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14. ABSTRACT
Aim #2, an in-lab study to assess the impact of short-duration and long-duration socket release on residual limb fluid volume compared with no release, was completed. Results showed that 62% of participants lost less limb fluid volume using either socket release strategy, 23% lost less limb fluid volume only with the short-duration release strategy, and 8% lost less fluid volume only with the long-duration release strategy. No relationship between the release strategy that induced the least fluid volume loss and participant physical characteristics or heart rate was identified. In preparation for Aim #3, the release and relock controller design was modified to include transitory states that enhanced reliability, increased battery life, and better delineated in the data stream how the system was used. A thicker tether and a tether guide were added to reduce the risk of tether damage during take-home use in Aim #3. Pilot Aim #3 studies demonstrated reliable performance in multi-day testing. Participant gains during partial doffs were evident in liner pin depth and liner-to-socket distance data.

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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TABLE OF CONTENTS

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 (delayed by COVID)	original TARGET	%COMPLETE
1. Conduct Aim #2 study		
Recruit participants	28 Mar 2020	100
Fabricate sockets	28 Mar 2020	100
Conduct monitoring sessions	31 May 2020	100
Process collected data	31 May 2020	100
Conduct statistical analysis and address hypotheses	30 June 2020	100
Milestone #3: Aim #2 study complete	31 July 2020	100
2. Disseminate findings		
Attend scientific meeting or DoD conference	31 July 2020	100
Submit manuscript	31 Aug 2020	50
Milestone #4: Manuscript submitted on Aim #2 study	31 Aug 2020	50
YEAR 3 GOALS & MILESTONES (delayed by COVID)	**original TARGET**	**%COMPLETE**
3. Conduct Aim #3 study		
Recruit participants	30 Nov 2020	6
Fabricate sockets	31 Dec 2020	6
Conduct monitoring sessions	31 Jan 2021	6
Process collected data	31 Jan 2021	6
Conduct statistical analysis and address hypotheses	28 Feb 2022	0
Milestone #5: Manuscript submitted on Aim #3 study	31 Mar 2022	0

What was accomplished under these goals?

Major activities: The major activities during Year 3 were to complete Aim #2 testing, solve instrumentation, training, and user interface issues for the Aim #3 release and relock system, and conduct pilot testing for Aim #3, a take-home study.

Specific objectives: The first specific objective was to complete Aim #2 testing. Data collection was completed on 05/14/2021. The number of participants was reduced from the 40 stated in the grant

application, in part because of University of Washington human subject testing restrictions introduced by COVID-19. Further, statistical significance was achieved in Aim #2 study results using the data that were collected. The reduced number of participants tested (16 full study participants) was considered acceptable towards the objective of Aim #2.

The second specific objective was to update the release and relock system and complete pilot testing (n=2) for the Aim #3 study. We completed all necessary modifications to the release and relock socket design and conducted multi-day at-home pilot studies to ensure proper function. The full Aim #3 take-home protocol started at the outset of Year 4.

Significant results or key outcomes: A total of 16 participants were tested in the Aim #2 full study. Thirteen completed testing under all three conditions: short-release rest, long-release rest, and no-release rest. Results demonstrated that 12 of the 13 participants achieved higher limb fluid volumes for at least one of the intervention conditions (short-release rest, long-release rest) compared with the control condition (no release), demonstrating that the developed technology accomplished its intended objective of reducing limb fluid volume loss. A detailed discussion of the Aim #2 results is provided below.

Detailed Report

Aim #2 Final Test Results

A total of 36 participants were recruited for Aim #2, 21 were screened, and 18 were enrolled. Data were collected from 16 participants. Thirteen of the participants completed all 3 sessions: short-duration socket release, long-duration socket release, and no release (control). Data were processed to determine which interventions reduced fluid volume loss compared with control. For 8 of the 13 participants, both the short-term and long-term socket release strategies reduced fluid volume loss compared with control (Fig. 1). For 3 participants only the short-term and not the long-term strategy was effective, and for 1 participant only the long-term and not the short-term strategy was effective. One participant demonstrated no meaningful difference for either socket release strategy v. control. No participant experienced greater fluid volume loss for both socket release strategies.

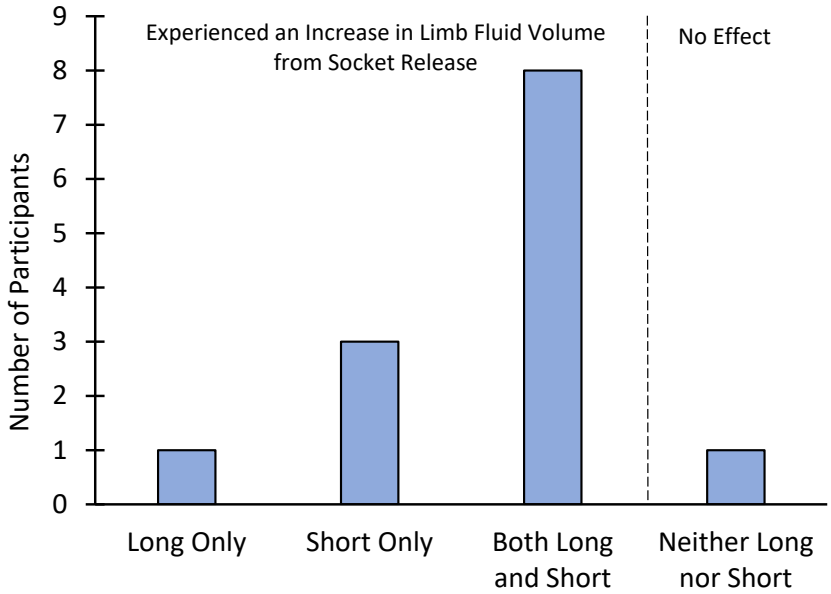


Fig. 1. Aim #2 Results. Participant limb fluid volume response to long-term and short-term socket release protocols.

The most effective release strategy for each participant was not related to heart rate during walking or sitting or to the difference in heart rate between walking and sitting. We are extending the analysis to investigate a relationship between treadmill speed and percent maximum heart rate with the thinking that this effort may help delineate subject physical condition, which may be related to which release strategy was most effective.

Most of the participants' self-report scores (relative socket comfort score (rSCS)) were zero over the duration of the test. There was no significant difference in socket comfort for intervention v. control.

