Energy-Harvesting Knee Prosthesis: Assist-Knee

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Grant PI:
Sarah Chang, PhD

Orthocare Innovations, LLC
123 Second Avenue South, Suite 220
Edmonds, WA 98020 USA

i. Purpose of the study and background

Geriatric individuals with transfemoral limb loss can find rising from a chair challenging due to a loss of knee and ankle musculature on the prosthetic side, and declining or marginal strength on the sound side. Transitioning from a sitting to a standing position is much more difficult for an individual with transfemoral limb loss than an individual with no limb loss. When rising from a chair, individuals with limb loss rely on their sound limb and upper limb strength to lift their body weight. Geriatric transfemoral prosthesis users could retain independence if a prosthetic knee was capable of assisting with sit-to-stand-to-sit transitions. Unfortunately, the current designs of non-powered prosthetic knees do not assist with the sit-to-stand-to-sit transition, a task that is fundamental for normal activities of daily living.

The objective of the *energy-harvesting knee prosthesis* (that we call **Assist-Knee**) is to create a lightweight, low-cost prosthesis that stores the prosthesis user's potential energy during the stand-to-sit (*SIT*) transition and appropriately returns that energy to assist with the sit-to-stand (*STAND*) transition. Assist-Knee combines a mechanical spring and damper with a safety interlock mechanism (**Figure 1**).

{ *figure redacted* }

Figure 1: CAD model of the Assist-Knee device

{ *text redacted* }

{ *figure redacted* }

Figure 2: Assist-Knee function during *STAND* transitions. { *text redacted* }

{ *text redacted* }

{ *figure redacted* }

Figure 3: { text redacted }

{ *text redacted* }

The purpose of the human subject testing will be to (1) validate the concept of the Assist-Knee design and function by testing the ability of Assist-Knee to harvest energy and return a sufficient amount of energy during the stand-to-sit-to-stand transition in a way that is clinically relevant, and (2) collect pilot data using the Assist-Knee device that can be included in a larger grant submission to perform a clinical trial with a larger representative population. We will also evaluate whether prosthetic users are able to wear and use the Assist-Knee device when walking.

ii. Criteria For Participant Selection

Our enrollment target for this pilot study will be 3 participants who are transfemoral prosthetic users. Our sampling plan for subjects will include both adult women and men (e.g. 1 adult woman and 2 adult men, or 2 adult women and 1 adult man). The target subject distribution represents the results of the United States Census 2010 for Seattle, Washington: Asian (8.6%), Black (4.1%), and Hispanic or Latino (12.4%). We will endeavor to recruit participants that match the local demographic distribution. However, researchers will consider persons of all racial and ethnic backgrounds as equal candidates for inclusion in this work. The work has the potential to benefit minorities and non-minorities equally.

The inclusion/exclusion criteria for the participants with lower limb loss are the following:

Inclusion Criteria

- Unilateral transfemoral limb loss
- Age 21 – 80 years
- At least one year post-amputation and currently successfully using a prosthesis
- Uses modular endoskeletal prosthetic components
- Has bilateral normal range of motion
- Ability to perform the following activities:
    - Walking ability or ability to take steps over 10 meters
    - Upright standing stability
    - Stand-to-sit stability (i.e. go from a standing position to a seated position independently)
    - Sit-to-stand stability (i.e. rise from a seated position independently)
- Ability to communicate individual perceptions in the English language
- Ability to provide informed consent

Exclusion Criteria

- Confounding injury or musculoskeletal problem
- Pregnancy
- Lower limb peripheral neuropathy
- Symptomatic cardiovascular disease or chronic obstructive pulmonary disease
- Not able to read and understand English
- Use of assistive devices for sit-to-stand and stand-to-sit (e.g. canes, walkers)

iii. Methods and Procedures

Recruitment of participants with lower limb loss

Recruitment will be by referral from collaborating prosthetists or Orthocare Innovations' study prosthetist. The prosthetist will either mail the attached letter (Assist-Knee solicitation letter.doc) or use the attached script (Assist-Knee solicitation script.doc) with patients that appear to meet the inclusion/exclusion criteria. If interested in participating in the study, the prosthesis users may choose to call Orthocare Innovations or choose to have Orthocare Innovations call them.

Once contact is made between the prosthesis user and Orthocare Innovations' research personnel, the Orthocare Innovations phone script will be followed (Assist-Knee solicitation script.doc). The research will be thoroughly described with opportunities for asking questions. Those interested in participating and those who meet our criteria will schedule an appointment for consenting at the Orthocare Innovations Biomechanics Laboratory. At this time, we will ask if they would like the consent document mailed or emailed to them so that they will have ample time to review the document prior to their visit. If they answer yes, we will mail or email a cover letter (Assist-Knee solicitation letter.doc) with a copy of the prosthesis user's consent document (Assist-Knee consent subject.doc).

