

Long-term activity in and among persons with transfemoral amputation

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Abstract—Although physical limitations associated with transfemoral amputation (TFA) have been studied in laboratory settings, little is known about habitual activity within free-living environments. A retrospective analysis of 12 mo of step activity data was performed to quantify activity levels, variations, and patterns in 17 adults with unilateral TFA. Yearly, seasonal, and monthly average daily step counts and coefficients of variation (CoVs) were examined to characterize mobility. Analysis by Medicare Functional Classification Level (MFCL) was performed to explore relationships between clinical classification and performance. Subjects averaged 1,540 prosthetic steps/day, and activity generally increased with MFCL. Activity between MFCL-2 and -3 subjects was not significantly different, suggesting that ability to engage in habitual physical activity may be similar for these groups. Relative variation (CoV) was 0.65 across subjects but was lower for those with higher activity levels. No significant differences in CoV by group were detected. Marked seasonal and monthly patterns in activity were identified. Warmer seasons and months generally promoted higher activity, but peak temperatures and humidity depressed activity. Results suggest that persons with TFA are greatly limited in regards to activity. Further, large variations within and between subjects may challenge the interpretation of step activity gathered over short periods of time.

Key words: activity monitor, ambulatory monitoring, amputation, artificial limb, mobility, outcome assessment, physical activity, rehabilitation, seasonal variation, step count.

INTRODUCTION

Limb loss is a life-altering condition with the potential to profoundly and irrevocably affect those who experience it. In addition to the acute physical impairments brought on

by amputation, loss of a limb induces considerable psychological and social challenges. As such, the goal of postamputation rehabilitation is not only to restore physical function but also to facilitate participation in life activities [1–2]. Achieving these objectives may be markedly affected by both the site (i.e., limb) and level of the amputation. Transfemoral amputation (TFA), for example, is associated with impaired strength [3–5], limited range of motion [6–7], diminished sensation [8–9], and pain [10–11] in the residual limb in addition to the loss of the distal limb (i.e., knee, leg, ankle, foot). Although a lower-limb prosthesis is traditionally provided to replace absent limb structures, its capability to restore function and fulfill users' needs is limited, variable, and not well defined.

The lower limb plays a critical role in control and movement of the body. These fundamental abilities are therefore considerably limited among persons with TFA. Use of a prosthesis may promote independence in activities that incorporate the lower limb (e.g., postural transitions, locomotion), but prominent deficits remain. Standing balance [12], level-ground walking [13–18], stair ascent and descent [19–21], hill ascent and descent [22], negotiation of uneven terrain [14], standing from

Abbreviations: CoV = coefficient of variation, MFCL = Medicare Functional Classification Level, SD = standard deviation, TFA = transfemoral amputation.

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and sitting in a chair [23], and obstacle avoidance [24] have been reported to be significantly impaired in persons with TFA compared to nondisabled control subjects. Documented limitations typically relate to the capacity of prosthetic users to engage in specified activities compared with those without amputation in controlled laboratory environments. While it is reasonable to assume that persons with TFA are similarly limited within their personal or lived environments, little evidence exists as to the performance of TFA prosthetic users in uncontrolled settings [25–26]. Such information is desirable so as to inform the degree to which prosthetic users are restricted in their ability to participate in situations at home, at work, or in their communities.

Obtaining information about how prostheses are used outside of a controlled setting (e.g., clinic, laboratory) is challenged by measurement of individual performance in and across the variety of locations, settings, and environments in which prosthetic users choose to live. Further, involvement in life situations is multidimensional and includes a range of important factors, including mobility; self-care; domestic life; interpersonal interactions and relationships; major life areas (e.g., education, vocation); and community, social, and civic life [27]. As a result, evaluation of individual participation is traditionally accomplished using global surveys or self-report instruments [2,28–30]. These subjective tools have suggested that restrictions are common among persons with lower-limb loss [31–36]. However, differences between self-report and assessed mobility outcomes in this population [25] suggest that surveys alone may be insufficient to fully characterize restrictions experienced by persons with TFA.

Direct measurement of persons' experiences may complement information derived from self-reports and has the potential to inform on specific aspects of participation. To the authors' knowledge, direct performance measures have not been used to assess participation among persons with lower-limb loss. This may be because performance instruments traditionally involve assessment of an activity (e.g., level-ground walking) deemed to be representative of a single trait or construct (e.g., locomotion). Given that such evaluations typically occur in a localized setting (e.g., laboratory) and within a brief time period (e.g., data collection session), it is challenging to extrapolate those results to the lived environment. However, using instruments capable of direct measurement in such settings and over extended periods of time (e.g., weeks, months, years) may reflect attributes

of participation that cannot be obtained using conventional measures or measurement techniques.

Various types of activity monitors have been developed to measure performance in the lived environment [37–38]. Such devices have been used to assess periods of activity, both among persons with TFA [25,39–42] and in other populations [43–45]. Although using activity monitors in research is becoming increasingly common [46], outcomes obtained by such devices are often restricted by the period of use. For example, use of step activity monitors in persons with TFA has been limited to periods of 6 [25], 7 [39,41], and 14 d [40]. Although it is acknowledged that standards for assessment duration are not well established and vary by population [43], the sampling periods used to measure persons with TFA are often below those recommended by activity monitor manufacturers [47] and activity researchers [48–49]. Further, while such measurements may reflect activity in the lived environment, these brief assessment periods may not well represent patterns or variations that are likely to be indicative of individual participation. At the very least, it must be acknowledged that relatively little is known about long-term activity in persons with TFA, including how individuals vary and how activity changes with month or season. Although such questions have been explored in nondisabled persons [48,50–51], school-age children [52], and elderly persons [53], no such studies of persons with lower-limb loss exist.

