CONSENT TO PARTICIPATE IN RESEARCH

Comparison of Various Prosthetic Foot-Ankle Mechanisms

You have been asked to participate in a research study conducted by Professor Hugh Herr from the MIT Media Lab at the Massachusetts Institute of Technology (M.I.T.).

You have been asked to participate in this study because you are a below-the-knee amputee who is in generally good health and is able to walk with variable cadence across variable surfaces. There will be up to 10 people in this study.

The information below provides a summary of the research. Your participation in this research is voluntary and you can withdraw at any time.

- **Purpose**
  Assess preference of various prosthetic foot-ankles through qualitative and quantitative feedback to inform future prosthesis design.
- **Study Procedures**
  Collect data about various ankles and assess their performance after each trial using a qualitative survey, then assess their biomechanical performance using inverse gait dynamics. Participation in the study will take place over two 4-hour sessions.
- **Risks & Potential Discomfort**
- As with any walking using a prosthesis, there is a small risk of falling during the trials. To reduce this risk, there will be handrails along all walking surfaces. Also, an assistant will be available to accompany you at all times.
- There is also the risk of prosthesis malfunction, as several are active devices. However, there are multiple safeguards in place to shut down electrical power in the event of a malfunction. The devices are designed so they behave much like conventional passive prostheses when electrical power is cut, in that the joint will become nearly rigid.
- Although the walking trials should not be stressful, there is the chance of fatigue. You may rest or stop at any time.
- As with your customary prosthesis, there is a risk of discomfort from wearing a powered prosthesis. A professional prosthetist can be made available if necessary to make prosthetic adjustments and alignment modifications.
- With walking on uneven variable surface, there is a risk of falling. Similarly, the variable impedance terrain poses a risk of uneven gait which could lead to injury. There will also be handrails on the track that you may grab to stabilize yourself.

You should read the information below, and ask questions about anything you do not understand before deciding whether or not to participate.

- **PARTICIPATION AND WITHDRAWAL**

Your participation in this research is completely VOLUNTARY. If you choose to participate you may subsequently withdraw from the study at any time without penalty or consequences of any

kind. If you choose not to participate, that will not affect your relationship with M.I.T. or your right to health care or other services to which you are otherwise entitled.

- **PURPOSE OF THE STUDY**

This study is to evaluate your ability to walk with various powered and passive ankle-foot prostheses. We are hoping to evaluate the performance of various foot-ankles, including a prosthesis that can change your ankle angle (variable-angle), a prosthesis that can change the amount of cushioning you feel (variable-dampening), a prosthesis that can change its effective stiffness (variable-stiffness), and a passive prosthesis during walking, stairs, slope, and obstacle trials. The aim is to determine the design aspects of a foot-ankle prosthesis that most directly impact user comfort over these different ambulation conditions. We are therefore interested in being able to take measurements during gait and other tasks that correspond to how easy or difficult it is to control and walk with the prosthesis and use these measurements to determine the ideal foot-ankle system.

- **PROCEDURES**

If you volunteer to participate in this study, we will ask you to do the following things:

Overview:
In summary, you will be asked to wear a number of sensors and use different ankle-foot prostheses in place of your customary prosthesis. Data will be collected from the wearable sensors, motion capture system, and force sensors in the ground as you walk on level-ground or on a treadmill and stairs. The controller of any powered prosthesis will be electronically adjusted between trials or while you walk to determine how your gait changes in response to these changes. Trials will also be conducted with standard passive prostheses that would be prescribed for a person of your height and weight.

Consent and Discussion of Project
Prior to the experimental sessions, we will ask you to read and sign this informed consent form, and we will explain the project to you and answer any questions that you have. You will also be given time to become familiar with the equipment being used before beginning any trials. If needed, you will be aligned and fitted by a professional prosthetist at A Step Ahead Prosthetics in Burlington, MA.

