



## Original Research

# Fluid Volume Management in Prosthesis Users: Augmenting Panel Release with Pin Release

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## Abstract

**Background:** Management of fluid in the limbs is a challenge faced by people with disabilities. In prosthetics, a means for transtibial prosthesis users to stabilize their residual limb fluid volume during the day may improve socket fit.

**Objective:** To determine if releasing the panels and locking pin of a cabled-panel adjustable socket during socket release significantly improved limb fluid volume recovery and retention over releasing the panels alone.

**Design:** Repeated-measures experiment to assess the effects on limb fluid volume retention.

**Setting:** Participants were tested in a laboratory setting while walking on a treadmill.

**Intervention:** Release of a locking pin tether during sitting as a limb volume accommodation strategy.

**Main Outcome Measure:** Percent limb fluid volume retention for panel and pin release compared with panel release alone at 2 minutes (short term) and 50 minutes (long term) after subsequent activity. Limb fluid volume was monitored using bioimpedance analysis.

**Results:** Median percent limb fluid volume retention for the panel and pin release was significantly greater than panel release alone for both anterior and posterior regions for the long term ( $P = .0499$  and  $.0096$ , respectively) but not the short term ( $P = .0712$  and  $.1580$ , respectively).

**Conclusion:** Augmenting panel release with pin release may be an effective accommodation strategy for prosthesis users with transtibial amputation to better retain limb fluid volume.

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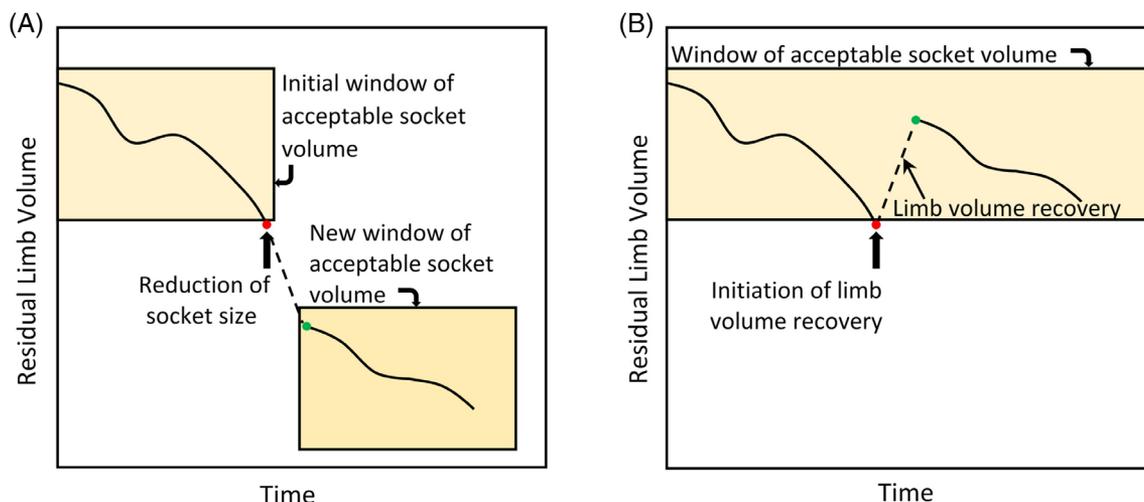
## Introduction

One of the most challenging problems faced by people with lower-limb amputation is changes in socket fit from residual limb volume loss. Volume loss may change how the residual limb fits within the prosthetic socket and lead to soft tissue injury or an unstable gait.<sup>1,2</sup> Fit of the prosthesis has been reported as the single most important issue related to successful use of a prosthetic limb.<sup>3</sup>

Prosthesis users may accommodate residual limb volume loss by either decreasing the size of the socket or by increasing the size of their residual limb (Figure 1). Adding prosthetic socks or pads to the inside of the socket is the most common means to decrease socket size. User-adjustable sockets with movable socket panels are also used. They eliminate the need for socket doffing to execute an adjustment.<sup>4-7</sup> However, adding socks has been

shown to decrease limb fluid volume that is not easily recovered.<sup>8</sup> Elevated vacuum systems, which apply vacuum pressure between the socket and liner using an electronic or passive mechanical pump in some studies have been shown to increase limb fluid volume during walking<sup>9,10</sup> and may improve limb health,<sup>11,12</sup> but the technology requires careful evaluation and maintenance to ensure a well-fitting sealed socket environment.<sup>12-14</sup>

