Informed Consent

TITLE OF RESEARCH:	Aerodentis Clinical Trial: Assessment of the Efficacy of Orthodontic Tooth Movement Using the Aerodentis System.
UAB IRB PROTOCOL NO.:	F160418007
INVESTIGATOR:	Dr. Chung How Kau BDS, MScD, MBA, PhD, FDS, FAMS(Ortho), FFD (Ortho)
CO-INVESTIGATORS:	Dr. Ejvis Lamani DMD, PhD, Cert (Ortho) Dr. Terpsithea Christou, DDS
SPONSOR:	Dror Orthodesign Ltd. 7 Hartom Street Jerusalem, Israel 9777507 972 (0) 74-700-6700

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 voluntary research study. We want to study the effectiveness of wearing a custom-made appliance, called Aerodentis, to move teeth into the desired, pre-determined position. We will also use a control group who will wear clear aligners, also known as Invisalign, to compare treatments between the two devices.

We are studying the effects of using the Aerodentis system to treat tooth movement. The Aerodentis system uses the same rules as traditional orthodontics, by applying force to move your teeth to the desired position. Instead of applying constant, uniform force through metal braces or aligners that must be regularly tightened or readjusted, Aerodentis works by using air pressure to move your teeth gently while you sleep. Because this pulsed air pressure works better than constant force, only approximately 10 hours per day of active treatment is needed. We will test the ability and safety of the Aerodentis system in treating orthodontic patients and compare treatment with a group using clear correctors.

This study will enroll 45 people to UAB School of Dentistry, Orthodontics department. Thirty people will be selected to wear the Aerodentis device and fifteen people will be selected to serve as the control group for this study, wearing the clear aligners.

This information is to help you understand what we are asking of you so that you can decide whether or not to participate in this study. Please read this consent form carefully. We want you to ask all the questions you have before deciding whether to participate.

Explanation of Procedures

Patients will be entered in a pool of eligible potential participants, after pictures are taken and reviewed. Participants will then be randomly selected to either wear the Aerodentis device, or the standard of care treatment with clear aligners (like the flip of a coin).

The Aerodentis device will be set according to the treatment plan, and used under dentist instructions, in an at home setting. The amount of pressure is set by the dentist, based on the same common orthodontic criteria considered in treatment with metal brackets. Whereas, in metal brackets the amount of pressure is changed by replacing the wires, in the Aerodentis device the amount of pressure is changed by increasing the air pressure within the inflatable balloon. In treatment with metal brackets, the applied force is usually between 50 to 200 grams and the doctor knows which force to apply according to the specific case. The Aerodentis device is pre-calibrated to apply an average force of 80 grams on all teeth that are in treatment. If needed, the force can be programmed to a lower (40 grams) or higher (100-160 grams) of pressure, depending on the treatment being done with the patient.

The clear aligners used with the Aerodentis device will be custom designed to fit your teeth. After the clear aligners are made for you, your dentist will show you how to wear the aligners, how to connect the different parts, and how to turn it on and off. You will find more detailed information about using the device in the Aerodentis User Guide for Patients. An easy to use smart card will allow your compliance monitoring. This is a small SD card that will stay inserted into the back of the device console. When you bring your device to your scheduled appointments, we will read the information on the card. This will tell us how long the device has run since your last appointment. You will need to come for scheduled periodical appointments lasting 30 minutes to an hour. The 1st visit will be scheduled after 10 days of treatment, the 2nd visit after 3 weeks of treatment and following that visits will occur once every four weeks for up to 15 months. At each 2nd visit we will take measurements of your teeth to record movement, a questionnaire will be given to you periodically to fill out on comfort and satisfaction, and progress pictures of the teeth and impressions will be taken before treatment, at mid treatment, at treatment completion and if required by the doctor according to the stage of treatment you are in.

If you are a part of the standard of care clear aligner (control) group, you will wear clear aligner trays as determined by your orthodontist. The clear aligner trays will be custom made to fit your teeth. At each visit, the orthodontist will check if your clear aligners are fitting properly and will give you the next two sets of clear aligner trays. You will need to come in for scheduled appointments lasting 30 minutes to an hour. The 1st visit will be scheduled after 3 weeks and after that once every four weeks for up to 15 months. At each 2nd visit we will take measurements of your teeth to record movement, a questionnaire will be given to you periodically to fill out on comfort and satisfaction, and progress pictures of the teeth and impressions will be taken before treatment, at mid treatment, at treatment completion and if required by the doctor, according to the stage of treatment you are in.

