Consent

Principal Investigator (PI): Dr. Flavio Uribe

PI Phone Number: 860-679-3656

Co-Investigator(s): Sara Greene

Title of Research Study: Characterizing orthodontic tooth movement in real time using Dental Monitoring scans: a pilot study

Name of Research Participant: _____

You or your child are being asked to provide consent to participate in a research study. Participation is voluntary. You or your child can say yes or no. If you or your child say yes now you can still change your mind later. Some key points to consider are summarized in this overview, but you should consider all of the information in this document carefully before making your decision.

Overview of the Research

This research is being done to determine if Dental Monitoring scans will be as accurate as iTero Element 2 scans in capturing the dental arch. It will also be used to characterize the types of tooth movement occurring during space closure mechanics.

Participation will involve approximately 10 minutes every 4 days over the period of the next 5 -6 weeks .

You or your child will be asked to take photos and videos of your teeth using Dental Monitoring cheek retractors and scan box and an app downloaded on your smartphone. You or your child will also be asked to spend an extra 30 minutes at this appointment to allow the study coordinator to instruct you or your child on using the Dental Monitoring devices and take an iTero digital scan. The next appointment will also require an extra 10 minutes to take another iTero digital scan. Your participation in the study will be no more invasive than a regular orthodontic adjustment visit.

The overall risk of this study is minimal with the most involvement requiring your time at home, using the cheek retractors/scan box provided by Dental Monitoring. Risks are described in more detail later in this form.

A more detailed description of this research follows.

Purpose of This Research

This is a pilot phase of a research study that seeks to determine the accuracy of Dental Monitoring scans compared to that of iTero Element 2 scans. It will also help characterize the

type of tooth movement occurring on a weekly basis during space closure orthodontic treatment. Ultimately, we hope this will help optimize treatment, reducing treatment time and cost.

Voluntary Participation

You or your child are invited to take part in this study because you are a patient undergoing space closure treatment following an extraction of a tooth as per the orthodontic treatment plan.

Participation in this study is voluntary. Before deciding whether to participate in this research study or not, please read this consent form carefully and discuss any questions you or your child have with the researcher. You may also want to talk with family members, your primary care physician or a friend before making a decision.

You or your child may choose not to participate in this study. If you or your child choose to participate in this research study, you can choose to withdraw from it at any time. If you or your child decide not to participate or later choose to withdraw from participation, your decision will not affect any present or future dental/medical care and there will be no penalty or loss of benefits to which you or your child are otherwise entitled.

Number of Other People Who Will Participate

We estimate that 40 people will participate in this study. This study is being conducted at the University of Connecticut School of Dental Medicine, Department of Orthodontics.

Length of Participation

Your or your child's participation will involve 2 in-office visits. The first participation will be approximately 30 minutes in addition to the regular adjustment appointment. The second (final) visit will be 10 minutes in addition to the next regular adjustment appointment 5 weeks later.

Your or your child's participation also involves about 10 minutes of your time at home to take the photographs and video scans of your teeth using the Dental Monitoring cheek retractor, scan box, and app every 4 days for the period between the first and second in-office visits.

Physical / Psychological Risks of Procedures

Participation in this study will involve the following procedures:

- **iTero scan:** The iTero Element 2 intraoral scanner will be used to fully scan the mouth, which involves using a small wand that identifies all the surfaces of all your teeth.

  Risks: There may be some mild discomfort or pressure during the scan.

  Safeguards: You or your child may stop the operator whenever necessary to recuperate

during the scan, which should take no longer than 10 minutes. Please be advised that the operators of the iTero Element 2 device in this project are proficient in its use.

- **Dental Monitoring devices (cheek retractor/scan box):** The study coordinator will give you or your child all materials (cheek retractor/scan box) necessary to perform the Dental Monitoring scans at home and ask you or your child to download the accompanying smartphone app. You or your child will be required to use the Dental Monitoring materials to take photographs and videos of your teeth, which will then be accessible on the app. The scans will be retrieved from the app through Dental Monitoring's encrypted online software and will be coded to protect your identity.

  Risks: You or your child may feel uncomfortable downloading the app onto your phone. You or your child may also feel some discomfort using the materials, such as the cheek retractor/scan box, which pulls your cheeks apart, that are needed to take the photos and videos for Dental Monitoring.

  Safeguards: You or your child may always choose not to participate in the study to avoid using the cheek retractors/scan box. The cheek retractor/scan box should be no more uncomfortable than appliances used in a typical orthodontic appointment. A parent/guardian can also help the subject use the cheek retractor/scan box as the subject needs. The cheek retractor/scan box should not be used if you or your child have any cuts/open sores in your mouth.

Other Consideration of Physical or Psychological Risks: Being in more than one research study at the same time, or even at different times, may increase the risks to you or your child. It may also affect the results of the studies. You or your child should not take part in more than one study without approval from the researchers involved in each study.

Other Types of Risk to Consider

Risk to Confidentiality: While we will protect the confidentiality of the information you or your child provide, confidentiality cannot be guaranteed. There is a chance that people outside of the research team may learn of your study participation. If this happens, you or your child may experience stigmatization.

