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Step Activity Monitor: Accuracy and test-retest reliability in persons with incomplete spinal cord injury

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Abstract—Recovery of walking after incomplete spinal cord injury (iSCI) is a common focus of rehabilitation, but few measurement tools capture walking performance outside the clinic or laboratory. This study determined the accuracy and test-retest reliability of the Step Activity Monitor (SAM), a microprocessor-driven accelerometer that measures walking activity. We evaluated 11 individuals with iSCI during replicate 6-minute walk tests (6MWTs) and 10-meter walk tests (10mWTs) scheduled <1 week apart. The SAM was 97% accurate compared with hand-tallied step counts. SAM values were stable across repeated walking performances (intraclass correlation coefficient = 0.97–0.99). Standard error of measurement values were 6.0 steps and 0.8 steps for the 6MWT and 10mWT, respectively. Ninety-five percent confidence intervals were 203.7 to 177.0 steps for the 6MWT and 16.1 to 12.7 steps for the 10mWT. The SAM is an accurate and reliable device for capturing walking activity in individuals with iSCI.

Key words: 6-minute walk test, 10-meter walk test, accuracy, ambulation, incomplete spinal cord injury, outcomes, rehabilitation, spinal cord injury, Step Activity Monitor, test-retest reliability.

INTRODUCTION

According to the World Health Organization, the ability to engage in home and community activities is an important aspect of quality of life [1]. After incomplete spinal cord injury (iSCI), individuals often have residual physical impairments that limit their activity and participation in such activities. Fortunately, various therapeutic interventions are emerging as viable options for reducing iSCI-related locomotor impairment [2–5]. How well these interventions improve walking activity remains unclear, in part because of a lack of accurate and reliable measurement tools that capture this effect.

Several tools are commonly used to quantify walking function after iSCI, including gait speed (10-meter walk [6]), endurance (6-minute walk [6–7]), level of assistance (Functional Independence Measure [FIM] [8]), or assistive orthotic device (Walking Index for Spinal Cord Injury) [9–10]. These measures, primarily used in a clinic or laboratory setting, capture only brief "snapshots" of

Abbreviations: 6MWT = 6-minute walk test, 10mWT = 10-meter walk test, CI = confidence interval, CV = coefficient of variation, FIM = Functional Independence Measure, ICC = intraclass correlation coefficient, iSCI = incomplete spinal cord injury, LED = light-emitting diode, MDC = minimal detectable change, SAM = Step Activity Monitor, SD = standard deviation, SEM = standard error of measurement, VA = Department of Veterans Affairs.

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walking performance and may not fully represent walking behavior outside the clinic. Few alternative measures, however, are available that measure walking function in the community. Self-report questionnaires are a quick and inexpensive method of assessment, but the subjective nature of the questionnaires hampers their reliability and validity [11–13]. Pedometers, or step counters, are problematic in that they underreport walking cycles [14] and are not reliable for use with individuals who have hemiparesis [15]. Basic accelerometers are limited in that they only record a gross total of daily steps that does not represent how active an individual was at specific times throughout the day [16].

For these reasons, we investigated the Step Activity Monitor (SAM) (Cyma Corporation, Seattle, Washington) as a potential measure of home and community ambulation in individuals after iSCI. Although the SAM is an effective measurement tool in those with stroke [15], its accuracy and reliability have not been established in those with iSCI. The need for the custom programming used for those with a hemiparetic gait pattern may be even greater for individuals with iSCI, who often lack regular lower-limb kinematics [17]. For individuals with stroke, the SAM is placed on the nonparetic leg; however, in those with iSCI, it may have to be placed on a leg with some degree of paresis.

This study determined the accuracy and test-retest reliability of the SAM in individuals with iSCI. In addition to test-retest reliability, we established the standard error of measurement (SEM) and minimal detectable change (MDC) for the SAM in individuals with iSCI. Also, because individuals with iSCI often demonstrate irregular lower-limb kinematics, we described the programming process necessary for optimal data collection in this population. We hypothesized that because of our ability to individualize the programming parameters, the SAM would demonstrate similar accuracy and reliability for iSCI populations as for nondisabled, aged, and hemiparetic populations.

