Survival and reasons for failure of amalgam versus composite posterior restorations placed in a randomized clinical trial

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ABSTRACT

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Background. Failure of dental restorations is a major concern in dental practice. Replacement of failed restorations constitutes the majority of operative work. Clinicians should be aware of the longevity of, and likely reasons for the failure of, direct posterior restorations. In a long-term, randomized clinical trial, the authors compared the longevity of amalgam and composite.

Subjects, Methods and Materials. The authors randomly assigned one-half of the 472 subjects, whose age ranged from 8 through 12 years, to receive amalgam restorations in posterior teeth and the other one-half to receive resin-based composite restorations. Study dentists saw subjects annually to conduct follow-up oral examinations and take bitewing radiographs. Restorations needing replacement were failures. The dentists recorded differential reasons for restoration failure.

Results. Subjects received a total of 1,748 restorations at baseline, which the authors followed for up to seven years. Overall, 10.1 percent of the baseline restorations failed. The survival rate of the amalgam restorations was 94.4 percent; that of composite restorations was 85.5 percent. Annual failure rates ranged from 0.16 to 2.83 percent for amalgam restorations and from 0.94 to 9.43 percent for composite restorations. Secondary caries was the main reason for failure in both materials. Risk of secondary caries was 3.5 times greater in the composite group.

Conclusion. Amalgam restorations performed better than did composite restorations. The difference in performance was accentuated in large restorations and in those with more than three surfaces involved.

Clinical Implications. Use of amalgam appears to be preferable to use of composites in multisurface restorations of large posterior teeth if longevity is the primary criterion in material selection.

Key Words. Amalgam; composite; randomized controlled clinical trials; dental restoration failure.

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The performance of dental restorations is influenced by several factors, including the restorative materials used,[1-3] the clinician's level of experience,[4] the type of tooth,[5,6] the tooth's position in the dental arch,[7,8] the restoration's design,[9] the restoration's size,[6] the number of restored surfaces[10,11] and the patient's age.[4,11] Failure occurs when a restoration reaches a level of degradation that precludes proper performance either for esthetic or functional reasons or because of inability to prevent new disease.

Failure of dental restorations is of major concern in dental practice. It has been estimated that the replacement of failed restorations constitutes about 60 percent of all operative work.[12] Survival and failure rates may be used as measures of clinical performance. The reason why a restoration fails also is important, because it points to a specific weakness of the restoration-tooth system.

The two direct dental restorative materials most commonly used today are silver-mercury amalgam and resin-based composites. Amalgam is not suitable for visible resto-

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rations in anterior teeth for esthetic reasons, but it still is used widely for posterior restorations. In recent years, the use of resin-based composites for the restoration of posterior permanent teeth has increased significantly, although they are more technique-sensitive to place and more costly.[13] The reasons for this situation have to do with the better esthetic properties of the composites, and with the general concerns about the use of metals in the mouth. There is some evidence that the longevity of composite restorations is less than that of amalgam restorations in similar circumstances.[1,3] It is important to consider the impact of the increasing use of composites in posterior teeth and for clinicians to be aware of the longevity of these materials and likely reasons for their failure.

The Casa Pia Study of the Health Effects of Dental Amalgams in Children was a randomized clinical trial designed to assess the safety of low-level mercury exposure attributable to dental amalgam restorations.[14] It began in 1996 as a collaborative project between the University of Washington, Seattle; the University of Lisbon, Portugal; and the National Institute of Dental and Craniofacial Research, and it recently concluded with publication of its main findings.[15] As approved by the institutional review boards of the University of Washington and the University of Lisbon Faculty of Dental Medicine, this study enrolled 507 children and provided comprehensive dental care for each of them for a period of seven years.

Because one-half of the subjects received only composites and the other one-half only amalgams for posterior restorations, this study provided the opportunity to compare the survival and the reasons for failure of posterior amalgam and composite restorations in a randomized, controlled clinical trial with seven years of follow-up.

SUBJECTS, METHODS AND MATERIALS

The study sample consisted of 472 children born from 1986 through 1989. We obtained consent from parents or guardians as well as assent from the children for participation in the study. The children attended seven different schools in Lisbon, all belonging to the same school system. In addition to age, eligibility criteria included

- at least one carious lesion in a permanent posterior tooth;
- no prior exposure to dental amalgam;
- urinary mercury concentration of less than 10 micrograms per liter;
- blood lead concentration of less than 15 µg per deciliter;
- an IQ score of at least 67 on the Comprehensive Test of Nonverbal Intelligence;
- no interfering health conditions.

