UNIVERSITY OF MINNESOTA

Twin Cities Campus

Division of Orthodontics
School of Dentistry

6-320 Moos Health Sciences Tower
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CONSENT FORM

Use of a "flash-free" adhesive resin for orthodontic bracket bonding: a clinical study of bonding time, bond survival, and adhesive remnant cleanup

You are invited to participate in a research study, which compares a new "flash-free" adhesive with a conventional adhesive for orthodontic bracket bonding. You were selected as a possible participant because you are seeking orthodontic treatment at the University of Minnesota. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Thorsten Gruenheid, DDS, Dr med dent, PhD and Brent Larson, DDS, MS, researchers at the University of Minnesota, Division of Orthodontics, Department of Developmental and Surgical Sciences.

Some of the materials used in the study, such as the brackets and adhesives, were donated by 3M Unitek, the manufacturer of these materials. The flash-free adhesive is a light-cure orthodontic adhesive, which the Food and Drug Administration has approved to market for use in bonding appliances for orthodontic treatment.

Study Purpose

The purpose of this study is to compare the time required to bond brackets on upper teeth, success rate of these brackets, amount of adhesive remaining on the tooth surface once the brackets are removed, and time required for adhesive remnant cleanup between the new flash-free and the conventional adhesive. About 30 subjects will be involved in the study.

Study Procedures

If you agree to participate in this study, we will ask you to have orthodontic brackets bonded to your upper teeth with the flash-free adhesive on one side and the conventional adhesive on the other side. This procedure will be timed as well as the time necessary to remove the adhesive from your teeth once the treatment is completed. Bonding orthodontic brackets to your teeth is required for orthodontic treatment, regardless of your participation in this research study.

During treatment, you will be asked to be seen at standardized intervals of 4 weeks for adjustment of the orthodontic appliance. During these adjustment visits, possible bond failure will be recorded. A time of 1–2 minutes is estimated to be required for recording of bond failure per adjustment visit. Regular adjustment of the orthodontic appliance at 4–6 weeks intervals is necessary to achieve an adequate orthodontic result regardless of your participation in this research study. Study participation does not involve withholding the standard of care, which includes bonding orthodontic brackets to your teeth as outlined above.

Risks of Study Participation

This study involves no greater than minimal risk as the new adhesive has been approved for marketing and is being used in accordance with its approved labeling. However, risks cannot be completely eliminated. The risks associated with the new adhesive include a mild reaction of the gum tissue to monomers of the adhesive. However, this risk is not directly associated with the study and similar reactions may occur in response to any other orthodontic adhesive as well.

A risk associated with record keeping is breach of confidentiality. All efforts will be made to keep your information private. Moreover, your name will be made anonymous and replaced with a unique identification number. All data will be reported using this number and only the investigators will know which identification number corresponds to which individual.

Benefits of Study Participation

If you decide to participate in this study, you will be treated with tooth-colored ceramic brackets without additional charge ($200 value). You will receive no other direct benefit for participating in this study. However, future orthodontic patients could benefit from the knowledge acquired as the results of this study may help develop better orthodontic materials.

Alternatives to Study Participation

If you choose not to participate, your status to receive orthodontic treatment will not be affected.

Study Costs/Compensation

If you participate in this study, you will not incur any costs as a result of study participation. Neither will you receive any monetary compensation or other type of compensation for your involvement. However, you will be reimbursed for parking expenses up to $120 and will receive a $50 gift card upon completion of orthodontic treatment.

Research Related Injury

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 researchers know right away.

Confidentiality

The records of this study will be kept private. Any publications that may result from this study will not include any information that will make it possible to identify you as a subject. However, your record for the study may be reviewed by University departments with appropriate regulatory oversight. Study information will not be recorded in your orthodontic record.

Protected Health Information (PHI)

Your PHI created or received for the purposes of this study is protected under the federal regulation known as the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Refer to the attached HIPAA authorization for details concerning the use of this information.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Contacts and Questions

The researchers conducting this study are Thorsten Gruenheid, DDS, Dr med dent, PhD and Brent Larson, DDS, MS. You may ask any questions you have now, or if you have questions later, you are encouraged to contact the researchers at 612-625-5110. If you would like to talk to someone other than the researchers, you are encouraged to contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at Fairview Research Administration, 2433 Energy Park Drive, St. Paul, MN 55108.

