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**TITLE:** A Release/Relock Socket to Enhance Volume Management and Facilitate Patient Self-Care

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**CONTRACTING ORGANIZATION:** University of Washington

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**13. SUPPLEMENTARY NOTES**

**14. ABSTRACT**
During Year 4 ten participants completed the Aim #3 take-home testing, and three prosthetist participants completed Aim #4 clinical assessment of patient take-home data. Additional instrumentation issues were solved, and the release-relock system was updated so that each night the system automatically uploads data to the researchers. Computational algorithms were created to determine prosthesis use from the collected data – more specifically time spent in each category: walking bout, weight shift, standing, sit shift, sitting, partial doff, and full doff (non-use). The percentage time in each category was determined for the intervention (release-relock motor active) and the control (motor not active). These results will be used to address the hypotheses once all study data are collected. Prosthetist participants were excited about the collected data because it provided meaningful clinical insight about how their patients used their prosthesis, not just how active they were. The Aim #2 study was submitted for publication, and a manuscript on the Quick Pin system is in preparation.

**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 1 GOALS & MILESTONES | 100% complete |
| YEAR 2 GOALS & MILESTONES | 100% complete |

| YEAR 3 GOALS & MILESTONES (delayed by COVID) | original TARGET | %COMPLETE |
|---|---|---|
| Task 7. Conduct Aim #3 study | | |
| Recruit participants | 30 Nov 2020 | 100 |
| Fabricate sockets | 31 Dec 2020 | 86 |
| Conduct monitoring sessions | 31 Jan 2021 | 79 |
| Process collected data | 31 Jan 2021 | 71 |
| Conduct statistical analysis and address hypotheses | 28 Feb 2022 | 0 |
| Milestone #5: Aim #3 study completed | 31 Mar 2022 | 0 |
| Task 8. Disseminate findings | | |
| Attend scientific meeting or DoD conference | 31 Mar 2022 | 100 |
| Milestone #6: Manuscript submitted on Aim #3 study | 31 Mar 2022 | 0 |

| YEAR 4 GOALS & MILESTONES (delayed by COVID) | original TARGET | %COMPLETE |
|---|---|---|
| Task 10. Conduct Aim #4 study | | |
| Recruit from approved Aim #2 participants' prosthetists | 31 Jan 2022 | 29 |
| Conduct pre-interview assessments | 28 Feb 2022 | 21 |
| Conduct interviews | 28 Feb 2022 | 21 |
| Process collected data | 28 Feb 2022 | 21 |
| Conduct statistical analysis and address hypotheses | 30 Apr 2022 | 0 |
| Milestone #7: Aim #4 study completed | 31 May 2022 | 0 |
| Task 11. Disseminate findings | | |
| Attend scientific meeting or DoD conference | 31 Aug 2022 | 0 |
| Milestone #8: Manuscript submitted on Aim #4 study | 31 Aug 2022 | 0 |
| Milestone #9: Final report submitted | 31 Aug 2022 | 0 |

**What was accomplished under these goals?**

*Major activities:* The major activities during Year 4 were to test a total of 11 participants in Aim #3 take-home testing, test 3 practitioner participants in Aim #4, solve additional instrumentation and user interface issues, and achieve automatic daily upload of field data every 24 h. A manuscript was submitted on Aim #2 study results.

*Specific objectives:* The first specific objective for Year 4 was to complete testing on at least 8 participants in

Aim #3 testing and at least 4 prosthetist participants in Aim #4 testing. Data collection for the full study was initiated at the outset of Year 4. The total number of participants to test will need to be reduced from the initial 40 stated in the grant application, in part because of University of Washington human subject testing restrictions introduced by COVID-19 that delayed progress of the research. We are now facing financial constraints to complete testing. We expect to complete about 14 participants in Aim #3 and 7 to 14 prosthetist participants in Aim #4 before all funds are depleted. The 14-participant estimate was used to calculate % complete in the table above.

The second specific objective was to eliminate any remaining instrumentation and user interface issues affecting Aim #3 testing. We also sought to complete testing of the Quick Pin mechanism, a mechanical unit that allows the liner to be quickly released or relocked to the tether, on study participants and to begin preparation of a manuscript on that technology.

*Significant results or key outcomes:* The most significant outcome is that the system is functioning properly in Aim #3 take-home testing without major incident. Issues that have occurred are minor, e.g., an incorrect date stamp in the data file. We demonstrated in laboratory testing that participants learned to use the Quick Pin rapidly – within four uses they connected and disconnected the release-relock tether in 3 to 15 s. This was a major advance compared to the prior method of twisting the pin into the liner which took several minutes. The Quick Pin also eliminated problems from pin loosening experienced by some participants. Data processing algorithms were completed for Aim #3 results. The code creates a series of plots that indicate how participants used their prosthesis, providing unique new information relevant to clinical care. The algorithms also indicate how frequently and when participants operated the release-relock system. To date, we have found that distinguishing active bout steps from weight shift steps provides a more complete picture of how participants use their prosthesis compared with total step count. Distinguishing partial doff from full doff helps to distinguish non-use from accommodation. From the instrumented ratchet dial that measures changes in socket size, we demonstrated in take-home testing that all but two participants kept the socket size during active use within approximately 1.0% of the fully closed position, following study guidelines. The two participants who used the ratcheting dial for socket size adjustment introduced this second variable into their data analysis, which will be managed in analysis accordingly.

*Detailed Report*

Results from Aim #3 and Aim #4 are presented by showing an example series of plots and tables for a participant. Resolved instrumentation issues and system improvements are discussed, the final design of the Quick Pin is presented, followed by a detailed presentation of our data processing and computational algorithms.

*Aim #3 Test Results to Date*

We expect to complete a total of 14 full study participants. Table 1 summarizes progress in testing.

**Table 1. Aim #3 Participants to Date.** Numbers in right six columns indicate days of use. PP=pre-pilot study. F=full study.

| Participant consented | Socket fabrication and fitting | Calibration | Intervention | | | Control | | |
|---|---|---|---|---|---|---|---|---|
| | | | Day 3 download | Week 1 download | Week 2 download | Day 3 download | Week 1 download | Week 2 download |
| Pre-Pilot: | | | | | | | | |
| PPI1 | X | X | 1-day | | | | | |
| PP2(2x) | X | X | 1-day, 3-day | | | | | |
| Pilot: | | | | | | | | |
| F1 (2x) | X | X | 2-day | 5-day | | | | |
| F2 (2x) | X | X | | 6-day, 7-day | | | | |
| Full: | | | | | | | | |
| F3 | X | X | 5 | 7 | 7 | 4 | 1 | 8 |
| F4 | X | X | 4 | 8 | 8 | 4 | 12 | 8 |
| F5 | X | X | 0 | 0 | 0 | 3 | 8 | 7 |
| F6 | X | X | 5 | 8 | 3 | 5 | 7 | 8 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| F7 | X | X | 1 | 9 | 6 | 8 | 6 | 8 |
| F8 | X | X | 5 | 9 | 7 | 6 | 4 | 9 |
| F9 | X | X | 3 | 4 | 5 | 3 | 6 | 12 |
| F10 | X | X | 0 | 0 | 0 | 4 | 0 | 0 |
| F11 | X | X | | | | | | |
| F12 | X | | | | | | | |
| F13 | | | | | | | | |
| F14 | | | | | | | | |

