

**AWARD NUMBER:** W81XWH-18-1-0595

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

**PRINCIPAL INVESTIGATOR:** Joan Sanders PhD

**CONTRACTING ORGANIZATION:** University of Washington  
Seattle, WA 98195

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**TYPE OF REPORT:** Annual

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# REPORT DOCUMENTATION PAGE

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<b>13. SUPPLEMENTARY NOTES</b>						
<b>14. ABSTRACT</b> Residual limb volume loss during the day is an important challenge faced by Warfighters with transtibial limb amputation. Partial doffing the prosthesis during resting may facilitate recovery and retention of residual limb fluid volume. The purpose of this research is to develop a system to allow for easy locking pin and socket panel release during sitting and quick relock upon standing. The system was designed, fabricated, and pilot tested. A motor-driven system (<300 g) housed within the socket adjusts locking pin tether length, and an instrumented ratcheting dial adjusts socket panel positions. The user operates the release/relock system using buttons and a dial on the socket. Pin tether length and ratcheting dial rotation adjustments are recorded on board for later analysis. Testing on three people with transtibial amputation demonstrated that locking pin release (5 cm partial doffing) was accomplished within 1.5 s and socket relock within 1.5 s. During relock, participants preferred to pull in the locking pin tether and then tightened the socket panels rather than vice versa.						
<b>15. SUBJECT TERMS</b> 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 limb amputation. The purpose is to create and test electronic release and relock sockets for transtibial prosthesis users. A second objective is to test new outcome assessment tools used in clinical testing. A novel motorized “release and relock” mechanism is mounted within participants’ prostheses to allow users to quickly loosen their socket and partially withdraw their residual limb without losing contact with their prosthesis. Prostheses are instrumented so that they continuously measure prosthesis use, accommodation practices, and activity. A study in a controlled test setting is conducted to characterize the sockets’ impact on morning-to-afternoon fluid volume change. A direct crossover study in the field is executed to determine if use of release and relock sockets enhances patient outcomes relative to traditional sockets. The clinical value and technical quality of outcomes data summaries are characterized by sharing results with practitioners of willing participants.
2. **KEYWORDS:** Amputee, prosthesis, limb volume, accommodation, control system, adjustable socket, release and relock, limb/socket interface, skin breakdown, accommodation

3. **ACCOMPLISHMENTS:**

**What were the major goals of the project?**

YEAR 1 GOALS & MILESTONES	TARGET	%COMPLETE
1. Reduce form factor and power consumption of current design		
Design and acquire mechanical hardware for release and relock mechanism.....	28 Feb 2019	100
Instrument ratcheting dial .....	28 Feb 2019	100
Complete electronic design and fabrication.....	28 Feb 2019	100
Complete microcontroller programming .....	28 Feb 2019	100
Add the capability for manual operation .....	30 Apr 2019	100
2. Characterize performance, enhance and document design		
Create design and performance report .....	31 Aug 2019	100
Submit manuscript .....	31 Aug 2019	100
3. Obtain human subjects approval		
UW IRB .....	30 Nov 2018	100
HRPO .....	30 Jun 2019	100
Milestone 1: Enhanced design completed.....	31 Aug 2019	100
Milestone 2: Manuscript submitted on release and relock socket design.....	31 Aug 2019	100

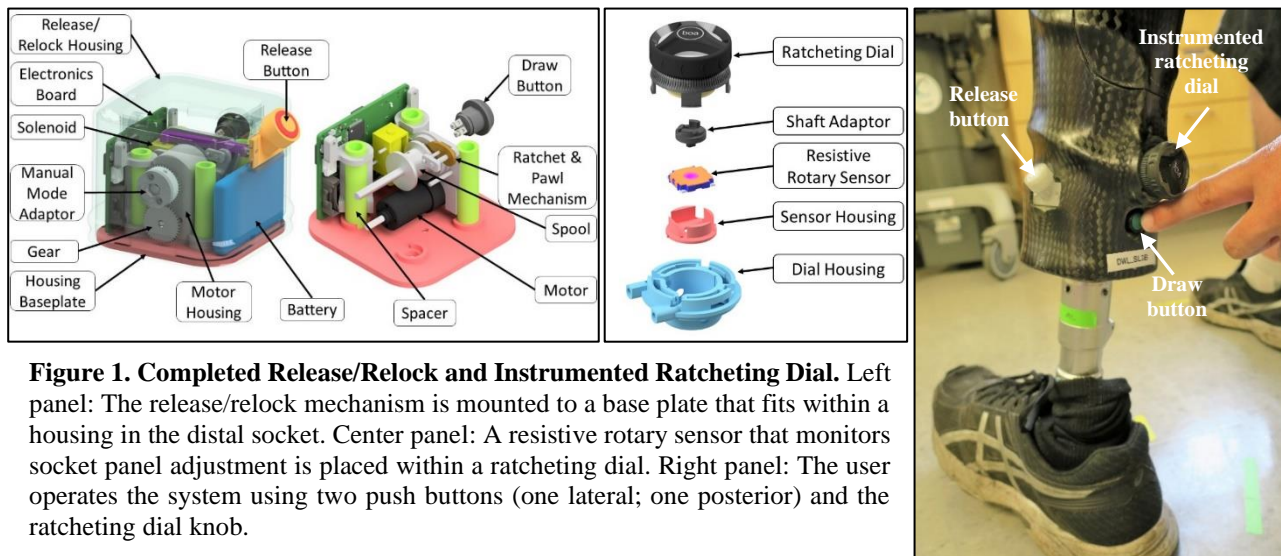
**What was accomplished under these goals?**

*Major activities:* The major activities during Year 1 were focused on design, fabrication, and testing of the novel mechanisms. A lightweight release and relock mechanism that fit within the distal section of a transtibial prosthesis was designed and constructed. An instrumented ratcheting dial that attached to the outside of the socket was also created. Bench testing in the laboratory and pilot testing on participants with limb amputation were performed. A manuscript on the technology was prepared for a peer-reviewed journal.

*Specific objectives:* The specific objectives were to create and evaluate a motorized release and relock socket that allows prosthesis users to quickly enlarge and pin-release their socket, and to quickly pin-lock and reduce their socket size for ambulation.

