Comparison of Prosthetic Feet for People With Syme's Amputation

NCT04086641

10/04/2019

5 PROCEDURES

5.1 Study procedures. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), drug dosing information (if any), use of records, time required, and setting/location. If it is available and you think it would be helpful to the IRB: Upload a study flow sheet or table to the **Supporting Documents** SmartForm in ***Zipline***.

*For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB **POLICY: Risks of Harm from Standard Care** and the draft guidance from the federal Office of Human Research Protections, **"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";** October 20, 2014.*

The proposed pilot randomized crossover study will assess biomechanical gait parameters, self-reported health outcomes, and qualitative feedback in participants with Syme's amputation under two prosthetic foot conditions: (1) a traditional low-profile Syme's foot, and (2) a high-profile crossover foot. Participants will already own a high-profile crossover foot or a low-profile energy storing foot. An additional prosthesis with the other study foot and an equivalent socket will be fabricated by the participant's certified prosthetists to facilitate unique socket attachment requirements. The order in which the participants will receive the prostheses will be randomly assigned. Participants will be instructed to wear the assigned prosthesis for at least two weeks prior to data collection to experience the function of the prosthetic foot under a variety of environments and activities. After each period of wear, biomechanical data will be collected for the respective prosthetic condition. Participant perspectives of the prosthetic feet will be assessed through a standardized self-reported measures and a qualitative semi-structured interview.

Screening and consent. Interested participants will be screened for study eligibility via telephone interview. Eligible participants will be sent a consent form via email or mail for their review. At a later time, the study will be explained in detail over the phone and verbal consent will be obtained.

Prosthetic fabrication. Participants will coordinate with *** for fabrication of a duplicate prosthesis that incorporates the study foot that the participant does not currently own (either a low-profile foot, Össur Flex-Symes or a high-profile crossover foot, Össur Cheetah Xplore).

Baseline assessment and verification of equivalence. Once the study prosthesis is finalized, participants will be invited to the Amplifying Mobility and Performance (AMP lab) to collect baseline information and assess the two prostheses for equivalence. A self-report survey of basic demographic and health questions and standardized health instruments will then be administered to characterize the sample at baseline. Then, a study prosthetist will verify fit, alignment, function, and equivalence of the study prostheses. If study prostheses are determined to be equivalent, the participants will be randomly assigned to one prosthetic condition to use exclusively for a period of two weeks. Study researchers will retain the other prosthesis to ensure full time use of the assigned prosthesis.

First data collection session. After two weeks of use, participants will return to the AMP lab for assessment of walking performance and self-reported health outcomes in the first assigned prosthetic condition. Participants will be fit with retroreflective markers and asked to walk at their self-selected slow, comfortable, and fast speeds over force plates until a minimum of 10 clean captures are collected for both the prosthetic and sound side. Marker position will be captured using a 10-camera Qualisys motion capture system; force date will be collected over a series of four Kistler instrumented force plates. After data collection, the participant will switch to the second prosthetic conditions for use over a two-week period. During this period, the first prosthesis will remain with study researchers.

Second data collection session. After two weeks of use, participants will return to the AMP lab for assessment of walking performance and self-reported health outcomes in the second prosthetic condition. Following gait data collection, a qualitative interview will be conducted, where participants will be asked which prosthetic foot they preferred overall, and their experience using both prostheses for various daily activities.

5.2 MRI scans. Will any subjects have a Magnetic Resonance Imaging (MRI) scan as part of the study procedures?

This means scans that are performed solely for research purposes or clinical scans that are modified for research purposes (for example, using a gadolinium-based contrast agent when it is not required for clinical reasons).

X	**No**	→ If no, go to question **5.3**.
	Yes	→ If yes, answer questions **a** through **c**.

a. Describe the MRI scan(s). Specifically:

- What is the purpose of the scan(s)? *Examples: obtain research data; safety assessment associated with a research procedure.*
- Which subjects will receive a MRI scan?
- Describe the minimum and maximum number of scans per subject, and over what time period the scans will occur. *For example: all subjects will undergo two MRI scans, six months apart.*

b. Use of gadolinium. Will any of the MRI scans involve the use of a gadolinium-based contrast agent (GBCA?)