Instrumentation Modifications

From experience completing Aim #2 and bench testing the Aim #3 system in the lab, we identified several additional issues beyond those described in the Year 2 report that were deemed necessary to correct before the release and relock socket was ready for Aim #3 take-home testing. The primary challenges are summarized in the paragraphs below. Other challenges that were addressed are listed in Table 6.

Mechanical damage issues: Because of the limited number of release and relock units available during Aim #2 testing (electronic part supplies were limited as a result of COVID-19), we were continually removing release and relock units from participants' sockets and installing them in other participants' sockets. Fatigue of the motor housing continued to be an issue thus the material was changed from plastic to aluminum. Because of wire impingement problems within the unit, particularly for the solenoid connections, the housing was redesigned to include a cable routing channel and hangers. Mechanical bending of the circuit boards caused components to loosen and the boards to fail. Spacers and O-rings were added to the board mounts and Loctite was used to hold the boards in place rather than tightened screws that tended to stress and bend the boards.

Necessity for a Control design: Because of the need for a size and weight-matched system for the control configuration in Aim #3, a Control unit was designed (Fig. 2). When equipped with a Control unit, the socket is the same size and weight as a socket with the normal release and relock system. However, the Control unit houses a traditional mechanical pin-lock instead of the motor assembly and tether. The unit is wired like the normal release and relock system so that button presses (pin releases) executed by the participant are recorded.

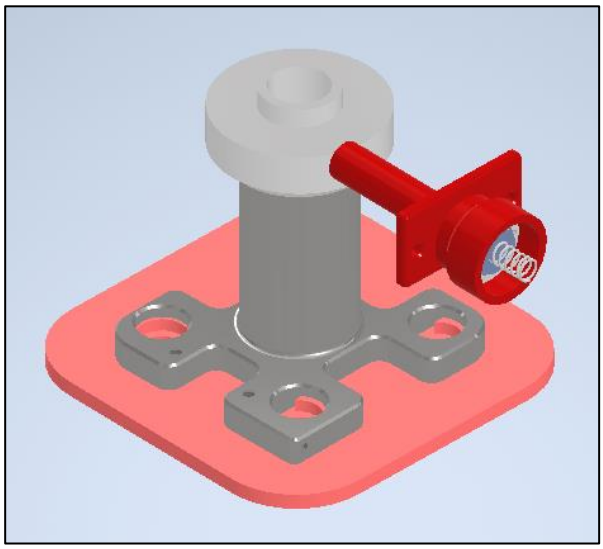


Fig. 2. Control unit used in Aim #3. The motor and tether are replaced with a pin-lock unit.

Board occasionally crashes when solenoid operated under battery power + poor battery life: The release and relock system firmware was modified to include transition states in the controller code, which helped to clarify the release and relock sequences. This change helped us to better manage events between don, doff, and partial doff states that were expected the cause of the board crash problems. The new design, illustrated in Fig. 3, manages all possible user actions, showing the event combinations and timings that occurs between states. A series of bench tests was executed to evaluate and tune the firmware for each path in the diagram so that it functioned reliably (Fig. 4).

As indicated in the diagram, alternative strategies were implemented in the event transitions between states were not achieved (the four path pairs with circled numbers in Fig. 3). These strategies help to ensure the release and relock system does not lock up from unforeseen circumstances that cause the target state not to be achieved. Firmware was added so that if the target state is not achieved, the system simply returns to its prior state.

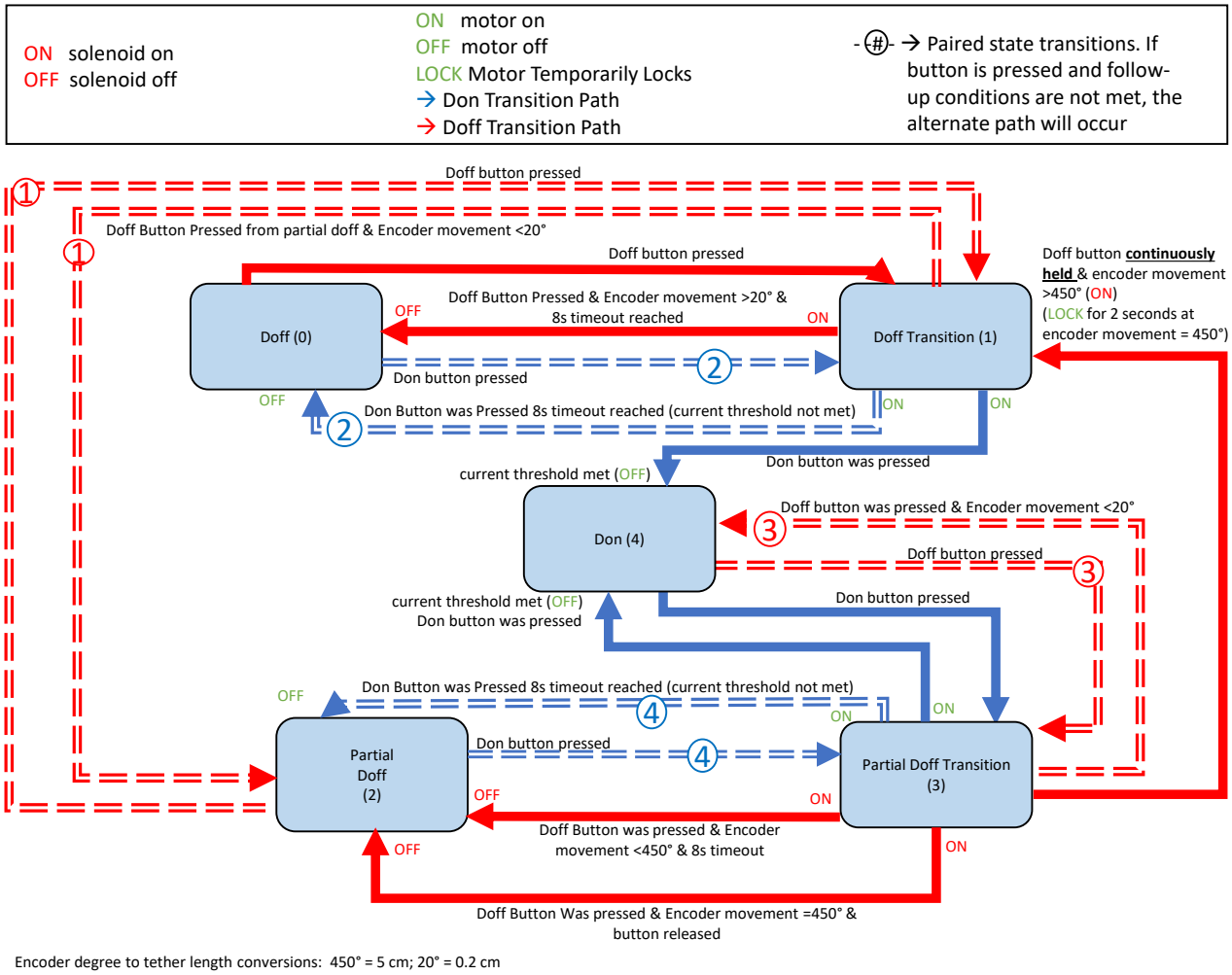


Fig. 3. State diagram showing the release and relock sequences for all possible user actions in the release and relock system.

