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Clinical performance and chemical-physical properties of bulk fill composites resin —a systematic review and meta-analysis

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ABSTRACT

Objectives: The objective of this study was to perform a meta-analysis of clinical and laboratory studies to compare the performance of bulk-fill and conventional composite resins in terms of polymerization shrinkage, polymerization stress, cusp deflection, marginal quality, degree of conversion, microhardness, flexural strength, fracture strength and clinical performance. Data: One hundred three articles were included in this study, and the Peto method was used to compare the bulk-fill and conventional composites using the RevMan software. Sources: Searches were performed in the PubMed and Scopus databases. Study selection: Laboratory studies and randomized clinical trials comparing one of the previous detailed outcomes between bulk-fill and control composites were included. Conclusions: The bulk-fill composite resins showed less shrinkage, polymerization stress, cusp deflection and microhardness than conventional composites, while both materials presented a similar marginal quality, flexural strength and fracture strength. Also, bulk-fill materials with regular viscosity showed similar shrinkage. The conversion of bulk-fill materials with flowable consistency were similar to conventional composite resins with a thickness of up to 2 mm and greater than conventional composites with a thickness greater than 2 mm. Despite these in vitro differences, the clinical performance of bulk-fill and conventional composite resins was similar in randomized clinical trials, with one to ten years of follow up. In conclusion, the bulk-fill materials show better or similar performance to the conventional

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materials in clinical trials and laboratory studies in terms of volumetric shrinkage, polymerization stress, cusps deflection and marginal quality, with the only exception being the lower level of microhardness observed for bulk-fill composites with thickness up to 2 mm.

Contents

1. Introduction

In recent decades, restorative composite resins have undergone considerable evolution regarding both their optical properties (resulting in better aesthetics) and their mechanical properties [1,2]. However, some of the remaining limitations of composite resins are their fracture strength, the inherent volumetric shrinkage that results from the polymerization of the material [3,4], and the development of polymerization stress [5].

The magnitude of volumetric shrinkage and mechanical properties depend on the type, size and concentration of the monomers involved [6,7], as well as the filler concentration in the restorative composite [8]. Although the mechanical properties of the restorative composites have been directly associated with degree of conversion [9,10], others factors also affect the behavior of the materials, such as the linearity of the polymer chain, crosslinking density, secondary bonds, and other factors, all of which depend on the composition of the materials [11–13]. On the other hand, the volumetric shrinkage is directly related to the polymerization stress that develops at the bonded interface between the tooth and restoration, potentially leading to several clinical disadvantages, such as postoperative sensitivity, microleakage, cusp deflection and marginal gaps [3].

In the past decade, bulk-fill composite resins have been launched in the dental market as a new restorative concept [14–16]. According to the manufacturers, the bulk-fill composite resins are restorative materials that can be inserted in increments of up to 4 mm in thickness without compromising conversion or mechanical properties at this depth. This effect is achieved through a few different strategies: the development of a more translucent material [17,18]; the use of lower filler concentrations, which facilitates light penetration at greater depths [14,15]; and the use of more efficient photoactivation systems [16]. Although these changes in composition have been introduced to allow greater conversion at increasing depths, they also potentially alter the mechanical properties, volumetric shrinkage and other related properties, including the clinical performance of the materials [19,20]. For example, several studies have reported the occurrence of greater polymerization stress for restorations composed of larger volumes of material [21]. Since the introduction of the bulk-fill materials in the market, several studies have been conducted to evaluate their performance by measuring different properties [20,22,23]. Since different studies still report contradictory results [24–26], the clinical dentist is still insecure about the adoption of this new class of materials in clinical practice. Therefore, the aim of this study was to perform a systematic review of studies evaluating the clinical and in vitro performance of bulk-fill composite resins compared to conventional resins in randomized clinical trials examining the following properties in vitro: volumetric shrinkage, polymerization stress, marginal quality, cusp deflection, degree of conversion, microhardness, flexural strength and fracture strength. The null hypothesis of this study is that there is no difference between the two types of restorative composite resins.

2. Materials and methods

Randomized clinical trials and laboratory studies that compared bulk-fill and conventional restorative composites were included in this meta-analysis. The outcomes evaluated were clinical performance, volumetric shrinkage, polymerization stress, cusp deflection, marginal integrity, degree of conversion, microhardness, flexural strength and fracture strength. A literature search of the PubMed (National Center for Biotechnology Information, NCBI) and Scopus (Elsevier B.V.) databases was conducted by two independent researchers (FG and ASCS) using the following terms: (“resin” OR “composite”) AND “bulk” AND “fill”. The publication date and language were not restricted. Four hundred thirty articles were retrieved from PubMed and 521 from Scopus, yielding 579 unique articles; the last search was conducted on May 7, 2019. A search of unpublished and nonpeer-reviewed literature was conducted in the database OpenGray (INIST-CNRS) and in the database from the authors' institutions, and no additional publications were identified. Initially, the articles were screened by title and abstract according to the inclusion and exclusion criteria, and the full text of articles that met the criteria was evaluated. The inclusion criteria were the evaluation of the performance of the bulk-fill composite resin in one of the following outcomes: shrinkage, polymerization stress, cusp deflection, marginal quality, degree of conversion, flexural strength, fracture strength, hardness or randomized clinical trials. The exclusion criteria were studies that did not employ a control group treated with a conventional composite resin and studies that did not perform a statistical analysis. In case of disagreements between the researchers, a specialist was consulted (LCCB).

The assessment of the risk of bias for the clinical studies were evaluated using the Risk of Bias Table from the RevMan software (Review Manager 5.3, The Nordic Cochrane Center, Copenhagen, Denmark), and only the studies that presented a low or intermediary risk of bias were included. This tool considered the following aspects: patients/tooth randomization, allocation concealment, blinding, incomplete outcome data, selective reporting, and other potential sources of bias. Table S1 (supplemental materials) shows a summary of the risk of bias for the included clinical studies. The risk of bias for the laboratory studies was assessed using a previously described method [27]. The following aspects were analyzed: tooth randomization and the use of teeth free of caries and restorations, when applied; materials were used according the manufacturer's instruction; specimens with similar dimensions; specimens were prepared by a single operator; sample size calculation; blinding of outcome assessments. Table S2 (supplemental materials) shows a summary of the risk of bias for the included laboratorial studies. The methodologies and materials evaluated were very distinct, and therefore, instead of using a continuous variable for the meta-analysis, the Peto method for calculating the weight effect was used. This method does not require data correction, even when events equal to zero exist. The meta-analysis was performed using RevMan software. For all the in vitro analyses comparing the bulk-fill with conventional composite resins, dichotomous events were considered. An event was counted in favor of bulk-fill composites when a numerical value that was statistically greater than the conventional composite was observed, and an event was counted for conventional materials when it presented a numerical value that was statistically greater than the bulk-fill materials. As clinical studies are already dichotomous, each restoration was considered individually, and an event was counted if the restorations presented a better or worse score for marginal integrity for both types of composite. Marginal integrity was the criteria selected because it was coincidentally the worst criteria in the majority of the studies. The diamond is inserted automatically in the forest plot on the side with fewer events, indicating that the value obtained in a particular study coincided with the material with lower numerical values registered.

The restorative composites were classified according the consistency (regular or flowable) according the commercial presentation of the material and viscosity. The bulk-fill materials SonicFill and ExerX Posterior were considered highly viscous materials. A complete list of the materials included in each category is presented in Table S3 of the supplemental materials.

3. Results

Table S4 (supplemental materials) shows a description of all the included studies. Ultimately, 148 articles were included in this review, with 32 evaluating polymerization shrinkage (Fig. 1), 20 measuring polymerization stress (Fig. 2), 21 analyzing cusp deflection (Fig. 3), 44 evaluating the marginal quality (Fig. 4), 19 evaluating the degree of conversion (Fig. 5), 26 measuring the microhardness (Fig. 6), 19 observing the flexural strength (Fig. 7), 12 evaluating the fracture strength of the materials (Fig. 8) and 11 performing randomized clinical trials (Fig. 9).