The information collected for this research study will be accessible to authorized persons. Authorized persons include study team members, representatives of UConn Health; and as may be applicable representatives of the Sponsor and/or representatives of Federal agencies when required by law, such as representatives from the Food and Drug Administration for research involving a drug, device or biologic and/or the Department of Health and Human Services when the research is federally funded or supported. Representatives from these areas have access to the information so they may ensure that the study is being done correctly.

Consent forms, HIPAA forms, and any hard copy identifiable data forms will be part of you/ or your child's research record. These will be kept in the IRB binder independent of the data

collection forms. Data collection forms will be labeled with a randomly generated code to protect confidentiality. All electronic research files will be kept on password protected and encrypted computers. Only researchers appointed to work on this project will have access to any paper and electronic records. A master list will depict a randomly generated code for each patient – this list will be kept in a secure, locked location, apart from the IRB binder in the UConn Orthodontic department in the Outpatient Pavilion and accessible only to the study coordinator and principal investigator.

You or your child should also know that:

- At the conclusion of this study the researchers may publish their findings. Information will be presented in summary format and you or your child will not be identified in any publications or presentations.
- Your or your child's own actions may also pose a risk to your confidentiality. For example, you may submit a claim to your insurance company to cover certain costs. By doing so, the insurance carrier may learn of your or your child's study participation.
- If you discuss this with your employer or co-workers your or your child's study participation may become known to others.

Possible Benefits from Participating

You or your child will not benefit directly from the information we gather in the study. Other people may benefit in the future from the results of this study. Results from this study may help future studies find a more efficient way to treat orthodontic patients and reduce treatment time and cost. There is also the possibility that no benefit will come from this study.

Cost of Participating

There is no cost to you or your child for participating in this study.

You or your child may have to take time from work/school in order to participate in study visits. You may incur some travel costs to get to study visits. There will be no costs to you or your child for any study procedures.

You or your insurance carrier will be billed for the costs of all routine clinical services provided. This includes regular adjustment visits that you or your child would have needed even if you or your child were not part of the study. You will be responsible for paying all co-pays, deductibles, or co-insurance that are a normal part of your health insurance plan.

Before you or your child decide to participate, you should check with your health plan or insurance company to find out what costs will be covered. You can also ask the Principal Investigator to provide you with assistance with this process.

Payment for Participating

You or your child will not be compensated for participation in this study.

Alternatives

You or your child have the option not to participate in this study. You or your child may also choose not to participate in the study to avoid any discomfort during any of the procedures. You or your child may stop the procedure completely at any time.

Withdrawing from Participation

You or your child can always choose to stop participating in this study. While we are doing this research, if we learn new information that may influence your decision about participation we will share that with you. For example, if we learn about new risks, we will share that information with you. If we think you or your child need to know quickly, the researcher or study coordinator may call you or send you a letter. If we do not think you or your child need to know quickly, we will tell you or your child at your next visit. If you or your child still want to participate we may ask you to sign a new consent form.

If you or your child want to withdraw, inform the study coordinator immediately. All records that link your or your child's identity to the research will be destroyed. The anonymous information will continue to be part of the research data. Withdrawing from this study will not affect the quality of remaining treatment.

Sharing Information

Information obtained during this study will become the property of UConn Health. When your or your child's involvement with the study ends, the information you provided, even if stripped of identifiers so that no link can be made to your identity, will not be used or distributed for future research studies.

Results of This Research

You or your child will be provided with overall results of the study. You or your child will be provided with your individual result if it is considered clinically applicable, significant, and reliable.

You or your child may have the right not to receive information that we learn in this study. If you or your child would prefer not to be made aware of the results please initial here. _____

Adverse Events

UConn Health does not provide insurance coverage to compensate for injuries incurred during this research. However, compensation may still be available. A claim may be filed against the State of Connecticut seeking compensation. For a description of this process contact a representative of the UConn Health Institutional Review Board at 860-679-4849 or 860-679-8729.

UConn Health does not offer free care. However, treatment for a research related injury can be obtained at UConn Health for the usual fee. In the case of any adverse events, contact the UConn Department of Orthodontics at 860-679-2664.

Questions

The Principal Investigator is willing to answer any questions you or your child have about the research. You or your child are encouraged to ask questions before deciding whether to take part. You or your child are also encouraged to ask questions during your study participation. If you or your child have questions, complaints or concerns about the research, you should call the Principal Investigator at 860-679-3170.

If you or your child have questions about your rights as a research subject, you may contact a coordinator at the Institution Review Board at 860-679-8729, or 860-679-4849. You may also call a coordinator at the Institutional Review Board if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions, or obtain information about participation in clinical research studies.

Please do not call the IRB number for medical related issues or to schedule or cancel an appointment.

Consent To Participation:

By signing this form, you (the participant, legally authorized representative, parent(s) or guardian) acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them answered, and voluntarily consent to participate in this project as described in this form. You will be provided with a copy of this document after it has been signed and dated by both parties as well as a copy of the Research Participant Feedback Form.

Role	Name	Signature	Date	Time
Subject				
Parent/Guardian				
Parent				
Co-investigator or Study Coordinator				

Assent form attached if aged 12 or under.