Bioimpedance as a Diagnostic Tool for Assessing the Need for Socket Modification in Transtibial Amputees

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Study Protocol

The purpose of the proposed study is to conduct a study on individuals with lower limb amputation evaluating if residual limb fluid volume data collected using a novel non-invasive device is beneficial towards prosthetic prescription, fit, and comfort as determined by amputee test subjects and practitioners (prosthetists). Residual limb volume/mass changes typically affect prosthetic limb fit of people with limb amputation, and changes in limb volume/mass can put the limb at risk of injury and preclude use of the prosthesis.

Participants' residual limb fluid volume will be monitored through segmental bioimpedance analysis both before and after a practitioner-issued modification to the prosthesis as an observational cohort study and a blinded randomized clinical trial in which the data may or may not be shared with the practitioner before the modification is made to the prosthesis.

The Specific Aims are to:

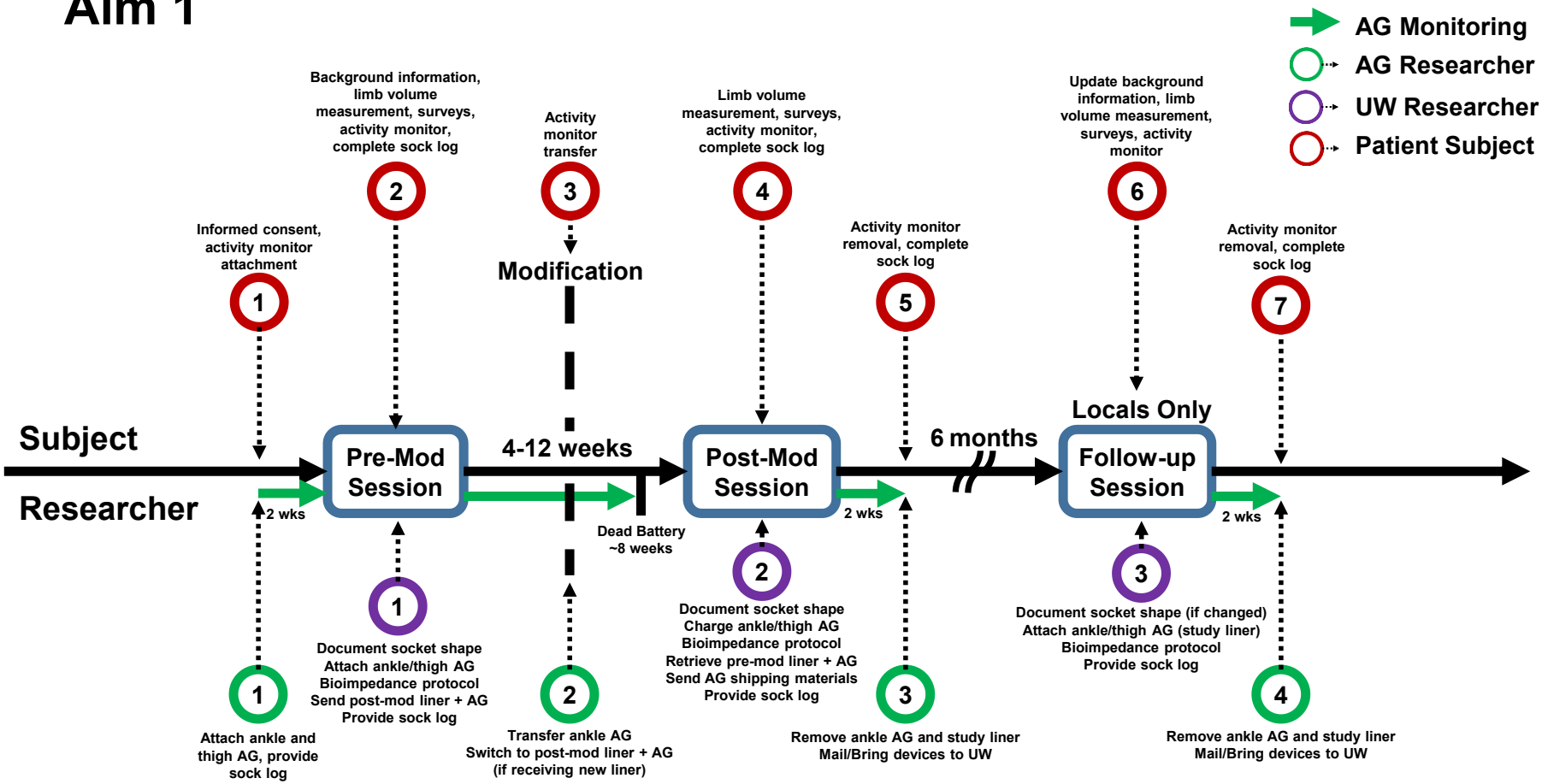
Aim 1. Characterize residual limb volume accommodation strategies and associated clinical outcomes experienced by prosthetic users with different activity/volume profiles. Changes in users' limb volume, prosthetic fit, performance, and satisfaction will be used to determine which strategies are most predictive of positive clinical outcomes. This aim will be accomplished using an Observational Cohort Study.