Another strategy is to facilitate limb fluid volume recovery through socket release. Socket release is the temporary relief of limb-socket pressures. Doffing the socket between periods of activity for 30 minutes, one means of socket release, was shown to increase limb fluid volume compared with no doffing in a group of 16 participants with transtibial limb loss and, further, to retain significantly greater ( $P < .001$ ) fluid volume after 8 minutes and 24 minutes of additional standing and walking.<sup>15</sup> Six-hour studies



**Figure 1.** Prosthesis users may accommodate for limb fluid volume loss by (A) decreasing the size of their socket (eg, adding socks or pads; reducing an adjustable socket), or (B) increasing the size of their residual limb (eg, using an elevated vacuum socket; conducting socket release).

conducted outside the lab demonstrated that doffing the socket for 20 minutes every 1.5 hours increased limb fluid volume over no doffing for 7 of 9 locking pin users compared with no intervention.<sup>16</sup> Removing the socket during the day, however, is inconvenient and may be socially unacceptable for many people wearing a prosthesis. Releasing liquid from bladders positioned inside of the socket, a socket release technology that does not require the socket to be doffed, did not significantly increase limb fluid volume retention over no liquid release, but in this study the locking pin was kept in the shuttle lock during socket release and may have contributed to the lack of fluid volume retention.<sup>17</sup> With the pin in the shuttle lock, the small distal socket may have contributed to high distal interface stresses. Further, the liner may have pulled the distal limb, increasing pressures and restricting fluid volume recovery. Releasing the panel of a “clamshell” socket that hinged about the posterior distal region and at the same time releasing the locking pin tether 4 cm for 10 minutes significantly increased short-term limb fluid volume retention (after 2 min of additional walking) but not long-term retention (after 38 min of additional walking and sitting) compared with projected no intervention results.<sup>18</sup> Long-term retention was not more favorable possibly because the hinged-panel socket design limited the depth that recovered fluid traveled into the residual limb during socket release.

In this study we investigated a socket that allowed distal pressure relief and locking pin release without doffing. A cabled 3-panel adjustable socket with an adjustable length pin tether was used. The objective was to determine if releasing the panels and locking pin during socket release significantly improved limb fluid volume recovery and retention over releasing the panels alone.

## Methods

All study procedures were approved by an institutional review board (protocol # 49624.5b). Written informed

consent was obtained from participants before any study procedures were initiated.

## Participants

Participants were included in this study if they had a transtibial amputation at least 18 months prior, regularly used a definitive prosthesis and were capable of walking continuously on a treadmill for at least 5 minutes and intermittently for at least 2 hours. Participants were excluded if they had sores on their residual limb or used an assistive device while walking. Inclusion criteria were evaluated by the study prosthetist during an initial session (described later).

## Sockets

Test sockets duplicate in shape to participants’ traditional socket were fabricated. The traditional socket was scanned using a commercial 3D scanner (FARO Platinum Arm, Faro Technologies, Lake Mary, FL), then from the scan a foam positive was carved (C7, Provel, Cle Elum, WA). A series of three layups was implemented. A 4-ply Nyglass stockinette was applied to the positive and infused with resin. After the layers cured, an inductive sensor that was used to identify stance phase in collected data was placed in the posterior medial midlimb region. A carbon fiber layer (1-ply) was applied, then once it cured, tubing for the cable to adjust the panels was applied. Finally, an outer layup of 1-ply carbon fiber, 2-ply Nyglass, and 1-ply carbon fiber was applied, infused with resin, and cured. The research prosthetist designed the shapes of three panels cut in the socket wall at anterior medial, anterior lateral, and posterior locations (Figure 2A). The panel locations were strategically placed where practitioners typically add pads. These areas of the residual limb are known to be load tolerant. Panel size was maximized in order to affect socket volume change while

avoiding the bony prominences at the anterior distal tibia, tibial crest, and fibular head that may be sensitive to compressive stress. The cable running through the 3 panels was connected to a motor. The motor and mechanical hardware, developed in a previous study,<sup>19</sup> were positioned beneath the socket. The motor and hardware weighed 648 g. The motor adjusted cable length in 4.75-mm increments at a rate of 38.0 mm/min using a mobile phone app. A tether and custom connector to the liner extended through the distal socket to a shuttle locked mounted beneath the socket (Figure 2B). A clip was put on the tether so that when the socket was doffed and the pin released, the tether was controlled to a set distance (approximately 5 cm) (Figure 2C).