Fig. 4. Bench test set up showing how the state diagram illustrated in Fig. 3 was evaluated.

While this modification improved operation of the release and relock system, the excessive power draw and board crashes after minor battery voltage reduction remained issues. Additional bench testing demonstrated that solenoid operation was the primary initiator of these problems. Firing the solenoid caused a sudden power surge which affected operation of the rest of the system. To resolve the problem, in the firmware we reduced the duty cycle of the solenoid from 100% to 30%. This change eliminated board crash problems and excessive power consumption. Also in firmware, we decreased the threshold current draw at which battery charging stopped when the battery charger was plugged in, and that increased storage capacity and enhanced battery life. A power analysis of the system demonstrated that standard operation (powering the board, sensors, and data acquisition componentry) was the primary power draw assuming five dons, doffs, and partial doffs were executed each day (Table 1).

Table 1. Power Draw Calculations

Event name	Operations	Current draw (A)	Duration (s)	Load on battery /h or /event (mA·h)	Load on battery for 1-day use (24 h) + 5 dons, doffs and partial doffs (mA·h)
Standard operation	Board and sensor power & SD card writes	0.04 A	60.0	40.00	960.0
Partial doff	Firing the solenoid	2.04 A	2.5	1.42	7.1
Full doff	Firing the solenoid	2.04 A	5.0	2.84	14.2
Don	Running the motor at least twice + removing slack	0.18 A	10.0	0.50	2.5
					Total = 983.8

Note: All current draw values were taken from a multimeter running at a sampling rate of approximately 100 Hz. It should be noted there will be some variation in the duration of the partial doff and don events since the event durations depend upon characteristics of individual user operation.

Additional evaluations were conducted to determine if an alternate solenoid provided more force than the current product. Two new solenoids (Geeplus models M144c-6V and M192-6V) were tested and compared to the current solenoid (from ZonHen). Results showed that the M144-6V supported only 30 g and the M192-6V only 20 g, much less than the 70 g of the current product, thus no change to solenoid selection was made.

We evaluated three different sized batteries to determine the smallest size that operated the release and relock system for a minimum of approximately 2 days of continuous use. A duration of 2 days was selected because from prior investigations developing related technologies, we found that participants could be expected to charge a prosthesis reliably at a minimum of every two days. Test results showed that a 2000 mA·h battery, which was of dimension 62 x 38 x 9 mm and weighed 34 g, met the need (Table 2). It was selected for use in Aim #3. The battery charging interval is expected to increase when power management strategies (e.g., lowering the sampling rate when the person is not active) are implemented. This will be done in the next board revision of the Aim #3 system. This change was not made in Year 3 because of delays anticipated in making and acquiring parts for a new circuit board.

Table 2. Discharge for Batteries of Different Capacity

Battery capacity (mA·h)	Ideal Lifespan (h)	Actual Lifespan (h)	Percent Effective (%)	Notes
2000	50.0	42.5	85%	From wall charge with new firmware
2500	62.5	60.0	96%	From wall charge with new firmware
6400	160.0	38 (test stopped early)	NA	From wall charge with new firmware

Tether impingement, damage, and breakage: For some of the Aim #2 participants, we found that the tether was not well-aligned with the hole in the distal socket going to the release and relock unit, causing the tether to break during long-term walking. A detailed inspection of participants' sockets revealed that the problem occurred only at very high or very low tether lengths (i.e., distance from the take-up reel to the tether pin fastened into the liner). We further determined that the liner umbrella played a major role in establishing tether length. If the liner umbrella diameter was excessively large, then participants did not fully seat the liner in the distal socket and a long tether length ensued. Too small an umbrella diameter caused anterior-posterior or medial-lateral misalignment or motion of the liner relative to the take-up reel in the release and relock system. These problems sometimes caused the tether or tether pin to mechanically stress the tether guide or elements within the unit during walking, leading to mechanical damage and occasionally failure of the tether. The source of the problem was that the liner umbrella was not matched to the socket design.

To rectify the problem, we changed our procedures during fitting to include measurement of the participant's regular umbrella diameter (Fig. 5). We now match that diameter to the umbrella diameter in the ferrous liner ordered for the participant. In discussion with our ferrous liner manufacturer, who we contract to make the ferrous liners for this project as described in prior reports, we changed procedures to incorporate this umbrella specification into their fabrication process. Three umbrella sizes (small, medium, large) have accommodated all test participants to date.

While this change solved most of the issues related to tether performance, we found that overstressing the tether on its path to the take-up reel continued to be an issue for some participants. Switching the tether guide material to PTFE and increasing the radius of curvature of the tether guide helped resolve

the issue.

To prevent overstressing the tether at its exit from the pin into the distal socket, another potential site of tether failure, we implemented a new pin design that has a fillet at the base of the pin rather than the chamfer used earlier (Fig. 6). All other sharp edges were removed and replaced with smooth fillets. Chamfers were also added at the pass-through hole on the take-up reel to increase the bend radius as the tether wraps around the spool (Fig. 7).

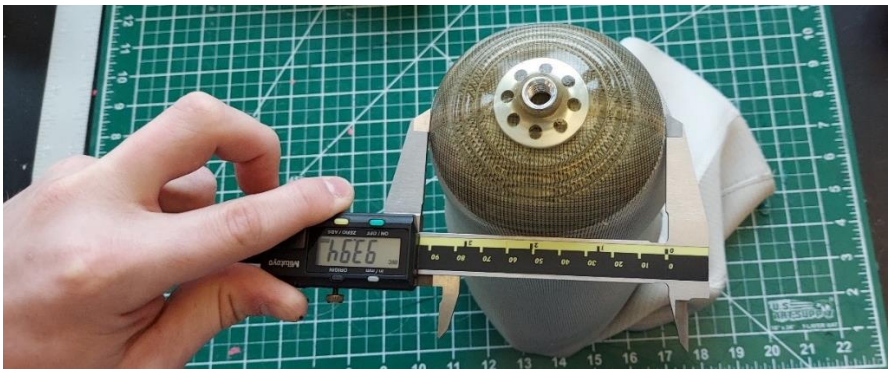


Fig. 5. Measurement of umbrella diameter for use in ferrous liner fabrication.

