Title: Biomechanical Evaluation of a Novel, Compliant Low Profile Prosthetic Foot

NCT #: NCT06468059

Document Date: 08/13/2025

Protocol and Statistical Analysis Plan

1. Study Aim, Background, and Design

The behavior of the human ankle and foot during the mid-stance phase of walking is well characterized by a spring-like function. Inspired by this observation, modern prosthetic feet are generally designed as composite spring structures. To achieve the appropriate compliance necessary for walking, modern prosthetic feet typically adopt curved shapes extending into the shank region of the body. These feet therefore have a tall build height to achieve the appropriate compliance without exceeding material stress limits. Curved feet perform well for individuals with residual limbs that can accommodate their build height. However, for individuals with long residual limbs, the available space for a prosthesis is limited, and they must use low-profile feet, which are stiffer than their curved counterparts. These stiff low-profile prosthetic feet result in decreased energy return during late stance as well improper rollover behavior. Therefore, although conventional wisdom holds that individuals with longer residual limbs retain greater function, they are actually confined to low-profile feet that poorly replicate the function of an anatomical foot.

Little Room Innovations has developed a new approach to the design of low-profile prosthetic feet that allows for both increased compliance and lower material stress. This improved functionality is achieved through a design inspired by uniform strength beam theory in which stress is evenly distributed along the length of a loaded beam. Multiple layers of composite material have been used to recreate the uniform stress beam in a form factor that fits within the anthropomorphic envelope. This layered Low-Profile Foot (LPF) better replicates the compliant behavior of the intact ankle and foot, and it opens the door for individuals with long residual limbs to experience the compliant behavior present in commercial prosthetic feet with tall build heights.

The aim of this project is to conduct a preliminary investigation into the potential mobility benefits of the layered LPF for prosthesis users with long residual limbs. Kennesaw State University and Little Room Innovations have partnered to perform a pilot study to quantify the efficacy of the novel low profile feet as compared to conventional low profile feet.

2. Participant Population

The participant population consists of adults (aged between 18 and 89 years) who have a unilateral transtibial amputation and who have long residual limbs (residual limb length only allows posterior mount prosthetic componentry or low-profile feet). All subjects are expected to be healthy individuals.

Participants were recruited from around the Atlanta area through Kennesaw State University's established MS program in Prosthetics and Orthotics, which utilizes an extensive network of prosthesis users and clinicians. Upon identification of a potential participant, the laboratory screener initiated contact to assess eligibility based on inclusion and exclusion criteria and, if appropriate, scheduled the first visit. During the study, participants underwent prosthetic fitting, training, and outcomes testing at the Kennesaw State University Biomechanics Laboratory.

3. Study Procedures

Subjects will be recruited and provide informed consent before enrolling in this study. After informed consent, a prosthetist will fit each subject with the layered LPF using the subject's prescribed socket or a custom-made socket in the case of individuals who typically use posterior mount style prostheses (1-2 sessions). The layered LPF size will be determined by the subject's contralateral foot size, while the stiffness category will be selected to match the stiffness of commercially available feet that would be prescribed to the participant (based on manufacturer-published prescription tables). The prosthetist will confirm proper fit of both prostheses before training. The training will focus on safe and effective ambulation over different terrains and level ground. Training will include device alignment and adaptation to the needs of each subject. After training, clinical outcomes and gait laboratory data will be collected.

The same protocol will be performed by subjects with both their prescribed feet and the layered LPF, in an order randomly determined for each subject. Furthermore, the devices will be blinded to the user during the gait analysis through the use of a shroud over the foot. This study will compare the performance of the layered LPF with that of the subjects' prescribed feet with respect to a number of clinically relevant outcome measures. During the assessment, each

subject will walk overground at a self-selected walking speed while wearing the current test device (layered LPF or prescribed foot). Full-body kinematic and kinetic data will be recorded for each trial using a pair of floor-mounted 6-axis AMTI force plates to measure ground reaction forces, in combination with an 8-camera Vicon T10 motion capture system to measure motion. Data collected from these systems will be used as inputs into a Vicon Nexus software suite to conduct inverse-dynamics analysis. A minimum of 15 strides will be collected for each condition and subject.

4. Statistical Analysis Plan

This preliminary pilot study is intended to gather the initial data necessary for proper statistical design and power calculations in a subsequent Phase II proposal. In order to maximize the quality of sample size calculations for a Phase II study, we have allocated Phase I resources to enroll the largest feasible number of subjects for this pilot study.

The primary outcome measure for this work is the Total Energy Stored (TES). We are interested in determining if there are intra-subject differences in TES between the interventions. We hypothesize that transtibial users with long residual limbs will exhibit *increased* TES when using the layered LPF for a given subject by a significant margin relative to that subject's daily use prosthesis. Adamczyk, et al., showed that the internal moment of the ankle remained relatively constant when walking with various foot stiffnesses, which means TES should scale linearly with stiffness [1]. As a result, we can consider the distributions of stiffnesses as a proxy for TES in order to estimate an effect size. Since the distribution of stiffnesses available in the layered LPF family is designed to accommodate the full range of stiffnesses seen in standard profile feet, we expect an effect size for TES of greater than 0.8 relative to the more limited distribution of commercially available low profile feet [2].

