Title: The Utility of Activity Profiling in Rehabilitation Research: Measurement Immediately Following Trans-tibial Amputation

Meegan G Van Straaten, PT, MSPH
Motion Analysis Laboratory, Division of Orthopedic Research, Mayo Clinic, Rochester, MN

Emma Fortune, PhD
Motion Analysis Laboratory, Division of Orthopedic Research, Mayo Clinic, Rochester, MN

Irina Shakhnovich, MD,
Department of Medical Research, Gundersen Medical Foundation, La Crosse, Wisconsin

Kara J. Kallies, MS
Department of Medical Research, Gundersen Medical Foundation, La Crosse, Wisconsin

Andy L. Steele, MBA, CPO, LPO
Clark and Associates Prosthetics and Orthotics, Waterloo, IA

Dennis Clark, CPO, LPO
Clark and Associates Prosthetics and Orthotics, Waterloo, IA

Kenton R. Kaufman, PhD, PE
Motion Analysis Laboratory, Division of Orthopedic Research, Mayo Clinic, Rochester, MN

Abstract

Objective: To report inpatient activity in the immediate post-operative time frame following trans-tibial amputation.

Design: Observational study.

Setting: Multi-site, tertiary medical center and non-profit community hospital.

Participants: Older adults (N=4) who had acutely undergone a unilateral trans-tibial amputation.

Intervention: Not applicable.

Main Outcome Measures: Patients wore tri-axial accelerometers for four to five consecutive days on their waist and thigh of their sound limb. Posture and activity were tracked to document activity patterns, including daily time spent in static and dynamic upright and non-upright postures, daily distribution of postures, step counts and activity bouts.

Results: Subjects spent a median (IQR) of 4.8 (4.9) minutes a day in an upright posture, 0.5 (1.4) minutes active while upright, and 10.3 (7.4) minutes active while not upright. A median (IQR) of 29 (73) steps per day were observed. Time spent while upright occurred in a small number of concentrated periods. Changes in activity levels during the observation period were not observed.

Conclusions: Profiling activity as demonstrated may be used to measure the amount of activity needed to avoid effects of disuse and immobility in order to minimize poor outcomes following lower-limb amputation.

Keywords: Amputation, Physical activity, Postoperative period, Inpatients, Accelerometry

Abbreviations:

- CMS Center for Medicare and Medicaid Services
- IRB institutional review board

- BMI body mass indices
- IQR interquartile range

INTRODUCTION

The incidence of major lower limb amputation in the United States due to dysvascular disease is rising[1-3]. These individuals are typically older, with characteristics, such as multiple co-morbidities and reduced pre-operative ambulatory status, associated with poor post-operative outcomes[2-5]. Poor outcomes include high rates of mortality, reamputation, and hospitalization, as well as a low likelihood of achieving successful prosthetic fitting and use[2, 4]. Only one year after amputation, a 46% mortality rate has been reported[3]. Reamputation rates of 25% have been reported[1, 3], and prosthetic fittings of trans-tibial amputees have ranged from 23% to 47%[2, 3]. As a result of these poor outcomes, as well as the substantial resources required for inpatient hospitalization, rehabilitation, and prosthetic fabrication, there is a need to better understand the modifiable factors associated with poor outcomes. Since poor outcomes have been reported within the first year after amputation, it is important to identify potentially modifiable factors that can be altered in the immediate post-operative time frame in order to maximize positive patient outcomes.

Activity levels and the types of activities performed have been linked to health outcomes in many patient populations[6, 7]. Bed rest as a result of hospitalization of older adults is estimated to reduce muscle strength by 5% per day and may affect lower limbs more than upper limbs[8]. Older patients, especially those who have an acute lower limb amputation of vascular origin and may have had previous limited ambulation due to extended wound treatment, are often admitted to the hospital with a decreased physiological and functional reserve. Therefore any loss of strength or balance may significantly contribute to loss of functional independence. Despite these risks, bed-based hospital care is common[8].

Prosthetic preparation can occur while waiting for the wound to heal and the residual limb volume to stabilize. If a patient is to have a successful prosthetic fitting, hip and knee flexion contractures need to be avoided and deconditioning due to reduction in activity needs to be minimized. Previous studies have highlighted the ability to stand on the sound leg as one of the most important factors affecting positive outcomes and prosthetic fitting[3, 9]. Therefore, documenting out of bed activities, including upright postures will provide new insight into understanding outcomes in individuals with dysvascular disease leading to lower limb amputation.

