REFRAME RPD Post-Market Clinical Study

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WIRB Informed Consent Form
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INFORMATION AND CONSENT FORM

TITLE: REFRAME RPD Post-Market Clinical Study

PROTOCOL NO.: DS002
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SPONSOR: Solvay Dental 360™

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INTRODUCTION

We would like to invite you to take part in a research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. **One of our team will go through this information sheet with you and answer any questions you have.** We'd suggest this should take you about 30 minutes. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

WHAT IS THIS STUDY ABOUT?

The purpose of this study is to gather information on the oral health of patients using a new polymer removable partial denture (RPD). Tooth loss is prevalent, especially in adults 65 years and older. Tooth loss affects the individuals overall oral health and quality of life. Removable partial dentures (RPDs) are commonly made for people with few to several missing teeth as a cost-effective method for replacing teeth. In addition to being more affordable than fixed partials and dental implants, Removable Partial Dentures (RPDs) are a less invasive treatment and may be easier to maintain by the users. Removable Partial Dentures (RPDs) allow individuals to regain oral function and health.

You have been invited to participate in this study as you are a current wearer of a Removable Partial Denture (RPD), and your dentist thinks this new type of Removable Partial Denture (RPD) would be suitable for you to wear. There will be a minimum of 10 people participating at your center, with 40 people participating in the whole study.

WHAT ARE YOUR ALTERNATIVE TO BEING IN THIS STUDY?

Your alternative is not to be in the study.

The alternative for treatment is your current removable partial denture (RPD), which is made from Cobalt Chrome (CoCr). Cobalt Chrome is the current standard of care for this treatment.

WHO IS PAYING FOR THIS STUDY?

A company called Solvay Dental 360™, the sponsor of the study, is paying for this study. Solvay Dental 360™ is also paying the investigator to do this study.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

While you are in the study, you still need to get regular medical care. You (and/or your health care payer) will still have to pay for the costs of your regular medical care that are not a part of this study.

You do not have to pay for the study device (polymer RPD frames). All study visits are standard of care for patients receiving a standard metal denture frame. To find out more about costs, you can ask the investigator or study staff. You may have to pay the costs of diagnosing and treating a condition or injury that you or others think is a direct result of your being in the study. This could happen if:

- The sponsor and/or the investigator do not think the condition or injury is a direct result of your being in the study.
- You have not followed the directions the investigator or study staff gave you about the study.

If, as a result of tooth movement that may occur during the study, a new metal RPD may need to be created for you after study completion. You will not be responsible for the cost of replacing your metal RPD. The study sponsor will cover all costs associated with your metal RPD replacement, if applicable.

HOW DO YOU KNOW IF YOU CAN BE IN THIS STUDY?

The first part of the study visit is called a screening period. During this time, the investigator will decide if you qualify to be in the main part of the study.

HOW LONG WILL YOU BE IN THE STUDY?

Your participation in the study will last for approximately 12 -16 weeks.

It will be necessary for you to come to the centre to meet with your dentist or another member of the research team during the study for scheduled visits that will last between 30 minute and 60 minutes.

WHAT WILL HAPPEN DURING THIS STUDY?

As a participant in this study you will be asked to:

- Follow the instructions of your dentist and/or the research team
- Keep your study appointments. If for any reason you cannot attend a scheduled appointment, please contact the research team to reschedule as soon as you know you will miss the appointment.

- Tell your dentist or a member of the research team about any side effects, doctor visits, or hospitalizations that you may have
- Complete any questionnaires as instructed
- Ask questions as you think of them
- Tell your dentist or any member of the research team if you change your mind about staying in the study

Your participation in this study will have no effect on any medicinal health products you are using or dietary habits.

While participating in this research study, you should not take part in any other research project without approval from your dentist. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, or other similar hazards.

Visit Schedule:

Before your treatment (Visit 1):
A member of the study team will discuss your medical history with you in order to determine whether or not you can participate in the study. If after discussion with your dentist you wish to participate in the study, you will then be asked to sign an informed consent form. Following this your dentist will perform an initial examination and take some primary dental impressions, which will be sent to the laboratory for design purposes.

This visit will take approximately 1 hour.

Treatment (Visit 2):
If the study team find no issues with you entering the study, you will return to the center for the dentist or dental technician to perform some further assessments, including the taking of photographs with and without your current Removable Partial Denture (RPD). A working dental impression will be taken at this visit. You will also be asked to complete an assessment of your current Removable Partial Denture (RPD) during this visit.

This visit will take approximately 1 hour.

Visit 3:
During this visit the dentist/dental technician will perform some assessments of the Removable Partial Denture (RPD) framework in and out of your mouth, including photographic evidence of the fit. There will also be some laboratory work done following the visit for tooth set-up.

This visit will take approximately 1 hour.

Visit 4:
You will attend the center to try your new Removable Partial Denture (RPD), and your dentist will assess. Following your visit, the Removable Partial Denture (RPD) will be taken to the lab and the technician will begin the process to finish the denture.