Therefore, the purpose of this study was to objectively characterize the mobility dimension of participation in persons with TFA using long-term step activity data. A secondary purpose of this study was to determine how activity of persons with TFA varies over extended periods of time. The authors hypothesized that persons with TFA are restricted in their mobility and that level of and variations in activity are reduced when compared with those of persons without amputation described in the literature. The results of this study are expected to enhance understanding of mobility limitations and restrictions in persons with TFA and inform future research protocols that include activity monitoring as an outcome.

METHODS

Study Design

A retrospective analysis was conducted of 12 mo of longitudinal step activity data collected in a previous

study [40,54] to assess the specified hypotheses. The original study was a prospective, crossover study of two different prostheses worn by persons with TFA. The study was divided into two phases, a period of alternating prosthetic interventions and an extended evaluation period where both prostheses were available to study subjects at all times. While the variable accommodation time described in the original study [40] led to unequal overall periods of observation for each subject, the extended evaluation period was comparable (i.e., 12 mo) across subjects. Therefore, data was extracted from the extended evaluation period to use for this analysis.

Subjects

Seventeen persons with TFA completed the original study [54] and are included in this analysis. Details regarding subject selection criteria are described elsewhere [40,54]. In short, inclusion criteria included unilateral TFA, ≥ 18 yr old, ≥ 2 yr postamputation, Medicare Functional Classification Level (MFCL)-2 or -3, and regular prosthesis use. Exclusion criteria included health or skin issues that may have prevented use of a prosthesis for ambulatory activities. Study subjects used different socket designs and suspension methods, but individual subjects maintained the same style of socket and suspension system throughout the study period. For the period of assessment in this analysis (i.e., the extended evaluation period), each subject had two well-fitting, comfortable prostheses available to them for daily use. The prostheses were similar in all respects, save one. One included a non-microprocessor-controlled (i.e., mechanical) knee and the other included a microprocessor-controlled knee (i.e., C-Leg model 3C98, Otto Bock; Duderstadt, Germany).

Instrumentation

Long-term step activity was measured using the StepWatch 2 activity monitor (Orthocare Innovations; Oklahoma City, Oklahoma) [47]. The StepWatch 2 is a small ($5.0 \times 6.5 \times 1.5$ cm), lightweight (65 g) accelerometer-based device. The activity monitor is capable of recording a maximum of 28 d of continuous activity, at which time the unit's data must be downloaded and the memory cleared before additional data can be collected. For this study, activity monitors were programmed to record activity in 1 min intervals until the memory was depleted. Monitors were individually programmed for each subject according to the manufacturer's instructions. One moni-

tor was attached to each prosthesis available to the subjects' lateral (for right-leg amputation) or medial (for left-leg amputation) aspect of the prosthetic pylon proximal to the foot, consistent with the manufacturers' instructions [47]. Therefore, step activity presented here is representative of data obtained from one limb only.

Protocol

During the 12 mo extended observation period [54], study subjects were provided with both prostheses and asked to go about their normal lives in the manner to which they were accustomed. Subjects were encouraged to use either or both prostheses as desired throughout the evaluation period. Subjects were asked to return to the laboratory every 4 wk for download of the activity monitor data.

Data Manipulation/Reduction

Activity monitor data were downloaded using the manufacturer's software at each subject visit. Data for each subject, prosthesis, and period were exported from the StepWatch 2 software into Excel (Microsoft; Redmond, Washington) for analysis. Each subject's total daily step counts for both prostheses were combined. Because subjects each started the period of extended evaluation at different times of the year, subjects' data were standardized to an equivalent annual cycle (i.e., January 1 to December 31) (Figure 1).

If subjects' activity monitors were not downloaded before the memory was depleted, dates that occurred after the memory had been filled were not associated with activity of any kind. These gaps in the data were interpreted as missing and were not included in subsequent analyses. If the total daily step count recorded by an activity monitor was 10 steps or fewer, these data were assigned a zero value and included in subsequent analyses. This threshold was applied to remove data that may have recorded if an activity monitor was bumped and errantly registered a small number of steps. Lastly, activity data from both prostheses were summed for each day in the annual cycle. If summed activity was zero, this was interpreted to mean that subjects elected not to use either prosthesis (or elected to take fewer than 10 steps on either prosthesis).

Analyses

Daily step activity means and standard deviations (SDs) were computed over annual, seasonal, and monthly

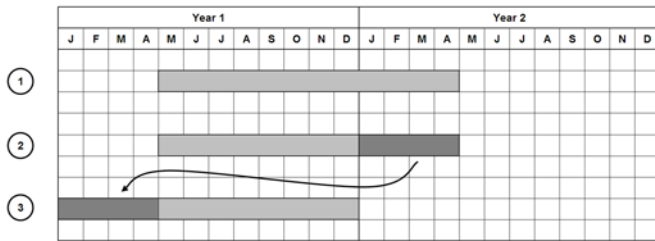


Figure 1.

Illustration of step activity data manipulation to standardize periods of analysis. (1) Original period of data collection extended between May (year 1) and April (year 2). (2) Data segmented into periods in years 1 (May–December) and 2 (January–April). (3) Data from year 2 (January–April) transposed to precede data in year 1 (May–December), thereby creating standardized “annual” cycle (January–December).

periods for each subject. Annual periods were based on the annual cycle described previously (i.e., January 1 to December 31). Seasonal (i.e., winter, spring, summer, autumn) periods were based on the equinoctial points of the years in which the data were collected (i.e., 2002–2004). Monthly periods were based on the calendar dates in the month in which the data were collected. Daily step activity over seasonal and monthly periods were contrasted with those computed over annual periods to assess the relative fluctuations in activity that occurred during the year. These fluctuations were expressed as nondimensional ratios (e.g., daily activity during the winter months/daily activity over the year). Variations in daily step activity for each subject and time period (i.e., year, season, month) were also quantified via the coefficient of variation (CoV), a measure of the relative variations in data with respect to the mean [55].

