IRB NUMBER: STUDY20221174
IRB APPROVAL DATE: 3/17/2023
IRB EFFECTIVE DATE: 3/17/2023
IRB EXPIRATION DATE: None

CASE WESTERN RESERVE UNIVERSITY EST. 1826

INFORMED CONSENT DOCUMENT

Immediate versus Delayed Loading of 4 Guided Implants Supporting a Maxillary Overdenture with a Novalock Retention System: a Randomized Controlled Study

You are being asked to participate in a research study conducted by researchers at Case Western Reserve University, Department of Periodontics with funding provided by or sponsored by Straumann, USA. This consent form contains important information about this project and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. Your participation in this research is voluntary.

KEY INFORMATION FOR YOU TO CONSIDER:

The purpose of the study is to evaluate the clinical, radiographic and patient-related outcomes of implant-retained immediately-loaded versus conventionally (delayed)-loaded upper complete dentures. This means we are comparing the outcomes of implants attached to the semi-detachable denture connections on the same day as implant placement versus 12 weeks after implant placement. Dentures are often esthetically and functionally not satisfying because of problems of retention and stability. Implant-retained dentures are a good alternative treatment option because they solve these inconveniences by enabling the denture to connect to the implants, yet the denture can still be removed for daily cleaning. In this protocol, four dental implants are placed in the upper jaw and the connection of the denture to the implants takes place immediately: this approach, called immediate-loading, or the dentures are attached 12 weeks after implant placement. In this study you will be randomized, similar to the flipping of a coin, to either the immediate denture placement or the delayed denture placement.

DETAILED CONSENT

You were selected as a possible participant because you are interested in having your existing upper denture converted to an overdenture with four dental implants. We hope to recruit 18 people to volunteer for this research.

Procedures

The participation in the study implies 8 visits over the course of 1 year, as well as a 2 and 3 year follow-up. If needed additional visits may be scheduled by your Study Doctor. It is important that you tell the dental/medical staff about any medication that you are taking before and during the study.

You will be asked to fill out a questionnaire regarding your denture. This will take approximately 10-15 minutes. You are free to answer only the questions you are comfortable to answer. You will have the opportunity to see the questionnaire before signing this consent form.

All of the procedures performed and the x-rays/scans obtained during the study represent the standard of care in implant dentistry.

If you are smoking, a maximum of 10 cigarettes per day are allowed. Elective treatment like implant surgery is not recommended if you are pregnant. Your Study Doctor must be informed immediately if you become pregnant. All the materials used in this study are approved by FDA. During the study, you will be asked if you have had any health problems since the last visit. If you choose to participate in this study, you will be asked to take or given medications that are part of standard clinical care. These medications are local anesthetic (2% lidocaine with 1:100,000 epinephrine) which are injected into the area in order to numb the site, and antibiotic medications consisting of 2 grams of amoxicillin 1 hour before the surgical procedure. If you are allergic to penicillin or penicillin derivatives, azithromycin or other classes of antibiotics will be administered according to ADA guidelines. No experimental drugs will be used.

You will be randomly assigned to have your implants "immediately-loaded" (on the same day as your implant surgery" or "conventionally-loaded/delayed" (at 12 weeks post-surgery). The randomization will be computer-generated and your assignment will be placed in a sealed envelope. On the day of surgery, after the implants are placed, we will open the envelope to see which group you have been assigned to and proceed accordingly.

The 10 visits are the following:

Visit 1: (Screening and pre-surgical planning)	Informed consent will be signed. Medical/surgical history, Oral examination, denture evaluation, intraoral photographs and CBCT (Cone Beam Computer Tomography) will be performed, and you will be evaluated for eligibility for participation in the study. The CBCT is a radiographic examination that provides a 3-D view of your jaws to measure the amount of bone available to place the implant in proper position. You will be asked to fill a questionnaire regarding your denture.
Visit 2: (Surgery)	Implant placement will be performed. The test group will have the denture immediately attached. Intraoperative photographs and X-rays will also be taken.
Visit 3: (1-week post-surgery)	Routine post-operative follow-up and care as required. Intraoperative photographs will also be taken.
Visit 4: (2-week post-surgery)	Routine post-operative follow-up. You will be asked to fill a questionnaire regarding your denture Intraoperative photographs will also be taken.
Visit 5: (4-week post-surgery)	Routine post-operative follow-up. Intraoperative photographs will also be taken.
Visit 6: (12-week post-surgery)	Routine post-operative follow-up. You will be asked to fill a questionnaire regarding your denture Intraoperative photographs will also be taken. Attachment of the denture