METHODS

Subjects

Subjects were 11 individuals between the ages of 21 and 63, 8 to 68 months postinjury (mean ± standard deviation [SD] = 24.0 ± 19.7 months), with a diagnosis of iSCI (American Spinal Injury Association Impairment Scale C or D) [18]. All subjects could walk with no more than minimal assistance, either with or without an assistive device. Of the individuals tested, 9 had previously participated in research in our laboratory during which we monitored daily self-selected walking behavior over a 4-day period, and participants varied widely in their level of daily ambulation (mean ± SD = 1,640.2 ± 433.7 steps, range = 68–4,468 steps). In addition, variable use of assistive and/or orthotic devices was noted, and variable self-selected walking speed (mean ± SD = 0.52 ± 0.33 m/s, range = 0.12–1.06 m/s) (**Table 1**) indicated mild-to-severe gait disability in the sample population. All participants

Table 1.
Participant demographics.

Subject No.	Age (yr)	Sex	Self-Selected Speed (m/s)	Mean Steps/24 h	Assistive Device	Orthotic Device	Primary Mobility	Physical Assistance
1	47	F	0.69	4,468	Single Point Cane	Unilateral AFO	Ambulation	Independent
2	21	M	1.06	3,089	None	None	Ambulation	Independent
3	41	F	0.16	68	Platform Rolling Walker	Bilateral AFOs	Wheelchair	Minimal
4	21	M	0.56	1,498	Single Point Cane	None	Ambulation	Independent
5	45	M	0.60	1,072	Bilateral Forearm Crutches	Unilateral AFO	Wheelchair	Independent
6	59	M	0.14	453	Rolling Walker	None	Wheelchair	Minimal
7	63	M	0.97	NT	None	None	Ambulation	Independent
8	57	M	0.78	1,961	Single Point Cane	None	Ambulation	Independent
9	62	M	0.27	NT	Rolling Walker	None	Wheelchair	Independent
10	46	M	0.41	1,536	Rolling Walker	None	Wheelchair	Independent
11	39	M	0.12	616	Platform Rolling Walker	None	Wheelchair	Independent

AFO = ankle-foot orthosis, F = female, M = male, NT = not tested.

were community dwellers, medically stable, able to follow multistep directions, and without pain that would limit involvement in the testing protocol. Subjects provided written informed consent, and the study was approved by the University of Florida Institutional Review Board.

Procedures

The SAM is a small, lightweight device (about the size of a pager) that is worn on the ankle and does not interfere with the gait cycle. It is a microprocessor-driven accelerometer that allows for programming of the motion and cadence parameters that are essential for accurately capturing walking activity in individuals with any type of gait impairment. The programming capabilities permit the clinician/researcher to count steps during predetermined time spans, which allows step detection at various points in the day and not just a summation of activity [16]. In previous studies of nondisabled individuals [19], older adults [20], and individuals with stroke [15], the SAM demonstrated greater than 95 percent accuracy and remarkably stable output during repeated testing (correlation ranges 0.84–0.98). In addition, the SAM is sensitive to changes in walking performance in individuals poststroke for up to 3 months postdischarge from acute rehabilitation, even in the absence of change in other ambulation outcome measures [21].

Previous reports have described the "Easy Start Programming" software offered by the SAM manufacturer [15]. In the case of persons poststroke, Macko et al. advised that the SAM be placed on the nonparetic leg so the accelerometer could respond to the relatively normal kinematics (**Figure**) [15].

Because of the bilateral involvement seen in those with iSCI, both legs often demonstrate gait deviations and standard programming was not reliable. Therefore, we needed to customize the programming for each individual. The device was programmed per the manufacturer's default "Advanced Programming" settings at a 6-second recording period. If the person took <30 steps/minute, we increased the cadence parameter by 10 to prevent overcounting. The cadence parameter turns the device off for a set amount of time, during which it does not look for another step. An increase of 10 in the cadence parameter turns the device off for an additional 1/10 of a second, which decreases the chance of overcounting. If the person took >65 steps/minute, we decreased the cadence parameter by 10 to turn the device off for a shorter period of time, thus the device looked for the next step more quickly. For extremely slow ambulators (<15 steps/minute), cadence was increased by 20. The device was programmed so that a light-emitting diode (LED) display was illuminated for every step taken and was attached to the participant's less involved lower limb above the malleolus, either on the lateral side of the right or the medial side of the left. We asked the participant to walk a brief distance in the laboratory so we could observe the LED display, which should have illuminated at a similar point during each gait cycle. If the device overcounted steps, sensitivity was increased by one unit, and if the device undercounted, sensitivity was decreased by one unit. This process was continued until the LED illuminated at a similar point during each gait cycle.

