CLINICAL INVESTIGATION OF

A NEW BULK FILL COMPOSITE RESIN

IN THE RESTORATION OF POSTERIOR TEETH

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UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
DEPARTMENT OF OPERATIVE DENTISTRY

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ABSTRACT

Polymerization shrinkage remains one of the primary disadvantages of composite resin restorative materials. To minimize the effects of polymerization shrinkage and consequently allow clinicians to expedite the restorative treatment, the 3M ESPE company has developed a bulk fill composite resin called Filtek™ Bulk Fill Posterior Restorative. This clinical trial is designed to evaluate the performance of the new composite resin in Class II restorations. A conventional composite resin material, Filtek™ Supreme Ultra Universal Restorative, will be used as the control. Restorations will be placed and evaluated using defined criteria at one, two, three, and five years after placement.

INTRODUCTION

Polymerization of resin-based composite resin restoratives leads to shrinkage of the material on setting. Conversion of monomers to long chain polymers results in a reduction in volume as the material sets. The clinical effects of this shrinkage can include postoperative sensitivity, marginal gap formation and leakage, cuspal strain, and microcracks in enamel [1,2]. Since Bowen noted polymerization shrinkage of resin bonded to etched enamel [3], much research has been carried out to gain understanding of the kinetics of polymerization shrinkage. Polymerization stress of composite resins during light-curing is considered to be an important factor in bond failure of an adhesive restoration [2]. Recent work has shown that the effects of polymerization shrinkage stress on tooth structure are highly complex. With direct composite resins, stress levels in the tooth increase with increasing restoration size [4,5], stresses in the restoration itself, and at the adhesive interface, tending to diminish with increasing cavity size [5]. Clinical methods to reduce the effects of shrinkage stress include sealing the restoration margins with unfilled resin [6], using a stress-absorbing liner [7,8], using reduced light intensity for curing the composite resin restoration [9-11], and placing the composite resin in increments [12].

The desirability of a reduced shrinkage restorative material is widely acknowledged [2,13-15]. The potential advantages of a low shrink composite resin would include less stress on the adhesive bond, leading to better margin adaptation, a reduction in postoperative sensitivity, and reduced stress build-up in the tooth itself [15], all features that might lead to enhanced longevity of the restoration in clinical service.

The continuing development of direct composite resin restoratives has resulted in the availability of a new material from 3M ESPE with significantly reduced polymerization shrinkage and shrinkage stress level.

AIM OF STUDY

The aim of this randomized, controlled clinical investigation is to evaluate the performance of 3M ESPE Filtek™ Bulk Fill Posterior Restorative composite resin in the restoration of moderate-sized Class II cavities in the permanent teeth of adult patients. This material will be compared with Filtek™ Supreme Ultra Universal Restorative (3M ESPE), an established and widely used composite resin restorative material. Restorations performed with both composite resins will be bonded with Scotchbond Universal Adhesive.

Dr. Ricardo Walter of the Department of Operative Dentistry, University of North Carolina (UNC) will be the principal investigator (PI) with overall responsibility for the conduct and reporting of the study. Dr. Walter and other Operative Dentistry personnel at UNC will undertake the clinical elements of the study. The study will be of five years duration.

ETHICAL STANDARDS

The study will be conducted in accordance with the Declaration of Helsinki (1964) as revised in Venice in 1983. IRB approval will be obtained prior to commencing the study and written informed consent will be obtained from all patients prior to recruitment into the study. Implicit in giving informed written consent, each patient will reserve the right to withdraw from the study at any time.

RISK ASSESSMENT

Filtek™ Bulk Fill Posterior Restorative is assessed as minimal risk. There is no anticipated clinical benefit of use of Filtek™ Bulk Fill Posterior Restorative over conventional composite resin materials except for the reduced time needed for the restorative procedure.