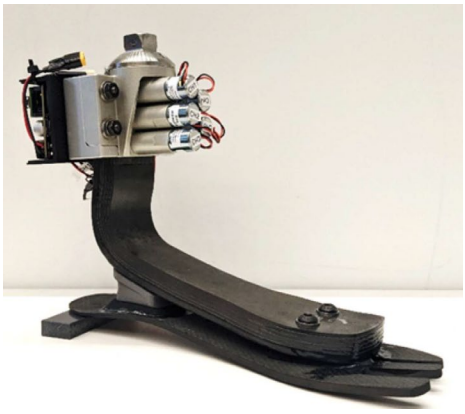
Experimental attire:
We will ask you to wear tight-fitting clothes, such as a skin-tight shirt, running shorts and low-profile shoes. If this is not possible, clothes will be provided according to your needs. We will provide and may require you to wear a skin-tight Velcro outfit that allows us to place reflective balls for video camera capture.

Locations:

Experimental sessions will be conducted in the MIT Biomechatronics Laboratory (E14-274), 75 Amherst St., Cambridge, MA 02139. Any alignment and fitting of prosthetic devices will take place at A Step Ahead Prosthetics, 21 A. St., Burlington, MA 01803.

Powered Prostheses:
You will be given two computer-controlled, powered ankle-foot prostheses to attach in place of your customary prosthesis during a session. These include the Blatchford Elan as well as a variable-stiffness prosthesis developed in the Biomechatronics lab. These powered prostheses have the capability of providing active assistance or changing mechanical properties during walking. Controls can be adjusted either through a wireless link or hardwire connection depending on the device. You will be given as much time as necessary to practice using the prostheses before the experiments begin.

Blatchford Elan. From blatchfordmobility.com



Variable-Stiffness Prosthesis

Passive Prostheses:
You will be given three passive prostheses to attach in place of your customary prosthesis during a session. These include the Ossur Pro-flex XC, a passive sliding-beam prosthesis, and a passive prosthesis that can change ankle equilibrium angle manually You will be given as much time as necessary to practice using the prosthesis before the experiments begin.

Ossur Pro-flex XC

Variable-Anlge Prosthesis

Data collection:

Comparative Ankle Study
Data collection is expected to take place in two segments. The first segment consists of level-ground walking on a treadmill at 0.75 m/s (slow walking), 1.25 m/s (normal, daily walking), and 1.5 m/s (fast walking). At each speed, all five prostheses will be tested, randomly selected, for 2mins each. Gait data will be collected using the VICON motion tracking system and force plates. Video and photographs will be taken by researchers for the purpose of syncing optical video with motion capture as well as documentation purposes. For each speed, once all prostheses have been tested, you will be given a secure, IRB-approved REDcap questionnaire to ascertain how each prosthesis performed at heel strike (early stance), roll over (mid stance), and toe off (late stance). In addition, you will be asked how each prosthesis generally performed, and your personal preference. This testing will occur across the three walking speeds, randomly selected, resulting in three completed questionnaires.
The second segment consists of walking up and down stairs and slopes. You will ascend and descend stairs and an 8° ramp at your preferred speed, repeated twice. All five prostheses will be tested, randomly selected, for a total of 8 walking trials per device. After testing all prostheses on each terrain type, you will be given a secure, IRB-approved REDcap questionnaire to ascertain how each prosthesis generally performed, and your personal preference. This testing will occur across the four walking conditions, randomly selected, resulting in four completed questionnaires.

- **POTENTIAL RISKS AND DISCOMFORTS**

Walking Trials
As with any walking using a prosthesis, there is a small risk of falling during the trials. To reduce this risk, there will be handrails along all walking surfaces. Also, an assistant will be available to accompany you at all times.
There is also the risk of prosthesis malfunction, as active devices will be used. However, there are multiple safeguards in place to shut down electrical power in the event of a malfunction. The devices are designed so they behave much like conventional passive prostheses when electrical power is cut, in that the joint will become nearly rigid.
Although the walking trials should not be stressful, there is the chance of fatigue. You may rest or stop at any time.
As with your customary prosthesis, there is a risk of discomfort from wearing the powered prosthesis. A professional prosthetist can be made available if necessary, to make prosthetic adjustments and alignment modifications.
With walking on uneven variable surface, there is a risk of falling. Similarly, the variable impedance terrain poses a risk of uneven gait which could lead to injury. There will also be handrails on the track that you may grab to stabilize yourself.