The subjects included in the trial ranged in age from 8 through 12 years. Forty-three subjects were aged 8 years, 122 subjects were aged 9 years, 156 subjects were aged 10 years, 136 subjects were aged 11 years, and 15 subjects were aged 12 years.

We randomly assigned subjects to one of two treatment groups for restoration of posterior permanent teeth: one-half of the children received only amalgam restorations, and the other one-half received only composite restorations. Only resin-based composite and amalgam restorations of permanent posterior teeth were considered for the purposes of this study, although any anterior teeth needing restoration were treated (with composite in both groups). The reason for placement of all the restorations was primary caries.

Figure 1 shows the composition of the treatment groups and the number of restorations done at baseline within each group. For purposes of the comparison of restoration failures presented here, we chose to include only the restorations placed at baseline. Restorations placed at baseline were done under the same initial conditions and were observed for the same period, allowing for direct comparisons between restorative materials.

During follow-up, we instituted oral hygiene and prevention programs to decrease disease rates. This meant that restorations placed during follow-up were done in oral environments altered from those at baseline, which could in turn make longevity of newer restorations different from that of those placed at baseline.

All dental care was provided at the University of Lisbon Faculty of Dental Medicine, using existing standards of care common to both the United States and Portugal. We chose the materials used in the study, Dispersalloy (Caulk/Dentsply, Milford, Del.) and Z100 MP + Scotchbond Multi-Purpose (3M ESPE, St. Paul, Minn.), to be representative of those most commonly in use at the time the study began; they still are representative of materials in use today.

ABBREVIATION KEY. mAFR: Mean annual failure rates.

Study dentists placed restorations using rubber dam isolation whenever possible, and they used the materials according to the manufacturers' instructions. All subjects in both groups received the same preventive measures in all respects throughout the study.

The restorative procedures were standardized, and because of the group assignment, clinical decisions were limited. This meant that dentists could not decide which material to use in each specific case. Fourteen dentists with varying levels of practice experience placed the restorations. One dentist (M.B.) was involved in the treatment planning and assessment of all the subjects.

The study dentists saw the subjects annually for follow-up oral examinations and bitewing radiographs, at which time they performed complete dental charting and noted any new treatment needs. We considered restorations needing replacement to be failures. The study dentists carefully considered and recorded differential reasons for restoration failure as they occurred, starting during the second year of follow-up. We subsequently classified failures occurring before that point through review of the clinical record.

We noted several tooth and restoration characteristics to further investigate their relationship with failure. These characteristics included the arch (maxillary or mandibular), the type of tooth (premolar or molar), the number of restored surfaces and the size of the restoration (small, medium or large). For each restored surface, we considered the restoration "small" if the proportion of the area restored was less than one-quarter of the total surface area, "medium" if the same proportion ranged from one-quarter to one-half, and "large" if the restored area occupied one-half or more than one-half of the entire surface. The score attributed to the entire restoration consisted of the maximum size considering all the restored surfaces of each tooth.

We calculated mean annual failure rates

$$mAFR = 1 - \sqrt[7]{1 - x}$$

according to the formula in which x expresses the total failure rate at seven years.[16] For the calculation of relative risks (RR) and confidence intervals (CI) for them, we fit a Poisson distribution model and obtained the P values from a Wald test. To adjust the RR for the effects of covariates, we used Poisson regression models. We used generalized estimation equation methods to account for correlation between restorations placed in the same person. The failure rates we used to calculate the RR consisted of the ratio of the number of events (frequency of failures) to the number of restoration-years. We followed restorations from the time of placement to the last examination at which each restoration was found either to be sound or to have failed. The time to failure for the two kinds of restorations was displayed through Kaplan-Meier survival curves.

