

Preliminary investigation of residual-limb fluid volume changes within one day

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Abstract—The purpose of this research was to investigate rates of residual-limb fluid volume change within one day for people with transtibial limb loss. Rates of fluid volume change during 30 min test sessions of sitting, standing, and walking activities were measured twice a day, once in the morning and once in the afternoon, on 12 regular prosthesis users with the use of bioimpedance analysis. Between test sessions, all subjects consumed food and drink, and subject activity ranged from low to high. The rate of fluid volume change within sessions ranged from -8.5 to 5.9 %/h (median: -2.2 %/h). The rate of fluid volume change between sessions ranged from -2.7 to 0.9 %/h (median: -1.0 %/h). The between-session rate of fluid volume change correlated highly with afternoon within-session rates of change ($r = 0.9$) but was not well correlated with morning within-session rates of change ($r = 0.8$). Subjects with peripheral arterial complications showed greater fluid volume loss rates during test sessions than between sessions. Rate of fluid volume change may be affected by sitting, standing, and walking activities; presence of peripheral arterial complications; being female; time since amputation; and wearing the socket without doffing for extended periods.

Key words: amputation, bioimpedance analysis, diurnal, fluid volume, prosthesis, shrinkage, swelling, transtibial, volume accommodation, volume change.

INTRODUCTION

Some individuals with limb loss experience large changes in residual-limb volume during the course of a day.

The change may detrimentally affect the quality of prosthesis fit and the prosthesis user's skin health. Patients are advised to be mindful of their skin health and to add socks when the prosthesis feels loose [1–2]. New ways to control residual-limb volume change are being encouraged [3]. The presence of commercial volume accommodation technologies (e.g., elevated vacuum, fluid inserts [4–7]) suggests a need to meet the clinical demand for overcoming the detrimental effect of residual-limb volume fluctuation.

There is a single report in the literature about residual-limb volume changes measured from morning (AM) to afternoon (PM) in the same day [8]. Residual-limb volume changes measured 5 h apart every 5 wk for 6 mo on eight subjects, all of whom had their amputation >2 yr prior as a result of traumatic injury, ranged from a 1.5 percent volume loss to a 2.0 percent volume gain (absolute mean: 0.4%). This result suggests much variability in the data and, consistent with clinical experience, that residual-limb volume change may be strongly subject-dependent and/or day-dependent.

Abbreviations: ABI = ankle brachial index, AM = morning, BMI = body mass index, OBP = orthostatic blood pressure, PM = afternoon, SD = standard deviation.

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Recently, we developed a technique to measure residual-limb fluid volume change continuously while a subject wears his or her prosthetic limb [9–12]. This method potentially allows for further insight into within-day residual-limb fluid volume change and variables that affect it. The purpose of this research was to assess residual-limb fluid volume in sessions of sitting, standing, and walking activities 3 to 5 h apart within the same day; to investigate how the fluid volume change rate (percent volume change per hour) varied among subjects; and to explore whether the variation was related to subject health. We also compared between-session rates of change with within-session rates of change. This observational effort is an attempt to gain insight into how time, activity, subject health, and other subject characteristics affected residual-limb fluid volume, helping to identify potential variables to study in more depth in larger research studies.

METHODS

Subjects

Volunteers were eligible for inclusion in the study if they had a transtibial limb amputation at least 12 mo prior and were a limited community-level ambulator or more active (\geq K-2 on the Medicare Function Classification Level scale [13]). Other inclusion criteria were the ability to walk on a treadmill for at least 2 min at a self-selected walking speed and the ability to negotiate a 10 cm step (to step onto the treadmill). Exclusion criteria included current skin breakdown and/or a residual-limb length that did not allow at least 5.5 cm distance between voltage-sensing electrodes (described later).

Apparatus

We measured residual-limb fluid volume using a multifrequency bioimpedance analyzer (Hydra 4200, Xitron Technologies; San Diego, California) that we modified to measure extracellular fluid volume change on residual limbs. We prepared custom electrodes using conductive tape (0.09 mm thickness) (ARCare 8881, Adhesives Research Inc; Glen Rock, Pennsylvania) and custom multistranded silver-plated copper wire (32 AWG) with an Aramid core strand and PVC insulation (0.76 mm outer diameter) (New England Wire Technologies; Lisbon, New Hampshire). We attached the wire to the electrode by splicing its ends and then sandwiching it between two pieces of the conductive tape. We covered the underside of

