

Longevity of bulk fill and ormocer composites in permanent posterior teeth: Systematic review and meta-analysis

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ABSTRACT: Purpose: To evaluate the clinical longevity of bulk-fill resins and ormocer composites compared to conventional nanofill and nanohybrid resins in posterior permanent teeth. **Methods:** PubMed, Web of Science, Scopus, Science Direct, Cochrane Library, and Scielo were electronically searched for randomized clinical trials, without language restrictions. The extracted data were analyzed using Review Manager, comparing the clinical behavior of bulk fill or ormocer restorations with nanofill or nanohybrid resins. Statistical analysis was performed with a significance level of 5% for all analyses ($P= 0.05$). The risk of bias was assessed using the Cochrane assessment tool. **Results:** 11 randomized clinical trials were included, with an average follow-up time of 40.36 months. A total of 812 restorations were evaluated and 58 failures were analyzed: 18 of the 253 bulk-fill restorations (7.11%), 21 of the 173 (12.3%) ormocer restorations, and 20 of the 386 (5.18%) control group (nanofill or nanohybrid composites) restorations failed. In the meta-analysis, there was no significant difference between the bulk-fill and the control group (statistical power = 24.38%; $P= 0.206$; IC = 95%); whereas, when comparing between ormocer and control group, the control group exhibited better performance (statistical power = 81.62%; $P= 0.0042$; IC = 95%). (*Am J Dent* 2022;35;89-96).

CLINICAL SIGNIFICANCE: Conventional nanofill and nanohybrid resins exhibited better clinical longevity than ormocer composites in posterior restorations, but when compared to bulk fill, they had similar performance.

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Introduction

Dental caries treatment is complex and may involve choosing among several options of direct restorative materials, such as composite resin, glass-ionomer cement, or amalgam.¹

Resin composite is considered a good option for posterior restorations because clinical evidence confirms its adequate clinical performance.²⁻⁴ However, problems inherent to the restoration, such as secondary caries, fracture of the restorations, marginal infiltration, and marginal discoloration, may occur.⁵ These limitations are believed to be the result of the material's polymerization shrinkage,⁶⁻⁸ which can be transferred to the bonding interface between the restoration and the remaining dental tissues, leading to adhesive failures.^{9,10} Conventional composite resins, such as nanofill or nanohybrid, require the operator to use an incremental filling technique to reduce the shrinkage stress and allow for more efficient polymerization.^{11,12}

To reduce operator error and chairside time, new composite materials have been developed, with modifications in their composition to reduce polymerization shrinkage.^{4,14} Among these materials, resins with modified monomers, such as bulk-fill composites and ormocer are viable options available to the clinician.^{14,15}

Bulk fill composites have monomers that act as modulators in the polymerization reaction, resulting in a considerable reduction in shrinkage.^{16,17} In addition, a greater polymerization depth can be ensured due to their translucency,¹⁷ which explains the high conversion of the material in the 4 mm one-step filling technique which is recommended for use.¹⁶

On the other hand, ormocer composites or organically modified ceramics are composed mainly of inorganic silicon dioxide fillers and a reduced amount of organic monomers, thus resulting in a lower polymerization shrinkage when compared to methacrylate-based resins.¹⁸⁻²¹ Due to their lower shrinkage stress and high inorganic load content, these composites are recommended for high-stress masticatory areas, such as posterior occlusal restorations.^{18,22}

Due to the simplicity of the restorative technique and the reduction of polymerization shrinkage, a gradual increase in the use of these materials in clinical practice is observed. Therefore, it is appropriate to evaluate the long-term success of these restorative materials, compared to conventional materials like nanofill and nanohybrid resins. Currently, there is a lack of consensus among the published studies, which do not show superiority of one material over the others.

This systematic review and meta-analysis evaluated the clinical longevity of bulk-fill and ormocer restorations and to compare them with conventional nanofill and nanohybrid resins in posterior permanent teeth; the null hypothesis of this study was that there was no difference between the materials studied.

Materials and Methods

Protocol and registration - This protocol was developed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA).²³ The study was registered in the International Prospective Register of Systematic Review database (CRD42019134990).

Eligibility criteria - The central question of this review was: Do bulk fill and ormocer composites have greater clinical longevity

Table 1. Search strategy in PubMed database.