*Summary of protocol:* Participants test the socket in two configurations: intervention (release-relock motor active) and control (release-relock motor not active). The control configuration is run first. The participant wears the research prosthesis for a break-in period of 3 d. The researcher visits the participant, downloads and inspects the data, and makes adjustments to the instrumentation if necessary. The participant continues to wear the prosthesis in the control configuration for ~2 weeks, then returns to the lab. The participant completes a questionnaire and interview, the staff switch the research prosthesis to the intervention configuration and train the participant how to use the release-relock system. The participant leaves the lab and undergoes a break-in period for 3 d. The researcher visits the participant, answers participant questions (if any), downloads and inspects the data, and makes adjustments to the instrumentation if necessary. The participant continues to wear the prosthesis in the intervention configuration for ~2 weeks, then returns to the lab to complete a questionnaire and interview and return to their traditional prosthesis.

A series of plots were created from the collected data. The instrumentation in the release-relock system allows an extended analysis from the usual step count information provided by activity monitors. We characterize if steps were during walking bouts (a continuous series of at least 3 steps) or if they were during low commotion (weight shifts and bouts of 1 or 2 steps). Moving around a kitchen while cooking would be an example of low commotion. For the example participant shown in Fig. 1, for the intervention compared with the control, he executed more steps during walking bouts than during low commotion, suggesting that he conducted more strenuous activity when using the intervention configuration.

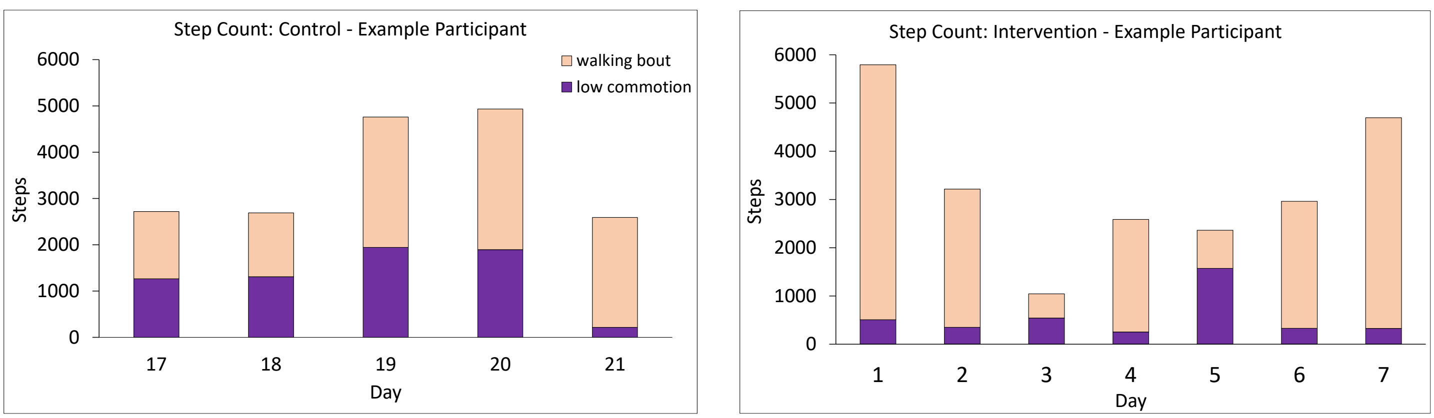



*Fig. 1. Step count data during walking bouts and low commotion.* For the intervention compared with the control, the participant took more steps during walking bouts than during low commotion.

His prosthesis use distribution also changed (Fig. 2). For the intervention compared with the control, he conducted more active use (green bars), less sit use (blue bars), and frequently used the release-relock system for partial doffing (gray bars).

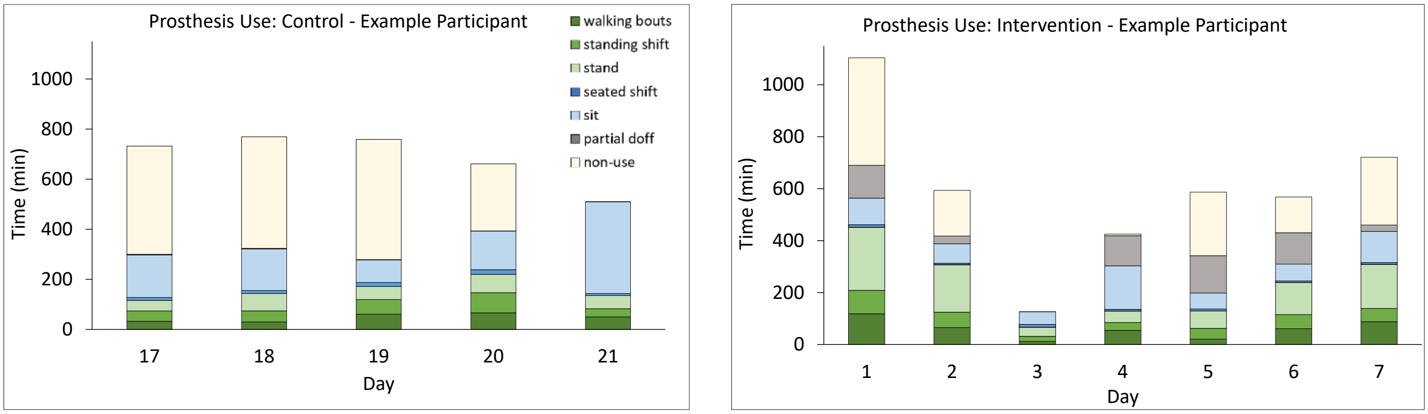



*Fig. 2. Prosthesis use.* For the intervention compared with the control, the participant conducted more active use (green bars) and less sit use (blue bars). He frequently used the release-relock system for partial doffing (gray bars).

For all wear days for the example participant, percentage at each of the seven uses is shown in Fig. 3. The percentage of non-use plus partial doff for the intervention (44%) was comparable to non-use for the control (48%), but the active use percentage (sum of green sections) was greater (39% for intervention, 25% for control). A possible explanation is that the improved limb volume stabilization from execution of socket release improved socket fit and allowed for greater activity. The presentation strategies for the data (Fig. 1-3) provide a platform to address the Aim #3 hypotheses.

