Official Title: SCANREP: Reliability of 3D Lower Limb Scanning

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SCANREP

PI: Jason Wilken
IRB ID #: 201905871

Project Details

I. Project Introduction

I.1 ***Project to be reviewed by:***
IRB-01

I.2 ***Project Title:***
SCANREP: Reliability of 3D lower limb scanning

I.3 ***Short Title (optional):***
SCANREP

I.4 ***Provide a short summary of the purpose and procedures of the study proposed in this IRB application.***

- ***DO NOT include information on studies not proposed in this application.***
- ***Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.***
- ***DO NOT cut and paste technical abstracts from funding applications that may not be understood by a general audience.***

3D limb scanning systems have recently been implemented for the clinical fitting of prosthetic and orthotic devices due to substantial decreases in costs. However, little data is available regarding the repeatability and validity of systems currently in use. In this study we seek to evaluate the repeatability and validity of multiple lower limb measurements obtained using low-cost 3D limb scanning technology.

Two groups of subjects will be recruited for this study. The first group (Group 1) will consist of healthy able-bodied individuals with no history of lower extremity trauma. The second group (Group 2) will consist of individuals with unilateral, below knee functional deficits that require an AFO for daily activities (e.g. fracture, muscle and/or nerve injury, ankle arthritis, or peripheral neurologic disease).

We will obtain a brief medical history to identify major medical conditions or prior injuries that could influence limb geometry, and lead to reliance on an AFO for Group 2 participants.

A 3D representation of each participant's lower limb geometry will be obtained using a Structure Core scanner (Occipital, Inc.) which uses an infrared structured light projector to construct a 3D image of an object. The scanner is connected to an iPad; to operate the user rotates the iPad camera around the desired object. In seconds, the entire geometry is digitally reconstructed. Measurements will be evaluated using digital imaging analysis software (Standard Cyborg, Inc.). We will evaluate concurrent validity by directly comparing software-based measurements from limb scans, with direct measurements on the same individual collected using digital calipers. We will determine repeatability of each technique by conducting three identical limb scans and actual physical measurements at two time points on the same day in each individual, and then comparing the results between time points.

Validity and repeatability will be assessed using measurements at multiple locations on the lower leg. Limb measurements will include 1) width of the metatarsal heads, 2) width of the calcaneus, 3) foot length, 4) foot height, 5) arch height, 6) medial-lateral width between ankle malleoli, 7) minimum circumference above the ankle malleoli, 8) maximum calf circumference , 9) medial-lateral width of the knee condyles 10) anterior-posterior width at mid patellar tendon, 11) distance from bottom of foot to tibial tubercle.

Concurrent validity will be determined using the intra-class correlation coefficient and absolute error (root mean square error) for comparisons between measurements from limb scanning and the calipers. Reliability will be determined using the intra-class correlation coefficient and the minimal detectable change value for comparisons over time.

Study activities will either occur at American Prosthetics and Orthotics, or the Human Performance and Clinical Outcomes Laboratory (21D EMRB).

I.5 ***Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")***
AIM #1: To determine the test-retest and inter-rater reliability (Intraclass correlation coefficient) and minimal detectable change values for multiple measures of limb geometry as determined using 3D limb scanning and digital image analysis.

AIM #2: To determine the test-retest and inter-rater reliability (Intraclass correlation coefficient) and minimal detectable change values for multiple measures of limb geometry as determined using digital calipers or a tape measure.

AIM #3: Determine the concurrent validity of measures obtained using 3D limb scanning and digital caliper-based measurements or a tape measure.

I.6 ***Background and significance and/or Preliminary studies related to this project. (do not indicate "see protocol")***

Ankle foot orthoses (AFOs) are braces that are used to maintain or restore mobility for individuals with lower limb pathology. A well-fitting device is essential for proper comfort and function. Unfortunately, the fitting process has seen little advancement in recent years. It is common for an orthotist to take a cast of a patient's lower leg and foot to create the geometry for the AFO. Due to the craft based fitting process, each cast and device is unique, and it is difficult to objectively refine or improve the fitting process.

3D limb scanning is being implemented in the clinical setting for calculating residual limb volume [1]. Similar affordable scanning technology has been tested for the reliability and validity of its measurements for obtaining residual limb volume, using the gold standard of water displacement as comparison [2]. A study comparing 3D laser scanning for measuring limb volume against the water displacement method suggests that scanning can provide accurate and reproducible measurements [3].

Custom orthotic devices manufactured with 3D scanning and rapid prototyping have been found to be a better geometrical fit, and have similar function, when tested against prefabricated orthotics [4]. Using 3D scanning methods for casting can be more economical and time efficient [4,5]. Additive manufacturing (AM) is a promising technique to mass produce custom AFOs; however, there is little data to quantitatively and qualitatively compare the AM approach to traditional casting methods [5]. There is a clear lack of technological data, as well as clinical acceptance, to the AM method of producing a custom AFO [6]. The ability to use AM approaches to consistently provide quality fitting AFOs is dependent on the ability to obtain accurate and reliable limb geometry using 3D limb scanning. Therefore, in this study we seek to evaluate the repeatability and validity of multiple lower limb measurements obtained using low-cost 3D limb scanning technology.

