UNIVERSIDADE FEDERAL DE PELOTAS

Faculdade de Odontologia

Programa de Pós-Graduação em Odontologia

Tese

Compósitos odontológicos do tipo *Bulk fill*: estado da arte e da técnica

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Pelotas, 2017

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Tese apresentada ao Programa de Pós-Graduação em Odontologia da Faculdade de Odontologia da Universidade Federal de Pelotas, como requisito parcial à obtenção do título de Doutor em Odontologia, área de concentração em Dentística.

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Pelotas, 2017

Universidade Federal de Pelotas / Sistema de Bibliotecas
Catalogação na Publicação

M495c Meereis, Carine Tais Welter

Compósitos odontológicos do tipo bulk fill : estado da arte e da técnica / Carine Tais Welter Meereis ; Evandro Piva, orientador ; Fabrício Aulo Ogliari, Giana da Silveira Lima, coorientadores. — Pelotas, 2017.

153 f. : il.

Tese (Doutorado) — Programa de Pós-Graduação em Dentística, Faculdade de Odontologia, Universidade Federal de Pelotas, 2017.

1. Compósitos bulk fill. 2. Resinas compostas. 3. Materiais restauradores temporários. 4. Revisão sistemática. 5. Meta-análise. I. Piva, Evandro, orient. II. Ogliari, Fabrício Aulo, coorient. III. Lima, Giana da Silveira, coorient. IV. Título.

Black : D151

Elaborada por Fabiano Domingues Malheiro CRB: 10/1955

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Tese apresentada, como requisito parcial, para obtenção do grau de Doutor em Odontologia, área de concentração em Dentística, Programa de Pós-Graduação em Odontologia, Faculdade de Odontologia, Universidade Federal de Pelotas.

Data da defesa: 25 de maio de 2017

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Agradecimentos

A **Universidade Federal de Pelotas** e ao **Programa de Pós-graduação em Odontologia,** pela oportunidade me tornar cirurgiã-dentista, mestre e doutora em uma instituição de excelência.

Ao meu orientador e meus co-orientadores, **Prof. Dr. Evandro Piva, Prof. Dr. Fabrício Aulo Ogliari e Prof. Dr[a]. Giana da Silveira Lima** pelos ensinamentos, prestatividade e por acreditar em meu trabalho, me proporcionando oportunidades que com certeza contribuíram para o meu crescimento pessoal e profissional.

Aos colegas e co-autores, pela atenção e contribuição na conclusão deste trabalho.

A **equipe do Centro de Desenvolvimento e Controle de Biomateriais, do Laboratório de Microbiologia e do Laboratório de Cultivo Celular e Biologia Molecular** da Universidade Federal de Pelotas, por abrirem as portas dos seus laboratórios com admirável atenção, permitindo a utilização de seus equipamentos e o desenvolvimento do presente trabalho.

Aos colegas de graduação, pós-graduação e colegas do laboratório CDC-Bio pela troca de conhecimento, pela amizade e por tornarem a rotina mais divertida.

À minha família e namorado, **Celso, Salete, Estele, Felipe e Jardel,** por todo o suporte sempre. Vocês são o maior presente que a vida me deu. O amor nos une e não há distância que nos separe...

Muito obrigada!

Notas Preliminares

A presente tese foi redigida segundo o Manual de Normas para Dissertações, Teses e Trabalhos Científicos da Universidade Federal de Pelotas de 2013, adotando o Nível de Descrição 3 – estrutura em “Capítulos convencionais”, descrita no Apêndice D do referido manual. <http://sisbi.ufpel.edu.br/?p=documentos&i=7> Acesso em: 15 de maio de 2017.

O projeto de pesquisa que originou essa Tese foi apresentado dia 3 de junho de 2016 e aprovado pela Banca Examinadora.

Resumo

MEEREIS, Carine Tais Welter. **Compósitos odontológicos do tipo *Bulk fill*: estado da arte e da técnica.** 2017. 153f. Tese (Doutorado em Odontologia, área de concentração Dentística) – Programa de Pós Graduação em Odontologia. Universidade Federal de Pelotas, Pelotas, 2017.

Os compósitos odontológicos do tipo *bulk fill* foram desenvolvidos como uma alternativa para simplificar a técnica restauradora. Comercialmente eles estão disponíveis como materiais restauradores diretos ou como materiais temporários, sendo indicados para restauração definitiva de dentes posteriores ou para selamento provisório de cavidades, respectivamente. A simplificação da técnica restauradora só foi possível a partir da melhoria dos materiais. Diante disso, o primeiro artigo visou revisar sistematicamente estudos *in vitro* com o propósito de avaliar potenciais alternativas relacionadas à modificação da composição do material, para reduzir e/ou controlar a tensão de contração de materiais restauradores resinosos. A busca na literatura foi conduzida em sete bases de dados: PubMed, Web of Science, Scopus, SciELO, LILACS, Ibecs e BBO. Um total de 62 estudos foram incluídos na análise qualitativa, e a meta-análise foi realizada com 58 estudos. A modificação da composição da matriz resinosa contribuiu mais para minimizar a tensão de contração do que a modificação da composição das partículas de carga ou interface resina-carga. A tecnologia utilizada nos compósitos de baixa contração e nas resinas *bulk fill* apresenta uma aplicação promissora para reduzir/controlar a tensão de contração. Além disso, no segundo artigo foi feita uma revisão sistemática de estudos *in vitro* e clínicos com o propósito de avaliar o desempenho de compósitos do tipo *bulk fill* comparados às resinas compostas convencionais. Um total de 45 estudos *in vitro* e 5 estudos clínicos foram incluídos na análise. De maneira geral, os estudos *in vitro* e clínicos sugerem que as resinas *bulk fill* parecem ter um desempenho semelhante ou melhor que as resinas compostas convencionais. Por fim, foi feita a prospecção tecnológica com a descrição da patente de invenção de um compósito odontológico do tipo *bulk fill* com alta profundidade de polimerização, excelente selamento marginal e com propriedades antimicrobianas para uso como material restaurador temporário. Além disso, este material apresenta a vantagem de ser facilmente aplicado e removido na cavidade dental. O uso de compósitos odontológicos do tipo *bulk fill* apresentou potencial aplicação para restauração de dentes posteriores com a vantagem de simplificar a técnica e reduzir o tempo clínico.

Palavras-chave: Compósitos *bulk fill*; resinas compostas; materiais restauradores temporários; revisão sistemática; meta-análise.

Abstract

MEEREIS, Carine Tais Welter Meereis. **Bulk fill dental composites: state of the art and technique.** 2017. 153p. Thesis (PhD in Dentistry). Graduate Program in Dentistry.Federal University of Pelotas, Pelotas, 2017.

The bulk fill dental composites were developed as an alternative to simplify the restorative technique. Commercially they are available as direct restorative materials or as temporary materials, being indicated for definitive restoration of posterior teeth or for temporary sealing of cavities, respectively. The simplification of the restorative technique was only possible from the materials improvement. Therefore, this study aimed initially to review systematically in vitro studies with the purpose of evaluating chemical composition strategies available to reduce/control contraction stress development in dental resin-based restorative materials. The literature search was conducted in seven databases: PubMed, Web of Science, Scopus, SciELO, LILACS, Ibecs and BBO. A total of 62 studies were included in the qualitative analysis, and the meta-analysis was performed with 58 studies. The modification of the resin matrix contributes more to minimize stress development than filler phase and resin-filler interface. The stress decreasing technology used for low-shrinkage formulations and bulk-fill materials shows promising application for reducing/controlling stress development. In addition, a systematic review of in vitro and clinical studies was carried out to evaluate the performance of bulk fill composites compared to conventional composite resins. A total of 45 in vitro studies and 5 clinical trials were included in the analysis. In general, the in vitro and clinical studies suggest that bulk fill materials seem to perform similarly or better than conventional composite. Finally, it was developed a bulk fill dental composite with high polymerization depth, antimicrobial properties, and excellent marginal sealing for use as a temporary restorative material. In addition, it has the advantage of being easily applied and removed in the dental cavity. The use of bulk fill dental composites presented a potential application for posterior restoration purposes with the advantage of simplifying the operative technique and reducing the clinical time for restoration building up.

Key-words: Composite bulk fill; Composite resins; Temporary restorative materials; systematic review; meta-analysis.

Sumário

1 Introdução

Os compósitos odontológicos do tipo *bulk fill* foram desenvolvidos como uma alternativa para simplificar a técnica restauradora (MARGEAS, 2015). Diversos fatores relacionados à composição química do material foram modificados para permitir o seu uso em incremento único para restauração direta de dentes posteriores (ALSHALI et al., 2015, ALSHALI et al., 2015, ENGELHARDT et al., 2016, LEMPEL et al., 2016). Quantidade e tamanho das partículas de carga (ALSHALI, et al., 2015, BUCUTA; ILIE, 2014, FRONZA et al., 2017, GAROUSHI et al., 2015, LEPRINCE et al., 2013, MILETIC et al., 2016, YAP; PANDYA; TOH, 2016), constituição da matriz resinosa (ALSHALI, et al., 2015, ILIE; HICKEL, 2011, LEMPEL, et al., 2016), características do sistema de iniciação (MOSZNER et al., 2008) e o agente de união, são fatores que podem influenciar no desempenho do material. Apesar das melhorias alcançadas, a profundidade de polimerização, a contração volumétrica e a tensão de contração gerada, ainda são algumas das principais limitações de compósitos com matriz orgânica a base de metacrilatos (FERRACANE, 2011, PARK et al., 2008, SCHNEIDER; CAVALCANTE; SILIKAS, 2010).

A profundidade de polimerização pode ser limitada devido a dificuldade de penetração da luz através do material restaurador (FRONZA, et al., 2017, GAROUSHI, et al., 2015, LEPRINCE, et al., 2013). Uma polimerização satisfatória do incremento em toda a profundidade é crucial para a obtenção de propriedades físicas, mecânicas e biológicas adequadas (AL SUNBUL; SILIKAS; WATTS, 2016, LEMPEL, et al., 2016, RODRIGUEZ-LOZANO et al., 2013, ZORZIN et al., 2015). Além disso, a contração volumétrica é uma propriedade intrínseca de compósitos com matriz orgânica a base de metacrilatos, sendo provocada pela aproximação de moléculas monoméricas durante o processo de polimerização (FERRACANE, 2011, PARK, et al., 2008, SCHNEIDER; CAVALCANTE; SILIKAS, 2010). Em ambiente confinado, como a cavidade dental ou o canal radicular, a contração volumétrica do material gera tensões na interface dente/restauração e tem sido associada como causa de fenda marginal, deflexão de cúspides, hipersensibilidade pós-operatória e,

consequentemente, falha das restaurações (BRAGA; BALLESTER; FERRACANE, 2005, CRAMER; STANSBURY; BOWMAN, 2011, FERRACANE, 2008, FERRACANE; MITCHEM, 2003, GONÇALVES et al., 2012). Embora a evidência clínica da associação entre tensão de contração e falha de restaurações possa ser difícil de coletar (FERRACANE, 2008), os resultados in vitro mostram a necessidade de desenvolver estratégias para reduzir e/ou controlar a tensão de contração.

A tecnologia utilizada nas resinas compostas *bulk fill* apresenta uma aplicação promissora para reduzir/controlar o desenvolvimento da tensão de contração e aumentar a profundidade de polimerização, com a vantagem de simplificar a técnica restauradora e reduzir o tempo clínico. Entretanto é questionável se o desempenho laboratorial e clínico destes materiais é semelhante ao das resinas compostas convencionais. Diante disso, a presente tese está dividida em três capítulos que abordam o estado da arte e da técnica de compósitos odontológicos do tipo *bulk fill*. O primeiro capítulo teve como objetivo revisar sistematicamente a literatura sobre as potenciais alternativas, relacionadas à modificação da composição química do material, para reduzir e/ou controlar a tensão de contração de materiais restauradores à base de resina. No segundo capítulo, foram analisados estudos in vitro e clínicos para avaliar o desempenho de compósitos do tipo *bulk fill* comparado às resinas compostas convencionais.

Enquanto no último capítulo, foi feita a prospecção tecnológica com a descrição da patente de invenção referente ao desenvolvimento de um compósito odontológico do tipo *bulk fill* com alta profundidade de polimerização, propriedades antimicrobianas e com excelente selamento marginal para uso como material restaurador temporário. Além de apresentar adesão ao substrato dental, também tem uma expansão higroscópica controlada que compensa a contração volumétrica sofrida pela matriz resinosa do material.

2 Capítulo 1*

Title.

Composition strategies available to reduce/control contraction stress of resin-based dental materials – A systematic review with meta-analyses

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*Artigo formatado Segundo as normas do periódico *Polymer*, disponível em: https://www.elsevier.com/journals/polymer/0032-3861/guide-for-authors

Abstract

A systematic review was conducted to determine whether composition strategies may be available to reduce/control contraction stress development in dental resin-based restorative materials. Two reviewers performed a literature search up to December 2016 in seven databases: PubMed, Web of Science, Scopus, SciELO, LILACS, Ibecs, and BBO. A total of 62 studies were included in the qualitative analysis, and the meta-analysis was performed with 58 studies. A global comparison was performed with random-effects models ($\alpha = 0.05$). The strategy was subdivided according to the modified part of the material: filler phase, resin-filler interface, or resin matrix. The modification of the resin matrix contributes more to minimize stress development. The stress decreasing technology used for the formulation of low-shrinkage and bulk-fill materials shows promising application for reducing/controlling stress development. Finally, there are other formulations that have not been yet translated to commercial materials such as the thiol-ene, thio-urethane, tetraoxaspiroalkane, or trithiocarbonate systems; therefore, it can be expected further improvements in the formulation of new stress decreasing restorative materials.

1. Introduction

As a brief definition composites materials it presents a basic composition comprised of two distinct phases: an organic matrix mainly constituted of resin monomers, and an inorganic phase composed of filler particles; both the organic and inorganic phases can be chemically bonded to each other upon the presence of a coupling agent [1]. Notably, dental resin formulations have been evolved since their introduction in dentistry, resulting in materials with equilibrated structural characteristics. Notwithstanding, despite all improvements in physic-mechanical properties (e.g., strength, wear resistance), witch that has been shown in last years, modern materials still demonstrate a concerning limitation: they shrink in volume [2].

Volume/Polymerization shrinkage is an intrinsic property of conventional resin-based materials caused by the approximation of monomers during polymerization, i.e., when the distance between monomers is reduced due to the conversion of the weak van der Waals forces into covalent bonds [3]. However, it is important to note that the polymerization shrinkage itself is not the most deleterious factor, but the stress generated at the tooth/restoration interface while the material is undergoing shrinkage in a confined environment such as tooth cavities or root canals [4]. This foregoing phenomenon is usually defined as polymerization/contraction stress, and it has been increasingly associated as one of the reasons for failure of resin-based restorations [5], especially for resin composites or resin cements. Indeed, several negative effects may occur, including but not limited to restoration/post de-bonding, cuspal deflection, microleakage, and post-operatory hipersensitivity [6-8]. Consequently, contraction stress should be reduced and/or controlled as much as possible in order to prevent the occurrence of those consequences, favoring the clinical success of the restorative treatment.

During the last few decades, several strategies have been presented in the literature in an attempt to solve or control the aforementioned problematic. Some of the strategies reported are related to the modification of the composition of the material. To the knowledge of the authors, there is no previous report on a meta-analysis study regarding this subject. Therefore, and considering that valuable information can be collected and produced upon reviewing those studies, the purpose of the present study was to systematically

review the literature regarding the potential alternative composition to reduce and/or control the contraction stress phenomenon associated to resin-based restorative materials.

2. Materials and methods

This systematic review is reported following the guidelines of the PRISMA statement [9]. The research question was as follows: Is there any composition strategy available to reduce/control contraction stress development in dental resin-based restorative materials?

2.1 Systematic literature search

This study was aimed to identify all studies that reported on alternative formulations/ composition (hereafter referred to as “strategy”) that reduced the contraction stress phenomenon of resin-based materials. The search was systematically performed in seven distinct electronic databases by two independent reviewers, i.e., PubMed, ISI Web of Knowledge, Scopus, SciELO, LILACS, IBECS, and BBO (*Biblioteca Brasileira de Odontologia*). The keywords related to the search strategy in PubMed are listed in Table 1. The last search in the databases was performed in December 2016. The reviewers hand-searched the reference lists of included articles for additional papers. After the screening of articles, all studies were imported into Endnote x7 software (Thompson Reuters, Philadelphia, PA, USA) to remove duplicates.

All abstracts were read to verify the inclusion criteria: in vitro studies that reported on contraction stress reduction after application of an alternative strategy. If this information was not clear in the abstract, the papers were retrieved in full text. Only papers that evaluated contraction stress by direct testing were included; consequently, studies that used indirect methods (e.g., microleakage and/or cuspal deflection measurements) were excluded. Studies reporting on finite elemental analyses or theoretical/mathematical models were also excluded since they are predictive analyses. Only papers written in English and Portuguese languages were considered for this review, without restriction of the year of publication. Any disagreement regarding the eligibility of the included studies was resolved through discussion and consensus or one third

reviews is contacted. Only papers that fulfilled all of the eligibility criteria were included.

2.2 Data recorded from the selected studies

For each included study, the following data/information was recorded using a standardized form in the Microsoft Office Excel 2013 software (Microsoft Corporation, Redmond, WA, USA): the strategy used to reduce contraction stress, and the magnitude of the stress reduction, which was given in approximated percentage values, i.e., range between minimum and maximum values. Data related to the contraction stress mean (±standard deviation/SD) values, in MPa, and number of specimens, were also tabulated. If any information was missing, the authors of the included studies were contacted twice via e-mail to retrieve the missing data; if authors had not given an answer by one month after the first contact, the respective study was promptly excluded from the review.

2.3 Meta-analysis

The values of contraction stress with the alternative strategy were compared to the control(s) used in each study. Subgroup analyses were performed in order to decrease heterogeneity. Pooled-effect estimates were obtained by comparing the mean difference between alternative strategies and the control groups within each study. A *P* value ≤.05 was considered statistically significant. The global analysis was carried out using a random-effect model using Review Manager Software version 5.1 (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark). Statistical heterogeneity of the treatment effect among studies was assessed using the Cochran's Q test and the inconsistency I^2 test, in which values greater than 50% were considered as indicative of substantial heterogeneity [10]. Qualitative analysis was performed to elucidate the effect of each alternative strategy on the contraction stress phenomenon.

2.4 Quality assessment

The methodological quality of each included study was assessed and adapted from another systematic review of in vitro studies [11]. The risk of bias was

evaluated according to the articles' description of the following parameters: "informed number of specimens", "informed mean ±SD values", "presence of a clear control group", "informed specimen dimension", "monitored stress kinetic", and "informed about testing compliance". If the authors reported the parameter, the article had a "Yes" on that specific parameter; if it was not possible to find the information, the article received a "No." Articles that reported up to two items were classified as having a high risk of bias, three to four as a medium risk of bias, and five to six as a low risk of bias.

3. Results

3.1 Literature search

The results of the search are shown in Figure 1 according to the PRISMA Statement [9]. In total, 6113 publications were retrieved in all databases. From those publications, and after duplicates removal, a total of 3550 papers were examined by the titles and abstracts, 3457 studies were excluded because they did not fulfill the eligibility criteria, and 93 papers were assessed by full-text reading. From the 93 studies retained for detailed review, 31 studies were not included because of the following reasons: one study was related to theoretical calculation [12], two studies were related to finite elemental analysis [13, 14], two studies were presented in a foreign language [15, 16], six studies did not demonstrate stress reduction results [17-22], three studies evaluated stress by using indirect measurements [23-25], two studies could not be retrieved in full-text version [26, 27], five studies did not evaluate contraction stress [28-32], and ten studies did not inform some requested information for the qualitative analysis [33-42]. A total of 62 studies were included in the qualitative analysis, and four of these studies [43-46] did not inform requested information for the quantitative analysis, so only 58 studies were included for the meta-analyses.

3.2 Meta-analyses

In total, meta-analyses were performed with 58 in vitro studies, which main results are described in Tables 2, 3 and 4. The results were separated into subgroups according to the modified part of the material: 'filler phase', 'resin-filler interface', or 'resin matrix'. There were statistically significant differences of

the strategies when compared to the respective control groups ($p<0.05$), and heterogeneity values ranged from 84 to 100% depending on the subgroup. The only subgroup that did not show statistical difference between the alternative strategy and the control was ‘the use of alternative photo-initiators’ ($p=0.29$).

3.3 Qualitative/Descriptive analysis

All studies that were included in the review as well as their respective main strategies used to reduce contraction stress and the approximate stress reduction percentage range are demonstrated in Tables 2, 3, and 4. Among all strategies associated with significant contraction stress reduction, one main category was drawn: the partial/total modification of the material’s composition (composition category, n=62), and after the studies were grouped within one or more additional subgroups. The stress reduction percentage values ranged from 2.1 to 59.4%, 8.4 to 46.3%, and 0.2 to 98.7% for the ‘filler phase’, ‘resin-filler interface’, and ‘resin matrix’ subgroups, respectively. Within the filler phase subgroup (Table 2), the studies were also subdivided into four classes: (1) studies that increased the content of fillers [47-50]; (2) studies that increased the size of fillers [51]; (3) studies that incorporated alternative fillers [52-54]; and (4) studies that incorporated nanogels into the material [55, 56]. From these foregoing classes, the incorporation of nanogels showed the most effective approach to reduce stress development. Within the resin-filler interface subgroup (Table 3), the studies were subdivided into two additional classes: (1) studies that used non-bonded/unsilanized fillers instead of silanized fillers [57, 58]; and (2) studies that used alternative functionalization systems of fillers [57, 59, 60]. From these studies, the latter strategy resulted in overall higher stress reduction than the former. Lastly, within the resin matrix subgroup (Table 4), the studies were subdivided according to the following classes: (1) studies that modified the composition ratio of conventional formulations [47, 61-64]; (2) studies that used alternative photo-initiators [65-67]; (3) studies that used silorane-based monomers/materials [45, 65, 68-74]; (4) studies that used thiol-ene-based monomers [43, 44, 60, 75-82]; (5) studies that used thio-urethane oligomers [83-85]; (6) studies that used alternative monomers/molecules [68, 86-90]; (7) studies that used low-shrink compositions [69, 72, 74, 91-96]; and (8) studies that used bulk-fill technology [3, 46, 70, 96-103]. From these

foregoing studies, the “alternative monomers” class presented higher potential to reduce stress development when compared to the other technologies/classes.

3.4 Quality assessment

Twelve from the 62 studies (approximately 19%) included in this systematic review were scored with a medium risk of bias [43, 45, 54, 61, 65, 71, 75, 81, 84, 85, 91, 94], whereas all of the other 50 studies were all considered with low risk of bias (Figure 2). Different materials were evaluated in each included study, and they were not identified as control or experimental group. Due to this the presence of a “clear control group” was the most frequent parameter did not report in around 33% of all studies.

4. Discussion

According to the present systematic review, there are three general components of the material composition that may affect the contraction stress phenomenon of light-sensitive resin-based materials, which are illustrated in Figure 3: the filler phase, resin-filler interface, and resin matrix. Furthermore, several strategies were found to be positively associated with significant contraction stress reduction, which will be hereafter discussed in order to present the mechanisms and consequences involved in their stress reduction effect.

4.1 Filler phase

4.1.1 Increasing the content of fillers

Four studies included in this review demonstrated a up to 26.4% [48], up to 14.3% [47], up to 41.9% [49], or up to 11.9% [50] stress reduction upon the increase in the content of fillers. Indeed, there is a strong inverse relationship between filler content and polymerization shrinkage suffered by the resin, since the greater the concentration of fillers, the lower the total amount of resin matrix prone to shrink, thus producing less stress. Notwithstanding, this strategy may not always be suggested since increasing the content of fillers may also increase stiffness and modulus development within the material. As consequence, the reducing compliance of the system leads to higher levels of

stress. Important to mention, the stress reduction range presented in Table 2 for the included studies was obtained only from groups that showed double/half or one third filler content compared to each other, method that was intended in order to simplify presentation of data; however, the studies demonstrated that even upon a slight increase (e.g., 5 vol.%) in the concentration of fillers, a significant stress reduction can be obtained.