Experimental procedures

Since each participant's prosthesis is unique, the prosthesis users will act as their own controls. All participants will have at least one visit to the Orthocare Innovations Biomechanics Laboratory, with each visit expected to last a minimum of four hours. The participants will first complete a baseline data collection using their existing habitual prosthesis. The participant's individual power harvesting performance, kinematic data, and kinetic data will be measured in the Orthocare Innovations Biomechanics Laboratory for baseline comparisons, using a motion capture system (Vicon, Centennial, CO and force plates (AMTI, Watertown, MA). The participants will be asked to perform a variety of common activity tasks that may include: sit-to-stand maneuvers, walking on level-ground; turns during walking on level ground; initiating gait from a standstill; and stand-to-sit maneuvers. The main focus of the data collection is during the sit-to-stand-to-sit maneuvers. The participants will also be asked to complete the Timed Up and Go (TUG) test, which requires the participant to stand up from a chair, walk 3 m, turn around, walk 3 m back to the chair, turn around, and sit down onto the chair. After baseline data have been collected, the prosthesis user will then wear Assist-Knee and complete the same data collection in the Biomechanics Laboratory. Subjects will be asked to complete the Prosthesis Evaluation Questionnaire (PEQ) and a custom survey after completing the data collection for each habitual or Assist-Knee condition (Assist-Knee_ParticipantQuestionnaire.docx). Subjects will also be asked to complete a demographic survey (Assist-Knee_Demographics.doc).

Participants will wear the Assist-Knee system (**Figure 4**), which is designed to fit in place of their existing knee prosthesis and ankle-foot prosthesis. {*text redacted*}

{ *figure redacted* }

Figure 4: Representation of participant using Assist-Knee

An Orthocare Innovations study research prosthetist will fit each participant with the Assist-Knee device. The participant will be trained by the research prosthetist on how to use Assist-Knee with an acclimation period of at least 60 minutes, with rest periods as needed, or until the subject feels comfortable using the system independently for gait and sit-to-stand-to-sit transitions. We intend to provide ample training on the system before independent use and will provide an operator for the clinical study if necessary. We will then test the effect of Assist-Knee on various movements (sitting down, standing up, gait via TUG test) and collect kinetic, kinematic, and temporal-spatial data. The data will be collected using the Orthocare Innovations' Biomechanics Laboratory motion capture system (Vicon, Centennial, CO), force plates (AMTI, Watertown, MA), and a commercially available sensor (Smart Pyramid with Compas, Orthocare Innovations, Edmonds, WA) attached to the Assist-Knee.

To mimic current clinical practice, the Assist-Knee device will be aligned by the prosthetist in static alignment to an optimal state by consensus of the research prosthetist and participant. { *text redacted* } The subject will be given an acclimation period of at least 10 minutes, with rest periods as needed, or until the subject feels comfortable using the system with each new combination. When performing the activities during the entire experiment, the participant will wear a gait belt held by the clinician for safety. Kinematic and kinetic data will be recorded.

For each combination, subjects will perform a variety of tasks that may include: sit-to-stand maneuvers, walking on level-ground; turns during walking on level ground (e.g. for the TUG test); initiating gait from a standstill; and stand-to-sit maneuvers. The participants will not be allowed to use an assistive device during the sit-to-stand and stand-to-sit transitions, but the participants will be allowed to use an assistive device during the walking portion of the TUG test. The data

capture process is anticipated to take no more than three hours. An additional hour may be required to fit the prosthetic device and does not require active walking by the participant. Participants will be allowed to rest as needed. The collected data will be used to determine the effectiveness of the experimental device.

After testing { *text redacted* }, the participants will be encouraged to provide feedback on their perception of the device verbally and through the custom survey as well as complete the relevant questions from the PEQ.

The following table (**Table 1**) describes a representative order of events and the outcome measures collected. { *text redacted* }. At least five satisfactory trials of motion analysis data and at least three satisfactory trials of TUG test for each {*text redacted* } combination will be collected.