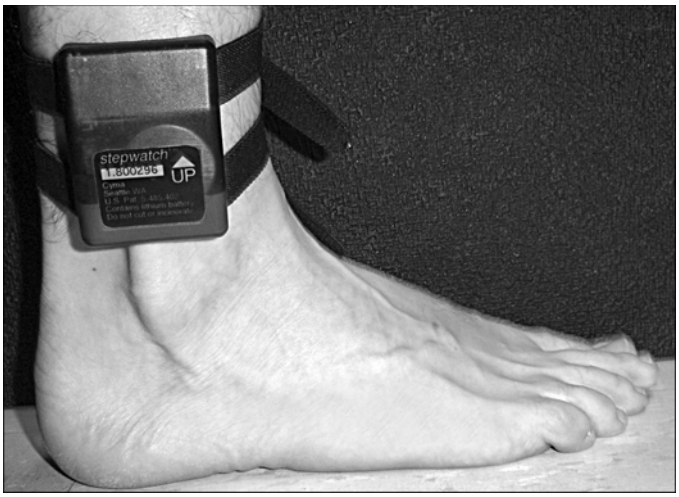

Figure.
Step Activity Monitor (Cyma Corporation, Seattle, Washington) placement: device is placed proximal to malleolus on lateral border of right leg or medial border of left leg.

Once the SAM was programmed, we assessed each participant using two standardized measures of ambulation: subjects performed one 6-minute walk test (6MWT) and two 10-meter walk tests (10mWTs) at two different times. Each testing session was separated by at least 4 hours and no more than 1 week. To control for the effect of fatigue from the testing, we randomized the test order.

Six-Minute Walk Test

The 6MWT is a measure that was originally developed to assess cardiopulmonary function [7,22] but has been used as a measure of walking ability in older adults and in individuals with stroke [23] and iSCI [6]. We chose

this assessment to establish accuracy during sustained periods of walking. Subjects performed the 6MWT using a previously standardized protocol [23]. In this test, subjects were allowed 6 minutes to walk as far as they could at their usual pace with their customary assistive devices and orthoses. The walk was performed over a nonstandardized series of hallways that consisted of straight passages of at least 50 ft and only 90° turns. The distance they covered in 6 minutes was recorded. The number of steps calculated by the SAM was compared with that from a handheld manual counter.

10-Meter Walk Test

We chose the 10mWT to establish accuracy for bursts of activity that often occur during the course of the day [6,24]. In this test, the participants were instructed to walk at a comfortable, self-selected pace for 10 meters and were given a 3-meter warm-up distance before the 10 meters and 3 meters beyond the 10 meters to assure constant velocity. The number of steps calculated by the SAM was compared with that from a handheld manual counter. Two 10mWTs were performed during each session.

During each walking trial, a therapist guarded the participant, provided assistance when necessary, and observed the number of steps. Each walk was preceded and followed by a 30-second static position that established the beginning and end of each trial. The data were then downloaded into a spreadsheet with the manufacturer's software and prepared for data analysis that compared observed steps with those calculated by the SAM. The SAM reports the steps taken by the leg on which the device is placed, not the total number of steps taken bilaterally, and all data in this report represent actual SAM output (unilateral step counts).

Data Analysis

We established the accuracy of the SAM by comparing the number of steps counted by the SAM with the observed steps on the same side. Neither the SAM-counted steps nor the observed steps were consistently higher, so we calculated accuracy by expressing the smaller quantity as a percentage of the larger quantity in both the 6MWT and 10mWT. Test-retest reliability of the steps counted by the SAM was also analyzed with the intraclass correlation coefficient (ICC). Specifically, we used the ICC (2,1), a two-way random effects model analyzed for absolute agreement. We chose this ICC model to increase generalization of results to raters beyond the one in this study. We calculated coefficients of variation (CVs) for the 6MWT and 10mWT between day 1 and day 2 to examine within-subject variability. SEM was calculated for the SAM using the formula $s(1 - r)^{-1}$, where s = SD of the test and r = reliability coefficient of the test [25–26].

From the SEM, we calculated the MDC using the 95 percent confidence interval (CI), which was calculated as mean ± (t × SEM), where t = critical value for the given degrees of freedom. We used Statistical Package for the Social Sciences, version 11.0 (SPSS Inc, Chicago, Illinois), to calculate ICCs.

