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14. ABSTRACT

Towards the objective of creating and testing an electronic release and relock socket for transtibial prosthesis users, we completed Aim #2 testing, a 3.5 h in lab study protocol, on four participants. Results showed that all subjects experienced improved limb fluid volume for sessions with socket release and relock compared with no intervention. Participants varied as to the benefits of a 4-min vs. 10-min release duration. Heart rate data collected during testing did not well explain 4-min and 8-min differences among participants. COVID-19 restrictions prevented further Aim #2 data collection so Aim #3, an at-home study using the release and relock socket, was conducted instead. Training videos and reference cards used to teach and refresh participants on operation of the release and relock socket were updated based on participant and practitioner feedback. Participants identified necessary user interface modifications, which were implemented. Other identified modifications, in particular the release button design, will be made in the coming months while Aim #2 testing restarts.

15. SUBJECT TERMS
Amputee, prosthesis, limb volume, accommodation, control system, adjustable socket, release and relock, limb/socket interface, skin breakdown, accommodation

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1. **INTRODUCTION:** The subject of the research is the reduction of limb volume fluctuation problems experienced by people with lower limb amputation. Changes in limb volume cause changes in prosthetic fit, which may be detrimental to prosthesis users' residual limb health and induce gait instability. The purpose of this research is to create and test electronic release and relock sockets for transtibial prosthesis users. A second objective is to test new assessment metrics used in clinical testing. A novel motorized "release and relock" mechanism is mounted within participants' prostheses to allow users to quickly loosen their socket and partially withdraw their residual limb without losing contact with their prosthesis. Prostheses are instrumented so that they continuously measure prosthesis use, accommodation practices, and activity. A study in a controlled test setting is conducted to characterize the sockets' impact on morning-to-afternoon fluid volume change. A direct crossover study in the field is executed to determine if use of release and relock sockets enhances patient outcomes relative to traditional sockets. The clinical value and technical quality of outcomes data summaries are characterized by sharing results with practitioners of willing participants.

2. **KEYWORDS:** Amputee, prosthesis, limb volume, accommodation, control system, adjustable socket, release and relock, limb/socket interface, skin breakdown, accommodation

3. **ACCOMPLISHMENTS:**

What were the major goals of the project?

YEAR 2 GOALS & MILESTONES	TARGET	%COMPLETE
1. Conduct Aim #2 study		
Recruit participants	28 Mar 2020	88
Fabricate sockets	28 Mar 2020	23
Conduct monitoring sessions	31 May 2020	10
Process collected data	31 May 2020	10
Conduct statistical analysis and address hypotheses	30 June 2020	0
Milestone #3: Aim #2 study complete	31 July 2020	5
2. Disseminate findings		
Attend scientific meeting or DoD conference	31 July 2020	0
Submit manuscript	31 Aug 2020	0
Milestone #4: Manuscript submitted on Aim #2 study	31 Aug 2020	0
YEAR 3 GOALS & MILESTONES	**TARGET**	**%COMPLETE**
3. Conduct Aim #3 study		
Recruit participants	30 Nov 2020	5
Fabricate sockets	31 Dec 2020	5
Conduct monitoring sessions	31 Jan 2021	5
Process collected data	31 Jan 2021	5

What was accomplished under these goals?

Major activities: The major activities during Year 2 were to conduct Aim #2 and #3 testing and to address instrumentation, training, and user interface issues.

Specific objectives: The initial specific objective was to complete Aim #2 testing. However, restrictions introduced by COVID-19 from March to September 2020 prevented that objective from being pursued. The objectives shifted to initiating Aim #3 pilot testing (allowed under COVID-19 restrictions in June 2020) to generate initial data and also to identify instrumentation, training, and user interface issues that needed to be modified.

Significant results or key outcomes: Early in Year 2, complete Aim #2 datasets were collected on four amputee participants. Results demonstrated greater limb fluid volume in all participants when socket release and relock was conducted compared with when it was not conducted. Thus, the hypothesis that the release and relock system improves limb fluid volume management was supported by these initial data. During early amputee participant testing, we identified and managed a number of instrumentation issues. A primary challenge that was overcome was to reduce error in the instrumented dial data. It is described in detail below. Other issues and our solutions or work arounds are summarized in Table 1. Results from Aim #2 and #3 studies are then described.

Error in Instrumented Dial Data

The dial sensor is located within the housing of the ratchet knob that the participant uses to control socket panel position. We developed this custom sensing system to fit within the commercial RevoDial product, the most commonly used cabled paneled, socket size adjustment system in clinical prosthetics. The sensor keeps track of rotations of the rotary dial which is proportional to cable length and related to socket size. The sensor allows us to detect if the socket is brought back to the fully closed position after a socket release-relock is completed. The sensor uses two rotation sensing elements offset by 90° that each record over a 330° range. To simplify analysis and reduce error, we now merge data from the two sensors by specifying a threshold value in one sensor above which data from the other sensor is used instead. Because the end regions of the sensing elements (at 0° and 360°) have inherent non-linearity, we use the 90° to 270° range of each sensor to produce the single channel of dial sensor data.

Other sources of error in the dial sensor data resulted from a sampling rate issue. A sampling rate of 32 Hz proved insufficient during panel release and introduced both aliasing problems and missed rotations. Aliasing problems caused the dial to appear to be tightened rather than released. Missed rotations caused us to lose the absolute position in the dial for the rest of the trial. Dial rotation was particularly fast if the participant or researcher pulled outwards on the panel during a socket release to quickly relieve socket pressure. This was implemented frequently during Aim #2 testing. The problem will be resolved by modifying our electronic circuit board to at least triple the sampling rate on the dial sensor (next board run to be implemented by March, 2021). We will then analyze collected data from subsequent participants to determine if a lower rate is sufficient and can be used instead, thereby reducing the power demand.

For data already collected and data to be collected before the new circuit board is fabricated, we developed a post-processing strategy to identify aliasing and missed rotation counts in collected data. Identification of a problem is identified computationally, and then each problem is resolved on a case by case basis. Using the dial rotation speed collected right before and right after the error, we can easily establish how many rotations occurred. Each user typically has between 8 and 20 rotations that span their overall cable length range.

Other Instrumentation Errors Identified and Addressed

The solution or work around for each of the other instrumentation issues listed in Table 1 proved effective, allowing data to be collected for Aims #2 and #3.