*Significant results or key outcomes:* The significant result was the completion of a functional release and relock system, and the completion of an instrumented ratcheting dial. Bench testing in the lab and pilot testing on people with transtibial amputation were completed.

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 Warfighters to accommodate limb volume changes with minimal disruption and distraction.

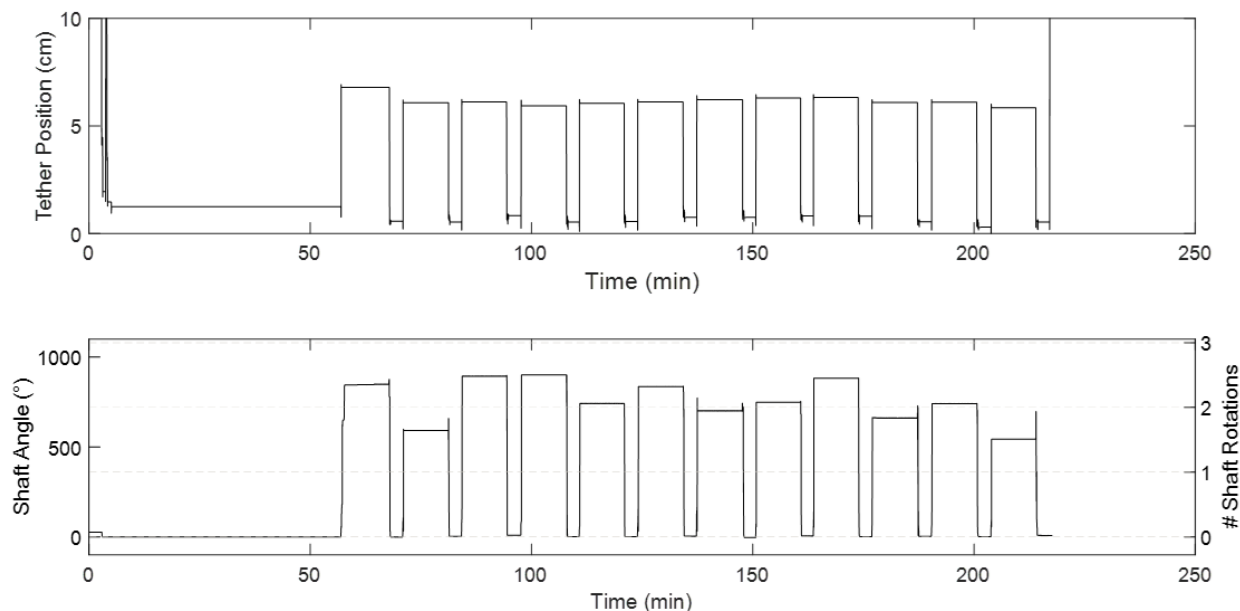


The release/relock mechanism is described in detail in the attached manuscript submitted for publication (Appendix 1). It takes approximately 7.5 s for the release/relock motor to change the socket from the doffed to donned state (assuming a 45 cm tether length), and approximately 01.5 s to change from the partially donned to 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 1 week 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 ( $5.1 \pm 0.13$  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 Test on a Participant with Transtibial Amputation.** 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.

*Other achievements:* None.

All stated goals were met.

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

Nothing to Report.

**How were the results disseminated to communities of interest?**

Nothing to Report.

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

During Year 2, the release and relock system will be tested on participants with transtibial limb amputation in a controlled setting as described in the original proposal. The focus is to characterize the sockets' impact on morning-to-afternoon limb fluid volume change. Participants will come to the lab for three sessions, each lasting up to 3 hours.

#### **4. IMPACT:**

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

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

##### **What was the impact on other disciplines?**

Nothing to Report.

##### **What was the impact on technology transfer?**

Nothing to Report.

##### **What was the impact on society beyond science and technology?**

Nothing to Report.

#### **5. CHANGES/PROBLEMS:**

##### **Changes in approach and reasons for change**

Nothing to Report.

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

Nothing to Report.

##### **Changes that had a significant impact on expenditures**

Nothing to Report.

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

###### **Significant changes in use or care of human subjects**

Initial Approval:

- UW IRB: Submitted 4/9/2018, Approved 5/15/2018
- HRPO: Submitted 5/29/2018, Approved 11/28/2018

Continuing Review Approval:

- UW IRB: Approved 3/28/19
- HRPO: Acknowledged 5/17/19

Mod #1:

- UW IRB: Submitted 5/25/2018, Approved 5/25/2018
- HRPO N/A, not a substantive modification

Mod #2:

- UW IRB: Submitted 9/4/2019, Approved 9/5/2019
- HRPO N/A, not a substantive modification

Mod #1 included the addition of a Data Safety Monitoring Plan (DSMP). The initial

protocol was approved by UW IRB, however they requested that we then submit this modification to add the DSMP.

Mod #2 was a change to the practitioner's phone number on the Consent Form.

**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.**

Gurrey CJ, Garbini JL, Bennett SP, Wang HY, Allyn KJ, McLean JB, Larsen BG, Sanders JE. Socket release/relock: An innovative mechanism to maintain residual limb volume. *Med Engi Phys.* 2019 (submitted) (yes)

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

Nothing to Report.

**Other publications, conference papers and presentations.**

Nothing to Report.

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

Nothing to Report.

• **Technologies or techniques**

Socket release and relock mechanism and instrumented ratcheting dial mechanism, and means for fabrication and installation into a prosthetic socket.

• **Inventions, patent applications, and/or licenses**

Nothing to Report.

• **Other Products**

Nothing to Report.

