



UNIVERSITY OF ALBERTA

PARENT INFORMATION SHEET & CONSENT

**SKELETAL, FUNCTIONAL AND DENTAL CHANGES DURING TREATMENT OF MILD TO MODERATE CLASS II MALOCCLUSIONS WITH FIXED CLASS II CORRECTORS: A RANDOMIZED CLINICAL TRIAL.**

---

Principal Investigator: Dr. Paul Major

Phone: 780.492.3312

Study Co-investigator: Dr. Mohammed Al-Saleh

Phone: 780.993.8844

Email: [m.alsaleh@ualberta.ca](mailto:m.alsaleh@ualberta.ca)

---

**Why has your child been asked to participate in this study?**

Your child has been asked to take part in this study because he/she has a mismatch in the way their upper and lower teeth bite together that requires orthodontic treatment to be solved. Using braces with a bite corrector to better match his/her jaws is a common and successful treatment option. The bite correctors guide the lower jaw to grow in a specific way to correct the mismatch in the way their upper and lower teeth bite together. Different types of bite correctors are used today, but we need more research to know which one is the better option.

**What is the purpose of this study?**

This study will collect data to try to assess which treatment option (that involves braces with the bite corrector) works better. The first option involves the use of rigid bite corrector first and then braces, the second option involves the use of flexible bite corrector first and then braces, while the third option involves braces first with the bite corrector at the same time. We currently do not clearly know if there are important effects of the proposed treatment approaches on the mouth tissues and functions. All approaches are typically used in orthodontic practices. The information collected in this study will be used to compare the different effects of the different appliances on the mouth health and functions.

**Where will the study occur?**

The orthodontic treatment will be provided in the Graduate Orthodontic Clinic at the University of Alberta. The study will simply follow the standard orthodontic timelines to treat your child's type of bite problem. The orthodontic treatment of this type of bite problem is usually composed of two main steps: 1: Treatment of bite problem (24 to 36 months), 2: Follow up stage (around two years).

**What orthodontic procedures will happen?**

Department of Dentistry  
Faculty of Medicine and Dentistry

25Mar2014  
1 of 6



## UNIVERSITY OF ALBERTA

If you agree to allow your child to be in this study, which of the three treatment options they get will be randomly decided (like flipping a coin).

Group One and Two will receive only the bite corrector (either flexible or rigid bite corrector) for the first few months (6 to 12 months) and thereafter braces to finalize for bite detailing and aesthetic smile finishing (18 to 24 months). Thereafter, routine follow up visit for 2 years after treatment will be offered.

Group Three will wait for 12 months and receive braces first and bite corrector at the same time (24 to 30 months). In other words all the identified aesthetical and bite problems will be solved simultaneously. Thereafter, routine follow up visit for 2 years after treatment will be offered.

To help track changes in teeth and mouth functions, routine x-ray images taken at different times will be used to look for changes. For this study, x-ray images are required before treatment, one year after treatment started, at the end of treatment, 2 years after treatment is completed. The x-rays will be taken in a lab in the Edmonton Clinic and will require approximately 30 minutes each visit.

Also, orthodontic treatment is strongly associated to the appearance of face, jaws and chin projection. To closely evaluate the orthodontic treatment on your child's appearance, multiple photographs of the face, teeth, chin and smile will be routinely taken for our patients. This procedure will be repeated 4 times, before, during and after your child's treatment (approximately 4-5 years).

### **What other non-routine procedures my child will be asked to do?**

Because we are not sure how the different types of bite correctors affect the shape and functions of growing jaw joint, 3 extra steps will be applied:

- (1) Clinical check up of mouth functions
- (2) Magnetic resonance imaging (MRI) of the jaw.
- (3) Complete a survey to know the child experience when having bite correctors (comfort, pain, and difficulties while speaking or eating).

These steps will be repeated 4 times in the approximately 4 to 5-year period: 1: Before using the bite corrector; 2: After bite corrector treatment is completed (12 months); 3: After braces treatment is completed (18-30 months); 4: 2-years after treatment is completed.

### **Why does my child need to have MRI?**

MRI produces excellent detailed views of the soft tissues of the human body. The cartilage inside the jaw joint is best seen by MRI and we need this information to know best about the jaw joint changes.

