Consent Form (includes HIPAA Authorization)

Title of Research Study: In vivo Assessment of the Tooth-Resin Composite Interface Using Optical Coherence Tomography

Investigator Team Contact Information: Hooi Pin Chew, BDS, FDSRCS, PhD
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are a patient at the University of Minnesota School of Dentistry and need a filling that meets the study requirements.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of the study is to compare two ways to prepare your tooth for a filling. But, it is hard to see the microscopic changes to a filling clinically. We want to look at your filling with a special tool to see how the edges of a filling change over 18 months. This tool will help us to evaluate the edges of you filling.

How long will the research last?

We expect that you will be in this research study for 3 appointments over 18 months; your procedure appointment and two (2) follow-up appointments at 6 months and 18 months.

What will I need to do to participate?

You will be assigned to one of two groups that will have your tooth prepared for a filling and to come to the dental school for 3 visits; one to do the filling and two for us to look at the filling 6 and 18 months after the filling is placed. We will also ask you to complete a survey about your visit. More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

This study includes usual care dental restorative work.

In addition as a part of the study procedures, you will wear a scan guide during the appointments, before and after the procedure and during follow-up appointments that will allow the positioning of the special instrument, which is an Optical Coherence Tomography (OCT) scanner. The scan will take less than thirty (30) seconds. There have not been any reported risks with use of the OCT scanner intraorally. We expect minimal discomfort with the use of the scan guide where mouth opening is not expected to be wider than your normal opening. While OCT is not normally used in dental care, it is commonly used in other clinical settings and will be used according to its approved indications for use in this study.

There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research.

What happens if I do not want to be in this research?

Participating in research is voluntary. You do not have to participate in this research. You may still receive your filling at the University of Minnesota dental clinics according to standard care that are involved in the provision of a dental filling.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 36 people at the University of Minnesota will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

You will be asked to:

- Come to the dental school 7th floor Oral Health Clinical Research Center clinic for three (3) appointments over the next 18-20 months.
- Be available for the duration of the study and to receive phone calls and emails from study staff regarding appointments.
- As a part of the research, you will have a physical or digital impression taken of your teeth at today's appointment.
- You will also be randomized into one of two groups that will receive different filling preparations. Randomization is like flipping a coin to place you in one of two groups. You will not know which group you are in for this study.
- As part of usual care, you will have a composite (white) filling placed in your tooth which includes local anesthesia, marking the tooth, removal of the decayed part of the tooth, and polishing of the restoration after it is completed. All other procedures being done are a part of the study.

Your study visits and the study procedures that will be completed at each visit are displayed in the table below. Standard care will be used when your filling is completed by the study dentists.

Procedure	Visit 1 (2 hours)	Visit 2 at 6 Months (1 hour)	Visit 3 at 18 Months (1 hour)
Brush teeth	X	X	X
Be randomized into one of two groups	X		
Collect information about your tooth and cavity before filling is started by study dentists	X		
Digital photo is taken of the tooth	X		
Wear scan guide for OCT scan	X		
Filling is prepared and placed by one of two study dentists (not the PI/coPI) as a part of standard care	X		
PI/coPI collect information about your	X	X	X

tooth			
Digital photo is taken	X	X	X
PI/coPI will check the filling using OCT	X	X	X
Participant completes experience survey	X	X	X
Bite-wing digital xray			X

The filling preparation you have will be chosen by chance, like flipping a coin. Neither you nor the study dentist, or the study PI/coPI will choose what type of preparation is done. You will have an equal chance of being given either filling preparation type. In addition, the study PI and coPI will complete the study evaluations of the filling at each study visit.

What happens if I say "Yes", but I change my mind later?

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future dental care, your academic standing as a student, or your present or future employment.

If you stop being in the research, information about you that has already been collected may not be removed from the study database.

Can I be removed from the research?

It's possible that we will have to ask you to leave the study before you finish it. If this happens, we will tell you why.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

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If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☐ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☐ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)

☐ My HIV/AIDS testing records _____ (initial)

☐ My genetic testing records _____ (initial)

☐ My mental health diagnosis/treatment records ____ (initial)

☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on

the research with us;

- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);

- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;
  The University of Minnesota School of Dentistry Veden Grant

- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and

- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data when this study is over?

Your data will not be used for any future research after this study is complete.
Do I have to sign this Consent Form and give my permission to make my information, including my

health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include your name or any other direct identifiers such as your contact information. The Web site may include a summary of the results of this research. You can search this Web site at any time.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the

Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you a total of $160 in Target gift cards for your time and effort. In addition, we will provide parking vouchers to help cover the cost of your parking at each appointment. You will receive a Target gift card for $10 after your study screening, $20 Target gift card after your filling is completed, and $50 Target gift card after the 6 month follow-up appointment and $80 Target gift card after your 18 month follow-up appointment for a total of $160. Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent