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EPA Consensus Project Paper: Failure Rates of Direct Versus Indirect Single-Tooth Restorations. A Systematic Review and Meta-Analysis

Keywords

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ABSTRACT

Introduction: The purpose of this systematic review and meta-analysis was to evaluate and compare the failure rates of direct and indirect restorations for single-tooth restorations. Methods: A literature search was conducted by using electronic databases and relevant references for clinical studies on direct and indirect dental restorations with a follow-up of at least 3 years. The risk of bias was assessed with the ROB2 and the ROBINS-I tools. The I2 statistic was used for the assessment of heterogeneity. The authors reported summary estimates of annual failure rates of single-tooth restorations using a random-effects model. Results: Of 1415 screened articles, 52 (18 RCTs, 30 prospective, 4 retrospective) met the inclusion criteria. No articles with direct comparisons were identified. No significant difference was found in the annual failure rates of single teeth restored with either direct or indirect restorations, which were calculated as 1% using a random-effects model. High heterogeneity was found, ranging from 80% (P<0.01) for studies on direct restorations to 91% (P<0.01) for studies on indirect restorations. Most of the studies presented some risk of bias. Conclusions: Annual failure rates were similar for direct and indirect single-tooth restorations. Further randomized clinical trials are needed to draw more definitive conclusions.

INTRODUCTION

Despite the advances in prevention and oral health, caries remains the primary reason for loss of tooth structure with high prevalence especially among underprivileged groups, affecting a high number of adults around the world.[1] Loss of tooth structure may also arise from non-carious lesions such as erosion, abfraction, attrition as well as fractures and developmental disorders.[2,3] Dental procedures to restore carious and non-carious tooth defects are necessary for biological, functional, esthetic and psychosocial reasons.[4] Direct or indirect restorations with different advantages, disadvantages and indications have been used to replace missing tooth structure.[4-6]

The extent of missing tooth structure has been considered as the predominant factor affecting the selection among direct and indirect techniques.[5] Small and medium-size defects are usually restored with direct restorations with amalgam and direct resin-based composite (RBC) being the most commonly materials used.[5] Although amalgam has been widely used for the restoration of posterior teeth as a predictable and low-cost

treatment, its use decreased over the years due to the lack of adhesive properties, the unesthetic appearance and concerns relating to potential mercury toxicity.[7] For these reasons, direct RBCs have been increasingly used over the last years as a tooth-colored alterative, offering higher esthetics, reduced need of sound tooth removal, repairability and good clinical performance.[8,9] The indications of RBCs have expanded from anterior and small posterior restorations to larger stress-bearing posterior restorations.[9,10]

For the restoration of teeth with larger defects and inadequate remaining tooth structure, indirect complete and partial coverage restorations have been recommended.[5] Metal-ceramic crowns have been the gold standard for full-coverage restorations demonstrating a survival rate of 94.7% after 5 years.[11-13] All-ceramic crowns are considered an alternative to metal-ceramic crowns with better esthetics and similar survival rates for most types of all-ceramic materials, for both anterior and posterior teeth.[11,14,15] Zirconia has also been extensively used for monolithic or bi-layered single crowns due to its' increased flexural strength and fracture toughness.[16,17]

However, complete coverage restorations require the removal of large amount of healthy dental tissue in order to provide adequate retention and resistance form to the restorations.[18] Considering this, adhesively bonded indirect partial coverage restorations requiring less tooth removal have been used with high survival rates.[4,19] Partial indirect restorations such as inlays, onlays and overlays for posterior teeth as well as veneers for anterior teeth can be fabricated with either ceramic or RBC materials.[4,20,21]

The selection of the most suitable restoration and restorative material is challenging, and several different direct and indirect techniques/materials have been used for single tooth restorations. This implies the need for an evidence-based study evaluating and comparing the clinical performance of these alternatives. Several systematic reviews compared direct versus indirect RBC restorations in the literature.[5,22,23] A previous systematic review comparing direct and indirect restorations on single posterior endodontically treated teeth[24] reported that there was no difference in failures based on low-quality evidence. Another systematic review found lower failure rates for crowns on teeth with fewer than two remaining walls compared to direct restorations.[25] However, there is no systematic review comparing broadly direct and indirect restorations for vital single teeth.

Therefore, the aim of this systematic review and meta-analysis was to assess the failure rates of direct and indirect restorations for single tooth restorations.

MATERIALS AND METHODS

This systematic review aimed to compare the failure rate of direct as compared to indirect single tooth-supported restorations. The focused question was based on the patient, intervention, comparison, outcome (PICO) question: "Is there a difference in the survival (O) of direct (C) versus indirect (I) restorations in adult patients receiving single-tooth dental restorations (P)?". The databases included MEDLINE-PubMed, Scopus, and Cochrane Central Register of Controlled Trials (CENTRAL). Inclusion criteria were prospective or retrospective and/or randomized clinical trials (RCTs) reporting on survival or failure rate of direct and indirect restorations, for a follow-up of at least 3 years published since 1980. In vitro studies, case reports studies, case series studies, experts' opinions and reviews, studies with not well described clinical work steps and studies on flowable or bulk fill or chemical cured composites, or glass-ionomer cements, on cast full or partial coverage restorations on non-carious cervical lesions, on teeth with developmental disorders and on removable partial denture abutment teeth and studies not reporting on were excluded from the search string. Studies on single teeth (anterior and posterior) without root canal treatment were included when the type of restorative material was mentioned in the study while articles in language other than English were excluded *(Table 1)*. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (26) were followed and the study protocol was registered in PROSPERO (CRD42021288545), to perform a systematic search of indexed literature.

Electronic database searches were conducted to identify studies reporting on survival of direct or indirect restorations on single permanent teeth. An advanced search was performed as follows: ((amalgam OR composite OR ceramic OR crown OR onlay OR inlay OR overlay OR veneer OR zirconia OR direct restoration* OR indirect restoration*) AND (tooth OR teeth)) AND (survival OR longevity OR complication*). The search was limited to English language and clinical studies. The search period was from January 1, 1980, to March 1, 2022. In addition to the electronic search, database citations and the references of the selected after title and abstract selection studies were also searched. A reference manager software program (Endnote 20, Clarivate Analytics, Philadelphia, PA) was used and the duplicates were discarded electronically.

A calibration exercise with two reviewers (KC, IP) was conducted prior to commencing screening. Using the inclusion criteria, a random sample of 10% of citations from the search were screened independently by both reviewers. Screening only began when percent agreement was >90% across the two reviewers. A similar calibration exercise was completed prior to screening full-text articles for inclusion. The two reviewers screened independently titles and abstracts for potential inclusion. Any disagreement was resolved by means of discussion with the other two reviewers (PK, ABB) and, in case of doubt, the full text of the articles in question was obtained. Full-text reading of the selected publications was carried out independently by the two reviewers. The electronic search was also supplemented by search of the database citations and the references of the selected articles. In cases of missing information, the authors were contacted by email. Inter-reviewer agreement was determined using the Cohen kappa statistics.

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Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Prospective, retrospective and randomized clinical trials reporting on survival or failure rate of direct and indirect restorations (January 1, 1980, to March 1, 2022)	Laboratory studies
Follow-up of at least 3 years	Case-reports, case-series, case-control studies, expert opinions, reviews
Published since 1980	Studies in a language other than English or without an English-language abstract
Studies conducted in human adults (age≥18yrs)	Studies with not well described clinical work steps
Studies on single permanent teeth (posterior/ anterior) without root canal treatment	Studies on flowable or bulk fill or chemical cured composites, or glass-ionomer cements
Type of restoration indicated	Studies on cast full or partial coverage restorations
Published in English	Studies on non-carious cervical lesions
	Studies on teeth with developmental disorders
	Studies on removable partial denture abutment teeth

Data from the articles that met the inclusion criteria was collected into structured tables using Microsoft Excel. The extracted data was double checked (KC, IP), and any discrepancies were resolved with discussion with the other two reviewers (PK, ABB). The following information was extracted from the selected articles: author(s), year of publication, study design, study setting, mean age, gender, number of patients at baseline, number of patients at follow-up, number of restorations at baseline, number of restorations at follow-up, number of failed restorations, type of restoration, type of prosthesis, teeth location, jaw location, follow-up time, material, survival and failure rate. The impact of type of restoration (direct or indirect), type of prosthesis, teeth location, jaw location and study design were extracted from the included studies and their impact on failure rates was analyzed. The authors initially intended to analyze the impact of these factors on survival rates. However, the included studies did not mention the number of survived restorations but reported failure events, so survival rates could not be calculated. Failure was defined as the restoration not remaining in situ during the observation period due to loss or replacement, while survival was defined as the restoration being still in place.

The events of failed restorations within the reported timeframes from the selected studies were combined using random effect model in terms of annual failure rate and its 95% confidence interval. The amount of heterogeneity between the combined studies were reported using I-square along with its significance at 0.05. Subgroup analyses were performed using direct/indirect type of restoration, study design, type of prosthesis coverage, tooth location, jaw location, and restoration site. Meta-regression analysis was performed using age as the moderator. Publication bias was executed using a funnel plot. Risk of bias of the selected studies was assessed using Cochran's ROB2 and ROBINS-I for RCT and observational studies respectively.[27,28] Bias assessment was performed independently by two reviewers (KC, IP) and the third examiner (PK) was consulted to resolve lack of consensus.