I.7 ***Literature cited / references (if attaching a grant or protocol enter N/A).***

1. Armitage, L., et al. (2019). "Reliability and validity of the iSense optical scanner for measuring volume of transtibial residual limb models." Prosthet Orthot Int 43(2): 213-220.
2. Armitage, L., et al. (2019). "Reliability and Validity of Measurement Tools for Residual Limb Volume in People With Limb Amputations: A Systematic Review." Phys Ther.
3. Mestre, S., et al. (2014). "Validation of lower limb segmental volumetry with hand-held, self-positioning three-dimensional laser scanner against water displacement." J Vasc Surg Venous Lymphat Disord 2(1): 39-45.
4. Mavroidis, C., et al. (2011). "Patient specific ankle-foot orthoses using rapid prototyping." J Neuroeng Rehabil 8: 1.
5. Totah, D., et al. (2017). "Manufacturing Choices for Ankle-Foot Orthoses: A Multi-objective Optimization." Procedia CIRP 65 145-150.
6. Jin, Y.-a., et al. (2015). "Additive Manufacturing of Custom Orthoses and Prostheses – A Review." Procedia CIRP 36 199-204.

II. Research Team

II.1 ***Principal Investigator***

Name	E-mail	College
Jason Wilken	jason-wilken@uiowa.edu	Carver College of Medicine

II.2 ***Team Members***

UI Team Members

Name	E-mail	College	Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Deactivated
Jason Wilken, PHD, MPT	jason-wilken@uiowa.edu	Carver College of Medicine	Yes	Yes	No		Yes	No
Kirsten Anderson, BSE	kirsten-m-anderson@uiowa.edu	Graduate College	Yes	Yes	No		Yes	No
Megan Grunst, High School	megan-grunst@uiowa.edu		No	No	No		Yes	No

Name	E-mail	College	Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Deactivated
Molly Pacha, BS, MS	molly-pacha@uiowa.edu	Carver College of Medicine	No	No	No		Yes	No
Olivia Powers, High School	olivia-powers@healthcare.uiowa.edu	Graduate College	Yes	Yes	No		Yes	Yes

Non-UI Team Members

Name	Institution	Location	FWA	Role	DHHS Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Email
Jeff Palmer	American Prosthetics & Orthotics	University of Iowa Hospitals and Clinics		Involved in the consent process by identification of potential participants, distribution of recruitment material, and answering any study related questions that patients have. Involved in conception and design of the study, and will provide clinical expertise to drafting and revision of the manuscript based on reviewing de-identified data.	No	No	Yes	No		Yes	jeffp@apoinc.com

II.3 ***The Principal Investigator of this study is:***
Faculty

II.6 ***Identify the key personnel. The system will automatically designate the PI and all faculty members on the project as "key personnel." For information about other team members who should be designated as "key personnel" please click on the help information.***

Name	Is Key Personnel
Jason Wilken, PHD, MPT	Yes
Kirsten Anderson, BSE	Yes
Megan Grunst, High School	No
Molly Pacha, BS, MS	No
Olivia Powers, High School	Yes
Jeff Palmer	Yes

II.5 ***Select research team member who is the primary contact for study participants.***
Jason Wilken

III. Funding/Other Support

III.1 ***Funding Sources***

Source Entered as Text	DSP Link	Type	Source Grant Title	Name of PI on Grant
Source is entered as text	no	No Funding		

* new source name

III.3 ***Does any member of the research team have a financial conflict of interest related to this project according to the Conflict of Interest in Research policy? If yes, please indicate which members below.***

Name	Has Conflict of Interest
Jason Wilken, PHD, MPT	No
Kirsten Anderson, BSE	No
Megan Grunst, High School	No
Molly Pacha, BS, MS	No
Olivia Powers, High School	No
Jeff Palmer	No

IV. Project Type

IV.1 ***Do you want the IRB to give this project***
Regular (expedited or full board) review

IV.2 ***Enter the date you will be ready to begin screening subjects/collecting data for this project. (If you do not have a specified date, add "upon IRB approval")***
06/1/2019

IV.3 ***Are you requesting a waiver of informed consent/authorization (subjects will not be given any oral or written information about the study)?***
Yes, but only for some of the subjects

IV.5 ***Describe the different study populations (subjects who are and are not giving consent)***
All potentially eligible individuals who contact the study team will be asked to complete a pre-screening process. Although we anticipate many individuals will consent for the study and become participants, a portion will not be eligible. We are requesting a partial waiver of consent for individuals who complete and fail the pre-screening process.

IV.6 ***Will subjects be provided with additional pertinent information after participation?***
No

IV.8 ***Indicate type of study (check all that apply)***
- Other - The project involves responses to screening questions before the subject gives consent to participate in order to determine eligibility for the study.

IV.9 ***List the earliest (beginning) date the data you wish to review were created:***
01 July 2019

IV.10 ***List the latest (ending) date the data you wish to review were created:***
01 December 2019

IV.11 ***Indicate sources of your data or specimens (check all that apply)***
- Other UI record sources - We will obtain screening information directly from the potential participant.

IV.12 ***List ALL of the variables, including any identifiers not previously entered or links to identifiers you plan to obtain/use for purposes of this study. (The information accessed should be the minimum data variables necessary for performing the desired analysis.)***
Pre-screening information collected for Group 1:
1. Are you able to read and write in English and provide written informed consent?
2. Are you between the ages of 18 and 75?
3. Are you healthy without current complaint of lower extremity pain, spine pain, active infections or medical or neuromusculoskeletal disorders that have limited your participation in work or exercise in the last 6 months?
4. Are you able to perform a full squat without pain?
5. Have you been diagnosed with a moderate or severe brain injury?
6. Have you been diagnosed with a physical or psychological condition that would preclude functional testing (e.g. cardiac condition, clotting disorder, pulmonary condition)?

