University at Buffalo
The State University of New York

Permission To Take Part in a Human Research Study

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Assent to be in a Research Study - (for Children 14-17 yrs of age)

Title of research study: A comparison between TiNbTaZr (GUMMETAL) and stainless-steel alloy for space closure with sliding mechanics A pilot randomized clinical

Version Date: Version 1.2 Date: 08-12-2020

Investigator: Dr. Lubomyr Ravlyk

Who am I?
My name is *Dr. Lubomyr Ravlyk* and I work in the Department of Orthodontics at University at Buffalo School of Dental Medicine.

Why are we meeting with you?
We want to tell you about a study that involves children like yourself. We want to see if you would like to be in this study too.

Why are we doing this study?
We are doing this study to see how a new type of wire compares to a standard wire when we use it to close spaces between our teeth. We are hoping to see if there is a difference in the speed of space closure between the two types of wires.

What will happen to you if you are in the study?
Before we begin your treatment, we will take some pictures of your teeth, your face, and a couple of x-rays to come up with a plan on how we can straighten your teeth. On your bottom and top teeth, you will get braces. The first few months we will begin straightening your teeth and helping you get used to your braces. Once we have leveled and aligned your teeth, we will begin the research part of the treatment. On the upper teeth, one half will have the new type of wire, and the other half will have the standard wire. Your upper canine teeth will be pulled backwards to help close the spaces next to them. To close these spaces, we will use a spring to help pull on those teeth lightly. You will have this happening on both sides of your upper teeth for a total of three visits. At each visit you will have a tooth scan happen and some measurements will be taken. The scan is just a small camera that goes into your mouth to take many pictures of your teeth and create a 3D model of your teeth. Once the fourth visit has been done, we will stop the research part of the treatment and you will continue your orthodontic treatment regularly.

What are the good things that may happen to you if you are in the study?
One good thing is that you will continue to get your teeth straightened during the research study as you would have had without and it will continue after the study is completed. Also, there might be faster space closure on one side versus the other and can shorten treatment time on one side.

What are the bad things that may happen to you if you are in the study?
You would be getting treatment whether you take part in this study or not. There are risks to this orthodontic treatment. The most likely risks are:

- Tooth pain and discomfort
- Cheek and gum irritation (from brackets or wires)
- White discoloration on the teeth
- Root resorption
- Allergies and infection

There is also a risk that your private data could be leaked. We protect your data by not labeling it with your name, and by keeping it password protected in our locked office.

Do you have to be in the study?
No, you don't. No one will get angry or upset with you if you don't want to do this. Just tell us if you don't want to be in the study. And remember, you can change your mind later if you decide you don't want to be in the study anymore.

Do you have any questions?
You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study. You can call:

Name of contact person on the study: Dr. Lubomyr Ravlyk

Phone Number: 585-746-8599

* * * * * * * * * * * * * * * * * * * *

Signature Block for Assent of Child

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining assent	Date
Printed name of person obtaining assent	

Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Parent Permission for a Child to Participate in a Research Study

Title of research study: *A comparison between TiNbTaZr (GUMMETAL) and stainless-steel alloy for space closure with sliding mechanics A pilot randomized clinical trial*

Version Date: *1.0, 6-15-2020*

Investigator: *Dr. Lubomyr Ravlyk*

Key Information: The following is a short summary of this study to help your child decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

Your child is being invited to take part in a research study because they meet all required criteria. Your child is the appropriate age range, have the needed dental spaces needed for closure, and do not possess any dental or health related contraindications for treatment.

What should I know about a research study?

- Someone will explain this research study to you and your child.
- Whether or not your child takes part is up to them.
- You or your child can choose not to take part.
- You or your child can agree to take part and later change your mind.
- You or your child's decision will not be held against them.
- You and your child can ask all the questions you want before they decide.

Why is this research being done?

A new wire for braces has recently been approved for clinical use. There are many wires that are used to straighten teeth and close spaces with braces. Not much is known on all that this new wire can do and the benefits it can give. By being in our study your child will help us understand how this new wire can be used. This new wire might show to be more comfortable, cheaper and work faster than other wires used today. All of the wires used in the study are FDA approved for clinical use.

How long will the research last and what will I need to do?

We expect that your child will be in this research study for four total months, with three adjustment visits.