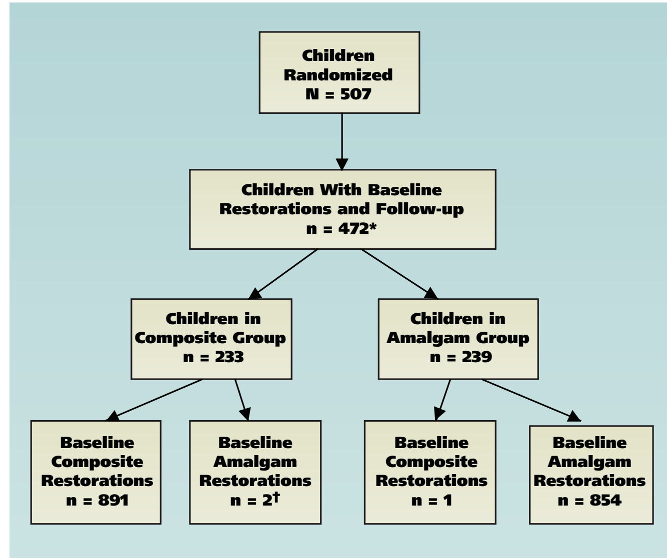

Figure 1. Number of subjects in each group and number of each type of restoration included in the analysis for each group. *Nineteen subjects had no dental examinations after baseline and 16 subjects had no restorations to permanent posterior teeth at baseline. †Two amalgam restorations accidentally were placed in posterior teeth in subjects in the composite group.

RESULTS

The study dentists placed 1,748 posterior restorations during the baseline phase of the Casa Pia study, which we followed for a period of up to seven years. Table 1 shows the number of restorations placed by restorative material, tooth and restoration characteristics.

Overall, 177 (10.1 percent) restorations failed during the course of the study. The survival rate of the amalgam restorations was 94.4 percent at seven years (Table 2). The survival rate for composite restorations was 85.5 percent. Amalgam restorations with only one surface or of small size had the highest survival rates, of 98.8 percent and 98.9 percent, respectively. We found that among the amalgam restorations, large restorations and restorations with three or more restored surfaces had the lowest survival rates. Survival rates of the composite restorations followed the same trend

TABLE 1

Number of posterior restorations placed for each restorative material, by arch, tooth type and restoration characteristics.

RESTORATION CHARACTERISTIC	RESTORATION TYPE		
	Amalgam	Composite	All
Arch			
Maxillary	439	453	892
Mandibular	417	439	856
Tooth Type			
Premolar	91	112	203
Molar	765	780	1,545
Number of Restored Surfaces			
1	429	450	879
2	338	356	694
3	78	74	152
4 or more	11	12	23
Size			
Small	263	282	545
Medium	460	431	891
Large	133	179	312
ALL	**856**	**892**	**1,748**

but were lower than those of amalgam restorations in all instances. We found that among the composite restorations, single-surface and small restorations had the highest survival rate (93.6 percent) and restorations with four or more surfaces had the lowest survival rate (50.0 percent).

Mean annual failure rates ranged from 0.16 to 2.83 percent for amalgam restorations and from 0.94 to 9.43 percent for resin-based composite restorations (Table 2). The reasons for failure are shown in Table 3. All restorations failed because of either secondary (recurrent) caries or restoration fracture. Secondary caries was the main reason for failure in both amalgam and composite restorations, accounting for 66 percent (32 of 48) and 88 percent (113 of 129) of all failures, respectively. This was true independently of the arch, tooth type, number of surfaces restored and restoration size.

Proportionally, more composite restorations than amalgam restorations failed because of secondary caries. Of the failures due to secondary caries, 77.9 percent were in the composite group, while only 22.1 percent were in the amalgam group. On the other hand, among the restorations that failed because of fracture, exactly one-half were composite restorations and the other one-half were amalgam restorations. Table 4 presents the RR of failure due to secondary caries in composite versus amalgam

TABLE 2

Mean annual failure rates and survival at seven years, by arch, tooth type and restoration characteristics.

RESTORATION CHARACTERISTIC	SURVIVAL AT SEVEN YEARS (%)		MEAN ANNUAL FAILURE RATES (%)	
	Amalgam	Composite	Amalgam	Composite
Arch				
Maxillary	95.2	84.5	0.70	2.37
Mandibular	93.5	86.6	0.95	2.04
Tooth Type				
Premolar	94.5	85.7	0.80	2.18
Molar	94.4	85.5	0.82	2.21
Restored Surfaces				
1	98.8	93.6	0.17	0.95
2	90.5	80.6	1.41	3.03
3	88.5	66.2	1.74	5.72
4 or more	81.8	50.0	2.83	9.43
Size				
Small	98.9	93.6	0.16	0.94
Medium	93.3	84.9	0.99	2.31
Large	89.5	74.3	1.58	4.15
ALL	**94.4**	**85.5**	**0.82**	**2.21**

TABLE 3

Reasons for failure, by arch, tooth type and restoration characteristics.