4.1.2 Increasing the size of fillers

Only one of the studies included in this systematic review investigated the effect of the size of fillers on contraction stress [51]. According to the study, a decrease in filler particle size directly increases the surface area of the dispersed phase, thus increasing the constraint of fillers upon the resin matrix. This constraint effect concentrates stress, thereby increasing the development of stress within the material. Interestingly, the positive effect that the progressive increase in fillers size have on stress reduction was more pronounced for spherical fillers (from 20.5 to 48.0%) over irregular fillers (from 9.9 to 17.4% only), and this was mainly attributed because the former undergo more translation and rotational movement within the resin matrix than the latter do, thus allowing more stress relaxation to occur. Worth mentioning, current resin-based filled materials have been prepared using quite small fillers especially due to better stability and aesthetical characteristics that may be obtained when compared to larger fillers [1]. Consequently, the strategy presented here may not be that useful to control/reduce contraction stress in currently used dental materials.

4.1.3 Incorporation of alternative fillers

Conventionally used fillers such as quartz, silica, and glass particles are rigid compounds that increase modulus acquisition within the material, thus developing high levels of contraction stress. However, three studies that were included in this systematic review have demonstrated significant stress reduction upon the application of alternative fillers. One of the studies incorporated up to 20 wt.% of high-density polyethylene (HDPE) spheres [52], and the authors concluded that because of the less rigid polymeric nature of the HDPE spheres, plastic deformation during stress buildup was more possible to

occur, favoring stress relaxation; unfortunately, mechanical properties were also reduced, thus limiting their application as reinforcing fillers. By contrast, the study of Szaloki et al. [54] have synthesized cross-linked polymeric nanoparticles and tested their effects on several physic-mechanical properties and contraction stress developed by experimental resin composites. The authors demonstrated that upon incorporation of 5 to 25 wt.% of the nanoparticles, volumetric shrinkage was reduced from 7 to almost 30%, and contraction stress was reduced from 2.3 to 18.2%. Surprisingly, flexural strength and flexural modulus were considerably increased when compared to the control (nanoparticle-free composite). According to the authors, the nanoparticles acted as stress relaxing particles, i.e., they were able to absorb the stress during polymerization; furthermore, it was revealed that the nanoparticles have embedded into the resin matrix by swelling ability, which may have enhanced the cohesiveness of the material, and consequently, the mechanical properties. In summary, the authors suggested that the prepared nanoparticles are attractive for the formulation of new reinforced, resin-based dental materials. The last study included within this subdivision of the review was the study by Garoushi et al. [53], which investigated the effect of short fiber fillers on contraction stress of resin composites with semi-IPN-polymer matrix. Although stress was only slightly reduced (4.5%), the authors suggested that the fiber fillers may absorb the stress that is transferred from the resin matrix during polymerization shrinkage, thus facilitating stress relaxation. Something important to consider regarding to this subject is that the authors used E-glass fibers which may present similar stiffness/modulus properties when compared to glass fillers [104]; however, the use of polymer-based fibers instead of E-glass fibers may produce, perhaps, a more pronounced effect in reducing stress, which may be worth of future investigations.

4.1.4 Incorporation of nanogels

Two studies included in the review reported on effective stress reduction upon the incorporation of nanogels into experimental resin-based materials [55, 56]. Nanogels are internally cross-linked and cyclized single or multi-chain polymeric particles that allow physical entanglement and chemical cross-linking with the resin network. Despite their polymeric nature, nanogels were revealed

to improve mechanical properties of nanogel-modified systems. Moreover, they have the ability to induce delayed production of modulus and vitrification, which in turn results in their successful stress reduction ability. Indeed, this potential increases with increasing concentration of nanogels incorporated into the resin, and probably due to lower polymerization shrinkage. Another important aspect of nanogels is their applicability for tissue engineering [105] and drug delivery systems [106], which make them very attractive for biomedical applications.

4.2 Resin-filler interface

4.2.1 Use of non-bonded/unsilanized fillers

It is well-known that coupling agents allow stress transfer from the resin matrix to the fillers, thus favoring mechanical reinforcement and chemical stability for the material [107]. On the other hand, intrinsic forces originated from polymerization shrinkage are also transferred to the fillers, especially if a strong interaction between resin and fillers is present. In light of this, and considering that fillers will be constrained by the resin undergoing shrinkage, contraction stress may be produced and concentrated within the resin-filler interface, thereby compromising the stability of the system. Taking this into consideration, two studies included in the review have investigated the effect of non-bonded/unsilanized fillers on stress developed by experimental resin composites [57, 58]. Indeed, the stress reduction range was quite similar for both studies (10.2–30.9% and 12.3–26.5%, Table 3). The authors explained that the absence of coupling agent increased the stress-relieving ability of the material, and probably due to a higher translation and rotational ability of fillers within the resin; this mechanism may also increase the overall compliance of the system [108], thus dissipating most of the stress produced. Despite this positive effect on reducing stress phenomenon, it is important to note that the use of non-bonded fillers instead of functionalized fillers may significantly compromise the mechanical performance of the material [58].

4.2.2 Use of alternative functionalization system

Differently from the previous section, some studies have reported on effective stress reduction upon the use of non-functional coupling agents instead of functionalized ones [57]. The main mechanism involved in this

positive effect is that non-functional agents may reduce the chemical interaction between resin and fillers, which may increase the compliance of the system. Moreover, it was suggested that non-functional silane facilitates pre-gelation contraction, thus producing less amount of stress. Lastly, it is worth to mention that as compared to non-bonded/unsilanized fillers, non-functional silanized fillers may produce satisfactory strength characteristics to the material.

Other studies have reported on effective stress reduction upon the use of alternative filler functionalization [59, 60]. The use of flexible hyperbranched oligomer functionalized filler and the thiol functionalized filler with additional hyperbranched oligomer is able to reduce the contraction stress by 30% while maintaining equivalent modulus to control system (unfilled composite) [59]. According to the authors, the hyperbranched oligomer provides additional mobility and capability to relax the network, relieving the contraction stress in both filled systems. Due to the capability of reducing shrinkage stress without sacrificing mechanical properties, the authors suggested that this composite system would be a great candidate for dental composite applications. The another study included within the alternative filler functionalization class [60], investigated the effect of filler functionalization with thiol and ene functionalities as an interfacial layer between resin matrix and glass filler on contraction stress of thiol-ene composites. Interestingly, the thiol-ene-based composites exhibit significantly lower shrinkage stress values (8.4 - 45.8%) than the methacrylate control with the same filler loading. The authors concluded that because of the step-growth polymerization mechanisms, a more homogeneous network formation was allowed to occur with consequent increased conversion of monomers, reduced polymerization shrinkage, and a delayed gel point since most of the shrinkage occurs prior to gelation, favoring stress delay; unfortunately, mechanical properties were also reduced, thus limiting their application.

4.3 Resin matrix

4.3.1 Modification of the composition ratio of conventional formulations

Generally speaking, the resin matrix of resin-based materials is the main protagonist responsible for polymerization shrinkage, so any modification related to its composition ratio may be a potential alternative to minimize/control

stress development. According to four from the five related studies included in the review, stress may be reduced from 15.8 to 46.3% if TEGDMA content is reduced to approximately the half [47, 62-64]. Indeed, TEGDMA is a typical dimethacrylate monomer used as diluent of more viscous monomers such as Bis-GMA, UDMA, and Bis-EMA [1], and the lower molecular weight and viscosity of the former was revealed to increase the reactivity and the overall polymerization shrinkage of the system, thus contributing to increase the contraction stress phenomenon. Consequently, the reduction in the content of TEGDMA directly affects the total amount of stress developed by the material. Another study that showed a stress reducing effect upon the modification of the ratio of components found within the material revealed that increasing the concentration of inhibitor (e.g., butylated hydroxytoluene/BHT) may decrease the reaction speed, thus extending the pre-gel phase with consequent stress reduction/delay [61]. Inhibitors are usually present at small concentrations in light-sensitive resin-based materials, especially as a preventive approach against accidental polymerization. Although the presented strategy showed effectiveness in minimizing stress development, other polymerization parameters may be negatively affected, so this strategy should be cautiously considered before application under clinical conditions.

4.3.2 Use of alternative photo-initiators

Camphorquinone/CQ has been thoroughly used as photo-initiator for resin-based dental materials, especially due to satisfactory reactivity and ability to initiate the polymerization reaction when combined to a co-initiator system. However, their polymerization reaction is directly related to CQ/amine ratio. It was reported that reduction in CQ/amine content to approximately the half reduces degree of conversion, rate of polymerization, and contraction stress from 5.5 to 17.6% [67]. Despite the initiator ratio, the type of initiation system has also a direct influence on the polymerization kinetic of the resin [109-111], so it is reasonable to assume that alternative photo-initiators may also affect the development of contraction stress. Indeed, two studies included in the review demonstrated that experimental resins containing 1-phenyl-1,2-propanedione/PPD [65] or monoacylphosphine/MAPO [66] produced less stress when compared to a CQ-based system (control). While PPD was revealed to

slow down the polymerization reaction of the resin, thus allowing more stress relaxation, MAPO showed a more complicated mechanism for stress reduction, which involved in both the delaying of the diffusion-controlled propagation step of polymerization and in the increase of reaction temperature, allowing higher reaction mobility, greater stress relief, and delayed onset of vitrification when compared to the CQ-based resin. Despite this stress reducing effect (qualitative data), the meta-analysis showed no statistical difference between the alternative photo-initiator groups and the control (p=0.29), thus demonstrating that the presented strategy may not be a significant approach to reduce contraction stress.

4.3.3 Use of silorane-based monomers

Conventional dimethacrylates such as Bis-GMA, TEGDMA, and UDMA usually undergo moderate to severe polymerization shrinkage due to their free radical polymerization reaction; indeed, it has been revealed that homopolymers constituted of each of these foregoing monomers would shrink approximately 5, 14, and 9% in volume, respectively [112]. As a consequence, their presence in the resin system would account for significant polymerization shrinkage to the material, thus contributing for stress development. Differently from these monomers, low-shrinkage silorane-based monomers polymerize through a cationic ring-opening reaction, resulting in polymerization shrinkage values below 1% [113], which in turn may produce less stress when compared to dimethacrylate-based materials. According to the nine related studies included in this review, silorane-based resin composites showed an important stress reduction potential of up to 97% [45, 65, 68-74]. Besides their cationic ring-opening reaction, the authors also suggested that silorane-based composites have improved ability to flow during initial curing stages and before reaching the gel point, thereby contributing to reduce stress [68, 73]. Despite the significant stress-reducing potential here presented, there are also some studies that did not demonstrate beneficial effects about using silorane-based materials with regards to stress reduction [72, 91], and reduced mechanical performance was also reported [68]. Worth mentioning, siloranes were introduced in dentistry as a promising alternative to overcome the negative effects of contraction stress; however, this technology is not currently as attractive as it was some years ago.

4.3.4 Use of thiol-ene-based monomers

The characteristic chain growth nature of the free radical polymerization process of methacrylate systems is usually associated to important drawbacks, including but not limited to high polymerization shrinkage, presence of extractable, unreacted monomers following cure, early gelation, and inhibition of the polymerization by oxygen; overall, the combination of these drawbacks results in considerably high levels of contraction stress [114]. Conversely, the step growth nature of thiol-ene and/or methacrylate-thiol polymerization, which involves in a chain-transfer reaction of the thiol group to the ene/vinyl group, allows for more homogeneous network formation with consequent increased conversion of monomers, reduced polymerization shrinkage, and a delayed gel point since most of the shrinkage occurs prior to gelation. Ultimately, the combination of the latter factors promotes significant reduction in contraction stress development. From the eleven studies included in the review that used thiol-ene chemistry, two studies presented a low-to-moderate (up to 35%) stress reduction [76, 81] and the others reported on a much more significant potential to reduce stress (up to 93.9%) [43, 44, 60, 75, 77-80, 82]. Regarding to thiol-ene systems, it has been revealed that they have rapid rate of polymerization, high overall functional group conversion, and little sensitivity to oxygen inhibition [43, 60, 82], although some reduction in mechanical properties were also reported [43, 79, 80]; nonetheless, when combined with methacrylates or oligomers, the hybrid nature of the methacrylate-thiol-ene or oligomeric thiol-ene polymerization may result in even greater reductions in contraction stress without jeopardizing important mechanical properties of the system [60, 79, 80, 82]. Collectively, the included studies demonstrated that thiol-ene systems have potential applicability for the development of stress-reducing dental materials, which will likely result in superior longevity and clinical performance relative to methacrylate-based systems.

4.3.5 Use of thio-urethane oligomers

Basically, thio-urethanes follow a similar polymerization mechanism as presented for thiol-ene systems, thereby allowing chain-transfer reactions from the pendant thiols to the thio-urethane structure, which delays

gelation/vitrification and produces low levels of stress at the later stages of polymerization [40]. The applicability of thio-urethanes as stress-reducing agents was recently introduced to dentistry, so only three related studies were included in the review. However, the included studies showed satisfactory potential to reduce stress: from 22.5 to 65.6% [84], from 10.4 to 86.1% [83] and from 18.8 to 44.0% [85]. Differently from thiol-ene systems, thio-urethanes have a urethane composition, which implies in higher toughness and strength characteristics to the material. Moreover, thio-urethanes were revealed to have higher chemical stability than thiol-ene-based monomers, thus overcoming some important drawbacks of the latter systems; as a consequence, they can be interestingly used to minimize/control stress development by resin-based materials without jeopardizing the overall performance of the material.

4.3.6 Use of alternative monomers/molecules

Despite all alternative stress-reducing monomers presented throughout the previous sections (i.e., siloranes, thiol-ene, thio-urethanes), studies have reported on additional alternative compositions that do not fit within those sections but still demonstrate significant effect in reducing contraction stress; these alternatives were all allocated in the present subdivision.

Two studies used monomers based on tetraoxaspiroalkanes, which demonstrated an overall excellent ability to reduce stress: from 48.4 to 98.7% in the study of Chappelow et al. [86], and from 78.8 to 97.0% in the study of Eick et al. [68]. The authors explained that tetraoxaspiroalkanes polymerize via cationic reaction, i.e., similarly to siloranes. Furthermore, they reduce elastic modulus development during polymerization, as well as the glass transition temperature and the polymerization rate of reaction; consequently, they increase the gel point and allow stress relaxation, producing very low amount of stress. Other three studies included within this subdivision of the review reported on monomers/functionalities that undergo addition-fragmentation chain-transfer (AFCT) reactions, likewise to thiol-ene and thio-urethane systems. Leung and Bowman [87] demonstrated that the incorporation of only 1.5 to 2 wt.% of a trithiocarbonate-based monomer into a dimethacrylate-based system allowed network rearrangement to occur, thereby relieving and reducing stress from 25 to approximately 54%. Park et al. [89], on the other hand, used

the same strategy, but with a considerably higher concentration of the alternative monomer (30 wt.%), resulting in 64.7% less stress than the conventional Bis-GMA/TEGDMA system used as control. Differently from the trithiocarbonate-based systems prepared in the previous studies, the study of Park et al. [88] revealed that the incorporation of an allyl sulfide functional group into a norbornene-methacrylate monomer system reduced stress development from 34.4 to 95.5%; in fact, increasing the content of the allyl sulfide-containing species in the resin progressively reduced stress, as well as progressively increased flexural modulus of the system. Therefore, the authors stated that this strategy holds significant promise for the formulation of dental restorative materials. Finally, Wilder et al. [90] used an organogelator (i.e., dibenzylidene sorbitol/DBS) to induce physical gelation in the polymer system; indeed, DBS is an organic molecule able to form self-assembled networks, which therefore reduces the total conversion of monomers of the material, thus reducing stress. However, stress reduction obtained by the expenses of lower degree of conversion may not be considered an attractive alternative, thereby limiting the application of DBS molecules as a feasible stress-reducing strategy.

4.3.7 Use of low-shrink compositions

Over the years, several efforts have been made in order to develop resin-based materials that produce minimal levels of stress. For instance, low-shrinkage materials, which are also known as stress decreasing resins (SDR™ technology), became very popular nowadays. The first examples of low-shrinkage materials were the siloranes, but they have been already discussed in a previous subdivision of the review. Even so, there are other certain strategies that may be interestingly used to reduce the polymerization shrinkage suffered by conventional formulations, and consequently, the contraction stress phenomenon produced by the material. From the studies included in this systematic review, nine were allocated within the present subdivision. Two strategies were firstly reported in the study of Ernst et al. [94], which involved in increasing the filler content of the material or using less reactive solvents. The stress-reducing effect that greater content of fillers has on stress reduction was already discussed before and it is based on the concomitant reduction of the total amount of resin matrix prone to shrink [47]. On the other hand, the use of

less reactive solvents was associated to an overall decreased reactivity of the system, directly influencing the stress rate and kinetic of stress development [94]. In the study of Cadenaro et al. [93], the low-shrinkage resin composite Ælite LS (Bisco Inc., Schaumburg, IL, USA) was compared to micro-hybrid (Filtek Z250, 3M ESPE, St. Paul, MN, USA) and nano-filled (Filtek Supreme, 3M ESPE) composites. The low-shrinkage material produced considerably lower stress than the others, which was attributed due to its lower resin matrix volume (26% *versus* 40 and 42% of the other composites, respectively); once again, the lower resin volume that is prone to shrink was accompanied by a higher filler loading, which resulted in less stress. Although the main strategy used to reduce stress was the modification of the filler content, the foregoing materials are recognized by their manufacturers as low-shrinkage materials.

Differently from the aforementioned strategies, there are some alternative monomers that exhibit lower polymerization shrinkage when compared to those conventionally used, so they have also been recognized as low-shrinkage materials. One example is the monomer found in the composition of a nanohybrid composite (Venus Diamond, Heraeus Kulzer GmbH, Hanau, Germany), i.e., bis-(acryloyloxymethyl) tricycledecane) (TCD-DI-HEA) [5.2.1.02,6], which is a low-viscosity monomer that shows potential to replace TEGDMA from dental formulations; indeed, it is well-known the negative effect that TEGDMA, as a very reactive monomer with intrinsic high polymerization shrinkage ability, has on contraction stress development [62], so its replacement by a low-shrinkage component brings potential applicability to reduce stress. According to six studies included in the review, the TCD-DI-HEA-containing material developed less stress than the control materials used in each study [69, 72, 91, 92, 95, 96]. The authors have also suggested that the TCD-DI-HEA monomer has an increased flexibility due to the presence of three connected rings within its central molecular structure, which accommodates shrinkage; additionally, the low elastic modulus derived from its lower cross-linking potential may also play a significant role in reducing the overall stress produced by the material. Other two examples of low-shrinkage monomers are the so-called DX-511 and the dimer dicarbamate dimethacrylate. While the former is a modified UDMA monomer found in the commercial composite Kalore (GC America Inc., Alsip, IL, USA), the latter is a dimer acid derivative found in

N'Durance (Septodont, Louisville, CO, USA). Although both monomers were revealed to reduce contraction stress because of their high molecular weight and consequent low polymerization shrinkage [74, 95, 96], different mechanisms are also involved: DX-511 has low reactive group concentration available for reaction [74, 95], whereas the dimer acid derivative allows polymerization-induced phase separation to occur, thus producing heterogeneity within the system, and the greater the heterogeneity, the greater the stress relaxation [74, 96].

4.3.8 Use of bulk-fill technology

Despite all modifications performed in the organic and/or inorganic content of low-shrinkage materials, which directly contributed for significant contraction stress reduction, there are other modifications that have also improved additional characteristics of these materials. For example, the initiation system and filler amount/size were also modified in order to increase light transmission properties, thus increasing the material's polymerization depth of cure, which is usually inferior to 2.0 mm. To that end, materials known as "bulk-fill" were developed, and they may be placed into the tooth cavity using one layer of up to 4–5 mm in thickness without compromising their polymerization performance [3, 97, 100, 102]. Generally speaking, bulk-fill materials were introduced to dentistry in an attempt to simplify the time-consuming incremental technique, and according to the related studies included in the review, their optimized composition resulted in significant stress reduction (Table 4) [3, 46, 70, 96-103].

One important aspect of these materials relates to their overall viscosity: while on one hand low viscous compositions may allow more flow and stress relaxation during polymerization, the low filler content of flowable materials may, on the other hand, increase shrinkage, thus minimizing stress relaxation to occur; the same happens for the inverse situation, since high viscous compositions usually have high filler content, thereby increasing modulus, and consequently, stress. Four studies included in the review [3, 96, 102, 103] investigated the effect of viscosity on the stress reducing potential of four bulk-fill resin composites; surprisingly, the authors demonstrated that the high-viscous materials resulted in similar stress values compared to a high-viscous

conventional composite, whereas the low-viscous bulk-fill composites produced less stress than the low-viscous conventional composite used as control. Overall, it seems that bulk-fill resins display better potential to reduce stress if materials with low elastic modulus are used, thereby favoring the use of flowable materials. However, and according to Cadenaro et al. [115], flowability of resin composites is not guarantee for contraction stress reduction, thus confirming that this subject is complex since it depends on several intrinsic factors related to the material's composition. Moreover, two studies have shown that the polymerization stress also is dependent upon the compliance of the testing instrument [46, 101]. High compliance of the constraint eliminates the difference in the polymerization stress between the bulk fill flowable and conventional packable composites. Nevertheless, the bulk fill flowable composites develop less stress than the packable composite under lower compliance [46]. Clinically speaking, the compliance is characterized by the geometry of the prepared tooth cavity and the stiffness (or compliance) of the remaining tooth structure [32, 116], Therefore, it seems that bulk fill flowable composites may be used as a base material at the inner or corner part of a prepared cavity, where the compliance is low, thereby reducing the final contraction stress.

Taking into consideration that bulk-fill materials are considerably new in dentistry, additional studies must be conducted regarding their usage, but from current literature, it seems that they may be satisfactorily used to reduce stress.

Gathering together all the meta-analyses performed within the present review, the use of alternative monomers/molecules demonstrated the highest mean difference (5.96), followed by the use of thio-urethane oligomers (mean difference = 5.73). Consequently, these foregoing strategies seem to be the most effective approaches related to the modification of the materials' composition. By contrast, the incorporation of alternative fillers exhibited the lowest mean difference of this review (0.06), and the use of alternative photo-initiators did not contribute to significantly reduce contraction stress. Once again, these results should be interpreted with caution since heterogeneity was high for all analyses performed.

5 Conclusion

The findings of the present systematic review and meta-analyses revealed the existence of several strategies that may positively reduce/control contraction stress of resin-based restorative materials. From the modification of the filler phase and the resin-filler interface to the modification of the resin matrix formulation, it seems that the latter strategy contributes more to minimize stress development than the former ones. Indeed, the stress decreasing technology used for the formulation of low-shrinkage and bulk-fill materials has optimized the conventional chemistry of current dental materials, showing promising application for reducing/controlling stress development.