the conductive tape with a hydrogel (KM10B, Katecho Inc; Des Moines, Iowa) to ensure good electrical coupling with the skin. We applied a very thin layer of ultrasonic coupling gel (Couplant D, GE Panametrics; West Chester, Ohio) between the hydrogel and skin. We covered the outside of the conductive tape with Tegaderm (0.03 mm thickness) (Transparent Film Dressing, 3M; St. Paul, Minnesota) such that the edges of the Tegaderm extended over the edges of the electrodes, preventing the electrode edges from peeling up during strenuous activity. We used different electrode dimensions depending on the electrode's function and position on the residual limb. The proximal current injecting electrode was 15.0×2.0 cm, while the distal current injecting electrode was 3.5 cm in diameter. The voltage sensing electrodes were both 7.5×2.0 cm. To reduce signal noise caused by mechanical movement of the wires, we created a custom four-pin Delrin flat connector (9.0×11.5 mm, 2.5 mm thickness) that accommodated gold-plated pins (WPI, Cooper Interconnect; Moorpark, California) to attach the four insulated lead wires from the bioimpedance instrument cable to the electrodes. We modified the cable to include a robust cable connector (MS3116F106S, Burndy; Manchester, New Hampshire) at the unit to minimize noise at this connection from cable motion. These enhancements ensured that a stable and consistent signal was recorded while the subject walked on the treadmill wearing the electrodes. The peak-to-peak fluctuation in signal while the subject stood bearing weight was typically <0.1 percent of the residual-limb fluid volume.

We plotted the bioimpedance data in approximately real time (3 s delay) at a 0.5 Hz sampling rate using custom MATLAB version 7.10 (The MathWorks Inc; Natick, Massachusetts) code implemented on a personal computer (Latitude D620, Dell; Round Rock, Texas). The custom MATLAB code implemented a Cole model [14], similar to that used in the postprocessing program [15]. Visualization of the data during the test session helped us to identify any existing setup problems.

Procedures

On a separate day before bioimpedance testing, but not more than 12 mo prior, we conducted a series of vascular tests. We asked subjects to refrain from consuming alcohol or caffeine before arriving at the laboratory on the test day. To test for high blood pressure, we conducted orthostatic blood pressure (OBP) assessment. We measured the subject's systolic and diastolic blood pressures

and heart rate using an electronic blood pressure measurement unit (HEM-775, Omron; Kyoto, Japan) during sitting, resting supine, and standing. To test for arterial disease, we assessed ankle brachial index (ABI) and segmental limb pressures on the contralateral limb using a commercial system (TD312 Cuff Inflator, MV10 Manifold Selector, and SC12 and SC10 cuffs, D. E. Hokanson Inc; Bellevue, Washington) and a Doppler flow meter (MD6 Doppler, D. E. Hokanson Inc). We did not conduct ABI testing on subjects with bilateral amputation. A practicing endocrinologist using standard clinical procedures interpreted collected data for the presence of high blood pressure and peripheral arterial complications [16–18]. We consulted subject health records to identify any major medical conditions (e.g., congestive heart failure, kidney failure, diabetes, cancer).

On the day of bioimpedance testing, we asked subjects to refrain from consuming alcohol or caffeine before arriving at the laboratory on the test day. After arriving for testing, the subject continued to wear his or her prosthesis while we recorded mass and height. The research practitioner assessed socket fit, ensuring pistonning was within clinically acceptable limits. If socket fit was deemed unacceptable, we referred the subject to his or her regular practitioner for modification. Afterward, the subject sat with the prosthesis supported on the floor. The research prosthetist recorded medical and prosthetic history in an interview lasting approximately 10 min.

We then conducted OBP assessment. If the results indicated instability relative to the OBP test results recorded during the vascular tests, we repeated the vascular tests and scheduled bioimpedance testing for a different day. After the subject doffed the prosthesis, we rubbed the skin gently with sandpaper (Red Dot Trace Prep 2236, 3M) at the sites electrodes were to be placed in order to achieve good electrical coupling [19]. We placed four electrodes on the residual limb. The outer pair injected current while the inner pair sensed voltage (**Figure 1**). We positioned the proximal voltage-sensing electrode at the level of the patellar tendon proximal to the fibular head. This position maximized the length over which we monitored, ensuring a clinically relevant measurement while at the same time avoiding error to the volume change measurement induced by knee flexion. By avoiding bony prominences, we minimized stress concentrations in the electrode and thus minimized risk of electrode mechanical failure. We placed the distal current injecting electrode on the bottom of the residual

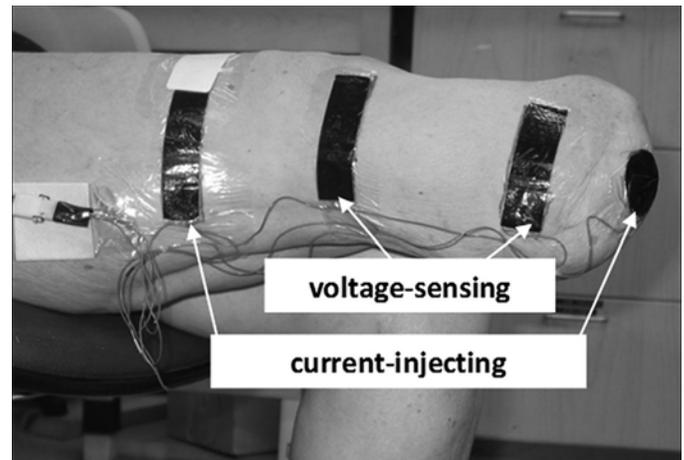


Figure 1.
Electrode configuration for bioimpedance analysis.