As a secondary analysis, these methods were also applied to groups of subjects defined by their MFCL [56]. The MFCL denote a subject’s ability or potential to ambulate with a prosthesis. Subjects originally classified at the beginning of the study as MFCL-2 or -3 were re-evaluated and subsequently classified as MFCL-2, -3, or -4 based on consensus of the study prosthetist and physical therapist at the end of the assessment period [54]. Differences in daily step activity means and CoV between these groups were assessed using a one-way analysis of variance and a Tukey honestly significant difference post hoc analysis. Statistical analysis was performed with

SPSS version 17.0 (IBM Corporation; Armonk, New York). Significance level was set at $p < 0.05$.

RESULTS

Seventeen subjects with unilateral TFA completed the 12 mo longitudinal assessment period (Table). Subjects were predominantly male ($n = 13$) and were between 21 and 77 yr old (mean \pm SD: 49.1 ± 16.4 yr). Reasons for amputation included trauma (58%), malignancy (18%), infection (12%), dysfunction (6%), and vascular disease (6%). Time since amputation ranged from 2 to 67 yr (17.6 ± 18.4 yr). Study subjects were evaluated for MFCL at the end of the assessment period. Subjects were classified as MFCL-4 (18%), -3 (47%), or -2 (35%) by consensus of the study prosthetist and physical therapist.

An average of 265 ± 56 days of step count activity was recorded per person over the evaluation period. The number of days recorded per individual ranged from 145 (40% of the period) to 359 (98% of the period). Days in which no steps were recorded on either prosthesis ranged from 0 to 90 (mean: 26). As such, it was assumed that subjects elected to not wear a prosthesis between 0 and 28 percent (mean: 9.6%) of the days in which they were measured.

Individual subjects averaged from 497 ± 275 to $2,675 \pm 992$ prosthetic steps/day over the 12 mo study period (Figure 2(a)). Subjects’ relative variation in annual step count activity, as described by the CoV, ranged between 0.37 and 1.17 (Figure 2(b)). The population, as a whole, averaged $1,540 \pm 726$ steps/day and showed a mean CoV of 0.65. Subjects classified as MFCL-2, -3, and -4 averaged $1,154 \pm 538$, $1,446 \pm 641$, and $2,560 \pm 100$ steps/day, respectively, and exhibited CoVs of 0.66, 0.72, and 0.47, respectively. Significant differences in mean daily step count were noted between subjects classified as MFCL-4 and those classified as MFCL-3 ($p = 0.03$) and those classified as MFCL-2 ($p = 0.01$). Conversely, differences in activity between subjects classified as MFCL-2 or -3 were not significant ($p = 0.61$). No significant differences in relative variation in activity (i.e., CoV) were detected among MFCL subgroups.

Analysis of temporal periods (e.g., seasons, months) revealed elevated and depressed activity when compared with annual means but markedly varied among subjects. Subjects showed changes in activity up to 46.1 percent

Table.

Demographics of subjects included in retrospective analysis. Sex, age, time since amputation, residual-limb length, etiology of amputation, and employment status were collected at enrollment, as reported in Hafner et al. [40]. Medicare Functional Classification Level (MFCL) was reported at conclusion of study, as reported in Hafner and Smith [54].

Subject	Sex	Age (yr)	Time Since Amputation (yr)	Residual-Limb Length*	Etiology of Amputation	Employment Status	MFCL
1	F	50	2	Short	Trauma	Part-time	2
2	M	46	2	Long	Trauma	On Disability [†]	2
3	M	58	21	Long	Dysfunction [‡]	Retired	3
4	M	59	7	Short	Trauma	Retired	3
5	F	62	5	Medium	Trauma	Retired	2
6	M	77	30	Long	Trauma	Retired	3
7	M	33	3	Medium	Trauma	On Disability [†]	3
8	M	33	33	Short	Malignancy	Full-time	4
9	M	39	2	Long	Trauma	Full-time	3
10	F	39	37	Medium	Malignancy	Full-time	3
11	M	31	3	Medium	Trauma	Student	4
12	M	21	12	Short	Trauma	Student	3
13	M	36	6	Medium	Infection	Full-time	2
14	M	67	37	Medium	Trauma	Part-time	3
15	F	45	27	Medium	Malignancy	Full-time	4
16	M	71	67	Long	Infection	Retired	2
17	M	67	6	Medium	Vascular Disease	Part-time	2

*Relative to nonamputated thigh length, i.e., short: <1/3, medium: 1/3–2/3, long: >2/3.

[†]Temporary or permanent disability-related level.

[‡]Amputation performed to address physical deformity and chronic musculoskeletal weakness resulting from polio.

F = female, M = male.

higher and up to 51.4 percent lower than their annual mean (**Figure 3**). Monthly changes were more extreme, ranging from 128.9 percent higher to 98.8 percent lower than subjects' annual means (**Figure 4**). The majority of the study sample showed increased activity (i.e., greater number of steps compared with subject's annual mean) in spring and summer and in the months April, May, June, September, and December. Similarly, the majority of the sample showed depressed activity (i.e., fewer number of steps compared with the subject's annual mean) in autumn and winter and in the months January, February, March, July, August, October, and November. The **Appendix** (available online only) shows raw monthly, seasonal, and yearly data for subjects.