A previous study by Dillingham and colleagues using data from the Center for Medicare and Medicaid Services (CMS) found that among transtibial amputees, those who received inpatient rehabilitation had a significantly higher survival rate and were more likely to receive a prescription for a prosthesis[1]. Additionally, improved outcomes, including fewer re-amputations and fewer hospitalizations for issues not related to their amputation, were seen in transfemoral amputees, indicating a more stable health status. These findings support the notion that intense therapy services and continued medical care provided by inpatient rehabilitation units can improve the poor prognosis and facilitate greater medical stability in this population. Among the 949 persons whose data were analyzed, only 22% of transtibial amputees were discharged to inpatient rehabilitation. This study by Dillingham and colleagues highlights the need to quantify activity in the acute inpatient, post-amputation setting.

Therefore, the purpose of this study is to report inpatient acute care activity captured during the days immediately following trans-tibial amputation. These data will add to the limited body of knowledge about patient activity in the immediate post-operative time frame. We hypothesized that during this time period activity levels would increase over time. Additionally, since the individuals in this study were ambulatory prior to surgery and deemed candidates for a prosthesis by their care team, we hypothesized that several of these activities would be performed in an upright posture.

METHODS

Subjects

Older adult subjects who had acutely undergone a unilateral trans-tibial amputation were recruited for participation in this study. Inclusion criteria included the cognitive ability to apply activity monitors and respond to surveys, a minimum of household ambulation with or without an assistive device prior to amputation, and the clinical care team's opinion that the subject would again be ambulatory with a prosthesis following amputation surgery. Exclusion criteria included post-surgical restrictions, disabilities or co-morbidities that would affect the participant's activity level, such as ordered bedrest, rheumatoid arthritis, or a neurological degenerative disorder. This was a multi-site study approved by the participating sites' institutional review boards (IRBs) and hospital administration. Written informed consent was obtained from all study subjects prior to participation.

Equipment and Protocol

Acceleration data were captured from the subjects using ActiGraph GT3X+ activity monitors, which each contain a tri-axial accelerometer with an acceleration range of +/-6g. The subjects wore the activity monitors for four to five consecutive days during the first eight days following amputation. Subjects wore one activity monitor on the waist and a second activity monitor on the thigh of the sound limb. Subjects were instructed to wear the thigh monitors on the anterior mid-thigh with the vertical axis of the activity monitor aligned with the superior-inferior anatomical axis of the thigh when in the neutral anatomical position. Subjects were also instructed to wear the activity monitors during typical daytime hours, and were told the activity monitors could be removed during nighttime sleeping and bathing. Additionally, instructions were written on room whiteboards to the nursing staff instructing that the monitors be worn during hours that the patient was awake. Monitors were secured to the subjects' bodies with elastic adjustable straps and were programmed to sample each axis at 50 Hz.

Data Analysis

All post-processing of accelerometer data were performed using MATLAB (Version 7.11.0, Mathworks, Natick, MA, USA). A valid activity detecting hour was defined as ≤30 minutes of consecutive 'zero' values (no activity) and a valid day as ≥10 wear hours per day [10]. Posture, dynamic activity and steps were calculated from accelerometer data using our previously developed and validated algorithm [11, 12]. As described in our algorithm development studies [11, 12], the raw accelerometer data were calibrated and median filtered, with a window size of 3, to remove any high-frequency noise spikes [12]. The resulting filtered signal was separated into its gravitational component by using a third-order zero phase lag elliptical low pass filter, with a cut-off frequency of 0.25 Hz, 0.01 dB passband ripple and -100 dB stopband ripple. Subtracting the gravitational component from the original median filtered signal provided the bodily motion component [13].

Dynamic activity was detected when the signal magnitude area (SMA) of the bodily motion component of the waist acceleration signal exceeded a threshold of 0.135g for epochs of 1 s [12]. For the epochs classified as non-activity, a continuous wavelet transform using a Daubechies 4 Mother Wavelet was applied to the waist acceleration data. Data which were within a range of 0.1 to 2.0 Hz was additionally identified as activity if it exceeded a scaling threshold of 1.5 over each second. Angle estimations from the gravity component of the thigh acceleration data were used to distinguish lying down and sitting postures from upright postures [12]. For each segment of data classified as upright dynamic activity, steps were detected using peak detection with adaptive acceleration and timing thresholds to detect foot-strikes from the thigh anteroposterior acceleration signal using the timing thresholds (adaptive and non-adaptive) described in [11]. In this study, consecutive steps were classified as a bout of steps if they occurred with less than 10 s intervals between them. Of particular interest, were bouts of steps with 4 or more consecutive steps as these have previously been defined as 'purposeful ambulating' [12].

