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Review Article

CLINICAL DURABILITY OF BULK FILL COMPOSITE MATERIAL USED IN RESTORATIVE DENTISTRY- A SYSTEMATIC REVIEW

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ABSTRACT

Introduction: In an effort to overcome many of the downsides associated with an incremental approach of to placing resins, new restorative materials have been marketed as “Bulk-Fill” composites. Bulk-fill composites are resin-based, tooth-colored restorative materials that incorporate increased polymerization depth, decreased polymerization shrinkage stresses, and cuspal deflection rates. They can be inserted into prepared cavities in layers that are up to 4 or 5 mm thick. The main aim of this review is to assess Clinical Durability of Bulk Fill Composite material used in Restorative Dentistry.

Method: Electronic search of PubMed, Google Scholar, Institutional Library, CTRI, Ind Med, Google and manual search using DPU college library resources and E-mail to authors revealing information about Clinical Durability of Bulk Fill Composite material used in Restorative Dentistry. All cross reference lists of the selected studies were screened for additional papers that could meet the eligibility criteria of the study.

Result: Total of 37 articles were searched out of which 19 articles were selected after reading title and abstract. As a second step, full text papers were obtained. However studies in which different bulk fill composite materials durability was tested were selected. Finally a total of 19 articles were included out of which 12 articles were excluded on basis of insufficient data and 7 articles were selected for final synthesis.

Conclusion: Bulk fill composite material of 4mm increments showed a good clinical durability.

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INTRODUCTION

In many countries resin composites do have almost totally replaced amalgam as a restorative material in posterior teeth¹. As a result of an increased focus on the aesthetic qualities of dental restorations, tooth-colored resin composite materials are increasingly being used for posterior teeth, instead of the more traditional amalgam fillings.²

The majority of the resin composites today are methacrylate based and cure by means of a free radical polymerization. During curing of the monomers, a network of polymers is formed which becomes rigid due to increasing cross-linking of the polymer chains. In the post-gel contraction phase, the shrinkage mani-fests as a strain on the resin composite and cavity walls which may result in interfacial deficiencies, enamel fractures, cuspal movements and cracked cusps. Gap formation may increase the potential for post-operative

sensitivity, microleakage and secondary caries. The resulting stress depends on factors like: resin monomers involved, filler technology, gel point, C-factor of the cavity, elastic modulus of the resin composite, curing technique and conversion rate.⁹⁻¹⁵

It has been stated that posterior Class II and especially Class I cavities with a high C-factor will result in greater stresses due to a larger number of bonded surfaces¹⁶. However, the correlation of interfacial stress and the clinical outcome is weak, as shown in long-term follow-ups. Resin composites with a lower modulus of elasticity or slower curing rate may reduce the polymerization stress¹⁷.

In an effort to overcome many of the downsides associated with an incremental approach to placing resins, restorative materials have been marketed as “Bulk-Fill” composites. Bulk-fill composites are resin-based, tooth-colored restorative materials that incorporate increased polymerization depth, decreased polymerization shrinkage stresses, and cuspal

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deflection rates⁶. They can be inserted into prepared cavities in layers that are up to 4 or 5 mm thick. However to the best of our knowledge there was no systematic review on Clinical Durability of Bulk Fill Composite material used in Restorative Dentistry been conducted so aim of this systematic review is on Clinical Durability of Bulk Fill Composite material used in Restorative Dentistry.

Focused Question

Does Bulk Fill Composite material used in restorative dentistry has a good clinical durability?

Objective

To assess the literature regarding the Clinical Durability of Bulk Fill Composite material used in Restorative Dentistry.

METHODS

Inclusion Criteria

1. Articles in English or those having detailed summary in English
2. Studies published between 1st January 2010 and 30th September 2017.
3. In-vivo studies done on human teeth.
4. Studies evaluating clinical durability of bulk fill resin composites.

