




Performance of an auto-adjusting prosthetic socket during walking with intermittent socket release

Journal of Rehabilitation and Assistive Technologies Engineering
Volume 9: 1–14
© The Author(s) 2022
Article reuse guidelines:
sagepub.com/journals-permissions
DOI: 10.1177/20556683221093271
journals.sagepub.com/home/jrt


Ethan J Weathersby¹, Andrew C Vamos¹, Brian G Larsen¹, Jake B McLean¹, Ryan V Carter¹, Katheryn J Allyn¹, Daniel Ballesteros¹ , Horace Wang¹, Nicholas S deGrasse¹, Janna L Friedly², Brian J Hafner², Joseph L Garbini³, Marcia A Ciol² and Joan E Sanders¹ 

Abstract

Introduction: A challenge in the engineering of auto-adjusting prosthetic sockets is to maintain stable operation of the control system while users change their bodily position and activity. The purpose of this study was to test the stability of a socket that automatically adjusted socket size to maintain fit. Socket release during sitting was conducted between bouts of walking.

Methods: Adjustable sockets with sensors that monitored distance between the liner and socket were fabricated. Motor-driven panels and a microprocessor-based control system adjusted socket size during walking to maintain a target sensed distance. Limb fluid volume was recorded continuously. During eight sit/walk cycles, the socket panels were released upon sitting and then returned to position for walking, either the size at the end of the prior bout or a size 1.0% larger in volume.

Results: In six transtibial prosthesis users, the control system maintained stable operation and did not saturate (move to and remain at the end of the actuator's range) during 98% of the walking bouts. Limb fluid volume changes generally matched the panel position changes executed by the control system.

Conclusions: Stable operation of the control system suggests that the auto-adjusting socket is ready for testing in users' at-home settings.

Keywords

prosthesis, amputee, adjustable socket, residual limb, volume accommodation, socket release, prosthetic, control system, trans-tibial, socket fit, interface stress, pressure, pistoning

Date received: 25 June 2021; accepted: 24 March 2022

Introduction

Prosthesis users report that socket fit is the single-most important issue related to use of their prosthesis.^{1,2} A primary source of socket fit problems is a change in residual limb volume. A socket that automatically adjusts its size in response to residual limb volume change and maintains fit may benefit people using a lower limb prosthesis. Unlike traditional methods to accommodate volume fluctuation

¹Department of Bioengineering, University of Washington, Seattle, WA, USA

²Department of Rehabilitation Medicine, University of Washington, Seattle, WA, USA

³Department of Mechanical Engineering, University of Washington, Seattle, WA, USA

Corresponding author:

Joan E Sanders, Bioengineering 355061, University of Washington, 3720 15th Ave NE, Seattle WA 98195, USA.

Email: jsanders@uw.edu



Creative Commons Non Commercial CC BY-NC: This article is distributed under the terms of the Creative Commons Attribution-NonCommercial 4.0 License (<https://creativecommons.org/licenses/by-nc/4.0/>) which permits non-commercial use, reproduction and distribution of the work without further permission provided the original work is attributed as specified on the SAGE and Open Access pages (<https://us.sagepub.com/en-us/nam/open-access-at-sage>).

(e.g., changing sock ply; manually adjusting socket panels; and hand pumping bladders), an auto-adjusting socket relieves users of the burden of continually sensing their socket fit and determining if and how much adjustment is needed. An auto-adjusting socket may improve satisfaction and limb health and reduce the risk of a fall, particularly for people with poor limb sensation who have difficulty sensing their socket fit.

The first commercial auto-adjusting prosthetic socket was a purely mechanical system that used a series of bladders and mechanical valves to adjust socket size.³ Several research groups extended from this work to pursue electronic automatic size-adjusting sockets that used a powered actuator to change socket size and a pressure sensor for feedback control.^{4–14} A handful achieved a closed-loop control system,^{5–7,10,13} but only Pirouzi et al.⁵ tested a system on people with lower limb amputation. Pirouzi et al.⁵ demonstrated that vertical limb displacement at the posterior brimline of the socket varied linearly with actuator pressure during standing with cyclic weight bearing, suggesting that actuator pressure could be used to control vertical limb displacement. However, no walking tests were conducted. In testing on a participant with transhumeral amputation, Razak et al.'s¹⁰ control system was unstable and had to be changed to open-loop operation to avoid saturation, that is, the actuator moving to and staying at the end of its range. More recently, Gu et al.'s¹³ transhumeral control system, tested on an able-bodied participant, was shown to maintain consistent limb contact pressures during lifting.

We extended from this work to create an automatic movable-panel socket that adjusted the socket size for people with transtibial amputation based on liner-to-socket distance data collected using sensors embedded within the surrounding socket wall. We term the measurement “sensed distance.” We used inductive distance sensing rather than pressure sensing because it has better sensitivity and resolution, and during testing on participants with transtibial amputation consistently demonstrated a linear relationship with socket size.^{15–17} The linear relationship between the actuator variable (panel position) and the sensed variable (distance) overcame at least part of the control system instability problem experienced by Razak.¹⁰ In clinical testing on 10 people with transtibial amputation, when socket size was gradually increased or decreased, the sensor picked up the initial degradation of fit sooner than a practitioner visually inspecting the participant's gait or the participant sensing a need for socket adjustment.¹⁸

Towards the objective of developing a socket capable of automatically adjusting socket size before the user detects a change in socket fit, we integrated sensors into a motor-driven adjustable panel socket operated using a microprocessor-based control system.¹⁹ The microprocessor was programmed to adjust the radial position of the

socket panels to maintain a target sensed distance during walking. In this previous study, the target distance was specified by the researcher based on results from interactive fitting sessions with each participant. The feedback variable used in the control system, termed the “socket fit metric (SFM),” was the sensed liner-to-socket distance at a posterior mid-limb location. The control system adjusted panel position to maintain the SFM at the target distance. The integral of absolute error (IAE) was used as a metric for characterizing how well the control system performed. IAE is a standard measure in control system engineering.²⁰ It indicates how well a closed-loop control system maintains the feedback variable (i.e., SFM) at its target value (i.e., the target distance specified by the researcher). Results from 10 transtibial prosthesis users walking on a treadmill for bouts of at least 4 min demonstrated that the automatic-adjusting system achieved an IAE in socket panel position of 0.001 mm–0.005 mm¹⁹. The control system maintained the SFM at its target within about 1.1% of the thickness of a 1-ply cotton sock,²¹ which would be adequate for this application.

While the control system performed well and was stable, it did not account for disturbances to the limb-socket system that would be introduced during clinical use. In their free-living environments, prosthesis users do not walk continuously. Instead, their walking is interrupted by bouts of sitting and standing. Bodily position and activity changes may perturb and destabilize the control system. Conducting socket release between walking bouts would also be expected to accentuate instability since it has been shown that releasing socket pressures on a transtibial residual limb by partially or fully doffing the socket, or by releasing socket panels increases limb fluid volume.^{22–24} An increase in limb fluid volume would be expected to disturb the sensed distance and challenge the control system at the outset of the next walking bout.

The primary objective of this study was therefore to determine if, in a group of participants with transtibial amputation, conducting socket release during sitting and then retightening in preparation for walking destabilized the control system for a socket that automatically changed size during walking to maintain fit. If the socket demonstrated good stability in a group of prosthesis users, it would be considered ready for at-home testing.

Methods

Participants

People were included in this study if they were at least 18 years old, had a transtibial amputation at least 6 months prior, were using a definitive prosthesis, and were capable of walking on a treadmill for one 5-min bout and then multiple 2-min bouts separated by 10-min sits. Their residual limb

needed to be at least 9 cm long from the mid-patellar tendon to the distal end of the limb (for bioimpedance analysis). Exclusion criteria included presence of skin breakdown and use of a walking aide (e.g., cane or walker). Participants were required to have locking pin suspension in their traditional socket. We also required participants had few or no pads inside their socket so that we could accurately scan and duplicate the socket. A University of Washington Institutional Review Board approved all study procedures (IRB #00001779), and written informed consent was obtained from each participant before study procedures were initiated. Given the objective to determine if the auto-adjusting socket was ready for take-home testing, we elected to study a sample of six individuals. If the socket demonstrated stable performance on all six participants, then we would consider it appropriate to continue testing in user take-home environments.