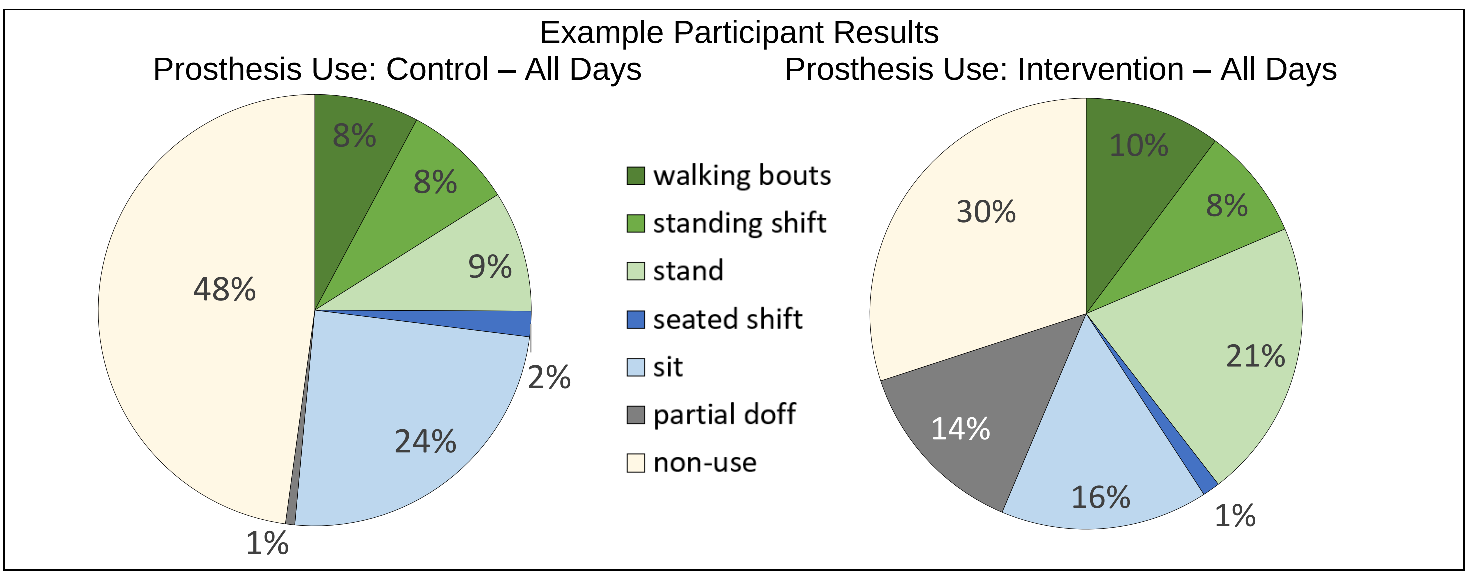



*Fig. 3. Percentage time at each of the seven prosthesis uses for control and intervention conditions.*

*__Aim #4 Test Results to Date__*

Three prosthetist participants have completed Aim #4 (Table 2).

**Table 2. Aim #4 Prosthetist Participants to Date.**

| Participant Prosthetist | Contacted | Signed Consent Form | Received Data | Completed Interview |
|---|---|---|---|---|
| P3 | X | X | X | X |
| P4 | | | | |
| P5 | | | | |
| P6 | X | X | X | X |
| P7 | X | X | X | X |
| P8 | | | | |
| P9 | X | | | |

Example results from one prosthetist participant are presented below. Before the meeting, the prosthetist was sent a formatted report, similar to Fig. 1-3 above. A Zoom discussion session was scheduled. The researchers fielded questions and clarifications. The practitioner was queried to interpret the presented information and asked for feedback on the display, potential uses of the data, and additional information (Table 3). Once interviews for all participants have been completed, we will group the results into common themes for analysis and dissemination.

**Table 3. Example Data: Summary of Responses from an Aim #4 Participant (Prosthetist)**

| **Topic** | **Feedback** |
|---|---|
| **Display/ Visualization of Data** | -Confused on the term Weight Shifting and what kind of activity were classified as such but picked up on the meaning<br>-Understood partial doff but needed further explanation of how the tethered socket system implemented it<br>-Enjoyed color scheme but it did not translate over to his printed black and white copy |
| **Potential Uses** | **- Release/Relock System:**<br>**-** Ease of partial doffing will be very useful to managing socket fit<br>-May also be useful for people on their hands and knees a lot. Partial doff would allow them to rotate their foot so it is not an obstruction as they crawl<br>-**Activity Monitoring System:**<br>**-**Can be used to refit participants' new socket though may not work for initial fittings as limb shifts drastically<br>-Can be used to justify need for more/less dynamic socket systems based on patient activity<br>-Can be used as part of insurance claims to justify care decisions<br>-Would allow users and practitioners to set goals such as walking more or sitting less<br>-Can be used to better classify patient activity outside of standard Medicare K levels |
| **Additional Useful Metrics** | -The addition of when the user shifts cadence and how often may be helpful<br>-Identify when heavy objects are being carried would be meaningful<br>-identify when user is running may be helpful |

*Instrumentation – Resolved Issues and System Improvements*

A number of mechanical, electronic, and firmware issues developed and were resolved during Year 4. We also executed a key system improvement – automated daily uploading of collected data. When the participant plugs in the unit for recharging each evening, the data are automatically uploaded to the cloud and communicated to our lab's data storage disk. Computer programs for immediate download and inspection of collected data are executed, and the staff notified if there are abnormalities that suggest research prosthesis performance issues that need to be addressed.

- *Board Revision 2C RTC Issue:* The Board Real Time Clock would not properly update to the correct time and would not progress as expected during data collection. This was caused by the IMU attempting to write to the same pin on the MCU as the RTC. Since the IMU is not used for data collection, it was removed from the board and the issue was resolved.
- *Board Revision 2C Tether Overtightening:* Initial testing of a new board revision showed that the tether would not stop retracting when resisted. This was caused by a minor component change that affected the current sensing functionality of the board. It caused a higher current threshold to stop the donning process. The firmware was updated using a lower current threshold and the issue was resolved.
- *Data Restart Issue:* To keep file size manageable and below data write limits on the board a daily 3:00 AM restart was implemented. Unfortunately, this method of managing the file sizes resulted in inconsistent board restarts and at times the data collection would not resume. This was attributed to the varying time it would take for the board to come back online following a full restart and its dependence upon the RTC for restart time. To mitigate the issue a new method was devised to restart data collection as file size approached 1GB. This method does not require the board to be completely restarted and bypasses the issue.