7. Do you have a current complaint of pain or numbness in the spine?
8. Do you have any uncorrected visual or hearing impairment?
9. Do you require use of an assistive device?
10. Do you have a body mass index (BMI) over 35?
11. Do you have any open/unhealed wounds on any part of your lower extremity?

Pre-screening information collected for Group 2:
1. Are you between the ages of 18 and 75?
2. Do you use an ankle foot orthosis (AFO) to address unilateral, below knee functional deficits (e.g. fracture, muscle and/or nerve injury, ankle arthritis, or peripheral neurologic disease).
3. Are you able to standstill without using an assistive device (Cane or crutch)?
4. Will your affected leg tolerate full weight bearing without the use of an AFO?
5. Are you able to read and write in English and provide written informed consent?
6. Do you have an open/unhealed wound on any part of your lower extremity?
7. Does your AFO include a knee brace or go up on to your thigh?
8. Do you have any uncorrected visual or hearing impairments?
9. Do you have a body mass index (BMI) over 35?
10. Have you ever been diagnosed with a moderate or severe brain injury?

IV.13 ***A minimal risk study is a study in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.***

Explain why this study involves no more than minimal risk to subjects or to their privacy.
The pre-screening process has a low probability of loss of privacy and/or breach of confidentiality. Only yes/no responses will be recorded on forms without identifiers. The screening form does not contain any identifiable information, only information necessary to screen subjects will be collected.

IV.14 ***Explain why this consent waiver will not adversely affect the subject's rights and welfare.***
The form does not contain any personally identifiable information, and will be shredded if the potential participant does not enroll.

IV.15 ***Explain why it is impracticable (not possible) to conduct this research without a waiver of consent/waiver of authorization.***
We are only requesting a waiver for the screening process. It would be a meaningful additional burden for every potential participant to undergo the entire consent process if they do not meet the basic pre-screening criteria. The waiver would increase the feasibility of completing this student project and reduce the burden of individuals who are interested but clearly not eligible to participate.

IV.16 ***Will you be accessing any medical records or medical information, or do any of the data you plan to access meet the federal regulatory definition of protected health information (PHI)?***
No

IV.18 ***Describe your plan to protect any subject and/or specimen identifiers from improper use and disclosure. (Identifiers include but are not limited to names, addresses, dates directly related to the subject [such as birth date, date of admission/discharge, date of clinic visit/procedure/diagnosis], social security number, medical record number, pathology accession number, or other account numbers, etc.)***
There are no subject identifiers collected during the screening process.

IV.19 ***Describe your plan to destroy subject identifiers at the earliest opportunity consistent with the conduct of the research, or explain the health or research justification for retaining subject identifiers.***
There are no subject identifiers collected during the screening process.

V. Other Committee Review

V.1 ***Does this project involve any substance ingested, injected, or applied to the body?***

- ***Do not answer yes, if the involvement includes a device, wire, or instrument***

No

V.2 ***Are any contrast agents used for any purpose in this study?***
No

V.9 ***Will any subject be asked to undergo a diagnostic radiation procedure (including radiographic, nuclear medicine, DEXA)?***
No

V.14 ***Will any subject be asked to undergo a radiation therapy procedure (including external beam therapy, brachytherapy, or nuclear medicine therapy)?***
No

V.20 ***Does this project involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participant?***
No

V.21 ***Will any portion of this project be conducted in the CRU, or does it use any CRU resources?***
No

V.22 ***Will this project use:***

- ***any resource/patients of the Holden Comprehensive Cancer Center***
- ***involve treatment, detection, supportive care, or prevention of cancer***

No

V.25.a ***Will the study involve <u>any</u> of the following activity at UI Health Care, even if subjects or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with departmental or no funding)?***

- ***Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit; or***
- ***Physician services or services provided by non-physicians who are credentialed to bill (ARNPs, Physician Assistants, etc.)***

No

V.26 ***The study involves Department of Nursing Services and Patient Care nursing, nursing resources or evaluates nursing practices at UI Health Care.***
No

VI. Subjects

VI.1 ***How many adult subjects do you expect to consent or enroll for this project?***
60

VI.2 ***What is the age of the youngest adult subject?***
18.0

VI.3 ***What is the age of the oldest adult subject?***
75.0

VI.4 ***What is the percentage of adult male subjects?***
50

VI.5 ***What is the percentage of adult female subjects?***
50

VI.6 ***How many minor subjects do you expect to consent or enroll for this project?***
0

VI.13 ***Describe EACH of your subject populations***

- ***Include description of any control group(s)***
- ***Specify the Inclusion/Exclusion criteria for EACH group***

GROUP 1
Patient Inclusion criteria
• Ages: 18-75
• Healthy individuals without a current complaint of lower extremity pain, spine pain, active infections or medical or neuromusculoskeletal disorders that have limited participation in work or exercise in the last 6 months
• Ability to perform a full squat without pain
• Able to read and write in English and provide written informed consent

Patient Exclusion criteria
• Diagnosed moderate or severe brain injury
• Diagnosis of a physical or psychological condition that would preclude testing (e.g. cardiac condition, clotting disorder, pulmonary condition)
• Current complaint of pain or numbness in the spine
• Uncorrected visual or hearing impairments that limit the ability to understand or comply with instructions given during testing
• Require an assistive device
• Open/unhealed wounds on lower extremity.
• BMI greater than 35

