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# Longevity of posterior direct versus indirect composite restorations: A systematic review and meta-analysis

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ARTICLE INFO	A B S T R A C T					
Keywords: Composite Indirect restoration Direct restoration Failure Clinical studies/trials Meta-analysis Operative Dentistry Systemic reviews and evidence-based medicine	Objectives: The goal of this systemic review and meta-analysis was to compare the longevity of direct and indirect composite restorations in posterior teeth.Data: Randomized controlled trials (RCT) investigating direct and indirect composite restorations in permanent posterior teeth.Sources: Three electronic databases (PubMed, CENTRAL (Cochrane) and Embase) were screened. No language or time restrictions were applied. Study selection, data extraction and quality assessment were done in duplicate. Risk of bias and level of evidence was graded using Risk of Bias 2.0 tool and Grade Profiler 3.6.Results: A total of 3056 articles were found by electronic databases. Finally, five RCTs were selected. Overall, 627 restorations of which 323 were direct and 304 indirect composite restorations have been placed in 279 patients (age: 28–81 years). The highest annual failure rates (AFR) were found for indirect restorations ranging from 0 % to 15.5 %. Lower AFR were found for direct restorations ranging from 0 % to 5.4 %. The most frequent failures were found to be chipping and fracture of the restoration followed by caries. Meta-analysis revealed that the failure rate for direct restorations was significantly lower than for indirect restorations (Risk Ratio (RR) [95 %CI] = 0.61 [0.47; 0.79]; very low level of evidence). Furthermore, all studies showed a high risk of bias. Conclusion: Direct and indirect composite restoration. Meta-analysis revealed significantly lower relative risk to fail for direct composite restorations than for indirect restorations but results are with high risk of basis.					

## 1. Introduction

The longevity of restorations is dependent on several factors. In previous studies, material-, tooth- and patient-related factors have been identified [1,2]. For instance, the mechanical load on posterior teeth is significantly higher than on anterior teeth [3]. Focusing specifically on posterior teeth, the challenge intensifies when restoring defects while maintaining a maximum of dental hard tissue. The choice of restauration material and technique (direct or indirect) is highly dependent on the number of surfaces, the location of the lesion, and the remaining dental hard tissues.

One site laboratory-processed or CAD/CAM manufactured restorations provide clinical benefits, e.g. marginal integrity, color stability, wear resistance similar to enamel, wear compatibility with the residual natural dentition, compressive strength, fracture resistance, and elastic modulus [4–6]. Additionally, indirect restorations are superior predominantly considering the design of lager restorations, showing ideal anatomic morphology with optimal proximal adaptation and occlusion compared to direct composite restorations [7].

Subgingival margins are still a challenge in every restorative treatment. Without proper accessibility and sufficient drainage, the placement of direct or indirect restorations is impaired. Poor margin adaptation increases the risk for bacterial accumulation and thus the risk of gingival inflammation and/or secondary caries increases [8].

Although direct restorations are minimal invasive there is a parameter of polymerization shrinkage during light curing for the composite, whereas indirect restorations have minimal shrinkage due to the thin layer of luting cement [9]. Besides material-, tooth- and patient-related factors, there are also technique or operator related factors, influencing the longevity. For instance, the method of placement of the restoration,

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accessibility, and experience of the operator during treatment influences the success rate of direct and indirect restorations [10,11]. In the literature heterogenous results and recommendations regarding direct and indirect composite restorations can be found. In most reviews and meta-analyses no statistically significant differences on the failure rate of these types of restorations were found for posterior teeth [12–15]. Only one systemic review found higher failure rates for direct and indirect composite restorations in molars compared to premolars [16]. However, there is still a lack of information to conclude whether indirect and/or direct composite restorations should be preferred in premolars and/or molars. These insights might help in treatment decisions finding the appropriate restoration material and technique for restoring premolars and molars with the preferably highest rate of restoration and tooth survival.

We hypothesized, that indirect composite restorations have longer times to first (repairable or non-repairable) failure and lower annual failure rates compared to direct composite restorations.



Fig. 1. Prisma Flow Diagram.

