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14. ABSTRACT A motor-driven release-relock system was developed that allowed people with transtibial amputation to quickly and easily partially doff or fully doff their prosthesis. The design implemented a control system to allow users to change prosthesis states (donned, partially doffed, fully doffed) with the push of a button. The unit also recorded prosthesis use - walks, weight shifts, stationary and doffs. Testing in the lab using a scripted protocol demonstrated a significant decrease in residual limb fluid volume loss when 4-min or 10-min partial doffs were executed compared with no socket release. Take home testing showed differences in prosthesis use when release-relock was available compared with a locked control, though the activity changes varied among the participants. Prosthetist participants were excited about the collected data because it provided meaningful clinical insight about how their patients used their prosthesis, information they considered useful for insurance justification, to help set activity goals and to monitor progress.					
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 was to create and test electronic release and relock sockets for transtibial prosthesis users. A second objective was to test new assessment metrics used in clinical testing. A novel motorized "release and relock" mechanism was 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 were instrumented so that they continuously measured prosthesis use, accommodation practices, and activity. A study in a controlled test setting was conducted to characterize the sockets' impact on morning-to-afternoon fluid volume change. A direct crossover study in the field was executed to determine if use of release and relock sockets enhanced patient outcomes relative to traditional sockets. The clinical value and technical quality of outcomes data summaries were 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?

A list of tasks and milestones from the Statement of Work is included below:

Task 1. Reduce form factor and power consumption of current design

Task 2. Characterize performance, enhance and document design

Task 3. Obtain human subjects approval for Aim #2

Milestone 1: Enhanced design completed

Milestone 2: Manuscript submitted on release and relock socket design

Task 4. Conduct Aim #2 study

Milestone #3: Aim #2 study completed

Task 5. Disseminate findings

Milestone #4: Manuscript submitted on Aim #2 study

Task 6. Obtain human subjects approval for Aim #3

Task 7. Conduct Aim #3 study

Milestone #5: Aim #3 study completed

Task 8. Disseminate findings

Milestone #6: Manuscript submitted on Aim #3 study (now part of Aim #4 study)

Task 9. Obtain human subjects approval for Aim #4

Task 10. Conduct Aim #4 study

Milestone #7: Aim #4 study completed

Task 11. Disseminate findings

Milestone #8: Manuscript submitted on Aim #3 and #4 study

Milestone #9: Final report submitted

What was accomplished under these goals?

All tasks were completed except for submission of the manuscript for the Aim #3 and #4 study (Milestones #6 and #8). A combined manuscript that includes results from both aims has been prepared and should be ready for submission shortly.

DETAILED REPORT

The release/relock unit (TARPIN) is of dimension 8.1 cm x 8.1 cm x 6.6 cm and adds a total of 290 g to a traditional cabled-panel adjustable socket prosthesis (including battery). It fits within the distal end of the socket, similar to the vacuum pump of an elevated vacuum system (Fig. 1). The user operates the TARPIN system using two buttons – a draw button and a release button – that adjust the state of the socket. The three states are donned, partially doffed, and doffed. The advantages of using this technology over existing practices include: the

capability to adjust state without having to remove overlying clothing; more rapid transitioning between states; and automatic alignment of the locking pin in the shuttle lock. These features should allow Service members and civilians to accommodate limb volume changes with minimal disruption and distraction.

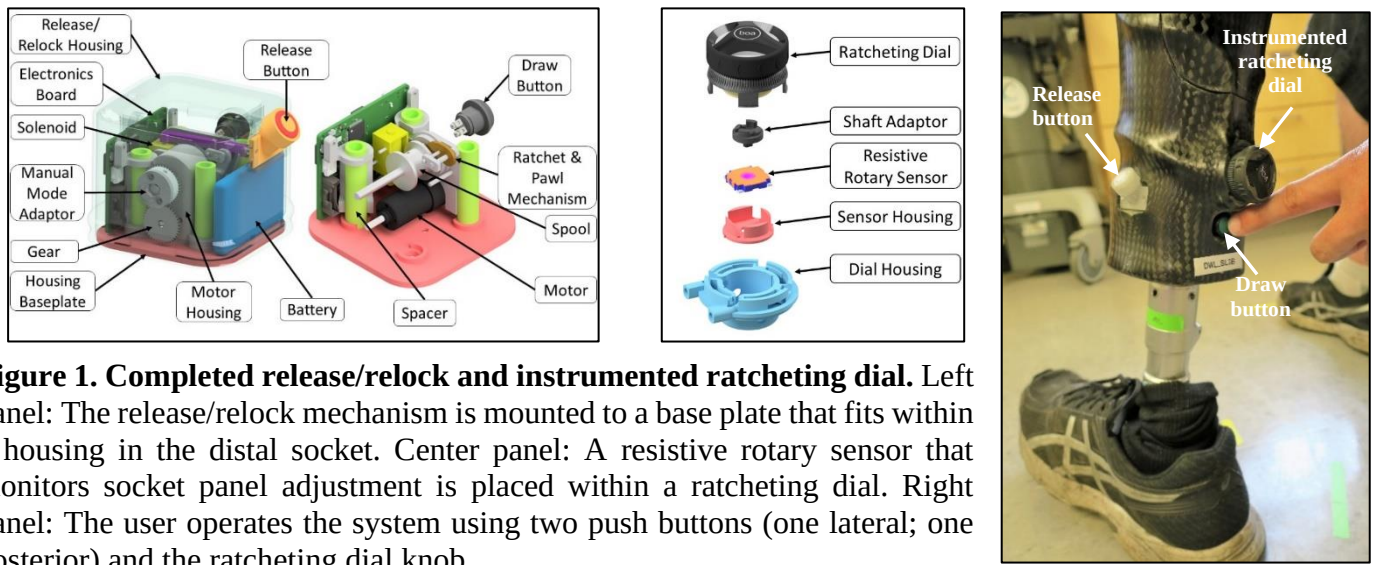


Figure 1. Completed release/relock and instrumented ratcheting dial. Left panel: The release/relock mechanism is mounted to a base plate that fits within a housing in the distal socket. Center panel: A resistive rotary sensor that monitors socket panel adjustment is placed within a ratcheting dial. Right panel: The user operates the system using two push buttons (one lateral; one posterior) and the ratcheting dial knob.

The release/relock mechanism takes approximately 7.5 s for the release/relock motor to change the socket from the doffed to donned state (assuming a 45 cm tether length), and approximately 1.5 s to change from the partially donned to the donned state. Current draw under loads of 0%, 50%, and 90% of the motor's maximum allowable torque range from 56 to 509 mA. Without any power management code in the microcontroller, the system runs about 40 h on a single battery charge.

Pilot testing on people with transtibial amputation demonstrated that the system performed as designed. In a study where participants repeatedly walked for 3 minutes and then sat and doffed their prosthesis for 10 minutes, the motor returned to the same locked position in the socket within a 0.3 cm distance (Fig. 2). The TARPIN mechanism accomplished the same partial doff release distance (5.1 ± 0.13 cm) across the session.

To accomplish the technology described above, a series of design iterations were conducted. The first prototype extended from that described in the initial proposal. The TARPIN was enclosed within an aluminum cylinder of diameter comparable to that of a distal socket, though the unit was still positioned underneath the socket during testing. Testing results on amputee participants suggested that the motor size could be reduced without a meaningful loss in function or usability. Motor speed needed to be increased so that the time to release and relock the socket was shorter, and weight needed to be further reduced closer to participants' normal prostheses. In the second iteration, a square housing encased the TARPIN, a smaller high-speed motor was used, and the mechanical components were drawn in tighter to create a more compact unit. Many parts continued to be made using a 3D printer. Modifications to the original control strategy were implemented, notably we made the motor stop command at the partial doff setting during donning and doffing optional. Users appreciated this enhancement because it reduced the time required for donning and doffing. With the smaller motor, the system did not pull the socket up off the ground while donning during sitting, but users did not mind this change since the socket was more lightweight. In the final iteration, weight was further reduced by making the design more compact and reducing the wall thickness of the housing, bringing the total weight including the battery down to 290 g.

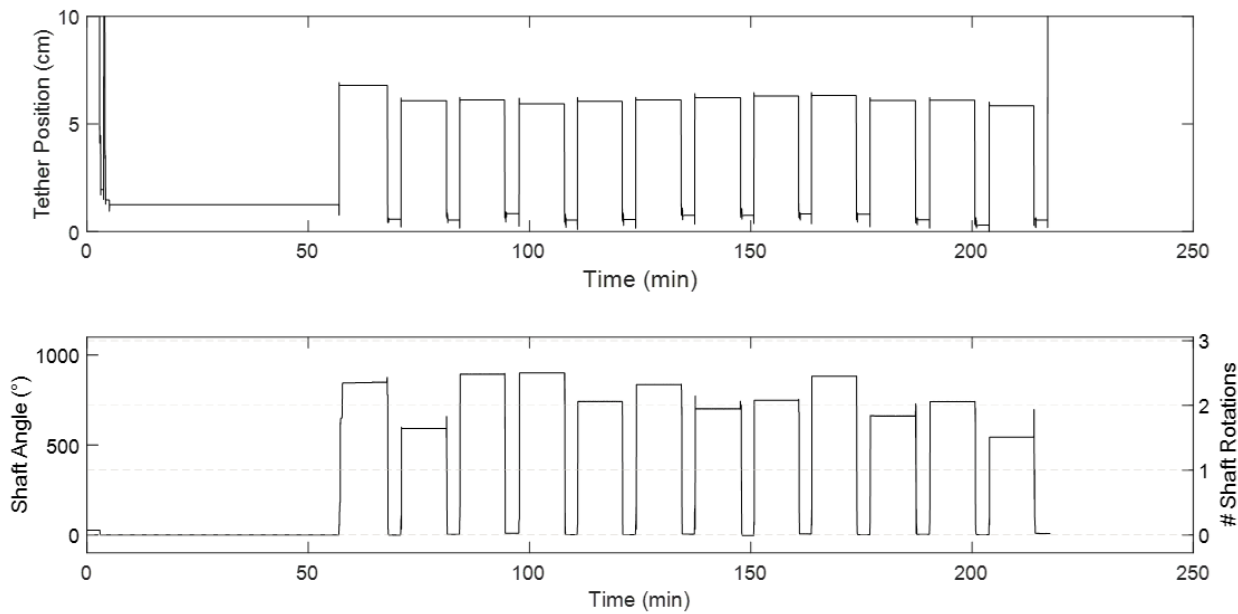


Figure 2. Data from the ratcheting dial during a test on a participant. Twelve cycles of sitting for 10 minutes and walking for 3 minutes are shown. Sits are at high values and walks are at low values. Upper panel: Length of the locking pin tether in mm. Lower panel: Rotation of the shaft within the instrumented ratcheting dial in degrees and number of rotations.

Error Correction in Instrumented Dial Data

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

Other sources of error in the dial sensor data resulted from a sampling rate issue. A sampling rate of 32 Hz proved insufficient during panel release and introduced both aliasing problems and missed rotations. Aliasing problems caused the dial to appear to be tightened rather than released. Missed rotations caused us to lose the absolute position in the dial for the rest of the trial. Dial rotation was particularly fast if the participant or researcher pulled outwards on the panel during a socket release to quickly relieve socket pressure. This was executed frequently during Aim #2 testing. The problem was resolved by creating post-processing code to identify aliasing and missed rotation counts in collected data. The presence of a problem was identified computationally, and then each problem was resolved on a case-by-case basis. Using the dial rotation speed collected right before and right after the error, we easily established how many rotations occurred. Each user typically had between 8 and 20 rotations spanning their cable length range.

Other Instrumentation Errors Identified and Addressed

The solutions or work arounds for other instrumentation issues listed in Table 1 proved effective, and data were successfully collected during Aims #2 and #3. Some of these issues are discussed in more detail below.

TABLE 1. Instrumentation Issues and Solutions or Work Arounds

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

When battery dies, must connect to HTERM to restart which is time consuming during a test session	Solution: Modified the firmware so that data storage picks up from where it left off after a restart
Inconsistent wall power charging	Solution: Firmware issues. Used hardware solutions implemented in a related project here
Solenoid board crashes	Solution: Modified firmware to ensure restart after a crash, but effectiveness depended on battery power
Motor pulls only half of the weight specified by the manufacturer; can pull 71 N not 178 N	Work around: Had participants lean forward during socket release in Aim #2 study to relieve excessive tether tension Solution implemented: Identified the source of the problem as a combination of terrible gearbox efficiency (69%) and losses within additional gears within the design. Since this problem only affected socket release, manual release was implemented instead. All other systems remained as is
Participant cut tether cable because did not follow manual release procedures	Solution: Simplified design of manual release so that it is more intuitive
Participant got tether stuck by disconnecting liner and then pulling the tether deep into the socket	Solution: Modified the spacer disc so that the tether cannot fall through the distal hole in the socket
Sampling rate on the dial	Increased to ~128 Hz in the next board design
Inability to download data through USB port is inconvenient	Added this capability to the next circuit board revision
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. Redesigned 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 was now different from the Aim #2 enclosure

Release button durability	Upgraded 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) overshadowed the charging light. The LEDs were 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 due 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 occurred with long duration data sets. The firmware was changed to reset the data file at 3:00 am
Participant attempted to use a non-wall charger, which did not work	Require future participants to plug in the charger instead
RAFT upload time too long	RAFT zips the files before sending
Socket fabrication issue – enclosure fills with resin	Completely fill the enclosure with silicone epoxy

Human subjects approval for Aim #2 was received from the University of Washington IRB (Nov 30 2018) and HRPO (Jun 30 2019).

Aim #2 Study

Participant Inclusion/Exclusion Criteria

Human subject approval from an institutional review board and informed consent from each participant were obtained before test procedures were initiated (University of Washington, Seattle WA, USA, STUDY00007008). Participants were recruited locally from our registry and by referral through flyers placed in local clinics. Participant recruitment was limited by the financial and time constraints of the project. Thirteen participants were enrolled. Criteria for inclusion were a transtibial amputation performed at least 18 months prior, use of a properly fitting definitive prosthesis for walking at least 7 hours per week, the ability to walk unaided for 2 min on a treadmill, the ability to sit and stand unaided, residual limb length of at least 9.0 cm (for conducting limb fluid volume monitoring (bioimpedance analysis)), and considered by the research practitioner through traditional clinical evaluation techniques to be a Medicare Functional Classification Level of Limited Community Ambulator

(K-2) or higher. Presence of skin breakdown or regular use of a walking aide (e.g., cane, walker) excluded participants from this study.

Protocol

Limb fluid volume was monitored using bioimpedance analysis. Custom electrodes made of a thin conductive tape (ARCare 8881, Adhesives Research, Glen Rock PA, USA) and an underlying hydrogel (9880, 3M, St. Paul MN, USA) were placed on the residual limb. Voltage sensing electrodes were placed to monitor the anterior and posterior residual limb regions independently, and current injecting electrodes were placed proximally at the thigh and distally on the inferior surface of the residual limb, using placement techniques described in detail in our prior work. Electrical current was injected in packets at 26 different frequencies across a range of 3 kHz to 1 MHz at a rate of 30 packets/s using a custom portable bioimpedance unit worn in a waist belt pack (400 g). Collected data were demodulated on board the unit then converted to extracellular fluid volume in post-processing using de Lorenzo's form of the Cole model and a geometric limb model. Error in the extracellular fluid volume measurement was less than 0.1% fluid volume.

Each participant visited the lab for three separate visits starting at approximately the same time of day. Participants were asked not to drink caffeine or alcohol before coming to the lab and to standardize their morning routine for the three visits. Upon arrival, they were instructed to sit for 10 min to allow their residual limb to reach a homeostatic condition. During this time, the research practitioner collected general health information. Body weight and blood pressure were measured. After the prosthesis was doffed and bioimpedance electrodes were placed on the residual limb, participants donned a liner, either their own liner or a lab-provided liner that had a proper thread size for the release/relock tether connection. Participants then donned the test socket.

At the start of the first session, a brief fitting was performed where the research practitioner inspected and adjusted the alignment if needed. Proper sock ply (if needed) was determined, using only new laboratory socks and not the participants' socks for adjustment. Participants were instructed to walk briefly on a treadmill to determine their preferred walking speed. Once established, this same speed and sock thickness were used for all treadmill walking tests in the study. The time spent finding a proper walking speed and sock ply was documented for each initial visit, and the walking and standing durations were repeated at the outset of each of the subsequent two visits to control for any unanticipated effects fitting activities had on the limb homeostasis.

Following the fitting or fitting-control, all three sessions started the same – the participant was instructed to carry out a series of four controlled rest-walk cycles. During the rests, which were 10 min, participants sat with the test prosthesis donned. The walks, which were 2 min, were executed on the treadmill. Immediately following the four rest-walk cycles, participants completed one of three protocols (one per visit), consisting of twelve rest-walk cycles. For the “No Release” protocol, the rest-walk cycles were the same as the controlled rest-walk cycles. For the “Long Rest” and “Short Rest” protocols, participants partially doffed the test prosthesis during the rest segments. Partial doffing duration was 10 min for the Long Rest and 4 min for the Short Rest. Each participant completed all protocols, the order of which was randomized using MATLAB's (Natick, MA, USA) random number generator.

The partial doffing process was executed entirely by the study team by first releasing the back socket panel (releasing the ratcheting dial) to its maximum outward position and then pressing the tether release button once and pulling the socket to partially doff the residual limb to a 5-6 cm tether length. The test prosthesis was placed so that participants were seated comfortably with their limb loosely in the socket without excessively misaligning their residual limb with the socket and inducing concentrated pressures on their residual limb. The heel and toe positions were marked on the floor with tape so that both the prosthetic foot and contralateral foot were placed at the same location in each cycle. After the rest cycle was completed, the study team aided in the donning process by pushing the button to activate the motor (drawing in the tether) and guiding the test prosthesis onto the participant's limb, ensuring a consistent procedure was performed across cycles and across participants. The back panel was tightened by turning the ratcheting dial until it was fully closed. The participant was instructed to stand, and the researcher pushed the tighten button to take up any remaining slack in the tether.

The Aim #2 study design is shown below in Fig. 3. The sit durations during socket release were 4 min (Short

Rests) and 10 min (Long Rests), and the walks were 2 min long. These durations ensured that Long Rests and no release (Control) were executed at the same time into the trial as some of the Short Rests, simplifying comparison of results between the interventions.

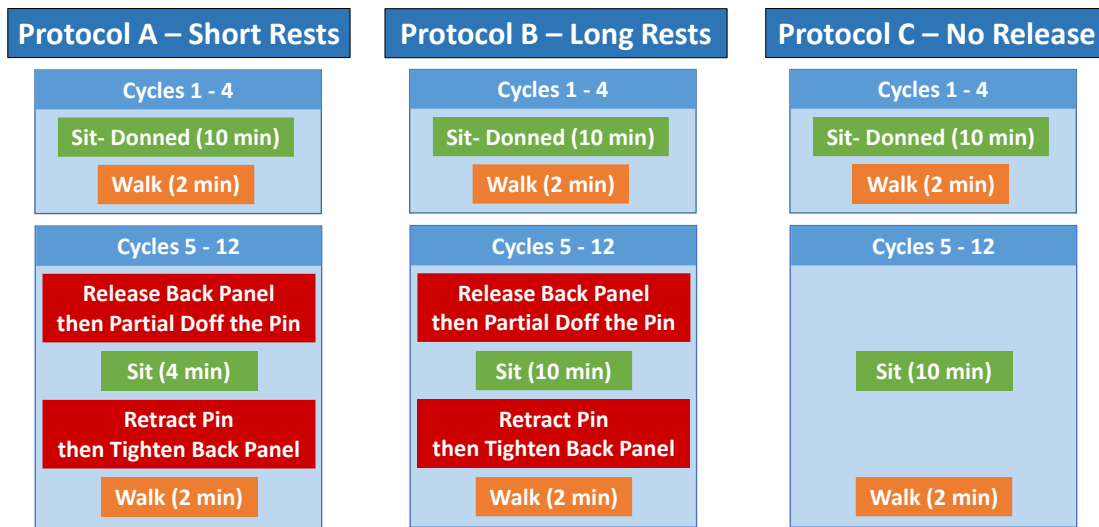


Fig. 3. Study design for Aim #2. Cycles 1-4 are “conditioning” cycles, intended to bring the participant to a consistent state before the intervention part of the test (cycles 5-12).

The extracellular limb fluid volume data were segmented into steps, and the first and last five steps from each walking cycle were removed. This was done to avoid including steps where participants were increasing or decreasing their walking speed. The minimum limb fluid volume (which occurred during stance phase) for each of the remaining steps in a cycle was determined and a mean calculated. The twelve means were expressed as a percentage change from a reference that we defined as the mean fluid volume from the last (4th) controlled rest-walk cycle, i.e., the start of the intervention part of the test. Change in percent limb fluid volume was evaluated for normalcy using a Shapiro-Wilk test. A repeated measures analysis of variance (ANOVA) was conducted to compare the three protocols in the mean percent limb fluid volume change relative to the reference at approximately 84 min, which was the longest time data point common to all three protocols. Subsequently, pairwise comparisons with Bonferroni correction were conducted to assess differences in percent fluid volume for Short Rest v. No Release, Long Rest v. No Release, and Short Rest v. Long Rest. Results for all cycles were plotted over time for the three socket test conditions for each participant. These plots were visually inspected to identify patterns over time, and participants were classified into groups based on the results. As an exploratory analysis, we investigated if participant characteristics age, time since amputation, body mass index, and limb length differed for the different groups.

Data from the instrumented ratcheting dial were processed, 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.

Participant Test Results

A total of 35 participants were recruited for Aim #2, 19 were screened, and 13 completed the study, 12 males and 1 female. Eleven participants had their amputation as a result of trauma, one as a result of an infection after a traumatic injury, and one from a Charcot foot. Median age was 54 y (range 35 to 74), and median time since amputation was 16 y (range 4 to 52). All participants regularly used an energy storage and return (ESAR) prosthetic foot, though not necessarily the same model as used in the present study. Participant characteristics are listed in Table 2.

Table 2. Participant Characteristics.

Characteristic	Median	Range
Age (y)	54	35 – 74
Time since amputation (y)	16	4 – 52
BMI (kg/m ²)	28.4	20.4 – 37.7
Limb length (cm)	15.0	11.0 – 21.8

Characteristic	Description
Gender	1 female, 12 males
Cause of amputation	11 trauma, 1 trauma + infection, 1 DM and Charco Foot
Health issues	6 high blood pressure, 3 smokers, 2 diabetes mellitus, 2 nerve pain, 1 each upper limb amputation, heart surgery, seizures, abnormal ankle-brachial index, depression and high cholesterol

Table 3 shows the summaries for percent fluid volume change for each condition for posterior and anterior regions. Mean percent fluid volume change were -1.2% for No Release, 2.7% for Short Rest, and 1.0% for Long Rest in the posterior region, and -1.2%, 3.5%, and 2.2% in the anterior region, respectively.

Table 3. Summary Results for Percent Fluid Volume Change

Summaries	Percent Change (from reference) in Limb Volume					
	Posterior			Anterior		
	No Release	Short Rest	Long Rest	No Release	Short Rest	Long Rest
N	13	13	13	13	13	13
Mean	-1.2	2.7	1.0	-1.2	3.5	2.2
Median	-1.1	2.7	1.3	-1.7	4.4	2.1
Std. Deviation	1.9	2.9	2.2	1.9	1.9	2.7
Minimum	-4.5	-1.3	-3.2	-3.5	-0.2	-4.7
Maximum	1.7	7.1	3.6	2.2	5.7	5.7

The ANOVA identified a significant difference in percent fluid volume change ($P < 0.01$), indicating that at least two of the conditions were statistically different from each other. Pairwise comparisons showed that for the posterior region, the mean percentage fluid volume change was statistically larger for Short Rest than No Release and Long Rest than No Release. Short Rest was not statistically different from Long Rest at the 0.05 level (Fig. 4a). Statistical differences for Short vs. No Release and Long vs. No Release were also observed for the anterior region, but Short Rest vs. Long Rest was not statistically different (Fig. 4b). Twelve of the thirteen participants experienced a higher percent fluid volume gain for at least one of the release protocols compared with No Release. It was noticed that there was a minor difference in the time that data were collected for the three conditions, but the difference did not seem to affect the results (Appendix 1).

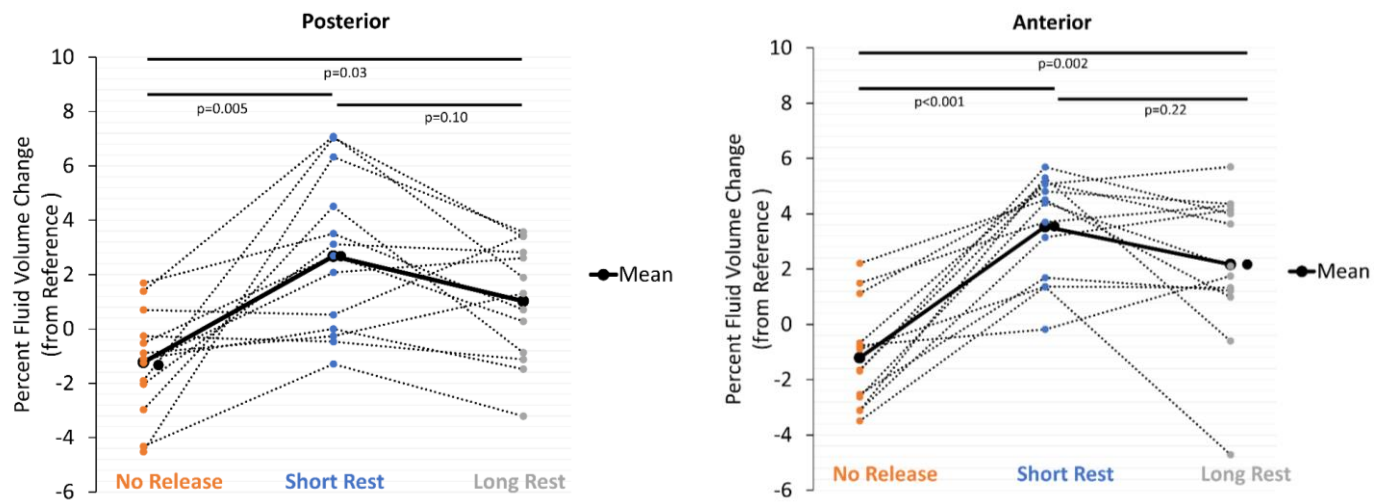


Fig. 4a,b. Comparison of percent limb fluid volume change results for the three test conditions. Results for the (a) posterior region and (b) anterior region are shown.

We conducted an exploratory analysis to identify which participants benefited the most from each release strategy. Participants were classified into four groups based on their results for the three test conditions (Table 4, example data for each group provided in Appendix 2). Seven participants experienced the highest percent fluid volume gain for Short Rest (Group 1), three for Long Rest (Group 2), two approximately the same for both Short and Long Rest (Group 3), and one for No Release (Group 4) (Fig. 5). The only participant who did not experience a greater percent fluid volume gain for either release protocol compared to No Release (Group 4) was the only person who regularly used an elevated vacuum socket.

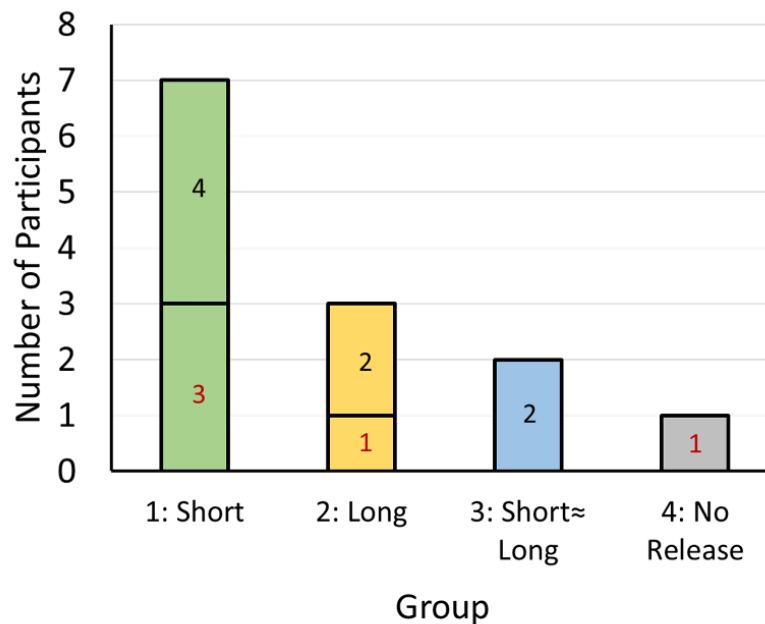


Fig. 5. Participant Groups 1 to 4. Participants were grouped by the test condition that induced the highest percent fluid volume relative to the reference. Participants experienced the highest percent fluid volume for Short Rest ($n=7$ total), Long Rest ($n=3$ total), approximately the same for Short Rest and Long Rest ($n=2$ total), or No Release ($n=1$). The black numbers in each column indicate the number of participants for which both conditions, Short Rest and Long Rest, had higher percent fluid volume than No Release. The red letters indicate that the number of participants for which only the group label in that column had higher percent fluid volume than No Release.

Plots investigating if participant variables age, time since amputation, body mass index (BMI), and residual limb length were related to group number are shown in Fig. 6. Knowing age or time since amputation does not seem to give any information on which group a person would tend to belong. Individuals with higher values of BMI tended to be in groups 1 and 2, while individuals with longer limb length tended to be in group 1. These are preliminary observations in a study with small sample size, and larger studies are needed to either corroborate or refute the findings.

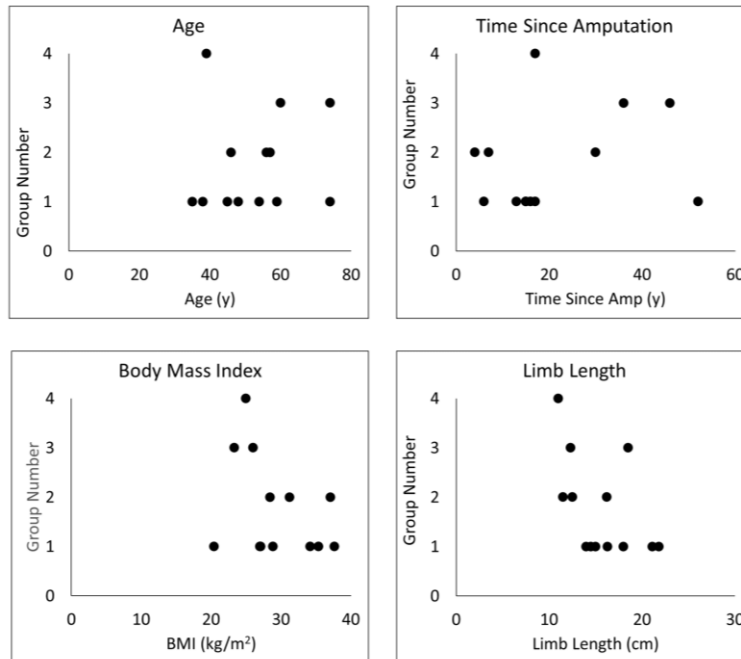


Fig. 6. Participant characteristics for Group 1 to 4. There were few participants in Groups 3 and 4, making it difficult to identify differences in those groups compared with other groups. Participants in Group 2 had shorter limb lengths than participants in Group 1, suggesting that limb length should be investigated in future studies as a variable that may influence participants’ optimal release duration.

Dial angle data were successfully collected in 20 sessions, approximately the first half of the sessions conducted. Results demonstrated that the dial angle while the socket was tightened was consistent across walk cycles (Appendix 3). For all sessions, the deviation in socket volume during walking for all cycles was less than $\pm 0.8\%$ of the median for all cycles in the session. In 96% of the cycles, the deviation was less than $\pm 0.5\%$. Since these percent socket volume changes were lower than those expected to induce a clinically detectable change in socket fit and the procedure for setting the dial angle was demonstrated consistent, dial angle was not monitored for the remaining sessions.

Interpretation of Aim #2 Study Results

Partial doffing using a motor-driven release-relock mechanism may be a more convenient means to accommodate limb fluid volume fluctuation than the traditional strategies available to people with lower-limb amputation (i.e., changing sock ply) because the socket does not need to be fully doffed. Users can make adjustments quickly and conveniently without drawing attention to themselves. The purpose of this study was to determine the effects that different durations of partial doffing had on limb fluid volume. This effort is therefore relevant towards creating guidelines for clinical care.

