A 24-Month Clinical Evaluation of an Ultra-rapid Polymerizing Resin Composite

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ABSTRACT

The aim of this investigation is to characterize the restoration of posterior teeth using a novel, ultra-rapid polymerizing composite tooth restoration material by its comparison to restoration of posterior teeth using a conventional polymerizing composite tooth restoration material.

This prospective comparative clinical investigation uses a 'split mouth', within-subject design to evaluate an ultra-rapid polymerizing composite tooth restoration material for restoration of posterior tooth cavities and defects. Each participant will receive one conventional polymerizing (20-40 second) composite tooth restoration and one ultra-rapid polymerizing composite tooth restoration in different quadrants of their mouth (**Figure 1**). The primary outcome measure will be post-operative, self-reported tooth sensitivity. The polymerization light source is of high intensity; heat produced is limited by the 3-second exposure. While in vitro studies suggest little rest, heat-related sensitivity may be observed. Further, polymerization contraction can deform the vital tooth, causing fluid flow in the cells restricted in the tooth mineral that stimulates pain perception. Secondary outcome measures include a battery of measures that report on the integrity of the restorations over the 2-year evaluation period.

Rationale: Resin composite polymeric restorations have many major advantages for posterior tooth restoration including the ability to provide a more esthetic restoration, a lack of mercury, and the conservation of more of the remaining tooth. A major disadvantage is their technique sensitivity related to the assurance that the light-activated polymerization is complete. Large (posterior) restorations must be created incrementally, requiring significant time and effort. Alternative composites, so-called Bulk Fill composites, can be placed in large increments, but require extended polymerization times and may risk incomplete polymerization leading to failure. Polymerization is affected by the composite type, color, translucency and distance from the polymerization light source. The ability to cure composite increments in thicker increments and shorter time periods would allow for a more efficient and less time-consuming restoration insertion procedure. An ultra-rapid polymerizing composite offers clinical advantages. One consideration, however, is how the temperature and rate of polymerization influences the tooth response to heat and polymerization contraction. Transient temperature rises may elicit sensitivity and rapid changes in micron-scale tooth dimension may cause tooth sensitivity or pain.

BACKGROUND

Research problem and rationale: Placing direct (in the oral cavity of the patient) composite fillings is one of most frequently performed interventions of a dentist in a dental office. Given the many intermediate steps, which have to be carried out under dry conditions in the wet mouth environment, this type of intervention is technique dependent. Many steps are time dependent due to polymerization of the composite resins and required bonding agents. The simplification and the increased efficiency of the procedure is, therefore, desirable from the point of view of the user and the patient and may influence positively the restoration quality through improved compliance (time). The objective of the ultra-rapid polymerizing composite (F-Composite 2 system) is to reduce this period of time. Hence, the individual layers of the filling, which may be up to 4 mm thick, and the adhesive (bonding agent) can be polymerized in 3 seconds. At present, curing times of up to 40 seconds are common. Composite polymers undergo polymerization contraction. Micron-level contraction of the restored tooth and causes fluid flow in the cells restricted in the tooth mineral which stimulates pain perception. The primary outcome measure of this study is self-reported post-operative tooth sensitivity or pain. The polymerization-related quality of the restoration will be evaluated over 2 years using clinical parameters and intraoral photographs.

Experience / history relevant to the research. To assure restorative integrity and quality, light-curing composite restoratives are usually applied in layers less than 2 mm in thickness. This increment technique, with each layer being separately cured assured complete polymerization. Few restorative composites currently on the market permit a higher layer thickness and the experiences from clinical studies are sparse. Even though some materials allow increment thicknesses of 4 mm, longer curing times are required and these are influenced by clinical factors such as compliance to time, polymer color, distance of curing light to polymer, and the curing light power. Generally, it has been impossible to cure 4 mm composites in less than10 seconds. The main reason is that the upper limit of the available polymerizing light intensities is approximately 2,000 mW/cm2.

Here, we will evaluate an ultra-rapid polymerizing composite system (F-Composite 2 system) composed of three components: F-Composite 2, Tetric EvoFlow Bulk Fill composites and the bonding agent, Adhese Universal. All are polymerized with a new type of curing light (Bluephase PowerCure) that emits blue light with a 1.5 times higher intensity than the currently strongest curing lights. The Bluephase PowerCure curing light emits an intensity of 3050 mW/cm2. In conjunction with F-Composite 2, Bluephase PowerCure enables curing of the filling material to 4 mm thickness in only 3 seconds.

As the laboratory tests and technical data of F-Composite 2 have shown promising results, clinical results are now being gathered. As stated above, the focus here is the assessment of the frequency of postoperative sensitivity and the examination of the restoration quality over 2 years.

OBJECTIVES

Objective: The objective of this 2 year split mouth comparative study is to determine whether the simplified placement procedure of a ultra-rapid polymerizing "F-Composite 2" System in single increments of up to 4mm with a reduced light polymerization time (3 seconds) yields the same clinical results as a widely used commercially available dental composite (Tetric EvoCeram Bulk Fill, Tetric EvoFlow Bulk Fill) requiring up to 40 seconds of light polymerization time.