TABLE 1. Instrumentation Issues Addressed during Year 2

Issue	Solution or Work Around
System will start when connected to cable	Work around: Use USB cable to start the

power only, but not battery	system during test sessions Solution to be implemented later: Redesign power management in next round of circuit board design
Electronic release button prematurely releases pawl/spool when participant pushes the button too hard and activates manual release	Solution: Redesign to decouple electronic partial doff and manual release buttons
Structural breakdown of motor housing	Solution: Change lever/pawl axle design; make housing design more robust
Wires impinge motion of solenoid and causes board crashes	Solution: Redesign housing to include a cable routing channel to prevent impingement
System crashes when solenoid operated under battery power	Temporary work around: Use cabled power system during Aim #2 studies Solution: Firmware modified to control timing events of motor and solenoid during socket release
Release button not operating because encoder not updating	Solution: Broken wire replaced; participant prosthesis preparation practices modified to avoid frequent switching in and out of parts so as to reduce wear
Tether impinges movement of lever/pawl, preventing firing of solenoid	Solution: Tether guide installed at bottom of socket to restrict movement of lanyard bolt; washers installed to limit motion of the lanyard bolt
Tether extends more than 5 cm during a partial doff, likely due to the ratchet not locking down and excessive tension on the tether	Work around: Tether marked with ink during test sessions to visually inspect tether length during sessions, and tether not pulled as hard during Aim #2 test sessions
Spool bearing press fit into the end bearing support loose and pinching the pawl between the motor housing and spool, causing the pawl to not release	Solution: Exchange end bearing support for a new part, and machine components out of metal instead of plastic
Lanyard bolt physically blocks the lever arm when the solenoid is at its upper stroke limit	Solution: Lanyard bolt shortened to allow clearance
Motor fell apart into pieces	Solution: This motor was used for many years. Motor usage now tracked
Broken internal coupling between rotary dial and sensor	Solution: Plastic coupling replaced with metal coupling
Battery moves around in the housing	Solution: Battery holder part added
Release button broken off during participant take-home testing due to impact with a table	Solution: Design modified so button does not stick out so far, it is more mechanically robust, and the bolt is made of metal

When battery dies, must connect to HTERM to restart which is time consuming during a test session	Solution: Modify the firmware so that data storage picks up from where it left off after a restart
Inconsistent wall power charging	Solution: Firmware issues. Used solutions implemented in a related project here;
Solenoid board crashes	Solution: Modified firmware to ensure restart after a crash, but effectiveness depends on battery power
Motor pulls only half of the weight specified by the manufacturer; can pull 71 N not 178 N	Work around: Have participants lean forward during socket release in Aim #2 study to relieve excessive tether tension Solution to be implemented: Identified the source of the problem as a combination of terrible gearbox efficiency (69%) and losses within additional gears within the design. Since this problem only affects socket release, manual release will be implemented instead. All other systems will remain as is
Participant cut tether cable because did not follow manual release procedures	Solution: Simplified design of manual release so that it is more intuitive
Participant got tether stuck by disconnecting liner and then pulling the tether deep into the socket	Solution: Modify spacer disc so that the tether cannot fall through the distal hole in the socket

Aim #2 Participant Test Results

The Aim #2 study design was modified slightly from that described in the original grant application and is summarized in Figure 1 below. The sit durations during socket release are 4 min (Short Rests)

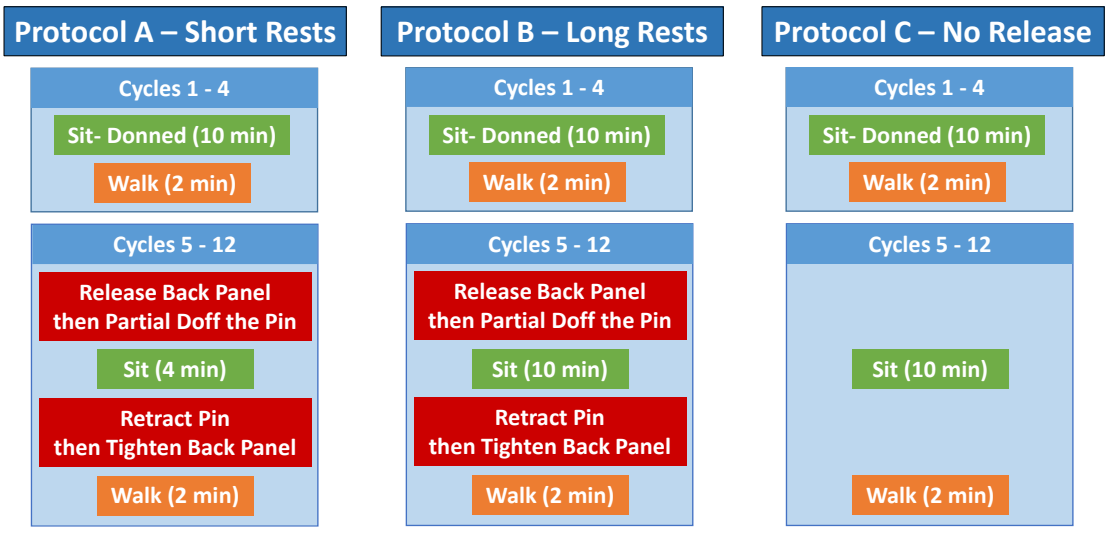


Figure 1. Study design for Aim #2. Cycles 1-4 are "conditioning" cycles, intended to bring the participant to a consistent state before the intervention part of the test (cycles 5-12).

[in the original protocol they were 3 min] and 10 min (Long Rests), and the walks are 2 min long. These durations ensured that Long Rests and no release (Control) were executed at the same time into the trial as some of the Short Rests, simplifying comparison of results between the interventions across the duration of the session.

To date, a total of 35 participants were recruited for Aim #2, 19 were screened, and 16 were enrolled. Data was collected from 14 test sessions on 5 participants. We were slowed between March and September 2020 by COVID-19 restrictions, thus only 4 of the participants completed all 3 sessions (Protocols A, B, & C). Limb fluid volume results from those participants are summarized in Figure 2.

