

INFORMED CONSENT FORM

TITLE OF RESEARCH: Retention and Durability of the Anterior Zirconia Wing Bridge

PRINCIPAL INVESTIGATOR: David McMillan

COLLEGE AND CAMPUS: Roseman University School of Dentistry

SUMMARY

- The purpose of the research is to learn about the durability and retention of the resin-bonded zirconia wing-bridge. If you proceed with the study and have a bridge bonded to your teeth, it is imperative that you return for follow-up appointments every 6 months for 2 years for the researchers to monitor and evaluate the bridge.
- Potential benefits include esthetically pleasing smile with minimal tooth preparation, cost savings for a tooth replacement, avoidance of surgery for implant, prevention of misalignment of teeth and helping with eating and speech.
- Potential risks include damage to abutment teeth, tooth decay in abutment teeth (teeth next to the missing tooth that the bridge is attached to), gum disease, jaw or chewing soreness, overexposure to x-rays, and privacy risks.

RESEARCH STATEMENT

You have qualified to take part in a research study. Being in this study is voluntary. Refusing to be in the study will involve no penalty or loss of benefits to which you are otherwise entitled as a patient at Roseman University College of Dental Medicine. You may withdraw from the study at any time. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully. Please ask the principal investigator if there is anything that is not clear or if you need more information.

PURPOSE OF THE RESEARCH

The purpose of this study is to examine the durability and retention of the resin-bonded zirconia wing-bridge.

RESIN-BONDED ZIRCONIA WING BRIDGE

Dental wing bridges were performed over the past several decades primarily with metal wings. With the advancement of zirconia as a dental restorative material during the last decade, dental labs and dentists have started to fabricate and place zirconia wing bridges. The zirconia wing bridges placed at Roseman University as part of this study have the unique characteristic of

having countersunk holes in the wings, which is hypothesized to increase bond strength and thus longevity of the bridge.

The resin bonded wing bridge consists of an artificial tooth made out of zirconia and porcelain with two zirconia wings that are bonded (glued) onto the back of the two adjacent teeth in the patient's mouth. It involves drilling two small preparation holes on the backside of the adjacent teeth that are approximately .5 to 1 mm deep and approximately 1 mm wide. The purpose of the tooth preparation is to ensure that the bridge is bonded properly.

PARTICIPANTS

You agree to participate because you are a patient at the Roseman College of Dental Medicine and meet the criteria for the bridge, which includes 1) one missing anterior tooth 2) adjacent non-restored or minimally-restored abutment teeth in periodontal health.

STUDY PROCEDURES

If you agree (or consent) to participate in this research study, you will:

- On appointment #1 have a consultation where we will examine your missing tooth area to determine if you are a candidate for the study.
- On appointment #2, you will have photos taken and two small preparation holes, 1 mm wide and .5-1 mm deep, will be drilled on the back side of each tooth adjacent to the missing tooth followed by impressions and tooth shade selection.
- On appointment #3, you will have the bridge bonded on the adjacent teeth, followed by photos.
- On recall appointments, which are every 6 months for 2 years, we will examine the bridge to determine if there are any issues with the durability and retention.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Agreeing to this document means you allow us, the researchers, and others working with us, to use some information about your health for this study.

This is the information we will use and include in our research records:

- Demographic and identifying information like name, address, telephone number, and email address
- Related medical information about you including family medical history, allergies, current and past medications or therapies, and information from physical examinations, such as blood pressure, heart rate and lab results
- All photos, x-rays, notes, and procedures that will be done in the study

If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at Roseman University of Health Sciences.

POTENTIAL BENEFITS AND RISKS:

- Potential benefits include esthetically pleasing smile with minimal tooth preparation, cost savings for a tooth replacement, avoidance of surgery for implant, prevention of misalignment of teeth and helping with eating and speech.

Physical risks:

- Loss of bridge
- Damage to abutment teeth: this will be minimized by careful operator technique during the procedure. Once the bridge is bonded, the researchers will use a blue articulating paper ensure occlusal (biting) forces from the opposing tooth arch are appropriate on the bridge.
- Tooth decay in abutment teeth: this will be minimized by ensuring an adequate seal with the resin and doing follow-up procedures to examine the integrity of the tooth-resin interface.
- Gum disease: this will be minimized by patient education on flossing and caring for the bridge as well as doing follow-ups
- Jaw or chewing soreness from opening the mouth for long periods during the appointment: this will be minimized by having the patient take frequent breaks from opening the mouth.
- Unmet expectations with esthetics: this will be minimized by showing pictures of the bridge and having open, thorough conversations during the consultation.
- If pregnant, x-rays have the potential to harm a fetus: this will be minimized by following the ALARA principle in prescribing radiographs (As Low As Reasonably Achievable).

Privacy risks:

- There is always risk when sharing personal information. The research team has procedures to protect that information to the best of their ability: this will be minimized by password protection on devices that have access to the Google Drive where the information is stored.

