TUFTS UNIVERSITY SCHOOL OF DENTAL MEDICINE

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Clinical Evaluation of Kerr SonicFill™ 2 vs 3M ESPE Filtek™ Supreme Ultra Universal Restorative

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Study team telephone number: (617) 636-0870

INTRODUCTION

You are being invited to take part in a research study comparing two types of materials used to fill cavities, because you have at least 2 back teeth with cavities that need filling.

Taking part in this research study is entirely your choice. You can decide to refuse to participate in this study. If you decide to participate in this study, you can then choose to stop taking part in the study at any time for any reason. If you refuse to participate in the study or stop being in this study, it will not affect your care or treatment outside this study, payment for your health care, or your health care benefits.

Please read all of the following information carefully. Ask Dr. Kugel, or his representative, to explain any words, terms, or sections that are unclear to you. Ask any questions that you have about this study. Do not sign this consent form unless you understand the information in it and have had your questions answered to your satisfaction.

If you decide to take part in this research study, you will be asked to sign this form. You will be given a copy of the signed form. You should keep your copy for your records. It has information, including important names and telephone numbers, to which you may wish to refer in the future.

New things might be learned during this study that you should know about. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you are eligible to participate and decide to be in the study, the Principal Investigator may still choose to stop your participation in this study if he thinks it is in your best medical interest. The Principal Investigator might also decide to stop your participation in this study if an unanticipated adverse device effect occurs, if a clinical pulp exposure occurs during the restoration visit, or due to non-compliance.

If you withdraw or are withdrawn from the study, any data collected from you before your withdrawal will still be used for the study.

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As a participant in this study, your identity, medical records, and data relating to this study will be kept confidential, except as required by law. The U.S. Food and Drug Administration, which regulates investigational drug and device studies, and the study sponsor may also look at records that identify you.

If you have question about your rights as a research study subject, call the Tufts Medical Center and Tufts University Health Sciences Institutional Review Board (IRB) at (617) 636-7512. The IRB is a group of doctors, nurses, and non-medical people who review human research studies for safety and protection of people who take part in the studies. Federal law requires the IRB to review and approve any research study involving humans. This must be done before the study can begin. The study is also reviewed on a regular basis while it is in progress.

This research study has been reviewed and approved by the IRB of Tufts Medical Center and Tufts University Health Sciences.

PURPOSE OF STUDY

The purpose of this study is to compare two different materials that are used to fill cavities. You are being invited to participate in this study because at least two of your back teeth that have cavities and need fillings. Two of your qualifying teeth will be chosen for this study. One of your teeth will be randomly selected to receive one filling material, and the second tooth will be randomly selected to receive the second material. Both of these materials have been approved by the FDA, but are not typically used in the Tufts University School of Dental Medicine (TUSDM) clinic for filling cavities.

Traditionally, cavities are filled with resin composite (tooth colored filling material) in layers. A small amount of the dental composite material (up to 2mm) is placed in the cavity, and UV light is used to harden the filling. This process would be repeated until the cavity is filled. In the TUSDM clinic, this is the standard of care process, and we use a composite named Filtek™ Supreme Ultra Universal Restorative. In this study, we will be using Filtek™ Supreme Ultra Universal Restorative (Group 1) as the traditional resin composite that will be used in the standard of care procedure noted above.

SonicFill™ 2 (Group 2) is a different type of composite. It is known as a bulk fill composite, which allows up to 5mm of material to be used for the filling. SonicFill™ 2 is also applied to the tooth in a different way. The material is dispensed using a hand piece (SonicFill 2010) which turns the material from a solid to a fluid form using sound waves. Once the material has been placed into the cavity in 1 layer, it is hardened using UV light. SonicFill™ 2 and SonicFill 2010 have been approved by the FDA as non-significant risk medical devices to be used for the direct placement in cavities. However, this composite material and filling technique is not used in the TUSDM clinic.

We want to compare these two filling materials and see if they are similar in how they look and how effective they are in filling your cavity.

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This study will be conducted at the Research Department, Tufts University School of Dental Medicine at 1 Kneeland Street, Boston, MA.

