RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Effect of clear aligner attachment design on extrusion of maxillary lateral incisors: a randomized prospective clinical trial.

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NOTE: In this consent form, "you" always refers to the research participant. If you are a parent or legal guardian, please remember that "you" refers to the child study participant.

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is intended to assist you in thinking about whether or not you want to be in this study. **Please ask the study doctor or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty and will not affect the treatment you are receiving from proceeding normally or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

What are clear aligners?

Clear aligners are an alternative to traditional braces and help guide teeth into their proper positions. Similar to braces, clear aligners use a gradual force to control tooth movement, but without metal wires or brackets. The system uses a series of custom-made trays that snaps on to the teeth and attachments added to the teeth by your doctor in the upper and lower jaws to effect desired tooth movement.

What are attachments?

Attachments are small tooth-colored shapes that are bonded (attached) to your teeth before or during treatment with clear aligners. They are like handles, giving aligners something to gently push teeth into correct positions. The clear aligners fit smoothly and tightly around the attachments, so they're barely noticeable. The shapes and positions of the attachments differ depending on how the teeth need to be moved. Below is a cartoon showing upper and lower teeth each with 2 attachments (small nubs on the teeth).

Why is this study being done?

The second tooth on either side of the upper front teeth is referred to as the maxillary lateral incisor (upper teeth with attachments in the above photograph). Everyone has two upper lateral incisors (one on each side). You are being asked to participate in this study because at least one of your upper lateral incisors is too close to the gums and needs to be pushed down as part of clear aligner therapy (referred to as extrusion). There are 4 different shapes of attachments that can be used to accomplish this extrusion (incisally-beveled, gingivally-beveled, optimized and horizontal). The purpose of this research is to test which of the four attachment types is more efficient in getting these teeth into correct positions. It is important to understand that all 4 of these different designs are successful in extruding lateral incisors but there is not enough research evidence to know for sure which attachment would be ideal for a specific circumstance. It is also important to understand that if your lateral incisor needs some other type of movement (besides extrusion), you may not be able to participate in the study.

What will happen if I participate?

You will have your mouth (teeth and gums) scanned using the intraoral scanner to establish the baseline positions of the teeth within the jaws. Even though you have 2 upper lateral incisors, only one (or both) may need to be extruded (pushed down). Each maxillary lateral incisor that needs to be extruded will be randomly assigned (like the flip of a coin) and will have an equal

chance of being assigned to any one of the four attachments. So, it is possible that you may have different attachments on each of your lateral incisors (if both require extrusion).

Once assigned to a group, you will continue to receive care from your orthodontist. You will be treated with a first series of aligners that may last anywhere between 20-25 weeks. At this time, we will record new, corrected positions of your teeth by another scan using the same intraoral scanner. We will use computer software to compare the initial and final tooth positions and evaluate the efficiency of the attachment. The study team will collect copies of the initial and final intraoral scans, your orthodontic diagnosis, treatment plan and progress from your electronic dental record.

A point to remember is that your treatment will be longer than the duration of the study. After the first series of aligners, the orthodontist will continue to provide care until all the treatment objectives are accomplished. Your participation in this study may last up to 6 months (about 25 weeks). A maximum of 80 individuals may participate in this study.

What alternative treatments or procedures are available?
If you decide not to enter this study, you can receive the usual care that you would receive even if you were not in the study. The treating orthodontist will select a specific type of attachment based on his/her clinical experience and judgement. You do not have to participate in this study to be treated with clear aligners.

What are the risks and benefits of participating?
The study is a no greater than minimal risk in terms of physical risk. Even though we are investigating 4 different attachments, all of these are routinely used in clinical practice. There is no evidence that any of the attachments is better or worse (in terms of plaque retention, staining, patient comfort or bond failure) compared to the others. Attachments will be bonded to teeth following routine clinical protocols. In the unlikely event that an attachment falls off, we would place a new one at no additional cost.

Participation in research might involve some loss of privacy. We will minimize this risk by screening in a semi private office space. There is a small risk that someone outside the research study could see and misuse information about you. We will reduce the risk of loss of confidentiality by maintaining the research data in password protected storage devices that only members of the study team can access.