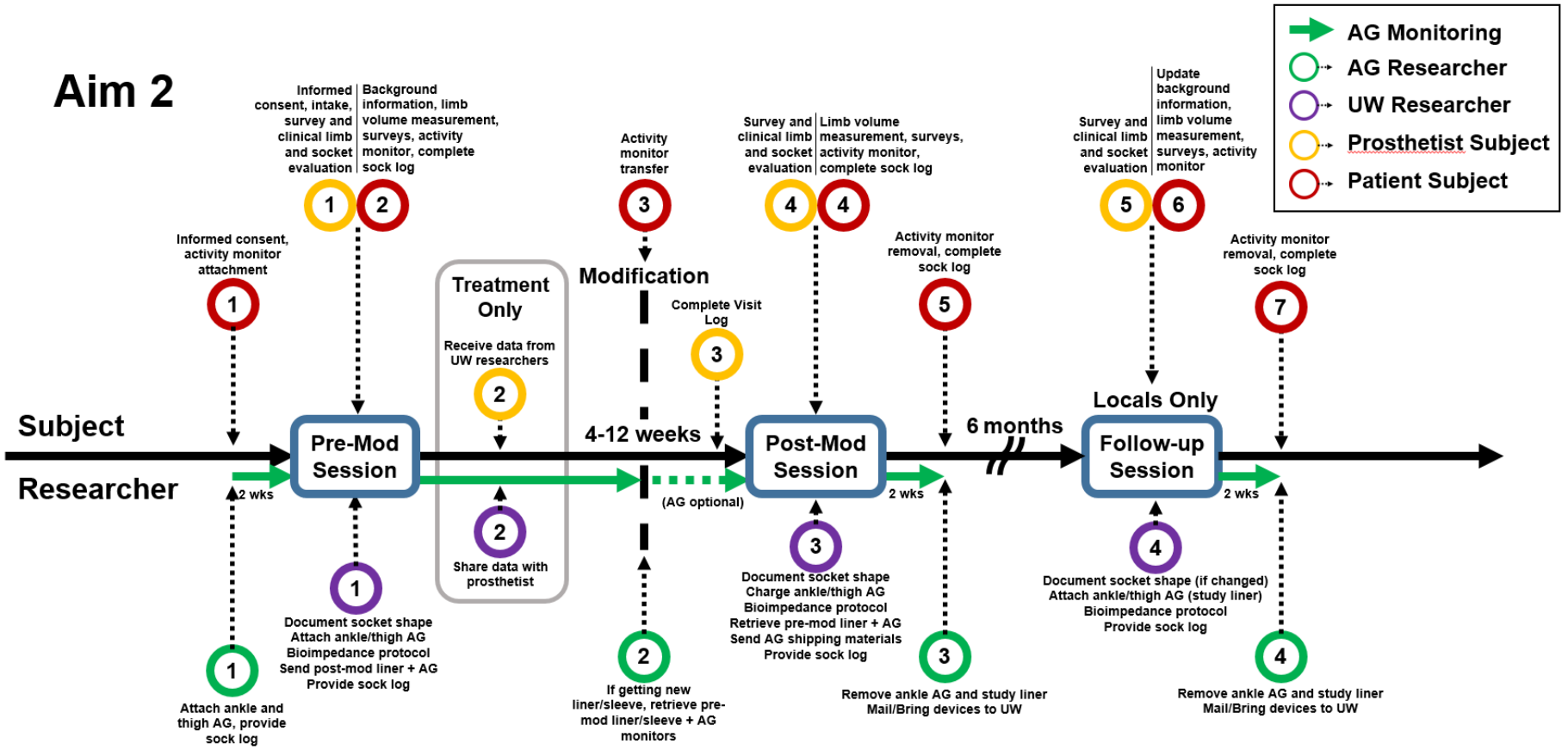
Aim 2. Compare the effectiveness of bioimpedance-enhanced and traditional prosthetic evaluation, design, and fitting practices for lower limb participants who require adjustment or replacement of their volume management system. Differences in participants' limb volume, prosthetic fit, performance, and satisfaction will be used to assess if bioimpedance-enhanced fitting produces superior outcomes compared to traditional, experience-based fitting methods. This aim will be accomplished by using a Randomized Controlled Trial (RCT).