For almost all of the participants (twelve of thirteen), at least one of the release durations (4 min or 10 min) produced a meaningful increase in limb fluid volume over No Release. The median of the maximum percent fluid volume increase (5.7%) was comparable to the mean increase in studies where the prosthesis was fully doffed instead of partially doffed for a much longer duration (30 min) between cycles of activity (5.5% in the posterior

region). In a different study, the locking pin and three panels of an adjustable socket were released during one cycle for 10 min between bouts of activity and produced a median fluid volume increase of about 0.4%, approximately one-twelfth of the increase in the present study of twelve cycles ($5.6\%/12 = 0.5\%$). These results suggest that intermittent partial doffing may produce comparable fluid volume increases to intermittent full doffing. Some participants demonstrated an increase in percent fluid volume for both release durations while others demonstrated an increase for just one. It is unclear, however, the reason for this result. The differences were not due to inconsistent performance of the socket size adjustment mechanism. The error in returning the socket to the same size in each cycle for 96% of the cycles was less than $\pm 0.5\%$ of the socket volume (i.e., equivalent to adding or removing $\frac{1}{2}$ the thickness of a sock sheath). Results suggest the differences were not related to participant characteristics, but more participants better distributed across the variable ranges would need to be tested to draw definitive conclusions. It may be that a combination of physiological qualities and socket characteristics influence limb fluid volume response to socket release duration. It is also possible that participants' residual limbs physiologically adapt to different interface conditions. They may respond most favorably to conditions comparable to those to which they are accustomed. The result that the only person in the study who regularly used elevated vacuum showed minimal difference in percent limb fluid volume for the three different release durations support this hypothesis.

It is also unknown why some participants gained limb fluid volume for only one of the release durations. It would seem reasonable to suspect that if planning to use partial doffing as a regular accommodation strategy, prosthesis users would benefit from a fitting process that established their optimal release parameters, possibly a process similar to the protocol executed in this study. Alternatively, participants may try different release durations and frequencies in their at-home setting and discuss results with their prosthetist to hone in on release durations that produce the best outcome for them.

The finding here that Short Release (4 min) was effective on most participants (10 of 13) may broaden the application of socket release. Active users might not tolerate an interruption that required them to sit still for 10 min at a time, but they might release their socket while sitting for a few minutes during their busy day. The motor-driven release-relock unit used in this study or another convenient means for quick and easy socket release and relock may be necessary for compliance in these individuals. Additional investigation would be needed to identify who might need longer release times or who simply might not benefit from socket release.

In the present study, socket-release included release of both the tether and the panel. In a study using three-panel adjustable sockets (anterior lateral, anterior medial, posterior), adding tether release to panel release accentuated limb fluid volume gain, demonstrating that panel release and tether release each contributed to limb fluid volume stabilization. A separate study is needed to evaluate the clinical effectiveness of tether release alone. If tether release alone stabilized limb fluid volume, then the size-adjustable socket would not be needed, and the release-relock socket could be simplified.

Results from this study are relevant only to people with transtibial amputation. A study on individuals with transfemoral amputation would need to be conducted to assess their percent limb fluid volume changes upon socket release. All walking in the study was conducted on a treadmill at a consistent walking speed, unlike in user at-home settings where walking speed would be expected to vary. However, this difference was not expected to meaningfully affect study results since our previous limb fluid volume results during walking of participants with transtibial amputation have shown similar trends in the lab on the treadmill and outside the building in the surrounding environment. The small sample size in this population, which has large variation for the variables, may affect the results, but it does not take away from the value of the work in highlighting the potential importance of socket release duration on participant outcome.

Conclusion from Aim #2 Study

A release duration of just 4 min induced meaningful fluid volume changes in 10 of 13 participants tested, suggesting that even short release durations may be effective to stabilize limb volume. Stabilization of limb volume may improve prosthesis users' socket fit, comfort, and overall health. A next step is to extend to at-home clinical trials to compare outcomes when a partial doffing unit is worn compared to when it is not worn.

Extension Analysis of Heart Rate Data Collected during the Aim #2 Study

Heart rate data were collected during Aim #2 testing in an effort to understand if the data helped explain why some participants' limb fluid volume was more stable for 4-min rests than for 10-min rests. Heart rate was monitored continuously during the test sessions. The results were inconclusive but an extension of the analysis revealed an interesting relationship that effectively normalized participant exertion and distinguished participants' 'capability.'

We investigated the relationship between preferred treadmill speed and active heartrate (aHR) as a percentage of participants' age-normalized maximum heartrate (Fig. 7). Age-normalized maximum heartrate is a metric used in exercise physiology and is most commonly quantified using the equation $HR_{max} = 220 - age$ or $HR_{max} = 221 - 0.64 * age$. We found that the two heartrate equations produced comparable findings thus we implemented only the first one in the results presented below.

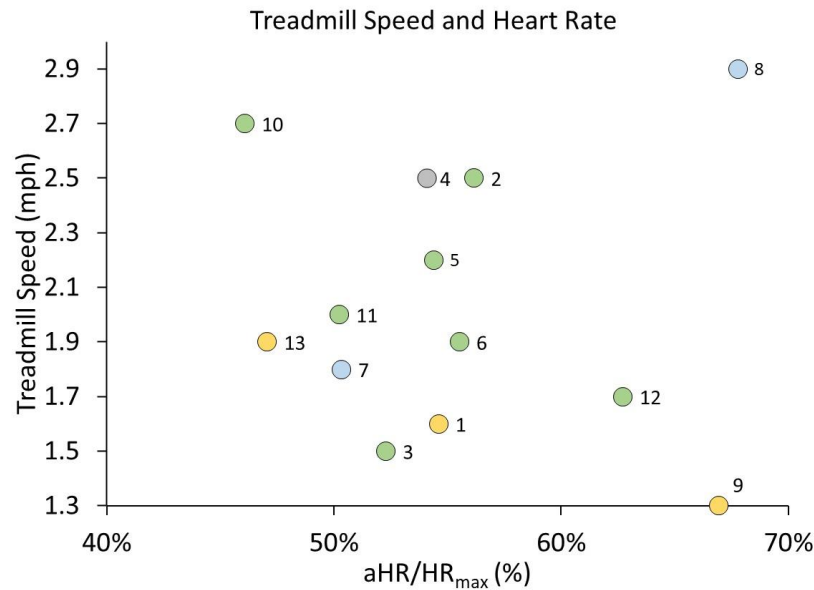


Fig. 7. Heartrate results from the Aim #2 study. The data were scattered rather than clustered by limb fluid volume response group (color), indicating the lack of a strong relationship between heartrate and treadmill speed.

The plot of treadmill speed and active heartrate as a percentage of age-normalized maximum heartrate showed a negative slope (Fig. 8a). An able-bodied marathon runner would be at the top left of this plot, while a person whose lifestyle involved little movement each day would be at the bottom right. As a person's physical condition improves, his or her data moves upward and to the left in the plot. Individuals who exerted themselves more relative to other participants would be expected to be above the average, i.e., above the least-squares fit (dashed) line (Fig. 8a), while those who exerted themselves less would be expected below the dashed line. Because one participant (#8) was an outlier in the plot, his data were not included in the least-squares fit calculation, though his data were included in the plot.

Next, we created a line connecting the aHR/HR_{max} (%) and the age-normalized resting heartrate (rHR/HR_{max} (%)) data points for each participant. The resting heartrate was the heartrate during sitting (treadmill speed= 0). This line was termed the participant's "exertion line." Upward and to the right reflects higher exertion (trying harder) while walking, downward and to the left reflects lower exertion (trying less hard). The part of this line segment between the original aHR/HR_{max} (%) data point and its intersection with the least-squares fit (dashed) line was added to the plot for each participant (Fig. 8b). The ordering of participants along the dashed line ranked them by their capability, corrected for differences in their exertion. We termed the intersection of the exertion line with the dashed line the participant's "capability index." This index is similar in concept to Vesterinen's "heart rate-running speed index," which was used to assess endurance athletes as they underwent a training regime to improve their fitness. The explored metric was found well correlated with other variables including VO_{2max} and maximum

running speed. The index reflects participants' physiological capabilities normalized to their exertion level, allowing participants to be compared to one other.

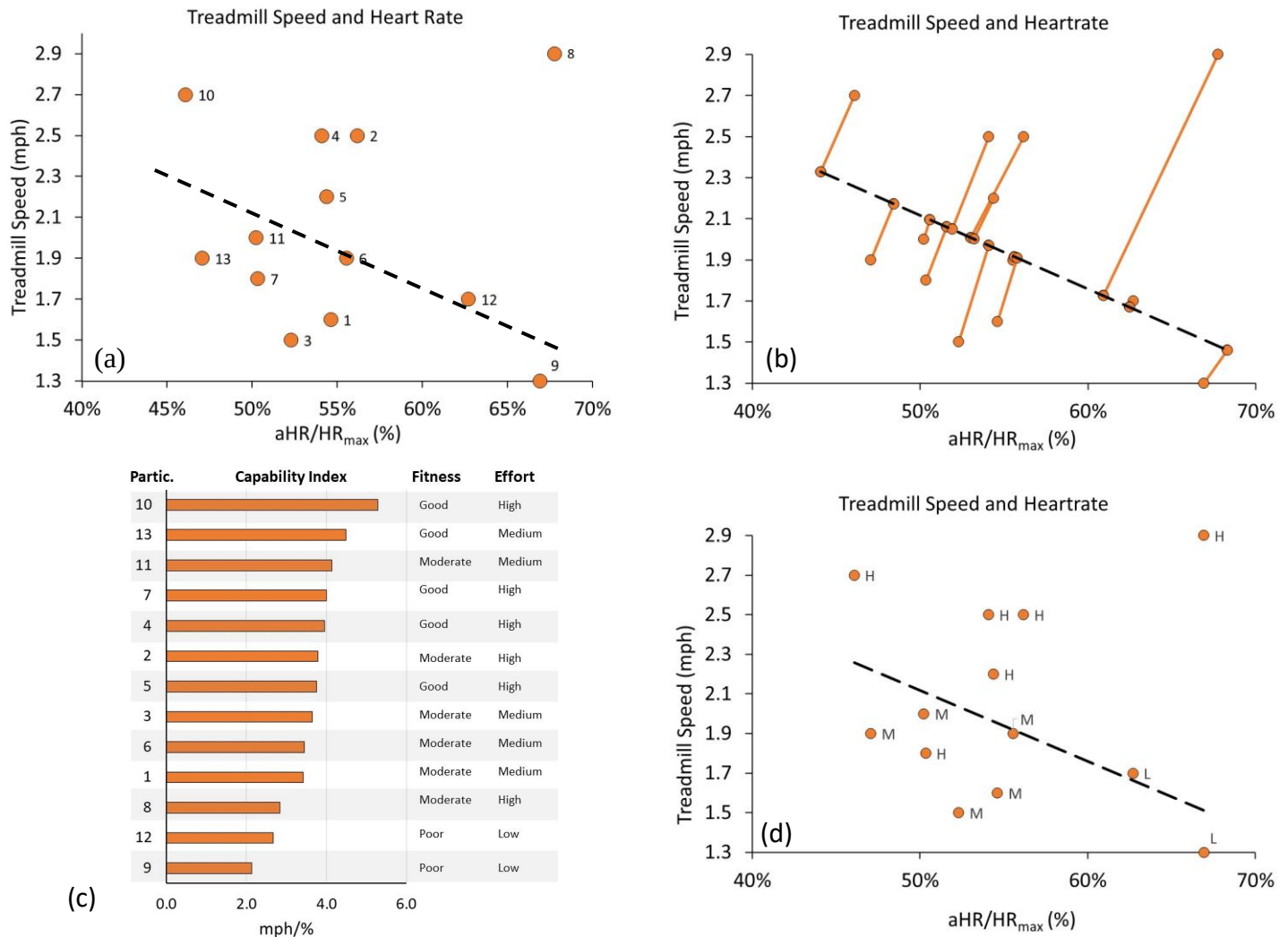


Fig. 8a-d. Results from a prior study analysis to establish a capability index. (a) A least-squares fit to the data is generated. (b) The original data is projected onto the least-squares fit line along a line connecting the aHR/HR_{max} data point to the rHR/HR_{max} data point, correcting for differences in exertion among participants. Along the line from top left to bottom right, the data are ordered by capability index. (c) The participants are listed by capability index (high to low) and the research prosthetist's ratings of their fitness and effort listed. In general, data sort from high to low fitness. (d) Participants who exerted greater effort are, in general, above the least squares line while those who exerted less effort are below the line.

There was a moderate-to-high match between the sorted capability index data and the research prosthetist's notes about participants' fitness and effort (Fig. 8c). We note that the research prosthetist knew this group of participants well through their >1 year of participation in various prosthetics research studies. Those participants with a "good" fitness rating by the research prosthetist were on the upper left part of the capability index line, while those with "moderate" or "low" fitness ratings (other than participants 2 and 11) were on the lower right (Fig. 8d). Participants with an effort rating of "high" in general were above the least-squares (dashed) line (except for participant 7) while those with a medium or low rating were very near or below the dashed line.

Capability index may have clinical application towards prosthetic fitting to select and match componentry to individual prosthesis users' capabilities.

Aim #3 Participant Study – Pilot Phase 1

In June 2020, we initiated Aim #3, in part because we were still restricted from continuing Aim #2 due to COVID-

19 regulations. Aim #3, however, was not restricted by COVID-19 regulations because data collection did not require participants come to our laboratory. We travelled to participant's homes to drop off the test prosthesis so that they could begin testing. The disadvantage of this approach was that insight to be gained from Aim #2 was not applied to Aim #3. However, we saw value in implementation of the TARPIN system in user free-living environments since other issues (instrumentation, training, user interface) could be tested.

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

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

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

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

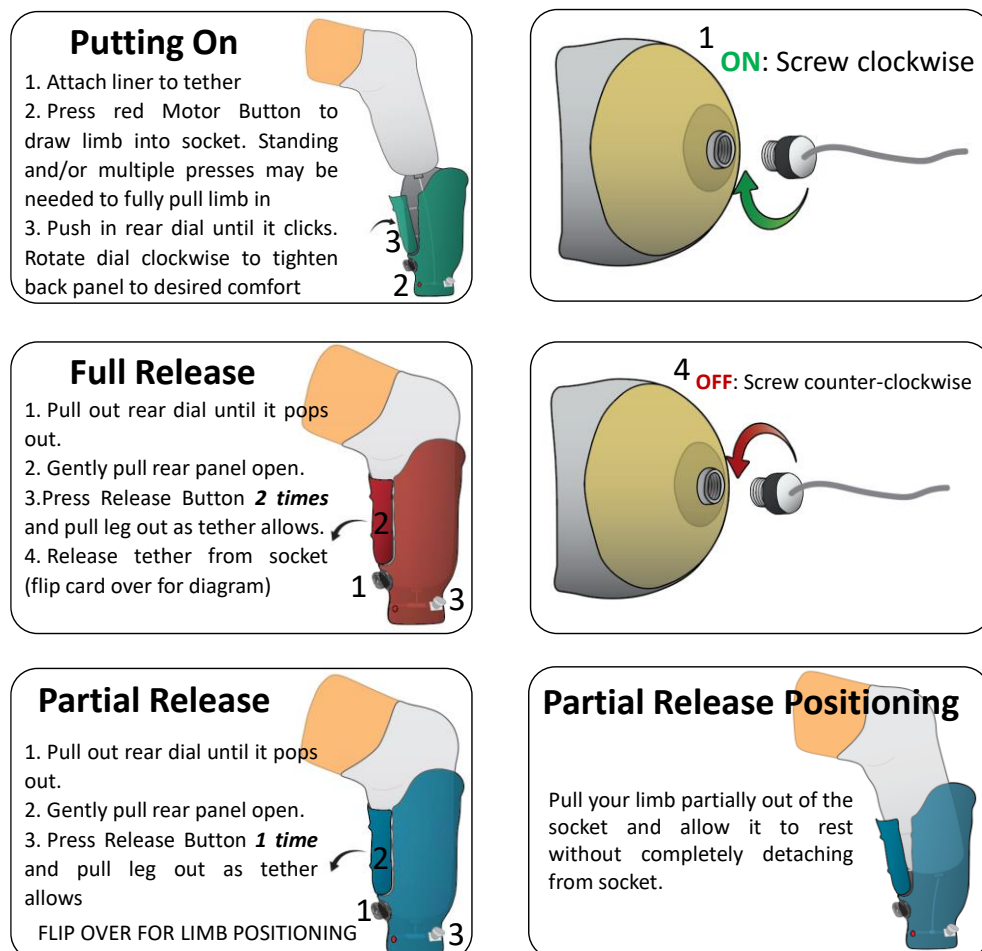


Fig. 9. Instructional cards provided to participants during Aim #3 at-home testing.

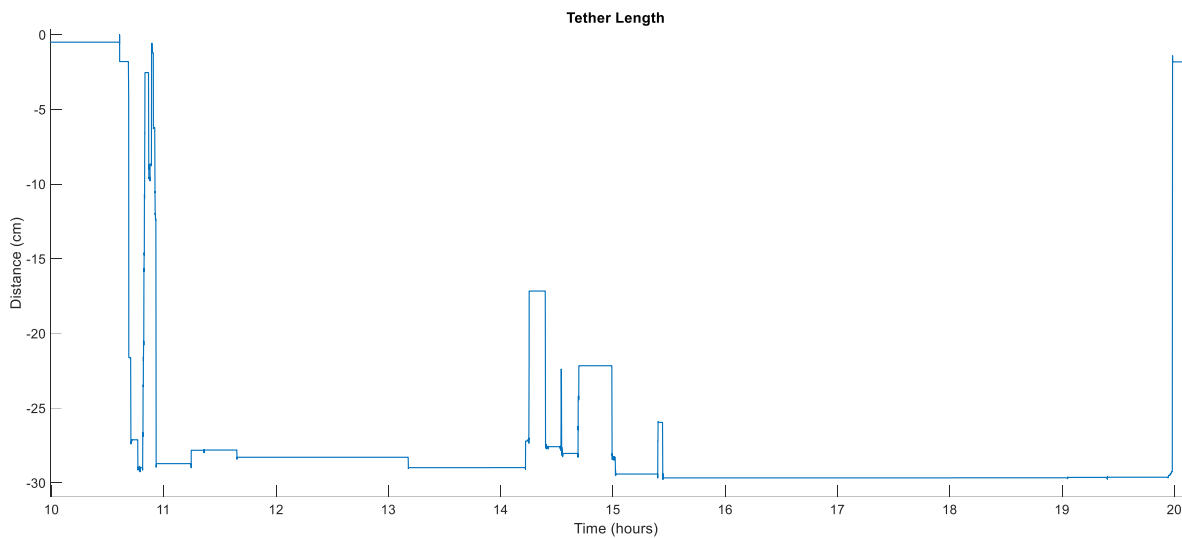


Fig. 10. Tether length from testing Participant #1 in Aim #3. Day 1, 1st test session. The Time (hours) corresponds to time of day.

Inspection of inductive (STM) sensor data (shown in LDC counts in Fig. 11, top graph) showed how STM data changed in response to adjustment of panel position (~15.004 h) and tether length (15.022 h). At 15.004 h, the panel is loosened then tightened and corresponding changes in liner-socket distance occur. When the TARPIN motor button is pushed at 15.022 h, the distal sensors (Lat Dist & Med Dist in Fig. 11) show a decrease in distance while the proximal sensors (Med Prox & Lat Prox in Fig. 11) show no change. The results are encouraging towards understanding how adjustments of panel position and tether length affect socket fit.

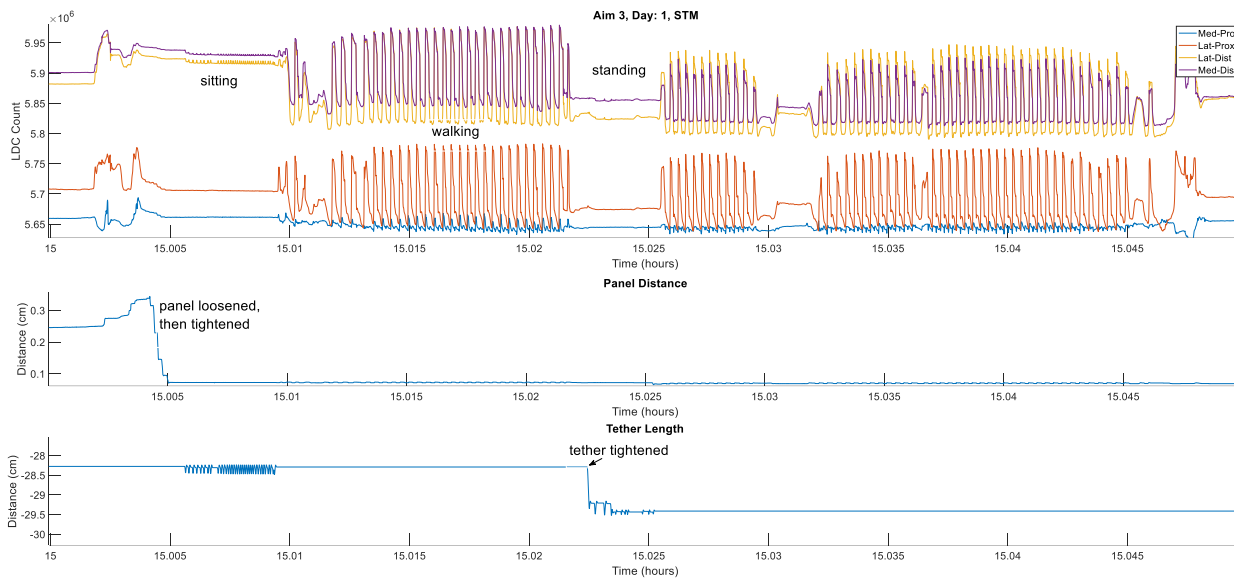


Fig. 11. Zoomed in section for Participant #1, Day 1, 1st test session. Data from the liner-socket distance sensors (STM), cable dial sensor (panel distance), and motor tether (tether length) are shown.

In the post-use interview, the participant noted that he conducted a partial doff at least 12 times over the 3 days of use, stating it was a way to “relax the leg.” To don the socket, he claimed that he pulled the posterior panel open, secured the locking pin, and then closed the panel. Compared to his current socket which has a smooth pin and sometimes inadvertently unlocks and releases when kneeling, the instrumented socket did not behave

unexpectedly. As such, the participant indicated he felt more confident in the test socket. He did not, however, like having to deal with the battery in the test socket. In particular, he stated that he did not know when it was insufficiently charged (i.e., he felt it needed a battery indicator). He liked not having to adjust his sock ply during the day and instead use the tether length to adjust fit.

Participant #2. The second participant made adjustments to both the panel distance and the tether length, as shown below in data from the 1st day (Fig. 12). In general, the participant released the panel first, and then released the tether during doffing. In donning, he preferred to tighten the tether first and then tighten the panel last. The participant did not completely follow the provided instructions to keep the panel all the way open during partial and full release. He partially opened the panel during full releases. However, he did tighten the panel all the way when donned and subsequently walking or standing.

Similar to Participant #1, when Participant #2 tightened the panel, the STM sensors indicated the liner-to-socket distance decreased, as shown in Fig. 12, top panel. When the tether was released, all of the STMs reported an increased distance, consistent with this participant's conical residual limb with minimal soft tissue at the distal end.

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

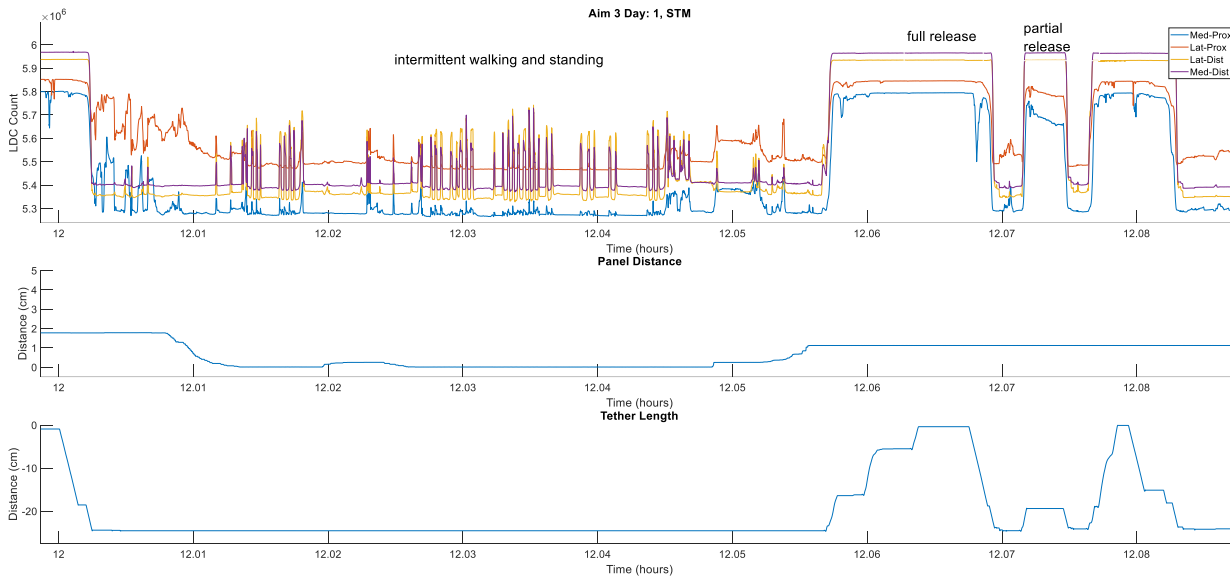


Fig. 12. Zoomed in section for Participant #1, Day 1, 1st test session. Data from the liner-socket distance sensors (STM), cable dial sensor (panel distance), and motor tether (tether length) are shown.

Recognized Performance Problems – Solutions Implemented for Aim #3

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

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

Poor motor performance caused jamming during tether release in some test subjects. The difficulty was that when some participants sat down and executed a partial or full release, the tension in the tether was excessive (>89 N). This tension jammed the pawl into the ratchet such that it could not release. We attempted a number of solutions to this problem including modifying the firmware so that the motor rotated a short distance in the opposite direction first before returning to the proper direction to attempt pawl release, modifying the tether path to ensure it was in line with the socket axis, and changing the support materials to create a stiffer system. These efforts

improved the problem but did not resolve it for all participants. Upon bench testing of the motor isolated from the rest of the system, we found that the motor held about half of the maximum allowable force specified by the manufacturer (which was 178 N), and it failed to draw in a load greater than 71 N. We further noted that the motor was not executing its current limit detection strategy properly, possibly missing current overloading because the current impulse was fast. We were unable to identify a replacement motor of acceptably small size and weight. We therefore modified the design so that release of the pawl was executed manually by the users, similar to how users would execute pin lock release in a shuttle lock socket. The rest of tether adjustment continued to be executed normally using the motor, consistent with the original application.

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

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

Some of the power issues originated from the first problem – insufficient motor performance. When excessive tension was induced in the tether and the motor force was unable to move and release the pawl, protections within the motor and solenoid caused problems within the microcontroller that resulted in the abnormal battery behavior. A thorough search of motor products demonstrated that no replacement motor was available to meet the need. To solve the problem, we eliminated the requirement to unlock the pawl as a necessary motor function. To release the pawl, the user pushed a manual release button that released the pawl from the ratchet and fired the solenoid, allowing the participant to back drive the motor and pull out the tether. After pawl release, the system functioned as originally designed. By firing the solenoid right after the pawl was released, we ensured that a 5 cm partial doff release was executed, i.e., the system transitioned from the don state to the partial doff state. A subsequent second button push caused the motor to release again, now transitioning the system from the partially doffed state to the fully doffed state.

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

We originally designed an “emergency release” as part of the motor release button. If users pushed the electronic motor release and it failed to operate then users were instructed to push the same button harder to execute an emergency manual release. Having the manual release on the same mechanism as the electronic release was a clinical benefit because users easily remembered what to do if the tether did not release. However, users had difficulty distinguishing these two settings and tended to push the button too hard from the start, accidentally executing a manual release and causing motor rotation information to be lost and tether length to be unknown. This problem was solved by isolating the manual release and moving the associated button to a new location. This experience is relevant because it demonstrated that the design of the prior manual release button was acceptable and was used as a base design to solve issue (2) above.

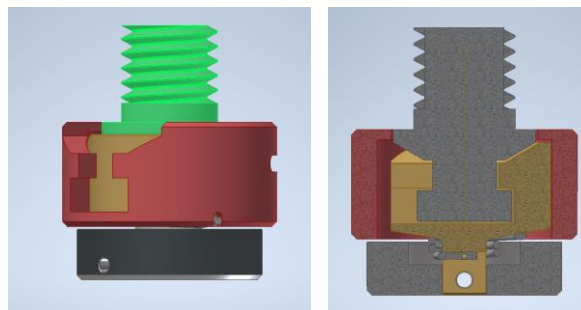


Fig. 13. Design of the quick-release connector for the tether-liner connection.

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

A modified mechanism to connect the tether to the liner was necessary to replace the current screw-in connector.

Some participants lacked the manual dexterity to put the pin into the liner, thus this revision was necessary to increase the pool of candidate participants for Aim #3. The designed device is shown in Fig. 13 below. It is a modified carabiner, requiring less than 1 full twist to lock the mechanism in place.

Instrumentation Modifications

From experience completing Aim #2 and pilot studies in Aim #3, several additional issues were deemed necessary to correct before the release and relock socket was ready for Aim #3 take-home testing.

List of Issues

Mechanical damage: 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 unit 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. 14). When equipped with a Control unit, the socket was the same size and weight as a socket with the normal release and relock system. However, the Control unit housed a traditional mechanical pin-lock instead of the motor assembly and tether. The unit was wired like the normal release and relock system so that button presses (pin releases) executed by the participant were recorded.

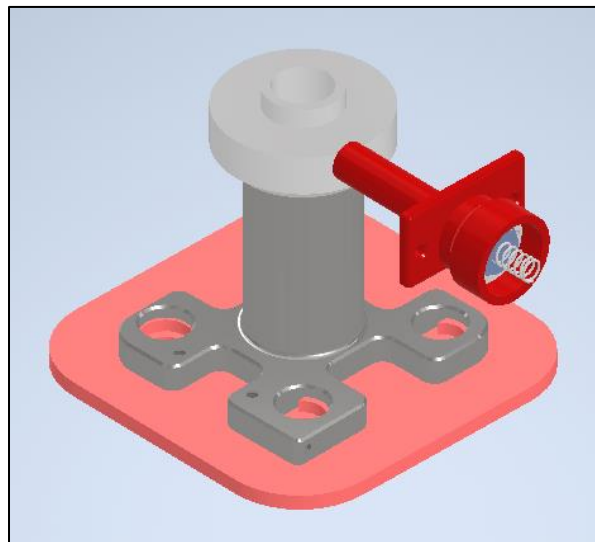


Fig. 14. Control unit used in Aim #3. The motor and tether were replaced with a pin-lock unit.

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. 15, managed all possible user actions, showing the event combinations and timings that occurred 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. 16).

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. 15). These strategies helped to ensure the release and relock system did not lock up from unforeseen circumstances that caused the target state not to be achieved. Firmware was added so that if the target state was not achieved, the system simply returned to its prior state.