limb. We used a circular electrode for the distal current-injecting electrode instead of a rectangular one positioned more proximally, as done previously [9–12], to allow a longer portion of the residual limb to be monitored. We positioned the distal voltage-sensing electrode at least 3.5 cm proximal to the distal current-injecting electrode and always proximal to the distal end of the tibia. We placed the proximal current-injecting electrode 7 to 12 cm proximal of the proximal voltage-sensing electrode such that it was outside of the socket brim but under the liner or suspension sleeve. To ensure no loss of suction from air escaping along the lead wires extending out at the thigh from under the liner or sleeve, we placed Tegaderm over the four wires from the electrodes, making sure the wires were not bundled, which could have created channels for air to escape. The bioimpedance instrument applied current at between 50 and 700 μA across 50 frequencies (5 kHz to 1 MHz) each second and measured amplitude and phase differences between the injected and sensed signals at a 1 Hz sampling rate.

We collected data during two 30 min test sessions spaced 3 to 5 h apart, with the first session starting during the AM hours (between 8:30 and 10:30) and the second session starting during the PM hours (between 12:30 and 2:30). We selected these times because they were the longest intervals allowed by the participants' schedules. The test protocol was the same for both sessions. After we started collecting data with the bioimpedance analyzer, the subject donned the prosthesis and sat without talking for 2 min with the foot supported by the floor. Care was

taken to ensure good sitting posture, since too much knee flexion occludes blood flow and too much knee extension causes a slouching posture. The subject underwent five repeated cycles of sitting (90 s), standing with equal weight-bearing (90 s), walking on a treadmill at a self-selected walking speed (90 s), and standing with equal weight-bearing (10 s). We asked subjects not to talk because in pilot studies we found that some subjects got excited while talking, causing them to move their residual limb and affecting residual-limb fluid volume measurement. The total time of bioimpedance analysis sampling during a session was 38 ± 1 min (mean \pm standard deviation [SD]).

We left the electrodes on the residual limbs between sessions. We put the lead wires and thin custom connector under the proximal portion of the elastomeric liner or suspension sleeve so that they were not within the socket and were flush on the skin (no instrumentation was exposed). Because the electrodes were low profile, they did not cause skin irritation and were well tolerated by the subjects. At the end of the AM session, we instrumented the first six tested subjects' prostheses with a gait monitor (StepWatch, Orthocare Innovations; Oklahoma City, Oklahoma). However, because of performance problems caused by battery deterioration as a result of many years of disuse, we did not use the gait monitors on the remaining subjects.

We instructed the subject to conduct activities between sessions consistent with his or her normal lifestyle. Subjects could leave the laboratory for 3 to 5 h, and they were permitted to add socks between sessions if they considered it necessary but were otherwise asked not to doff their prosthesis. They were asked not to consume alcohol or caffeine between sessions. Upon returning to the laboratory, the subject sat with the prosthesis doffed for 10 min to mimic the doffing period during the AM session when electrodes were put on the residual limb. We inspected the electrodes to make sure they were intact and functioning properly. The research practitioner assessed socket fit; inspected the residual limb for injury; and queried the subject about sock changes, activity, and food and liquid consumption since the AM session. Based on his or her description, the subject's between-session activity was rated as low, medium, or high, with high considered standing or walking for at least half of the time between sessions. We noted that the activity within a test session was more intense than any subject's between-session activity. Low activity between sessions

indicated that the subject sat in a lobby near the laboratory for the time between sessions. We removed the gait monitor and downloaded the data. We started data collection with the bioimpedance analyzer, the subject donned the prosthesis, and we conducted the same test protocol as described earlier for the AM session.

Analysis

We calculated body mass index (BMI) as the quotient of mass (in kilograms) and the square of height (in meters) [20]. Because subjects wore their prosthesis while we measured mass, no correction was made to BMI for the lack of an intact limb. We processed bioimpedance data using custom code that implemented a Cole model to calculate extracellular fluid resistance [14]. Our algorithm was similar to that used by the commercial instrument manufacturer (version 2.2, Xitron Technologies). We developed our own code because of performance and processing speed problems encountered using the commercial software. We then converted the data to extracellular fluid volume using residual-limb circumference and segment length measurements in a well-accepted geometric limb model [21].

We used residual-limb fluid volume measured during equal weight-bearing within the 10 s standing periods after the 90 s walking intervals and the time of the measurement in analysis. These were the only data used for the quantitative results presented later. We considered the fluid volume (in milliliters) measured after the first walk cycle to be the reference volume for each subject. All fluid volume data were expressed as a percentage of that reference:

$$V_{\%}(t) = 100\% \times (V_{mL}(t) - V_{mL,ref})/V_{mL,ref}, \quad (1)$$

where V = residual-limb fluid volume and t = time. We used percent change instead of an absolute measure because bioimpedance measures fluid volume only within the region between voltage-sensing electrodes. The size of the region varied among subjects and depended on their residual-limb size and shape. Thus, we needed to normalize the data to a consistent reference for each subject. To determine the rate of fluid volume change within each session (AM_{%/h} and PM_{%/h}), we used the slope of a linear fit (lowest root-mean-square error) of the five data points within each session, denoted by $V_{\%}(i), t_i$, where $i = 1 \dots 5$ and represent the data points during the 10 s standing periods. We calculated the rate of fluid volume change between

sessions (Between_{%/h}) using the difference in residual-limb fluid volumes after the first cycle in the AM and PM sessions and dividing by the reference volume and the time between the two measurements:

$$\left(\frac{[V_{\text{mL},1\text{st cycle PM}} - V_{\text{mL},1\text{st cycle AM}}]}{V_{\text{mL,ref}}} \right) / t_{\text{between sessions}} \quad (2)$$

We performed descriptive analyses (summary statistics and visual displays) for all variables. The linear association between variables was assessed by Pearson correlation. Because of the exploratory nature of the study and the small sample size, the data analysis focused on exploratory and descriptive methods.