**7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

**What individuals have worked on the project?**

Name: Joan Sanders PhD

Project Role: PI

Researcher Identifier (e.g. ORCID ID): <https://orcid.org/0000-0002-8850-243X>

Nearest person month worked: 2

Contribution to Project: Project management and mechanical design

Name: Clement Gurrey

Project Role: Research Engineer/Scientist  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: 3  
Contribution to Project: Mechanical design of the release/relock mechanism and sensing element for the ratcheting dial

Name: Samuel Bennett  
Project Role: Research Engineer/Scientist  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: 1  
Contribution to Project: Electronic design of the release/relock mechanism and sensing element for the ratcheting dial

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

Name: Horace Wang  
Project Role: Research Engineer/Scientist  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: 4  
Contribution to Project: Modification of board layout, firmware code for release/relock operation and sensing element

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

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

Name: Ryan Carter  
Project Role: Research Scientist  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: 1  
Contribution to Project: Fabrication of test sockets

Name: Daniel Ballesteros

Project Role: Research Engineer/Scientist  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: 1  
Contribution to Project: Testing of release/relock mechanism

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

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

SANDERS, JOAN E

Previous active grants that have closed:

R01HD060585 (Sanders)

NIH/NICHD

“Measuring in-socket residual limb volume fluctuation”

A112491 (Sanders - PI on subcontract; Wheeler – PI on grant)

Sandia National Laboratories

“Development of instrumented liners and bladder-liners for people with limb loss”

New grant that has started:

W81XWH-18-1-0595 (Sanders)

Department of Defense

“A release/relock socket to enhance volume management and facilitate patient self-care”

GARBINI, JOSEPH L

Previous active grants that have closed:

Boeing Company

“Confined Space Automation”

Boeing Company

“Sanding Assistance Device”

New grants/contracts that have started:

W81XWH-18-1-0595 (Sanders)

Department of Defense

“A release/relock socket to enhance volume management and facilitate patient self-care”

Boeing Advanced Research Center (contract)

“In tank mechanic assist”

Boeing Advanced Research Center (contract)

“Tube bending in process inspection”

Boeing Advanced Research Center (contract)  
“Semi-automated sanding assist device 2019”

HAFNER, BRIAN J

Previous active grant that has closed:

W81XWH-15-1-0458 (Hafner)

Department of Defense

“A novel prosthetic foot designed to maximize functional abilities, health outcomes, and quality of life in people with transtibial amputation”

New grants that have started:

Industry-sponsored grant (Morgan)

Otto Bock Healthcare LP

“Do microprocessor knees improve long-term outcomes following amputation compared to non-microprocessor knees?”

Industry Sponsored Project (Sawers)

Otto Bock and Össur hf

“Development and administration of a fall survey to record and report fall frequency, circumstances, and consequences among lower limb prosthesis users”

W81XWH-18-1-0595 (Sanders)

Department of Defense

“A release/relock socket to enhance volume management and facilitate patient self-care”

FRIEDLY, JANNA L

Previous active grants that have closed:

CE-12-11-4469 (Friedly)

PCORI

“Long term outcomes of lumbar epidural steroid injections for spinal stenosis”

W81XWH-15-1-0291 (Mourad)

USAMRAA

“Non-invasive assessment of sensitized tissue within the residual limbs of amputee patients”

R01HD060585 (Sanders)

NIH/NICHD

“Measuring in-socket residual limb volume fluctuation”

New grants that have started:

W81XWH-18-1-0595 (Sanders)

Department of Defense

“A release/relock socket to enhance volume management and facilitate patient self-care”

2 P30 DK 017047-42 (Morgan)

NIH

“Effects of a community exercise program on physical, physiological, and psychosocial health outcomes in people with diabetic foot ulcers”

1015219\_UWA (Chou; Site PI: Devine)

AHRQ

“Noninvasive nonpharmacological treatments for chronic pain: An update”

**What other organizations were involved as partners?**

Nothing to Report.

**8. SPECIAL REPORTING REQUIREMENTS  
COLLABORATIVE AWARDS:**

Not Applicable.

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

**A Release/Re-Lock Socket to Enhance Volume Management and Facilitate Patient Self-Care**

Log Number: OR170197

Award Number: W81XWH1810595

PI: Joan Sanders Ph.D.

Org: University of Washington

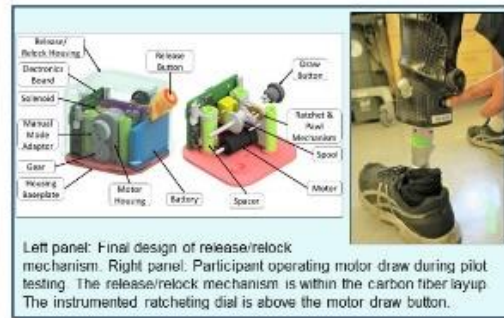
Award Amount: \$2M

**Study/Product Aim(s)**

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

**Approach**

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



**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					█
<b>Estimated Budget (\$K)</b>		<b>\$457</b>	<b>\$514</b>	<b>\$512</b>	<b>\$517</b>

Updated: 09/30/2019

**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 (10% to date)
- CY19 Goals** – Complete lab study, begin field testing
- Complete assessment of release/relock impact on limb fluid volume
  - Recruit trans-tibial amputee participants for field testing
- CY20 Goals** – Continue field testing, begin to assess outcomes data
- Continue outcomes evaluations of release/relock in field tests
  - Conduct interviews to assess value and quality of outcomes data
- CY21 Goals** – Complete field testing, assessment of outcomes data
- Disseminate results
  - Prepare final report
- Comments/Challenges/Issues/Concerns**
- none
- Budget Expenditure to Date - \$253k**

**9. APPENDIX: Submitted manuscript**

Gurrey CJ, Garbini JL, Bennett SP, Wang HY, Allyn KJ, McLean JB, Larsen BG, Sanders JE. Socket release/relock: An innovative mechanism to maintain residual limb volume. *Med Engi Phys.* 2019, submitted

Manuscript Number:

Title: Socket release/relock: An innovative mechanism to maintain residual limb volume

Article Type: Technical Note

Section/Category: Regular Issue Paper

Keywords: residual limb; volume; socket; accommodation; amputee; prosthesis; elevated vacuum; socket fit

Corresponding Author: Dr. Joan E. Sanders, PhD

Corresponding Author's Institution: University of Washington

First Author: Clement J Gurrey

Order of Authors: Clement J Gurrey; Joseph L Garbini, PhD; Samuel P Bennett; Horace Y Wang; Katheryn J Allyn, LCPO; Jake B McLean; Brian G Larsen; Joan E. Sanders, PhD

Abstract: Management of socket fit is challenging for people using lower-limb prostheses because of residual limb volume loss over the day. Releasing socket pressures during sitting (partial doffing) may facilitate recovery and retention of limb fluid volume. The purpose of this research was to develop a system to allow for easy locking pin and socket panel release during sitting and quick relock upon standing. A motor-driven release/relock system (<300 g) housed within the socket, termed the TARPIN, adjusts locking pin tether length, and an instrumented ratcheting dial adjusts socket panel positions. The user operates the release/relock system using buttons on the socket. Pin tether length and ratcheting dial rotation adjustments are recorded on board for later analysis. Testing on three people with transtibial amputation demonstrated that locking pin release (tether lengthened between 5 and 6 cm depending on the participant) was accomplished within 1.5 s and socket relock within 1.5 s. Participants found that their socket fit was more comfortable if they first pulled in the tether and then tightened the panels rather than vice versa.