Fig. 1 presents the forest plot of volumetric shrinkage, with a heterogeneity index of 54%. Data were subdivided according to the viscosity of the material (regular consistency or flowable composite resin). Among the materials with a regular consistency, bulk-fill versions presented similar shrinkage to conventional materials. When flowable bulk-fill composites were considered, greater shrinkage was observed for conventional composite resins than bulk-fill. Fig. 2 shows data from the polymerization stress meta-analysis. A higher stress level was observed for the conventional materials compared to the bulk-fill, with a heterogeneity index of 52%. Fig. 3 presents the forest plot of the cusp deflection of bulk-fill and conventional materials. Bulk-fill materials presented a lower cusp deflection than the conventional materials, and the heterogeneity index was 53%. Fig. 4 shows the meta-analysis of marginal gap, with a heterogeneity index of 0%. Even with this low heterogeneity value, no statistically significant differences were observed between bulk-fill and conventional materials. The degree of conversion meta-analysis data are presented in Fig. 5. Data were subdivided according to thickness of the specimen and viscosity of the material. A higher degree of conversion was observed for the bulk-fill materials than for the conventional materials at a thickness of 2 mm for materials with a regular viscosity and a thickness greater than 2 mm, regardless of the viscosity. The conversion was similar in both groups at a thickness of up to 2 mm for flowable materials only, showing a heterogeneity index ranging from 0 to 49%. Data for microhardness are shown in Fig. 6. Data were divided in subgroups according to the thickness of the specimen and viscosity of the material, and the heterogeneity index ranged from 41 to 74%. For regular and flowable materials, greater microhardness was observed for conventional materials with a thickness of up to 2 mm, and a similar microhardness was observed for materials with a thickness greater than 2 mm. The forest plot of flexural strength is presented in Fig. 7, and the heterogeneity index was 56%. A similar flexural strength was observed for both conventional and flowable materials. The fracture strength data are plotted in Fig. 8. No difference was observed between bulk-fill and conventional materials, and the heterogeneity index was 0%. The meta-analysis of clinical trials is presented in Fig. 9. The data were subdivided according to the maximum follow up time. No significant differences were observed in clinical

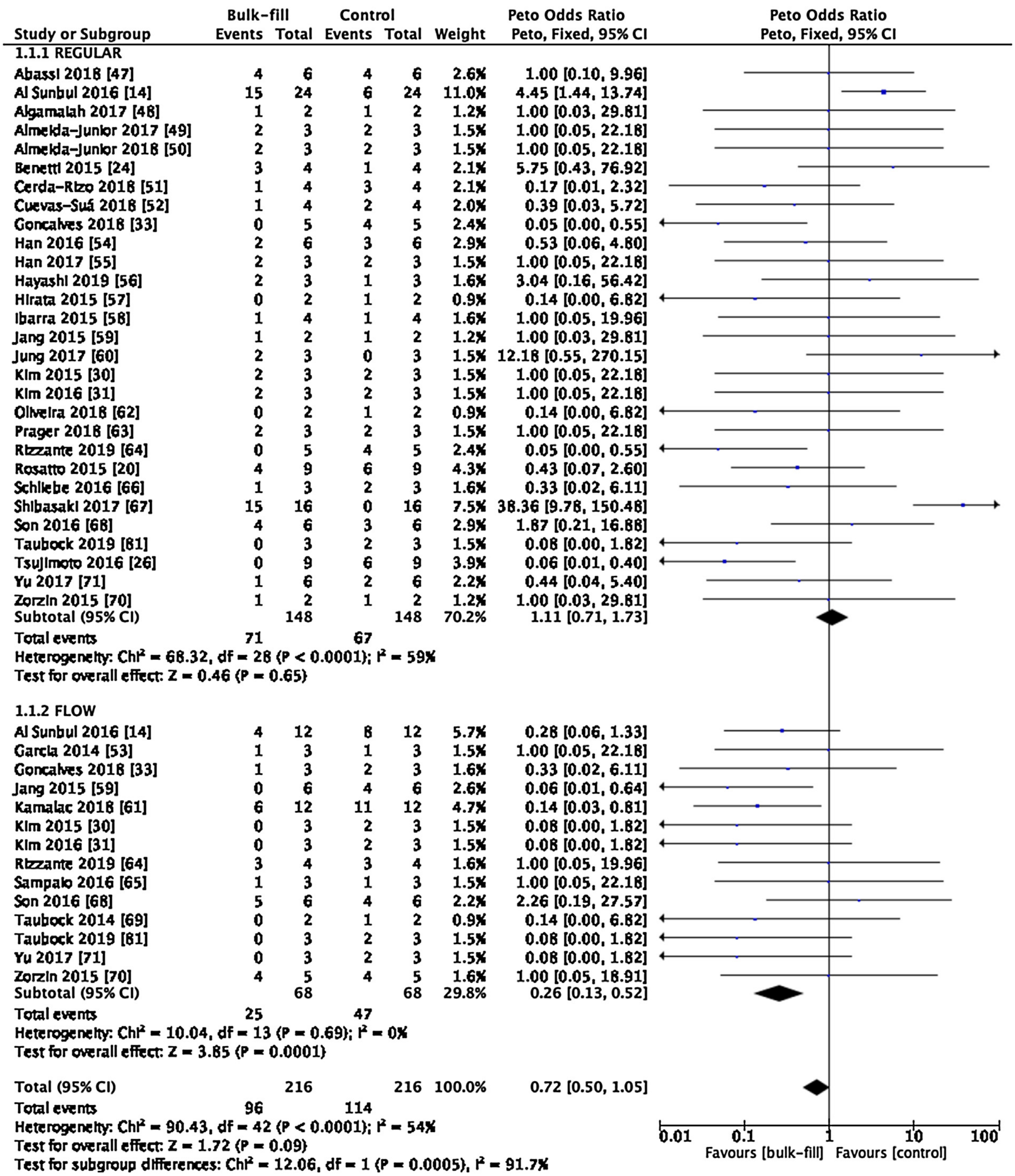

Fig. 1 – Foresnkt plot for volumetric shriage [47–71,81].

performance between bulk-fill and conventional composites. Two clinical studies were excluded due the high risk of bias and lack of randomization, blinding of examiners and allocation concealment [28,29]; the other clinical studies showed low or medium risk. The majority of laboratory studies presented a high risk of bias. Only 7 of the 137 studies (5.1%) stated the blinding of outcome assessments, 8 (5.8%) described the sample size calculation, and 21 (15%) declared that the samples were prepared by a single operator.