☐ **No**

☐ **Yes** → If yes, which agents will be used? *Check all that apply.*

	Brand Name	Generic Name	Chemical Structure
☐	Dotarem	Gadoterate meglumine	Macrocylic
☐	Eovist / Primovist	Gadoxetate disodium	Linear
☐	Gadavist	Gadobutro	Macrocyclic
☐	Magnevist	Gadpentetate dimeglumine	Linear
☐	MultiHance	Gadobenate dimeglumine	Linear
☐	Omniscan	Gadodiamide	Linear
☐	OptiMARK	Gadoversetamide	Linear
☐	ProHance	Gadoteridol	Macrocyclic
☐	Other, provide name:		

1.) The FDA has concluded that gadolinium is retained in the body and brain for a significantly longer time than previously recognized, especially for linear GBCAs. The health-related risks of this longer retention are not yet clearly established. However, the UW IRB expects researchers to provide a compelling justification for using a linear GBCA instead of a macrocyclic GBCA, to manage the risks associated with GBCAs.

Describe why it is important to use a GBCA with your MRI scan(s). Describe the dose you will use and (if it is more than the standard clinical dose recommended by the manufacturer) why it is necessary to use a higher dose. If you plan to use a linear GBCA, explain why you cannot use a macrocyclic GBCA.

2.) Information for subjects. Confirm by checking this box that you will either provide subjects with the FDA-approved Patient Medication Guide for this GBCA you are using or that the same information will be inserted into the consent form.

☐ **Confirmed**

c. MRI facility. At which facility(ies) will the MRI scans occur? Check all that apply.

☐ UWMC Radiology/Imaging Services (the UWMC clinical facility)

☐ DISC Diagnostic Imaging Sciences Center (UWMC research facility)

☐ BMIC Biomolecular Imaging Center (South Lake Union research facility)

☐	Harborview Radiology/Imaging Services (the Harborview clinical facility)
☐	SCCA Imaging Services
☐	Northwest Diagnostic Imaging
☐	Other: identify in the text box below:

Personnel. For MRI scans that will be conducted at the DISC or BMIC research facilities: The role, qualifications, and training of individuals who will operate the scanner, administer the GBCA (if applicable), and/or insert and remove the IV catheter should be listed on the Study Team addendum.

5.3 Data variables. Describe the specific data you will obtain (including a description of the most sensitive items). If you would prefer, you may upload a list of the data variables to the **Supporting Documents** SmartForm instead of describing the variables below.

Biomechanical parameters. Three-dimensional position and force data will be collected and used to calculate the following gait parameters: step length asymmetry (i.e., the difference between prosthetic and sound side step lengths), prosthetic ankle range of motion (i.e., the total angular motion of the ankle in the sagittal plane during stance phase), prosthetic-side energy return (i.e., intersegmental flow of power out of the prosthesis), and peak sound-side limb loading (i.e., maximum vertical ground reaction force in early stance).

Patient-reported measures and interviews. To assess patient perspectives, a survey of standardized self-reported health outcomes will be administered at each visit. The survey will inquire about mobility (Prosthetic Limb Users Survey of Mobility, PLUS-M, 12-item Short Form version 1.2), balance confidence (Activities-Specific Balance Confidence Scale, ABC), functional and aesthetic satisfaction (Trinity Amputation and Prosthesis Experience Scales- Revised, TAPES-R-AES, TAPES-R-FUN), and activity restrictions (TAPES-R-AR). At the end of the study, participants will engage in a qualitative interview with closed- and open-ended questions to elicit preferences and experiences with both feet.

Variables to characterize the sample. A self-report survey including basic demographic (e.g., age, sex) and health questions (e.g., amputation etiology, time since amputation, hours of prosthesis use per day) will be administered at baseline. Participants will also be asked about socket comfort at each appointment using the Socket Comfort Scale (SCS) measures of current, best, worst, and average comfort.

The most sensitive questions will be questions about their amputation (e.g., etiology, time since amputation, etc.). Participants may refuse to answer any question. Photographs of participants will be taken only if participants agree. Photos will be used as indicated in the signed the photo/video consent form.

5.4 Data sources. For all types of data that you will access or collect for this research: Identify whether you are obtaining the data from the subjects (or subjects' specimens) or whether you are obtaining the data from some other source (and identify the source).

If you have already provided this information in Question 5.1, you do not need to repeat the information here.

All data will be obtained from the participants

5.5 Retrospective/prospective. For all types of data and specimens that you will access or collect for this research: do all data and specimens to be used in the research exist (for example, in subjects' medical records) at the time this application is being submitted for initial review?