## Highlights

- A technology to facilitate limb volume recovery during sitting was created
- The motor-driven system weighs <300 g and fits within a cavity in the distal socket
- Locking pin release (5-6 cm partial doff) and relock are both accomplished in <1 s
- An instrumented ratcheting dial tracks cabled-panel socket adjustments
- Pin tether length and ratcheting dial rotation are continuously recorded

1 **Abstract**

2 Management of socket fit is challenging for people using lower-limb prostheses because of  
3 residual limb volume loss over the day. Releasing socket pressures during sitting (partial  
4 doffing) may facilitate recovery and retention of limb fluid volume. The purpose of this research  
5 was to develop a system to allow for easy locking pin and socket panel release during sitting  
6 and quick relock upon standing. A motor-driven release/relock system (<300 g) housed within  
7 the socket, termed the TARPIN, adjusts locking pin tether length, and an instrumented  
8 ratcheting dial adjusts socket panel positions. The user operates the release/relock system  
9 using buttons on the socket. Pin tether length and ratcheting dial rotation adjustments are  
10 recorded on board for later analysis. Testing on three people with transtibial amputation  
11 demonstrated that locking pin release (tether lengthened between 5 and 6 cm depending on the  
12 participant) was accomplished within 1.5 s and socket relock within 1.5 s. Participants found that  
13 their socket fit was more comfortable if they first pulled in the tether and then tightened the  
14 panels rather than vice versa.

15

16 Keywords: residual limb, volume, socket, accommodation, amputee, prosthesis, elevated  
17 vacuum, socket fit

## 18 **Introduction**

19 Prosthesis users report socket fit is the single-most important issue related to use of their  
20 prosthesis<sup>1</sup>. One of the most common causes of prosthetic socket fit problems in people with  
21 limb amputation is residual limb volume loss. The traditional management strategy is to add  
22 prosthetic socks to reduce socket size and accommodate the smaller residual limb. But  
23 reducing socket size further reduces limb fluid volume and may accentuate limb atrophy<sup>2</sup>,  
24 necessitating socket replacement.

25 An alternative accommodation strategy to manage socket size is for prosthesis users to manage  
26 their limb volume. Elevated vacuum (EV) systems do that by drawing soft tissues outward  
27 during ambulation using a mechanical or electric pump to apply vacuum pressure between the  
28 liner and socket. Elevated vacuum has been suggested an effective suspension method and  
29 has been shown to reduce vertical displacement during ambulation [3,4,5,6]. However, EV has  
30 drawbacks, the most common of which is its fault intolerance to air leaks [7,8,9]. EV's continual  
31 maintenance need requires a knowledgeable and often technically savvy user. EV systems may  
32 be replaced after a short time because of user frustration with inconsistent performance.

33 An alternative means to management of limb volume loss is to periodically doff the socket to  
34 allow for limb volume recovery. In transtibial prosthesis users with pin lock suspension, doffing  
35 the socket during 20 to 30-minute rest periods after activity induced significantly greater limb  
36 fluid volume during subsequent ambulation than not doffing [10,11]. However, if the socket was  
37 enlarged but the pin was not released then fluid volume recovery and retention were reduced  
38 [12,13]. These results suggest that pin release is a key aspect of partial doffing as an effective  
39 accommodation strategy.

40 Partial doffing with pin release can be challenging to perform in user free-living environments.  
41 particularly for people who are active and do not have time to repeatedly remove clothing to  
42 partially doff their socket during the day.

43 The purpose of this research was to create a technology to overcome these challenges. We  
44 created a mechanism to easily partially doff and re-don a transtibial prosthesis with pin lock  
45 suspension. The system tracks the release and tightening of the locking pin as well as the  
46 panels of a cabled-panel adjustable socket, creating a record of socket adjustment that may be  
47 useful towards patient care.

## 48 **System Design**

49 The system allows rapid donning, partial doffing, and full doffing with easy-to-use mechanisms.  
50 It is made up of: (1) a release/relock system, termed the TARPIN, that executes locking pin  
51 release and relock and records tether length changes over time; and (2) an instrumented  
52 ratcheting dial that executes socket panel release and panel retightening and records dial angle  
53 changes over time.

### 54 *TARPIN Release/Relock Mechanism*

55 The main component of the release/relock mechanism is a motor assembly that drives two  
56 stainless steel gears connected to a stainless-steel spool (Fig. 1). The motor selected  
57 (1724A006SRIEH2-4096, Micromo, Clearwater, Florida) provides sufficient torque and speed to  
58 assist the donning (relock) process in a timely manner while still fitting inside an embedded  
59 housing in a prosthetic socket. The motor assembly output torque is 359 mN·m, and the output  
60 speed is 57.2 RPM. The motor assembly includes a gearhead with a 152:1 gear ratio and a 2-  
61 channel magnetic encoder with 4096 counts per revolution on the motor shaft, producing  
62 622,592 counts per revolution at the output shaft.

63 A tether extends between the spool and the distal end of the user's prosthetic liner. It is  
64 connected to the prosthetic liner via a threaded custom locking pin. When the user activates the  
65 mechanism via the draw button on the posterior distal socket (Fig. 2), the motor drives the  
66 spool, and the tether winds around the hub of the spool (12.70 mm diameter). The tether

67 (TwinLine Braided Vectran 200, Kuraray, Tokyo, Japan) is a high strength multifilament yarn  
68 spun from liquid crystal polymer and has a diameter of 0.9 mm. Each spool rotation draws in 4.0  
69 cm length of cable. The cable draw rate is 6.0 cm/s. The system is controlled via a  
70 microcontroller on a surface-mount electronics board located on the medial side of the  
71 assembly. The board includes a microSD card to store motor rotation data. A 3.7V, 2000 mA-h  
72 battery is mounted on the lateral side of the assembly. The system operates for about 1 week  
73 on a single charge, depending on how frequently the user makes an adjustment. This time  
74 duration may be enhanced using power management strategies, e.g. powering down the  
75 system when the prosthesis is not worn.