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Figures

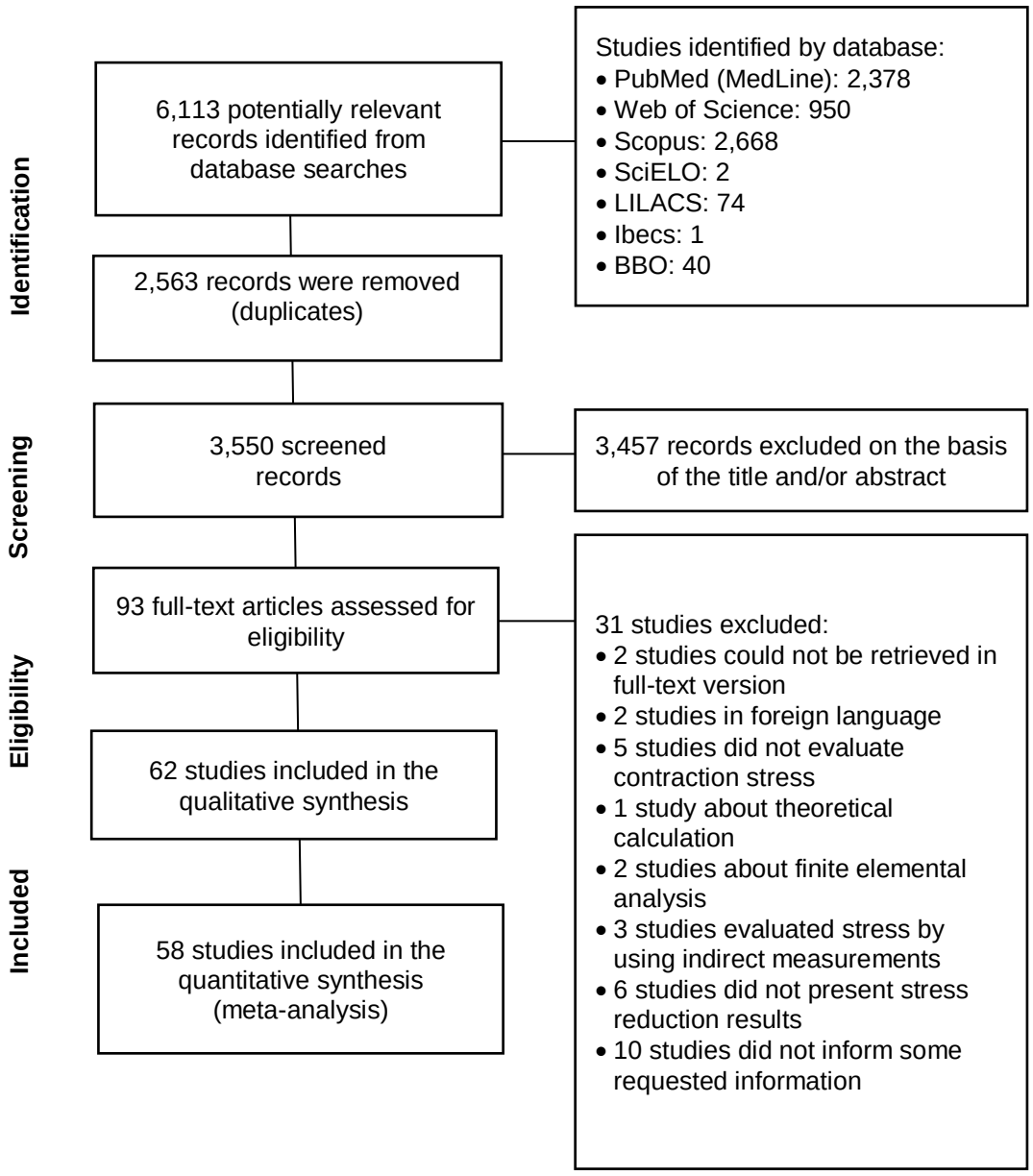


Figure 1. Search flow (as described in the PRISMA statement) [9]

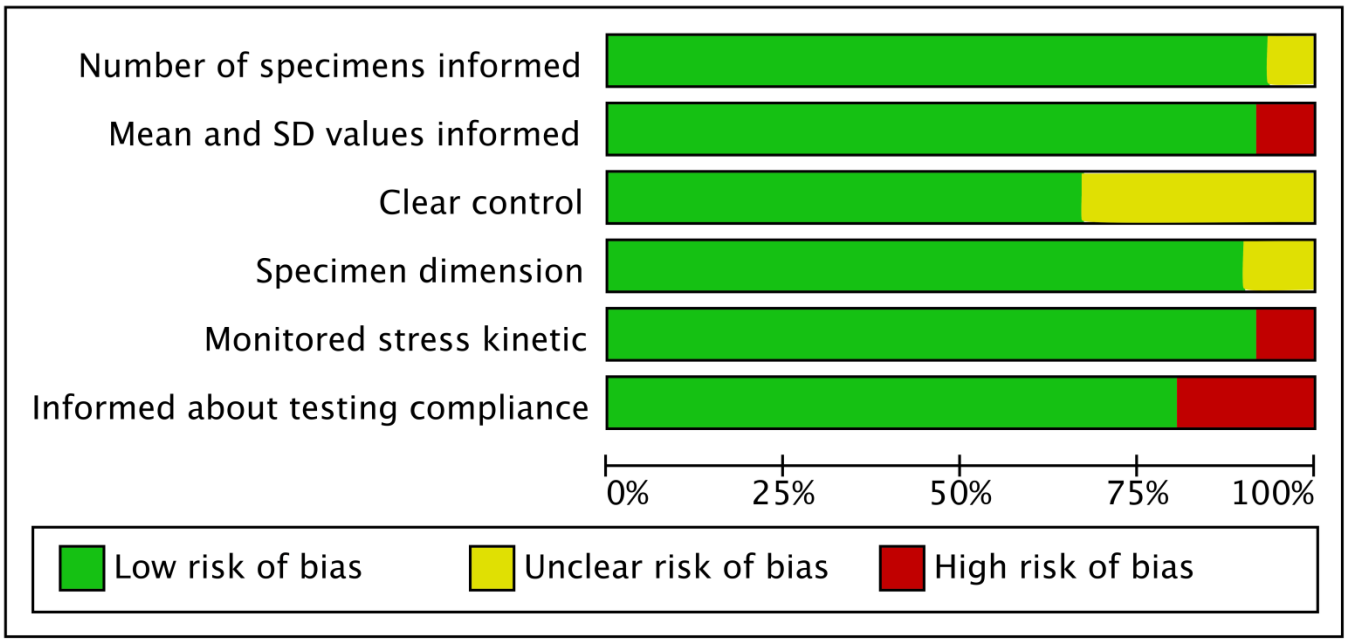


Figure 2. Review authors' judgments about each risk of bias item for each included in vitro study.

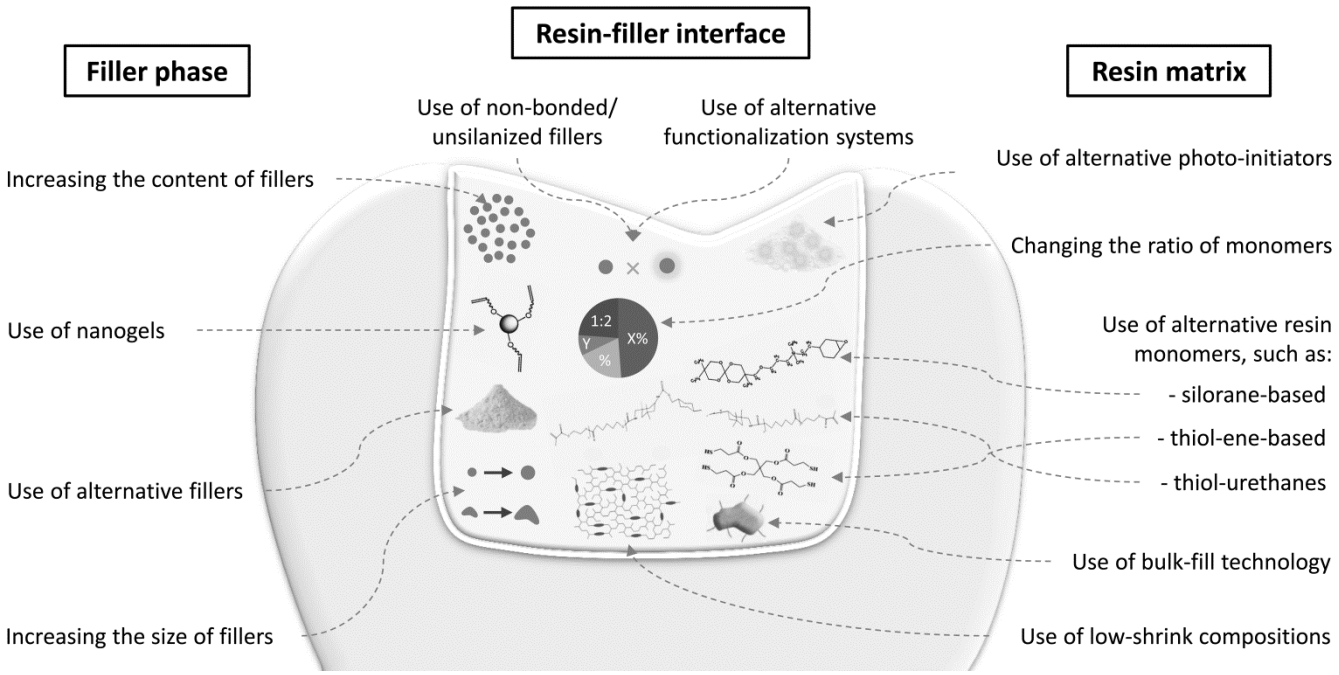


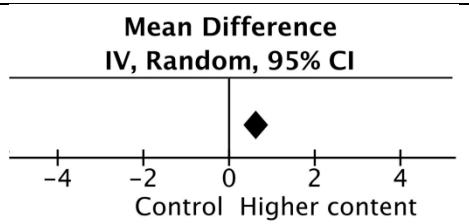
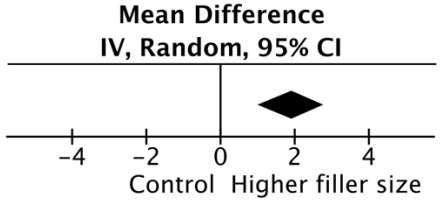
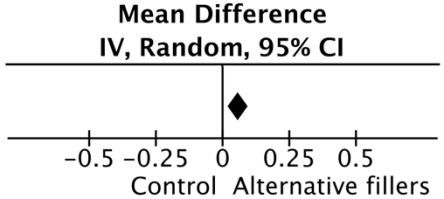
Figure 3. General components of the material composition that may affect the contraction stress phenomenon of light-sensitive resin-based materials: the filler phase, resin-filler interface, and resin matrix.

Tables

Table 1. Search strategy used in PubMed (MEDLINE)

	Search terms
#4	Search #1 AND #2 AND #3
#3	Reduction OR Reduce OR Reduc$ OR Control OR Minimize OR Decrease
#2	Composite Resins OR Resins, Composite OR Dental Resins OR Dental Resin OR Resin, Dental OR Resins, Dental OR Resin composite
#1	Dental Stress Analysis[MeSH Term] OR Analysis, Dental Stress OR Stress Analysis, Dental OR Analyses, Dental Stress OR Dental Stress Analyses OR Stress Analyses, Dental OR shrinkage stress OR polymerization shrinkage stress OR contraction stress OR polymerization stress

Table 2. Studies that reduced contraction stress by modifying the filler phase of resin-based dental restoratives, allocated by the strategies and main mechanisms used, the stress reduction range and results for the meta-analyses.

Strategy	Study	Main mechanism proposed	Stress reduction range (%)	Meta-analyses results
Increasing the content of fillers	Gonçalves 2010 [48]	The higher the concentration of fillers, the lower the content of resin matrix prone to shrink, thereby developing lower contraction stress	22.4 – 26.4	 **Mean Difference**: 0.64 [0.38, 0.91] **Heterogeneity:** Tau^2=0.26; Chi^2=202.40, df=15 (p<0.01); I^2=93% **Test for overall effect:** Z=4.73 (p<0.01)
	Gonçalves 2011 [47]		6.2 – 14.3	
	Gonçalves 2012 [49]		2.3 – 41.9	
	Lu 2004 [50]		11.9	
Increasing the size of spherical fillers	Satterthwaite 2012 [51]	Smaller fillers also increase the surface area of the dispersed phase, thus increasing the fillers constraint upon the resin matrix, increasing stress	20.5 – 48.0	 **Mean Difference**: 1.91 [1.02, 2.80] **Heterogeneity:** Tau^2=1.13; Chi^2=66.81, df=5 (p<0.01); I^2=93% **Test for overall effect:** Z=4.20 (p<0.01)
Increasing the size of irregular fillers	Satterthwaite 2012 [51]	Filler particles, themselves constrained by the resin matrix, undergo translation and rotational movement, thereby relaxing stress within the material; this effect seemed to increase with increasing sphericity of the dispersed phase	9.9 – 17.4	
Incorporation of alternative fillers	Ferracane 2003 [52]	The incorporation of high-density polyethylene spheres facilitate plastic deformation during stress buildup derived from polymerization contraction	7.2 – 28.9	 **Mean Difference**: 0.06 [0.02, 0.10] **Heterogeneity:** Tau^2=0.00; Chi^2=89.68, df=13 (p<0.01); I^2=86% **Test for overall effect:** Z=2.98 (p<0.01)
	Garoushi 2008 [53]	The incorporation of short E-glass fiber fillers into the resin matrix increases stress transfer from polymer matrix to fibers	4.5	
	Szaloki 2013 [54]	Reactive polymeric nanoparticles can absorb stress	2.3 – 18.2	

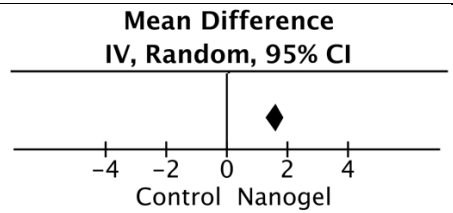
Incorporation of nanogels	Liu 2012 [55]	Nanogels are internally crosslinked and cyclized single or multi-chain polymeric particles that induce delayed production of modulus and vitrification, which in turn decreases the resultant stress developed by the nanogel-modified composition	2.1 – 59.4	
	Moraes 2011 [56]		26.6 – 45.3	**Mean Difference**: 1.61 [1.33, 1.89] **Heterogeneity:** Tau^2=0.41; Chi^2=465.05, df=21 (p<0.01); I^2=95% **Test for overall effect:** Z=11.11(p<0.01)

Table 3. Studies that reduced contraction stress by modifying the resin-filler interface of resin-based dental restoratives, allocated by the strategies and main mechanisms used, as well as the stress reduction range and results for the meta-analyses.

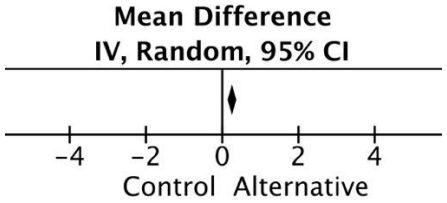
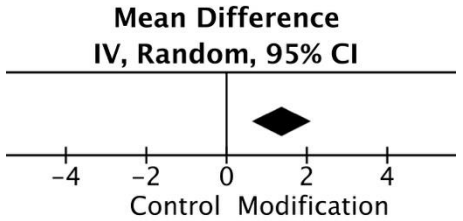
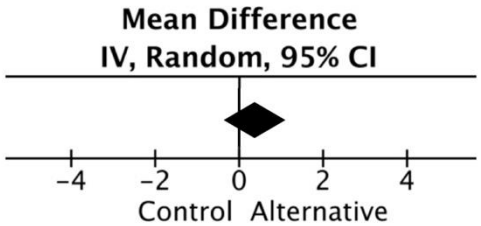
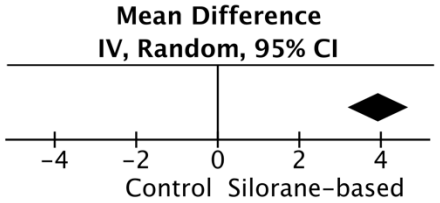
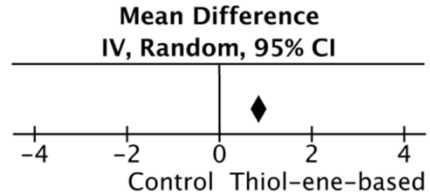
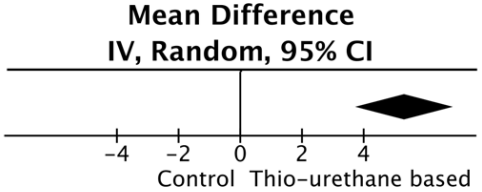
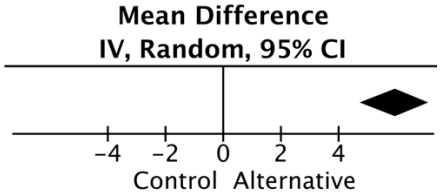
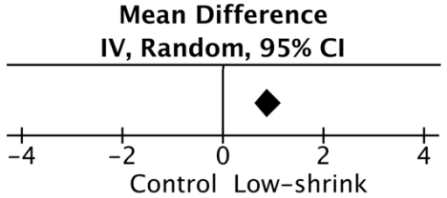
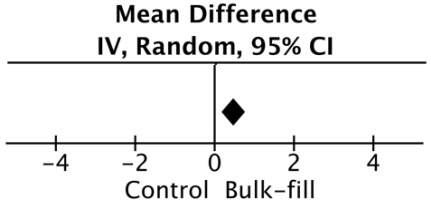
Strategy	Study	Main mechanism proposed	Stress reduction range (%)	Meta-analyses results
Use of non-bonded/ unsilanized fillers	Condon 1998 [57]	The absence of chemical bond between the fillers and the resin matrix may increase the stress-relieving capability of the material	10.2 – 30.9	 **Mean Difference**: 1.40 [0.59, 2.20] **Heterogeneity:** Tau^2=1.12; Chi^2=55.76, df=7 (p<0.01); I^2=87% **Test for overall effect:** Z=3.39 (p<0.01)
	Condon 2002 [58]		12.3 – 26.5	
Use of alternative functionalization system	Condon 1998 [57]	The use of non-functional *versus* functional silane may contribute to reduce interaction between resin and fillers, thus facilitating pre-gelation and stress reduction	8.7 – 46.3	 **Mean Difference**: 0.30 [0.17, 0.42] **Heterogeneity:** Tau^2=0.03; Chi^2=137.57, df=11 (p<0.01); I^2=92% **Test for overall effect:** Z=4.71 (p<0.01)
	Ye 2012 [59]	The use of flexible hyperbranched oligomer as an interfacial layer between resin matrix and glass filler provides higher compliance and enough mobility for the system, thus reducing stress	33.3	
	Podgórski 2015 [60]	The use of filler functionalization with thiol, and ene functionalities as an interfacial layer between resin matrix and glass filler in thiol-ene composites *versus* methacrylate composite with the same filler loading provides delayed gel point conversions (step-growth polymerization mechanism), thus stress delay	8.4 – 45.8	

Table 4. Studies that reduced contraction stress by modifying the resin matrix of resin-based dental restoratives, allocated by the strategies and main mechanisms used, as well as the stress reduction range and results for the meta-analyses.

Strategy	Study	Main mechanism proposed	Stress reduction range (%)	Meta-analyses results
Modification of the composition ratio of conventional formulations	Braga 2002 [61]	The increase in inhibitor (BHT) concentration decreases the reaction speed, thus extending the pre-gel phase with consequent stress delay	2.3 – 38.6	 **Mean Difference**: 1.38 [0.66, 2.11] **Heterogeneity:** Tau^2=2.66; Chi^2=1960.50, df=19 (p<0.01); I^2=99% **Test for overall effect:** Z=3.73 (p<0.01)
	Charton 2007 [62]	The decrease in the ratio of TEGDMA from 50 to 30 wt.% reduces the polymerization shrinkage of the system, thus reducing stress	46.3	
	Gonçalves 2010 [63]	Halving TEGDMA concentration directly decreases polymerization shrinkage, thus reducing stress	15.8 – 42.2	
	Gonçalves 2011 [47]		31.7 – 35.6	
	Gonçalves 2015 [64]	The decrease in the ratio of TEGDMA from 50 to 40, 30 or 20 wt.% reduces the polymerization shrinkage, thus reducing stress	17.6 – 39.3	
Use of alternative photo-initiators	Oliveira 2012 [65]	The use of PPD as photoinitiator produces a slower polymerization reaction when compared to CQ-based systems, allowing more stress relaxation	0.3 – 5.2	 **Mean Difference**: 0.15 [-0.13, 0.43] **Heterogeneity:** Tau^2=0.19; Chi^2=125.85, df=10 (p<0.01); I^2=92% **Test for overall effect:** Z=1.06 (p=0.29)
	Palin 2014 [66]	The use of MAPO as photoinitiator delays diffusion-controlled propagation step during polymerization and increases the reaction temperature, thus allowing higher reaction mobility and greater stress relief by delaying the onset of vitrification when compared to CQ-based systems	6.8 – 23.6	
	Pfeifer 2009 [67]	Halving CQ/amine ratio decreases rate of polymerization and degree of conversion, thus reducing stress	5.5 – 17.6	
Use of silorane-based monomers	Eick 2007 [68]	The incorporation of TOSU, which is a spiroorthocarbonate monomer that polymerize via cationic polymerization, reduced stress probably due to lower shrinkage and factors such as low elastic modulus, high gel point, and low glass transition temperatures	81.7 – 97.0	 **Mean Difference**: 2.86 [2.39, 3.32] **Heterogeneity:** Tau^2=0.84; Chi^2=1776.22, df=17 (p<0.01); I^2=99% **Test for overall effect:** Z=12.10 (p<0.01)
	Gao 2012 [69]	The cationic ring-opening reaction generates lower polymerization shrinkage, thereby reducing stress development. Moreover, siloranes-based materials have improved ability to flow during the initial curing stage before reaching the gel point, thus possessing the largest potential for stress relief	45.4	
	Ilie 2011 [70]		32.1	
	Li 2012 [71]		23.8	
	Marchesi 2010 [72]		16.4 – 21.9	
	Min 2010 [73]		56.8 – 68.8	
	Oliveira 2012 [65]		3.4 – 14.4	
	Xiong 2011* [45]		46.9	
	Yamasaki 2013 [74]		38.1	

Use of thiol-ene-based monomers	Boulden 2011 [76]	Thiol-ene-based systems polymerize via a step-growth mechanism, rather than the chain-growth mechanism characteristic of dimethacrylate-based resins, resulting in reduced polymerization shrinkage, a delayed gel point since most of the shrinkage occurs prior to gelation, and enhanced control of the polymerization; all of these factors together lead to stress reduction	21.7 – 34.8	 **Mean Difference**: 0.85 [0.71, 1.00] **Heterogeneity:** Tau^2=0.14; Chi^2=11558.46, df=27 (p<0.01); I^2=100% **Test for overall effect:** Z=11.64 (p<0.01)
	Beigi Burujeny 2015 [75]		45.2 -74.2	
	Carioscia 2005 [77]		89.3 – 93.9	
	Carioscia 2007 [78]		90.0	
	Cramer 2010 [79]		36.8 – 73.7	
	Cramer 2010 [80]		60.7	
	Lu 2005* [43]		86.2	
	Schreck 2011* [44]		38.7 – 52.7	
	Ye 2011 [81]		14.3 – 21.4	
	Podgórski 2015 [82]		12.1 – 58.6	
	Podgórski 2015 [60]		8.4 – 45.8	
Use of thio-urethane oligomers	Bacchi 2014 [84]	The presence of thio-urethane oligomers within methacrylate-based resins allow chain transfer reactions from the pendant thiols on the thio-urethane structure to the surrounding methacrylate matrix, delaying gelation/vitrification, which in turn reduce stress development at the later stages of polymerization	22.5 – 65.6	 **Mean Difference**: 5.73 [4.77, 6.69] **Heterogeneity:** Tau^2=3.04; Chi^2=96.27, df=15 (p<0.01); I^2=84% **Test for overall effect:** Z=11.69 (p<0.01)
	Bacchi 2015 [83]		10.4 – 86.1	
	Bacchi 2016 [85]		18.8 – 44.0	
Use of alternative monomers/ molecules	Chappelow 2008 [86]	The use of monomers based on tetraoxaspiroalkanes, which polymerize via cationic reaction, reduces elastic modulus, glass transition temperatures, as well as the polymerization rate of the reaction, thus increasing gel point and stress relaxation	48.4 – 98.7	 **Mean Difference**: 5.96 [4.75, 7.17] **Heterogeneity:** Tau^2=3.64; Chi^2=3127.58, df=9 (p<0.01); I^2=100% **Test for overall effect:** Z=9.65 (p<0.01)
	Eick 2007 [68]		78.8 – 97.0	
	Leung 2012 [87]	The incorporation of 1.5 to 2 wt.% of trithiocarbonate-based monomers into a dimethacrylate-based network allowed a reversible AFCT reaction to occur, thus promoting network rearrangement and stress relaxation	25.0 – 53.8	
	Park 2012 [88]	The use of an allyl sulfide-based system allowed the AFCT reaction to occur, thus relieving stress via network rearrangement	34.4 – 95.5	
	Park 2012 [89]	TTCDMA is capable of undergoing AFCT reaction, which allows stress relaxation	64.7	
	Wilder 2005 [90]	The incorporation of DBS (up to 3.13 wt.%) induces physical gelation by forming self-assembled networks, causing the decrease in conversion, thus reducing stress	26.1	