Filtek™ Bulk Fill Restorative is considered safe when used as indicated. The biocompatibility assessment for the material has been conducted in accordance with the testing guidelines outlined in (1) the FDA General Program Memorandum G95; (2) ISO 10993-1:2009(E) Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process with detailed guidance in ISO Standards 10993-3:2003 (Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity), 10993-5:2009 (Tests for In Vitro Cytotoxicity), 10993-10:2010 (Tests for Irritation and Skin Sensitization), and 10993-11:2006 (Tests for Systemic Toxicity); (3) ISO 7405:2008 Dentistry – Evaluation of Biocompatibility of Medical Devices in Dentistry; (4) Japan: PFSB/ELD/OMDE Notification No. 0301-1 from March 1, 2012; and (5) 3M ESPE Standard Operating Procedure 04-200. Filtek™ Bulk Fill Posterior Restorative was assessed as an external communicating device that is intended to be in contact with the body for greater than 30 days (ISO 10933 and ISO 7405, G95) and a coupling instrument between the inside and outside of the body (PFSB).

The data from these tests support the view that Filtek™ Bulk Fill Posterior Restorative is safe for its intended use.

PRECLINICAL TESTING

Extensive laboratory testing has been carried out to compare Filtek™ Bulk Fill Posterior Restorative with other composite resin materials. Filtek™ Bulk Fill Posterior Restorative compares favorably with Filtek™ Supreme Ultra Universal Restorative (the control material to be used in this study) for physical properties such as flexural modulus, fracture toughness, and flexural strength. Further internal data has shown wear and cusp deflection comparable to 3M ESPE Filtek™ Z250 Universal Restorative. In regards to the ability to light cure the composite resin in bulk, a study from Oregon Health Sciences University (unpublished "internal" data) has indicated that additional 10 s light curing from buccal and lingual allow Class II restorations to be placed in 5-mm increments. That should improve the physical

properties (microhardness) of the composite resin that otherwise has a depth of polymerization of approximately 4 mm (internal data).

HYPOTHESIS TO BE TESTED

The hypothesis is that Filtek™ Bulk Fill Posterior Restorative composite resin, when used to restore posterior teeth, will exhibit similar clinical performance – in terms of wear resistance, marginal integrity, durability, and other clinical characteristics – to Filtek™ Supreme Ultra Universal Restorative composite resin, a restorative material in everyday use in dentistry.

STUDY OBJECTIVES

The purpose of this study is to compare the clinical performance of Filtek™ Bulk Fill Posterior Restorative with a commercially available conventional composite resin restorative material when used to restore Class II preparations in molar and premolar teeth.

STUDY DESIGN

The study design is a randomized, controlled, comparative effectiveness clinical trial investigation of the test materials used to restore moderate-sized Class II cavities in posterior permanent teeth in adult dental patients. The study will be of five years duration.

Primary outcome measures

The primary endpoint is the clinical performance of the restorations measured according to the rating system published by Hickel et al. [16].

In the past, USPHS (or Ryge) criteria have been used to evaluate the clinical performance of restorative materials. These criteria were developed as a standardized method to clinically evaluate the quality of an amalgam or resin restoration shortly after placement. The word “quality” means the degree of excellence or degree of conformance to a standard. The rating system is based on an operational approach to quality assessment, which a dentist would use when examining any restoration in the mouth of a new patient. The dentist must decide whether to retain or replace the restoration [17].

This rating system has been in use for over 30 years of clinical investigation. Because the clinical performance of restorative materials has continuously improved, the original Ryge criteria have been modified frequently, which makes it difficult to compare studies on modern restorative materials.

Hickel et al. have offered a new approach to controlled clinical studies of restorative materials. Their publication deals with, among other issues, an adaptation of the established Ryge-criteria of restorative materials [16]. With this rating system, which will be used in this

study, restorations are evaluated scoring for their esthetic, functional and biologic properties.

Secondary outcome measures

All (serious) adverse events or (serious) adverse device effects will be documented on the appropriate "Adverse event/Adverse device effect form." Safety parameters of this clinical trial are predominantly based on the documentation of adverse events, serious or non-serious, as well as expected and unexpected reactions. Also, near incidents will be reported.

SUBJECT POPULATION AND SAMPLE SIZE

Subjects in the study will be recruited within the UNC School of Dentistry Predoctoral and Graduate clinics. Up to 50 adult subjects (18 years of age and older) will be recruited to provide at least 50 sets of matched or unmatched paired teeth in need of study restorations. Fifty restorations available at baseline and 40 at the 18-month follow-up visit are the minimum number recommended in the 2001 ADA guidelines for clinical trials on resin-based composite resins for posterior restorations. Subjects will be in need of two or four medium-sized Class II restorations in molar and/or premolar teeth.