This visit will last approximately 30 minutes.

Visit 5 (Fitting):
You will return to the center for the new Removable Partial Denture (RPD) to be fitted. When the new denture is fitted, the dentist will make some assessments, including an intra-oral scan on the denture in position and photographs of the mouth without the denture. At this time your metal RPD will be taken, properly labelled and securely stored at the University of Illinois Chicago College Of Dentistry for the duration of the study. Your metal RPD will be tried on at each in-clinic study visit (1 week, 4 week and 8 week recall visits).

This visit will last approximately 45 minutes.

Visit 6 (1 week recall):
You will be asked to return to the center 1 week following the fit of the denture to complete a patient satisfaction assessment and for the dentist to perform an assessment too. This visit will again include photographs being taken of the denture in-position.

You will be asked questions relating to the Removable Partial Denture (RPD) including aesthetics, function, speech, eating, general comfort and compliance with wearing.

Your dentist will try your original metal RPD in your mouth to make sure it is still fitting and to assess any changes in tooth position.

This visit will last approximately 45 minutes.

Visit 7 (4 week recall):
You will be asked to return to the center 4 weeks following the fit of the denture to perform a patient satisfaction assessment and for the dentist to perform an assessment too. This visit will again include photographs being taken of the denture in position.

You will be asked questions relating to the Removable Partial Denture (RPD) including aesthetics, function, speech, eating, general comfort and compliance with wearing.

Your dentist will try your original metal RPD in your mouth to make sure it is still fitting and to assess any changes in tooth position.

This visit will last approximately 45 minutes.

Visit 8 (8 week recall):
You will be asked to return to the center 8 weeks following the fit of the Removable Partial Denture (RPD) to perform a patient satisfaction assessment and for the dentist to perform an assessment too. During the visit the dentist will also perform some of the same assessments as performed in Visit 2. This visit will again include photographs being taken of the denture in position.

You will be asked questions relating to the Removable Partial Denture (RPD) including aesthetics, function, speech, eating, general comfort and compliance with wearing.

Your dentist will try your original metal RPD in your mouth to make sure it is still fitting and to assess any changes in tooth position. Your metal RPD will be returned to you at this time.
This visit will last approximately 1 hour.

WILL BEING IN THIS STUDY HELP YOU?

We cannot promise the study will help you but the information we get from this study will help improve the treatment of people with a removable partial denture in the future.

ARE THERE RISKS TO YOU IF YOU ARE IN THIS STUDY?

Tooth movement may occur from the 1 week to 8 week recall visit that may result in your original metal RPD not fitting as it used to. If this occurs a new metal RPD may have to be created for you after the study has been completed.

There are no additional risks to the patient for participating in the study which he/she would not otherwise encounter with standard removable partial denture (RPD) assessment and fitting. Standard procedures for a removable partial denture includes an oral exam, impressions of the jaws, wax bite block, trial insertion of the framework and teeth, fitting and placement of the denture frame, followed by a final review visit.

Could you have any other problems with my health if you do this research study?
It is possible that you could have problems and side effects of the Study Device that nobody knows about yet. If the investigator learns any new information about the Study Device that might change your mind about continuing in the study, the investigator or study staff will tell you about it.

DO YOU HAVE TO BE IN THIS STUDY?

Your decision to be in this study is voluntary. You do not have to be in the study if you don't want to, and you can change your mind at any time. If you refuse to be in this study or decide to leave the study early, there will be no penalty to you and you won't lose any medical benefits. Your regular medical care will not change if you decide not to be in the study.

The investigator, sponsor, IRB or FDA can remove you from the study at any time, even if you want to stay in the study. This could happen if:

- The investigator believes it is best for you to stop being in the study.
- You do not follow directions about the study
- The sponsor stops the study for any reason.

If you want to stop being in the study, tell the investigator or study staff. If you stop being in the study early, the investigator or study staff may ask you some questions about being in the study. To help you leave the study safely, the investigator may ask you to participate in more tests.

WILL YOU GET PAID?

You will receive $50.00, including a parking sticker which will cover your parking fee, at each completed study visit 1 through visit #7. At the final visit (visit #8), you will be compensated $200, and a parking sticker, for participating in and completing all aspects of this study. If you complete the study, you will receive a total of $550. The investigator or study staff can tell you more about when you will receive compensation.

WHAT IF YOU GET HURT OR SICK WHILE YOU ARE IN THIS STUDY?

If you get ill from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Jiyeon Kim at (424) 777-5231.

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

If you get ill or injured as a direct result of the study, the study sponsor (Solvay Dental 360TM) will pay the costs for your medical treatment of the illness or injury if it:

a) Is not a medical condition that you had before the study;
b) Is not a result of the natural progression of your disease or condition;
c) Is not caused by your failure to follow the study plan; and
d) Is not proved to be directly caused by the negligence of a UIC employee. “Negligence” is the failure to follow a standard duty of care.

UIC has not set aside any money to pay you or pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of an UIC employee.