Use of low-shrink compositions	Aleixo 2014 [91]	The presence of TCD-DI-HEA combines low polymerization shrinkage with low viscosity, thus reducing stress development	76.0	 **Mean Difference**: 0.52 [0.30, 0.75] **Heterogeneity:** Tau^2=0.36; Chi^2=1614.99, df=31 (p<0.01); I^2=98% **Test for overall effect:** Z=4.53 (p<0.01)
	Boaro 2010 [92]		3.6 – 20.9	
	Cadenaro 2008 [93]	The resin characteristics of low-shrink composites associated with a low resin matrix volume can be used to reduce stress	39.4 – 41.1	
	Ernst 2004 [94]	Increasing filler load or using less reactive solvents may produce low-shrink materials that undergo less stress	13.5 – 45.9	
	Gao 2012 [69]	The presence of TCD-DI-HEA allows a slow cure rate with long gel and vitrification times; in addition, it is a high molecular weight monomer that reduces conversion and the crosslinking nature of the network, thus reducing elastic modulus, and stress	45.4	
	Marchesi 2010 [72]		20.5 – 48.3	
	Watts 2014 [95]	The monomers DX-511 in Kalore and TCD-DI-HEA in Venus Diamond give to the material a low-shrinking ability, thus reducing stress	16.2 – 18.7	
	Yamasaki 2013 [74]	The presence of DX-511 in Kalore decreases the concentration of reactive groups available for reaction, and the presence of *dimer dicarbamate dimethacrylate* in N'Durance, which is a high molecular weight monomer, induces heterogeneity in the material; both strategies allow stress reduction	14.3 – 35.7	
	Al Sundul 2016 [96]	The presence of TCD-DI-HEA in Venus Diamond give to the material a low-shrinking ability , and the presence of *dimer dicarbamate dimethacrylate* in N'Durance, which is a high molecular weight monomer, induces heterogeneity in the material; both strategies allow stress reduction	9.3 – 35.4	
Use of bulk-fill technology	El-Damanhoury 2014 [97]	Bulk-fill materials are similar to conventional dimethacrylate-based materials, although they have been optimized with regards to their resin matrix and initiator chemistry as well as filler technology, which result in distinct properties that directly influence stress development; in special, stress is considerably reduced when materials with low elastic modulus are used	9.3 – 31.8	 **Mean Difference**: 0.81 [0.66, 0.95] **Heterogeneity:** Tau^2=0.26; Chi^2=6367.04, df=58 (p<0.01); I^2=99% **Test for overall effect:** Z=10.96 (p<0.01)
	Ilie 2011 [70]		79.2	
	Kim 2015 [3]		0.8 – 52.1	
	Tauböck 2014 [98]		47.8 – 51.0	
	Zorzin 2015 [99]		13.0	
	Fronza 2015 [100]		5.4 – 29.7	
	Guo 2016* [46]			
	Jang 2015 [102]		15.7 – 23.4	
	Kim 2016 [103]		2.1 – 66.7	
	Han 2016 [101]		7.3 – 37.1	
	Al Sunbul 2016 [96]		0.2 – 47.5	

BHT: butylated hydroxytoluene; TEGDMA: tryethyleneglycol dimethacrylate; PPD: 1-Phenyl-1,2-propanedione; CQ: camphorquinone; MAPO: monoacylphosphine oxide; TOSU: 3,9-Diethyl-3,9-bis(trimethylsilylpropyloxy-methyl)-1,5,7,11-tetraoxaspiro[5.5]undecane; AFCT: addition-fragmentation chain transfer; TTCDMA: trithiocarbonate dimethacrylate; DBS: dibenzylidene sorbitol; TCD-DI-HEA: Bis-[acryloyloxymethyl] tricyclo[5.2.1.02,6]decane.

3 Capítulo 2*

Title.

Bulk Fill composite resin – A systematic review and meta-analyses

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*Artigo formatado segundo as normas do periódico *Journal of Dentistry* disponível em: https://www.elsevier.com/journals/journal-of-dentistry/0300-5712/guide-for-authors

Abstract

Objectives. A systematic review was conducted to evaluate the in vitro and clinical performance of bulk fill composites compared to conventional composite resins.
Data. A total of 60 studies were included in the qualitative analysis, and the meta-analysis was performed with 45 in vitro and 5 clinical studies.
Sources. Two reviewers performed a literature search up to April 2017 in nine databases: PubMed, ISI Web of Science, Scopus, Cochrane Library, Google Scholar, SciELO, LILACS, IBECS, and BBO (*Biblioteca Brasileira de Odontologia*).
Study selection. Only in vitro studies or clinical trials that evaluated bulk fill materials compared to conventional composite were included. Analyses were carried out using a random-effect model, and pooled-effect estimates were obtained by comparing the outcome difference between flowable or sculptable bulk fill materials and conventional composite (α=0.05).
Results. The analysis demonstrated that flowable and sculptable bulk fill had a higher depth of cure than conventional composite ($p<0.001$). The % bottom-to-top of degree of conversion and hardness was similar for flowable bulk fill up to 6 mm, and lower for sculptable bulk fill at 4 mm, both compared to conventional composite at 2 mm depth. Contraction stress was lower for flowable bulk fill ($p<0.001$) and similar for sculptable bulk fill ($p=0.08$). The mechanical strength of bulk fill materials was similar than conventional composite. Also, the clinical performance of bulk fill did not show any statistically significant difference of conventional composite in up to 1 or 3 years of follow-up ($p=0.52$).
Conclusions. The in vitro and clinical studies suggest that bulk fill materials seem to perform similarly or better than conventional composite.
Clinical significance. The bulk fill composites are suitable materials for posterior restoration purposes with the convenience of simplifying the operative technique and reducing the clinical time for restoration building up.
PRÓSPERO: CRD42017064424

Keywords: Bulk fill composites; Composite resin; Dental materials; Systematic review.

1. Introduction

The placement of direct composite resin restorations in posterior teeth demands a time-consuming restorative protocol with the horizontal and/or oblique incremental filling technique (1). This incremental build-up technique up to 2 mm thick is required to minimize the effects of polymerization shrinkage and to allow an efficient in depth polymerization of the composite layer. On this scenario, there is the concern about the overall effect of curing depth, volumetric shrinkage and the stress generated by the polymerization (2-4) over the clinical longevity of composite restorations.

Alternatively, other restorative approaches have been suggested, including the simplified restorations building-up using bulk fill composite resins. The Bulk fill composites have been recently introduced as an attempt to simplify and to accelerate the restoration process (1, 5). Different from the maximum 2-mm increments recommended for conventional composite resins, bulk-fill composites are claimed to be used for increased thickness layers, also called as bulk placement of up to 4 – 5 mm thickness. The development of composite resin advocated to bulk fill technique had been guided by the substitution of traditional canforoquinone/amine initiation system (6), responsible by provide some yellow shade content, by alternative initiators. Aslo, the presence of polymerization modulators, such as urethane-based methacrylate monomers are capable of interacting with the photoinitiator resulting in a higher polymerization depth (7). Moreover, the use selected filler content with increased optic translucency in such formulations also contribute to increase translucency (8-13). This approach provides less scattering and absorption of light emitted by light curing unit and consequently higher deep of polymerization allowing increasing the increments thickness on the restorative protocol.

The bulk placement of restorative composite can be performed in single or two-steps (14, 15) according to the material chosen, i.e., flowable (low-viscosity) and sculptable (high-viscosity) bulk fill composite. Flowable bulk fill composite generally adapts better on the cavity wall and exhibit lower mechanical properties due to their lower filler contents (16, 17). Thereby an additional 2-mm capping layer with a conventional composite resin when restoring areas are subject to occlusal stress is required (15, 18-21). While sculptable bulk fill composite exhibits high mechanical properties due to their

higher filler load (16, 17). Due to this, it does not need an additional capping layer and can be used as a single-step bulk filling material (14, 15). Clinically, the use of bulk fill materials reduces the number of increments required to fill a cavity and the need for material manipulation during insertion (1, 5), thereby simplifying the restorative procedure and saving clinical time.

Nowadays, there is still a small number of pre-clinical studies and scarce clinical evidence about bulk fill composites available in the literature when compared to the representative number of studies, especially from long lasting clinical evaluations obtained from traditional composites (22). Despite the increased availability of bulk fill materials and relatively small number of studies, the question that remains is whether clinicians should consider using bulk fill materials instead of incremental filling technique with conventional composite resins. Moreover, it should be considered that important information can be collected and produced upon reviewing those studies to promote the evidence-based practice in operative dentistry. Hence, the purpose of the present study was to evaluate if the performance of bulk fill materials is comparable to conventional composite resins through a systematic review of in vitro and clinical studies. The hypothesis tested was that bulk fill would present in vitro and clinical performance comparable to conventional composite resins.

2. Materials and methods

This systematic review is reported in accordance with the guidelines of the PRISMA statement (23), and the protocol was registered in the PROSPERO international database for systematic reviews (CRD42017064424). The research question was: Do bulk fill composite resins show in vitro and clinical performance comparable to conventional composite resins?

2.1. Literature search

The search was systematically performed by two independent reviewers until 21 April 2017 (considering unlimited publication years). Nine distinct electronic databases were screened: PubMed (MedLine), ISI Web of Science, Scopus, Cochrane Library, Google Scholar, SciELO, LILACS, IBECS, and BBO (*Biblioteca Brasileira de Odontologia*). The search strategy used in PubMed and adapted for other databases is listed in Table 1. The reviewers hand-searched

the reference lists of included articles for additional papers. After the screening of articles, all studies were imported into Endnote x7 software (Thompson Reuters, Philadelphia, PA, USA) to remove duplicates.

2.2. Study selection

Two reviewers independently assessed the titles and abstracts of all studies. All titles/abstracts were read to verify the eligibility criteria. As selection criteria, any in vitro or clinical study with bulk full composite resin compared with conventional composite resin were included. If this information was not clear in the title or abstract, the papers were retrieved in full text. Besides, it was included only in vitro studies that evaluated at least one of the following properties: depth of cure, degree of conversion, hardness, contraction stress, shrinkage polymerization, elastic modulus, flexural strength, fracture toughness, water sorption and solubility. Regarding contraction stress, studies that used indirect methods (e.g., microleakage and/or cuspal deflection measurements) or studies reporting on finite elemental analyses or theoretical/mathematical models were excluded since they are predictive analyses. Studies that evaluated only polymerization shrinkage, without contraction stress, were also excluded. Only papers that evaluated hardness or degree of conversion in depth (top and bottom evaluation in at least 4 mm for bulk fill and 2 mm for conventional composite resin) were included. Case reports, case series, pilot studies, and reviews were excluded. Only papers written in English, Portuguese and Spanish languages were considered for this review. Any disagreement regarding the eligibility of the included studies was resolved through discussion and consensus.

2.3. Data extraction

For each included study, the following data was recorded using a standardized form were tabulated: bulk fill composite resin, type of bulk fill material (flowable or sculptable), composition and manufacturer. Besides, the type of study, demographic data (year, country), outcomes evaluated, the bulk fill and the conventional composite resin used were also tabulated. Additionally, it was recorded data related to the clinical performance of materials used, such as study design, follow-up, number of teeth, number of alive and failure

restorations, and reasons for failure. If any information was missing, the authors of the included studies were contacted twice via e-mail to retrieve the missing data. If authors had not given an answer by two weeks after the first contact, the missing information was not included in this systematic review.

2.4. Quality assessment

The methodological quality of each included in vitro study was assessed by two reviewers and adapted from other systematic reviews (24, 25). The risk of bias of in vitro studies was evaluated according to the articles' description of the following parameters: specimens' randomization, sample size calculation, blinding of the examiners, informed number of specimens, incomplete outcome data, and other bias (including industry sponsorship bias).

Clinical trials were evaluated and classified according to Cochrane guidelines (26) into the following items: selection bias (sequence generation, allocation concealment), performance and detection bias (blinding of operators or participants and personnel), bias due to incomplete data, reporting bias (selective reporting, unclear withdrawals, missing outcomes), and other bias (including industry sponsorship bias).

2.5. Statistical analysis

The meta-analyses were performed using Review Manager Software version 5.1 (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark). For in vitro studies, the analyses were carried out using a random-effect model, and pooled-effect estimates were obtained by comparing the mean difference between flowable or sculptable bulk fill materials and the conventional composite resin. The following outcomes were evaluated: depth of cure, degree of conversion, hardness, contraction stress, shrinkage polymerization, elastic modulus, flexural strength, fracture toughness, water sorption and solubility. All outcomes were evaluated comparing flowable or sculptable bulk fill with conventional composite resin.

The analysis between % bottom-to-top of degree of conversion of flowable or sculptable bulk fill composites at 4 mm depth and conventional composite resin at 2 mm depth were performed. Also, the analysis for % bottom-to-top of degree of conversion of sculptable bulk fill in up to 6 mm depth

compared with conventional composite resin at 2 mm depth were performed. The analysis between % bottom-to-top of hardness of flowable or sculptable bulk fill composites at 4 mm or up to 6 mm depth and conventional composite resin at 2 mm depth were performed.

For clinical studies, the global analysis was carried out using a random-effects model, and pooled-effect estimates were obtained by comparing the risk difference of failure after bulk fill composite resin or the conventional composite resin. Subgroup analysis were also performed considering only flowable bulk fill compared with flowable conventional composite resin in up to 1 or 3 years of follow-up. Besides, sculptable bulk fill were compared to conventional composite resin in up to 1 year of follow-up. A *P* value ≤.05 was considered statistically significant. Statistical heterogeneity of the treatment effect among studies was assessed using the Cochran's Q test and the inconsistency I^2 test.

3. Results

3.1. Literature search

The results from the search flowchart that summarizes the studies selection process according to the PRISMA Statement (23) are shown in Fig. 1. In total, 2811 publications were retrieved in all databases. From those publications, and after duplicates removal, a total of 2070 papers were examined by the titles and abstracts, 1824 studies were excluded because they did not fulfill the eligibility criteria, and 246 papers were assessed by full-text reading. From the 246 studies retained for detailed review, 186 studies were not included (Appendix A). Sixty studies were included in the qualitative analysis, and 10 of these studies (20, 27-35) did not inform requested information for the quantitative analysis, so 45 in vitro and 5 clinical trials were included for the meta-analyses.

3.2. Qualitative/Descriptive analysis

Fifteen different bulk fill composite resins were evaluated in this review, 7 flowable and 8 sculptable (Table 2). All resins are light-cured, except the Fill-up! (Coltene-Whaledent, Altstätten, Switzerland) that is dual-cured.

Of the in vitro studies included in the review (Table 3), a total of 8 studies evaluated depth of cure (9, 10, 36-41), 8 evaluated degree of conversion in

depth (9, 42-48), and 17 evaluated hardness in depth (8-10, 16, 35, 37, 43, 47-56). Additionally, 13 studies evaluated contraction stress (7, 44, 48, 57-66), 7 evaluated polymerization shrinkage (48, 57, 60, 61, 63-65), and 7 evaluated elastic modulus (17, 39, 41, 58, 62, 64, 67). The other properties of bulk fill composite resins evaluated were flexural strength in 8 studies (17, 38, 39, 41, 58, 62, 67, 68), fracture toughness in 4 (39, 41, 67, 69), water sorption and solubility in 4 (70-73).

Six clinical trials were included in the qualitative analysis. They were published between 2014 and 2016 (Table 3). Follow-up periods were up to 1 year (14, 15, 18), 3 years (18, 20, 21) or 5 years (19) showing a success rate of restorations with bulk fill composite resins varying from 78.9 to 100%. Of a total of 488 posterior restoration (85 Class I and 328 Class II) evaluated in five clinical studies (14, 15, 18, 19, 21), only 8 restorations with bulk fill materials failed due to caries, tooth fracture, endo/pain and other (marginal discoloration), as showed in Table 4.

3.3. Meta-analyses

A meta-analysis was performed with 45 in vitro studies and 5 clinical trials, which main results are described in Fig. 2-6. Either flowable or sculptable bulk fill showed higher and statistically significant different depth of cure than conventional composite resin ($p<0.001$; Fig. 2a and Fig. 3a). Moreover, the analysis of degree of conversion in depth demonstrated no statistically significant difference between % bottom-to-top of degree of conversion of both flowable or sculptable bulk fill composites at 4 mm depth and conventional composite resin at 2 mm depth ($p>0.05$; Fig. 2b and Fig. 3b). Sculptable bulk fill composite resin at 6 mm depth, in contrast, demonstrated statistically significant lower % bottom-to-top of degree of conversion compared to conventional composite resin at 2 mm depth ($p=0.001$; Fig. 3c). For hardness in depth, the flowable bulk fill materials at 4 ($p=0.28$) or up to 6 mm depth ($p=0.11$) showed no statistically significant difference than the conventional composite resin at 2 mm depth (Fig. 2c-d). On the other hand, the hardness of sculptable bulk fill at 4 mm ($p=0.02$) or up to 6 mm depth ($p<0.001$) were significantly lower than the conventional composite resin at 2 mm depth (Fig. 3d-e).

In addition, flowable bulk fill showed higher and statistically significant different contraction stress than conventional material ($p<0.001$; Fig. 4a). However, no statistically significant difference between sculptable bulk fill and conventional composites were observed in relation to contraction stress ($p=0.08$;Fig. 4b). For shrinkage polymerization, there was no difference between any type of bulk fill and conventional composite resin ($p>0.05$; Fig. 4c-d). Meanwhile, flowable and sculptable bulk fill composite resin showed statistically significant lower elastic modulus than conventional material ($p=0.001$ and $p=0.05$, respectively; Fig 4 e-f).

The analysis of the flexural strength and fracture toughness showed no statistically significant differences between groups evaluated ($p>0.05$; Fig. 5 a-d). For water sorption and solubility, only water sorption of flowable bulk fill composites demonstrated statistically significant differences than the conventional composite resin ($p=0.006$).

The global analysis of clinical performance of bulk fill composite resin did not show statistical difference compared to the conventional composite resin ($p=0.52$; Fig 6a). Also, subgroup analysis showed that flowable and sculptable bulk fill composites presented clinical performance similar to conventional composite resin in up to 1 ($p=0.51$; $p=0.99$, respectively) or 3 years of follow-up ($p=0.78$).

3.4. Quality assessment

Of the 54 included in vitro studies, the majority of them showed low risk of bias regarding number of specimens informed, incomplete outcome data, evaluated methodologies informed, and other bias. An unclear risk of bias in the majority of studies was observed for sample size calculation, blinding and specimens randomization (Fig. 7a). Therefore, most clinical studies included showed a low risk of bias in all parameters analyzed (Fig. 7b).

4. Discussion

The studies analyzed suggests that bulk fill materials present increased depth of cure and similar performance than composite resins regarding mechanical strength, with a lower contraction stress for flowable bulk fill and similar for sculptable bulk fill when compared with the conventional composite

resin. Also, bulk fill materials showed similar clinical performance than composite resins in up to 1 and 3 years of follow-up. Therefore, the hypothesis tested was partially accepted, once the performance of bulk fill materials showed higher depth of cure, and was similar than conventional composite resin at most of the analyzed outcomes evaluated, but different regarding contraction stress and water sorption.

The most included studies have showed depth of cure greater than 4 mm for flowable (9, 36-38, 41) and sculptable bulk fill materials (9, 38-41), which was also observed by our analyses. The depth of cure was assessed in these studies by scraping method according to ISO 4049 (10, 36, 37, 39-41) or Acetone Shake test (9, 38). However, the suitability of this method for bulk fill composites has been criticized for providing an overestimation of depth of cure values (9, 10, 29, 37, 38). Due to this, a method involving the determination of degree of conversion (9, 42-48) or hardness in depth (8-10, 16, 35, 37, 43, 47-56) has been preferred, and it was used by most included studies. When its values are obtained, a mean % bottom/top ratio are usually determined to establish the depth of cure, reflecting the relative extent of polymerization of the deeper surfaces in relation to the top surface. The analysis of % bottom-to-top of degree of conversion and hardness demonstrated no statistically significant difference for flowable bulk fill materials, while a lower performance for sculptable bulk fill was demonstrated, both compared to conventional composite resin at 2 mm depth. In most included studies, flowable (8, 9, 16, 43-46, 48, 52-55) and sculptable bulk fill material (8, 9, 16, 45, 47-49, 53) showed bottom-to-top ratios above 80%, the minimum standard ratio claimed as being suitable polymerization (10, 36, 37, 39-41). These results suggest that bulk fill composite could be used in 4 mm bulk fill placement. However, this data must be interpreted with caution, since the performance varied greatly according to each material.

Several factors may be associated with an increased polymerization depth of cure of flowable and sculptable bulk fill materials, including but not limited to the filler amount/size (8-13), resin matrix (7), and initiation system (6). Among strategies used to increase the polymerization depth of bulk fill materials, increased translucency through the use of mixed fillers with a refractive index closely matching the resin matrix favored light penetration

through the material (8, 9). Moreover, the presence of pigments in shaded composite materials should also have an effect on depth of cure because pigments are opaque particles that will limit light penetration and reduce the degree of polymerization at greater depths within a cavity preparation (10). Also, reduced filler loading and increased filler size may influence adequate light transmittance, decrease light scattering allowing full curing of a restoration (11-13). High efficiency initiator systems, with a higher photocuring activity result in increased polymerization rate and depth of cure (6). Furthermore, the presences of polymerization modulators, such as urethane-based methacrylate monomers, are capable of interacting with the photoinitiator resulting in a higher polymerization depth (7) and homogeneous hardness.

Regarding contraction stress of bulk fill composites, one important aspect of these materials is related to their overall filler loading: flowable compositions may allow flowability and stress relaxation during early stages of polymerization (7). However, the low filler content of these materials may increase shrinkage, which could prevent further stress relaxation (57). A similar process occurs for the sculptable bulk fill composites, since these composites have a high filler content, which could increase their elastic modulus considerably, and consequently, the polymerization stress (57, 58, 63, 64). In this context, the effect of filler loading on the polymerization stress reduction potential has been investigated. Surprisingly, the meta-analysis demonstrated that the sculptable bulk fill materials resulted in similar stress values when compared to a conventional composite resin, whereas the flowable bulk fill composites produced less stress than control. Overall, it seems that bulk fill materials display better potential to reduce stress if materials with low elastic modulus are used, thereby favoring the use of flowable bulk fill materials. However, flowability of composite resins is not guarantee for contraction stress reduction (7, 44, 48, 57, 61, 63, 64), and this subject is complex since it depends on several intrinsic factors related to the material's composition. In addition to the properties of the material, another factor involved in the generation of polymerization stress is the compliance of the prepared tooth cavity, which varies according to the remaining tooth structure and its geometry (74). Overall, this finding also favors the use of flowable bulk fill composites as a base material in clinical situations in which compliance is low (31, 58, 60, 64), such

as high C-factor restorations. It seems that the use of these type of composites will result in a reduced final contraction stress, different from what occurs with conventional composite resin. Consequently, reduced contraction stress should be prevent the occurrence of restoration de-bonding (28, 63, 75), cuspal deflection (1), microleakage (59), and thereby post-operatory hypersensitivity, favoring the clinical success of these restorative treatments.