RESULTS

The flow chart for the inclusion process is shown in Figure 1. Characteristics of the included studies are presented in Table 2. A total of 52 articles met the inclusion criteria and were included in the final analysis. Thirty prospective studies,[19,29-57] 4 retrospective studies[58-61] and 18 randomized clinical studies were included.[62-79] Mean follow-up time for these studies varied from 3 to 30 years.[20,29-79] Thirty-nine studies were conducted in academic settings[29-31,34-37,39-42,45-48,50, 53-55,60-79] while 13 studies in private practice.[19,32,33,38,43,44,49,51,52,56-59] With respect to the selection of articles by reviewing titles/abstracts and full text, there was significant agreement between the 2 investigators with Cohen Kappa equal to 0.98 (P<.001) and 0.97 (P<.001) respectively.

Each of the included studies evaluated either direct and/or indirect restorations while none of these studies compared direct and indirect restorations in a split-mouth design. Twenty-three studies evaluated direct restorations while 26 studies evaluated indirect restorations. Three studies evaluated both direct and indirect restorations.[42,49,69] Regarding the studies evaluating direct restorations, all 26 studies used RBCs, and none of them used amalgam or other restorative material.[30,32,35,36,38,39,41,44,46-48,50,51,58,63,65-68,70,72,77,78] For the studies evaluating the indirect restorations, 3 evaluated full-coverage crowns[43,71,76] while 23 evaluated partial coverage restoratio ns.[19,29,31,33,34,37,40,43,45,52-57,59-62,64,71,73-76,79]

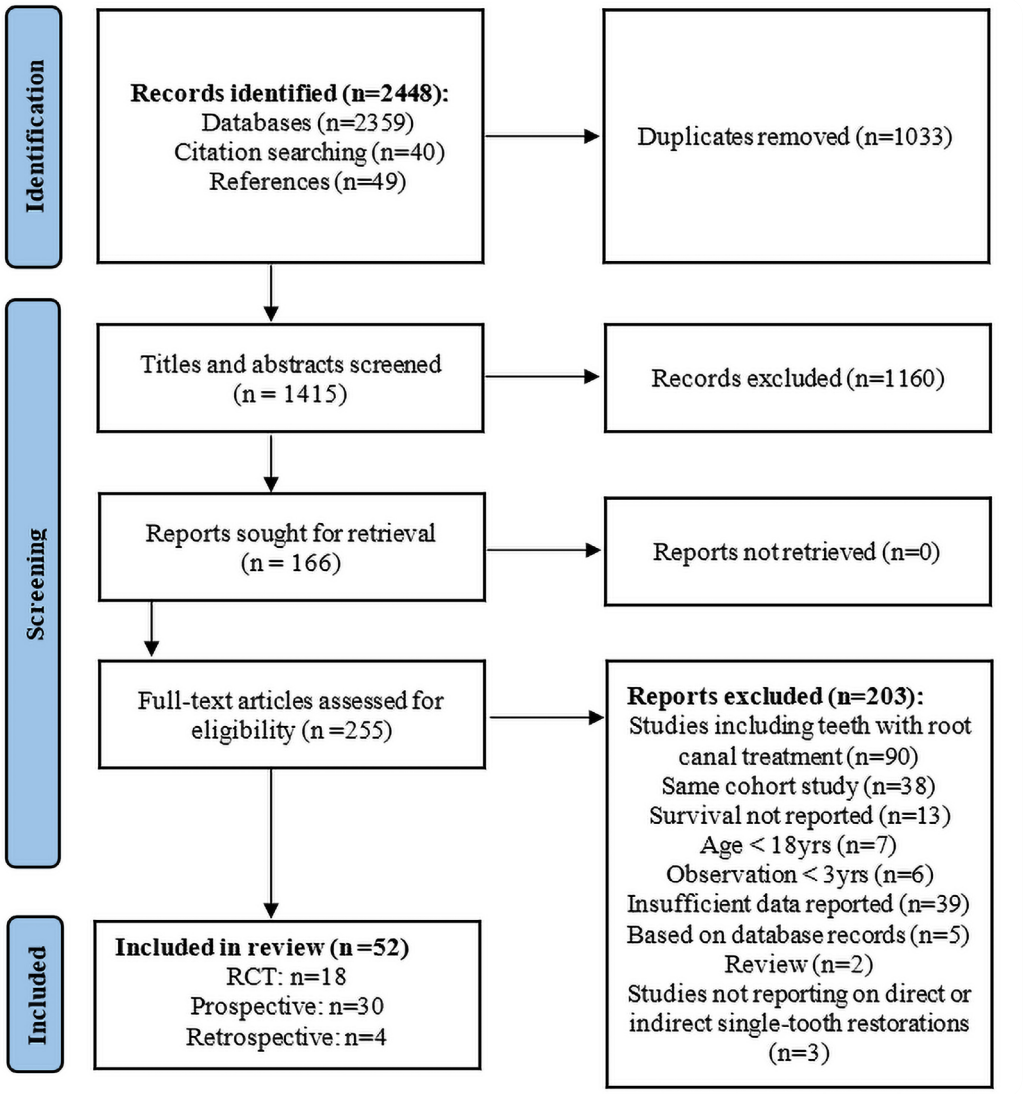

Figure 1: PRISMA flow diagram with information through phases of study selection.

Bias due to the followed randomization process, deviations from intended intervention, missing outcome data, outcome measures, selection of the reported result were assessed for the randomized trials through the Cochrane RoB 2 (from low to serious risk). Risk of bias for the randomized clinical trials are given in Figure 2. Eleven studies were scored as "Low bias",[62-71,74] and 7 studies as "Some concerns"[72,73,75-79] mainly due to the randomization process and missing data. Bias due to baseline confounding, participant selection, intervention classification, deviation from intended intervention, missing data and measurement outcome and selection of reported data were assessed for the observational studies through ROBINS-I (from low to serious risk). Risk of bias for the prospective and retrospective studies are given in Figure 3. Ten of them were scored as overall "Low bias".[39,42,43,49,51,52,54-56,61] Twenty-one studies were judged as "Moderate bias"[19,29-38,44-47,50,53,57-60,79] and 3 studies as "Serious bias"[40,41,48] primarily due to bias in confounding and missing and reporting data. Two studies had serious risk of bias[40,48] due to missing data since a great number of restorations were lost to follow-up.

Regarding failure rates of restorations pertaining to type of restoration, 28 studies[19,29,31,33,34,40,42,43,45,49,52-57,59-62,64,69,71,73-76,79] evaluating indirect restorations demonstrated 1% annual failure rate (95% CI: 0.01, 0.01) using a random effect model and had a high significant heterogeneity of I2=80% (P<0.01) while 24 studies[30,32,35,36,38,39,41,42,44,46-51,58,65-70,77,78] evaluated direct restorations with 1% annual failure rate (95% CI: 0.01, 0.01) having also a high significant heterogeneity of I^2=91% P<0.01 *(Table 3)*. No direct comparisons were able to be performed as no articles with direct comparisons were identified. No survival rates could be calculated since all studies reported on failure events. One study (57) reported significantly higher failure rates than all others *(Figure 4)* . In this study, 25 posterior Mirage feldspathic inlays were inserted at a private clinic and were evaluated for a mean observation period of 40 months. Twelve of the 25 porcelain inlays failed, 10 of them due to inlay fracture, 1 due to secondary caries, and 1 due to a marginal gap between the inlay and proximal tooth surface.

Regarding failure rates of restorations pertaining to study design, prospective studies[19,29-36,38-57] demonstrated 1% annual failure rate (95% CI: 0.01, 0.01) using a random effect model

Table 2. Characteristics of included studies.

Study	No. of Patients (baseline)	No. of Patients (f/u)	No. of Restorations (baseline)	No. of Restorations (f/u)	No. of Failed Restorations (f/u)	Restoration Type	Prosthesis Type	Teeth Location	Jaw Location	Follow-up (y)	Material
Isidor and Brøndum 1995	NR	NR	25	25	12	Indirect	PC	P:25	Mixed	3.36	Porcelain inlays, onlays
Fradeani M. 1998	21	21	83	83	1	Indirect	PC	A:83	Mixed	6	Leucite reinforced ceramic veneers
Hayashi et al, 2000	25	25	45	45	6	Indirect	PC	P:45	Mixed	8	Feldspathic inlays
Molin and Karlsson 2000	20	20	60	60	5	Indirect	PC	P:60	NR	5	Ceramic inlays
Peumans et al, 2004	25	23	87	81	3	Indirect	PC	A:87	Mx	10	Ceramic veneers
Sjögren et al, 2004	27	25	66	61	7	Indirect	PC	P:66	Mixed	10	Feldspathic inlays
Krämer et al, 2006	31	29	94	90	4	Indirect	PC	P:94	Mixed	4	Leucite-reinforced ceramic inlays
Signore et al, 2007	43	43	43	43	3	Indirect	PC	P:43	Mixed	6	Indirect CR onlays
Peumans et al, 2007	29	NR	100	84	1	Direct	CR	P:100	Mixed	5	Class V CRs
Opdam et al, 2008	41	40	41	40	2	Direct	CR	P:41	Mixed	7	Cracked teeth CRs
Schirrmeister et al, 2009	43	27	86	54	3	Direct	CR	P:86	Mixed	4	Class I, II CRs
Lange and Pfeiffer 2009	109	100	264	250	4	Indirect	PC	P:264	NR	4.75	Ceramic inlays
	68	61	145	135	5	Direct	CR	P:145	Mixed	4.75	Class I, II CRs

Table 2 continued overleaf...

