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14. ABSTRACT The purpose of this project is to improve the lives of people with above-knee limb loss. The scope of work includes two parts: First, testing 30 transfemoral amputees to determine how in-socket mechanics are related to comfort/function and identifying readily available clinical measurements that are associated with residual femur motion, skin strain, and peak pressure within the socket during dynamic activities, and second, developing a quantitatively informed design optimization process that will be evaluated and compared to the current standard of care in a pilot clinical trial. Progress during this period includes obtaining IRB-approval to perform the study and finalizing a contract with the company that will provide test sockets and fitting for our research participants.					
15. SUBJECT TERMS Amputee, transfemoral, biplane radiography, ultrasound, patient-reported outcomes, kinematics residual femur motion, skin strain, socket, prosthesis, pressure					
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1. Introduction

The purpose of this project is to improve the lives of people with above-knee limb loss. The first part of the project involves testing 30 transfemoral amputees in a laboratory setting. Participants will walk on a treadmill wearing their current socket plus 8 different check sockets with designed changes in different structural measurements that will very likely induce changes in residual limb motion, skin strain, and pressure distribution within the socket. The magnitudes of these changes, as well as changes in other pertinent variables, will be determined for each socket (see Data Collection and Socket Modifications below). These different sockets will affect physical performance as well as patient-reported comfort and function. We will use dynamic biplane radiography and pressure sensors to measure in-socket residual limb mechanics (residual femur motion, skin strain, pressure distribution) for each socket. We will also collect patient-reported outcomes after wearing each socket. Aim 1 will identify the in-socket mechanisms associated with better and worse comfort and function (Figure 1, green background). To address the second Aim, we will use more readily available measurement tools, applied to every check socket and obtained at the same sessions as Aim 1

measurements, to characterize residual limb morphology and function. We will then identify which of those readily available measurements best predict in-socket mechanics that can only be measured using expensive and complicated research equipment

(Figure 1, green background). We will then develop a predictive algorithm that will use the readily available clinical measurements to guide a quantitatively informed socket design and optimization process. The second part of the project will be a pilot clinical trial to evaluate the efficacy and cost of a

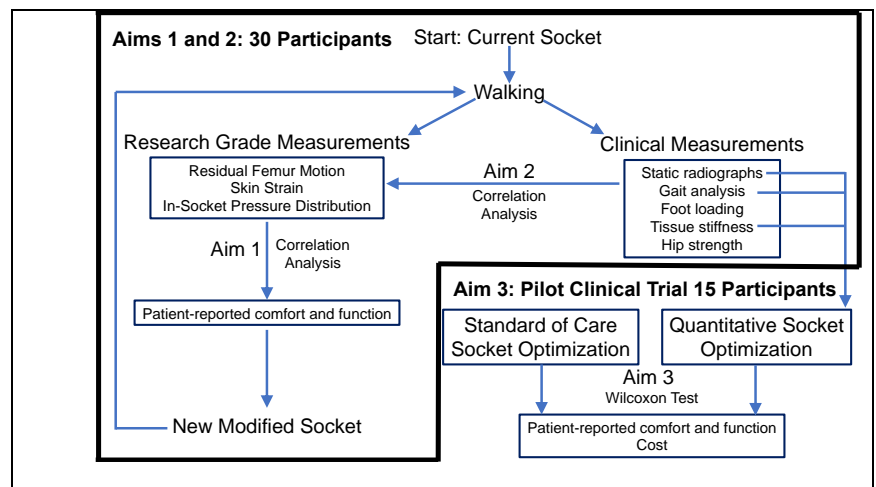


Figure 1: Flowchart showing the relationship between Aims 1 and 2 (green background), and the pilot clinical trial, Aim 3 (orange background). As an example, the flowchart shows three clinical measurements identified in Aim 2 that correlate to in-socket mechanics obtained from research grade measurements. In this example, those three clinical measures will then be used as predictors to guide the quantitative socket design.

quantitatively informed socket design and optimization process (based upon the predictive model) compared to the current clinical standard of care. The pilot clinical trial will involve a new cohort of 15 transfemoral amputees (Figure 1, orange background).

2. Keywords

Amputee, transfemoral, biplane radiography, ultrasound, patient-reported outcomes, kinematics residual femur motion, skin strain, socket, prosthesis, pressure.

3. Accomplishments

What were the major goals of the project? The major goals and target completion dates are provided below from the Statement of Work. We are currently in month 15 of the project.

Specific Aim 1(Identify the in-socket mechanics associated with physical performance and patient-reported comfort and function.)	Timeline	Milestone Progress
Recruitment	Months	
IRB application	1-3	Done
Trial registration/advertisement	4-6	Done
Screening/enrollment	7-18	In progress (5 participants identified)
Milestone(s) Achieved		
Local IRB/IACUC Approval	1	Done
Milestone Achieved: HRPO/ACURO Approval	6	Done
Milestone Achieved: 18 subjects enrolled	18	In Progress
Milestone Achieved: 30 subjects enrolled	24	
Data collection		
Socket fabrication	7-24	
CT/Ultrasound scans	7-24	
Dynamic X-ray, motion capture, plantar pressure, hip strength, static radiographs, data collection	7-24	
Milestone(s) Achieved:		
First 10 subjects completed data collection	12	
First 20 subjects completed data collection	18	
All 30 subjects completed data collection	24	
Data analysis and dissemination		
Data processing	7-30	
Statistical analysis	16-30	
Interpretation and reporting	30-32	
Milestone(s) Achieved:		
Post processing completed for first 10 subjects	16	
Post processing completed for first 20 subjects	23	
Post processing completed for all 30 subjects	30	
Preliminary statistical analysis for first 10 subjects	18	
Statistical analysis for complete data (all subjects)	32	
Conference abstract/Manuscript submitted	32	
Specific Aim 2 (Identify readily available clinical measurements that are associated with residual femur motion, skin strain, and peak pressure within the socket during dynamic activities)		
Data collection		
Obtain clinical measures concurrent with data	7-24	