Up to 100 subjects will participate in this study. To participate in the study, you must be at least 18 years of age, be in good general health, and have a pair of molars or pre-molars with cavities in need of fillings.

This study is sponsored by Kerr Kavo Group.

Subjects will be eligible to receive a filling at TUSDM even after the study is over or if they are terminated from the study at normal clinic fees.

PROCEDURES TO BE FOLLOWED

Visit 1: Screening (Approximately 1 hour)

You will be asked to read this informed consent form (ICF). You will be given ample time to have any questions answered. If you decide to participate, you will be asked to sign this ICF and will be given a copy. You will be asked to complete a medical history form and provide demographic information about yourself. We will also ask you to provide us with your contact information, as well as the contact information of someone else you know, so that we can reach you to schedule or re-schedule appointments during the course of the study.

An oral examination will be conducted, in which a study team member will look at the inside of your mouth, teeth and gums. This will be completed following standard of care procedures using a mouth mirror and dental explorer.

Radiographs (x-rays) of your teeth will be taken to confirm the presence of cavities. It is standard of care to take x-rays for the detection of cavities if you have not had one taken within the past year. If you have had an x-ray within the past year and can provide the study team with an electronic copy and it is of good quality, we will use that x-ray and not take a new one.

We will then review your information to see if you are eligible to participate in this research study.

If you are eligible to continue in the study, two of your teeth with cavities will be selected for the study. It will be randomly chosen by a computer-generated randomization table which tooth will be in Group 1 (Filtek™ Supreme Ultra) and which tooth will be in Group 2 (SonicFill™ 2). Neither you nor the study dentist can choose which tooth receives which composite material. This is for research purposes only.

Visit 2: Restoration Placement (May occur the same day as Visit 1 and up to 1 month after Visit 1, approximately 1.5-2 hours)

Your medical history will be reviewed and eligibility/withdrawal criteria will be evaluated.

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An oral examination will be conducted as at Visit 1.

Photographs of your teeth will be taken before your fillings are placed (the photographs will only be of your mouth and not include your face).

You will be asked to rate the sensitivity of your two randomized teeth (if applicable).

Each of your two randomized teeth will have fillings placed. Local anesthesia (a numbing shot) will be given, and standard of care preparation of the tooth before filling placement will occur, including removal of decay using handpieces and dental instruments and using a dental adhesive before placing the filling material. Both of the fillings for group 1 and group 2 will be completed following manufacturer's instructions.

Photographs of your teeth will be taken again after your fillings are placed (the photographs will only be of your mouth and not include your face. This is for research purposes.

A different study team member will look at and evaluate the fillings. They will look at the fillings in your mouth and record how the fillings look. You will be asked a few questions about how you think the fillings look, and if you are experiencing any sensitivity. These activities are typically done as standard of care after a filling is placed, but we are recording the observations for research purposes.

Visit 3: Follow-up (6 months ± 1 month after Visit 2, approximately 30 minutes)

Your medical history will be reviewed and eligibility/withdrawal criteria will be evaluated. You will be asked if there have been any issues with your fillings, teeth or gums since your last study visit.

An oral examination will be conducted as at Visit 1. Your fillings will be evaluated by a study team member who did not place the fillings as in Visit 2.

Photographs will be taken of your teeth (the photographs will only be of your mouth and not include your face).

Visit 4: Follow-up (1 year ± 1 month after Visit 2, approximately 45 minutes)

Your medical history will be reviewed and eligibility/withdrawal criteria will be evaluated. An oral examination will be conducted as at Visit 1. You will be asked if there have been any issues with your fillings, teeth or gums since your last study visit.

X-rays will be taken of your teeth. It is standard of care to have x-rays yearly after receiving a filling.

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An oral examination will be conducted as at Visit 1. Your fillings will be evaluated by a study team member who did not place your fillings as in Visit 2.

Photographs will be taken of your teeth (the photographs will only be of your mouth and not include your face).

Visit 5: Follow-up (2 years ± 2 months after Visit 2, approximately 1 hour)

You will be asked to complete a new medical history form. Eligibility/withdrawal criteria will be evaluated. You will be asked if there have been any issues with your fillings, teeth or gums since your last study visit.