Table 2 continued...

Kiremitci et al, 2009	33	31	47	44	2	Direct	CR	P:47	Mixed	6	Class II CRs
van Dijken J.W. 2010	29	23	90	76	5	Direct	CR	P:90	Mixed	12	Class I CRs
Etman and Woolford 2010	48	48	90	90	2	Indirect	FC	P:90	Mixed	3	Lithium disilicate, alumina-based, metal ceramic crowns
Shi et al, 2010	32	27	100	80	6	Direct	CR	P:100	Mixed	3	Class I CRs
Huth et al, 2011	89	45	155	86	16	Indirect	PC	P:155	NR	4	Class I, II CRs
van Dijken and Pallesen 2011	48	46	118	114	17	Direct	CR	P:118	Mixed	7	Class II CRs
Beier et al, 2012	74	74	292	292	20	Indirect	PC	A:292	NR	18	Feldspathic,leucite-reinforced, lithium dislicate veneers
D'Arcangelo et al, 2012	30	27	119	111	3	Indirect	PC	A:119	Mx	7	Feldspathic veneeers
Laegreid et al, 2012	74	73	74	73	9	Direct	CR	P:74	NR	3	Extensive molar CRs
Vigolo and Mutinelli 2012	60	58	60	58	3	Indirect	FC	P:60	Md	5	metal ceramic, zirconia crowns
Van Dijken J.W. 2013	54	52	115	111	14	Direct	CR	P:115	Mixed	6	Class II CRs
Al-Khayatt et al, 2013	18	15	89	85	13	Direct	CR	A:89	Md	7	Anterior CRs
Peumans et al, 2013	31	30	62	60	3	Indirect	PC	P:62	NR	4	Glass ceramic inlays, onlays
Cetin et al, 2013	NR	NR	41	41	1	Indirect	PC	P:41	NR	5	Indirect CRs
	NR	NR	67	67	1	Direct	CR	P:67	Mixed	5	Class I, II CRs

Table 2 continued overleaf...

Table 2 continued...

Guess et al, 2013	25	14	80	48	1	Indirect	PC	P:80	NR	7	Lithium disilicate, leucite-reinforced partial crowns
van Dijken and Pallesen 2014	52	48	122	114	22	Direct	CR	P:122	Mixed	10	Class II CRs
Scholtanus and Ozcan, 2014	88	88	118	118	4	Direct	CR	P:118	NR	3.35	Extensive posterior CRs
Guess et al, 2014	25	9	66	28	1	Indirect	PC	A:66	Mixed	7	Leucite reinforced glass ceramic veneers
Selz et al, 2014	60	53	149	133	11	Indirect	FC	P:149	NR	5	Alumina-based ceramic crowns
Fennis et al, 2014	81	69	84	78	15	Indirect	PC	P:84	Mx	6	Class II CRs
	82	76	92	80	8	Direct	CR	P:92	NR	5.6	Class II CRs
Mahmoud et al, 2014	40	40	160	160	5	Direct	CR	P:160	NR	3	Class I, II CRs
Pallesen and van Dijken 2015	30	25	99	84	28	Direct	CR	P:99	Mixed	30	Class II CRS
van Dijken and Lindberg 2015	50	42	106	91	21	Direct	CR	P:106	NR	15	Class II CRs
van Dijken and Pallesen 2015	78	75	165	158	21	Direct	CR	P:165	Mixed	8	Class II CRs
Barabanti et al, 2015	23	23	48	48	0	Indirect	PC	P:48	NR	10	Class II CRs
Montag et al, 2018	NR	NR	194	51	21	Direct	CR	P:194	NR	29	Class I, II CRs
Ergin et al, 2018	23	19	76	58	3	Direct	CR	A:76	Mixed	4	Anterior CRs
Heck et al, 2018	NR	NR	50	30	4	Direct	CR	P:50	NR	10	Class I, II CRs
Aslan et al, 2019	41	41	364	364	6	Indirect	PC	A:364	NR	10	Lithium disilicate veneers
van den Breemer et al 2019	30	30	60	60	1	Indirect	PC	P:60	Mixed	3.13	Lithium disilicate partial restorations

Table 2 continued overleaf...

Table 2 continued...

Gresnigt et al, 2019	118	104	444	341	14	Indirect	PC	A:444	Mx	11	Feldspathic veneers
Ferrari Cagidiaco et al, 2020	105	96	170	161	9	Indirect	PC	P:170	Mixed	4	Lithium disilicate partial crowns
Rinke et al, 2020	37	31	130	101	10	Indirect	PC	A:130	Mixed	10	Leucite-reinforced glass-ceramic extended veneers
Frankenberger et al, 2020	30	27	68	59	2	Direct	CR	P:23	Mixed	12.1	Extended Class II CRs
Fatma Dilsad et al, 2020	18	16	72	64	0	Direct	CR	P:72	NR	5	Class I CRs
Scholz et al, 2021	48	31	144	144	23	Indirect	PC	P:144	NR	3.25	Partial ceramic crowns
Malament et al, 2021	304	304	556	556	6	Indirect	PC	P:556	Mixed	10	Pressed lithium disilicate inlays and onlays
Mehta et al, 2021	34	33	1269	1269	29	Direct	CR	P:593, A:676	Mixed	5.2	Anterior, posterior CRs
Korkut and Türkmen, 2021	53	46	216	180	20	Direct	CR	A:216	Mx	4	Anterior CRs
Rinke et al, 2022	45	40	61	54	5	Indirect	PC	P:61	Mixed	5	Zirconia reinforced lithium silicate partial crowns

Y, year; f/u, follow-up; CR, composite restoration; PC, partial coverage; FC, full coverage; P, posterior; A, anterior; Mx, maxilla; Md, mandible

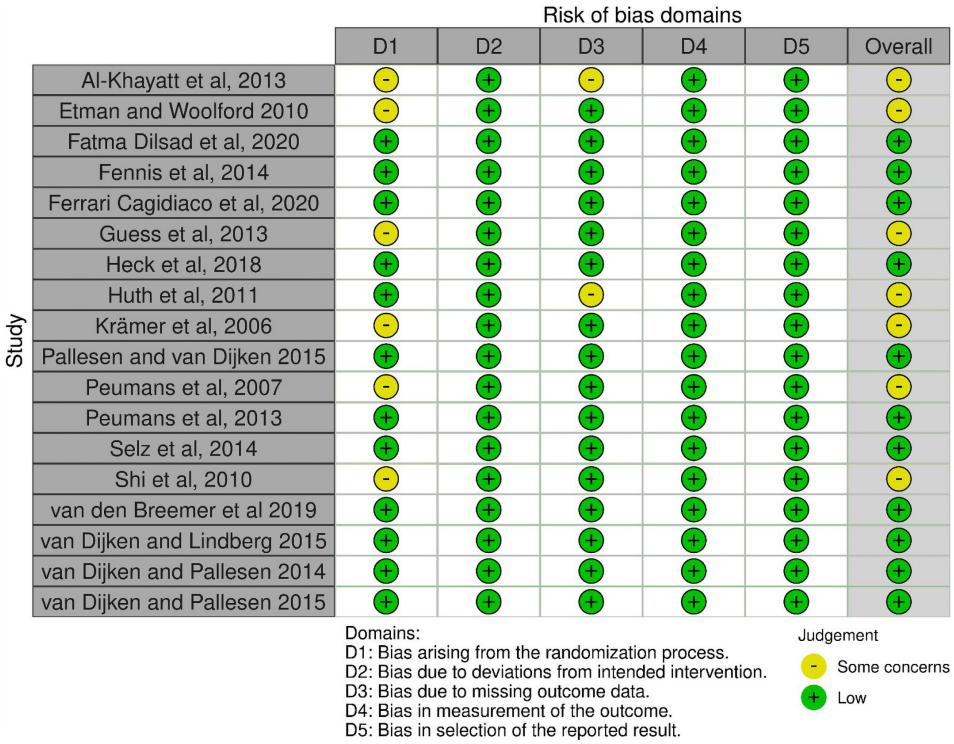

Figure 2: Risk of bias (RoB 2) assessment for randomized clinical trials.

and had a high significant heterogeneity of I^2=91% (P<0.01), while RCTs[62-79] demonstrated 1% annual failure rate (95% CI: 0, 0.02) having a heterogeneity of I2=91% (P<0.01) *(Figure 5)*. An annual failure rate of 1% (95% CI: 0.01, 0.01) was also found in retrospective studies (58-61) with a heterogeneity of I2=51% (P<0.01).

Regarding failure rates of restorations pertaining to type of prosthesis coverage, 25 studies[19,29,31,43,52,54,55,57,61,62,64,71,73-76,79] evaluated partial coverage restorations with 1% annual failure rate (95% CI: 0.01, 0.01) using a random effect model and had a high significant heterogeneity of I2=92% (P<0.01), while 24 studies[30,32,35,36,38,39,41,42,44,46-51,58,65-70,77,78] evaluated RBC restorations with 1% annual failure rate (95% CI: 0.01, 0.01) having a heterogeneity of I^2=80% (P<0.01) *(Figure 6)*. An annual failure rate of 1% (95% CI: 0.01,0.02) was also found in 3 studies[43,71,76] evaluating full-coverage crowns with a non-significant heterogeneity of I^2=0% (P=0.61).