### Protocol

Participants visited the lab for an initial session to ensure they met the inclusion criteria, to gather demographic information, and to obtain a digital scan of their traditional socket. Participants returned to the lab for testing after the investigational prosthesis was fabricated and when they were available, which was a median of 7 months later (range 0.5 to 8 mo).

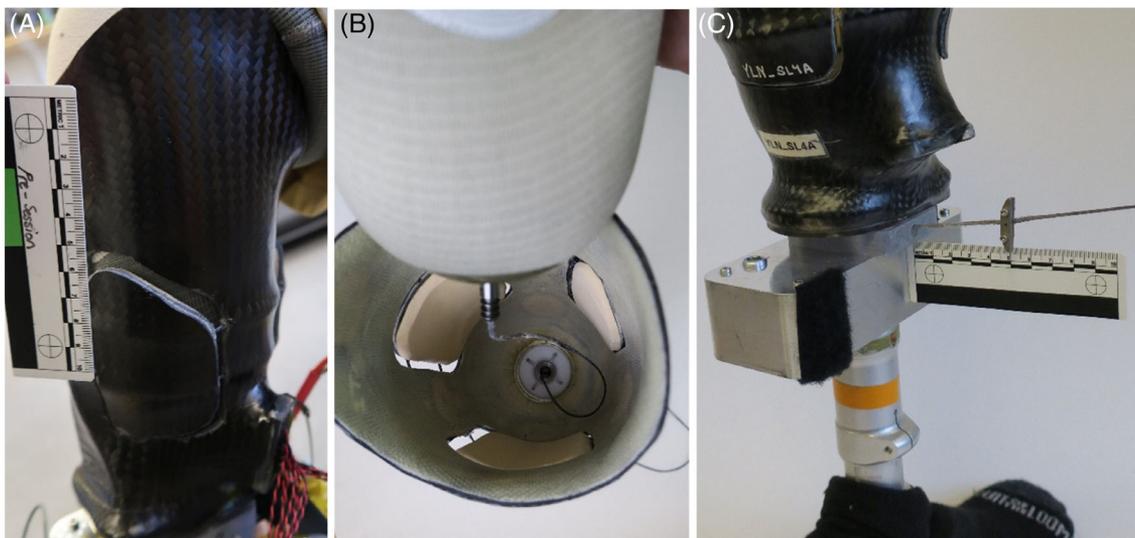
A testing strategy similar to that used previously to evaluate limb fluid volume recovery using clamshell socket release/relock was implemented.<sup>18</sup> A single walk/sit cycle with the intervention was conducted in between several walk/sit cycles without the intervention. If the intervention cycle caused disruption, it was clearly distinguished in the data. Projected no intervention control data were generated from results from the first half of the intervention testing session as described below. A protocol with extended walking periods between sits, as executed in a previous socket release

study,<sup>16</sup> would be an appropriate next step if the intervention were shown to have a beneficial effect here.

At the outset of each testing session, the research prosthetist queried participants about recent changes in limb health and fit the investigational prosthesis to ensure a proper fit. If participants no longer met inclusion criteria, then they were not continued in the study. Participants were instrumented for bioimpedance analysis by placing thin tape electrodes on their residual limb. Current injection electrodes were positioned on the proximal thigh and the distal end of the limb, as in our previous study.<sup>18</sup> Voltage sensing electrodes were placed on the anterior and posterior aspects. A small electrical current (~300  $\mu$ A peak-to-peak) across a frequency range of 3 kHz to 1 MHz was injected and voltage sensed at a sampling rate of approximately 30 Hz.<sup>20</sup> Current and voltage data were demodulated, and a model implemented to calculate extracellular and intracellular impedance changes over time.<sup>21</sup> Limb fluid volume was calculated from that data using an anatomical model.<sup>22,23</sup> Fluid volume data were expressed as a percent change relative to a reference partway through the testing session as described later.