Mechanical properties of bulk fill material can be estimated by several in vitro studies included through the assessment of flexural strength (17, 30, 38, 39, 41, 58, 62, 67, 68) and fracture toughness (30, 39, 41, 67, 69). Concerning differences in filler loading and composition, the mechanical properties can be expected to vary quite largely among the available flowable or sculptable bulk-fill composites. Some materials present lower filler load with flowable consistency to be used as dentin-replacement and enable self-adaptation to cavity walls, while other materials have a higher filler load (17), or present short glass fibers for reinforcement (30, 41, 67) to be used as bulk restoration. The meta-analysis of included studies demonstrated that both flowable and sculptable bulk fill materials resulted in similar flexural strength and fracture toughness compared to composite resin. Therefore, many studies (17, 30, 38, 39, 41, 58, 62, 67) demonstrated flexural strength for flowable and sculptable bulk fill materials over the minimum of 80 MPa established in ISO 4049/2009 for polymer-based restorative materials claimed by the manufacturer as suitable for restorations involving occlusal surfaces (76). Also, enhanced fracture toughness indicates the relative resistance to crack initiation and propagation from the surface or inherent flaws in the materials (41, 67, 69). Nevertheless, some included studies suggest that high filler content does not necessarily reflect into superior mechanical properties (30, 38, 41). In this context, other factors besides filler content, such as short glass fibers for reinforcement, stress transmission between filler particles and matrix, as well as adhesion between these components was suggested to play a relevant role (30, 38, 67). Moreover, cross-linked resin matrix chemistry also influences on the composites mechanical properties (12). Thus, enhanced mechanical properties are especially important since bulk-fill composites will represent most, if not all of the restoration. The mechanical properties of the sculptable bulk fill materials are comparable to conventional composite resin, while flowable bulk fill

materials seem to exhibit properties closer to control with flowable conventional composite resin. Since flowable conventional composite resins are never recommended to represent most of the restoration bulk, it is questionable whether this should be the case for bulk fill composite resins, and their use for restorations under high occlusal load should remain subject to caution. Sculptable bulk fill composites, in contrast, are designed to be used as final posterior restorative materials in comparison to the recommended use of flowable bulk fill composites as base materials, requiring a covering of conventional composite resin (15, 18-21).

The exposure of the composite to the oral environment may also have an impact on the physical and mechanical properties of the polymer due to water sorption and solubility (70-73). From included studies, only water sorption of flowable bulk fill composites demonstrated statistically significant differences than the conventional composite resin. The amount of water sorption in a polymeric structure is related to degree of conversion, crosslink density, porosity of network and hydrophilicity from monomers or fillers (70-73). The water sorption also contributes to the hygroscopic expansion of the material and hygroscopic stress that can result in micro cracking (70, 71). Overall, bulk fill composite resins with enhanced mechanical properties will be better able to withstand high stress levels and thus have improved clinical outcomes.

The current evidence available suggests that clinical performance of bulk fill materials is similar to conventional composite resins with the advantage to simplify the time-consuming incremental technique these materials can be placed into the tooth cavity using one increment of up to 4 mm of thickness without compromising its depth of cure. However, only few clinical trials evaluated bulk fill materials, and the current available evidence is with short follow-up periods (15, 18-21). In addition, for bulk fill composites, the main reasons of failure were caries and tooth fracture. Some studies (19-21) reported that these failures occurred in patients with high caries risk and bruxism habits. Previously studies that investigate longevity of posterior composite restoration also reported that patient risk factor increase the risk of restoration failure, while material factors did not harm survival of dental restorations (77-79). Most clinical trials showed higher clinical success rates (98.8 to 100% in up to 5 years) (15, 18-21), and only one study (14) reported lower clinical success rate

(78.9 % up to 1 year) for sculptable bulk fill composite. In these studies, marginal discoloration and postoperative sensitivity were the reasons for failure. However, considering marginal discoloration as restoration failure for posterior teeth is minimally questionable, the need for clinical re-intervention is subjective (22, 80). Furthermore, the marginal discoloration is clinically significantly when present in anterior teeth and is the patient's aesthetic complaint (80). So far, restoration fracture or retention loss of restorations with bulk fill composite resins is not reported. Due to this, further clinical trials with long follow-up periods are of utmost importance to clarify the usage of restorations with bulk fill composites for rehabilitation of posterior teeth. It is important to highlight that the findings of the present review cannot be extrapolated to all materials since performance may be material-dependent. Future studies are required to evaluate the effect of each material and its in vitro and clinical performance. Finally, considering that restorations with bulk fill composites may be faster and simpler when compared to other incremental technique with conventional composite resins, the current available evidence suggest these materials and bulk protocol thereof may be an adequate treatment option as restorative material for posterior teeth.

CONCLUSION

Respecting the limitations of current study, the outcomes suggesting that bulk fill composite resins present increased depth of cure and similar performance than composite resins regarding mechanical strength, with a lower contraction stress for flowable bulk fill and similar for sculptable bulk fill. Besides, bulk fill materials showed similar clinical performance than composite resins in up to 1 and 3 years of follow-up, and could be used in posterior teeth in one increment more than 4 mm in thickness, which facilitate the restorative procedure, reduce the clinical time and, consequently, simplify the operative technique. However, the evidence of these results must be considered with caution and may vary among different materials evaluated. Clinical studies with long follow-up periods must be performed to evaluate if the performance of bulk-fill materials are comparable to composite resins at long-term.

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Figures

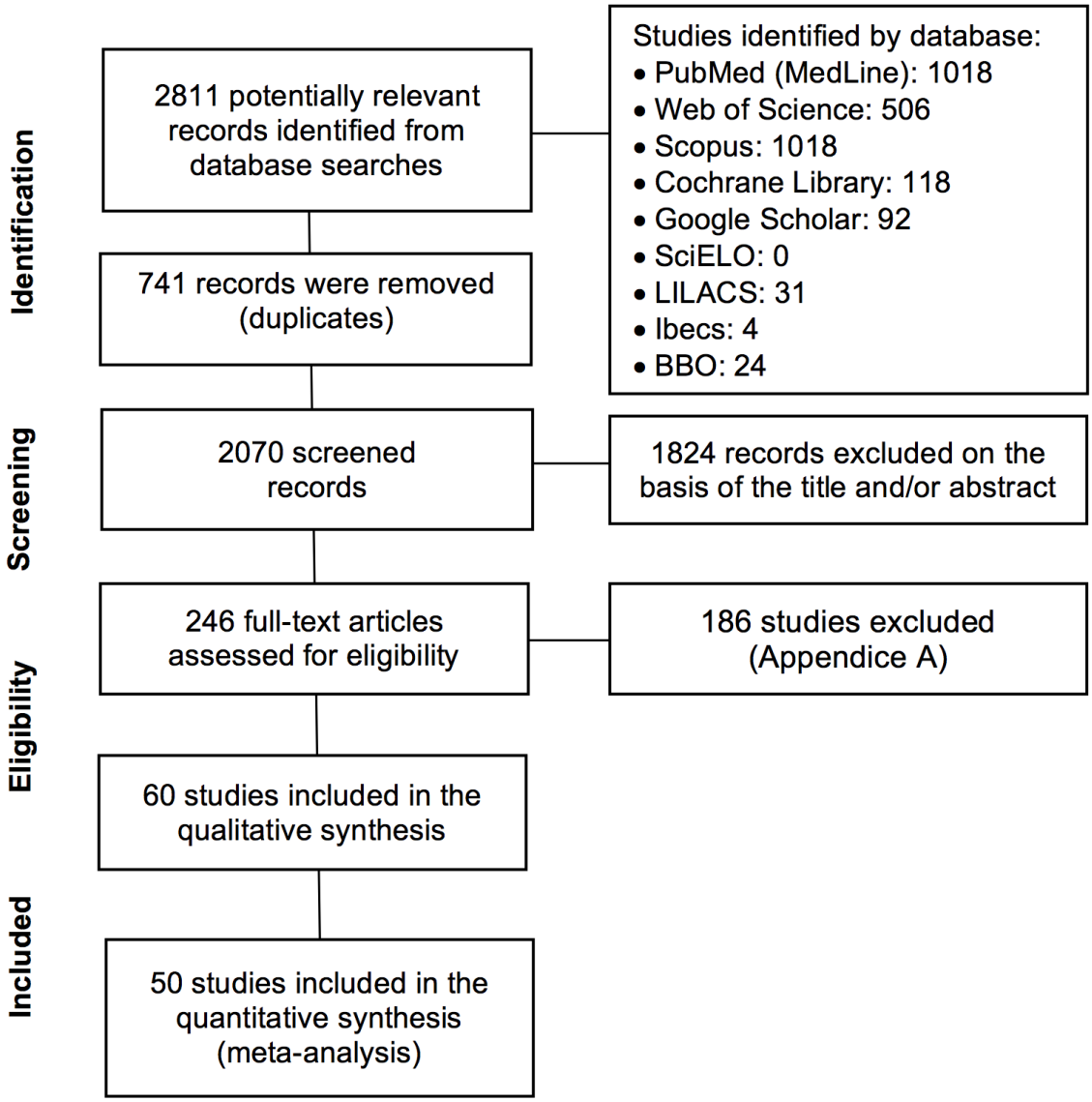


Figure 1. Search flow (as described in the PRISMA statement) (16).

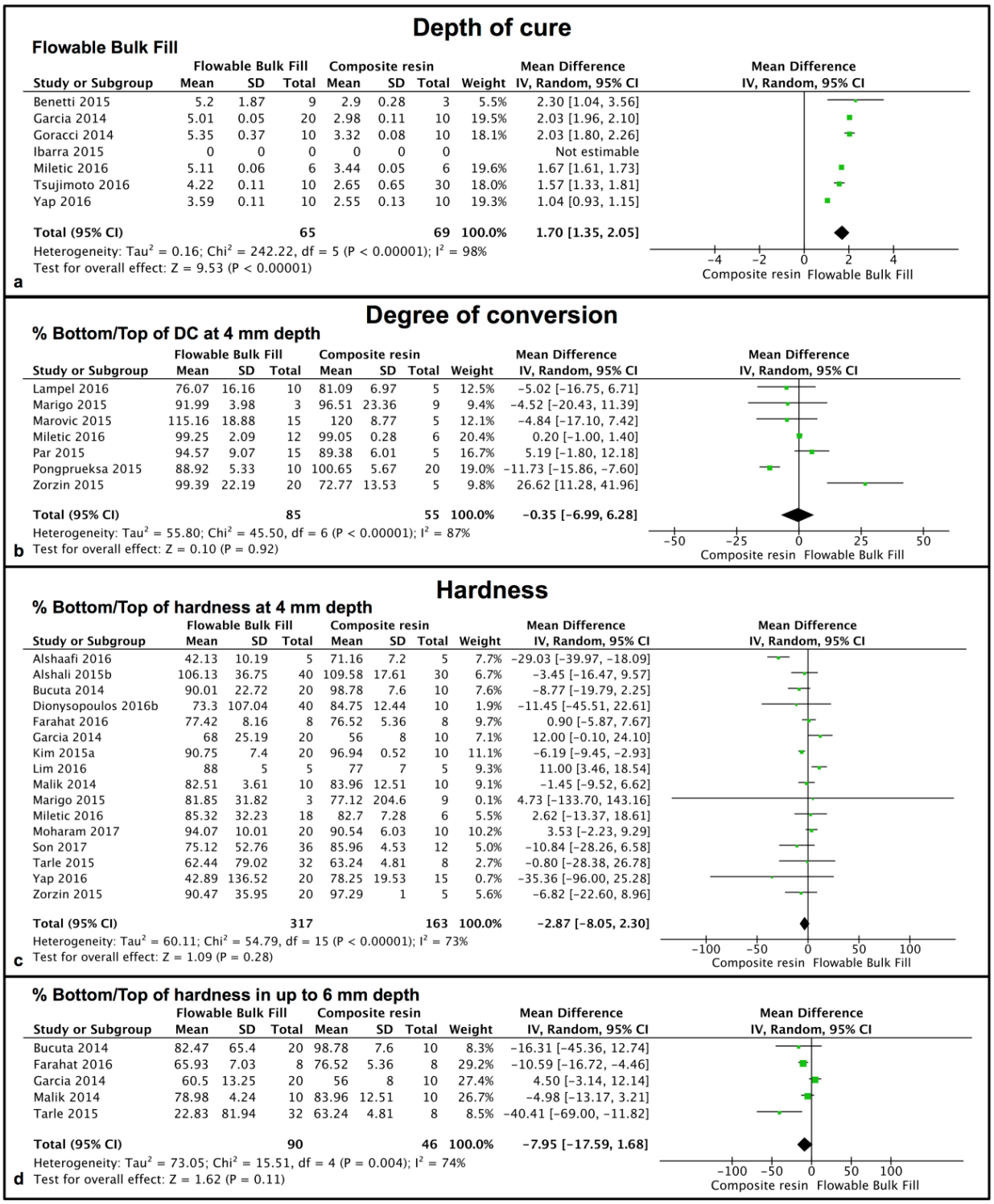


Figure 2. Results for the analysis of the depth of cure (a), % bottom-to-top of degree of conversion at 4 mm depth (b), % % bottom-to-top of hardness at 4 mm (c) and 6 mm depth (d) of flowable bulk fill composite compared to conventional resin composite used as control.

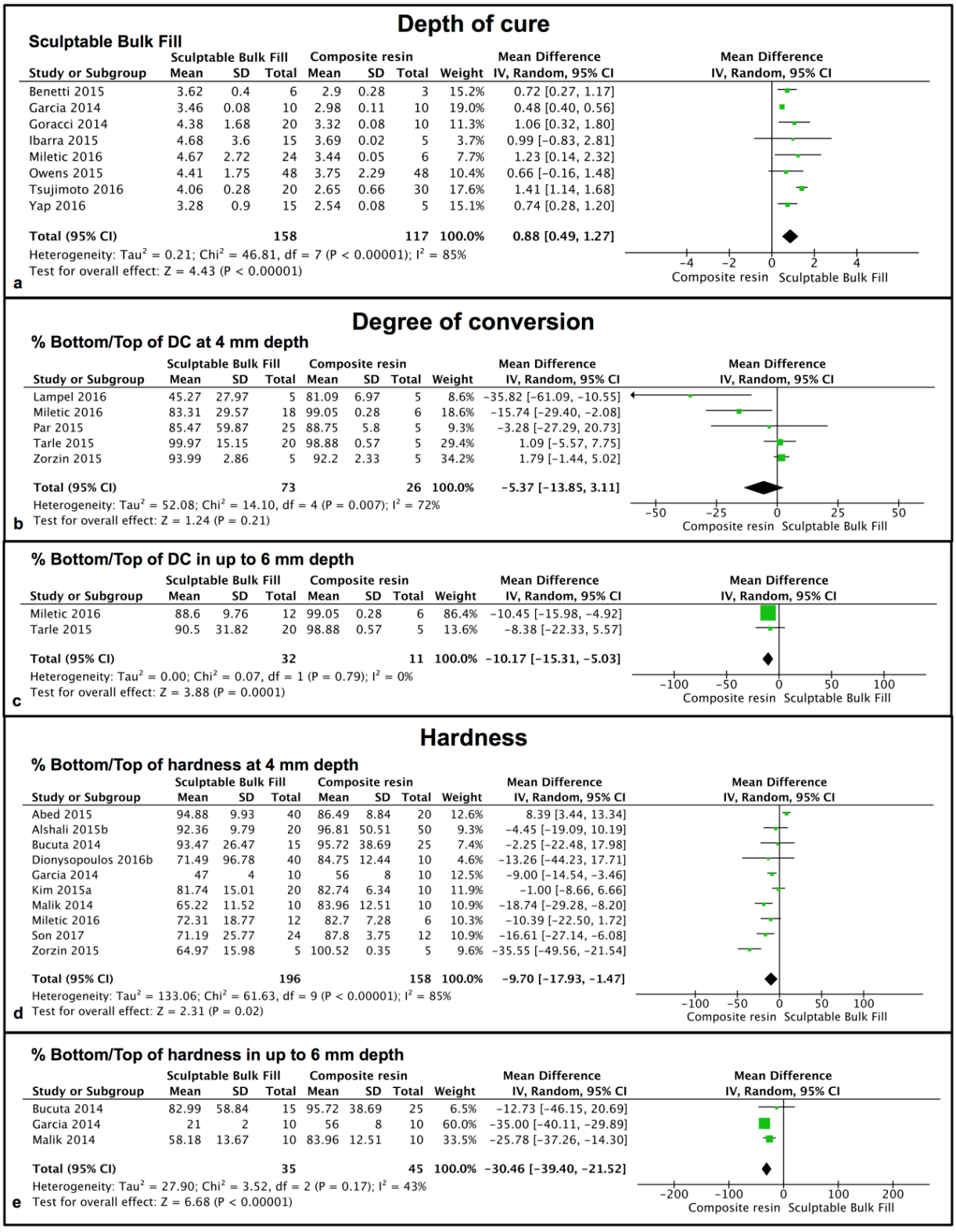


Figure 3. Results for the analysis of the depth of cure (a), % bottom-to-top of degree of conversion at 4 mm (c) and 6 mm depth (c), % bottom-to-top of hardness at 4 mm (d) and 6 mm depth (e) of sculptable bulk fill composite compared to conventional resin composite used as control.

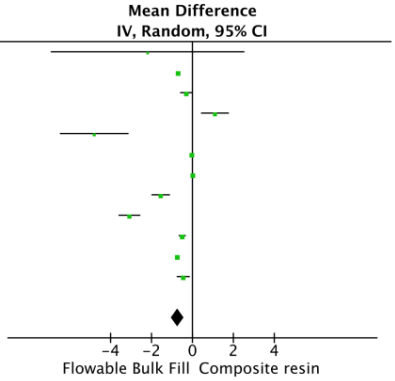
Contraction stress

Flowable Bulk Fill

Study or Subgroup	Flowable Bulk Fill Mean	SD	Total	Composite resin Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Al Sunbul 2016	6.43	2.11	9	8.62	8	12	0.4%	−2.19 [−6.92, 2.54]
El-damanshoury 2014	1.66	0.11	6	2.36	0.04	3	10.7%	−0.70 [−0.80, −0.60]
Fronza 2015	3.4	0.4	10	3.7	0.2	5	9.8%	−0.30 [−0.60, 0.00]
Han 2016	3.5	0.2	5	2.4	1.3	15	7.1%	1.10 [0.42, 1.78]
Illie 2011	1.1	0.01	10	5.9	3.83	20	2.6%	−4.80 [−6.48, −3.12]
Jang 2015	0.36	0.12	16	0.39	0.04	8	10.7%	−0.03 [−0.10, 0.04]
Jung 2017	0.08	0.01	8	0.06	0.01	8	10.8%	0.02 [0.01, 0.03]
Kim 2015b	1.96	0.59	10	3.51	0.3	5	8.8%	−1.55 [−2.00, −1.10]
Kim 2016	1.99	0.62	10	5.07	0.42	5	8.2%	−3.08 [−3.61, −2.55]
Marovic 2015	0.95	0.34	15	1.45	0.03	5	10.4%	−0.50 [−0.67, −0.33]
Taubock 2014	0.71	0.04	6	1.45	0.03	6	10.8%	−0.74 [−0.78, −0.70]
Zorzin 2015	1.49	0.61	20	1.94	0.2	5	9.7%	−0.45 [−0.77, −0.13]
Total (95% CI)			**125**			**97**	**100.0%**	**−0.73 [−1.04, −0.41]**

Heterogeneity: $Tau^2 = 0.23$; $Chi^2 = 1735.56$, df = 11 ($P < 0.00001$); $I^2 = 99\%$

a Test for overall effect: $Z = 4.57$ ($P < 0.00001$)

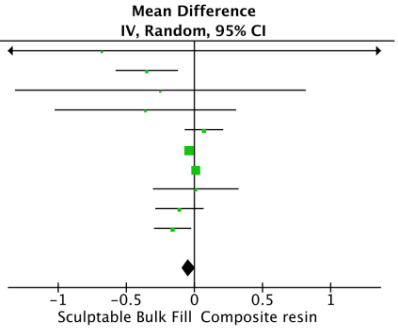


Sculptable Bulk Fill

Study or Subgroup	Sculptable Bulk Fill Mean	SD	Total	Composite resin Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Al Sunbul 2016	4.63	1.32	6	5.31	4.08	18	0.1%	−0.68 [−2.84, 1.48]
El-damanshoury 2014	2.01	0.28	6	2.36	0.04	3	4.1%	−0.35 [−0.58, −0.12]
Fronza 2015	3.45	1.7	10	3.7	0.2	5	0.2%	−0.25 [−1.32, 0.82]
Han 2016	2.03	0.12	5	2.39	1.3	15	0.5%	−0.36 [−1.03, 0.31]
Illie 2011	0.69	0.32	20	0.62	0.025	5	9.1%	0.07 [−0.07, 0.21]
Jang 2015	0.2	0.02	8	0.24	0.01	8	34.7%	−0.04 [−0.06, −0.02]
Jung 2017	0.07	0.06	24	0.06	0.01	8	32.9%	0.01 [−0.01, 0.03]
Kim 2015b	2.39	0.2	10	2.38	0.33	5	2.3%	0.01 [−0.30, 0.32]
Taubock 2015	2.77	0.22	10	2.88	0.13	5	6.4%	−0.11 [−0.29, 0.07]
Zorzin 2015	1.07	0.1	5	1.23	0.12	5	9.6%	−0.16 [−0.30, −0.02]
Total (95% CI)			**104**			**77**	**100.0%**	**−0.04 [−0.09, 0.01]**

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 26.56$, df = 9 ($P = 0.002$); $I^2 = 66\%$

b Test for overall effect: $Z = 1.73$ ($P = 0.08$)



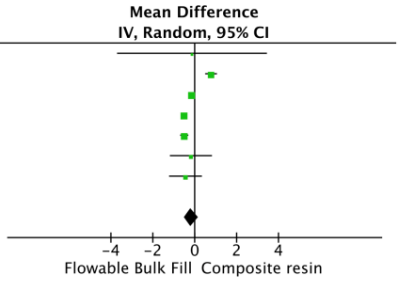
Shrinkage polymerization

Flowable Bulk Fill

Study or Subgroup	Flowable Bulk Fill Mean	SD	Total	Composite resin Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Al Sunbul 2016	3.63	1.32	9	3.76	6.86	15	0.8%	−0.13 [−3.71, 3.45]
Han 2016	2.27	0.11	10	1.49	0.76	30	18.9%	0.78 [0.50, 1.06]
Jang 2015	0.62	0.15	16	0.77	0.05	8	21.7%	−0.15 [−0.23, −0.07]
Kim 2015b	3.02	0.12	10	3.53	0.09	5	21.5%	−0.51 [−0.62, −0.40]
Kim 2016	3.02	0.31	10	3.52	0.04	5	20.4%	−0.50 [−0.70, −0.30]
Taubock 2014	2.26	0.1	6	2.44	1.77	12	7.1%	−0.18 [−1.18, 0.82]
Zorzin 2015	3.48	1.48	18	3.92	0.48	6	9.7%	−0.44 [−1.22, 0.34]
Total (95% CI)			**79**			**81**	**100.0%**	**−0.15 [−0.48, 0.17]**

Heterogeneity: $Tau^2 = 0.13$; $Chi^2 = 86.29$, df = 6 ($P < 0.00001$); $I^2 = 93\%$

c Test for overall effect: $Z = 0.92$ ($P = 0.36$)

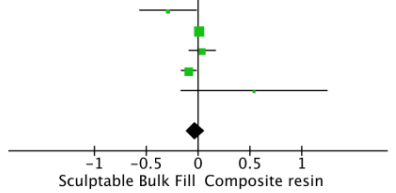


Sculptable Bulk Fill

Study or Subgroup	Sculptable Bulk Fill Mean	SD	Total	Composite resin Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Al Sunbul 2016	2.81	1.07	6	2.22	1.55	18	0.6%	0.59 [−0.53, 1.71]
Han 2016	1.21	0.09	10	1.5	0.76	30	8.1%	−0.29 [−0.57, −0.01]
Jang 2015	0.25	0.03	8	0.24	0.02	8	38.2%	0.01 [−0.01, 0.03]
Kim 2015b	2.13	0.18	10	2.09	0.08	5	21.1%	0.04 [−0.09, 0.17]
Kim 2016	2.09	0.09	10	2.18	0.06	5	30.5%	−0.09 [−0.17, −0.01]
Zorzin 2015	2.85	0.96	12	2.31	0.57	6	1.5%	0.54 [−0.17, 1.25]
Total (95% CI)			**56**			**72**	**100.0%**	**−0.03 [−0.12, 0.06]**

Heterogeneity: $Tau^2 = 0.01$; $Chi^2 = 13.75$, df = 5 ($P = 0.02$); $I^2 = 64\%$

d Test for overall effect: $Z = 0.59$ ($P = 0.55$)



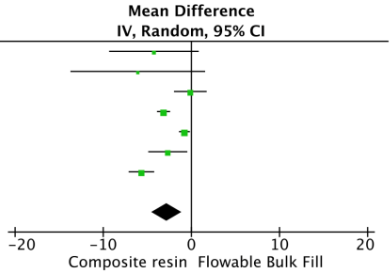
Elastic modulus

Flowable Bulk Fill

Study or Subgroup	Flowable Bulk Fill Mean	SD	Total	Composite resin Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Bijelic 2016	4.7	0.9	8	8.95	10.3	16	7.1%	−4.25 [−9.34, 0.84]
El-damanshoury 2014	5.57	4.5	15	11.65	8.32	5	3.9%	−6.08 [−13.72, 1.56]
Ibarra 2015	10.74	5.12	30	10.86	0.46	10	16.4%	−0.12 [−1.97, 1.73]
Jung 2017	2.82	1.2	16	5.98	0.66	8	19.7%	−3.16 [−3.90, −2.42]
Kim 2016	5	0.98	10	5.79	0.11	5	19.9%	−0.79 [−1.41, −0.17]
Leprice 2014	5.27	4.35	15	7.95	0.28	5	15.1%	−2.68 [−4.90, −0.46]
Tsujimoto 2016	6.7	0.6	15	12.37	4.85	45	17.8%	−5.67 [−7.12, −4.22]
Total (95% CI)			**109**			**94**	**100.0%**	**−2.75 [−4.44, −1.07]**

Heterogeneity: $Tau^2 = 3.60$; $Chi^2 = 54.87$, df = 6 ($P < 0.00001$); $I^2 = 89\%$

e Test for overall effect: $Z = 3.21$ ($P = 0.001$)



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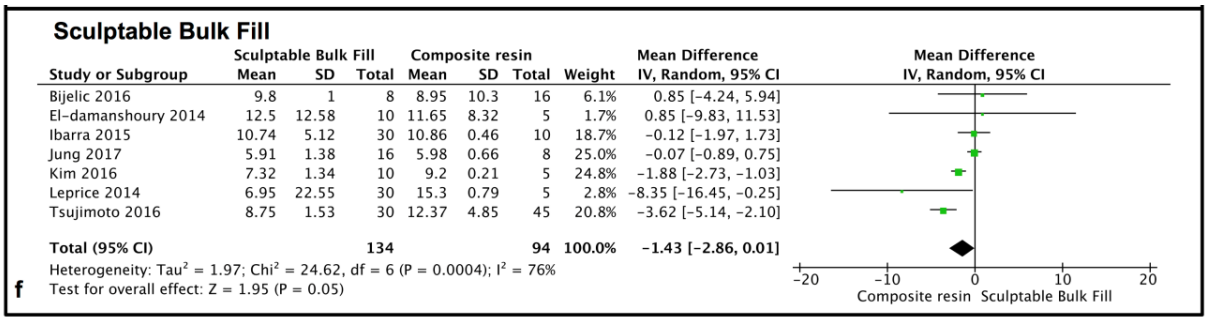

Figure 4. Results for the analysis of the contraction stress (a-b), shrinkage polymerization (c-d), and elastic modulus (e-f) of flowable or sculptable bulk fill composite, respectively, compared to conventional resin composite used as control.