RESTORATION CHARACTERISTIC	NUMBER (%) OF TEETH WITH RESTORATION FAILURE			
	Amalgam		Composite	
	Secondary Caries	Fracture	Secondary Caries	Fracture
Arch				
Maxillary	15 (3.4)	6 (1.4)	64 (14.1)	6 (1.3)
Mandibular	17 (4.1)	10 (2.4)	49 (11.2)	10 (2.3)
Tooth Type				
Premolar	5 (5.5)	0 (0)	16 (14.3)	0 (0)
Molar	27 (3.5)	16 (2.1)	97 (12.4)	16 (2.1)
Restored Surfaces				
1	2 (0.5)	3 (0.7)	26 (5.8)	3 (0.7)
2	22 (6.5)	10 (3)	59 (16.6)	10 (2.8)
3	6 (7.7)	3 (3.8)	23 (31.1)	2 (2.7)
4+	2 (18.2)	0 (0)	5 (41.7)	1 (8.3)
Size				
Small	2 (0.8)	1 (0.4)	16 (5.7)	2 (0.7)
Medium	23 (5)	8 (1.7)	57 (13.2)	8 (1.9)
Large	7 (5.3)	7 (5.3)	40 (22.3)	6 (3.4)
ALL	**32 (3.7)**	**16 (1.9)**	**113 (12.7)**	**16 (1.8)**

restorations. Table 5 presents the same information for failures due to fracture.

The RR of developing secondary caries was significantly higher in composite restorations for both arches, for molars, for restorations involving up to three surfaces and for all restoration sizes ($P < .05$). The risks were not significantly different in restorations with four or more surfaces involved (owing to small numbers) or in premolars. The overall risk of secondary caries was 3.5 times greater in composite restorations than in amalgam restorations. Even after adjustment for sex, baseline age, and tooth and restoration characteristics, the RR was still 3.4 (95 percent CI, 2.1-5.4). Figure 2A (page 781) shows the diverging survival curves due to secondary caries.

On the other hand, the overall risk of fracture for composite restorations was slightly (0.9 times) lower than that for amalgam restorations. After adjustment, the RR was 1.1 (95 percent CI: 0.5-2.4), but neither risk ratio is significantly different from a "no-effect" ratio of 1.0. Figure 2B (page 781), in which the survival curves for fractures in the two kinds of restorations are superimposed, shows the lack of effect.

TABLE 4

Relative risk of secondary caries in composite restorations compared with amalgam restorations, by arch, tooth type and restoration characteristics.

RESTORATION CHARACTERISTIC	RELATIVE RISK	95% CONFIDENCE INTERVAL	*P* VALUE
Arch			
Maxillary	4.3	(2.4-7.5)	< .0001
Mandibular	2.8	(1.6-4.8)	.0003
Tooth Type			
Premolar	2.6	(0.9-7.1)	.0639
Molar	3.6	(2.4-5.5)	< .0001
Restored Surfaces			
1	12.4	(2.9-52.1)	.0006
2	2.7	(1.6-4.3)	< .0001
3	4.3	(1.7-10.5)	.0015
4 or more	2.6	(0.5-13.5)	.2482
Size			
Small	7.4	(1.7-32.3)	.0075
Medium	2.7	(1.6-4.3)	< .0001
Large	4.8	(2.1-10.7)	.0001
ALL	**3.5**	**(2.3-5.1)**	**< .0001**

DISCUSSION

Our study used data collected in a randomized, controlled clinical trial designed to assess the safety of low-level mercury exposure arising from

TABLE 5

Relative risk of fracture in composite restorations compared with amalgam restorations, by arch, tooth type and restoration characteristics.

