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ABSTRACT

The aim of this meta-analysis, based on individual participant data from several studies, was to investigate the influence of patient-, material-, and tooth-related variables on the survival of posterior resin composite restorations. Following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, we conducted a search resulting in 12 longitudinal studies of direct posterior resin composite restorations with at least 5 years' follow-up. Original datasets were still available, including placement/failure/censoring of restorations, restored surfaces, materials used, reasons for clinical failure, and caries-risk status. A database including all restorations was constructed, and a multivariate Cox regression method was used to analyze variables of interest [patient (age; gender; caries-risk status), jaw (upper; lower), number of restored surfaces, resin composite and adhesive materials, and use of glass-ionomer cement as base/liner (present or absent)]. The hazard ratios with respective 95% confidence intervals were determined, and annual failure rates were calculated for subgroups. Of all restorations, 2,816 (2,585 Class II and 231 Class I) were included in the analysis, of which 569 failed during the observation period. Main reasons for failure were caries and fracture. The regression analyses showed a significantly higher risk of failure for restorations in high-caries-risk individuals and those with a higher number of restored surfaces.

KEY WORDS: resin-based composite materials, restorative materials, risk factor(s), clinical outcomes, clinical studies/trials, operative dentistry.

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Longevity of Posterior Composite Restorations: A Systematic Review and Meta-analysis

INTRODUCTION

Posterior resin composites are widely considered the first-choice material for posterior direct restorations (Lynch *et al.*, 2014). Their survival is good, since reviews have concluded that mean annual failure rates vary between 1% and 3% (Manhart *et al.*, 2004; Heintze and Rousson, 2012). Most clinical studies focused on comparing different brands and types of resin composites, and observation times seldom exceeded 5 years. In recent times, with growing evidence that the material properties in themselves are more than adequate, we focus more on other factors that may determine the survival of restorations, such as patient risk factors (Demarco *et al.*, 2012).

Such factors, possibly related to longevity, were rarely the subject of investigation in specific studies; however, they were sometimes recorded by authors or presented as a general variable in specific studies. Caries risk was assessed in several studies, but only a few included this in the analysis as a variable (Opdam *et al.*, 2007, 2010; Opdam *et al.*, 2010; van de Sande *et al.*, 2013). The application of a liner or base of glass-ionomer cement was often included in the protocol, sometimes as a standard procedure for all restorations (Andersson-Wenckert *et al.*, 2004; Da Rosa Rodolpho *et al.*, 2011), sometimes as an optional procedure (Van Nieuwenhuysen *et al.*, 2003). Only 2 clinical studies have evaluated this factor (Opdam *et al.*, 2007; Pallesen *et al.*, 2013). The same is valid for some other variables that may be important, such as differences between molar and premolar restorations, number of surfaces, etc.

Several reviews on the performance of dental composites have been published (Manhart *et al.*, 2004; Heintze and Rousson, 2012), but their outcome is naturally dependent on the information given in the published papers on which the review is based. Since the factors in which we are now more interested have often not been the primary focus of attention in these studies, they have not been reported on in detail. To include these factors in a review, one

needs the ‘raw’ individual participant data from the studies. We are not aware of any review having been performed including raw data on restoration survival, investigating the above-mentioned variables.

The aim of the present meta-analysis was to include and combine raw data from long-term follow-up studies of at least 5 years’ observation time on posterior resin composite restorations in 1 database to investigate failure rates, failure reasons, and the influence of patient-, materials-, and tooth-related variables on restoration survival.

MATERIALS & METHODS

Data Sources

The guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement—Transparent Reporting of Systematic Reviews and Meta-Analyses (Moher *et al.*, 2009) were followed whenever possible. The search was conducted in the Cochrane Library, PubMed, the Web of Science (ISI), and Scopus for full articles published in English from January 1990 up to February 2013. Hand-searching included the reference list of selected papers and review articles on the subject.

Inclusion and Exclusion Criteria

The eligibility criteria for inclusion were:

- longitudinal studies of direct class II or classes I and II restorations in permanent dentition;
- at least 5 years of follow-up;
- a minimum of 20 restorations evaluated at the last recall; and
- original datasets available, with information regarding date of placement/failure/censoring of all included restorations, restored surfaces, materials used, use of base/liner, reasons for clinical failure, and, when available, the patient’s caries risk status.