4. Discussion

The hypothesis of the study was partially verified. Although no differences in the flexural and fracture strength, marginal gap meta-analysis, or in clinical trials were observed between the different materials, in vitro analyses produced significant differences. Lower polymerization stress and cusp deflection were observed for bulk-fill materials. Additionally, conversion,

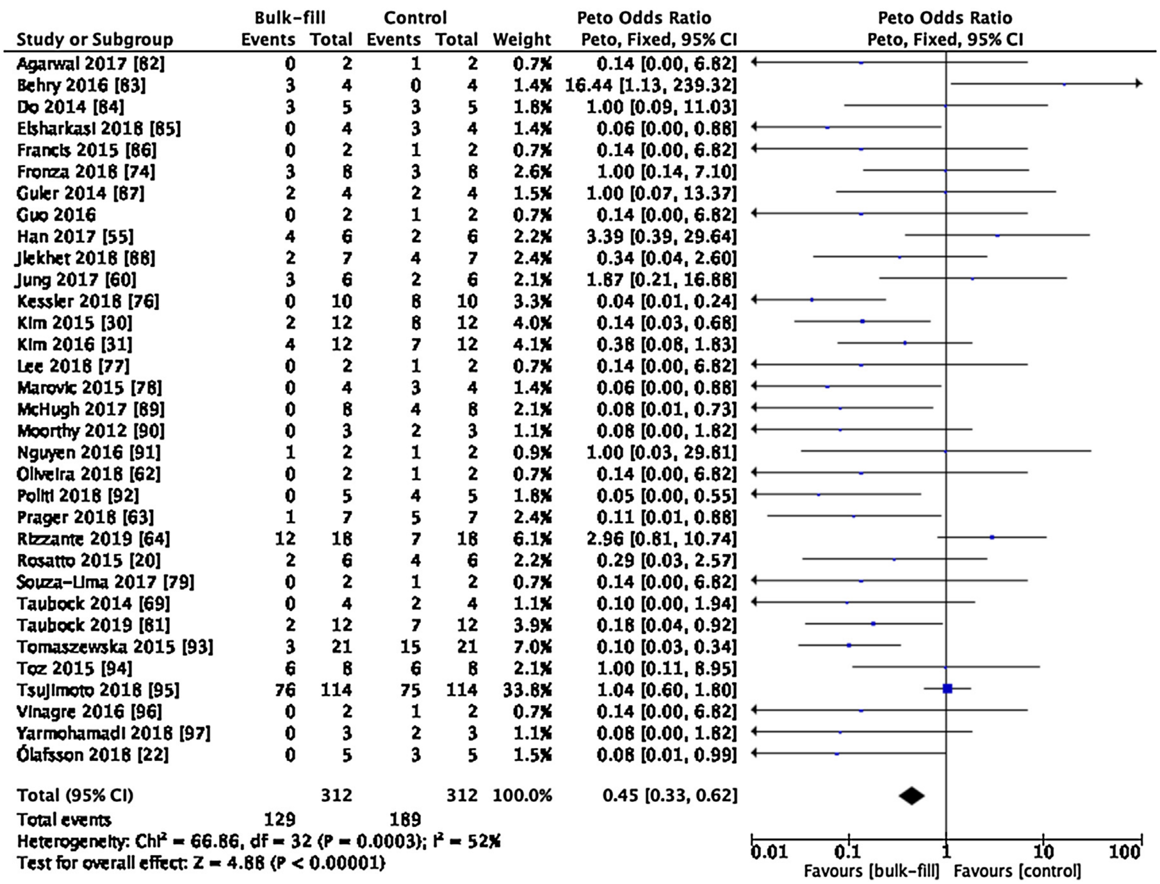

Fig. 2 – Forest plot for Polymerization stress [55,60,62–64,69,74,75–79,81,82,84–97].

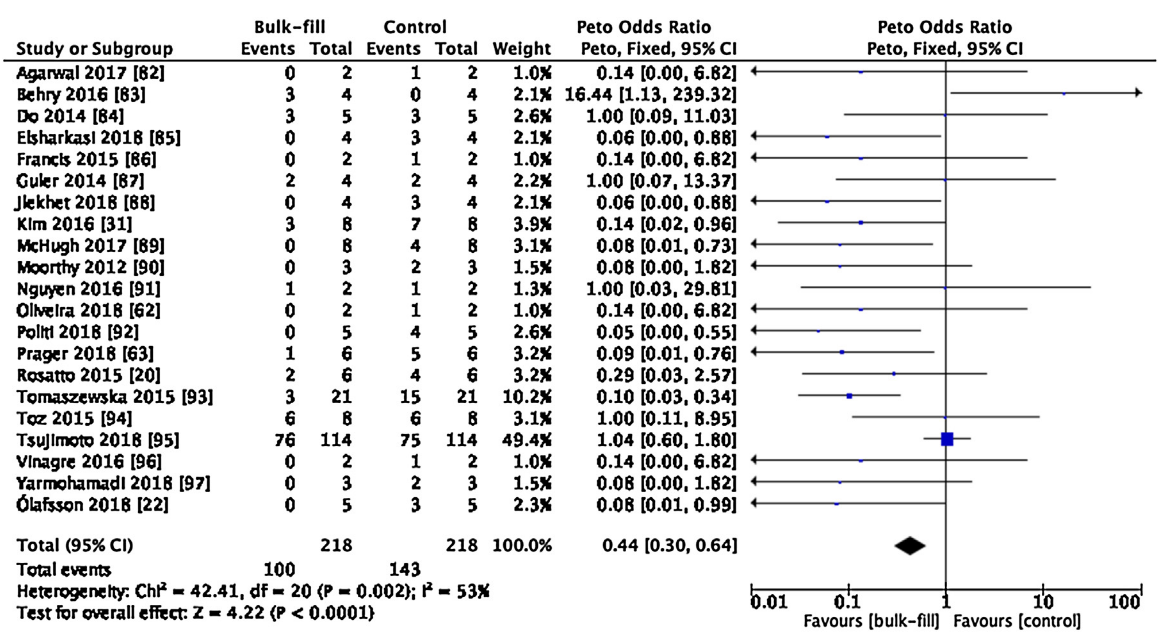

Fig. 3 – Forest plot for cusp deflection [62,63,82–97].

hardness and volumetric shrinkage varied according to the thickness and/or viscosity of the materials.

The studies differed in the methods used, photoactivation mode, specimen size, and test parameters, each of which can change the mean value of the material for the outcome evaluated. Therefore, the same material can show different values, depending on the test conditions. Due of these differences in methodology and variability in the control groups, commercial