RESTORATION CHARACTERISTIC	RELATIVE RISK	95% CONFIDENCE INTERVAL	*P* VALUE
Arch			
Maxillary	0.9	(0.3-2.9)	.9139
Mandibular	0.9	(0.4-2.2)	.8483
Tooth Type			
Premolar	NA*	NA	NA
Molar	1.0	(0.5-1.9)	.8858
Restored Surfaces			
1	0.9	(0.2-4.6)	.9182
2	0.9	(0.4-2.2)	.8667
3	0.7	(0.1-3.9)	.6460
4 or more	NA	NA	NA
Size			
Small	1.8	(0.2-2.0)	.6260
Medium	1.0	(0.4-2.7)	.9659
Large	0.6	(0.2-1.9)	.4139
ALL	**0.9**	**(0.5-1.9)**	**.8350**

* NA: Not applicable.

dental amalgam restorations. Even though this study had different objectives, the fact that one-half the subjects had posterior teeth restored with amalgam restorations and the other one-half with resin-based composite—and that the group assignment was randomized—makes the data valid for the purposes of our study. Additionally, the restorative materials and techniques were predetermined and standardized, and all the treatments were performed in the same university clinic, as they would be in a controlled clinical study designed to compare both types of restorations. The only less standardized condition was the fact that the restorations were placed by a larger number of dentists than is usual in clinical studies. On the other hand, the larger number of dentists participating may make the results more comparable with what would be seen in clinical practice.

The identification of the dentist who placed each restoration, though noted on the clinical charts, was never recorded in the computer database. This is the reason why we did not introduce dentist identification as a covariate in the analysis. It has been reported that the dentist's level of experience may influence the clinical performance of dental restorations.[4] All the dentists participating in this study graduated from the Lisbon School of Dental Medicine, but their dates of graduation spanned 15 years, so it is possible that their training in the placement of composite restorations may have varied. Nevertheless, the subjects' assignment to the dentists was completely random. We evaluated the distribution of the dentists by restorative material in a study subsample and found that this distribution was even.

The mean annual failure rates we found in this study for amalgam and composite restorations placed in posterior permanent teeth over a seven-year period of follow-up were, respectively, 0.82 percent and 2.21 percent. These values are in agreement with those found in the dental literature and may be considered as small. In clinical studies, the annual failure rates of stress-bearing restorations have ranged from 0 to 7 percent for amalgam restorations and from 0 to 9 percent for composite restorations.[1,16-25] Some studies that compared posterior amalgam restorations and composite restorations have shown that amalgam restorations have lower annual failure rates.[1,3,18,26] This also was true in our study, in which the mean annual failure rates of composite restorations were almost three times greater than those of amalgam restorations.

Survival results obviously are consistent with the mean annual failure results. Of the amalgam restorations, 94.4 percent remained intact and were considered as clinically successful after seven years, while only 85.5 percent of the composite restorations were so. Other survival rates in studies with approximately the same duration as this study have varied between 80 and 95 percent for amalgam restorations, and between 50 and 92.9 percent for composite restorations.[1,3,19,27-30] In almost all of these studies, survival of amalgam restorations was greater than that of composite restorations. Only one of the cited studies found a better survival for composite restorations.[30]

The reported approximate median survival times ranged from three to eight years for composite restorations and from five to 15 years for amalgam restorations.[2,4,31-35] Since most published clinical studies have reported follow-up times of three years or less, those studies yielded higher survival rates for composite restorations than ours did. Our study had a follow-up period that was twice as long, which exacerbated the observed differences between amalgam and composite restoration survival.

Even though the failure rates we found for composite restorations seem to be among the lowest reported, large restorations and restorations with three or more surfaces involved had mean annual failure rates ranging from 4.15 to 9.43 percent. Norman and colleagues[6] also reported that larger restorations performed more poorly, regardless of material. Even though the mean annual failure rates for both amalgam and composite restorations increased as the size and the number of restored surfaces increased, this increase clearly was more accentuated for composite restorations.