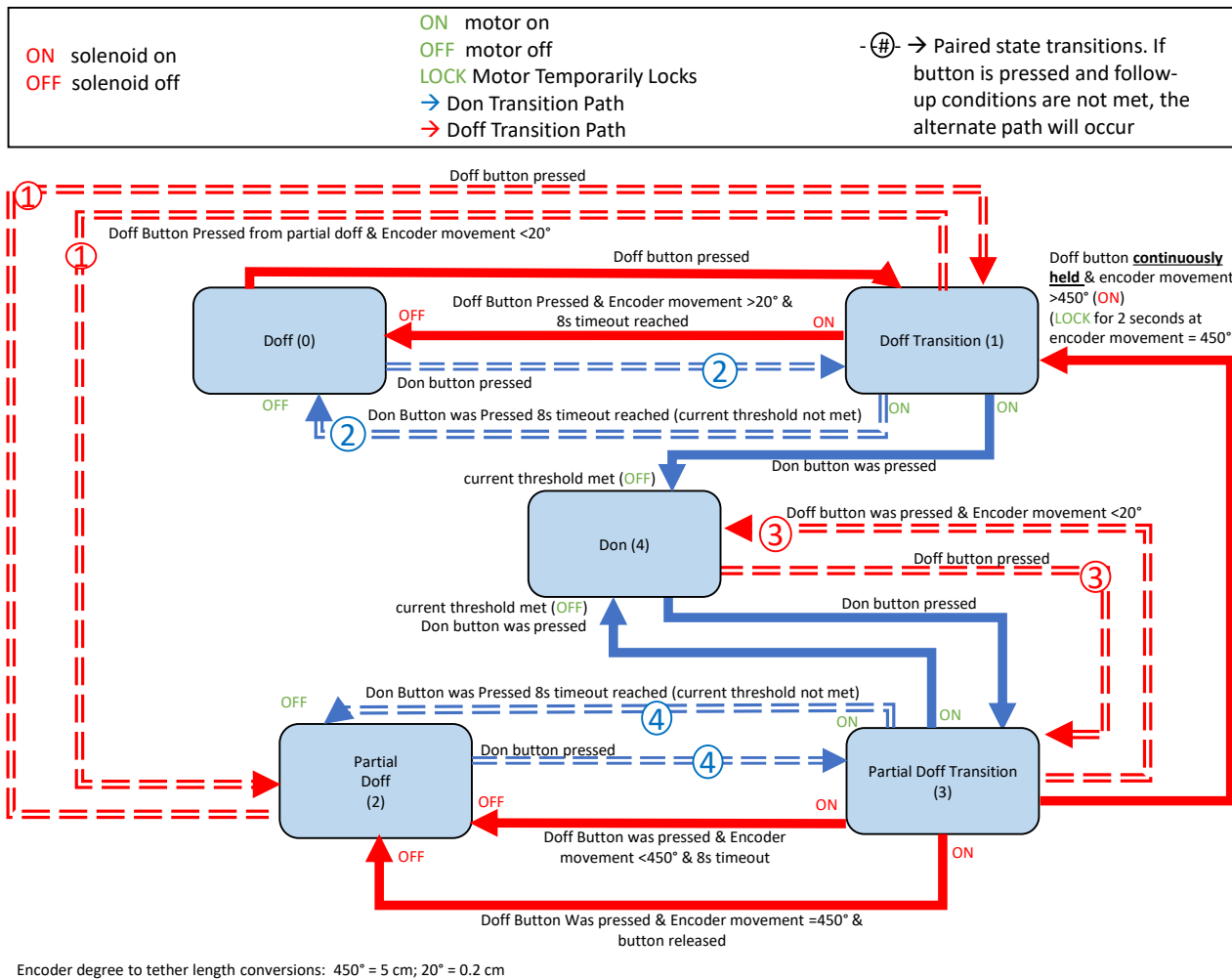


Fig. 15. State diagram showing the release and relock sequences for all possible user actions in the release and relock system.

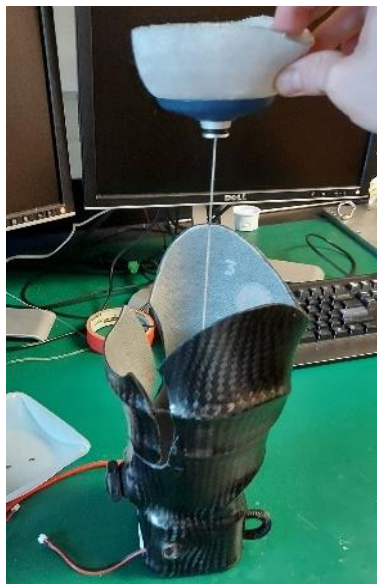


Fig. 16. Bench test set up showing how the state diagram illustrated in Fig. 15 was evaluated.

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 4).

Table 4. 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 was some variation in the duration of the partial doff and don events since the event durations depended 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 N and the M192-6V only 20 N, much less than the 70 N 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 5). 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 change was not made in Year 3 because of delays in making and acquiring parts for the new circuit board.

Table 5. 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 before execution of Aim #3, we changed our procedures during fitting to include measurement of the participant's regular umbrella diameter (Fig. 17). We matched that diameter to the umbrella diameter in the ferrous liner ordered for the participant. In discussion with our ferrous liner manufacturer, who we contracted to make the ferrous liners for this project, we changed procedures to incorporate this umbrella specification into their fabrication process. Three umbrella sizes (small, medium, large) accommodated all test participants.

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 a chamfer used earlier (Fig. 18). 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 wrapped around the spool (Fig. 19).



Fig. 17. Measurement of umbrella diameter for use in ferrous liner fabrication.

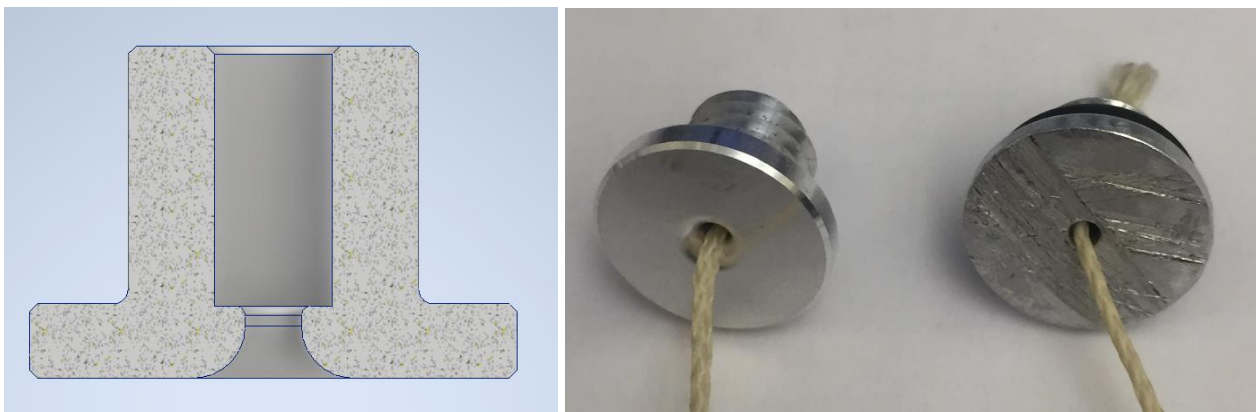


Fig. 18. Tether pin modification. Left: Fillet on the inside surface to reduce stress on the tether. Right: Photo

showing the final design on the left and the old design on the right.

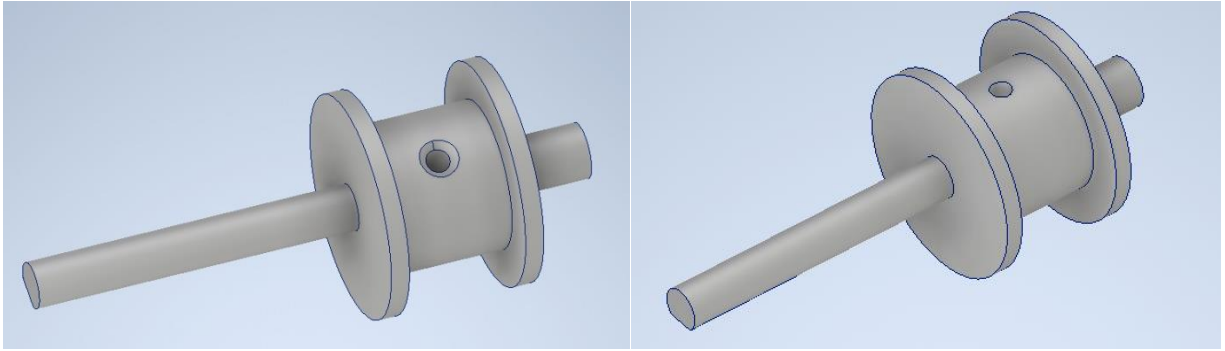


Fig. 19. Spool modification. Left: Final spool. Right: Old spool.

Knot slippage: Knot slippage through the tether pin proved to be problematic for one participant (Fig. 20). 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. 21).



Fig. 20. Knot slippage. Left image: Knot slipping through the hole that holds the tether. Right image: Knot sitting above hole and not pulling out.



Fig. 21. Knots tested. From left to right: 8x overhand knot; figure 8 on a bight knot; Ashley 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 6.

Table 6. 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 was 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 was spiraled around a core within the tether material, this may have been a natural progression of the knot as it was compressed into the hole. The figure 8 however looped 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. 22). The knot did not pull through and no cut fibers were found upon inspection using a microscope after testing (Fig. 23).

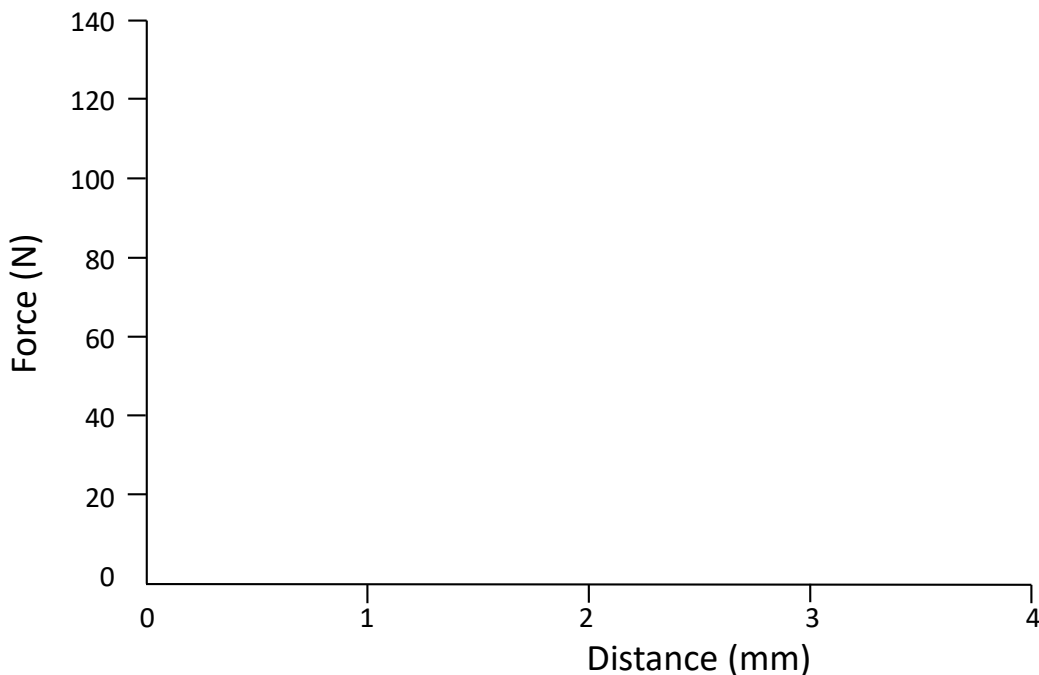


Fig. 22. Mechanical testing of figure 8 on a bight. 25,000 cycles were applied over 5 days. Each color is a different day.



Fig. 23. 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 7. Test results are summarized in Table 8.

Table 7. 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 8. 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 affected 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
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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. 24 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 Quick Pin release needed to be added to this system to reduce tether twisting during take-home use.



Fig. 24. Tether testing setup. The tether was run through the tether guide, and weights were hung at the bottom. There was 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. The tether diameter for Aim #3 testing was 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 were worth the slight tether diameter increase. This change was 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.

Quick Pin Version 2: The Quick Pin fastened the tether pin to the liner such that a single twisting action locked or unlocked the pin, avoiding the tether twisting issue described above. This design was an improvement over the previous version that required multiple turns of the pin to fasten it into the liner umbrella. The new design was made up of five parts that assembled as shown in Fig. 25. The Quick Pin was spring loaded to help keep it locked in place. To release the pin, the user twisted the middle section $\frac{1}{4}$ turn (orange arrow in Fig. 25) with respect to the bottom piece (green arrow in Fig. 25). The system was unaffected by a rotational or axial load applied to the bottom piece, thus ensuring that it remained secure on the pin during prosthesis use. A design modification was made to shorten the Quick Pin, reducing the likelihood of contact with the tether guide during ambulation (Fig. 26).

A 5-day cyclic loading test was conducted on the new design. Results showed a consistent load-deformation slope over the testing period (Fig. 27). The increase in strain over time was due to elongation of the tether.



Fig. 25. Final Quick Pin design.

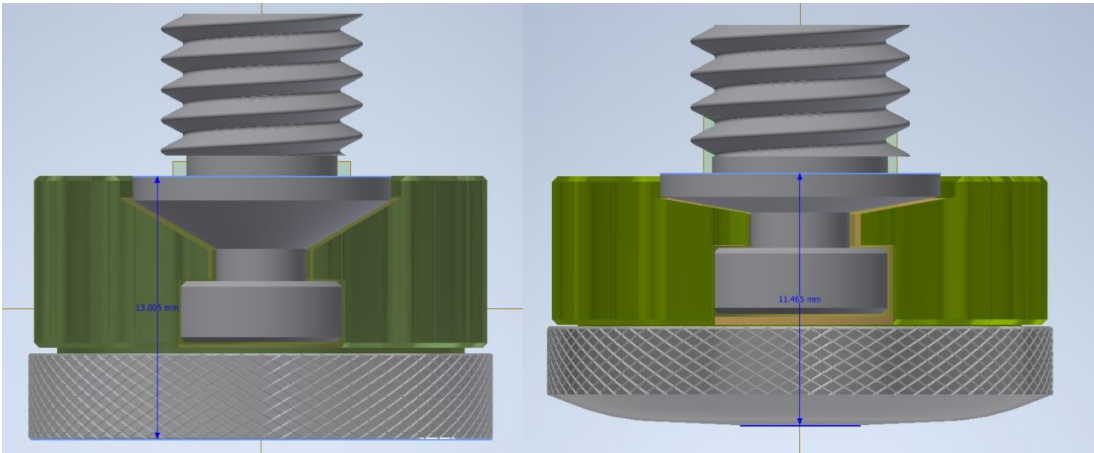


Fig. 26. Side-view of shortened Quick Pin design. Left: old design. Right: final design.

Incorporating the Quick Pin into the release and relock system required the tether guide design to be modified to ensure it did not contact the Quick Pin mechanism. Repeats of the bench and field tests needed to be conducted. Since these tests were not completed until near the end of Aim #3, the Quick Pin was not used in any of the Aim #3 participants. Studies to evaluate the design on a small group of participants are described below.

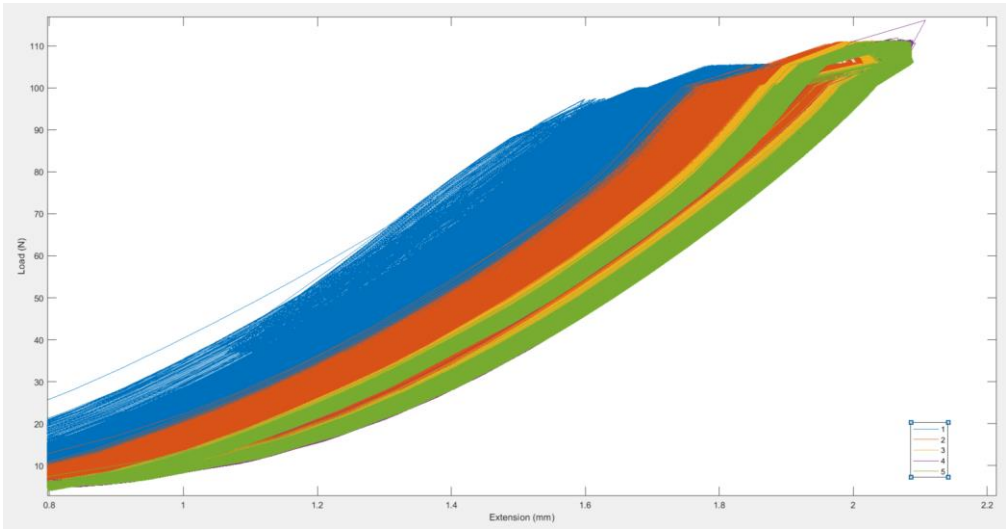


Fig. 27. 25,000-cycle test of the new Quick Pin.

Aim #3 Participant Study – Pilot Phase 2

Additional test sessions beyond the three test sessions on two participants described above 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 results over a day are shown in Fig. 28. 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. 29. The tether did 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 were also higher than earlier, suggesting that the residual limb was hung up on the socket in the proximal region as a result of the limb volume increase from the partial doff.

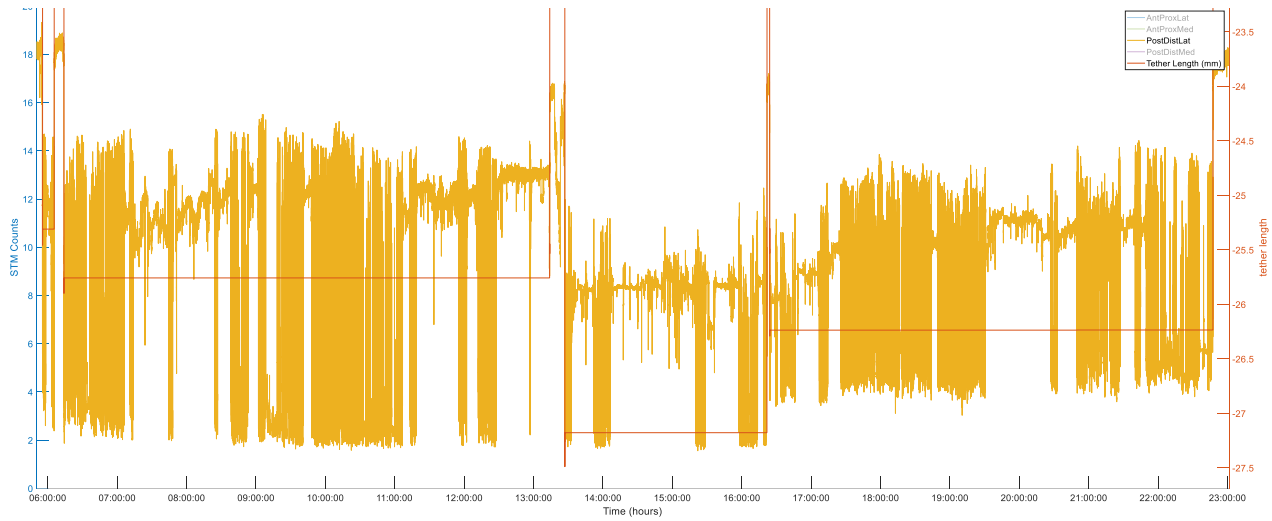


Fig. 28. Results from a day of field use. Red line is tether length. Yellow line is data from a liner-to-socket distance sensor located in the posterior distal lateral region of the socket.

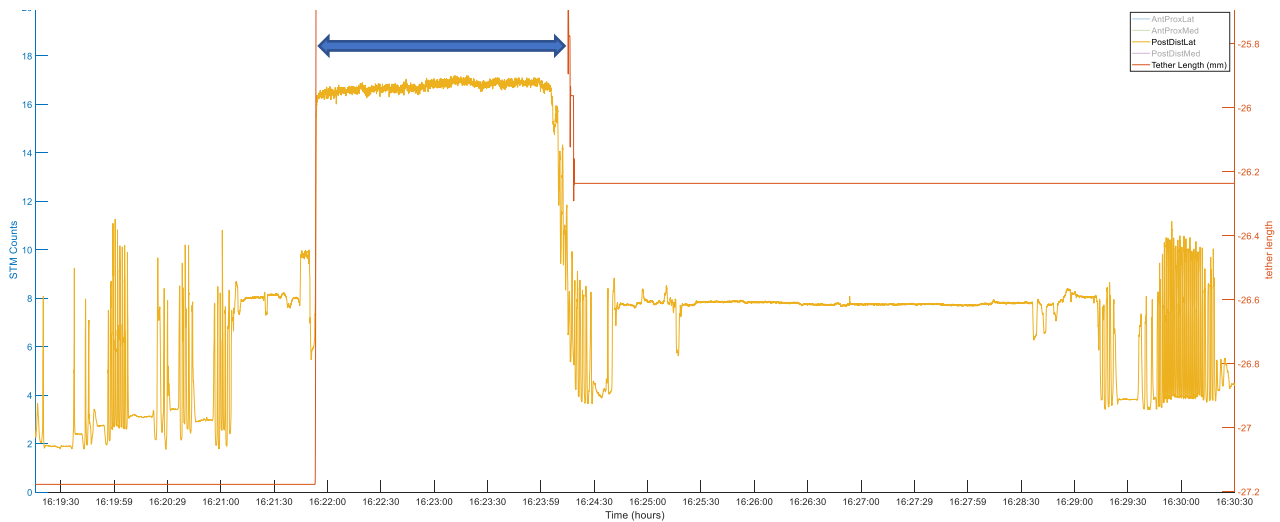


Fig. 29. Zoom in of Fig. 28. Tether length (red line) and liner-to-socket distance (yellow line) are shown before, during, and after a partial doff (blue arrow).

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. We reduced the break-in period to less than 1 week and shortened the duration of take-home testing.

Aim #3 and #4 Test Results

Table 9 summarizes testing completed in Aim #3. Table 10 lists participant characteristics for the Aim #3 study.

Table 9. Aim #3 Participants. 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
<u>Pre-Pilot:</u>								
PPI1	X	X	1-day					
PP2(2x)	X	X	1-day, 3- day					
<u>Pilot:</u>								
F1 (2x)	X	X	2-day					
F2 (2x)	X	X	5-day 6-day, 7- day					
<u>Full:</u>								
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	3*	8*	7	3*	9*	10
F12	X	X	3*	7*	7	3*	7*	7

*Data uploaded remotely thus no check sessions needed

Table 10. Participant Characteristics.

Partic.	Gender	side	Age (y)	Time since Amp (y)	Etiology	K-Level	BMI (kg/m ²)	RL Length (cm)	Co-Morbidities
1	M	LTTA	60	14	trauma	K-3	30.1	13.3	HBP, gout
2	M	LTTA	59	32	trauma	K-4	32.1	11.5	HBP
3	M	LTTA	75	53	trauma	K-3	28.9	21.8	HBP, aortic valve replacement
4	F	RTTA	40	17	trauma	K-4	22.7	14	none
5	M	RTTA	62	38	trauma	K-3	23.6	18.5	none
6	M	LTTA	75	47	trauma	K-3	26.2	12.3	HBP
7	M	LTTA	57	5	trauma	K-3	37.4	16.2	DM, smoker
8	M	RTTA	48	9	trauma	K-3	24.6	15.6	HBP, smoker
9	M	LTTA	61	18	Charcot foot infect.	K-3	34.6	21.1	HBP, DM
10	M	RTTA	50	8	trauma	K-4	29	15	HBP

Results from Aim #3 and Aim #4 are presented below by showing an example series of plots and tables for a participant.

Summary of protocol: Participants tested the socket in two configurations: intervention (release-relock motor active) and control (release-relock motor not active). The control configuration was run first. The participant wore the research prosthesis for a break-in period of 3 d. The researcher visits the participant, downloaded and inspected the data, and made adjustments to the instrumentation if necessary. The participant continued to wear the prosthesis in the control configuration for ~2 weeks, then returned to the lab. The participant completed a questionnaire and interview, the staff switched the research prosthesis to the intervention configuration and trained the participant how to use the release-relock system. The participant left the lab and underwent a break-

in period for 3 d. The researcher visits the participant, answered participant questions (if any), downloaded and inspected the data, and made adjustments to the instrumentation if necessary. The participant continued to wear the prosthesis in the intervention configuration for ~2 weeks, then returned 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 allowed an extended analysis from the usual step count information provided by activity monitors. We characterized 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. 30, 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.

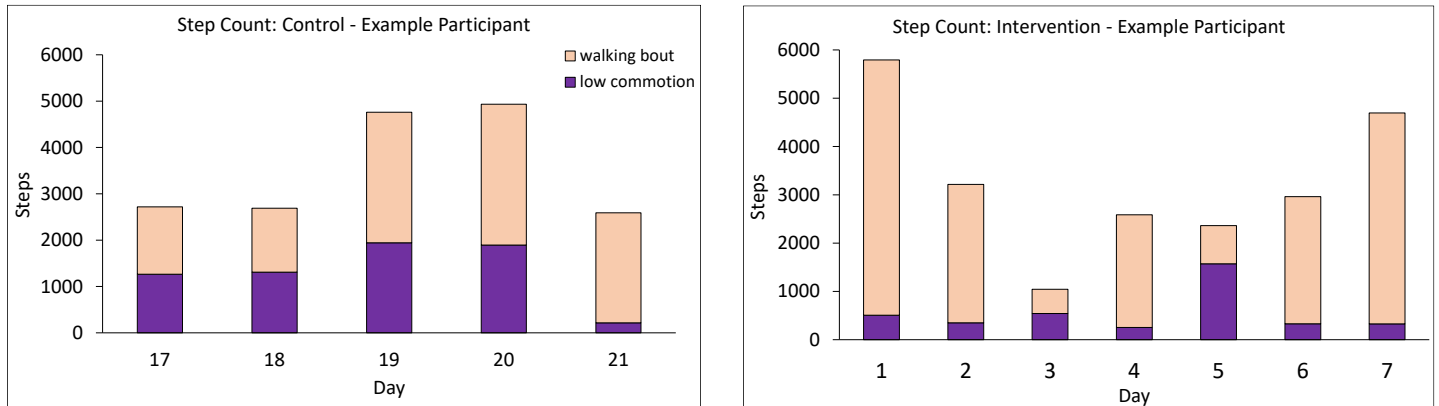


Fig. 30. Step count data during walking bouts and low commotion. For the intervention compared with the control, the participant took more steps during walking bouts than during low commotion.

His prosthesis use distribution also changed (Fig. 31). 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).

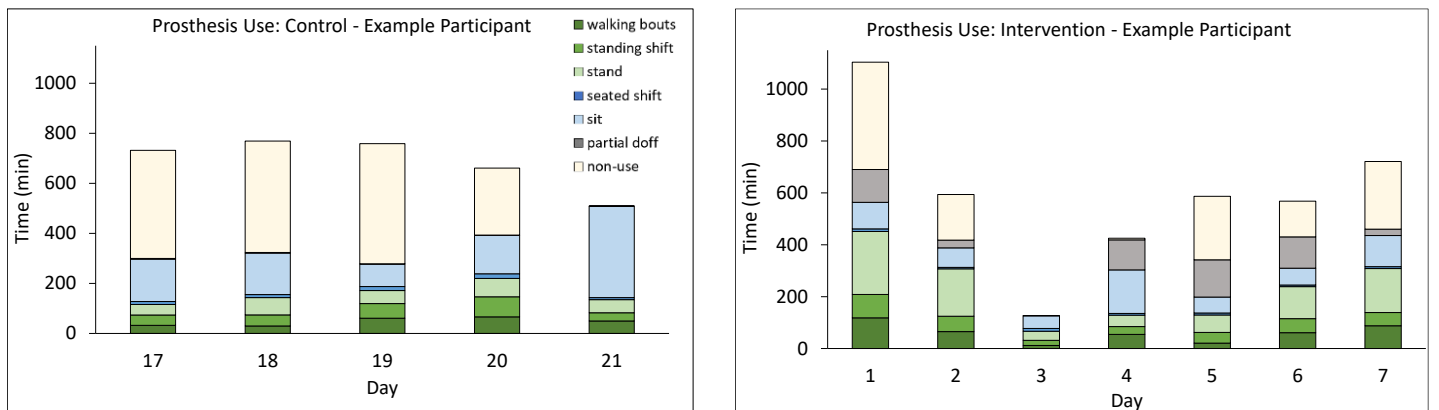


Fig. 31. Prosthesis use. For the intervention compared with the control, the participant conducted more active use (green bars) and less sit use (blue bars). He frequently used the release-relock system for partial doffing (gray bars).

For all wear days for the example participant, percentage at each of the seven uses is shown in Fig. 32. 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. 30-32) provide a platform to address the Aim #3 hypotheses.

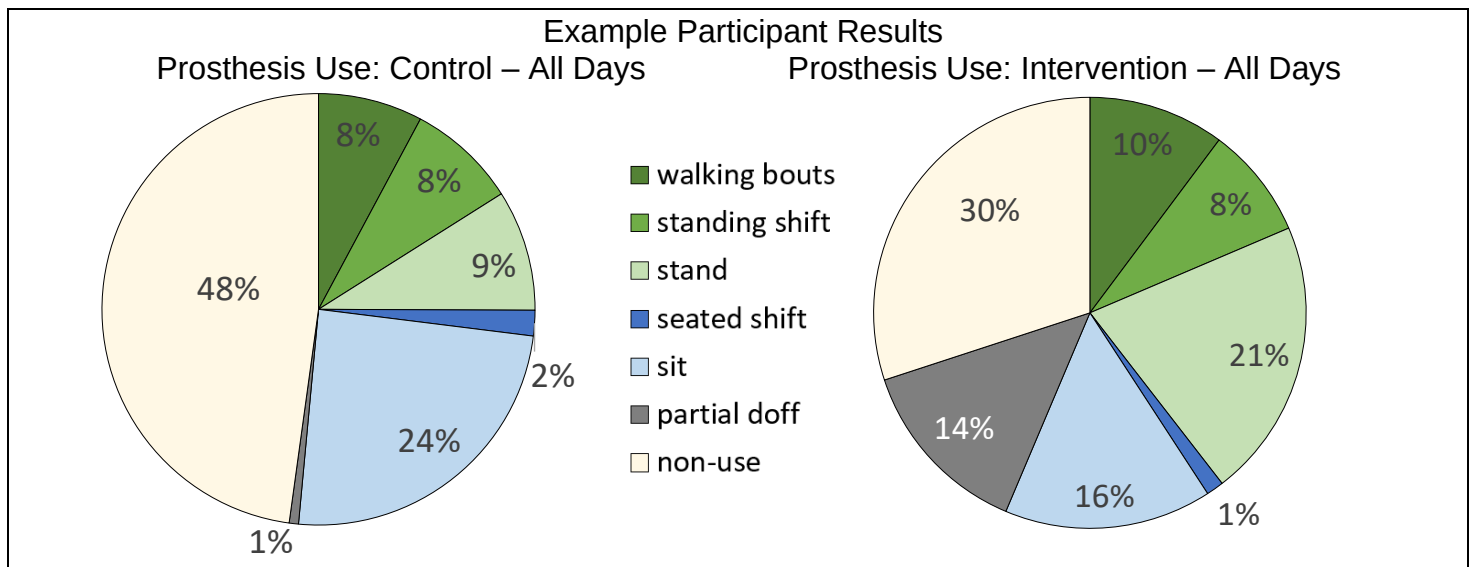


Fig. 32. Percentage time at each of the seven prosthesis uses for control and intervention conditions.

Aim #4 Test Results

Prosthetist participants completed Aim #4 (Table 10).

Table 10. Aim #4 Prosthetist Participants.

Participant Prosthetist	Contacted	Signed Consent Form	Received Data	Completed Interview
P3	X	X	X	X
P4				
P5	X	X	X	X
P6	X	X	X	X
P7	X	X	X	X
P8	X	X	X	X
P9	X	X	X	X
P10	X			
P11	X	X	X	X
P12	X	X	X	X

Example results from one prosthetist participant are presented below. Before the meeting, the prosthetist was sent a formatted report, similar to Fig. 30-32 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 11). Once interviews for all participants were completed, we grouped the results into common themes for analysis and dissemination.

