

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Influence of Vertical dimension of Occlusion changes on the direction of walking

PROTOCOL NO.: None
WIRB® Protocol # 20091904

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Indian Harbour Beach, Florida
United States

INVESTIGATOR: Claire Stagg-Ruda, D.D.S.
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United States

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**STUDY-RELATED
PHONE NUMBER(S):** Claire Stagg-Ruda, D.D.S.
321-777-2797
321-536-1473 (24 Hours)

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this consent form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form.
- Having the study doctor or staff explain the research study to you.
- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the research;
- What device or procedures will be used;
- Any possible benefits to you;
- The possible risks to you;
- How problems will be treated during the study and after the study is over.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate the effect of adding a removable rubbery material on one side of your mouth and how this affects the direction of your walking. You will be tested with this rubbery material first on one side of your mouth and then on the other.

PROCEDURES

You are being asked to join this study because we wish to find out what happens when we change the height of your bite in relation to the direction of your walking with your eyes closed.

You will be one of 50 people between the ages of 18-55 in the study.

This study consists of two visits.

The first visit will last from 2-3 hours during which time you will fill out a form that will determine if you are a good candidate for this study.

In this session impressions of your teeth will be taken to make models that will be used later in the study along with a bite model.

There will also be photographs of your face and teeth and the study doctor will do a basic dental examination to make sure that you have the correct amount of teeth necessary for the study and that the teeth are not loose.

The second visit a week later will last 30-40 minutes. At that visit you will be filmed walking ten times down a corridor with 3 different rubbery bites in your mouth while blindfolded. This will be filmed.

Location

You will be asked to come to Dr. Stagg-Ruda's Dental office at 2120 Highway A1A Indian Harbour Beach 2 weeks in a row.

RISKS AND DISCOMFORTS

This is a non-invasive study and includes minimal risks. There is a small risk that you could swallow alginate material during the impressions.

There is the risk of loss of confidentiality. The research team will make every effort to keep all the information you tell us during the study strictly confidential, as required by law. All subject records will be maintained under lock and key by the study doctor and will be available only to the investigators and research staff. After analyzing the results of the study, all data which can possibly identify you will be destroyed.

There may be risks or side effects which are unknown at this time.

NEW INFORMATION

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS

There is no direct benefit from participation.

COSTS

There is no cost to you for your participation in this study.

PAYMENT FOR PARTICIPATION

You will not be paid for being in this study.

ALTERNATIVE TREATMENT

This is not a treatment study. Your alternative is not to participate in this study.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records (models of teeth, video of walking)
- Records about your study visits.
- Information gathered for this research about:
 - Dental exams
 - Questionnaires
 - Photographs

Who may use and give out information about you?

The study doctor and the study staff.

Who might get this information?

- The sponsor of this research. “Sponsor” means any persons or companies that are:
 - Working for or with the sponsor, or
 - Owned by the sponsor

Your information may be given to:

- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?

- to do the research
- to study the results, and
- to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.

COMPENSATION FOR INJURY

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide emergency medical treatment. However, such medical care will not be provided free of charge, even if the injury or illness is a direct result of this research study. No other payment is routinely available from the study doctor or sponsor.

No funds to provide financial compensation for research-related injury or illness are available.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Taking part in this study is voluntary. You may decide not to take part or you may leave the study at any time. Your decision will not cause any penalty or loss of benefits to which you are entitled.

The study doctor or the sponsor may stop your participation in this study at any time without your consent for any of the following reasons:

- it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some of the end of study procedures done.

SOURCE OF FUNDING FOR THE STUDY

The sponsor Dr. Claire Stagg-Ruda will pay for this research study.

QUESTIONS

Contact Dr. Claire Stagg-Ruda at 321-777-2797 or 321-536-1473 (24 hours) for any of the following reasons:

- if you have any questions about this study or your part in it
- if you feel you have had a research-related injury or
- if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who independently review research.

WIRB will not be able to answer some types of questions, such as questions about appointment times. You may contact WIRB if you cannot reach the research team or if you want to talk to someone else.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

CONSENT

I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Subject Name

CONSENT SIGNATURE:

Signature of Subject

Date

Signature of Person Conducting Informed Consent Discussion

Date