RESULTS

The data of four older adult subjects (2 males, 2 females, aged 61 to 83) were analyzed (Table 1). The study participants had body mass indices (BMI) ranging from 24 to 30 kg/m^2. The subjects' ambulatory status ranged from community ambulation without a device to in-home ambulation with an assistive device. All subjects were able to ambulate without assistance from a care provider prior to their amputation.

Of the four subjects, three of them were treated by the same surgeon and received post-operative care in the same facility. Subject 4 had her amputation performed by a different surgeon in a different facility. Due to this difference, activity monitor data were collected immediately after amputation for Subjects 1, 2 and 3 (beginning on post-operative day #1.) Subject 4's data collection began on post-operative day #5. Subjects 1, 2, and 4 wore the monitors for four consecutive days. Subject 3 wore the monitors for five consecutive days. All subjects were transferred from in-patient acute care to in-patient rehabilitation within the same facility. This transfer occurred during the data collection for all four subjects. The time point at which this occurred is listed in Table 1.

Subjects spent a median (IQR) of 4.8 (4.9) minutes per day in an upright posture, 0.5 (1.4) minutes per day active while in an upright posture, and 10.3 (7.4) minutes per day active while in a non-upright posture (sitting or lying down) each day (Figure 1). There were no obvious changes in the daily amount of time spent in an upright posture, active while in an upright posture, or active while in a non-upright posture for any subject. Time spent in upright postures occurred in a small number of concentrated periods throughout each day (Figure 2). Subjects took a median (IQR) of 29 (73) steps per day (Figure 3). There was no obvious change in the daily number of steps, median number of steps per bout, or number of daily stepping bouts with 4 or more steps, for any subject (Figure 3).

DISCUSSION

This study adds to the limited body of knowledge quantifying activity levels immediately following trans-tibial amputation in older adults. The subjects in this study were ambulatory prior to surgery and deemed candidates for a prosthesis by their care team. Upright activities (which includes, standing, stand-pivot transfers, and hopping while using a walker) were documented, demonstrating the ability of our objective activity monitoring algorithms to track the subjects' posture and activity distribution throughout the day in the acute care setting. Although we expected to see activity levels increase during the observation period, these trends were not observed (Figures 1 and 3).

All subjects exhibited upright postures at some time during each day (Figure 1a). Upright posture, which includes standing, is important for facilitating lower extremity and trunk co-contractions in maintaining balance and posture. It is a good position for maintaining hip extension and ankle dorsiflexion flexibility of the sound limb. It can be performed with the use of devices such as walkers, parallel bars and rails to maintain safety. Therefore, we anticipated observing upright postures in this population who are expected to retain the ability to ambulate with a prosthesis. The amount of total upright time per day performed by our subjects was limited, ranging from 2 minutes to 14 minutes. Since time and activity spent in an upright posture is not typically reported, it is not known how to interpret these values. Presently, there are no clinical guidelines for the amount of time that a patient should spend in an upright position to (a) maintain or gain sound limb and trunk strength and balance, (b) maintain hip and ankle flexibility, or (c) maximize the success of utilizing a prosthesis. This is an obvious area for future research.

The amount of ambulation that occurred while upright was limited and did not change over time. The lack of increased step counts across time and daily stepping bouts may in fact be driven by care-provider instructions to mobilize via a wheelchair to avoid falls. Although no well-reported ambulatory guidelines for the pre-prosthetic use lower-limb amputee exist, experts often advise against "hopping" in this population due to the increased risk of falls and the high forces that are placed on the sound limb[14]. The methods used to collect the data in this study may be useful to document whether patients are following recommendations, and whether increased hopping is predictive of falls. Future studies should additionally record use of assistance (device and human) while hopping. In this study, a 'step' is detected from the acceleration data recorded by the activity monitors using acceleration characteristics typical to those observed before and during foot-strike, i.e. a sharp increase in acceleration followed a sharp decrease. It is therefore, not possible to distinguish between hopping with a walker and a modified hopping during stand pivot transfers from the bed to commode or chair or vice versa. Our methods of analyzing bouts of 4 consecutive steps minimized the possibility that stand pivot transfers would be included in the stepping analysis. It is difficult to compare the results in this study to other studies on amputees since literature reviews to date often only report step counts[15, 16]. Caution should be taken when comparing step counts (Figure 3) of amputees prior to prosthetic fitting, to amputees using prostheses[15-17], as well as to other populations receiving acute care and in-patient rehabilitative services[18].