76 A housing fabricated using a 3D printed polymer (VeroClear, Stratasys, Eden Prairie,  
77 Minnesota) surrounds the entire mechanism and is embedded into the prosthetic socket during  
78 fabrication. The housing is designed so that it envelopes a 4-hole adaptor (L-67400 Icelock  
79 Alloy 4-hole 674, Ossur, Reykjavik, Iceland) in the distal socket. Load from the socket is  
80 transferred through the 4-hole adaptor through the aluminum spacers on the baseplate to a  
81 pyramid adaptor beneath the socket. The design adds 4.6cm height to the prosthesis.  
82 Lamination within the carbon fiber prosthesis reinforces the structure and protects the internal  
83 components of the release/relock mechanism. The dimensions of the housing are 8.1cm X  
84 8.1cm X 6.6cm.

85 To simplify positioning the mechanism into the socket during installation, we attached the  
86 mechanism to an aluminum baseplate so that the entire TARPIN unit is easily attached or  
87 removed from the socket. The mechanism including the housing and battery weighs 290 g.

88 The user operates the mechanism using two buttons mounted to the walls of the housing that  
89 extend through holes in the socket. The draw button on the posterior aspect activates the  
90 winding action of the motor under controller operation as discussed below (Fig. 2). The release  
91 button, which looks similar to a traditional pin lock release button, activates the solenoid to

92 release the pawl so that the user can back drive the motor and partially doff or fully doff the  
93 socket. A USB-C port from the electronics board is externally accessible on the medial side,  
94 allowing the battery to be recharged when needed.

#### 95 *Instrumented Ratcheting Dial*

96 The purpose of instrumenting the ratcheting dial is to track the socket size adjustments made by  
97 the user and store that data with release/relock data on the electronics board in the TARPIN  
98 housing. The combination of data from the ratcheting dial and release/relock system monitor  
99 user socket size adjustments, doffs, and partial doffs over time for later analysis by patients and  
100 their prosthetists.

101 To create the instrumented ratcheting dial, we modified a commercially available ratcheting dial  
102 (RevoFit, Steamboat Springs, Colorado) from its original configuration by instrumenting it with a  
103 sensor to track rotation during use (Fig. 3). This modification requires a custom dial housing. The  
104 housing holds a single resistive rotary sensor (potentiometer) of dimension 15.3 mm X 15.9 mm  
105 X 3.0 mm (RDC803101A, Alps Electric, Santa Clara, California). The ratcheting dial attaches to  
106 the rotary sensor using a custom shaft adaptor that is press fit into the grooves on the bottom of  
107 the dial. The shaft end of the adaptor is press fit into the rotating center of the sensor, locking in  
108 with tabs on the original part of the ratcheting dial. A small hole is drilled to allow the tab to be  
109 easily unlocked to service the rotary sensor as necessary. As the ratcheting dial is rotated by  
110 the user, the inside of the sensor rotates relative to the dial housing and outputs a signal. Wires  
111 run from the rotary sensor through tubing in the socket to the electronics board within the  
112 TARPIN mechanism described above. The housing for the instrumented dial sensor is  
113 laminated within the walls of the prosthetic socket during socket fabrication. The custom dial  
114 housing increases the distance the sensor protrudes from the socket compared with the original  
115 ratcheting dial by 7.5 mm.

116 The resistive rotary sensor outputs a two-phase signal where the two phases, each spanning a

117 range of 330 degrees, are offset by 180 degrees. The signal is run through an ADC on the  
118 electronics board and then to the microcontroller for data storage. As a post-processing effort,  
119 the data are converted to number of rotations. Rotations during both tightening and release are  
120 recorded.

#### 121 *Incorporation of Hardware during Socket Fabrication*

122 The release/relock housing, the 4-hole adaptor, and the instrumented dial housing are  
123 incorporated into the socket during fabrication. The remaining parts – the metal baseplate,  
124 release/relock mechanism, electronics board, battery, release button, draw button  
125 (MMP0120/AGNP, Bulgin/Elektron Technology, Santa Fe Springs, California), and the  
126 remaining parts of the instrumented ratcheting dial – are added after the socket is completed.

127 A traditional layup procedure on a foam positive is used to make the socket. Two layers of  
128 carbon fiber are laminated over the positive. After sanding to provide a rough surface, the  
129 technician affixes the instrumented dial housing and plastic tubing for the dial cable to the  
130 surface using an adhesive (PLUSeries™, Fabtech Systems LLC, Everett, Washington). The  
131 TARPIN housing is attached to the 4-bolt adaptor. Another two layers of carbon fiber separated  
132 by two layers of Nyglass lamination are added. The socket is sanded down to expose the  
133 cavities for the release/relock button and the instrumented ratcheting dial. Panels are cut from  
134 the socket and attached to a cable threaded through the plastic tubing to the ratcheting dial.

#### 135 *TARPIN Electronic Hardware and Control System*

136 The TARPIN system runs on an NXP LPC54114 microcontroller. A TI DRV8835 motor driver is  
137 used to drive the motor and solenoid. There is an LSI/CSI LS7183N quadrature decoder to read  
138 back the encoder output. There is also a TI ADS7828 ADC to handle the analog inputs of the  
139 resistive rotary sensor and the motor. The motor runs at 6.0 V. A detailed schematic of the  
140 electronic system is shown in Appendix 1.

141 The control system that operates the TARPIN is illustrated in Fig. 4. The user dons an  
142 elastomeric liner with the custom locking pin tethered to the TARPIN mechanism. The tether  
143 passes through the hole in the distal socket (tether length up to 45cm, typically 30cm is used).  
144 While sitting or standing, the user dons the prosthesis. The user pushes the draw button on the  
145 posterior aspect of the socket once to activate the motor. The motor winds the tether around the  
146 spool, drawing the user's residual limb and liner into the prosthesis. The system monitors motor  
147 current to determine when a threshold (high) is met, indicating that the tether is sufficiently  
148 taught to lock the solenoid. After transitioning from sitting to standing (if initially sitting), the user  
149 may press the draw button again if there is slack in the tether, e.g. from the liner umbrella  
150 compressing upon standing. To partially doff the socket, the user pushes the release button  
151 once. This action powers on the solenoid that pushes the pawl off the ratchet. The system will  
152 now allow the user to pull the residual limb out of the socket, back driving the motor. When the  
153 partial doff threshold (distance specified in controller software) is met, the system powers off the  
154 solenoid and locks. To fully release the tether and doff the socket, the user presses the release  
155 button. If the system is previously in partial doff mode, then a single button push will fully  
156 release the tether. Otherwise, the user holds the release button continuously. This action  
157 activates the solenoid to allow the user to pull the limb out of the socket.