The exclusion criteria were:

- studies that were not related to the questions addressed, *i.e.*, presenting different outcome, other cavity designs, primary teeth, anterior teeth, indirect restorations, orthodontic and endodontic reports;
- earlier follow-ups from the same study; and
- impossibility to contact the authors after 5 attempts.

Search

The following terms (controlled vocabulary and free terms) were used to search for articles: “composite”, “amalgam”, “restoration”, “clinical”, “longevity”, “longitudinal”, “follow-up”, “prospective”, “retrospective”, “evaluation”, “posterior teeth”, “molar” and “premolar”. PubMed search was performed as follows: ‘((((“composite”) OR “amalgam”) AND “restoration”)) AND (((“posterior teeth”) OR “molar”) OR “premolar”)) AND

“clinical”) AND “longitudinal”) OR “follow up”) OR “prospective”) OR “retrospective”) AND “evaluation”) OR “survival”) OR “longevity”) OR “long term”) OR “annual failure rate”) OR “restoration failure”)). Filters: From 1990/01/01 to 2013/02/31, English. Updates on the search were scheduled weekly on PubMed.

Study Selection

The articles identified in all databases were screened for duplicates that were automatically excluded. Titles were screened by two reviewers (N.O., M.C.) independently. Those that were considered of interest for this review were printed as abstracts or, if the abstract was missing, as full articles. After abstracts were screened, the remaining articles were ordered in full text. During the evaluation process, the reasons for exclusion were noted, and disagreements were identified by a third reviewer (F.S.), after which the three reviewers (N.O., M.C., F.S.) reached consensus. After selection, the reference lists of included studies were hand-searched, and 7 further studies with potential for inclusion were screened in the same way.

Original Datasets

After critical appraisal, which was carried out by two reviewers (F.S., N.O.), authors from the selected studies were contacted by e-mail, letter, and/or telephone call. If there was no response from the corresponding author after 3 attempts, 2 additional attempts were made to contact other authors from the same study. To join the study, the authors were asked to provide pilot-tested tables with the information required (inclusion criteria), which included: patient variables (identification code, gender, date of birth, and caries-risk status), tooth number, restored surfaces, date of restoration placement, date of restoration evaluation, and date of failure (or time in service of successful and failed restorations), reason for failure, and materials-related variables (restorative materials used, including the use of base-liner).

Data Analysis

Included studies are presented in tables. Qualitative analysis included the reasons for failure, survival and annual failure rates according to caries-risk status, and use of base/liner for resin composite restorations. We used a multivariate Cox regression method to analyze the variables of interest [patient (age; gender; caries-risk status), jaw (upper; lower), number of restored surfaces, composite and adhesive materials, and use of glass-ionomer cement as base or liner (present or absent)] according to tooth type (molar; premolar) and the outcome variable (annual failure rate). The hazard ratios with respective 95% confidence intervals were determined.

The annual failure rate (AFR) of the investigated restorations and subgroups was calculated according to the formula: $(1-y)^z = (1-x)$, in which ‘y’ expresses the mean AFR and ‘x’ the total failure rate at ‘z’ years.

Table 1. List of Included Studies

	Design	Time, yr	N	Alive	Failed	Reasons for Failure					
						Caries	Fracture-		Endo/		
							Tooth	Restor.	Pain	Extr.	Other
Andersson-Wenckert <i>et al.</i> , 2004	Prosp	7	200	160	40	9	8	16	2	1	4
Bottenberg <i>et al.</i> , 2007	Prosp	6	119	97	22	6	5	5	0	0	6
Da Rosa Rodolpho <i>et al.</i> , 2011	Retrosp	22	362	242	120	27	19	52	7	3	12
Gaengler <i>et al.</i> , 2001	Prosp	10	185	144	41	16	0	18	4	2	1
Lindberg <i>et al.</i> , 2007	Prosp	9	138	128	10	5	0	2	3	0	0
Opdam <i>et al.</i> , 2010	Retrosp	12	866	706	160	96	14	14	26	5	5
Opdam <i>et al.</i> , 2007	Retrosp	9	458	381	77	37	13	11	7	6	3
Pallesen and Qvist, 2003	Prosp	11	56	45	11	3	0	4	0	1	3
van Dijken and Sunnegårdh-Grönberg, 2006	Prosp	6	69	55	14	5	5	4	0	0	0
van Dijken and Pallesen, 2011a	Prosp	7	112	90	22	5	6	5	1	3	2
van Dijken, 2000	Prosp	11	132	101	31	7	1	11	0	4	8
van Dijken and Pallesen, 2011b*	Prosp	7	119	98	21	5	6	6	2	0	2
Total	-	-	2,816	2,247	569	221	77	148	52	25	46