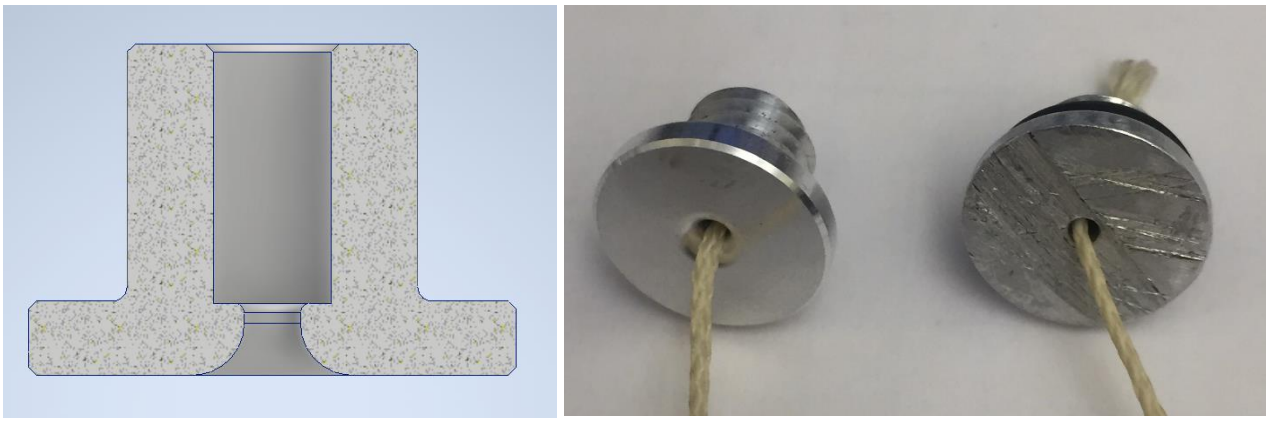


Fig. 6. Tether pin modification. Left: Fillet on the inside surface to reduce stress on the tether. Right: Photo showing the new design on the left and the old design on the right.

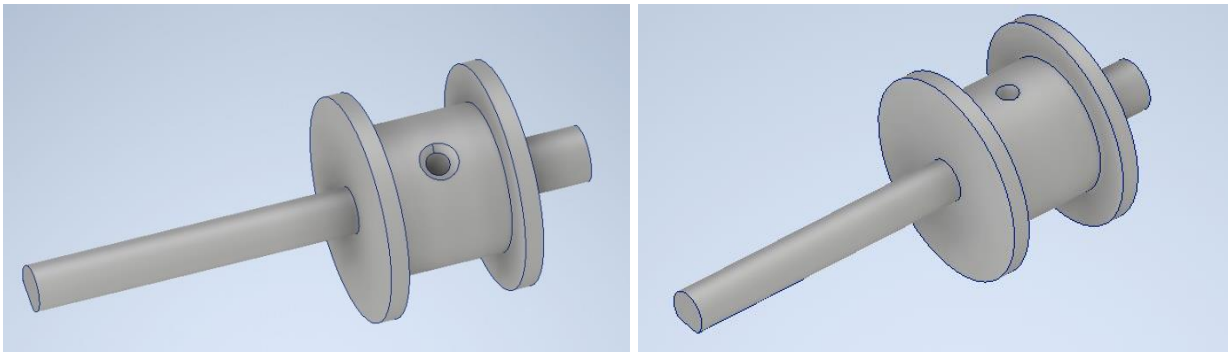


Fig. 7. Spool modification. Left: New spool. Right: Old spool.

Knot slippage: Knot slippage through the tether pin proved to be problematic for one participant (Fig. 8). Thus, a series of tests were conducted to identify a knot that was unlikely to slip through the hole. Four different knots were tested: 8x overhand, figure 8 on a bight, Ashley stopper, and Stevedore stopper (Fig. 9).

Fig. 8. Knot Slippage. Left image: Knot slipping through the hole that holds the tether. Right image: Knot sitting above hole and not pulling out.

Fig. 9. Knots Tested. From left to right: 8x overhand knot; figure 8 on a bight knot; Ashely stopper knot; Stevedore stopper knot.

Three samples of each knot were tested in a tensile testing machine cyclically loaded under force control. One hundred cycles at 1.5 Hz were applied to a maximum force of approximately 100 N. The sample was allowed 10 s to recover and then an additional 100 cycles at 1.5 Hz were applied. The sample was removed from the testing machine and inspected under a microscope. All knots held through the 200 cycles except for two of the three Stevedore samples. Results are summarized in Table 3.

Table 3. Knot Testing Results.

Knot	Result
8x overhand	Knot began to pull through. Knot began to thin out near the bottom, forming a wedge at the bottom of the threaded pin
Figure 8 on a bight	Bottom of the knot slightly deformed but this is not visible through the bottom of the threaded pin
Ashely stopper	Knot diameter was small but effectively held the position
Stevedore stopper	The knot almost immediately came through the hole during loading. The hole size may have been too large for the tether diameter being used

Knots that did well tended to be approximately 3 mm in diameter or larger. The hole on the threaded pin was just under 2 mm. Based on the results, Stevedore knots were dismissed. Ashley knots were dismissed because they were considered unsafe. Due to their shorter overall length, pulling through the hole would cause catastrophic failure.

The overhand knot began to conform to the threaded tether guide hole, increasing its risk of pulling through. Since the cable is spiraled around a core within the tether material, this may be a natural progression of the knot as it is compressed into the hole. The figure 8 however loops through itself at several different angles, preventing this alignment problem and reducing the risk of pull through. Although some of the cable did conform to the threaded tether guide, much less was pulled into the hole. We also noted that the figure 8 knot had less extension than the overhand knot. A 25,000-cycle test (1.5 Hz) was conducted on the figure 8 on a bight knot. Results showed repeatable mechanical behavior with minimal strain over the 5-day test period (Fig. 8). The knot did not pull through and no cut fibers were found upon inspection using a microscope after testing (Fig. 9).