GROUP 2
Patient Inclusion criteria
• Ages: 18-75
• Daily AFO use to address unilateral below knee functional deficits (e.g. fracture, muscle and/or nerve injury, ankle arthritis, or peripheral neurologic disease)
• Ability to stand independently without use of an assistive device (Cane, crutch, etc)
• Ability to safely bear full body weight on affected limb without use of an AFO or other protection
• Able to read and write in English and provide written informed consent

Patient Exclusion criteria
• Use of an AFO that crosses the knee (includes Knee brace or similar)
• Open/unhealed wounds on lower extremity
• Uncorrected visual or hearing impairments that limit the ability to understand or comply with instructions given during testing
• BMI greater than 35
• Diagnoses of a moderate to severe brain injury

VI.14 ***Provide an estimate of the total number of subjects that would be eligible for inclusion in each of your study populations (include your control population if applicable)***
For Group 1, the precise number of potential participants is not fully known; however, there are thousands of individuals in the local community who would be eligible. For group 2, AFOs are commonly used to treat lower extremity deficits in individuals who have experienced musculoskeletal or peripheral nervous system injury or disease. Discussions with local orthotists confirm that hundreds of individuals meeting the proposed inclusion and exclusion criteria receive care at local prosthetics and orthotics clinics.

VI.15 ***Describe how you will have access to each of your study populations in sufficient number to meet your recruitment goals.***
For Group 1, we expect a sufficient number of community members will volunteer. We will use a range of recruitment tools to identify individuals including paper flyers, broadcast email through the UI mass email service, and face-to-face interaction with study team members.
For Group 2, study recruitment efforts will be coordinated with the Iowa City branch of American Prosthetics and Orthotics (APO). Hundreds of individuals receive orthotic care from the Iowa City branch of APO, greatly exceeding the number of individuals who would be required for the study. APO has records of all individuals with AFOs seen in their clinic and maintains all necessary contact information.

VI.16 ***Do you plan to recruit/enroll non-English speaking people?***
No

VI.18 ***Do you propose to enroll any of the following in this study as subjects?***

- ***Employee of the PI or employee of a research team member***
- ***Individual supervised by PI or supervised by member of research team***
- ***Individual subordinate to the PI or subordinate to any member of the research team***
- ***Student or trainee under the direction of the PI or under the direction of a member of the research team***

No

VI.20 ***Will subjects provide any information about their relatives?***
No

VI.23 ***Will anyone (other than the subject) provide you with information about the subject (e.g. proxy interviews)?***
No

VI.26 ***Is this project about pregnant women?***
No

VI.27 ***Will this project involve fetuses?***
No

VI.28 ***Does this project involve adult subjects who may be incompetent or have limited decision-making capacity on initial enrollment into the study?***
No

VI.32 ***Does this project involve subjects whose capacity to consent may change over the course of the study?***
No

VI.37 ***Does this project involve prisoners as subjects?***
No

VII.A. Project Description (A)

VII.A.1 ***Where will project procedures take place (check all that apply)?***
- Other UI campus site - Human Performance and Clinical Outcomes Lab 21D EMRB
- U.S. off-campus - American Prosthetics and Orthotics, Iowa City, IA 52242

VII.A.2 ***Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?***
No

VII.B. Project Description (B)

VII.B.1. ***Does this project involve any of the following (Check all that apply):***
- ☐ **Interventional** – Includes **Clinical (or Treatment) trial**, **Physiology intervention/study**, **Behavioral intervention/study**, **Diagnostic Trial**.
- ☐ **Observational**
- ☐ **Expanded Access** – A process regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial. Examples of expanded access include non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access to investigational drug, and parallel track (ClinicalTrials.gov & FDA).
- ☑ **Registry** – The collection and maintenance of data (not including biologic samples) in which: (1) the individuals in the registry have a common or related condition(s), and/or (2) the individuals in the registry are interested in being contacted for future studies by investigators other than those listed in Section II of this project.(UI Guide)
- ☑ **Repository** – The collection, storage, and distribution of human biologic samples and/or data materials for research purposes. Repository activities involve three components: (i) the collection of data and/or specimens such as blood, tissue, saliva, etc.; (ii) the storage of data or specimens, and data management function; and (iii) the sharing of data/specimens with recipient investigators other than the original investigators. (paraphrased from OHRP)
- ☐ **Other**

VII.B.2 ***Does this project involve a drug washout (asking subject to stop taking any drugs s/he is currently taking)?***
No

VII.B.11 ***Is there a separate, written protocol that will be submitted in addition to this IRB New Project form? (Note: a grant application is not considered to be a protocol)***
No

VII.B.18 ***Does this project involve testing the safety and/or efficacy of a medical device?***
Yes

VII.B.19 ***Describe in detail procedures in place for maintaining device shipment and receipt records:***
The device will not be provided to study participants. Study staff will use the Wilken Lab structure scanner to take optical scans of the limb.

VII.B.20 ***Who will be responsible for maintaining these shipment and receipt records?***
Not applicable. The device will not be provided to study participants. Study staff will use the Wilken Lab structure scanner to take optical scans of the limb.

VII.B.21 ***Describe in detail procedures in place for tracking use and disposition of devices described in this study:***
Not applicable. The device will not be provided to study participants. Study staff will use the Wilken Lab structure

scanner to take optical scans of the limb.