Examining individual subjects' activity revealed that variations by season and month were difficult to predict based on visual inspection of step activity data, mean step activity, or relative variation. **Figure 5** highlights three cases of subjects with visually distinct activity presentations (**Figure 5(a)**). Subjects 7, 14, and 16 showed mean daily step counts of 1,724, 2,564, and 497 steps/day, respectively, and relative variation of 1.00, 0.37, and

0.55, respectively, over the study period. Despite notable differences in activity and variation, each subject exhibited approximately 20 to 25 percent reduced activity in winter and approximately 10 to 15 percent increased activity in spring (**Figure 5(b)**). Monthly variations showed similar cyclical patterns, but the magnitude of the changes differed among the cases (**Figure 5(c)**).

DISCUSSION

This study examined the mobility dimension of participation in persons with TFA. Mobility was characterized by daily step counts and relative variation in activity as measured over a 12 mo period. The authors recognize the challenges associated with characterizing participation in such a manner, especially in light of the ongoing debate concerning distinctions between activity and participation [57–59]. Although the fundamental unit of measurement in this study (i.e., a step) would likely be classified by many as an activity, the authors believed that measurement of step activity levels over longer

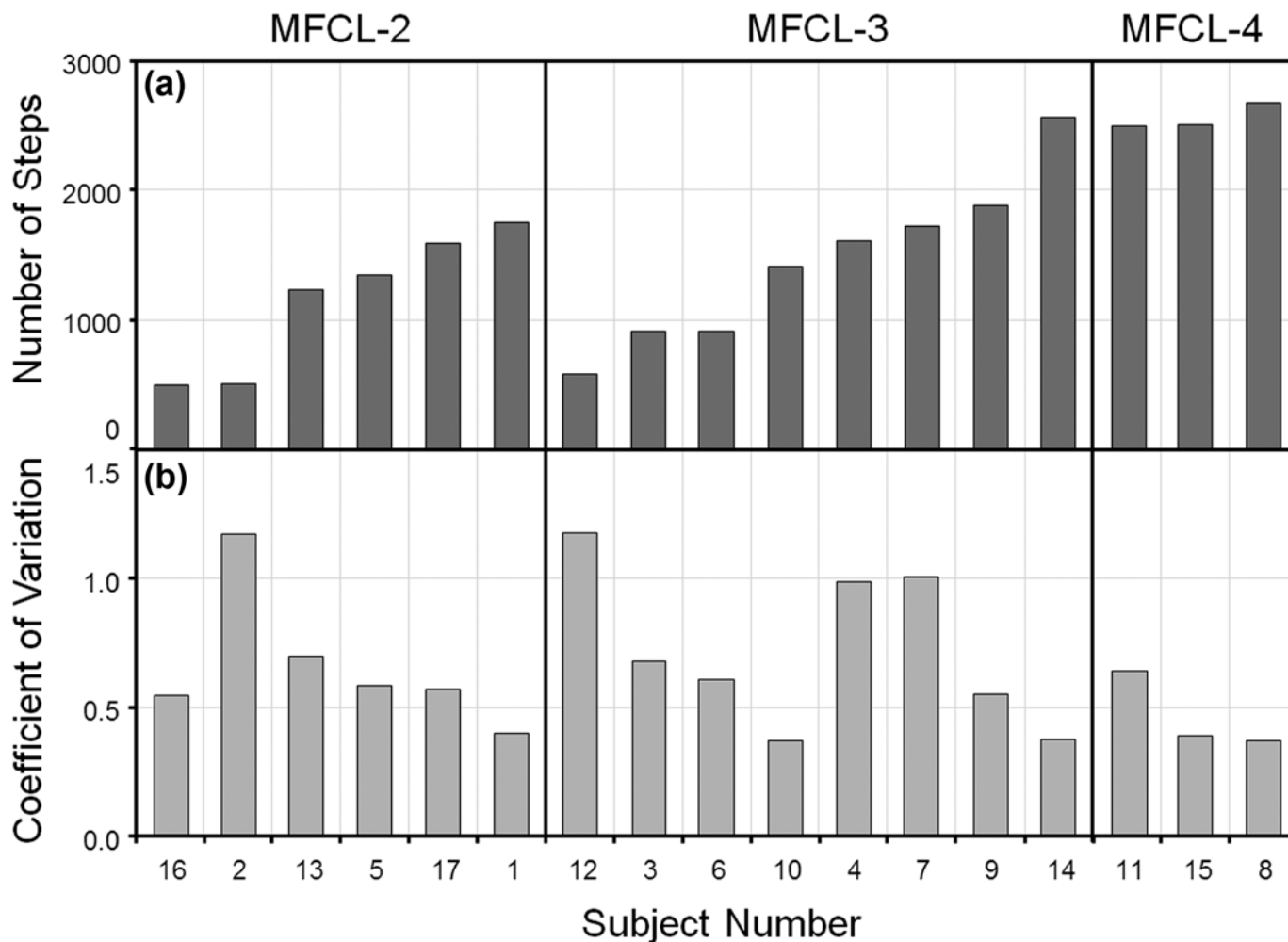


Figure 2.

Annual activity by subject over 12 mo period of study. (a) Mean daily step count and (b) annual coefficient of variation. Subjects' data are grouped by Medicare Functional Classification Level (MFCL) and ordered by increasing mean daily step count within groups to illustrate overlap in step activity between groups.

periods of time and examination of the resultant activity patterns may intimate aspects of participation. Given the well-documented impairments associated with lower-limb amputation, it was expected that persons with TFA would exhibit long-term step activity limitations and clinically relevant challenges with participation when compared with persons without amputation. Review of long-term activity revealed that persons with TFA took an average of 1,540 prosthetic steps/day. These data are lower than the 2,108 to 3,063 steps/day reported among persons with lower-limb amputation [25,39,41]. These

studies included mixed samples of persons with transtibial amputations and TFAs, and it is logical to assume that activity of persons with TFA alone would be lower in comparison. Further, these studies only measured activity for up to 7 d, a much shorter time than the data presented here. It is conceivable that such short-term observation may have been influenced by a Hawthorne effect that stimulated activity above normal levels [60].

