Ful-Fil material. X-55 appears to match the primary tooth

TABLE 5. Failures at 48 Months by Cavity Design, Material, and Classification of Preparation

	Ful-Fil		*X-55*		*Total*	
Conv						
Class I	0/20	(0%)	0/22	(0%)	0/42	(0%)
Class II	2/31	(6.4%)	7/29	(24%)	9/60	(15%)
Class V	0/3	(0%)	0/5	(0%)	0/8	(0%)
Total	2/54	(3.7%)	7/56	(12.5%)	9/110	(8.2%)
Conv/bevel						
Class I	0/20	(0%)	2/18	(11.1%)	2/38	(5.3%)
Class II	5/37	(13.5%)	1/35	(2.8%)	6/72	(8.3%)
Class V	0/4	(0%)	0/5	(0%)	0/9	(0%)
Total	5/61	(8.2%)	3/58	(5.1%)	8/119	(6.7%)
Modified						
Class I	1/28	(3.5%)	2/29	(6.8%)	3/57	(5.3%)
Class II	9/31	(29%)	10/25	(40%)	19/56	(34%)
Class V	0/10	(0%)	0/5	(0%)	0/15	(0%)
Total	10/69	(14.5%)	12/59	(20.3%)	22/128	(17.2%)
Grand total	17/184	(9.2%)	22/173	(12.7%)	39/357	(10.9%)
Classes only						
Class I	1/68	(1.4%)	4/69	(5.7%)	5/137	(3.6%)
Class II	16/99	(16.1%)	18/89	(20.2%)	34/188	(18.0%)
Class V	0/17	(0%)	0/15	(0%)	0/32	(0%)
Grand total	17/184	(9.2%)	22/173	(12.7%)	39/357	(10.9%)

better; however, the difference is not significant nor is the difference between an Alfa and Bravo rating critical for this category.

Both materials changed significantly over time in the interfacial staining category, but it was felt that this was not significant clinically because the stain was superficial and was not associated with recurrent caries. The X-55 material showed more marginal integrity deterioration over 48 months, which was statistically significant.

It is impossible to assess wear accurately using the USPHS criteria. However, Ful-Fil exhibited 100% Alfa at 48 months and X-55, 92% Alfa. Although these values indicate little wear, they are better than the values at the 36-month recall. An accurate assessment of wear must rely on measurements made in vitro using models or other replicating techniques (Vann et al. 1986).

Table 5 illustrates the total number of failures by material, cavity design, and class occurring during the 48-month study. Ful-Fil was slightly superior to X-55 because there were 17 (9.2%) failures with Ful-Fil compared to 22 (12.7%) failures with X-55. In comparing cavity designs, the modified preparation had the most failures 22/128 (17.2%) with most of these occurring in the X-55 material. The conventional bevel preparation was superior; however, it is not statistically better than the conventional preparation.

The authors cannot recommend the modified preparation for use in the primary molars; however, it should be noted that no attempt was made to develop cavity retention form in this preparation. Because many of these restorations failed early, resulting in total loss of the restoration, a modified cavity design with an attempt to develop retention might be more successful.

Of the 39 failures, 34 occurred in Class II restorations which resulted in a failure rate of 18%. This rate was very high; however, this was influenced greatly by the large number of failures in Class II modified preparations (19/56—34%). The results favored the Class II conventional bevel preparation with only an 8.3% (6/72) failure rate. An overall cavity failure rate of 10.9% (39/357) compares favorably when one looks at the failure rate of amalgam in primary teeth. Few studies have reported similar data but clinical experience indicates that there is a rather high failure rate of amalgam in Class II preparations in primary molars.

The technique for placement of posterior composite resins has been refined since this study began. Some of the failures may have been technique related rather than a material shortcoming. The use of a glass ionomer cement as a base, clear plastic matrix bands, and transparent wedges might have improved the quality of the restorations (Lutz et al. 1986). In addition, an incremental placement technique has proven to be superior to the technique used in this study (Krejci et al. 1986).

The conventional bevel preparation appears to

be slightly superior to the conventional preparation. When all categories are analyzed, marginal integrity has a higher Alfa rating even though interfacial staining ratings are slightly lower. The failure rate of the conventional bevel preparation is also lower, particularly in the Class II preparation.

Conclusions

Under the conditions of this study:

1. Interexaminer reliability was excellent at 48 months.
2. For successful restorations, statistically significant changes took place over 48 months in the color match category for Ful-Fil and X-55.
3. Marginal integrity of X-55 at 48 months showed statistically significant changes. All other category changes were not statistically significant.
4. A total of 39 failures occurred over the 48-month period. More failures occurred in the X-55 material and the modified cavity design.
5. The Class II modified preparation cannot be recommended because it had the largest number of failures 19/56 (34%).
6. The conventional preparation with a bevel is recommended for composite restorations of primary molars.

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