VII.B.22 ***Who will be responsible for maintaining these use and disposition tracking records?***
Not applicable. The device will not be provided to study participants. Study staff will use the Wilken Lab structure scanner to take optical scans of the limb.

VII.B.23 ***Describe in detail procedures in place to limit access to authorized study personnel for the storage, control, and dispensing of the investigational devices. (For example, investigational devices are kept in a locked area away from approved devices or have a keyed interlock, and only study personnel authorized to dispense the device have the keys)***
Not applicable. The device will not be provided to study participants. Study staff will use the Wilken Lab structure scanner to take optical scans of the limb.

VII.B.24 ***Is the device FDA-approved for the way it will be used in this study?***
No

VII.B.25 ***Is there an IDE (Investigational Device Exemption) for this device in this research project?***
No

VII.B.29 ***Indicate the appropriate FDA status you and/or the sponsor are requesting for the use of this device in this study.***
Non-Significant Risk (NSR) device/software

VII.B.31 ***Provide a detailed rationale for why this device meets the FDA definition of a Non-Significant Risk Device (NSR)***
The device is an optical scanner. The device does not contact individuals, emit radiation or interact with the individual in any manner.

Consistent with 21 CFR 812.3(m)It is not an implant, it does not interact with the individual, it does not presents a potential for serious risk to the health, safety, or welfare of a subject; is not purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject, is not for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject and does not present a potential for serious risk to the health, safety, or welfare of a subject.

VII.B.32 ***Provide a summary of prior investigations with this device.***
Although our current study team has not conducted prior investigations with this device, it is currently in use by American Prosthetics and Orthotics and many other clinics nationally for patient care purposes. The scanner is used to determine initial geometry, however, a clinician is responsible for determining the final prosthetic or orthotic geometry for patient care purposes.

VII.B.33 ***Have there been any prior IRB reviews (at UI or elsewhere) and/or determinations made with regard to this device?***
No

VII.B.35 ***Has the FDA made an assessment of risk with regard to this device?***
No

VII.B.36 ***Has this device/software been approved by the FDA for another indication or in another form from its use in this project?***
No

VII.C. Project Description (C)

VII.C.1 ***Does this project involve any research on genes or genetic testing/research?***
No

VII.D. Project Description (D)

VII.D.1 ***Check all materials/methods that will be used in recruiting subjects (you will need to attach copies of all materials at the end of the application):***

- Referral from colleague - Other CPO's at APO may distribute flyers, but only IRB approved APO staff will call potential participants as follow up.

- Other - IRB approved APO staff will use APO PHI to identify and contact potential subjects. Recruitment letters may be mailed to provide an introduction to the study and will include research team contact information and define a timeline for response, after which the research team may follow up. If individuals approach the study team member in person, a response consistent with the phone script will be used.
- Posters -
- E-mail -
- Letter -

VII.D.8 ***Will a member of the research team discuss the study with the subject in person prior to the subject agreeing to participate?***
Yes

VII.D.9 ***Describe the physical location where the consent process will take place:***
The consent process will be an individual face-to-face interaction with one of the research team members and will take place at a private location identified to ensure comfort and privacy, allowing the potential participant the ability to freely ask questions. The location for consent will be at either the Human Performance and Clinical Outcomes Lab (WilkenLab) at 21D EMRB or APO.

VII.D.10 ***Will a member of the research team discuss the study with the subject by phone prior to the subject agreeing to participate?***
Yes

VII.D.11 ***Describe:***
Potential participants can contact the study team to express interest in the study after seeing the flyer, letter, or emails If they contact the study team, potential participants will be provided a general overview of the intent of the study consistent with the phone script or email response. Potential participants will also be contacted by individuals from APO after an introductory letter is provided, as described in section VII.D.1.

VII.D.12 ***Who will be involved in the consent process (including review of consent document, answering subjects' questions)?***

Name	Consent Process Involvement
Jason Wilken, PHD, MPT	Yes
Kirsten Anderson, BSE	Yes
Megan Grunst, High School	Yes
Molly Pacha, BS, MS	Yes
Olivia Powers, High School	Yes
Jeff Palmer	Yes

VII.D.15 ***Check all materials that will be used to obtain/document informed consent:***
- Consent Document

VII.D.16 ***Are you requesting a waiver of documentation of consent (either no subject signature or no written document)?***
No

VII.D.19 ***Before the subject gives consent to participate are there any screening questions that you need to directly ask the potential subject to determine eligibility for the study?***
Yes

VII.D.20 ***List any screening questions you will directly ask the potential subject to determine eligibility.***
GROUP 1
Inclusion Criteria: All must be checked YES to be eligible for study
1. Are you able to read and write in English and provide written informed consent?
2. Are you between the ages of 18 and 75?
3. Are you healthy without current complaint of lower extremity pain, spine pain, active infections or medical or neuromusculoskeletal disorders that have limited your participation in work or exercise in the last 6 months?
4. Are you able to perform a full squat without pain?

Exclusion Criteria: All must be checked NO to be eligible for study
1. Have you been diagnosed with a moderate or severe brain injury?
2. Have you been diagnosed with a physical or psychological condition that would preclude functional testing (e.g. cardiac condition, clotting disorder, pulmonary condition)?
3. Do you have a current complaint of pain or numbness in the spine?
4. Do you have any uncorrected visual or hearing impairment?
5. Do you require use of an assistive device?
6. Do you have a body mass index (BMI) over 35?