RESULTS

A total of 12 subjects (9 male and 3 female) with lower-limb amputation (11 unilateral and 1 bilateral) and age 54 ± 11 yr (range: 25–65 yr; median: 55 yr) participated in this research. Eight subjects had their amputation as a result of traumatic injury, and one subject each had their amputation as a result of thrombosis subsequent to trauma, arterial disease subsequent to diabetes, MRSA (Methicillin-resistant *Staphylococcus aureus*) infection, and osteomyelitis. Subject mass averaged 97 ± 26 kg (median: 100 kg). Time since amputation was 11 ± 13 yr (median: 6 yr), with six of the subjects between 1 and 3 yr postamputation. Subjects used their regular prosthesis in the study, which was deemed in the AM session by the research prosthetist to be of acceptable fit for regular use. Eight subjects used an elastomeric liner with lock and pin suspension, one used a Pelite liner with neoprene sleeve suspension, two used a suction socket with a gel liner, and one used a gel liner with no pin. All subjects used dynamic response prosthetic feet.

All electrodes functioned properly, and none needed to be replaced during or between tests on any subject. No subjects complained of discomfort or skin irritation from the instrumentation. The temperature in the room during testing was approximately 23°C. Relationships between percent residual-limb fluid volume versus time were approximately linear (**Figure 2**). Root-mean-square errors in linear fits to the percent volume versus time curves for within-session data averaged 0.15 ± 0.06 percent for AM sessions and 0.16 ± 0.08 percent for the PM sessions.

Of the 12 subjects tested, 9 subjects demonstrated fluid volume losses over time (apparent as a negative rate

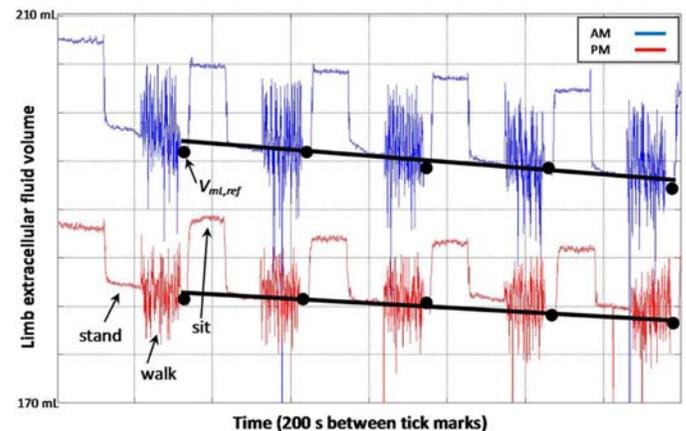


Figure 2.

Exemplary bioimpedance data collected during test sessions. Black dots indicate points during 10 s stand interval after each 90 s walk used in analysis. Rate of fluid volume (V) change was slope of linear fit to those five data points for each session. AM = morning, PM = afternoon.

of fluid volume change) for AM_{%/h}, 9 subjects for PM_{%/h}, and 10 subjects for Between_{%/h}. The direction of fluid volume change (loss or gain) for Between_{%/h} was the same as the direction of fluid volume change for AM_{%/h} for 9 subjects and the same as the direction of fluid volume change for PM_{%/h} for 11 subjects. **Figure 3** shows data illustrating fluid volumes over time as a percentage of the reference volume for all subjects. **Table 1** lists the range, median, and mean \pm SD fluid volume changes for each test condition. We found a strong Pearson correlation ($r = 0.9$) between PM_{%/h} and Between_{%/h} and a moderate correlation ($r = 0.8$) between AM_{%/h} and Between_{%/h} (**Figure 4**).