INCLUSION AND EXCLUSION CRITERIA

To be included in the study, a potential subject must satisfy the criteria described below and be available for the various follow-up visits. A record will be maintained of the reasons for the loss of subjects from the study.

Inclusion Criteria

To be considered for inclusion in the study, subjects must:

- Be older than 18 years of age.
- Have a pair of similar lesions or failed restorations in vital permanent molar or premolar teeth requiring Class II restorations of moderate size that extend between one-quarter and one-third of the way up one or more of the cuspal slopes. Any Class II restoration must have a proximal portion with at least one margin that obviously extends into an interproximal embrasure. (Note: A tooth will be considered vital for the purposes of the study if it is clinically and/or radiographically free of any signs and symptoms of periapical pathology and responds to routine vitality testing.)
- Be capable of giving written informed consent.

Exclusion Criteria

Subjects will be excluded from participating in the study if they:

- Have a history of any adverse reaction to clinical materials of the types to be evaluated.
- Have a medical or dental history that could possibly complicate the provision of the proposed restorations and/or influence the behavior and performance of the restorations in clinical service.
- Have advanced periodontitis affecting the mobility of the teeth.
- Have xerostomia caused by medications, Sjögren's syndrome, etc.
- Are individuals with special needs.

Distribution of restorations

Each subject shall have a minimum of one pair and a maximum of two pairs of permanent molar or premolar teeth requiring moderate sized Class II restorations. No tooth shall require more than one restoration. Sufficient subjects will be recruited to ensure 50 pairs of test and control study restorations are placed. Although desirable, the pairs are not required to be precisely matched. For example, for purposes of the study, paired restorations can be placed in teeth #15 and #31 (upper left second molar and lower right second molar).

All teeth and restorations in the study will have occlusal contacts. All restorations, with the exception of disto-occlusal restorations in the most distal molars, will have a proximal contact with the adjacent tooth. No two test restorations of either material will be in occlusal or proximal contact with each other.

Selection of Teeth

In addition to the above criteria, the following will apply in tooth selection:

- The tooth must be vital, as determined by thermal test (Hygenic Endo-Ice, Coltène/Whaledent AG).
- The tooth must be of typical size, appearance and morphology.
- The tooth must share, where appropriate, sound proximal contacts with adjacent teeth.
- The tooth must be free of cracks and other defects and lesions necessitating operative intervention other than the restoration to be undertaken as part of the study.
- Proper isolation must be possible.

MATERIALS

The test material is Filtek™ Bulk Fill Posterior Restorative, a bulk fill, low-shrink, light-cured, radiopaque composite resin restorative indicated for use in direct posterior situations. The control material is Filtek™ Supreme Ultra Universal Restorative, a conventional composite resin. Restorations will be bonded with Scotchbond Universal Adhesive.

Manufacturers' instructions for use will be followed for all restoration placements included in the study. Manufacturers' instructions for use for Filtek™ Supreme Ultra Universal Restorative and Filtek™ Bulk Fill Posterior Restorative, and Scotchbond Universal Adhesive are given in the Investigator's Brochure.

PRE-OPERATIVE PROCEDURES

In the screening visit, written informed consent will be obtained from each subject. Each subject will be allowed to ask questions concerning the evaluation and to consider the answers given before signing the consent form.

The pre-operative status and a periapical radiograph (where clinically indicated) of each tooth to be included in the study will be evaluated and a pre-treatment status form will be completed (Patient Registration Form). The condition of the gingival tissue adjacent to each tooth to be restored will be assessed (four sites: facial, lingual, mesial and distal) and recorded as pre-treatment measurements (Patient Registration Form). Oral hygiene status including plaque index will be determined after periodontal evaluation. Appropriate vitality and radiographic assessments will be completed where indicated clinically, and will be recorded. A pre-operative photographic record will be made.

The restorative material to be used will be allocated by means of a randomization scheme based on computer generated random numbers (Appendix 1). Before starting the study, the PI will decide, by means of a toss of a coin, whether even or odd numbers indicate the test or control treatment. For each set of paired teeth, the lowest numbered tooth (Universal Numbering System) will be selected first. Before cavity preparation, the first randomization number in the sequence will be noted and the allocated treatment procedure carried out as indicated by the random number obtained. The second cavity is then prepared and restored using the second treatment option (next number in the row). Restorative treatments will be randomly assigned to the study teeth at the same visit at which pre-treatment gingival condition, vitality, etc., are determined.