Risks and Discomforts

Since the Aerodentis device is a non-significant risk device, unwanted effects, or health problems are not expected.

If you are, or will be, using any medication, herbal or "natural" remedy, during the course of this study, let Dr. Kau know immediately. Also, check with Dr. Kau before you start taking new medication while in this study.

As in any clinical test procedure, there may be additional unforeseen risks involved in taking part in this study. By signing this Informed Consent, you, as parent or guardian agree to be present (and monitor) your child, to make certain that the aligners are being worn the same way the dentist showed you and for the amount of time that was instructed.

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

Possible risks may include:

1. Gums, cheeks, or lips may become irritated by mouthpiece.
2. Failure to wear the appliance for the required treatment time and/or not using the product as directed by your doctor can lengthen the treatment time and affect the ability to achieve the desired results.
3. Occasional mild soreness from standard tooth movement.

No risks or discomforts, other than occasional mild soreness from standard tooth movement, are expected with the standard of care clear aligner (control) group. The clear aligner group will be following standard clear aligner treatment.

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

Pregnant women are not allowed to take part in the study. If you are pregnant or become pregnant, you must let your study doctor know immediately.

Orthodontic treatment is not recommended or advised during pregnancy. Hormonal changes that take place during this time can affect tooth movement, the unborn fetus can be affected during mandatory x-rays due to radiation, and unexpected complications in pregnancies may arise that could affect the orthodontic treatment.

Benefits

You may not benefit directly from taking part in this study. Although your orthodontic treatment may be shortened by wearing the Aerodentis device, this is not guaranteed.

You will not benefit financially from any commercial gains from sales of any product resulting from this study. Research carried out on your results may lead to the development of marketable procedures or devices. Any benefit from the commercial product will remain with the sponsor.

Alternatives

You may choose not to participate in the Aerodentis study and still receive standard orthodontic treatment with metal brackets in the UAB Orthodontic Clinic.

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 the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of Dror Orthodesign Ltd. and 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.

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, if you are a part of the Aerodentis group, you should return the Aerodentis device to Dr. Chung How Kau so you can be removed from the protocol and be returned to standard orthodontic treatment procedures. If you are a part of the Invisalign group, you should inform Dr. Kau so you can be removed from the protocol, and given other orthodontic treatment options.

You may be removed from the study without your consent if any of the following apply:

- sponsor ends the study,
- if the Aerodentis device is approved by the FDA,
- if the study doctor decides it is not in the best interest of your health,
- or if you are not following the study rules (among them wearing the Aerodentis device for the required 10 treatment hours daily)

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

The cost of treatment for both the Aerodentis group and the clear aligner group will be $5000.00.

A payment plan can be made with the PI, Dr. Kau's approval. You can talk with Dr. Kau and Carol Williamson on payment plan options. Carol Williamson is located in the UAB Orthodontics Department and is the orthodontics patient coordinator.

Payment for Participation in Research

Participants of the standard of care, clear aligner control group, will not be paid to be in the study.

The Aerodentis participants, or parents whom sign the Informed Consent of the child wearing the Aerodentis device will be reimbursed in the following way:

- As soon as the patients are recruited for the study, they will be requested to pay an amount of $5,000. They will then receive a check from the study for $1000.00 as first reimbursement.
- After that, they will receive 3 reimbursements of $550 each, once in 2 months of treatment – depending on their compliance of a minimum of 10 treatment hours a day.
- The final reimbursement of $ 850 will be given at the treatment completion.

You are responsible for paying any state, federal, Social Security or other taxes on the payments you receive. You will receive a form 1099 in January of the year following your participation in this study. This form is also sent to the IRS to report any money paid to you. No taxes are kept from your payment.

Significant New Findings

You will be told by your 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, you may contact the research coordinator, Brooke Brasher at 205-975-3336 or Dr. Kau at 205-934-2782 during normal business hours, 8:00am to 5:00pm CT, Monday through Friday. Brooke Brasher can also be reached after hours at 205-503-3686. We will be glad to answer any of your questions.

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. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

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

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 14-17 Years of Age Date

Signature of Parent or Guardian Date

Signature of Principal Investigator Date

Signature of Witness Date

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

Participant Name: _____
Research Protocol: Aerodentis Clinical Trail: Assessment of the Efficacy of Orthodontic Tooth Movement Using the Aerodentis System

UAB IRB Protocol Number: F160418007
Principal Investigator: Dr. Chung How Kau
Sponsor: Dror Orthodesign Ltd.

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: _____