Socket fabrication

Each participant's traditional socket was scanned so that we could duplicate its shape for the investigational prosthesis. The investigational prosthesis was fabricated with three adjustable panels located on load-tolerant areas of the residual limb (anterior medial, anterior lateral, and posterior midline) (Figure 1). Panel size was maximized so as to impact socket volume change while avoiding bony prominences at the anterior distal tibia, fibular head, and tibial crest—areas that may be sensitive to compression. Sensors that measured the distance between the liner and socket,^{16,25–27} termed socket fit sensors, were positioned within the socket wall during fabrication at the posterior medial mid-limb, the posterior lateral mid-limb, and the anterior distal limb (Appendix 1). The stance phase minima from the two posterior channels were used in the automatic, panel position adjustment algorithm. The anterior distal channel was used to detect walking, implemented the same way as in our previous study.¹⁶ All sockets were made with tether suspension.

To adjust the socket size, we placed direct current (DC) micromotors in frames that spanned over each panel. Each frame was affixed to the outside of the socket using custom threaded mounts positioned within the socket wall during fabrication (Figure 1, right panel). Each motor included an encoder and gearhead and weighed 26 g (model 1717006SR 1EH2-4096 15A152:1+MG03, Faulhaber (Micromo), Clearwater, Florida). The motor unit was of diameter 17.1 mm and length 40.8 mm. The frames and motors added 865 g to the overall weight on the socket. The motor drove gearing and a winch assembly that translated the motor's rotation into radial displacement of the panel, as described in our prior work.²⁸ Unlike cabled-panel sockets, this design allowed the panel to be pulled radially outward beyond the surrounding socket and relieve panel contact with the residual limb. Further, a universal joint at the connection of

the panel to the winch minimized stress concentrations at the edge of the panel. Because of these design features, no cushioning material needed to be placed on the inside surface of each panel as with a traditional cabled-panel socket. A cable connection to a PC ran a virtual instrument (VI) (LabVIEW National Instruments) that adjusted the panels in 1-step increments.²⁸ Each step induced a 0.25-mm radial displacement in each of the three panels. A panel position of 0.00 mm was defined as the position where the panels were flush with the surrounding socket. When the socket was put in auto mode, which was activated using the VI, the control scheme described below was implemented.

Auto-adjustment algorithm

The auto-adjustment algorithm operated during all walking bouts. It started when continuous walking was detected. It operated using the VI, implementing a custom program similar to that described in our previous work.¹⁹ The diagram in Figure 2 illustrates how the auto-adjusting socket operated. Consider a user who starts with a comfortable socket fit at point "A" in the diagram. The socket fit metric (SFM) value at this proper fit is termed the "set point." The user then gains limb volume during walking and the limb shifts closer to the socket wall, moving to position "B" on the diagram. The auto-adjusting socket reacts by increasing socket size to return the user to the SFM set point, traveling along the blue line to arrive at position "C." The SFM is now the same as at the start, but the socket is larger because of the person's increase in limb volume. Later, the user sits for an extended period (without socket release), moving to position "D" on the diagram. The person starts walking, and the auto-adjusting socket reacts by decreasing socket size to return the user to the SFM set point, traveling along the green line to arrive at position "E." The user is now again at the same SFM as at the start, but the socket size is smaller because of the decrease in limb volume during sitting. The auto-adjusting socket sampled at 32 Hz. The maximum adjustment rate was 1 change per second.

To program the auto-adjusting socket for an individual user, we first executed a test in the lab to characterize the user's plant gain, the change in SFM induced by a change in socket volume (slope of the red, blue, and green lines in Figure 2). The participant walked at a self-selected speed on a treadmill while the researcher adjusted the socket in 0.25-mm increments across the user's tolerated socket size range.¹⁶ The plant gain is the slope of the least-squares fit to SFM (in counts) plotted against panel position (in mm). Programmed into the socket's microcontroller, the plant gain is used to calculate in real time the change in panel position the auto-adjusting socket should make when the user's SFM deviates from its set point.

As described in the testing protocol below, the researcher operated the VI via a computer interface to adjust socket size

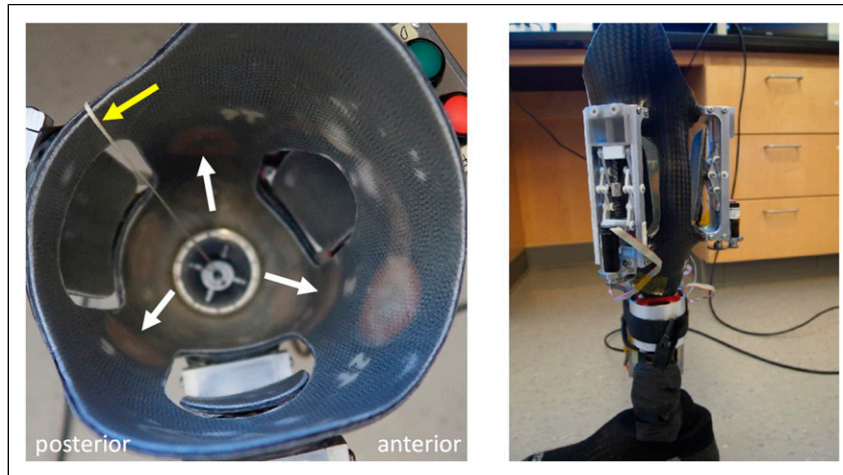


Figure 1. Instrumented investigational prosthesis. Left: Inside view of socket showing sensors at two posterior mid-limb and one anterior distal location (white arrows). The tether (yellow arrow) connects to a short pin (not shown) that provides suspension. The red and green buttons at the top right are for operation of the powered tether system. Right: Motors supported to frames mounted to the socket move the panels radially inward and outward based on socket fit. The mechanism to control tether length (gray cylinder) is mounted beneath the socket.

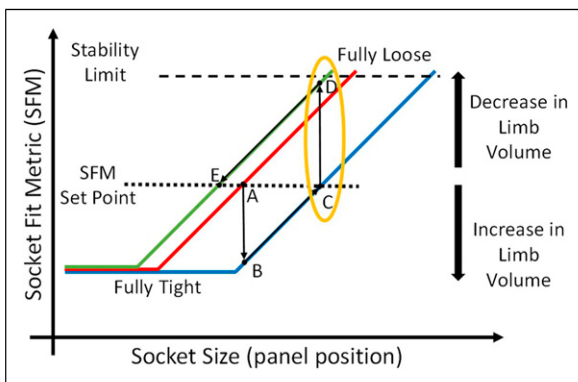


Figure 2. Diagram illustrating the design of the control system. The socket fit metric (SFM) is the mean of the measurements from the two posterior mid-limb sensors. Slopes of the green, red, and blue lines are the plant gain. Deviations from the set point reflect changes in socket fit. An increase in limb fluid volume (“A” to “B”) causes the controller to increase socket size to return to the set point (“B” to “C”). A decrease in limb fluid volume (“C” to “D”) causes the controller to decrease socket size to return to the set point (“D” to “E”). A goal of socket release/relock is to reduce volume loss during sitting, that is, retard the change from “C” to “D.”

during sitting between bouts of walking. In addition, a motor-driven system mounted beneath the socket, similar to that described in our prior publication,²⁹ was used to draw in and release a tether to the liner.

Testing protocol

Once the investigational prosthesis was fabricated and instrumented, the participant visited the lab for a fitting and

evaluation session. The research prosthetist evaluated the participant’s gait and adjusted alignment of the foot and length of the prosthesis if needed. The participant walked on the treadmill at different panel positions (socket sizes) to ensure the socket was comfortable and to ensure the instrumentation performed properly.