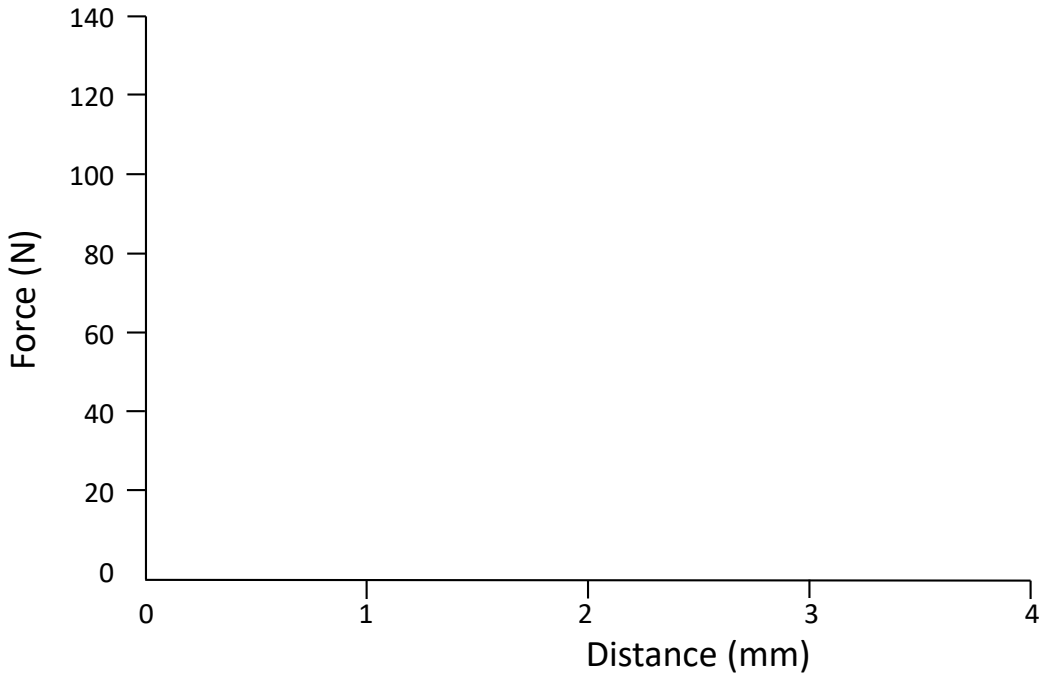


Fig. 8. Mechanical testing of figure 8 on a bight. 25,000 cycles were applied over 5 days. Each color is a different day.

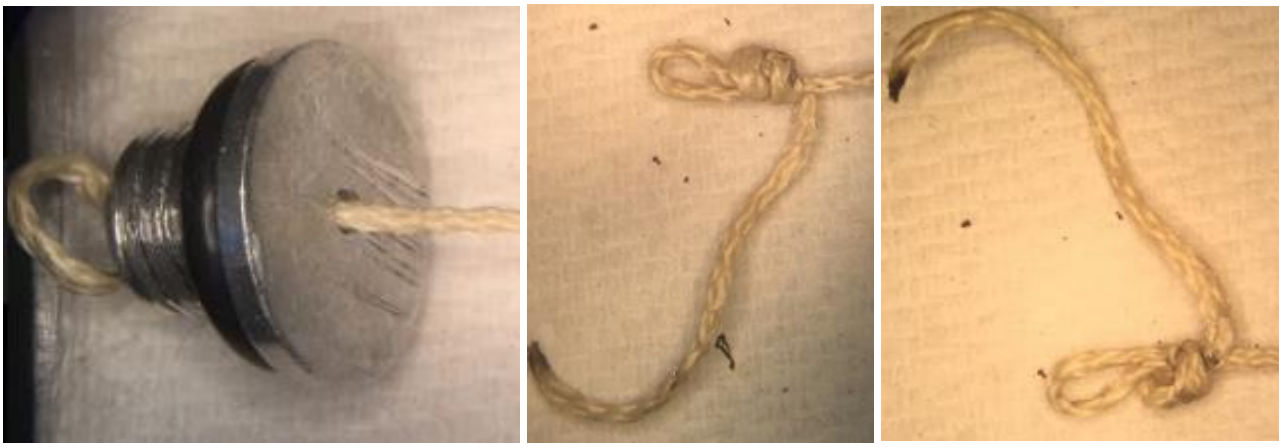


Fig. 9. Figure 8 on a bight knot after testing 25,000 cycles at 120-140 N max force.

New tether materials: We tested new tether materials to find candidates with increased durability and reduced risk of breakage for use in Aim #3. Materials were loaded in a tensile testing machine until failure. The materials tested and their relevant manufacturer-provided characteristics are listed in Table 4. Test results are summarized in Table 5.

Table 4. Tether Materials Tested

Product	Supplier	Weave Type	Diameter (mm)	% Elongation at break	Tensile Strength (N (lbf))
Vectran200 (current)	Twinline	Standard braid	0.90	2.00	894 (201)
Vectran400	Twinline	Flat hollow core	1.04 x 1.42 (rectangular)	2.00	2113 (475)
Excel Vectran 1.5	Marlow	8 plait Vectran & 16 plait polyester	1.50	3.00	1148 (258)
Spectra Lace	Click Med	Unknown	0.96	<6.00	1334 (300)

Table 5. Tether Material Test Results

Material	Rotation Test Notes	Instron/Loading Notes	Destructive Testing
Vectran 200	No noticeable wear at the pin. Some compressive wear at the tether pass-thru, but this is standard	Significant abrasion 8.5 cm from the pin. Most likely caused from rubbing against itself during tightening	New Sample: 374 N (84 lbf) Break occurred at knot
Vectran 400	No noticeable abrasion at the pin interface. Some standard compressive wear at tether pass-thru. Discoloration more noticeable due to black coloring	No fraying along length of cable. Some compressive wear along length of cable. No fraying or significant damage compared to Vectran 200	New Sample: 801 N (180 lbf) Break occurred at knot

Excel Vectran 1.5	Some fraying at the knot. Better than Vectran 200; however worse than Vectran 400. Note fraying only affects the Polyester Sleeve	Vectran Core became visible during testing. Fraying along length. Sharp angles imprinted into polyester sleeve	New Sample: 596 N (134 lbf) Break occurred mid-sample
Click Medical Spectra Lace	Performed very well no noticeable failure	Performed well. Despite negative elongation results, cable was in good condition	New Sample: 396 N (89 lbf) Failure due to repeated knot slipping creating a functional tensile limit

Participants twisted the tether pin when fastening it to the liner, inducing twists in the tether. We conducted additional testing to evaluate the influence of tether twisting since we expected that damage seen in a tether returned from the field was from this source. We used the apparatus shown in Fig. 10 to twist the tether 25,000 rotations. We saw the same mode of damage in this sample as seen in the field-tested tether. The QuickPin release (described in earlier reports) needs to be added to this system to reduce tether twisting during take-home use.

