

CLINICAL EVALUATION OF THE NANO HYBRID BULK FILL COMPOSITE AND NANO HYBRID FLOWABLE COMPOSITE IN CLASS I RESTORATIONS--- AN IN VIVO STUDY

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Abstract

Objectives: The aim of this study was to evaluate the clinical performance of a nano filled flowable and nano hybrid bulk fill resin composite in class I restorations.

Methods and Materials: Twenty patients were selected for this in vivo study. Each patient received at least one pair of restorations, restored with nano hybrid bulk fill resin composite (IPS Empress direct [IED]) and nano hybrid Tetric N Ceram flowable composite [TNC]. Each restorative resin system was used with its respective adhesive system according to manufacturers' instructions.

A total of 40 class I restorations were placed by one operator. Restorations were blindly evaluated by two examiners at baseline and 3, 6, and 12 months respectively using modified US Public Health Service Ryge criteria.

The data obtained was statistically analyzed using Chi square test to compare the two restorative materials for each category.

Results: At 3, 6 and 12, months, recall rate was 100%, 95% and 85%, respectively, with a retention rate of 100%. There were statistically significant differences between the two restorative resins in terms of marginal adaptation and marginal discoloration ($p < 0.05$).

No differences were observed between the restorative resins in terms of retention ($p < 0.05$). None of the restorations showed postoperative sensitivity, or loss of anatomic form.

Conclusion: Within the limitations of this study, nano hybrid bulk fill composite resin viz. IPS EMPRESS DIRECT showed better clinical performance than nano filled flowable composite in terms of marginal discoloration and marginal adaptation.

Keywords: direct composite, bulk, hybrid filled resin

Introduction

With the elimination of Amalgam, the utilization of composites is the option of decision and routine technique for the restoration of posterior teeth.^{1,2} Resins have demonstrated us promising esthetics, improved mechanical properties as good as amalgam, and have conquered worries over mercury toxicity.^{2,3} Moreover, their preparation is very conservative. Various advancements in composites are by and large consistently created to improve their mechanical and physical properties, be that as it may, conquering polymerization shrinkage despite everything stays a primary challenge.^{4,5} Polymerization shrinkage stresses aggregated at the adhesive interface can prompt marginal breakdown, peripheral spillage, and even cuspal crack, secondary caries, and restoration loss.^{6,7} To defeat polymerization shrinkage stresses, incremental placement of resin composite is the basic method embraced to avoid depth-of-cure limitations. Nonetheless, there are different impediments to this strategy, for example, voids that can be entangled between these layers, contamination between

layers, difficulty in the placement of increments in small cavities that are difficult to access and increased chair time.¹¹ One of the significant changes in resin based composite innovation is the development of bulk fill composites which have conquered numerous issues like polymerization shrinkage and increased chair time. Bulk fill composites can be set up to 4-mm in thickness with uniform polymerization and low polymerization shrinkage.^{11,12}

The addition of stress-mitigating monomers, more responsive photo-initiators, and pre-polymerized particles bring about lower polymerization shrinkage. Besides, the expanded clarity of these resins permits more prominent light transmission and sufficient profundity of cure.¹⁹ For resin composites, satisfactory polymerization as well as appropriate negligible transformation is imperative to guarantee ideal clinical conduct.

In the majority of the investigations, the exhibition of bulk fill restorative resins was discovered to be like incremental placed conventional resins regarding marginal integrity.²⁰⁻²³ Although the mechanical and physical properties of bulk fill

helpful pitches have been assessed under in vitro conditions,²⁴⁻²⁹ a definitive test for a dental restorative material is its clinical toughness and viability. Hence, the point of this clinical examination was to analyze the clinical presentation of a mass fill gum composite with a nano filled flowable pitch composite for a long time. The invalid speculation was that there would be no distinction between nano mass fill and nano filled flowable composites. In addition, the expanded clarity of these tars permits more prominent light transmission and satisfactory profundity of cure.¹⁹ For resin composites, sufficient polymerization as well as appropriate minimal shrinkage is essential to guarantee ideal clinical conduct. In the majority of the investigations, the presentation of bulk fill resins was discovered to be similar to conventional resins as far as negligible integrity.²⁰⁻²³ Along these lines, the aim of this clinical investigation was to look at the clinical presentation of a bulk fill resin composite with a nano filled flowable resin composite for a long time. The null hypothesis was that there would be no difference between nano bulk fill and nano filled flowable resin composites

Materials and methods:

Approval for this in vivo study was obtained from the Human Ethics Committee of the Divya Jyoti College of Dental Sciences and Research. Written consent was obtained from all patients.