N, number of followed restorations; Alive, clinically acceptable restorations at the last recall; Failed, clinically failed restoration at the last recall. *Of this study, seven-year data, provided by the author, were used.

RESULTS

In total, 1,551 papers were originally identified. After duplicates were removed, 1,194 remained for title screening. At that stage, 858 titles were excluded and 336 abstracts were selected for reading, resulting in 54 full-text articles assessed for eligibility. Of these, 25 studies were selected as meeting the inclusion criteria, and the corresponding authors were contacted. Six authors stated that they could not provide the datasets (Rasmusson and Lundin, 1995; Mair, 1998; Lundin and Koch, 1999; Wilder *et al.*, 1999; Wassell *et al.*, 2000; Bernardo *et al.*, 2007). One author (Van Nieuwenhuysen *et al.*, 2003) replied positively but could not provide the data according to the inclusion criteria, being therefore excluded. Six authors could not be contacted after 5 attempts (Nordbo *et al.*, 1998; Raskin *et al.*, 1999; Köhler *et al.*, 2000; Fagundes *et al.*, 2009; Kiremitci *et al.*, 2009; Krämer *et al.*, 2011). In total, eight authors agreed to participate and provided 11 datasets for the meta-analysis (Andersson-Wenckert *et al.*, 2004; Bottenberg *et al.*, 2009; Da Rosa Rodolpho *et al.*, 2011; Gaengler *et al.*, 2001; Lindberg *et al.*, 2007; Opdam *et al.*, 2007, 2010; Pallesen and Qvist, 2003; van Dijken, 2000; van Dijken and Sunnegårdh-Grönberg, 2006; van Dijken and Pallesen, 2011a). One of the authors offered seven-year data on a previously published study, which was included as another study (van Dijken and Pallesen, 2011b). The 12 included studies are summarized in Table 1, with the respective observation period, number of restorations followed and recorded as clinically acceptable or failed, and reasons for failure. In total, 2,816 restorations (2,585 Class II and 231 Class I restorations) were included in the analysis, of which 569 had failed at the end of the observation periods.

The distribution of failure reasons in the first 6 years after restoration is presented in Fig. 1, showing that in the first year

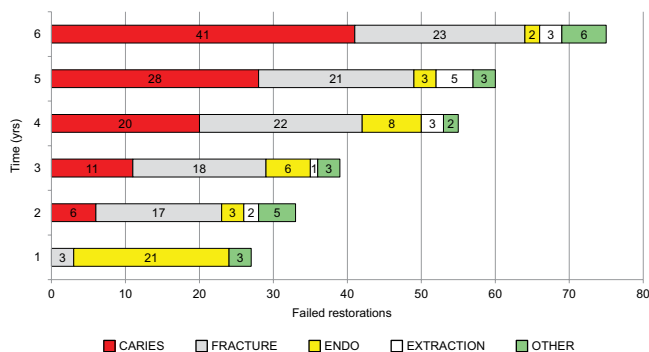


Figure 1. Number of failed restorations with type of failure during the first six-year observation time.

after restoration placement, the reason for failure is almost exclusively endodontic complications, while in later years few endodontic failures are seen and caries and fractures are the main failure reasons.

To cluster types of composite resin and adhesives from the large variety of brands, we decided to divide composites in materials with a higher filler load (> 60% vol) and composites with a filler load < 60 vol%, identified as compact-filled and midway-filled composites according to Willems *et al.* (1992). For adhesives, it was not possible to distinguish among different types of adhesives. The adhesives used included single-step enamel bondings and dentin bondings including total etching and selective etching, with various components and steps, making it impossible to form relevant groups for statistical analysis.