Exclusion Criteria

1. Review, case reports, abstracts, letters to editors, editorials and animal studies.
2. In-Vitro studies.

The PICOS guidelines that were selected are:

- P (Participants):** Patient with class I and class II cavities.
I (Intervention): Bulk Fill Composite material
C (Comparison): -
O (Outcomes) : Clinical Durability

Information Sources

Two Internet sources of evidence were used in the search of appropriate papers satisfying the study purpose: the National Library of Medicine (MEDLINE PubMed) and the Cochrane Central Register of Controlled Trials (CENTRAL), Google Scholar, Google, Clinical trials registry and manual search using DPU college library resources. All cross reference lists of the selected studies were screened for additional papers that could meet the eligibility criteria of the study. The databases were searched up to and including September 2017 using the search strategy.

Search

The following databases were searched on PubMed (the limits used were all full text articles in English dated from 1st January 2010 to September 30th 2017), EBSCO HOST, SCOPUS and Google Scholar. For the electric search strategy, the following terms were used as keywords in several combinations.

Study Selection Process

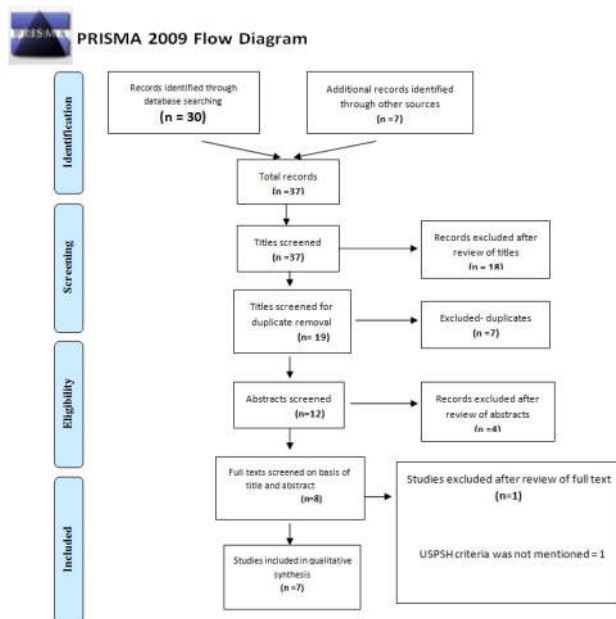
Preliminary screening consisted total of 37 articles out of which 19 articles were selected.

At first the papers were screened by title and abstract. Fulltext papers were obtained when they fulfilled the criteria of the study aim. In-vivo studies done on human teeth in which clinical durability of bulk fill resin composite was assessed.

1. USPHS criteria for restoration evaluation.
2. Finally a total of 12 articles were included. out of which 7 articles was finally synthesized in this systematic review.

Data Collection Process

A standard pilot form in excel sheet was initially used and then all those headings not applicable for review were removed. Data extraction was done for one article and this form was reviewed by an expert and finalized. This was followed by data extraction for all the article



Sr. No.	Search Strategy	Number of Articles	Number of Selected Articles	After Duplicate Removal
Search Strategy 1	Class 1 And Class 2 And Clinical Durability And Bulk Fill Composite	2	2	0
Search Strategy 2	Class 1 And Class 2 And Clinical Evaluation And Bulk Fill Composite	10	6	0
Search Strategy 3	Posterior Restoration And Clinical Evaluation And Bulk Fill Composite	4	4	1
Search Strategy 4	Restorative Dentistry And Clinical Evaluation And Bulk Fill Composite	7	4	1
Search Strategy 5	Restorative Dentistry And Clinical Quality And Bulk Fill Composite	4	2	0
Search Strategy 6	Class 1 And Class 2 And Clinical Quality And Bulk Fill Composite	2	0	2
Search Strategy 7	posterior restoration AND clinical durability AND bulk fill composite	1	1	1
Other Sources		7	0	7
Total		37	19	12

RESULT

Total of 37 articles were searched out of which 19 articles were selected after reading title and abstract. As a second step, full text papers were obtained. However studies in which different bulk fill composite materials durability was tested were selected. Finally a total of 19 articles were included out of which 12 articles were excluded on basis of insufficient data and 7 articles were selected for final synthesis.

DISCUSSION

One of the goals of adhesive dentistry is to obtain a tight interfacial adaptation. Inferior adaptation may increase the risk of microleakage, debonding, secondary caries and postoperative sensitivity. Therefore, there is a need for materials and methods which decrease stress formation during placement and curing procedures. The longevity of dental restorations is dependent on many factors. These include the materials and techniques used, patient compliance with oral hygiene, and the patient's susceptibility to caries²⁴.

