"Clinical Evaluation of a Bulk-filled Dental Filling Material"

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Introduction

The long taught dogma for placing composite restorations has been to place the composite material incrementally in 2mm layers. Part of the theory behind this teaching was that it would reduce the total amount of polymerization shrinkage of the composite. As one layer of composite is placed and cured, all surfaces of that composite layer not bonded to tooth structure could contract freely. In this way, stress relief could be achieved at each layer of cured composite, as opposed to a single cured layer with a bulk-filling technique. Despite the merits of this theory, the actual benefits of incremental filling to reduce the clinical effects of composite shrinkage have been questioned.[1] A more substantial claim for the 2mm composite increment is the ability of a curing light to effectively polymerize a composite to this depth. Both polymerization shrinkage and depth of cure are important clinical parameters. Excessive polymerization shrinkage could lead to open margins, microleakage, and post-operative sensitivity or cuspal deflection and enamel fracture. Inadequate depth of cure could leave composite at apical margins soft and susceptible to wear, dissolution or fracture.

The impetus for bulk-filling composites is driven by a desire to reduce the time required for composite placement and eliminate the possibility of voids between composite layers. The time savings allowed by placing a single layer of composite can be appreciated by both the dentist and the patient receiving the treatment. Additionally, an unwanted side effect of the incremental placement technique is the introduction of voids between composite layers. For universal handling composites, the stickiness of the composite to the placement instrument can make it difficult to completely adapt the new layer of composite to the previous layer. When placing additional layers of flowable composite, air can become entrapped between layers. Internal voids may be innocuous in some clinical cases, however, in stress bearing areas, a void may act as a site of stress concentration and eventual fracture.[2] Voids or gaps present on the external surface of a composite restoration may be more prone to staining.

Purpose

This randomized, controlled, prospective clinical trial will compare the clinical success of a new formulation of an ultra-rapid polymerization time bulk-fill composite ("F-Composite 2", Ivoclar Vivadent) with a bonding agent, to a previous formulation of the same material and a commercially successful dental composite (Tetric EvoCeram, Ivoclar Vivadent, Buffalo, NY) for surface luster, surface staining, color match, material fracture, occlusal wear, tooth integrity, caries, marginal adaptation, marginal staining, contact point, post-operative hypersensitivity, patient's satisfaction, and radiographic examination (pre-operative and at 3 years) using modified FDI criteria. The three year clinical evaluation will evaluate the restorations using direct and indirect methods. Digital images will be made of each restoration and stored by patient if acceptable to patient and deemed clinically necessary.

Study Objectives

The purpose of this randomized controlled clinical trial is to compare the clinical success of a new formulation of a composite with an ultra-rapid polymerization time (F-Composite 2, Ivoclar Vivadent) to a commercially successful nanohybrid composite (Tetric EvoCeram, Ivoclar Vivadent, Buffalo, NY) and a previous formulation of the material ("Flash Composite", Ivoclar Vivadent) placed in Class I and Class II cavities in permanent teeth. The F-composite 2 material is a newly developed material from Ivoclar Vivadent. The objective of the study is to determine whether a simplified placement procedure of the F-composite 2 in a single increment of at most 4mm with a reduced amount of time of light polymerization (3 seconds) yields the same results as a widely used commercially available dental composite (Tetric EvoCeram). The new procedure would significantly facilitate and shorten the clinical procedure and potentially reduce voids between layers of composite. The restorations will be evaluated directly in the oral cavity at baseline (1

week), 6 months, 1 year, 2 years, and 3 years using modified FDI criteria. Casts made from impressions of the preparations will be analyzed to verify anatomic form and marginal integrity. Primary clinical outcome measures are frequency of post-operative hypersensitivity, pulp integrity, and the overall survival rate of the restorations in relation to the material. The secondary outcome measures of the study are surface luster, surface staining, color match, material fracture, occlusal wear, tooth integrity, caries, marginal adaptation, marginal staining, contact point, patient's satisfaction, and radiographic examination.

Ethical Standards

The study will be conducted in accordance with the Declaration of Helsinki (1964) as revised in Venice in 1983. Institutional Review Board approval has been obtained prior to commencing the study. Informed written consent will be obtained from all subjects prior to registration for participation in the evaluation. Implicit in giving informed written consent, each patient reserves the right to withdraw from the study at any time (See consent form).