On a separate day, the testing protocol was conducted. After arriving at the lab, participants sat for at least 10 min with their traditional prosthesis donned to achieve a homeostatic condition. Participants then doffed their prosthesis, and their residual limb was instrumented with thin surface electrodes that are part of a bioimpedance system which was used to monitor limb fluid volume as described in detail in prior publications.^{23,30} The electrodes were configured to monitor the anterior region and the posterior region of the residual limb. Data collection from the limb fluid volume monitoring system and the socket fit sensors was initiated. A plant gain test was conducted, then the socket was returned to the participant-preferred socket size. The researcher then used the VI to put the socket in the auto-adjustment mode.

A series of eight sitting and walking cycles was conducted (Figure 3). At the beginning of each sit, the panels were loosened, and the locking pin tether was released 5 cm. The participant then sat for 10 min in a relaxed position with his or her thighs horizontal, knees positioned at roughly the same level as the hips, and feet touching the floor. At the end of the 10-min sit, the researcher drew in the tether using the motor-driven system mounted beneath the socket. The participant stood, then the researcher tightened the panels to the preferred socket size recorded after the plant gain test. The participant stood briefly (5 s) and then walked on the

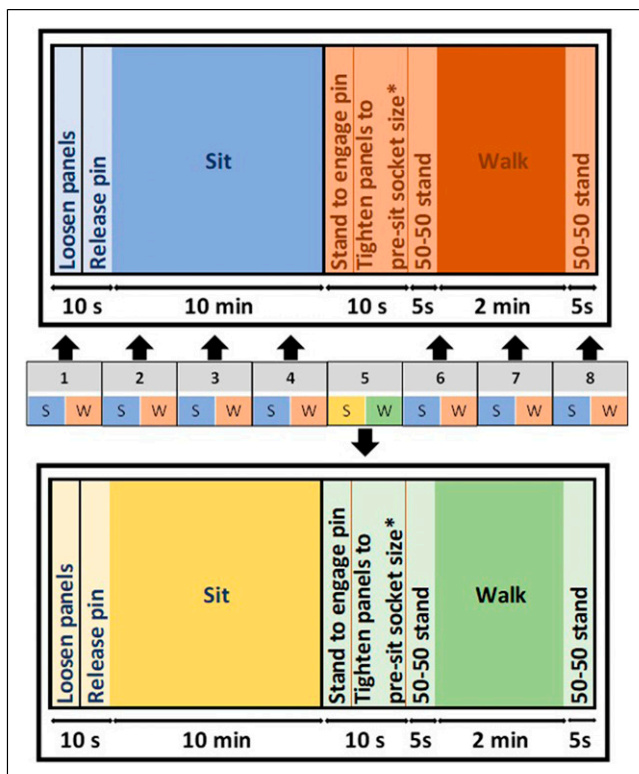


Figure 3. Test protocol. Eight cycles of sit and walk were conducted. The protocol used for cycles 1–4 and 6–8 is shown in the upper figure. The protocol used for cycle 5 is shown in the lower figure. During cycle 5 after the sit, the panels were tightened to the pre-sit socket volume plus 1.0% socket volume. S = Sit, W = Walk.

treadmill at a self-selected walking speed for 2 min, activating the control system on the auto-adjusting socket. This sit/walk cycle was repeated, except that at the end of the sit the researcher returned the socket to its size at the end of the prior walk rather than that recorded at the outset of the session. The cycles were repeated until the fifth cycle, where the socket was returned to a size of +1.0% volume larger than that at the end of the prior walk. The appropriate panel adjustment to achieve a +1.0% change was determined using a geometric model of the socket shape.³¹ The sixth through eighth cycles were identical to the earlier second through fourth cycles. After the session, participants were returned to their traditional socket and left the lab.

As a subjective measure of the effect of the intervention, participants were asked to provide a relative socket comfort rating (RSCR) at the end of each walking bout in cycles 5–8. RSCR has been used previously in prosthetics research to study relative changes in socket comfort within a session.^{32,33} The RSCR query was phrased, “Compared to

the end of the prior walk, is your socket comfort a lot better, a little better, the same, a little worse, or a lot worse?”

Data processing and analysis

Data collected across the test session, including the SFM, set point, and panel position, were downloaded from the auto-adjusting socket and plotted over time for visual inspection. The walking portion of each cycle was extracted for further analysis. For each session, the range of panel position was calculated. For each bout, the absolute error of the auto-adjusting socket control system (SFM minus set point) was plotted over time and the IAE calculated as

$$\overline{IAE} = \frac{1}{N} \sum_{i=0}^N |SFM_i - SFM_0|$$

where SFM_i is the measured SFM of the i^{th} temporal index, SFM_0 is the SFM set point, and N is the number of data points in the analysis. Thus, N for an IAE calculated during the first 30 s of a bout included all data points up to 30 s, while N for an IAE calculated during a whole bout included all points in the bout.

Limb fluid volume data from the bioimpedance system were downloaded and converted to extracellular fluid volume using de Lorenzo’s form of the Cole model.³⁴ The data were time-synchronized with the SFM data. The minimum fluid volume during stance phase of each step was determined for both the anterior and posterior limb regions and a mean calculated for each bout. The means for a session were expressed as a percentage change relative to the mean fluid volume during cycle 4, the cycle before the 1.0% relock socket size increase. This strategy allowed a consistent reference across participants for the percent fluid volume change between cycle 4 and subsequent cycles, a variable of interest in this study.

Relative socket comfort rating data were expressed as a change relative to cycle 4, the cycle before the relock socket size increase was executed. “A little better” and “a little worse” were defined as a plus one-unit change and a minus one-unit change, respectively. No participants responded with “a lot better” or “a lot worse,” so no unit change was defined for them.

Results

Participants

Six people with transtibial amputation (5 males and 1 female) participated in this study. All participants had their limb amputation as a result of trauma. Median age was 44 years (range 36–76), median time since amputation was 14 years (range 2–40), and median body mass index³⁵ (BMI) was 23.6 (range 21.9–26.5) (Table 1). Median residual limb

Table 1. Participant characteristics and plant gains.

Participant	Gender	Age (y)	Height (cm)	Weight (kg)	BMI (kg/m ²)	Time since amputation (y)	RL Length ^a (cm)	RL Circumf. ^b (cm)	Shape	Co-Morb.	Plant gain (counts/mm)
1	M	44	175.0	72.9	24.6	5	12.5	32.3	Cylindrical	HBP	737
2	F	36	160.0	58.2	23.4	13	14.0	26.1	Bulbous	None	2470
3	M	58	188.0	77.3	22.5	34	18.5	28.2	Conical	None	5621
4	M	42	162.5	60.6	23.7	2	11.8	27.3	Cylindrical	Smoker	6332
5	M	43	182.9	71.2	21.9	15	16.3	28.2	Conical	Smoker	7456
6	M	76	180.3	83.2	26.5	40	18.1	28.6	Conical	HBP	8693

^afrom the mid-patellar tendon to distal end.

^bat 4 cm distal of mid-patellar tendon, 170° knee flexion.

BMI= body mass index, RL= residual limb, M= male, F= female, HBP= high blood pressure.

length was 15.2 cm (range 11.8–18.5) and median mid-limb circumference was 28.2 cm (range 26.1–32.3). Descriptions of prosthesis componentry are listed in [Appendix 2](#).

Participants' median plant gain was 5977 counts/mm (range 737–8693) ([Table 1](#)). The higher the plant gain the more sensitive the person's socket fit was to changes in socket size.

Control system error

Integral of absolute error increased right after the auto-adjusting socket became active and then, in general, decreased over time for the rest of the bout ([Figure 4](#)). Out of the 48 bouts, 4 of them (bout 6 for participant #1; bouts 6 and 8 for participant #2; bout 5 for participant #4) did not demonstrate this result and instead showed a gradual increase in IAE over time that did not stabilize until late in the bout ([Appendix 3](#), lower panels). The maximum IAE during the first 30 s of a bout (median 0.008, range 0.002–0.058) was greater than the IAE at the end of the bout (median 0.006, range 0.001–0.034) by a median of 1.4 times (range 0.5–5.0) ([Appendix 4](#)). In 77% of the bouts, IAE was greater during the first 30 s than later in the bout.