Hypothesis: The rapid polymerization of a bulk fill composite system provides clinical posterior tooth restoration equivalent to conventional polymerization composite systems.
Primary outcome measure: post-operative tooth sensitivity.
Secondary outcome measures: restoration quality evaluation.
Study duration: 2 years.

ELIGIBILTY

Subject population and source: Subjects for this investigation will be recruited from patients seeking care within the clinics of the Dental School at the University of Illinois at Chicago. Fifty subjects ranging in age from 18 to 80 years of age will be recruited for this study.
The study PI and investigators will determine the eligibility of potential study participants.
Eligibility will be recorded in the recruitment log and will be maintained by the study coordinator. The recruitment log will be stored as part of the study documentation in a locked file cabinet in the locked office of the study coordinator. An eligibility checklist is attached.

INCLUSION CRITERIA

Each subject must need at least 2 restorations in a vital posterior tooth.
Restorations may be indicated for caries removal and restoration, replacement of defective restorations (i.e. fractured, stained, unaesthetic), or requested replacement of unaesthetic restorations.
Must have given written consent to participate in the trial
Must be available for the required two 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
One, two or three surfaces per restoration
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 with evidence of bilateral posterior tooth contacts
Teeth that require one or no cuspal build-ups
Vital tooth
Preoperative Sensibility on the teeth to be treated at maximum 3 on visual analog scale (10 = maximum).
Patient wishes to be treated in this clinical trial after oral information by the operator und after signing the informed patient form.

EXCLUSION CRITERIA

Allergy against ingredients of the materials under investigations (monomers)
Do not meet all inclusion criteria above
Have medical complications (organ transplants, long term antibiotic or steroid treatment, cancer or immunocompromised) or disabilities rendering them unable to tolerate the time required to complete the restorations or to provide adequate oral hygiene
Suffer from xerostomia either by taking medications known to produce xerostomia or those with radiation induced or Sjögren's syndrome subjects.
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 contraindicate the dental procedures included in this study
Patients reporting having severe bruxing or clenching or need of TMJ related therapy
Have tooth with exposed pulp during preparation or caries removal or require indirect pulp capping.
Inclusion of teeth that are non-vital or that exhibit signs of pulpal pathology (pulpitis)
If the working field cannot be maintained in a dry state for treatment.

STUDY DESIGN

There are no collaborating sites

The study is a 2 year prospective, split-mouth, comparative study that will compare the clinical outcomes of two different posterior composite tooth restorative systems. The study involves recruitment, one intervention visit and three additional evaluations over the two-year period.
The study will be performed in the clinical research center. Subjects will participate over 2 years in 5 clinical visits that requires a total of approximately 5 hours.
Two dental fillings per patient will be placed and evaluated in this study. The F-Composite 2 system, optimized for bulk placement (up to 4mm increments) and three-second polymerization and the conventional Tetric EvoCeram Bulk Fill / Tetric EvoFlow Bulk Fill (Ivoclar Vivadent) will be evaluated. They will be placed with the bonding agent Adhese Universal (Ivoclar Vivadent) in self 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 F-Composite 2 system material will be cured with the prototype (Bluephase PowerCure) of a new curing device (3,050mW/cm2) while the conventional Tetric material will be cured with the same device at a lower power setting (High Power mode 1,200mW/cm2).

Evaluation
Each restoration will be evaluated directly and indirectly (photographs) at baseline (one week after restoration placement), 6 months, 1 year, and 2 years.

Post-operative hypersensitivity of the teeth will be evaluated in the following way. The subject is asked to rate on a visual analogue scale VAS (0-10) whether the restored tooth suffers from pain due to cold, heat, sweet, biting or clenching. Additionally, the restored tooth will be tested with a stream of cold air (air syringe) and the subject is asked to bite on a cotton roll. For both tests the subject is asked to rate on a visual analogue scale VAS (0-10) whether the restored tooth suffers from pain. Additional elicitation of sensitivity will be achieved by cold stimulus (cold refrigerant spray) and VAS assessment.

STATISTICAL CONSIDERATION

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. The published reports of post-operative sensitivity (primary outcome measure) range from 0 - 20% using the (Costa TRF 2017). However, "there is inconsistent, low-quality evidence regarding the difference in postoperative hypersensitivity subsequent to placing a dental cavity liner under Class I and Class II posterior resin-based composite restorations in permanent posterior teeth in adults."(Schenkel AB et al, Cochrane Database Syst Rev. 2016 Oct 25;10:CD010526) Selecting an informed 4% response of sensitivity with a 5% error at a 90% confidence interval, we would require 50 individuals to identify a significant response of sensitivity. Notably, a sample size of 50 subjects is not based on a statistical plan, but rather on guidelines put forth by the American Dental Association. Additionally, a Kaplan-Meier survival analysis will be performed to estimate the lifetime of the material based on clinical failures

APPENDIX 1
SCHEDULE OF EVENTS

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

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