From Table 1, it can be seen that 1,324 out of 2,816 included restorations originated from 1 dental practice. Therefore, 2 Cox

Table 2. Separate Regression Analyses for Premolars and Molars

Cox-Regression and Hazard Ratios (HR)	Premolars			Molars		
	HR	<i>p</i>	95% CI	HR	<i>p</i>	95% CI
All Studies						
Age (\pm 1 yr)	1.004	.607	[0.988, 1.02]	1.001	.833	[0.988, 1.015]
Gender (M = 0; F = 1)	0.94	.72	[0.67, 1.32]	1.16	.296	[0.88, 1.53]
Caries risk (1 = M/H)	2.44	< .001	[1.62, 3.68]	3.04	< .001	[2.21, 4.17]
No. of surfaces (\pm 1)	1.46	< .001	[1.22, 1.75]	1.24	.002	[1.09, 1.42]
Upper jaw	1.07	.684	[0.79, 1.44]	1.09	.462	[0.87, 1.37]
Lining_excl CALHX (0 = no, 1 = yes)	4.93	< .001	[2.24, 10.85]	2.87	< .001	[1.66, 4.95]
HYHF (0 = no, 1 = yes)	0.73	.128	[0.49, 1.09]	1.63	.009	[1.13, 2.34]
	Premolars			Molars		
Reduced No. of Studies	HR	<i>p</i>	95% CI	HR	<i>p</i>	95% CI
Age (\pm 1 yr)	1.002	.848	[0.983, 1.021]	1.017	.095	[0.997, 1.037]
Gender (M = 0; F = 1)	0.91	.64	[0.61, 1.36]	0.94	.752	[0.64, 1.38]
Caries risk (1 = M/H)	1.96	.005	[1.23, 3.12]	1.73	.029	[1.06, 2.81]
No. of surfaces (\pm 1)	1.61	< .001	[1.3, 1.99]	1.35	< .001	[1.13, 1.6]
Upper jaw	0.95	.783	[0.66, 1.37]	0.98	.914	[0.74, 1.31]
Lining_excl CALHX (0 = no, 1 = yes)	1.83	.341	[0.53, 6.34]	0.59	.46	[0.15, 2.38]
HYHF (0 = no, 1 = yes)	0.9	.704	[0.52, 1.55]	1.67	.074	[0.95, 2.92]

Regression analyses were made, 1 including all studies, and 1 without these 1,324 restorations, so that we could analyze the possible influence of this large group of restorations on the final outcome. Because of the different behaviors for molars and premolars for each group, separate regression analyses were made for these tooth categories (Table 2).

The analyses including all restorations were performed on 2,816 restorations except for the caries risk, for which data were missing for 68 restorations. For premolars, the analysis showed more failure for high caries risk (HR 2.44, $p < .001$), presence of lining cement (HR 4.9, $p < .001$), and number of restoration surfaces (HR 1.45 for every extra surface, $p < .001$). For molars, this outcome was similar, with HR 3.04 for caries risk ($p < .001$), 2.87 for lining ($p < .001$), and 1.24 for surfaces ($p = .002$). Additionally, for molars, the compact-filled resin composites showed a higher risk of failure compared with the normal hybrids (HR 1.62, $p = .009$).

The analysis excluding 2 large retrospective studies from 1 research group (Opdam *et al.*, 2007, 2010) showed, for premolars, more failure for high caries risk (HR 1.96, $p = .005$) and number of restoration surfaces (HR 1.61 for every extra surface, $p < .001$). For molars, this outcome was similar, with HR 1.73 for caries risk ($p = .029$), and 1.35 for surfaces ($p < .001$). For both molars and premolars, no influence of the presence of a liner cement as well as type of composite could be established, when these studies were excluded.

Annual failure rates as presented in Table 3 show the influence of high/medium caries risk, with 10-year AFR of 4.6/4.1% compared with 1.6% for low-risk patients. The differences in AFR between high- and low-risk patients are illustrated in the Kaplan-Meier survival graphs in Fig. 2.