Comparing IAE before to after the 1.0% relock socket size increase, three participants (#1, #2, #4) demonstrated an increase in IAE for cycle 5 compared with cycle 4, and three participants (#3, #5, #6) demonstrated a decrease for cycle 5 compared with cycle 4 ([Figure 5](#)). For participant #2, IAE for all cycles after the 1.0% relock socket size increase was greater than that for all cycles before the 1.0% relock socket size increase. No other participant showed this trend.

In one bout, cycle 7 for participant #2, while the auto-adjusting socket was active, the control system at the outset of the bout held the panels at their maximum distance and needed to be reset 1 min into cycle 7 using the VI. This happened because at the end of the preceding cycle 6, the panel position maximized ([Appendix 3](#)). Per the defined protocol, the panels started at that position at the start of

cycle 7. No other cases of control system saturation occurred during the study.

We note from the analysis above that IAE at the end of a bout was not of a consistent magnitude across all participants ([Figure 5](#)). As an exploratory effort, we investigated if end-of-bout IAE was related to participant characteristics. Plots of limb length, plant gain, age, height, years since amputation, limb circumference, and the quotient of limb circumference divided by diameter demonstrated a weak correlation (Pearson) with participant median end-of-bout IAE ($R < 0.4$ for all variables). Body mass index (BMI) was moderately correlated ($R = 0.6$). In some bouts for some participants, the IAE oscillated about the set point (e.g., [Appendix 5](#)). This hysteresis may have contributed to the inconsistent IAE for some participants.

During some bouts, there were intermittent connection issues, typically less than a few seconds, between the VI and the controller, causing the controller to briefly turn off and restart, resetting the set point. These instances are shown as discontinuities in figures of controller error (IAE) plotted over time ([Appendix 3](#)). These events were later demonstrated to be a result of an issue in the VI software, not the control system.

Participant panel positions, limb fluid volume, and pistoning

For 5 of the 6 participants, the range of panel position (maximum–minimum) during walking across the test session was between 2.26 mm and 6.01 mm ([Appendix 6](#)). For the remaining participant (participant #2), the control system saturated at the maximum panel radial distance (10.00 mm) for part of one walking bout, contributing to a higher range, 8.75 mm. Panel position range was not well-correlated with plant gain ($R = 0.38$).

From visual inspection of the data, we note that panel position reduced from cycles 1 to 4 and from cycles 5 to 8 for three participants (#1, #3, #4) and increased from cycles

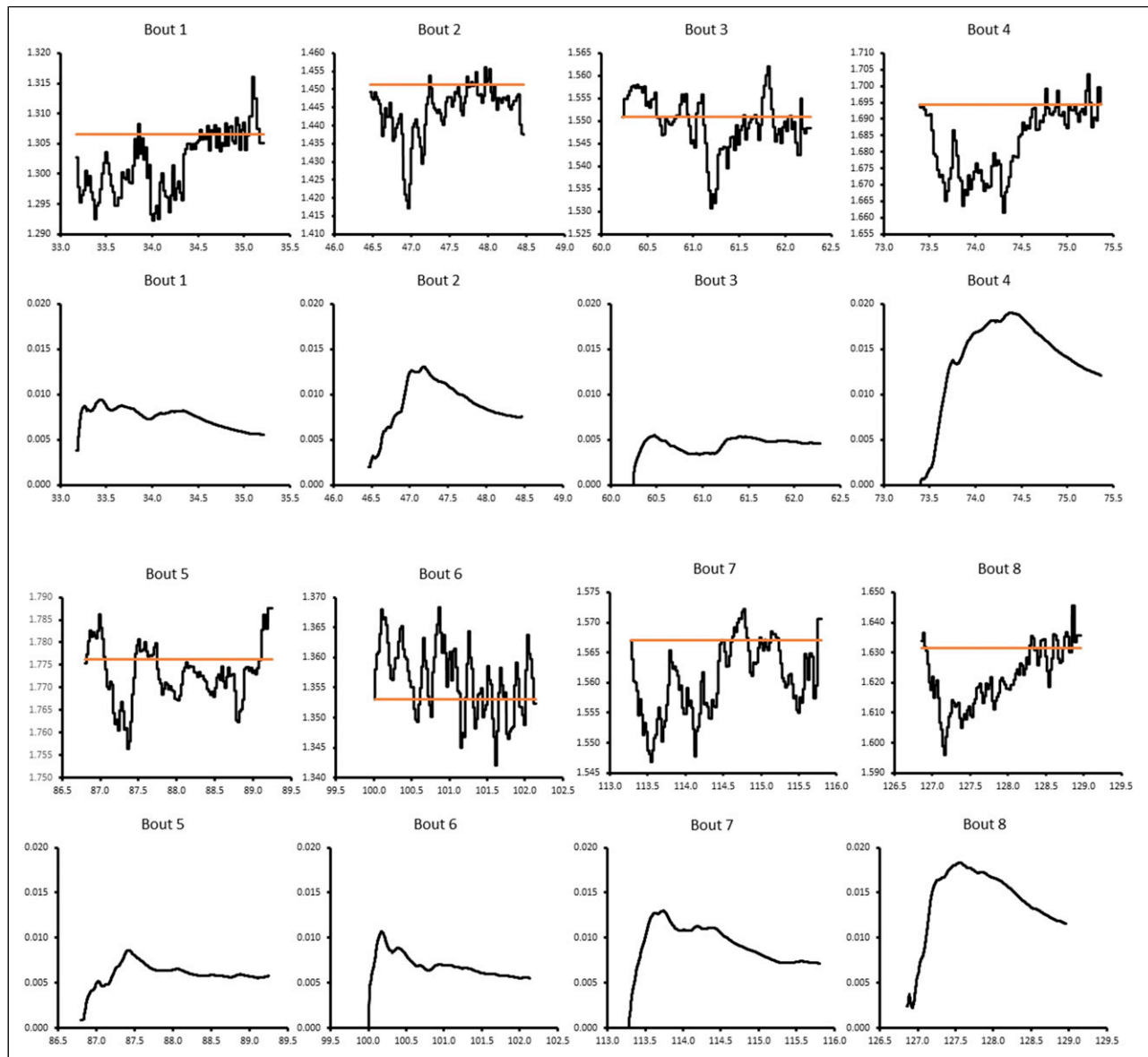


Figure 4. Example plots illustrating control system performance during the eight walking bouts. Upper panel: SFM data (black) and control system set point (orange), both in mm. A consistent set point is not used across bouts so that the shapes of the curves are clearly visible. The SFM is closer to the set point at the end of the bout than at the outset, demonstrating that the control system is performing well. Lower panel: IAE in mm plotted over the course of each bout. The shape of the IAE curves over time, a rise and maximum followed by a decrease to a stable value, is typical for a properly functioning engineered control system.

1 to 4 and from cycles 5 to 8 for three participants (#2, #5, #6) (Figure 6). Per the specified protocol, the panel position was increased during cycle 5 when the 1.0% relock socket size increase was executed. Panel position data were back onto their trajectory from earlier cycles 1 to 4 by cycle 6 for participants #4 and #6 and by cycle 7 for participants #2 and #3. Participant #1 did not demonstrate this behavior and instead maintained a larger panel position (larger socket size) compared with cycles 1–4. Panel position for participant #5 stabilized to a consistent

distance during cycles 5–8 that was larger than that during cycles 1–4.

Limb fluid volume change over time followed a similar pattern to the panel position data, that is, the patterns of change in Figure 7 are similar to those in Figure 6. The shapes of the plots for anterior and posterior regions were similar to each other for each participant except for participant #5 who after the intervention experienced a much greater percent limb fluid volume increase in the anterior region than the posterior region.

