Consent Form for the Protocol:

Antiseptic Effects on the Dental Implant Internal Surface Microbiome

NCT05024760

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MADIGAN ARMY MEDICAL CENTER
CONSENT TO PARTICIPATE IN RESEARCH &
AUTHORIZATION TO USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

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KEY INFORMATION FOR PROTOCOL: Antiseptic Effects on the Dental Implant Internal Surface Microbiome

You are invited to take part in a research study. Your participation is voluntary. This page gives you key information about the study to help you decide whether to participate. Detailed information follows this page. Ask the researchers questions you have. If you have questions later, the contact information for the research investigator is below.

WHAT ARE THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

We hope to learn if applying antiseptic to the inside of a dental implant will decrease or alter the types of bacteria inside it. This may decrease the incidence of implant failure associated with bone loss, infection, and other complications. During implant placement, we will apply an antiseptic (chlorhexidine wash or hydrogen peroxide gel) or no antiseptic to the inside of your new dental implant before covering it with a cover screw or healing abutment. 3-6 months later, when we remove the hardware, we will swab the implant's internal cavity. Your participation in this research will last about 3-6 months and require one additional minute during implant insertion and hardware exchange.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO PARTICIPATE IN THIS STUDY (BENEFITS)?

The benefits of participation in this study include possible decreased risk of 1) damage to adjacent teeth and 2) implant failure due to bone loss, infection, or other complications. The procedure may also decrease the risk of additional surgeries such as explantation of the implant and bone grafting, delaying the need for additional care or tooth replacement.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE NOT TO PARTICIPATE IN THIS STUDY (RISKS AND ALTERNATIVES)?

The risks of participating in this study include the possibility of hypersensitivity to chlorhexidine or hydrogen peroxide, Allergic reaction to chlorhexidine wash or peroxide oral gel including itching, burning, swelling, mouth irritation, oral lesion, and oral mucosa ulcer may occur.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have at Madigan Army Medical Center if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

The person in charge of this study is Kevin Smith. If you have questions, suggestions or concerns about the study, his contact information is: 253-968-0181, and mailing address: Madigan Army Medical Center, 9040 Jackson Avenue, Tacoma, WA 98431.

If you have any questions about your rights as a research subject or if you have concerns or complaints about the research, please contact the Madigan IRB Office at: 253-968-0149, Department of Clinical Investigation, 9040 Jackson Avenue, Tacoma, WA 98431-1100.

Please tell the researchers if you are taking part in another research study.

If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

DETAILED CONSENT:

1. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you have missing teeth and chose implant therapy to replace missing teeth. The purpose of this research study is to learn about the bacteria of the internal cavity of the implant and how our methods influence implant success. Your participation will require one additional minute during implant insertion and one additional minute during hardware removal (3-6 months after implant insertion).

There will be about 200 people taking part in the study at Madigan Army Medical Center's Oral Maxillofacial Surgery Clinic, over a period of 1-2 years.

During the study, there are no additional visits needed. During implant placement, you may or may not have chlorhexidine wash or peroxide gel placed inside the dental implant. This will add less than one minute to your procedure time.

At the end of this research study the clinical results, including research results about you will not be shared with you.

2. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process". These tests may have been done or this information collected as a part of your regular medical care. The screening process includes clinical chart review and health physical assessment. This is the same screening used for all dental implant patients.

3. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

During implant placement, we will apply an antiseptic (none, chlorhexidine wash, or hydrogen peroxide gel) inside the implant then cover the implant with a cover screw or healing abutment. 3-6 months later, we will recover/remove the hardware and culture the bacteria that are inside of the implant with a swab. This process takes less than one minute to complete.

You will be randomly assigned to one of 3 groups. Randomization is a process like flipping a coin and means you will have a chance (33%) of being assigned to any of the 3 groups. Groups include 1- no treatment, 2-chlorhexidine wash, and 3-hydrogen peroxide gel applied to the inside of the implant.

4. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there is a risk of hypersensitivity to chlorhexidine or hydrogen peroxide, possible microleakage which may cause irritation and chemical burns, and delayed wound healing. There are no known additional risks associated with this study.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

There may also be other risks of taking part in this study that we do not yet know about.

5. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

The possible benefits to you as a research participant in this research study include possible decreased incidence of both damage to adjacent teeth and implant failure associated with bone loss, infection, or other complications. It may also decrease the risk of additional surgeries such as explantation of the implant and bone grafting, ultimately delaying care and tooth replacement. However, there is no guarantee that you will benefit from being in this research.

6. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Choosing not to take part in this research study is also an option.

7. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation for participating in this study.

8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

9. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study): Kevin Smith, DMD

10. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data): None

11. SOURCE OF FUNDING: Advanced Medical Technology Initiative Extended Innovation Fund; Madigan Army Medical Center, Department of Clinical Investigation

12. LOCATION OF THE RESEARCH: Madigan Army Medical Center, JBLM, WA 98431

13. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

The research team will keep your research records. These records may be looked at by staff from the Madigan Army Medical Center Human Research Protections Office

(HRPO), the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: Removal of personal information, computer and data file password protection, and the restriction of access privileges to study personnel. All identifiable information will be stored on computers secured by the government's firewalls. All hard copy data will be stored in a HIPAA approved locked box/cabinet within a locked office. Only approved study personnel will have access to these documents.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

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

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Only IRB approved study team members will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data.

14. AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR THIS RESEARCH: You are being asked for permission to use and disclose your protected health information (PHI) for this research study. Protected health information is defined as individually identifiable health information.

The Health Insurance Portability & Accountability Act of 1996, Public Law 104-191 (also known as HIPAA), establishes privacy standards to protect your health information. This law requires the researchers to obtain your authorization (by signing this document) before they use or disclose your protected health information for research purposes in the study listed above.

WHAT PERSONAL IDENTIFIERS AND/OR PROTECTED HEALTH INFORMATION (PHI) MAY BE USED AND DISCLOSED IN THIS RESEARCH?

The identifiers and/or PHI collected, used, or disclosed are below:

• *Names and DoD ID* • *Dates (except year) directly related to an individual such as birth date*	• *Medical history* • *Surgical history* • *Laboratory results* • *Imaging results*

HOW WILL YOUR PROTECTED HEALTH INFORMATION BE USED OR DISCLOSED IN THIS RESEARCH?

Your name and DoD ID are necessary to associate your lab results with your other data. Dates are needed to determine if age impacts success rates or bacterial content. Medical and surgical history may reveal if factors other than treatment affect surgical outcomes. The lab results identify the bacteria inside the dental implant. The bone x-ray imaging results taken at your 3-5 month post-implant follow up as part of standard of care will be used determine if the implant was successful or not and to identify the presence of peri-implantitis

The use and disclosure of your protected health information is necessary in order to be able to conduct the research described. Records of your participation in this research may only be disclosed in accordance with state and federal law, including the Privacy Act (5 U.S.C. 552a) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations (45 CFR 160 & 164).

Note: Protected health information of military service members may be used or disclosed without your authorization to military command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

By signing this document, you give your permission for information gained from your participation in this research to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

WITH WHOM MAY YOUR PROTECTED HEALTH INFORMATION BE SHARED THROUGH THIS RESEARCH?

- The Madigan Army Medical Center Institutional Review Board
- Madigan Army Medical Center or Department of Defense representatives
- State and Federal Government representatives, when required by law (such as the Food and Drug Administration (FDA))

Those listed above who are covered entities under HIPAA agree to safeguard your protected health information by using and disclosing it only as permitted by you in this Authorization or as directed by state and federal law.

You need to be aware that some parties receiving your protected health information may not have the same obligations to safeguard your protected health information and may re-disclose your protected health information to parties not named above. If your protected health information is re-disclosed, it may no longer be protected by state or federal privacy laws.

