Cover Page for ClinicalTrials.gov

Document:
Informed Consent Form

Official Study Title:
Short dental implants (5 mm) versus Long dental implants (10 mm) in combination with sinus floor elevation: A Randomized Clinical Trial

NCT Number:
NCT04144322

Document Date:
October 14, 2021

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:

Short dental implants (5mm) versus Long dental implants (10mm) in combination with sinus floor elevation: A Randomized Clinical Trial

Company or agency sponsoring the study:

Zimmer Biomet

Names, degrees, and affiliations of the principal investigator and study coordinator:

Principal Investigator: Tae-Ju Oh, DDS, MS, Department of Periodontics, University of Michigan School of Dentistry

Study Coordinator: Alice Ou, RDH, MS, Department of Periodontics, University of Michigan School of Dentistry

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Recently, some doctors have used dental implants that are short in length when replacing missing teeth in areas without enough bone or with a low sinus cavity (air-filled cavities located within the bone of each cheek). The placement of short (5 mm, height of a pencil top eraser) dental implants represents a viable, minimally invasive alternative treatment solution for replacing missing teeth in the upper jaw area. In addition, they prevent the need of a sinus lift and bone graft to make room for a dental implant. The goal of this study is to compare clinical outcomes of short dental implants (5 mm) in length without a sinus lift compared to long dental implants (greater or equal to 10mm, or the height of two pencil top easers) after a sinus lift is completed.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

To take part in this study you must:

- Be at least 20 years of age
- Have overall good general health
- Have good dental home care
- Need of one dental implant in the upper jaw area that is a premolar, 1st molar, or 2nd molar (first, second, third, or forth to last tooth)

- Have a neighboring natural tooth or dental implant on one side of the planned implant site
- Have natural teeth or implants on the opposite arch of the planned implant site
- Need more bone under your sinus than what you have in order to place the implant.

You can't take part in this study if you:

- Have any reason you cannot comply with the study visits
- Have a history of allergic reactions to dental local anesthetics
- Have uncontrolled oral conditions
- Had head or neck chemotherapy within the last 5 years
- Have any condition or medications that may delay healing
- Have an uncontrolled diabetes (HbA1c >8)
- Smoke more than 10 cigarettes/day or have a current alcohol or drug addiction (self-reported)
- Are pregnant, planning to become pregnant, or unsure of your pregnancy status (self- reported)
- Have any medical conditions that may affect the outcome of the study.

3.2 How many people are expected to take part in this study?

There will be up to 50 subjects recruited to participate in this study. Half of the subjects will be randomized into each of the two groups.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

This is a randomized trial in which subjects will be selected at random (flip of a coin) to receive one of two standard of care treatment methods of a dental implant placement. If you qualify for the study, you will be randomly selected to be in one of two groups (1:1). An implant has three parts; the implant, the crown, and the abutment (holds the crown to the implant). You will receive all three parts as part of the study.

If you are in Group Short: You will receive a single short dental implant (5mm) in length and no sinus lift. The implant will be left to heal below the gum for 4 months, after which the implant will be surgically exposed, and impressions (mold and digital) will be taken to fabricate the final screw-retained metal-ceramic or metal-composite crown for the implant.

If you are in Group Long: You will receive a 10 mm long implant after sinus lifting and grafting with donor bone, which is a standard of care procedure. The implant will be left to heal below the gum for 4 months, after which the implant will be surgically exposed, and impressions (mold and digital) will be taken to make the final screw-retained metal-ceramic or metal-composite crown for the implant.

Screening & Pre-surgical visit (V1)

If you decide to take part in this study, a study team member will go over the inclusion criteria for your participation in this study. Then we will review your medical history and record your vital signs (blood pressure and heart rate). A dental exam of your teeth and gums will be completed and we will take photos (no one will be able to tell it is you) of your oral cavity. We will also take a CBCT radiograph (3D full head scan) and an x-ray of the missing tooth and future implant-bearing area in your mouth. The CBCT scan will be used for research measurements of your bone structures and to help the surgeon in planning implant placement. Impressions (dental molds) of your teeth will be taken to make a guide that will fit your teeth. The CBCT scan may be scheduled separately due to the availability of the CBCT machine. This visit will take approximately 1.5-2 hours.

Surgical visit (V2)

We will review your medical history and check your vitals (blood pressure and heart rate). The surgeon will numb your tissues with local anesthetic before placing the dental implant. Based on prepared random allocation, you may either receive a short implant or a long implant combined with a sinus lift procedure and bone graft.