Table 11. Summary of Responses from Aim #4 Participants (Prosthetist)

Topic	Feedback
Potential Uses	-Justify alterations to prosthesis such as upgrading feet or swapping suspension systems -Helps remove the subjectivity in classification, normally rely heavily on patient self-reporting to determine activity -Insurance justification -Realizing issues in patient fit -Useful to know how often the patient is wearing the socket for justification -Allows for correct componentry selection -Could diagnose fit issues early

Other Insights	-Makes it clearer that he is not using socket as often as expected, could allow a shift in K level -Can help with determining appropriate suspension since selection is based on activity -Too much sitting means the person is not happy with the socket – helps prosthetist identify this issue -Could use for wheelchair patients to assess seated shifting, important to pressure ulcer development -Participant behavior from activity data tells prosthetist where to look for issues -Transfemoral patients would benefit to justify getting new/better knees -Would be useful on bilateral patients to see how they shift their weight during sitting -Tells practitioner if the socket should be designed for sitting or ambulation, affects trimline for example -Help patients set activity goals, e.g., ratio of sedentary time to active use time
Other Information	-Accurate picture of limb volume -Times of day they partially doff - Cadence shifting/speed -Carrying something heavy, trotting, running -Detecting stairs -Length of wear -Walking on uneven ground -Varied cadence -Turning, rounding corners -Looser fit of socket over time -Add socket fit metrics to patient prosthesis use data -What activities precipitate a socket size change -Alert to indicate dramatic changes that might be an indicator of health issues

Instrumentation – Resolved Issues and System Improvements

We executed a 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 performance issues that need to be addressed. The following issues were resolved:

- 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 did not require the board to be completely restarted and bypassed the issue.
- Tether Pin Threaded into Liner Unscrewed 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 were able to wear the socket for weeks at a time without the pin becoming loose or the need for retightening. Nonetheless, participants were provided with a crescent wrench to tighten down the pin in the event of an emergency and were instructed to check the tightness of the pin daily. As an additional precaution, participants were instructed to not unscrew the tether from the liner during donning or doffing, but to instead invert the liner while the tether was 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 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: During cold weather conditions, there was greater static charge build-up in participants' sockets than during warm conditions. The charge could create issues while the person walked 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 triggered switches in the firmware that could freeze up the board, for example. This issue was addressed by changing the electronics to add a path for discharge that avoided 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 were 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 created a short and instability such that the internal voltage, the rail voltage, changed. To fix the latch up, the power was 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 reset 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 helped debug the latch issue.

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 provided redundant protections against this issue. When we implemented these system features, no issues were observed with the socket structure, and ADC latch up was not 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 was essential so that the electronics sent the data to us each evening automatically when participants recharged the system. We used a Raspberry Pi to create a functional prototype. The USB download electronics, which we termed the RAFT (Remote Access File Transfer unit), was kept in a box with a cable extending from it that the user plugged in each evening. The RAFT detected the release/relock unit, saved its operating state, put the release/relock unit into a data transfer mode, copied the files and uploaded them to Microsoft OneDrive, and then restored 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 could 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 was 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, the USB download system was implemented. In addition to the above-described functions, the unit, upon plug in, monitored 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 included 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 was plugged in (this was relevant because when plugged in data collection stops, and we needed 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 files, using the RAFT to write a new runconfig file to the release-relock unit if the runconfig file was 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 was that if the release-relock system SD card could not mount in 16 tries then the RAFT reset the MCU and tried 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 tightened 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 were triggered to occur 10 minutes after the socket was donned, 50 minutes later, and then once per hour until the socket was doffed. Each auto-don burst was 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 retracted the tether at 10 min after the socket was donned, then at 1 h intervals until the socket was doffed. During a sequence, the socket retracted the tether until a motor current threshold was met in six attempts. Implementation of this strategy improved participant comfort per feedback collected during follow up interviews.
- *Tether Breakage Issue*: From successful testing several participants in Aim #3 without problems, tether breakage became a non-issue.
- *RTC Timestamp Issues*: Some of the circuit boards had time stamp issues caused by faulty RTC parts and were 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 was as follows: when data collection was started, the MCU timer was set based on the RTC time. After the sampling of the RTC timer at the beginning of the data collection the timestamps were generated solely based on the internal MCU timer. If the board went offline for a period of time, then came back online without a change in time it was difficult to determine when the period of no data

occurs, especially if this happened at night when the socket was doffed.

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

- *Socket Fabrication Enclosure Fills with Resin (minor issue)*: During the final stage of fabrication of the sockets with embedded sensors, there was a potential risk that resin filled the enclosure, ruining the socket. The enclosure was sealed using silicone and clay prior to the final layup to keep resin out of the enclosure. However, if a hole in the enclosure was not properly sealed then this could result in the enclosure filling with resin. The risk of this happening and the consequences of failure were detrimental to the effectiveness of the release-relock socket. The solution we implemented was to temporarily fill the enclosure with silicone. The silicone was removed after fabrication was complete.
- *Clicking Noise (minor issue)*: The pin lock used in the control configuration of the release-relock unit created a clicking noise that was audible to people wearing loose fitting sockets. This was 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 12 and 13 below.

Table 12. 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 MCU pin 45	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 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 13. 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 now transferred more quickly, and the 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 during transition from donned to full doff 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 final design of the Quick Pin is illustrated in Fig. 33, and a summary from internal design review and participant testing is provided in Table 14.

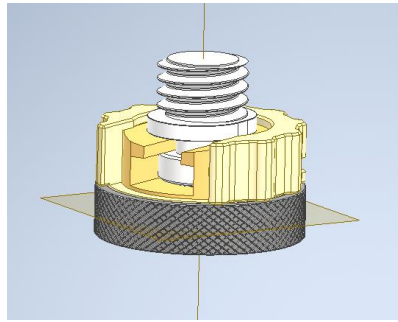


Fig. 33. Quick Pin final design. The user rotated the yellow knob, slid the pin into the slot, and then released the yellow knob to lock the pin in place.

Table 14. 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 (1 participant)	The section above the pin was thickened
	The dowel rod should be removed, covered, or shortened (2 participants)	This part was used only for assembly of the system, so no change was made
	It would be better if the Quick Pin were bigger (2 participants)	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 (1 participant)	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 (1 participant)	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
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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 15. By the 4th trial, time to execute a don or doff ranged from 2s to 15s. These times were reasonable for clinical implementation and were substantially less than the alternative method – the threaded fastener in the distal liner.

Table 15. Participant Time to Don and Doff Using the Quick Pin

Partic.	Time Metric (s)								Avg Don Avg Doff	
	Don 1	Doff 1	Don 2	Doff 2	Don 3	Doff 3	Don 4	Doff 4		
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 were determined for each walking bout and used as an “envelope” for characterization (Fig. 34). A threshold distinguishing sitting from standing was determined for each participant from calibration tests before the participant left the lab, and then implemented in processing of data from at-home use. The threshold was defined as a percentage of the range between the upper and lower bounds of the envelope. A doff threshold was specified (usually 8-10 cm) based from calibration data. A partial doff was distinguished from a full doff by contact at the proximal sensors on the medial and lateral flaps of the socket (Fig. 35). The motor distance data was used to verify the results.

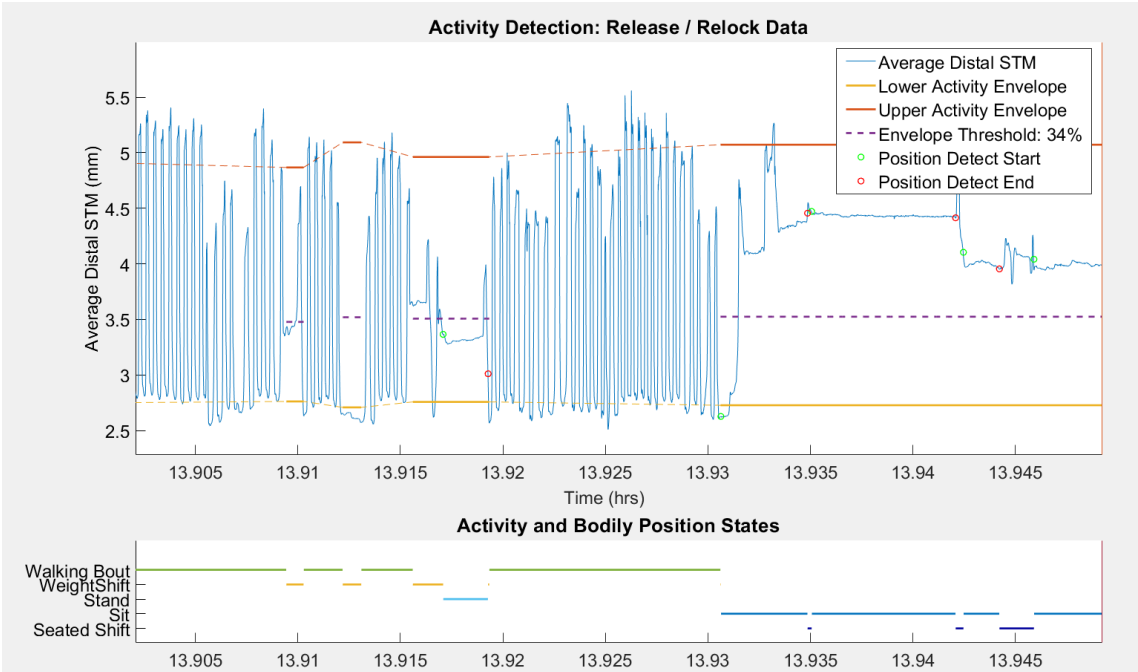


Fig. 34. Bodily position and activity detection. Upper panel: Liner-to-socket distance sensor data, showing the upper and lower bounds of the envelope (red and orange lines) as well as the sit-stand threshold line (purple dashed line). Lower panel: Record of detected activity.

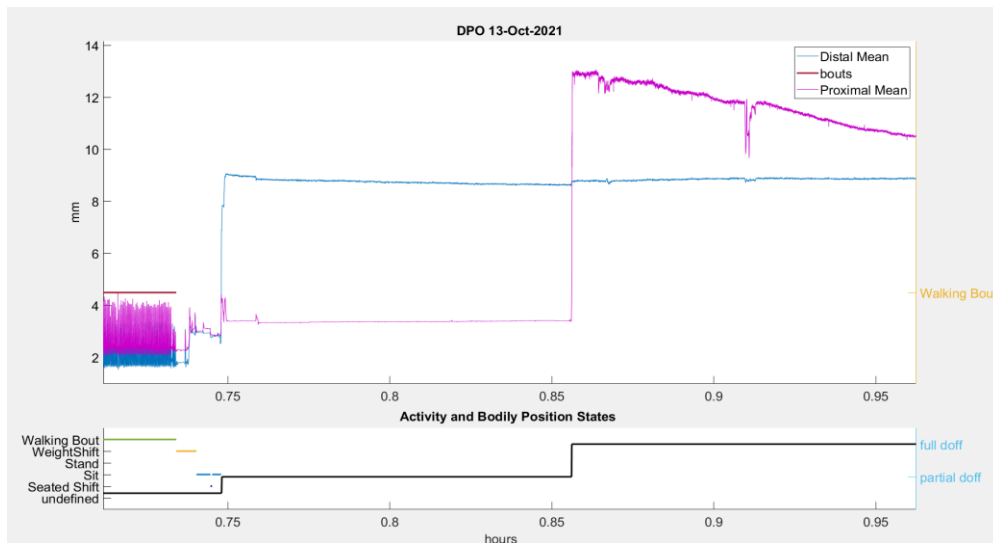


Fig. 35. Distinguishing partial doffing from full doffing. The distal sensor mean shows no contact for both partial doff and full doff. The proximal sensor mean shows a transition from contact to no contact, indicating transition from a partial doff to a full doff.

We further enhanced our code to determine the start and end of a prosthesis day. The method was identical to that used in our prior work [J Prosthet Orthot 2018;30(4):214-230]. Distinguishing when the prosthesis was initially donned at the outset of the day and when it was doffed at the end of the day simplified 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 was defined within a section of non-walking bout data. When 5 data points showed an increase greater than 2x the standard deviation from the mean of the previous 5 data points, the beginning of a weight-shift was defined. If there existed 3 seconds of data that did not exceed the standard deviation threshold then the weight-shift was ended, and the subsequent data were classified as stable, i.e., a sit or a stand. Once the sections of stability were identified, a sit-to-stand transition threshold was 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 were compiled into both daily plots as well as weekly plots.

Aim #3 Hypotheses

For release/relock sockets compared to traditional sockets, participants:

- i. wear their prosthesis more often (longer prosthesis day)

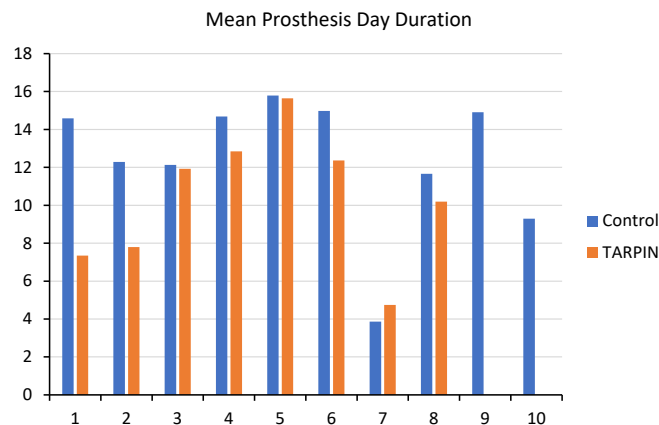


Fig. 36. Prosthesis day duration.

The hypothesis is not supported by the data (Fig. 36). All but one participant wore the prosthesis for a longer

prosthesis day for the Control than the TARPIN.

- ii. are more satisfied, functional, and comfortable with their prosthesis (higher PEQ scores in subscales satisfaction, utility, residual limb, and ambulation; higher SCS)

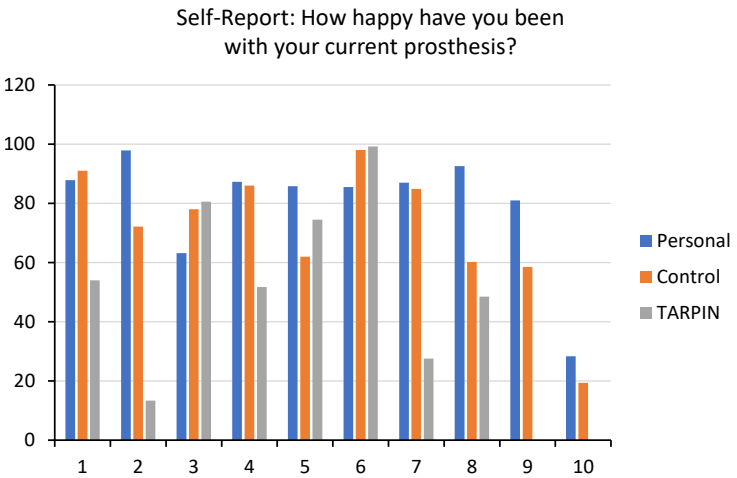


Fig. 37. Self-reported rating on happiness with the prosthesis.

Three participants were happier with the TARPIN than the Control (#3,5,6) (Fig. 37). Two participants (#3,6) were happier with the TARPIN than their personal prosthesis. The rest, in general, rated the Control lower than their personal prosthesis, and the TARPIN lower than the Control. Since the main difference between the Control

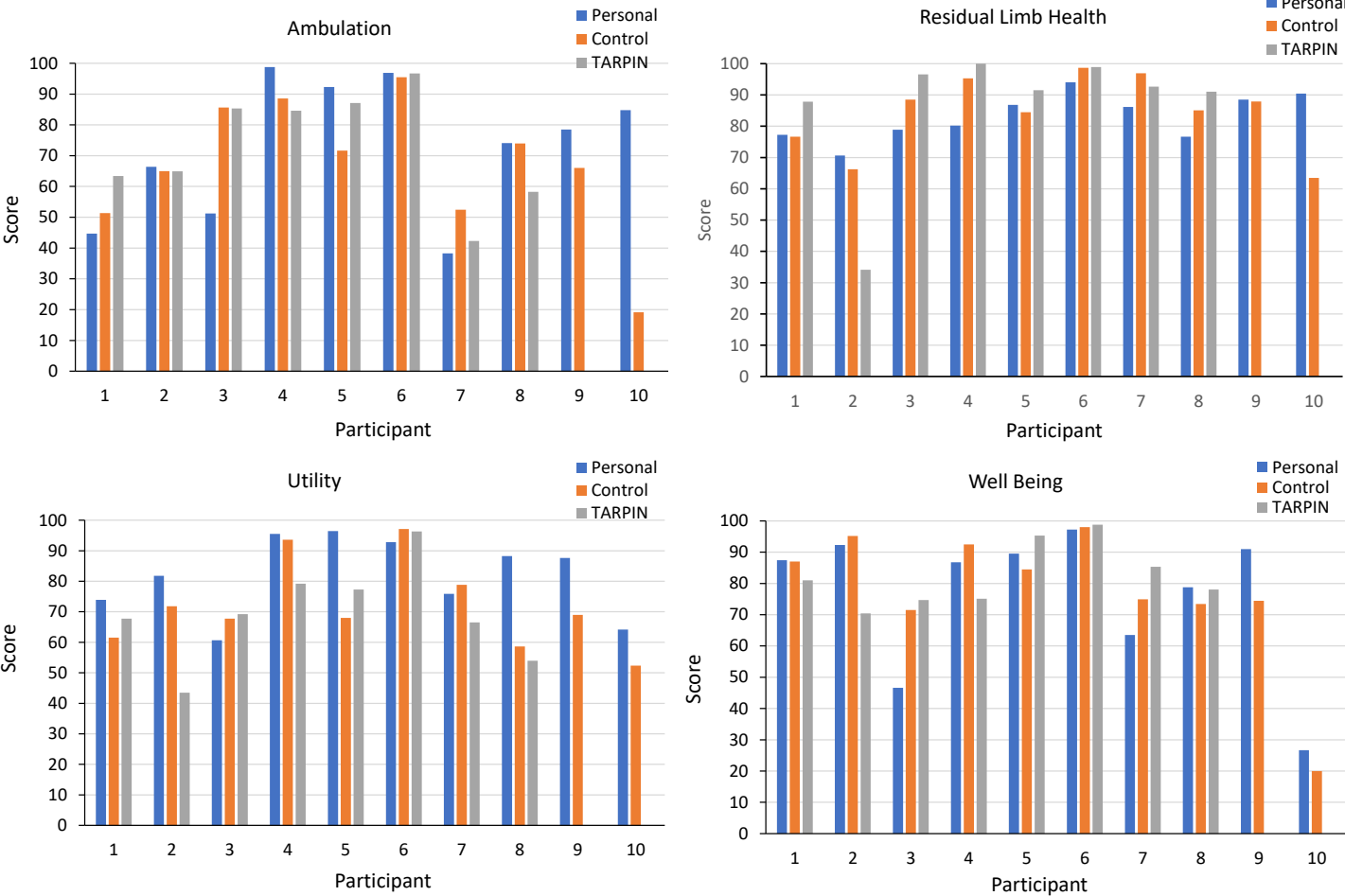


Fig. 38a-d. Prosthesis Evaluation Questionnaire results.

and the personal was the increased weight, we expect score differences between these two configurations to reflect this variable. The decrease for TARPIN v. Control may have reflected the requirement to use a tether instead of a pin lock, most participants' personal prosthesis suspension.

The hypotheses are not supported by the data except for the residual limb health category which tended to be higher for the TARPIN than the Control (Fig. 38). All other categories were mixed.

iii. are more active (longer walk and stand daily total, and shorter sit and doff daily total)

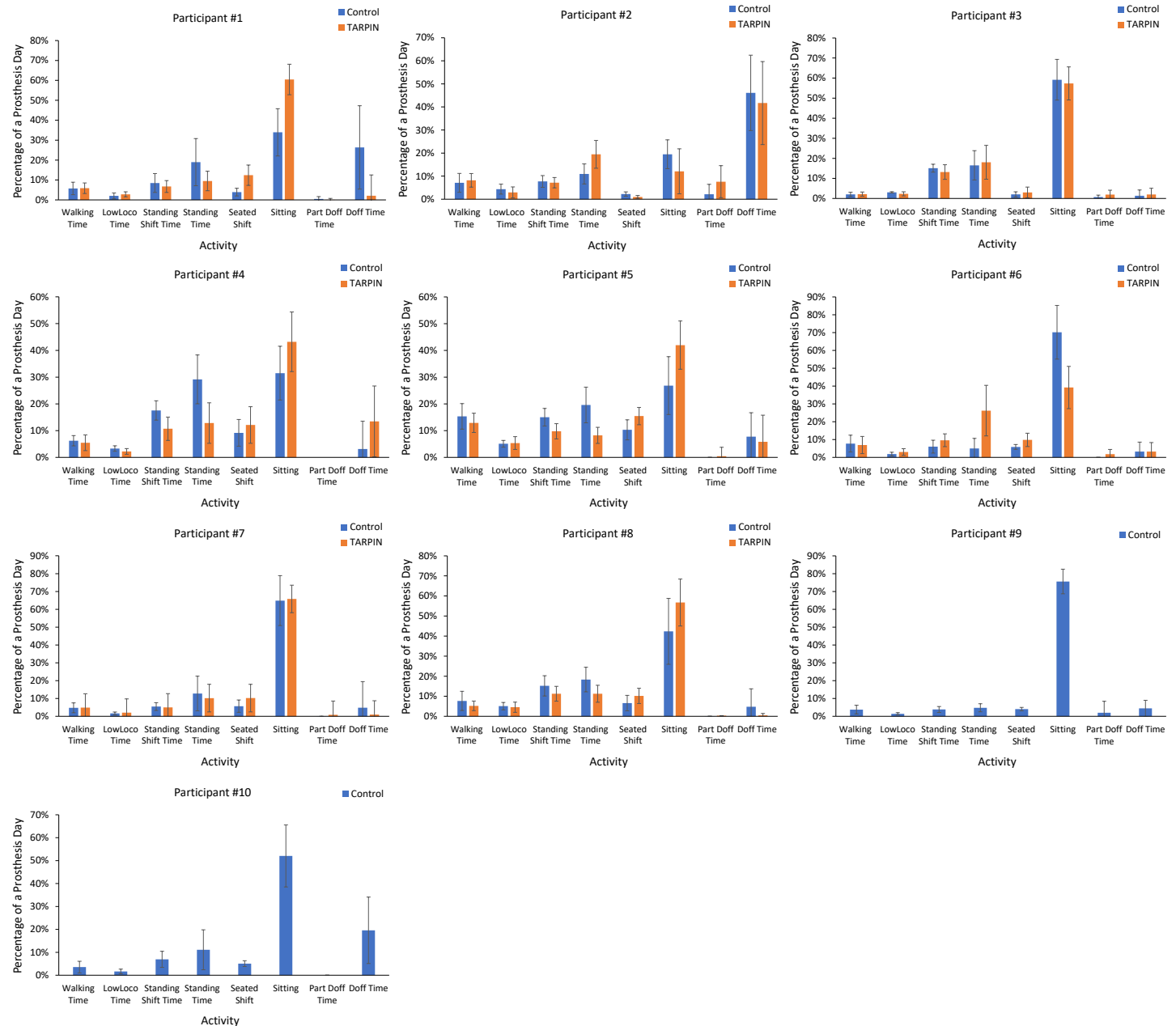


Fig. 39. Activity results.

In general, the data do not support the hypotheses (Fig. 39). In general, participants were more active using the Control than the TARPIN.

Aim #4 Hypotheses

(a) Practitioners will estimate their patient's prosthesis day accurately (± 1 h), and will overestimate their patient's h/day walking, and underestimate their h/day sitting

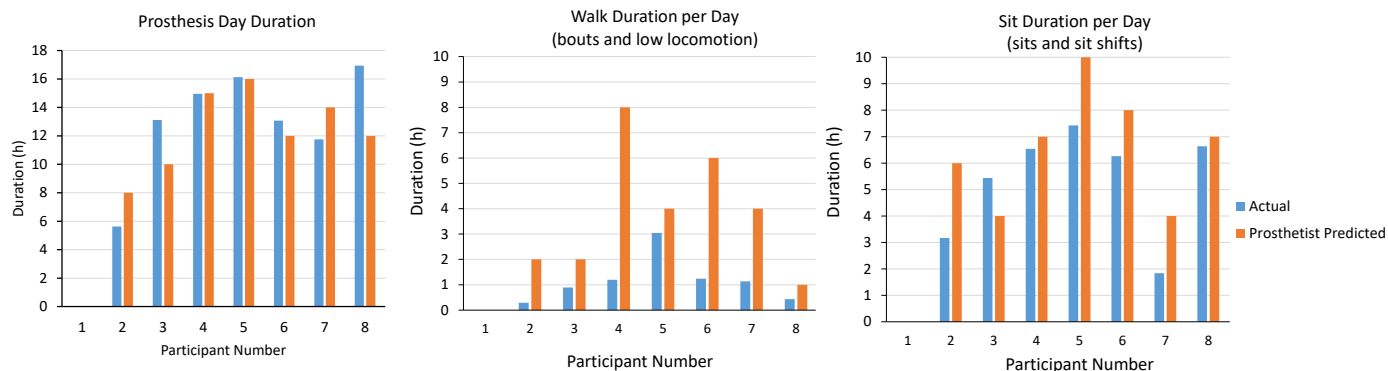


Fig. 40. Prosthetist predictions and measured participant activity.

Prosthetists' predictions of their patients' prosthesis day duration varied as to if they overestimated or underestimated compared to the sensor data. Both walking and sitting durations tended to be overestimated by the prosthetist compared to participant measured use (Fig. 40).

(b) Prosthetists' confidence in estimates will increase with years of clinical experience

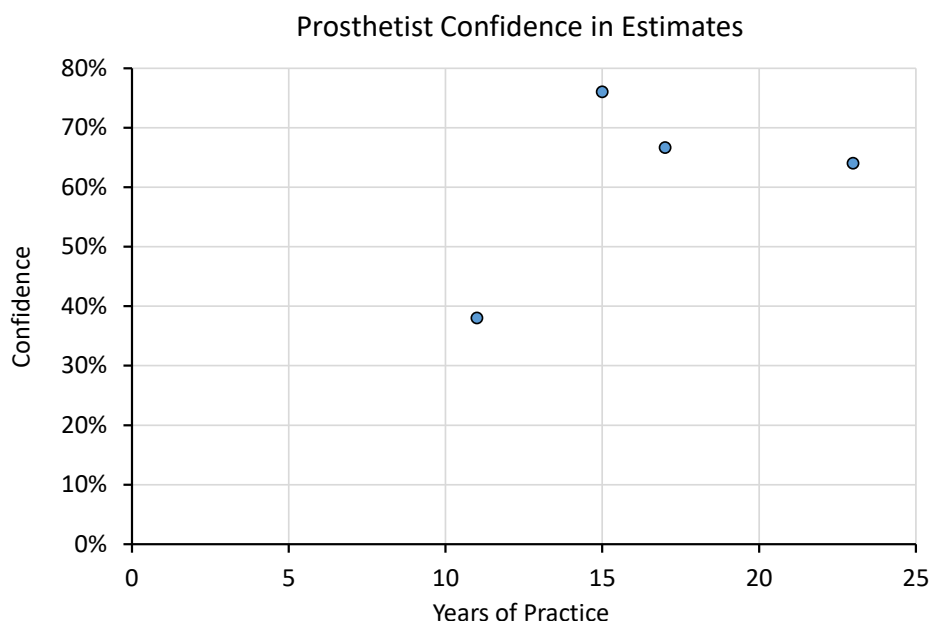


Fig. 41. Relationship between prosthetists' years of clinical practice and confidence in predicted activity results.

There is insufficient data to draw a conclusion (Fig. 41).

(c) Prosthetists will consider the collected data useful to at least three types of applications

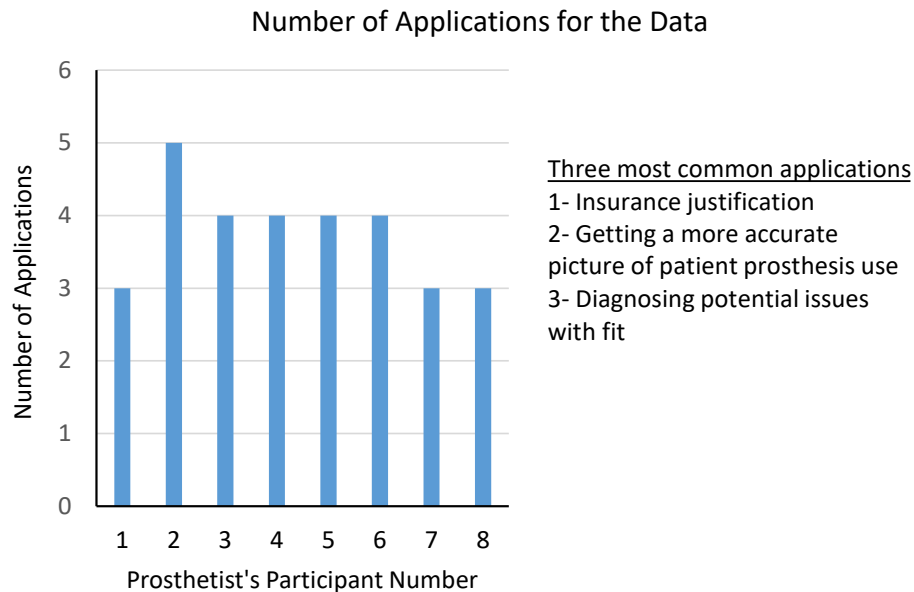


Fig. 42. Prosthetists' perceptions of applications of the collected data.

The data support the hypotheses (Fig. 42). Prosthetists were enthusiastic about the data and its utility.

(d) Practitioners will prefer to see the data during socket fitting, and early on when participants begin to experience symptoms

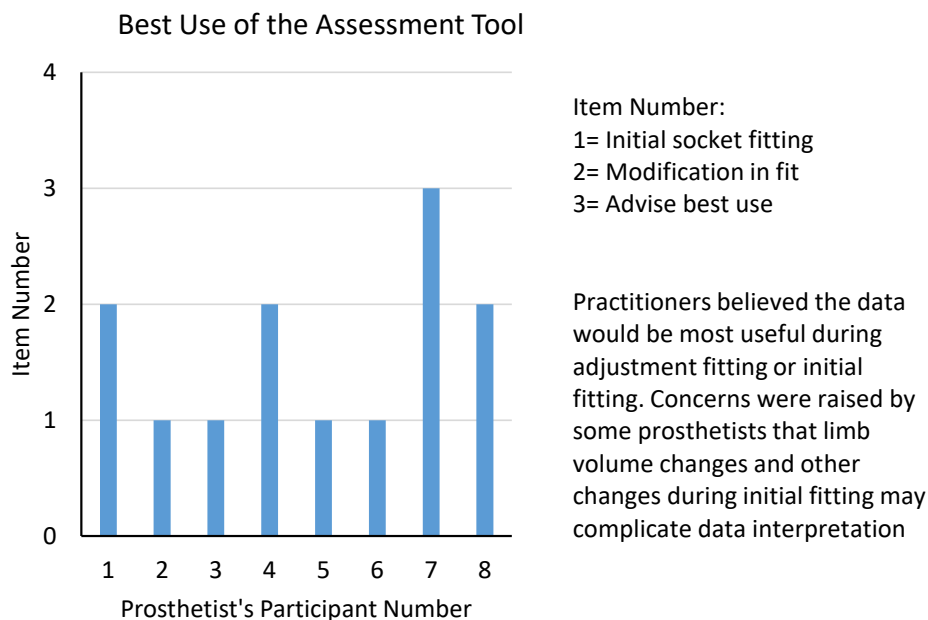


Fig. 43. Best uses of the assessment data according to prosthetist participants.

The data support the hypothesis (Fig. 43). About half of the participants saw utility towards initial socket fitting, and about half saw utility towards identifying modifications in fit.

(e) Practitioners will recommend the clinical data be made available to patients so as to help identify problems and encourage them to schedule an appointment.

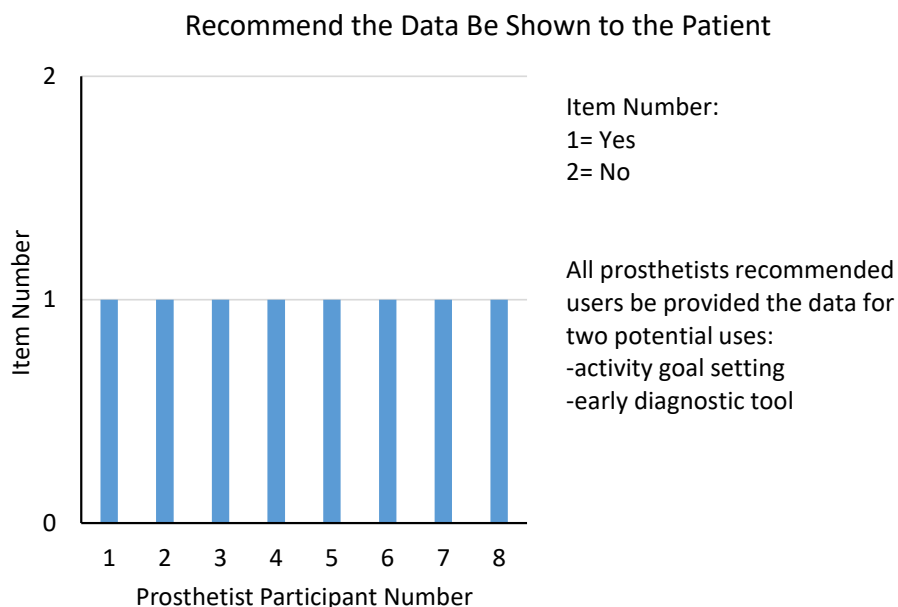


Fig. 44. Prosthetists' recommendation for showing data to patients.