Fig. 10. Tether testing setup. The tether was run through the tether guide, and weights were hung at the bottom. There is a motor at the top of the apparatus that applied rotations to the tether.

Based on the results of all of the tests, the Vectran 400 material was selected for Aim #3 use. Thus, the tether diameter for Aim #3 testing will be 1.42 mm, greater than the 0.90 mm used in Aim #2. The reduced damage from abrasion compared with the other materials, no fraying or breakage at the pin interface, and the simplified installation of the rectangular cross-section material are worth the slight tether diameter increase. This change is expected to increase the longevity of the tether and reduce the negative effects from tether wear. Adjustments were made to the tether length calculation in the data processing software to correct for the increased tether diameter.

QuickPin design update: The QuickPin fastens the tether pin to the liner such that a single twisting

action locks or unlocks the pin, avoiding the tether twisting issue described above. This design is an improvement over the previous version that requires multiple turns of the pin to fasten it into the liner umbrella. The new design is made up of five parts that assemble as shown in Fig. 11. The QuickPin is spring loaded to help keep it locked in place. To release the pin, the user twists the middle section ¼ turn (orange arrow in Fig. 11) with respect to the bottom piece (green arrow in Fig. 11). The system is unaffected by a rotational or axial load applied to the bottom piece, thus ensuring that it remains secure on the pin during prosthesis use. A design modification was made to shorten the QuickPin, reducing the likelihood of contact with the tether guide during ambulation (Fig. 12).

A 5-day cyclic loading test was conducted on the new design. Results showed a consistent load-deformation slope over the testing period (Fig. 13). The increase in strain over time is due to elongation of the tether.

Fig. 11. New QuickPin design.

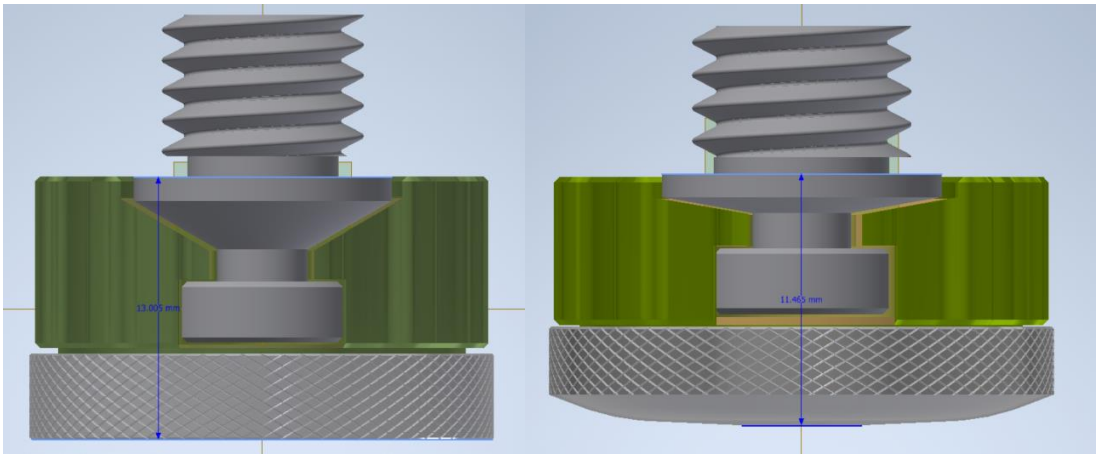


Fig. 12. Side-view of shortened QuickPin design. Left: old design. Right: new design.

Incorporating the QuickPin into the release and relock system will require the tether guide design to be modified to ensure it does not contact the QuickPin mechanism. Repeats of the bench and field tests will need to be conducted. We note that the QuickPin will be required for only a few participants in Aim #3, since most participants do not remove the pin from the liner. Thus, we expect the QuickPin addition to start partway through Aim #3.

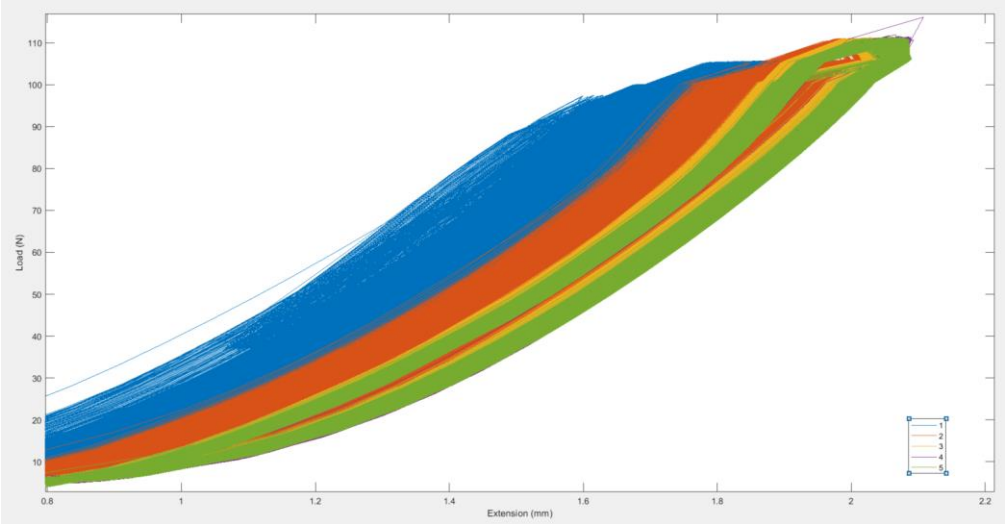


Fig. 13. 25,000-cycle test of the new QuickPin.

A number of other minor instrumentation issues were addressed during Year 3, some of which were resolutions to Year 2 items. They are listed in Table 6.