Study Design

The study will be a randomized, controlled clinical evaluation of class I and class II dental fillings in a single patient using one restorative materials: F-Composite 2 (Ivoclar Vivadent) placed with a dental adhesive ExciTE F (Ivoclar Vivadent) in a total-etch mode. This data will be compared to previously placed restorations in the first part of this study which compared two groups: Flash Composite (Ivoclar Vivadent) placed with a dental adhesive ExciTE F (Ivoclar Vivadent) in a total-etch mode and a commercially available dental composite, Tetric EvoCeram (Ivoclar Vivadent) placed with a dental adhesive ExciTE F (Ivoclar Vivadent) in a total-etch mode. One restoration will be placed in subjects with carious teeth or defective posterior restorations needing replacement. The study will be conducted in the Department of Clinical and Community Sciences, University of Alabama at Birmingham (UAB), School of Dentistry clinical research clinic. 60 restorations in adult subjects aged 19 years or older will be recruited into the study. Based on previous clinical trials, the average subject attrition rate at the three year recall is approximately 20%. To achieve 50 restorations per group at the three year recall, 60 restorations will be placed assuming a 20% drop out rate.

Investigators

Dr. Lawson will act as the Principal Investigator and will conduct the calibration exercises. Four experienced operators will place the restorations in the study (Drs. John Burgess, Nathaniel Lawson, Augusto Robles, and Chin-chuan Fu). All operators will place the same percentage of the restorations. One calibrated operator (Dr. Nathaniel Lawson) will complete the baseline, 6 month, 1, 2, and 3 year recall examinations. Baseline evaluations will be conducted approximately one week after the restorations are placed.

Background and Significance

In response to the clinical demand for materials compatible with bulk-filled placement, a new class of dental composites has been developed. In general, these materials are characterized by lower shrinkage stress and a higher depth of cure than conventional composites. Shrinkage stress is defined as the amount of force per area exerted on the walls of a cavity preparation by a composite as it polymerizes. Volumetric shrinkage, on the other hand, is the volume difference between an uncured and cured specimen of composite. The importance of this distinction is that shrinkage stress is more clinically important than volumetric shrinkage because a material that shrinks substantially when cured on your countertop may not exert large forces when cured inside a bonded restoration.[3] Methods that manufacturers may employ to produce composites that do not exert high stress during polymerization are: 1. Increasing "flexibility" of polymer networks in the composite resin, 2. Incorporating "flexible" fillers in the composite, 3.

Slowing the polymerization reaction to allow polymers time to disperse prior to crosslinking.[4-6] Many of the commercially available bulk fill composites incorporate one or more of these techniques to reduce polymerization shrinkage. Several research studies have compared polymerization shrinkage of conventional composites and bulk-fill composites. Broadly, the bulk-fill flowables have less polymerization shrinkage stress than conventional flowables; and the high-viscosity bulk-fill composites demonstrate similar or less polymerization stress than comparable conventional composites.[5, 7-9]

Bulk-fill materials are marketed with claims of 4mm of curing depth. Depth of cure is commonly measured by measuring the hardness or degree of double bond conversion at the surface of a composite exposed to a curing light and comparing it to locations at various depths of the restoration. Several studies have determined that bulk-fill composites have a degree of conversion (indicating adequate crosslinking) of at least 80% of their surface value at 4mm depths.[9-11] Other studies have determined that hardness values at 4mm were at least 80% of the surface hardness for most bulk-fill materials.[5, 12-15] Some studies suggested that not all high-viscosity bulk-fill composites could achieve acceptable hardness all the way to 4mm.[11, 13, 15] All bulk-fill composites showed higher depths of cure than conventional composites used as a control.[5, 9, 13-15]

Manufacturers have achieved this depth of cure by modifying the translucency of the composite and including more effective light initiators. When a composite is light cured from the occlusal direction, light energy from the curing light must be transmitted through the bulk of the composite without being absorbed or deflected before reaching the bottom of the restoration. By adjusting the translucency of the composite or matching the refractive index of the filler and the resin, light can travel through an increased depth of a bulk-filled composite.[16, 17] An inadvertent side effect of this modification is that several of these materials appear more visually translucent than tooth structure.

