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The American Academy of Pediatric Dentistry
Volume 7 Number 2

SCIENTIFIC articles

Composite restorations for primary molars: two-year results

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Abstract

Two experimental composite resins were placed in the primary molars of 50 children aged 4 to 8 years. Three cavity preparations were used and 357 restorations were placed. The restorations were evaluated by 2 investigators at 0, 6, 12, and 24 months using the USPH evaluation criteria.

At 24 months, 297 (83.1%) restorations were available for recall (48 patients). Discounting restorations lost by natural exfoliation (39) the recall rate was 93.4%.

There were no statistically significant changes between 0 and 24 months in the 3 preparations or the 2 materials except for the color match category. Color match deteriorated ($p<0.05$) significantly in all cavity preparations and for both materials. At 24 months there were no statistically significant differences ($p<0.05$) between the 2 materials or among the 3 cavity preparations.

At 24 months 23 failures had occurred. The overall failure rate was 6.4% (23/357). The failure rate for conventional preparations was 4.5% (5/110); for conventional bevel, 2.5% (3/119); and for modified preparations, 11.7% (15/128).

Posterior composite resins have been advocated in recent years as a substitute for dental amalgam in certain clinical situations. One factor that has intensified the search for such a substitute is the bleak forecasts about the future cost and availability of materials necessary to produce amalgam.[1] Another factor adding importance to the search for an amalgam substitute centers on recent concerns relative to the potential for systemic absorption of mercury from dental amalgam restorations.[2] While these concerns remain somewhat speculative, the quest for an amalgam substitute is a reasonable research goal.

It has been noted that the use of composites in posterior teeth drastically could change pediatric dentistry because amalgam is used widely as the restorative material of choice for posterior primary teeth.[3] This study extends research efforts on this topic.

Literature Review

Nelson's report[4] of a 3-year clinical trial comparing posterior composites and amalgams in primary teeth stimulated the need for additional posterior composite studies in children. In comparing 2 composites[a] with amalgam[b] in 50 sets of Class II preparations over 3 years, Nelson et al. concluded that composite was a reasonable substitute for amalgam when a primary tooth is expected to be functional for 3 years or less. As a result of this study, many investigators have initiated clinical studies in primary molars, examining posterior composites with no amalgam controls.

The specific cavity design for composites in primary molars is a subject of much interest and recently has been addressed in a study by Paquette et al.[3] They used a modified preparation wherein only carious enamel and infected dentin were removed. Cavity walls were extended only for visual and mechanical access and acid-etch techniques were employed for restoration retention and resistance. While they reported excellent success for this preparation in Class I restorations, the Class II restorations had a failure rate of 16.7-25%.

Vliestra et al.[5] reported a similar failure rate after 1 year in a similar cavity preparation in which they used glass ionomer cement as a restorative material. Leifler and Varpio[6] reported a 34% failure rate of composites in Class II modified preparations in primary

[a] Adaptic, Radio-Opaque Adaptic — Johnson & Johnson; East Windsor, NJ.
[b] Dispersalloy — Lee Pharmaceuticals Corp.; South Elmonte, CA.

teeth after 2 years. While the modified cavity preparation offers the potential to save tooth structure, clinical trials investigating this design modification for primary teeth have been disappointing.

Another cavity design modification is the use of the enamel bevel. Beveling prior to acid etching has been credited with decreasing the incidence of enamel fractures at cavity margins,[7,8] decreasing marginal leakage,[9] and increasing retention.[10] However, these studies have been limited to investigations on permanent teeth, and most studies have examined only anterior teeth in vitro. Thus, although the use of the enamel bevel offers theoretical advantages, the scientific basis for the use of such a modification for primary molars is unexplored.

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[3] and Nelson[4] are the largest reported for composites in primary molars, and these studies employed different approaches to the cavosurface bevel. Nelson used no bevel in his study and Paquette beveled the cavosurface margins of his conventional preparations. Because this cavity design feature may have implications for retention and marginal leakage and the ultimate success of the restoration, determination of its value is timely and relevant.

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 new visible light-cured composite resin materials. Both materials were manufactured for 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 a topical fluoride treatment. 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 different cavity designs were used in the study.