#1	(Resins[All Fields] OR Resin[All Fields] OR Composite resins[MeSH Terms] OR resins composite[All Fields] OR Composite Restorative System[All Fields])
#2	(Organically Modified Ceramics[MeSH Terms] OR Ceramic Organically Modified[All Fields] OR Ceramics Organically Modified[All Fields] OR Modified Ceramic Organically[All Fields] OR Modified Ceramics Organically[All Fields] OR Organically Modified Ceramic[All Fields] OR Ormocer[All Fields] OR Ormocers[All Fields] OR Bulk Fill*[All Fields] OR Bulk-Fill[All Fields])
#3	(Nanofilled[All Fields] OR Nanofill[All Fields])
#1 AND #2 AND #3	

Table 2. Modified United States Public Health Service Criteria (USPHS).

Categories/scores	Criteria
Anatomical shape	Alfa ^a Continuous restoration with an anatomical shape ^{32,33,36-38,40}
	Bravo ^a Non-continuous restoration with anatomical shape and absence of dentin exposure ³²⁻³⁴
	Charlie ^b Sufficient loss of material exposing dentin ^{32-34,36,40}
	Delta ^b Restoration is partially or totally absent; fracture of the tooth structure; Traumatic occlusion; Restoration is causing pain ^{37,38}
Marginal adaptation	Alfa ^a No visible evidence of ditching along the margin ^{32,37,38}
	Bravo ^a Visible evidence of ditching along the margin and not dentin exposure ^{32,34,36,37}
	Charlie ^b Explorer retention in the ditching and dentin exposure ^{32,37}
	Delta ^b Restoration is mobile, fractured or missing ³⁸
Marginal discoloration	Alfa ^a No discoloration along the margin ^{32-34,37}
	Bravo ^a Discoloration present, but, superficial ^{32-34,36}
	Charlie ^b Discoloration present and deep a long the margin, towards pulp ^{32-34,38}
	Delta ^b Coloration "Gross" ^{32,41}
Secondary caries	Alfa ^a No caries ^{32-34,37,38}
	Bravo ^a Evidence of caries along the margin of restoration ³⁶
	Charlie ^b Caries present ^{32-34,36}
Postoperative sensitivity	Alfa ^a No postoperative sensitivity ^{32,33,38}
	Bravo ^a Presence of mild and transient hypersensitivity ³⁵ ; Increased sensitivity to cold; ⁴⁰ Sensitivity that is decreasing in intensity ³³
	Charlie ^b Spontaneous pain; ⁴⁰ Presence of strong and intolerable hypersensitivity; ³⁶ Uncomfortable, but there is no need for replacement; ³⁴ Constant sensitivity, with no reduction ³³
	Delta ^b Presence of postoperative sensitivity; ³⁷ Replacing the required restoration; ³⁴ Non-vitalized tooth ³⁴
Retention/fracture	Alfa ^a Restoration present ^{32-34,36,37}
	Charlie ^b Restoration partially or totally absent ^{32,33,36}
	Delta ^b Clinically unacceptable ^{32,33,35,37}

a. Clinically acceptable; b. Clinically unacceptable.

than conventional nanofill or nanohybrid resins in permanent posterior restorations?. The articles selected for this systematic review were analyzed using the PICO question (population, intervention, comparison, and outcomes). For each article, the study population ("P") was described based on the inclusion criteria (Class I or II restorations in posterior permanent teeth). The intervention section ("I") included ormocer or bulk-fill restorations. The comparison criterion ("C") included conventional nanofill and nanohybrid restorations. The outcome of the study ("O") would be the marginal integrity, marginal discoloration, anatomical shape, secondary caries, postoperative sensitivity, and debonding/fracture of the restorations, as evaluated by the Modified United States Public Health Service Criteria (USPHS).

Studies were selected according to the following inclusion criteria: (1) randomized controlled trials; (2) articles that used bulk fill or ormocer composites as the experimental group and nanofill or nanohybrid resins as the control group; (3) studies evaluating integrity/adaptation, marginal discoloration, anatomical shape, secondary caries, postoperative sensitivity, and debonding/fracture of restorations; (4) articles with Class I or Class II restorations; (5) studies that had a validated instrument as an evaluation tool.

Eligibility was determined after full-text assessment and rejection of inappropriate studies according to the following exclusion criteria: (1) evaluation time less than 12 months, (2) studies performed on primary teeth, and (3) studies with endodontically treated tooth restorations.

Database - To obtain relevant studies, the following electronic databases were searched: PubMed, Web of Science, Scopus, Cochrane Library, Science Direct, Lilacs, and Scielo. Searches were saved in RIS format and transferred to the Mendeley reference management program,^a to allow the exclusion of duplicates and abstract evaluations.