All prosthetists recommended the data be shown to the participants (Fig. 44).

Additional Analysis

Based on feedback from the participants and our knowledge of the release-relock socket, we suspect that the inability of the tether to be made very tight so that essentially all motion was removed affected TARPIN socket use and socket comfort. Inspection of the sensed distance data suggests that there was greater limb cyclic motion at distal locations for the TARPIN compared with the Control, supporting this interpretation.

We also note that the TARPIN held the liner in the socket differently than the locking pin in the Control configuration. The TARPIN held the tether at a point, i.e., where the tether wrapped into the take-up spool. This configuration allows the tether to arc through a range of angles relative to the attachment point during ambulation, unlike the locking pin where only upward and downward motion was possible.

Conclusion

This project was extremely successful. We created a mechanism that accomplished socket release and relock, albeit having to overcome numerous engineering issues. A primary reason for the problems was an underestimation at the start of the tensile force in users' locking pins during sitting. While we expected a maximal force of perhaps 67 N (15 lb), participants often applied forces more than double and sometimes triple this value. This force data is of strong clinical relevance. This high tensile force will likely create shear stresses in distal residual limb soft tissues which, given the magnitude of tensile force, almost certainly will impact limb health. It is well accepted that presence of shear stress reduces the force necessary to cause blood flow occlusion. Thus, prosthesis users sitting with their locking pin in the shuttle lock may be partially or fully occluding their distal limb blood flow, detrimentally affecting their limb health. The result helps explain our earlier limb fluid volume study findings where we found that some people lost limb fluid volume while sitting. This may be a reason why. During prolonged sitting, distal limb stresses must be minimized, and socket release is one means to accomplish that.

Results from Aim #2 clearly showed strong limb volume stabilization results using socket release compared with control, even for just 4 min of rest. This result is relevant because it opens up socket release to a new set of users

– people who are very busy and can take only short breaks during their workday. These users can improve their limb volume stability through brief periods of intermittent socket release. This result should strongly encourage commercial manufacturers to incorporate socket release into their products.

While the data from Aim #3 did not support the hypotheses, i.e., better outcomes for the TARPIN configuration than the Control configuration, the project was designed and executed in such a way that we are well informed as to why this result happened. In short, presence of the tether was a problem. It was a problem both in terms of participant ease of use compared with a locking pin (to which they were accustomed) and in terms of mechanical performance. Clearly, a better solution would be to incorporate the locking pin concept within the design of the release-relock mechanism, i.e., allow participants to easily uncouple from their socket. A simple mechanism, either purely mechanical or electromechanical, that lifted the distal section of the socket hardware 5 cm proximal during partial donning is needed. While one design that accommodated every type of adjustable socket on the market would be difficult to engineer, it is likely that individual manufacturers of adjustable sockets could accomplish this objective within their own designs. The research in this grant facilitates their efforts by accomplishing two objectives: showing that release-relock stabilizes limb fluid volume well, and identifying specifications for the design, e.g., ~5 cm of proximal motion is needed.

The release and relock system, or a modification of it, would likely perform better on new prosthesis users who are not already accustomed to pin lock. They would likely learn to use release-relock, quickly execute state transitions properly and experience improved limb health.

What opportunities for training and professional development has the project provided?

A PhD graduate student in Bioengineering gained relevant training and professional development through participation on this project. This included giving presentations at professional conferences and writing peer-reviewed manuscripts showing the data and interpreting the results.

How were the results disseminated to communities of interest?

Results were disseminated through scientific conference presentations and peer-reviewed publications. We also included material at our lab website: <http://depts.washington.edu/jsweb/>

What do you plan to do during the next reporting period to accomplish the goals?

Nothing to Report.

4. IMPACT:

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

The project meaningfully impacted the prosthetics discipline and industry. The technology extended 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 intending to do so. When manufacturers begin to market release-relock sockets, it will have been data presented from this project that encouraged them to do so.

What was the impact on other disciplines?

The impact on other disciplines is to serve as an example of how scientific discoveries in the lab can be translated into clinical tools for clinical care.

What was the impact on technology transfer?

A patent has been filed, and we are in the process of transferring the technology to the prosthetics industry.

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

Restrictions introduced by COVID-19 from March to September 2020 prevented completion of Aim #2 in a time frame consistent with our scope of work. The objective shifted to initiating Aim #3 pilot testing (allowed under COVID-19 restrictions in June 2020) to generate initial data and also to identify instrumentation, training, and user interface issues that needed to be modified. Further, statistical significance between release-relock and control groups 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, thus we moved onto Aim #3 and completed that aim with a 3-month no-cost extension period.

Actual or anticipated problems or delays and actions or plans to resolve them

University of Washington COVID-19 restrictions required us to halt Aim #2 testing during the 2nd quarter of Year 2. By that time, we had completed all three test sessions on a total of 4 participants. As University of Washington COVID-19 restrictions began to lift in June 2020, we realized that the Aim #3 study met the criteria for return to testing but Aim #2 did not. Thus, we shifted our focus to Aim #3. We gained important insight from the Aim #3 pilot tests. We then conducted two objectives in parallel: Aim #2 testing, and engineering design modification of the Aim #3 system. By the time Aim #2 was completed, the engineering design modifications were done, and we carried out Aims #3 and #4.

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 reduced the take-home data collection period in Aim #3 in part because of the impact on expenditures. Electronic part supply availability and quality issues, a result of COVID-19, slowed progress and substantially increased electronics costs, restricting the number of participants that we tested in Aim #3 to less than proposed in the original grant application.

Significant changes in use or care of human subjects

- 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, Approved 09/28/2021
 - HRPO N/A, not a substantive modification
- Mod #15:
 - UW IRB: Submitted 01/12/2022, Approved 01/21/2022
 - HRPO N/A, not a substantive modification
- Mod #16:
 - UW IRB: Submitted 04/14/2022, Approved 04/25/2022
 - HRPO N/A, not a substantive modification
- Mod #17:
 - UW IRB: Submitted 05/27/2022, Approved 05/31/2022
 - 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 made a 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).

Mod #15 improved the clarity in the Aim #4 consent form on recruitment procedures.

Mod #16 added the RAFT charging/data uploading system to the study. The IRB did not require a supplemental device form to be completed.

Mod #17 added a checkbox to the consent form to record whether participants accepted all study compensation or just travel compensation.

Significant changes in use or care of vertebrate animals

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.

6. PRODUCTS:

• Publications, conference papers, and presentations

Journal publications

Lanahan CL, 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. *Clin Biomech* 2023 (in press).

Coburn KA, Weissinger MJ, Krout A, Hafner BJ, Garbini JL, Allyn KJ, Sanders JE. Design and testing of a simple quick connect for a prosthetic liner tether. *Prosthet Orthot Int* 2023 (in press).

Lanahan CL, Hafner BJ, Allyn KJ, Friedly JL, Sanders JE. Normalizing variance of self-selected exertion utilizing the metric capability index. *Gait Posture* 2023, in preparation.

Krout AJ, Allyn KJ, Lake GL, Weissinger MJ, Mertens JC, Lanahan CL, Carter RC, Ballesteros D, DeGrasse NS, Hafner BJ, Friedly JL, Garbini JL, Sanders JE. Take-home use of a motor-driven release-relock socket to facilitate limb volume stabilization. *Disabil Rehabil* 2023, in preparation.

Books or other non-periodical, one-time publications.

“Improving daily comfort and mobility for lower-limb amputees using novel release-relock system.” Peer Reviewed Orthopaedic Research Program highlights, CDMRP website. Posted April 11, 2023.

Conference papers

Coburn K, Allyn KJ, Wang H, Ballesteros D, Larsen BF, Mertens JC, Lanahan C, Weissinger M, Garbini JL, Hafner BJ, Friedly JL, 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.

Sanders JE, Coburn KA, Wang H, Ballesteros D, Allyn KJ, Garbini JL, Friedly JL, Hafner BJ. A motor-driven release/relock socket: Effectiveness as an accommodation tool for transtibial prosthesis users. *International Society of Prosthetists and Orthotists 18th World Congress*, virtual edition, Nov 1-4, 2021.

Krout AJ, Coburn KA, Mertens JC, Lake GL, Allyn KJ, Friedly JL, Hafner BJ, Garbini JL, Sanders JE. Release/relock for socket fit management: Evaluation in user at-home settings. *American Academy of Orthotists & Prosthetists 48th Academy Annual Meeting & Scientific Symposium*, March 2-5, 2022.

Sanders JE. Adaptive socket for people with transtibial limb loss. *Blatchford Award, the International Society of Prosthetists and Orthotists 19th World Congress*, April 24-27, 2023.

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

Sanders Lab website, University of Washington. “Adjustable Sockets: Release-Relock”

<https://jsanders06.wixsite.com/uwsanderslab/adjustable-sockets-1>

• Technologies or techniques

*Socket release and relock mechanism and a means for fabrication and installation into a prosthetic socket.

*Socket release strategy execution during clinical use – timings and durations.

*Instrumented ratcheting dial mechanism and a means for installation into a prosthesis.

*Quick connect mechanism to easily and rapidly connect or disconnect the participants’ tether from their liner.

*A capability index to characterize participant exertion.

*A remote access file transfer unit (RAFT) for automatic daily upload of collected data.

• Inventions, patent applications, and/or licenses

Provisional and full patent application

Sanders JE, Garbini JL, Gurrey C, Allyn KJ, McLean JB, Larsen BG. “Prosthetic socket release/relock system.” U.S. Patent Application No. 18/178,138 filed March 3, 2023, extending from US Provisional Patent Application No. 63/316,309 filed on March 3, 2022.

• Other Products

Grant application titled, “A capability index for selection of componentry for individual prosthesis users,” was submitted to the Orthotics and Prosthetics Outcomes Research Program (OPORP) in May 2022 but was not funded.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project? Put in total months for 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: 5

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: 4
 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: 3
 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: 6
 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: 8
 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: 3
 Contribution to Project: Participant recruitment, socket fitting, clinical data collection and analysis

Name: Kendrick Coburn
 Project Role: Research Engineer/Scientist
 Researcher Identifier (e.g. ORCID ID):
 Nearest person month worked: 20
 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: 7
 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, data analysis and interpretation
Name:	Joseph Mertens
Project Role:	Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	8
Contribution to Project:	Study execution
Name:	Nicholas DeGrasse
Project Role:	Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to Project:	Data processing
Name:	Adam Krout
Project Role:	Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	4
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:	6
Contribution to Project:	Board design, electronic design and debugging
Name:	Bailey Ramesh
Project Role:	Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	3
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
Name:	Horace Wang
Project Role:	Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	7
Contribution to Project:	Electronics and firmware
Name:	Matthew Van Ginneken
Project Role:	Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	4
Contribution to Project:	Ratchet dial data processing for Aim #3 data

Name: Clement Gurrey
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3
Contribution to Project: Mechanical design

Name: Jake McLean
Project Role: Research Engineer/Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3
Contribution to Project: Mechanical design

Name: Luna Acquavella
Project Role: Research Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2
Contribution to Project: Socket fabrication

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

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

Name: Sharon Hubbard
Project Role: Program Manager
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Fiscal management, operations

Name: Samuel Bennett
Project Role: Research Scientist/Engineer
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Electronics

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

Nothing to Report.

What other organizations were involved as partners?

Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS
COLLABORATIVE AWARDS:

Nothing to Report.

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

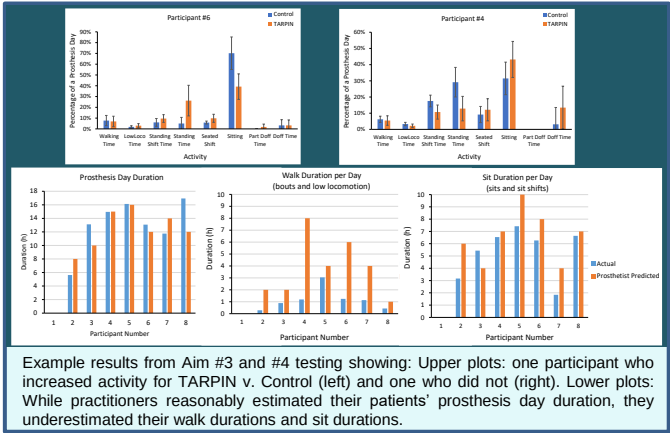
Award Amount: \$2M

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 were not visible to outside observers and operated multiple days on a single charge, we tested participants in the lab to determine if the sockets reduced limb fluid volume loss compared to traditional sockets. We conducted 2-3-week field tests to determine if the sockets enhanced patient outcomes compared with a control. Finally, we shared data with prosthetists of Aim 3 participants (who agreed to allow us to share) and assessed clinical value and technical quality of the collected outcomes data.



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: 05/12/2023

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 - \$2M

9. APPENDICES

Appendix 1. Impact of timing differences between conditions

Because the duration of the sit for the Short Rest (4 min) was not a multiple of that for the Long Rest and No Release (10 min), there was a slight difference in the timing of the walks used for comparison. Calculations of the timings verified this expectation – the median timing of the Short Rest walk was 84.4 min, while that of the closest No Release walk was 89.2 min (4.8 min *after* the Short Rest) and that of the Long Rest walk was 81.0 min (3.4 min *before* the Short Rest) (Fig. A1).

To investigate if the differences in timing produced meaningful differences in the limb fluid volume results, we calculated the percent change in limb fluid volume from the reference for the earlier and later timings for each condition – No Release and Long Rest. The differences in percent limb fluid volume were minimal for No Release (Fig. A2) and Long Rest (Fig. A3). Similar findings were demonstrated for the anterior region. Therefore, the slight difference in the timing of the walks used for comparison was not considered relevant to the study conclusions.

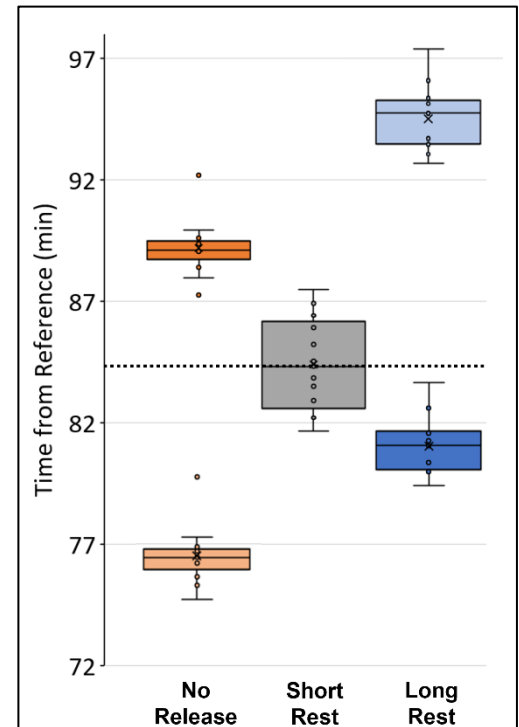


Fig. A1. Timings for bouts nearest the final Short Release bout. For No Release, the upper time point is from bout X and the lower time point is from bout Y. For Long Rest, the data are from bouts X and Y, respectively.

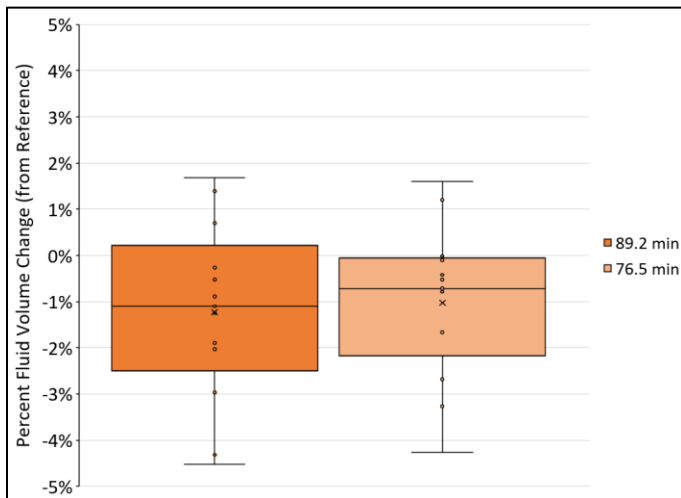


Fig. A2. No Release results. Percent fluid volume change for the timing 89.2 min compared with the timing 76.5 min. Posterior region.

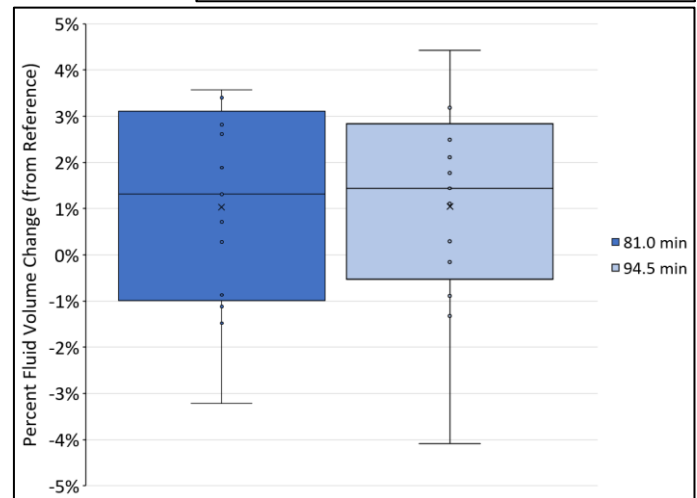
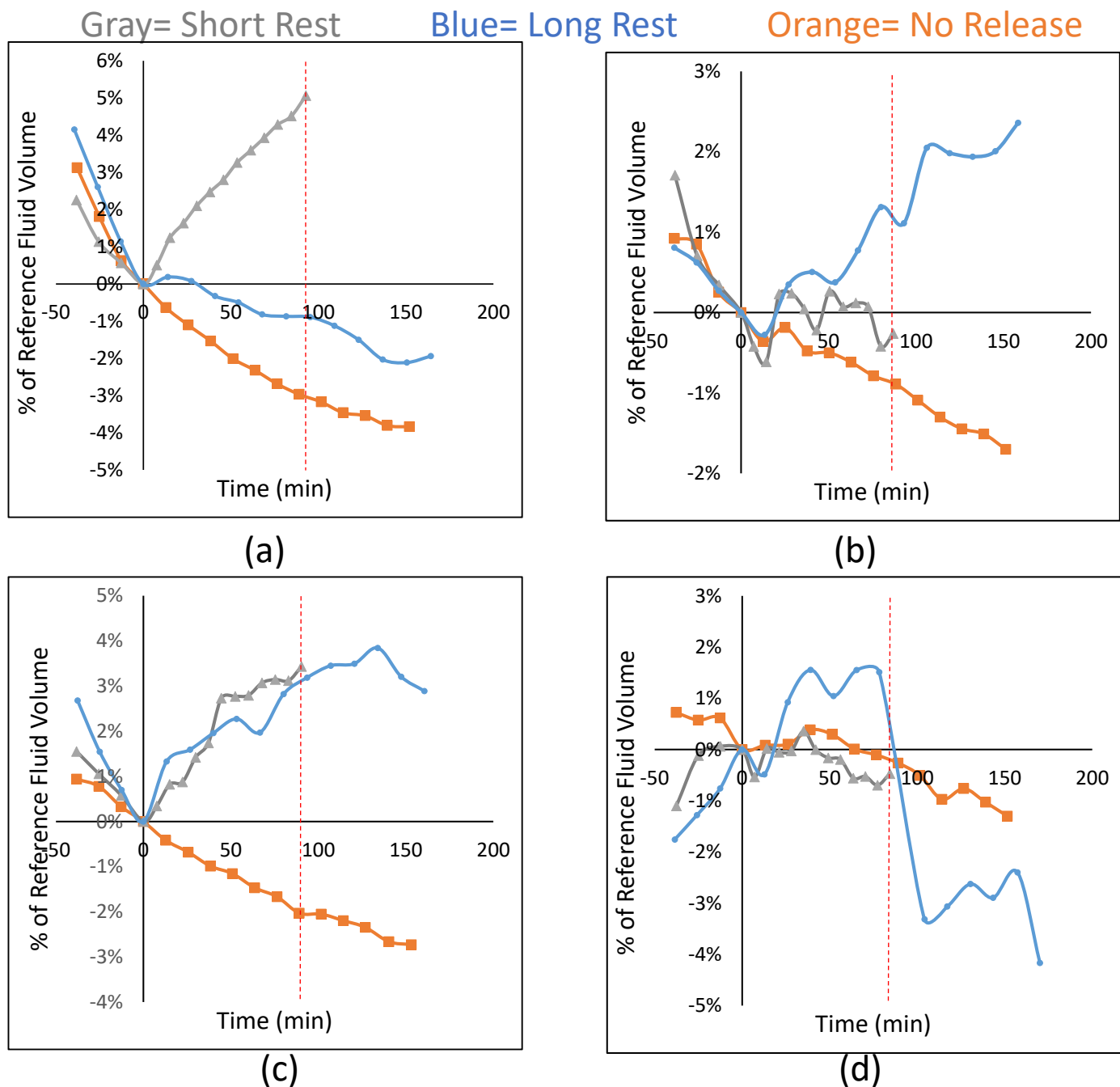


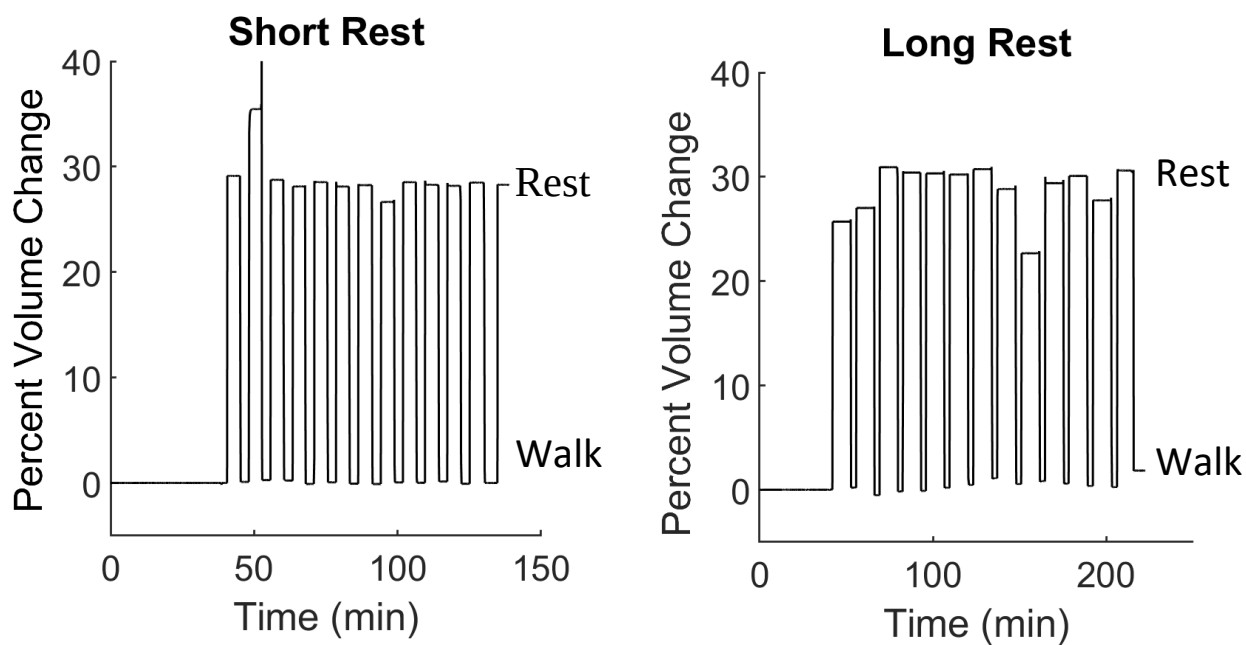
Fig. A3. Long Rest results. Percent fluid volume change for the timing 81.0 min compared with the timing 94.5 min. Posterior region.

Appendix 2. Example data from each participant group (1 to 4).



Participants were grouped by condition(s) with the highest percent fluid volume increase relative to the reference. (a) Group 1 example, gained the least fluid volume during the No Release test and gained more fluid volume during the Short Rest test compared with the Long Rest. (b) Group 2 example, gained the least fluid volume during the No Release test, and gained more fluid volume during the Long Rest test compared with the Short Rest. (c) Group 3 example, gained the least fluid volume during the No Release test, and gained comparable fluid volume during the Short Rest and Long Rest tests. (d) Group 4 example, gained less fluid volume during the Short Rest and Long Rest tests than during the No Release test.

Appendix 3. Example dial data over time plotted as a percentage of the socket volume change relative to the closed position for a Short Rest (left) and a Long Rest (right) test session



Clinical Biomechanics

Short partial doffs of release/relock sockets may effectively stabilize limb fluid volume in prosthesis users with transtibial amputation

--Manuscript Draft--

Manuscript Number:	CLBI-D-22-00741R1
Article Type:	Research Paper
Section/Category:	
Keywords:	Amputee; residual limb volume; prosthesis; locking pin suspension; socket release; partial doffing
Corresponding Author:	J. Sanders Seattle, WA UNITED STATES
First Author:	Conor R. Lanahan
Order of Authors:	Conor R. Lanahan Kendrick A. Coburn, MS Brian J. Hafner, PhD Daniel Ballesteros Katheryn J. Allyn, LCPO Janna L. Friedly, MD, MPH Marcia A. Ciol, PhD Ryan V. Carter Joseph C. Mertens Adam J. Krout J. Sanders
Abstract:	Background: A challenge often faced by people with lower extremity amputation is management of prosthetic socket fit due to changes in fluid volume within their residual limb. Prior research suggests that intermittently doffing the prosthetic socket may help stabilize daily residual limb fluid volume. Methods: To assess the effects of partial doff duration on residual limb fluid volume retention, participants with transtibial amputation were tested by walking on a treadmill in a controlled, laboratory setting in three conditions. An automated system to release the locking pin and enlarge the socket was used to produce the partial doffing. Percent limb fluid volume changes after partial doffing for 4 min (Short Rest) and for 10 min (Long Rest) were compared with no partial doffing (No Release). Limb fluid volume was monitored using bioimpedance analysis. Findings: Mean percent fluid volume changes in the posterior region were -1.2% for No Release, 2.7% for Short Rest, and 1.0% for Long Rest. Short and Long Rests had larger increases than No Release ($P=0.005$ and 0.03, respectively); Short and Long Rests were not statistically different ($P=0.10$). Eight of the thirteen participants experienced a higher percent fluid volume gain for both release protocols while four experienced a higher percent fluid volume gain for only one release protocol. Interpretation: A partial doff duration as short as 4 min may be an effective strategy to stabilize limb fluid volume in prosthesis users with transtibial amputation. Trials in at-home settings should be pursued.
Suggested Reviewers:	H Gholizadeh gholizadeh@um.edu.my Conducts research in the field Matthew Miller ude.fscu@4rellim.wehttam Conducts research in the field

Highlights

- The effects of partial doff duration on residual limb fluid volume change were tested
- Short Rest and Long Rest induced a greater fluid volume increase than No Release
- Short Rest (4 min) did not induce a different fluid volume change than Long Rest (10 min)
- Ten of 13 participants experienced a greater fluid volume increase for at least one release duration

Title:

Short partial doffs of release/relock sockets may effectively stabilize limb fluid volume in prosthesis users with transtibial amputation

Short running title:

Release/relock sockets

Authors:

Conor R. Lanahan¹, Kendrick A. Coburn¹ MS, Brian J. Hafner² PhD, Daniel Ballesteros¹,
Katheryn J. Allyn¹ LCPO, Janna L. Friedly² MD, MPH, Marcia A. Ciol² PhD, Ryan V. Carter¹,
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Funding source:

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Acknowledgements:

None.

Word count abstract: 243 Word count main text: 3,691

ABSTRACT

Background: A challenge often faced by people with lower extremity amputation is management of prosthetic socket fit due to changes in fluid volume within their residual limb. Prior research suggests that intermittently doffing the prosthetic socket may help stabilize daily residual limb fluid volume.

Methods: To assess the effects of partial doff duration on residual limb fluid volume retention, participants with transtibial amputation were tested by walking on a treadmill in a controlled, laboratory setting in three conditions. An automated system to release the locking pin and enlarge the socket was used to produce the partial doffing. Percent limb fluid volume changes after partial doffing for 4 min (Short Rest) and for 10 min (Long Rest) were compared with no partial doffing (No Release). Limb fluid volume was monitored using bioimpedance analysis.

Findings: Mean percent fluid volume changes in the posterior region were -1.2% for No Release, 2.7% for Short Rest, and 1.0% for Long Rest. Short and Long Rests had larger increases than No Release ($P= 0.005$ and 0.03 , respectively); Short and Long Rests were not statistically different ($P= 0.10$). Eight of the thirteen participants experienced a higher percent fluid volume gain for both release protocols while four experienced a higher percent fluid volume gain for only one release protocol.

Interpretation: A partial doff duration as short as 4 min may be an effective strategy to stabilize limb fluid volume in prosthesis users with transtibial amputation. Trials in at-home settings should be pursued.

KEYWORDS: Amputee, residual limb volume, prosthesis, accommodation, adjustable socket, locking pin suspension, socket release, partial doffing

INTRODUCTION

For many transtibial prosthesis users, socket fit varies over time and is considered the most significant rehabilitation challenge they face.^{1,2} Socket fit changes occur, in part, because of volume fluctuations within the residual limb. Volume changes as low as one percent may induce clinically detectable changes in socket fit.³ It has been observed that morning-to-afternoon limb fluid volume loss in people with transtibial limb amputation is as much as 2.7%/h⁴ and has been shown to be dependent on socket size, sock thickness, and health characteristics of the user.^{5,6,7} Therefore, a means to stabilize residual limb fluid volume is an important capability for prosthesis users to have at their disposal to better control their prosthesis, improve socket fit and accomplish successful rehabilitation.

Most prosthesis users manage their limb volume fluctuation by interchanging socks of different thickness throughout the day. For both methods, users are required to fully doff their prosthesis which can be time consuming, difficult, or infeasible in certain situations. For example, prosthesis users must generally wait until it is practical or socially acceptable to doff, which in the interim may cause them pain and/or reduce their overall function.

Multiple studies have shown that modifying socket volume by doffing the socket during resting has definitive effects on residual limb fluid volume fluctuation.⁸⁻¹¹ In a study of sixteen transtibial prosthesis users, doffing the socket during a 30-min rest period after periods of activity caused significantly less fluid volume loss in subsequent ambulation compared to resting with the socket donned.⁸ In transtibial amputee participants who used locking pin suspension, doffing the socket for 20 min once every 2 h stabilized posterior fluid volume over a 5.5-h test period compared with not doffing.⁹ Doffing after activity also stabilized posterior fluid volume better than doffing after resting.¹⁰ However, increasing socket size by maintaining the socket donned and pin locked but releasing liquid from bladders embedded within participants' prosthetic liner increased limb fluid volume during resting but that limb fluid was not well

maintained upon subsequent walking.¹¹ Results from a partial socket release study, where an adjustable “clamshell” socket (with a single large posterior panel) was enlarged, the locking pin released, and the residual limb only partially pulled out of the socket, suggest that socket release may counter fluid volume loss.¹² When participants conducted socket release for 10 min during sitting and then returned the socket to its pre-release size before ambulating, they maintained a more stable limb fluid volume compared with no doffing at all. While these studies demonstrate that 10 to 20 min rests with an increased socket volume have definitive effects on limb fluid volume fluctuations, some prosthesis users may not have time during their busy day for 10 to 20 min sits with the prosthesis partially doffed. A shorter partial doff rest duration (<10 min) should be investigated.