Regarding failure rates of restoration pertaining to tooth location, 37 studies[19,29,31,35,38,39,41-44,46-52,54,55,57,61,62,64-71,73-79] evaluated posterior restorations with 1% annual failure rate (95% CI: 0.01, 0.02) using a random effect model and had a high significant heterogeneity of I^2=84% (P<0.01), while 10 studies[33,34,36,40,45,53,56,58-60] evaluated anterior restorations with 1% annual failure rate (95%CI: 0, 0.01) having a high significant heterogeneity of I^2=86% (P<0.01) *(Figure 7)*. Only 2 studies[30,32] evaluated both anterior and posterior restorations with an annual failure rate of 0% (95% CI: 0, 0.01) and a non-significant heterogeneity of I^2=0% (P=0.42).

Regarding failure rates of restoration pertaining to jaw location, 29 studies[19,30-33,36,40-42,45-53,55-59,61,62,64,66-70,76,78,79] evaluated restorations in the maxilla and mandible with 1% annual failure rate (95% CI: 0.01, 0.01) using a random effect model and had a high significant heterogeneity of I^2=85% (P<0.01) *(Figure 8)*. Five studies[33,45,53,58,69] evaluated only restorations in the maxilla with 1% annual failure rate (95%CI: 0, 0.02) having a high significant heterogeneity of I^2=93% (P<0.01) while 1 study[43] evaluated restorations only in the mandible demonstrated an annual failure rate of 1% (95% CI: 0, 0.03).

Regarding failure rates of direct restorations pertaining to tooth location, 20 studies[35,38,39,41,42,44,46-51,65-70,77,78] evaluated direct restoration in the posterior region with 1% annual failure rate (95% CI: 0.01, 0.02) using a random effect model and had a high significant heterogeneity of I^2=74% (P<0.01) *(Figure 9)*. Two studies[36,58] evaluated anterior direct restorations with 2% annual failure rate (95% CI: 0.01, 0.04) and a non-significant heterogeneity of I^2=47% (P=0.17). Two studies[30,32] reporting on both anterior and posterior restorations demonstrated an annual failure rate of 0% (95% CI: 0, 0.01) with I^2=0% heterogeneity (P=0.42).

Regarding failures rates of indirect restorations pertaining to tooth location, 20 studies[19,29,31,42,43,49,52,54,55,57,61,62,64,69,71,73-76,79] evaluated posterior indirect restorations with 1% annual failure rate (95% CI: 0.01, 0.02) using a random effect model and had a high significant heterogeneity of I^2=88% (P<0.01) *(Figure 10)*. Eight studies[33,34,40,45,53,56,59,60] evaluated anterior indirect restorations with 0% annual failure rate (95% CI: 0, 0.01) and a non-significant heterogeneity of I^2=35% (P=0.15). There were no studies reporting on anterior or posterior indirect restorations included in the quantitative analysis.

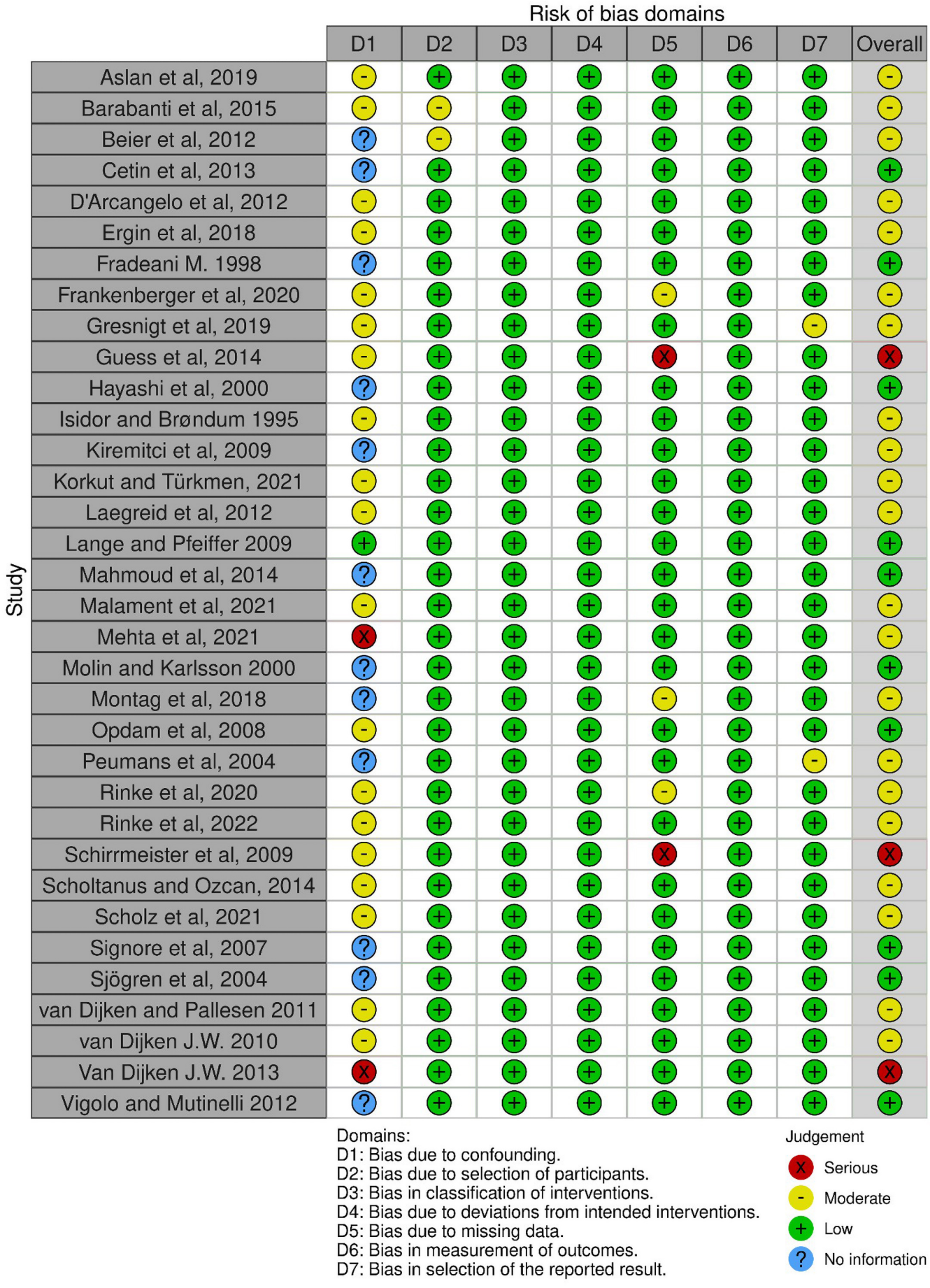

Figure 3: Risk of bias (ROBINS-1) assessment for prospective and retrospective studies.

Table 3. Moderator Summary Table

Moderator	Levels	No. of studies	No. of restorations	Annual Failure Rate	95% UL	95% LL	I^2%	p-Value
Restoration Type	Direct	24	5729	0.01	0.01	0.01	91	<0.01
	Indirect	28	6874	0.01	0.01	0.01	80	<0.01
Prosthesis Type	Full Coverage	3	281	0.01	0.01	0.02	0	0.61
	Partial Coverage	25	3263	0.01	0.01	0.01	92	<0.01
	Composite	24	3330	0.01	0.01	0.01	80	<0.01
Teeth Location	Anterior	10	1639	0	0	0.01	86	<0.01
	Posterior	37	3907	0.01	0.01	0.02	84	<0.01
	Mixed	2	1328	0	0	0.01	0	0.42
Jaw Location	Maxilla	5	791	0.01	0	0.02	93	<0.01
	Mandible	1	58	0.01	0	0.03		
	Mixed	29	3944	0.01	0.01	0.01	85	<0.01
Study Design	RCT	16	161	0.01	0.01	0.02	51	<0.01
	Prospective	29	1269	0.01	0.01	0.01	91	<0.01
	Retrospective	4	154	0.01	0	0.02	91	<0.01

DISCUSSION

The objective of this systematic review and meta-analysis was to analyze the current literature and assess the failure rates of direct and indirect restorations for single tooth restorations. It appears that there is no significant difference in the annual failure rates of single teeth restored with either direct or indirect restorations which were calculated as 1%. Similar results were reported on a systematic review and meta-analysis on studies comparing direct and indirect restorations on single posterior endodontically treated teeth.[24] In this systematic review the authors reported that there was no difference in the tooth failure and that most of the included studies were of low-quality evidence, while the overall risk of bias was critical to serious mainly due to confounding factors. This is in contrast with a previous systematic review reporting on prospective and retrospective clinical studies of direct and indirect restorations on endodontically treated teeth with an observation period of at least 3 years.[80] Based on low quality evidence, indirect restorations exhibited higher survival than direct restorations. In our systematic review, clinical studies on endodontically treated teeth were excluded due to the fact that endodontically treated teeth are more brittle due to loss of structural integrity associated with access preparation or caries that may be a confounding factor for failure.[81]. Thus comparisons of the findings of the present review with the two aforementioned studies cannot be made.