Search strategy - The MeSH terms with their respective entry terms were used as the search strategy. Keywords, such as Resins, Bulk Fill, Nanofilled, and Nanofill, were used, even though they were not on PubMed's list of MeSH terms, as they increased the scope of the studies. The final strategy used to search PubMed is shown in Table 1. For the other databases, the search had to be adapted to the format required by these platforms.

The electronic search was complemented by manually searching journals. In addition, the lists of the included studies were checked to identify possible studies that were not initially located, with no language restrictions. An electronic search was performed on studies published up to January 2020.

Studies selection - Two independent and calibrated examiners (NMRA and RVM) performed the literature review, data collection, and study qualification phases. The titles and abstracts of the articles were evaluated, and the abstracts which were potentially eligible, as well as those that provided sufficient information on the eligibility criteria were selected for full-text screening.

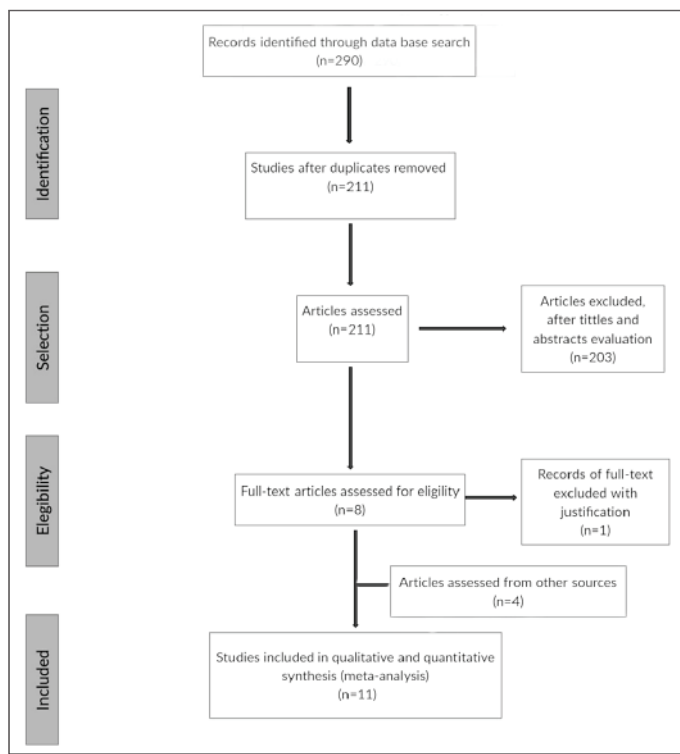


Fig. 1. Flow diagram of study selection according to PRISMA statement.

Assessment of risk of bias - The risk of methodological bias was assessed using the tool presented in the Cochrane Handbook.²⁴ The risk of bias in the included studies were categorized as low, uncertain, or high in each specific domain.

Data collection process - Two reviewers (NMRA and RVM) performed the data collection. General study information was extracted, including the details of the authors and year of publication. In addition, specific data were collected, including the location of the study, number of patients treated, number of restorations performed and evaluated, material used in the experimental and control groups, inclusion and exclusion criteria, restorative procedure methodology, type of restoration and location, length of clinical follow-up, type of failures, and tool used to assess restoration quality.

Data analysis - The extracted data were analyzed using Review Manager Software (RevMan^b version 5.3 software), comparing the clinical behavior of bulk fill or ormocer restorations with nanofill or nanohybrid resins.

The results of the eligible studies were described using the modified versions of the United States Public Health Service (USPHS) evaluation criteria, established as an evaluation tool in all trials (Table 2). For each trial, differences between the intervention and control groups were considered. The restorations were analyzed for each clinical parameter, and Alpha and Bravo scores were considered as acceptable, while Charlie or Delta scores were considered failures. For each group (intervention or control), the proportion of failures in restorations was calculated using the sum of all types of failed restorations divided by the total number of restorations.