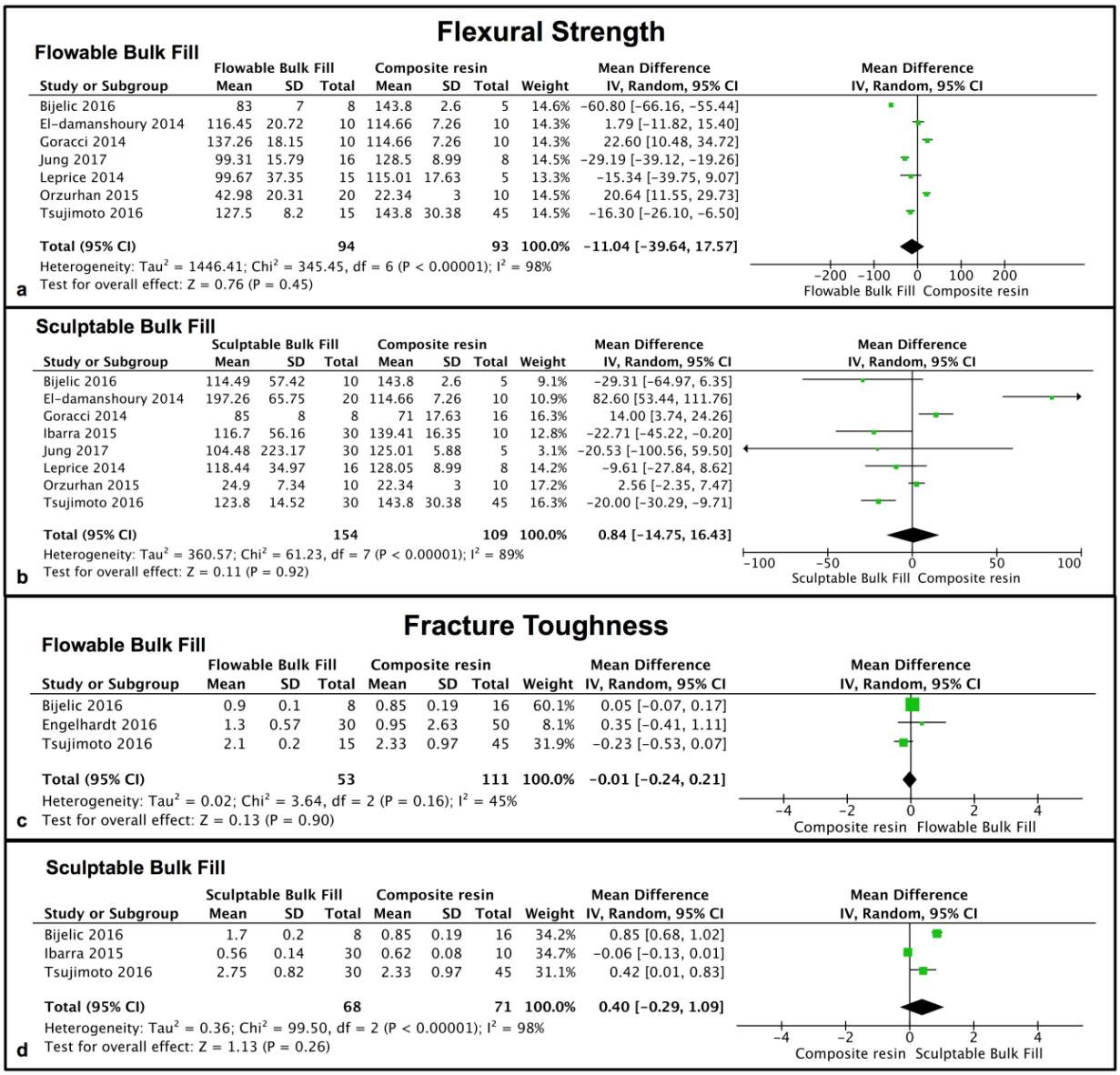

Figure 5. Results for the analysis of the flexural strength (a-b) and fracture toughness (c-d) of flowable or sculptable bulk fill composite, respectively, compared to conventional resin composite used as control.

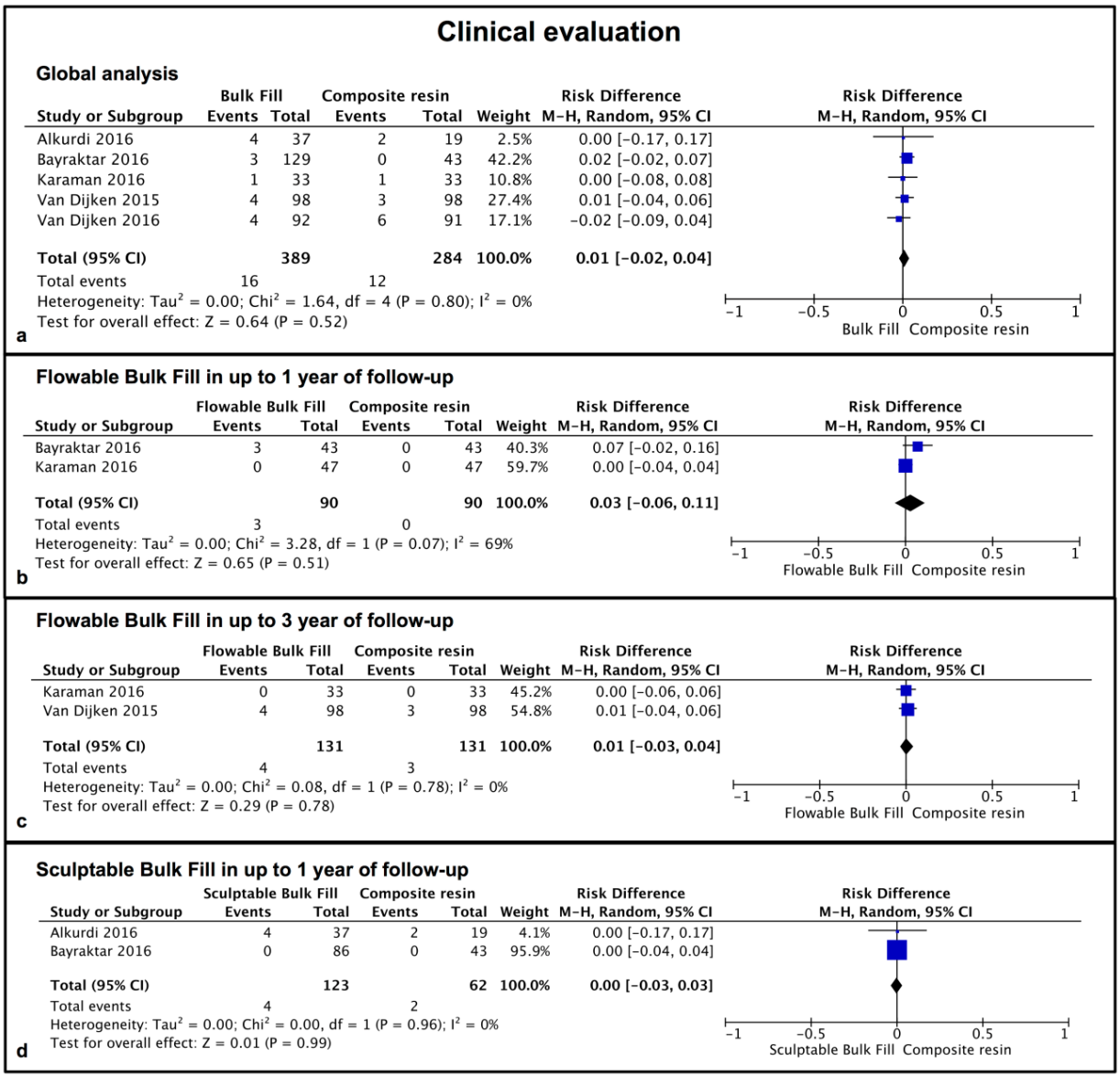

Figure 6. Results for the clinical evaluation analysis. Global analysis (a), flowable bulk fill composite in up to 1 (b) and 3 year of follow-up (c), and sculptable bulk fill composite in up to 1 year of follow-up compared to conventional resin composite used as control.

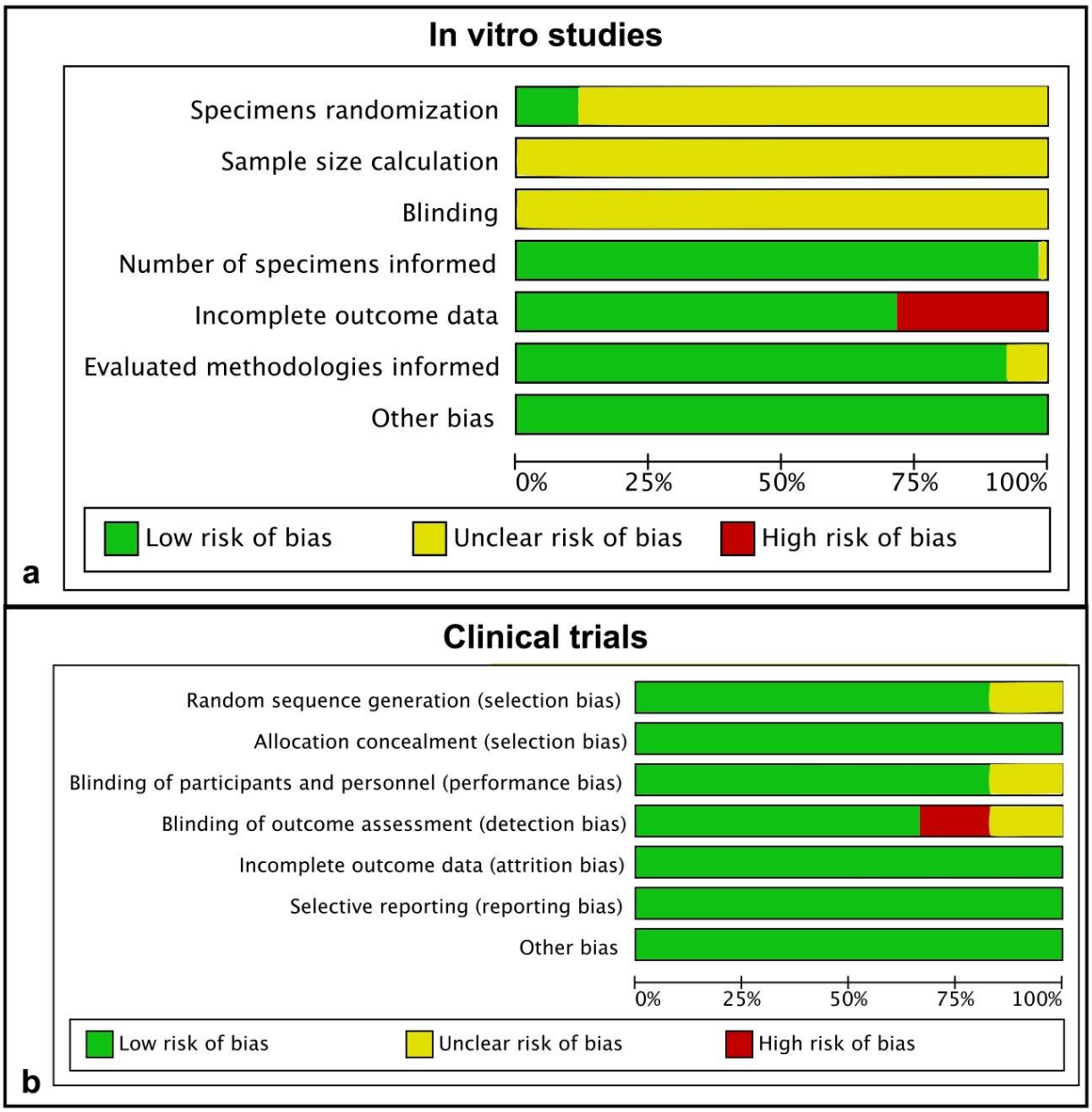

Figure 7. Review authors' judgments about each risk of bias item for each included in vitro study (a) and clinical trial (b).

Tables

Table 1. Search strategy used in PubMed (MEDLINE).

	Search terms
#1	Bulk fill OR Bulk-fill OR Bulkfill OR Bulk composite OR Bulk resin OR GrandioFlow OR TetricFlow OR Tetric EvoCeram Bulk-Fill OR Venus Bulk-Fill OR Surefil SDR OR X-Tra Base OR GC EverX Posterior OR Filtek Bulk-Fill OR Filtek Bulk Fill OR SonicFill OR Beautiful Bulk OR Opus Bulk Fill OR Tetric N-Ceram Bulk Fill OR X-tra fill OR Aura bulk fill OR Sonic Fill

Table 2. Composition and classification of bulk fill resin composites.

Material	Type	Resin matrix	Filler type	Filler loading (wt/vol.%)	Manufacturer
Beautiful Bulk Flowable	Flowable	Bis-GMA, UDMA, Bis-MPEPP, TEGDMA	Fluoroborosilicate glass	72.5 / 62	Shofu Inc.
Fill-Up!	Flowable*	TMPTMA, UDMA, Bis-GMA, TEGDMA.	Dental glass, Amorphous silicic acid, Zinc oxide	65 / 49	Coltene-Whaledent
Filtek Bulk Fill	Flowable	Bis-GMA, Bis-EMA, UDMA, TEGDMA, Procrylat resins	Zirconia/silica, ytterbium trifluoride	64.5 / 42.5	3M ESPE
SureFil SDR (Smart dentin replacement)	Flowable	Modified UDMA, Bis-EMA, TEGDMA	Barium glass, Strontium glass	68 / 45	Dentsply Caulk
Venus Bulk fill	Flowable	UDMA, Bis-EMA	Nano-hybrid barium glass, Ytterbium trifluoride, Silicon dioxide	65 / 38	Heraeus Kulzer
Xenius Base	Flowable	PMMA, Bis-GMA, TEGDMA	Ba-B-silicate fillers, glass fibers (length 1.3 mm)	74 / 53.6	Stick Tech Ltd
X-tra base	Flowable	MMA, Bis-EMA	Inorganic fillers	75 / 58	Voco
Beautifil Bulk Restorative	Sculptable	Bis-GMA, UDMA, Bis-MPEPP, TEGDMA	Fluoroborosilicate glass	87 / 74.5	Shofu Inc,
EverX Posterior	Sculptable	Bis-GMA, TEGDMA, PMMA	Hybrid filler, fractions, E-glass fibers	74.2 / 57	GC Corporation
HyperFIL	Sculptable	Bis-EMA, UDMA, other dimethacrylate monomers	Barium glass, silica. 15 nm to 3.5 μm	70-75 / NR	Parkell Inc.
Injectafil DC	Sculptable	Mixture of methacrylate resins and Bis-GMA	Silica glass (submicron to 5 μm)	75 / NR	Apex Dental Materials, Inc
QuiXfil	Sculptable	Bis-EMA, UDMA, TEGDMA, TMPTMA, BTA and TCB	Strontium-alumino-sodium-fluoro-phosphate-silicate glass (0.1- 4; 5 - 50 mm)	86 / 66	Dentsply
SonicFill	Sculptable	Bis-EMA, Bis-GMA, TEGDMA	Barium glass, Silicon dioxide	83.5 / NR	Kerr
Tetric Evoceram bulk fill	Sculptable	Bis-GMA, UDMA, Bis-EMA	Nano-hybrid barium glass, Ytterbium trifluoride, Mixed oxide Prepolymer	79-81 / 60	Ivoclar Vivadent
X-tra Fil	Sculptable	Bis-GMA, UDMA, TEGDMA	Ba–B–Al silicate glass (0.05–10 lm)	86 / 70.1	Voco

Bis-GMA: Bisphenol A dimethacrylate; Bis-EMA: ethoxylated bisphenol-A-dimethacrylate; UDMA: urethane resin dimethacrylate; TEGDMA: triethylene glycol dimethacrylate; TMPTMA: trimethylolpropane trimethacrylate; BTA: butane-1,2,3,4-tetracarboxylic acid; TCB: bis-2-hydroxyethyl methacrylate; MMA: methyl methacrylate; PMMA: poly methyl methacrylate; Bis-MPEPP: Bisphenol A polyethoxy methacrylate; NR: Not reported; *Dual-cure flowable composite.

Table 3. Demographic and study design data of the included studies.

Author	Year	Country	Outcome evaluated	Bulk fill resin composite*	Conventional resin composite
In vitro studies					
Abed (42)	2015	Egypt	Hardness	X-tra Fil[1], QuiXfil[2]	Grandio Flow[11]
Al Sunbul (65)	2015	United Kingdom	Water sorption and solubility	SureFil SDR[2], Venus Bulk Fill[3], Tetric EvoCeram Bulk Fill[4], EverX Posterior[5]	Tetric EvoCeram[4], G-aenial Universal Flow[5], G-aenial Anterior[5], G-aenial Posterior[5]
Al Sunbul (51)	2016	United Kingdom	Contraction Stress, Shrinkage polymerization	Venus Bulk Fill[3], SureFil SDR[2], X-tra base[1], EverX Posterior[5], Tetric EvoCeram Bulk Fill[4]	G-aenial Universal Flow[5], Filtek Supreme XTE Flowable[6], Estelite Flow Quick[7], Beautifil Flow Plus[8], Grandio SO Heavy Flow[1], Gradia Direct Posterior[5], G-aenial Posterior[5], G-aenial Anterial[5] Tetric EvoCeram[4], Spectrum TPH[2], Premise[2], Venus Diamond[3], N' Durance[9]
Alqahtani (18)	2015	Arabia	Hardness	Tetric EvoCeram Bulk Fill[4]	Filtek Z100[6]
Alshaafi (43)	2016	Arabia	Hardness	Tetric EvoCeram Bulk Fill[4]	Filtek Supreme Ultra Flowable[6]
Alshali (66)	2015	United Kingdom	Whater sorption and solubility	SureFil SDR[2], Venus Bulk Fill[3], X-tra base[1], Filtek Bulk Fill Flowable[6], Tetric EvoCeram Bulk Fill[4], SonicFill[10]	Grandioso Flow[1], Venus Diamond Flow[3], X-Flow[2], Filtek Supreme XTE Flowable[6], Grandioso[1], Venus Diamond[3], TPH Spectrum[2], Filtek Z250[6]
Alshali (8)	2015	United Kingdom	Hardness	SureFil SDR[2], Venus Bulk Fill[3], X-tra base[1], Filtek Bulk Fill Flowable[6], Tetric EvoCeram Bulk Fill[4], SonicFill[10]	Grandioso Flow[1], Venus DiamondFlow[3], X-Flow[2], Filtek Supreme XTE Flowable[6], Grandioso[1], Venus Diamond[3], TPH Spectrum[2], Filtek Z250[6]
Arregui (67)	2016	Spain	Water sorption and solubility	SonicFill[10], Venus Bulk Fill[3], SureFil SDR[2], Filtek Bulk Fill[6]	Premise Flowable[10], Vertise Flow[10], Venus DiamodFlow[3], Tetric EvoCeram[4], Filtek Supreme XTE Flowable[6]
Benetti (27)	2015	Denmark	Depth of cure	Venus Bulk Fill[3], SureFil SDR[2], X-tra base[1], Tetric EvoCeram Bulk Fill[4], SonicFill[10]	Tetric EvoCeram[4]
Bijelic (62)	2016	Finland	Fracture Toughness, Flexural Strength, Elastic Modulus	Filtek Bulk Fill Flowable[6], EverX Posterior[5],	G-aenial Anterior[5] Filtek Supreme XTE Flowable[6]
Bucuta (44)	2014	Germany	Hardness	X-tra base[1], Venus Bulk Fill[3], Filtek Bulk Fill Flowable[6], X-tra Fill[1], SonicFill[10], Tetric EvoCeram Bulk Fill[4]	GrandioSO[1], Premise[10], Tetric EvoCeram[4], Venus Diamond[3], CeramXmono[2], GrandioSO Heavy Flow[1], Clearfil Majesty Flow[11]
Dionysopoulos (26)	2016	Greece	Hardness	X-tra Fil[1], EverX Posterior[5], Tetric EvoCeram Bulk Fill[4], Beautifil Bulk Restorative[8],X-tra base[1], Beautifil Bulk Flowable[8], Filtek Bulk Fill Flowable[6], Venus Bulk Fill[3]	Filtek Z550[6]
Dionysopoulos (82)	2016	Greece	Hardness	Tetric EvoCeram Bulk Fill[4], Beautifil Bulk Restorative[8], X-tra Fil[1],EverX Posterior[5], Venus Bulk Fill[3], Beautifil Bulk Flowable[8], X-tra base[1], Filtek Bulk Fill Flowable[6]	Filtek Z550[6]
El-damanhoury(52)	2014	Egypt	Contraction Stress, Flexural Strength, Elastic Modulus	SureFil SDR[2], Venus Bulk Fill[3], Tetric EvoCeram Bulk Fill[4], X-tra Fil[1], Experimental Bulk Fill[6]	Filtek Z250[6]