The treating clinician will complete the preparation and placement of restorations, and the arrangements for the subsequent follow-up of the patients.

OPERATIVE PROCEDURES

Local anesthesia will be administered unless declined by the patient. The teeth to be restored will be prepared using conventional instruments and techniques, and no bevels will be placed on any of the cavosurface margins. Shades will be selected before the procedure is started and the tooth is still moist. Rubber dam will be used.

A sectional metal matrix (Garrison Dental or similar) and bitine ring will be placed along with plastic or wooden wedges. At the operator's discretion (e.g., if the preparation is

too wide for a sectional matrix), a thin circumferential metal matrix (Convexi-T, Clinician's Choice or similar) may be used. The bonding system will be used in the selective etch mode according to manufacturer's instructions.

Restoration placement will be completed in accordance with the recommended procedure for the materials under investigation and in a standardized fashion. After application of the adhesive, a bulk increment (up to 5 mm in thickness) of Filtek™ Bulk Fill Posterior Restorative will be placed and adapted with suitable instruments. Additional increments will be placed as needed. Filtek™ Supreme Ultra Universal Restorative will be incrementally placed in layers (no thicker than 2 mm). The composite resin (each increment of Filtek™ Supreme Ultra Universal Restorative) will be light cured following the recommended exposure time using a device provided by the sponsor. Additional light curing will be performed from facial and lingual for Filtek™ Bulk Fill Posterior Restorative after matrix removal per instructions for use.

Excess material will be removed with suitable instrumentation. Occlusion will be checked and adjusted as needed. Restorations will be polished with diamond abrasives, flexible polishing discs and finishing strips with progressively decreasing grit size (e.g. Sof-Lex™, 3M ESPE), ultra-fine grain diamonds, and/or silicone polishers at the clinicians' discretion. Impressions of restorations using the 3M True Definition Scanner and Imprint™ 3 VPS Impression Material will be taken at each follow-up visit for evaluation of wear over time. Models will be poured and wear determined using the Leinfelder method [18]. The models will also be assessed for wear via optical profiling at the Minnesota Dental Research Center for Biomaterials and Biomechanics. Digital impressions of the restored teeth will be taken at each follow-up visit using the 3M True Definition Scanner. The digital data will be analyzed for wear at 3M ESPE.

The placements and baseline assessments will be completed within 6-12 months of the agreed starting date of the evaluation.

FOLLOW-UP ASSESSMENT

During the follow-up investigation, two examiners will evaluate the restorations relative to the criteria provided by Hickel. The two examiners who undertake the reviews will work independently and will be masked to the treatment conditions. In the event of disagreement between the examiners, agreement will be reached based on discussion. The final result will be marked on the Case Report Form.

To determine the clinical acceptability of the restoration they are evaluated scoring for their esthetic, functional and biologic properties, which are shown in Table 1. The test requires a sharp explorer plus visual inspection, aided by a mouth mirror as needed. A photographic record will be made of each restoration. For evaluation of marginal adaptation a set of

explorers with different blunt tips of 50, 150 and 250 μm is recommended by Hickel et al. [16]. For assessment of contact point metal strips of different thicknesses of 25 μm, 50 μm and 100 μm can be used. The explorers and metal strips will be provided by the sponsor.

The two masked examiners will use a two-step approach for assigning scores for each parameter. The first step is to assess the restoration and to determine the level of clinical acceptability for each parameter in each of the categories. The result becomes unacceptable whenever re-treatment is necessary.

If a parameter is judged to be acceptable, as a second step, a further distinction can be made between an excellent, good, or clinically satisfactory result. Score 1 means that the quality of the restoration is excellent and fulfils all quality criteria and the tooth and/or surrounding tissues are adequately protected. Score 2 should be selected when the quality of the restoration is still highly acceptable, although one or more criteria deviate from the ideal. The restoration could be modified by polishing and upgraded to an “excellent” rating, but this is not normally necessary. There is no risk of damage to the tooth and/or surrounding tissue. Score 3 means that the quality of the restoration is sufficiently acceptable but with minor shortcomings. Because of their location/extent, however these cannot be eliminated without damage to the tooth, although no adverse effects are anticipated. Scores 1 and 2 would correspond to Ryge´s Alfa rating; Score 3 is equivalent to Bravo.