The 2 experimental resins were condensable, visible light cured, and contained .04-10 μ filler particles. The resins were filled approximately 75-80%. The only difference in the composites was that F-70 contained barium glass particles[c] 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 enamel was removed only for access to decay. The modified preparation also was beveled. The cavity designs are illustrated in Figures 1, 2, and 3.

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

Clinical Technique

All restorations were placed using 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. Traditional Class I and 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

TABLE 1. Physical Properties and Composition of F-70 and X-55

Product Description	*F-70*	*X-55*
Manufacturer	L.D. Caulk Co.	L.D. Caulk Co.
Particle Size (Microns)	0.04 – 10U	0.04 – 10U
Filler % (Weight)	77.3	76.0
Filler composition	Ba Glass SiO_2	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

[c] Fulfill — L.D. Caulk Co.; Milford, DE.

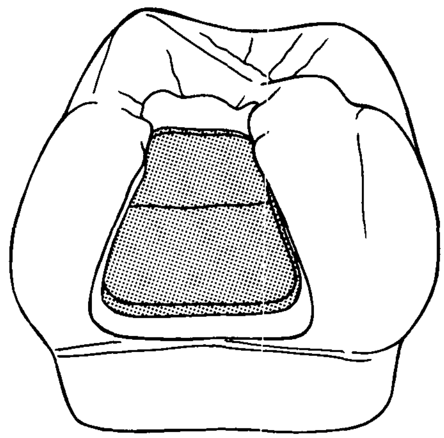

FIG 1. Conventional Preparation.

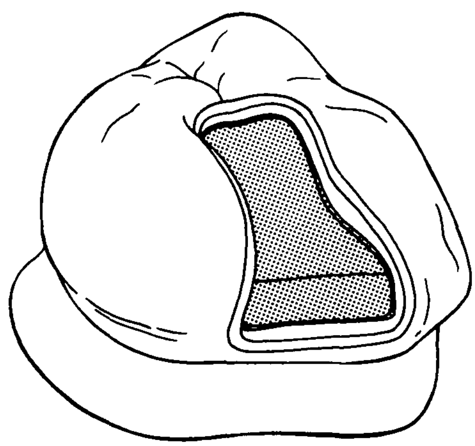

FIG 2. Conventional preparation with bevel.

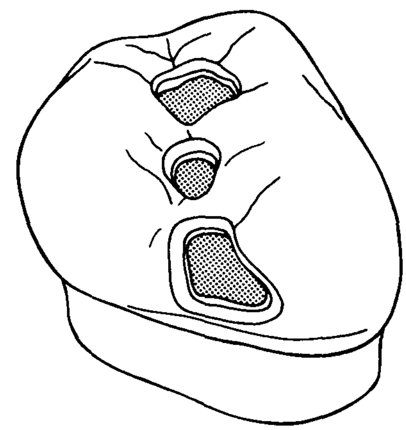

FIG 3. Modified preparation with bevel.

bevel in accessible enamel at approximately 45° to the cavosurface margin.

The modified preparations were prepared 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.

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.

Stainless steel matrix bands (0.002 in) were adapted for all Class II cavity preparations and interproximal wedges were placed to seal the gingival margins. A calcium hydroxide base[d] 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 placed over the exposed enamel margins and a gentle blast of air assisted in distributing the bonding agent over the etched surfaces, preventing pooling of the bonding agent in the proximal box area.

The experimental composite resins were placed on a paper pad and transferred to the preparation with a plastic instrument. Amalgam condensers were used to condense the composite into the preparations. The resin was polymerized utilizing a light.[e] 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 the visible light for 20 sec.

All composite restorations were finished with fluted carbide finishing burs, and cups[f] and discs with petroleum jelly were used to smooth and polish the surfaces. Composite finishing strips improved interproximal contours. After removal of the rubber dam, occlusal contact was adjusted.

Evaluation Procedures

Following completion of all restorative treatment, patients returned for a baseline evaluation of the restorations. 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.[11] However, the USPHS system was modified to include a category for clinical evaluation of axial contour (Table 2).

At baseline, 6, 12, and 24 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 taken at a magnification of 1.5x were obtained at the recall intervals (Figs 4, 5, 6).

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 24-month data will be presented and discussed. A McNemar's test was used to analyze changes over time from baseline to 24 months.[12] For all other analyses, the Mantel-Haenszel chi-square test was used as the test statistic.[13] An alpha of 0.05 was used as the level of significance for all tests.