We conducted an exploratory analysis to investigate relationships between rate of fluid volume change and aspects of subject health. Subjects with peripheral arterial complications and female subjects tended to have greater between-session (Between_{%/h}) and within-PM session (PM_{%/h}) loss rates than subjects without peripheral arterial complications and male subjects (**Table 2**). Participants who had their limb amputation >5 yr prior tended to have greater between-session (Between_{%/h}) and within-PM session (PM_{%/h}) loss rates than those with amputation <5 yr prior, though we expect this result may reflect, in part, a less favorable health condition. Activity between sessions, K-level, use time of current socket, presence of high blood pressure, and presence of obesity or being overweight did

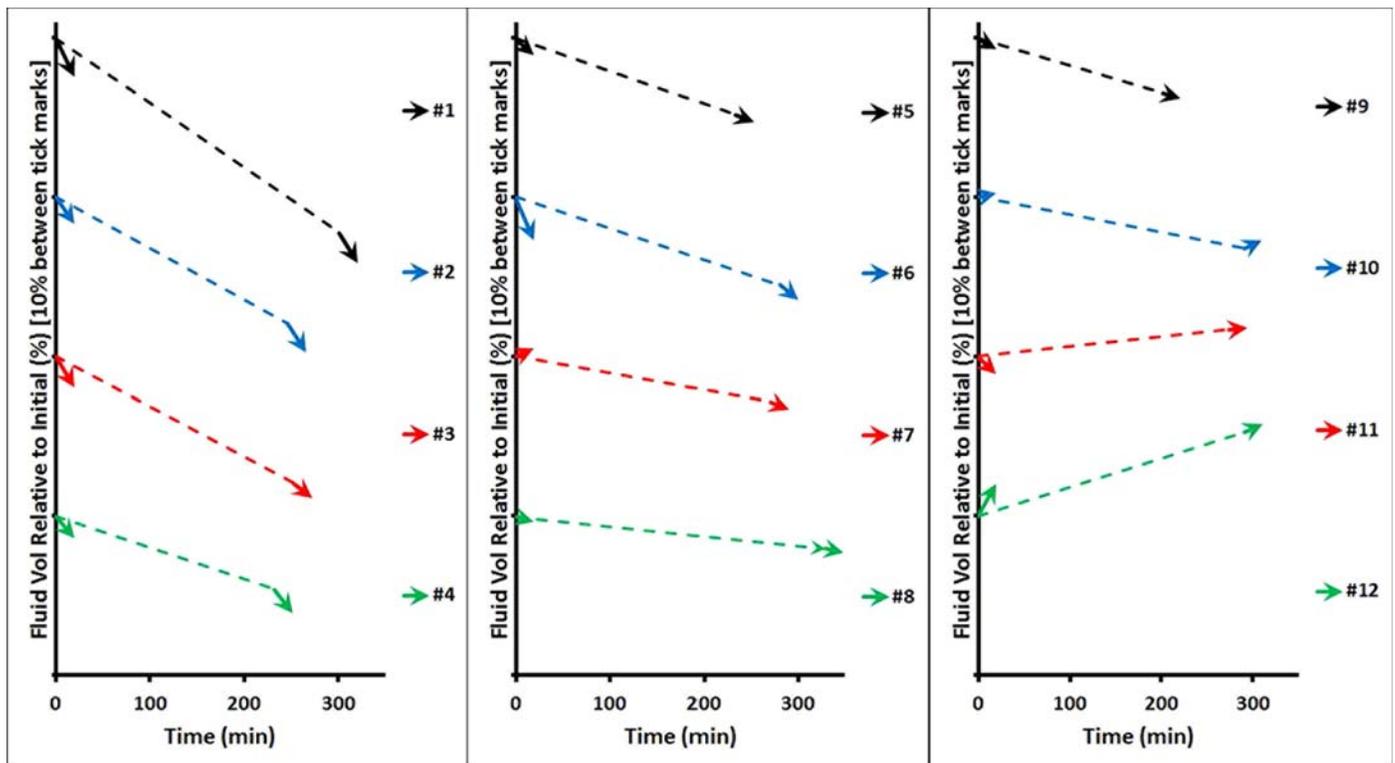


Figure 3.

Percent residual-limb fluid volume (Vol) change versus time for all subjects tested. Arrowed lines illustrate within-session fluid volume changes (morning and afternoon) and dashed lines represent between-session changes. Subjects are ordered from least to greatest between-session rate of change ($\text{Between}_{\%/\text{h}}$).

not appear to show a trend with $\text{AM}_{\%/\text{h}}$, $\text{PM}_{\%/\text{h}}$, or $\text{Between}_{\%/\text{h}}$ in this pilot study.

All five of the subjects with arterial disease (1, 2, 3, 4, and 6), and only those five subjects, demonstrated faster rates of fluid volume loss within sessions than between sessions (**Figure 5**). Two subjects (7 and 12) demonstrated fluid volume gains with sessions greater than fluid volume gains between sessions.

Only two of the subjects added socks between sessions (7 and 8). These two subjects showed lower rates of fluid

volume change than most of the other subjects. Interestingly, the research prosthetist's clinical inspection of socket fit during the PM session revealed that most of the subjects should have added socks but chose not to do so.

DISCUSSION

This preliminary investigation represents an extension from previous work quantifying residual-limb volume change in people with transtibial amputation [22]. We used a very sensitive in-socket measurement method, bioimpedance analysis, to quantify fluid volume changes within and between sessions conducted on the same day.

We considered several sources of error in our measurement and their effect on results and interpretation. In the presented analysis, we only used bioimpedance data collected while the subjects were in a consistent position, standing with equal weight-bearing. We used this strategy to help ensure that other potentially influential variables,

Table 1.

Rates of fluid volume change.

