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Effect of Restoration Size on the Clinical Performance of Posterior "Packable" Resin Composites Over 18 Months

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Clinical Relevance

No association between restoration size and failure of the two posterior restorative systems was found over 18 months.

SUMMARY

Fifty predominantly moderate or large Class II or multiple-surface Class I resin composite restorations were placed in molars under rubber dam isolation. The restorative systems used were: Alert Condensable (Jeneric/Pentron) and SureFil (Dentsply/Caulk). The restorations were classified according to size, with 7 small, 25 moderate and 18 large, of which 8 were cusp replacement restorations. Baseline, 6, 12 and 18-month double-blinded clinical evaluations were carried out using modified USPHS criteria. The independent variables: restorative material, restoration size and three other clinical factors, were tested using a Multiple Logistic Regression procedure to determine if any were predictive of failure. Of the 50 restorations, four failed by the 18-month recall, three failed due to fracture of the restoration and one due to secondary caries. Both restorative systems demonstrated a 92% success rate. No association between restoration size (p=0.99) or restorative material (p=0.65) and failure was found. Similarly, the additional variables, occlusal contact type, presence of occlusal wear facets and first or second molar, were not predictive of failure.

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Table 1: *Size Classification of Restorations**

Small	
Occlusal	Extension of less than half the intercuspal distance.
Proximal	Facio-lingual extension of less than 1 mm clearance.
Moderate	
Occlusal	Extension of half to two-thirds the intercuspal distance.
Proximal	Facio-lingual extension greater than 1.0 mm clearance, either facial or lingual, but less than half the distance to the line angle.
Large	
Occlusal	Extension of greater than two-thirds the intercuspal distance.
Proximal	Facio-lingual extension greater than half the distance to line angle.
Cusp Replacement	
Occlusal	To or beyond the cusp tip.
Proximal	Beyond the facio- and/or linguo-proximal line angle.

**(Defined according to the final extension of the occlusal and interproximal cavosurface margins. Restorations with different-sized occlusal and proximal portions received the larger of the two classifications.)*

INTRODUCTION

Posterior resin composites are considered to be effective restorations, with a number of long-term controlled clinical studies of conventional hybrid resin composite materials documenting a survival rate of at least 85% over three-to-seven years.[1-4] Lacking from such studies is any specific evaluation of large Class I and Class II resin composite restorations of molars, which are commonly placed in many dental practices. Some studies have categorized the size of restorations and the number of molars included,[4-5] which are usually mixed, but size has not been related to clinical performance, except where one study has stated that there is a greater risk of failure in large posterior resin composite restorations.[5]

"Packable" resin composites differ little from hybrid resin composites in filler loading or physical properties, but they have a stiffer viscosity and less of a tendency to stick to instruments, owing primarily to modifications in filler geometry.[6-8] These traits facilitate sculpting of the resin prior to light curing and are clinically desirable for large restorations, because less contouring is necessary after curing. Manufacturers also claim that packable resin composites may be "bulk-cured" in increments of 5-6 mm, but this is without scientific basis, as adequate polymerization of resin composites beyond a 2-3 mm increment thickness has not been demonstrated.[9]

Most packable resin composite products have performed about the same as conventional hybrid products in two-to-three year trials of posterior restorations, with survival rates greater than 90%.[10-13] All of these studies make some reference to the size of restorations included and the percentage of molars within the study, but these factors are not correlated to the risk of failure.

This study evaluated the clinical performance of two "packable" resin composites in moderate and large posterior restorations of molars over 18 months and also evaluated the hypothesis that restoration size, occlusal contact type, occlusal wear facets and type of molar are predictive of failure.

METHODS AND MATERIALS

Following the Medical College of Georgia regulations for the ethical treatment of human subjects, 50 healthy patients needing a single moderate or large Class II or multiple-surface Class I restoration in a first or second molar were recruited for the study. Patients were included if their teeth were in occlusion, and it was anticipated that the extension of their restorations would be at least half of the intercuspal distance on the occlusal surface or at least half way to the line angle on either the facial or lingual wall interproximally.

All restorations were placed under local anesthesia and rubber dam isolation by four restorative dentistry faculty trained in adhesive dentistry, with each placing an approximately equal number of restorations. The patients were randomly assigned to receive restorations of either Alert Condensable (Jeneric/Pentron, Wallingford, CT, USA) or SureFil (Dentsply/Caulk, Milford, DE, USA) resin composite, both of which have demonstrated favorable physical properties in laboratory studies.[6-8] The cavities were prepared only to include areas of caries and old restoration, with rounded internal line angles, 90° cavosurface angles and clearance of the contact attained for all proximal margins. Cusps and marginal ridges judged to be 1 mm or less thick were reduced a minimum of 2 mm and restored.