	will take place at this time if it has not already taken place.
Visit 7: (24-week post-surgery)	Follow up visit. You will be asked to fill a questionnaire regarding your implant-supported maxillary overdenture. Intraoperative photographs and X-rays will also be taken.
Visit 8: (12-month post-surgery)	Follow up visit. You will be asked to fill a questionnaire regarding your implant-supported maxillary overdenture. Intraoperative photographs and Xrays will also be taken.
Visit 9: (24-month post-surgery)	Follow up visit. You will be asked to fill a questionnaire regarding your implant-supported maxillary overdenture. Intraoperative photographs and Xrays will also be taken.
Visit 10: (36-month post-surgery)	Follow up visit. You will be asked to fill a questionnaire regarding your implant-supported maxillary overdenture. Intraoperative photographs and X-rays will also be taken.

Foreseeable Risks and Discomforts

All treatments and procedures may involve some level of risk to you. The risks are the same for this procedure regardless of participation of the study. We have listed below the foreseeable risks, but there may be some that are unforeseeable.

There are possible risks and/or discomforts associated with the procedures described in this study include: pain, swelling, bruising, bleeding, infection, damage to the adjacent sinus cavity, permanent or prolonged numbness or altered sensation, failure and removal of the dental implant, imprecise implant placement when compared to the pre-surgical planning, and exposure to radiation.

If you take part in this research, you will have one or more medical imaging studies that use radiation. The tests you will have include a CBCT scan of your upper airway. This CBCT scan is standard procedure for implant placement whether or not a patient is in the study. The radiation dose from this research is about 70 micro-Sieverts for the study. To give you an idea about how much radiation you will get, we will make a comparison with an everyday situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally occurring radioactive forms of water and minerals. This research gives your body the equivalent of about 8 days' worth of this natural radiation. The radiation dose we have discussed is what you will receive from this study only and does not include any exposure you may have received or will receive from other tests. If you have concerns about the overall radiation exposure, you should discuss them with your physician.

Anticipated Benefits

The possible benefits you may experience from the procedures described in this study include improved retention and stability of upper denture, slower bone resorption, increased chewing efficiency, improved speaking ability and comfort, improved general quality of life. You may not receive any direct benefit from this study. The knowledge gained from this study may eventually benefit others.

Compensation

You will not be paid for taking part in this study. You will receive a discount on the cost of your care, which will be subsidized by the study sponsor.

The standard treatment that you were already receiving prior to, and continue to receive during the study, will be charged to you/your insurance company as before. While the study has received partial funding to pay for many expenses, it cannot cover all the costs of this research. Some of the procedure costs will be charged to you: you will be responsible for the cost of a new denture if it is deemed necessary at the screening visit; at the time of the implant surgery, you will pay $2800 for the surgical procedure and for any denture modifications that will be done after. The implants, CBCT examination, and the x-rays taken during the study will be paid by the sponsor.

If you have dental insurance, you may submit your payment receipt to your carrier to attempt to receive reimbursement. Please note that not all insurance companies cover implant treatment and if they do, they may reimburse you for only a portion of the procedure fee. We recommend that you contact your dental insurance carrier to determine your coverage benefits. You will be asked to return for follow up visit after, 4, 12, 24 weeks, 12, 24 and 36 months (visit 5-10) after implant placement. You will receive $100 payment via Zelle for visit 6, 7, 8, 9, and10 scheduled follow up visit as reimbursement for travel expenses for a total of $500. If you decline to receive the compensation via Zelle, you will receive at $100 Walmart gift card.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from CWRU or another medical facility, but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Alternative(s) to Participation

If you choose to not participate in this study, treatment will still be available to you outside of the study parameters.