The present study extended from prior investigations to determine if the time the socket is partially doffed affects limb fluid volume. We expected that a 4-min partial doff duration would effectively stabilize limb volume as well as a 10-min partial doff duration. A custom automated system for releasing a locking-pin tether 5-6 cm was used. Variables such as limb length and time since amputation were considered when evaluating partial doff duration and residual limb fluid volume stability.

METHODS

Participants

Human subject approval from an institutional review board and informed consent from each participant were obtained before test procedures were initiated (University of Washington, Seattle WA, USA, STUDY00007008). Participants were recruited locally from our registry and by referral through flyers placed in local clinics. Participant recruitment was limited by the financial and time constraints of the project. Thirteen participants were enrolled. Criteria for inclusion were a transtibial amputation performed at least 18 months prior, use of a properly fitting definitive prosthesis for walking at least 7 hours per week, the ability to walk unaided for 2 min on a treadmill, the ability to sit and stand unaided,

residual limb length of at least 9.0 cm (for conducting limb fluid volume monitoring (bioimpedance analysis)), and considered by the research practitioner through traditional clinical evaluation techniques to be a Medicare Functional Classification Level of Limited Community Ambulator (K-2) or higher.¹³ Presence of skin breakdown or regular use of a walking aide (e.g., cane, walker) excluded participants from this study.

Instrumentation

A test prosthesis was fabricated for each participant using a digitized scan of their practitioner-prescribed socket. Following traditional methods for fabricating adjustable panel sockets, we incorporated a single posterior, adjustable, cabled panel, into each test prosthesis. The panel was released and retightened via a ratcheting dial that was customized with a two-phase resistive rotary sensor to record dial angle changes over time.¹⁴ Additionally, a custom motor-driven release/relock system was encased at the distal portion of the socket.

The custom motor-driven release/relock system took 4.6 cm of build height in the distal end of the socket¹⁴ (Fig. 1a). The release/relock unit weighed 290 g. A tether (Vectran 200, Kuraray America, Houston TX, USA) was routed from the mechanism's take-up spool through a tether guide in the socket and connected to the participant's liner via a custom, threaded fastener (Fig. 1b). The tether was shortened by the winding motor action, which operated at a speed of 6 cm/s via a don button on the back of the socket. A release button was built into the test prosthesis on the lateral aspect of the socket. The release button allowed participants to back drive the motor and pull their residual limb out of the socket. A single button push released the tether 5-6 cm (partial doff), and a second button push caused the tether to extend to its maximum length of 30-40 cm (full doff). Motor position and ratcheting dial angle were recorded to an SD card on the electronics board within the release/relock unit. The sampling rate was 32 Hz. All test prostheses were equipped with a traditional energy storage and return (ESAR) prosthetic foot

(RUSH Lo-Pro 81, Proteor, Tempe AZ, USA).

Limb fluid volume was monitored using bioimpedance analysis. Custom electrodes made of a thin conductive tape (ARCare 8881, Adhesives Research, Glen Rock PA, USA) and an underlying hydrogel (9880, 3M, St. Paul MN, USA) were placed on the residual limb. Voltage sensing electrodes were placed to monitor the anterior and posterior residual limb regions independently, and current injecting electrodes were placed proximally at the thigh and distally on the inferior surface of the residual limb, using placement techniques described in detail in our prior work.¹² Electrical current was injected in packets at 26 different frequencies across a range of 3 kHz to 1 MHz at a rate of 30 packets/s using a custom portable bioimpedance unit worn in a waist belt pack (400 g).¹⁵ Collected data were demodulated on board the unit then converted to extracellular fluid volume in post-processing using de Lorenzo's form of the Cole model and a geometric limb model.^{16,17} Error in the extracellular fluid volume measurement was less than 0.1% fluid volume.¹⁵

Protocol

Each participant visited the lab for three separate visits starting at approximately the same time of day. Participants were asked not to drink caffeine or alcohol before coming to the lab and to standardize their morning routine for the three visits. Upon arrival, they were instructed to sit for 10 min to allow their residual limb to reach a homeostatic condition. During this time, the research practitioner collected general health information. Body weight and blood pressure were measured. After the prosthesis was doffed and bioimpedance electrodes were placed on the residual limb, participants donned a liner, either their own liner or a lab-provided liner that had a proper thread size for the release/relock tether connection. Participants then donned the test socket.

At the start of the first session, a brief fitting was performed where the research practitioner inspected and adjusted the alignment if needed. Proper sock ply (if needed) was determined, using only new

laboratory socks and not the participants' socks for adjustment. Participants were instructed to walk briefly on a treadmill to determine their preferred walking speed. Once established, this same speed and sock thickness were used for all treadmill walking tests in the study. The time spent finding a proper walking speed and sock ply was documented for each initial visit, and the walking and standing durations were repeated at the outset of each of the subsequent two visits to control for any unanticipated effects fitting activities had on the limb homeostasis.

Following the fitting or fitting-control, all three sessions started the same – the participant was instructed to carry out a series of four controlled rest-walk cycles. During the rests, which were 10 min, participants sat with the test prosthesis donned. The walks, which were 2 min, were executed on the treadmill. Immediately following the four rest-walk cycles, participants completed one of three protocols (one per visit), consisting of twelve rest-walk cycles (Fig. 2). For the “No Release” protocol, the rest-walk cycles were the same as the controlled rest-walk cycles. For the “Long Rest” and “Short Rest” protocols, participants partially doffed the test prosthesis during the rest segments. Partial doffing duration was 10 min for the Long Rest and 4 min for the Short Rest. Each participant completed all protocols, the order of which was randomized using MATLAB's (Natick, MA, USA) random number generator.

The partial doffing process was executed entirely by the study team by first releasing the back socket panel (releasing the ratcheting dial) to its maximum outward position and then pressing the tether release button once and pulling the socket to partially doff the residual limb to a 5-6 cm tether length. The test prosthesis was placed so that participants were seated comfortably with their limb loosely in the socket without excessively misaligning their residual limb with the socket and inducing concentrated pressures on their residual limb. The heel and toe positions were marked on the floor with tape so that both the prosthetic foot and contralateral foot were placed at the same location in each cycle. After the rest cycle was completed, the study team aided in the donning process by pushing the button to activate the motor (drawing in the tether) and guiding the test prosthesis onto the participant's limb, ensuring a consistent

procedure was performed across cycles and across participants. The back panel was tightened by turning the ratcheting dial until it was fully closed. The participant was instructed to stand, and the researcher pushed the tighten button to take up any remaining slack in the tether.

Data Analysis

The extracellular limb fluid volume data were segmented into steps, and the first and last five steps from each walking cycle were removed. This was done to avoid including steps where participants were increasing or decreasing their walking speed. The minimum limb fluid volume (which occurred during stance phase) for each of the remaining steps in a cycle was determined and a mean calculated. The twelve means were expressed as a percentage change from a reference that we defined as the mean fluid volume from the last (4th) controlled rest-walk cycle, i.e., the start of the intervention part of the test. Change in percent limb fluid volume was evaluated for normalcy using a Shapiro-Wilk test. A repeated measures analysis of variance (ANOVA) was conducted to compare the three protocols in the mean percent limb fluid volume change relative to the reference at approximately 84 min, which was the longest time data point common to all three protocols. Subsequently, pairwise comparisons with Bonferroni correction were conducted to assess differences in percent fluid volume for Short Rest v. No Release, Long Rest v. No Release, and Short Rest v. Long Rest. Results for all cycles were plotted over time for the three socket test conditions for each participant. These plots were visually inspected to identify patterns over time, and participants were classified into groups based on the results. As an exploratory analysis, we investigated if participant characteristics age, time since amputation, body mass index, and limb length differed for the different groups.

Data from the instrumented ratcheting dial were processed as described in our prior work,¹⁴ 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.

RESULTS

Thirteen individuals, twelve males and one female, participated in this study. Eleven participants had their amputation as a result of trauma, one as a result of an infection after a traumatic injury, and one from a Charcot foot. Median age was 54 y (range 35 to 74), and median time since amputation was 16 y (range 4 to 52). All participants regularly used an ESAR prosthetic foot, though not necessarily the same model as used in the present study. Participant characteristics are listed in Table 1.

Table 2 shows the summaries for percent fluid volume change for each condition for posterior and anterior regions. Mean percent fluid volume change were -1.2% for No Release, 2.7% for Short Rest, and 1.0% for Long Rest in the posterior region, and -1.2%, 3.5%, and 2.2% in the anterior region, respectively.

The ANOVA identified a significant difference in percent fluid volume change ($P<0.01$), indicating that at least two of the conditions were statistically different from each other. Pairwise comparisons showed that for the posterior region, the mean percentage fluid volume change was statistically larger for Short Rest than No Release and Long Rest than No Release. Short Rest was not statistically different from Long Rest at the 0.05 level (Fig. 3a). Statistical differences for Short vs. No Release and Long vs. No Release were also observed for the anterior region, but Short Rest vs. Long Rest was not statistically different (Fig. 3b).

Twelve of the thirteen participants experienced a higher percent fluid volume gain for at least one of the release protocols compared with No Release. It was noticed that there was a minor difference in the time that data were collected for the three conditions, but the difference did not seem to affect the results (Appendix 1).

We conducted an exploratory analysis to identify which participants benefited the most from each release strategy. Participants were classified into four groups based on their results for the three test conditions (Table 3, example data for each group provided in Appendix 2). Seven participants experienced the highest percent fluid volume gain for Short Rest (Group 1), three for Long Rest (Group 2), two approximately the same for both Short and Long Rest (Group 3), and one for No Release (Group 4) (Fig. 4). The only participant who did not experience a greater percent fluid volume gain for either release protocol compared to No Release (Group 4) was the only person who regularly used an elevated vacuum socket.

Plots investigating if participant variables age, time since amputation, body mass index, and residual limb length were related to group number are shown in Fig. 5. Knowing age or time since amputation does not seem to give any information on which group a person would tend to belong. Individuals with higher values of BMI tended to be in groups 1 and 2, while individuals with longer limb length tended to be in group 1. These are preliminary observations in a study with small sample size, and larger studies are needed to either corroborate or refute the findings.

Dial angle was successfully collected in 20 sessions, approximately the first half of the sessions conducted. Results demonstrated that the dial angle while the socket was tightened was consistent across walk cycles (Appendix 3). For all sessions, the deviation in socket volume during walking for all cycles was less than $\pm 0.8\%$ of the median for all cycles in the session. In 96% of the cycles, the deviation was less than $\pm 0.5\%$. Since these percent socket volume changes were lower than those expected to induce a clinically detectable change in socket fit³ and the procedure for setting the dial angle was demonstrated consistent, dial angle was not monitored for the remaining sessions.

DISCUSSION

Partial doffing using a motor-driven release-relock mechanism may be a more convenient means to accommodate limb fluid volume fluctuation than the traditional strategies available to people with lower-

limb amputation (i.e., changing sock ply) because the socket does not need to be fully doffed to better maintain residual limb fluid volume. Users can make adjustments quickly and conveniently without drawing attention to themselves. The purpose of this study was to determine the effects that different durations of partial doffing had on limb fluid volume. This effort is therefore relevant towards creating guidelines for clinical care.

For almost all of the participants (twelve of thirteen), at least one of the release durations (4 min or 10 min) produced a meaningful increase in limb fluid volume over No Release. The median of the maximum percent fluid volume increase (5.7%) was comparable to the mean increase in studies where the prosthesis was fully doffed instead of partially doffed for a much longer duration (30 min) between cycles of activity (5.5% in the posterior region⁸). In a different study, the locking pin and three panels of an adjustable socket were released during one cycle for 10 min between bouts of activity and produced a median fluid volume increase of about 0.4%¹⁸, approximately one-twelfth of the increase in the present study of twelve cycles (5.6%/12= 0.5%). These results suggest that intermittent partial doffing may produce comparable fluid volume increases to intermittent full doffing. Some participants demonstrated an increase in percent fluid volume for both release durations while others demonstrated an increase for just one. It is unclear, however, the reason for this result. The differences were not due to inconsistent performance of the socket size adjustment mechanism. The error in returning the socket to the same size in each cycle for 96% of the cycles was less than $\pm 0.5\%$ of the socket volume (i.e., equivalent to adding or removing $\frac{1}{2}$ the thickness of a sock sheath¹⁹). Results suggest the differences were not related to participant characteristics, but more participants better distributed across the variable ranges would need to be tested to draw definitive conclusions. It may be that a combination of physiological qualities and socket characteristics influence limb fluid volume response to socket release duration. It is also possible that participants' residual limbs physiologically adapt to different interface conditions. They may respond most favorably to conditions comparable to those to which they are accustomed. The result that the only

person in the study who regularly used elevated vacuum showed minimal difference in percent limb fluid volume for the three different release durations may support this hypothesis.

It is also unknown why some participants gained limb fluid volume for only one of the release durations. It would seem reasonable to suspect that if planning to use partial doffing as a regular accommodation strategy, prosthesis users would benefit from a fitting process that established their optimal release parameters, possibly a process similar to the protocol executed in this study. Alternatively, participants may try different release durations and frequencies in their at-home setting and discuss results with their prosthetist to hone in on release durations that produce the best outcome for them.

The finding here that Short Release (4 min) was effective on most participants (10 of 13) may broaden the application of socket release. Active users might not tolerate an interruption that required them to sit still for 10 min at a time, but they might release their socket while sitting for a few minutes during their busy day. The motor-driven release-relock unit used in this study or another convenient means for quick and easy socket release and relock may be necessary for compliance in these individuals. Additional investigation would be needed to identify who might need longer release times or who simply might not benefit from socket release.

In the present study, socket-release included release of both the tether and the panel, as in our initial investigation¹². In a study using three-panel adjustable sockets (anterior lateral, anterior medial, posterior), adding tether release to panel release accentuated limb fluid volume gain¹⁸, demonstrating that panel release and tether release each contributed to limb fluid volume stabilization. A separate study is needed to evaluate the clinical effectiveness of tether release alone. If tether release alone stabilized limb fluid volume, then the adjustable socket would not be needed, and the release-relock socket could be simplified.

Results from this study are relevant only to people with transtibial amputation. A study on individuals with

transfemoral amputation would need to be conducted to assess their percent limb fluid volume changes upon socket release. All walking in the study was conducted on a treadmill at a consistent walking speed, unlike in user at-home settings where walking speed would be expected to vary. However, this difference was not expected to meaningfully affect study results since our previous limb fluid volume results during walking of participants with transtibial amputation have shown similar trends in the lab on the treadmill and outside the building in the surrounding environment⁴⁻⁹. The small sample size in this population, which has large variation for the variables, may affect the results, but it does not take away from the value of the work in highlighting the potential importance of socket release duration on participant outcome.

CONCLUSION

A release duration of just 4 min induced meaningful fluid volume changes in 10 of 13 participants tested, suggesting that even short release durations may be effective to stabilize limb volume. Stabilization of limb volume may improve prosthesis users' socket fit, comfort, and overall health. A next step is to extend to at-home clinical trials to compare outcomes when a partial doffing unit is worn compared to when it is not worn.

REFERENCES

1. Legro MW, Reiber G, del Aguila M, et al. Issues of importance reported by persons with lower limb amputations and prostheses. *J Rehab Res Dev*. 1999;36(3):155-163.
2. Turner S, McGregor AH. Perceived effect of socket fit on major lower limb prosthetic rehabilitation: a clinician and amputee perspective. *Arch Rehabil Res Clin Transl*. 2020;2(3):10059.
3. Sanders JE, Severance MR, Allyn KJ. Computer-socket manufacturing error: how much before it is clinically apparent? *J Rehabil Res Dev*. 2012;49(4):567-582.
4. Sanders JE, Allyn KJ, Harrison DS, Myers TR, Ciol MA, Tsai EC. Preliminary investigation of residual limb fluid volume changes within a day. *J Rehabil Res Dev*. 2012;49(10):1467-1478.

- 294 5. Sanders JE, Youngblood RT, Hafner BJ, et al. Effects of socket size on metrics of socket fit in trans-tibial
295 prosthesis users. *Med Engi Phys.* 2017;44:32-43.
- 296 6. Sanders JE, Harrison DS, Allyn KJ, Myers TR, Ciol MA, Tsai EC. How do sock ply changes affect residual-
297 limb fluid volume in people with transtibial amputation? *J Rehabil Res Dev.* 2012;49(2):241-256.
- 298 7. Sanders JE, Cagle JC, Allyn KJ, Harrison DS, Ciol MA. How do the walking, standing, and resting
299 influence transtibial amputee residual limb fluid volume? *J Rehabil Res Dev.* 2014;51(2):201-12.
- 300 8. Sanders JE, Hartley TL, Phillips RH, et al. Does temporary socket removal affect residual limb fluid
301 volume of trans-tibial amputees? *Prosthet Orthot Int.* 2016;40(3):320-28.
- 302 9. Youngblood RT, Hafner BJ, Allyn KJ, et al. Effects of activity intensity, time, and intermittent doffing
303 on daily limb fluid volume change in people with transtibial amputation. *Prosthet Orthot Int.*
304 2019;43(1):28-38.
- 305 10. Sanders JE, Harrison DS, Cagle JC, Myers TR, Ciol MA, Allyn KJ. Post-doffing residual limb fluid volume
306 change in people with trans-tibial amputation. *Prosthet Orthot Int.* 2012;36(4):443-49.
- 307 11. Sanders JE, Redd CB, Cagle JC, et al. Preliminary evaluation of a novel bladder-liner for facilitating
308 residual limb fluid volume recovery without doffing. *J Rehabil Res Dev.* 2016;53(6):1107-20.
- 309 12. Brzostowski JT, Larsen BG, Youngblood RT, et al. Adjustable sockets may improve residual limb fluid
310 volume retention in transtibial prosthesis users. *Prosthet Orthot Int.* 2019;43(3):250-256.
- 311 13. Medicare region C durable medical equipment prosthetics orthotic supplier (DMEPOS) manual.
312 Columbia (SC): Palmetto GBA; 2005. P. 53.5–6.
- 313 14. Gurrey CJ, Garbini JL, Bennett SP, et al. Socket release/relock: An innovative mechanism to help
314 maintain prosthesis user residual limb volume. *Med Engi Phys.* 2021;90:100-106.
- 315 15. Hinrichs P, Cagle JC, Sanders JE. A portable bioimpedance instrument for monitoring residual limb

- 316 fluid volume in people with transtibial limb loss: A technical note. *Med Engi Phys.* 2019;68:101-107.
- 317 16. De Lorenzo A, Andreoli A, Matthie J, Withers P. Predicting body cell mass with bioimpedance by using
318 theoretical methods: a technological review. *J Appl Physiol.* 1997;82(5):1542-58.
- 319 17. Hanai T. Electrical properties of emulsions. In: Sherman, P. (Ed.), *Emulsion Science*. Academic Press,
320 London, England, pp. 354-477.
- 321 18. McLean JB, Larsen BG, Weathersby EJ, et al. Fluid volume management in prosthesis users:
322 Augmenting panel release with pin release. *PM R.* 2020;12:1236-1243.
- 323 19. Sanders JE, Cagle JC, Harrison DS, Karchin A. Amputee socks: How does sock play relate to sock
324 thickness? *Prosthet Orthot Int.* 2012;36(1):77-86.

TABLES

Table 1. Participant characteristics.

Characteristic	Median	Range
Age (y)	54	35 – 74
Time since amputation (y)	16	4 – 52
BMI (kg/m ²)	28.4	20.4 – 37.7
Limb length (cm)	15.0	11.0 – 21.8

Characteristic	Description
Gender	1 female, 12 males
Cause of amputation	11 trauma, 1 trauma + infection, 1 DM and Charco Foot
Health issues	6 high blood pressure, 3 smokers, 2 diabetes mellitus, 2 nerve pain, 1 each upper limb amputation, heart surgery, seizures, abnormal ankle-brachial index, depression and high cholesterol

Table 2. Summary statistics for percent fluid volume change

Summaries	Percent Change (from reference) in Limb Volume					
	Posterior			Anterior		
	No Release	Short Rest	Long Rest	No Release	Short Rest	Long Rest
N	13	13	13	13	13	13
Mean	-1.2	2.7	1.0	-1.2	3.5	2.2
Median	-1.1	2.7	1.3	-1.7	4.4	2.1
Std. Deviation	1.9	2.9	2.2	1.9	1.9	2.7
Minimum	-4.5	-1.3	-3.2	-3.5	-0.2	-4.7
Maximum	1.7	7.1	3.6	2.2	5.7	5.7

Table 3. Descriptions of participant groups

Group	<i>n</i>	Description
1	7	Gained the least fluid volume during the No Release test, and gained more fluid volume during the Short Rest test compared with the Long Rest
2	3	Gained the least fluid volume during the No Release test, and gained more fluid volume during the Long Rest test compared with the Short Rest
3	2	Gained the least fluid volume during the No Release test, and gained comparable fluid volume during the Short Rest and Long Rest tests
4	1	Gained less fluid volume during the Short Rest and Long Rest tests than during the No Release test

FIGURE LEGENDS

Fig. 1a,b. Investigational prosthesis. (a) The motor-driven release-relock unit. (b) Socket in the donned configuration (left) and the socket release configuration (right).

Fig. 2. Testing protocol. Upper section: Testing protocol for the three different conditions. Sit duration and tether length varied for the No Release, Short Rest, and Long Rest cycles. Lower section: Content of a single partial doff rest-walk cycle.

Fig. 3a,b. Comparison of percent limb fluid volume change results for the three test conditions. Results for the (a) posterior region and (b) anterior region are shown.

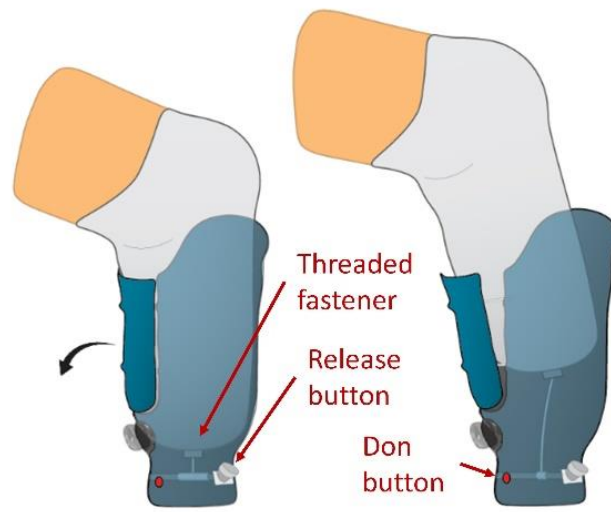
Fig. 4. Participant Groups 1 to 4: Participants were grouped by the test condition that induced the highest percent fluid volume relative to the reference. Participants experienced the highest percent fluid volume for Short Rest ($n=7$ total), Long Rest ($n=3$ total), approximately the same for Short Rest and Long Rest ($n=2$ total), or No Release ($n=1$). The black numbers in each column indicate the number of participants for which both conditions, Short Rest and Long Rest, had higher percent fluid volume than No Release. The red letters indicate that the number of participants for which only the group label in that column had higher percent fluid volume than No Release.

Fig. 5. Participant characteristics for Group 1 to 4. There were few participants in Groups 3 and 4, making it difficult to identify differences in those groups compared with other groups. Participants in Group 2 had shorter limb lengths than participants in Group 1, suggesting that limb length should be investigated in future studies as a variable that may

influence participants' optimal release duration.



(a)



(b)

Fig. 1a,b

**Rest-Walk Cycles 1-4
(acclimation)**

**Rest-Walk Cycles 5-16
(experimental)**

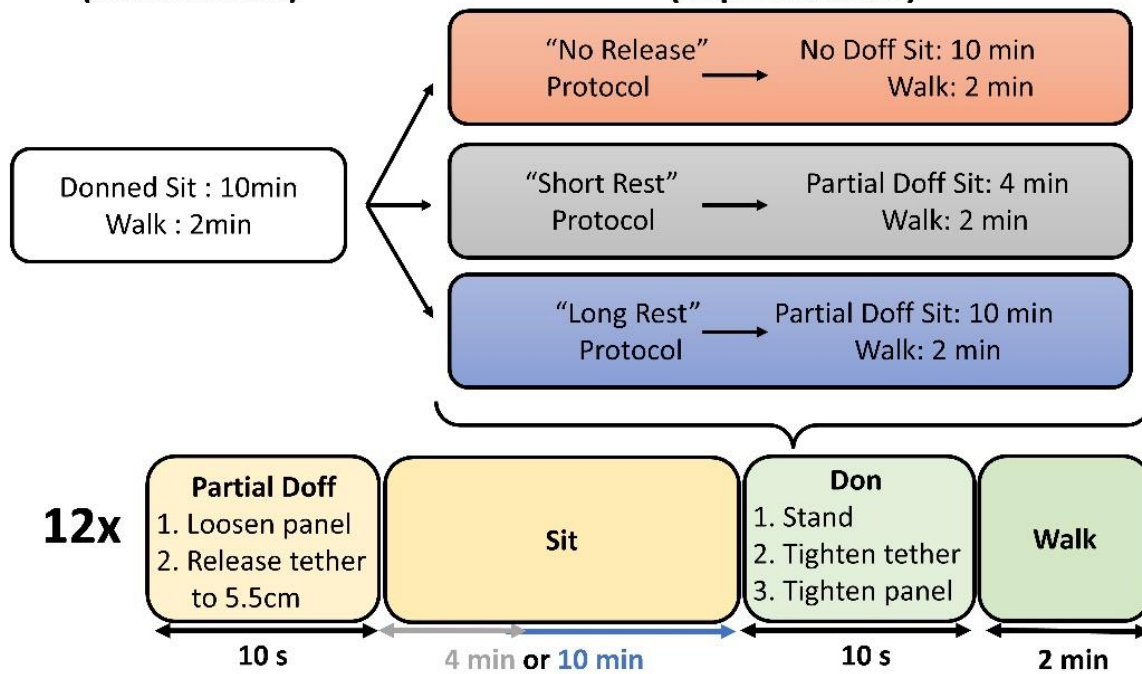


Fig. 2

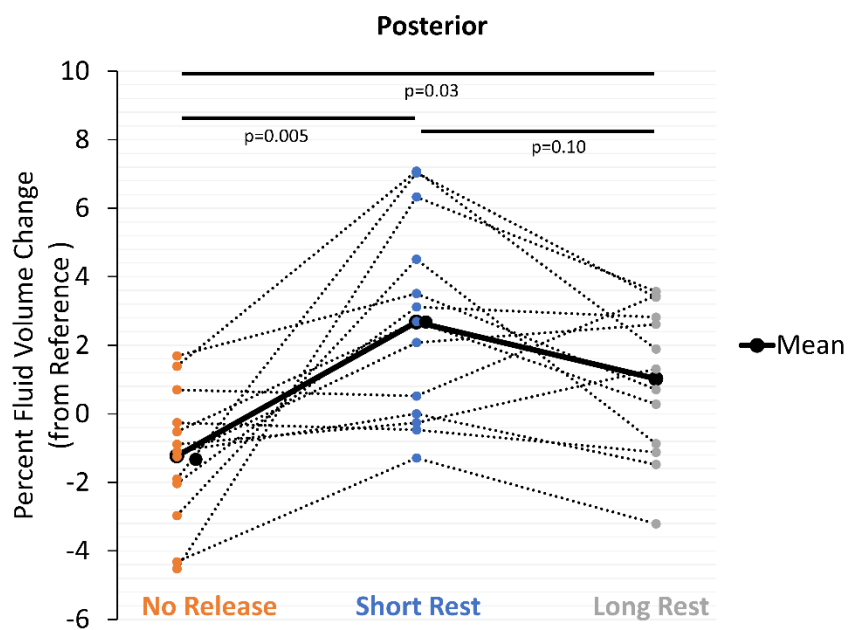


Fig. 3a

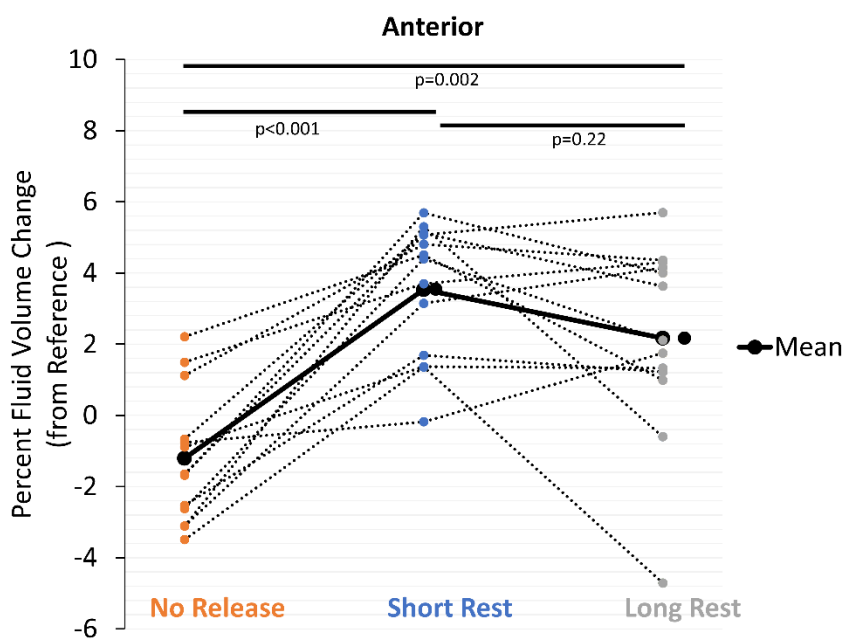


Fig. 3b

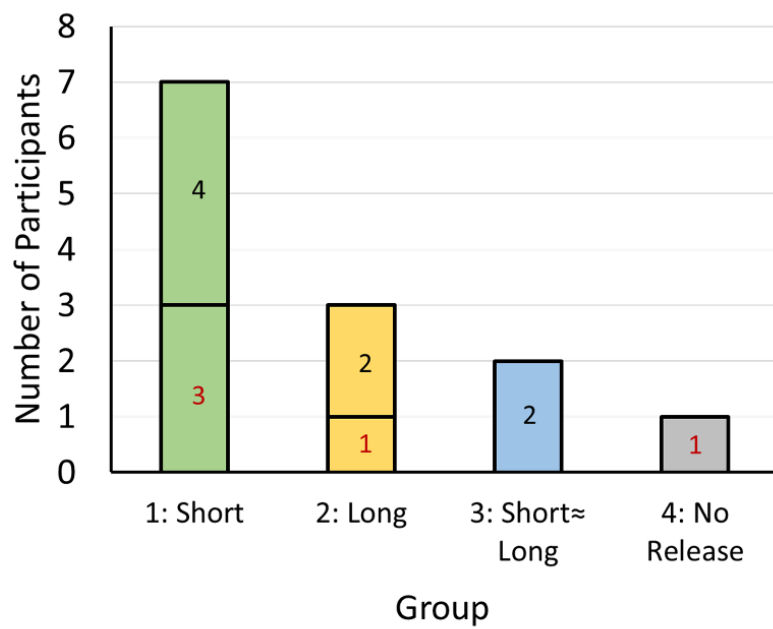


Fig. 4

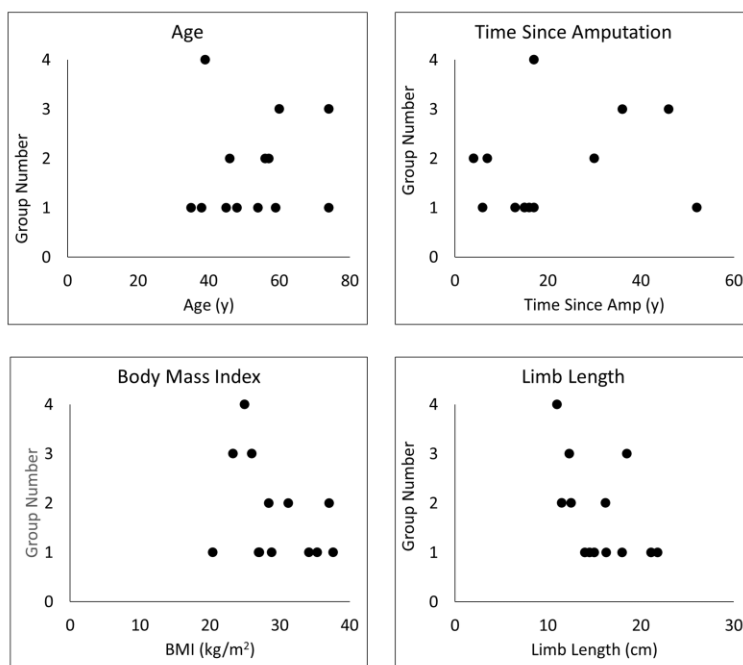


Fig. 5

Appendix 1. Impact of timing differences between conditions

Because the duration of the sit for the Short Rest (4 min) was not a multiple of that for the Long Rest and No Release (10 min), there was a slight difference in the timing of the walks used for comparison. Calculations of the timings verified this expectation – the median timing of the Short Rest walk was 84.4 min, while that of the closest No Release walk was 89.2 min (4.8 min *after* the Short Rest) and that of the Long Rest walk was 81.0 min (3.4 min *before* the Short Rest) (Fig. A1).