At least 3 standard dental x-rays will be taken of the implant site before, during and after surgery to verify the angle of the implant and final placement. In addition, photographs of the inside of your mouth and measurements will be taken during the surgery. After the implant placement, stitches will be placed, and you will be given home care instructions and prescriptions of an antibiotic, pain medication, and a mouth rinse. Also, we will send you home with a pain diary form to fill out each day and bring back at your 2 week post-op visit. This visit will take about 4 hours.

2-week post-op (V3)

You will return in 2 (±2 day) weeks for follow up care. We will ask for any changes to your medical history, your stitches will be removed, and photographs of the inside of your mouth will be taken. You will return your completed pain diary and complete a satisfaction survey. This visit will take about 1 hour.

4-month post-op (V4)

At 4 (±1) months following implant placement, we will ask for any changes to your medical history. The surgeon will numb your tissues with local anesthetic before exposing the implant by opening a small flap. The healing cap will be connected to allow the emergence of the implant through the soft tissue, thus allowing access to the implant from the oral cavity. Stitches will be placed, and you will be given home care instructions. Clinical photographs and a standardized radiograph will be taken. This visit will take about 1 hour.

4-month post-op (V5)

You will return in 2 (±2 day) weeks from (V4) for follow up care. We will ask for any changes to your medical history, your stitches will be removed and photographs of the inside of your mouth will be taken.

5-month post-op (V6)

At 5 (±1) months following implant placement, we will ask for any changes to your medical history and take impressions (mold and/or digital) of your teeth in order to make the final crown which will be supported by the implant. This visit will take about 1 hour.

5-month post-op (V7)

You will return for crown delivery (placement) 2 (±1) weeks after the impression visit (V6). This could be more than one visit to make sure that the color and shape of the final crown is acceptable. We will ask for any changes to your medical history and take a standardized x-ray of the implant area, photographs of the inside of your mouth, and research measurements. You will also receive a free dental cleaning. This visit will take about 2 hours.

6-month post-op after crown delivery (V8)

You will return for a follow-up visit at 6 months (±1) months after crown placement. We will ask for any changes to your medical history. This visit will include photographs of the inside of your mouth, research measurements, and an x-ray taken of the implant site. You will also receive a free dental cleaning and be asked to complete a patient satisfaction survey. This visit will take about 90 minutes.

12-month post-op after crown delivery (V9)

You will return for follow-up visit at 18 months (±1) months after crown placement. We will ask for any changes to your medical history. You will also receive a free dental cleaning. This visit will take about 1 hour.

18-month post-op after crown delivery (V10)

You will return for follow-up visit at 24 months (±1) months after crown placement. We will ask for any changes to your medical history. This visit will include photographs of the inside of your mouth, measurements, and an x-ray taken of the implant site. We will also take a CBCT radiograph (3D full head scan). You will also receive a free dental cleaning and be asked to complete a patient satisfaction survey. This visit will take about 2 hours.

4.2 How much of my time will be needed to take part in this study?

There are 10 study visits total that will take place over two years.

4.3 When will my participation in the study be over?

Your participation in the study is voluntary. You may refuse to participate. Your participation in the study will end after visit 10.

4.4 What will happen with my information used in this study?

Your collected information may be shared with Zimmer Biomet.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

Risks associated with dental x-rays

In this study, you will have at least eight standard dental x-rays and two CBCT scans. You should experience no more discomfort related to the x-rays than you would with x-rays taken during your regular dental visits. The only discomfort may be related to the x-ray film or film holder pressing on your soft tissues.

The biologic effect of radiation is termed “effective dose” (EF) and is expressed in milliSieverts (mSv). The amount of radiation for one dental x-ray is about 0.005 mSv and 5.3mSv for CBCT scan. This is considered to be a very small risk. The average radiation exposure that includes the natural background radiation an individual receives is about 3.1 mSv per year and about 0.008 mSv per day. The total amount of radiation exposure to you from this study x-ray is minimal.

The researchers will try to minimize these risks by providing a lead apron that will be mandatory to wear during x-rays.

Risk associated with surgery

You will be assigned to a treatment program by chance. The treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments. The likelihood that you will be assigned a treatment that will be less effective than other study treatments or other available treatments is unknown. Both surgery methods are the standard of care. Mild to moderate pain and swelling is expected for both groups. There is a very low risk of uncontrolled bleeding that may occur with subjects that are in general good health and not taking medications that are classified as a blood-thinner. In some cases, you may feel some temporary sensitivity with the teeth next to the implant.