The experimental procedure(s) performed in this study are for specific research purposes and are not designed to diagnose or treat any medical conditions. Although some of the investigators for this project are trained clinicians, they are not acting as your doctor, but as research staff with

relevant clinical knowledge to administer risk assessments and to act on them in urgent/emergent instances. The research staff are not responsible for any medical evaluation or treatment.

- **ANTICIPATED BENEFITS TO SUBJECTS**

You may receive no direct benefit from participating in this study.

- **ANTICIPATED BENEFITS TO SOCIETY**

This research may help better inform researchers in designing prosthetic foot-ankles so they are as close to biomimetic as possible, increasing ambulation abilities for people with amputations.

- **ALTERNATIVES TO PARTICIPATION**

Your alternative is to not participate in this study.

- **PAYMENT FOR PARTICIPATION**

You will receive $20 per hour in monetary compensation for your time and effort. To receive compensation, you must complete the informed consent process (of which this document is a part) and participate for a minimum of one hour. We can assist in arranging your transportation but will not be able to pay your transportation costs. You should receive payment for your participation approximately one month after the study has been completed. Should you decide to withdraw from the study, or are withdrawn by the investigator, you will be paid $20/hour for the time and effort put in prior to withdrawal.

- **POSSIBLE COMMERCIAL PRODUCTS**

The findings of this study may some day be used to inform the design and manufacturing of a commercial product. The institution or researchers may benefit if this happens. There are no plans to pay you if your information is used for this purpose.

- **FINANCIAL OBLIGATION**

Neither you nor your insurance company will be billed for your participation in this research.

- **PRIVACY AND CONFIDENTIALITY**

The only people who will know that you are a research subject are members of the research team and, if appropriate, your physicians and nurses. Identifiable information may be shared with members of the Biomechatronics group who are actively working on human clinical trials for the purposes of recruitment to our other studies and reliable record-keeping. Currently there are 17 IRB trained Biomechatronics members who will have access to the data, and all of them are MIT personnel. The data will exist in the Media Lab network hub folder, which is managed by the

Media Lab IT department. Only IRB trained Biomechatronics group MIT personnel will have access to this folder. Individuals who no longer have a valid IRB certificate, or who leave the group, will not be able to access this folder anymore. Identifiable data will not be copied to local computers or shared in any other way. Data is not planned to be destroyed, it is saved for record keeping. No information about you, or provided by you during the research will be disclosed to others outside of the aforementioned group without your written permission, except: if necessary to protect your rights or welfare, or if required by law.

Once the study is completed, the data will remain in the Biomechatronics Group for future processing. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audio-tape recordings of you will be used for educational purposes, your identity will be protected or disguised by blurring or blocking your face. The videotapes and photos will be under the control of the MIT Media Laboratory's Biomechatronics Group. After the results are published, a copy of the photos and videos will be kept on a password-protected computer in the laboratory for future reference. The data will be only linked to you through a code which will only be accessible to the investigators of this study. The code will be stored in a password-protected file on a computer in the Biomechatronics Group. Reported data will not have any information that can be linked to you. If any other uses of the data are contemplated, you will be contacted by phone, mail or email requesting specific consent from you to do so.