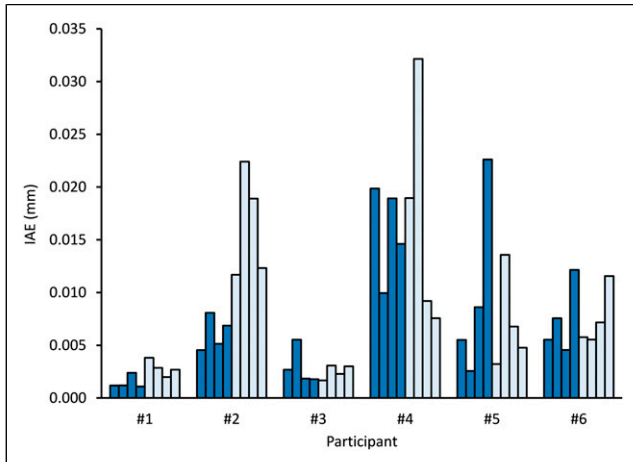


Figure 5. Integral of absolute error at the end of each bout. Dark bars are from bouts before the 1.0% socket size increase. Light bars are from bouts after the 1.0% socket size increase. Participants are ordered from low to high plant gains. There was no consistent trend across participants of a higher IAE after v. before the 1.0% socket size increase suggesting that control system performance was not sensitive to this perturbation.

SFM was controlled during walking bouts thus it did not follow trends similar to those for panel position or limb fluid volume. As an exploratory effort, we investigated if there was a trend in the change in peak-to-trough SFM (pistoning) from before to after the 1.0% relock socket size increase. For the participants who experienced a loss of limb fluid volume from cycle 1 to cycle 4 (#1, #3, #4), peak-to-trough SFM increased from before to after the 1.0% relock socket size increase (cycle 4 compared to cycle 5) (Appendix 7). For the participants who experienced a gain of limb fluid volume from cycle 1 to cycle 4 (#2, #5, #6), peak-to-trough SFM decreased from before to after the 1.0% relock socket size increase.

While enlarging the socket by +1.0% after cycle 4 increased limb fluid volume, 4 of 6 participants reported a worsened socket comfort right after it was executed (Figure 8). Only participant #4 reported an improvement in socket comfort, stating that his socket felt a bit more tightly coupled to his residual limb. Participant #2 reported feeling rubbing on the proximal brim line, participant #3 reported pistoning, and participant #6 reported looseness at the distal end and back part of his limb. Despite the decrease in socket comfort while walking after the 1.0% relock socket size increase, none of the participants decreased their socket comfort score in cycle 8 compared with cycle 5.

As an exploratory effort, we investigated the relationship between percent limb fluid volume change from before to after the 1.0% relock socket size increase (cycle 5–cycle 4) and RSCR (Figure 9). The four participants with percent fluid volume changes greater than 1.0% (#

1,2,3,6) all reported reduced RSCR, while the participant with a small increase (#4) (0.6%) reported an increased RSCR. The participant with essentially no percent fluid volume change (#5) (−0.1%) reported no change in RSCR.

Discussion

In this study, conducting socket release during sitting between bouts of walking was shown to have the intended effect of changing participants' limb fluid volume. In general, the auto-adjusting socket responded well to these perturbations and maintained stable performance and low error. We believe the results warrant advancing to testing on prosthesis user participants in their at-home environments, increasing the number of participants and determining the long-term clinical outcomes in terms of comfort, prosthesis use, skin health, and other related outcomes.

Part of the reason the control system demonstrated stable performance and low error was because fluid volume change followed panel position change as shown by the similarity of curve shapes in Figures 6 and 7. Our prior work and the plant gain tests in the present study showed that, when socket size adjustments were made, the distance sensed by our custom sensors changed linearly with socket size.^{16,17} Taken together, these results suggest that the control system operated as intended for all participants—adjusting panel position based on information from the distance sensors served to adjust limb fluid volume.

It is recognized that clinically it may not be desirable to increase limb fluid volume over time, as occurred for participants #2, #5, and #6 (Figure 7). However, what is relevant to note (and was the purpose of the present study) is that the auto-adjusting socket is capable of being used to control limb fluid volume. The auto-adjusting socket worked in harmony with the residual limb to take advantage of the limb's capability for fluid volume change to accomplish this result. In clinical practice, the auto-adjustment algorithm would be programmed to maintain a consistent sensed distance over the day.

We expect that the use of distance sensing and the practice of not placing the sensing elements on the actuators are two key reasons the auto-adjusting socket in this study performed better than other systems described in the literature.^{4–13} Distance sensing may be more effective than pressure sensing because the measurement is very sensitive to small changes in socket fit, and presence of the sensors does not disrupt the regular limb-socket interface.¹⁸ We did not consider placing the sensing elements on the actuators an appropriate strategy. The actuators are located at load-tolerant areas of the residual limb, thus sensing at those locations would not be expected to provide a clinically meaningful and sensitive measurement of socket fit. In the present study, the

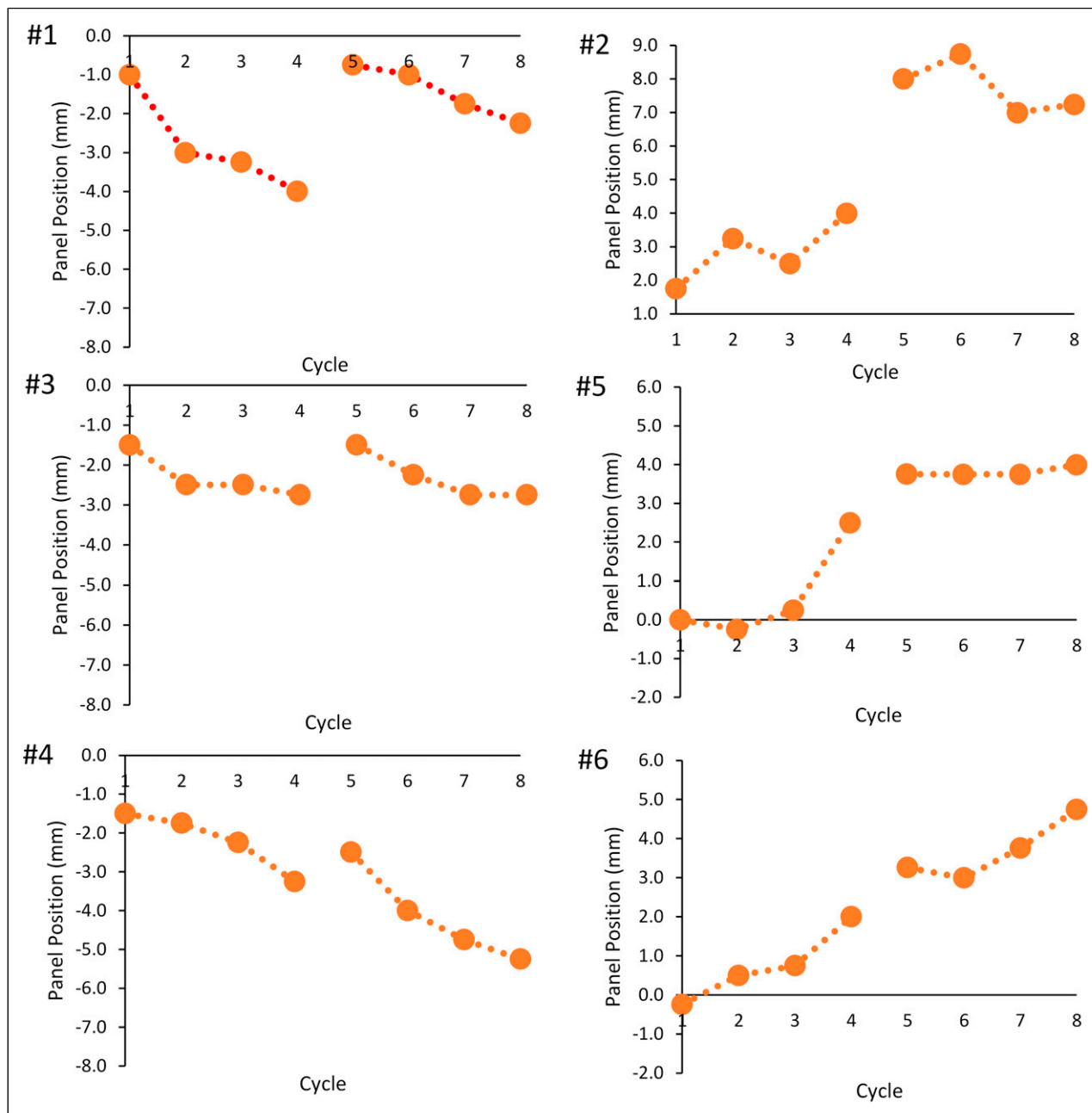


Figure 6. Panel position at the end of each walking bout. Participants #1, #3, and #4 experienced a socket reduction from the beginning to the end of the test session. Participants #2, #5, and #6 experienced a socket enlargement.

sensors used for auto adjustment were located at a posterior location off of the midline. It is possible that data from other sensors, for example that monitor distal limb superior-inferior motion (pistoning) or limb angulation in the sagittal plane, may be necessary, although results in the present study do not support such a need. These interpretations are preliminary, however, and need to undergo rigorous scientific testing on a larger group of participants.