[d] Dycal — L.D. Caulk Co.; Milford, DE.
[e] Prisma Lite — L.D. Caulk Co.; Milford, DE.
[f] Quasite — Shofu Dental Co.; Menlo Park, CA.

TABLE 2. Criteria for Rating Composite Resin Restorations*

Category	Rating	Restoration
Color Match	Alpha	Restoration matches adjacent tooth structure in color and/or translucency
	Bravo	Mismatch in color and/or translucency is not outside the normal range of tooth color and translucency
	Charlie	Mismatch in color and/or translucency is outside normal range of tooth color and/or translucency
Marginal Adaptation	Alpha	Restoration appears to adapt closely (marginal integrity) to tooth along periphery of restoration, explorer does not catch when drawn across margins; if it does catch, it will catch in only one direction, no crevice is visible
	Bravo	Explorer catches, and there is visible evidence of crevice into which explorer will penetrate; however, dentin and base are not visible
	Charlie	Explorer penetrates into crevice that is of such depth that dentin or base is exposed
	Delta	Restoration is fractured, mobile, missing
Anatomical form	Alpha	Restoration is continuous with existing anatomic form
	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
Cavosurface margin discoloration (interfacial staining)	Alpha	No discoloration anywhere on margin between restoration and tooth structure
	Bravo	Discoloration has not penetrated along margin in pulpal direction
	Charlie	Discoloration has penetrated along margin in pulpal direction
Axial contour	Alpha	Axial contour continuous with existing tooth form proximal embrasures
	Bravo	Slightly undercontoured, axial surface, proximal line angles flattened or composite low, not continuous with enamel or slightly overcontoured, axial surface full, proximal line angles overaccentuated or composite high, not continuous with enamel
	Charlie	Moderately undercontoured or moderately overcontoured
	Delta	Decidedly undercontoured, axial surface, proximal line angles (tissue trauma evident) or decidedly overcontoured, soft tissue impinged or axial grossly under- or overcontoured

* Using USPHS system as modified by Oldenburg, Vann, and Dilley.

Results

Three evaluators performed all evaluations. At baseline, the overall agreement for all evaluation categories was 99% and all disagreements were in the color-match category. At 24 months, the overall agreement for all evaluation categories was 92.9%. This reliability was influenced heavily by disagreements on color match; for that evaluation category, agreement was only 78.8%. Agreement for the other categories was: marginal integrity — 94.8%, wear — 99.6%, interfacial staining — 91.6%, and axial contour — 100%. Color-match disagreements were restricted to disagreement between alphas and bravos.

Of the 50 patients treated at baseline, 48 were available at the 24-month recall. At baseline 357 restorations were evaluated and at 24 months 297 restorations were evaluated. At the 24-month recall, 39 restorations were not evaluated because they were in teeth which had exfoliated naturally and 21 restorations were unavailable for recall. Thus, the 24-month recall rate was 83.1% (297/357); however, discounting exfoliated teeth, the recall rate was 93.4% (297/318).

Of the 297 restorations evaluated at 24 months, 23 failed at various intervals before the 24-month evaluation period and 274 restorations were clinically successful. The successful restorations and failures will be presented and discussed separately.

The 274 successful restorations included 91 conventional alloy preparations, 90 conventional bevel preparations, and 93 modified alloy preparations. If examined by material, the successful restorations included 148 F-70 restorations and 126 X-55 restorations. One hundred twenty restorations were Class I, 124 were Class II, and 30 were Class V.

At baseline, the goal of the operator was to place an ideal restoration. Thus, with the exception of the color-match category, the baseline evaluations for all

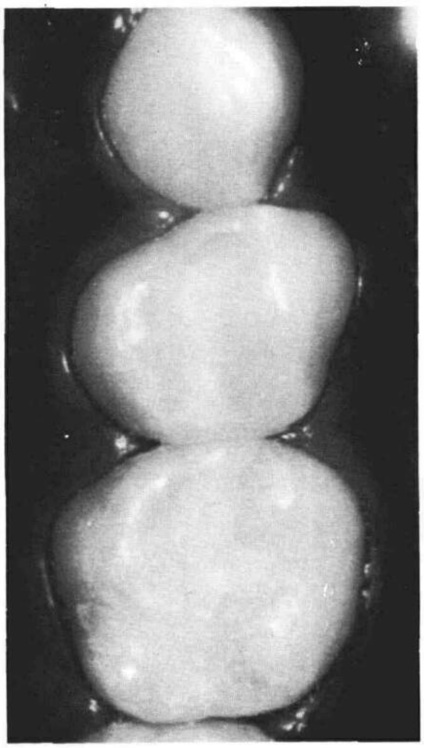

FIG 4. Conventional mesio-occlusal and occlusolingual preparation restored with F-70 on second primary molar. Conventional disto-occlusal preparation restored with X-55 on first primary molar (taken at baseline).