DISCUSSION

To our knowledge, this is the first time that a meta-analysis has been performed on raw data from different clinical longevity studies on dental restorations. Although PRISMA guidelines were followed for study selection and reporting of selected studies, these guidelines were not applicable for all aspects of the present study. Meta-analyses are considered the highest degree of evidence, but the design of our present study leads to a number of restrictions on its generalizability. For inclusion, retrospective studies and prospective studies were allowed, practice- as well as university-based, to provide a sufficient number of included restorations. However, differences in practice settings, survival criteria, number of included restorations *per* study, and the fact that 10 of the 12 studies were delivered by only 3 research groups lead to possible bias. Therefore, the authors want to make clear that this is not the ultimate degree of evidence for considering the longevity of posterior resin composites, which might be suggested from its meta-analytic design. In the authors' opinion, the relevance of the present study is that it might bring us a step further in clarifying the overall picture on how long posterior composites survive and what factors may influence their survival. To overcome the most obvious bias in the study, the relatively large proportion of restorations provided by 2 retrospective studies from the first author of this review, we performed 2 separate statistical analyses, 1 on the total sample of included restorations and 1 based on the dataset excluding those 2 studies, which originated from 1 dental practice and did not use Ryge/FDI criteria for evaluation. This resulted in some differences but also confirmed the validity of those findings that were present in both analyses.

Table 3. Annual Failure Rates for the Restorative Groups

Annual Failure Rates	Five-year, %	Ten-year, %
All restorations (n = 2,816)	1.8	2.4
Restorations in high-carries-risk* patients (n = 547)	3.2	4.6
Restorations in medium-carries-risk* patients (n = 385)	3.5	4.1
Restorations in low-carries-risk* patients (n = 1,815)	1.2	1.6
Lining/base GIC present (n = 963)	2.2	2.7
No lining/base GIC present (n = 1,853)	1.7	2.2
Compact-filled hybrid resin composites (n = 1,170)	1.6	2.2
Midway-filled hybrid resin composites (n = 1,646)	1.9	2.3

*For 68 individuals, the caries risk could not be established.

Another example of possible bias is caries diagnosis as a reason for failure. Some studies used Ryge/USPHS criteria, but this is dependent on the judgment of the evaluators, who were not calibrated among the different studies. Second, some of the included studies relied on the judgment of the treating dentist to define a failure due to caries.

Caries leading to replacement of a restoration led to the status ‘failed’ for the restoration in all studies, while the caries might have been located in a surface of the tooth not located next to the restoration. We decided not to differentiate on this, mainly because not all datasets provided these details, but this is also a weak point in the study, demonstrating the lack of standardization in evaluating dental restorations in clinical studies and practice.

The analyses showed that caries risk plays a dominant role in restoration survival (Fig. 2). This was further statistically addressed in 1 of the included studies (Opdam *et al.*, 2010), but since it had not been analyzed or reported in the other studies, this is a valuable confirmation of the importance of this factor. With high or medium caries risk associated with a 2- to 3-times-higher risk of restoration failure, this patient risk factor is probably more important than material factors for survival of dental restorations (Demarco *et al.*, 2011). In a recent study by van de Sande *et al.* (2013), caries risk and bruxism as a risk factor resulted in restoration failure hazard ratios of 4.4 and 2.8, respectively, which confirm the finding of the present study. In our study, we included secondary caries (next to the restoration) as well as primary caries (elsewhere in the tooth, not related to the filling) in the reasons for failure “caries”. As a result, not all of these failures are related to the quality of the restoration, but meanwhile resulted in repair or replacement of the restoration.

For materials factors important for survival, the presence of a liner or base from glass-ionomer cement was shown to have a negative influence on survival of the restoration. However, without the 2 large practice-based studies, this effect was not found, indicating that this finding was related to those datasets and may be related to operator factors. There is 1 other practice-based study, not a part of this meta-analysis, which confirms that restorations with a liner (in that study primarily calcium hydroxide) showed a lower survival (Pallesen *et al.*, 2013). The glass ionomer cement (GIC) sandwich-type restorations were the preferred way for achieving bonding between dentin and composite resin at a time when dentin adhesives were still of inferior