Study or Subgroup	Bulk-fill Events	Bulk-fill Total	Control Events	Control Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Agarwal 2017 [82]	3	5	2	5	2.6%	2.05 [0.20, 21.58]
Al-Harbi 2016 [98]	8	12	8	12	5.3%	1.00 [0.19, 5.27]
Almeida-Junior 2017 [49]	2	3	2	3	1.5%	1.00 [0.05, 22.18]
Alquadaihi 2019 [99]	4	5	2	5	2.5%	4.48 [0.41, 49.42]
Alsagob 2018 [100]	2	3	2	3	1.5%	1.00 [0.05, 22.18]
Arora 2018 [101]	0	2	1	2	0.9%	0.14 [0.00, 6.82]
Arslan 2013 [102]	2	4	2	4	2.2%	1.00 [0.07, 13.37]
Bartsch 2016 [104]	1	2	0	2	0.9%	7.39 [0.15, 372.38]
Behery 2018 [103]	3	4	3	4	1.6%	1.00 [0.05, 19.96]
Benetti 2015 [24]	5	7	3	7	3.5%	2.95 [0.38, 22.72]
Campos 2014 [105]	4	6	3	6	3.0%	1.87 [0.21, 16.88]
Cantekin 2014 [106]	1	2	1	2	1.3%	1.00 [0.03, 29.81]
de Assis 2016 [107]	1	2	1	2	1.3%	1.00 [0.03, 29.81]
Do 2014 [84]	3	5	3	5	2.5%	1.00 [0.09, 11.03]
Fernandez 2016 [108]	1	2	1	2	1.3%	1.00 [0.03, 29.81]
Francis 2015 [86]	1	2	1	2	1.3%	1.00 [0.03, 29.81]
Fronza 2015 [73]	4	6	2	6	3.1%	3.39 [0.39, 29.64]
Fronza 2018 [109]	2	5	1	5	2.2%	2.36 [0.18, 30.67]
Guler 2014 [87]	1	4	2	4	2.0%	0.39 [0.03, 5.72]
Haak 2018 [110]	3	4	3	4	1.6%	1.00 [0.05, 19.96]
Han 2016 [54]	11	16	6	16	7.8%	3.37 [0.86, 13.23]
Han 2017 [55]	4	6	3	6	3.0%	1.87 [0.21, 16.88]
Hayashi 2019 [56]	2	6	3	6	3.0%	0.53 [0.06, 4.80]
Heintze 2015 [111]	1	2	1	2	1.3%	1.00 [0.03, 29.81]
Jawaed 2016 [112]	2	5	3	5	2.6%	0.49 [0.05, 5.11]
Jung 2017 [60]	1	3	2	3	1.7%	0.33 [0.02, 6.11]
Kalmowicz 2015 [113]	1	2	1	2	1.3%	1.00 [0.03, 29.81]
Kapoor 2016 [114]	0	5	3	5	2.2%	0.08 [0.01, 0.99]
Koyuturk 2014 [115]	1	2	1	2	1.3%	1.00 [0.03, 29.81]
Moorthy 2012 [90]	2	3	2	3	1.5%	1.00 [0.05, 22.18]
Mosharrafian 2017 [116]	2	4	2	4	2.2%	1.00 [0.07, 13.37]
Ozel 2016 [117]	0	2	1	2	0.9%	0.14 [0.00, 6.82]
Patnana 2017 [118]	1	4	2	4	2.0%	0.39 [0.03, 5.72]
Peutzfeldt 2018 [119]	3	6	2	6	3.0%	1.87 [0.21, 16.88]
Politi 2018 [92]	2	3	0	3	1.5%	12.18 [0.55, 270.15]
Rengo 2015 [120]	6	10	6	10	4.8%	1.00 [0.17, 5.72]
Rodrigues 2017 [121]	2	4	2	4	2.2%	1.00 [0.07, 13.37]
Scotti 2014 [122]	1	4	2	4	2.0%	0.39 [0.03, 5.72]
Scotti 2016 [123]	2	4	2	4	2.2%	1.00 [0.07, 13.37]
Shafie 2018 [124]	4	8	4	8	4.0%	1.00 [0.15, 6.67]
Tekce 2018 [125]	2	3	2	3	1.5%	1.00 [0.05, 22.18]
Tomaszewska 2015 [93]	2	4	0	4	1.6%	10.31 [0.52, 205.87]
Vianna-de-Pinho 2017 [126]	4	6	4	6	2.8%	1.00 [0.10, 9.96]
Yarmohamadi 2018 [97]	2	3	2	3	1.5%	1.00 [0.05, 22.18]
Total (95% CI)		200		200	100.0%	1.21 [0.83, 1.77]
Total events	109		99			

Heterogeneity: $Chi^2 = 21.95$, $df = 43$ ($P = 1.00$); $I^2 = 0\%$
Test for overall effect: $Z = 0.97$ ($P = 0.33$)

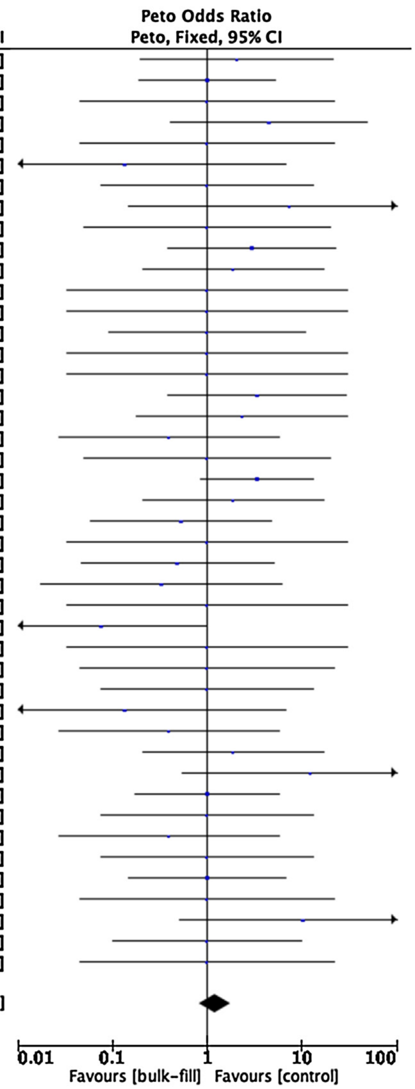

Fig. 4 – Forest plot for marginal quality [49,54,55,56,60,73,82,84,86,87,90,92,93,97–126].

brands and viscosity of the materials, a meta-analysis with a Peto calculation method was used for the laboratory studies. The heterogeneity index ranged from 0 to 77%. When the heterogeneity exceeded 60%, the analysis was repeated after separating the materials into subgroups according to viscosity (regular or flow) or thickness to reduce the heterogeneity.

The shrinkage of bulk-fill compared to conventional composite resins depended on the viscosity of the material. Bulk-fill composite resins with regular viscosity showed similar shrinkage to conventional resins, whereas flowable bulk-fill materials showed lower shrinkage than the conventional flowable materials. The first class of bulk-fill materials developed had a flowable consistency, and the strategy used to reach a bulk-fillcharacteristic increased the translucency and decreased the filler size and amount [18]. This approach leads to greater conversion and greater polymerization shrinkage compared with regular-consistency composites, but the shrinkage is still less than conventional flowable composites [30,31]. To date, these materials have achieved some clinical success, which has prompted the manufacturers to develop strategies to synthetize bulk-fill materials with regular viscosity, including new types of monomers, fillers and photoinitiators systems [32,33]. These changes allowed a higher conversion to be achieved [1,32], but resulted in a similar shrinkage [14,24]. Although shrinkage has been pointed as one of the main factors responsible for polymerization stress [5,14], this relationship was not observed in the present meta-analysis. Lower polymerization stress was observed for bulk-fill materials than conventional materials. Others factors influence these outcomes, such as the composition of the materials, including the type, molecular weight and concentration of monomers, as well as filler size and amount; the properties of the materials, including the elastic modulus, degree of conversion and viscosity; and restoration or test system variables, including the volume of remaining teeth, adhesion area, substrate of adhesion, material volume, and compliance of the system, among others. In several studies, the bulk-fill materials, regardless of their viscosity, were compared with controls with a regular consistency. In this case, the elastic modulus represents a confounding factor