Primary quantitative data will be collected via custom study instruments, such as a bioimpedance measurement system to assess limb volume changes. Qualitative data will be collected from participants directly through self-report of their health history, during study procedures. All data for this research will be collected prospectively.

A more detailed timeline of the study procedures is given on the following pages.

Aim 1


AG Monitoring
AG Researcher
UW Researcher
Patient Subject
Subject
Researcher
Informed consent, activity monitor attachment
1
Attach ankle and thigh AG, provide sock log
Background information, limb volume measurement, surveys, activity monitor, complete sock log
2
Pre-Mod Session
2 wks
1
Document socket shape
Attach ankle/thigh AG
Bioimpedance protocol
Send post-mod liner + AG
Provide sock log
Activity monitor transfer
3
Modification
4-12 weeks
2
Transfer ankle AG
Switch to post-mod liner + AG
(if receiving new liner)
Dead Battery ~8 weeks
Limb volume measurement, surveys, activity monitor, complete sock log
4
Post-Mod Session
2 wks
2
Document socket shape
Charge ankle/thigh AG
Bioimpedance protocol
Retrieve pre-mod liner + AG
Send AG shipping materials
Provide sock log
Activity monitor removal, complete sock log
5
3
Remove ankle AG and study liner
Mail/Bring devices to UW
6 months
Update background information, limb volume measurement, surveys, activity monitor
6
Locals Only
Follow-up Session
2 wks
3
Document socket shape (if changed)
Attach ankle/thigh AG (study liner)
Bioimpedance protocol
Provide sock log
Activity monitor removal, complete sock log
7
4
Remove ankle AG and study liner
Mail/Bring devices to UW


Aim 2
AG Monitoring
AG Researcher
UW Researcher
Prosthetist Subject
Patient Subject
Informed consent, intake, survey and clinical limb and socket evaluation
Background information, limb volume measurement, surveys, activity monitor, complete sock log
Activity monitor transfer
Survey and clinical limb and socket evaluation
Limb volume measurement, surveys, activity monitor, complete sock log
Survey and clinical limb and socket evaluation
Update background information, limb volume measurement, surveys, activity monitor
Informed consent, activity monitor attachment
Activity monitor removal, complete sock log
Activity monitor removal, complete sock log
Treatment Only
Receive data from UW researchers
Share data with prosthetist
Modification
Complete Visit Log
4-12 weeks
(AG optional)
Locals Only
6 months
Subject
Researcher
Pre-Mod Session
Post-Mod Session
Follow-up Session
2 wks
2 wks
2 wks
Attach ankle and thigh AG, provide sock log
Document socket shape
Attach ankle/thigh AG
Bioimpedance protocol
Send post-mod liner + AG
Provide sock log
If getting new liner/sleeve, retrieve pre-mod liner/sleeve + AG monitors
Document socket shape
Charge ankle/thigh AG
Bioimpedance protocol
Retrieve pre-mod liner + AG
Send AG shipping materials
Provide sock log
Remove ankle AG and study liner
Mail/Bring devices to UW
Document socket shape (if changed)
Attach ankle/thigh AG (study liner)
Bioimpedance protocol
Provide sock log
Remove ankle AG and study liner
Mail/Bring devices to UW

Statistical Analysis Plan

Aim 1

Aim 1 is an exploratory study with the objective of generating potential volume management strategies based on the measurement of limb fluid volume fluctuations via bioimpedance. As such, it does not involve statistical hypothesis testing per se, and therefore, no power analysis is involved. The primary outcome measure of socket comfort score (SCS), pre and post socket modification will be analyzed. A Shapiro-Wilk test will be used to determine normalcy. Normally distributed data will be compared using paired t-tests. If data is not normally distributed, a Wilcoxon Signed Rank Test will be used to make comparisons. A significance level of 0.05 will be used to determine whether measured differences in limb volume were statistically significant between interventions.

Aim 2

Data collected at each assessment (i.e., pre-implementation, 1-month follow-up, and 6-month follow-up) in Aim 2 will be visually analyzed using histograms and boxplots. Next, we will test data for normality using a Shapiro-Wilk test. If the data is found to be normally distributed, our hypothesis will be evaluated using clinical outcome measure scores (e.g., SCS) in a repeated-measures analysis of variance (rmANOVA) to assess differences in outcomes achieved by participants assigned to the treatment (i.e., bioimpedance-enhanced fitting) group vs. control (i.e., traditional fitting) group over time. In the event that data are not normally distributed, we will use a nonparametric Friedman test to assess differences in outcomes between bioimpedance-enhance and traditional fitting. Significance for statistical tests will be set at $\alpha < 0.05$. Our hypothesis will be evaluated using outcome variables of number of visits and total visit time. We will compare the total number of visits and total time over the 6-month period between the treatment and control groups using a t-test for independent samples.