#### 158 *Manual Operation*

159 The release/relock system allows the user to manually draw in the tether in case of emergency,  
160 power failure, or malfunction. An adaptor piece is mounted to the spool shaft (Fig. 1), allowing a  
161 removable crank to be attached through the anterior aspect of the socket. The crank allows the  
162 user to manually turn the spool, winding the cable to draw the tether into the prosthetic socket  
163 (Appendix 2). Currently, the manual crank is not part of the mechanism described above and  
164 must be carried separately.

165 A push and hold of the release button beyond the pressure required to electronically activate the

166 release mechanism allows the user to doff the prosthesis even if there is no power. This strong  
167 pressure applied by the user actuates the release plunger.

## 168 **Characterization of Sensitivity and Bench Testing**

### 169 *Release/relock*

170 Sensitivity of the motor encoder on the TARPIN is determined using the step counts per  
171 revolution of the digital motor encode and the diameter of the spool winding the tether. The  
172 tether cable flattens from use from 0.9 mm to 0.5 mm. Every three revolutions of the spool add  
173 one layer of cable thickness. Assuming a cable length of 30cm, at the fully donned position, the  
174 sensitivity of the motor encoder is 0.0128 cm/degree. This information is used to convert motor  
175 encoder data that was stored to the SD card during operation to units of distance (cm).

176 To determine the length of tether to release for execution of partial doffing, the microcontroller  
177 uses the tether distance measured when the pin was most recently donned (fully seated in the  
178 socket) as a reference. This reference is used because the depth of the pin may vary slightly  
179 from one don to another. The partial doffing distance is maintained.

180 Bench tests were performed to determine the electrical current draw of the release/relock  
181 system under load. The socket with the incorporated release/relock mechanism was inverted  
182 and mounted to the bottom of a steel plate fastened to a lab bench such that it overhung the  
183 bench (Appendix 3). The tether hung downward and was statically loaded with weights. Loads  
184 of 0 N, 28 N, and 51 N were applied, corresponding to 0%, 50%, and 90% of the motor's  
185 maximum allowable torque. Current draw for each of the load levels (data collected over 10 s) is  
186 summarized in Table 1.

187 During clinical use, the TARPIN's current draw varies according to the user's actions. To move  
188 from the fully doffed to the fully donned position, the current draw is about 75.0 mA until the pin  
189 reaches the bottom of the socket. Then there is a current spike of 550 mA over about 0.33 s,

190 after which the motor shuts off. If the tether length is 45.0cm in the doffed state (the maximum  
191 length used in participant studies to date) then it takes approximately 7.5 s to reach the donned  
192 state, and the power consumption is approximately 3.1 W/s. From the partial doffed to the fully  
193 donned state (~5cm), it takes about 1.5 s and the power consumption is about 0.9 W/s.

#### 194 *Instrumented dial*

195 A bench setup is used to characterize the sensitivity of the resistive rotary sensor in the dial  
196 (Appendix 4). The resistive rotary sensor is mounted to a digital reference sensor (DRS), a  
197 rotary encoder that has a resolution of 1024 pulses per revolution (E6B2-CWZ3E, Omron,  
198 Kyoto, Japan). A shaft adaptor links the rotation of the resistive rotary sensor to that of the DRS  
199 shaft. Signals from both the resistive sensor and the DRS are sent to the electronics board and  
200 data stored to the microSD card. A custom routine written on the microcontroller is used to  
201 execute the calibration.

202 During calibration, the shaft is rotated three consecutive revolutions clockwise and then three  
203 revolutions counterclockwise back to the starting position. Three rotations is representative of  
204 that executed by people with transtibial amputation adjusting their socket panels from tight to  
205 fully released. Note that there is a 1:4 gear ratio between the shaft and the dial, thus three  
206 revolutions of the shaft correspond to 12 revolutions of the dial. The data are downloaded, and a  
207 processing script in MATLAB (MathWorks, Natick, Massachusetts) is used to perform a least-  
208 squares fit to dial sensor and DRS data. The instrumented dial sensor has a theoretical  
209 sensitivity of 12.4 counts/degree (4096 counts per 330 degrees). The resolution of the  
210 measurement is less than 0.1 degree.

#### 211 **Amputee Participant Testing**

212 The system was tested on three participants with transtibial amputation. The study was  
213 approved by an Institutional Review Board, and all participants signed approved informed

214 consent forms before study procedures were initiated. Sockets were fabricated as described  
215 above and a testing protocol conducted in the laboratory on a treadmill. Data from the TARPIN  
216 and instrumented ratcheting dial were collected continuously. After donning their test prosthesis  
217 and ensuring the fit was comfortable, participants conducted 12 walk/sit cycles – walking for 3  
218 minutes and sitting for 10 minutes. During each sit, participants fully released the socket panels  
219 (pulled out the ratcheting dial) and released the tether from the donned to the partial doffed  
220 position (5.1cm) using the release button. After 10 minutes, participants drew in the tether to the  
221 donned position using the draw button and adjusted the socket panels to a comfortable setting  
222 by rotating the instrumented ratcheting dial.

223 All users were satisfied with the functionality of the system and appreciated the range of  
224 adjustability with the tethered pin and socket panels. Participants found that their fit was more  
225 comfortable if they first pulled in the tether and then tightened the panels rather than vice versa.

226 Exemplary data from one participant showed that the limb did not achieve exactly the same  
227 depth into the socket during each don cycle (Fig. 5). It varied over a range (maximum–  
228 minimum) of 0.3cm. This was likely due to changes from cycle to cycle in the amount of weight  
229 bearing of the liner umbrella when the tether locked. Despite changes in the don reference over  
230 time, the TARPIN system released the tether to the partial doff position a mean (standard  
231 deviation) distance of 5.1 ( $\pm 0.13$ )cm (target 5.1cm). Variability in the partial doff tether distance  
232 from one cycle to the next may have resulted from different levels of tension in the tether when  
233 the participant pulled the liner and limb out of the socket.