Inclusion criteria:

- Good oral hygiene
- Minimal periodontal disease
- Absence of deleterious habits (e.g. mouth breathing, nail biting, bruxism, and tooth clenching or grinding)

Exclusion Criteria

- Teeth with secondary caries or in need of replacement of existing restorations.
- Patients having a history of adverse reaction to the test material.
- Poor oral hygiene or presence of systemic disease and severe periodontal disease
- Patients unable to attend recall visits.

A total of 20 patients—15 males and 5 females— aged 20 to 50 years were included in this study.

Preoperative radiographs of the teeth to be restored were taken. Teeth having class I carious lesion on either molar and premolar were selected. The teeth to be restored had a normal class I occlusal relationship with natural dentition. The minimal sample size of each group was taken as 20 restorations. The teeth to be restored were first cleaned with a non-fluoridated prophylaxis paste on a rubber cup and then rinsed with water. Class I cavity preparations were completed with a diamond straight (flat end) and round burs at high speed with water coolant. Outline form of the preparation was determined by the extent of caries. Caries removal was completed using a round diamond bur.

Isolation was accomplished using a rubber dam. Two different restorative resins were placed in each patient, resulting in a total of 40 restorations. Half of the preparations were restored using nano hybrid flowable resin composite i.e. Tetric N Ceram flowable resin (TNC), Ivoclar Vivadent, Schaan, Liechtenstein) (n=20), and the other half were restored with nano hybrid bulk fill composite i.e. IPS Empress direct bulk fill composite resin (Ivoclar Vivadent, Schaan, Liechtenstein) (n=20) with their respective etch-and-rinse adhesives according to the manufacturers' instructions.

IPS empress direct was polymerized for 20 seconds with an LED light-curing unit (440-465nm). The restorative material Tetric N Ceram Flowable was placed in bulk up to 4-mm thickness and cured for 20 seconds with the same curing unit. The randomization of restorative material was done using a table of random numbers. Occlusal adjustments were made using articulating paper. Composite finishing and polishing kit from SHOFU (Dentsply) was used for final finishing and polishing of the restorations. The complete procedure was performed by the same operator.

Two experienced double-blinded dentists not involved with the placement of the restorations performed the evaluation. The dentists were calibrated to a predetermined level of inter- and intra -examiner agreement of at least a Kappa value of 95% for each criterion. The restorations were evaluated at baseline, at 3, 6 and 12 months respectively using modified US Public Health Service Ryge criteria 30 and scored as Alpha, Bravo, or Charlie. Alpha corresponds to excellent, Bravo to clinically acceptable, and Charlie to clinically unacceptable results. Postoperative sensitivity was assessed by blowing a stream of compressed air for three seconds at a distance of 2 to 3 cm from the restoration under isolation from the adjacent teeth with gauze and by moving the probe over the restored tooth surface. Subjects were also questioned regarding sensitivity to cold/hot or stimuli. Color photographs at 1:1 magnification were taken at baseline and each recall.

Results:

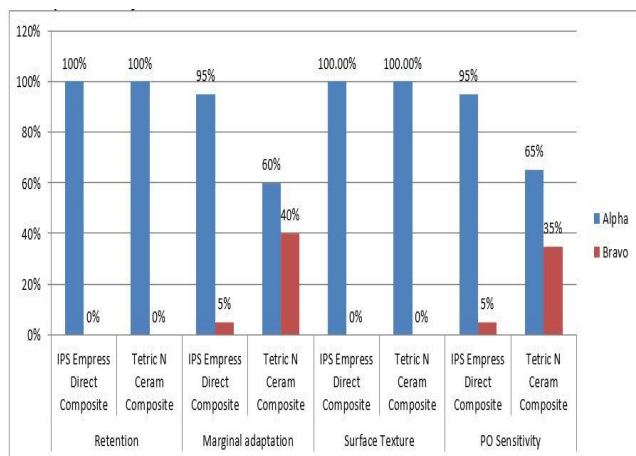
Statistical analysis was performed using IBM SPSS version 22.0 software package (SPSS, Chicago, IL, USA). The restoration groups for each category were compared using Chi Sq est.

A total of 40 restorations were placed in 20 patients. 23 restorations (55%) were placed in molars, whereas 17 (45%) were placed in premolars.

The clinical parameters of retention, marginal adaptation, surface texture and postoperative sensitivity were evaluated at baseline, 3 months, 6 months and 12 months for all the three groups.