There is no guarantee that you will receive any individual benefits from being in this study. However, possible benefits include your lateral incisor may move into the correct position more

quickly. We hope the information learned from this study will provide more information about appropriate choice of attachments for lateral incisor extrusion.

WHAT ARE THE COSTS?

There are no costs to being a part of the study.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be paid $50 by gift card for each lateral incisor that needs extrusion (and thus receiving one of the four attachments). It is possible to get paid up to $100 if both of your lateral incisors require extrusion. You will receive this compensation when you complete the second intraoral scan taken at the end of first series of aligner therapy.

Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop. If you leave the study before the final regularly scheduled visit, any data that has been collected will remain with the study team.

Your participation in this study may be stopped at any time by the study doctor without your consent. The reasons might include:

- the study doctor thinks it necessary for your health or safety
- you are found to not be eligible for the study
- you have not followed study instructions
- administrative reasons require your withdrawal

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases according to VCU's policies (i.e. for a minimum of 5-6 years). It is only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed. In general, we will not give you any individual results from the study. The information collected about you as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

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

HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires and added to your healthcare records. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

☐ Complete health record	☐ Diagnosis & treatment codes	☐ Discharge summary
☒ History and physical exam	☐ Consultation reports	☒ Progress notes
☐ Laboratory test results	☐ X-ray reports	☐ X-ray films / images
☒ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill
☐ Information about drug or alcohol abuse	☐ Information about Hepatitis B or C tests	
☐ Information about mental health	☐ Information about sexually transmitted diseases	
☐ Other physical or mental health information (specify):		

Who will use or share protected health information about me?

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?
This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights
You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at
Dr. Steven J Lindauer
Virginia Commonwealth University Department of Orthodontics
520 N 12th St #111, Richmond, VA 23298-0566
Phone: (804) 828-9326
Email: sjlindau@vcu.edu

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator named below is the best person to contact if you have any questions, complaints, or concerns about your participation in this research:
Dr. Steven J Lindauer
Virginia Commonwealth University Department of Orthodontics
520 N 12th St #111,
Richmond, VA 23298-0566
Phone: (804) 828-9326
Email: sjlindau@vcu.edu

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
(804) 827-2157; https://research.vcu.edu/human-research/

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT [AND/OR PARENT/LEGAL GUARDIAN PERMISSION]

I have been provided with an opportunity to read this consent form [permission form] carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form [permission form], I have not waived any of the legal rights or benefits to which I [and/or my child] otherwise would be entitled. My signature indicates that I freely consent to participate [and/or give permission for my child to participate] in this research study. I will receive a copy of the consent form [permission form] for my records.

Signature Block for Enrolling Adult Participants	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date

Signature Block for Enrolling Child Participants - Parent/Guardian Permission	
_____ Name of Child/Youth Participant	
_____ Name of First Parent/Legal Guardian (Printed) *Study team – verify that this individual is the child's parent or legal guardian.*	
_____ **Required** First Parent/Legal Guardian Signature	_____ Date
_____ **Optional** Second Parent /Legal Guardian's Signature	_____ Date
_____ Name of Person Conducting Parental Permission Discussion (Printed)	
_____ Signature of Person Conducting Parental Permission Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date

Signature Block for Enrolling Child Participants (Ages 7-17) – Assent by Child	
STATEMENT OF ASSENT BY CHILD PARTICIPANT The person doing this research study has explained what will happen to me if I participate in this study. My signature below means that I want to be in this study. I can decide not to be in this study if I do not want to. Nothing will happen to me if I do not want to participate.	
_____ Child Participant's Signature	_____ Date
_____ Name of Person Conducting Assent Discussion (Printed)	
_____ Signature of Person Assent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date

Signature Block for Short Form Consent – Participants with Limited English Proficiency	
_____ Name of Participant (Printed)	
_____ Witness or Interpreter's Signature *(NOTE: The witness may be the interpreter or a family member of the LEP subject who can speak both English and the participant's language. The witness cannot be the member of the study team conducting the consent process.)*	_____ Date
_____ Name of Person Conducting Consent/Assent Discussion (Printed)	
_____ Signature of Person Conducting Consent/Assent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date