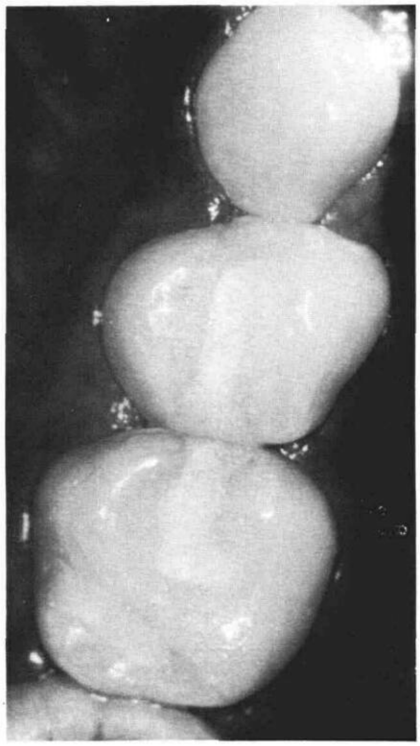

FIG 5. Same restorations as Fig 4 (taken at 24 months).

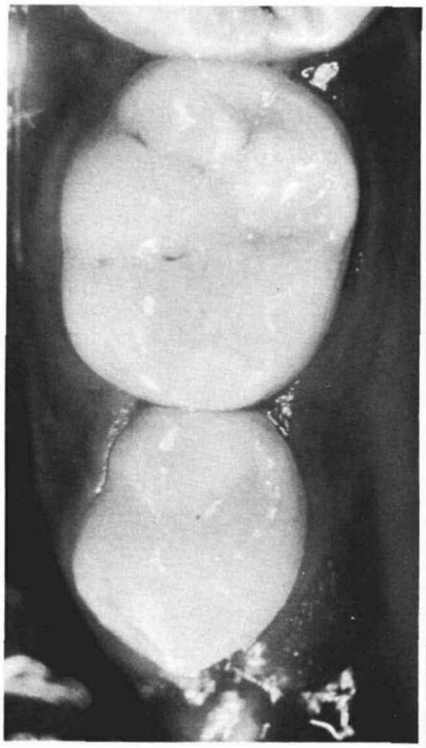

FIG 6. Modified mesio-occlusal preparation restored with F-70 on second primary molar. Conventional disto-occlusal preparation restored with X-55 on first primary molar (taken at 24 months).

categories were near 100%. The baseline color match was approximately 85% Alpha and 15% Bravo. There were no significant statistical differences in preparations or materials at baseline. Because all categories were essentially the same at baseline, the baseline evaluation categories are not illustrated. Table 3 illustrates 24-month evaluation findings for the successful restorations by cavity design and material. There were no postoperative pain or secondary caries to report.

There were no statistically significant differences among the 3 preparations or between the 2 materials at 24-months. The statistical test to examine the change over time from baseline to 24 months revealed no statistically significant changes over time for the 3 cavity designs or the 2 materials, except for the color-match category. Color match deteriorated from 0 to 24 months in all cavity preparations and for both materials, and this change was statistically significant.

The overall failure rate was 6.4% (23/357). A restoration was considered a failure when it needed to be replaced because it was missing or fractured, or recurrent caries was present. Ten failures occurred between baseline and 6 months, 4 occurred between 6 and 12 months, an 9 occurred between 12 and 24 months. In order to study the 23 failures more closely, failures were examined by cavity design, material, and preparation classification as illustrated in Table 4. The failure rate for conventional preparations was 4.5% (5/110); for conventional bevel preparations 2.5% (3/119); and modified preparations 11.7% (15/128). When materials were compared, the failure rate for F-70 was 4.3% (8/184) and for X-55, 8.7% (15/173). The failure rate by classifications was: Class I - 3.6%, Class II - 9.5%, and Class V - 0%.