If a parameter is judged to be unacceptable, a further distinction can be made between a clinically unsatisfactory and clinically poor result. Scores 4 and 5 correspond to Ryge´s Charlie and Delta scoring, which means that a restoration scored 4 is unacceptable but repairable whereas a restoration scored 5 must be replaced [16].

In the event of a restoration being considered to be clinically unsatisfactory, this restoration will be excluded from the study and arrangements made to replace or, if appropriate, repair the defective or failed restoration. The mode of failure of the restoration will be documented (Failed Restoration Form).

The examiners assigned to review the restorations will have been trained in the evaluation system to be used, and will be capable of achieving at least 85% reproducibility in their assessments.

The reviews will take place at one, two, three, and five years ± 1 month after placement.

Adverse events or adverse device effects

The Investigators are responsible for identifying adverse events, any untoward medical occurrence, that occurs to each subject throughout the study. Adverse events must be documented on the (Serious) Adverse Event Form (Appendix 2). Serious adverse events must be reported to the Sponsor within 24 h. Study subjects who have experienced an adverse event may remain in the study as long as the safety, rights and /or welfare of subjects

are not put at risk and/or the restoration is unaffected concerning its quality and function. Serious adverse events are adverse events that (a) led to a death; (b) led to a serious deterioration in the health of the subject, or (c) led to fetal distress, fetal death or a congenital abnormality or birth defect.

A device-related adverse event is one considered by the investigator to have a reasonable likelihood of being associated with the investigational device and is called an adverse device effect. Adverse device effects must be documented on the Adverse Device Effect Form. Serious adverse device effects must be reported within 24 h to the contact person at **3M ESPE, telephone number (651) 733-3384**. A serious adverse device effect is an effect that resulted in any of the consequences characteristic of a serious adverse event.

(Near) Incident is any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or instruction for use, which might lead or might have led to the death of a patient or user or to a serious deterioration in his state of health.

Any incident that led to any hazard for the patient has to be regarded as adverse device effect and documented accordingly. The Investigator reports serious (near) incidents as soon as possible and no later than 24 h to 3M ESPE.

SUBJECT INCENTIVES

All restorations carried out in this study will be at no cost to the subjects. Subjects will be expected to attend the one-, two-, three-, and five-year follow up visits. Compensation of $50 will be paid to each subject at baseline and each follow-up visit (total of $250).

MONITORING

The study will be monitored at appropriate intervals by Dr. Rolf H. Halvorson, Scientific Affairs Manager, 3M ESPE Dental Products, 3M Center, Bldg. 275-2SE-03, St. Paul, MN, 55144 [rhhalvorson@mmm.com], or his designee, by means of regular contact to evaluate study data and photographs.

DATABASE MANAGEMENT

Each subject recruited into the study will be given a unique identifying code number and the subject's identity will be kept confidential as far as is practical.

ANALYSIS OF THE RESULTS

The demographic and baseline measurements, and the study data obtained, will be analyzed by means of tables of percentages to summarize the characteristics of the patients and the baseline data. Tables of percentages will be prepared to illustrate the follow-up and retrospective analysis findings. Cross tabulation will be prepared as necessary.

Statistical analyses

Chi-square (x^2), McNemar and Mann-Whitney-U tests will be applied as appropriate to compare the baseline and follow-up/review findings regarding the two types of restorations.

PROBLEM CASES

In the case of an experimental Filtek™ Bulk Fill Posterior Restorative or Filtek™ Supreme Ultra Universal Restorative composite resin restoration being found to have failed or to be clinically unsatisfactory on review, the investigator will:

- Complete the failed restoration form.
- Make a photographic and silicone impression record of the failed restoration.
- Make arrangements to replace or, if appropriate, repair the restoration.

Replacements of failed restorations will not form part of the study.

In the case of failure of restorations placed using either restorative system, the tooth will be re-restored at no cost to the subject or investigator. The contact person at 3M ESPE (Rolf H. Halvorson, (651) 733-3384) should be notified before this treatment is done.

ADVERSE EVENTS

If an adverse event occurs any decision as to whether to prematurely stop the study will be taken jointly by the PI, 3M ESPE, and IRB. Changes to the protocol will be by arrangement between the PI, IRB, and 3M ESPE, and will take the form of a signed amendment.