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## 2. Material and methods

#### 2.1. Review design

This review aimed at systematically retrieving and analyzing randomized controlled trials (RCT) investigating direct and indirect composite restorations in permanent posterior teeth. The review was conducted according to the guidelines by the Cochrane Collaboration [17,18]; reporting followed the PRISMA statement (Preferred Reporting Items for Systematic Reviews and Meta-analyses) [19]. No study registration is necessary for this review. The inclusion criteria were based on the following elements of PICOS:

- 1. Population (P): permanent posterior single teeth (premolars and/or molars) in adults
- 2. Intervention (I): adhesively-luted indirect resin composite single tooth restorations.
- 3. Comparison (C): direct resin composite single tooth restorations
- 4. Outcome (O): time to first repairable or non-repairable failure of the restoration and annual failure rate
- 5. Study design (S): Retro- and prospective, (non-)randomized (un-) blinded clinical trials with at least three years of follow-up; Sufficient information extractable e.g.: number of restorations placed, outcome assessment, reason for failure

## 2.2. Exclusion criteria

The following exclusion criteria were adopted to PICOS:

- Other than in-vivo studies (e.g.: in vitro, in situ, case report, reviews)Case reports
- Restorations with one surfaces, e.g. class I or class IV restorations
- Studies with less than 3 years follow

## 2.3. Data sources

As described in a previous study, the electronic search was conducted through PubMed (Medline), CENTRAL (Cochrane) and Embase in November 2021 and updated in June 2024 as described in our previous study [18]. Detailed search strategies were developed and appropriately revised for Medline/PubMed (Fig. 1). The search strategies for CENTRAL and Embase were adapted from the strategy for Medline but revised appropriately for both databases to take account to the differences in vocabulary and syntax rules.

The search was continued and updated until June 2024 independently and in duplicate by three authors (LS, CT, CM). We adapted the same requirements as in our previous study [18]: The reviewers were not blinded to the identity of the journal names or article authors, their institutions, or the results of their research. No language or time restrictions were applied. A detailed sequence of filtering search results to include relevant articles can be found in the supplementary material. In order to further identify potential articles for inclusion, grey literature was searched in the register of clinical studies hosted by the US National Institutes of Health (www.clinicaltrials.gov), the multidisciplinary European database (www.opengrey.eu), the National Research Register, and Pro-Quest Dissertation Abstracts and Thesis databases. Selected articles were screened full-text. Furthermore, grey literature was searched and cross-referencing was performed to identify further articles to be assessed (Fig. 1).

#### 2.4. Data extraction

The data extraction has been performed as described in our previous study [18]. Only available data given in the articles were used. If needed, the authors were contacted twice per e-mail for additional information. Three authors performed data extraction till June 2024

independently and in duplicate (LS, CT, CM). Following data were extracted in predefined structured excel sheets:

- Study name, year of publication and study type
- · Setting and country
- Number of participants, sex, age, general health condition and caries risk assessment if available in the article
- · Localization of the cavo-surface margin
- · Cavity type and reason of the intervention/treatment
- Methods of treatments and materials
- Author of placement, evaluator and evaluation criteria
- Follow- up, primary and secondary outcomes
- Lesion extension: surfaces of restoration
- Lesion margin: enamel or dentin
- Materials: restorative materials, adhesive technique, resin based luting agent and base material if the information were available
- Technical issues: e.g., beveled cavity margins or use of rubber dam, etc.

#### 2.5. Definition of failure

All studies indicated whether reintervention was required. Therefore, in the present study, the originally placed restoration was considered successful if no clinical or radiographic evidence of technical failure (e.g. loss of retention, root fracture or post fracture) was reported.

In contrast, if the originally placed restoration was renewed, repaired, or recemented due to fracture, loss of restoration, secondary caries, and/or other reasons, the restoration was counted as (biological) failure. However, endodontic procedures and chipping, that did not result in renewal, repair or recementation of the restoration were not viewed as biological failures, but the observation period was censored as described in our previous study [18].