X-rays will be taken of your teeth. It is standard of care to have x-rays yearly after receiving a filling.

An oral examination will be conducted as at Visit 1. Your fillings will be evaluated by a study team member who did not place your fillings.

Photographs will be taken of your teeth (the photographs will only be of your mouth and not include your face).

RISKS

There is the risk of loss of confidentiality from participating in this study. This risk will be minimized by following the procedures listed under the confidentiality section.

You may experience the usual post-operative pain or sensitivity that is typically associated with the standard of care placement of fillings, including: tooth pain, bite pain/sensitivity, gum sensitivity/tenderness/redness, or discomfort from the anesthetic. These events are expected to be localized and temporary. The risks of getting your cavities filled in this study are no greater than if you had your cavities filled using the standard of care restoration composite.

You may experience standard of care risks such as partial loss, chipping, or fracture of the filling, trauma to the tooth with the filling or teeth next to it, or total loss of the filling. This standard of care risk is not expected to be increased due to participation in this study.

You should report any side effect or issue with your restoration that occurs following the placement of the restorations and for up to 2 years after placement by contacting Dr. Kugel at (617) 636-0870.

RADIOGRAPHS (X-RAYS)

All radiographs will be taken digitally following standard of care procedures, including the subject wearing a lead apron. The radiographs used in this study contain no more radiation than

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would be used in a customary dental procedure. It is within standard of care to take radiographs (bitewings) for detection of cavities if x-rays from within the past 1 year due not exist. It is standard of care to have periapical radiographs prior to class II restorations to ensure there are no signs of periapical pathology. It is within standard of care to take x-rays yearly for evaluation after fillings are placed. X-rays will be taken at the one-year and two-year follow-up visits. In the event an adverse event is suspected, it is clinically necessary, or due to a dental emergency a radiograph may be taken at that time but it is not the norm for this trial. If you become pregnant during the study, x-rays will be postponed until after pregnancy.

BENEFITS

There are no medical benefits to you for participating in this study. Participation may contribute to more knowledge by allowing us to better understand these materials and procedures.

ALTERNATIVES

You may choose to not participate in this study. You may receive standard of care for your cavities at Tufts University School of Dental Medicine clinics. You may stop being in the study at any time for any reason.

RESEARCH RELATED INJURY

Emergency medical treatment will be given to you if you are hurt or get sick as a direct result of being in this research study. You or your insurance carrier will be required to pay for any such medical care. Any needed medical care is available at the usual cost. All needed facilities, emergency treatment, and professional services are available to you, just as they are to the general public. The institution will not pay for your treatment if you become ill or injured as part of this study.

COSTS

Fillings and all study-related activities will be provided free of charge. You and/or your insurance will be responsible for paying all procedural costs not study related, as well as costs incurred after the study expires. No travel reimbursement or transportation costs will be paid. Expenses, such as parking and transportation costs, will be paid by the subject at all times.

If during the course of the study (2 years) you require additional treatment for either tooth that was in the study, you will be responsible for any root canal and/or post and core treatment. However, Kavo Ker Group will reimburse the School of Dental Medicine for the cost of the filling (up to $175 per unit depending on the type of filling material) which will be credited to you towards the cost of your new restoration. In order to receive this level of support, you must attend all initial appointments and all recall appointments for the duration of the study, otherwise this policy is voided.

Before any re-treatment is initiated, a second dentist not associated with the study, will be selected by the Investigator in consultation with Kavo Kerr Group. That individual will evaluate

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the cause of failure and determine the need for a new filling. The study sponsor or the School of Dental Medicine at Tufts University will not be held responsible for any re-treatment when trauma or injury are determined to be the cause of failure and that failure is unrelated to participation in the study.

PAYMENT

If you complete all study visits, you will receive $245 in gift cards. This will be given as follows: $25 at screening; $50 at baseline; $50 at six-month recall; $50 at one year; and $70 at two years. Compensation will be provided in person in the form of Target gift cards at the end of each the specified visits.