The manufacturers' supplied adhesive systems, including placement of a flowable resin composite prior to Alert, were used as directed. These products were Prime&Bond NT (Dentsply/Caulk) for SureFil and Bond-1 and Flow-It ALC (Jeneric/Pentron) for Alert. The resin composites were placed incrementally, with increment thickness limited to less than 3 mm. Each

Table 2: *Modified USPHS Criteria*

Color Match	
Alpha	The restoration appears to match the shade and translucency of adjacent tooth structure.
Bravo	The restoration does not match the shade and translucency of adjacent tooth structure, but the mismatch is within the normal range of tooth shades.
Charlie	The restoration does not match the shade and translucency of adjacent tooth structure, and the mismatch is outside the normal range of tooth shades and translucency.
Interfacial Staining	
Alpha	There is no visual evidence of marginal discoloration different from the color of the restorative material and from the color of the adjacent tooth structure.
Bravo	There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration that has not penetrated along the restoration in a pulpal direction.
Charlie	There is visual evidence of marginal discoloration at the junction of the tooth structure and the restoration, but the discoloration has penetrated along the restoration in a pulpal direction.
Secondary Caries	
Alpha	The restoration is a continuation of existing anatomic form adjacent to the restoration.
Charlie	There is visual evidence of dark, deep discoloration adjacent to the restoration (but not directly associated with cavo-surface margins).
Marginal Integrity	
Alpha	The explorer does not catch when drawn across the surface of the restoration toward tooth structure or, if the explorer does catch, there is no visible crevice along the periphery of the restoration.
Bravo	The explorer catches and there is visible evidence of a crevice, which the explorer penetrates, indicating that the edge of the restoration does not adapt closely to the tooth structure. The dentin and/or the base are not exposed, and the restoration is not mobile.
Charlie	The explorer penetrates a crevice defect which extends to the dentino-enamel junction.
Surface Texture	
Alpha	Surface texture similar to polished enamel as determined by means of a sharp explorer.
Bravo	Surface texture gritty or similar to a surface subject to a white stone or similar to a resin composite containing supramicron-sized particles.
Charlie	Surface pitting is sufficiently coarse to inhibit the continuous movement of an explorer across the surface.
Proximal Contact (MODs receive lowest score)	
Alpha	The contact is consistent with others in the quadrant.
Bravo	The contact is present but is lighter than others in the quadrant.
Charlie	The contact is open, clinically unacceptable, necessitating replacement or repair of the restoration.
Fracture	
Alpha	No fracture evident.
Charlie	Fracture which renders the restoration clinically unacceptable, necessitating replacement or repair of the restoration.

(Clinical evaluations are made visually, with the aid of an explorer, shade guide and/or floss.)

increment was cured for 40 seconds using an Astralis 10 (Ivoclar Vivadent, Inc, Amherst, NY, USA) fast halogen curing light rated at 650 mW/cm^2. Where indicated, finishing and polishing were carried out wet, with fine finishing diamond and carbide burs, polishing points, aluminum oxide paste and abrasive strips. The restorations were classified according to size of proximal and occlusal portions according to the criteria in Table 1.

Baseline, 6, 12 and 18-month evaluations were performed by two blind calibrated independent evaluators using modified USPHS criteria (Table 2). A forced consensus was obtained before the patients were dismissed. Future recalls at 36 and 60 months are planned.

Restorations receiving a score of "Charlie" for any criterion were classified as failures for statistical purposes. The independent variables, restorative material and restoration size, were tested using a Multiple Logistic Regression procedure to determine if any were predictive of failure. Three other variables were also tested by the same method: the presence of excursive occlusal contacts on the restoration, the presence of occlusal wear facets on the restored tooth and whether the restored tooth was a first or second molar.

RESULTS

All patients completed the study. Of the 50 restorations placed, 7 were classified as small, 25 as moderate and 18 as large, with 8 being cusp replacements (Table 3). Four restorations were classified as failures at the

18-month recall, three due to fracture of the restoration and one due to secondary caries.