## 2.6. Data analysis and grading

The statistical analyses were conducted in Review Manager (RevMan version 5.4 software, Cochrane Collaboration, Copenhagen, Denmark, 2014) as done previously [20]. Meta-analyses were conducted if studies with similar comparisons reported the same outcomes. For dichotomous outcome data (e.g. failure vs no failure), the primary measures of effect was risk ratios (RR) and 95% confidence intervals (95%CI). Statistical significance was defined as a p-value  $\leq 0.05$  (Z test) and heterogeneity was assessed with  $Chi^2$  test and  $I^2$  [21]. As done previously the fixed-effect model was chosen ( $I^2 < 35\%$ : fixed-effects;  $I^2 > 35\%$ : random-effect) [18,22]. The number of events was considered as the number of failures. To avoid unit-of-analysis errors the guidelines outlined by the Cochrane collaboration (chapter 9.3.4.) were followed [17]. Therefore, baseline data were compared with data of a single time point (mostly longest follow-up period). Forest plots were created to illustrate the meta-analysis. Risk of bias for interventional, randomized controlled trials (RCTs) was performed independently and in duplicate (R.J.W, T.S. C.) using the Risk of Bias 2.0. tool [23] and for interventional, non-randomized controlled trials using the ROBINS-I-tool [24]. Grading of evidence was performed according to the GRADE network levels using Grade Profiler 3.6 [25].

#### 2.7. Heterogenity

As done previously clinical and methodological heterogeneity were assessed by examining the characteristics of the studies, the similarity between the types of participants, the interventions, and the outcomes as specified in the inclusion criteria for considering studies for this review [18]. Statistical heterogeneity would have been assessed using a Chi<sup>2</sup> test and the I<sup>2</sup> statistic, where I<sup>2</sup> values over 50% indicated substantial heterogeneity [26].

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## 2.8. Assessment of reporting bias

In the presence of more than 10 studies in a meta-analysis, the possible presence of publication bias was investigated for the primary outcome. Publication bias was assessed by Funnel plots [18, 20, 26, 27].

#### 2.9. Sensitivity analysis

We explored whether or not the analysis of studies stratified by (1) risk of bias or (2) study design yielded similar or different results. For this (1) studies at high risk of bias or (2) studies using a split-mouth design were eliminated in a second/third analysis [18, 20, 26].

#### 3. Results

A total of 3056 articles were found on PubMed (Medline), CENTRAL (Cochrane) and Embase (Fig. 1). A total of 186 records and additionally 21 records through cross-references and 22 found by hand-search were full-text screened. Of these, 114 articles were assessed for eligibility and finally, five randomized controlled clinical trials were selected [28–32]. Reasons for exclusion are shown in Fig. 1. Of these, three studies were parallel-arm [28, 29, 32] and two with a split-mouth design [30,31].

The included studies were published between 2003 and 2021. Overall, 627 restorations of which 323 were direct and 304 indirect composite restorations have been placed in 279 patients (age: 28–81 years).

The results of the included studies are represented in Table 1. The observation periods ranged from 3.5 years up to 11 years. Between the studies the dimensions of the restorations varied. One study observed indirect and direct restorations including one cusp in premolars [32]. Another study compared indirect and direct tabletop restorations [29]. The remaining three studies included class II direct and indirect restorations (28, 30, 31]. Concerning indirect composite restorations, three studies didn't provide information about temporary restorations over the period of manufacturing the indirect restorations [29–31], while the other two included studies used temporary restorations [28, 32].

The annual failure rates (AFR) of the included studies ranged from 0% to 15.5% with a maximum follow up of 11 years. All indirect restorations were composite restorations. The AFR for direct composite restorations ranged from 1.6% to 5.4%, whereas the AFR for indirect restorations ranged from 0% up to 15.5%. The highest failure was observed in indirect restorations with 15.5% after 3.5 follow up years [29]. The most frequent reason of failure observed in direct restorations were inadequate marginal adaptation followed by fractures. Fracture of the restoration and secondary caries were the most frequent failures

#### Table 1

Overview over included studies.

observed in indirect restorations [28-32].

Meta analysis revealed that the relative risk to fail for direct restoration was significantly lower than for indirect restorations (visual-tactile assessment): Risk Ratio (RR)[95%CI]= 0.61 [0.47 to 0.79)]) (Fig. 2).

No sensitivity analysis was performed because all studies revealed a high risk of bias and a split mouth design (Fig. 3).

#### 4. Discussion

The present systemic review and meta-analysis on the longevity of posterior direct and indirect composite restorations revealed that the relative risk to fail for direct restorations is significantly lower than for indirect restorations. Thus, our previous hypothesis, stating that indirect composite restorations might have a lower annual failure rates than direct restorations was rejected. The main cause of failure in indirect restorations were found to be fractures of the restoration and secondary caries, whereas in direct restorations most failures were caused by fracture of the restoration or inadequate marginal adaptation [28–32].