It was surprising that the amount of time spent in non-upright activities did not increase over time (Figure 1c). Since the non-upright postures (lying and sitting) are not detrimental to the safety of the patient, it would be expected that activity such as therapeutic exercises in these postures would increase with each day of recovery. The amount of time spent active in these postures was very low, ranging from 2 to 18 minutes per day. Determining the reason for such limited activity in these safe postures is beyond the scope of this study, but is worthy of future investigation. It is highly desirable to learn if the limiting factor for more activity in a non-upright position is related to the patient, such as pain, fatigue, motivation, or the in-patient hospital environment, such as lack of clinical care staff, limited post-operative activity protocols, or hospital equipment. Further, the best dosage of activity to minimize the effects of immobilization and disuse and to minimize poor outcomes including rehospitalization, reamputation, and prosthetic disuse needs to be determined in order to improve patient outcomes.

Reporting the distribution of activities has gained recent attention. For example it is reported that activity distributed throughout the day can have greater health benefits than activity with the same energy expenditure during concentrated periods of time[19]. This study has shown the distribution throughout the day of the subjects' upright posture (Figure 2). As might be expected in an in-patient setting, upright posture time most likely occurs during meal or rehabilitation therapy times. As an in-patient, patients are expected to request assistance before getting out of bed and mobilizing both in and outside of the room, therefore this distribution profile may be expected. Gathering the daily distribution of upright activities may also have great use after discharge from the in-patient setting. Knowledge of the activity distribution and posture in a home setting may be correlated with independence, recovery, functional outcomes, and patient health.

It is important to recognize the limitations of this study when interpreting the findings. Data were only collected for four to five days in the acute care setting. Longer data collections, either continuous or at multiple time points, may be required to detect meaningful changes in activity and upright postures, which ultimately contribute to patient outcomes. It was beyond the scope of this study to report longer-term patient outcomes including hospital readmissions, mortality, and prosthetic usage. Longer term studies with larger sample sizes will be required to determine if activity levels immediately post-operatively are correlated with patient outcomes. Nonetheless, this study may be the first to objectively measure activity of trans-tibial amputees in the acute care setting. The knowledge gained illustrates the potential of using activity monitors to inform rehabilitation decisions, inform patient care algorithms, and provide objective evidence to guide treatment outcomes.

CONCLUSION

This hypothesis generating study demonstrated the successful use of tri-axial accelerometers to document activity patterns in the immediate post-operative period following trans-tibial amputation of older adults. Daily time spent in both static and dynamic upright and non-upright postures, the distribution of these upright postures, and step counts and bouts were reported. Active time in any posture was less than 20 minutes a day with essentially all upright bouts lasting less than 4 minutes. The ability to acquire this type of data will now make it possible to measure the amount of activity required to avoid the effects of disuse and immobility and, subsequently, minimize poor outcomes among a patient population that traditionally experiences high rates of poor outcomes following lower limb amputation.

SUPPLIERS

- ActiGraph GT3X, ActiGraph, LLC.
- MATLAB software version 7.11.0, Mathworks.

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Figure Captions

Figure 1. Total daily time spent (a) in an upright posture, (b) active while in an upright posture, and (c) active while in a sitting or lying posture for study subjects in the days following surgery. Upright posture includes standing still, standing while fidgeting, or stepping/walking.

Figure 2. Daily distribution of time spent in an upright posture, including the length of time each upright posture was maintained.

Figure 3. (a) Total daily step number, (b) median number of steps per bout, and (c) the number of daily stepping bouts with ≥ 4 steps for study subjects in the days following surgery.

Figure 1.