Data on failure rates and sample size by group for each study were used to calculate the effect of size on the difference between proportions using the Cohen's H effect size (difference between arcsin ratio transformation: $[\arcsin(\sqrt{p_1}) - \arcsin(\sqrt{p_2})]$) and statistical power, following the equations described in the literature.²⁵

The level of significance was set at 5% for all analyses ($P=0.05$). The 95% confidence interval for Cohen's H was calculated using the formula for the sample variance described in another study.²⁶ Considering that failure rates in the controls were less than 10%, the risk rate (attributable risk) was not computed because it overestimated the size of the effect when the proportion of controls was less than 10%.²⁷

Statistical power was calculated and a threshold of 80% was used to determine whether the studies were conclusive (power $\geq 80\%$), that is, an acceptable probability of an effect on the population.²⁵ In addition, following the published statistical procedures,^{25,26,28} we calculated the effect size (Cohen's H; es), standard error, sample variance, individual study weights (w), weighted effect sizes ($w \cdot es$) and the corresponding square values (w^2 and $w \cdot es^2$).

Cochran's Q test and I² were computed,²⁸ and the level of heterogeneity was classified as low (25%), moderate (50%), or high (75%).²⁹ When heterogeneity was low, the summary outcome was calculated using the fixed-effects. Otherwise, the random-effects model was used for the analyses when I² was higher than 50%.²⁸ The statistical power of each meta-analysis was also computed.³⁰ A forest plot was prepared using the calculated parameters.

Results

Study selection - Search strategies identified 290 relevant studies, with 83 studies in PubMed, 34 in Scopus, 72 in Cochrane Library, 43 in Web of Science, 54 in Science Direct, 2 in Lilacs, and 2 in Scielo (Fig. 1). After removing duplicate records, 211 studies were selected. Eight studies were selected for full-text reading, of which only one was excluded because the control group was not restored with nanofill or nanohybrid resins.³¹ Four studies were included from other sources, two from the references of the studies previously included after full-text reading, and two from manual searches of online articles.

Characteristics of studies - Eleven studies³²⁻⁴² were considered for qualitative and quantitative analysis, with an average follow-up time of 40.36 months (12-120 months). A total of 962 restorations were performed in 502 patients, aged between 7 and 87 years, of which only 812 were used (84.4%), due to the withdrawal or non-comparison of participants in the follow-up (Table 3).

In the restorative procedures, the use of a rubber dam for moisture control was reported in only four studies,^{32,34,35,42} whereas, six^{33,36-38,40,41} reported the use of cotton rolls and saliva ejector tips, and only one reported the use of both methods, depending on the clinical situation.³⁹ Regarding the use of base materials or liners, four articles^{32,37,39,41} reported the absence of base materials, one³⁴ reported the use of calcium hydroxide-based material, and two^{36,40} reported the use of calcium hydroxide-based material in deep cavities along with glass-ionomer cement lining. Other studies have not reported the use of any base material.

Regarding the use of the adhesive system, self-conditioning systems were used only in the experimental group,^{37,38,40,42} only in the control group,³⁵ and in both groups (experimental and control).^{32-34,36,39,41} Universal systems were applied only in the

Table 3. Characteristics of included studies.