If any complications arise, you will be given help in getting care. If you need treatment or hospitalization as a result of being in this study, you are responsible for payment of the cost for that care. If you have insurance, you may bill your insurance company. You will have to pay any

costs not covered by your insurance. Roseman University will not pay for any care, lost wages, or provide financial compensation.

ALTERNATIVES

Alternative treatments includes 1) traditional bridge, 2) implant, 3) removable partial denture, 4) no treatment.

WITHDRAWAL

If you decide to withdraw from the study after the tooth preparations have been made, you will need small fillings in the preparations where the bridge would have gone. You will be charged for these fillings.

If you decide to withdraw from the study after the bridge has been made, you will not be entitled to a refund.

CONFIDENTIALITY:

- Your data will be confidential. All researchers will have training in all confidentiality measures of this study.
- The research data will reside on a shared drive available only to the researchers where no identifying information, other than the chart number, will be present.
- Research data will be stored for three years or more.
- Members of the Roseman Institutional Review Board will have access to the records and information about this study.
- The data obtained from this study regarding the durability and retention of the resin-bonded zirconia wing bridge may be published in a professional journal as well as presented in a poster at symposia or conferences.
- Any reports of the study will not include identifying patient information.
- Your information will not be used in future studies.

COST

- Participant will be responsible to provide their own transportation to and from appointments. The cost for the bridge is \$300, which will be the participant's responsibility to pay. The normal cost of the bridge is over \$1200.
- Follow-up appointments for examination of the bridge are included in the \$300. Full exams and cleanings are not included in the fee of \$300.
- If the bridge needs maintenance, repair or replacement during the first two years, it will be covered at no additional cost. After two years, the patient will be responsible for any costs associated with repair, maintenance or replacement.



COMPENSATION:

- The participant will not be compensated to participate in this study.

WHO TO CONTACT WITH QUESTIONS:

1. Principal Investigator: David McMillan
801-878-1447
2. If you have questions regarding your rights as a research subject, or if problems arise which you do not feel you can discuss with the Principal Investigator, please contact the Institutional Review Board at:
Roseman University Institutional Review Board
Phone: (702) 968-6630
irb@roseman.edu

CONSENT

The purposed of this study, what I will be asked to do, and the risks and benefits have been explained to me. I have had a chance to ask questions. I understand my participation is voluntary. My signature also indicates that I can change my mind and withdraw my consent to participate at any time without any penalty. I give my permission to the researchers to use my medical/dental records as described in this consent form. I have received a copy of this signed, dated, consent form.

I hereby give my consent to be a subject of the research described in this document.

Participant's Name

Participant's Signature

Date

Person Obtaining Consent

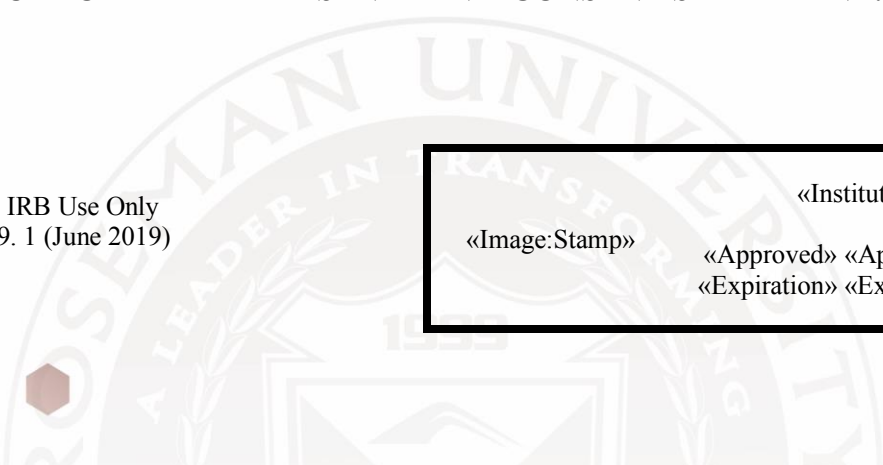
Person Obtaining Consent's Signature

Date

LEGALLY AUTHORIZED REPRESENTATIVE CONSENT STATEMENT:

Footer for IRB Use Only
Version 19.1 (June 2019)

«Image:Stamp»	«Institution»
	«Approved» «ApprovedDate»
	«Expiration» «ExpirationDate»



I confirm that I have read this consent and authorization document. I have had the opportunity to ask questions and those questions have been answered to my satisfaction. I am willing and authorized to serve as a surrogate decision maker for

_____.

Participant's Name

I have been informed of my role and my obligation to protect the rights and welfare of the participant. I understand that my obligation as a surrogate decision maker is to try to determine what the participant would decide if the participant were able to make such decisions or, if the participant's wishes cannot be determined, what is in the participant's best interests. I will be given a signed copy of the consent and authorization form to keep.

Name of Authorized Personal Representative:

Signature of Authorized Personal Representative:

Date:

Indicate the legal representative's authority to act for the individual:

- Spouse
- Adult (18 years of age or over) for his or her parent
- Individual with power of attorney
- Guardian appointed to make medical decisions for individuals who are incapacitated