Voluntary Nature of the Study

Participation in this study is voluntary. Before deciding about whether to participate in this research study, please read this consent form carefully and discuss any questions you have with the researcher. You may also want to talk to family members, your primary care physician, or a friend before making a decision.

If you decide to participate in the study, you are free to withdraw from it at any time. If you decide not to participate or withdraw from the study, your decision will not affect your present or future care you receive at Case Western Reserve University and there will be no penalty or loss of benefits.

If you decide to withdraw, we ask that you let us know by calling Dr. Gian Pietro Schincaglia at 216-368-4412 or by sending a written notice to Dr. Gian Pietro Schincaglia of Department of Periodontics, Room 239 H, 9601 Chester Ave, Cleveland, OH 44106

The researcher and Straumann USA, LLC may prevent you from continuing in this study. This may happen if:

- You become ineligible to continue in the study,
- You fail to follow the instructions of the Study Doctor,
- You experience a failure of all the implants,
- You experience a study related injury.

When you stop taking part of the study you will be required to go through the termination procedures the Study Doctor considers necessary for your safety. This may include attending a separate follow up visit to assess your medical/dental condition and ensure your safety.

Privacy of Protected Health Information (PHI)

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of Case Western Reserve University and West Virginia University. This Authorization form is specifically for a research study entitled "Immediate versus Delayed Loading of 4 Guided Implants Supporting a Maxillary Overdenture with a Novalock Retention System: a Randomized Controlled Study" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Gian Pietro Schincaglia, and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at Case Western Reserve University. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally, the Principal Investigator and study staff at Case Western Reserve University and West Virginia University who are working on this research project will know that you are in a research study and they will see and use your PHI. The researchers working on this study will collect the following PHI about you: name, address, dates such as birthday and date of admission, and telephone number. This PHI will be used to keep track of study participates, communicate with study participates, and correlate data with ages of patients. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Gian Pietro Schincaglia, Elysha

Pomerantz; other staff from the Principal Investigator's medical practice group; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization, you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter or email to Dr. Gian Pietro Schincaglia of Department of Periodontics, Room 239 H, 9601 Chester Ave, Cleveland, OH 44106 or at gxs486@case.edu; If you have a complaint or concerns about the privacy of your health information, you may also write to the University's Director of Privacy Management, Lisa Palazzo at lisa.palazzo@case.edu or 216-368-4286 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office for Civil Rights, US Department of Health and Human Services, 233 N. Michigan Ave., Suite 240, Chicago, IL 60601.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. Case Western Reserve University and West Virginia University are committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of, Case Western Reserve University and West Virginia University, there is a risk that your PHI may no longer be protected.

Confidentiality

Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Research records will be kept in a secure location and access will be limited to the researchers, the University review board responsible for protecting human participants, regulatory agencies, and Straumann USA, LLC. In any sort of report we might publish, we will not include any information that will make it possible to identify a participant.

Subject Identifiable Information

All information that identifies you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. The identifiers will be maintained to correlate follow-up data with initial treatment. De-identified data, including your gender, age, and clinical data will be shared with the research team at the other study center at West Virginia University. At the end of the study, cumulative (a summary of all patients in the study), de-identified data will be shared with the study sponsor (Straumann). Again, this data will be de-identified and will not include your name, address, date of birth, or other information used to identify you.

Data Retention

The researchers intend to keep the research data until the research is published and/or presented.

Contacts and Questions

The researchers conducting this study are Gian Pietro Schincaglia (Primary Investigator) and Elysha Pomerantz (Co-Investigator and resident in the Department of Periodontics). You may ask any questions you have now. If you have any additional questions, concerns, or complaints about the study, you may contact the researchers at the Department of Periodontics, Room 239 H, 9601 Chester Ave, Cleveland, OH 44106

If you would like to talk to someone *other than the researchers* about questions or complaints regarding this study, research participant rights, research-related injuries, or other concerns, please contact:
Case Western Reserve University Institutional Review Board
10900 Euclid Ave.
Cleveland, OH 44106-7230
(216) 368-4514

Statement of Consent

Your signature below certifies the following:

- You are at least 18 years of age.
- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

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

_____
Printed Name of Participant

_____ Date: _____
Signature of Participant

_____ Date: _____
Signature of Person Obtaining Consent