Control system performance

The shape of the IAE curves over time as shown in Figure 4, a rise and maximum followed by a decrease to a stable value, is typical for a properly functioning engineered control system. The range of end-of-bout IAE, from 0.001 to 0.034, corresponded to a median socket volume error of 0.001%–0.033% for the six participants tested here. For

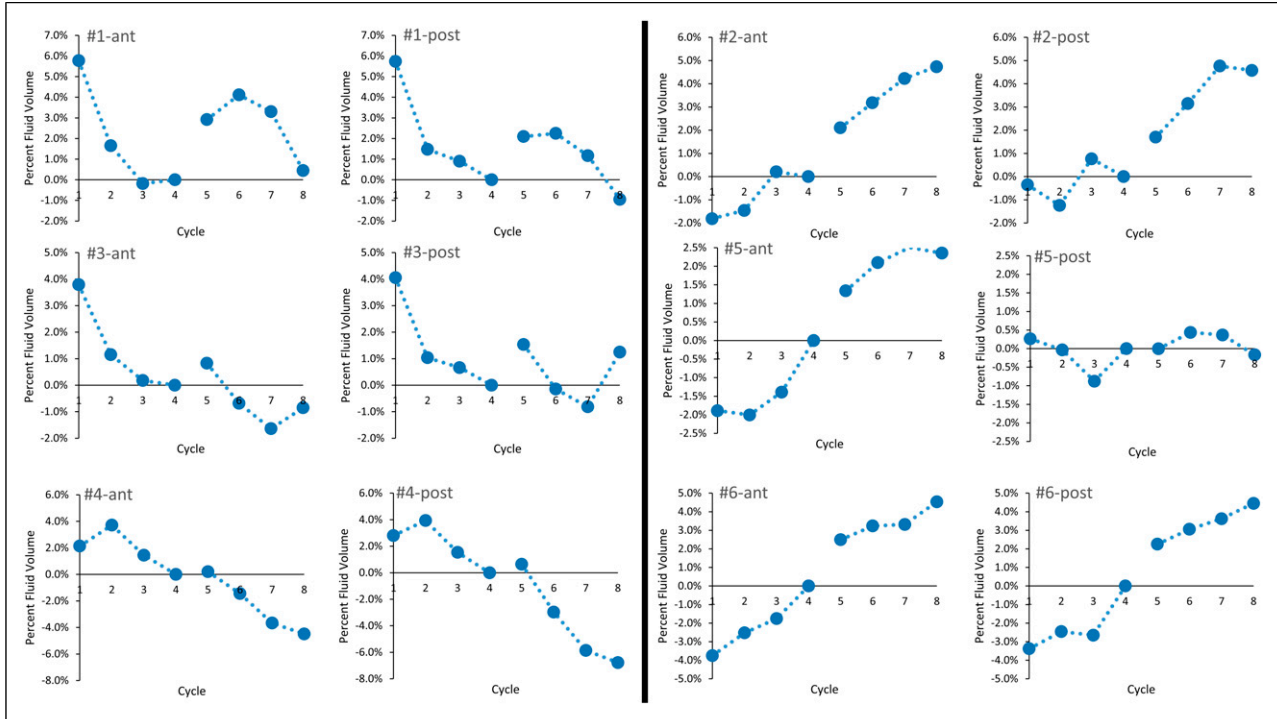


Figure 7. Percent limb fluid volume during stance phase minima for each bout. Results from the anterior region (ant) and posterior region (post) are shown. Participants #1, #3, and #4 lost limb fluid volume over the session while participants #2, #5, and #6 gained. Differences are likely a result of participant physiological characteristics. All participants (#1 to #6) demonstrated an increase in limb fluid volume from the intervention (between bout 4 and bout 5), suggesting a common mechanism. However, the changes in both the anterior and posterior regions for participant #4 and the posterior region for participant #5 were less than for other participants.

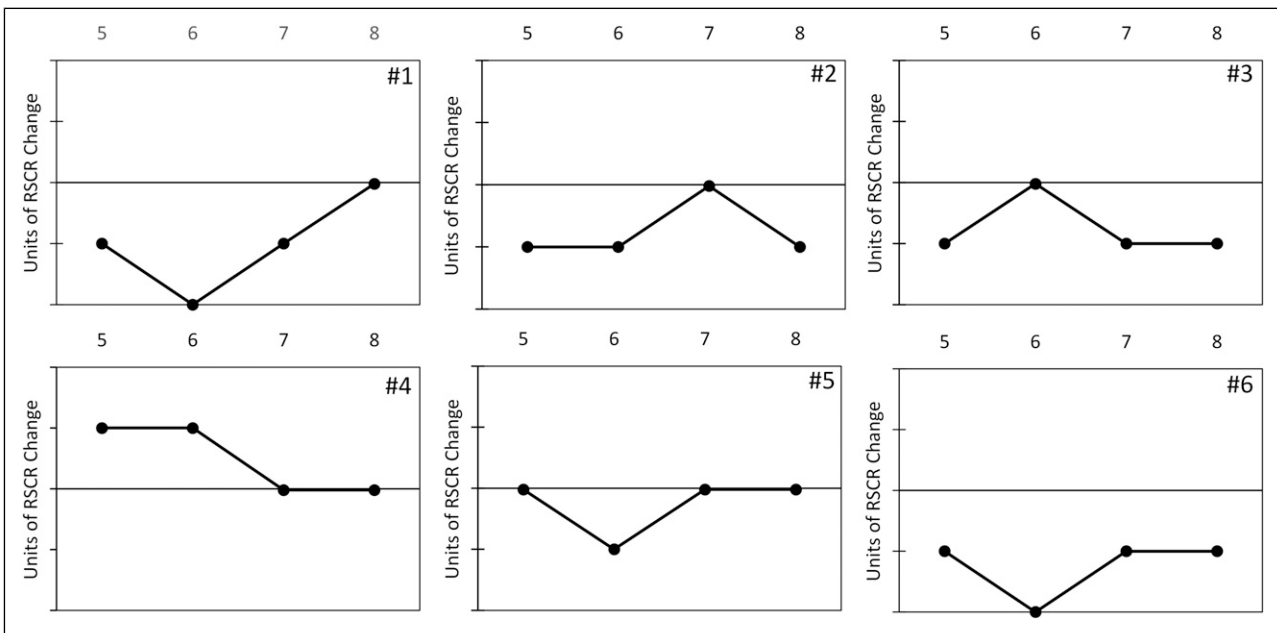


Figure 8. Change in socket comfort relative to cycle 4 for all participants. The central horizontal line represents the reference, that is, the socket comfort during cycle 4 right before the 1.0% relock socket size increase. The distance between adjacent tick marks on the y-axis is a relative socket comfort rating “unit change.” A positive unit change in RSCR is “a little better,” and a negative unit change in RSCR is “a little worse.” Upon the 1.0% relock socket size increase, four participants indicated a worsened RSCR, one no change, and one a more favorable RSCR.