In clinical studies, the success of a material is indicated by its longevity in the oral cavity; as such, retention rates represent the most important evaluation criteria. The American Dental Association guidelines for submitted dentin and enamel adhesive materials specify provisional acceptance, means that no more than 5% of the restorations should have been lost at the 6 months recall and, to obtain full acceptance, the cumulative incidence of clinical failures in each of the two independent clinical studies needs to be <5% of the restorations lost by the 6 months recall visit and <10% by the 18 months recall²⁶.

The stress reducing effect of the incremental filling techniques have been questioned and finite element calculations showed that an oblique layering technique produced more stress concentration at the interface compared to a horizontal filling technique^{5,20}. Several materials and techniques have been introduced to simplify the resin composite procedure which concerned fewer steps and a self etching function of adhesive systems. "Bulk-Filling" resin composites for current marketed materials means in practice placement of layers up to 4 mm thickness and have higher translucency and incorporation of a photoactive group^{21,22}.

The layering technique makes the restorative procedure time consuming, voids may be included and the failure risk increases. The main concern regarding applying thicker increments is whether the resin composite cures enough in the deeper parts to obtain acceptable mechanical, physical and biocompatible properties²³.

To gain insight into the effectiveness of restorations performed in clinical trials, it is important to develop objective, reliable, and relevant criteria by which the outcomes are assessed. The modified USPHS criteria, a long-established method used in clinical trials was applied in the studies for the purpose of evaluating the restorations. This method remains the most commonly-used system for evaluating the important characteristics of dental restorations, such as color match, secondary caries, marginal discoloration, and postoperative sensitivity, and is widely regarded as representing a reliable means of generating data that is of significance^{24,25}.

*Van Dijken JW et al. (2014)*²⁷ conducted randomized controlled prospective clinical trial to evaluate the efficacy of a flowable resin composite (SDR) bulk fill technique in posterior restorations and to compare it intraindividually with a conventional 2 mm resin composite curing technique in a 3-year follow up. In this, thirty-eight pairs Class II and 15 pairs Class I restorations were placed in 38 patients with a mean age of 55.3 years (range 32-87). Each patient received at random at least two, as similar as possible, Class II or Class I restorations of two restorative techniques. In all cavities a single step self-etch adhesive (Xeno V) was applied. In one of the cavities of each pair, a flowable resin composite (SDR) was placed, in bulk increments up to 4 mm as needed to fill the cavity 2 mm short of the occlusal cavosurface. The occlusal part was completed with a nano-hybrid resin composite (Ceram X mono) layer. In the second cavity, the hybrid resin composite was placed in 2 mm increments. The restorations were evaluated using slightly modified USPHS criteria at baseline and then yearly during 3 years. Caries risk and parafunctional habits of the participants were estimated. Results were that after three years, 76 Class II and 28 Class I restorations could be observed. One molar resin composite-only tooth showed post-operative sensitivity during 3 weeks for temperature changes and occlusal forces. Two failed Class II molar restorations in the resin composite-only group were observed during the first year, one cusp fracture and one resin composite fracture. An annual failure rate of 1.3% was found for the resin composite only restorations and of 0% in the bulk-filled restorations (n.s.). Ten participants were estimated as having high caries risk and eleven showed active bruxing habits. They concluded that the 4 mm bulk-fill technique with the flowable resin composite SDR showed highly clinical effectiveness, which was comparable during the 3-year follow-up with the 2mm resin composite layering technique.