7. Do you have any open/unhealed wounds on any part of your lower extremity?

GROUP 2
Inclusion Criteria: All must be checked YES to be eligible for study
1. Are you between the ages of 18 and 75?
2. Do you use an ankle foot orthosis (AFO) to address unilateral, below knee functional deficits (e.g. fracture, muscle and/or nerve injury, ankle arthritis, or peripheral neurologic disease).
3. Are you able to standstill without using an assistive device (Cane or crutch)?
4. Will your affected leg tolerate full weight bearing without the use of an AFO?
5. Are you able to read and write in English and provide written informed consent?

Exclusion Criteria: All must be checked NO to be eligible for study
1. Do you have an open/unhealed wound on any part of your lower extremity?
2. Does your AFO include a knee brace or go up on to your thigh?
3. Do you have any uncorrected visual or hearing impairments?
4. Do you have a body mass index (BMI) over 35?
5. Have you ever been diagnosed with a moderate or severe brain injury?

VII.D.21 ***Will you keep a screening log or other record that would include information on people who do not enroll in the study?***
No

VII.D.25 ***After the subject agrees to participate (signs consent), are there any screening procedures, tests, or studies that need to be done to determine if the subject is eligible to continue participating?***
Yes

VII.D.26 ***List and describe screening***
Group 1
Additional post-screening questions and activities will be completed consistent with the attached enrollment checklist

We will verify their age is between 18 and 75 and record their gender.
We will record their height and weight, and verify their BMI is less than 35.
We will have the subjects complete a full squat and verify that they are able to squat without pain.

Group 2
Additional post-screening questions and activities will be completed consistent with the attached enrollment checklist.
We will have participants answer questions on a patient history questionnaire asking about their AFO use, and the nature of their medical condition.

Post-screening questions:
We will verify their age is between 18 and 75 and record their gender.
We will record their height and weight, and verify their BMI is less than 35.
We will have the subjects stand with their AFO and no other assistive device, and verify they can accomplish this task safely.
We will have the subjects stand without their AFO and no other assistive device, and verify they can accomplish this task safely.

Patient history questionnaire:
We will record the date or injury or start of the condition requiring AFO use.
We will record the duration of AFO use.
We will record how long they have been using their current AFO.
We will record the nature of their medical condition.

VII.D.27 ***Discuss how much time a potential subject will have to agree to consider participation and whether or not they will be able to discuss the study with family/friends before deciding on participation.***
Data collection will take place at scheduled times. If an individual would like additional time to consider participation and/or request additional time to speak with family or friends, their visit will be rescheduled at a later date.

VII.D.28 ***How long after the subject agrees to participate do study procedures begin?***
Immediately following consent.

VII.D.29 ***Provide a description of the enrollment and consent process for adult subjects***

- ***Describe each study population separately including control population***
- ***Include when recruitment and consent materials are used***
- ***Use 3rd person active voice "The Principal Investigator will identify subjects. For example, the principal investigator will identify potential subjects, the study coordinator will discuss the study with subjects over the telephone and schedule the first study visit, etc..."***

- ***Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process***

The study population for each group will consist of individuals that meet all of the listed inclusion and none of the exclusion criteria as verified using the pre-screening and post-consent questions and brief assessment as listed on the enrollment checklist.

Participants for this proposed study for Group 1 will be recruited through paper flyers posted around the UI campus, and in APO spaces, word of mouth, and broadcast email (UI mass email service). If a team member is approached by an interested party they will respond in a manner following the HPCO phone script. They will be invited to contact a member of the study team through email or by phone. A time will be identified for the potential participant to meet with a member of the study team to review the consent form. The consent process will take place in a comfortable setting where the potential participant is able to ask as many questions they deem fit without pressure. A study team member will review the consent form with the potential participant and the participant will sign the consent form only after all questions are addressed.

We expect a majority of the participants for Group 2 of the proposed study will be recruited through CPOs' contact with potential subjects that meet the inclusion/exclusion criteria via paper flyer handouts at appointments, mailed recruitment letters or follow up phone calls. A follow up phone call will only be placed if there is no response from the potential subject two weeks after having received the recruitment letter. Potential participants may be given a flyer by either IRB approved staff, listed in II.2, or by colleagues who are not listed as study team members during their visit to the APO clinic. Informational letters and follow up phone calls will only be conducted by IRB approved APO staff at APO. Potential subjects receiving the recruitment letter will be informed they can let the study team know if they do not wish to participate or be called. Additionally, a broadcast email sent through the UI mass email service and paper flyers posted and handed out in the APO clinic may be used in the event that not enough subjects are recruited through American Prosthetics and Orthotics. All recruitment materials will contain contact information for the research study team and potential subjects will be invited to contact a member of the study team through email or by phone. If the potential participant encounters a study team member distributing flyers the study team member will respond in a manner consistent with the phone script. A study team member will initially use the pre-screening checklist to assess eligibility. If they are eligible or wish to complete the pre-screening in person a study team member will work with the potential participant to identify a time for them to meet with a member of the study team.

The study team member will conduct the consent process in a comfortable setting (21D EMRB or APO) where the potential participant is able to ask as many questions they deem fit without pressure. To minimize the risk of coercion, the clinical providers will not be involved in the consenting process and will specify that the patient's participation or lack thereof, in the study will have no effect on the care they receive. The study team member will verify that the potential participant meets all inclusion and exclusion criteria using the questions and activities listed on the enrollment checklist. Before reviewing the informed consent document, Group 2 subjects will be provided a consent summary, to review in addition to the consent document. Then for both groups a study team member will review the entire consent form with the potential participant and the participant will sign the consent form only after all questions are addressed. No methods of coercion shall be used for recruitment.