RESULTS

Actual values obtained during testing are seen in **Table 2**. The SAM counts were 97 percent accurate in both the 6MWT and 10mWT. For the test-retest reliability, the ICC for the 6MWT was 0.99 (95% CI = 0.97 to 0.10) and the ICC for the 10mWT was 0.97 (95% CI = 0.92 to 0.99). **Table 2** also illustrates the within-subject variability for each test with CV values that ranged from 0 to 13.2 percent. The SEM for the 6WMT was 6.0 steps and for the 10mWT was 0.8 steps. The 95 percent CI was 203.7 to 177.0 steps and 16.1 to 12.7 steps for the 6MWT and 10mWT, respectively (**Table 3**).

In this study, we chose to compare the SAM-counted steps with observed counts during standardized clinical evaluations. As such, the ICC values may reflect variability in subject performance as well as variability in the SAM. To examine this effect, we also calculated ICCs for the observed counts during the standardized tests. ICCs for the observed steps were 0.97 and 0.99 for the 6MWT and 10mWT, respectively, which demonstrate concurrent validity and illustrate that the SAM measures actual stepping activity.

DISCUSSION

Our findings indicate that the SAM is accurate and reliable when evaluated during a 6MWT and a 10mWT, and this testing is the first step toward establishing a measure that captures the self-selected walking behavior of individuals following iSCI. By examining accuracy and reliability using established ambulation measures of endurance and speed, we can use the SAM to monitor the

Table 2.
Raw data for actual and SAM-counted steps for 6-minute walk test (6MWT) and 10-meter walk test (10mWT). Note that 10mWT was performed twice for each test date.

Subject No.	6MWT Day 1 (Steps)		6MWT Day 2 (Steps)		10mWT Day 1 (Steps)				10mWT Day 2 (Steps)				6MWT CV(%)		10mWT CV(%)	
					Actual		SAM		Actual		SAM					
	Actual	SAM	Actual	SAM	T1	T2	T1	T2	T1	T2	T1	T2	Actual	SAM	Actual	SAM
1	230	231	237	239	10	10	10	10	10	10	10	10	2.1	2.4	0.0	0.0
2	304	304	307	308	10	10	9	10	10	11	10	11	0.7	0.9	4.9	8.2
3	111	103	92	91	23	23	22	23	23	24	25	22	13.2	8.8	5.4	3.6
4	286	290	297	299	12	11	12	11	10	11	10	11	2.7	2.2	7.4	7.4
5	178	182	176	185	14	14	14	14	13	12	13	12	0.8	1.2	7.2	7.2
6	94	93	103	108	20	19	21	20	20	19	20	19	6.5	10.6	3.0	4.1
7	265	261	272	273	12	13	13	13	12	13	12	12	1.8	3.2	4.1	3.9
8	239	237	236	238	17	17	16	17	14	14	14	14	0.9	0.3	11.2	9.8
9	128	107	145	129	14	14	14	12	11	12	12	12	8.8	13.2	8.9	10.3
10	181	190	188	190	14	13	13	14	14	12	14	13	2.7	0.0	4.3	7.2
11	106	104	114	115	20	18	18	18	17	16	17	16	5.1	7.1	9.6	5.6
Mean	192.9	191.1	197.0	197.7	15.1	14.7	14.7	14.7	14.3	13.8	14.0	14.0	4.1	4.5	6.0	6.1
SD	76.4	79.5	78.0	79.1	4.3	4.1	4.2	4.3	4.7	3.7	4.3	4.2	—	—	—	—

CV = coefficient of variation, SAM = Step Activity Monitor, SD = standard deviation, T1 = time 1, T2 = time 2.

Table 3.
Analysis of accuracy, reliability, and standard error of measurement of 6-minute walk test (6MWT) and 10-meter walk test (10mWT).

Assessment	Accuracy (%)	Reliability (ICC)	SEM (Steps)	95% CI (Steps)
6MWT	97	0.99	6.00	203.7 to 177.0
10mWT	97	0.97	0.76	16.1 to 12.7

CI = confidence interval, ICC = intraclass correlation coefficient, SEM = standard error of measurement.

number of steps taken in the home and community across a broad spectrum of activity levels, for bursts of activity (walking short distances in the home) and for longer distances outside of the home. Results from this study do not reflect functionality of walking within the community, and further research will be needed to quantify whether the SAM accurately counts steps in the community as well as the laboratory. This study, however, establishes the accuracy and reliability of the SAM with laboratory-based tests in the iSCI population, a necessary step in the process of true quantification of walking activity.