Please add your initial and date if you give permission for your photograph, audio or video to be recorded for this study. **Initial:** _____ **Date:**_____

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 any information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

Authorized representatives of the Food and Drug Administration (FDA) may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

- **FUTURE DATA USE**

Your non-identifiable data such as your information, demographics data, photographs, videos, audios, etc.) collected as part of the research might be stored, used for future research studies, and/or shared with other researchers for future research studies without additional informed consent from you or your legally authorized representative. Your data might be shared with academic research institutions, non-profit entities, and/or for-profit entities.

Traditionally used identifying information about you such as your name, address, phone number, medical record, social security number, identifiable audio and video recordings, etc. will be removed before storing, using or distributing for future research. When the study is completed, all identifiable data will be destroyed after the required data retention period.

Your samples and information will be available for any research question, such as research aimed at understanding the development and causes of many diseases and conditions or the development of new scientific methods. Only de-identified data or data that does not contain personally identifiable information will be shared. Data sharing will be in accordance with MIT and COUHES policies, and may require a COUHES review as well as a DUA between MIT and the receiving institution.

If you choose to withdraw from the study early, we plan to retain and analyze already collected data relating to you up to the time of your withdrawal. Requests to destroy data relating to you or that the investigator exclude your data from any analysis will will be reviewed on a case-by-case basis. When your participation is complete and data analysis has concluded, our ability to honor a request to withdraw from the study is limited. All such requests will be reviewed on a case-by-case basis.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If you experience any side effects or if you become ill during the research, you may have to drop out, even if you would like to continue. The investigator, Hugh Herr, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If you must drop out because the investigator asks you to or because you have decided on your own to withdraw, you will be paid $20/hour for the time and effort that you have accrued.

- **NEW FINDINGS**

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

If you feel you have suffered an injury, which may include emotional trauma, as a result of participating in this study, please contact the person in charge of the study as soon as possible.

In the event you suffer such an injury, M.I.T. may provide itself, or arrange for the provision of, emergency transport or medical treatment, including emergency treatment and follow-up care, as needed, or reimbursement for such medical services. M.I.T. does not provide any other form of compensation for injury. In any case, neither the offer to provide medical assistance, nor the

actual provision of medical services shall be considered an admission of fault or acceptance of liability. Questions regarding this policy may be directed to MIT's Insurance Office, (617) 253-2823. Your insurance carrier may be billed for the cost of emergency transport or medical treatment, if such services are determined not to be directly related to your participation in this study.

- **IDENTIFICATION OF INVESTIGATORS**

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact Hugh Herr at (617) 258-6574, 75 Amherst Street Room 374L, Cambridge MA; Ellen Clarrissimeaux at (206) 612-4841, 75 Amherst Street Room 274, Cambridge MA; Duncan Lee at (972) 979-5552, 75 Amherst Street Room 274, Cambridge MA; Christian Landis at (847) 644-3929, 75 Amherst Street Room 274, Cambridge, MA; Daniel Levine at (206) 612-4841, 75 Amherst Street Room 274, Cambridge, MA; Christopher Shallal at (704) 904-6112, 75 Amherst Street Room 274, Cambridge MA.

- **RIGHTS OF RESEARCH SUBJECTS**

You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you feel you have been treated unfairly, or you have questions regarding your rights as a research subject, you may contact the Chairman of the Committee on the Use of Humans as Experimental Subjects, M.I.T., Room E25-143B, 77 Massachusetts Ave, Cambridge, MA 02139, phone 1-617-253 6787.

SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

_____
Name of Subject

_____
Name of Legal Representative (if applicable)

_____ _____
Signature of Subject or Legal Representative Date

SIGNATURE OF PERSON OBTAINING INFORMED CONSENT

I have explained the research to the subject or his/her legal representative, and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

_____
Name of Person Obtaining Informed Consent

_____ _____
Signature of Person Obtaining Informed Consent Date (must be the same as subject's)

SIGNATURE OF WITNESS (If required by COUHES)

My signature as witness certified that the subject or his/her legal representative signed this consent form in my presence as his/her voluntary act and deed.

_____
Name of Witness

_____ _____
Signature of Witness Date (must be the same as subject's)