Engelhardt (64)	2016	Germany	Fracture toughness	X-tra base[1], SureFil SDR[2], Venus Bulk Fill[3]	ENAMEL plus HFO Flow[12], ENAMEL plus HRI Flow[12], G-aenial Flo[5], G-aenial Universal Flo[5], Tetric EvoCeram Flo[3], Sinfony Enamel[6]
Farahat (45)	2016	Iran	Hardness	Tetric EvoCeram Bulk Fill[4]	Tetric EvoCeram[4]
Flury (20)	2012	Switzerland	Depth of cure, Hardness	SureFil SDR[2], Venus Bulk Fill[3], QuiXfil[2], Tetric EvoCeram Bulk Fill[3]	Filtek Supreme Plus[6], Filtek Silorane[6]
Flury (19)	2014	Switzerland	Hardness	SureFil SDR[2], Filtek Bulk Fill Flowable[6], X-tra Fil[1], Tetric EvoCeram Bulk Fill[6]	Filtek Supreme XTE Flowable[6]
Fronza (53)	2015	Brazil	Contraction Stress	SureFil SDR[2], Filtek Bulk Fill Flowable[6], Tetric EvoCeram Bulk Fill[3], EverX Posterior[5]	Herculite Classic[10]
Garcia (28)	2014	USA	Depth of cure, Hardness	SureFil SDR[2], Venus Bulk Fil[3], SonicFill[10]	Filtek Supreme Ultra Flowable[6]
Garoushi (21)	2013	Finland	Depth of Cure, Elastic Modulus, Flexural Strength, Fracture Toughness	X-tra base[1], Venus Bulk Fill[4], Tetric EvoCeram Bulk Fill[3], SureFil SDR[2], Filtek Bulk Fill Flowable[6], SonicFill[10], Xenius base[14]	Filtek Supreme Ultra Flowable[6], Alert[13], Filtek Z250[6]
Goracci (29)	2014	Italy	Depth of Cure, Flexural Strength	SonicFill[10], SureFil SDR[2], EverX Posterior[5]	Filtek Silorane[6], Kalore[5]
Guo (22)	2016	China	Contraction Stress	Filtek Bulk Fil Flowable[6]	Filtek Z250[6]
Hamlin (23)	2016	USA	Depth of cure	SonicFill[10]	Herculite Ultra[10]
Han (54)	2016	Korea	Contraction Stress, Polymerization Shrinkage	Tetric EvoCeram Bulk Fill[3], Venus Bulk Fill[4]	Filtek Supreme Ultra Flowable[6], Charisma Diamond[4], Amelogen Plus[15]
Ibarra (30)	2015	USA	Depth of cure, Elastic Modulus, Flexural Strength, Fracture toughness	SonicFill[10], Tetric EvoCeram Bulk Fill[3], QuiXfil[2]	Filtek Z250[6], Filtek LS[6]
Illie (55)	2011	Germany	Contraction Stress	SureFil SDR[2]	EsthetX plus[2], EsthetX Flow[2], Filtek Supreme Plus[6], Filtek Supreme Plus Flow[6], Exp-Flow[2], Filtek Silorane[6]
Jang (56)	2015	Korea	Contraction Stress, Polymerization Shrinkage	SureFil SDR[2], Venus Bulk Fill[2], Tetric EvoCeram Bulk Fill[3]	Tetric EvoCeram[2], Filtek Supreme Ultra Flowable[6], G-aenial Universal Flow[5]
Jung (57)	2017	Korea	Contraction Stress, Elastic Modulus, Flexural Strength	SureFil SDR[2], Venus Bulk Fill[4], Tetric EvoCeram Bulk Fill[3], SonicFill[10]	Filtek Z350[6]
Kelic (24)	2016	Croatia	Hardness	Tetric EvoCeram Bulk Fill[3], X-tra Fil[1], QuiXfil[2], Venus Bulk Fill[4], SureFil SDR[2], X-tra base[1]	GrandioSO[1], X-Flow[2]
Kim (47)	2015	Korea	Hardness	Venus Bulk Fill[4], SureFil SDR[2],Tetric EvoCeram Bulk Fill[3],SonicFill[10]	Charisma Flow[4], Tetric EvoCeram[3]

Kim (58)	2015	Korea	Contraction Stress, Polymerization Shrinkage	SonicFill[10], Tetric EvoCeram Bulk Fill[3], SureFil SDR[1], Filtek Bulk Fill Flowable[6]	Filtek Z250[6], Filtek Z350 XT Flowable[6]
Kim (59)	2016	Korea	Contraction Stress, Polymerization Shrinkage, Elastic Modulus	SonicFill[10], Tetric EvoCeram Bulk Fill[3], SureFil SDR[1], Filtek Bulk Fill Flowable[6]	Filtek Z250[6], Filtek Z350 XT Flowable[6]
Lempel (35)	2016	Hungary	Degree of Conversion	X-tra base[1], SureFil SDR[3], Filtek Bulk Fill Flowable[6]	Filtek Ultimate Flowable[6]
Leprince (9)	2014	Belgium	Elastic Modulus, Flexural Strength	Tetric EvoCeram Bulk Fill[3], Venus Bulk Fill[4], SureFil SDR[2], X-tra Fil[1], X-tra base[1], SonicFill[10], Filtek Bulk Fill Flowable[6], Xenius Base[5], Coltene Dual-cure Bulk Fill[16]	Grandio SO[1], Grandio Flow[1]
Li (25)	2015	Belgium	Degree of conversion	EverX Posterior[5], Filtek Bulk Fill Flowable[6], SureFil SDR[2], Tetric EvoCeram Bulk Fill[3]	Herculite Ultra[10]
Lim (48)	2016	Singapore	Hardness	SureFil SDR[2]	Spectrum TPH[2]
Malik (46)	2014	Iraq	Hardness	Tetric EvoCeram Bulk Fill[3], SureFil SDR[2]	Filtek Z250[6]
Marigo (36)	2015	Italy	Degree of Conversion, Hardness	SureFil SDR[2]	Venus Diamond Flow[4], Filtek Supreme XTE Flowable[6], Enamel plus HRI[17]
Marovic (37)	2015	Switzerland	Contraction Stress, Degree of Conversion	SureFil SDR[2], Venus Bulk Fill[4], X-tra base[1]	EsthetX Flow[2]
Miletic (31)	2016	Belgium	Depht of Cure, Degree of Conversion, Hardness,	Tetric EvoCeram Bulk Fill[3], SureFil SDR[2], SonicFill[10], Xenius Base[5], Filtek Bulk Fill Flowable[6]	Tetric EvoCeram[3]
Moharam (49)	2017	Egypt	Hardness	X-tra Fil[1], SonicFill[10]	Filtek Z250[6]
Owens (32)	2015	USA	Depth of cure	SonicFill[10]	Herculite Ultra[10]
Oznurhan (63)	2015	Turkey	Flexural Strength	SureFil SDR[2], Tetric EvoCeram Bulk Fill[3], X-tra base[1]	Tetric EvoCeram[3]
Par (38)	2015	Croatia	Degree of Conversion	Tetric EvoCeram Bulk Fill[3], QuiXfil[2], X-traFil[1], Venus Bulk Fill[4], X-tra base[1], SureFil SDR[2], Filtek Bulk Fill Flowable[6]	GrandioSO[1], X-flow[2]
Pongprueksa (39)	2015	Belgium	Degree of Conversion	Filtek Bulk Fill Flowable[6]	Filtek Z250[6], Filtek Supreme XTE Flowable[6]
Son (50)	2016	Korea	Hardness	Filtek Bulk Fill Flowable[6], SureFil SDR[2], Venus BulkFill[4], SonicFill[8], Tetric EvoCeram Bulk Fill[3]	Tetric EvoCeram, Filtek Z350[6]
Tarle (40)	2015	Croatia	Degree of Conversion, Hardness	Tetric EvoCeram Bulk-Fill[3], X-tra Fil[1], QuiXfil[2], SonicFill[10]	Tetric EvoCeram[3]

Taubock (60)	2014	Switzerland	Contraction Stress, Polymerization Shrinkage,	SureFil SDR[2]	EsthetX Flow[2], EsthetX HD[2], Rebilda[1]
Taubock (61)	2015	Switzerland	Contraction Stress	Tetric EvoCeram Bulk Fill[3], X-tra Fil[1], QuiXfil[2], SonicFill[10]	Tetric EvoCeram[3]
Tsujimoto (33)	2016	Japan	Depth of cure, Flexural Strength, Fracture Toughness	Tetric EvoCeram Bulk Fill[3], SureFil SDR[2], EverX Posterio[5]	Filtek Z100[6], Tetric EvoCeram[3], Clearfil-AP-X[11]
Yantcheva (68)	2016	Bulgaria	Water sorption and solubility	SonicFill[10]	FiltekP60[6], Filtek Ultimate[6], Kalore[5], Venus Diamond[4], Filtek Silorane[6]
Yap (34)	2016	Singapore	Depth of cure, Hardness	Beautifil Bulk Flowable[8], Beautifil Bulk Restorative[8], SureFil SDR[2], Tetric EvoCeram Bulk Fill[3], EverX Posterior[5]	Filtek Z350 XT Flowable[6], Filtek Z350 XT Universal[6]
Zorzin (41)	2015	Germany	Contraction Stress, Polymerization Shrinkage, Degree of Conversion, Hardness	Filtek Bulk Fill Flowable[6], SureFil SDR[2], Tetric EvoCeram Bulk Fill[3], Venus Bulk Fill[4], X-tra base[1]	Filtek Supreme XTE Flowable[6], Filtek Z250 Universal Restorative[6]
Clinical trials					
Alkurdi (6)	2016	Syria	Modified USPHS criteria	Tetric EvoCeram Bulk Fill[3], SonicFill[10]	Tetric EvoCeram[3]
Bayrakatar (7)	2016	Turkey	Modified USPHS criteria	Filtek Bulk Fill Flowable[6] and Filtek P60, Tetric Evo Ceram Bulk Fill[3], SonicFill[10]	Clearfil Photo Posterior[11], Filtek P60[6]
Karaman (10)	2016	Turkey	Modified USPHS criteria	X-tra base[1]	Aelite Flo[18], GrandioSO[1]
Van Dijken (12)	2014	Sweden	Modified USPHS criteria	SureFil SDR[2]	Ceram Xmono[2]
Van Dijken (13)	2015	Sweden	Modified USPHS criteria	SureFil SDR[2]	Ceram Xmono[2]
Van Dijken (11)	2016	Sweden	Modified USPHS criteria	SureFil SDR[2]	Ceram Xmono[2]

[1]Voco; [2]Dentsply; [3]Heraeus Kulzer; [4]Ivoclar Vivadent; [5]GC Corporation; [6]3M ESPE; [7]Tokuyama DC; [8]Shofu; [9]Septodont; [10]Kerr Corporation; [11]Kuraray Dental; [12]GDF; [13]Jeneric; [14]Stick Tech; [15]Ultradent; [16]Coltene; [17]Micerium; [18]Bisco. USPHS: United States Public Health Service criteria.

Table 4. Principal outcomes of included clinical studies.

							Reasons for failure					
								Fracture		Endo/		
Study	**Study Design**	**Follow-up (y)**	**Material**	**n**	**Alive**	**Failed**	**Caries**	**Tooth**	**Restor.**	**Pain**	**Extr.**	**Other**
Alkurdi 2016 (6)	CT	1	SonicFill	20	20	0	0	0	0	0	0	0
			Tetric EvoCeram Bulk Fill	19	15	4	0	0	0	2	0	2
			Tetric EvoCeram	19	17	2	0	0	0	0	0	0
Bayraktar 2016 (7)	RCT	1	SonicFill	43	43	0	0	0	0	0	0	0
			Tetric EvoCeram Bulk Fill	43	43	0	0	0	0	0	0	0
			Filtek Bulk Fill Flowable	43	43	0	0	0	0	0	0	0
			Clearfil Photo posterior	43	43	0	0	0	0	0	0	0
Karaman 2016 (10)	CCT	1	X-tra base + GrandioSO	47	47	0	0	0	0	0	0	0
			Aelite Flo + GrandioSO	47	47	0	0	0	0	0	0	0
		3	X-tra base + GrandioSO	33	33	0	0	0	0	0	0	0
			Aelite Flo + GrandioSO	33	33	0	0	0	0	0	0	0
Van Dijken 2014 (12)	CCT	3	Surefil SDR + Ceram X Mono	52	52	0	0	0	0	0	0	0
			Ceram X Mono	52	50	2	0	1	1	0	0	0
Van Dijken 2015 (13)	CCT	3	Surefil SDR + Ceram X Mono	98	94	4	2	2	0	0	0	0
			Ceram X Mono	98	95	3	0	2	1	0	0	0
Van Dijken 2016 (11)	CCT	5	Surefil SDR + Ceram X Mono	52	52	0	0	0	0	0	0	0
			Ceram X Mono	52	50	3	0	1	1	0	0	0
			Total Bulk Fill composites	448	440	8	2	2	0	2	0	2
			Total Conventional composites	344	335	10	0	4	3	0	0	0

RCT: Randomized Clinical Trial; CCT: Controlled Clinical Trial; CT: Clinical Trial;

Appendices

Appendix A. Studies were not included.

Reason	Studies
14 studies could not be retrieved in full-text version	(1-14)
2 studies were presented in a different language than English, Portuguese or Spanish	(15, 16)
70 studies did not evaluate the properties of interest	(17-86)
57 studies did not meet with methodology inclusion criteria (evaluated stress by using indirect methods or predictive analyses; or did not evaluate hardness or degree of conversion in depth: top and bottom evaluation at least 4 mm for bulk fill and 2 mm for conventional resin composite)	(87-132)
43 studies did not compare bulk fill and conventional resin composites	(133-175)
7 were review study	(176-182)
3 studies were a case report or case series	(183-185)
1 was experimental material	(186)

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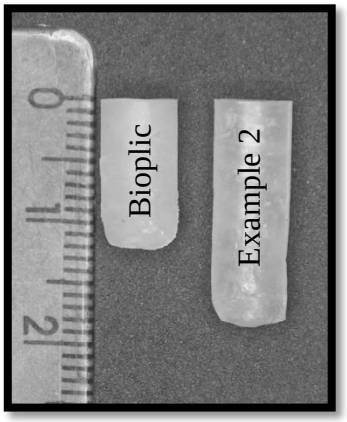
4 Capítulo 3

LOW ELASTIC MODULUS COMPOSITES WITH HIGH POLYMERIZATION DEPTH, SELF-ADHESIVE BEHAVIOR AND ANTIBACTERIAL PROPERTIES: FORMULATIONS AND RESTORATIVE METHODS

ABSTRACT

The present invention relates a polymerizable low elastic modulus dental restorative compositions with increased deep of cure, antibacterial properties, excellent sealing, due its controlled volume expansion, and its self-adhesive characteristics. The materials have translucent or clear-color aspect and elastomeric behavior after cured, which allows to the dentist easy identification and to remove it easily through hand instruments. Add to that, relates its use in the form of bulk-fill application.



THECNICAL FIELD

The present invention relates to polymerizable composite formulations for dental use. This invention particularly relates to a dental composite resin material which can be used as temporary filling material, as material for sealing of prepared cavities, as material for sealing of root canal entrances, and as material to seal the screw access channel of prosthetic implant abutments.

Also, the present invention particularly relates composite formulations that are excellent in sealing, since it's can adhere to mineralized tooth structures and undergoes a hygroscopic expansion after curing. Sealing cavity margins is improved by its self-adhesive properties or concomitant to application specific self-adhesive primers. These materials are also characterized by its high polymerization depth, easy visual identification and its

easy removability of the cured material due its low elastic modulus and flexible behavior. In addition, it avoids bacterial infiltration due its antibacterial properties. The composition is suitable to be used in the form of bulk-fill application, in condensable, medium or flowable presentations.

BACKGROUND ART

Temporary sealing materials are used to temporarily seal the cavity during several dental treatments. Before to restorative procedures, there are many clinical situations that demand for temporary materials usage, i.e., when dealing with complex restorations, there may be a delay until the final restoration is performed, and a temporary material should be placed between appointments or when endodontic treatment is not concluded in one single session and a temporary restoration is required in order to avoid the penetration of fluids, organic materials and microorganisms from the oral cavity into the root canal system. Additionally, easy removable materials are necessary to seal the screw access channel to protect the screw head of the abutment and crown screw in implanted-retained restorations.

Currently, a wide variety of materials are used for temporary restorations. They include zinc oxide eugenol (ZOE) based materials, calcium sulfate based materials, glass ionomer materials and composite resin based materials. ZOE-based materials are recognized for its sedative, anti-bacterial and anti-inflammatory properties, however, its present low mechanical properties, low abrasion resistance, hardness and poor marginal sealing. Besides, its major properties depend largely on the powder to liquid ratio used, and incorrect manipulation may increase the potential cytotoxicity due to excess of eugenol.

Calcium hydroxide based materials exhibit minor leakage due its high hygroscopic set after permeation with water, nevertheless, it has been founded that these type of materials present long setting time, high solubility and quickly disintegrates, which decreases its mechanical properties. Thus, its usage in large cavities or in teeth weakened by extensive loss of mineral structures should be avoided.

About glass ionomer (GIC) materials, they have some advantages compared to ZOE and Calcium sulfate based materials. GIC materials

possesses antibacterial properties due to fluoride release and is ability to bond to hard tissues, preventing marginal leakage. However, the chemical adhesion mechanism and major mechanical properties make its removal very difficult, many times resulting in enlargement of the tooth cavities.

Regarding composite resin based materials, they were introduced to overcome some disadvantages related to the other types of temporary materials. Mainly those disadvantages related to the working time, sealing capability and the difficulty to remove. In fact, in the last years, some resin based temporary materials have been related into the patent literature. For example, the patent US 2011/0070563 relates an easily removable dental curable composition with long working time and excellent x-ray contrast. Another example can be founded in the document US 2015/0342840 A1, where a dental resin temporary sealing material composition with adhesion to the tooth substance and preventing function by releasing ions is described. On the other hand, the patent WO 2006/045646 discloses a temporary sealing material based in addition-crosslinking silicones. Moreover, the document US 5,865,623 relates a flexible dental composite compositions and restorative compositions which exhibit good bonding to tooth dentin and enamel and which also possess good tensile and compressive strengths. Also, the document US 6,133,339 describes a transparent, elastomeric dental cement composition suitable for temporary or provisional restorations with high translucency great flexibility. Finally, the patent number US 6,136,886 discloses a novel biorestorative material which is a rubber elastic material for restoring the living body, and is specifically used as dental prosthetic materials.

None of the documents mentioned discloses a polymerizable low elastic modulus dental restorative compositions with increased deep of cure, antibacterial properties, excellent sealing, due its controlled volume expansion, and its self-adhesive characteristics for use as temporary restorative material.

SUMMARY OF INVENTION

Technical problem

Nowadays, several materials can be used as a temporary restorative material, however, they present some drawbacks as poor sealing, difficult of handling,

unsatisfactory mechanical properties, low biocompatibility, difficult for visual detection, long setting time, difficult to remove and lack of antibacterial properties. Moreover, some of them are incompatible with light-cured polymeric materials and can inhibit its free radical polymerization.

Solution to problem

The present invention relates to composite formulations which can attend the several properties demands in one single presentation. These composites formulations are easy handling and easy application as it can be used in the form of one-paste photopolimerizable or two-paste dual polymerizable material. It has adequate sealing capacity due its hygroscopic expansion and due its self-adhesive properties; this sealing capacity can be improved by using a specific self-etching adhesive. In addition, the formulation described in the present invent can prevent bacterial infiltration due its antibacterial properties. Also, these presentations can be applied using a bulk-fill technique once they present high depth of cure. Finally, they are easily identifiable due its color-less aspect and easy to remove due its flexible behavior after curing.

These formulations include: (a) 10 % to 95% by weight of an elastomeric di-methacrylate monomer; (b) 5% to 40% by weight of a crosslinking monomer; (c) 0% to 50% by weight of an acidic-functional monomer; (d) 1% to 20% by weight of a hydrophilic mono-methacrylate monomer; (e) 5% to 35% by weight of plasticizers; (f) 1% to 90% by weight of fillers; (g) 0.1% to 10 % by weight of a polymerization catalyst system; (h) 0.01% to 1% by weight of a polymerization inhibitor; and (i) 0.5% to 10% by weight of an antibacterial agent.

Moreover, the present invention includes a restorative method which can improve the sealability properties of the formulation described above. Where such restorative method involves the use of a single or multiple layer of a self-adhesive composition on the enamel margins of the cavity and if necessary, this self-adhesive composition can be used on dentin to improve the retention of the restoration.

Such self-adhesive composition includes: (a) 10 % to 60% of an acidic-functional monomer; (b) 5 to 70% of hydrophilic monomer; (c) 5 to 70% of hydrophobic monomer and (d) 40 to 90% of a solvent.

DETAILED DESCRIPTION OF THE INVENTION

The formulations and methods of the present invention have particular application in the field of endodontic, prosthesis and restorative dentistry. The formulations according to the present invention comprise at least an elastomeric monomer with high molecular weight, an acidic-functional monomer, a hydrophilic mono-methacrylate monomer, a crosslinking monomer, a plasticizer, fillers, a polymerization catalyst system, a polymerization inhibitor and antibacterial agents. Preferably, the formulation of the present invention consists of a single paste, although it is also possible to obtain in a two-paste presentation. Moreover, all the formulations can be used in the form of bulk-fill application, comprising condensable, medium or flowable viscosities to be used according each clinical case demand.

Elastomeric monomers give elastic properties to cured material. These types of monomers have elongation and toughness properties which implies mobility and capability to relax the polymer network. Moreover, these monomers have the potential of acquiring high depth degree conversion, which associated to an appropriated initiators system, may improve physical and biological cured polymer properties. The elastomeric monomers of the present invention are not particularly limited. Examples of monomers which can be used in the formulation include high-molecular weight ethyl acrylates, butyl acrylates or methoxy ethyl acrylates having at least one unsaturated bonds. Monomers with two unsaturated groups are preferred because cross-linked polymers with higher stability are obtained. Specific samples of elastomeric monomers include DDDMA (1,12-Dodecanediol dimethacrylate), UDMA (urethane dimethacrylate), PPGMA (Polypropyleneglycol Monomethacrylate), DDDMA10 (1,10-decanediol dimethacrylate), LMA (Lauryl methacrylate), polyethylene glycol dimethacrylates (PEGDMA), ethoxylated bisphenol A diglycidyl dimethacrylates (Bis-EMAs) with variable oxyethylene units, PEG 400 Extended Urethane Dimethacrylate and

Exothane™ Elastomers. These monomers may be used singly or in combination. The content of the elastomeric monomer is preferably in the range of 10% to 95% by weight, and more preferably in the range of 60% to 90% by weight with respect to the total weight of the formulation.

Acidic-functional monomers allow the material to self-adhere to unetched tooth mineralized tissues. This feature improves the sealing ability of the material. The acidic-functional monomers of the present invention are not particularly limited. Examples of monomers which can be used in the formulation include acrylate or methacrylate compound with phosphoric, carboxylic or sulfonic acidic groups. Specific examples of the acidic-functional monomers include12-methacryloyloxy-dodecyl-dihydrogen phosphate, methacryloyloxy-tetraethylene-glycol-dihydrogen phosphate, methacryloyloxy-caprolactone dihydrogen phosphate, 2-methacryloyloxy-ethyl-dihydrogen phosphate, Bis [2-(methacryloyloxy) ethyl] phosphate, Phosphoric acid 2-hydroxyethyl methacrylate ester and 2-Acrylamido-2-methylpropane sulfonic acid. The content of the acidic functional monomer is preferably in the range of 5% to 50% by weight, and more preferably in the range of 10% to 30% by weight with respect to the total weight of the formulation.

The formulations of the present invention also include suitable co-monomers containing one or more unsaturated bonds capable of copolymerize with the elastomeric monomers. To achieve desirable properties of the formulations described in this invention, three different types of co-monomers are preferred. First, hydrophilic polymerizable monomers which gives the ability to the material of swelling, second, crosslinking monomers which enhances the mechanical properties of the polymer network and, finally, metallic polymerizable monomers, which gives the antibacterial feature to the material.