- *Tether Pin threaded into Liner unscrews during Activity:* Several participants noted that after a day of heavy activity the tether pin began to unscrew from the bottom of the liner, creating a potentially hazardous event. To mitigate this issue, flats were machined into the sides of the pin to allow for a wrench to be used to tighten the pin and compress the O-ring to prevent unscrewing. This modification was found to constrain the pin much more securely than using pliers or hand tightening, and participants have been able to wear the socket for weeks at a time without the pin becoming loose or the need for retightening. Nonetheless, participants are provided with a crescent wrench to tighten down the pin in the event of an emergency and are instructed to check the tightness of the pin daily. As an additional precaution, participants are instructed to not unscrew the tether from the liner during donning or doffing, but to instead invert the liner while the tether is still attached. This change required a longer tether length, but it eliminated issues with loosening of the threaded plug into the liner. In the long-term, the Quick Pin release unit, recently completed as described later in this report, will overcome this problem. It was not implemented in the present study because we would have had to execute a design modification of the release-relock system to create additional space to hold the Quick Pin hardware.
- *Static Charge Build-Up in the Socket:* With the colder weather in the area, there is greater static charge build-up in participants' socket than during warmer months. The charge can create issues while the person walks with the prosthesis. Once high enough, the static charge may discharge into our embedded electronic components and be transmitted to the circuit board. High voltage spikes trigger switches in the firmware that may freeze up the board, for example. This issue was addressed by changing the electronics to add a path for discharge that avoids causing these problems. This strategy, however, did not solve the root of the problem. We intermittently encountered the issue again. We conducted a series of bench tests to evaluate if a change in spacer material (replacing the hotmelt with Devthane, considered a strong insulator) eliminated the static charge problem. Tests were conducted on flat samples made up of 2-ply Nyglass and 2-ply carbon fiber. Results showed that the static charge issue could be created by applying an electrostatic shock to the carbon fiber side of the sample. Results for Devthane and hotmelt were comparable. The comparable results for the two materials suggest that the problem may be a result of how the material is applied, not the material itself. During fabrication of subsequent sockets, we added additional hotmelt over the thermistor, capacitor, and connections between the wires and antennas. We also created a test socket for a participant where we replaced the 1-ply carbon fiber layer over the antennas with two layers of Nyglass – moving the carbon fiber further away from the sensors. The sensors are sandwiched between 2-ply Nyglass on each side.

  There were two simultaneous issues at work here: static charge build-up in the carbon fiber; and a latch up issue on the board. The latch up issue likely resulted from the static charge release through the electronics. Through bench testing the electronics, we found that a sudden high input voltage on the ADC caused a silicone bug, a path triggered from power to ground that creates a short and instability such that the internal voltage, the rail voltage, changes. To fix the latch up, the power must be briefly disconnected from the electronics unit and the unit restarted. To resolve the issue, we added a trace connecting a pin on the microcontroller to a special pin on the battery charging component that resets the power on the board. Further, because we suspected that the latch up was caused by an incorrect electrical current reading on the board (in response to the static charge release), we added a separate circuit to monitor current draw at the battery leads. This addition will help debug the latch up issue should it be seen in the future.

  Participant testing with the new carbon fiber / Nyglass layup procedure effectively reduced the conductivity of the material surrounding the embedded sensors. This in combination with the updates to the board hardware and firmware provide redundant protections against this issue. Since implementing these system features, no issues have been observed with the socket structure, and ADC latch up has not been observed.
- *USB Download:* To avoid having to remove the SD card to download collected data, which may mechanically stress the release-relock components and increase the risk of damage, we modified the board to include a USB download cable. This addition is essential so that the electronics send the data to us each evening automatically when participants recharge the system. We used a Raspberry Pi to create a functional prototype. The USB download electronics, which we term the RAFT (Remote Access File Transfer unit), is kept in a box with a cable that the user plugs in each evening. The RAFT detects the release/relock unit, saves its operating state, puts the release/relock unit into a data transfer mode, copies the files and uploads them to Microsoft OneDrive,

and then restores the release/relock unit to its normal state. Several issues implementing this technology in the release/relock system were resolved. We resolved connectivity issues between the Raspberry Pi and the release/relock unit by adding a low-pass filter on one of the signals. A SD card support issue was resolved so that many SDHC cards from mainstream brands can be used. A T-Mobile internet connection was implemented through a Raspberry Pi modem HAT. A UPS circuit (uninterrupted power supply) was added to safely shut down the Raspberry Pi to avoid SD card corruption in the event of a power outage or hot-unplugging event. An enclosure (approximately 15 x 11 x 9 cm) was fabricated to hold the electronics. There is a wall plug on one side of the unit and the release/relock unit connector on the other side (USB-C), a straightforward interface.

After obtaining IRB consent for the additional hardware required for USB download from the sensors and upload to the lab, and effectively debugging the potential pitfalls described in earlier reports, the USB download system was implemented. In addition to the above-described functions, the unit, upon plug in, monitors the system to identify potential bugs. The system has the capability to be expanded to monitor multiple participants, increase storage capacity, compress data for faster file uploads, and execute contingencies for cases of low internet bandwidth. Other enhancements we implemented include creating a connect/disconnect log to monitor when the system was connected to the release-relock system, monitoring the USB port power when the release-relock unit is plugged in (this is relevant because when plugged in data collection stops, and we need to know for how long so as to line up the data properly during post-processing), zipping files prior to upload to decrease the time required to upload large file, using the RAFT to write a new runconfig file to the release-relock unit if the runconfig file is corrupted, and adding a hot-plug solution (restarting power on the unit if it did not connect properly to the RAFT). The hot plug fix is that if the release-relock system SD card cannot mount in 16 tries then the RAFT will reset the MCU and try again.

- *Tether Loosening:* Some participants experienced loosening of the tether cable over time after donning the socket, potentially creating discomfort at the end of their residual limb during ambulation. We suspect that the high tension in the tether cable during walking tightening the tether wrapped around the take-up spool in the release/relock unit. To resolve the issue, we created automated tether retraction code to periodically apply tighten bursts (auto-don bursts) to the tether. Auto-don bursts are triggered to occur 10 minutes after the socket is donned, 50 minutes later, and then once per hour until the socket is doffed. Each auto-don burst is six electronic bursts at 1-second intervals. From bench tests and field tests, it operated as intended, removing slack from the tether generated from repeated pulling on the lanyard during walking. The sequence retracts the tether at 10 min after the socket is donned, then at 1 h intervals until the socket is doffed. During a sequence, the socket retracts the tether until a motor current threshold is met in six attempts. Implementation of this strategy improved participant comfort per feedback collected during follow up interviews.
- *Tether breakage issue:* We reported on this issue and a solution during Year 3. Part of that solution was inspecting the tether weekly to look for signs of damage and replace the tether if necessary. From successful testing several participants in Aim #3 without problems, this is now considered a non-issue. We no longer conduct weekly inspections, but we continue to inspect the tether during participant visits.
- *RTC Timestamp Issues:* Some of the 20 circuit boards ordered during Year 4 had time stamp issues. We are not able to print the time stamp correctly on command or in the data files, and the timestamp does not update properly. Either it remains the same or does not increment correctly. The boards demonstrating this hardware issue were removed from circulation and an in-depth analysis of the RTC was conducted. The issue was caused by faulty RTC parts and are not repairable. Due to limitations in our ability to replace these RTC's, the boards were permanently labeled as defective. All data collected from the defected boards was repaired in post processing and new timestamps were generated independent from the original data.

  Another RTC timestamp issue was identified. After collecting week-long out of lab data from some participants it was found that the length of the file was several hours shorter than expected. From analysis of the data, there was a noticeable difference in the timestamp from the RTC, which was accurate, and the timestamps stored in the data which was several hours behind. The possibility of long-term timestamp drift was eliminated as a cause based on lab test results showing a maximum disagreement between the MCU timer and RTC timer of only a few seconds per day. Therefore, it was inferred that the board went offline for an indeterminate amount of time and when it came back online, the MCU timer picked up from the last timestamp. The source of this problem is as follows: when data collection is started, the MCU timer is set based on the RTC time. After the sampling of the RTC timer at the beginning of the data collection the timestamps are generated solely based on the internal MCU timer. If the board goes offline for a period of time, then comes back online without a change in time it is difficult to determine when the period of no data occurs, especially if this happens at night when the socket is doffed.