Both restorative systems demonstrated a 92% success rate over the length of the study (Figures 1 and 2). Among the clinically successful restorations, there was approximately a 30% incidence of slight interfacial staining, a 40% incidence of a slight color mismatch and evidence that the Alert restorations were of a rougher surface texture than SureFil, with a 32% versus 4% incidence of bravo scores. Scores of alpha were assigned at a rate of at least 92% for all other categories. Complete results are presented in Table 4.

Although all three fractured restorations were large, and two were cusp replacements, no statistical association between restoration size and failure was found (p=0.99). Neither was restorative material found to be predictive of failure (p=0.65). Similarly, the additional clinical factors of occlusal contact type, presence of occlusal wear facets and first or second molar were not predictive of failure (p=0.94, 0.82 and 0.99, respectively).

DISCUSSION

For this study, adhesives and resin composites from the same manufacturer were paired, because this would most likely be how clinicians use such products. This also eliminated the risk of incompatibility between the adhesive and resin composite, but it dictated the study being an evaluation of restorative systems.

It is encouraging that, despite the deliberate inclusion of a significant number of larger restorations in this study, an overall success rate of 92% was attained. Clinicians who select resin composites for this type of restoration, in order to gain the advantages of retention of the restoration and reinforcement of weakened areas of the tooth through adhesion, can probably expect good results. However, the authors suggest caution, as this is a relatively short-term study and more failures may become evident over time. In all probability, the results of this study would generalize to the performance of conventional hybrid resin composites, which, according to previous studies, would be at least as fracture-resistant as "packable" formulations.[7-8]

In designing this study, the authors hoped that, in addition to evaluating restoration size versus risk of restoration failure, evaluation of larger

Table 3: *Size/Classification Distribution of Restorations*

	Small	Moderate	Large	Cusp Replacement	Class I	Class II
Alert (n = 25)	3	11	11	7	3	22
SureFil (n = 25)	4	14	7	1	7	18

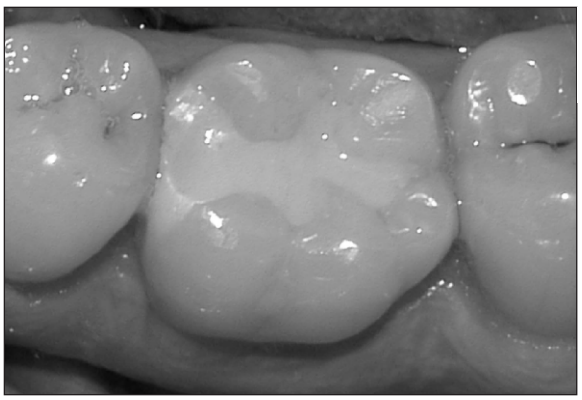

Figure 1: *Alert restoration after 18 months, which had been classified as moderate in size.*

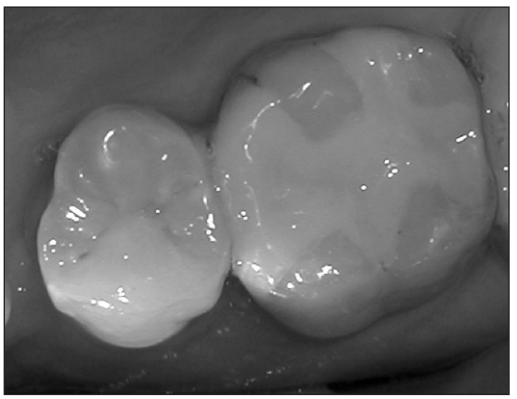

Figure 2: *SureFil restoration after 18 months, which had been classified as large in size.*

Table 4: *18-Month Results*

Restorative Material	Rating	Color Match	Inter Stain	Sec Caries	Marg Integ	Surf Texture	Prox Cont	Fracture
Alert	Alpha	60%	68%	100%	96%	68%	92%	92%
(n = 25)	Bravo	40%	32%		4%	32%	4%	0%
	Charlie	0%	0%	0%	0%	0%	4%	8%
SureFil	Alpha	60%	72%	96%	92%	96%	96%	96%
(n = 25)	Bravo	40%	28%		8%	4%	4%	0%
	Charlie	0%	0%	4%	0%	0%	0%	4%

restorations might prove a model for accelerated clinical evaluation of resin composite systems. However, the lack of any difference between materials and the relatively small number of failures meant that there were very few unique independent variable combinations to be analyzed, which precludes such a model, at least at an 18-month interval. This could change substantially at later intervals.

CONCLUSIONS

Among the posterior resin composites placed in this study, there was no difference observed between the two restorative systems, and no association was found between restoration size and clinical failure.

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