Variable	Range (%/h)	Median (%/h)	Mean \pm SD (%/h)
$\text{AM}_{\%/\text{h}}$	-8.5 to 5.9	-3.1	-2.4 \pm 4.0
$\text{PM}_{\%/\text{h}}$	-5.5 to 1.6	-1.4	-1.8 \pm 2.4
$\text{Between}_{\%/\text{h}}$	-2.7 to 0.9	-1.0	-1.0 \pm 1.0

AM = morning, PM = afternoon, SD = standard deviation.

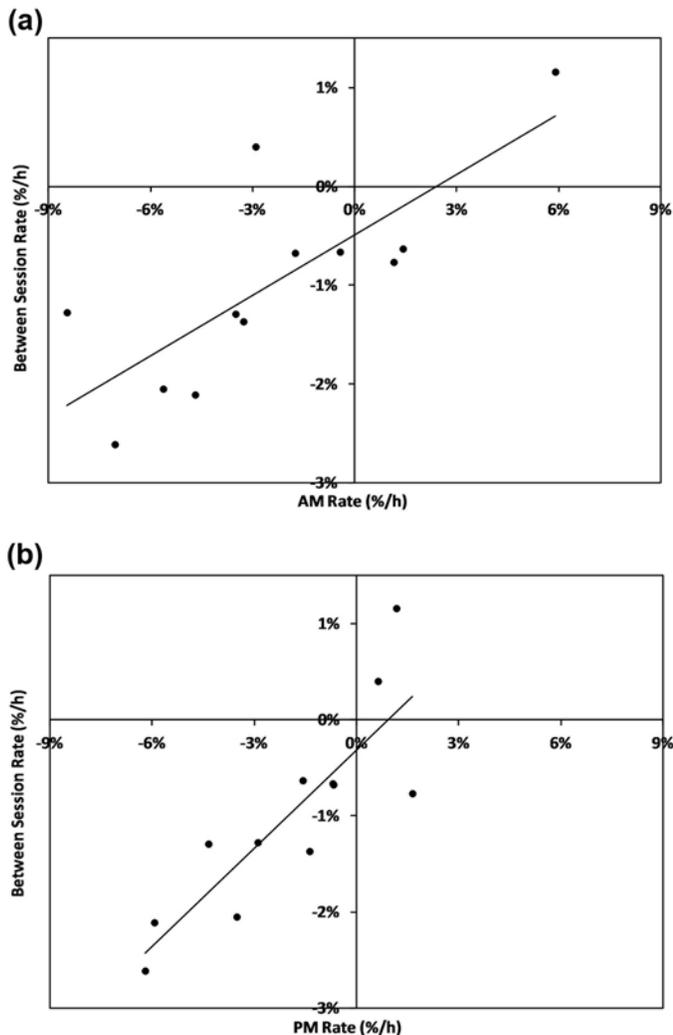


Figure 4. Relationships between rates of fluid volume change. (a) Morning (AM) session data correlated moderately well with between-session data ($r = 0.8$). (b) Afternoon (PM) session data correlated strongly with between-session data ($r = 0.9$).

e.g., different limb-socket interface stress distributions from different postures, did not distort the data of interest. We expect that bioimpedance data, presented here as percentage residual-limb fluid volume change per hour, were minimally sensitive to the anthropometric model used to convert extracellular fluid resistance to residual-limb fluid volume [21], since fluid volume is proportional to extracellular fluid resistance. Since most subjects decreased in residual-limb fluid volume within and between test sessions, it is unlikely that sweating affected instrument performance. If subjects sweated, conductivity between the

skin and electrodes would be enhanced, reducing extracellular fluid resistance and increasing residual-limb fluid volume, opposite of the within-session or between-session trends seen here.

The median rate of fluid volume change between sessions measured here, $-1.0\%/h$, is larger than the rate of residual-limb volume change measured in a previous study using an optical scanner, -0.3 to $0.4\%/h$ [8]. However, a different modality was used in that study (optical imaging) and out-of-socket data were collected rather than in-socket data.

Fluid volume gain (edema) over the day, as occurred for two subjects in the present study (11 and 12), might initially seem counterintuitive. However, a related trend, increase in limb fluid volume both after sock addition and after sock removal, was demonstrated in a related study investigating effects of sock addition and removal on residual-limb fluid volume in 5 of 28 subjects with amputation tested [12]. Also, residual-limb fluid volume gain over the day occurs in nondisabled individuals [23–25] and was demonstrated in the contralateral limb of a person with unilateral amputation [10]. In nondisabled people, this increase is thought to result from gravity pulling fluid distally into the limb during standing and walking.

The result that the slope of the plot relating between-session rate of fluid volume change ($\text{Between}_{\%/h}$) and PM within-session rate of change ($\text{PM}_{\%/h}$) was less than 1.0 (i.e., 0.3) and that subject activity within sessions was typically greater than that between sessions suggests that the high activity within test sessions increased fluid volume change. This result is consistent with clinical experience. However, because subjects still lost fluid volume between sessions when they were minimally active, the result also suggests that factors other than activity induced between-session fluid volume losses. It may be that wearing the socket without doffing for extended periods contributed to the residual-limb fluid volume decrease that occurred between sessions. With the socket donned, interstitial pressures will be elevated, reducing arterial to interstitial fluid transport and increasing interstitial to venous fluid transport. The net result is a fluid volume loss. A subject's posture while sitting might also reduce residual-limb fluid volume if a major vessel was restricted for a prolonged interval. Noteworthy in the present study and potentially relevant to the development

Table 2.

