CONSENT FORM

Title of Research: A clinical trial on the use of a commercial available tooth positioner for the treatment of simple orthodontic relapse

Principal Investigator: Dr. Chung How Kau, BDS, MScD, MBA, PhD, FDS, FAMS(Ortho), FFD (Ortho). Professor and Chair
Department of Orthodontics

Sponsor: UAB Department of Orthodontics

For Children (persons under 18 years of age) participating in this study, the term "You" addresses both the participant ("you") and the parent or legally authorized representative ("your child").

Purpose of the Research

We are asking you to take part in a research study. The purpose of this research study is to prospectively analyze the treatment result of consecutive treated patients who have had active orthodontic relapse. This research study will compare two groups of patients, one using a commercially available tooth positioner and the other from previously treated patients who were in the alignment phase of orthodontics. We will evaluate whether there is any difference in the alignment of teeth in the two treatment groups. This study will help orthodontist to evaluate the efficacy of using a commercially available tooth positioner to treat simple orthodontic relapse.

Orthodontic Tooth positioners have been used in the Orthodontic Industry for many years. These positioners are used for small minor movements to complete the final smile. These positioners are made from a biocompatible and FDA approved clear silicone material after the teeth have been set to the final position.

During the study, we will look at movement of teeth, any side effects or discomfort the individual may be facing. This study will enroll 20 participants to the UAB Orthodontics Department, who have experienced Orthodontic relapse and are seeking to realign their teeth.

Explanation of Procedures

If you meet the inclusion criteria during the screening process and agree to participate in the study, you will receive the tooth positioner treatment in the UAB Orthodontics Department.

20 people will be recruited in this study. You will wear the tooth positioner at home. It is mandatory that the patient adheres to a daily treatment session for the duration of the orthodontics treatment. Unless otherwise instructed by your doctor, you should wear your Tooth Positioner for 10 hours daily.

Your study doctor will show you how to properly wear the tooth positioner, and how to clean the appliance by washing in water to remove saliva. You will be scheduled for monthly follow-up visits. During these visits, we will look at the movement of your teeth, inspect your appliance as needed during orthodontic treatment, and ask you questions about your experience using the appliance.

The records to be collected will comprise of clinical pictures and pre and post study casts. Both intraoral (teeth only) and extraoral (entire face) pictures will be taken during certain time points of the study. An intra-oral dental scan will be taken for the set-up of the final tooth positions by using a 3D computer.

You will need to come in 30 minute appointments, every four weeks. The duration of the treatment will be up to 10 months.

Risks and Discomforts

The use of tooth positioner may involve some of the risks outlined below:

- Gums, cheeks, or lips may be irritated by the appliance;
- Failure to wear the appliance for the required treatment time and/or not using the device as directed by the doctors can lengthen the treatment time and affect the ability to achieve the desired results.
- Although not reported in the clinical studies, allergic reactions may occur with any product-talk to your orthodontist if you have allergy concerns.

If you experience any adverse reaction (unwanted effect or health problem) or notice any unusual sign or symptom, contact Dr. Kau immediately.

Information for Women of Childbearing Potential, Nursing Mothers, and/or Men Capable of Fathering a Child

Pregnant women cannot participate in this study. If you suspect that you have become pregnant, you must notify the study doctor immediately.

Orthodontic treatment is not recommended or advised during pregnancy. Hormonal changes that take place during this time can affect tooth movement, and unexpected complications in pregnancies may arise that could affect the orthodontic treatment.

Benefits

The tooth positioners are relatively more comfortable to wear as compared to the traditional Orthodontic Braces. More importantly, tooth positioners enable the patients to brush and floss so that oral hygiene is easier to maintain, reducing the chance of plaque accumulation and tooth decay. The results of this research will help us to better understand the effectiveness of using a commercial available tooth positioner for the treatment of simple orthodontic relapse as compared to the use of the Orthodontic Braces.

Alternatives

Your alternative is to not participate and work with your orthodontist on a different treatment plan.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- the UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- the Food and Drug Administration (FDA)
- the Office for Human Research Protections (OHRP)

The information from the research may be published for scientific purposes; however, your identity will not be given out.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution. However, you should return to see Dr. Kau for safety reasons so you can be taken off the study and referred for follow-up care.

You may be removed from the study without your consent if the Dr. Kau decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study. All appliances and treatment costs related to this study will be covered by UAB orthodontics.

Payment for Participation in Research

You will not be paid for your participation in this study.

Payment for Research-Related Injuries

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. Chung How Kau. He will be glad to answer any of your questions. Dr. Kau's number is 205-934-2782.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Or

You are making a decision whether or not to have your child participate in this study. Your signature indicates that you have read (or been read) the information provided above and decided to allow your child to participate. You will receive a copy of this signed consent form.

Signature of Participant Date

Signature of Participant 16-17 Years of Age Date

Signature of Parent or Guardian Date

Signature of Principal Investigator Date

Signature of Witness Date

University of Alabama at Birmingham

AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____
UAB IRB Protocol Number: _____
Research Protocol: A clinical trial on the use of a commercial available tooth positioner for the treatment of simple orthodontic relapse
Principal Investigator: Dr. Chung How Kau
Sponsor: University of Alabama at Birmingham, Department of Orthodontics

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____
or participant's legally authorized representative: _____ Date: _____
Printed Name of participant's representative: _____
Relationship to the participant: _____