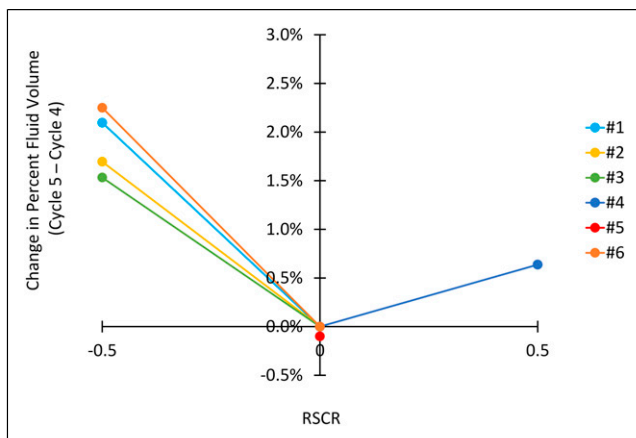


Figure 9. Relative socket comfort rating (RSCR) v. change in percent fluid volume. Participants who experienced >1.0 change in percent fluid volume between cycles 4 and 5 reported a worsened socket comfort rating while those with a change $<1.0\%$ reported no change or a more favorable socket comfort rating.

comparison, adding a sock sheath (0.2 mm thickness under stance phase loading²¹) would change socket volume by an average of 0.97% for participants in the present study (range 0.80%–1.03%). Thus, the IAE error in this investigation would be expected to be acceptable in clinical application of the auto-adjusting socket.

The two bouts that showed the greatest increase in IAE over time were both from the only participant with a bulbous residual limb (participant #2). Unlike the other five people in the study, this participant found the relock protocol uncomfortable—drawing in the tether before closing the socket panels—because it tended to trap her soft tissue distally in the socket. Other participants, during preliminary investigations prior to this study and during the study itself, held the opposite opinion, preferring to draw in the tether first and then close the panels. The high IAE and discomfort stated by participant #2 suggest a need to investigate if a different auto-adjusting control strategy is necessary for people with much redundant soft tissue in their residual limb.

The oscillation of the SFM about the set point observed in some bouts (e.g., Appendix 5) may be eliminated by setting a threshold for execution of a socket size adjustment (known as a “hysteresis band” in control systems engineering). Because the peak-to-trough range of oscillation observed in the data collected in this study was typically less than 0.20 mm, we would expect that a hysteresis band and step size of 0.20 mm would be appropriate. It is possible that because of the different plant gains across participants, the threshold size adjustment may need to be tuned to each user, though rigorous scientific investigation would need to be conducted to test if this is clinically necessary.

As shown in Figure 9, we observed an interesting relationship between RSCR and percent limb fluid volume

change in the posterior region from before to after the 1.0% socket size increase (Cycle 5–Cycle 4). The results suggest that matching the socket volume increase at the start of a new walking bout to the fluid volume increase experienced by the individual participant between bouts may improve comfort. In other words, the socket size should be adjusted so that the socket is still relatively snug on the residual limb and may even restrict its fluid volume increase. The four participants who experienced increases in percent fluid volume (cycle 5–cycle 4) of more than 1.0% (#1, #2, #3, and #6) all indicated that their socket felt too loose during cycle 5. Possibly the high fluid volume increase they experienced reduced their soft tissue compressive stiffness, made their limb-socket interface unstable, and caused this sensation. RSCR scores for the two participants who experienced lower percent fluid volume increase, #4 (–0.1% limb fluid volume change) and #5 (0.6%), were more favorable. Possibly, participant #4 and #5’s sockets were tight on their residual limb after the 1.0% socket size increase, helping to ensure a more stable interface. This interpretation is preliminary, based upon results from a small number of participants, and would need to be verified in more extensive clinical studies.

We note that by cycle 7 most participants returned to the limb fluid volume trajectory established before the +1.0% socket size intervention. Thus, while 10-min socket releases helped to reduce limb fluid volume loss, they may not have been long enough to promote a meaningful limb size increase such that a socket enlargement in preparation for further walking was warranted. Longer release durations, however, may show a benefit, though this hypothesis would need to be tested through rigorous scientific investigation.

The increase in peak-to-trough SFM (maximum swing phase SFM minus minimum stance phase SFM) from before to after the intervention (from cycle 4 to cycle 5) for participants who experienced a reduction in limb fluid volume over time (#1, #3, and #4) means that, as expected, these participants’ limb pistoned more in the socket after the +1.0% relock socket size increase was executed than before it. The result points to the utility of SFM peak-to-trough data as an additional socket fit metric for use in future auto-adjusting socket systems.

A related prosthetic socket technology, electronic elevated vacuum (EV), applies a negative pressure between the socket and liner-to-draw residual limb soft tissues outward. Both EV and the auto-adjusting socket in the present study attempt to maintain limb volume within a narrow range over time, but they optimize different metrics to facilitate adjustment, and they use different actuators (vacuum pressure, panel displacement) to effect change. Results from the present study indicate that in-socket limb fluid volume response to automated control of socket size is immediate, while a different investigation reported in the literature showed that in-socket limb

fluid volume response to automated control of EV is much slower.³² As research and development of both auto-adjusting sockets and EV sockets continue, it will be important to quantify their control system performance (i.e., capability to maintain a set point based on a socket fit metric), their capability to manage limb volume, and their benefit to clinical outcomes like residual limb health.^{36–38}

A limitation of the study design was that the system was tested on only six participants. This number of participants was considered acceptable because the objective of the study was to warrant at-home testing with a large number of participants.

The time between walking bouts in this study was short, approximately 10 min. A more challenging situation, expected to be encountered during at-home use, is when there are much longer time periods of sitting, standing, and weight-shifting between walking bouts, that is, between automatic panel position changes. In these cases, a more substantial change in the residual limb may occur and the SFM at the outset of the next walk may be much different than the set point. If the difference is too great, then the residual limb may not be able to adjust size quickly, risking control system instability and necessitating a modification in the control system strategy.

The auto-adjusting socket used in this study was heavier than a normal socket. The instrumentation on the socket added a median of 885 g to the traditional socket weight (median 589 g). The weight may have affected participant RSCR scores late in the session because of the accumulated effect of a greater pull on limb soft tissues compared with users' traditional sockets. We would not expect the added weight to have affected control system performance since the auto-adjusting socket adapts to a change in socket fit. A reduced size frame and motor and replacement of the control system components with a custom electronics board could easily be created to reduce the weight since from experience in the present study the displacement range and resolution needs of the auto-adjusting socket are now better specified (e.g., Appendix 6). For the revised system, we would expect the weight difference compared to a traditional prosthesis to be comparable to the difference between a powered ankle and traditional ankle prosthesis. The LabVIEW VI instability issue during some bouts in the present study should be resolved using an on-board microprocessor dedicated to auto-adjustment instead of the LabVIEW software package.

Conclusion

In this study, the auto-adjusting socket maintained good stability despite perturbation of panel and tether release/lock during sitting and achieved a low IAE during subsequent bouts of walking. Therefore, the auto-adjusting socket is ready for field testing in participant at-home settings.

Acknowledgments

Assistance from Clement Gurrey in data collection is gratefully acknowledged.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This material is based upon work supported by the US Army Medical Research Acquisition Activity (USAMRAA) under Contract No. W81XWH-16-C0020. Any opinions, findings and conclusions or recommendations expressed in this material are those of the authors and do not necessarily reflect the views of the US Army Medical Research Acquisition Activity (USAMRAA).

Guarantor

JE Sanders PhD

Contributorship

JM provided socket fabrication expertise and helped with protocol planning and data collection. EW helped with data collection, control system implementation and initial data processing. BL placed electrodes, processed bioimpedance data, and helped prepare the manuscript. RC fabricated and assembled the sockets and collected bench test and calibration distance sensor data. KA recruited participants, decided panel sizes and locations, and fit the investigational prosthesis to participants. DB assisted with calibration and data presentation. HW built the electronics and wrote the firmware. ND processed the control system data and prepared it for presentation. AV and JG assisted with control system and distance sensor data analysis. JF provided clinical expertise towards data interpretation. BH, JF, and MC advised on study design and data interpretation, reviewed and edited the manuscript. JS provided project management, advised on data analysis, wrote and edited the manuscript.