A post-hoc pairwise comparison test will be performed comparing the TES of the layered LPF to that of the subjects' daily use prostheses. Because we are performing separate tests for each group. Statistical significance will be assessed using alpha and Beta values of 0.05 and 0.8, respectively.

5. Research Risks

The risks of the experimental part of the study are small.

• The largest risk is the risk of falling, which is a risk for all lower limb prosthesis users.

• Other risks include minor skin irritation, minor muscle soreness, and fatigue.

• There is some risk that subjects' identities may be revealed as a result of participating in this study.

• There are no other known social, legal, or other risks in these experiments.

6. Funding Sources

This work is funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development through a Phase I SBIR award.

7. References

[1] Adamczyk, P. G., Roland, M., and Hahn, M. E., Sensitivity of Biomechanical Outcomes to Independent Variations of Hindfoot and Forefoot Stiffness in Foot Prostheses. Hum Mov Sci, 2017. 54: p. 154-171.

[2] Bartlett, H. L., King, S. T., Goldfarb, M., and Lawson, B. E., Model Based Design of a Low Cost and Compliant Low Profile Prosthetic Foot. J Biomech Eng, 2022. 144(3).14.

KENNESAW STATE UNIVERSITY
CONSENT FORM

Title of Research Study: Evaluation of a Novel Layered Low-Profile Prosthetic Foot

Researcher's Contact Information: Mark Geil, (470) 578-4805, mgeil@kennesaw.edu

You are being asked to take part in a research study. The information in this form will help you decide if you want to be in the study. Please ask the researchers if there is anything that is not clear or if you need more information.

The purpose of the study is to observe walking using motion capture software comparing your existing prosthetic foot to a new, compliant low-profile prosthetic foot. You will visit the laboratory twice within one week. One visit will allow you to get used to the new foot. Then, on the second visit, we will track your motion while you walk and go up and down stairs and slopes.

We will measure your height, weight, and the size of your limbs. Then, we will stick small markers on your arms, torso, legs and feet. We will ask you to first stand still for a few seconds, and then walk around the lab several times while special cameras record your walking.

If you are interested in participating in the study, please read the additional information on the following pages, and feel free to ask questions at any point.

Explanation of Procedures

If you agree to participate in this study:

- In the laboratory, a Certified Prosthetist will remove your current prosthetic foot and attach the new foot to your prosthesis and ensure safe alignment. We will also measure your height and weight and the size of your limbs.
- You will walk around the laboratory for about 30 minutes to get accustomed to the new foot. This walking will include going up and down stairs and sloped walkways.
- The prosthetist will then swap back to your current prosthesis and restore the original alignment.
- Within one week, you will return to the lab for data collection.
- You will complete the motion trials twice, once with your current foot and once with the new foot. We will attach small reflective markers to your arms, hands, torso, legs, and feet for the cameras to track. Then, you will walk across the laboratory on a smooth level surface, up four stairs, down two different slopes, then up the slopes and down the stairs. You will complete the circuit five times with each foot.
- We will ask you to complete a brief survey twice, once about your current prosthetic foot and again about the new prosthetic foot.

Participation is voluntary. You can refuse to take part or stop at any time without penalty. The study has nothing to do with your current clinical care, and your decision to participate, not participate, or stop participating at any time will have no influence on your prosthetic treatment.

We will be recording your movement, but the special cameras only track the reflective markers, and do not record any identifiable images.

Time Commitment

The study will take place on two visits to the Biomechanics Laboratory. Each visit will take about an hour and a half.

Risks and discomforts

The risks are the same as those encountered by a healthy adult walking along a smooth, level walkway and around an office building, which are minimal. Walking with the new prosthetic foot might feel a little different. The foot has passed materials testing measurements similar to those used to test all prosthetic feet for safety during walking.

You will have markers taped to their skin for motion capture which could cause some discomfort when removed.

Benefits

You will not receive a direct benefit from the study. The results will help the designer of the new prosthetic foot understand its effectiveness for individuals like you.

Compensation

Upon completion of the first (training) visit, you will receive $100. Upon completion of the second (data collection) visit, you will receive an additional $200.

Confidentiality

The results of this participation will be confidential. We will keep your records private to the extent allowed by law. Dr. Geil will have access to the information you provide. Information may also be shared with those who make sure the study is done correctly (KSU Institutional Review Board, the Office for Human Research Protection (OHRP). We will use a code rather than your name on study records. The information you provide will be stored in the biomechanics laboratory on password- and firewall-protected computers. All study information will be destroyed five years following the end of the study. Your name and other facts that might point to you will not appear when we present this study or publish its results. The findings will be summarized and reported in group form. You will not be identified personally.

It is possible that the information from the study will be used or shared after identifiers have been removed as part of future grant proposals and studies.

Research at Kennesaw State University that involves human participants is carried out under the oversight of an Institutional Review Board. Questions or problems regarding these activities should be addressed to the Institutional Review Board, Kennesaw State University, irb@kennesaw.edu.

If you agree to participate in this research study, please sign below:

_____

Signature of Participant or Authorized Representative, Date

_____

Signature of Investigator, Date

_____

PLEASE SIGN BOTH COPIES OF THIS FORM, KEEP ONE AND RETURN THE OTHER TO THE INVESTIGATOR