Up to date, there is no systematic review comparing broadly direct and indirect restorations for vital single teeth. However, two previous reviews compared the clinical performance of certain types of direct and indirect restorations on vital posterior teeth.[5,25] A systematic review of Afrashtefar *et al.*, assessed direct restorations versus full-coverage crowns and reported lower failure rates for crowns on teeth with fewer than two remaining walls.[25] Another systematic review evaluating randomized clinical trials comparing direct versus indirect resin composite restorations, with at least 2 years of follow-up concluded that there was no difference in their longevity regardless of the type of material and the restored tooth.[5]

In our systematic review, most of the included retrospective and prospective studies were judged to be at moderate risk of bias[19,29-38,44-47,50,53,57-60] mainly due to inappropriate measurement and controlling of confounding factors, while 3 studies were at serious risk of bias.[40,41,48] Most of the included randomized clinical trials were considered as "Low bias"[62-71,74] and 7 studies as "Some concerns"[72,73,75-79] mainly due to inappropriate randomization and missing data. Thus, the overall quality of evidence was considered as moderate. On the other side, the observed heterogeneity was high ranging from I2=80% (P<0.01) for studies on direct restorations to I^2=91% for studies

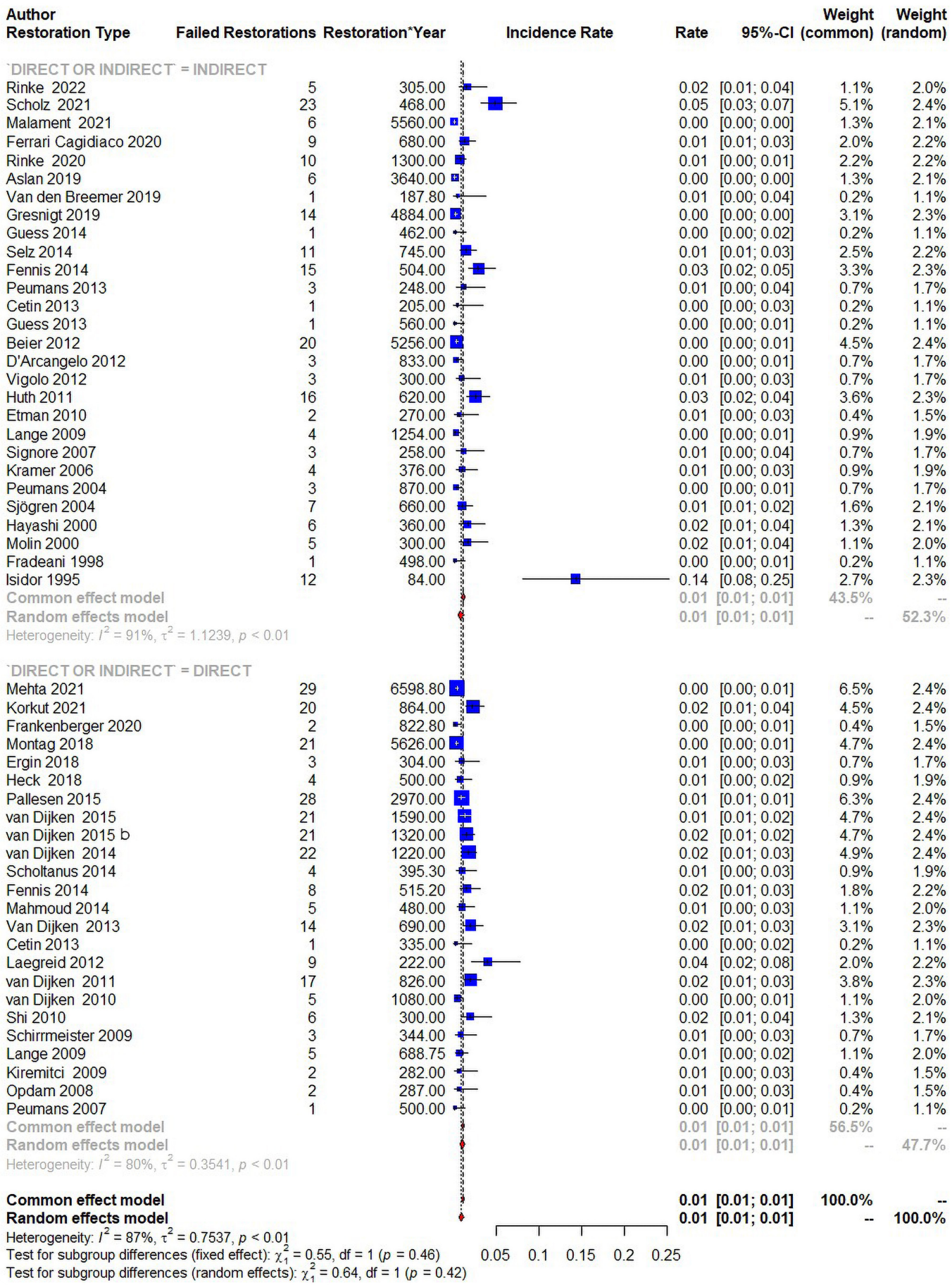

Figure 4: Forest plot of the annual failure rates of direct and indirect restorations. The annual failure rate was estimated as 1% for indirect and direct restorations, ranging from 0 to 14% for indirect and from 0 to 4% for indirect restorations. The 95% confidence intervals for failure rates are given in parentheses.

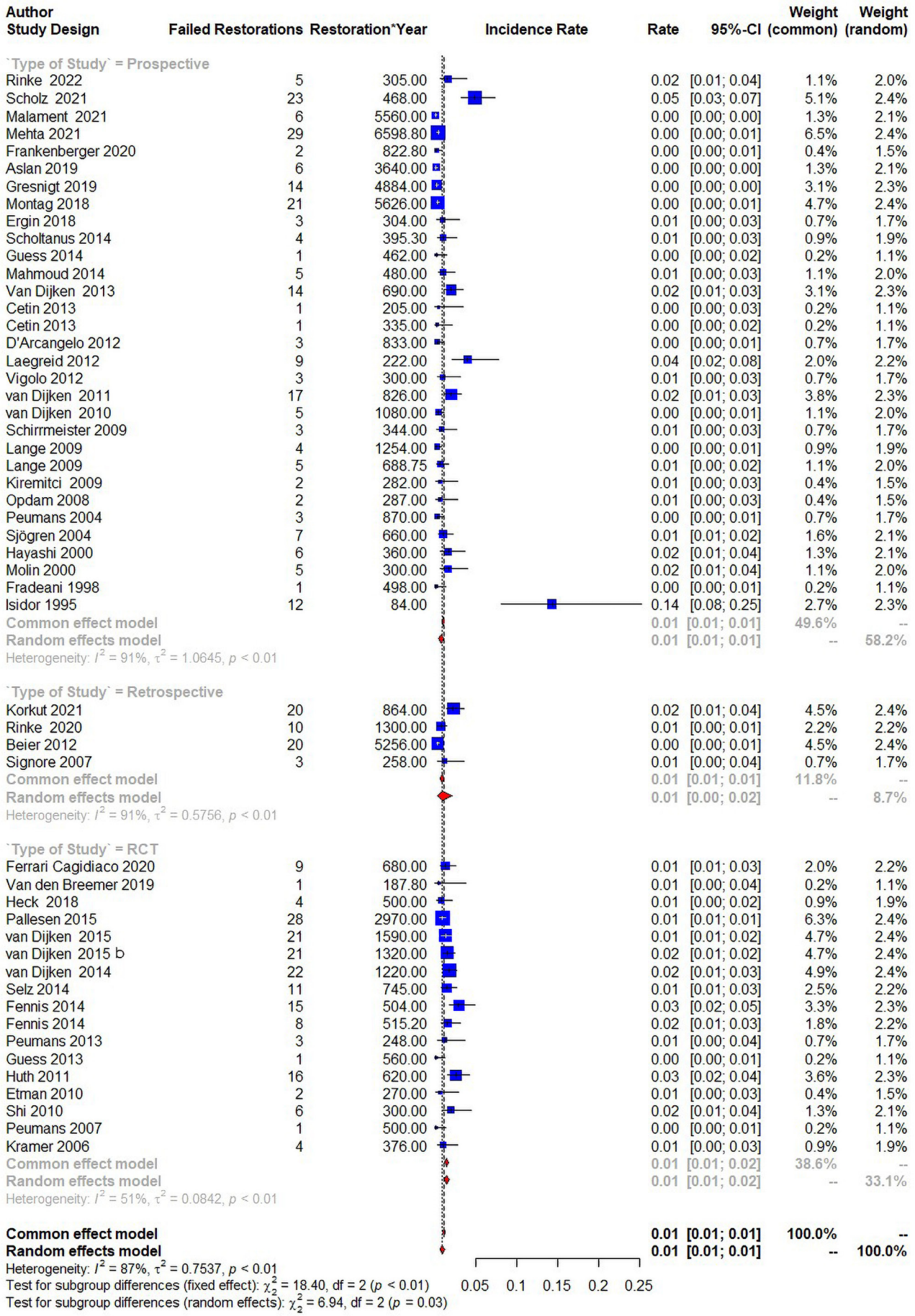

Figure 5: Forest plot of the annual failure rates of restorations pertaining to study design. The annual failure rate was estimated as 1% for all study designs, ranging from 0 to 14% for prospective studies, from 0 to 2% for retrospective studies and from 0 to 3% for RCTs. The 95% confidence intervals for failure rates are given in parentheses.