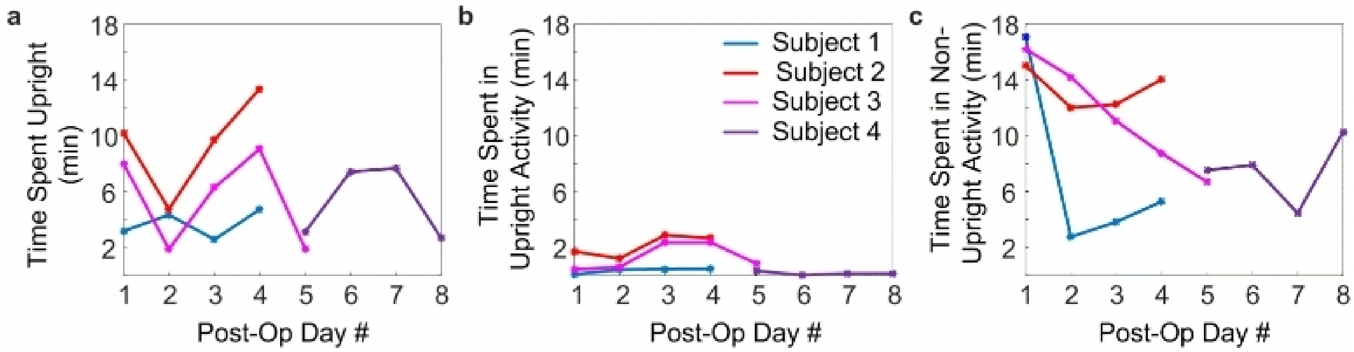
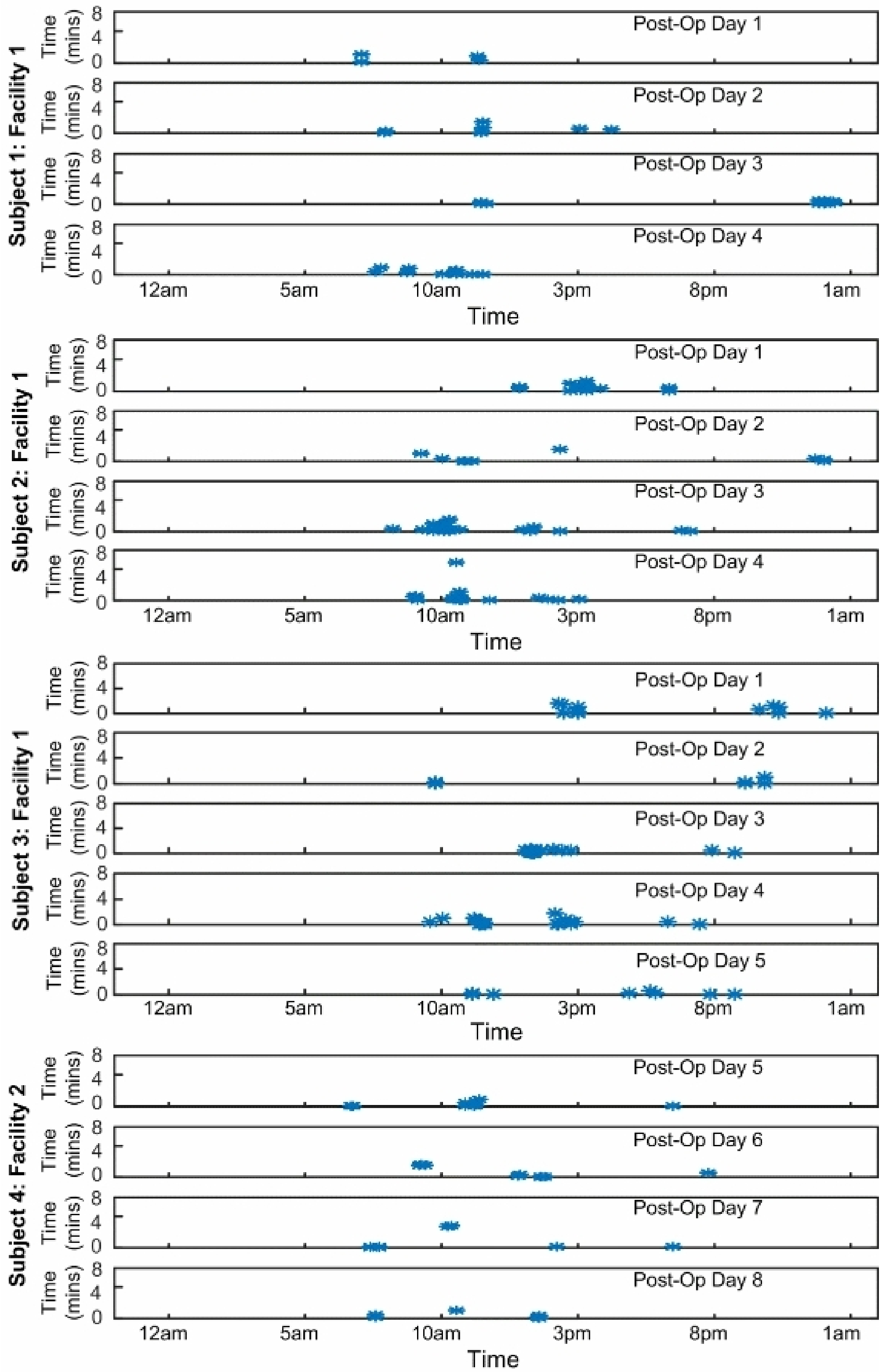

a
Time Spent Upright (min)
18
14
10
6
2
1 2 3 4 5 6 7 8
Post-Op Day #
b
Time Spent in Upright Activity (min)
Subject 1
Subject 2
Subject 3
Subject 4
Post-Op Day #
c
Time Spent in Non-Upright Activity (min)
Post-Op Day #

Figure 2.