VII.D.37 ***Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?***

Examples:

- ***Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.***
- ***Participants will be provided with false information regarding the particular behaviors of interest in the research.***
- ***Procedures include a confederate pretending to be another participant in the study.***
- ***Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.***
- ***Study is designed to introduce a new procedure (or task) that participants are not initially told about.***
- ***If yes, a waiver of informed consent must be requested under question IV.3.***

No

VII.E. Project Description (E)

VII.E.1 ***Will subjects be randomized?***
No

VII.E.3 ***Will any questionnaires, surveys, or written assessments be used to obtain data directly from subjects in this study?***
Yes

VII.E.4 ***List all questionnaires, surveys, written assessments and ATTACH each one to the application. (NOTE: You are NOT prohibited from attaching copyrighted materials to this application)***
Group 2 - Patient History Questionnaire

VII.E.5 ***Does this project involve creating any audiotapes, videotapes, or photographs?***
Yes

VII.E.6 ***Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.***

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

DESCRIBE:

- ***What subjects will be asked to do/what happens in the study (in sequential order)***
- ***The time period over which procedures will occur***
- ***The time commitment for the subject for individual visits/procedures***
- ***Long-term followup and how it occurs***

The approximate time required to complete all study activities (including consent) is 30-60 minutes.

Potential participants will answer pre-screening questions as listed on the Enrollment Checklist, these questions offer no inconvenience to the participant if after answering they are deemed ineligible to participate in the study. If they meet all inclusion and exclusion criteria they will be consented to participate. It is possible that additional information may come to light during study participation that indicates the individual does not meet the inclusion criteria, at which point their participation would end.

Following consent, post-screening questions will be completed to further verify a subject's eligibility in the study. These questions are asked post-consent because of the more involved nature of the materials, height and weight measurement, simple movement tasks to confirm eligibility. If the subject does not meet the post-screening question requirements, then their participation in the study will be terminated.

For group 2, personal and demographic factors collected in the Patient History Questionnaire will be used to characterize the study participants. We will collect multiple variables including age, gender, height, weight, and pathology to characterize the cohort. All patient health and demographic information will be self-reported by the patient while they are present in the study space, and no information will be collected from the patient's medical record at UIHC or APO.

All consent and data collection for Group 1 will be conducted at 21D EMRB. Group 2 consent and data collection will take place at either APO or 21D EMRB.

At time point 1, three scans using the Structure Core sensor will be obtained. Similarly, a digital caliper will be used to obtain three measures at pre-identified landmarks. A tape measure will be used to obtain limb circumference measures. Measurements that will be taken are 1) width of the metatarsal heads, 2) width of the calcaneus, 3) foot length, 4) foot height, 5) arch height, 6) medial-lateral width between ankle malleoli, 7) minimum circumference above the ankle malleoli, 8) maximum calf circumference, 9) medial-lateral width of the knee condyles 10) anterior-posterior width at mid patellar tendon, 11) distance from bottom of foot to tibial tubercle.

At time point 2 (same day as time point 1) the three scans using the Structure Core sensor will be obtained, precise calipers and a tape measure will again be used to obtain three measures at pre-identified landmarks.

The order of obtaining digital scans and physical measurements will be randomized across subjects to account for potential changes in limb volume during the course of testing.

All physical measurements will be stored for future data analysis. All limb scans will be stored for a 30 day period before being deleted; allowing time to extract digitally analyzed measurements. This set period for retention of the scans is mandatory for participation in this study. All personal identifiers will be kept separately from other data. Only a limited access master key document will link two data sets. Identifiable information will be kept in hard copy within locked file cabinets in restricted access areas or in a password protected database in restricted access of Dr. Wilken's lab in 21D EMRB. Dr. Wilken has used these procedures for multiple funded grants.

VII.E.7 ***Will you attempt to recontact subjects who are lost to follow-up?***
No - followup is not required in this study

VII.E.9 ***Will subjects be provided any compensation for participating in this study?***
No

VIII. Risks

VIII.1 ***What are the risks to subjects including***
- emotional or psychological
- financial

- legal or social
- physical?
The proposed study activities are considered no more than minimal risk which presumes that risks of the research are not greater, in and of themselves, than those ordinarily encountered in daily life. The risk benefit ratio of this proposed study is considered justifiable as it is relatively low risk and will provide valuable data, and lay an important knowledge framework for future AFO casting for patient populations.

The primary risks to study participants are loss of privacy and/or breach of confidentiality, which are known risks inherent to all research studies. To protect privacy and prevent breaches of confidentiality, we will use the minimal amount of identifiable information possible while still meeting the needs of the study. All study personnel will demonstrate knowledge of applicable regulations by completing courses of instruction through the CITI program. A code (e.g. P001) will be used to represent individuals on all study forms and files. Research team members will use standard practices to preserve the privacy of the participant as much as possible, such as refraining from discussing sensitive topics, referring to private health information or other personally identifiable information. Further, the scans of participants will be kept in a restricted access location.

Secondary risks to study participants are the possibility of injury or physical discomfort during implementation of study assessments. Subjects will be asked to stand on a platform without an AFO to conduct the 3D scanning methods.