Three of the four participants exhibited greater fluid volumes for the protocols executing TARPIN release (Short Rests and Long Rests) than the Control protocol, providing evidence that supports benefit of the TARPIN release/relock system. The blue and orange lines in Figure 2 show greater

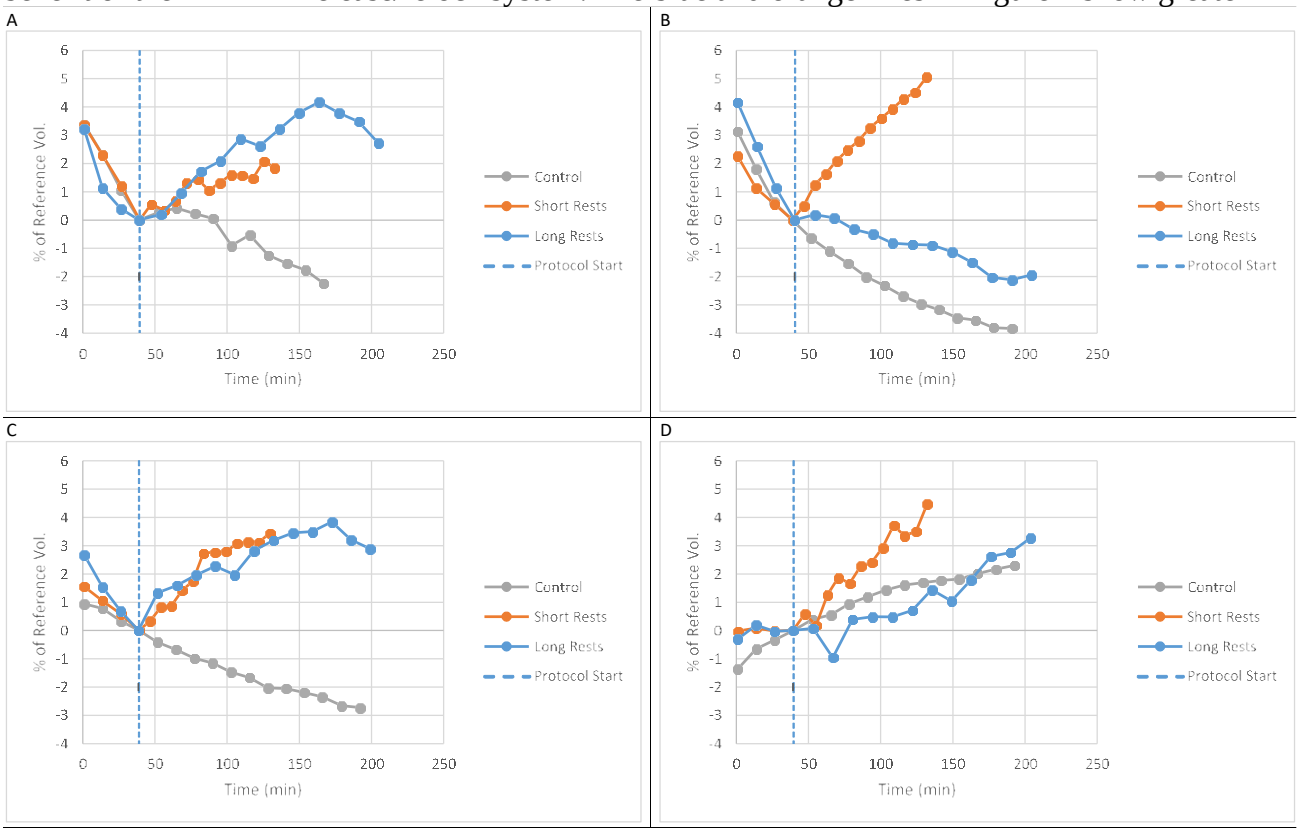


Figure 2. Each point is the mean limb fluid volume during stance phase, calculated as a percentage from the reference (dotted line).

percent limb fluid volume after the start of the intervention (vertical dashed line) than the gray lines. Participant D had verrucous hyperplasia, possibly explaining why his data is dissimilar from the others. We note that participants A and C demonstrated comparable results for the Short Rests and Long Rests, a gradual increase in limb fluid volume, suggesting that the duration of the rest was not meaningful to their response. These two participants also showed a decrease in limb fluid volume during the last few cycles of the Long Rests protocol, suggesting that the maximum benefit of Long Rests release/relock was achieved at about 160 min. After this time, limb fluid volume began to

reduce in each cycle rather than increase. Participants B and D did not show either of these behaviors. Participants B and D gained more fluid volume when Short Rests were executed compared to Long Rests.

Heart rate data collected during testing were analyzed to determine if differences in heart rate helped to explained why Participant B's and D's Short Rests results were so much more favorable than their Long Rests results, unlike the results from Participant A's and C's where the Short Rests and Long Rests results were comparable. Results from the heart rate data did not support this hypothesis. There were no consistent meaningful differences in heart rate among interventions or subjects. Our interpretation was that though participants' physical conditioning may have been relevant to their fluid volume response, some participants worked harder than others during the sessions. Their effort during testing affected the result more than their physical condition.

Relative socket comfort score (RSCS) data collected during each cycle are plotted in Figure 3. The score is termed relative because participants are asked to rate their socket comfort relative to the last time they indicated their socket comfort. There are 5 possible answers: much better (+1.0), somewhat better (+0.5), the same (no change), somewhat worse (-0.5), and much worse (-1.0). Use of relative