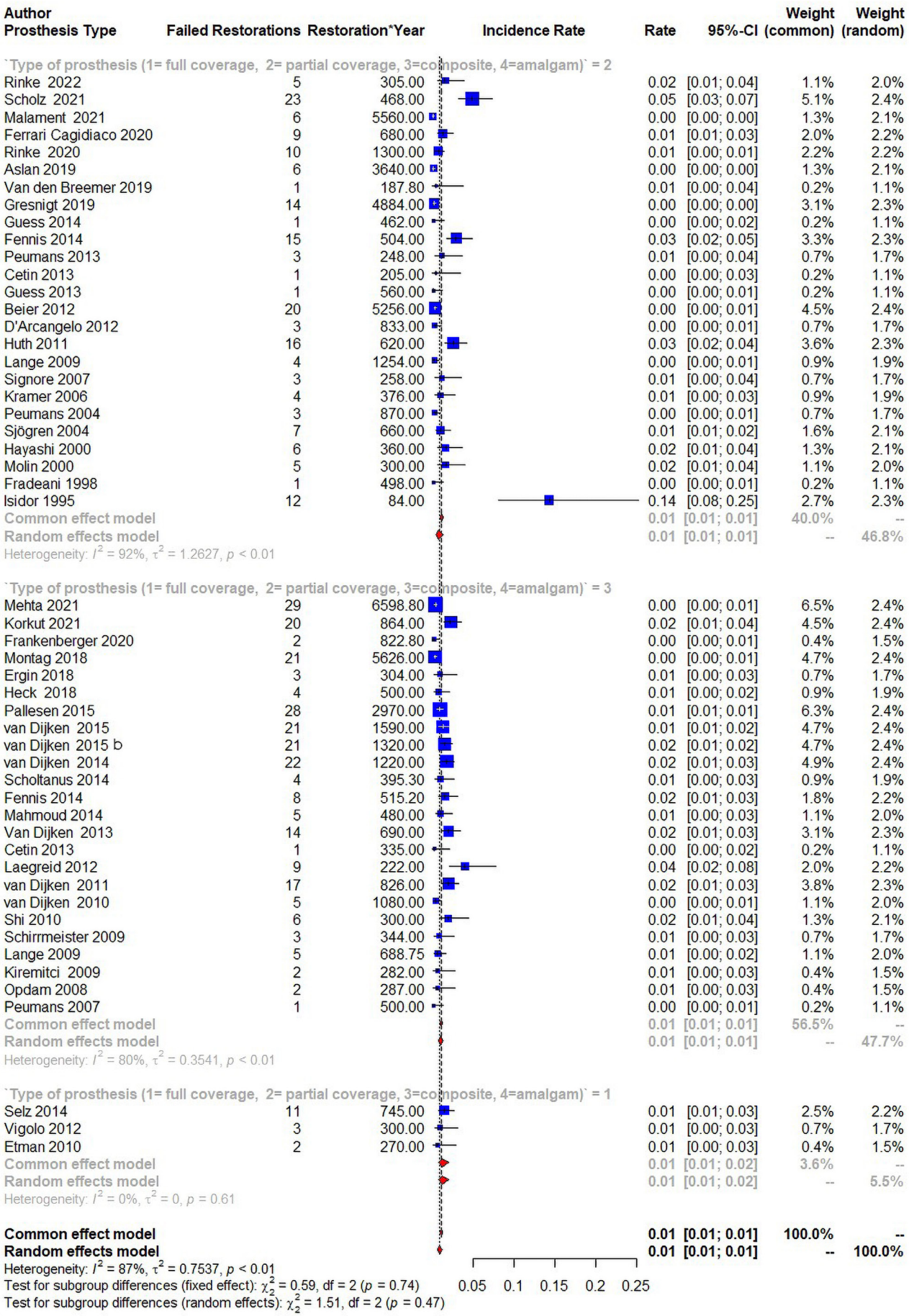

Figure 6: Forest plot of the annual failure rates of restorations pertaining to type of prosthesis coverage. The annual failure rate was estimated as 1% for all types of prosthesis. The 95% confidence intervals for failure rates are given in parentheses.

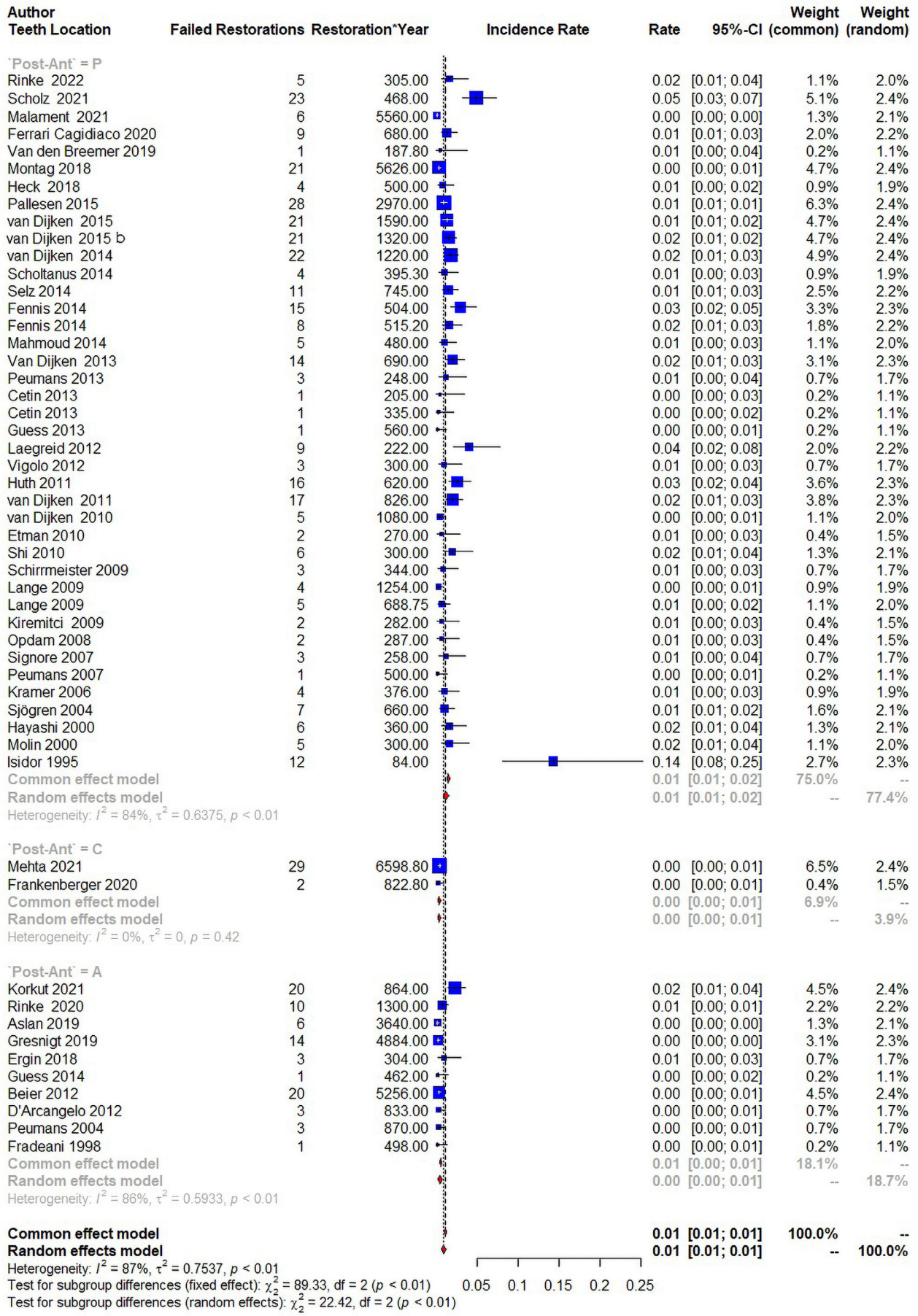

Figure 7: Forest plot of the annual failure rates of restorations pertaining to tooth location. The annual failure rate was similar for posterior and anterior restorations, ranging from 0 to 14% for posterior and from 0 to 2% for anterior restorations. An annual failure rate of 0% was found in studies evaluating both anterior and posterior restorations. The 95% confidence intervals for failure rates are given in parentheses.