Author/year	Country	Restoration (n*)	Patients n	Mean age (year)	Follow-up (months)	Control resin / adhesive system (n**)	Experimental resin / adhesive system (n**)	No. of surfaces	Location	Assessment criteria
Alkurdi & Abboud, 2016 ³²	Syria	60	60	20-50	12	(G1) Tetric Eo Ceram ^c + N bond ^c (n=19)	(G2) Tetric N ceram bulk fill ^c + N bond ^c (n=17); (G3) Sonic fill ^d + N bond ^c (n=20)	II	PM & M	Modified USPHS
Arhun et al, 2010 ³³	USA	82	31	16-60	24	(G1) Grandio ^e + Futurabond NR ^e (n=35)	(G2) QuixFill ^f + XenoIII ^f (n=35)	I or II	PM & M	Modified USPHS
Atabek et al, 2017 ³⁴	Turkey	60	30	7 - 16	24	(G1) Herculite Ultra ^d + OptiBond All-In-One ^d (n=30)	(G2)Sonic fill ^d + OptiBond All-In-One ^d (n= 30)	I	M	Modified USPHS
Bottenberg, et al, 2009 ³⁵	Belgium	132	32	19-56	60	(G1) Tetric Ceram ^c + Syntac Sprint ^c (n=27)	(G2) Admira ^e + Admira Bond ^e (n=24) (G3) Definite ^g + Etch & Prime 3.0 ^g (n=32)	II	PM & M	Modified USPHS
Çolak, et al 2017 ³⁶	Turkey	74	34	23-56	12	(G1)Tetric Evo Ceram ^c + AdheSE Bond ^c (n=35)	(G2) Tetric Evo Ceram bulk fill ^c + AdheSE Bond ^c (n=35)	II	PM & M	Modified USPHS
Efes et al, 2006 ³⁷	Turkey	60*	90	18-48	24	(G1) Filtek Supreme ^h + Single Bond ^g XT ^h (n=29)	(G2)Admira ^e + Admira Bond ^e (n=29)	I	M	Modified USPHS
Efes, et al, 2006 ³⁸	Turkey	108	54	18-48	24	(G1) Filtek Supreme ^h + Single Bond ^h (n=26) (G2) Filtek Supreme ^h + Filtek Flow ^h + Single Bond ^h (n=26)	(G3) Admira ^e + Admira Bond ^e (n=24) (G4)Admira ^e + Admira Flow ^e + Admira Bond ^e (n=24)	I	M	Modified USPHS
Heck et al 2018 ³⁹	Germany	96	43	19-67	120	(G1) Tetric Ceram ^c + Syntac Sprint ^c (n=30)	(G2) Quix Fill ^f + Xeno III ^f (n=26)	I & II	M	Modified USPHS
Mahmoud et al, 2014 ⁴⁰	Egypt	80	40	20-54	36	(G1) Filtek Supreme ^h + Single Bond XT ^h (n=40)	(G2)Admira ^e + Admira Bond ^e (n=40)	I & II	PM & M	Modified USPHS
Van Dijken & Pallesen, 2017 ⁴¹	Sweden	106	38	32-87	72	(G1) Ceram X Mono ^h +Xeno V ^h (n=49)	(G2) SDR Flowable ^h + Ceram X mono ^h +Xeno V ^f (n=49)	I e II	PM e M	Modified USPHS
Yazici et al 2017 ⁴²	USA	104	50	24-55	36	(G1) Filtek ultimate + Adper Single Bond 2 ^h (n=40)	(G2)Tetric Evo Ceram bulk fill ^c + Excite F ^c (n=41)	II	PM & M	Modified USPHS

n* Number of initial study restorations.

n** Number of restorations evaluated in the recall.

PM: Premolar; M- Molar; Mod- Modified; G1 - Group 1; G2- Group 2; G3 - Group 3.

USA: United States of America.

control group,^{37,38,40,42} and prime-adhesive systems were used only in the intervention.³⁵ Matrix and wedge were used in all Class II restorations.

Regarding the methodology of composite insertion, one trial⁴¹ used flowable bulk-fill composites in increments of up to 4 mm, and the occlusal portion was filled with nanohybrid resin, which was compared with complete nanohybrid resin fillings. One study³⁷ evaluated four groups, comparing these to each other: the first group was composed of nanofill resin filling the cavity, the second with a fluid nanofill resin up to 4 mm covered by conventional nanofill resin making the occlusal part, the third group had cavities filled by a conventional ormocer composite, and the last group had cavities filled with a fluid ormocer composite up to 4 mm, with the occlusal part covered by the conventional ormocer. Other studies^{32-36,38-40,42} compared the intervention composite in all cavities with nanofill or nanohybrid resins using the incremental technique with the same cavity configuration.

Halogen light-curing was used to cure the restorations in five studies;^{33,35,37,39,40} the others used light-emitting diode (LED) curing units. Occlusal adjustments, finishing, and polishing of the restorations were performed in all included studies.

A total of 812 restorations were evaluated in different follow-ups, and 58 were considered failures (7.1%). Eighteen of the 253 evaluated bulk-fill restorations were considered failures (7.1%), 21 ormocer failures were detected in 173

restorations (12.1%), and in the control group (nanofill or nanohybrid composites), 20 out of 386 restorations failed (5.2%).

The most prevalent failures reported in all materials were discoloration (17.2%) and marginal integrity failure (17.2%), followed by restoration dislocation/fracture (15.5%), loss of anatomical shape (15.5%), postoperative sensitivity (13.8%), secondary caries (12.1%), and discoloration associated with secondary caries (8.6%). Failures by study and materials are shown in Table 4.

Risk of bias assessment - The four studies^{32,34,36,37} included in this review did not describe the randomization process. Only two studies^{35,40} mentioned the method used to allocate concealment. Eight trials^{32,34,40} were unclear regarding the blinding of participants and personnel. Three studies^{32,37,38} did not provide clarification regarding blinding in the evaluation of results and only one³⁵ did not perform this blinding. Two articles^{33,42} did not clarify the reasons for the loss of patients during the assessment, thus leaving the domain of incomplete results data uncertain. All studies had a low risk of selective reporting bias (Fig. 2).