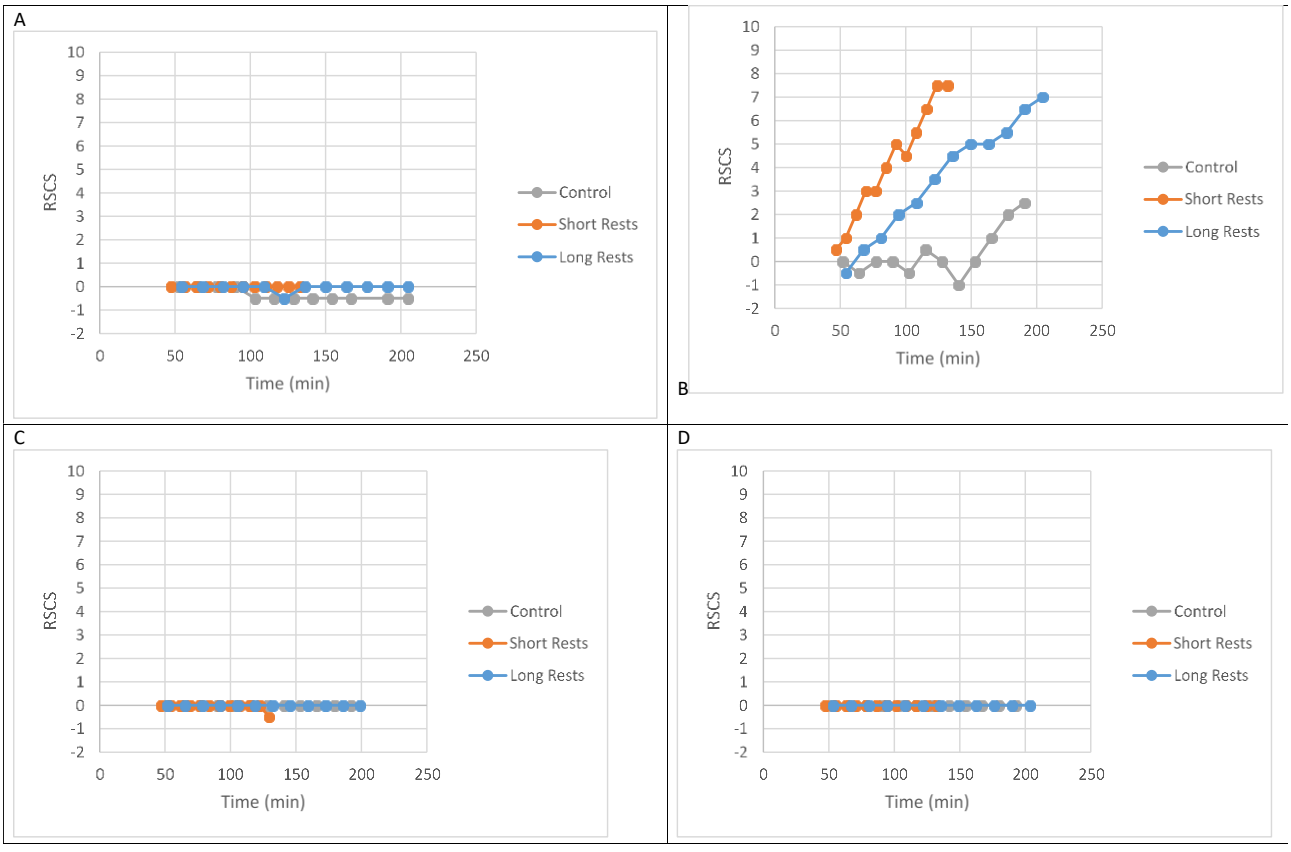


Figure 3. Relative Socket Comfort Score results.

socket comfort provides a more sensitive measure than whole number socket comfort scores. Participants C and D showed no change in RSCS over the test session. Participant A had a decrease in socket comfort at 100 min for the Control session but otherwise no meaningful changes. Participant B showed improvement in socket comfort over time for all sessions. The greatest improvement was

during Short Rests, the session with the greatest percent limb fluid volume gain (Figure 2). However, we note that we asked RSCS more frequently in this session because of the timing of the test points. We noted that Participant B is a very detail-oriented person, possibly explaining why he shows so much more change in RSCS compared to the other participants.

We found that some participants generated considerable tension in the tether cable when they sat down, which sometimes jammed the ratchet and pawl mechanism, preventing socket release. This problem was overcome by having the participant lean forward slightly to relieve the tension before doffing. The mechanism then released properly. We consider advising the participant to lean forward when releasing the TARPIN mechanism as an acceptable strategy for the purposes of the in-lab Aim #2 study.

Aim #3 Participant Test Results – Pilot

In June 2020, we initiated Aim #3, in part because we were still restricted from continuing Aim #2 due to COVID-19 regulations. Aim #3, however, was not restricted by COVID-19 regulations because data collection did not require participants come to our laboratory. We travelled to participant's homes to drop off the test prosthesis so that they could begin testing. The disadvantage of this approach was that insight to be gained from Aim #2 was not applied to Aim #3. However, we saw value in implementation of the TARPIN system in user free-living environments since other issues (instrumentation, training, user interface) could be tested. Because the two participants tested had taken part in Aim #2, no modification to their test prosthesis was required, ensuring that testing could be completed within COVID-19 requirements. Participants did, however, need to be trained on how to use the TARPIN system.

To facilitate training, we created instructional material and provided it to participants, both in written form and on the mobile phone they used to operate the TARPIN prosthesis. Detailed written instructions and abbreviated small (credit-card size) cards (Figure 4) were developed and provided to each participant. The cards were put in a plastic pouch on the back of the mobile phone so that they were immediately available to participants should they forget how to operate the system. We also created an instructional video that participants viewed before they received the system and could refer to when using the system at home. The 9-min video is at this link:

https://www.youtube.com/watch?time_continue=9&v=mq2Pu1p_f4w&feature=emb_logo

Three test sessions were conducted on two participants in their at-home environment. The first participant wore the TARPIN for 3 days in the first session and 1 day in the second session. The second participant wore the TARPIN for 1 day in one session.

Participant #1. The participant "experimented" with the TARPIN tether on the first day, first adjusting across the range of the tether (between the 10:00 o'clock (10.0) and 11:00 o'clock (11.0) marks in Figure 5), and then making minor adjustments over the course of the afternoon. After about 15.5 hours, the participant made no other changes for the rest of the day before doffing at night (at 20.0 hours). The participant did not often make adjustments to the panel position. Data from the instrumented dial was essentially flat, i.e. always flush panels.

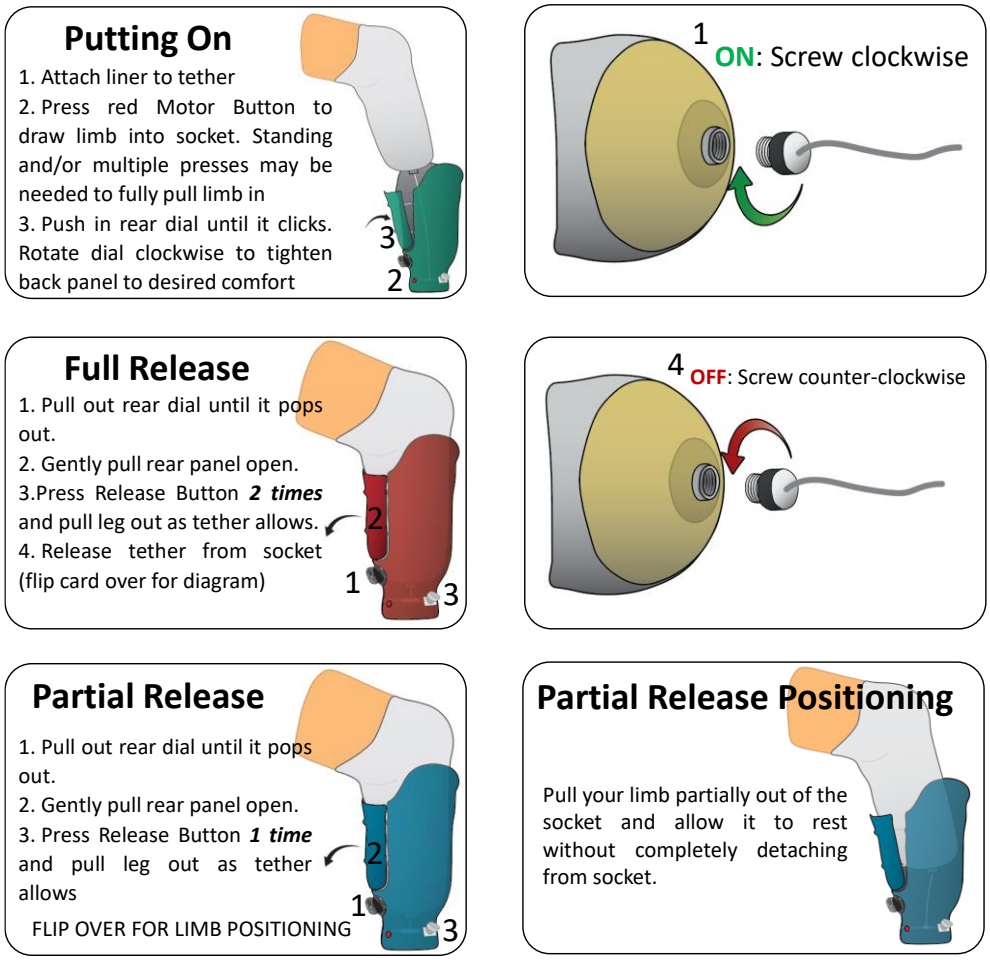


Figure 4. Instructional cards provided to participants during Aim #3 at-home testing.