Table 1: Representative Experimental Protocol
Survey: Prosthesis Evaluation Questionnaire (PEQ) and custom survey

Visit #	**Activities to take place**	**Outcome Measures Collected**
Hour 1	Screening, consent process, collection of demographic and anthropometric information, and administer survey for baseline prosthesis	Demographic and anthropometric information, baseline survey responses
Install Europa+ sensor in **baseline** prosthesis		
Hours 1-3	Collect motion analysis data on a variety of tasks with ***baseline*** prosthesis, perform TUG test	Kinematic and kinetic data, TUG test
	Training period with **Assist-Knee** *{ text redacted }*	
	Collect motion analysis data on a variety of tasks with ***Assist-Knee*** prosthesis, perform TUG test, administer survey, open-ended discussion with prosthesis user	Survey responses, kinematic and kinetic data, TUG test, Assist-Knee settings
	Acclimation period with **Assist-Knee** *{ text redacted }*	
	Collect motion analysis data on a variety of tasks with ***Assist-Knee*** prosthesis, perform TUG test, administer custom survey, open-ended discussion with prosthesis user	Survey responses, kinematic and kinetic data, TUG test, Assist-Knee settings
	Acclimation period with **Assist-Knee** { *text redacted* }	
	Collect motion analysis data on a variety of tasks with ***Assist-Knee*** prosthesis, perform TUG test, administer custom survey, open-ended discussion with prosthesis user	Survey responses, kinematic and kinetic data, TUG test, Assist-Knee settings
	Acclimation period with **Assist-Knee**	

	{ text redacted }	
	Collect motion analysis data on a variety of tasks with ***Assist-Knee*** prosthesis, perform TUG test, administer survey, open-ended discussion with prosthesis user	Survey responses, kinematic and kinetic data, TUG test, Assist-Knee settings
Return to **baseline** prosthesis		

iv. Data Analysis and Data Monitoring

Data collected for the subjects with limb loss will be: contact information, age, sex, race, ethnicity, anthropometric measurements (height, distance from distal end of socket to knee center and knee center to ground), body mass, description of current prosthesis, time since limb loss, and cause of limb loss (scientifically relevant). The outcome measures collected from the subject experiment include kinematic, kinetic, and temporal-spatial parameters of gait; various data from the sensor installed on the Assist-Knee device; a record of verbal feedback regarding perceptions of the device; and written feedback with the Prosthesis Evaluation Questionnaire (PEQ) and custom survey.

All subjects will be assigned a de-identified number that can be used to refer to subjects outside the research group, in order to protect confidentiality of the participant. Investigators solely participating in the human subjects experiments will only have access to subjects' first names. The research coordinator, study prosthetist, and principal investigator will have access to first and last name, telephone number, email address, and mailing address. The research coordinator will use the mailing address (or email address) for mailing (or emailing) the consent prior to the first visit so the subject can review it at his/her leisure prior to the official consenting visit. All personal identifying information will be coded, keyed, and kept in locked file cabinets and/or on a password-protected computer.

v. Risk/Benefit Assessment

The risk to the participants will be minimal. The potential health risks to the participant with transfemoral limb loss are similar to those during routine prosthesis fittings. The difference is that the testing may go longer than the usual clinical visit. Therefore, fatigue from walking and performing the sit-to-stand-to-sit transitions more than usual is a risk. Subjects will be told that they can sit and rest at any time. There are no foreseen psychological, social, or legal risks for participants.

There is always a risk of privacy and confidentiality being breached. The privacy and confidentiality of subjects will be preserved using standard procedures for research data collection and storage. Uniquely identifying information will be coded and keyed. The key will be kept on a single password-protected computer

and destroyed at the termination of the study. Unique identifiers will not be included in study data files other than the coding key and the consent forms. All data will be maintained on secure password-protected computers and locked file cabinets. HIPAA regulations will be observed for any personal, identifiable health information collected from the subjects.

There are no direct medical benefits for participating in this study and, therefore, no alternative therapies or courses of action should the subject elect not to participate in this study. The primary benefit from participation is the advancement of prosthesis technology through the evaluation of our novel Assist-Knee device.

vi. Subject Identification, Recruitment, And Consent

Recruitment of individuals with limb loss will be by referral from collaborating prosthetists or Orthocare Innovations' study prosthetists. The prosthetist will either mail the attached letter (Assist-Knee solicitation letter.doc) or use the attached script (Assist-Knee solicitation script.doc) with prosthesis users that appear to meet the inclusion/exclusion criteria. If interested in participating in the study, the prosthesis users may choose to call Orthocare Innovations or choose to have Orthocare Innovations call them.

Once contact is made between the prosthesis user and Orthocare Innovations research personnel, the Orthocare Innovations phone script will be followed (Assist-Knee solicitation script.doc). The research will be thoroughly described with opportunities to ask questions. Those interested in participating and those who meet our criteria will schedule an appointment for consenting at Orthocare Innovation's Biomechanics Laboratory. At this time, we will ask if they would like the consent document mailed or emailed to them so that they will have ample time to review the document prior to their visit. If they answer yes, we will mail or email a cover letter (Assist-Knee solicitation letter.doc) with a copy of the patient's consent document (Assist-Knee consent subject.doc).

Aside from the participant's time and transportation, there will be no cost to the participant. To compensate the participant's time and transportation costs, the prosthesis user subjects will be paid { *text redacted* } at the end of the study or at the time of withdrawal.