In order to improve timestamp accuracy, the code was altered so that the RTC timer, which operates on an internal battery independent of the release-relock system, is sampled once an hour and if there is a disagreement the MCU time is reset based on the RTC timer. This modification allows us to better determine any point during which data is lost to be identified and increases timestamp accuracy based on an independent system.

*Minor Issues Being Resolved*

- *Socket Fabrication Enclosure Fills with Resin:* During the final stage of fabrication of the sockets with embedded sensors, there is a potential risk that resin will fill the enclosure, ruining the socket. The enclosure is sealed using silicone and clay prior to the final layup to keep resin out of the enclosure. However, if a hole in the enclosure is not properly sealed then this can result in the enclosure filling with resin. The risk of this happening and the consequences of failure are detrimental to the effectiveness of the release-relock socket. The solution we implement is to temporarily fill the enclosure with silicone. The silicone is removed after fabrication is complete.
- *Clicking Noise:* The pin lock used in the control configuration of the release-relock unit creates a clicking noise that is audible to people wearing loose fitting sockets. This is caused by the pin movement, the pin lock hitting the bottom of the upper pin notch during swing phase.

*Circuit Board Update:* For use in Aim #3 take-home studies, we designed new circuit board hardware and made changes to the firmware to enhance the performance of the release-relock socket system. The modifications and the reasons for the changes are summarized in Tables 4 and 5 below.

**Table 4. Release-relock system V3 hardware updates.**

| | Hardware: V3revA changes from V2revC | Description/System Impact |
|---|---|---|
| 1 | 5.1k resistor installed on the enable pin of the load switch that switches on the system voltage source to the 6V regulator | Prevents a premature 6V power up condition by preventing the load switch from allowing the 6V regulator to power on and enable the solenoid to fire before MCU initialization. This fixes a bug that caused the solenoid to erroneously fire upon board power up, which at a mid to low battery level, subsequently caused the battery voltage to drop below the system minimum, in turn causing a MCU brown out and preventing the MCU from resetting properly until the battery is recharged. Avoiding this scenario increases the system battery life substantially. |
| 2 | Installed pull down resistor (5.1kohm) on 5V regulator U5 (TPS610997) | Prevents a premature 5V power up condition. |
| 3 | Installed a 20kohm pull-down resistor to device U2A pin 6 (74LVC1G175) | 20k resistor and 10nF capacitor form a low pass filter circuit that fixes a signal propagation timing error in the digital circuit that sends the USB detect signal to the MCU. |
| 4 | Installed a 10nF capacitor between BQ25895 DSEL pin and GND | This capacitor fixes a hardware bug in the USB detect circuit, allowing USB detection during any connection conditions. Previously, the board could not connect via USB on the first connection attempt. |
| 5 | Re-routed the motor control signal | Re-routing the motor controller PWM signal trace avoids crosstalk noise coupling to the thermistor signal traces. |
| 6 | Routed a trace between BQ25895 pin 12 and the | The BQ25895 is able to briefly toggle an internal switch to the battery, resetting the power to the board. This trace to the MCU allows the user to issue a board power |

| | | |
|---|---|---|
| | MCU pin 45 | reset command, locally (as in through the PC command interface) or through remote access to the board. |
| 7 | Updated the footprint for the ICM-20608-G | The footprint was adapted for this component to update the IIC address and resolve an address clash conflict with another component. |
| 8 | Implemented the TI TMCS1101 signal path and layout | The TMCS1101 was integrated into the signal path between the battery input and BQ25895 BMS component to allow real-time battery current diagnostics, act as a motor current sensing backup device, and enable battery capacity monitoring. Sensor output was routed to an available ADC input. |
| 9 | Installed a protection diode near the thermistor power off-board connection | Diodes were installed to protect three components against ESD transient voltages coupled onto the power signal path embedded in the STM sensor in the socket wall. 5 diodes were placed, 1 on the power that connects to the thermistors off-board and powers the ADC and ratcheting dial circuitry, and 1 on each of the 4 thermistor inputs to the ADC. |

**Table 5. Release-relock system V3 firmware updates.** Changes made to the LPC54115 MCU.

| | **Firmware: V3revA changes from V2revC** | **Description/System Impact** |
|---|---|---|
| 1 | 1GB data file size limit | Files are transferred more quickly, 4GB file size limit is avoided. |
| 2 | Composite USB device feature | Data files may be downloaded onto a host computer when a command is sent to the release-relock unit. Allows switching between sending commands and reading files from the release-relock unit. 220kB/s read speeds. |
| 3 | Thermistor monitoring feature | Implemented a system feature to monitor the thermistor ADC readings to check for semiconductor latch-up on the ADC and to recover with an automated power reset of the board. Set up system monitoring foundation to also be able to easily implement additional system monitoring features in the future (such as low voltage monitoring). |
| 4 | Power reset command | Implemented a new command to reset the board power while operating from a battery—for use in remote board operation. |
| 5 | MCU reset command | Implemented a new command to reset the MCU—for use in remote board operation. |
| 6 | Update to SD card mounting | This expanded support for more SD card brands and allowed for SD card insertion/desertion while the board is powered. |
| 7 | Auto-don feature | The state machine was updated to support timed 1 second auto-don bursts, periodically, to keep the tether tight. |
| 8 | New command handling structure | The command processing structure was updated to drastically expand the command dictionary and add new commands easily. |
| 9 | USB connection bug fix | In conjunction with the hardware solution, this update made USB connections more robust. |
| 10 | Host Identification Command | This command is required for compatibility with our remote access file transfer tool (RAFT). It ensures that the release-relock board autonomously restarts its data collection after interfacing with the RAFT system to transfer data files. |
| 11 | Partial Doff Update | The partial doff was removed to enable a researcher the option of utilizing partial doff or not, in the system operation. A command was implemented that allows the researcher to put the board in DOD mode where it will force a partial doff. The partial doff state is still reachable by pressing the doff button. |

### *Quick Pin Final Design*

Modifications were made to the Quick Pin design based on initial feedback from engineering staff, participants ($n$=5), and the research scientists running the test sessions. The current design of the Quick Pin is illustrated in Fig. 4, and a summary from internal design review and participant testing is provided in Table 4.