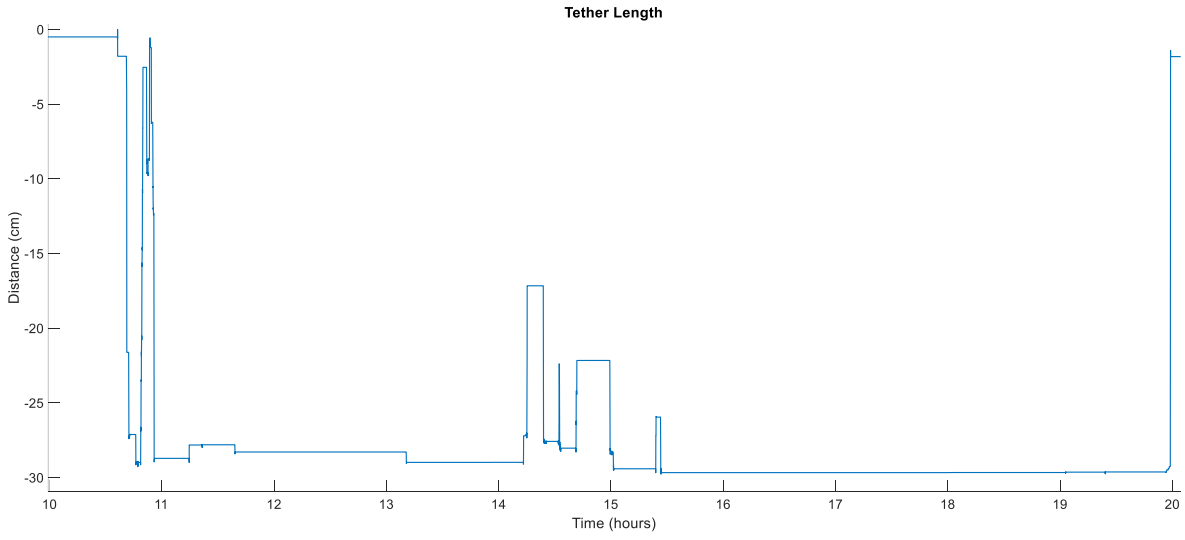


Figure 5. Tether length from testing Participant #1 in Aim #3. Day 1, 1st test session. The Time (hours) corresponds to time of day.

Inspection of inductive (STM) sensor data (shown in LDC counts in Figure 6, top graph) showed how STM data changed in response to adjustment of panel position (~15.004 h) and tether length (15.022 h). At 15.004 h, the panel is loosened then tightened and corresponding changes in liner-socket distance occur. When the TARPIN motor button is pushed at 15.022 h, the distal sensors (Lat Dist & Med Dist in Figure 6) show a decrease in distance while the proximal sensors (Med Prox & Lat Prox in Figure 6) show no change. The results are encouraging towards understanding how these adjustments affect socket fit.

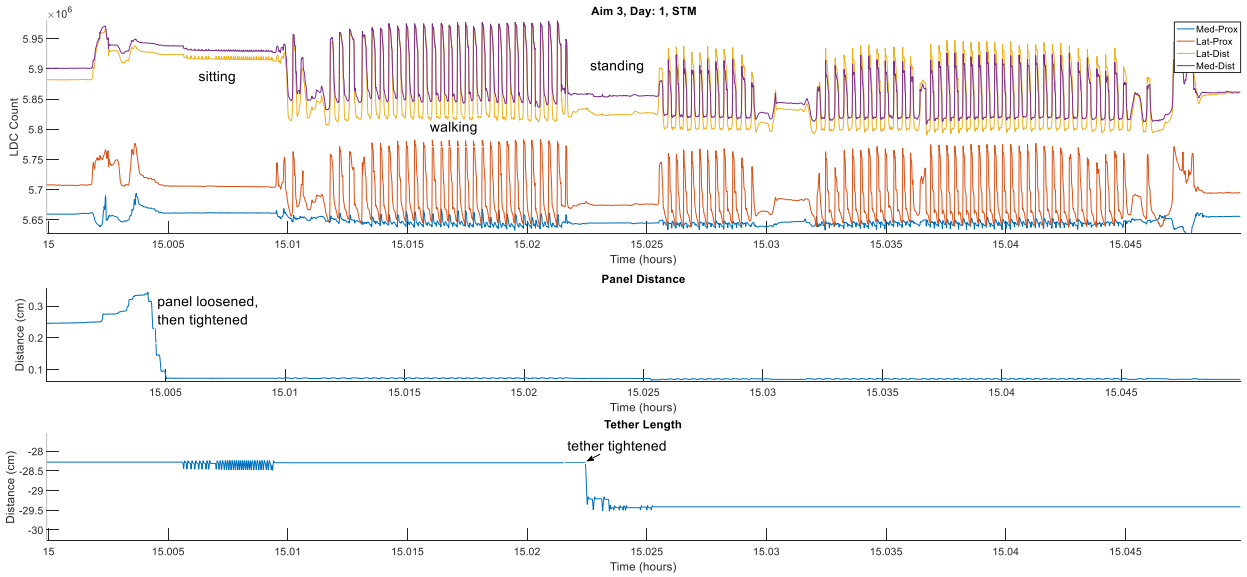


Figure 6. Zoomed in section for Participant #1, Day 1, 1st test session. Data from the liner-socket distance sensors (STM), cable dial sensor (panel distance), and motor tether (tether length) are shown.