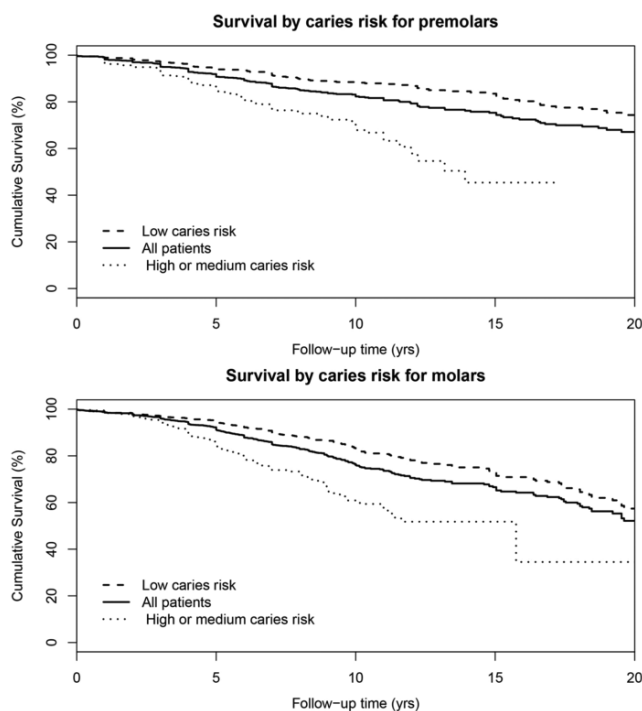


Figure 2. Kaplan-Meier graph showing survival of molar and premolar restorations. Separate graph lines express survival of low- and high- + medium-risk patients, including a line for combined risks.

quality. The later development of specific dentin adhesives has led to the demise of this sandwich technique. The application of such a layer was also considered favorable for compensation of polymerization stress in the past (Perdigão *et al.*, 1996), but this elastic layer concept has been challenged (De Munck *et al.*, 2005). A 12-year follow-up study showed that the elastic wall concept did not improve performance of restorations (van Dijken, 2010). The possible increased failure rate of restorations with a base or liner of a glass-ionomer cement has been attributed to more fatigue, related to the weaker cement layer (De Munck *et al.*, 2005).

A different behavior for resin composite materials with higher and lower filler loads was found for molars only when all

studies were included in the analysis. Even there, the effect was opposite to what might be expected, with the compact-filled materials showing an increased failure risk. Materials with a higher filler load had an elastic modulus of > 20 GPa, and because of their intrinsic strength, a better performance in stress-bearing areas could be expected. Therefore, the better performance of mid-filled hybrid composites is difficult to explain from a dental materials point of view. The fact that this finding was not replicated in the reduced analysis may point toward either a very limited effect, requiring a very large study to reach significance, or a study bias from the retrospective studies omitted in the reduced analysis. In any case, it may be safely stated that the hypothesis that high-modulus resin composites perform better than lower filled materials was not confirmed by the present study.

The AFR as reported in reviews for posterior composites varied between 0% and 6% according to Manhart *et al.* (2004) and was concluded to be 1% in a recent review by Heintze and Rousson (2012). When the AFR for all composites was considered in the present analysis, results showed a mean annual failure rate at 5 and 10 years of 1.8% and 2.4% for posterior composite restorations (mainly class II in contrast to the earlier reported studies), respectively, which matches the earlier reports and which can be considered satisfactory from a clinical perspective.

The outcome of the present study confirms that larger restorations have a higher risk for failure, since every extra surface included in a restoration increases this risk by 30%-40%.

Because of different behaviors for molars and premolars, separate regression analyses were made for these teeth categories, and therefore, a direct comparison between molars and premolars in the analysis was not possible. The Kaplan-Meier graphs of premolars and molars (Fig. 2) indicate that the risk for failure of restorations placed in molars is higher than that for restorations in premolars.

The graph showing the types of failure over time during the first 6 years shows that the most common failures – secondary caries and fracture – are typically failures that appear after a longer time of service (Fig. 1). From the second year onward, fracture is a constant important reason for restoration failure. For caries, the number of events increases over time. Endodontic complications are typically related to the first year of service, which can be explained by the pulpal damage of the condition that caused the restoration and the restorative procedure itself. The graph emphasizes that short-term studies (< 3 years' observation time) have limited relevance for clinical durability of restorations, since most acceptable materials remain failure-free in the first years. This is also expressed by the cumulative AFRs in Table 3, which are lower at 5 years' service compared with 10 years' service. However, short-term studies remain useful to exclude materials with initial catastrophic failures.

The conclusion of the present meta-analysis of 12 clinical studies based on raw data is that caries risk and number of restored surfaces play a significant role in restoration survival, and that, on average, posterior resin composite restorations show a good survival, with annual failure rates of 1.8% at 5 years and 2.4% after 10 years of service.

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