- [X] **No**
- [ ] **Yes**

Include any necessary comments or explanation below (Note that for most studies this can be left blank):

N/A

5.6 Identifiability of data and specimens. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and to assist you in identifying relevant compliance requirements. Review the following definitions before answering the questions:

__Access__ means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".
__Identifiable__ means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.
__Direct identifiers__ are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of your data that is (when taken together) identifiable.
__Indirect identifiers__ are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.
__Key__ refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.
__Obtain__ means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from __accessing__, which means to view or perceive data.

a. Will you or any members of your team have access to any direct or indirect identifiers?

[X] **Yes** → If yes, describe which identifiers and for which data/specimens.

Name, phone number, email, and date of birth; participants will be asked to provide this information

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

[ ] There will be no identifiers.

[ ] Identifiers or the key have been (or will have been) destroyed before you have access.

[ ] You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

[ ] There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

[ ] There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

b. Will you obtain any direct or indirect identifiers?

[X] **Yes** → If yes, describe which identifiers and for which data/specimens.

Name, phone number, email, and date of birth; participants will be asked to provide this information

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

[ ] There will be no identifiers.

☐ Identifiers or the key have been (or will have been) destroyed before you have access.

☐ You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

c. If you obtain any identifiers, indicate how the identifiers will be stored (and for which data). NOTE: Do not describe your data security plan here – we will ask for that information in section 9.6.

☐ You will store the identifiers with the data. Describe the data to which this applies:

☒ You will store identifiers and study data separately but you will maintain a link between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

Biomechanical, patient-reported measures and interviews, and variables to characterize the sample.

☐ You will store identifiers separately from the study data, with no link between the identifiers and the study data. Describe the data to which this applies:

d. Research collaboration. Will individuals who provide you with coded information or specimens for your research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

N/A

5.7 Newborn dried blood spots. Will you use newborn dried bloodspots collected in the United States on or after March 18, 2015 **AND** will you obtain the bloodspots before January 21, 2019?

☒ **No**

☐ **Yes** → If yes, is this research supported by any federal funding (including any fellowship or career development award that provides salary support)?

  ☐ **No**

  ☐ **Yes** → If yes, describe how you will ensure that the bloodspots were collected with parental permission (in compliance with a 2015 law that applies to federal-funded research).

5.8 Protected Health Information (PHI). Will you access, obtain, use, or disclose a participant's identifiable PHI for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually-identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral. ***If you will use UW Medical Records, you must answer yes to this question.***

[X] **No** → If no, skip the rest of this question; go to question **5.9**

[ ] **Yes** → If yes, answer all of the questions below.

a. Describe the PHI you will access or obtain, and the reason for obtaining it. *Be specific.*

b. Is any of the PHI located in Washington State?

[ ] **No**

[ ] **Yes**

c. Describe how you will access or obtain the PHI. *Be specific. For example, you might: directly view records; search through your department's clinical database; submit a request to Leaf.*

d. For which PHI will you obtain HIPAA authorization from the subjects by having them sign a HIPAA Authorization form, before obtaining and using the PHI?

Confirm by checking the box that you will use the UW Medicine HIPAA Authorization form maintained on the HSD website if you will access, obtain, use, or disclose UW Medicine PHI.

[ ] **Confirmed**

e. For which PHI will you NOT obtain HIPAA authorization from the subjects?

Provide the following assurances by checking the boxes.

[ ] You will access, obtain and/or use only the minimum necessary amount of PHI to accomplish the purposes described in this application.

[ ] The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

[ ] You will fulfill the HIPAA "accounting for disclosures" requirement. See UW Medicine Compliance Policy #104. THIS IS ONLY FOR UW RECORDS.

[ ] There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.9 Genomic data sharing. Will you obtain or generate genomic data (as defined at http://osp.od.nih.gov/scientific-sharing/genomic-data-sharing-faqs/)?

[X] **No**
[ ] **Yes** → If yes, answer the question below.

a. Do you plan to send genomic data from this research to a national database (for example, NIH's dbGaP database)?

[ ] **No**
[ ] **Yes** → If yes, complete the ***ZIPLINE* SUPPLEMENT Genomic Data Sharing** and upload it to the **Supporting Documents** SmartForm of ***Zipline***.