In the post-use interview, the participant noted that he conducted a partial doff at least 12 times over the 3 days of use, claiming it was a way to "relax the leg." To don the socket, he claimed that he pulled the posterior panel open, secured the locking pin, and then closed the panel. Compared to his current socket which has a smooth pin and sometimes inadvertently unlocks and releases when kneeling, the instrumented socket did not behave unexpectedly. As such, the participant indicated he felt more confident in the test socket. He did not, however, like having to deal with the battery in the test socket In particular, he stated that he did not know when it was insufficiently charged (i.e., he felt it needed a battery indicator). He liked not having to adjust his sock ply during the day and instead use the tether length to adjust fit.

Participant #2. The second participant made adjustments to both the panel distance and the tether length, as shown below in data from the 1st day. In general, the participant released the panel first, and then released the tether during doffing. In donning, he preferred to tighten the tether first and then tighten the panel last. The participant did not completely follow the provided instructions to keep the panel all the way open during partial and full release. He partially opened the panel during full releases. However, he did tighten the panel all the way when donned and subsequently walking or standing.

Similar to Participant #1, when Participant #2 tightened the panel, the STM sensors indicated the liner-to-socket distance decreased, as shown in Figure 7, top panel. When the tether was released, all of the STMs reported an increased distance, consistent with this participant's conical residual limb with minimal soft tissue at the distal end.

Participant #2 noted the extra weight of the test prosthesis but did not think it was difficult to use. He noted that the doff button was not intuitive because he had to remember to push the button twice, unlike the immediate release of his locking pin which is just one push.

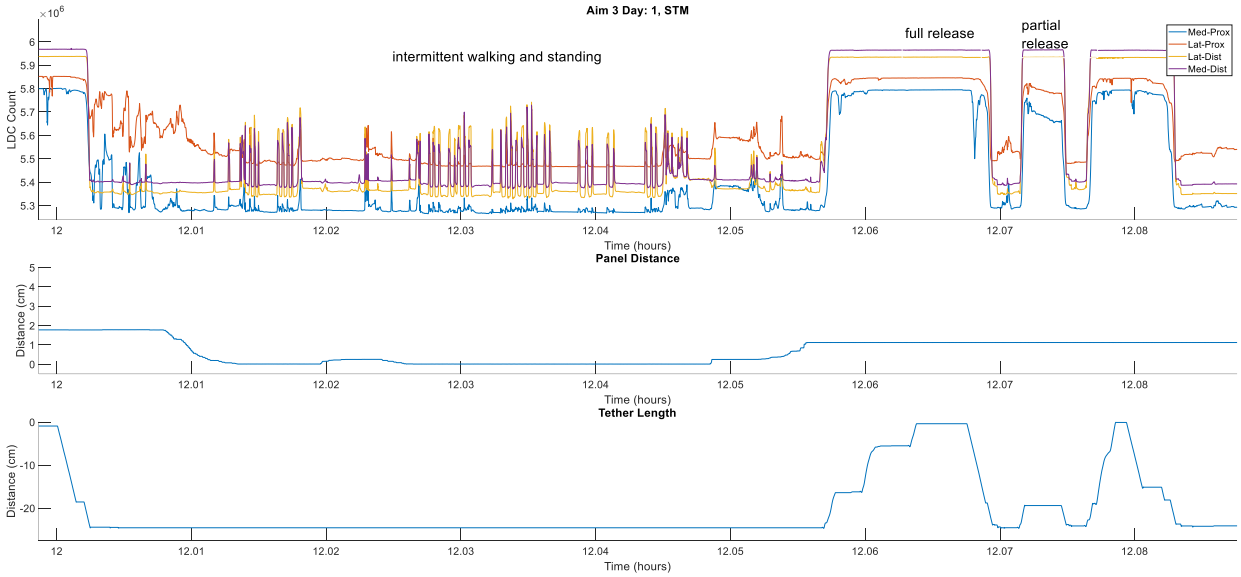


Figure 7. Zoomed in section for Participant #1, Day 1, 1st test session. Data from the liner-socket distance sensors (STM), cable dial sensor (panel distance), and motor tether (tether length) are shown.

Recognized Performance Problems – Solution to Be Implemented for Aim #3

A number of instrumentation issues were identified in studies to date that will need to be implemented before the full Aim #3 study is carried out. The minor issues are summarized in Table 2.

Table 2. Minor Issues and Solutions to Be Implemented in the Aim #3 System

Minor Issue	Solution
Sampling rate on the dial	Increase to ~128 Hz in the next board design (completed before 3-2021)
Inability to download data through USB port is inconvenient	Add this capability to the next circuit board revision (completed before 3-2021)

There are four major issues to be resolved before returning to Aim #3 investigations: (1) Occasional jamming of the ratchet and pawl during partial or full socket release; (2) Power management issues due to overloading of the motor from (1); (3) Non-intuitive manual socket release in the event of a power failure; (4) Slow to execute connector release for tether attachment to the liner. These engineering issues will be tackled while Aim #2 is being completed.

(1) Occasional jamming of the ratchet and pawl during partial or full socket release

Poor motor performance caused jamming during tether release in some test subjects. The difficulty was that when some participants sat down and executed a partial or full release, the tension in the tether was excessive (>89 N). This tension jammed the pawl into the ratchet such that it could not release. We attempted a number of solution to this problem including modifying the firmware so that the motor rotated a short distance in the opposite direction first before returning to the proper direction to attempt pawl release, modifying the tether path to ensure it was in line with the socket axis, and changing the support materials to create a stiffer system. These efforts improved the problem but did not resolve this problem for all participants. Upon bench testing of the motor isolated from the rest of the system, we found that the motor held about half of the maximum allowable force specified by the manufacturer (which was 178 N), and it failed to draw in a load greater than 71 N. We further noted that the motor was not executing its current limit detection strategy properly, possibly missing current overloading because the current impulse was fast. We were unable to identify a replacement motor of acceptably small size and weight. We therefore are modifying the design so that release of the pawl is executed manually by the users, similar to how they would execute pin lock release in a shuttle lock socket. The rest of tether adjustment continues to be executed normally using the motor, consistent with the original application.

(2) Power management issues due to overloading of the motor from (1)

A number of power issues were noted: The battery failed to turn on the system when running off battery power alone but would start when plugged in; the battery failed to charge when connected to a wall charger but did start off of computer power (via USB); the battery did not last the expected duration (>5 days); the system failed to operate when the battery ran below 85% charge. Some of these issues were solved by changes to the firmware, particularly better management of event timing, but other issues may have been the result of protection algorithms within the drivers for the motor and solenoid, which were not described in product information sheets or available to us.