Because 3 evaluators participated in the study, it was necessary to examine the operator effect on all performance variables. To make these comparisons, operators were compared for their evaluation ratings on cavity design and materials at both baseline and 24-months. These comparisons revealed no statistically significant operator effect. Failures were evenly distributed among operators; 1 operator had 7 failures and the other 2 had 8 each.

Discussion

Because the USPHS evaluation criteria require that the 2 evaluators reach a consensus when they disagree, most published reports of posterior composite

TABLE 3. Ratings by Evaluation Categories at 24 Months for Cavity Designs and Materials

Material	*F-70*			*X-55*			*Total*		
USPHS rating	A	B	C	A	B	C	A	B	C
	Color Match (N = 274)								
Conventional	18	27	0	23	23	0	41	50	0
Conventional/bevel	19	30	0	24	17	0	43	47	0
Modified	30	23	1	23	16	0	53	39	1
Total	67	80	1	70	56	0	137	136	1
	Marginal integrity (N = 274)								
	A	B	C	A	B	C	A	B	C
Conventional	42	3	0	37	8	1	79	11	1
Conventional/bevel	45	4	0	40	1	0	85	5	0
Modified	48	6	0	35	4	0	83	10	0
Total	135	13	0	112	13	1	247	26	1
	Interfacial staining (N = 274)								
	A	B	C	A	B	C	A	B	C
Conventional	42	3	0	36	10	0	78	13	0
Conventional/bevel	44	5	0	34	7	0	78	12	0
Modified	42	12	0	31	8	0	73	20	0
Total	128	20	0	101	25	0	229	45	0
	Wear (N = 274)								
	A	B	C	A	B	C	A	B	C
Conventional	45	0	0	46	0	0	91	0	0
Conventional/bevel	48	1	0	40	1	0	88	2	0
Modified	54	0	0	38	1	0	92	1	0
Total	147	1	0	124	2	0	271	3	0
	Axial Contour*								
	A	B	C	A	B	C	A	B	C
Conventional	21	1	0	23	0	0	44	1	0
Conventional/bevel	25	1	0	21	1	0	46	2	0
Modified	22	0	0	9	0	0	31	0	0
Total	68	2	0	53	1	0	121	3	0

* Rated only for proximal contours.

clinical trials have not reported interexaminer reliability. Yet, for the evaluation criteria to be valid, interexaminer reliability must be high. In this study the overall interexaminer reliabilities at baseline (99%) and 24 months (92.9%) were judged as high. The lower interexaminer reliability finding (78.8%) for color match negatively influenced the overall reliability findings; however, disagreements were between alphas and bravos. The difference between an alpha and bravo color is subtle and probably could not be distinguished by the lay person; furthermore, it is doubtful that this color difference, has any clinical significance.

Color match was the only evaluation criterion that significantly deteriorated over the 24-month evaluation period. Marginal integrity and interfacial staining underwent some deterioration over 24 months, but this deterioration was minimal and not statistically significant. This was an important finding because both marginal deterioration and interfacial staining are precursors to leakage, recurrent decay, and restoration failure.

There were essentially no changes in wear or axial contour. It should be noted that changes in wear are very difficult to determine using direct clinical evaluation methods; furthermore, wear of composites often is not evident until after 2 years. In this study, impressions of all restorations were obtained at each evaluation period and those will be used to assist in an indirect evaluation of wear using stone casts.

It was notable that for successful restorations there were no significant differences in cavity designs or materials at the baseline or 24-month evaluation periods. Thus, based strictly on successful restorations, both materials and all 3 cavity designs were found to give excellent clinical performance over the 2-year evaluation period. Notably, for successful restorations, there was no recurrent decay or postoperative sensitivity.