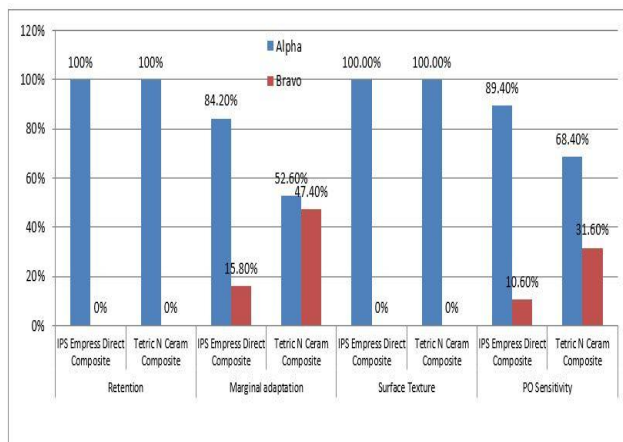
Graph 1 depicts the intergroup comparison at 3 months and shows that in terms of retention and surface texture there is no difference between the two groups at 3 months. In terms

of marginal adaptation, 95% cases show alpha scoring in IED Group whereas only 60% restorations showed alpha scoring in TNC group. While comparing postoperative sensitivity, it was seen that there was a statistically significant difference between the two groups with IED group showing alpha scoring in 95% cases.



Graph 1: Intergroup comparison between Group 1 and Group 2 at 3 months.

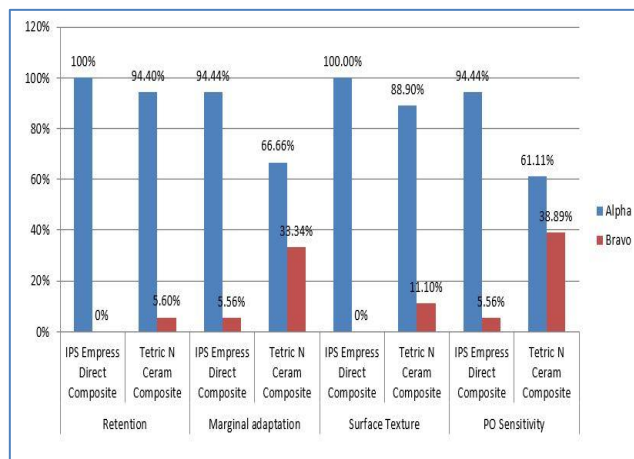
Graph 2 depicts the intergroup comparison at 6 months and shows that in terms of retention and surface texture, there is no significant difference between the two groups with 100% alpha scoring. In terms of marginal adaptation and postoperative sensitivity, IED group showed better performance than TNC group and the difference was statistically significant.



Graph 2: Intergroup comparison between Group 1 and Group 2 at 6 months.

Graph 3 depicts the intergroup comparison at 12 months and shows that in terms of retention, and surface texture, there was no statistically significant difference between the two groups. IED group showed statistically significant better performance than TNC group in terms of marginal adaptation and postoperative sensitivity at 12 months. In TNC group, only 66.6% cases showed alpha scoring in

terms of marginal adaptation while 33.34% showed bravo scoring.



Graph 3: Intergroup comparison between Group 1 and Group 2 at 12 months.

Discussion:

There are only limited studies that compare the clinical effectiveness of bulk fill resin composites. Two of them were conducted by van Dijken and Pallesen.^{31,32} In one of their studies, five-year clinical durability of the flowable bulk fill resin composite SDR capped with CeramX Mono was compared with CeramX Mono that had been placed incrementally. No difference was observed between restorations with and without SDR in any of the evaluated criteria. None of the restorations showed postoperative sensitivity. Tooth and restoration fracture were also observed.³¹ In their other clinical study, they also found that the bulk fill flowable SDR showed highly acceptable clinical results comparable to the conventional 2-mm incremental technique in the three-year follow-up. None of the restorations showed marginal discoloration. Although not statistically different, poor marginal adaptation was seen in incrementally placed restorations.³² The results of our study do not correlate with these previous studies mentioned above. This might be related to the bulk fill resin used in our study. In the mentioned studies, bulk fill flowable resin composites were compared. However, in our study, bulk fill resin without the need of capping was investigated, and significant differences were found between bulk fill and flowable resin composite that was placed incrementally in terms of marginal discoloration and marginal adaptation at the end of 12 months. The tested resin composites performed differently in these criteria over the 12-month evaluation period, leading to rejection of the tested hypothesis. In another short-term clinical study, bulk fill restorations demonstrated comparable performance to conventional posterior composite resin.³³ However, these results were obtained at the end of 12 months.

