UNIVERSITY OF ALBERTA

Dentistry and Dental Hygiene
Excellence in Dental Health

PARTICIPANT INFORMATION LETTER

Title of Study: Analysis of Dentofacial Changes and Nasal Function with two different bone-anchored maxillary expanders in Adults

Principal Investigator:

- Dr. Manuel Lagravere – Phone (780) 407-5600 ext 1

Why am I being asked to take part in this research study?

You have been asked to take part in this study because you have a crossbite in the back teeth requiring orthodontics. Before you make a decision, one of the researchers will go over this form with you. You are encouraged to ask questions if you feel anything needs to be made clearer. You will be given a copy of this form for your records

What is the reason for doing the study?

Crossbites are a common problem and can affect the bite, breathing patterns and other dental structures in your mouth. At your age there are two treatment options for your condition. The first treatment includes the placement of an expansion appliance that attaches directly to the palatal bone. The second treatment involves the separation of the roof of the mouth with surgery and placement of the expander attached to the teeth or bone. Since at 18 years old, the roof of the mouth is expected to be very hard to separate by just using an appliance attached to the teeth, for this reason, surgery is usually suggested. Presently, appliances attached to the roof of the mouth directly have been demonstrating the capability to separate the roof of the mouth without the need for surgery. There are different types of expanders that attach to the roof of the mouth. The purpose of this study is to compare two different types of these appliances, one that attaches by the middle of the roof of the mouth and that attaches on the sides of the roof of the mouth.

.

What will happen in the study?

Dentistry and Dental Hygiene
Excellence in Dental Health

If you agree to be in this study, you will first sign this consent document to indicate that you agree to participate. Once you have signed the consent form – you will be booked for records, to confirm that you have a crossbite, and confirm that you are eligible to participate in the study. If the records show that you do not qualify for the study, you will be treated at this clinic in the regular clinical stream (by one of the resident clinicians).

Once all of these tests are completed and it is confirmed that you qualify, you will be randomly assigned (like flipping a coin) to receive one of the two study treatment options:

- Treatment with an expansion appliance attached in the middle of the roof of the mouth
- Treatment with an expansion appliance attached at the sides of the roof of the mouth

Your complete orthodontic treatment will be provided by Dr. Lagravere in the Orthodontic Graduate Clinic at the University of Alberta. In addition to the standard procedures necessary to treat your type of bite problem, a series of dental diagnostic tests will be done including radiographs, photos, dental scans and airway measurements. Measurement of how well you breathe through the nose will also be made. You will be randomly selected for having the expander that is attached in the middle of the roof of the mouth or on the sides of the roof of the mouth. If by any chance the appliance fail, then the alternative treatment of surgery would be discussed being the traditional and standard path in practice.

The attachments will be placed with local freezing and the discomfort you are likely to experience is similar to having a tooth removed. A second minor surgery will be required to remove the attachments when the orthodontic treatment is completed. These two appointments will take approximately 45 minutes each. Once the correct upper jaw width has been achieved, typical full braces will be placed on the upper and lower teeth to complete bite correction and tooth alignment. To help track jaw and tooth position changes two additional three-dimensional x-ray will be taken.

The rate of airflow while breathing through the nose and dimensions of the inside of the nose will be measured at each record appointment, being four total (initial, at the end of expansion, at the end of all the treatment and 2 year follow-up after treatment is done). You will be asked to blow through the nose into a special mask that fits over the nose. A device that uses sound waves to measure the size of the inside of the nose will be placed close to the nostril and a recording is made. You should not feel any discomfort.

What are the risks and discomforts?

The risks associated with the attachments are similar to those expected with tooth removal and may include minor risk of infection or bleeding. The attachments are constructed from titanium and stainless steel and will not cause an allergic reaction.

The x-rays taken for this study are no different that if you were not in the study. As such, there is no additional risks to you as a result of these x-rays for being in the study. There are no risks or discomforts associated with the airflow measurements.

What are the benefits?

You will not benefit from the information obtained from this study. Information gained from this study will help us compare the effects of a bone-anchored upper jaw expander will help us treat other patients with your condition in the future.

What happens if I am injured because of this research

If you become ill or injured as a result of being in this study, you will receive necessary medical treatment, at no additional cost to you. By signing this consent form you are not releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

Do I have to take part in the study?

Dentistry and Dental Hygiene
Excellence in Dental Health

Being in this study is your choice. If you decide to be in the study, you can change your mind and stop being in the study at any time, and it will in no way affect the care or treatment that you are entitled to.

Can my participation in the study end early?
In addition to you being able to stop the study at any time, you may be withdrawn from the study if you don't show up for your appointments, if you don't brush your teeth or if other compliance issues come up with normal orthodontic treatment.

What will it cost me to participate?
There is no extra cost in participating in this study. The cost of the treatment and records is the same as if not participating in the study.

Will my information be kept private?
During the study we will be collecting health data about you. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your name will be released outside of the study doctor's office or published by the researchers. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your health information is kept private.

The study doctor/study staff may need to look at your personal health records held at the study doctor's office, and/or kept by other health care providers that you may have seen in the past (i.e. dentist/family doctor). Any personal health information that we get from these records will be only what is needed for the study.

During research studies it is important that the data we get is accurate. For this reason your health data, including your name, may be looked at by people from:

UNIVERSITY OF ALBERTA

Dentistry and Dental Hygiene

Excellence in Dental Health

The University of Alberta auditors and members of the Research Ethics Board
By signing this consent form you are giving permission for the study doctor/staff to collect, use and disclose information about you from your personal health records as described above.

After the study is done, we will still need to securely store your health data that was collected as part of the study. At the University of Alberta, we keep data stored for 5 years after the end of the study.

If you leave the study, we will not collect new health information about you, and the data collected will not be used in the study.

What if I have questions?
If you have any questions about the research now or later, please contact Dr. Manuel Lagravere, principal investigator at (780) 407-5600 ext 1.

If you have any questions regarding your rights as a research participant, you may contact the Health Research Ethics Board at 780-492-2615. This office is independent of the study investigators.

UNIVERSITY OF ALBERTA

Consent Form

Analysis of Dentofacial Changes and Nasal Function with two different bone-anchored maxillary expanders in Adults

Dentistry and Dental Hygiene

Excellence in Dental Health

Principal Investigator: Dr. Lagravere (780) 407-5600 ext 1

	Yes	No
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Sheet?	☐	☐
Do you understand the benefits and risks involved in you taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to leave the study at any time, without having to give a reason and without affecting your future medical or dental care?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to your records, including personally identifiable health information?	☐	☐
Do you want the investigator(s) to inform your family doctor that you are participating in this research study? If so, give his/her name _____	☐	☐

Who explained this study to you? _____

UNIVERSITY OF ALBERTA

Dentistry and Dental Hygiene

Excellence in Dental Health

I agree to take part in this study

Signature _____

(Printed Name) _____

Date: _____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Investigator or Designee_____

Date _____

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A SIGNED COPY GIVEN TO THE RESEARCH PARTICIPANT