VIII.2 ***What have you done to minimize the risks?***

- ***If applicable to this study ALSO include:***
  - ***How you (members of your research team at Iowa) will monitor the safety of individual subjects.***
  - ***Include a description of the availability of medical or psychological resources that subjects might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)***

Study staff will speak with participants throughout the testing session to ensure safety and comfort. Risks to participants in the study are low since the protocol involves standing. The subject will be informed to indicate in person, or when not immediately evident, inform over the phone if any adverse event occurs. The event will be monitored and reported to the IRB in accordance with the governing policy and procedures. If an event occurs during the implementation of study procedures the most senior person locally available will be notified and a study team member can help facilitate securing appropriate medical or professional intervention if needed. In addition, a report of the adverse event will be provided to the IRB as required.
To minimize the risk of loss of confidentiality of data study activities will take place in the HPCO lab, away from other individuals. Collected data will be logged and tracked using a non-identifying participant code and time date code (alphanumeric subject ID (e.g. S001) and/or YYYYMMDD_TTTT) to protect participants identity. Study files will be carefully secured, paper copies through locked storage and electronic copies in a password-protected environment. Access to this information will be limited to properly trained individuals on the study team who require access.

VIII.3 ***Does this study have a plan to have an individual or committee review combined data from all subjects on a periodic basis (such as summary or aggregate safety and/or efficacy data)?***
No

IX. Benefits

IX.1 ***What are the direct benefits to the subject (do not include compensation or hypothesized results)?***
Participants will not receive direct benefit from participating.

IX.2 ***What are the potential benefits to society in terms of knowledge to be gained as a result of this project?***
The results of this study will provide valuable data to for future clinical AFO casting optimization.

X. Privacy & Confidentiality

X.1 ***What are you doing to protect the privacy interests of the subjects?***
The informed consent process and study procedures will be conducted in a private and secured laboratory space (21D EMRB or APO) to minimize the likelihood of individuals observing their participation or overhearing the participant's personal information. All data collection files and paperwork are coded at the time of collection (alphanumeric subject ID and/or YYYYMMDD_TTTT) ensuring there are no readily available links to the individual. Consent forms will be kept separate from data files. The participant video will be kept on a password restricted drive only accessible to authorized individuals. Further, we seek to collect no more data than necessary to answer the research question.

X.2 ***Are you collecting the Social Security Number of any subjects for any purpose?***
No

X.4 ***How will information/data be collected and stored for this study (check all that apply):***

- Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.) - Data will be coded with links stored separately. Paper/hard copy study records will be stored in secured locations such as locked file cabinets in limited access locations within the Department of Physical Therapy and Rehabilitation Science (Wilken Lab space in MEB and/or EMRB). Only coded data will be retained. Additionally, the previously described contact information will be retained separately.
- Electronic records (computer files, electronic databases, etc.) - Electronic records (computer files, etc.) will be stored on password protected computers and/or Dr. Wilken's RDSS network server drive. Access to the network requires both individual access to a University of Iowa computer using Healthcare ID and password, and permission to access the study folder which is controlled by Dr Wilken via HCIS. These steps serve to limit access to only study team members who can and need to have access. Only coded data will be retained. Additionally, the previously described contact information will be retained separately.
    - Name - Shari Lewison
    - Title - Director, Information Security
    - University Job Classification - Faculty/Staff

X.5 ***Do the confidentiality protections indicated above allow only members of the research team to access the data/specimens?***
Yes

X.7 ***Does your study meet the NIH criteria for a Certificate of Confidentiality or will you be applying for Certificate of Confidentiality?***
No

XI. Data Analysis

XI.1 ***Describe the analysis methods you will use, including, if applicable, the variables you will analyze***
The data evaluation and statistical analysis for each aim is listed below:

Each 3D scan will be assessed by two raters to identify the digital landmarks of interest. The average of three values from time point 1 will be used to represent time point 1 and the average of three values at time point 2 will be averaged to represent time point two.

For Aim 1, the intraclass correlation coefficient (ICC) and minimal detectable change (MDC95) values will be calculated for each measure for comparisons between time point 1 and time point 2.

Measurements will be taken using the digital calipers or a tape measure at the identified landmarks of interest. The average of three values from time point 1 will be used to represent time point 1 and the average three measurements from time point 2 will be used to represent time point 2

For Aim 2, the ICC and MDC95 values will be calculated for each measure for comparisons between time point 1 and time point 2.

For Aim 3, concurrent validity will be determined by evaluating the correlation between measurements obtained using limb scanning and the calipers.

XI.2 ***Provide the rationale or power analysis to support the number of subjects proposed to complete this study.***
The total number of participants proposed for each group in this study is consistent with prior studies by Dr. Wilken related to AFO design. We are not aware of any existing data directly related to analyzing the repeatability and validity of 3D scanning for length and width measurement. Using the central limit theorem a total of 20 participants are required to get a stable estimate of the variability of a measure. It is for this reason we chose to enroll at least a total of 20 participants per group. 20 is the minimum target number, but due to a high volume of responses from the community more than 20 subjects can be enrolled.

XII. Future Research

XII.1 ***Do you wish to keep any information about subjects involved with this research project so that members of the current research team may contact them in the future for your own research projects?***
Yes

XII.2 ***Do you wish to keep any information about subjects involved with this research project so that other researchers may contact them for future research?***
No

XII.3 ***List the data or information you will keep:***
First and Last name, Preferred phone number, Secondary phone number, Email address, Gender, Birth month, Birth

year, Interest in contact for future studies.

XII.4 ***Does this project involve storing any data, tissues or specimens for future research?***
Yes – contribution for future use is mandatory for participation in the study