Study or Subgroup	Bulk-fill Events	Bulk-fill Total	Control Events	Control Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
11.2.1 REGULAR up to 2mm						
AlShaffi 2017 [127]	1	2	1	2	1.1%	1.00 [0.03, 29.81]
Borges 2019 [128]	2	3	0	3	1.3%	12.18 [0.55, 270.15]
Farahat 2016 [43]	1	2	0	2	0.8%	7.39 [0.15, 372.38]
Goncalves 2018 [33]	1	5	1	5	1.5%	1.00 [0.05, 18.91]
Goracci 2014 [129]	2	3	1	3	1.5%	3.04 [0.16, 56.42]
Kubo 2017 [130]	9	18	12	18	7.5%	0.51 [0.14, 1.90]
Lempel 2018 [132]	1	2	0	2	0.8%	7.39 [0.15, 372.38]
Leprince 2014 [46]	3	5	3	5	2.2%	1.00 [0.09, 11.03]
Miletic 2017 [134]	3	4	3	4	1.4%	1.00 [0.05, 19.96]
Nascimento 2018 [135]	5	6	1	6	2.7%	11.52 [1.32, 100.61]
Nascimento 2019 [136]	5	6	0	6	2.7%	23.17 [2.57, 208.60]
Par 2015 [25]	8	10	4	10	4.2%	4.87 [0.85, 27.86]
Taubock 2015 [80]	4	5	3	5	2.0%	2.36 [0.18, 30.67]
Taubock 2019 [81]	2	3	1	3	1.5%	3.04 [0.16, 56.42]
Vidhawan 2015 [137]	2	3	2	3	1.3%	1.00 [0.05, 22.18]
Yu 2017 [71]	1	6	4	6	2.7%	0.15 [0.02, 1.37]
Subtotal (95% CI)		83		83	35.4%	1.94 [1.06, 3.54]
Total events	50		36			
Heterogeneity: Chi² = 21.15, df = 15 (P = 0.13); I² = 29%						
Test for overall effect: Z = 2.15 (P = 0.03)						
11.2.2 REGULAR higher than 2mm						
Farahat 2016 [43]	1	2	0	2	0.8%	7.39 [0.15, 372.38]
Goracci 2014 [129]	2	3	0	3	1.3%	12.18 [0.55, 270.15]
Kubo 2017 [130]	6	9	2	9	3.9%	5.47 [0.90, 33.35]
Miletic 2017 [134]	3	4	3	4	1.4%	1.00 [0.05, 19.96]
Nascimento 2019 [136]	4	6	3	6	2.7%	1.87 [0.21, 16.88]
Par 2015 [25]	8	10	0	10	4.2%	23.73 [4.15, 135.72]
Yu 2017 [71]	3	6	3	6	2.7%	1.00 [0.11, 8.73]
Subtotal (95% CI)		40		40	17.2%	4.75 [2.00, 11.29]
Total events	27		11			
Heterogeneity: Chi² = 7.41, df = 6 (P = 0.28); I² = 19%						
Test for overall effect: Z = 3.53 (P = 0.0004)						
11.2.3 FLOW up to 2mm						
Alshali 2013 [41]	4	20	14	20	8.5%	0.14 [0.04, 0.48]
Goncalves 2018 [33]	2	3	1	3	1.5%	3.04 [0.16, 56.42]
Lempel 2016 [131]	2	4	2	4	1.9%	1.00 [0.07, 13.37]
Lempel 2018 [132]	0	3	2	3	1.3%	0.08 [0.00, 1.82]
Leprince 2014 [46]	4	6	2	6	2.7%	3.39 [0.39, 29.64]
Marigo 2015 [133]	6	8	5	8	3.1%	1.73 [0.22, 13.36]
Marovic 2015 [78]	3	8	5	8	3.6%	0.39 [0.06, 2.61]
Nascimento 2018 [135]	3	5	3	5	2.2%	1.00 [0.09, 11.03]
Nascimento 2019 [136]	4	5	0	5	2.2%	20.09 [1.82, 221.51]
Par 2015 [25]	6	10	4	10	4.4%	2.14 [0.39, 11.81]
Taubock 2019 [81]	1	3	1	3	1.3%	1.00 [0.05, 22.18]
Yu 2017 [71]	1	3	1	3	1.3%	1.00 [0.05, 22.18]
Subtotal (95% CI)		78		78	34.2%	0.82 [0.45, 1.52]
Total events	36		40			
Heterogeneity: Chi² = 21.70, df = 11 (P = 0.03); I² = 49%						
Test for overall effect: Z = 0.63 (P = 0.53)						
11.2.4 FLOW higher than 2mm						
Lempel 2016 [131]	3	4	0	4	1.8%	16.44 [1.13, 239.32]
Marigo 2015 [133]	3	4	0	4	1.8%	16.44 [1.13, 239.32]
Marovic 2015 [78]	3	4	1	4	1.9%	5.75 [0.43, 76.92]
Nascimento 2019 [136]	4	5	0	5	2.2%	20.09 [1.82, 221.51]
Par 2015 [25]	8	10	0	10	4.2%	23.73 [4.15, 135.72]
Yu 2017 [71]	1	3	1	3	1.3%	1.00 [0.05, 22.18]
Subtotal (95% CI)		30		30	13.3%	12.39 [4.64, 33.13]
Total events	22		2			
Heterogeneity: Chi² = 3.64, df = 5 (P = 0.60); I² = 0%						
Test for overall effect: Z = 5.02 (P < 0.00001)						
Total (95% CI)		231		231	100.0%	2.16 [1.51, 3.09]
Total events	135		89			
Heterogeneity: Chi² = 78.88, df = 40 (P = 0.0002); I² = 49%						
Test for overall effect: Z = 4.21 (P < 0.0001)						
Test for subgroup differences: Chi² = 24.97, df = 3 (P < 0.0001), I² = 88.0%						

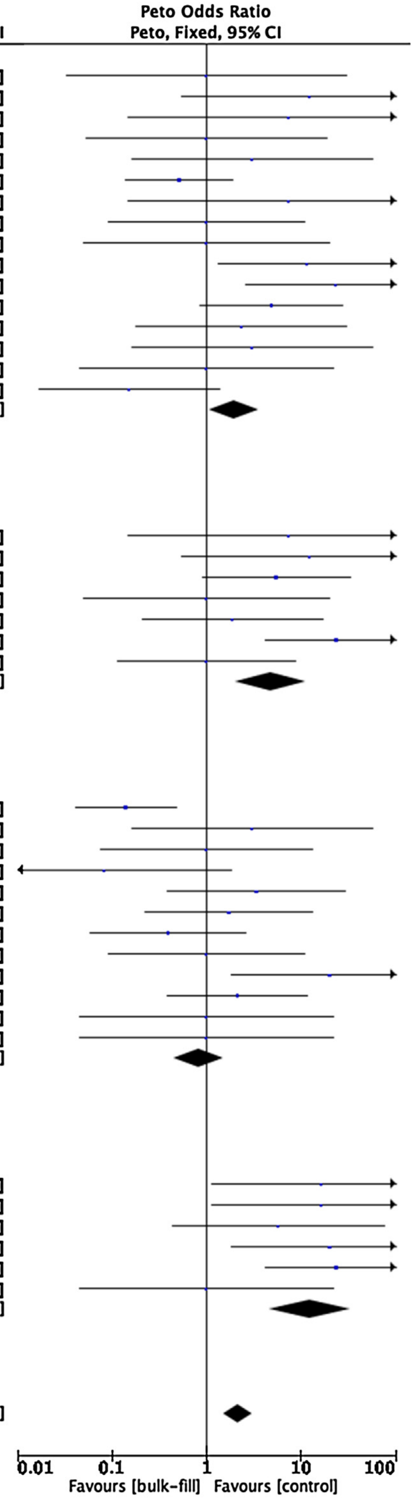

Fig. 5 – Forest plot for degree of conversion studies [71,78,80,81,127–137].

in the analysis of polymerization stress. Less rigid materials enable part of the stress to be relieved and consequently register a lower polymerization stress. The results from the cusp deflection analysis were consistent with the results for polymerization stress. The bulk-fill materials also showed lower cusp defection than the conventional materials. Apparently, the lower stress generated at the interface between teeth and restorations is translated into less of a displacement of the remaining tooth structure. Kim et al. have shown strong correlations between polymerization stress and the deflection of the aluminum mold for conventional and bulk-fill materials on the remaining wall thickness of several teeth, and a