Some of the power issues originated from the first problem – insufficient motor performance. When excessive tension was induced in the tether and the motor force was unable to move and release the pawl, protections within the motor and solenoid likely caused problems within the microcontroller that resulted in the abnormal battery behavior. A thorough search of motor products demonstrated that no replacement motor was available to meet the need. To solve the problem, we eliminated the requirement to unlock the pawl as a necessary motor function. To release the pawl, the user will now push a manual release button that releases the pawl from the ratchet and fires the solenoid, allowing the participant to back drive the motor and pull out the tether. After pawl release, the system functions as originally designed. By firing the solenoid right after the pawl is released, we ensure that a 5 cm partial doff release is executed, i.e. the system transitions from the don state to the partial doff state. A subsequent second button push causes the motor to release again, now transitioning the system from the partially doffed state to the fully doffed state. We are near completion of the design phase of this effort and expect to complete fabrication before returning to Aim #3 in 2021.

(3) Non-intuitive manual socket release in the event of a power or mechanism failure

We originally designed an “emergency release” as part of the motor release button. If users pushed the electronic motor release and it failed to operate then users were instructed to push the same button harder to execute an emergency manual release. Having the manual release on the same mechanism as the electronic release was a clinical benefit because users easily remembered what to do if the tether did not release. However, users had difficulty distinguishing these two settings and tended to push the button too hard from the start, accidently executing a manual release and causing motor

rotation information to be lost and tether length to be unknown. This problem was solved by isolating the manual release and moving the associated button to a new location. This experience is relevant because it demonstrates that the design of the prior manual release button was acceptable and should be used as a base design to solve issue (2) above.

(4) Easier to use quick-release connector for tether attachment to the liner

A modified mechanism to connect the tether to the liner is necessary to replace the current screw-in connector. Some participants lack the manual dexterity to put the pin into the liner, thus this revision is necessary to increase the pool of candidate participants for Aim #3. The device has been designed and is shown in Figure 8 below. It is a modified carabiner, requiring less than 1 full twist to lock the mechanism in place.

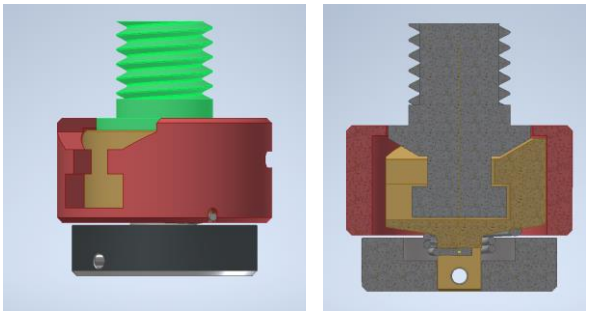


Figure 8. Design of the quick-release connector for the tether-liner connection.

Other achievements: None.
The stated goals were not met because University of Washington human subject testing restrictions resulting from COVID-19 prevented us from collecting data on amputee participants in Aim #2 from March 2020 through September 2020.

What opportunities for training and professional development has the project provided?
Nothing to Report.

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?
During Year 3, we will attempt to complete Aim #2. Continuing COVID-19 restrictions at the University of Washington increase the preparation time and execution time of data collection for Aim #2 beyond that originally proposed. Thus, in an effort to reduce the sample size without sacrificing quality of the science, we will continually evaluate the statistical power of our analysis results to determine if and when we achieve sufficient power to validate or refute the hypotheses. It is possible that a smaller sample size than that stated in the original proposal (n=40) will be adequate.

Insight gained from Aim #3 results to date demonstrated that mechanical and electrical design modifications to the TARPIN system are needed for Aim #3 – long-term testing in participant free-living environments. We plan to focus on revising the electro-mechanical design for approximately half of the year and then will progress into testing Aim #3 in the second half of the year. By the end of the year, we hope to complete and submit for publication Aim #2 and then be ready to focus the remaining year of the grant on Aims #3 and #4.

4. **IMPACT:**

What was the impact on the development of the principal discipline(s) of the project?

The developed technology is likely to make an impact on the prosthetics industry. The technology extends from the traditional manual tether used to don a socket, a nylon string that users pull through their shuttle lock and then clamp to hold in place, into a fast, easy to use, motor driven, donning and doffing system, and perhaps more importantly a new accommodation system that uses partial doffing as a means to recover limb fluid volume during the day. We suspect manufacturers will incorporate elements of the system into their commercial products.

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

University of Washington COVID-19 restrictions required us to halt Aim #2 testing during the 2nd quarter of Year 2. By that time, we had completed all three test sessions on a total of 4 participants. As University of Washington COVID-19 restrictions began to lift in June 2020, we realized that the Aim #3 study met the criteria for return to testing but Aim #2 did not. Thus, our action plan was to shift our focus to Aim #3. We gained important insight from the Aim #3 pilot tests. Continuing the Aim #3 studies at this time, however, is not appropriate because engineering design modifications must first be made. Our action plan is to conduct two objectives in parallel: Aim #2 testing, and engineering design modification of the Aim #3 system. By the time Aim #2 is complete, the engineering design modifications should be made, and we should be ready to carry out Aims #3 and #4.

Changes that had a significant impact on expenditures

COVID-19 slowed down the research, temporarily reducing spending. We expect an increase in research activity and spending in the coming months.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

- Initial Approval:
    - UW IRB: Submitted 04/9/2018, Approved 05/15/2018
    - HRPO: Submitted 05/29/2018, Approved 11/28/2018
- Continuing Review Approval:

    - UW IRB: Approved 03/06/2020
    - HRPO: Acknowledged 03/18/2020
- Mod #3:
    - UW IRB: Submitted 10/18/2019, Approved 10/24/2019
    - HRPO N/A, not a substantive modification
- Mod #4:
    - UW IRB: Submitted 11/8/2019, Approved 11/13/2019
    - HRPO N/A, not a substantive modification
- Mod #5:
    - UW IRB: Submitted 01/13/2020, Approved 01/15/2020
    - HRPO N/A, not a substantive modification
- Mod #6:
    - UW IRB: Submitted 03/10/2020, Approved 03/11/2020
    - HRPO N/A, not a substantive modification
- Mod #7:
    - UW IRB: Submitted 03/12/2020, Approved 03/12/2020
    - HRPO N/A, not a substantive modification
- Mod #8:
    - UW IRB: Submitted 06/02/2020, Approved 06/04/2020
    - HRPO N/A, not a substantive modification
- Mod #9:
    - UW IRB: Submitted 06/12/2020, Approved 06/15/2020
    - HRPO N/A, not a substantive modification
- Mod #10:
    - UW IRB: Submitted 08/14/2020, Approved 08/19/2020
    - HRPO N/A, not a substantive modification

Mod #3 was a change to allow the use of a commercial heart rate monitor during the study.

Mod #4 changed the wording regarding the number of visits to make it clearer that there was 1 fitting visit and 3 testing visits.

Mod #5 increased lab visits to be up to 6 hours long.

Mod #6 updated study data storage/sharing to allow for creation of instructional video of a lab procedure (electrode placement) to share with research personnel.