collection for Aim 1		
Data analysis and dissemination		
Statistical analysis	30-32	
Interpretation and reporting	30-32	
Milestone(s) Achieved:		
Data collected for all 30 subjects	24	
Conference abstract/Manuscript submitted	32	
Specific Aim 3 (Develop and evaluate an improved socket design process using a predictive model based upon clinical measurements)		
Recruitment	Months	
IRB application	32-34	
Trial registration/advertisement	32-34	
Screening/enrollment	34-36	
Process development		
Generate predictive model	32-34	
Define standardized protocol for socket fabrication	32-34	
Process validation		
Recruitment	34-46	
Socket fabrication	34-46	
Data collection	34-46	
Analysis, Interpretation	47-48	
Milestone(s) Achieved:		
Local IRB/IACUC Approval	33	
HRPO/ACURO Approval	34	
Fabrication process defined	34	
Data collected from all subjects	46	
Statistical Analysis completed	47	
Dissemination	48	

What was accomplished under these goals? The major accomplishments during this period were: 1) receiving HRPO approval, 2) completing the trial registration, 3) outside collaborator completing CITI training, 4) completing a mock data collection session with our outside collaborator, 5) submitting a protocol paper to the journal Trials, 6) identifying volunteers to participate in the study.

The mock data collection session was extremely valuable. We confirmed the feasibility of all of the data collection systems we plan to use and we acquired pilot data that we will use to develop computer code to analyze the data. Additionally, we are now confident we can test all of the proposed sockets in a single data collection session. Thus far we have identified 5 volunteers who are interested in participating.

What opportunities for training and professional development has the project provided? The co-PIs agreed to mentor a Graduate Engineering Education Scholarship student (Ruth Segall) who will gain research experience as part of this project. She will have opportunities to assist in recruitment, to observe data collection, and to contribute to processing and analyzing data.

How were the results disseminated to communities of interest? Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals? We will purchase some simple tools (a saw and sander) to perform modifications to the socket in our laboratory during testing. This will allow the participant to complete all testing in a single day. We will continue to develop computer code to process and analyze the data. We will screen and schedule participants and we plan to test several participants within the next reporting period.

4. Impact

What was the impact on the development of the principal discipline(s) of the project? Nothing to report.

What was the impact on other disciplines? Nothing to report.

What was the impact on technology transfer? Nothing to report.

What was the impact on society beyond science and technology? Nothing to report.

5. Changes/Problems

Changes in approach and reasons for change. Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them. There was a delay due to our outside collaborator needing to complete his CITI training (human subjects). That problem has been resolved.

Changes that had a significant impact on expenditures. Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents. Nothing to report.

Significant changes in use or care of human subjects. Nothing to report.

Significant changes in use or care of vertebrate animals. Nothing to report.

Significant changes in use of biohazards and/or select agents. Nothing to report.

6. Products

Publications, conference papers, and presentations.

Journal publications. Manuscript submitted to Trials: "Within-subject effects of standardized prosthetic socket modifications on physical function and patient-reported outcomes".

Books or other non-periodical, one-time publications. Nothing to report.

Other publications, conference papers, and presentations. Nothing to report.

Website(s) or other Internet site(s).

Clinical trials registration: <https://clinicaltrials.gov/ct2/results?pg=1&load=cart&id=NCT05041998>

Pitt+Me recruitment: <https://pittplusme.org/studyarms/publicdetails?guid=999b4c58-7916-45ae-a082-acd146f7028f>

Technologies or techniques. Nothing to report.

Inventions, patent applications, and/or licenses. Nothing to report.

Other Products. Nothing to report.

7. Participants & Other Collaborating Organizations

What individuals have worked on the project?

Name:	William Anderst
Project Role:	Co-PI
Researcher Identifier:	
Nearest person month worked:	3
Contribution to Project:	IRB application, organizing and participating in mock data collection, confirming in-socket sensors function correctly, report preparation, manuscript editing
Funding Support:	

Name:	Goeran Fiedler
Project Role:	Co-PI
Researcher Identifier:	https://orcid.org/0000-0003-1532-1248
Nearest person month worked:	3
Contribution to Project:	IRB application, organizing and participating in mock data collection, report preparation, manuscript writing, trial registration
Funding Support:	

Name:	Tom Gale
Project Role:	Engineer
Researcher Identifier:	

Nearest person month worked:	1
Contribution to Project:	Software development, pressure sensor testing
Funding Support:	

Name:	Lisa Tilford
Project Role:	Research coordinator
Researcher Identifier:	
Nearest person month worked:	1
Contribution to Project:	IRB submission and revisions, participant recruitment and screening
Funding Support:	

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period? Nothing to report.

What other organizations were involved as partners?

Organization Name: DeLaTorre P&O

Location of Organization: 300 Alpha Drive, Pittsburgh, PA, 15238

Partner's contribution to the project: In-kind support, collaboration.

8. Special Reporting Requirements

Quad Chart: Attached with appendices

9. Appendices