The important issue is to evaluate the performances and survival of restorative materials for a long time period to reach an accurate conclusion. The results might vary

according to the recall time. For the clinical success and survival of restorations, the adhesive bond at the tooth/resin interface plays a vital role. The reason for better marginal adaptation observed in bulk fill resin composite might be related to its lower polymerization stress. Moreover, the manufacturer states that IED contains a shrinkage stress reliever, which is a special filler functionalized with silane to minimize polymerization shrinkage (scientific documentation).³⁴ It is known that stresses are affected by the composition and filler content of resin composite, its elastic modulus.^{4,35} TNC contains a mixture of bisphenol-A diglycidyl dimethacrylate, urethane dimethacrylate, and ethoxylated bisphenol A dimethacrylate, all of which are high-molecular-weight monomers with high viscosity and low polymerization shrinkage. On the other hand, TNC beside these monomers has a diluent monomer, triethylene glycol dimethacrylate that reduces its viscosity. Because of its smaller molecules, it might have a negative effect on polymerization shrinkage.³⁶ Due to its low molecular weight, it increases water sorption.³⁷ The use of prepolymerized filler particles as in IED also contributes to a lower elastic modulus.³⁸ In a recent study comparing other bulk fill resins, the elastic modulus of TNC was found to be moderate.³⁹ A direct relationship between marginal integrity and polymerization contraction/stress has been reported in some in vitro studies.^{22,40,41} Although better performance of bulk fill resin composite was found in terms of marginal adaptation in the present study, comparable results with traditional incrementally placed resin composites were reported in most of the in vitro studies.^{21,42,43} In a recent in vitro study,²¹ Tetric N Ceram Bulk Fill demonstrated similar gap formation to conventional resin composite. Al-Harbi and others²³ also analyzed the cervical marginal integrity of class II preparations restored with bulk fill vs incrementally placed resin composites. They found similar marginal integrity compared to conventional incremental fill composites. Concurring with these results, Fronza and others²² also found that TNC was not different in percentage of internal gap formation from incrementally placed resin composite. However, in clinical conditions, restorations are subjected to temperature changes and, more important, masticatory stresses. These factors cause a strain accumulation that leads to chemical and mechanical degradation.⁴² Therefore, it might not be accurate to directly compare our findings with the results obtained from in vitro studies. There are only few in vitro studies evaluating the microleakage of bulk fill resin composites. In one of them, flowable bulk fill resin showed less leakage in comparison with nanohybrid bulk fill resin composite at dentinal margins. However, they showed similar microleakage values at enamel margins.⁴³ In another study, no difference was observed in cervical microleakage when an incrementally filled conventional resin composite was compared with a bulk fill flowable resin composite base in class II preparations.⁴⁴ However, in both studies, flowable bulk fill composites were used. In the present study, bulk fill restorations led to significantly better clinical outcomes

regarding marginal discoloration. This can be explained by the lower elastic modulus of TNC (10 GPa) than IED (12 GPa). Taking into account that the same restorations rated as Bravo for both marginal discoloration and adaptation, the higher marginal discoloration observed in the TNC group may have been related to the poor marginal adaptation. These defects along the margin might have facilitated susceptibility to staining. Although not statistically different, two restorations from the TNC group showed slightly rougher surfaces. This might be related to void entrapment during the increment filling technique. Surface texture is important since rougher surfaces would cause surface staining and increase plaque retention and bacterial adhesion. The intrinsic filler particle size of resin composites also determines the smoothness of restoration. It might have been expected that subjects with bulk fill restorative might have suffered from postoperative sensitivity more than incrementally placed restoratives. However, at the end of the study, none of the patients complained of sensitivity. Adequate depth of cure of the bulk fill resin used in the present study might have contributed to this result. The bulk fill resin Tetric N Ceram Bulk used in the present study contains a new photoinitiator system, Ivocerin, a dibenzoyl germanium compound that has a higher photocuring activity than camphorquinone, as it absorbs visible light over a wider range of wavelengths from 370 to 460 nm.^{17,34}

Conclusions

Within the limitations of this in vivo study, it was concluded that nano hybrid bulk fill resin composite (IPS Empress direct [IED]) showed better clinical performance than nano hybrid Tetric N Ceram flowable composite [TNC] in terms of marginal adaptation and postoperative sensitivity at all time intervals. However, there was not much difference in terms of retention and surface texture.

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