The average daily levels of activity measured in this study are substantially lower than the 3,500 to 7,500 and 3,000 to 4,250 single-limb steps averaged by nondisabled

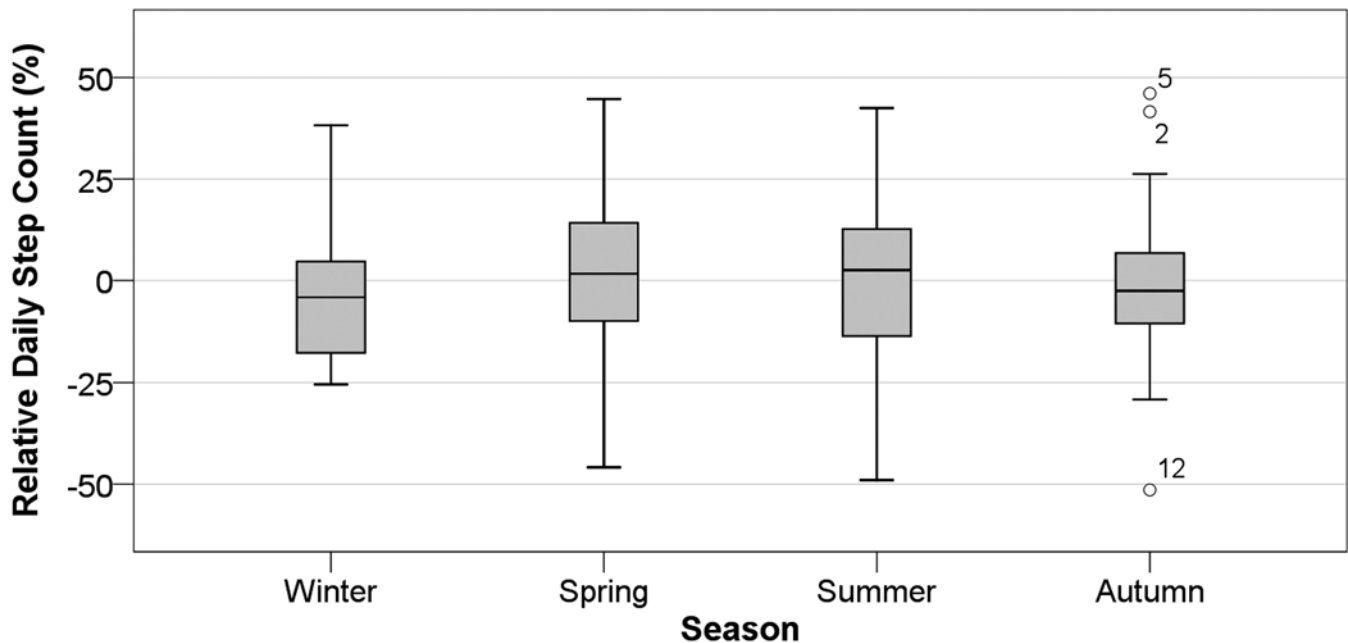


Figure 3.

Change in mean step activity by season. Subjects commonly experienced decreased activity in winter and autumn (i.e., median activity 4.1% and 2.5% below annual average, respectively) and increased activity in spring and summer (i.e., median activity 1.7% and 2.5% above annual average, respectively). However, not all subjects demonstrated same seasonal patterns. Subject numbers for outliers denoted by circles (those subjects who were more than 1.5 times the interquartile range [IQR] above the 75th quartile or more than 1.5 times the IQR below the 25th quartile).

younger adults and nondisabled older adults, respectively [43]. The observed data here are notably concerning given that they fall below the 2,500 steps/day threshold that has been defined as a “sedentary” activity level [51]. Note that the comparative data noted previously have been modified from data presented in the original publications to reflect the instrumentation used. Specifically, activity data collected with pedometers have been halved to allow comparisons with the single-limb steps (i.e., strides) measured by the monitor used in this study. The authors recognize that conversions and comparisons between pedometer-obtained and accelerometer-obtained data are not recommended [45,61] because the accelerometer-based activity monitor is believed to overestimate the number of steps taken by the wearer [61]. However, if anything, this limitation accentuates the described differences between persons with TFA and nondisabled persons.

Relative variation in long-term activity, as described by the CoV, was notably higher among persons with TFA (i.e., 0.65) than among nondisabled middle-aged adults

(i.e., 0.34) [50]. The relative variation over seasons (0.60–0.72) and months (0.59–0.80) among persons with TFA was similarly greater than among the nondisabled group described in the literature (0.33–0.35 and 0.32–0.50, respectively). These findings were in opposition to the stated hypotheses that variations in activity would be depressed among persons with TFA. Conversely, it appears that persons with TFA vary their activity more than nondisabled persons. At first glance, this would appear to indicate that persons with TFA may be physically able to vary their activity as desired to accommodate their daily, weekly, monthly, and seasonal habits. However, the authors instead propose that persons with TFA may regularly be functioning at or near their physical limits. As such, a day of elevated activity that might be needed to accomplish required or desired life activities (e.g., work, recreation, shopping) has an effect on subsequent days. Such behavior might explain observed variances in day-to-day activity seen in study subjects (**Figure 5(a)**). It was further noted that subjects with the