By signing this form, you are not giving up any legal rights to seek compensation for injury.

WHO WILL USE AND SHARE INFORMATION ABOUT YOU BEING IN THIS STUDY?

This section explains who will use and share your study-related health information if you agree to be in this study. If you do not sign this form, you cannot be in the study. During the study, the investigator and study staff will use, collect, and record health information about you (your “records”). Your records will include any information about you that the investigator needs to do the study, including information from the tests described above. Your records also will include other identifying information about you, such as your name and address. The information collected will be provided to the investigators conducting the study. Information collected about you during and for this study will not be used to market products or services to you and your name will not be placed on any mailing lists or sold to anyone else for marketing purposes.

If you sign this form:

You allow the investigator and study staff to use your records to carry out this study.

You allow the investigator to share your records with the sponsor, Solvay Dental 360™; people who work with or for the sponsor; and other researchers involved in this study. These people will use your records to review the study, to check the safety and results of the study, to improve the performance of the polymer RPD frames, for new medical research about the

polymer RPD frames and its design, for business purposes, and to seek government clearance of the polymer RPD frames. (Your information that is used for new medical research will be labelled with your participant ID number, not your name.).

You allow the investigator or sponsor to use some facts about your being in this study in books, magazines, journals, and scientific meetings. If this happens, no one will use your name or other information that could be used to identify you.

You allow the investigator to share all of your records and this signed consent form with the U.S. Food and Drug Administration (FDA) and other government agencies in the United States and other countries. The investigator may also share your records with regulatory agencies, like an Institutional Review Board (IRB). IRB is a group of people who review research studies to protect the rights and welfare of research participants. These agencies may use your records to check the study information, how researchers are doing the study, participants' safety, and the results of the study.

You allow the investigator to share your records with your health care payer to resolve your claim if you are hurt because of being in this study. If this happens, the investigator or the sponsor may share your records with their insurance carriers to resolve your insurance claim, and the investigator may also request medical records from your other health care providers to learn more about your condition.

Please note that the study doctor or study staff may share personal information about you if required by law. (For example, if the study doctor or study staff suspects that you are going to harm someone or yourself.) If you have questions about this, please ask the study doctor.

There are national and state laws that make the investigator protect the privacy of your records. However, you do not have a guarantee of absolute privacy because of the need to share your information. After the investigator shares your records with the sponsor and others, the laws may no longer protect the privacy of your records. The sponsor or others may share your records with other people who do not have to protect the privacy of your records.

All information gathered about you and your participation in this study is private and will only be seen and used by the investigator and study staff, the sponsor and people who work with and for the sponsor, and possibly the FDA, other government agencies, regulatory agencies, and IRB. If the FDA gets access to your records, your name and identity will be kept private. If you would like to know more about how the sponsor will protect the privacy of your records, ask the investigator how to get this information.

You have the right to see and copy your records. However, if you sign this form, you might not be able to see or copy some of your records until after all participants finish the study.

You can cancel this consent to use and share your records at any time. If you want to cancel your consent, you must write a letter to the investigator. If you cancel your consent:

You will not be able to continue in the study.
The investigator will not be able to use or share your records unless it is necessary to protect the integrity of the study.

Even if you leave the study early, the investigator and study staff will still be able to use and share your records as described above unless you cancel your consent to use and share your records.

This consent to use and share your records does not have an expiration date. If you do not cancel this consent form, then the investigator and the study staff will be able to use and share your records for as long as they want to.

You will receive a signed copy of this form for your records.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically.
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WHO CAN YOU TALK TO ABOUT THIS STUDY?

In the event of an emergency, dial 911 immediately.

If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the investigator as soon as possible.

Contact Dr. Jiyeon Kim or Amy Nowinski, Study Coordinator at (312) 996-5245 or 424-777-5231 (24 hours) or email address jkim439@uic.edu or molenda@uic.edu:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury (or a bad reaction to the study treatment), and/or
- if you have questions, concerns or complaints about the research.

APPROVED
AS MODIFIED
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VOLUNTEER'S STATEMENT:

I agree that I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. I may contact Dr. Jiyeon Kim if I have any more questions about taking part in this study. Dr. Jiyeon Kim or University of Illinois Chicago by is being paid by the sponsor for my participation in this study.

My participation in this research project is voluntary. I may quit the study at any time without harming my future medical care or losing any benefits to which I might be entitled. The investigator in charge of this study may decide at any time that I should no longer participate in this study.

If I have questions about my rights as a research subject, other concerns or complaints about the research, or I am unable to reach the investigator, I can contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

OR

If you have questions about your rights as a research subject or concerns, complaints, or to offer input you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

By signing this form, I have not waived any of my legal rights.

I agree to participate in this study. I will be given a copy of this signed and dated form for my own records.

_____ _____
Study Participant (signature) Date

_____
Print Participant's Name

_____ _____
Person who explained this study (signature) Date

_____
Print Person who explained this study's Name