*Van Dijken JW et al. (2015)*²⁸ conducted study on clinical durability of the flowable bulk-fill resin composite SDR in Class I and Class II restorations. Thirty-eight pairs of Class I and 62 pairs of Class II restorations were placed in 44 male and 42 female patients (mean age 52.4 years). Each patient received at least two extended Class I or Class II restorations that were as similar as possible. In all cavities, a one-step self-etching adhesive (XenoV+) was applied. One of the cavities of each pair was randomly assigned to receive the flowable bulk-fill resin composite SDR in increments up to 4 mm as needed to fill the cavity 2 mm short of the occlusal cavosurface. The occlusal part was completed with an ormocer-based nanohybrid resin composite (Ceram X mono+). In the other cavity, only the resin composite CeramX mono+ was placed in 2 mm increments. The restorations were evaluated using slightly modified USPHS criteria at baseline and then annually for 3 years. Caries risk and bruxing habits of the participants were estimated. Results were no post-operative sensitivity was reported. At the 3-year follow-up, 196 restorations - 74 Class I and 122 Class II - were evaluated. Seven restorations failed (3.6%), 4 SDR-CeramX mono+ and 3 CeramX mono+ only restorations, all of which were Class II. The main reason for failure was tooth fracture, followed by resin composite fracture. The annual failure rate (AFR) for all restorations (Class I and II) was 1.2% for the bulk filled restorations and 1.0% for the resin composite-only restorations ($p > 0.05$). For the Class II restorations, the AFR was 2.2% and 1.6%, respectively. They

concluded that the 4-mm bulk-fill technique showed good clinical effectiveness during the 3-year follow-up.

*Van Dijken JW et al.(2016)*²⁹ conducted a randomized controlled study on 5-year clinical durability of a flowable resin composite bulk-fill technique in Class I and Class II restorations. 38 pairs Class I and 62 pairs Class II restorations were placed in 44 male and 42 female (mean age 52.4 years). Each patient received at least two, as similar as possible, extended Class I or Class II restorations. In all cavities, a 1-step self-etch adhesive (Xeno V+) was applied. Randomized, one of the cavities of each pair received the flowable bulk-filled resin composite (SDR), in increments up to 4mm as needed to fill the cavity 2mm short of the occlusal cavosurface. The occlusal part was completed with the nano-hybrid resin composite (Ceram X mono+). In the other cavity, the resin composite-only (Ceram X mono+) was placed in 2mm increments. The restorations were evaluated using slightly modified USPHS criteria at baseline and then yearly during 5 years. Caries risk and bruxing habits of the participants were estimated. Result were No post-operative sensitivity was reported. At 5-year 183, 68 Class I and 115 Class II, restorations were evaluated. Ten restorations failed (5.5%), all Class II, 4 SDR-CeramX mono+ and 6 CeramX mono+-only restorations. The main reasons for failure were tooth fracture (6) and secondary caries (4). The annual failure rate (AFR) for all restorations (Class I and II) was for the bulk-filled-1.1% and for the resin composite-only restorations 1.3% ($p=0.12$). For the Class II restorations, the AFR was 1.4% and 2.1%, respectively. They concluded that the stress decreasing flowable bulk-fill resin composite technique showed good durability during the 5-year follow-up.

*Bayraktar Y et al.(2017)*³⁰ study to evaluate 1-year clinical performance of a conventional posterior composite resin and three bulk-fill composite resins. In this study fifty patients with four class II restorations under occlusion were enrolled in the present study. A total of 200 restorations were placed in the cavity, 50 for each material (Clearfil Photo Posterior, Filtek Bulk-Fill Flowable and Filtek P60, Tetric EvoCeram Bulk-Fill, and SonicFill). One operator placed the restorations in the cavity, and 1 week later the patients were called for baseline examination. Two calibrated examiners evaluated the restorations once every 3 months for 1 year, according to United States Public Health Service criteria. The data were analyzed using SPSS. Non-parametric tests (Kruskal-Wallis, Mann-Whitney U-test, and Friedman) were used for the analysis at a confidence level of 95%. Results were the 1-year recall rate was 86%. All restorations showed minor modifications after 1 year. However, no statistically-significant differences were detected between the materials' performance at baseline and after 1 year for all criteria ($P > 0.05$). They concluded that the bulk-fill composite resin materials showed similar clinical performance when compared with a conventional posterior composite resin. Further evaluations are necessary for the long-term clinical performance of these materials.