PRIVACY AND CONFIDENTIALITY

To ensure confidentiality of subject information, each subject enrolled in the study will be assigned a unique alphanumeric code. Subjects' files and all study paperwork will be kept in a secure, locked cabinet when the files are not being reviewed. All electronic files will be kept on a password protected computer in a secure, locked office. Only study team members will have access to the data. All HIPAA requirements will be followed.

Your information will be kept confidential. The study data will only be used for the purpose of the study. Dental records, source documents and case reports will be coded and will not have your name on them. Alphanumeric identification numbers will be assigned sequentially. The full subject identification number will consist of the three letters from the subject's initials and their enrollment number. This will be accessible by study personnel only.

Photographs will be taken of your teeth only (no facials). All study records will be maintained following the completion or termination of the study in accordance to state law and institutional policy (at least 7 years)

If you agree to take part in this research study, your personal information will not be given to anyone unless we receive your permission in writing. It will only be given if the law requires it. It will also only be given for regular hospital treatment, payment, and hospital management activities. Investigators will allow monitoring, audits, and regulatory inspections and will provide direct access to study related documentation.

We will make every effort to keep your information private, but it cannot be completely guaranteed. Certain government agencies [Office for Human Research Protections, Department of Health and Human Services, Food and Drug Administration, the study sponsor Kerr Kavo Group] and the Institutional Review Board of Tufts Medical Center and Tufts University Health Sciences, the study sponsor Kerr Kavo Group or the sponsor's designated representative may check records that identify you. This might include your medical or research records and the informed consent form you signed. The records of this study might also be reviewed to make sure all rules and guidelines were followed.

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A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by US Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

If you sign this document, you give permission to the Principal Investigator named above and research staff at Tufts University Health Sciences as well as other individuals at Tufts University Health Sciences who may need to access your information to do their jobs (such as for treatment, payment (billing) or health care operations) to use or disclose (release) your health information that identifies you for the research study described above.

The parties listed in the preceding paragraph may disclose the health information described below to the following persons and organizations for their use in connection with the research study:

- Individuals or organizations working under the direction of the Principal Investigator(s) for the study,
- Outside individuals or entities that have a need to access this information to perform activities relating to the conduct of this research, such as analysis by outside laboratories on behalf of Tufts University Health Sciences,
- Other researchers and institutions that are conducting or participating in this study,
- The study sponsor Kerr Kavo Group and any companies that they use to oversee, manage, or conduct the research,
- The Office for Human Research Protections in the U.S. Department of Health and Human Services, the United States Food and Drug Administration (FDA) and other federal and state agencies that have the right to use the information as required by law, and
- The members and staff of any Institutional Review Board (IRB) Board that oversee this study.

The health information that we may use or disclose (release) for this research study includes all information in your medical record related to the diagnosis and management of your teeth requiring fillings, including the record of your care, as well as any information collected or created during the course of this study.

Tufts University Health Sciences is required by law to protect your health information. By signing this document, you authorize Tufts University Health Sciences to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You may not be allowed to see or copy the information described on this form as long as the research is in progress, but you have a right to see and copy the information upon completion of the research in accordance with hospital policies.

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You can decide to sign or not to sign this form. However, if you choose not to sign this form, you will not be able to take part in the research study and you may not receive any research-related clinical care.

This authorization does not have an expiration date. You may change your mind and revoke (take back) this authorization at any time. Even if you revoke this authorization, this site's clinical, administrative and research staff may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this authorization, you must write to: HIPAA Privacy Officer for Research at One Kneeland Street, Room 334, Boston, MA 02111]. If you revoke this authorization, you may no longer be allowed to participate in the research described in this form.

WHOM TO CONTACT

		Daytime (9am-5pm)	24 Hours
Principal Investigator	Dr. Gerard Kugel	(617) 636-0870	617 510-5908
Study Coordinator	Courtney Thurell	(617) 636-3865	

Documentation of Consent

I have been given a copy of this form. I have read it or it has been read to me. I understand the information and have had my questions answered to my satisfaction. I agree to take part in this study.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study.

_____ _____
Date Participant's Signature

I have fully explained to _____ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____ _____
Date Principal Investigator or Representative's Signature

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