This study assessed the reliability and validity of the SAM, while the number of steps taken during two standardized evaluations was counted. An alternate methodology for establishing reliability and validity would have been to compare repeated measures data for a constant number of steps, a method which would have reduced the variability due to individual participant performance. In this study, we deemed that evaluating consistency within the context of standardized evaluations was more important than comparing a constant number of steps and instead compared findings with the "gold standard" of actual step counts by calculating the SEM and 95 percent CI as well as the ICC.

Although the data presented here demonstrate appropriate use of standardized testing, they limit the conclusions that may be drawn regarding device versus performance variability.

The SEM of 6.0 steps for the 6MWT and 0.8 steps for the 10mWT produce fairly large CIs of 203.7 to 177.0 steps (26.7 steps) for the 6MWT and 16.1 to 12.7 steps (3.4 steps) for the 10mWT. These numbers are higher than ICCs $\geq$0.97 might indicate and reflect the heterogeneity of walking ability (speed range of 0.12–1.06 m/s, average stepping activity of 68 to 4,468 steps/day, and a wide range of orthotic and/or assistive devices) within the sample tested (**Table 1**). By definition, the SEM is directly proportional to the SD of the sample, and the high SEM and 95 percent CI reflect that heterogeneity in

iSCI causes difficulty in establishing outcome measures with high psychometric properties. Although the reliability of the device is high, its application as a clinical outcome measurement tool may be limited somewhat by this heterogeneity.

On average, participants took 190 steps during the 6MWT and 1,640 steps during the course of the day. The 6MWT total translates to approximately 12 percent of the daily self-selected walking behavior. A 95 percent CI of 26.7 steps for the 6MWT extrapolates to 223 steps for a 24-hour period for an average member of this sample. This 95 percent CI illustrates a high measurement error relative to daily step counts in those with low self-selected walking activity. Therefore, reports of improved self-selected activity should be presented within the context of the 95 percent CI to determine whether changes are within the error of the measure.

Establishment of a valid and reliable tool for use in the home and community is important for adequately describing the ambulatory performance of individuals outside of the clinical and research environments. In the stroke population, the SAM is more sensitive to changes in ambulation activity than gait speed, endurance, or the FIM [21]. Researchers may also use the SAM as an outcome measure for research and clinical interventions to assess the effects of the intervention on the amount of ambulation activity by having the research participant wear the device for an established period of time pre- and postintervention [27]. These outcome measures are needed to capture an individual's gait recovery at a given participation level, as well as with previously established measures of impairment and activity [28].

Walking recovery post-iSCI is a heterogeneous phenomenon, and every person undergoing ambulation rehabilitation does not recover in the same fashion [17]. As Shaughnessy et al. reported, tremendous variations in ambulation profiles are found that may or may not exist concurrently with gait speed and other outcome variables [21]. Being able to quantify outcomes across the spectrum of the rehabilitation model is advantageous for clinicians and scientists to more completely describe how an individual is performing and improving [28].

This study is one step in the process of developing measures to capture "meaningful ambulatory behavior" and the effects of study interventions. The use of participation level measurements that describe self-selected behavior adds to our knowledge gained from laboratory and clinical assessments and may elucidate the effects of treatment in a real-world environment. Knowing the effect of interventions on actual skill usage is critical as clinical research moves beyond traditional "bench-to-bedside" approaches and examines all of the contributors to an individual's health status and quality of life.

CONCLUSIONS

The results of this study demonstrate the accuracy and the test-retest reliability of the SAM for use as an outcome measure in the rehabilitation of walking after iSCI. The device is 97 percent accurate when compared with actual number of steps taken during standardized walking tests, and ICC values for test-retest reliability of the 10mWT and 6MWT were 0.97 and 0.99, respectively. The SEM values (6.0 steps for the 6MWT and 0.8 steps for the 10mWT) produce CIs that are higher than ICCs $\geq$0.97 might indicate and reflect the heterogeneity of walking ability in this sample. Although the reliability of the device is high, its application as a clinical outcome measurement tool may be limited somewhat by the heterogeneity of those with iSCI. This study represents the first step toward developing accurate and reliable tools that describe the individual's performance outside of the clinical and research environments. Such tools are necessary so that clinicians and researchers may examine the effects of interventions on self-selected walking behavior in the home and community. Further work with the SAM needs to be completed so its reliability and validity within a community setting can be established.

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