Meta-analysis - The failure rates of composites with modified monomers (bulk fill and ormocer) and nanofill and nanohybrid resins were investigated by performing two analyses (Fig. 3). The first was performed by comparing the bulk-fill composites

Table 4. Failures occurred by groups of materials.

Author/year	Experimental group		Control group	
	Failure	Total	Failure	Total
Alkurdi & Abboud, 2016 ³² [BK]	G2- Marginal discoloration (n=2); Postoperative sensitivity (n=2). G3- 0	G2 = 17; G3=20	Marginal discoloration (n=1)	19
Arhun, Celik, Yamanel, 2010 ³³ [BK]	Secondary caries (n=2)	35	Retention/fracture (n=1)	35
Atabek et al, 2017 ³⁴ [BK]	0	30	0	30
Bottenberg, et al, 2009 ³⁵ [OR]	G2- Anatomical shape (n=2) Postoperative sensitivity (n=2); G3- Marginal discoloration (n=3), Anatomical shape (n=1) Marginal integrity (n=2); Postoperative sensitivity (n=3), Secondary caries (n=4)	G2=24; G3=32	Anatomical shape (n=2); Marginal integrity (n=1)	27
Çolak, et al 2017 ³⁶ [BK]	0	35	Marginal discoloration (n=1)	35
Efes, Dörter, Gömeci, 2006 ³⁷ [OR]	Retention/Fracture (n=1)	29	0	29
Efes, et al, 2006 ³⁸ [OR]	G3- Retention/Fracture (n=1); G4 – 0	G3=24; G4=24	0	52
Heck et al 2018 ³⁹ [BK]	Marginal discoloration and secondary caries (n=2), Retention/Fracture (n=3), Postoperative sensitivity (n=1)	26	Marginal discoloration and secondary caries (n=3), Marginal integrity (n=1)	30
Embaby et al 2014 ⁴⁰ [OR]	Retention/fracture (n=2)	40	Retention/fracture (n=1)	40
Van Dijken & Pallesen, 2017 ⁴¹ [BK]	Secondary caries (n=1), Anatomical shape (n=2), Marginal integrity (n=3)	49	Anatomical shape (n=2), Marginal integrity (n=3)	49
Yazici et al 2017 ⁴² [BK]	0	41	0	40
	[BK]= 18 [OR] = 21	426	20	386

[BK] Bulk fill; [OR] Ormocer.

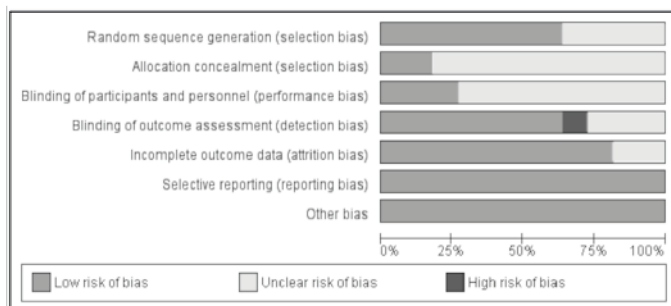


Fig. 2. Assessment of risk of bias in included studies.

with the control group, obtaining statistical power below 80%; that is, the result was inconclusive; Cohen’s H was less than 0.20 (H= 0.029), characterizing a small effect size (P= 0.206). (I²= 13.9%; P= 0.321; Z score = 1.264; P= 0.206; Power = 24.4%). The second analysis was performed comparing ormocer composites with the control group, and the statistical power was greater than 80%, which is a conclusive result, favoring the control group. However, the effect size Cohen’s H (H= 0.413) was small, and P= 0.0042 (I²= 40.3%; P= 0.413; Z score = 2.861; P= 0.0042; Power = 81.6%).

Discussion

This study followed the recent recommendations of the American Statistical Association on the statistical analysis of data, not relying only on P-values, but also calculating effect size and its 95% CI, and power (the probability that the phenomenon exists). The present analysis showed that the available published data on the comparison between bulk fill and control composites regarding dental restoration longevity are inclusive, with a low