To investigate if the differences in timing produced meaningful differences in the limb fluid volume results, we calculated the percent change in limb fluid volume from the reference for the earlier and later timings for each condition – No Release and Long Rest. The differences in percent limb fluid volume were minimal for No Release (Fig. A2) and Long Rest (Fig. A3). Similar findings were demonstrated for the anterior region. Therefore, the slight difference in the timing of the walks used for comparison was not considered relevant to the study conclusions.

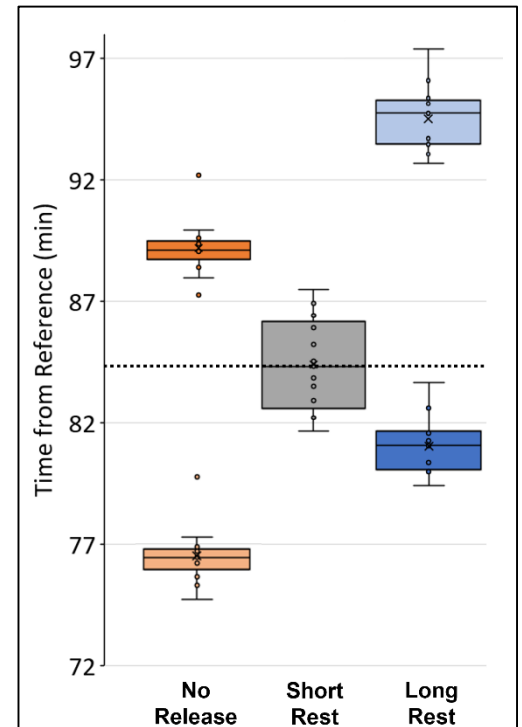


Fig. A1. Timings for bouts nearest the final Short Release bout. For No Release, the upper time point is from bout X and the lower time point is from bout Y. For Long Rest, the data are from bouts X and Y, respectively.

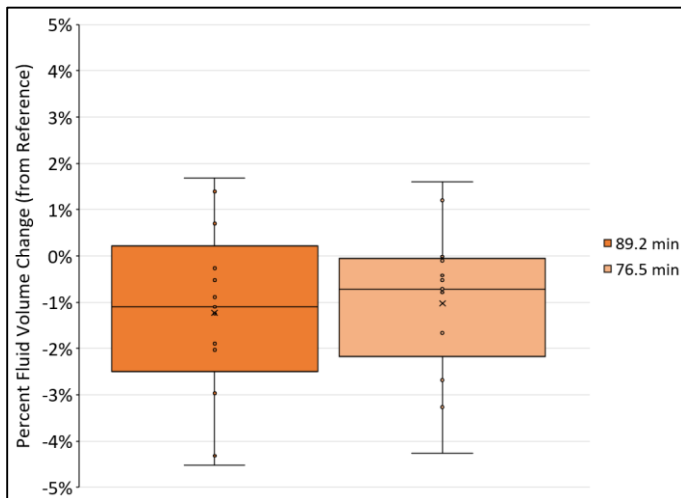


Fig. A2. No Release results. Percent fluid volume change for the timing 89.2 min compared with the timing 76.5 min. Posterior region.

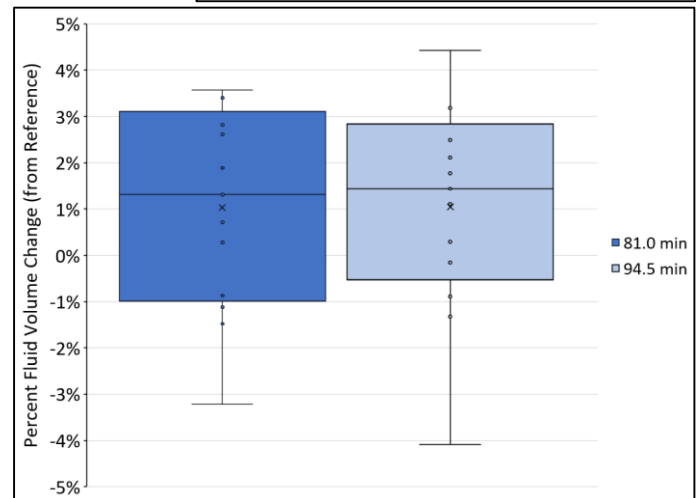
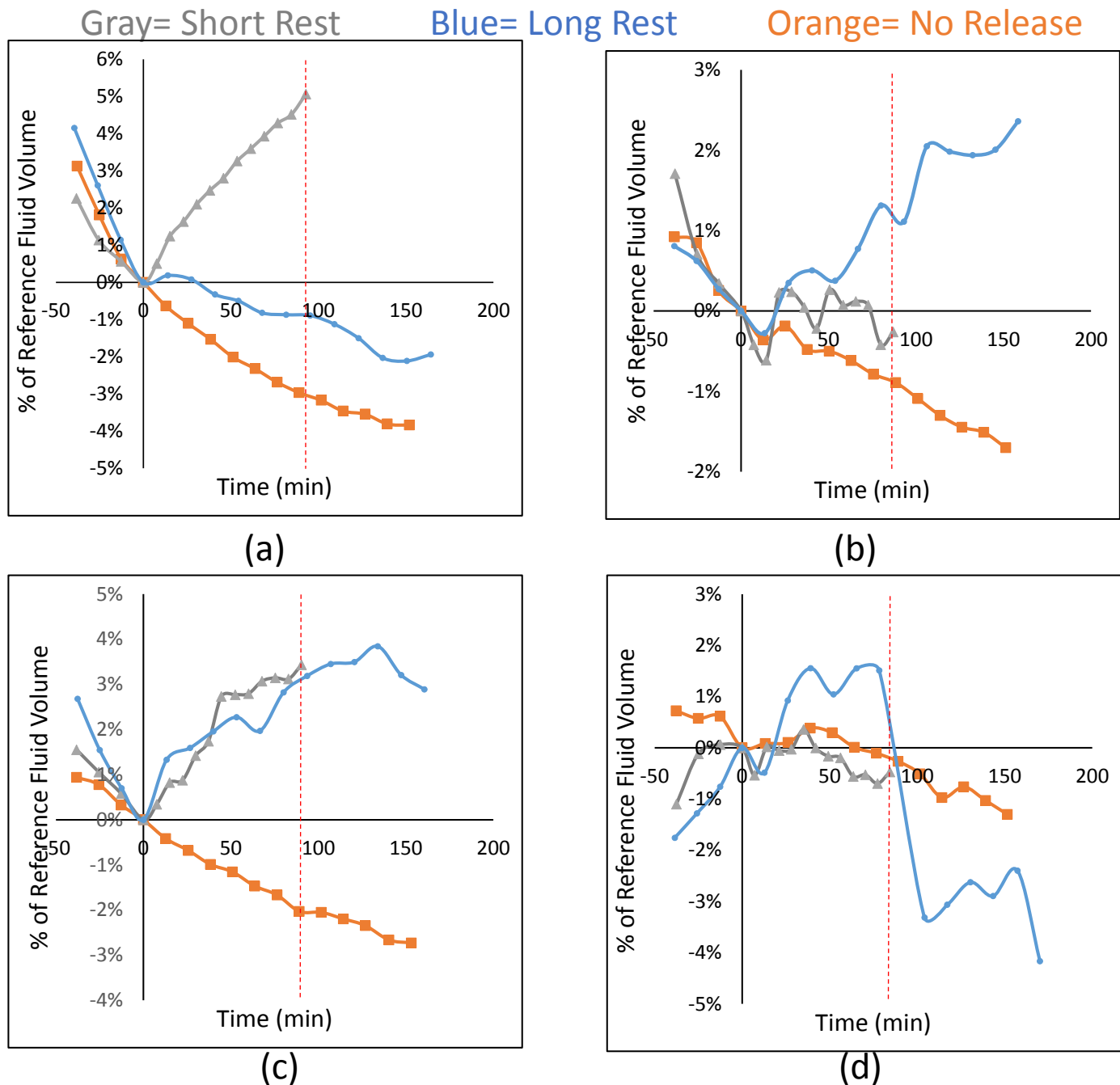


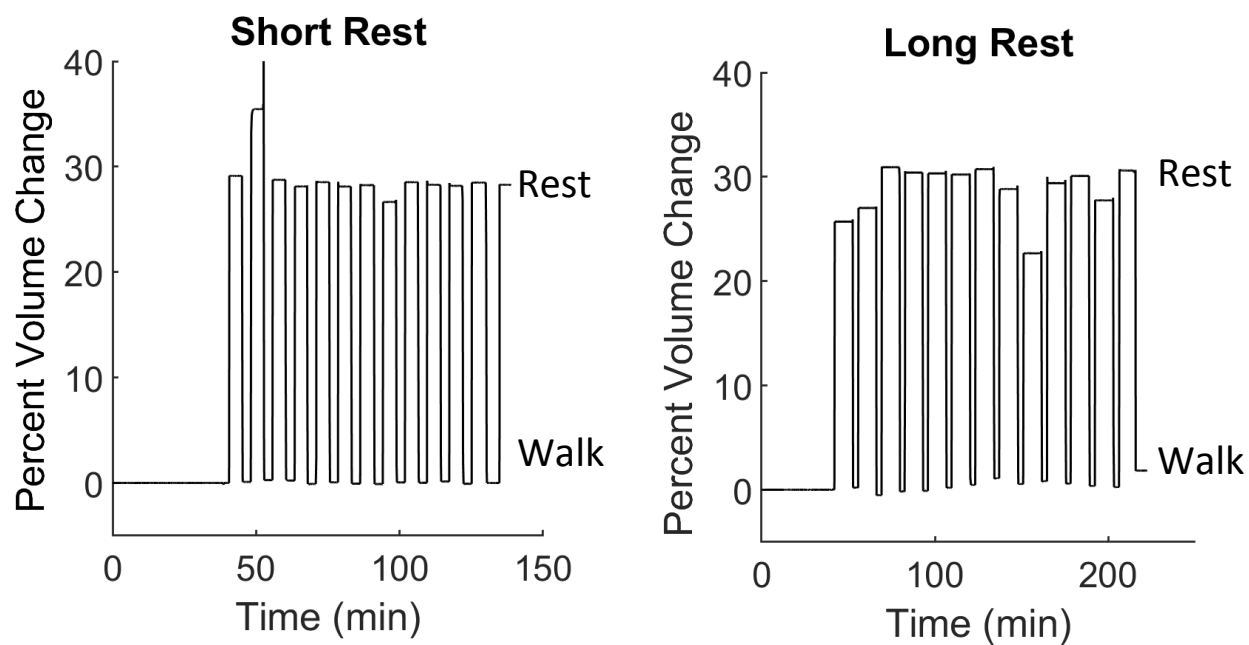
Fig. A3. Long Rest results. Percent fluid volume change for the timing 81.0 min compared with the timing 94.5 min. Posterior region.

Appendix 2. Example data from each participant group (1 to 4).



Participants were grouped by condition(s) with the highest percent fluid volume increase relative to the reference. (a) Group 1 example, gained the least fluid volume during the No Release test and gained more fluid volume during the Short Rest test compared with the Long Rest. (b) Group 2 example, gained the least fluid volume during the No Release test, and gained more fluid volume during the Long Rest test compared with the Short Rest. (c) Group 3 example, gained the least fluid volume during the No Release test, and gained comparable fluid volume during the Short Rest and Long Rest tests. (d) Group 4 example, gained less fluid volume during the Short Rest and Long Rest tests than during the No Release test.

Appendix 3. Example dial data over time plotted as a percentage of the socket volume change relative to the closed position for a Short Rest (left) and a Long Rest (right) test session



Prosthetics and Orthotics International

Design and Testing of a Simple Quick-Connect for a Prosthetic Liner Tether

--Manuscript Draft--

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Abstract:	Introduction: A limitation of tether lanyards is that fastening and unfastening the tether from the liner, which needs to be done to clean or replace the liner, is difficult for some users. The purpose of this research was to create a quick-connect that allows users to easily attach and detach the tether from the liner. Materials and Methods: A slide-and-lock mechanism was used. To operate the quick-connect, the prosthesis user turns open the lock, slides it onto a short pin extending from the liner, and releases the mechanism, causing it to spring back to the locked position. Results: Mechanical tests demonstrated that the system well-tolerated tensile loads of 25,000 cycles at 100 N and single cycles at 350 N. Five transtibial users trialed the system and took between 2 and 30 s to fasten and unfasten the quick-connect. They found the quick-connect intuitive to use, secure, relatively quiet, and stable. However, they preferred their traditional pin lock over the quick-connect system, mainly because the quick-connect required a multi-step procedure (twist-align-slide) that they considered more complex than operating the locking pin to which they were accustomed. Conclusion: In its current form, the quick-connect is likely to be used by K-2 users who struggle with the pin lock donning procedure. It also has potential use with powered tethers that use a motor to adjust tether length.

1 **Abstract**

2 Introduction: A limitation of tether lanyards is that fastening and unfastening the tether from the
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16 Conclusion: In its current form, the quick-connect is likely to be used by K-2 users who struggle
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19

20 *Keywords:* prosthesis, tether suspension, lanyard, amputee, pin lock, donning

21 Word count: 2,736

Introduction

A tether is a method of suspension that helps prosthesis users to secure their residual limb within their socket during activity¹. The tether extends from the distal end of the user's elastomeric liner through a hole in the socket to a take-up reel or a fastener mounted to the outside of the prosthesis. As the tether retracts, it draws the distal end of the liner into the socket.

A tether offers users a solution when a traditional pin lock is not effective. A key benefit of a tether is that users do not need to move the distal end of their residual limb around inside the socket to locate the shuttle lock opening. That process can be difficult and time-consuming for people with poor limb sensation, poor dexterity, limited range of motion, upper extremity weakness, limited mobility, or an inability to master the pin-insertion technique. The tether solves this problem by drawing the distal end of the liner into the proper position.

Though a tether may benefit some prosthesis users, it has an important limitation. Users may find it difficult to separate the tether from the liner when it needs to be removed (e.g., for cleaning, replacement, or to add a sock). Cleaning the liner daily is recommended for hygiene, and socks are added or removed during the day to accommodate limb volume change. The difficulty with removing a traditional tether is that the user must unscrew and then later screw back in the threaded pin that holds the tether to the bottom of the liner (Fig. 1d). From clinical experience, we have observed that this process may result in a lengthy don time, and if reassembly is done improperly the pin may loosen and disconnect during walking. Further, cross-threading the pin is a concern as it could potentially cause the pin to jam in the lock.

We designed a simple quick-connect for a tether to address this limitation. The quick-connect allows the tether to be separated from the liner within seconds. The mechanism is described, and results from both bench and participant testing are presented.

Methods

The quick-connect was designed to be compact and lightweight (Fig. 1a,b). It weighs 16g and is 13.0 mm in height and 22.9 mm diameter. It separates into two components during use: the quick pin and the locking mechanism (Fig. 1c). The quick pin is threaded into and stays in the distal end of the liner. The locking mechanism is attached to the end of the tether. The parts within the quick-connect are listed in Appendix 1, and mechanical drawings are provided in Supplement 1.

The quick pin slides radially into a slot in the clip in the locking mechanism within the locking mechanism. A lock within the mechanism is rotated clockwise 105° to close the opening and ensure the quick pin does not pull out of the slot. A torsion spring assists in this rotation, maintaining the lock in the closed position unless a counterclockwise force is applied by the user to rotate and hold the lock in its open position (Appendix 2). The torsion spring eliminates the need for the user to remember to lock the mechanism. A pin mounted into the side of the clip travels through a slot machined into the side of the lock. This pin restricts relative rotation between the lock and clip to 105° . The locking nut on the bottom of the assembly provides the dual functions of being a handhold for the user while operating the lock and creating a recess for the knot in the tether. The knot holds the tether in place within the locking mechanism (Fig. 1c). In preliminary tests, we evaluated several different knots, including an overhand knot, figure-8 on a bight knot, Ashley stopper, and Stevedore stopper. We found that a figure-8 on a bight knot best deterred pull-out.

To put the tether and quick-connect into the socket, users pass the distal end of the tether through a hole or slot in the socket to a ratcheting dial, take-up reel, strap, or other apparatus to hold the distal end of the tether in place. The quick pin, attached to the proximal end of the tether,

is then tightly screwed into the distal threaded recess of the liner. Loctite is used to secure this connection. To don the prosthesis, the user first puts on the liner. The user holds the locking nut in front of his or her residual limb and orients the slot so that the open end is next to the quick pin. With one hand gripping the locking nut and the other hand holding the liner near the quick pin, the user turns the lock counterclockwise, exposing the slot in the clip and moving the locking mechanism to the open position (Appendix 3). The user slides the locking mechanism onto the quick pin until the pin is fully inserted into the clip. The lock is released, and the spring rotates the mechanism back to the closed position. With the tether now secured to the liner, the user retracts the tether, pulling the residual limb into the socket.

To assess the mechanical performance and safety of the quick-connect, prototypes were tested using a tensile testing machine (5944, Instron). A tether made of Vectran 200 (Kuraray) material was used to connect the locking mechanism and the machine table as shown in Fig. 2.

Two tests were conducted. A cyclic fatigue test was executed to evaluate the wear of the quick-connect and attached tether. This test was intended to simulate continuous walking. A reference position (0.0 mm) was defined such that the tether was straight but under minimal tension. From the reference position, a tensile load was applied at a rate of 40 N/s until a 100 N maximum was reached. A magnitude of 100 N was approximately 5x higher than the force calculated from a combination of the socket weight and the angular acceleration of the lower limb during swing phase for a participant walking at 2 mph using a 2.0 kg prosthesis, thus was well above the load expected during normal clinical use. A loading rate of 40 N/s was used to avoid dynamic loading from affecting the data. Next, the load was reduced by displacing the crosshead down to a position of -2.0 mm. This position created slack in the tether. The crosshead was returned to the 0.0 mm position, and the process was repeated until a total of 25,000 cycles was reached.

25,000 cycles represented approximately 5 days of prosthesis use². After testing was completed, the tether and quick pin were inspected for wear using a 4.5x power microscope to determine if any fraying or other damage was visible under magnification.

The assembly was returned to the testing machine using the same tether, and a second test was conducted. A load of 350 N was applied for 5 single cycles to determine if the design was capable of withstanding high stress events. In clinical fitting using a tether cable instrumented to measure force, we found that participants generated as much as 178 N of tension in the tether while sitting. The load applied during this test was about twice that value, simulating a critical scenario.

Candidates were included in the pilot study if they were at least 18 y of age, had a transtibial amputation at least 18 months prior, wore a definitive prosthesis, and self-reported walking at least 7 h/wk. Participants were required to be at least at a K-2 activity level, a community-level ambulator³. An exclusion criterion was presence of skin breakdown. Institutional review approval was obtained, and all participants signed informed consent forms before any procedures were initiated.

The pilot test was conducted during a single visit to the lab. Before the participant arrived, a quick pin was placed in the threaded hole of a research liner matched to the person's size. The session was video recorded (GoPro HERO 5) so that participants' actions and verbal responses recorded on a data collection form could be later evaluated in detail. After arriving at the lab, participants sat for 10 min to achieve a homeostatic condition. A 10 min duration was effective in prior studies to achieve a stable limb fluid volume⁴. Demographic and clinical information were recorded. Participants were asked to doff their regular prosthesis and liner and don the research liner.

Participants were shown the quick-connect system, and a video and infographic on how to

use it. They were asked to handle the mechanism and became familiar with its operation. Participants selected their preferred chair height (low or high) and sat in the chair. Participants were asked to connect the locking mechanism to the quick pin. The researcher used a stopwatch (resolution 0.1 s) to record the time it took participants to do so. Any difficulties observed or unsolicited participant comments that the participants expressed were noted. The same procedure was conducted for unfastening the quick connect. Three additional trials were conducted.

After completing the pilot test, participants were asked questions about their experience using the quick-connect and given an opportunity to provide additional comments (Supplement 2). The researcher documented the participants' responses.

Results

There were no mechanical failures in either the quick pin or tether from either the 25,000 cycles of 100 N force or the single 350 N force tests. Example load-extension data are shown in Fig. 3a,b. The tether displayed less than 1 mm of extension in the linear region of the load-extension curve, i.e., in the region above 1.4 mm extension. There was a gradual increase in elongation (curves shifted to the right in Fig. 3a) over the cyclic test. From examination using the microscope, there was no evidence of tether fiber fraying or failure nor physical damage to the quick pin.

Five participants using traditional locking pin suspension systems took part in this study (Table 1). Only one of the five participants (participant 5) had previously used a tether, and this was during a one-month research study. All participants typically sat down to don and doff their liner.

Participants took between 2 s and 30 s to fasten the quick-connect (Fig. 4a). The fasten time was less for trial 4 than trial 1 for all participants except participant 5. Participant 5 had

difficulty sliding the quick pin into the clip during trials 2 and 3. He also had difficulty keeping the lock open with one hand during trials 2 and 3.

The time to unfasten the quick-connect ranged from 2 s to 25 s (Fig. 4b). All participants took less time to unfasten the quick-connect in trial 4 compared to trial 1 except participant 5. Participant 5 had difficulty keeping the lock open with one hand during trial 4. Participants 4 and 5, the only participants with co-morbidities, had slower fasten and unfasten times than the other participants.

The median participant ease-of-use scores were lower (easier) for doffing (score of 2, on a scale of 1 to 5) compared with donning (score of 3) (Table 2). Participants found the quick-connect intuitive to use, secure, relatively quiet, and stable. Three participants felt that the quick-connect was of reasonable size, while two participants would have preferred it to be larger. Individual participant responses are provided in Appendix 4.

Participants recognized that the quick-connect eliminated the pin screw-in challenge of existing tether systems, making donning faster and easier (Table 3). Participants felt that the system needed to be simplified by replacing the three-step fastening process (twist-align-slide) with a one-step process. There were comments that it would be convenient if the locking piece could be locked in the open position without the user having to hold it open, and then automatically lock in place once the quick pin was secure. Some participants made negative comments about tether systems in general because of safety concerns, for example the tether might break. Suggested revisions to the system also included changing the locking nut to have a rubberized cover, changing the color, and making the spring a little less stiff.

Discussion

The developed quick-connect is intended to improve the implementation and safety of

tether suspension by eliminating the requirement of screw-fastening the pin into the liner. This advance should make tethers attractive to a wider range of prosthesis users. People who find the pin-insertion technique challenging to master and need to remove and reattach their tether (e.g., to add or remove socks or to clean the liner) would be expected to benefit from this technology. Quick-connect may facilitate user acceptance of powered tethers that use push buttons on the socket to adjust tether length⁵. Powered tethers allow for quick discrete partial doffing, which has been shown on transtibial prosthesis users a means to stabilize daily limb volume⁶.

The hysteresis in the mechanical testing data (Fig. 3a,b) is likely a result of the elastic behavior of the tether, and is typical of tether suspension systems. The elongation is likely because the knot in the tether tightened over time. It is reasonable to expect that the durability of the quick-connect tether would be comparable to traditional tether systems since the strength in both systems depends on the mechanical properties of the tether material. The tether lengthening of 1 mm measured during loading is on the order of the displacement distance of a traditional pin lock. Notches in locking pins limit pin cyclic vertical displacements to less than 3 mm.

Participants learned quickly how to operate the quick-connect assembly, achieving times of 15 s or less for both fastening and unfastening by their 4th trial (Fig. 4a,b). Participants 4 and 5 took up to 13 s longer than the other participants possibly because of their health issues, though this is conjecture and would need to be tested through rigorous scientific investigation (Table 1). From our clinical experience, durations of 30 s or less are considerably shorter than the time it takes to align, screw in, and tighten a tether-pin into a liner, particularly if a tool or chemical adhesive needs to be applied. Participants found it easier to unfasten than fasten the quick-connect, probably because during unfastening they were not required to align the quick pin with the slot in the clip.

Many desirable features were implemented in this design. Participants found the quick-connect system intuitive to use and felt secure, the click-upon-lock closing was relatively quiet, and no unnecessary pin-to-lock movement was perceived. The larger size desired by two participants may have reflected their desire for something easier to grip. However, increasing the size of the system will add to the build height and decrease the size available for componentry. Other participant suggestions may encourage prosthesis users to be more receptive to the system – a rubberized lock surface, a different color, and a lower stiffness spring. Elimination of the holding part of the twist step during fastening, as suggested by some of the participants, would require that the size of the design be increased and not easily fit within the distal socket. We considered eliminating the spring and having the user manually twist and lock the mechanism closed. However, this was deemed problematic due to safety concerns; if the user forgot to lock the mechanism, the connection could become unstable during activity.

Limitations of this study were that a small group of participants was tested, they all used pin lock suspension, and not all of them had issues related to pin and tether use. Participants were tested after lab use, not after take-home use, thus different concerns may be voiced after more extensive periods of use at home or in the community. A next step would be to test the quick-connect on K-2 users who struggle with the pin lock donning procedure and have a need to simplify.

Conclusions

A quick-connect system for a prosthetic liner tether was successfully developed. The system eliminated the need to unscrew the pin at the distal end of the liner in a traditional tether-pin system. Fastening and unfastening times of less than 30 s were accomplished by users who pilot tested the system. Participants indicated that it is unlikely these individuals would switch

from their traditional pin system to the quick-connect system unless there were other benefits for them to do so. An example would be a powered tether that allowed for partial doffing to help stabilize daily limb fluid volume⁵. In its current form, the quick-connect is likely to be used by K-2 users who struggle with the donning procedure and have a need to simplify.

References

1. Gholizadeh H, Abu Osman N.A., Eshraghi A, Razak N.A. Transtibial prosthesis suspension systems: Systematic review of the literature. Clin Biomech 2014;29:87-97. doi: <https://doi.org/10.1016/j.clinbiomech.2013.10.013>
2. Wong CK, Rissland MS, Madagan DM et al. A scoping review of physical activity in people with lower-limb loss: 10,000 steps per day? Phys Ther 2021;101(8):pzab115. doi: 10.1093/ptj/pzab115
3. Medicare region C durable medical equipment prosthetics orthotic supplier (DMEPOS) manual. Columbia (SC): Palmetto GBA: 2005. p. 53.5-6.
4. Sanders JE, Cagle JC, Allyn KJ et al. How do walking, standing, and resting influence transtibial amputee residual limb fluid volume? J Rehabil Res Dev 2014;51:201-212. doi: 10.1682/JRRD.2013.04.0085
5. Gurrey CJ, Garbini JL, Bennett SP et al. Socket release/relock: An innovative mechanism to help maintain prosthesis user residual limb volume. Med Engi Phys 2021;90:100-106. doi: 10.1016/j.medengphy.2021.03.002
6. Lanahan CR, Coburn KA, Hafner BJ, et al. Release/relock sockets for transtibial prosthesis users: Release duration and residual limb fluid volume. Clin Biomech 2022; submitted.

Figure Legends

Figure 1a-d. The quick-connect system and a traditional attachment. (a) Quick pin seated in the locking mechanism. (b) Cross section view showing the quick pin and tether in place when the system is locked. (c) An exploded view showing the parts of the assembly. (d) A traditional locking pin and attachment in a prosthetic liner are shown.

Figure 2. Quick-connect system in the tensile testing machine. Left: The bottom end of the tether is attached to the table of the testing machine. Right: The mechanism is locked onto a quick pin mounted in the top of the testing machine.

Figure 3a,b. Results from cyclic tensile testing. (a) Five groups of test cycles (blue, red, yellow, purple, green) were conducted. There were 5000 cycles in each group thus a total of 25,000 cycles. The first cycle was blue, and the last cycle was green. (b) Results from the last two loading and unloading cycles. The curves are essentially on top of each other for the two cycles. The loading and unloading phase are indicated with arrows.

Figure 4a,b. Time to (a) fasten and (b) unfasten the quick-connect is shown. All participants decreased their times as they executed more trials, except for participant 5 who had difficulty sliding the quick pin into the clip and keeping the lock open with one hand.

Appendix 1.

Parts within the quick-connect

Part Name	Material	Vendor	Part Number
Quick pin	SS 316	Custom Machined	QPin-008*
Lock	Aluminum 6061-T6	Custom Machined	QPin-005
Clip	SS 316	Custom Machined	QPin-006
Locking nut	Aluminum 6061-T6	Custom Machined	QPin-007
Dowel locking pin	52100 alloy steel	McMaster	91595A008
Torsion spring	Music wire steel	TheSpringStore	PT028-571-2250-MW-RH-0970-N-IN

*Reference number in the mechanical drawings (Supplement 1)

Appendix 2.

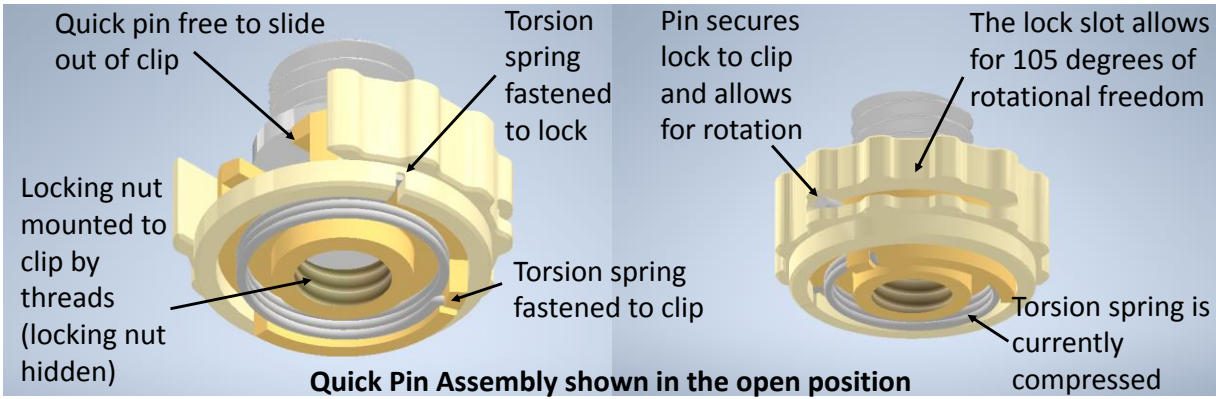


Figure A3. The spring in the locking mechanism. Front and back view of the assembly showing a bottom view of the locking mechanism in the open position. Details of component function and interaction are described.