You do not have to sign this document. If you decide not to sign this document:

- It will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
- You will not be allowed to participate in the research.

After signing this document, you can change your mind and:

- Notify the principal investigator in writing that you have withdrawn your permission to disclose or use your protected health information (revoke the Authorization).
- Send your written letter to Kevin Smith, DMD. Madigan Army Medical Center, 9040 Jackson Avenue, Tacoma, WA 98431 to inform him of your decision. Your revocation is not effective until your letter is received.
- Researchers may continue to use and disclose your PHI that was obtained before your revocation became effective to the extent that the researchers have taken action in reliance on your earlier authorization. Researchers may also continue to use or disclose your PHI as necessary to maintain the integrity or reliability of the current research, as, for example, to account for your withdrawal from the study, to conduct misconduct investigations, or to report adverse events.
- If you withdraw the Authorization, you will not be allowed to continue to participate in the research.

If you have not already received a copy of the brochure entitled "Military Health System Notice of Privacy Practices," you may request one, or it is available on-line at: https://www.health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/HIPAA-Compliance-within-the-MHS/Notice-of-Privacy-Practices

If you have any questions or concerns about your privacy rights, you should contact the MAMC HIPAA Privacy Officer, 9040 Jackson Avenue, Tacoma, WA, 98431. Telephone: 253-968-1642.

This Authorization does not have an expiration date.

Your signature at the end of this document acknowledges that you authorize Madigan Army Medical Center and IRB approved study team members to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.

15. USE OF INFORMATION AND SPECIMENS?

During this research study, you could be asked to provide the following types of samples (biological specimens): At the time of hardware removal, the internal cavity of the dental implant will be swabbed.

All identifiers will be removed from your specimens.

Each specimen will be labeled with your unique participant ID, which can be linked back to you only via a master key which will only be accessible by IRB approved study team members. The Master Key will never be printed and will only be stored electronically on a password protected CAC enabled government computer and protected by the DoD's firewalls

Research will not include human whole genome sequencing.

Although research that uses your samples may lead to the development of new inventions, products, or discoveries (some that might be patented and licensed), there are no plans to share any potential profits with you.

While this study is on-going, your samples will be handled in accordance with this study's protocol and applicable regulations at the following laboratory: Department of Clinical Investigation, Madigan Army Medical Center, 9040 Jackson Avenue, JBLM, WA, 98431.

The information and/or specimens that we obtain from you for this study will be deposited in a repository titled: Antiseptic Effects on the Dental Implant Internal Surface Microbiome. Your de-identified information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

Future studies using your samples or information will be limited to research involving dental disease.

If you do not want your information and/or specimens added to a repository for future use you should not sign this consent form.

16. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

17. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must notify the Principal Investigator, Kevin Smith, in writing. If you decide to no longer participate in this research study, the researcher will destroy your stored samples. Up and until the master key is destroyed, which contains your identifiers, we will also destroy your associated data. After the master key

is destroyed, however, there will be no way to determine which records correspond to your data.

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your personal physician to discuss medical treatment for your condition.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization section above.

The principal investigator of this research study may terminate your participation in this research study at any time if *he* determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

18. WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

CONTACT INFORMATION:

Principal Investigator (PI): The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Kevin Smith, DMD
Phone: 253-968-0181
Mailing Address: Madigan Army Medical Center, 9040 Jackson Avenue, Tacoma, WA 98431.

Madigan Human Research Protection Program (HRPP) Office: The Human Research Protection Program Office staff and/or Human Protections Director (HPD) will be available to answer questions or discuss concerns you may have about this research study. Please contact the Madigan HRPP Office at: 253-968-0149, Department of Clinical Investigation, 9040 Jackson Avenue, Tacoma, WA 98431-1100.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date

IRB NUMBER: 222059
IRB APPROVAL DATE: 05/12/2023