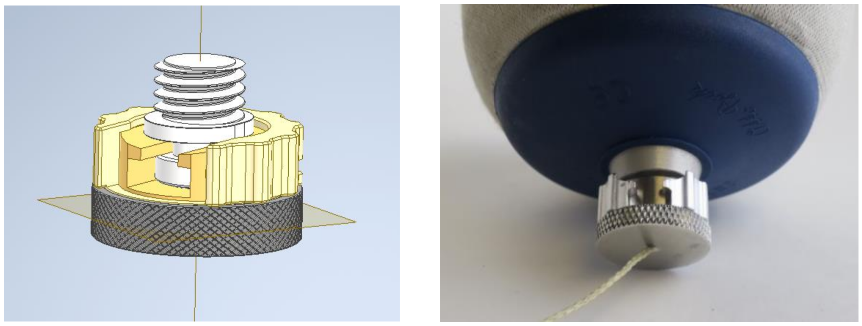


*Fig. 4. Quick Pin final design. The user rotates the yellow knob, slides the pin into the slot, and then releases the yellow knob to lock the pin in place.*

**Table 6. Feedback on Quick Pin Performance.** From internal design review and participant tests.

| Commenter | Comments | Changes Made |
|---|---|---|
| Staff engineers | The alignment of the slot with the dowel rod needs to be improved | The parts were more accurately machined to ensure alignment; spacers were used during assembly to properly align the pin in the liner (once aligned, these parts are not removed by the user) |
| | The gate should be undercut to simplify operation | The undercut was removed as suggested |
| | The T-pin in the slot is too tight because a cable with a different thickness is used | The part was modified to clear out more space for the cable and knot |
| | The gate gets caught on the pin, a combination of it not sliding in all the way and insufficient clearance for the knot | The pin shape was changed so that the flange was round rather than oblong |
| | The pin surface should be made smooth to reduce friction | The metal was anodized |

| Commenter | Comments | Changes Made |
|---|---|---|
| Participants in clinical tests | The liner would not allow the gate to close (participant #3) | The section above the pin was thickened |
| | The dowel rod should be removed, covered, or shortened (#2,#3) | This part is used only for assembly of the system, so no change made |
| | It would be better if the Quick Pin were bigger (#3,#4) | This comment was interpreted as ease of twisting. The part gripped by the user was made slightly larger, rubberized, and with less exposed metal |
| | The design needs to be changed so that it is easier to align the pin with the slot (#3) | The slot position was moved to a consistent position – anterior |
| | It would be better to color the materials so that the pin and slot are more easily visible | Anodizing the material improved the color difference between parts |
| | It would be difficult to use the Quick Pin in the dark (#3) | The part gripped by the user was made slightly larger, rubberized, and with less exposed metal |
| | The multi-step nature of the design is unfavorable (twist, hold, slide); it would be better to have 1 single motion | A different design concept would be needed; no change implemented |

| Commenter | Comments | Changes Made |
|---|---|---|
| Research scientist executing study | The liner would not allow the gate to close (1 partic) | See above |
| | The gate would not close unless the pin was fully seated (3 partic) | See above |
| | The gate would sometimes not go to the full 90-degree position if it was not fully seated | See above |
| | The alignment of the pin and slot must be made easier | See above |
| | It needs to be more obvious which part should be twisted | See above |

In addition to providing comments on Quick Pin performance, participants' don and doff execution times were tested. Results from four don-doff cycles are tabulated in Table 7. By the 4th trial, time to execute a don or doff ranged from 2s to 15s. These times are reasonable for clinical implementation and are substantially less than the alternative method – the threaded fastener in the distal liner. Preparation of a publication on the Quick Pin is in process.

**Table 7. Participant Time to Don and Doff Using the Quick Pin**

| | Time Metric (s) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Partic.** | **Don 1** | **Doff 1** | **Don 2** | **Doff 2** | **Don 3** | **Doff 3** | **Don 4** | **Doff 4** | **Avg Don** | **Avg Doff** |
| 1 | 10 | 10 | 5 | 3 | 3 | 3 | 3 | 3 | 5 | 5 |
| 2 | 15 | 5 | 10 | 3 | 5 | 4 | 2 | 2 | 8 | 4 |
| 3 | 30 | 20 | 30 | 20 | 30 | 20 | 15 | 10 | 26 | 18 |
| 4 | 30 | 25 | 25 | 20 | 25 | 20 | 15 | 15 | 24 | 20 |
| 5 | 10 | 10 | 30 | 10 | 30 | 10 | 15 | 15 | 21 | 11 |

*Data Processing and Computational Algorithms*

We enhanced our code to process data from the sensors embedded within the socket wall to determine participants' bodily position and activity. Upper and lower bounds of the stance phase signal are determined for each walking bout and used as an "envelope" for characterization (Fig. 5). A threshold distinguishing sitting from standing is determined for each participant from calibration tests before the participant leaves the lab, and then implemented in processing of data from at-home use. The threshold is defined as a percentage of the range between the upper and lower bounds of the envelope. A doff threshold is specified (usually 8-10 cm) based from calibration data. A partial doff is distinguished from a full doff by contact at the proximal sensors on the medial and lateral flaps of the socket (Fig. 6). The motor distance data is used to verify the results.

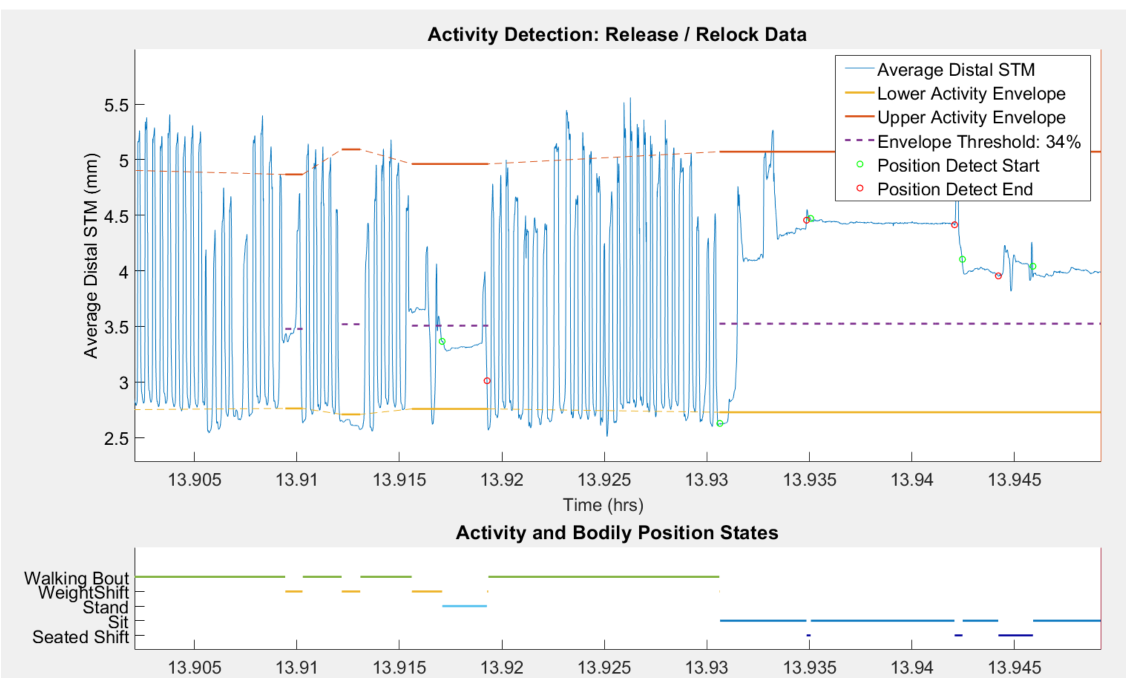



*Fig. 5. Bodily position and activity detection. Upper panel: Liner-to-socket distance sensor data, showing the upper and lower bounds of the envelope (red and orange lines) as well as the sit-stand threshold line (purple dashed line). Lower panel: Record of detected activity.*