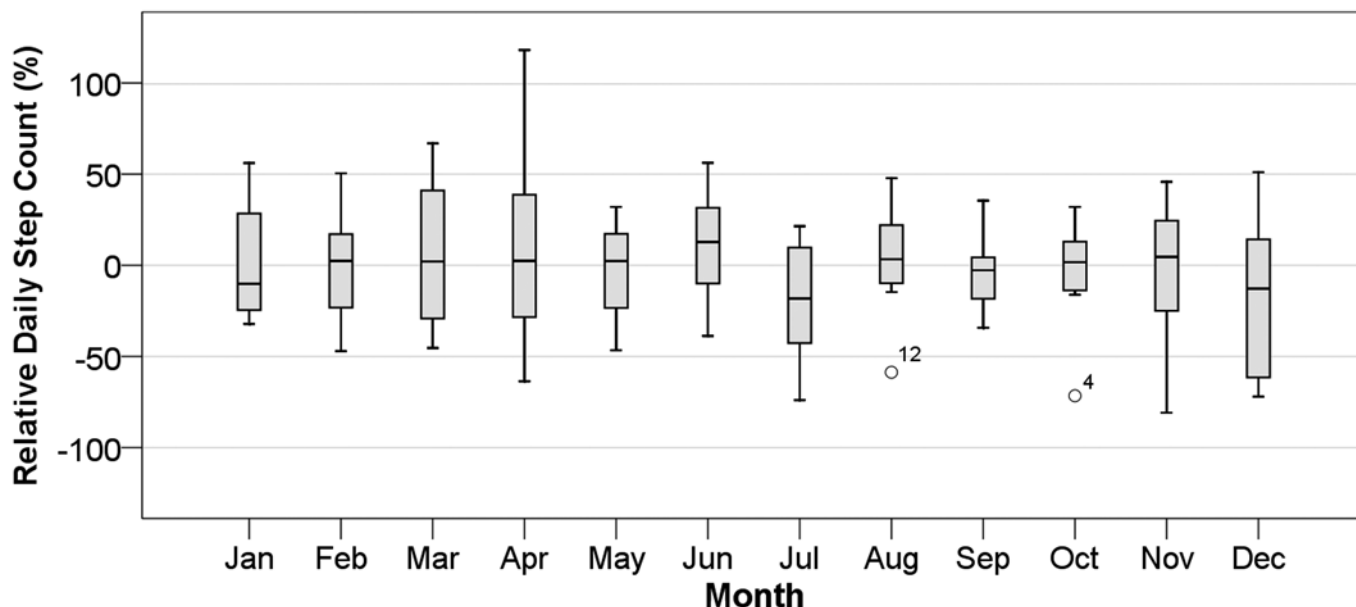


Figure 4.

Change in mean step activity by month. Subjects most often experienced decreased activity in January (−11.7%), February (−3.6%), March (−3.7%), July (−8.8%), August (−5.5%), October (−1.9%), and November (−1.3%) and increased activity in April (4.4%), May (1.0%), June (7.7%), September (2.2%), and December (3.6%). As with seasonal results, not all subjects demonstrated same monthly patterns in activity. Subject numbers for outliers denoted by circles (those subjects who were more than 1.5 times the interquartile range [IQR] above the 75th quartile or more than 1.5 times the IQR below the 25th quartile).

highest daily activity levels also showed lower relative variances (**Figure 2**). Thus, the combination of high activity and low relative variability in activity would appear to be a more meaningful indicator of mobility among persons with TFA than either characteristic alone.

Beyond levels and variability in activity, patterns of habitual activity were detected across study subjects both by season and month. As might be expected, subjects as a whole showed elevated activity in warmer seasons (i.e., spring and summer) and depressed activity in colder seasons (i.e., autumn and winter) (**Figure 3**). However, observed habitual patterns by month did not consistently mirror seasonal patterns. While activity in colder months was mostly depressed like in autumn and winter, subjects showed elevated activity in December. This notable deviation from the seasonal pattern may be due to increased activity associated with year-end holidays. Activity in warmer months also generally reflected seasonal patterns. However, activity in July and August contrasted the overall elevated activity pattern present in summer. These two months represent the warmest and most humid

months in the Pacific Northwest and the depressed activity may be due to discomfort that comes with wearing a prosthetic socket in such conditions [62]. These habitual observations are interesting in that they appear to reflect more about subjects' mobility than the action of taking a step. While the extent to which such observations imply participation in life situations is debatable, the authors propose that such information is useful to the characterization of at least an aspect of it.

The authors recognize that characterization of a complex, multidimensional concept such as participation of persons with TFA requires synthesis of different types of information. The work presented here, in effect, constitutes a “macro” view of prosthetic activity (as it occurs over a lengthy period of time) that has not been previously explored. Such information is well complemented by studies of prosthetic activity that applied a more focused approach to characterizing activity. For example, Klute et al. measured step activity of persons with TFA over a 7 d period using activity monitors similar to those used in this study [41]. The collected data were used to