Participants donned the socket with the panels flush with the surrounding socket (neutral position). If they felt comfortable walking, participants moved to the treadmill where they self-selected an optimal size by instructing the researcher to make changes as they walked. If the participant was not comfortable starting to walk at a neutral position, they verbally instructed the researcher to change the socket size while standing until they were ready to start walking on the treadmill and self-select an optimum socket size.

The test protocol consisted of 8 cycles of sitting and standing (Figure 3). During each cycle, the participant sat for 2 minutes while the socket volume was enlarged by



**Figure 2.** (A-C) Instrumented prosthesis. (A) Anterior media panel is shown. (B) The tether attached to the distal end of the locking pin and exited through a hole in the distal socket. (C) The tether exited through the side of the instrument box. A clip was attached to limit tether extension to 5 cm.

4.0%, using the phone app to operate the motor. The researcher pulled radially outwards on the panels to ensure the enlarged socket was achieved since during sitting pressure from the limb on the panels may not have been sufficient to overcome friction in the cable that might otherwise restrict panel radial motion. During sitting, participants' feet were on the floor and the knees were in approximately  $120^\circ$  of flexion. Participants sat for 10 minutes with the socket enlarged and sat for 2 more minutes while the phone app was used to return the socket to its original size. The basis for using 10-minute sits was that in prior socket release/relock investigation most participants demonstrated fluid volume recovery and retention for this duration of socket release.<sup>18,24</sup> We did not conduct shorter durations of socket release (eg, 90 s as used in some prior limb fluid volume testing protocols<sup>25-27</sup>) because participant physiologic variables may have confounded the results. Participants then stood for 10 seconds before walking on the treadmill for 2 minutes at a self-selected walking speed. For each participant, the same walking speed was used throughout testing. The sit and walk cycle was repeated three more times. The intervention was executed during the sitting portion of the fifth cycle. During the fifth cycle upon sitting, the locking pin tether was immediately released to 5 cm, and the socket size was enlarged by 4.0% by releasing the panels (~2 min). After the participant sat for 10 minutes with the pin and panels released, the researcher pulled the pin into the shuttle lock using the tether. Some of the participants needed to stand to push the pin all the way into the shuttle lock. In all cases, stomping the socket on the floor was avoided. After the pin was in the shuttle lock, the participant sat while the socket panels were returned to their original position (~2 min). The participant stood for 10 seconds before walking on the treadmill for 2 minutes. Three more cycles identical to the first 4 cycles were executed for a total of 8 cycles.

Three participants underwent a second test session, a protocol with no intervention, so that the curve fitting projection strategy could be evaluated. A curve fitting projection strategy was executed in our previous study.<sup>18</sup> Only three participants were tested because most of the participants could not be scheduled for a second session in a timely manner. The protocol described previously

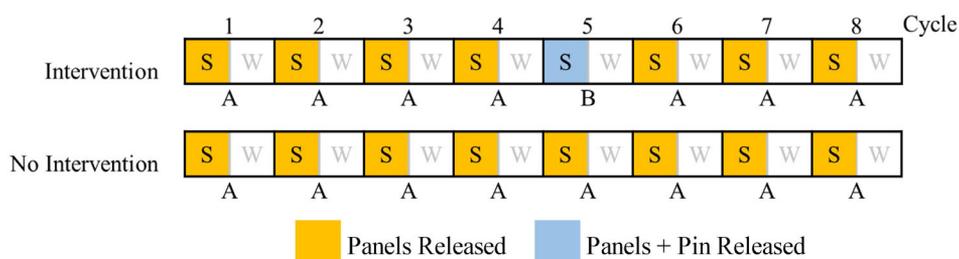
was conducted except that no intervention was executed during the fifth cycle. All 8 cycles were identical to the first cycle described.