Study or Subgroup	Bulk-fill Events	Bulk-fill Total	Control Events	Control Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
12.1.1 REGULAR up to 2mm						
Alshali 2015 [138]	10	30	13	30	8.6%	0.66 [0.24, 1.85]
Borges 2019 [128]	0	3	2	3	1.0%	0.08 [0.00, 1.82]
Bucuta 2014 [17]	11	20	8	20	6.1%	1.80 [0.53, 6.12]
Cerda-Rizo 2018 [51]	3	5	4	5	1.4%	0.42 [0.03, 5.52]
El Gewazi 2016 [140]	3	7	4	7	2.2%	0.59 [0.08, 4.43]
Farahat 2016 [43]	1	2	1	2	0.8%	1.00 [0.03, 29.81]
Garcia 2014 [53]	1	2	0	2	0.6%	7.39 [0.15, 372.38]
Kelic 2016 [142]	0	4	3	4	1.3%	0.06 [0.00, 0.88]
Kim 2015 [18]	2	3	1	3	1.1%	3.04 [0.16, 56.42]
Lee 2018 [77]	0	2	1	2	0.6%	0.14 [0.00, 6.82]
Leprince 2014 [46]	0	6	5	6	1.9%	0.04 [0.00, 0.39]
Moharam 2017 [143]	2	3	1	3	1.1%	3.04 [0.16, 56.42]
Nascimento 2018 [135]	2	6	5	6	1.9%	0.15 [0.02, 1.37]
Nascimento 2019 [136]	1	6	5	6	2.0%	0.09 [0.01, 0.76]
Par 2019 [146]	9	13	7	13	3.8%	1.87 [0.40, 8.80]
Rizzante 2019 [64]	0	5	4	5	1.6%	0.05 [0.00, 0.55]
Warangkulkasemkit 2018 [148]	0	2	1	2	0.6%	0.14 [0.00, 6.82]
Yap 2016 [149]	0	4	3	4	1.3%	0.06 [0.00, 0.88]
Subtotal (95% CI)		123		123	37.8%	0.48 [0.30, 0.79]
Total events	45		68			
Heterogeneity: $Chi^2 = 31.05$, $df = 17$ ($P = 0.02$); $I^2 = 45\%$						
Test for overall effect: $Z = 2.89$ ($P = 0.004$)						
12.1.2 REGULAR higher than 2mm						
Bucuta 2014 [17]	13	20	8	20	6.1%	2.66 [0.78, 9.05]
El Gewazi 2016 [140]	3	7	4	7	2.2%	0.59 [0.08, 4.43]
Farahat 2016 [43]	1	2	1	2	0.8%	1.00 [0.03, 29.81]
Kelic 2016 [142]	0	4	3	4	1.3%	0.06 [0.00, 0.88]
Kim 2015 [18]	2	3	0	3	1.0%	12.18 [0.55, 270.15]
Moharam 2017 [143]	2	3	0	3	1.0%	12.18 [0.55, 270.15]
Nagi 2015 [144]	1	2	0	2	0.6%	7.39 [0.15, 372.38]
Nascimento 2019 [136]	2	6	5	6	1.9%	0.15 [0.02, 1.37]
Par 2019 [146]	10	13	3	13	4.0%	7.93 [1.76, 35.83]
Rosatto 2015 [20]	1	2	1	2	0.8%	1.00 [0.03, 29.81]
Schliebe 2016 [66]	1	3	1	3	1.0%	1.00 [0.05, 22.18]
Silame 2017 [147]	1	2	1	2	0.8%	1.00 [0.03, 29.81]
Yap 2016 [149]	3	4	3	4	1.0%	1.00 [0.05, 19.96]
Subtotal (95% CI)		71		71	22.4%	1.70 [0.90, 3.23]
Total events	40		30			
Heterogeneity: $Chi^2 = 20.33$, $df = 12$ ($P = 0.06$); $I^2 = 41\%$						
Test for overall effect: $Z = 1.63$ ($P = 0.10$)						
12.1.3 FLOW up to 2mm						
Alshali 2015 [138]	13	30	20	30	9.0%	0.40 [0.14, 1.09]
Bucuta 2014 [17]	0	20	16	20	5.9%	0.04 [0.01, 0.14]
El-Safty 2012 [141]	5	6	6	6	0.6%	0.14 [0.00, 6.82]
Engelhardt 2016 [15]	13	16	7	16	4.6%	4.71 [1.15, 19.28]
Kelic 2016 [142]	3	8	4	8	2.5%	0.62 [0.09, 4.21]
Kim 2015 [18]	2	3	0	3	1.0%	12.18 [0.55, 270.15]
Leprince 2014 [46]	0	6	5	6	1.9%	0.04 [0.00, 0.39]
Nascimento 2018 [135]	3	5	3	5	1.6%	1.00 [0.09, 11.03]
Nascimento 2019 [136]	2	5	3	5	1.7%	0.49 [0.05, 5.11]
Nowak 2018 [145]	1	2	1	2	0.8%	1.00 [0.03, 29.81]
Rizzante 2019 [64]	1	4	3	4	1.4%	0.17 [0.01, 2.32]
Yap 2016 [149]	1	3	2	3	1.1%	0.33 [0.02, 6.11]
Subtotal (95% CI)		108		108	31.9%	0.38 [0.22, 0.65]
Total events	44		70			
Heterogeneity: $Chi^2 = 35.53$, $df = 11$ ($P = 0.0002$); $I^2 = 69\%$						
Test for overall effect: $Z = 3.55$ ($P = 0.0004$)						
12.1.4 FLOW higher than 2mm						
Bucuta 2014 [17]	0	10	8	10	3.0%	0.04 [0.01, 0.24]
Kelic 2016 [142]	2	4	2	4	1.4%	1.00 [0.07, 13.37]
Kim 2015 [18]	2	3	0	3	1.0%	12.18 [0.55, 270.15]
Nascimento 2019 [136]	4	5	2	5	1.6%	4.48 [0.41, 49.42]
Yap 2016 [149]	2	3	2	3	1.0%	1.00 [0.05, 22.18]
Subtotal (95% CI)		25		25	7.9%	0.55 [0.19, 1.60]
Total events	10		14			
Heterogeneity: $Chi^2 = 15.46$, $df = 4$ ($P = 0.004$); $I^2 = 74\%$						
Test for overall effect: $Z = 1.10$ ($P = 0.27$)						
Total (95% CI)		327		327	100.0%	0.60 [0.44, 0.81]
Total events	139		182			
Heterogeneity: $Chi^2 = 116.19$, $df = 47$ ($P < 0.00001$); $I^2 = 60\%$						
Test for overall effect: $Z = 3.32$ ($P = 0.0009$)						
Test for subgroup differences: $Chi^2 = 13.83$, $df = 3$ ($P = 0.003$), $I^2 = 78.3\%$						

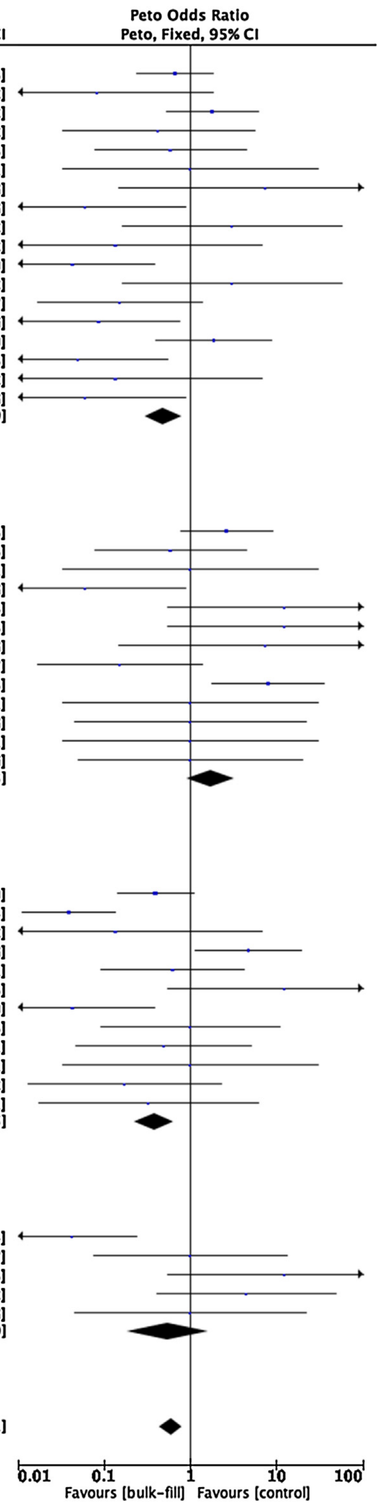

Fig. 6 – Forest plot for micro-hardness studies [51,53,64,66,77,128,135,136,138–149].

weak correlation between cups deflection and shrinkage data [31]. However, marginal gap development was similar for both materials, although the lowest stress was generated with the bulk-fill composites, suggesting that other factors influenced these results, such the adhesive system used [34], the viscosity of the material [35], the restorative technique [36], and operator experience [34], among others.