In the event of an adverse reaction being shown to be related to the proposed use of any restorative material, any indemnity will be borne by 3M ESPE in accordance with the contract.

REPORTS TO SPONSOR

The PI will be responsible for the preparation and submission of the one-, two-, three-, and five-year reports to the Sponsor.

PUBLICATION OF FINDINGS

The investigators will be entitled to publish the study findings; the data also may be presented as an abstract or oral presentation at appropriate Dental Research meetings. Any

manuscript, abstract or other form of presentation prepared for submission or public presentation will be submitted to the Sponsor for comment according to the contract. The data will be communicated internally in 3M ESPE to appropriate members of the Business Team, Research and Development, Marketing, Regulatory and Professional Services personnel.

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Table 1. FDI World Dental Federation criteria for evaluation of restorations.

a) Aesthetic properties	1. Surface luster	2. Surface staining	3. Color stability and translucency	4. Anatomic form
1. Clinically excellent / very good	1.1. Luster comparable to enamel.	2.1. No surface staining.	3.1. Good color match, no difference in shade and translucency.	4.1. Form is ideal.
2. Clinically good (very good after polishing)	1.2. Slightly dull, not noticeable from speaking distance.	2.2. Minor surface staining, easily removable.	3.2. Minor deviations.	4.2. Form is only slightly affected.
3. Clinically sufficient / satisfactory (minor shortcomings, no unacceptable effects but not adjustable without damage to the tooth)	1.3. Dull surface but acceptable if covered with film of saliva.	2.3. Moderate surface staining, also present on other teeth, not aesthetically unacceptable.	3.3. Clear deviation but acceptable. Does not affect aesthetics. 3.3.1. More opaque. 3.3.2. More translucent. 3.3.3. Darker. 3.3.4. Brighter.	4.3. Form differs but is not aesthetically displeasing.
4. Clinically unsatisfactory (but repairable)	1.4. Rough surface, cannot be masked by saliva film, simple polishing is not sufficient. Further intervention necessary.	2.4. Surface staining present on the restoration and is unacceptable. Major intervention necessary for improvement.	3.4. (Localized) clinically unsatisfactory but can be corrected by repair. 3.4.1. Too opaque. 3.4.2. Too translucent. 3.4.3. Too dark. 3.4.4. Too bright.	4.4. Form is affected and unacceptable aesthetically. Intervention (correction) necessary.
5. Clinically poor (replacement necessary)	1.5. Quite rough, unacceptable plaque, retentive surface.	2.5. Severe staining and / or subsurface staining (generalized or localized), not accessible for intervention.	3.5. Unacceptable. Replacement necessary.	4.5. Form is completely unsatisfactory and / or lost. Repair not feasible / reasonable, replacement needed.

b) Functional properties	**5. Fractures and retention**	**6. Marginal adaptation**	**7. Wear**	**8. Contact point / food impact**	**9. Radiographic examination (when applicable)**	**10. Patient's view**
1. Clinically excellent / very good	5.1. Restoration retained, no fractures / cracks.	6.1. Harmonious outline, no gaps, no discoloration.	7.1. Physiological wear equivalent to enamel (80-120% of corresponding enamel).	8.1. Normal contact point (floss or 25 µm metal blade can be inserted but not 50 µm blade).	9.1. No pathology, harmonious transition between restoration and tooth.	10.1. Entirely satisfied.
2. Clinically good (very good after polishing)	5.2. Small hairline crack.	6.2.1. Marginal gap (50 µm). 6.2.2. Small marginal fracture removable by polishing.	7.2. Normal wear with only slight difference to enamel (50-80 % or 120-150 % of corresponding enamel).	8.2. Slightly too strong but no disadvantage.	9.2.1. Acceptable excess present. 9.2.2. Positive / negative step present at margin < 150 µm.	10.2. Satisfied.
3. Clinically sufficient / satisfactory (minor shortcomings, no unacceptable effects but not adjustable without damage to the tooth)	5.3. Two or more or larger hairline cracks and / or chipping (not affecting the marginal integrity or proximal contact).	6.3.1. Gap < 150 µm not removable. 6.3.2. Several small enamel or dentin fractures.	7.3. Differing wear rate to enamel but within the biological variation (< 50 % or 150-300 % of corresponding enamel).	8.3. Slightly too weak, no indication of damage to tooth, gingiva or periodontal structures (50 µm metal blade can pass easily but not 100 µm).	9. 3. 1. Marginal gap < 200 µm. 9. 3. 2. Negative steps visible < 250 µm. No adverse effects noticed. 9.3.3. Poor radiopacity of filling material.	10.3. Minor criticism of aesthetics. 10.3.1. Aesthetic shortcomings. 10.3.2. Some lack of chewing comfort. 10.3.3. Time consuming procedure and / or similar. No adverse clinical effects.
4. Clinically unsatisfactory (but repairable)	5.4. Chipping that damage marginal quality or proximal contacts, bulk	6.4.1. Gap > 250 µm or dentin / base exposed.	7.4. Wear considerably exceeds normal enamel wear, or occlusal contact	8.4. Too weak (100 µm metal blade can pass) and possible damage (food	9.4.1. Marginal gap > 250 µm. 9.4.2. Excess accessible but not removable.	10.4. Desire for improvement (reshaping of anatomic