### **What is the MRI scan procedure?**

**Department of Dentistry**  
Faculty of Medicine and Dentistry

25Mar2014  
2 of 6



## UNIVERSITY OF ALBERTA

Unlike x-ray imaging test, MRI does not use radiation and has no known harm. An MRI scanner uses a powerful magnet to produce excellent detailed views of the human body, especially soft tissues. Your child will lie on a scanning table that moves into the middle of the MRI. Once the scan starts, a vibrating sound will be heard. Normally MRI scans lasts about 30 minutes.

### **What are the MRI risks and discomforts?**

Some discomfort may be experienced from having to lie still for about 30 minutes. The MRI scan takes place in an enclosed space, which some people may find uncomfortable. Your child will be in constant communication with the team that conducts the MRI. Our team will ensure that your child is comfortable. If he/she feel anxious or he/she is claustrophobic please let us know in advance.

### **What are the orthodontic treatment risks for my child?**

The risks associated with these procedures are similar to those expected with standard procedure needed to treat your child's type of bite problem.

### **What are the potential benefits for my child?**

Participating in this study will not alter the quality of your child's treatment. Information gained from this study will help us understand differences in the outcomes between treatment approaches, which may help us treat other patients with similar conditions in the future. If your child agrees to join this study, study procedures and orthodontic treatment can begin immediately.

### **Will my child's personal information be kept confidential?**

During the study we will be collecting health data about your child. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your child's 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 child's information with their name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your child's health information is kept private.

The study doctor/study staff may need to look at your child's personal health records held at the study doctor's office, and/or kept by other health care providers that your child may have seen in the past. 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 child's health data, including his/her name, may be looked at by people from the Research Ethics Board at the University of Alberta.



## UNIVERSITY OF ALBERTA

By signing this consent form you are saying it is alright for the study doctor/staff to collect, use and disclose information about your child from his/her 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.

### **Does my child have to participate in the study?**

Your child does not have to participate. Even if the decision was made to participate your child is free to withdraw from the research study at any time, and your continuing orthodontic care will not be compromised in any way. If your child leaves the study, we will not collect new information about him/her, but we will need to keep the data that we have already collected.

### **Will I get any financial benefit from my child's participation?**

No financial incentives will be provided.

### **Are there other choices to being in this research study?**

If you choose not to have your child take part in this study, your child will still receive orthodontic treatment. The orthodontist, who will deliver the treatment to your child, will discuss with you different treatment options and types of bite correctors. He/she will explain the best treatment plan for your child regardless of your decision to participate or not in the study.

### **What happens if something goes wrong during the orthodontic treatment?**

Normal procedures used in the Orthodontic Graduate Clinic will be followed. If your child becomes ill or injured as a result of being in this study, he/she will receive necessary medical treatment, at no additional cost to you. By signing this consent form you are not releasing the investigator(s), and/or institution(s) from their legal and professional responsibilities.

### **Contact Names and Telephone Numbers:**

If you have any questions about the study or study-related injury, you may contact Dr. Mohammed Al-Saleh at 780-993-8844.

If you have any concerns about your rights as a study participant, you may contact the Research Ethics Office, at (780) 492-2615. This office has no affiliation with the study investigators.



UNIVERSITY OF ALBERTA

CONSENT FORM

**EFFECTS OF CLASS II FIXED FUNCTIONAL APPLIANCE (FFA) TREATMENT ON  
TEMPOROMANDIBULAR JOINT: A RANDOMIZED CLINICAL TRIAL.**

---

Principal Investigator: Dr. Paul Major      Phone: 780.492.3312  
Study Co-investigator: Dr. Mohammed Al-Saleh      Phone: 780.993.8844

---

Please circle the answer:

Do you understand that your child has been asked to be in a research study?      Yes      No

Have you read the attached information sheet? You will received a signed copy  
of this document for your records.      Yes      No

Do you understand the benefits and risks involved in taking part of this  
research study?      Yes      No

Have you had the opportunity to ask questions and discuss the research study?      Yes      No

Do you understand that your child is free to refuse to participate or withdraw  
from the research study at any time?      Yes      No

Has the issue about confidentiality been explained to you? Do you understand  
who will have access to your child's records?      Yes      No

This research study was explain to me by: \_\_\_\_\_

I agree for my child to take part in this research study.

Child's Name: \_\_\_\_\_

---

Parent's Signature      Printed Name      Date

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

---

Signature of Person Obtaining Consent      Date

**Department of Dentistry**  
Faculty of Medicine and Dentistry

25Mar2014  
5 of 6



UNIVERSITY OF ALBERTA