The hydrophilic polymerizable monomer allows to the hardened material to absorb water and therefore, a controlled swelling of the material is achieved. Uniform swelling is useful in order to improve the sealing of the material. The hydrophilic elastomeric monomers of the present invention are not particularly limited. Examples of monomers which can be used in the formulation include

high-molecular weight ethyl acrylates, butyl acrylates or methoxy ethyl acrylates having at least one unsaturated bonds. Monomers with two unsaturated groups are preferred because cross-linked polymers less prone to hydrolytic effects are obtained. Specific examples of the hydrophilic polymerizable monomer include, 2-hydroxypropyl-1,3-di(meth)acrylate, 3-hydroxypropyl-1,2-di(meth)acrylate, pentaerythritol di(meth)acrylate, ethoxylatedbisphenol-A dimethacrylate (the number of oxyethylene groups is greater than or equal to 8) and polyethylene glycol di(meth)acrylate (the number of oxy ethylene groups isgreater than or equal to 20). The content of the hydrophilic monomer is preferably in the range of 5% to 40% by weight, and more preferably in the range of 10% to 30% by weight with respect to the total weight of the formulation. These monomers may be used singly or in combination.

The crosslinking monomers enhance the mechanical properties of the material, especially increasing the tear strength without increasing stiffness, thereby preventing its deviation when removed. The crosslinking monomers of the present invention are not particularly limited. Examples of monomers which can be used in the formulation include high-molecular weight ethyl acrylates, butyl acrylates or methoxy ethyl acrylates having two unsaturated bonds. Specific examples include, 2,2-bis[4-(2-hydroxy-3-methacryloxypropoxy)phenyl]propane, triethylene glycol dimethacrylate and urethane dimethacrylate. The content of the crosslinking monomer is preferably in the range of 5% to 40% by weight, and more preferably in the range of 10% to 30% by weight with respect to the total weight of the formulation. These monomers may be used singly or in combination.

The antibacterial metallic polymerizable monomers included in the related formulation gives an antibacterial ability to the material. Antibacterial compounds which remains bounded to the polymeric matrix are desirable because they are not eluted and the antibacterial activity its preserved. The metallic monomers of the present invention are not particularly limited. Examples of monomers which can be used in the formulation include acrylates, butyl acrylates or methoxy ethyl acrylates with metallic functional groups having at least one unsaturated bonds. Specific examples of the metallic polymerizable

monomer include: silver methacrylate, tin methacrylate, zinc methacrylate, iron methacrylate, zirconium methacrylate, titanium methacrylate and copper methacrylate. The content of the antibacterial metallic monomer is preferably in the range of 0.5% to 5% by weight, and more preferably in the range of 1% to 4% by weight with respect to the total weight of the formulation. These monomers may be used singly or in combination.

In order to improve flexibility and hygroscopic expansion of the hardened material a plasticizer is used in the present formulation. The plasticizers of the present invention are not particularly limited. Examples of plasticizers are saturated or inert liquid organic compounds including dicarboxylic/tricarboxylic ester-based plasticizers, trimellitates and low-molecular-weight polyglycols. Specific examples of plasticizers include bis(2-ethylhexyl) phthalate, di-n-butyl phthalate, dioctyl phthalate, n-octyltrimellitate, Tri-(2-ethylhexyl) trimellitate, polyethylene glycol (mean average molecular weight 500-4000) and polypropylene glycol (mean average molecular weight 500-4000). The content of the plasticizer is preferably in the range of 5% to 35% by weight, and more preferably in the range of 10% to 25% by weight with respect to the total weight of the formulation. These plasticizers may be used singly or in combination.

The formulations related in the present invention can be used in the form of condensable, medium or flowable bulk fill composite. The fillers in the formulation of the present invention are chosen primarily for viscosity modification. The filler of the present invention are not particularly limited. Fillers according to the present invention may include silicon dioxide and glasses. Examples of fillers are inorganic metal salts, inorganic oxides, silicates, aluminosilicates, aluminoborosilicates, fluoraluminosilicates, colloidal silica, precipitated silica and polymers. A preferred fillers size is nanometric (1 – 100 nm), sub-micrometric (0.1 – 1 μ), and micrometric (1 – 100μ). A preferred filler coating is with or without silane coupling agent. The content of the filler is preferably in the range of 1% to 90% by weight, and more preferably in the range of 20% to 40% by weight with respect to the total weight of the formulation. These fillers may be used singly or in combination.

Preferably, the formulation of the present invention consists of one component in the form of single paste, although it is also possible to obtain in a two paste form. In the single-paste presentation, a mixture of photoinitiators and accelerators are added to the formulation to make it light-curable. The photoinitiators of the present invention are not particularly limited. Examples of photoinitiators include camphorquinone, tioxanthone derivatives, bis-acylphosphine oxide, mono-acylphosphine oxide, propanedione derivates, iodonium antimonate derivates, and the benzoyl germanium derivatives. A preferred photoinitiator is the camphorquinone. In addition, at least one accelerator is used to improve the polymerization rate of the material. Examples of accelerators include sulfonic or barbituric acid derivatives, diphenyliodonium hexafluorophosphate, iodonium antimonate derivates, piperonyl alcohol derivates, benzodioxol derivates, 4-dimethylamino ethyl benzoate and tertiary amines. Additionally, more than one accelerator can be used to increase de degree conversion. The content of the photoactivation system is preferably in the range of 0.1% to 10% by weight, and more preferably in the range of 0.2% to 5% by weight with respect to the total weight of the formulation. Also, the amount of photoinitiators and accelerators used can be determinate according with the molecular weight of the methacrylate compounds.

When used in the two-paste form, an initiation system for chemical polymerization is used associated to the photoinitiators. Such initiation system is a redox system that comprises at least one polymerization initiator and one polymerization accelerator. The polymerization initiator is an organic peroxide such as benzoyl peroxide or hydrogen peroxide used singly or in combination. The polymerization accelerator is one tertiary amine such as the N, N-hydroxyethyl-p-toluidine, N, N-dimethyl-p-toluidine, cooper derivatives and sulfinic acid derivatives used singly or in combination. The content of the redox system is preferably in the range of 0.1% to 10% by weight, and more preferably in the range of 0.2% to 5% by weight with respect to the total weight of the formulation. Also, the amount of initiators and accelerators used can be determinate according the molecular weight of the methacrylate compounds.

The formulation related in the present invention also includes a polymerization inhibitor, which is used to scavenge free radicals during the storage and

therefore, to improve the shelf life of the formulation. Examples of polymerization inhibitors that may be employed are butylated hydroxytoluene, hydroquinone, hydroquinone monomethyl ether, and benzoquinone used singly or in combination. The content of the polymerization inhibitor is preferably in the range of 0.01% to 3% by weight, and more preferably in the range of 0.02% to 0.5% by weight with respect to the total weight of the formulation. Also, the amount of polymerization inhibitors used can be determinate according the molecular weight of the methacrylate compounds.

Improved sealability of above mentioned formulations can be increased when a single or multiple layer of an adhesive promotor composition on the enamel margin is applied. Such adhesive promotor composition includes at least a functional monomer with acidic group, a hydrophilic monomer, a hydrophobic monomer, and a solvent. The functional monomer with acidic group of the present invention are not particularly limited. Examples or functional monomer with acidic group are 10-methacryloyloxy-decyldihydrogen phosphate, 12-methacryloyloxy-dodecyl-dihydrogen phosphate, methacryloyloxy-tetraethylene-glycol-dihydrogen phosphate, methacryloyloxy-caprolactone dihydrogen phosphate, 2-methacryloyloxy-ethyl-dihydrogen phosphate, Bis[2-(methacryloyloxy) ethyl] phosphate, Phosphoric acid 2-hydroxyethyl methacrylate ester or 2-Acrylamido-2-methylpropane sulfonic acid. The content of the functional acidic monomer is preferably in the range of 5% to 50% by weight, and more preferably in the range of 10% to 30% by weight with respect to the total mass weight of the formulations. These functional acidic monomers may be used singly or in combination.

The hydrophilic monomer included in such adhesive composition is not particularly limited. Monomers with one unsaturated bonds are preferred because more wettability is expected. Examples of such monomers include hydroxylethyl methacrylate, hydroxyethyl acrylamide, propyleneglycol monomethacrylate or glycerol monomethacrylate. The content of the hydrophilic monomer is preferably in the range of 5% to 40% by weight, and more preferably in the range of 20% to 40% by weight with respect to the total mass

weight of the formulations. These hydrophilic monomers may be used singly or in combination.

The hydrophobic monomer included in such adhesive composition is not particularly limited. Monomers with one unsaturated bonds are preferred because more wettability is expected. Examples of such monomers include 1, 12 - Dodecanediol dimethacrylate, 1, 6- Hexanediol Dimethacrylate, Bisphenol A Glycidyl Methacrylate. The content of the hydrophobic monomer is preferably in the range of 20% to 50% by weight, and more preferably in the range of 5% to 70% by weight with respect to the total mass weight of the formulations. These hydrophobic monomers may be used singly or in combination.

Adhesive promotor composition for improve sealability includes solvents to facilitate penetrating of acidic monomers into dental tissues. The solvents are not particularly limited. Examples of solvents that can be used are ethanol, methanol, acetone or water. The content of solvent is preferably in the range of 40% to 95% by weight, and more preferably in the range of 60% to 80% by weight with respect to the total weight of the formulations. These solvents may be used singly or in combination.

Preferred methods for using the previously described flexible composite and self-adhesive formulations include their use as temporary restorations in conventional restorative procedures. The condensable bulk-fill application can be used as Class I, Class II, inlay/onlay temporary restorations, also it can be used as temporary material when endodontic treatment is not concluded in one single session or as a sealing material in non-vital bleaching procedures. Such methods include the cleaning of the tooth surface, followed optionally by application of the self-adhesive promote composition previously described, followed by application and curing of the flexible composite formulation described above.

Another method for using the previously flexible composite formulations include their use as material for identify and sealing of root canal entrances. The

flowable form of the material must be used for such application. Such method includes the cleaning of the tooth surface, followed by applying of one layer of the flexible formulation in the flowable form into to the root canal entrance and polymerizing and hardening said dental composition.

The following examples are given in order to provide a better understanding of the present invention. The results of different experiments carried out with respect to this invention are presented as examples. The results of this invention are presented compared to other commercially available temporary restorative material (Bioplic; Biodinâmica, Brazil). Such examples are presented only by way of illustration but without limitation.

EXAMPLE 1

One of the possible formulation in the single paste form is described below:

Component	Example of monomer	Preferred concentration (%)
Elastomeric monomer	Exothane 8	40 - 80
Hydrophilic monomer	BisEMA30	20 – 60
Crosslinking monomer	TEGDMA	1 – 20
Photoactivation system	Camphorquinone Ethyl 4-(dimethylamino)benzoate Diphenyliodoniumhexafluorophosphate	0.05 – 2 0.1 – 4 0.05 – 2
Inhibitor	Hydroquinone	0.005 – 0.5
Metal methacrylate	Zinc methacrylate	0.1 – 5
Filler	Aerosil 380	5 – 50

EXAMPLE 2

Another possible formulation in the single paste form is described below:

Component	Example of monomer	Preferred concentration (%)
Elastomeric monomer	Exothane 32	40 - 80
Hydrophilic monomer	BisEMA30	20 – 60
Crosslinking monomer	UDMA	1 – 20
Photoactivation system	Camphorquinone Ethyl 4-(dimethylamino)benzoate Diphenyliodoniumhexafluorophosphate	0.05 – 2 0.1 – 4 0.05 – 2
Inhibitor	Hydroquinone	0.005 – 0.5
Metal methacrylate	Di-m-butyl dimethacrylate	0.1 – 5
Filler	Aerosil 380	5 – 50

Material performance: degree of conversion.

The degree of conversion of the experimental materials was evaluated using Fourier-transform infrared. The degree of conversion was calculated based on the intensity of the carbon–carbon double-bond stretching vibrations (peak height) at 1635 cm^{-1} and using the symmetric ring stretching at 1610 cm^{-1} from the polymerized and non-polymerized samples as an internal standard (n=3).

Material performance: Depth of cure

The materials were filled into a cylindrical stainless mold (6 mm diameter and 20 mm high) and irradiated through a polyester strip for 20 s. The material was extracted from the mold and the uncured material was removed by scraping

method. The maximum thickness of the cured material was measured with a digital caliper and divided by two (n = 3).

Material performance: mechanical strength

Dumbbell-shaped specimens were prepared using stainless molds (10 mm long, 5 mm wide and 1 mm constriction). The top and bottom surfaces were light-activated for 20 s. After confection, a tensile test was conducted. Ultimate tensile strength values were calculated in MPa (n=10).

Material performance: dimensional alterations

Formulation was placed into cylindrical silicone molds (20 mm height, 6 mm diameter), covered with a polyester strip and cured with the LED curing unit for 20 s. The initial length of each specimen was measured with a digital caliper. Specimens were then stored in 100% humidity at 37 °C for 30 days. After that, specimens' final length was determined (n=8). The percentage of dimensional change was calculated and expressed in % according to the following formula:

$$\frac{.B\ F\ .\ i}{}$$

Where Li is the initial height of the samples and Lf is the final height.

Material performance: Water sorption and solubility

The materials were filled into a metal mold (1 x 5 mm) and photoactivated for 20 s. Samples were dry stored at 37 ºC and repeatedly weighed after 24 hr intervals on a digital analytical balance with an accuracy of 0.01 mg until a constant mass was obtained. The samples were then immersed individually in distilled water and stored at 37 °C. After 7 days the surface water of the samples was removed and the mass of each sample was again recorded. The samples were again stored dry at 37 ºC and weighed again until a constant mass was obtained. Water sorption and solubility were calculated as the percentage mass gain or loss during the sorption and desorption cycles (n=8).

Material performance: modified contact direct test.

Cylinder-shaped specimens (6.0 x 1.0 ±0.1 mm) were placed in the wells of a 96-wells plate. Subsequently 10µL bacterial suspension (Enterococcus faecalis)

was placed onto the surface of the materials tested. Samples were incubated aerobically for 1 and 24 hours at 37°C in >95% humidity; then 240 mL of TSB was added to each of the wells and gently mixed with a pipette for 1 minute. After aerobic incubation for 24 hours at 37°C, CFUs were contained, and CFU/mL was calculated (n=3).

Material performance: cytotoxicity test.

A cell line from L929 mouse fibroblasts was used. The cell culture medium used was DMEM (Dulbeccos's Modified Eagle Medium) supplemented with 10% fetal bovine serum (FBS), 2% L-glutamine, penicillin (100U/ml) and streptomycin (100 mg/ml). In each test well from a 96 well plate $2x10^4$ cells were placed in 200µl of DMEM plus 10% FBS. The plate was incubated in a CO_2 oven with temperature and pressure control in a humid environment at 37ºC, 95% air and 5% CO_2 for 24h in order to allow the adhesion of the cells to the bottom of the culture plate. The cytotoxicity test was done according to ISO 10993-5 (2009). Cell viability was assessed by the WST-1 colorimetric assay (Roche). The materials were filled into a mold (5 x 1mm), and photoactivated for 20 s (n=12). The specimens were placed into 24-well plates with 1 ml of DMEM and stored at 37 °C at pH 7.2. After 24 h, 200 µl of the eludate from each specimen was transferred to the 96-well plate containing the cells pre-primed. The plate was then incubated (37° C, 5% CO_2) for 24h. After this period, the medium was sucked and the WST-1 solution was applied. The results were read in a spectrophotometer with a wavelength of 450nm, where absorbance values were considered as an indicator of cell viability.

Material performance: shelf-life.

The material shelf life was evaluated through the accelerated aging test as previously described (See Clark, G.,1991. Shelf life of medical devices. Guidance Document. In: Division of small manufacturers assistance,C., FDA). The accelerated aging (60 ºC) time equivalent to the shelf life at room temperature (22 ºC) was calculated according to the following formula:

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Where r is the accelerated aging ratio, RT is room temperature (22 ºC), ET is heating temperature (60 ºC) and Q_{10} is reaction coefficient constant (2).
The material was stored in an oven at 60 ºC and after 0, 1, 2, 3, 4 and 5 weeks (equivalent to 0, 3, 7, 10, 14 and 17 months of aging at room temperature) was evaluated for the degree of conversion. In addition, the visual appearance of the material was analyzed by observing phase separation and auto-polymerization.

Results of the materials performance:

Table 1. Results of the materials performance (Mean ± SD)

	DC (%)	DOC (mm)	UTS (MPa)	W_S (%)	W_{SL} (%)	DS (%)
Ex. 1	97.33 ± 1.1	7.71 ± 0.05	10.5 ± 2.3	9.39 ± 0.61	0.22 ± 0.17	2.33 ± 0.1
Ex. 2	92.67 ± 0.92	8.59 ± 0.6	9.03 ± 1.05	5.12 ± 0.45	0.05 ± 0.01	2.26 ± 1.9
Bioplic	69.49 ± 2.81	5.61 ± 0.33	12.32 ± 2.16	5.83 ± 2.67	0.06 ± 0.03	1.39 ± 2.1

DC: Degree of conversion; DOC: Depth of cure; UTS: Ultimate tensile strength; W_S: Water sorption; WSL: Water solubility; DS: Dimensional stability.

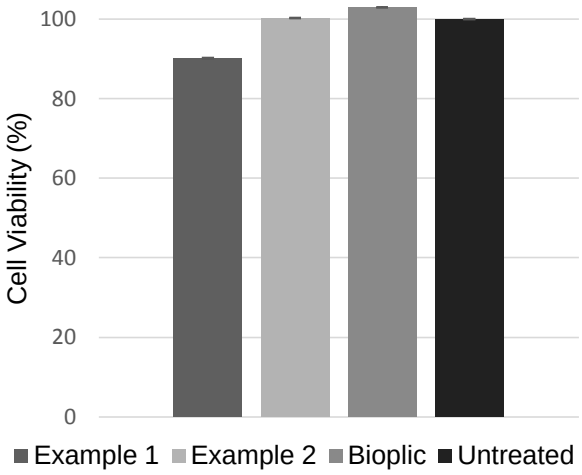

Fig 1. Cell viability.

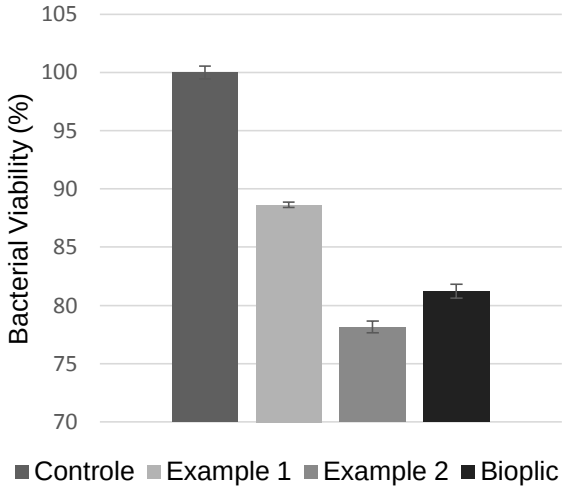

Figure 2. Antibacterial activity.

Table 2. Results of degree of conversion (Mean ± SD) of the material after accelerated aging

	Shelf life (months)					
	0	3	7	10	14	17
Ex. 2	92.67 ± 0.92	94.44 ± 0.92	94.98 ± 2.08	94.83 ± 3.26	92.67 ± 0.92	89.19 ± 2.12

CLAIMS

1. An antibacterial flexible temporary restorative dental composition with high polymerization depth and controlled volume expansion, comprising but not restricted to a resinous mixture composed of an elastomeric monomer, a hydrophilic monomer and a crosslinking monomer; at least one type of plasticizer, at least one type of filler, at least one polymerization catalyst system, at least one polymerization inhibitor and at least one antibacterial agent.
2. The dental composition according to claim **1** with incorporation of an acidic monomer resulting in a self-adhesive resin.
3. The dental composition according to claim **2**, where in the acidic monomer comprises an acrylate ester, methacrylate ester or acrylamide with phosphoric, carboxylic or sulfonic acidic groups in the range of 5 to 50%.
4. The dental composition according to claim **1** and **2**, which comprises an easily removable temporary material which can be used as high viscosity (condensable) or low viscosity (flowable) material according filler content.
5. The dental composition of claim **1**, wherein the elastomeric oligomer comprises a high molecular weight urethane acrylate compound in the range of 10 to 95 weight percent.
6. The dental composition of claim **1**, wherein the hydrophilic monomer comprises a high molecular weight acrylate compound with ether moieties in the range from 5% to 40% by weight.
7. The dental composition of claim **1**, wherein the plasticizer comprises phthalate esters, dibasic acid esters, glycerol esters, phosphate esters and carboxylate esters used singly or in combination in the range from 5 to 35% by weight.
8. The dental composition of claim **1**, wherein the filler comprises inorganic metal salts, inorganic oxides, silicates, aluminosilicates, aluminoborosilicates, fluoraluminosilicates, colloidal silica, precipitated silica and polymers used singly or in combination in the range from 1 to 50% by weight.

9. The dental composition of claim **1**, wherein the polymerization catalyst system comprises both chemical, photoinitiated and dual cured polymerization systems in the range of 0.1% to 10% by weight.
10. The dental composition of claim **9**, wherein the initiation system for chemical polymerization is a redox system that comprises a polymerization initiator and a polymerization accelerator.
11. The dental composition of claim **10**, wherein said polymerization initiator is an organic peroxide like the benzoyl peroxide or the hydrogen peroxide used singly or in combination.
12. The dental composition of claim **10**, wherein said polymerization accelerator is one tertiary amine like the N, N-hydroxyethyl-p-toluidine, N, N-dimethyl-p-toluidine and sulfinic acid derivatives used singly or in combination.
13. The dental composition of claim **9**, wherein the initiation system for photoinitiated polymerization comprises a mixture of a photoinitiator and photopolimerization accelerators.
14. The dental composition of claim **14**, wherein said photoinitiator comprises a diketone or phosphine oxide derivatives like camphorquinone, tioxanthone derivatives, bis-acylphosphine oxide, mono-acylphosphine oxide, propanedione derivates, iodonium antimonate derivates, and the benzoyl germanium derivatives used singly or in combination.
15. The dental composition of claim **13**, wherein said accelerator are sulfonic or barbituric acid derivatives, iodonium salts, aminespiperonyl alcohol derivates, benzodioxol derivates and terciary amines used singly or in combination.
16. The dental composition of claim **1**, wherein the antibacterial agent comprises a polymerizable monomer in the range of 0.5 to 5% by weight.
17. The dental composition of claim **16**, wherein the polymerizable antibacterial monomer comprises quaternary ammonium salts compounds and its derivatives.
18. The dental composition of claim **16**, wherein the polymerizable antibacterial monomer comprises silver methacrylate, tin methacrylate,

zinc methacrylate, iron methacrylate, zirconium methacrylate, titanium methacrylate and copper methacrylate used singly or in combination.

19. The dental composition of claim **1**, wherein the polymerization inhibitor is butylated hydroxytoluene, hydroquinone, hydroquinone monomethyl ether, and benzoquinone used singly or in combination in the range of 0.01 to 3% by weight.
20. The dental composition of claim **1**, which comprises an easily removable temporary material without the need of using hand piece and burs due its high-elastic feature after polymerization.

5 Considerações Finais

Há evidências na literatura sugerindo que existem diversas estratégias relacionadas a composição do material que podem reduzir/controlar a tensão de contração gerada por materiais restauradores resinosos. A modificação da matriz resinosa parece ter uma maior contribuição na redução da tensão de contração que a modificação das partículas de carga e da interface resina-carga. A tecnologia de redução de tensão utilizada na formulação de materiais comerciais de baixa contração e de resinas *bulk fill* também apesentou potencial aplicação para reduzir/controlar o desenvolvimento de tensão. De maneira geral, a revisão sistemática revelou que as resinas bulk fill apresentaram maior profundidade de polimerização e desempenho semelhante ao das resinas compostas convencionais em relação à resistência mecânica. Os estudos *in vitro* e clínicos sugerem que os materiais restauradores do tipo *bulk fill* parecem ter um desempenho semelhante ou melhor do que as resinas compostas convencionais. No entanto, a evidência destes resultados deve ser considerada com cautela e pode variar de acordo com o material avaliado. Além disso, estudos clínicos com longos períodos de acompanhamento devem ser realizados para avaliar se o desempenho das resinas *bulk fill* é comparável às resinas compostas convencionais em longo prazo.

Além disso, o material restaurador temporário do tipo *bulk fill* desenvolvido parece ter potencial aplicação na odontologia. Visto que, os resultados das propriedades avaliadas sugerem que ele apresenta um excelente selamento marginal, propriedades antimicrobianas, e a vantagem de ser facilmente aplicado e removido na cavidade dental.

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