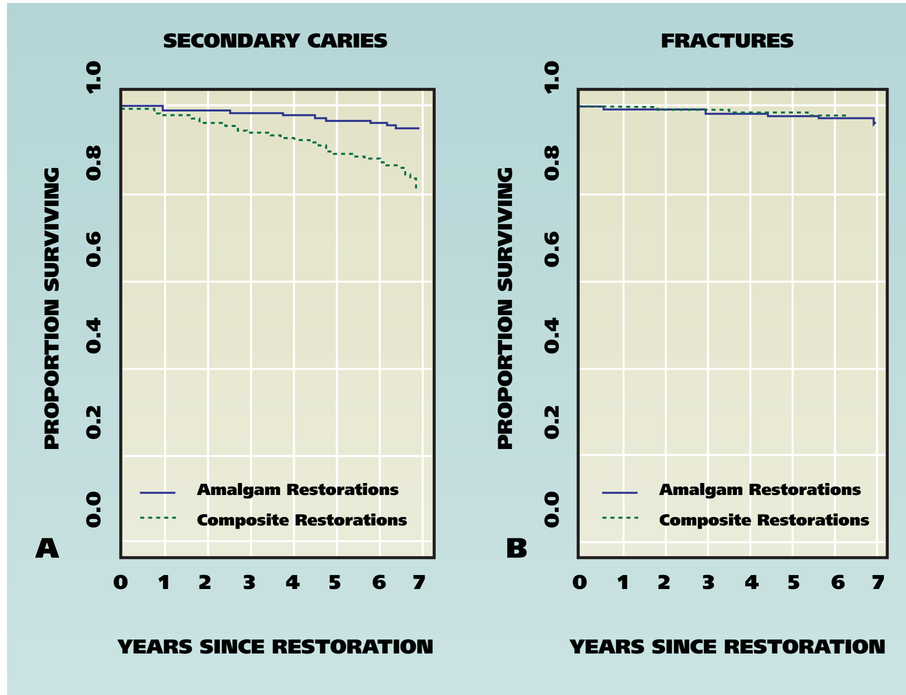

Figure 2. Survival curves. **A.** Secondary caries. **B.** Fractures.

Secondary caries and restoration fracture were the only two reasons we found for failure. We defined secondary caries as the presence of carious lesions located on the margins of existing restorations, and restoration fracture as the loss of material whose location or extension compromises function or the prevention of new disease. Other reasons for failure commonly reported include marginal defects, endodontic treatment, excessive wear and color changes. Most of these reasons are associated with earlier generations of resin-based composites, and they are becoming more rare and less significant in current materials.[36]

Fracture frequently is reported as a reason for failure in load-bearing restorations. The adhesive technique used in composite restorations produces a reinforcement of the restoration-tooth system, reducing the risk of fracture.[37] The fact that we found no significant difference in risk of fracture between composite and amalgam materials is consistent with the intended effect of this adhesive system.

Secondary caries was the main reason for failure in both amalgam and composite restorations. It accounted for 66.7 percent and 87.6 percent of the failures that occurred in amalgam and composite restorations, respectively. Substantial evidence has been reported to confirm that the clinical diagnosis of secondary caries is the principal reason for failure of both posterior composite and amalgam restorations.[2,18,30-32,34,35,38-48] Studies in which fracture was found to be more frequent than secondary caries are rare.[16,33,49]

In our study, amalgam restorations performed consistently better than composite restorations, independently of the type of tooth, number of restored surfaces or size of the restoration. Leinfelder[50] affirmed that the evolution of caries adjacent to composite restorations was faster than that of caries adjacent to amalgam restorations because some resin-based composite components have the ability to promote bacterial growth. Additional explanation for these findings may come from the age group of the subjects enrolled in this study. Poor oral hygiene habits, which are characteristic of teenagers, may have been responsible for the elevated rates of secondary caries in the more susceptible composite restorations. One study that compared longevity of amalgam and composite restorations in teenagers and adults found that the longevity of the restorations placed in teenagers was, on average, five to six years shorter than that of restorations in adults.[4]

CONCLUSIONS

After seven years of follow-up, the mean annual failure rates of posterior composite restorations was significantly higher than those of amalgam restorations, and the corresponding survival rate was significantly lower. This was true irrespective of the arch, type of tooth, number of restored surfaces or restoration size. The main reason for failure was secondary caries, followed by fracture. This was true for both amalgam and composite restorations. The overall risk of failure due to secondary caries was 3.5 times higher in composite restorations than in amalgam restorations. The risk of failure due to fracture was equal in amalgam and composite restorations.

On the basis of the results of this study and within its limitations, posterior amalgam restorations performed better than composite restorations. The difference in performance was accentuated in restorations with more than three surfaces restored and in large restorations. When one takes into consideration that certain factors such as poor training in adhesive procedures, a lack of adequate equipment and insufficient conditions required to execute highly technique-sensitive composite restorations (which still is a reality in many countries and regions of the world), amalgam more often seems to be preferable to resin-based composites for use in direct restoration of large posterior teeth, particularly when the restorations are large. This may be true even in environments in which human and technical conditions exist to produce high-quality dental restorations, as was the case in our study. ■

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