	fractures with or without partial loss (less than half of the restoration).	6.4.2. Chipping damaging margins. 6.4.3. Notable enamel or dentin wall fracture.	points are lost (restoration > 300 % of enamel wear or antagonist > 300 %).	impaction). Repair possible.	9.4.3. Negative steps > 250 μm and repairable.	form or refurbishing, etc.).
5. Clinically poor (replacement necessary)	5.5. (Partial or complete) loss of restoration.	6.5. Filling is loose but in situ.	7.5. Wear is excessive (restoration or antagonist > 500 % of corresponding enamel).	8.5. Too weak and / or clear damage (food impaction) and / or pain / gingivitis. Requires replacement.	9.5.1. Secondary caries, large gaps. 9.5.2. Apical pathology. 9.5.3. Fracture / loss of restoration or tooth.	10.5. Completely dissatisfied and / or adverse effects including pain.

c) Biological properties	**11. Postoperative (hyper) sensitivity and tooth vitality**	**12. Recurrence of caries, erosion, abfraction**	**13. Tooth integrity (enamel cracks)**	**14. Periodontal response (always compared to a reference tooth)**	**15. Adjacent mucosa**	**16. Oral and general health**
1. Clinically very good	11.1. No hypersensitivity, normal vitality.	12.1. No secondary or primary caries.	13.1. Complete integrity.	14.1. No plaque, no inflammation, no pockets.	15.1. Healthy mucosa adjacent to restoration.	16.1. No oral or general symptoms.
2. Clinically good (after correction very good)	11.2. Low hypersensitivity for a limited period of time, normal vitality.	12.2. Very small and localized areas of: 1. Demineralization, 2. Erosion, or 3. Abfraction. No operative treatment required.	13.2.1. Small marginal enamel split (< 150 μm). 13.2.2. Hairline crack in enamel (< 150 μm not probable).	14.2. Little plaque, no inflammation (gingivitis), no pocket development.	15.2. Healthy after minor removal of mechanical irritations (sharp edges, etc.).	16.2. Minor transient symptoms of short duration (of known or unknown origin) local or generalized.
		12.3. Larger areas of:				

3. Clinically sufficient / satisfactory (minor shortcomings with no adverse effects but not adjustable without damage to the tooth)	11.3.1. Premature / slightly more intense. 11.3.2. Delayed / weak sensitivity. No subjective complaints, no treatment needed.	1. Demineralization, 2. Erosion, or 3. Abrasion / abfraction. Only preventive measures necessary (dentin not exposed).	13.3.1. Enamel split < 250 μm. 13.3.2. Crack < 250 μm. No adverse effects.	14.3.1. Plaque accumulation at acceptable level. 14.3.2. Gingival bleeding acceptable. 14.3.3. Pocket formation acceptable.	15.3. Alteration of mucosa but no suspicion of causal relationship with filling material.	16.3. Transient symptoms, local and / or general.
4. Clinically unsatisfactory (repair for prophylactic reasons)	11.4.1. Premature / very intense. 11.4.2. Extremely delayed / weak with subjective complaints. 11.4.3. Negative sensitivity. Intervention necessary but not replacement.	12.4.1. Caries with cavitation. 12.4.2. Erosion in dentin. 12.4.3. Abrasion / abfraction in dentin. Localized and accessible and can be repaired.	13.4.1. Major enamel split (gap > 250 μm or dentin or base exposed). 13.4.2. Crack > 250 μm (probe penetrates).	14.4.1. Plaque accumulation not acceptable. 14.4.2. Gingival bleeding not acceptable. 14.4.3. Pocket depth increase > 1 mm.	15.4. Suspected mild allergic, lichenoid, or toxicological reaction.	16.4. Persisting local or general symptoms of oral contact stomatitis, lichen planus, or allergic reactions (or remitting). Intervention necessary but no replacement.
5. Clinically poor (replacement necessary)	11.5. Very intense, acute pulpitis or non-vital. Endodontic treatment is necessary and restoration has to be replaced.	12.5. Deep secondary caries or exposed dentin that is not accessible for repair of restoration.	13.5. Cusp or tooth fracture.	14.5. Severe / acute gingivitis or periodontitis.	15.5. Suspected severe allergic, lichenoid, or toxicological reaction.	16.5. Acute / severe local and / or general symptoms.