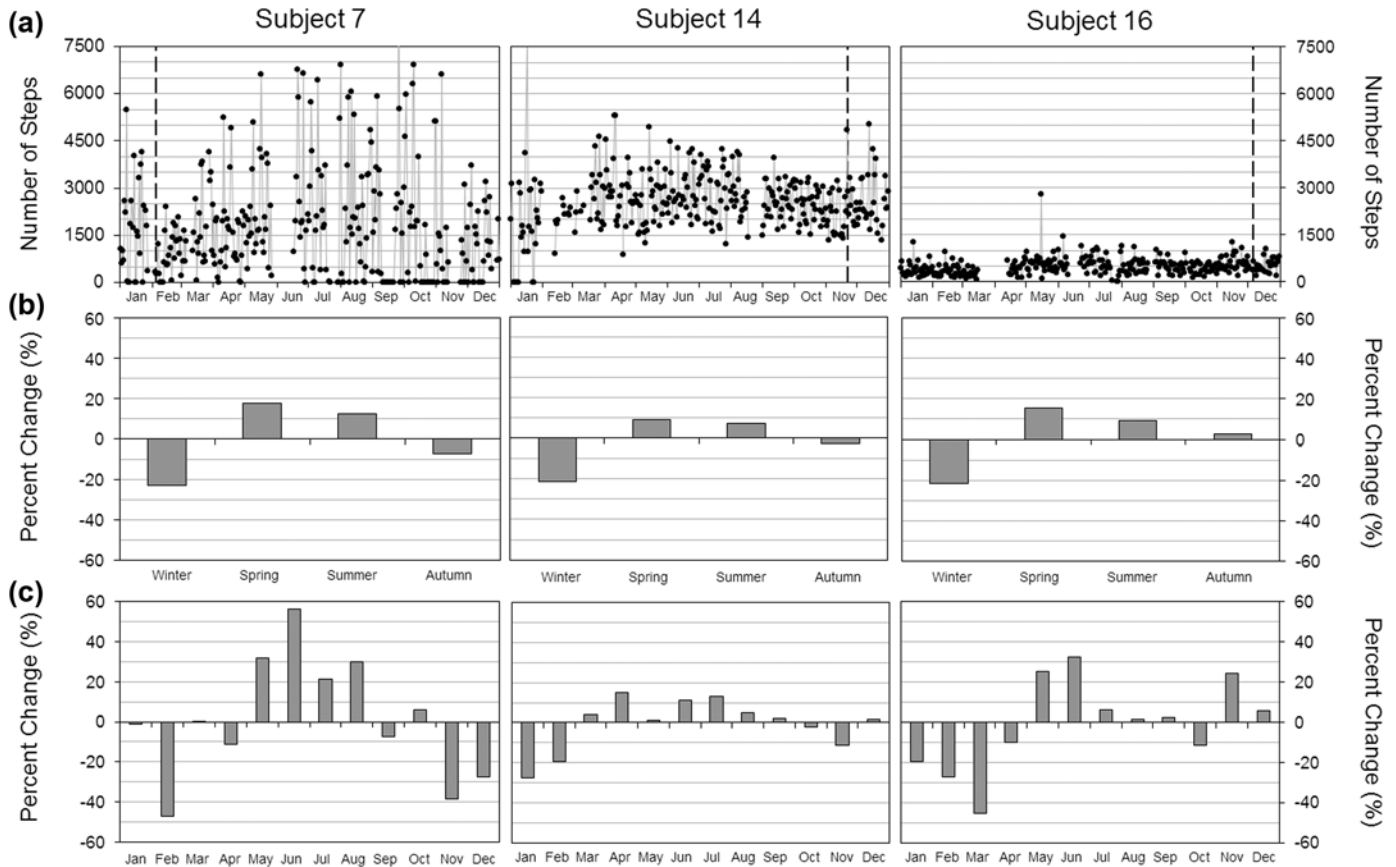


Figure 5.

Examples of variation in daily step activity. (a) Subjects' daily step activity over 12 mo extended evaluation period. Vertical dashed black lines denote date at which evaluation period started for each subject (Figure 1). (b) Subjects' daily step activity by season, relative to annual mean. (c) Subjects' daily step activity by month, relative to annual mean.

assess the frequency and duration of activity “bouts” performed by study subjects. Klute et al. found that activity of persons with TFA was characterized by frequent, short bouts of slow steps (i.e., <17 steps/min) and that longer periods of activity (i.e., >15 min of consecutive steps) were uncommon [41]. This is similar to the frequency and length of bouts undertaken by nondisabled adults [63]. Although more information is certainly needed, it appears that differences in activity between persons with TFA and those without amputation may be more readily measured using outcomes such as level and variability of step activity than frequency and intensity of activity bouts.

The findings of this study have important implications for clinical care and practice. Although few readers may be surprised that activity levels of persons with TFA

are lower than in those without amputation, the gap that exists between these populations is remarkable, particularly because each of the subjects had access to one of the most technologically advanced prostheses on the market (i.e., C-Leg). Even study subjects classified as MFCL-4 at the end of the assessment period (i.e., those with the “ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete” [56]) barely surpassed activity levels defined as “sedentary” on a regular basis [51,56]. Because depressed activity levels are commonly associated with detrimental long-term health outcomes, such as obesity [64–66], cardiovascular disease [67–69], and stroke [69–70], this further accentuates the potentially adverse effects of lower-limb loss on

the lives of those who experience it. It also suggests that improvements in technology, research, and clinical care are yet needed to restore persons with TFA to levels of function that are comparable with their nondisabled peers.

In addition to informing the authors' understanding of amputation activity and participation, the results presented here also have implications for future research. The monthly and seasonal patterns presented here suggest that measurement of activity over the traditionally short periods of time recommended by device manufacturers [47] or used in amputation research studies (i.e., 7–14 d) [25,39–41] may be limited in their ability to characterize mobility. Using activity monitors to assess outcomes at different time points may be confounded by the natural variations in activity present among persons with TFA. For example, differences in activity measured after exchange of a prosthetic intervention may be the result of month-to-month or season-to-season variability rather than a true effect of the intervention. Cautions may be similarly warranted when using step activity-based technologies (e.g., Orthocare Innovations Galileo [71]) to measure clinical outcomes until more thorough investigations of temporal stability of step activity are conducted in the target population(s).

The timing of activity assessment in clinical care and research should also incur careful considerations. In this study, measurement and evaluation of activity in May most closely reflected mean daily activity over the year (**Figure 4**). Interestingly, Kang et al. recommended activity measurement in May because measurements of activity taken in that month produced the lowest error when compared with annual averages of habitual activity [50]. Kang et al.'s study included nondisabled middle-aged persons in South Carolina and Tennessee. That measurement of activity in May has been shown to optimally reflect extended periods of time across populations and geographic regions is noteworthy and, thus, may serve as a recommendation of good practice for timing of measurement if representation of habitual activity is desired.