In two studies a split mouth design was used to compare the longevity of direct and indirect composite restorations, enabling that both restoration types were exposed to the same biological and mechanical factors for best comparability of the treatment techniques [28, 31]. Regarding evaluation criteria, two out of five studies used their own criteria, the other three had the same criteria (modified USPHC) [28, 30, 31]. In our systemic review and meta-analysis we defined our own failure criteria for homogeneity. We considered a restoration as failure if the originally placed restoration was renewed, repaired, or recemented due to fracture, loss of restoration, secondary caries, and/or other reasons, the restoration was counted as (biological) failure.

There are systematic reviews and meta-analyses investigating the performance and failure rates of posterior direct and indirect composite restorations. However, most of these reviews included studies with short-term follow up, meaning less than three years follow up [12, 14–16, 33]. However, some risk factors become visible only after longer follow-up periods [34]. Furthermore, risk patterns change over time and observational periods of at least 5 years in clinical studies have been recommended for indirect restoration [35]. This can specially be seen in the publications derived from the same cohort [32,36] in which the numbers of failures doubled within an additional observation period of 10 years. Furthermore, one of the mentioned systematic reviews investigated the survival rate of restorations on endodontically treated teeth [14], whereas another review examined the survival rate of different restoration materials in patients treating defects due to tooth wear [33]. Both factors (endodontically treated teeth as well as tooth wear) are

Author/ Year	Subjects (male/ female)	Subjects Age (years)	Number of total restorations	Tooth type Premolars/ Molars	Type of restoration	max. follow -up (years)	N Dropouts	N Restorations assessed (type of restoration)	N Restorations failed (type of restorarion)	% Restorations failed (type of restoration)	% Annual failure rate (type of restoration)
Cetin et al. 2013	54 (22/32)	20 - 28	108	0/108	Class II	5	0	26 (direct) 25 (indirect)	1 (direct) 1 (direct)	4 (direct) 4 (indirect)	1.6 (direct) 2.5 (indirect)
Crins et. al 2021	42 (N/A)	30 - 43	408	0/408	Tabletop	3.5	0	88 (direct) 76 (indirect)	14 (direct) 14 (indirect)	16 (direct) 8.5 (indirect)	5.4 (direct) 15.5 (indirect)
Hofsteenge et. al. 2023	157 (77/ 80)	35 - 81	157	157/0	Class II with cusp	20	45	69 (direct) 62 (indirect)	34 (direct) 37 (indirect)	49 (direct) 60 (indirect)	2.4 (direct) 3.3 (indirect)
Pallesen et al. 2003	28 (8/20)	19 –64	135	88/52	Class II	11	5	54 (direct) 74 (indirect)	11 (direct) 24 (indirect)	20.5 (direct) 32.5 (indirect)	2.0 (direct) 2.0 (indirect)
Spreafico et al.	11 (4/7)	18 – 27	44	30/14	Class II	3.5	0%	22 (direct) 22 (indirect)	0 (direct) 0 (indirect)	0 (direct) 0 (indirect)	0 (direct) 0 (indirect)



Fig. 2. Forrest plot for meta-analysis of included studies of direct composite versus indirect composite restorations in terms of failure of the restoration.



Fig. 3. Risk of bias summary. Review authors' judgment about each risk of bias item for each included study. Red (-) corresponds to high risk, green (+) to low risk and yellow (?) to uncertain risk of bias.

confounders in the analysis of annual failure rates and may obscure other factors that would be predominant under more generalized conditions. Nonetheless, both reviews are in line with the present meta-analysis. For teeth with special conditions no significant difference in the survival rates between direct or indirect composite restorations could be observed.