Table 6. Other Instrumentation Issues Addressed during Year 3 (including Year 2 unresolved items)

Issue	Solution
USB cable required to start system during sessions since system would not start off of battery power	Firmware changed – disabled sending into deep sleep when on battery power and prolonged no movement. Will need to redesign sleep mode elements to implement deep sleep mode in next generation of board
Pawl misalignment required excessive user pushing force on button to release pawl	Combined ratchet and pawl into one piece and made it out of steel. Changed pawl angle to reduce force necessary to pull the pawl off of the ratchet
Tether extends more than 5 cm during a partial doff, likely due to the ratchet not locking down and excessive tension on the tether	Tether guide redesigned to a machined plastic (PTFE), resolving the pawl arm impingement issue
Instrumented dial coupling too heavy	Coupling replaced with an ABS cast part
Battery needs capability to disconnect	Switch added to disconnect power as necessary. This required a modified enclosure, thus the Aim #3 release and relock system enclosure is now different from the Aim #2 enclosure
Release button durability	Upgrade material to ABS
Inconsistent wall power charging	Resistor network for thermal protection redone. There is now a 33k resistor in parallel with the thermistor and a 5.1k in series
Thermal compensation needed on sensor channels	Post-processing procedure and code implemented
The release button needs to consistently be on the lateral aspect	A “mirrored” release and relock unit was designed and implemented
Participants cannot see the light indicating battery recharging is necessary	The green LED light (system on) overshadows the charging light. The LEDs will be modified in the next generation of the board
Participant must push the motor draw-in button after standing to take up slack	Incorporated instructions into training material to do this

Knot slippage caused the tether to disconnect from the liner	Knot not properly tied. Added instructions on knotting to training material
Participants may have difficulty pushing the manual release button if the tether is under considerable tension	Incorporated instructions into training material that if the button to release the tether is difficult to press then the participant should lean forward to relieve the tension
Clicking noise	This occurred in one participant and was deemed dur to contact between the tether pin and the tether guide. It was resolved using a silicone coating on the outer lip of the tether pin
4GB SD write issue when storage space exceeded	This problem is anticipated with long duration data sets. The firmware was changed to reset the data file at 3:00 am

Additional electronic circuit boards were designed and fabricated in preparation for Aim #3 testing. However, the limited availability of parts (due to COVID-19 issues) limited progress towards board assembly. We expect new boards to be assembled by the vendor during the first month of Year 4.

Aim #3 Pilot Test Results

In Year 3, additional test sessions beyond the three test sessions conducted on two participants in Year 2 were conducted. The first participant wore the release and relock system for 2 days in a first test and 5 days in a second test. The second participant wore the release and relock system for 7 days in a first test and 6 days in a second test.

Example result over a day are shown in Fig. 14. The participant spent most of the day walking with intermittent stands and sits (high peak-to-peak sections of the data). A zoom-in of a partial doff is shown in Fig. 15. The tether does not go as deeply into the socket after the partial doff as evidenced by the higher red line than earlier. The stance phase minima of liner-to-socket distance are also greater than earlier, suggesting that the residual limb is hung up on the socket in the proximal region as a result of the limb volume increase during the partial doff.

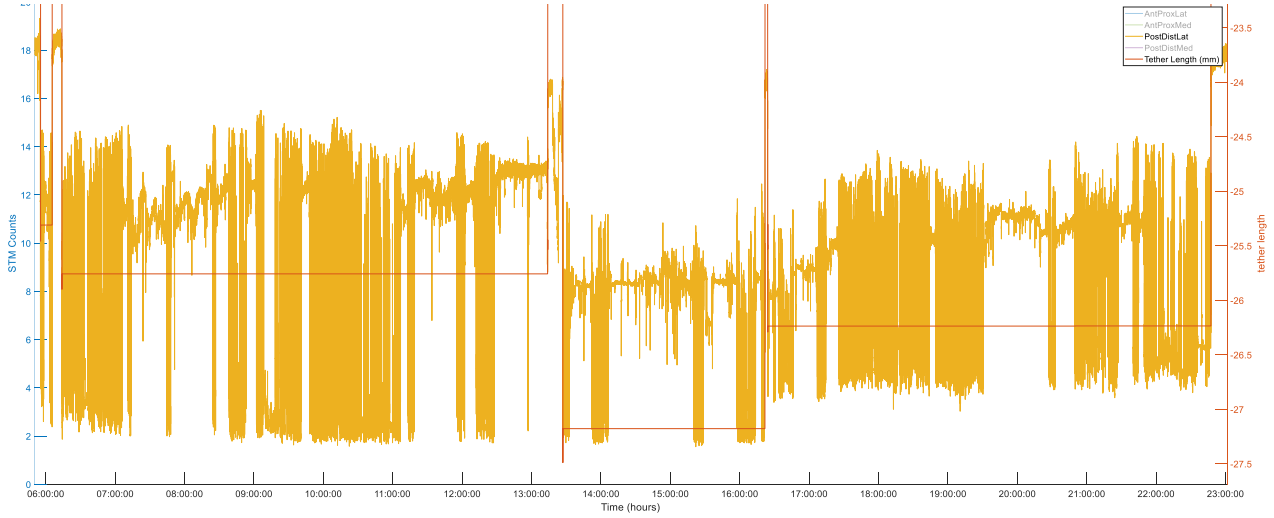


Fig. 14. Results from a day of field use. Red line is tether length. Yellow line is data from a liner-to-socket distance sensor located in the posterior distal lateral region of the socket.