The other method manufacturers have used to increase depth of cure is by incorporating more efficient and robust light initiators. The majority of dental composites polymerize by activating the photoinitiator camphorquinone (CQ). When the energy from a curing light excites CQ, it stimulates an amine co-initiator to release a free radical and initiate resin polymerization. Ivocerin, a new germanium-based photoinitiator patented by Ivoclar Vivadent, does not require a co-initiator and requires less energy from a curing light to produce crossliking of the resin composite.[6, 18] Therefore, composite at the bottom of a 4mm layer requires less light to achieve sufficient mechanical and physical properties.

Additionally, manufacturers have added blends of photoiniators which are activated at different wavelengths of light to optimize all of the light energy from a curing light. CQ is maximally stimulated at 468nm. Ivocerin has a maximum absorption of 410nm. The photoinitiators phenyl-propaneodione (PPD) and Lucerin TPO absorb a lower wavelength of light (385-400nm) and have been used in light and translucent shades of composite because they do not have the yellow tint associated with CQ. The range of maximum of absorption of different photoinitators has clinicians concerned that their curing lights will have the spectral output to effectively polymerize these composites. For reference, a typical LED curing light has a spectral output of utilizable wavelength from 430-480nm. New polywave or multiwavelength LEDs have expanded spectral outputs such as the VALO by Ultradent (395-480nm) and the Bluephase 20i by Ivoclar Vivadent (385-515nm). Internal testing by the author, however, has revealed that Tetric Evoceram Bulk Fill (containing the photoinitiator Ivocerin) could be effectively cured to 4mm with a traditional and polyphase LED curing light. Since Tetric Evoceram Bulk Fill is the only bulk-fill composite marketed with a new photoinitiator, the concern of composite and light compatibility may not be of clinical relevance with current materials. Clinicians, however, should be concerned about the power output (also called irradiance) of their curing light. The depth of cure of a bulk-fill composites measured in laboratory testing is typically determined with relatively new lights with a power output >600mW/cm^2. A recent study has shown that dental curing lights measured from

200 private practices had low outputs (200-400mW/cm^2) and were covered with composite residue.[19] Clinicians should monitor the output of their curing lights and keep their light tips clean with protective sleeves or acetone-based cleaners. Since every resin composite requires a minimum amount of energy, lights with lower outputs must be compensated by longer exposure time.[20]

It is apparent that a simpler more easily mastered material and technique for placing posterior composite restorations should be developed to improve patient care, decrease placement time and increase access to care by using a simpler material.

Duration of the Investigation

The duration of the study will be three years.

Class of Restorations

Restorations will be placed in Class I and Class II preparations in molars and premolars. All restored teeth will have natural teeth, crowns or bridgework as antagonists. For the clinical evaluation of the restorations, the criteria listed in Appendix 3 will be used to evaluate the restorations directly and indirectly.

Distribution of Restorations

Each patient must need at least 1 restoration, however, 2 restorations can be placed if that patient has more lesions. A minimum of 75% of the restorations will be class II, and the remainder may be class I restorations with approximately 75% molars and 25% premolars. Four clinicians will insert 60 restorations to have presumably at least 50 restorations available for the 3 year recall.

Size of Cavities

Moderate-large cavities with an isthmus width greater than 1/3 the intercuspal distance (1/3 the distance between the cusp tips) will be selected for this study.

Patient Population

Subjects for this investigation will be selected from subjects of the Dental School at the University of Alabama in Birmingham. Fifty subjects ranging in age from 19 to 90 years will be recruited for this study, about 50% women and 50% men.

Inclusion Criteria

- Each subject must need at least 1 restoration in a vital posterior tooth
- Must have given written consent to participate in the trial
- Replacement of defective restorations (ie fractured, stained, unaesthetic) with or without caries are acceptable
- Must be available for the required three year follow-up visits
- Restored teeth must have occlusal contact with opposing teeth or restored teeth
- Restoration width should be equal to or greater than 1/3 the distance from buccal to lingual cusp tips
- 75% of the restorations Class II (minimum) and 25% Class I
- Each Class II will have at least one proximal contact
- 75% in molars (minimum) and 25% in premolars
- All restored teeth must have at least one occlusal contact in habitual closure
- Must have 20 or more teeth