One important factor leading to failure might be the location of the restoration margin, since fracture of the restoration and secondary caries might be caused by reduced or poor adhesion of the restoration [37]. Two studies had restoration margins in dentin [30,32]. In one of the two studies the restoration margins were even subgingivally [32]. Restoration margins mostly in dentin have been shown to be of higher risk of failure than restoration margins in enamel due to the differences in adhesion properties between enamel and dentin, which clearly favours restoration margins in enamel for best adhesion of the adhesive-luted restoration. Dentin consists of fluid-filled tubules and a high proportion of collagene fibres and a lower proportion of minerals compared to enamel. Fluid from the dentinal tubules keep the surface of the exposed dentine naturally moist and hydrophilic [38,39]. This hydrophilicity represents one of the major challenges for the interaction of modern adhesives with dentine [37]. However, the influence of this challenge on the longevity could neither in the present nor in the recent meta-analysis [12, 14–16, 18, 33].

The insertion of an indirect composite restoration is a multi-step procedure requiring dentin and enamel adhesives, a dual-cured composite and an adhesive to the indirect composite restoration. This requires a precise handling by the operator and is sensitive to contamination with saliva and other fluids [40,41]. Adhesively-luted indirect (ceramic) restorations have been found to show marginal deterioration of the luting space in earlier studies [42-44]. This may lead to a significant decrease in marginal integrity over time [43] and might explain the present findings that indirect restoration showed a significantly higher risk to fail than direct restorations. Lack of adhesion of the restoration might increase the risk of fracture of the restoration, marginal gap formation, and secondary caries. The high occlusal forces and occlusal wear at molars have been found increase the risk of fracture of indirect restorations [41]. For composite restorations, secondary caries seems to be one of the major factors for failure/intervention. This is attributed to a patient-related factor, poor oral hygiene [45-47].

When inserting indirect adhesively-luted restorations, additional factors may influence the adhesion. For instance, a temporary restoration might be necessary before inserting the indirect restoration, unless the restoration will be digitally scanned and manufactured chairside. In the present meta-analysis, all included studies did silicon impressions of the cavities for indirect restorations, but only two studies provided information about temporary restorations. Cetin et al. and Fennis et al. used temporary restorations and inserted them using eugenol-free cement [28] or a spot etch technique. Impression materials, but moreover temporary cements may interfere the adhesion of the definitive restoration. They may not be removed completely from the cavity surface, since they may penetrate dentinal tubules and reduce the adhesion of the luting cement [48,49].

Another factor influencing the long-term performance of direct and indirect composite restoration might be the conversation rate of the adhesive system and the restoration material through light curing. When inserting indirect composite restorations the light source has to penetrate the restoration, the resin cement and the adhesive system applied to the dental hard tissues to successfully harden all materials. When this is not the case, a low conversation rate of the luting resin materials will decrease the adhesion of the restoration to the cavity [48]. Although, mostly resin cements used for inserting indirect composite and ceramic restorations are dual-cure materials, the self-curing components have not been able to compensate the low light irradiance and produce the same degree of conversion as through light-activation only [50]. Direct composite restorations might have a higher conversation rate, when they are inserted in increments and increments are cured properly as shown in previous investigations [51].

In conclusion, for indirect and direct restorations annual failure rates varied between good to moderate. Thus, both types of restoration can be recommended. Meta-analysis revealed that the relative risk to fail for direct composite restorations is significantly lower than for indirect composite restorations. The most frequent failures were found to be chipping and fracture of the restoration followed by caries. To further confirm these findings, more long-term studies are needed in order to evaluate direct and indirect composite restorations using standardized assessment criteria.

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## Ethical approval

This article does not contain any studies with human participants or animals performed by any of the authors.

#### Informed consent

For this type of study, formal consent is not required.

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#### CRediT authorship contribution statement

Tennert, Christian: contributed to conception, design, acquisition, analysis and interpretation, drafted and critically revised the manuscript, Christina Maliakal: contributed to design, acquisition, analysis and interpretation and critically revised the manuscript, Suárez Machado, Lázaro Humberto: contributed to design, acquisition, analysis and interpretation and critically revised the manuscript, Jaeggi, Thomas: contributed to conception, acquisition and critically revised the manuscript, Meyer-Lueckel, Hendrik: contributed to conception, acquisition and interpretation, critically revised the manuscript, Wierichs, Richard Johannes: contributed to conception, analysis and interpretation, drafted and critically revised the manuscript, All authors gave their final approval and agree to be accountable for all aspects of the work.

#### **Data Availability**

All data generated or analyzed during this study are included in this article [and/or] its supplementary material files. Further enquiries can be directed to the corresponding author.

#### Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.dental.2024.07.033.

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