Test results and demographics for all subjects. Subject data were ordered from least to greatest by between-session rate of fluid volume change (Between_{%/h}).

Subject	AM (%/h)	Between (%/h)	PM (%/h)	Sock Change (ply)	Between Sessions	
					Activity Level	Caffeine
1	-7.1	-2.7	-5.5	—	Med	No
2	-4.7	-2.2	-5.5	—	Low	No
3	-5.6	-2.0	-3.2	—	Med	No
4	-3.5	-1.4	-4.2	—	Med	No
5	-3.3	-1.4	-1.3	—	High	No
6	-8.5	-1.1	-2.7	—	Low	No
7	1.4	-0.8	-1.5	+3	High	No
8	-0.4	-0.7	-0.7	+5	Med	No
9	-1.8	-0.7	-0.7	—	Med	No
10	1.2	-0.7	1.6	—	Low	No
11	-2.9	0.6	0.6	—	Med	No
12	5.9	0.9	1.2	—	High	Yes

Subject	Sex	Reason for Amputation	K-Level	Time Since Amputation (yr)	Time Current Socket Used (yr)	Residual-Limb Length (cm)	Liner	Suspension
1	M	Trauma	3	44	4.1	15.0	Pelite	Neoprene sleeve
2	F	Trauma	3	31	4.0	17.3	Elastomeric (Iceross* Comfort)	Lock/pin
3	F	Trauma	2	3	1.0	16.0	Elastomeric (Iceross* Comfort)	Lock/pin
4	M	Trauma/Thrombosis	3	13	4.0	18.7	Elastomeric (Alpha†)	Suction socket
5	F	Trauma	3	11	0.9	9.0	Elastomeric (Iceross* Comfort)	Lock/pin
6	M	Vascular (diabetes)	2	9	0.0	13.5	Elastomeric (Alpha†)	Lock/pin
7	M	Trauma	4	2	0.6	17.0	Elastomeric (Iceross* Comfort)	Lock/pin
8	M	MRSA Infection	3	1	0.2	29.0	Elastomeric (Iceross* Comfort)	Lock/pin
9	M	Trauma	3	2	2.3	19.8	Elastomeric (Alpha†)	Suction socket
10	M	Trauma	2	2	2.1	15.0	Elastomeric (Iceross* Dermo)	Lock/pin
11	M	Osteomyelitis	3	2	1.5	22.5	Gel (Iceross* Sensil)	No pin
12	M	Trauma	3	9	1.4	12.5	Elastomeric (Easyliner‡)	Lock/pin

Subject	Peripheral Arterial Disease	High Blood Pressure	Major Disease (Diabetes/Other)	Overweight§	Smoker
1	A	Yes	CHF	o	Yes
2	A	No	—	o	Yes
3	A	Yes	—	—	No
4	A	Yes	D	O	No
5	—	Yes	—	—	Yes
6	A	Yes	D	O	No
7	—	No	—	o	No
8	Un (bilat)	Yes	—	O	Yes
9	—	No	—	—	No
10	—	Yes	—	O	No
11	—	Yes	D, CHF, KF	O	No
12	—	Yes	—	o	No

Note: Medicare Functional Classification Level (K-Level). 2 = Patient has ability or potential for ambulation with ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of limited community ambulator. 3 = Patient has ability or potential for ambulation with variable cadence. Typical of community ambulator who has ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion. 4 = Patient has ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of prosthetic demands of child, active adult, or athlete.

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§O: BMI >30; o: 25 < BMI < 30.

A = peripheral arterial disease, AM = morning, bilat = bilateral, BMI = body mass index, CHF = congestive heart failure, D = diabetic, F = female, KF = kidney failure, M = male, Med = medium, MRSA = methicillin-resistant Staphylococcus aureus, PM = afternoon, un = unilateral.

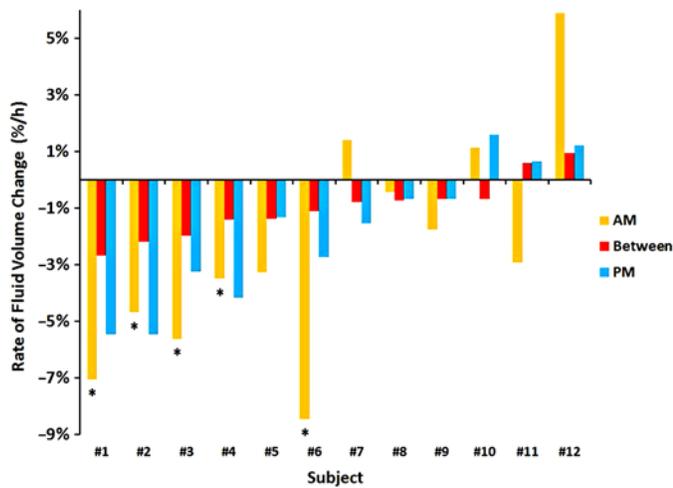


Figure 5.