ORCID iDs

Daniel Ballesteros  <https://orcid.org/0000-0002-0299-6775>

Joan E Sanders  <https://orcid.org/0000-0002-8850-243X>

Supplemental material

Supplemental material for this article is available online.

References

1. Legro MW, Reiber G, del Aguila M, et al. Issues of importance reported by persons with lower limb amputations and prostheses. *J Rehabil Res Dev* 1999; 36(3): 155–163.

2. Turner S and 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): 100059.
3. Greenwald RM, Dean RC and Board WJ. Volume management: smart variable geometry socket (SVGS) technology for lower limb prostheses. *J Prosthet Orthot* 2003; 15(3): 107–112.
4. Montgomery JT, Vaughan MR and Crawford RH. Design of an actively actuated prosthetic socket. *Rapid Prototyp J* 2010; 16(3): 194–201.
5. Pirouzi G, Abu Osman NA, Oshkour AA, et al. Development of an air pneumatic suspension system for trans-tibial prostheses, *Sensors (Basel)* 2014; 14(9): 16754–16765.
6. Candrea D, Sharma A, Osborn L, et al. An adaptable prosthetic socket: regulating independent air bladders through closed-loop control. In: IEEE International symposium on circuits and systems (ISCAS), Baltimore, MD, USA, May 28-31 2017, pp. 1–4.
7. Seo JH, Lee HJ, Seo DW, et al. A prosthetic socket with active volume compensation for amputated lower limb. *Sensors* 2021; 21: 407.
8. Ogawa A, Obinata G, Hase K, et al. Design of lower limb prosthesis with contact pressure adjustment by MR fluid. In: Proceedings of the 30th annual International IEEE EMBS conference, Vancouver, British Columbia, Canada, 20–24 August, 2008.
9. Mercier M, Shirley C, Stafford S, et al. Fluidic flexible matrix composites for volume management in prosthetic sockets. In: ASME 2014 conference on smart materials, adaptive structures and intelligent systems, Newport, Rhode Island, USA, Sep 8-10 2014, pp. V002T06A015.
10. Razak NAA, Osman NAA, Gholizadeh H, et al. Prosthetics sockets that incorporates an air splint system focusing on dynamic interface pressure. *Biomed Engi Online* 2014; 13: 108.
11. Carrigan W, Nothnagle C, Savant P, et al. Pneumatic actuator inserts for interface pressure mapping and fit improvement in lower extremity prosthetics. In: Proceedings of the IEEE International conference in biorobotics, University Town, Singapore, Jun 26-29 2016, pp. 574–579.
12. Kyudetskyy I, Antonova-Rafi Y, Melnyk H, et al. System for automatic adjustment of the volume of the receiving sleeve. In: 2020 IEEE international conference on problems of infocommunications, science and technology (PIC S&T), Kharkiv, Ukraine, 6–9 October, 2020, pp. 39–42.
13. Gu Y, Yang D, Osborn L et al. An adaptive socket with auto-adjusting air bladders for interfacing transhumeral prosthesis: a pilot study. *Proc Imeche Part H: J Engi Med*, 2019; 233(8): 812–822.
14. Wheeler JW, Mazumdar A, Marron LC, et al. Development and amputee validation of pressure and shear sensing liner for prosthetic sockets. In: IEEE engineering in medicine and biology society, Orlando, FL, USA, 2016.
15. Swanson EC, McLean JB, Allyn KJ, et al. Instrumented socket inserts for sensing interaction at the limb-socket interface. *Med Engi Phys* 2018; 51: 111–118.
16. McLean JB, Redd CB, Larsen BG, et al. Socket size adjustments in people with transtibial amputation: effects on residual limb fluid volume and limb-socket distances. *Clin Biomech* 2019; 63: 161–171.
17. Larsen BG, McLean JB, Allyn KJ, et al. How do transtibial residual limbs adjust to intermittent incremental socket volume changes? *Prosthet Orthot Int* 2019; 43(5): 528–539.
18. Larsen BG, Allyn KJ, Ciol MA, et al. Performance of a sensor to monitor socket fit: comparison with practitioner clinical assessment. *J Prosthet Orthot* 2021; 33(1): 3–10.
19. Weathersby EJ, Garbini JL, Larsen BG, et al. Automatic control of prosthetic socket size for people with transtibial amputation: implementation and evaluation. *IEEE Trans Biomed Engi* 2021; 68(1): 36–46.
20. Marlin TE. *Process control: designing processes and control systems for dynamic performance*. McGraw-Hill, New York, New York 2000.
21. Sanders JE, Cagle JC, Harrison DS, et al. Amputee socks: how does sock ply relate to sock thickness? *Prosthet Orthot Int* 2012; 36(1):77–86.
22. Sanders JE, Hartley TL, Phillips RH, et al. Does temporary socket removal affect residual limb fluid volume of transtibial amputees? *Prosthet Orthot Int* 2016; 40(3): 320–328.
23. Brzostowski JT, Larsen BG, Youngblood RT, et al. Adjustable sockets may improve residual limb fluid volume retention in transtibial prosthesis users. *Prosthet Orthot Int* 2019; 43(3): 250–256.
24. McLean JB, Larsen BG, Weathersby EJ, et al. Fluid volume management in prosthesis users: augmenting panel release with pin release. *PMR* 2020; 12(12): 1236–1243.
25. Weathersby EJ, Gurrey CJ, McLean JB, et al. Thin magnetically permeable targets for inductive sensing: application to limb prosthetics. *Sensors (Basel)* 2019; 19(18): 4041.
26. Henrikson KM, Weathersby EJ, Larsen BG, et al. An inductive sensing system to measure in-socket residual limb displacements for people using lower-limb prostheses. *Sensors (Basel)* 2018; 18(11): 3840.
27. Larsen B, McLean J, Brzostowski J, et al. Does actively enlarging socket volume during resting facilitate residual limb fluid volume recovery in trans-tibial prosthesis users? *Clin Biomech* 2020; 78: 105001.1–105001.7.
28. Sanders JE, Garbini JL, McLean JB, et al. A motor-driven adjustable prosthetic socket operated using a mobile phone app: a technical note. *Med Engi Phys* 2019; 68: 94–100.
29. 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.
30. Hinrichs P, Cagle JC and Sanders JE. A portable bio-impedance instrument for monitoring residual limb fluid volume in people with transtibial limb loss: a technical note. *Med Engi Phys* 2019; 68: 101–107.

31. Vamos AC, Gurrey CJ, Cagle JC, et al. An algorithm to calculate socket volume changes of adjustable sockets for transtibial prosthesis users. *J Prosthet Orthot* 2020; 32(1): 65–70.
32. Youngblood RT, Brzostowski JT, Hafner BJ, et al. Effectiveness of elevated vacuum and suction prosthetic suspension systems in managing daily residual limb fluid volume change in people with transtibial amputation. *Prosthet Orthot Int* 2020; 44(3): 155–163.
33. Youngblood RT, Hafner BJ, Czerniecki JM, et al. Mechanically and physiologically optimizing prosthetic elevated vacuum systems in people with transtibial amputation. *J Prosthet Orthot* 2021; online first.
34. De Lorenzo A, Andreoli A, Matthie J, et al. Predicting body cell mass with bioimpedance by using theoretical methods: a technological review. *J Appl Physiol* 1997; 82(5): 1542–1558.
35. Amputee Coalition. *About body mass index (BMI)*. <https://www.amputee-coalition.org/limb-loss-resource-center/resources-filtered/resources-by-topic/healthy-living/about-bmi/> (2016, accessed 4/21/2021).
36. Rink C, Wernke MW, Powell HM, et al. Elevated vacuum suspension preserves residual-limb skin health in people with lower-limb amputation: Randomized clinical trial. *J Rehab Res Dev* 2016; 53(6): 1121–1132.
37. Hoskins RD, Sutton EE, Kinor D, et al. Using vacuum-assisted suspension to manage residual limb wounds in persons with transtibial amputation: a case series. *Prosthet Orthot Int* 2014; 38(1): 68–74.
38. Trallesi M, Delussa AZ, Fusco A, et al. Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study. *Eur J Phys Rehabil Med* 2012; 48(4): 613–623.