5.10 Whole genome sequencing. For research involving biospecimens: Will the research include whole genome sequencing?

Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

[X] **No**
[ ] **Yes**

5.11 Possible secondary use or sharing of information, specimens, or subject contact information. Are you likely to use the information, specimens, or subject contact information you obtain or collect for any of the following:

- Future research not described in this application (in other words, secondary research)
- Submission to a repository, registry, or database managed by you, colleagues, or others for research purposes
- Sharing with others for their own research

You are strongly encouraged to consider the broadest possible future plans you might have, and whether you will obtain consent now from the subjects for future sharing or research uses (which you may or may not be able to describe at this time). Answer **YES** even if you will only share information without identifiers. Answer **NO** if you are unlikely to do any sharing, or if your only sharing will be through the NIH Genomic Data Sharing described in question 5.9.

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include (for example): informal arrangements to share your banked data/specimens with other investigators; establishing a repository from which you formally share with others through written agreements; or sending your data/specimens to a third party repository/archive/entity such as the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

[ ] **No**
[X] **Yes** → If yes, answer all of the questions below.

a. Describe <u>what you will store for future use,</u> including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

We will store deidentified biomechanical, patient-reported measures and interviews, and variables to characterize the sample for future use. Photographs will also be stored if consent given to use for either publication, educational materials, future study recruitment, or study records.

b. Describe <u>what will be shared with other researchers or with a repository/database/registry</u>, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

Data (including photographs) will not be shared with other researchers or with a repository/database/registry outside of scientific publications and presentations. In publications and presentations, we will present de-identified data. We may include photographs in publications and presentations, but only for participants who have

explicitly provided consent for use of their photographs for these purposes in our consent form.

c. Who will oversee and/or manage the sharing?

*** and *** will oversee storage

d. Describe the possible future uses, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.

Data will be used for future biomechanical analysis and comparative studies within Syme's amputees and between Syme's amputees and other levels of amputation

e. Consent. Will you obtain consent now from subjects for the secondary use, banking and/or future sharing?

[ ] **No**

[X] **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in your answers to the consent questions in Section 8.

f. Withdrawal. Will subjects be able to withdraw their data/specimens from secondary use, banking or sharing?

[ ] **No**

[X] **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

Example: data can be withdrawn from the repository but cannot be retrieved after they are released.

Photographs will be allowed to be withdrawn via written request; deidentified data will be maintained

g. Agreements for sharing or release. Confirm by checking the box that you will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement between you and the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data). Do not attach your template agreement forms; the IRB neither reviews nor approves them

[X] **Confirmed**

5.12 Communication with subjects during the study. Describe the types of communication (if any) you will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.

Email, texts, or telephone reminders about appointments and reminders regarding which prosthetic foot to be using

5.13 Future contact with subjects. Do you plan to retain any contact information you obtain for your subjects so that they can be contacted in the future?

[ ] **No**
[X] **Yes** → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to your team; if not, describe who else could be provided with the contact information. Describe your criteria for approving requests for the information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

Participants will be asked to consent to study investigator future contact. Participants may be contacted for the following reasons: 1. inform participants about other studies; 2. ask participants to clarify information provided during the study. Contact information for participants will be limited to the study team.

5.14 Alternatives to participation. Are there any alternative procedures or treatments <u>that might be advantageous</u> to the subjects?

If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.

[X] **No**
[ ] **Yes** → If yes, describe the alternatives.

5.15 Upload to the Supporting Documents SmartForm of ***Zipline*** all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points you will use to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records, or video recordings.

- ***Examples****: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE:*** *Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics you will cover and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***For materials that cannot be uploaded****: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*
- ***For data that will be gathered in an evolving way****: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to your research, provide a description of the process by which you will establish the data collection/questions as you interact with subjects, how you will document your data collection/questions, the topics you plan to address, the most sensitive type of information you will plan to gather, and the limitations (if any) on topics you will raise or pursue.*

Use this text box (if desired) to provide:

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process you will use for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instruments for which you are seeking general approval. (See the **NOTE** bullet point in the instructions above.)

The participant surveys and the final interview are uploaded.

5.16 Send HSD a Confidentiality Agreement if you will obtain or use any private identifiable UW records without subject's written consent (for example, screening medical records or class grades to identify possible subjects).

The Confidentiality Agreement form must be completed, printed, signed, and mailed to the Human Subjects Division at Box 359470. Your IRB application cannot be approved until we receive the Confidentiality Agreement.