Your child will be asked to show up to all appointments and on time to be able to participate and continue in the study. Furthermore, your child needs to maintain proper oral hygiene and care outside of the clinic and avoid certain foods and habits. Your child will have a total of three adjustment visits where orthodontic appliance manipulation will be done, along with an intraoral scan.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

There is a risk of confidentiality breach on this study. The physical risks that are associated with this study are the same risks for any patient when receiving their orthodontic treatment. Those risks are:

- Tooth pain / discomfort
- Irritation to tissues (gums, cheeks, tongue)
- White spot lesions (due to lack of hygiene)
- Root resorption
- Allergies
- Infections
- Reduced esthetics

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no direct clinical benefits to your child from participating in this study; all of the treatments are available as standard care.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. Your child may choose not to enroll in this study. Instead of being in this research study, their choices may include: continue with orthodontic treatment within our clinic with no study participation, get orthodontic treatment elsewhere, or not start any orthodontic treatment.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you or your child have questions, concerns, or complaints, or think the research has hurt your child, talk to the research team at UB Orthodontics Department at (716) 829-6192 or send an email to Lubomyrr@buffalo.edu. You or your child may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. Your child may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You or your child has questions about their rights as a participant in this research
- You or your child's questions, concerns, or complaints are not being answered by the research team.
- You or your child cannot reach the research team.
- You or your child wants to talk to someone besides the research team.
- You or your child wants to get information or provide input about this research.

How many people will be studied?

We expect about16 people here will be in this research study.

What happens if I say yes, I want to be in this research?

First your child will be given appropriate time to ask any questions and voice any concerns regarding the research study. There will be allotted time for you or your child to have full disclosure and understanding of what the study will strive to achieve and the timeline.

- What to expect?
    - Your child will be participating in a split mouth randomized study design. Half of their upper jaw will be assigned randomly to the wire under study [TiNbTaZr (GUMMETAL)] while the other to the control wire [stainless-steel alloy].
    - All orthodontic records (x-rays, images, intraoral scans, clinical examination) will be carried out per our facility standards and procedures in place for all our orthodontic patients. *[All part of standard of care treatment]*
    - Your child will be using traditional metal braces which they would get regardless of if they were in the study or not, unless they choose to go with ceramic, self-ligating, lingual or clear aligner therapy, which would exclude them from the research study. *[All part of standard of care treatment]*
    - There will be a bonding appointment, your child can expect metal brackets to be chemically bonded to the front of their teeth, both upper and lower. Your child will begin a phase of treatment known as leveling and aligning. *[All part of standard of care treatment]*
    - Your child will have a few months of a phase called leveling and aligning prior to beginning the research portion of treatment. (Leveling and aligning refers to fixing minor rotations, tips, and get teeth positioned better in the dental arch) *[All part of standard of care treatment]*
    - Once appropriate leveling and aligning has been achieved your child will begin the research portion of treatment which will last 4 visits (12 weeks). Adjustments will happen every 4 weeks and will last approximately 1 hour.
    - Adjustment visit expectations: (duration 60-75 minutes)
        - Arrive on time and be ready for their appointment
        - The research examiner will be doing their adjustment
        - The upper jaw wires will be kept in place, while a small spring system will be used to help bring the upper canines back and close the spaces present. The research examiner will use a measuring force gauge to make sure that the forces are equal on both the right and left sides.
        - Once the appropriate force has been recorded, all the brackets and retraction springs will be tied back together with the wires to be repeated at the next visit.
        - A 3D intraoral scan will be taken at every research adjustment visit (approximate time 5-10min), this is done for the research study.
    - Once your child has completed the research portion of treatment, subsequent orthodontic treatment will continue to complete the treatment plan and finish the case.

Your child will be getting both treatments at the same time. Which side of their mouth gets what treatment (Stainless steel vs. GUMMETAL archwire) will be chosen by chance, using a random number generator. Neither your child nor the study doctor will choose what treatment they get on what side. Neither you nor your child will be told which treatment your child is getting on what side of their mouth, but know that they are getting both treatments at the same time; however, your child's study doctor will know.

What are my responsibilities if I take part in this research?

If your child takes part in this research, they will be responsible to:

- Abide by our clinic and facility policies, rules and regulations
- Maintain proper oral hygiene habits (flossing, brushing, and going to get regular prophylaxis)
- Keep all appointments and come on time
- Communicate with research examiner if there are any concerns or problems during the course of the study
- Avoid eating foods that can cause damage to appliances (excessive sticky foods, hard foods, not wearing mouth guard during outdoor or sport activities)

What happens if I say yes, but I change my mind later?