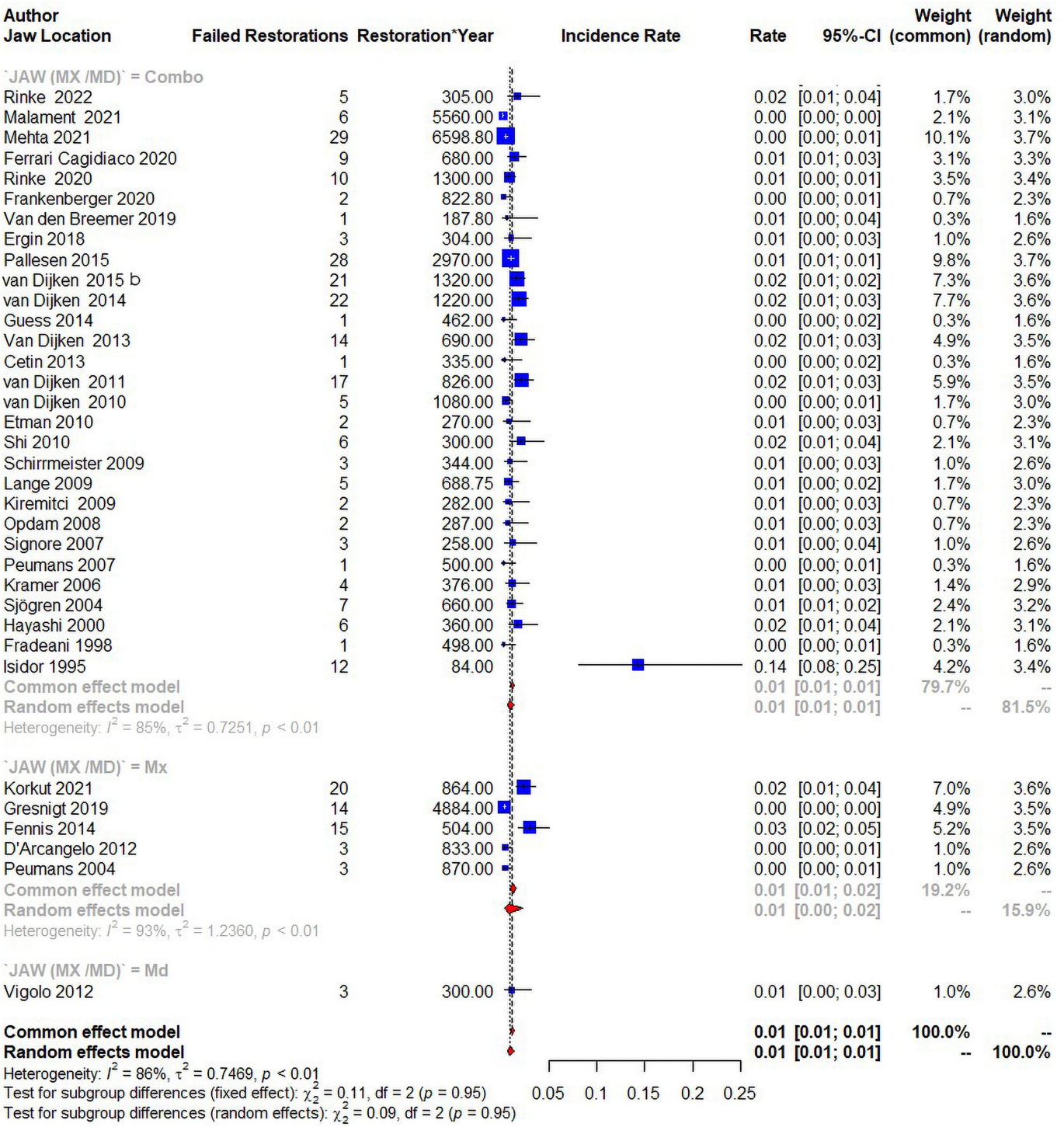

Figure 8: Forest plot of the annual failure rates of restorations pertaining to jaw location. The annual failure rate was similar for restorations in the maxilla and restorations in the mandible, ranging from 0 to 14% for maxillary and from 0 to 3% for mandibular restorations. The 95% confidence intervals for failure rates are given in parentheses.

on indirect restorations. Thus, the results of this meta-analysis should be interpreted with caution. In order to overcome heterogeneity among the selected studies, the random effect model was used for the meta-analysis.[4] Differences in settings, populations, operators, materials, teeth/jaw location, prosthesis' type, type and size of cavity, preparation protocols, cementation and bonding techniques could contribute to high heterogeneity. Different follow-up periods may also contribute to an increase in heterogeneity. The follow-up period of the included studies ranged from 3 to 30 years. Nevertheless, this was one of the strengths of the present review since most restorative materials present no failures during the first years of function.[25,82]

Deciding whether to place a direct or an indirect restoration requires an assessment of possible confounding factors. In the present review 18 randomized clinical trials were included. Two studies reported on crowns,[71,76] 7 studies reported on partial coverage restorations[62,64,69,73-75,79] and 9 studies on direct RBC restorations[63,65-70,77,78] Only one RCT reported on both

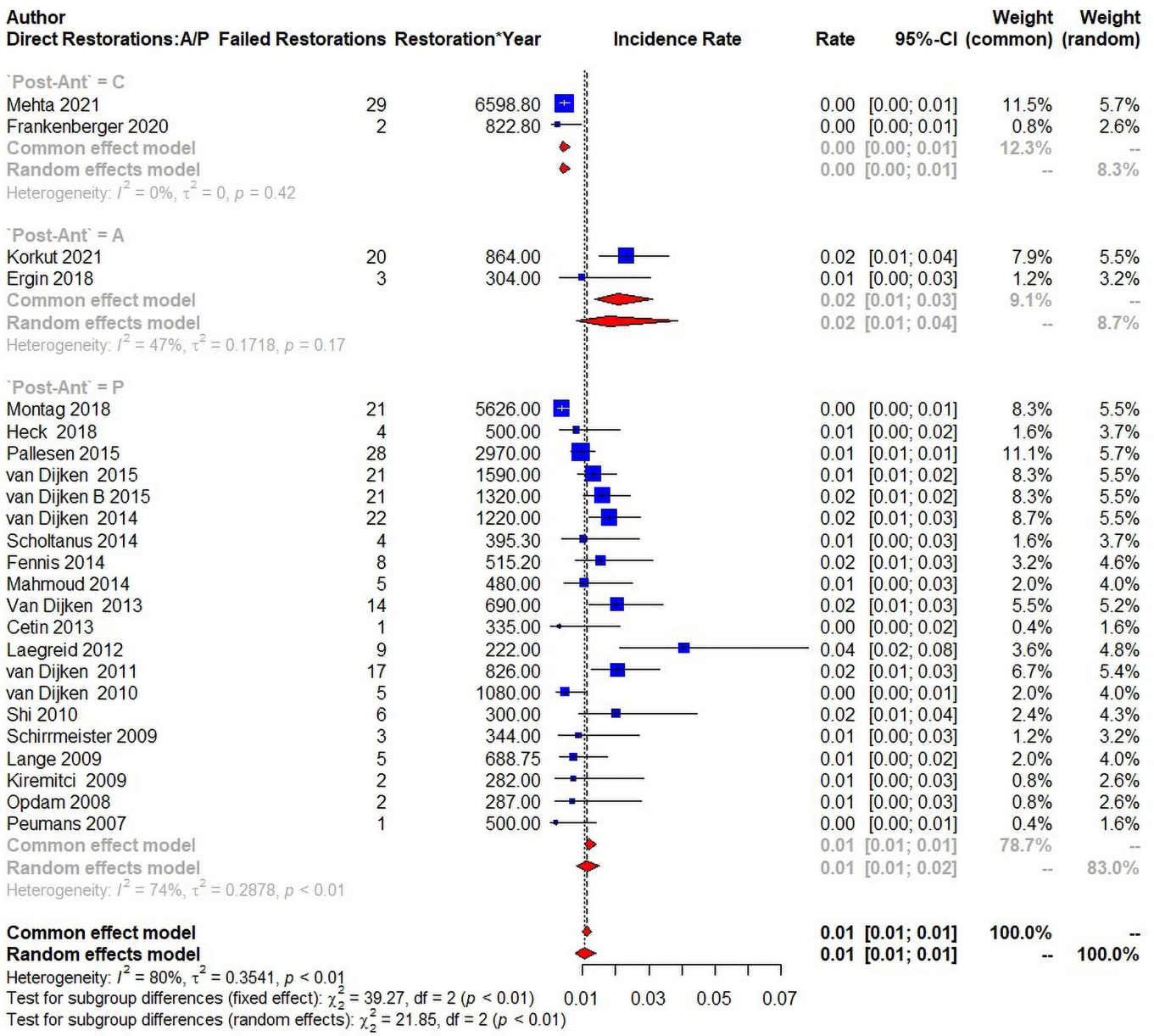

Figure 9: Forest plot of the annual failure rates of direct restorations pertaining to tooth location. The annual failure rate was 1% for posterior direct restorations and 2% for anterior direct restorations, ranging from 0 to 4% and from 1 to 2% respectively. The 95% confidence intervals for failure rates are given in parentheses.

indirect partial coverage restorations and direct RBC restorations for posterior teeth.[69] Inclusion criteria of the selected RCTs controlled several possible patient-related factors that could influence the longevity of the restorations. The selected RCTs included patients with good oral hygiene,[62,64,65,71,73-75,77,79] no signs of parafunction[62,76-78] absence of rampant caries[62,63,78] and medical disorders.[62,63,65,75-77] On the other hand, in 4 RCTs no patient was excluded because of high caries activity, periodontal condition or parafunctional habits.[66-68,70] However, only 4 studies clearly defined the term "high level of oral hygiene" with the use of different evaluation methods such as the OHI-S index,[77] the plaque index,[62,75] the modified sulcus bleeding index,[75] the papillary bleeding index[73] and the pocket depth.[73]

Another important factor that could influence the longevity of the restorations is the amount of remaining coronal tooth structure.[25,83] The authors of a previous systematic review on direct restorations reported that larger restorations had higher risk for failure and that every extra included surface increased the failure risk by 30-40%.[83] In our review, most of the included randomized clinical trials mentioned the type of the cavities restored but did not provide information on the number of remaining walls, the number of missing cusps or the amount of tooth structure remaining. In only few RCTs the authors tried to control the remaining amount of coronal tooth structure. Huth *et al* included Class I and II cavities with an isthmus size of at least half of the intercuspal distance,[75] while Shi *et al*. included Class I restorations extending between one-quarter and one-third of the way up one or more of the cuspal slopes.[77] Fennis *et al*., treated upper premolars with a Class II cavity and one missing cusp,[69] while Heck *et al*., restored Class I and II cavities with an isthmus size of at least one third of the intercuspal distance.[65] Controlling for the amount of tooth tissue remaining could lead to a more valid comparison between