*Karaman E et al. (2017)*³¹ they conducted a study to evaluate the clinical performance of direct resin composite restorations placed with different techniques (incremental or bulk) and different flowable linings (conventional or bulk-fill) in endodontically treated teeth. Forty-seven pair class II (mesio-occlusal or disto-occlusal) composite restorations were placed

in 37 patients. In all cavities, Adper Single Bond 2 was used. In one of the cavities of each pair, a conventional flowable composite, Aelite Flo, was applied in approximately 2 mm thick, and the remaining cavity was restored incrementally with GrandioSO. In the second cavity, a bulk-fill flowable composite, x-tra base, was applied in approximately 4 mm thick in bulk increments and the remaining 2-mm occlusal part of the cavity was restored with GrandioSO. All cavities were restored with open-sandwich technique by the same operator. At baseline and after 6-month, 1-, 2-, and 3-year follow-up visits, restorations were evaluated by modified USPHS criteria. Results were at 3-year recall, 33 restorations with Aelite Flo lining and 33 with x-tra base lining were available. Two restorations from each group (6.0 %) were scored as Bravo in terms of surface texture. One restoration's color match from x-tra base group scored as Bravo (3.0 %). All other evaluated criteria were scored as Alfa (100 %) for all restorations. No statistically significant difference between the two groups was found in all evaluated criteria during 3-year period ($p > 0.05$). They concluded that the Bulk-filling technique showed clinically acceptable performance comparable to the incremental technique.

*Colak H et al.(2017)*³² conducted a 12 months prospective randomized clinical trial that evaluated the clinical performance of one high-viscosity bulk-fill composite resin in Class II cavities of posterior teeth. Thirty-four participantshad at least two Class II cavities included the study. Class II cavities restored with either a Tetric EvoCeram bulk-fi fill or universal nano-hybrid resin composite (Tetric EvoCeram). A total of 74 restorations (37 with each material) on 34 patients were placed. Results were seventy restorations were evaluated after 12 months evaluation period. No postoperative sensitivity, anatomic form, retention, and secondary caries were observed after 6 and 12 months. Regarding the items color match, marginal discoloration, and marginal adaptation, the statistical analysis did not detect any statistical significance between two materials ($P > 0.05$). After 12 months of clinical service, all restorations evaluated for both materials were classified as ideal, receiving predominantly Alfa scores for all parameters analyzed. Thus, they concluded that the high viscosity bulk fill resin composites (RCs) perform just as well as nano hybrid RCs with the 2 mm RC layering technique, therefore could be alternative to conventional nano hybrid RCs.

*Van Dijken JWV et al (2017)*³³ conducted a randomized study evaluated a flowable resin composite bulk-fill technique in posterior restorations and compared it intraindividually with a conventional 2-mm resin composite layering technique over a 6-yr follow-up period. Thirty-eight pairs of Class II restorations and 15 pairs of Class I restorations were placed in 38 adults. In all cavities a single-step self-etch adhesive (Xeno V) was applied. In the first cavity of each pair, the flowable resin composite (SDR) was placed, in bulk increments of up to 4 mm. The occlusal part was completed with a layer of nanohybrid resin composite (Ceram X mono). In the second cavity of each pair, the hybrid resin composite was placed in 2-mm increments. The restorations were evaluated using slightly modified US Public Health Service (USPHS) criteria at baseline and then annually for a time period of 6 yr. Results were after 6 yr, 72 Class II restorations and 26 Class I restorations could be evaluated. Six failed Class II molar

restorations, three in each group, were observed, resulting in a success rate of 93.9% for all restorations and an annual failure rate (AFR) of 1.0% for both groups. The AFR for Class II and Class I restorations in both groups was 1.4% and 0%, respectively. The main reason for failure was resin composite fracture. It was concluded that bulk-filling technique based on SDR technology showed highly acceptable clinical results that were comparable with the conventional 2-mm incremental technique in this 6-yr follow-up study.

Limitations

The limitation of this systematic review is that there is lack of literature searched for systematic review and lack in the literature searched other than electronic databases.

CONCLUSION

The bulk-fill technique showed acceptable clinical results and was similar to the conventional layering technique during the 1 year, 3 year, 5 year, and 6 year evaluation period. Annual failure rates on an average were 1.0% for the conventionally filled and 1.4% for the bulk-filled restorations and the AFR at 6 yr was 0% for Class I restorations and 1.4% for Class II restorations.

Good surface characteristics, marginal adaptation, and color stability as well as a low frequency of secondary caries and low resin composite fracture rate was observed with bulk fill composite.

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