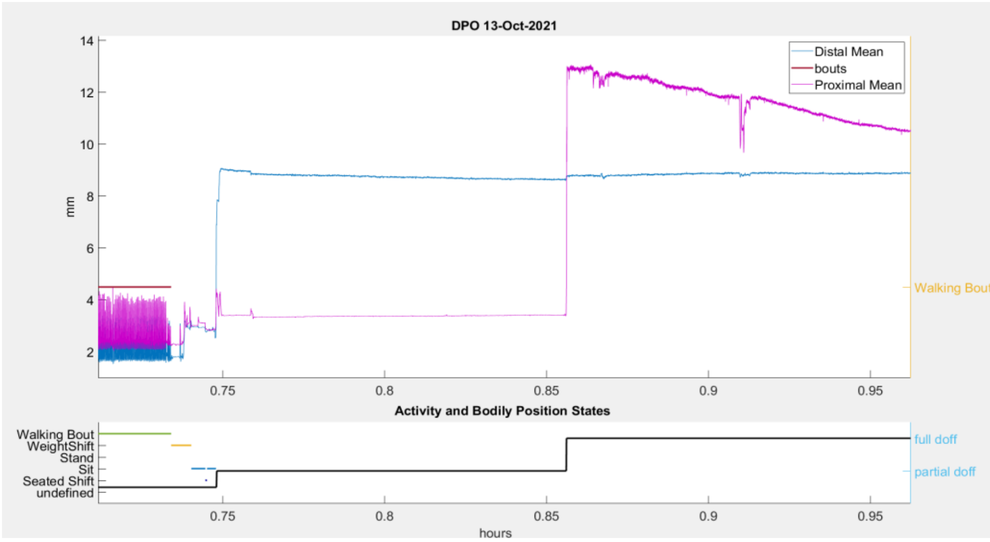



*Fig. 6. Distinguishing partial doffing from full doffing. The distal sensor mean shows no contact for both partial doff and full doff. The proximal sensor mean shows a transition from contact to no contact, indicating transition from a partial doff to a full doff.*

We further enhanced our code to determine the start and end of a prosthesis day. The method is identical to that used in our prior work [*J Prosthet Orthot* 2018;30(4):214-230]. Distinguishing when the prosthesis is initially donned at the outset of the day and when it is doffed at the end of the day simplifies interpretation by focusing computational analysis on the most clinically meaningful part of the data.

We enhanced our weight shift detection algorithm. Weight shifting is a new metric that we introduced to outcome assessment in prosthetics, extending beyond the standard step count and cadence data. A weight shift is defined within a section of non-walking bout data. When 5 data points show an increase greater than 2x the standard deviation from the mean of the previous 5 data points, the beginning of a weight-shift is defined. If there exists 3 seconds of data that do not exceed the standard deviation threshold then the weight-shift is ended, and the subsequent data are classified as stable, i.e., a sit or a stand. Once the sections of stability are identified, a sit-to-stand transition threshold is implemented (from a calibration procedure conducted in the lab prior to participants being sent out with the system). All data from a take-home interval are compiled into both daily plots as well as weekly plots.

*Aim #2 Instrumented Dial Results*

Data from the instrumented ratcheting dial were processed as done in our prior work [Med Eng Phys 2021;90:100-106], using the data from the two phases of the rotary sensor to count dial rotations. These data were converted to cable length using the spool diameter of the ratcheting dial and tether thickness around the spool. The mean cable length during the walking phase of each cycle was calculated. Results for the twelve cycles for each session were tabulated and a median calculated. A computational model of the socket was used to calculate the percent socket volume difference for each cycle relative to the median socket volume from the patellar tendon to the distal end of the limb.

In Aim #2, dial angle was successfully collected in 20 sessions, approximately the first half of the sessions conducted. Results demonstrated that the dial angle was consistent across walk cycles (Fig. 7). In these figures, the percent socket volume change for the closed position (minima) from one cycle to the next is small. For all sessions, the deviation in socket volume during walking for all cycles was less than ±0.8% of the mean for all cycles in the session. In 96% of the cycles the deviation was less than ±0.5%. Since these percent socket volume changes were lower than those expected to induce a clinically detectable change in socket fit and since the procedure for setting the dial angle was demonstrated consistent, dial angle was not monitored for the remaining sessions.

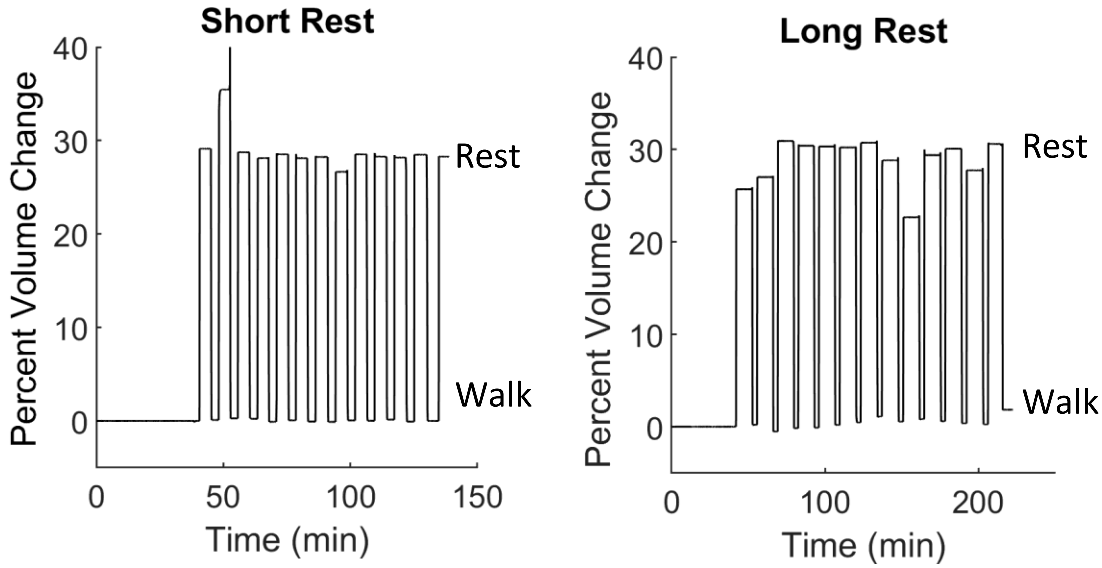



*Fig. 7. Example results from the instrumented dial during Aim #2 testing*.