Your child can leave the research at any time it will not be held against them. If they decide to leave the research, you will have to notify the Orthodontic department if they wish to continue treatment. If they do not wish to continue treatment, they will need to follow the protocols in place at the Orthodontic department for early termination of treatment. If your child decides to leave the research, contact the investigator so that the investigator can inform them what their next steps are. Your child will continue treatment at the Orthodontic clinic under a treating resident and supervising faculty.

Your child's research data collected to the point of withdrawal will not be kept on file. It will be destroyed and discarded properly and securely to ensure that no private confidential information gets out.

Is there any way being in this study could be bad for me? (Detailed Risks)

<u>Physical Risks:</u>

- No additional risks beyond orthodontic care
- Slower tooth movement
- Losing coil spring
- Discomfort from the coil spring irritation on the soft tissue mucosa

<u>Psychological Risks:</u>

- Anxiety – *low risk and likelihood*
- Depression – *low risk and likelihood*
- Lowered self-esteem – *low risk and likelihood*

<u>Privacy Risks:</u>

- Limited privacy risks (all personal data will be encrypted and stored on the department network with only the research team having access)

You, or your child's insurance company will be charged for the health care services your child receives that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your child's insurance to see what services will be covered by the insurance and what you will be responsible to pay.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your child's personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your child's information include the IRB and other representatives of this organization.

Data collected from the study will not be kept for future studies. This data will be securely stored on the Orthodontic Department network drives. These drives are encrypted and only those individuals with badge and credential privileges will have access. All information will be kept confidential and secure.

Aggregated study results can potentially be presented at professional conferences and published in scientific journal articles.

Your child's information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your child's medical records to conduct and oversee the research. By signing this document, your child is authorizing this access. We may publish the results of this research. However, we will keep your child's name and other identifying information confidential.

Federal law provides additional protections of your child's medical records and related health information. These are described in the HIPAA section of this document.

Can I be removed from the research without my OK?

The person in charge of the research study can remove your child from the research study without you or your child's approval. Possible reasons for removal include:

- Develop any indication of root resorption
- Develop any gum issues during the course of the study
- Develop any health-related issues during the study
- Voluntarily want to leave the study or cease treatment
- Do not come regularly as needed for the study

We will tell you and your child about any new information that may affect their health, welfare, or choice to stay in the research.

What else do I need to know?

What medical costs am I responsible for paying?

Permission to Take Part in a Human Research Study

The tests or procedures required by the research study that would not otherwise be part of your child's standard care will be covered by the study. The tests or procedures that would be provided to any patient with their condition, regardless of whether he/she was participating in the research study, are considered standard care and will be billed to you, or your child's private or public health insurance company. You will still be responsible for the cost of their usual ongoing medical care, including deductibles and co-payments. If you have any questions about what expenses are covered by the study and what expenses are the responsibility of you or your child's health insurance provider, please contact a member of the study staff and/or your child's health insurance provider.

What are my alternatives to participating in this research study?

Instead of being in this research study, your child's choices may include:

- receive comprehensive orthodontic treatment at the same clinic outside of the study
    - risks: same as participating in the research study
    - benefits: same as participating in the research study (will receive orthodontic treatment)
- do not receive any orthodontic treatment at this clinic, go elsewhere
    - risks: same risks exist if getting treatment at the UB Orthodontic Clinic, whether its participating in the research or just getting treatment.
    - benefits: same as participating in the research study (will receive orthodontic treatment).
- receive no orthodontic treatment
    - risks: do not resolve the dental / skeletal issues if present (receive no correction of chief complaint)
    - benefits: no additional out of pocket expense, no risks associated with receiving orthodontic treatment.

What will I be told about clinically relevant research results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your child's identifiable information or samples gives results that do have meaning for their health, the researchers will contact you to let you know what they have found.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about your child and about their health that will be obtained by the researchers when you participate in the research study. By signing this form, you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What individually identifiable health information will be collected about your child as part of this research study?