Ultimately, more information regarding activity-based outcomes and the ability of modern technologies to measure true and clinically meaningful changes is needed. At present, evidence about participation in life situations outside of laboratory environments among persons with lower-limb loss is scarce. Increasing the body of knowledge in this area is likely to benefit from carefully developed prospective research designs, long periods of activity assessment, and use of self-report

instruments or qualitative research techniques to solicit subjects' feedback regarding their habitual patterns and experiences. Initial efforts should also prioritize use of heterogeneous subjects to allow for more valid comparisons among desired population subgroups (e.g., age, MCFL, level of amputation, etiology of amputation). Results from such studies would provide much insight into the nature of amputation mobility within the lived environment and the factors that influence it.

Although the authors aspired to generally characterize mobility of persons with TFA, the recruited study sample may not represent the spectrum of patients receiving prosthetic care. To the authors' knowledge, the typical age of persons with TFA has not been reported, but subjects included in this study were of similar ages to those reported in one large cross-sectional sample of persons with limb loss [72] but younger than most included in another sample [73]. Clinical experience suggests that patients similar in age to the majority of subjects included in this study are less likely to be affected by age-related functional deficits that might exacerbate limitations and restrictions associated with TFA. Similarly, study subjects predominantly had amputations due to nondysvascular etiologies (e.g., trauma, malignancy, infection). This differs from the prevalent dysvascular [73] or oncologic [72] etiologies reported in the aforementioned contemporary cross-sectional studies. The authors believe that the selective sampling methods used in those studies may have over-represented nontraumatic etiologies but fairly recognize that the sample described here may reflect an atypical nondysvascular population. Thus, persons included in this study may have been less affected by compounding health-related comorbidities than those reported in the literature [72–73]. Lastly, most subjects in this study (i.e., 14 of 17) were classified as MFCL-2 or -3 and a smaller proportion (i.e., 3 of 17) at MFCL-4. Although information regarding the distribution of persons with limb loss by functional level is unavailable, the study subjects appeared to reflect the relative distribution of prosthetic users based on the authors' familiarity with this patient population.

One limitation to these findings is the retrospective design of this study. The step count data presented here were collected in a previous investigation of functional outcomes obtained using microprocessor-controlled and non-microprocessor-controlled prosthetic knees. Therefore, data collection methods were not explicitly intended to address the purpose and hypothesis of the current

study. The retrospective nature of this study also eliminated the possibility of supplementing objective step count data with qualitative feedback from subjects, thus challenging interpretation of the results. Common involvement of an investigator from both studies (B. H.) served to mitigate unfamiliarity with the original data collection protocol, a concern commonly associated with retrospective research. Further, because the purpose of this study was to characterize long-term activity, previously collected data were deemed sufficient to address the stated hypotheses. To more thoroughly explain these (or similar) findings, prospective research designs that combine quantitative measures of mobility with qualitative information or feedback from subject interviews may be considered.

Another potential limitation of this study is the sample size. While the number of subjects in this study ($n = 17$) is comparable with the numbers of persons with TFA included in other studies of step activity [25–26,39,41–42,74], the relatively small sample may have limited the statistical power and generalizability of these findings, particularly when the sample was divided into MFCL subgroups. That significant differences were observed in long-term activity between those classified as MFCL-4 and those classified as MFCL-2 or -3 in this small population suggests that marked functional differences exist between these groups. While the absence of significant differences between those classified as MFCL-2 and those classified as MFCL-3 conversely suggests that these functional classifications may be less distinct (at least when daily activity is considered as an outcome), additional research is warranted to substantiate this result.

The present study attempted to evaluate activity over an entire annual (i.e., 12 mo) period. On average, 265 d of activity were recorded per subject. Although all data sets were not complete (i.e., activity recorded for all 365 d in the study period), the presented data constitute the longest assessment of TFA activity to-date. The most common reason for missing data was the finite memory capacity of the activity monitors used in the original study [47]. Subjects were often unable to return to the laboratory to have the data downloaded before the memory was filled and the activity monitors suspended recording. Therefore, missing data often presented as a series of successive days or weeks, rather than intermittent days scattered throughout the collection period. This is relevant to the described results because the periods of missing data from the analysis used only lengthy periods

of consecutive use to identify the variations in activity that the authors believed to be indicative of subjects' participation. Future investigations of long-term amputation activity are likely to benefit from improvements in activity monitor hardware and memory capacity [75] that allow for longer monitoring periods between downloads.

Finally, the monthly and seasonal data collected in this study were likely influenced by the environment and climate in which they were recorded. The diverse terrain and temperate weather conditions associated with the Pacific Northwest (e.g., Seattle) may be uncommon to other regions. Such environmental conditions likely affect the relative activity and participation of inhabitants over the year. Therefore, extrapolation of these results to persons in other geographic locations should be made with caution.

CONCLUSIONS

This retrospective study of long-term activity showed that persons with TFA are, in general, substantially less active and more variable in their day-to-day activity than nondisabled people. This suggests that persons with TFA are greatly inhibited by the absence of limb structures and that, even using contemporary prosthetic technologies, a wide and concerning gap exists between this population and those without lower-limb amputation. Persons with TFA also exhibit notable monthly and seasonal changes in activity that may be related to temperature, humidity, and/or involvement in life situations. These findings indicate that, while step activity may be useful for characterizing aspects of prosthetic users' mobility, measurement of steps over brief periods may not be indicative of long-term habitual patterns. Inferences of habitual activity among persons with TFA using data collected over relatively short periods warrants caution until more is known about the temporal stability and interindividual variances in step activity within this population.

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