The instrumented dial data during take home use was used to determine if participants executed the testing protocol as instructed – release the dial when executing a socket release and return it to its normal size after socket release, but otherwise do not make adjustments to the dial. In testing to date we have found that all but two participants executed the instructions properly. We will adjust our analysis for the two participants who on at least one occasion did not follow the protocol.

The stated goals for Year 2 were completed. The stated goals for Year 3 were not met because of University of Washington human subject testing restrictions resulting from COVID-19. We are anticipating the remaining Year 3 and 4 goals to be accomplished during the extension period.

**What opportunities for training and professional development has the project provided?**
A PhD graduate student and three staff members in Bioengineering gained relevant training and professional development through participation on this project.

**How were the results disseminated to communities of interest?**
Results were disseminated through scientific conference presentation and peer-reviewed publication submission.

**What do you plan to do during the next reporting period to accomplish the goals?**
Our objective during Year 5 (through Dec 2022) is to complete testing of the remaining 4 prosthesis user participants in Aims #3 and the remaining prosthetist participants in Aim #4. All data should be processed and analyzed to address the hypotheses and a draft publication prepared. Manuscripts on the Quick Pin technology and on Aim #3 results will be submitted.

## 4. IMPACT:

**What was the impact on the development of the principal discipline(s) of the project?**
The project impacts the prosthetics discipline and industry. The technology extends from the traditional manual tether used to don and suspend 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. Of additional relevance is that the unit serves as a prosthesis use monitor, allowing characterization more advanced than traditional step monitors. We expect manufacturers will incorporate elements of the system into their commercial products. We have been contacted by companies to do so.

**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?**
The impact on society is demonstration of the use of advanced electro-mechanical technology to successfully address a long-standing issue in disability.

## 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**
We reduced the take-home data collection period and reduced the number of participants in Aim #3 because of the impact on progress and expenditures of prior COVID-related UW regulations on human subject testing.

**Changes that had a significant impact on expenditures**
Electronic part supply availability and quality, and cost resulting from COVID-related issues.

**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 #11:
    - UW IRB: Submitted 02/16/2021, Approved 02/19/2021
    - HRPO N/A, not a substantive modification
- Mod #12:
    - UW IRB: Submitted 04/20/2021, Approved 04/26/2021
    - HRPO N/A, not a substantive modification
- Mod #13:
    - UW IRB: Submitted 05/21/2021, Approved 05/25/2021
    - HRPO N/A, not a substantive modification
- Mod #14:
    - UW IRB: Submitted 09/15/2021, Pending
    - 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.

Mod #11 updated "Anticipated Risks" and added two device setup checklists to study documents, in accordance with the UW IRB's review of an adverse event report (see "iii")

Mod #12 added Aim 3B ICF, to allow for shorter testing of the Aim 3 device out of lab in preparation for full Aim 3 study.

Mod #13 updated compensation wording on Aim 3B ICF.

Mod #14 added optioned check-ins at 1-week intervals and shortened the overall time of take-home use to 3 weeks per configuration (intervention, control).

**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**

  **Publications**

  Lanahan DR, Coburn KA, Hafner BJ, Ballesteros D, Allyn KJ, Friedly JL, Ciol MA, Carter RV, Mertens JC, Krout AJ, Sanders JE. "Release/relock sockets for transtibial prosthesis users: Release duration and residual limb volume" *PM&R* (submitted)

  **Conference paper.**

  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)**

  http://depts.washington.edu/jsweb/ ("Adjustable Sockets: Release-Relock")

- **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: | Janna Friedly MD |
| Project Role: | co-Inv |
| Researcher Identifier (e.g. ORCID ID): | https://orcid.org/0000-0002-7483-7888 |
| Nearest person month worked: | 1 |
| Contribution to Project: | Clinical study design and interpretation of data |

| | |
|---|---|
| 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, outcome assessment

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

Name: Ryan Carter
Project Role: Research Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
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: 3
Contribution to Project: Testing of release and 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: Kendrick Coburn
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 8
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: 2
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

Name: Joseph Mertens
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 6
Contribution to Project: Study execution

Name: Nicholas DeGrasse
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Data processing

Name: Adam Krout
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2
Contribution to Project: Mechanical and electronic debugging, study execution

Name: Gabriel Lake
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 4
Contribution to Project: Board design, electronic debugging

Name: Bailey Ramesh
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2
Contribution to Project: Control system operation

Name: Nicholas McCarthy
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 4
Contribution to Project: Data processing

**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
New grant that has started:
R01HD103815 (Sanders)
National Institutes of Health – National Institute of Child Health and Human Development
“An automatically-adjusting prosthetic socket for people with transtibial amputation”

GARBINI, JOSEPH L
New grant that has started:
R01HD103815 (Sanders)
National Institutes of Health – National Institute of Child Health and Human Development
“An automatically-adjusting prosthetic socket for people with transtibial amputation”

HAFNER, BRIAN J
New grants that have started:
2122-UW-ASCENT (Wurdeman)
Hanger Institute for Clinical & Scientific Affairs
"ASCENT K2: Assessing Outcomes with Microprocessor Knee Utilization in a K2 Population"

FRIEDLY, JANNA L

New grant that has started:

R01HD103815 (Sanders)
National Institutes of Health – National Institute of Child Health and Human Development
"An automatically-adjusting prosthetic socket for people with transtibial amputation"

75D301-21-C-11341 (Scott)
Family Health Centers of San Diego, Centers for Disease Control and Prevention (Subcontract)
"Improving Clinical and Public Health Outcomes Through National Partnerships to Prevent and Control"

R34 AR 080279-01A1 (Suri)
NIH/NIAMSD
"A Superiority Trial of Radiofrequency Ablation for Low Back Pain (ASTRAL)"

**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

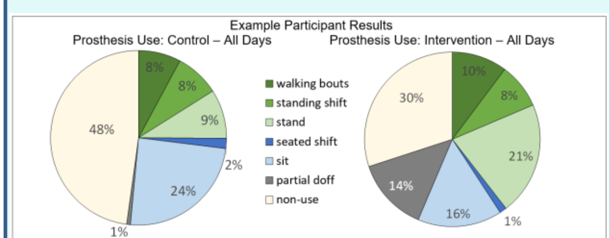
**PI:** Joan Sanders Ph.D. **Org:** University of Washington **Award Amount:** $2M

**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 multiple days 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 3-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 results from Aim #3 testing showing prosthesis use results for active and control release-relock configurations for a participant. Partial doff indicates use of the release-relock system.

**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)** | **$266** | **$470** | **$595** | **$669** |

**Updated: 08/31/2022**

**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
**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 (partial)
**CY20 Goals** – Continue field testing, begin to assess outcomes data
☒ Continue outcomes evaluations of release/relock in field tests (partial)
☒ Interviews to assess value and quality of outcomes data (*n*=1)
**CY21 Goals** – Complete field testing, assessment of outcomes data
☐ Disseminate results
☐ Prepare final report

**Comments/Challenges/Issues/Concerns**

- Challenge: COVID-19-related delays necessitated fewer total partic.

**Budget Expenditure to Date - $1,842,127**