In this meta-analysis, bulk-fill materials showed a higher conversion than conventional materials with any thickness for materials with a regular viscosity and a thickness greater

Study or Subgroup	Bulk-fill Events	Bulk-fill Total	Control Events	Control Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
5.1.1 REGULAR						
Bijelic-Donova 2016 [150]	2	3	0	3	2.1%	12.18 [0.55, 270.15]
Cabxeta 2015 [151]	1	3	1	3	2.1%	1.00 [0.05, 22.18]
Cuevas-Suá 2018 [52]	2	4	3	4	2.9%	0.39 [0.03, 5.72]
El Damanhoury 2014 [72]	1	3	2	3	2.4%	0.33 [0.02, 6.11]
Ewels 2019 [152]	3	4	3	4	2.3%	1.00 [0.05, 19.96]
Fronza 2017 [19]	0	3	2	3	2.1%	0.08 [0.00, 1.82]
Garaoush 2013 [32]	1	3	1	3	2.1%	1.00 [0.05, 22.18]
Goracci 2014 [129]	2	3	0	3	2.1%	12.18 [0.55, 270.15]
Ibarra 2015 [58]	4	8	5	8	5.6%	0.62 [0.09, 4.21]
Jung 2017 [60]	1	4	2	4	2.9%	0.39 [0.03, 5.72]
Leprince 2014 [46]	6	11	9	11	6.7%	0.30 [0.05, 1.74]
Meenakumari 2018 [153]	2	5	4	5	3.6%	0.22 [0.02, 2.46]
Shibasaki 2017 [67]	7	13	11	13	7.7%	0.25 [0.05, 1.28]
Tsujimoto 2016 [26]	2	7	6	7	4.9%	0.11 [0.01, 0.88]
Tsujimoto 2018 [95]	43	57	20	57	38.1%	5.04 [2.42, 10.52]
Warangkulkasemkit 2018 [148]	2	3	0	3	2.1%	12.18 [0.55, 270.15]
Yap 2018 [155]	2	3	2	3	2.1%	1.00 [0.05, 22.18]
Öznurhan 2015 [154]	1	2	1	2	1.8%	1.00 [0.03, 29.81]
Subtotal (95% CI)		139		139	93.9%	1.33 [0.83, 2.12]
Total events	82		72			
Heterogeneity: Chi² = 39.32, df = 17 (P = 0.002); I² = 57%						
Test for overall effect: Z = 1.19 (P = 0.23)						
5.1.2 FLOW						
Leprince 2014 [46]	2	6	5	6	4.3%	0.15 [0.02, 1.37]
Scribante 2019 [156]	1	2	1	2	1.8%	1.00 [0.03, 29.81]
Subtotal (95% CI)		8		8	6.1%	0.26 [0.04, 1.68]
Total events	3		6			
Heterogeneity: Chi² = 0.84, df = 1 (P = 0.36); I² = 0%						
Test for overall effect: Z = 1.41 (P = 0.16)						
Total (95% CI)		147		147	100.0%	1.21 [0.77, 1.90]
Total events	85		78			
Heterogeneity: Chi² = 42.91, df = 19 (P = 0.001); I² = 56%						
Test for overall effect: Z = 0.81 (P = 0.42)						
Test for subgroup differences: Chi² = 2.76, df = 1 (P = 0.10), I² = 63.8%						

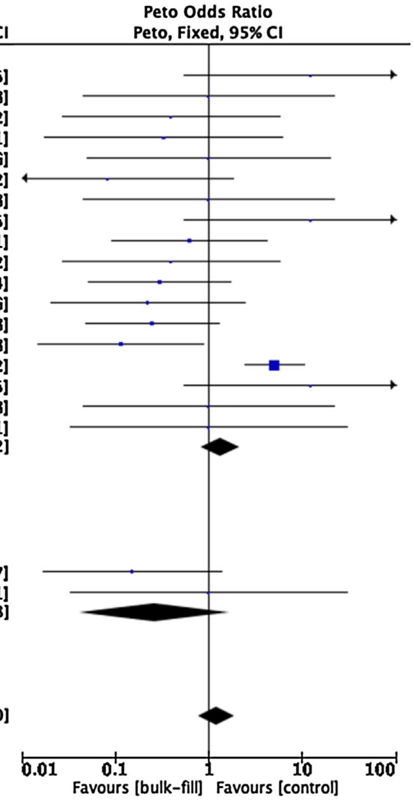

Fig. 7 – Forest plot for flexural strength studies [52,58,60,67,72,95,129,148,150–156].

Study or Subgroup	Bulk-fill Events	Bulk-fill Total	Control Events	Control Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Atalay 2016 [157]	3	5	3	5	9.7%	1.00 [0.09, 11.03]
Hegde 2017 [158]	1	3	2	3	6.6%	0.33 [0.02, 6.11]
Isufi 2016 [159]	1	2	1	2	4.9%	1.00 [0.03, 29.81]
Kemaloglu 2015 [160]	2	4	1	4	7.8%	2.54 [0.17, 37.01]
Lacerda2019 [161]	2	4	2	4	8.3%	1.00 [0.07, 13.37]
Mergulhão 2019 [162]	1	2	1	2	4.9%	1.00 [0.03, 29.81]
Rosatto 2015 [20]	4	6	0	6	10.6%	15.64 [1.57, 155.75]
Taha 2017 [164]	1	2	0	2	3.6%	7.39 [0.15, 372.38]
Tekce 2017 [165]	4	8	4	8	15.5%	1.00 [0.15, 6.67]
Toz 2015 [94]	6	8	6	8	11.7%	1.00 [0.11, 8.95]
Yasa 2016 [166]	4	6	0	6	10.6%	15.64 [1.57, 155.75]
Öztürk-Bozkurt 2016 [163]	2	3	2	3	5.8%	1.00 [0.05, 22.18]
Total (95% CI)		53		53	100.0%	1.93 [0.91, 4.07]
Total events	31		22			
Heterogeneity: Chi² = 10.07, df = 11 (P = 0.52); I² = 0%						
Test for overall effect: Z = 1.72 (P = 0.09)						

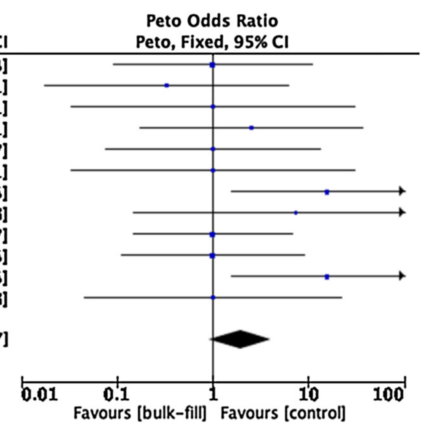

Fig. 8 – Forest plot for fracture strength studies [94,157–166].

than 2 mm for flowable materials. The degree of conversion of the restorative dental composite depends not only on the characteristics of the material, such monomer composition [37], filler concentration [38] and photoinitiator systems [39] but also factors related to photoactivation, as the curing lamp [40], photoactivation mode and radiant exposure [11]. Therefore, several studies have reported variations in the performance of bulk-fill materials, depending on the brand and the polymerization conditions of the materials [41,42]. Specific characteristics of some bulk-fill material contributed to these results. The cure depth directly correlates with the translucency of the bulk-fill materials [17,18]. The bulk-fill restorative composite Tetric also employs a new photopolymerization system composed of the interaction between camphorquinone and bis-(4-methoxybenzoyl), which, according to the manufacturer, is more photoreactive than camphorquinone and thus a higher conversion is somewhat expected [43]. Although differences in conversion were observed, no differences in mechanical properties were observed between bulk-fill and conventional composite resins. The only exception was the increased microhardness of regular and flowable conventional materials with a thickness greater than 2 mm compared with bulk-fill materials. The hardness value depends not only on the conversion but also