APPENDIX 1

Clinical investigation of a new bulk fill composite resin in the restoration of posterior teeth

RANDOM NUMBERS TABLE

30	89	34	43	98	79	50	49
98	07	53	64	54	23	87	50
91	54	58	41	06	79	69	90
13	38	59	44	46	25	38	19
65	48	27	62	58	51	79	30
78	05	73	70	42	19	74	41
75	26	79	66	12	05	88	07
15	62	76	89	23	14	38	65
63	40	79	60	02	89	31	50
10	55	17	44	07	76	62	37
05	34	19	54	27	96	52	47
27	70	88	07	10	45	77	28
71	66	24	27	16	73	03	98
43	04	83	14	13	96	53	98
65	28	89	34	06	75	17	70
51	46	21	60	13	84	32	47
06	71	33	46	59	78	29	16
21	82	98	23	75	90	10	63
69	01	90	21	57	14	98	64
92	43	88	01	29	12	45	58
16	81	70	31	43	02	93	10
35	12	65	24	50	71	43	04
72	79	96	25	39	14	21	88
20	31	03	98	60	51	93	62
89	68	51	28	99	30	67	48
46	81	92	79	93	02	71	26
19	98	34	59	48	29	03	22
46	93	59	42	41	42	13	74
07	30	41	50	11	80	23	78
06	22	74	23	59	70	18	05
36	97	60	89	07	24	48	17
06	31	70	27	37	18	53	94
05	08	53	09	70	88	63	02
20	82	16	77	29	58	37	50
17	60	07	20	21	10	90	13
94	09	87	30	12	53	62	91
31	26	50	29	52	19	41	98
70	07	17	36	92	21	14	29
81	18	51	12	67	04	21	72
03	44	27	40	58	17	32	01
29	78	41	60	37	88	51	02

APPENDIX 2

Clinical investigation of a new bulk fill composite resin in the restoration of posterior teeth

ADVERSE EVENT REPORT FORM

Subject #: _____ Date: ____/____/_____.

Examiner: _____

Tooth #: _____

Number of surfaces: ☐ 2 ☐ 3 ☐ 4 Specify: ☐ M ☐ D ☐ O ☐ F ☐ L

Material: ☐ 3M ESPE Filtek™ Bulk Fill Posterior Restorative

☐ 3M ESPE Filtek™ Supreme Ultra Universal Restorative

Radiograph(s) taken: ☐ Yes ☐ No Photographs taken: ☐ Yes ☐ No

Describe the Adverse Device Effect; provide chronology of events, actions taken and outcome. Use another form if needed.
Did the adverse device effect increase in severity? ☐ Yes ☐ No **If yes, to what degree?** ☐ Moderate ☐ Severe

Document the provision made for subjects in the event of injury arising from participation in the study:

Signature of clinician: _____ Date: ____/____/_____.

Fax completed form within five days of incidence of Adverse Event to study monitor Rolf H. Halvorson at (651) 733-3384.

APPENDIX 3

AGREEMENT TO PROTOCOL

_____	_____
Dr. Ricardo Walter Principal Investigator UNC School of Dentistry	Dr. Andreas Syrek Scientific Affairs Manager 3M ESPE Europe
Date _____	Date _____