234 Data from the instrumented ratcheting dial showed a relatively consistent shaft angle from one  
235 walking cycle to the next (Fig. 5). The shaft angle across all walks was within a 9.3-degree  
236 range, meaning the participant adjusted the outside dial consistently within a 37.2-degree range  
237 (less than 1/8 of a turn). Shaft angle was more variable when the instrumented ratcheting dial  
238 was released during sitting. This may reflect variability in cable tension at the time of panel

239 release.

240 **Conclusion**

241 The system executes socket release and relock, each within 1.5 s. Participants found that their  
242 socket fit was more comfortable if they first pulled in the tether and then tightened the panels  
243 rather than vice versa.

244

245 Word count: 3492

246

247 Competing interests: None declared

248 **References**

- 
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### Figure Legends

**Figure 1. Mechanical configuration of the TARPIN system.** Left panel: A plastic housing embedded in the socket during socket fabrication protects the release/relock mechanism. Right panel: Electronics, motor housing, and release button removed to show mechanism. The tether to the elastomeric liner wraps around the spool (tether not shown). The USB port (not shown) is on the back side of the electronics board at a similar height to the release button.

**Figure 2. Using the system for donning and doffing.** Left panel: A push button on the posterior distal aspect of the socket (draw button) activates the motor to draw in the tether. Right panel: A push button on the lateral aspect of the socket (release button) releases the tether to the partial doff or full doff position.

**Figure 3. Mechanical configuration of the instrumented ratcheting dial.** A resistive rotary sensor is mounted within a custom housing that also holds the ratcheting element.

**Figure 4. TARPIN Control Flowchart.**

**Figure 5. Data collected from a participant using the system.** Upper panel: TARPIN data showing tether position in mm. Lower panel: Instrumented ratcheting dial data showing shaft angle in degrees and number of complete rotations. Minima (socket panels drawn in) occur during the walking parts of the protocol, and maxima (socket panels released) occur during the sitting with socket and pin release.

Figure 1  
[Click here to download high resolution image](#)