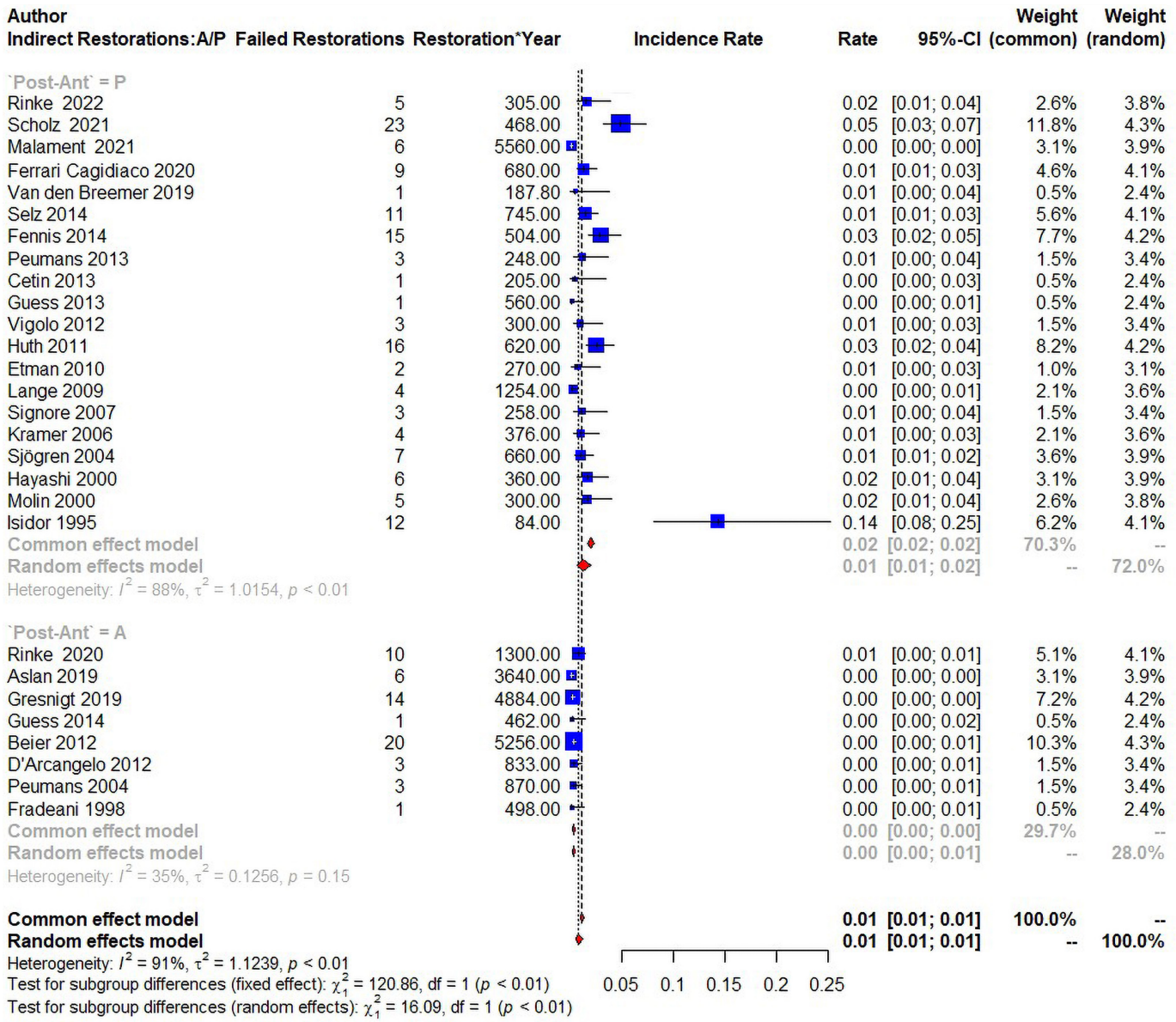

Figure 10: Forest plot of the annual failure rates of indirect restorations pertaining to tooth location. The annual failure rate was 1% for posterior indirect restorations and 0% for anterior indirect restorations, ranging from 0 to 14% and from 0 to 1% respectively. The 95% confidence intervals for failure rates are given in parentheses.

direct and indirect restorations.[24,80] A previous systematic review reported that in teeth with fewer than 2 remaining walls, full-coverage restorations performed better than direct restorations.[25] On the other side, in a randomized clinical trial the authors reported that there was no significant difference in the survival between direct and indirect Class II restorations with one missing cusp.[69] However, the amount of tooth tissue remaining cannot always be controlled beforehand because of the presence of caries, cracks, or thin walls.[24]

Twenty-five studies included in the meta-analysis reported on partial coverage restorations with follow-up ranging from 3.13 to 18 years. The investigated materials included feldspathic porcelain,[29,33,45,52,53,55,60] leucite-reinforced glass ceramics,[40,56,59,60,73,79] lithium disilicate ceramics,[19,34,60,62,64,73] zirconia-reinforced lithium silicate ceramics[31] and indirect RBC materials.[42,61,69,75] Seventeen studies reported on posterior partial coverage restorations[19,29,31,43,52,54,55,57,61,62,64,71,73-76,79] while 8 studies evaluated anterior veneers.[33,34,40,45,53,56,59,60] The annual failure rate of partial coverage restorations was estimated as 1% (95% CI: 0.01, 0.01) using a random effect model while the most common reason for failure was material fracture. This agrees with the results of previously published reviews.[4,21,84] Morimoto *et al.*, reported 91% 10-year survival rate of partial coverage restorations corresponding to an annual failure rate of 0.9%,[21] while an another systematic review reported 91-100% medium-term survival.[84] Furthermore, Vagropoulou *et al.* concluded that the 5-year survival rate of inlays/onlays exceeded 90%.[4] Similar to our review, these reviews reported that material fracture was the main reason for failure.[4,21,84]

Regarding full-coverage restorations, 3 studies investigated alumina-ceramic,[71,76] metal-ceramic,[43,76] zirconia-ceramic[43] and lithium disilicate posterior crowns.[76] No study evaluated crowns placed on anterior teeth. The mean follow-up period ranged from 3 to 5 years. The failure rate was calculated as 1%. Bulk fractures or fractures of the veneering material were the most common failures in all-ceramic restorations.[43,71,76] No failures were reported for metal-ceramic restorations. Similar to this review, another meta-analysis estimated 5-year survival rates of 94.7% for metal-ceramic, 96.6% for leucite-reinforced or lithium-disilicate glass ceramic crowns, 94.6% for glass infiltrated alumina and 96% for densely sintered alumina and zirconia SCs, corresponding to an annual failure rate of 0.8-1%.[11] In addition, in a systematic review of Vagropoulou *et al*., the authors reported a mean survival rate of 95.4%.[4] In consistency with our study, both reviews reported that fractures was the most frequent type of failure.[11]

Twenty-four studies on direct composite restorations were included in the quantitative analysis with a follow-up ranging from 3 to 30 years.[30,32,35,36,38,39,41,42,44,46-51,58,65-70,77,78] A great number of different RBC materials and adhesive techniques were investigated. Most of the included studies evaluated posterior Class I and Class II restorations. Only 2 studies included in the meta-analysis reported on anterior RBC restorations,[36,58] while a single study analyzed Class V restorations.The estimated annual failure rate for direct RBC restorations was 1% (95% CI: 0.01, 0.01) ranging from 0 to 4%, with a high heterogeneity of 80% (P<0.01). Overall, the main reasons for failures were material fractures and secondary caries. These findings are consistent with other reviews.[82,85,86] One meta-analysis on posterior composite restorations demonstrated mean annual failure rate ranging from 1.46% to 1.97%.[85] Two reviews by Demarco *et al*. reported annual failure rates ranging from 1 to 3%,[86] for posterior direct restorations and from 0 to 4.1% for anterior direct restorations.[82] Similarly to our study, secondary caries and fractures were identified as the main reasons for failure.[82,85,86]

The included studies and the present systematic review have certain limitations. First, none of the included studies directly compared direct and indirect restorations using a split mouth design. Second, the quality of evidence was considered as moderate because most of the included studies presented some degree of bias. Furthermore, a high and statistically significant heterogeneity was found among the included studies, while most studies failed to control several confounding factors. All these limitations make comparisons between direct and indirect restorations very challenging. Therefore, well-designed RCTs are needed to evaluate the treatment outcomes of direct and indirect restorations and assess possible risk factors associated with restoration failure. Clearly defined inclusion criteria for the placement of direct or indirect restorations and standardized evaluation criteria are necessary to make meaningful comparisons and draw definitive conclusions with clinical significance.

CONCLUSIONS

Based on the findings of this systematic review, the following conclusions were drawn:

1. Annual failure rates for single teeth restored with direct and indirect restorations were low.
2. Overall quality of evidence was moderate since most of the studies presented some risk of bias.
3. Due to the high heterogeneity of the included studies no clinical recommendation about the selection between direct or indirect restoration can be made.
4. Well performed RCTs with sufficient follow-up are needed.

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