Subject 1: Facility 1
Post-Op Day 1
Post-Op Day 2
Post-Op Day 3
Post-Op Day 4
Subject 2: Facility 1
Post-Op Day 1
Post-Op Day 2
Post-Op Day 3
Post-Op Day 4
Subject 3: Facility 1
Post-Op Day 1
Post-Op Day 2
Post-Op Day 3
Post-Op Day 4
Post-Op Day 5
Subject 4: Facility 2
Post-Op Day 5
Post-Op Day 6
Post-Op Day 7
Post-Op Day 8
Time (mins)
0
4
8
12am
5am
10am
3pm
8pm
1am
Time

Figure 3

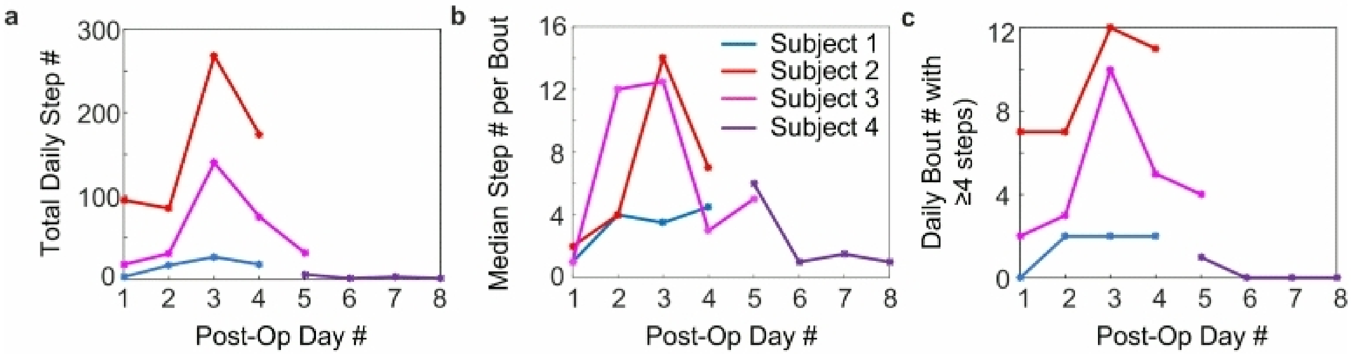

a
Total Daily Step #
300
200
100
0
1 2 3 4 5 6 7 8
Post-Op Day #
b
Median Step # per Bout
16
12
8
4
0
1 2 3 4 5 6 7 8
Post-Op Day #
Subject 1
Subject 2
Subject 3
Subject 4
c
Daily Bout # with ≥4 steps)
12
8
4
0
1 2 3 4 5 6 7 8
Post-Op Day #

Table 1

Table 1: Subject Characteristics

	Subject 1	Subject 2	Subject 3	Subject
Sex	M	M	F	F
Age (Years)	60.8	83.2	65.7	79.6
BMI	26.6	24.4	29.7	27.7
Amputation Etiology	Non-healing diabetic ulcer	Unknowingly Punctured foot due to peripheral neuropathy and insensate foot, infection	Bone infection secondary to diabetic ulcer	Drop foot and inversion contractures led to non-healing wounds and bone infection
Post op days of activity collected	1-4	1-4	1-5	5-8
Day patient transferred from in patient acute care to in-patients rehabilitation setting	3	3	2	6
Patient reported co-morbidities	DM, PN, O	PN, AN (mild_	DM	PN, O
Pre-Ambulatory status	Independent without assistive device in home and community	Independent without assistive device in home and community	Limited community ambulation with assistive device	In home ambulation with assistive device
Study site	1	1	1	2

DM = diabetes mellitus
PVD = peripheral vascular disease
RF = Renal failure or dialysis
PN = Peripheral neuropathy
AN = Anemia
O = other (drop foot, foot contractures, pre-existing back pain)