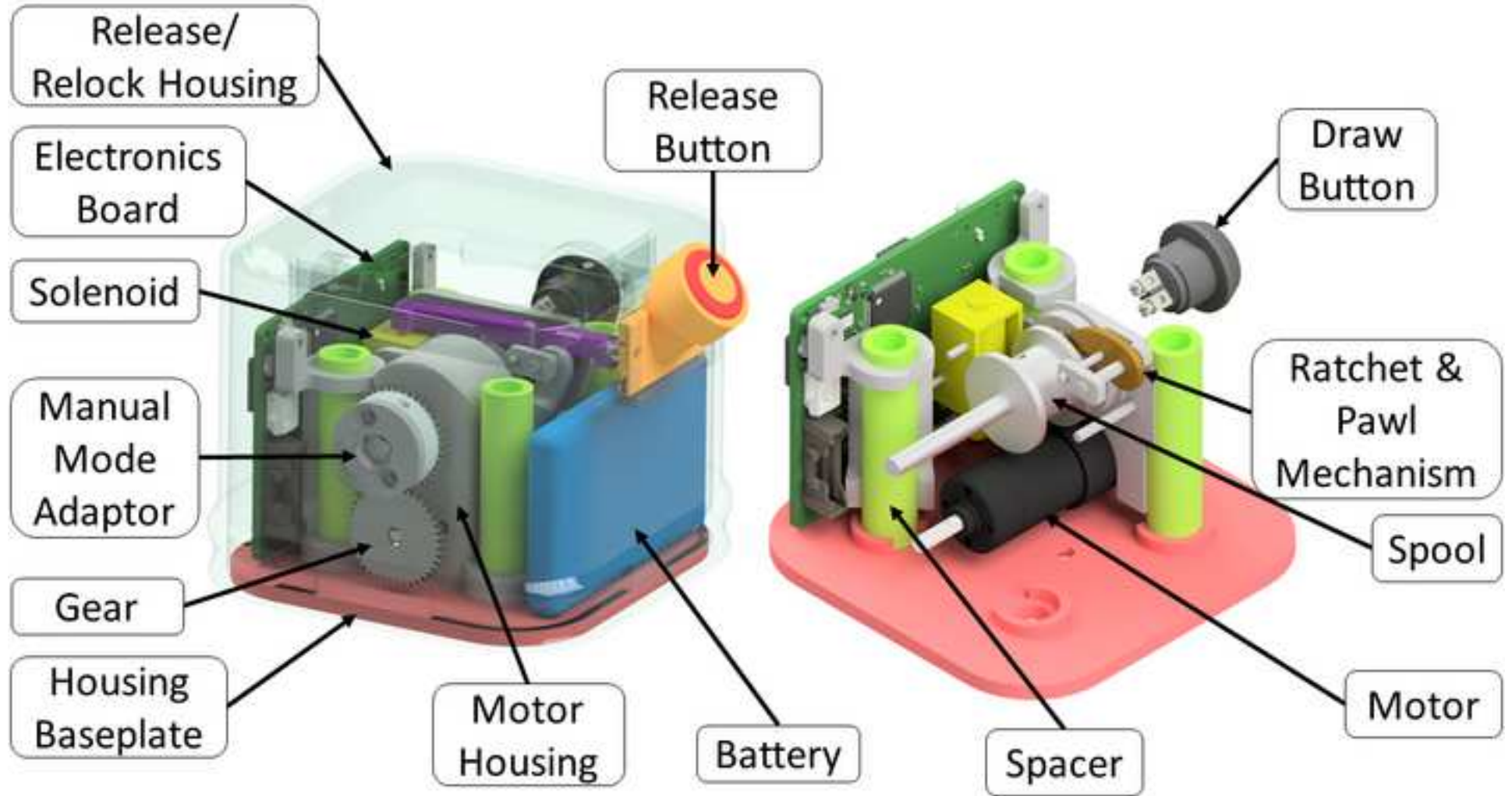


Figure 2  
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Figure 3  
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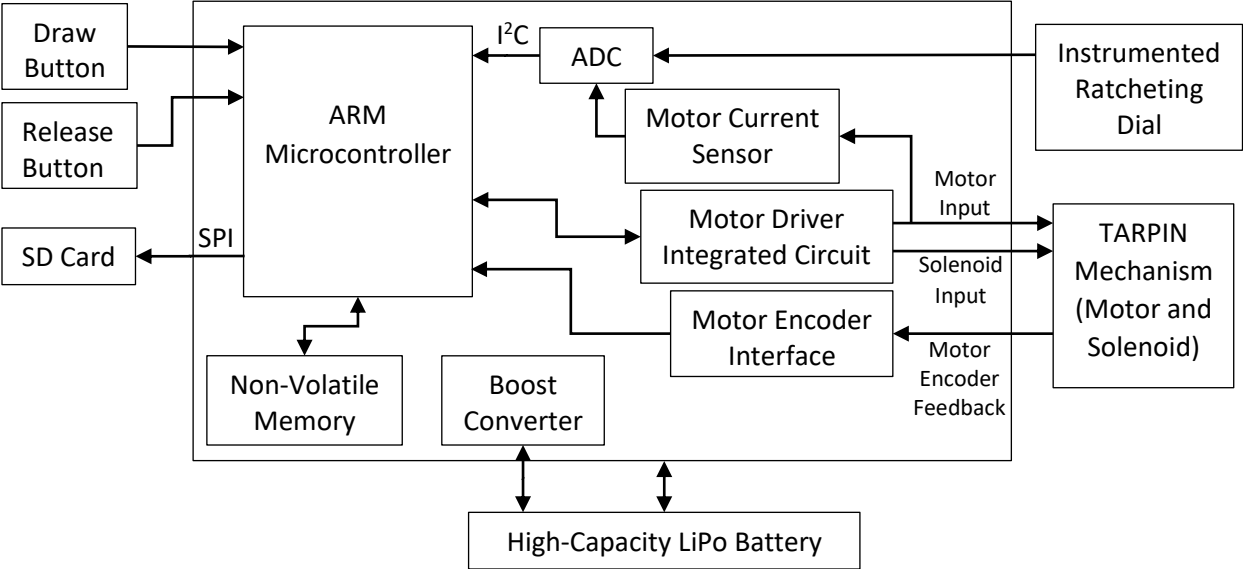




**Table 1. Current draw (in mA) from the motor to pull into the socket three applied loads**

	<b>Applied Load</b>		
	<b>0 g</b>	<b>1400 g</b>	<b>2000 g</b>
<b>Mean</b>	55.5	348.4	509.0
<b>SD</b>	2.9	18.0	18.4

**Appendix 1. Electronics schematic**



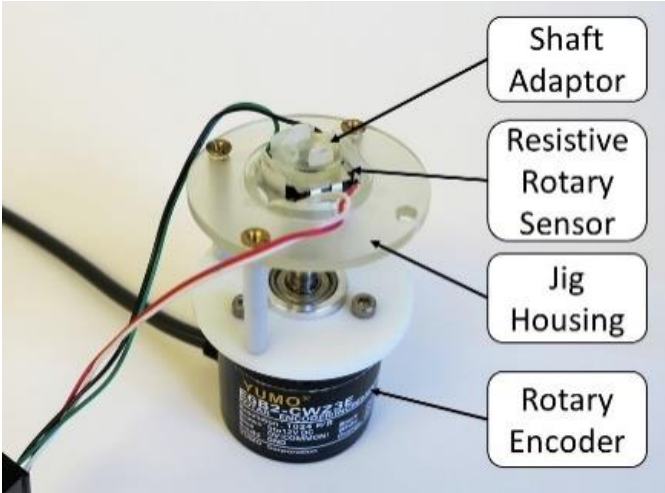
**Appendix 2. Crank for manual TARPIN operation**



**Appendix 3. TARPIN bench testing set up**



**Appendix 4.** Set up for calibration of instrumented ratcheting dial



# 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

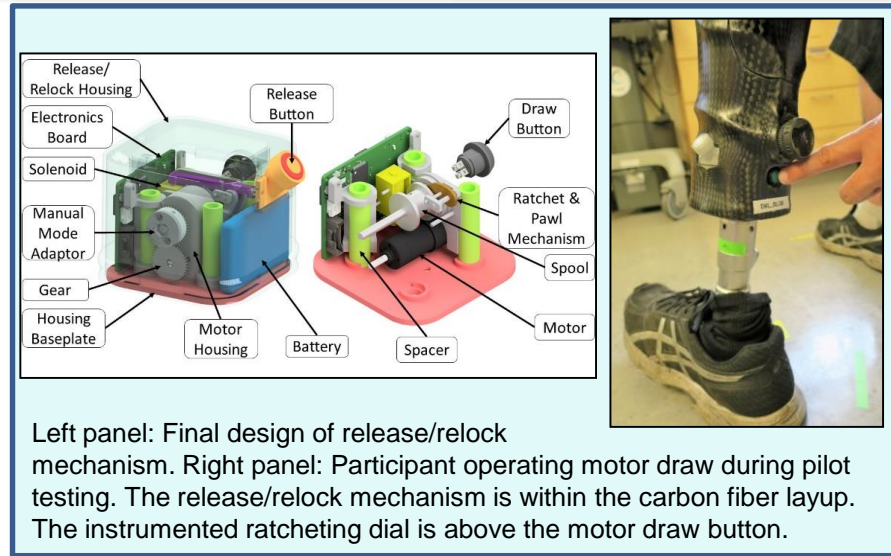
Award Amount: \$2M

## Study/Product Aim(s)

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

## Approach

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



## 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				■	
<b>Estimated Budget (\$K)</b>		<b>\$457</b>	<b>\$514</b>	<b>\$512</b>	<b>\$517</b>

Updated: 09/30/2019

## 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 (10% to date)

**CY19 Goals** – Complete lab study, begin field testing

- Complete assessment of release/relock impact on limb fluid volume
- Recruit trans-tibial amputee participants for field testing

**CY20 Goals** – Continue field testing, begin to assess outcomes data

- Continue outcomes evaluations of release/relock in field tests
- Conduct interviews to assess value and quality of outcomes data

**CY21 Goals** – Complete field testing, assessment of outcomes data

- Disseminate results
- Prepare final report

## Comments/Challenges/Issues/Concerns

- none

**Budget Expenditure to Date - \$253k**