Risk associated with Group Short:

1) Implant Failure

2) Complications such as sinus membrane perforations, persistent bleeding, sinus infection, pain, swelling, and inflammation around the dental implant including loss of bone.
3) Implant crown complications such as detachment, loosening of screws or healing caps, and fracture of the screw or crown.

Risk associated with Group Long:

1) Implant Failure
2) Complications such as sinus membrane perforations, persistent bleeding, sinus infection, not enough bone gain for long implant placement, pain, swelling, and inflammation around the dental implant including loss of bone.
3) Implant crown complications such as detachment, loosening of screws or healing caps, and fracture of the screw or crown.

Risk of Sinus Lift (Group Long)

A major risk of a sinus lift is that the sinus membrane could be pierced or ripped. There are other risks involved including infection, inflammation, hematoma (bruising), pain, graft failure, sinusitis, and hemorrhage (bleeding).

Risk of Bone Graft (Group Long)

We use donor bone (allograft) during this study. This material has been used for more than 30 years. Any pieces in the bone that may cause a reaction have been removed when it was made. There has been no report of people getting an infection from the donor bone. However, we cannot be sure that an infection or reaction won't happen to you. If you choose to take part, we will monitor you closely for any adverse events and provide appropriate care if they occur. There is a low chance that the bone graft may get infected or your body may reject the bone graft, which would result in removal of the graft.

The researchers will try to minimize these risks by taking a CBCT prior to surgery. All of these risks are possible for any implant placed and are standard of care risks.

Risk of loss of confidentiality

Additionally, there may be a risk of loss to confidentiality or privacy because your chart will be used and photographs will be taken. All of your information will be in a computer that cannot be accessed without a code. All paper documentation will be in a folder labeled "confidential" and stored in a locked office that only the researchers on this study have access to. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. By doing these possible risks are monitored and reduced. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

The data collected from this study may be beneficial to determine if short implants (5mm) are a reliable alternative to longer implants (>10mm) placed after sinus elevation. In case of no clinical difference between test and control, people would benefit by avoiding an additional surgical procedure (sinus lift).

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Taking part in this study is strictly voluntary. You do not need to participate if you do not want to. In addition, your care will not be affected by not taking part in this study. You may have other options to replace your missing tooth at your own cost.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information” (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No, there would be no harm to you if you decide to leave this study before it is finished. If you leave the study before the crown is made, no money will be given to you and you will receive no free cleanings. If you drop out of the study before the 12 month, 18 month, or 24 month visits, you will only receive one, two, or three free cleanings, respectively.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list.

The CBCT, x-rays, dental exam, dental implant, and surgeries will be at no charge to you. The crown supported by the implant will cost you $700. You will be responsible for covering the cost of any non-research related care that you might need during the study. You will also be responsible for the cost of the prescriptions that will be given to you. Your health plan will not be billed since you are already getting a reduced fee.

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you or your insurance provider will be billed for all costs of treatment as the study does not provide compensation for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

If you decide to take part in this study, you will receive a CBCT, x-rays, dental exam, dental implant, and implant surgery at no cost. If you are in group graft, you will also receive a sinus lift and bone graft at no cost. You will also have your teeth cleaned for free at the 5, 12, 18, and 24 month follow-up research visits.

If you leave the study before the crown is made, no money will be given to you and you will receive no free cleanings. If you drop out of the study before the 12 month, 18 month, or 24 month visits, you will only receive one, two, or three free cleanings, respectively.

8.3 Who could profit or financially benefit from the study results?

In the interest of transparency, Dr. Hom-Lay Wang and Dr. Furat George, co-investigators on this research project have received payments from Zimmer Biomet for activities outside the University of Michigan. This research is sponsored by Zimmer Biomet.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

All research records will be kept in a locked room in a locked cabinet with limited access and or in a password protected computer program. Only those directly involved with this research study will have access to the research records and password. 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 the results. You can search this Web site at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal Identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UM School of Dentistry record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission, or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan School of Dentistry system, it is protected by the Dental School's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Tae-Ju Oh, DDS, MS
Mailing Address: 1011 N. University; Rm. 1324; Ann Arbor, MI 48109
Telephone: 734-763-3325

Study Coordinator: Alice Ou, RDH, MS
Mailing Address: 1101 N University; Rm 1324B; Ann Arbor, MI 48109
Telephone: 734-763-3325

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road, Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)

Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Consent to Participate in the Research Study
I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Principal Investigator or Designee
I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____