__√___ Information from your child's full medical records:

- Medical & Dental Health History which includes:
    - Health conditions
    - Previous hospitalizations and illnesses
    - Primary care provider and Dentist contact information

- Family health and social history
- Current medications
- Any allergies to food or drugs
- Any information that would contraindicate participation in research study
- Dental history consisting of: type of dental work done, periodontal health status, frequency of recalls and any issues / concerns relating to the dentition

__√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to create or provide this information for research use?

___√__ University at Buffalo School of Dental Medicine
___√__ Principal Investigator or designee

C. Who is authorized to receive the information from the information providers identified in (B)?

__√__ Principal Investigator or designee
__√___ Other(s) (identify): Mentor and Statistician

D. With whom may your child's protected health information be shared?

Your child's health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__√___ Clinical staff not involved in this research study who may become involved in your child's care if it is potentially relevant to their treatment

Your child's information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your child's information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your child's individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your child's information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

E. How long are the information providers listed in (B) authorized to provide your child's information for this research project?

___√__ d. Your child's protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information. The researchers may continue to rely on this authorization to acquire protected health information about your child unless you revoke this authorization in writing.

F. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about your child will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

- Research Examiner (Dr. Lubomyr Ravlyk)
- University at Buffalo School of Dental Medicine
- 140 Squire Hall | Buffalo, NY 14214

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your child's individually identifiable health information.

G. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care your child receives at this institution and will not cause any penalty or loss of benefits to which your child is otherwise entitled. If you decide not to sign this authorization, they will not be able to participate in the research study.

Should you and your child agree to participate in this research, this consent document will be placed in their medical record.

Permission to Take Part in a Human Research Study

Signature Block for Parental Permission

Your signature documents your permission for the named child to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

Printed name of parent or individual legally authorized to consent to the child's general medical care

- ❑ Parent
- ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

[The Assent Box, which is applicable to the subject named in this consent document, must be checked]

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

Signature of person obtaining consent

Date

Printed name of person obtaining consent

University at Buffalo
The State University of New York

Permission To Take Part in a Human Research Study

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Assent to be in a Research Study - (for Children 7-13 yrs of age)

Title of research study: A comparison between TiNbTaZr (GUMMETAL) and stainless-steel alloy for space closure with sliding mechanics A pilot randomized clinical

Version Date: Version 1.2 Date: 08-12-2020

Investigator: Dr. Lubomyr Ravlyk

Who am I?
My name is *Dr. Lubomyr Ravlyk* and I work in the Department of Orthodontics at University at Buffalo School of Dental Medicine.

Why are we meeting with you?
We want to tell you about a study that involves children like yourself. We want to see if you would like to be in this study too.

Why are we doing this study?
We are doing this study to see how a new type of wire compares to a standard wire when we use it to close spaces between our teeth. We are hoping to see if there is a difference in the speed of space closure between the two types of wires.

What will happen to you if you are in the study?
Before we begin your treatment, we will take some pictures of your teeth, your face, and a couple of x-rays to come up with a plan on how we can straighten your teeth. On your bottom and top teeth, you will get braces. The first few months we will begin straightening your teeth and helping you get used to your braces. Once we have leveled and aligned your teeth, we will begin the research part of the treatment. On the upper teeth, one half will have the new type of wire, and the other half will have the standard wire. Your upper canine teeth will be pulled backwards to help close the spaces next to them. To close these spaces, we will use a spring to help pull on those teeth lightly. You will have this happening on both sides of your upper teeth for a total of three visits. At each visit you will have a tooth scan happen and some measurements will be taken. The scan is just a small camera that goes into your mouth to take many pictures of your teeth and create a 3D model of your teeth. Once the fourth visit has been done, we will stop the research part of the treatment and you will continue your orthodontic treatment regularly.

What are the good things that may happen to you if you are in the study?
One good thing is that you will continue to get your teeth straightened during the research study as you would have had without and it will continue after the study is completed. Also, there might be faster space closure on one side versus the other and can shorten treatment time on one side.

What are the bad things that may happen to you if you are in the study?
You would be getting treatment whether you take part in this study or not. There are risks to this orthodontic treatment. The most likely risks are:

- Tooth pain and discomfort
- Cheek and gum irritation (from brackets or wires)
- White discoloration on the teeth
- Root resorption
- Allergies and infection

There is also a risk that your private data could be leaked. We protect your data by not labeling it with your name, and by keeping it password protected in our locked office.

Do you have to be in the study?
No, you don't. No one will get angry or upset with you if you don't want to do this. Just tell us if you don't want to be in the study. And remember, you can change your mind later if you decide you don't want to be in the study anymore.

Do you have any questions?
You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study. You can call:

Name of contact person on the study: Dr. Lubomyr Ravlyk

Phone Number: 585-746-8599

* * * * * * * * * * * * * * * * * * * *

Signature Block for Assent of Child

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining assent	Date
Printed name of person obtaining assent	