### Data Processing and Analysis

Limb fluid volume data during the walking portions of the 8 cycles were segmented into steps, using procedures executed in our prior study.<sup>28</sup> One step was defined as the time between two adjacent maxima in inductive sensor data, identified using the MATLAB *findpeaks* function (Mathworks, Natick, MA). Minima, which occurred during stance phase, were calculated for each step and a mean value from all steps in each cycle was calculated. The first cycle was removed from analysis because it typically showed much variability.<sup>18,26,29</sup>

The mean stance phase minima from cycles 2, 3, and 4 were used to create the no-intervention projection for walks from cycles 5 through 8. We tested the performance of two modeling algorithms to create the projection. The two curve fitting functions used were a linear fit to data from cycles 3 and 4 (linear) and a logarithmic function fit to cycles 2 to 4 and then a linear continuation through to the end of cycle 8 (logarithmic/tangent) where the linear portion had a slope equal to the derivative of the logarithmic curve at cycle 4.<sup>18</sup> Performance of the two algorithms was tested by calculating the root-mean-square (RMS) error of the projected data compared with the experimental data for cycles 5 to 8. For the linear fit strategy, results demonstrated a median root mean square error (RMSE) of 0.35% fluid volume for the anterior region and 0.38% fluid volume for the posterior region, respectively. For the logarithmic/tangent strategy, results demonstrated a median RMSE of 0.71% for the anterior region and 0.63% for the posterior region, respectively. Because of its lower RMS error, the linear fit strategy was used to create projected results from testing session data.

Test (intervention) and projected (no intervention) data from cycle 5 (short-term) and from cycle 8 (long-term) were compared. Shapiro-Wilk tests were used to assess normality for the groups. Several of the groups were found to be non-normally distributed thus we chose to use the more conservative Wilcoxon signed rank test



**Figure 3.** The protocol included 8 cycles of sitting (S) and walking (W). The panels were released during every sit. During cycle 5 of the intervention protocol, the locking pin was also released. The projected no intervention control included 8 cycles of panel release only.

for all comparisons. A Wilcoxon signed rank test with a test statistic of 0.05 was used to test the hypothesis: The true median of the difference between the mean measured data and projected data is equal to zero.

## Results

Twelve individuals with transtibial amputation participated in this study. All had their amputation as a result of trauma. Ten were male, 2 were female. Median age was 45 years (range 26 to 75), median time since amputation was 19.5 years (range 2 to 49), and median weight was 84.3 kg (range 63.8 to 132.7). Three participants were classified at a functional classification level K4 and the remaining 9 were classified at K3. Median residual limb length was 15.0 cm (range 11.5 to 21.8), and median limb circumference was 27.6 cm (range 26.6 to 36.9).

For all 12 participants, variability (SD as percentage of the mean) in stance phase minima for a cycle averaged 0.32% (SD 0.29) at anterior sites and 0.27% (SD 0.11) at posterior sites.

Qualitatively, participants demonstrated two fluid volume responses to the intervention compared with the earlier cycles: (1) an immediate fluid volume increase that was maintained over time (through cycle 8) (Figure 4A) – 9 of 12 participants demonstrated this response at anterior and/or posterior locations; and (2) a decrease in rate of fluid volume loss over time (through cycle 8) (Figure 4B) – 7 of 12 participants demonstrated this response at anterior and/or posterior locations. Data of percent fluid volume change as a function of time for all participants are provided in Appendix S1.

In the short term, the median percent fluid volume for the test (intervention) and projected control (no intervention) were 0.21% and  $-0.50\%$  for the anterior region, respectively (Figure 5A). They were  $-0.12\%$  and  $-0.57\%$  for the posterior region, respectively. The measured limb fluid volume was not significantly different from the projected limb fluid volume ( $P = .0712$  for anterior,  $P = .1580$  for posterior) in the short term.

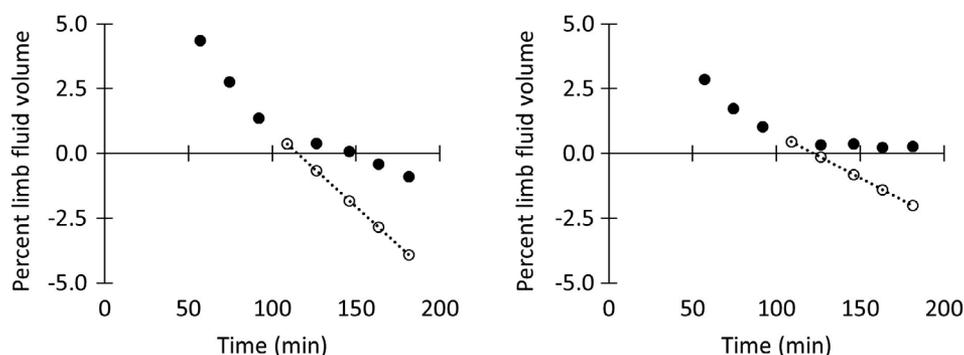
In the long term, the median percent fluid volume for the test (intervention) and projected (no intervention) were  $-0.32\%$  and  $-1.95\%$  for the anterior region, respectively (Figure 5B). They were  $-0.29\%$  and  $-2.12\%$  for the posterior region, respectively. The measured limb fluid volume was significantly different from the projected limb fluid volume ( $P = .0499$  for anterior,  $P = .0096$  for posterior) in the long term.