In comparing successful conventional preparations

TABLE 4. Failures at 24 Months: By Cavity Design, Material, and Classification of Preparation

	F-70		*X-55*		*Total*	
Conventional						
Class I	0/20	0%	0/22	0%	0/42	0%
Class II	2/31	6.4%	3/29	10.3%	5/60	8.3%
Class V	0/3	0%	0/5	0%	0/8	0%
Total	2/54	3.7%	3/56	5.3%	5/110	4.5%
Conventional/bevel						
Class I	0/20	0%	2/18	11.1%	2/38	5.2%
Class II	0/37	0%	1/35	2.8%	1/72	1.3%
Class V	0/4	0%	0/5	0%	0/9	0%
Total	0.61	0%	3/58	5.1%	3/119	2.5%
Modified						
Class I	1/28	3.5%	2/29	6.8%	3/57	5.2%
Class II	5/31	16.1%	7/25	28.0%	12/56	21.4%
Class V	0/10	0%	0/5	0%	0/15	0%
Total	6/69	8.7%	9/59	15.2%	15/128	11.7%
Grand Total	8/184	4.3%	15/173	8.6%	23/357	6.4%
Classes only						
Class I	1/68	1.4%	4/69	5.7%	5/137	3.5%
Class II	7/99	7.0%	11/89	12.3%	18/188	9.5%
Class V	0/17	0%	0/15	0%	0/32	0%
Grand Total	8/184	4.3%	15/173	8.6%	23/357	6.4%

which are beveled and unbeveled, there appears to be evidence that beveling does improve the marginal integrity but has little effect on marginal staining. Seventy-nine of 90 (87.7%) conventional preparations received an alpha rating in marginal integrity at 2 years compared to 85/90 (94.4%) for conventional/bevel preparations. Even though this difference is not statistically significant, it does show a trend for improved marginal integrity for beveled preparations.

The alpha ratings for interfacial staining at 2 years were similar for the beveled and nonbeveled preparations indicating that beveling may not affect marginal staining. Seventy-eight of 91 (85.7%) conventional preparations received alpha ratings while 78/90 (86.7%) conventional/bevel restorations received alpha ratings for interfacial staining.

Differences between cavity designs and materials became apparent when failures were examined. The percentage of failures in the modified preparation was 11.7%, almost 5 times higher than the failure rate for the conventional bevel preparation (2.5%), and more than 2.5 times higher than the failure rate for the conventional preparation (4.5%). Based on failures, the conventional bevel design was slightly preferable to the conventional design.

The F-70 material[g] experienced a failure rate (4.3%) which was half that of the X-55 material (8.6%). Furthermore, F-70 had a failure rate less than X-55 in each of the 3 cavity designs.

There were no failures in Class V preparations and the Class I failure rate was only 3.6%. The Class II failure rate of 9.5% suggests that the interproximal cavity preparation is at considerably more risk for failure. Of particular concern are the Class II modified preparations which failed at a rate of 21.4%.

Based on the failed restorations, trends support the F-70 material and the conventional bevel preparations. In this study, the modified cavity design had a disappointing failure rate which greatly was influenced by failures in Class II modified cavity preparations. These findings are in agreement with those of Paquette et al.[3] who concluded that the modified Class II cavity preparation cannot serve as a substitute for a conventional preparation.

Conclusions

Under the conditions of this study:

1. Interexaminer reliability was excellent at baseline and 24 months.
2. For successful restorations, there were no significant changes over time for the 2 materials or the 3 cavity designs except in the color-match category. Color match significantly deteriorated over time for both materials in all cavity designs.
3. For successful restorations, there were no signifi-

[g] Fulfill — L.D. Caulk Co.; Milford, DE.

cant differences at baseline or 24 months for the 2 materials or the 3 cavity designs.
4. There were more failures for the X-55 material and the modified cavity design.
5. An examination of failures revealed the conventional bevel cavity was slightly preferable to the conventional design.
6. The modified Class II cavity design cannot be recommended because of its high failure rate (21.4%).

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Quotable quote: Sudden infant death syndrome

The most frequent cause of death of infants between one week and twelve months of age is unexplained and is classified as Sudden Infant Death Syndrome (SIDS).

SIDS seems to occur most often in infants who are between one and four months of age, in winter months, at night, and while an infant is asleep in any position. However, this is also the peak age and time of year for infant death from other causes. Other factors indentified in SIDS are: being preterm, intrauterine growth retardation, amnionitis, low Apgar scores, the need for oxygen and resuscitation at birth, being second or third in the birth order or the product of a multiple birth — in particular being the second born of a twin pair. SIDS occurs more frequently in infants whose father and mother are poor and less than 20 years of age, whose mothers are unmarried, have had poor prenatal care, have been ill during the pregnancy, have short pregnancy intervals, have had previous fetal loss, and who are smokers or abusers of alcohol. These factors also increase the risk of infant death due to known causes and suggest that an altered physiology is affected by environment.

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