Rates of fluid volume change. Subjects with peripheral arterial complications (*) showed greater fluid volume loss rates within sessions than between sessions. Subject identification numbers are the same as in **Table 2**. AM = morning, PM = afternoon.

of new volume management strategies is that the magnitude of between-session change was relatively high even for subjects with low activity between sessions.

In the present study, given the wide range of rate of fluid volume changes measured among subjects, we cannot state that there is a typical within-session rate and a typical between-session rate. However, the correlation between the rate of within-session and between-session changes was strong for the PM session ($r = 0.9$). We do not know from the present investigation how consistent the rate of change between sessions relative to the rate of change within sessions is from day to day for a person, though the strong correlation across subjects here suggests that it may be day-independent. A study collecting data from subjects on multiple days is needed to address this issue.

The magnitude of the ratio (0.3) between $\text{Between}_{\%/\text{h}}$ and $\text{PM}_{\%/\text{h}}$ may reflect the controlled study conditions under which we evaluated our test subjects and might not occur when test subjects are outside of the laboratory conducting their normal routines. Future research studies investigating the variables one at a time determined in the present study to potentially affect the rate of fluid volume change would help clarify this issue; these variables include amount and nature of activity, food and liquid intake, presence of peripheral arterial complications, female sex, time since amputation, and presence and durations of periods of prosthesis doffing.

In the present study, the absolute rate of residual-limb fluid volume change tended to be larger in the AM than in the PM, though this pattern did not occur in all subjects. Our study design did not control subject activity before the AM session, though from verbal input we know that some subjects rose for the day <1 h prior to arriving at the laboratory while others had been active for several hours. Further investigation is needed to understand the time course of residual-limb fluid volume change over the day and how much it depends on activity.

The trend of a greater rate of fluid volume loss during periods within sessions of high activity than between sessions with presence of peripheral arterial complications is consistent with physiological changes induced by arterial difficulties. Arterial complications may restrict fluid transport from the arterial vasculature into the interstitial space during activity, thus off-balancing it with fluid transport from the interstitial space into the venous system. More fluid may leave than enter the interstitial space because of insufficient arterial drive, unlike unaffected individuals who increase arterial drive during activity. High blood pressure, presence of a major disease, and BMI did not show a relationship with rates of fluid volume change in the present study, though the low number of subjects may have limited our ability to identify a trend.

We expect prosthetic suspension to influence the rate of residual-limb fluid volume change. Suspension techniques that apply tension to the distal residual limb during swing phase (e.g., lock and pin, suction, and vacuum) would be expected to facilitate residual-limb fluid volume recovery. They should offset the fluid volume departure during stance phase. Thus, a lower rate of fluid volume loss should occur with these suspension systems than without them. However, in the present study, the subjects who did not use a lock and pin, suction, or vacuum suspension system (1 and 10) did not show consistently less residual-limb fluid volume recovery than the other 10 subjects. It is likely that other variables besides suspension (e.g., subject health characteristics) influenced the results. A study isolating suspension as the controlled variable would need to be conducted to quantify its effect on residual-limb fluid volume changes within the day.

An important need in future research is to investigate relationships between volume change and subject outcomes in a large sample of this population. How much less comfortable are subjects with limb loss who experience large volume fluctuations within one day than those without, particularly if they do not accommodate their prosthesis? Do

volume change and subject comfort improve when the patient is fit with a new socket or uses a volume accommodation strategy intended to stabilize residual-limb fluid volume over the course of the day [4–7]? Addressing these questions will help specify design needs of volume accommodation technologies.

CONCLUSIONS

Percent residual-limb fluid volume change during sessions of activity involving cycles of sitting, standing, and walking changed approximately linearly over time. The within-session rate of change ranged from -8.5 to 5.9 %/h (median: -2.2 %/h). Between-session (3–5 h) rates of change ranged from -2.7 to 0.9 %/h (median: -1.0 %/h). Of the 12 subjects with transtibial amputation, 10 decreased in residual-limb fluid volume between sessions and 2 increased. The direction of fluid volume change for the PM session was the same as that between sessions for 11 of the 12 participants, but the same as the AM session for only 9 participants. There was a strong correlation between the PM rate of fluid volume change ($PM_{\%/h}$) and the between-session rate of fluid volume change ($Between_{\%/h}$) ($r = 0.9$). The slope relating $Between_{\%/h}$ to $PM_{\%/h}$ was 0.3. The correlation between $AM_{\%/h}$ and $Between_{\%/h}$ was less strong ($r = 0.8$). Subjects with peripheral arterial complications ($n = 5$) experienced greater fluid volume losses during sessions than between sessions; subjects who did not have peripheral arterial complications ($n = 7$) did not. Only two subjects added socks between test sessions, but the practitioner deemed by clinical assessment that most subjects should have added socks to maintain a proper prosthetic fit.

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