## Discussion

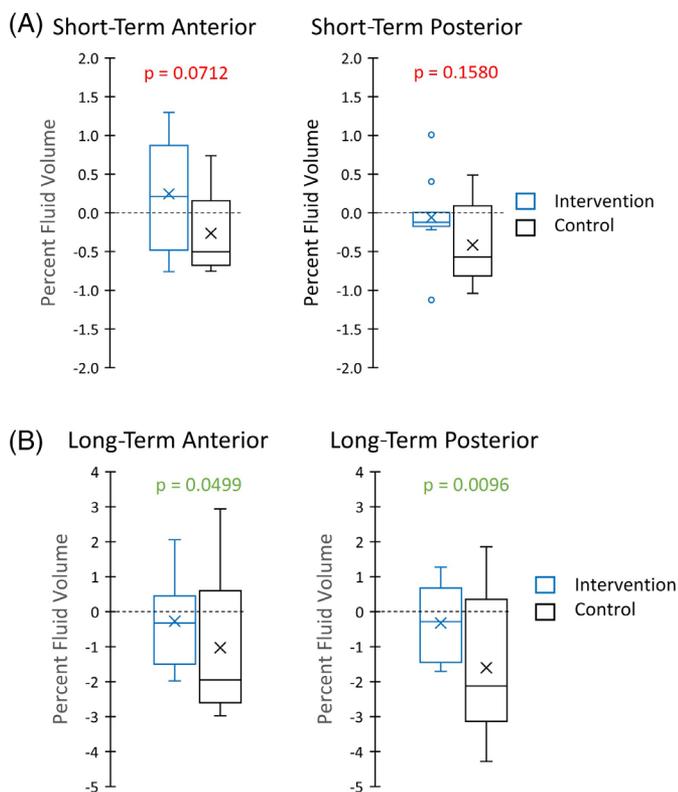
The purpose of this study was to determine if pin release executed with panel release facilitated limb fluid volume recovery and retention over panel release alone in people with transtibial limb amputation. Findings may facilitate the development of accommodation strategies to overcome diurnal fluid volume loss, one of the most challenging problems faced by prosthesis users.<sup>3</sup> Unlike adding socks or reducing socket size to accommodate volume loss, pin and panel release were expected to increase instead of decrease limb fluid volume.

In the present study, conducting both pin release and panel release likely improved subsequent percent fluid volume retention over panel release alone because interface stresses were better relieved during sitting. This relief may have allowed greater fluid volume recovery deep into the residual limb during the 10-minute sits. A locked pin keeps the residual limb pressed into the socket and may apply stresses distally, retarding fluid volume recovery. Further, the liner pulling the anterior distal limb may apply compressive stress and accentuate this behavior. This interpretation is consistent with results from a prior investigation where no improvement in limb fluid volume retention was observed when pin lock was maintained during sitting and liquid was removed from bladders inside the socket.<sup>17</sup>

It is unknown why long-term percent fluid volume retention was significantly improved but short term was not. We note that more than half of the participants demonstrated a more positive slope during cycles 5 to 8 for



**Figure 4.** (A, B) Example data demonstrating two common fluid volume responses to the intervention. The intervention was executed at approximately 110 minutes. Filled circles are intervention session test data. Open circles and dashed line are projected no intervention data. Data at approximately 110 minutes are coincident. In (A) there was an immediate fluid volume recovery that was well-maintained for the rest of the session. In (B) the rate of change of percent fluid volume increased.