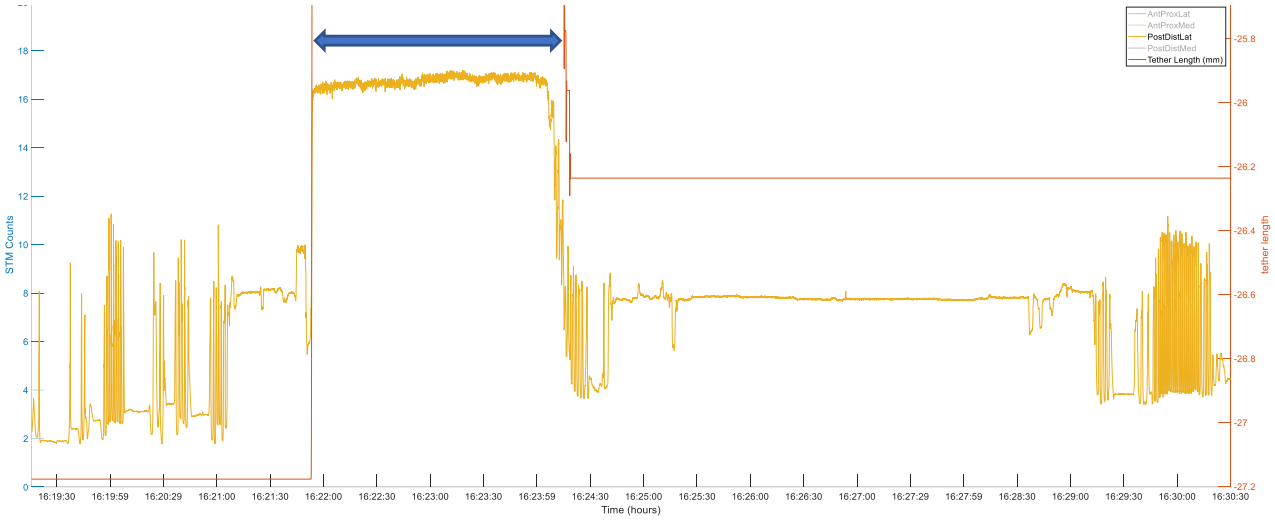


Fig. 15. Zoom in of Fig. 14. Tether length (red line) and liner-to-socket distance (yellow line) are shown before, during, and after a partial doff (blue arrow).

Expected Modifications to Aim #3 Study Protocol

Based on the pilot study take-home test results and experience completing Aim #2, we determined that participants adapted to the release and relock socket quicker than we expected and integrated it into their regular socket wear routine. It may be possible in Aim #3 to reduce the break-in period to less than 1 week and shorten the duration of take-home testing.

Other achievements: None.

The stated goals for Year 2 were met, except for manuscript submission. We expect the manuscript to be submitted before the end of 2021. 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 original Year 3 and 4 goals will be accomplished during Year 4.

What opportunities for training and professional development has the project provided?
A PhD graduate student in Bioengineering has 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.

What do you plan to do during the next reporting period to accomplish the goals?
Our objective during Year 4 is to complete 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?
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
Though Aim #3 is a take-home study, we need to scan the person's traditional socket so as to make test prostheses for participants and conduct an in-lab calibration session. If COVID-19 restrictions are increased, we may need to pursue alternative strategies for conducting these aspects of the protocol. The take-home portion of the protocol is not problematic. Users wear the test prosthesis in their at-home environment for several weeks at a time.

Changes that had a significant impact on expenditures
COVID-19 slowed down progress of Aim #2, though in the interim we debugged hardware and firmware issues in the Aim #3 system. We may need to reduce the take-home data collection period in Aim #3 because of the impact on expenditures.

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**

  Conference paper.

  Coburn K, Allyn KJ, Wang H, Ballesteros D, Larsen BF, Mertens JC, Lanahan C, Weissinger M, Garbini JL, Hafner BJ, Friedly BJ, Sanders JE. Pin release and relock as an accommodation strategy for transtibial prosthesis users. *American Academy of Orthotists & Prosthetists 47th Academy Annual Meeting & Scientific Symposium*, May 4-7, 2021.

  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:	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:	Horace Wang
Project Role:	Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to Project:	Board layout, firmware code for release and relock operation and sensing element

Name:	Ryan Carter
Project Role:	Research Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	3
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: 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: 6
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: 2
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: 1
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: 1
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: 1
Contribution to Project: Control system operation

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 grant that has closed:

W81XWH-16-C-0020 (Sanders)
JWMRP
"Automatic control of volume management systems for people with limb loss"

New grant that has started:

W81XWH-21-2-0003 (Childers)
OPORP
"Clinical translatability of reactive hyperemia measurements that can monitor adaptation of residual limb skin to socket wear"

GARBINI, JOSEPH L

Previous active grants that have closed:

Boeing Company (Garbini)
"Sanding Assist Automation"

W81XWH-16-C-0020 (Sanders)
JWMRP
"Automatic control of volume management systems for people with limb loss"

HAFNER, BRIAN J

Previous active grants that have closed:

W81XWH-17-1-0617 (Morgan)
Department of Defense
"Do microprocessor knees improve outcomes in early prosthetic rehabilitation compared to non-microprocessor knees?"

W81XWH-17-1-0547 (Sawers)
Department of Defense
"Can a novel beam-walking test improve fall risk assessment in Service Members, Veterans, and civilians who use lower limb prostheses?"

W81XWH-16-C-0020 (Sanders)
Department of Defense
"Automated control of volume management systems for people with limb loss"

W81XWH-16-1-0569 (Morgenroth)
Department of Defense
"A prosthetic foot emulator to optimize prescription of prosthetic feet in Veterans and Service Members with leg amputations"

W81XWH-17-1-0551 (Hafner)
Department of Defense
"Enhancing the Prosthetic Limb Users Survey of Mobility (PLUS-M) to improve measurement of Service members, Veterans, and civilians with high mobility"

Industry-sponsored grant (Morgan)
Otto Bock Healthcare LP
"Do microprocessor knees improve long-term outcomes following amputation compared to non-microprocessor knees?"

Industry Sponsored Project (Sawers)
Otto Bock and Ossur hf
"Development and administration of a fall survey to record and report fall frequency, circumstances, and consequences among lower limb prosthesis users"

New grants that have started:

W81XWH-20-1-0197 (Hafner)
"Department of Defense
Fall-related health outcomes in lower limb prosthesis users: a pragmatic clinical trial to assess effectiveness of microprocessor-controlled prosthetic knees"

W81XWH-21-10169 (Darter)
Department of Defense
"Exploring the impact of microprocessor-controlled knees on prosthesis awareness and overall health"

FRIEDLY, JANNA L

Previous active grant that has closed:

W81XWH-16-C-0020 (Sanders)
JWMRP
"Automatic control of volume management systems for people with limb loss"

New grant that has started:

1R01AG069891-01 (Rundell)
NIH/NIA
"Lumbar Stenosis Prognostic Subgroups for Personalizing Care and Treatment (PROSPECTS)"

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

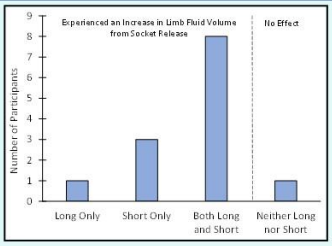
PI: Joan Sanders Ph.D. **Org:** University of Washington **Award Amount:** $2M

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.



Complete Aim #2 results showing that the release/relock system increased limb fluid volume in 11 of 12 participants. Participants varied as to if long-rest, short-rest, or both caused an increase.

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: 09/23/2021

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 (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 - $1,293,520