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature of patient/parent/guardian	Date
Signature of researcher obtaining consent	Date

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ASSENT FORM

Use of a "flash-free" adhesive resin for orthodontic bracket bonding: a clinical study of bonding time, bond survival, and adhesive remnant cleanup

We are asking you to participate in a study that will help us find out how well a new "flash-free" adhesive for bonding braces to teeth compares to a conventional adhesive. An adhesive is basically the glue that holds the braces on your teeth.

We will record the time it takes to put braces on your upper teeth as well as the time it takes to remove the glue from them once the braces are removed. During your treatment, we will see you every 4 weeks to adjust your braces. At these visits, possible breakage of the braces will be recorded. We expect this to take an extra 1–2 minutes per visit.

None of the activities involved in the study will hurt. It will just take some extra time at each visit as we need to collect some extra information.

We have also asked your parents for permission and we will show you the materials we will use in the study before we put the braces on. If you want, your parents can be in the room with you at all times. If there is anything you do not like during the study, you can ask us to stop at any time. You can also ask us questions about the study at any time. If you think of any questions later, you may call us at 612-625-5110.

By signing below, you confirm that you have read this form with us, we have explained your role in the study, and that you are willing to participate. Remember, being in this study is up to you. Nobody will be angry if you do not want to participate or if you change your mind later.

Signature of patient	Date
Signature of researcher obtaining assent	Date

IRB Code Number:
Version Date: 05/14/2013

HIPAA[1] AUTHORIZATION TO USE AND DISCLOSE INDIVIDUAL HEALTH INFORMATION FOR RESEARCH PURPOSES

1. Purpose. As a research participant, I authorize Thorsten Gruenheid, DDS, Dr med dent, PhD and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research project entitled "Use of a 'flash-free' adhesive resin for orthodontic bracket bonding: a clinical study of bonding time, bond survival, and adhesive remnant cleanup."

2. Individual Health Information to be Used or Disclosed. My individual health information that may be used or disclosed to conduct this research includes information on survival of orthodontic brackets bonded to my teeth and the time needed for adhesive remnant cleanup after bracket removal.

3. Parties Who May Disclose My Individual Health Information. The researchers will not obtain individual health information from other healthcare providers for the purposes of carrying out this research study.

4. Parties Who May Receive or Use My Individual Health Information. The individual health information disclosed by me during the course of the research may be received and used by 3M Unitek for product development and improvement.

5. Right to Refuse to Sign this Authorization. I do not have to sign this Authorization. If I decide not to sign, I may not be allowed to participate in this study. However, my decision not to sign this authorization will not affect any treatment, payment, or enrollment in health plans or eligibility for benefits.

6. Right to Revoke. I can change my mind and withdraw this authorization at any time by sending a written notice to Thorsten Gruenheid, DDS, Dr med dent, PhD, University of Minnesota, 515 Delaware Street S.E., Minneapolis, MN 55455 to inform the researcher of my decision. If I withdraw this authorization, the researcher may only use and disclose the health information already collected for this study. No further health information about me will be collected by or disclosed to the researcher for this study.

7. Potential for Re-disclosure. Once my health information is disclosed under this authorization, there is a potential that it will be re-disclosed outside this study and no longer covered by this authorization. However, the research team and the University's Institutional Review Board (the committee that reviews studies to be sure that the rights and safety of study participants are protected) are very careful to protect privacy and limit the disclosure of identifying information. There are other laws that may require individual health information to be disclosed for public purposes. Examples include potential disclosures if required for mandated reporting of abuse or neglect, judicial proceedings, health oversight activities, and public health measures.

This authorization does not have an expiration date.

I am the research participant or personal representative authorized to act on behalf of the participant. I have read this information, and I will receive a copy of this authorization form after it is signed.

Signature of research participant or personal representative	Date
Printed name of research participant or description of personal representative's authority to act on behalf of the research participant	Date

[1] HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information.