Exclusion Criteria

- If they have an allergy against ingredients of the materials under investigations (monomers)
- Do not meet all inclusion criteria above
- Have severe medical complications (organ transplants, long term antibiotic or steroid treatment, cancer or immunocompromised) or disabilities who may not be able to tolerate the time required to complete the restorations or to provide adequate oral hygiene
- Have xerostomia either by taking medications known to produce xerostomia or those with radiation induced or Sjögren's syndrome subjects since dry mouth increases tooth and restoration wear as well as the development of caries.
- Have teeth with advanced or severe periodontitis or rampant caries or poor oral hygiene which may require extraction of the teeth to be restored
- Present with any systemic or local disorders that contra-indicate the dental procedures included in this study
- Have an unstable occlusion
- Have severe bruxing or clenching or need of TMJ related therapy
- Have tooth with exposed pulp during preparation or caries removal
- Teeth that are non-vital or that exhibit signs of pulpal pathology for restoration
- Teeth that require cuspal build-ups involving more than one cusp

Screening

Each subject will be screened for compliance with the inclusion/exclusion criteria specified above. Subjects will be given the consent form and after careful reading any questions will be answered. We will additionally explain any terms, phases or descriptors the subject may not understand. After signing the consent form they will receive a copy of the form.

Risks to the Patient

Subjects will wear lead aprons as a protective measure during the radiographic procedure to minimize risk. Patient data will be monitored and if, during the course of the study, it becomes apparent that any restorative material has poor performance the patient will be informed and if needed the restorations replaced without any costs for the patient.

Consent

Consent for this study will be obtained prior to the initial examination and the initiation of any portion of the study. The PI or Co-investigator will explain the consent to the patient and answer questions they have. The consent forms and all records associated with this study will be maintained in the clinical research office (Room 610) under lock to ensure the records are confidential. Each subject will provide written consent to participate in this study in accordance with Federal regulations (21 CFR Parts 50 and 56).

Materials and Methods

One dental filling will be placed and evaluated in this study. The F-Composite 2, optimized for bulk placement (up to 4mm increments) and three second polymerization will be evaluated. It will be used with the bonding agent Adhese Universal (Ivoclar Vivadent) in a total-etch mode. All restored teeth will be in occlusion and at least one proximal surface of each class II restoration will be in contact with an adjacent tooth. Cavity preparations will be made the same way for all restorations following rubber dam isolation. A pre-operative photograph will be taken of all teeth in the study.

The experimental material will be cured with the prototype (Bluephase PowerCure) of a new curing device (3,400mW/cm^2).

Data Analysis

The categorized clinical assessment (data see above) will be summarized by computing percentages for each category and used to describe any trends noted in the performance of the groups. In the analysis of categorical data of surface luster, surface staining, color match, material fracture, occlusal wear, tooth integrity, caries, marginal adaptation, marginal staining, contact point, post-operative hypersensitivity, patient's satisfaction, and radiographic examination, the frequency distribution over various categories will be calculated and reported. A sample size of 60 subjects is not based on a statistical plan, but rather on guidelines put forth by the American Dental Association.

APPENDIX 1
SCHEDULE OF EVENTS

Procedure	Screening	Preparation	Baseline	6 month	1 year	2 year	3 year
Preoperative radiograph	X						
Subject assignment #	X						
Preoperative sensitivity	X						
Preoperative photograph		X					
Photograph of cavity preparation		X					
Treatment		X					
Photograph	x	x	X	X	X	X	X
Direct Assessment							
Surface Luster			X	X	X	X	X
Surface Staining			X	X	X	X	X
Color Match			X	X	X	X	X
Material Fracture			X	X	X	X	X
Occlusal Wear			X	X	X	X	X
Tooth Integrity			X	X	X	X	X
Caries			X	X	X	X	X
Marginal Adaptation			X	X	X	X	X
Marginal Staining			X	X	X	X	X
Contact Point			X	X	X	X	X
Sensitivity			X	X	X	X	X
Patients View			X	X	X	X	X
Post-op Sensitivity			X	X	X	X	X
Radiographic examination	X					X	X
Indirect Assessment							
BW Radiograph	X					X	X
PA Radiograph (if necessary)			(X)	(X)	(X)	(X)	(X)
Complaints			X	X	X	X	X
Adverse events			X	X	X	X	X
Unanticipated Advers			X	X	X	X	X

Effects							