Mod #7 Correction of Mod #6 by IRB.

Mod #8 allows for Aim 3 setup visits to be conducted remotely/at participant's home.

Mod #9 updated language in the compensation section of the Aim 3 consent form to clarify how participants are paid.

Mod #10 Added language to all consent forms that describes how tests will be conducted under the UW IRB's updated COVID-19 human subject testing guidelines.

Significant changes in use or care of vertebrate animals

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.

6. PRODUCTS:

- **Publications, conference papers, and presentations**

  Journal publications.

  Nothing to Report.

  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)**

  Nothing to Report.

- **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:	Joan Sanders PhD
Project Role:	PI
Researcher Identifier (e.g. ORCID ID):	https://orcid.org/0000-0002-8850-243X
Nearest person month worked:	2
Contribution to Project:	Project management and electro-mechanical design

Name:	Horace Wang
Project Role:	Research Engineer/Scientist

Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2
Contribution to Project: Modification of board layout, firmware code for release/relock operation and sensing element

Name: Brian Hafner PhD
Project Role: Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0001-6175-1869
Nearest person month worked: 1
Contribution to Project: Study design

Name: Sharon Hubbard
Project Role: Project Manager
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Manage purchasing and financial reporting, ensure UW human resources policies are followed

Name: Ryan Carter
Project Role: Research Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2
Contribution to Project: Fabrication of test sockets

Name: Daniel Ballesteros
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2
Contribution to Project: Testing of release/relock mechanism, data processing

Name: Katheryn Allyn CPO
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Pilot study socket fitting

Name: Joseph Garbini PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Mechanical an control system design

Name: Andrew Vamos
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1

Contribution to Project: Study execution

Name: Brian Larsen
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Data analysis and study management

Name: Kendrick Coburn
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 7
Contribution to Project: Mechanical design and study execution

Name: Matthew Weissinger
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Mechanical design

Name: Conor Lanahan
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Study execution

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

SANDERS, JOAN E

Previously active grants that have closed:

W81XWH-16-1-0585 (Sanders)
CDMRP
"Preliminary investigation of a diagnostic tool for prosthetics"

New grants that have started:

R01HD060585 (Sanders) (this is a continuation grant)
NIH/NICHD
"Measuring in-socket residual limb volume fluctuation"

W81XWH-19-2-0049 (Childers, Sanders)
CDMRP
"Do adaptable sockets improve military performance?"

GARBINI, JOSEPH L

Previous active grants that have closed:

Boeing Company
"Tube bending in process inspection"

Boeing Company
"Semi-automated sanding assistance device 2019"

New grants/contracts that have started:
Boeing Company
"Sanding Assist Automation"

R01HD060585 (Sanders) (this is a continuation grant)
NIH/NICHD
"Measuring in-socket residual limb volume fluctuation"

HAFNER, BRIAN J
New grants that have started:
W81XWH-20-1-0258 (Hafner)
Department of Defense
"Patient-centered measurement of mobility outcomes in lower limb orthosis users"

FRIEDLY, JANNA L
Previous active grants that have closed:
4UH3AR066795 - 02 (Jarvik)
NIH
"A pragmatic trial of lumbar image reporting with epidemiology (LIRE)"

81XWH-17-1-0617 (Morgan)
Department of Defense
"Do microprocessor knees improve outcomes in early prosthetic rehabilitation compared to non-microprocessor knees?"

What other organizations were involved as partners?
Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS
COLLABORATIVE AWARDS:

Not Applicable.

QUAD CHART (attached as a separate file and printed below):

A Release/Re-Lock Socket to Enhance Volume Management and Facilitate Patient Self-Care
Log Number: OR170197
Award Number: W81XWH1810595

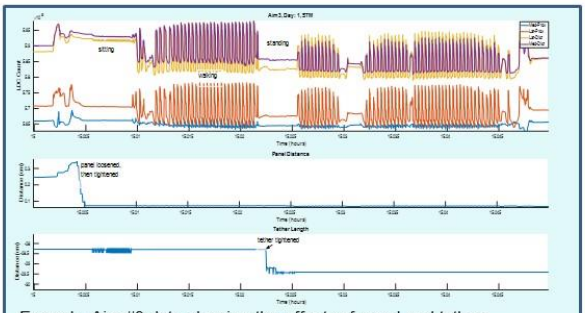
PI: Joan Sanders Ph.D. **Org:** University of Washington **Award Amount:** $2M

Study/Product Aims

- **Aim 1:** Enhance prototype sockets that allow motor-driven release and relock action and are instrumented to monitor prosthesis use, accommodation practices, and activity.
- **Aim 2:** Test the sockets in a lab randomized crossover study.
- **Aim 3:** Evaluate the sockets in the field in a direct crossover study.
- **Aim 4:** Assess clinical value and technical quality of outcomes data.

Approach

After enhancing release/relock prototype sockets so that mechanisms are not visible to outside observers and operate ~3 weeks on a single charge, we will test participants in the lab to determine if the sockets reduce limb fluid volume loss compared to traditional sockets. We will then conduct two 6-week field tests to determine if the sockets enhance patient outcomes. Finally, we will share data with prosthetists of Aim 3 participants (who agree to allow us to share) and assess clinical value and technical quality of the collected outcomes data.



Example Aim #3 data showing the effects of panel and tether adjustments on liner to socket distance. Distal sensors show reduced distance for closing the panel and for drawing the tether in tighter.

Timeline and Cost

Activities CY	18	19	20	21
Aim 1: Enhance prototype design				
Aim 2: Conduct lab study				
Aim 3: Conduct field testing				
Aim 4: Assess outcomes data				
Estimated Budget ($K)	**$457**	**$514**	**$512**	**$517**

Updated: 9/21/2020

Goals/Milestones

CY18 Goals – Finish design, IRB/HRPO approval, begin recruitment
☒ Reduce release/relock size and power needs
☒ Characterize quality of measurement and operation
☒ Accomplish IRB and HRPO approval
☒ Recruit trans-tibial amputee participants for lab study (65% to date)

CY19 Goals – Complete lab study, begin field testing
☐ Complete assessment of release/relock impact on limb fluid volume
☒ Recruit trans-tibial amputee participants for field testing (5%)

CY20 Goals – Continue field testing, begin to assess outcomes data
☒ Continue outcomes evaluations of release/relock in field tests
☐ Conduct interviews to assess value and quality of outcomes data

CY21 Goals – Complete field testing, assessment of outcomes data
☐ Disseminate results
☐ Prepare final report

Comments/Challenges/Issues/Concerns

- Challenge: Human subject testing shutdown from COVID-19

Budget Expenditure to Date - $615k