Study or Subgroup	Bulk-fill Events	Bulk-fill Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI
1.1.1 12 months						
Bayraktar 2016 [168]	2	43	1	43	1.0%	2.05 [0.18, 23.48]
Canali 2019 [169]	18	46	18	42	12.4%	0.86 [0.37, 2.01]
Franscino 2019 [171]	18	53	15	53	10.7%	1.30 [0.57, 2.97]
Oter 2018 [174]	13	50	7	50	5.6%	2.16 [0.78, 5.98]
Çolak 2017 [170]	1	35	4	35	4.2%	0.23 [0.02, 2.15]
Subtotal (95% CI)		227		223	33.9%	1.17 [0.73, 1.88]
Total events	52		45			
Heterogeneity: $Chi^2 = 4.21$, df = 4 (P = 0.38); $I^2 = 5\%$						
Test for overall effect: Z = 0.65 (P = 0.52)						
1.1.2 24 months						
Atabek 2017 [167]	1	30	2	30	2.1%	0.48 [0.04, 5.63]
Subtotal (95% CI)		30		30	2.1%	0.48 [0.04, 5.63]
Total events	1		2			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.58 (P = 0.56)						
1.1.3 36 months						
Karaman 2016 [173]	2	33	2	33	2.0%	1.00 [0.13, 7.55]
Yazici 2017 [23]	4	41	10	40	9.9%	0.32 [0.09, 1.14]
Subtotal (95% CI)		74		73	11.9%	0.44 [0.15, 1.25]
Total events	6		12			
Heterogeneity: $Chi^2 = 0.86$, df = 1 (P = 0.35); $I^2 = 0\%$						
Test for overall effect: Z = 1.54 (P = 0.12)						
1.1.4 5 years						
Van Dijken 2016 [175]	112	180	109	180	44.5%	1.07 [0.70, 1.64]
Subtotal (95% CI)		180		180	44.5%	1.07 [0.70, 1.64]
Total events	112		109			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.32 (P = 0.75)						
1.1.5 6 years						
Van Dijken 2017 [176]	94	98	85	98	3.8%	3.59 [1.13, 11.45]
Subtotal (95% CI)		98		98	3.8%	3.59 [1.13, 11.45]
Total events	94		85			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.16 (P = 0.03)						
1.1.6 10 years						
Heck 2018 [172]	12	26	7	30	3.8%	2.82 [0.90, 8.85]
Subtotal (95% CI)		26		30	3.8%	2.82 [0.90, 8.85]
Total events	12		7			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.77 (P = 0.08)						
Total (95% CI)		635		634	100.0%	1.18 [0.89, 1.55]
Total events	277		260			
Heterogeneity: $Chi^2 = 14.77$, df = 10 (P = 0.14); $I^2 = 32\%$						
Test for overall effect: Z = 1.17 (P = 0.24)						
Test for subgroup differences: $Chi^2 = 9.90$, df = 5 (P = 0.08), $I^2 = 49.5\%$						

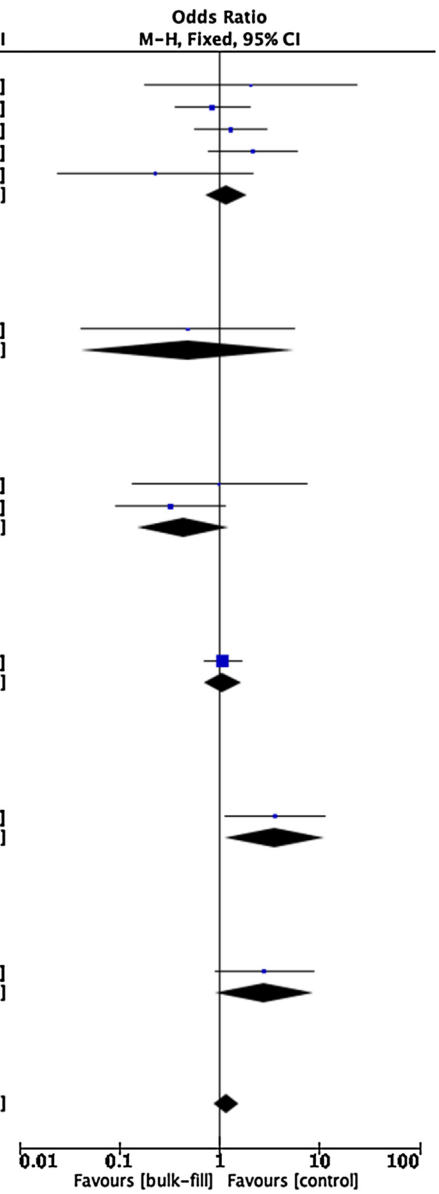

Fig. 9 – Forest plot for Clinical Trial [167–176].

on others factors, such as the filler composition [44], size and concentration [45]. Therefore, the lower filler concentration in the flowable bulk-fill materials may explain these outcomes, particularly at a thickness up to 2 mm, where the conversion values were similar for both categories. According to ISO 4049, flexural strength requires a sample thickness of 2 mm, but some dental composites are also tested in a simplified condition with a thickness of 1 mm. In both conditions, a conversion gradient is less likely to form in the bar specimen, which explains the lack of difference in flexural strength among the materials tested in those studies. Consistent with the flexural strength data, the fracture strength showed an extremely low heterogeneity index (0%), even when both materials (regular and flowable) were evaluated together, indicating that in materials with both consistencies, the bulk-fill materials behave similarly to conventional composites.

Table S3 in the supplemental materials shows the wide variety of restorative materials evaluated in the included studies. Importantly, the differences observes were not exclusively attributed to the type of restorative material, conventional or bulk-fill, but also included variables such as the composition of the materials, photoactivation mode, and viscosity, among others. The methodology used is also a critical factor; for example, ten different methods were used to measure the linear or volumetric shrinkage of the materials, and the magnitude of the results were not comparable. The rigidity of the bonding substrate used in the polymerization stress test affects the system compliance and substantially influences the resulting data [46]; the majority of the studies were performed with custom-made devices, without compliance system report. The marginal quality was assessed using several tests, one more robust than the others, and showed a heterogeneity index of 0%. Thus, the results for this parameter were consistent between studies. Therefore, these data represent a summary of the studied materials and other factors considered to express the final behavior of the material.

Finally, despite the differences in shrinkage, polymerization stress, cuspal deflection, conversion and microhardness, the interactions of all these factors did not exert a significant effect on the clinical performance of the materials at up to 10 years of follow up. These studies included both restorations completely composed of high viscosity bulk-fill resin and restorations with a liner of low viscosity bulk-fill materials covered with 2 mm of a conventional resin. Better performance was only observed for the conventional material at 6 years of follow up, but this result was obtained from only one clinical study. Another study with 10 years follow up did not confirm this result, and thus, randomized clinical trials with a longer follow-up period are still needed. In addition, only a limited number of studies were available and included in this meta-analysis. Additional clinical trials examining these materials with a longer follow-up period should be performed to obtain more robust data and stronger evidence.

5. Conclusions

Within the limitations of the present meta-analysis, the new class of restorative composites called bulk-fill composites are safe for use by the clinical dentist. Laboratory studies show similar or better performance of bulk-fill materials compared to the traditional composite resins in terms of polymerization stress, cuspal deflection, marginal gap, degree of conversion, flexural strength, and fracture strength. The only exceptions are the lower microhardness of bulk-fill materials with a thickness of less than 2 mm. Furthermore, clinical trials, despite the reduced number, did not detect differences in the performance of bulk-fill and conventional materials after one to 10 years of follow up.

Conflict of interest

The authors have no conflicts of interest to declare.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.dental.2019.07.007.

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