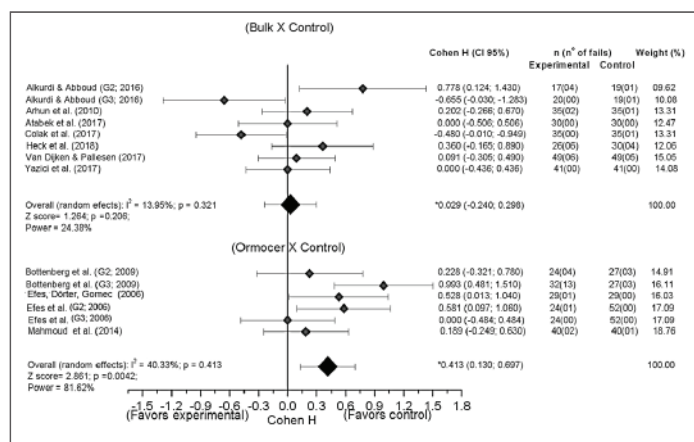


Fig. 3. Forest Plot of included studies.

effect size (Cohen’s H of 0.029) and low power (24.4%). The low statistical power for all but one study³² (G2) is a result of small sample sizes in studies, indicating poor study ad hoc planning as a routine in clinical trials in the field. The largest sample size per group was 49. In contrast, the required sample size for detecting, for instance, a low effect size Cohen’s H of 0.2 (closer to the overall effect size of 0.029, but still overestimated) with a power of 80%, and using a two-tailed significance level, would be 392 restorations.²⁵

One factor that probably contributed to the large number of underpowered studies was the widespread mistaken assumption that high P-values are indicative of “no difference”, and can be regarded as a conclusive result.⁴³⁻⁴⁵ This has serious consequences for evidence-based clinical practice in dentistry, mis-

guiding clinical practitioners towards procedures that lack strong scientific evidence. According to Amrhein et al⁴³ and Wasserstein et al,^{44,45} the use of the expression “not statistically significant”, should be avoided, since any difference/effect may be detected with a small P-value if the sample size is high enough and/or variation is low enough, and statistically nonsignificant differences do not prove a null hypothesis.⁴³ Any null hypothesis can be refuted depending on the sample size, and a study with a small sample size may not have enough power to detect a difference between treatments.⁴⁶ Most studies failed to report significant differences because they either lacked or inappropriately performed sample size calculations. In a review of 114 studies, only 17% reported the sample size calculation, and when they did, they presented a relatively small sample size (ranging from 8 to 456 participants).⁴⁷

For this reason, the interpretation of a result must be focused mainly on the effect size’s confidence interval and statistical power, which can be improved (confidence interval narrowed and power increased) with appropriate sample size.^{46,48} The single P-value is not the probability of whether a difference exists, and according to the American Statistics Association, it can lead to erroneous beliefs and poor decision-making.⁴⁴

A conclusive result was obtained with the ormocer experimental group (power of 81.6%, and small effect size Cohen’s H of 0.413), favoring the control group. In vitro studies have shown that cusp deflection,⁵⁰ fracture resistance,⁵¹ as well as other characteristics of ormocer, were superior to Bis-GMA resins. In contrast, a more recent study⁵² stated that conventional resins had better mechanical properties than ormocer, and this difference in clinical behavior was also measured in this meta-analysis.

It is worth mentioning that several factors related to polymerization shrinkage⁵³ can interfere with the longevity of the restoration, contributing to possible failure or clinical success.

Bulk fill composites have considerable translucency,¹⁸ which allows the curing of thicker increments, maintaining the degree of conversion of the material, resulting in adequate mechanical properties,^{54,55} and, consequently, increasing the longevity of restorations. Ormocer composites are inserted incrementally,⁵⁶ and similar to bulk-fill composites, present low polymerization shrinkage, unlike methacrylate-based resins.^{57,58} The volumetric shrinkage of Bis-GMA composites seems to be linked to the generation of stresses in the dentin wall, which can result in loss of marginal adaptation and retention, decreasing the clinical longevity of the restoration.⁵⁹

However, the longevity of a restoration is dependent on other factors, such as the patient’s characteristics, the operative technique, and the configuration of the cavity where the material will be inserted.³¹ Parafunctional habits (such as nail-biting or ice chewing, for instance), or sleep and awake bruxism, may lead to fracture or loss of retention of restorations,⁶⁰ and patients with a high risk of dental caries⁶¹ and poor oral hygiene may be susceptible to the development of secondary caries. This was reported by Van Dijken & Pallesen,⁴¹ where this condition was not used as an exclusion criterion for participants, and secondary caries was diagnosed in these patients.