**Figure 5.** (A, B) Percent fluid volume changes for intervention and projected no intervention. (A) Short term (after Cycle 5). (B) Long term (after Cycle 8). The box height represents the first to third quartile range. The whiskers represent the maximum and minimum values excluding outliers. The “x” within a box is the mean. The solid line within a box is the median. The open circles outside of the box are outliers in the data, that is, their distance from the edge of the box is more than 1.5 times the interquartile range (height of the box).

the intervention than the projected control. We propose a reason for this result is that the limb and socket were mechanically configured differently in the socket after the intervention. After pin and panel release were completed, socket re-donning was executed by first drawing in the locking pin tether, pulling the residual limb and liner deeper into the socket. Because socket volume was not yet reduced (the panels were still open), more residual limb soft tissue volume and more of the liner were in the distal socket than would have been if the panels had been closed before drawing in the tether. Subsequently, the panels were moved radially inward, applying compressive stress and holding deep in the socket distal residual limb soft tissues. This biomechanical configuration may have better retained limb fluid volume during subsequent activity. This explanation is conjecture and would need to be tested through rigorous scientific analysis.

Although the focus of this study was on comparison of panel and pin release to panel release alone, panel release alone may have improved limb fluid volume recovery and retention over no adjustment. The rate of limb fluid volume loss during cycles 2 to 4 in the present study was less (median of  $-2.10\%/h$ , range of  $-3.53\%/h$

to  $3.47\%/h$  for anterior; median of  $-1.14\%/h$ , range  $-4.16\%/h$  to  $1.25\%/h$  for posterior) than that in a prior investigation where no panel release was made during cycles 2 to 4<sup>18</sup> (median of  $-2.73\%/h$ , range of  $-9.92\%/h$  to  $-0.13\%/h$  for anterior; median of  $-2.78\%/h$ , range of  $-11.65\%/h$  to  $0.96\%/h$  for posterior). A rigorous investigation on a group of people with transtibial limb loss comparing panel release to no adjustment would need to be conducted to verify this result.

A variable that should be tested in future clinical research is the duration of pin and panel release. It also needs to be determined how long volume preservation lasts. In studies to date, 10 to 30-minute durations of socket release have been investigated.<sup>15,16,18,24</sup> However, results from 2 week monitoring 21 people with transtibial amputation in their free-living environments demonstrated that 50% of the doffs executed were less than 10 minutes long.<sup>30</sup> Does pin and panel release for durations less than 10 minutes also demonstrate improved fluid volume retention in the long term? It would also be relevant to determine if the speed of fluid volume recovery and the magnitude of retention can be accentuated by actively pulling the panels and liner outward during pin and panel release, inducing a vacuum-like action on the limb during sitting.

## Limitations

Most of the participants in this study had their limb amputation as a result of trauma; thus, it is unknown if comparable results would be achieved for people whose limb amputation was the result of a different etiology. Sockets worn in the present study were heavier than participants’ normal socket, which may have influenced the results. The curve fitting strategy used here may have affected the results. However, using the alternative strategy of a logarithmic function fit to cycles 2 to 4 and then a linear continuation through to cycle 8 produced a comparable interpretation. Posterior short-term and anterior long-term test statistic changes were not meaningfully different (from 0.158 to 0.209 for posterior short term; from 0.0499 to 0.0120 for anterior long term). Anterior short-term test statistic changes decreased (from 0.0712 to 0.0340) whereas posterior long-term changes increased (from 0.0096 to 0.0770). Although both of the anterior variables crossed the 0.05 test statistic criteria, one to statistical significance and one away from it, the changes are not drastic. Our interpretation of the data is consistent with either curve fitting strategy - adding pin release to panel release may enhance limb fluid volume recovery and retention. An appropriate next step is to test it under conditions more representative of regular use.

## Conclusion

Releasing the panels and locking pin of a cable-driven adjustable socket during sitting significantly improved

limb fluid volume retention over panel release alone in the long-term in the present study, suggesting that panel and pin release may be an effective accommodation strategy for prosthesis users. A next step is to evaluate use of panel and pin release and relock on participants who typically lose limb fluid volume over the day to determine if it improves their limb fluid volume retention, socket fit, and comfort over their current strategy for accommodation.

## Acknowledgment

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 USAMRAA.

## Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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**Disclosure**

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