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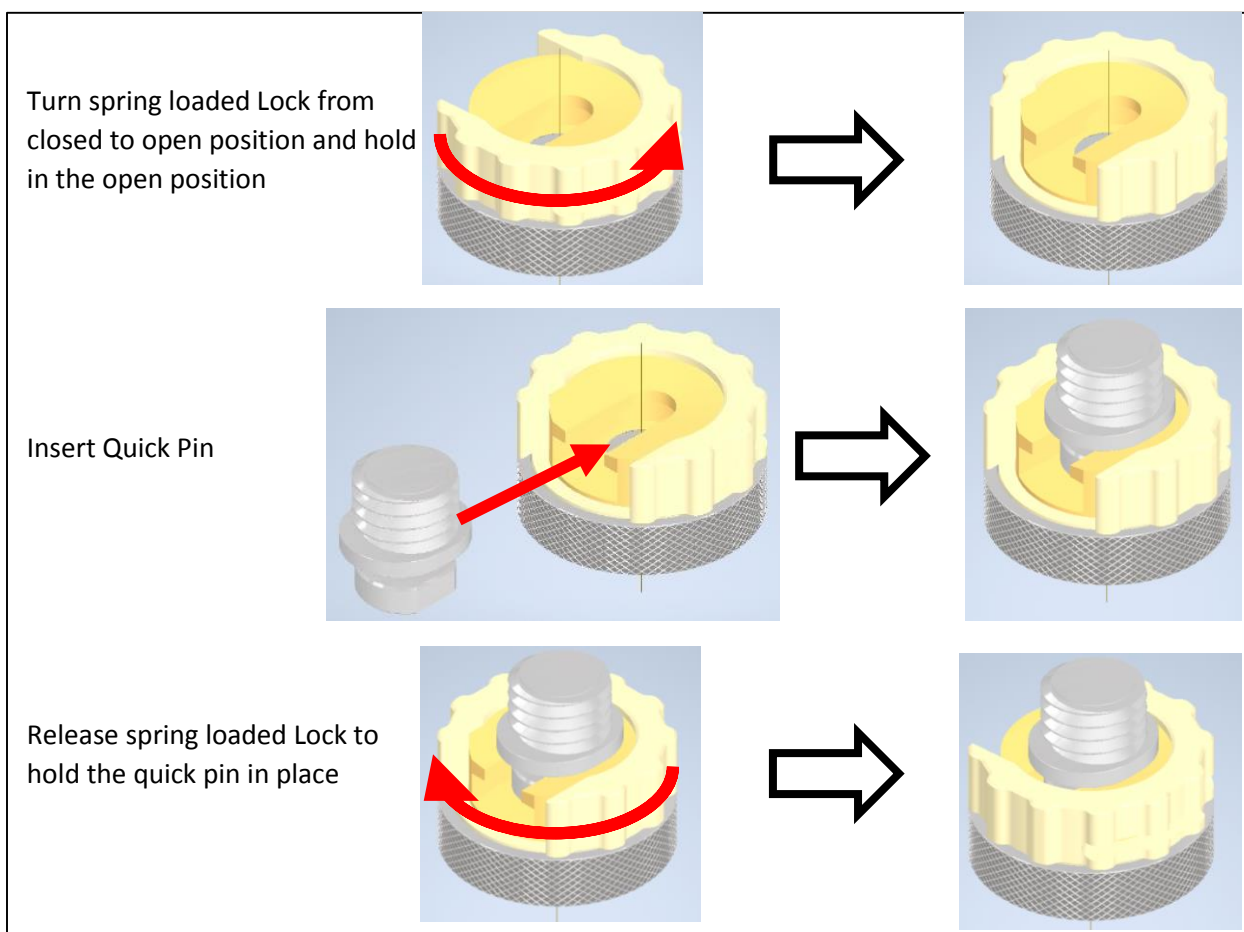


Figure A4. User operation. Instructions provided to the user to lock the quick pin in place.

Appendix 4.

Participant responses to self-report questions

Self-Report Questions	Participant				
	1	2	3	4	5
Dons per day?	1x AM	3x	1x AM	2x	1x AM
Doffs per day?	1x PM	3x	1x PM	2x	1x PM
Ave. sock ply?	5 by PM	0.5 to 1	2-3 every day; does not change sock ply during the day	2-8	Wears a fabric brace around the brim, like a sock
Bodily position during don/doff?	Sitting down	Sitting down or standing	Sitting down	Sitting down	Sitting down. Used to do standing up
Prior lanyard use? Liner left attached to tether?	-	-	-	-	Yes, in a take-home research study. Liner not left attached
Execute partial doffs?	No	No	Yes, when sitting for long periods	No	2x/day, usually when driving

Participant quick-connect scores and responses. First four questions were on a scale of 1 to 5

Quick-connect variable	1	2	3	4	5
Difficulty of fastening process	3	5	2	3	3
Difficulty of fastening mechanism (twist, hold)	3	2	2	4	3
Difficulty of unfastening process	2	3	2	3	2
Difficulty of unfastening mechanism (twist, hold)	2	2	2	4	2
Intuitive to use? (Y/N)	Y	Y	Y	N	Y
Good size? (Y/N)	Y not smaller	N prefer bigger	Y	Maybe prefer bigger	Y
Feel secure? (Y/N)	Y	Y	Y	Y	Y
Make too much noise? (Y/N)	-	N	N	N	N
Unnecessary movement of the locking mechanism relative to the pin? (Y/N)	N	N, but if gate was stuck it would slide	N	N	N

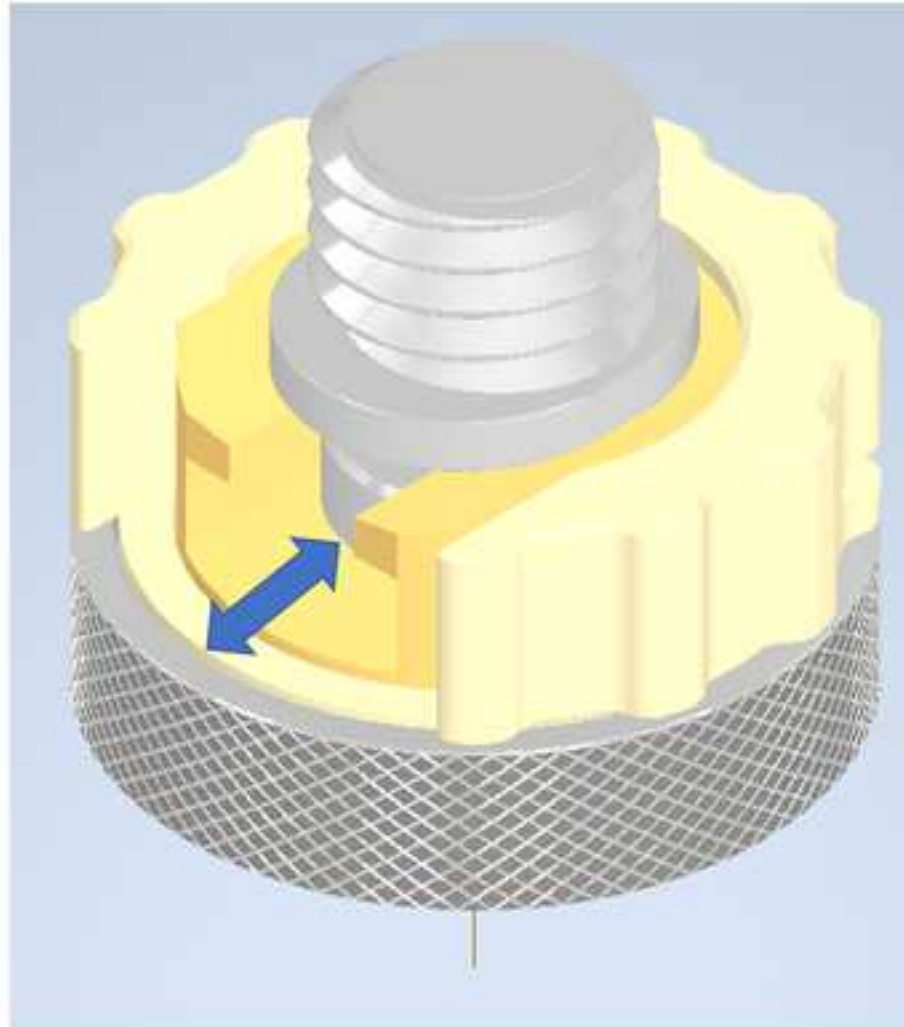
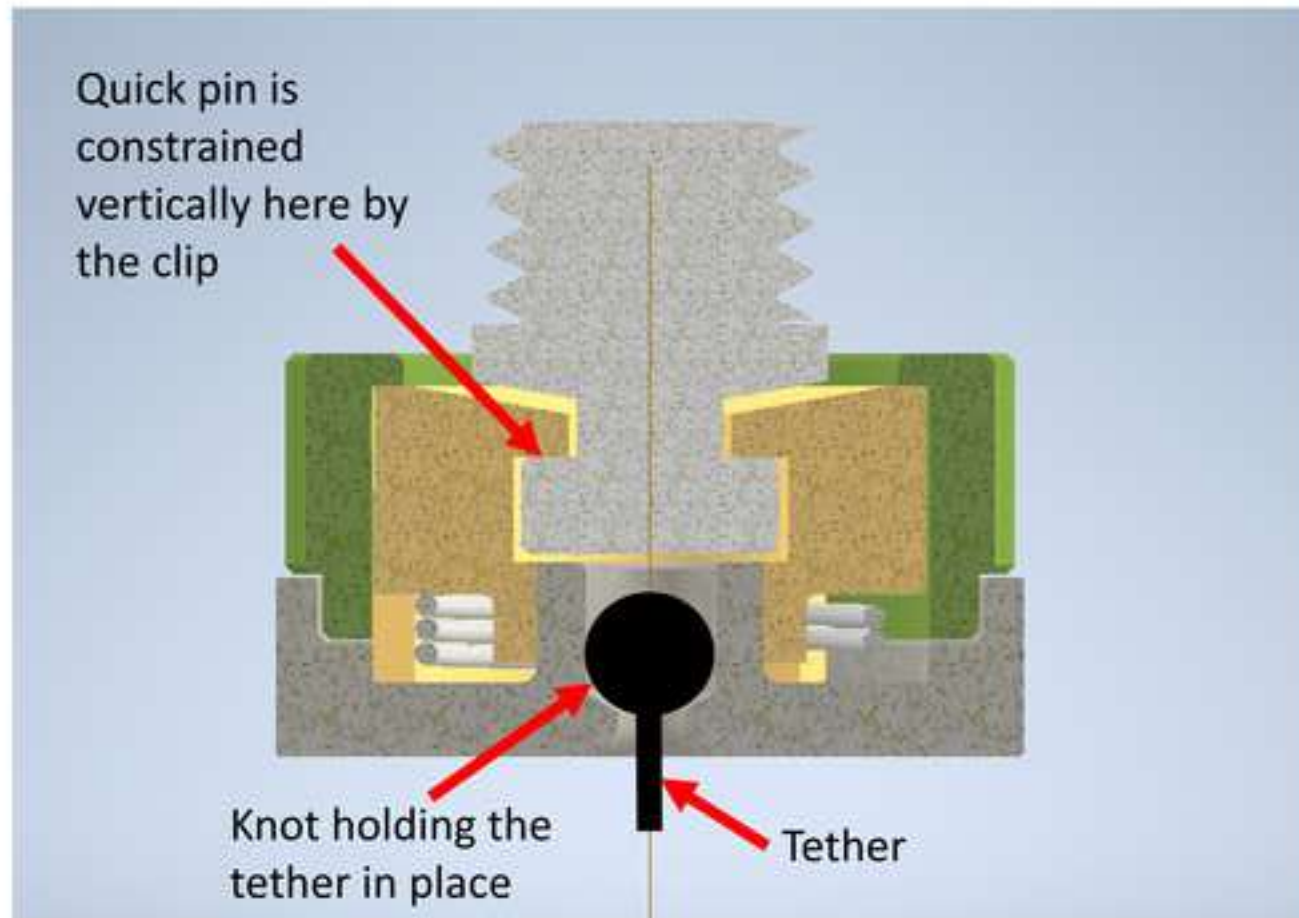


Fig. 1a.



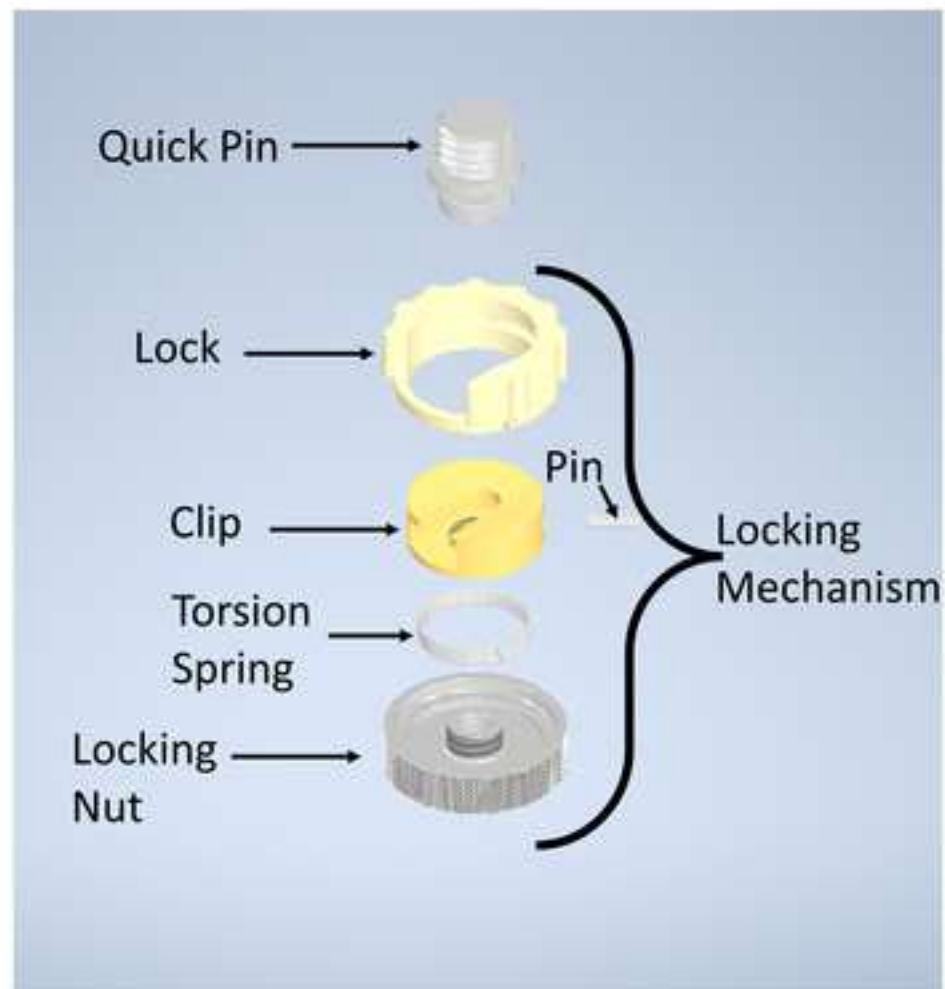
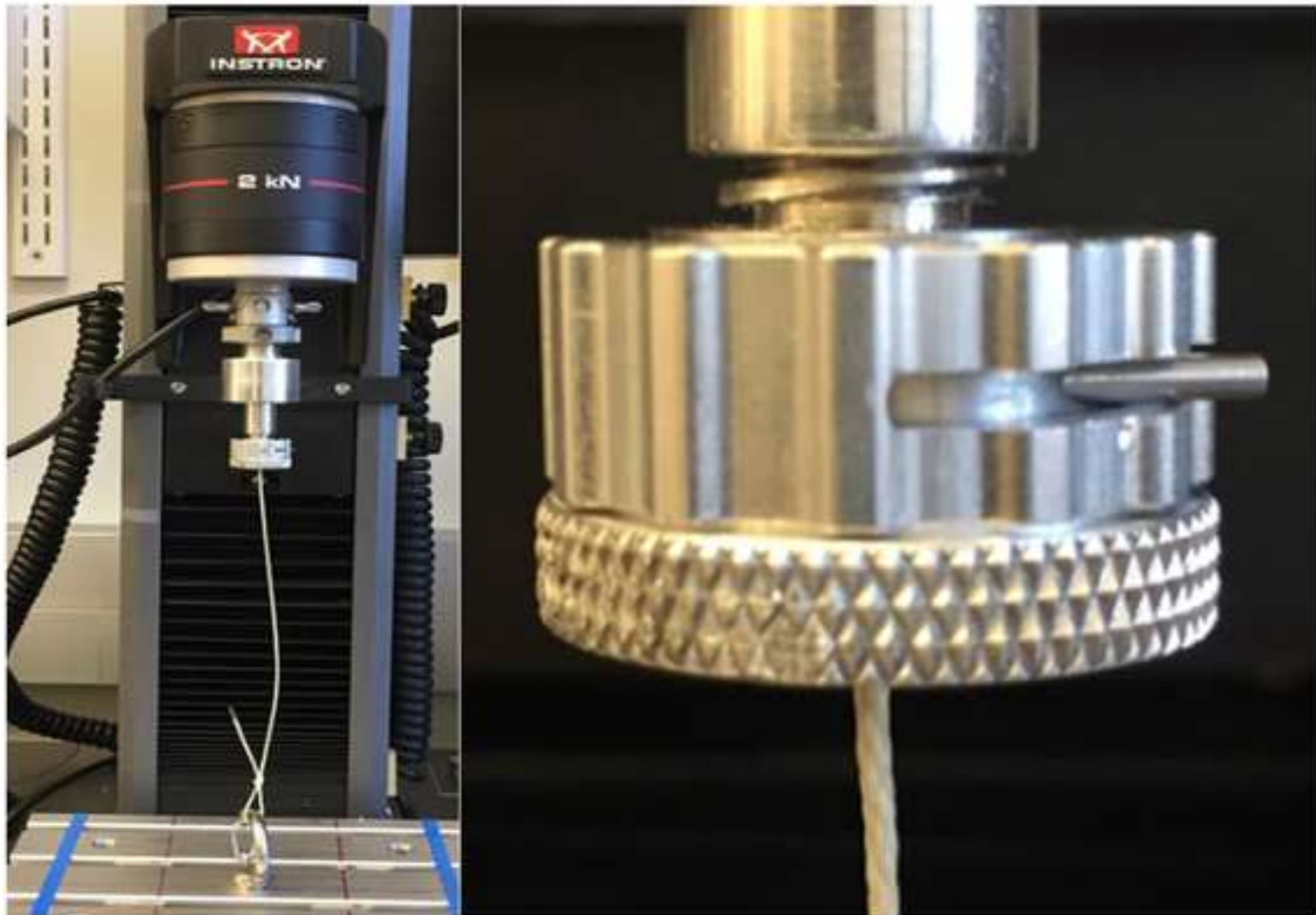


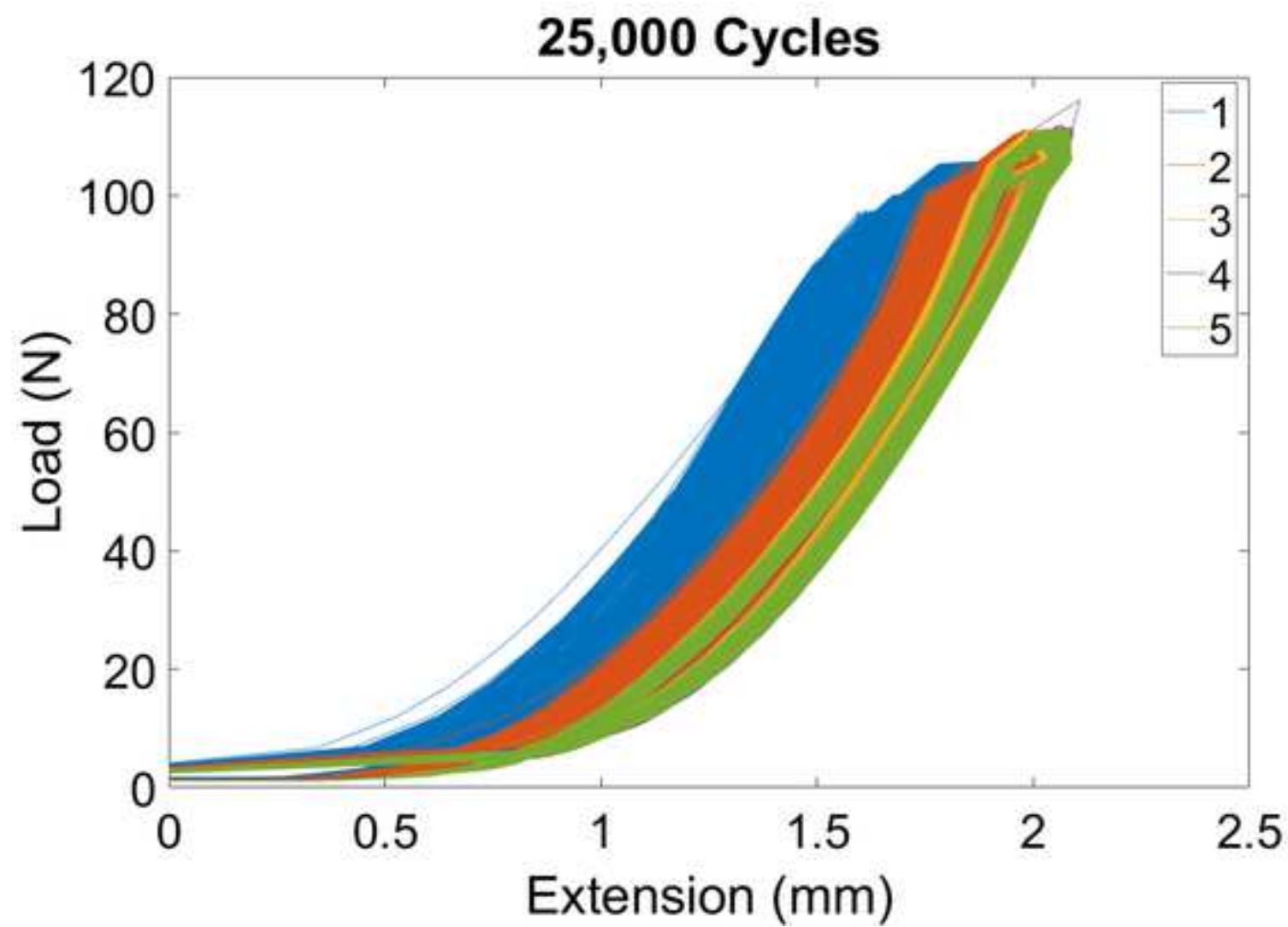


Fig. 1d.

Figure 2

[Click here to access/download;Figure;Figure 2_TIFF.tif](#)





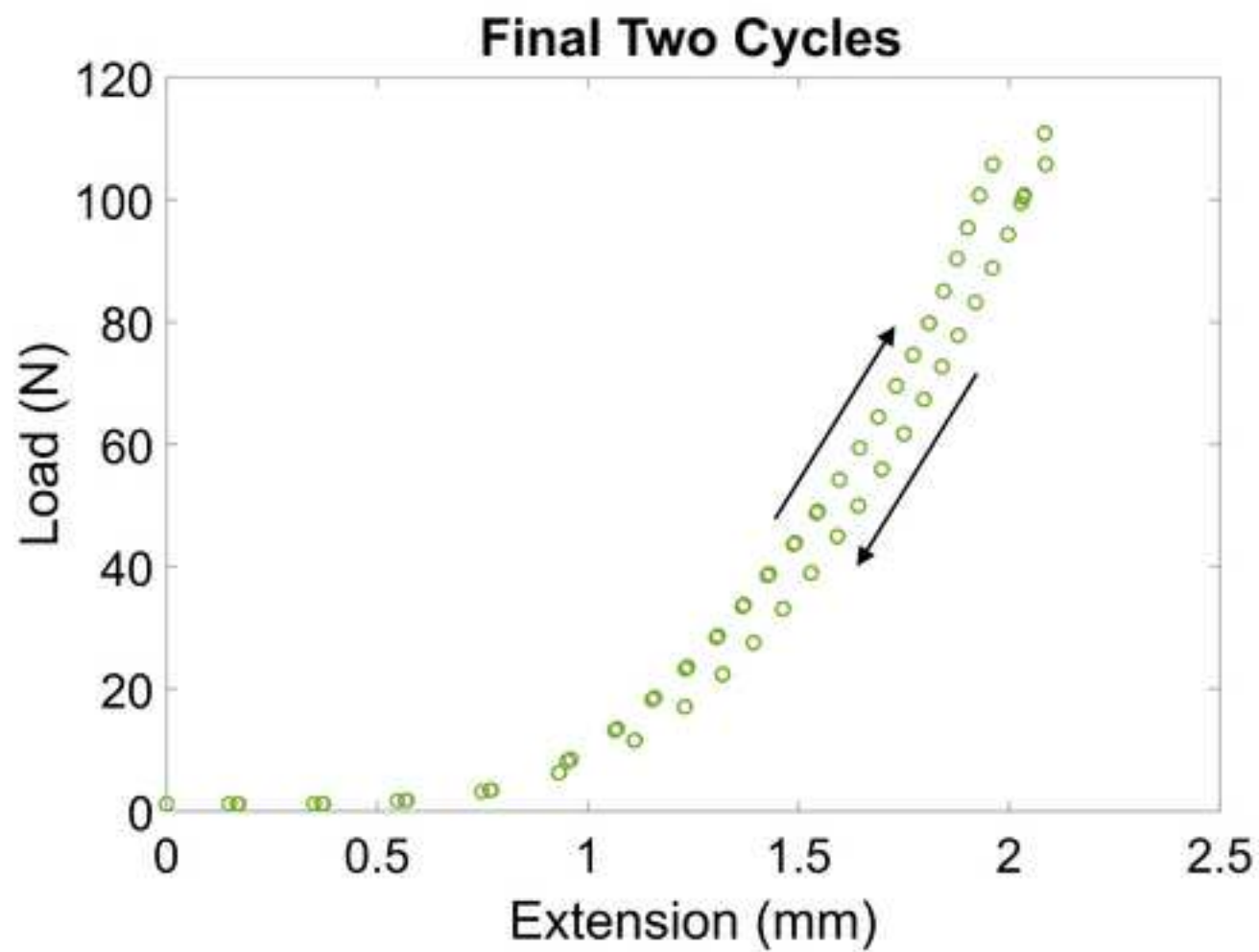
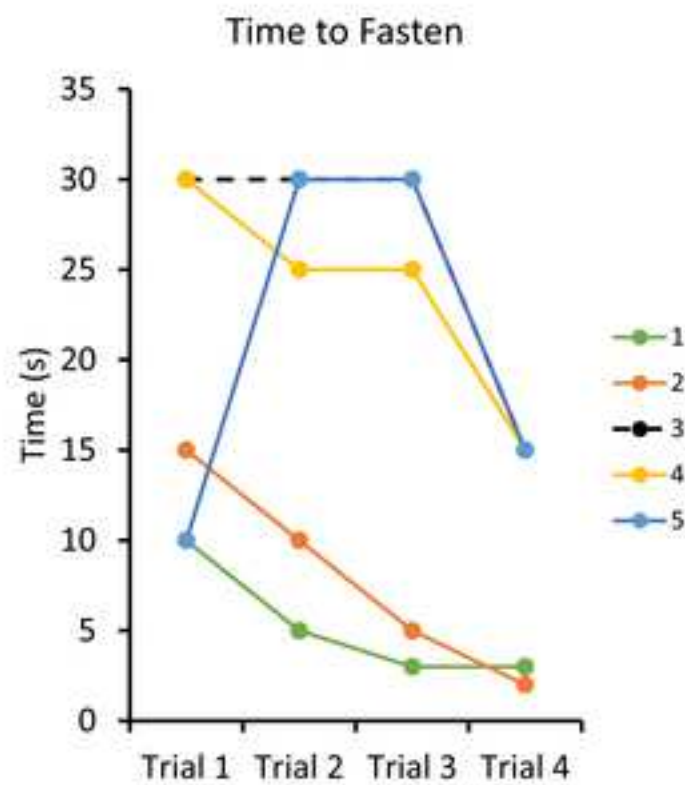


Fig. 3b



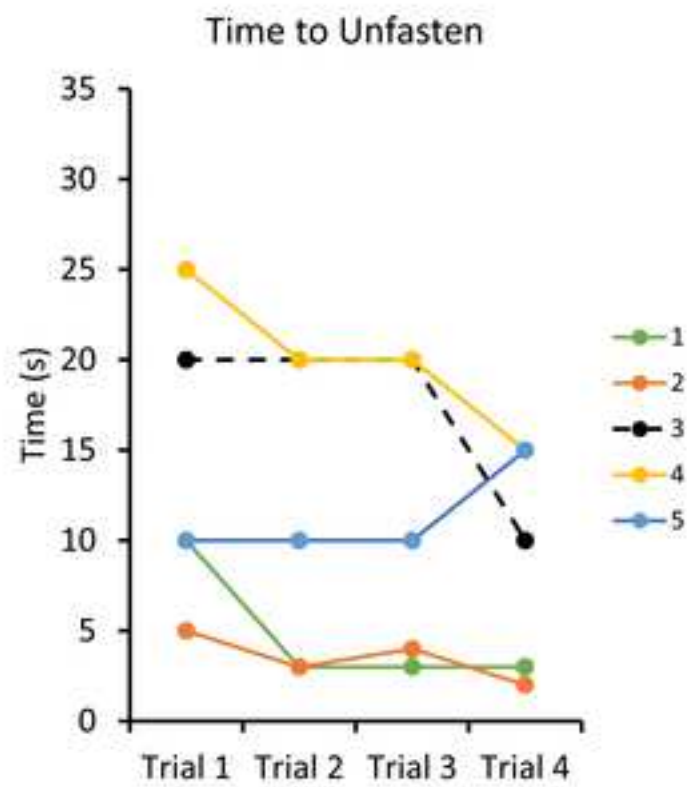


Table 1. Participant descriptions.

Participant	Gender	Age	Time Since Amputation (y)	Residual Limb Length (cm)	Health Issues Related to Pin and Tether Use
1	M	36	16	18.0	None, no co-morbidities
2	M	61	37	18.5	None, no co-morbidities
3	F	39	16	14.0	None, no co-morbidities
4	M	64	42	9.0	Had two strokes, 5 and 6 y ago; presence of DM Type 2 and HBP; lifetime smoker; specific directions from researcher required
5	M	75	47	12.3	MVA injury (not related to amputation) one year ago that resulted in hip fracture, concussion, and memory loss; specific and thorough directions from researcher required

M= male; F= female; DM= diabetes mellitus; HBP= high blood pressure; MVA= motor vehicle accident

Table 2. Participant responses to rating and yes/no questions. 1= easiest; 5=most difficult

<i>Rating Questions (1-5) – Please rate the difficulty of:</i>	<i>Median</i>	<i>Range</i>
The fastening process?	3	2 – 5
Operating the mechanism during fastening?	3	2 – 4
The unfastening process?	2	2 – 3
Operating the mechanism during unfastening?	2	2 – 4
<i>Yes/No Questions: Was the quick-connect system:</i>	<i># of Yes</i>	<i># of No</i>
Intuitive to use?	4	1
Device of proper size?	3	2
Feel secure?	5	0
Makes too much noise (click when lock closes)?	4	0
Unnecessary pin-to-lock movement?	5	0

Table 3

Table 3. Participant responses to questions

Question		Participant				
		1	2	3	4	5
What do you like/dislike about the quick connect?	Like:	Simple, good size	Thought it would be interesting if it could be simplified	Faster than thread, good size, easy to use	Thought it would be cool, and there is potential to simplify	No twisting like screw, it's faster and will click
	Dislike:	Still working out kinks	Awkward, laborious, must think it through. Twist, align, slide	Potential choking hazard, texture (would have preferred rubberized cover), can feel dowel	Twist, hold, slide on	Lanyard system, little faith
What do you like/dislike about pin lock?	Like:	Just works	-	Straightforward	-	Fast, for active people
	Dislike:	-	-	-	-	-
If you were to choose one, which would you select?		Locking pin	Locking pin	Locking pin	Locking pin	Locking pin
Describe how you feel about the quick connect		Think it can break, worried about multiple moving parts	-	Clever, dislike threading in devices, and this would alleviate that	-	Great for users that are not active or stay in a seated position
How would you change the quick connect?		Add an "open position" locking feature. Pin stays locked in the open position until the pin slides in, then snaps closed	Change pin sticking out of side (sticking out for easy assembly and disassembly for lab personnel). Seemed to be in the exact positions needed to push quick connect onto T slot pin. Would be good if there was some color to the device. All silver parts are difficult to see if they are lined up	Would like a more tactile-friendly cover	Make donning and doffing process a single step instead of twist, align, slide; limit rotation and holding features	Would change the quick connect device by making the spring a little softer. Would also like to optimize or choose pin alignment with hi hand position
What other feedback would you like to provide?		-	Would like to participate in the next usability / feedback session. Would like it to be fully functional and use it while walking. What if subject needs to don device in the dark? What if subject needs glasses? Needs an easier way for alignment	This may be a challenge to use if there is limited height available in the socket. Do not want the device to get too much larger or too much smaller	Would like to participate in next usability feedback session. It was difficult to twist because of my limited dexterity	-
How would you use your device differently if using the quick connect?		More worried about the tether than locking system. Would like quick connect to line up with the liner position better	Would need to doff/don differently. Typically, am seated and/or standing up with the pin system. Would need to be seated and be sure the device is able to close	Morning Usage would be the same. Evening may be more challenging especially in the dark or after drinking	Don't think it would change unless there were issues with functionality	It would take approximately 30 seconds longer in the day. Would be more comfortable when doffed or partial doffed