The presence of some failures in this review (such as adaptation/integrity of restorations, secondary caries, and mar-

ginal discoloration) may be related to adhesive failures,^{9,10} and/or saliva contamination during the restoration process.³¹ Other factors, such as the type of resin, viscosity, and insertion technique,⁶³ may lead to failures of adaptation/marginal integrity; however, the operator can also influence the process. Van Dijken & Pallesen⁴¹ reported the use of the manufacturer’s recommendation for inserting the materials in the cavity; however, the absence of the rubber dam isolation may have promoted their relatively high number of failures in the experimental group. Considering that the same moisture control was used in the control group, this might indicate a higher sensitivity to salivary contamination by one of the tested composites. In this context, it is interesting to note that Alkurdi & Abboud³² used a rubber dam and obtained a lower number of failures in the control group, suggesting that the lack of rubber dam use might have contributed to more failures in the control group.

The use of cotton rolls and saliva ejector tips to isolate the cavity resulted in higher rates of failure due to secondary caries compared to the use of rubber dams.⁶⁴ For failures related to secondary caries in the included studies, only one trial³⁵ reportedly used a rubber dam.

Casselli & Martins⁶⁵ stated that postoperative sensitivity may result from polymerization stress. However, the highest rate of this failure occurred in the experimental group, where less shrinkage was expected. Among the trials in this review, Bottenberg et al³⁵ presented the worst results. However, the effect of polymerization shrinkage on restorations in clinical settings remains controversial. Ferracane & Hilton⁵³ claimed that there was no conclusive evidence indicating that polymerization shrinkage may decrease the longevity of restorations.

On the other hand, the use of base materials in deep cavities can influence longevity, as they can modulate postoperative sensitivity. The use of these materials has been reported in some studies,^{33,36,40} in which no postoperative sensitivity has been reported. Only one study⁴¹ claimed to have deep cavities in their sample and the absence of any base material, and only one molar presented sensitivity during the first week, with subsequent regression. Other studies did not describe the cavity depth. The type of adhesive used, and resin insertion technique did not seem to influence postoperative sensitivity.⁶⁶

However, marginal discoloration may be related to the nature of the adhesive system used in restorations, as well as the presence of excess restorative material, poorly adapted margins, “gaps”, and the lack of finishing and polishing.⁶² In this review, the studies by Alkurdi & Abboud³² and Bottenberg et al³⁵ presented the worst results. However, all studies performed finishing and polishing the restorations, and this result may be related to the adhesive system, or problems in the insertion of the restorative material.

Certain cavity characteristics, such as extension and location, can also affect the longevity of restorations. The failure rate in Class I restorations is lower than that in Class II restorations, which are more prone to the development of secondary caries.³ In the included studies, among the three evaluating Class I, only one³⁴ did not report any failures. However, one trial⁴¹ analyzed both configurations and reported that none of its failures occurred in Class I; four studies evaluated Class II, and only one³⁶ had no failure; while the others evaluated both classes and had failures in both.

Finally, it is worth mentioning that this review has some limitations that must be considered. The included trials were predominantly considered to have a low risk and uncertain risk of bias. Randomization, allocation concealment, and blinding of participants and evaluators are fundamental to the design of clinical trials to avoid selection, performance, and detection bias.⁴⁷ However, some included studies did not report the procedures performed in these areas. According to Göstemeyer et al,⁴⁷ in an evaluation of randomized trials, a high risk of bias is common, mainly in the domains of allocation concealment (93%), blinding of participants and personnel (99%), or blinding of the evaluators (46%). However, in the Consolidated Standards of Reporting Trials (CONSORT) rules, these data must be transparent to help the readers make their decisions.⁶⁷ Besides, USPHS assessment criteria have shown limited sensitivity, with clinical trials that used other criteria tending to detect failure rates four times higher than that produced by USPHS,⁴⁷ thus demonstrating that it can underestimate the failures that are present clinically, hindering clinical decision making.

Available data on the clinical longevity of bulk-fill composites compared to the control group, demonstrated clinical similarity, thus requiring further studies with a larger sample size to reduce the level of uncertainty. Regarding ormocer composites, the available data indicate a better clinical performance of the control group over time.

- a. Elsevier, Amsterdam, The Netherlands.
- b. Cochrane Collaboration, Copenhagen, Denmark.
- c. Ivoclar, Vivadent, Schaan, Liechtenstein.
- d. Kerr, Orange, CA, USA.
- e. Voco GmbH, Cuxhaven, Germany.
- f. Dentsply, Caulk Milford, DE, USA.
- g. Degussa, Hanau, Germany.
- h. 3M Oral Health, St Paul, MN, USA.

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