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Accuracy of a custom-designed activity monitor: Implications for diabetic foot ulcer healing

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Abstract—The relationship between repetitive trauma and propensity for ulceration and ulcer healing is unknown in part because of the lack of accurate information on activity level. The Step Activity Monitor (SAM) is a newly designed accelerometer to record activity level, but its accuracy is questionable. The purpose of this study was to determine the accuracy of the SAM under varying footwear and walking surface conditions. Ten healthy subjects consented to walk over 530 m of flat ground and up and down two flights of stairs, while wearing an athletic shoe or a fiberglass total contact cast (TCC). The accelerometer, programmed for a subject's cadence and leg motion, was secured to the distal, lateral aspect of the right lower leg. Two observers using hand-held digital counters followed the subject and recorded steps taken with the right leg on all walking surfaces. With the use of a repeated measures analysis of variance (ANOVA), the SAM and hand-held digital counters similarly recorded steps taken, regardless of walking surface condition. While the SAM was highly accurate (94 to 96 percent), the percent error was greater (p = 0.007) for the stair-climbing condition with the use of the TCC because of two subjects using a step-to-gait pattern. Overall, the SAM is an accurate accelerometer that will accurately record activity level, even with the application of a TCC. However, its accuracy may vary with deviations from a normal gait pattern.

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INTRODUCTION

Repetitive loading and foot pressures have been identified as factors contributing to the incidence and rate of diabetic foot ulcer healing [1]. Numerous methods to accurately quantify pressures have given the clinician and researcher valuable insight into the relationship between the effects of these pressures and ulcer healing [2–6]. However, effects of repetitive trauma or of the number of loading events on diabetic foot ulcer healing have not been adequately explored because of limitations in technology to record activity levels.

Methods available to the clinician to monitor activity level include survey questionnaires, daily logs, and activity rating scales [7–11], indirect calorimetry [12], heart-rate monitoring [13], and numerous types of (prosthetic limb) accelerometers or pedometers [9,10,12–16]. Inherent drawbacks to these devices include daily logging or memory of the subject, indirect inferences on gait, or the lack of established accuracy of the devices. For the few devices that do monitor gait, their capability to monitor is often short term and represents a single, overall measure of activity [10,17–20].

The pedometer, a device worn at the waist, measures step increments scaled according to a selected stride-length setting [10,21–24]. The device has been used to quantify the ambulatory activity of populations and to determine functional outcomes [10,15,25]. However, its use has been limited to study populations of average body characteristics and gait patterns [10,15]. The accuracy of the pedometer has additionally been questioned because its accountability is often influenced by movement style, such as pelvic oscillations, walking speed, mode and location of attachment, and the amount of soft tissue at the attachment site [10,21].

The accelerometer increments a unidirectional-based measure using electronic mercury tilt switches [24]. In contrast to the pedometer, the accelerometer has been used in a greater variety of study populations and body types with increasing levels of accuracy [10]. However, available data either provide a single overall measure of activity for a given monitoring period or record changing patterns of activity that cannot be equated directly with functionality of gait [21].

A new custom-designed accelerometer, reported to supersede the limitation of previous devices, has recently been reported. The Step Activity Monitor (SAM) (Prosthetics Research Study, Seattle, WA) has a purported accuracy of 99 percent when properly adjusted for the gait style (cadence, leg motion) of healthy subjects with normal gait patterns [10,21]. The parameter of “cadence” determines the refractory interval between step counts, and “leg motion” determines how much acceleration is required for a step to be detected. The device is also reported to be easy to use, highly accurate, unobtrusive for the wearer, and capable of continuously recording data over short time intervals (daily) or for periods up to 4 weeks [21].

Although the SAM is reported to be accurate for a cross section of study populations [21], its accuracy has never been verified in a study population where variations in gait patterns, such as with immobilization, might influence gait and thus the accuracy of the device. The purpose of this study was to determine the accuracy of the custom-designed SAM with the use of varying walking surfaces and footwear. We are particularly interested in determining if the SAM can be accurately used to measure the activity level of subjects immobilized in walking casts.

METHODS

Ten healthy subjects (**Table 1**) with normal gait parameters and no history of musculoskeletal or neuromuscular pathology to either lower limb consented to participate. The study was approved by the Institutional Review Board at the University of Iowa. Subjects were requested to wear an athletic shoe with minimal wear patterns.

The custom-designed accelerometer studied was the SAM (Prosthetics Research Study, Seattle, WA). This device is reported to detect and count steps for a variety of gait styles, ranging from a slow shuffle to a fast run. Approximately the size of a pager, the SAM is designed for long-term use without maintenance by the user. The sensitivity to movement of the sensor in the accelerometer can be adjusted by varying the cadence and leg motion settings. This is possible with an infrared optical link and docking station connected to the custom-designed computer software program loaded on a laptop computer. The cadence setting limits the frequency with which steps are detected, and the leg motion setting determines how much acceleration is required for a step

Table 1.
Demographics of 10 subjects.

Variables	Mean	SD	Range
Age (y)			
Men	48.33	22.37	24–68
Women	41.00	10.54	25–53
Overall	43.20	14.06	24–68
Height (m)			
Men	1.89	0.06	1.82–1.92
Women	1.68	0.07	1.59–1.79
Overall	1.74	0.12	1.59–1.92
Weight (kg)			
Men	96.21	26.92	79.55–127.27
Women	60.01	19.31	47.27–102.27
Overall	70.87	26.75	47.27–127.27
Body Mass Index*			
Men	26.92	6.74	21.56–34.49
Women	21.14	5.91	17.74–33.75
Overall	22.87	6.42	17.74–34.49

*BMI = weight (kg)/[height (m)]^2
SD = standard deviation

to be detected. A full description of the device is provided by Coleman et al. [21].

Initially, each subject wore his or her own athletic shoes for testing. The SAM was programmed for a subject's "average adult" cadence (75 steps/min) and "normal" leg motion as according to the manufacturer's protocol [26]. With the subject in a non-weight-bearing position, the SAM was secured to the distal, lateral aspect of the right lower leg with the use of two elastic straps provided. The subject walked a distance of 530 m at a self-selected walking pace over flat ground. Two observers followed behind the subject and independently counted the number of steps taken by the subject's right leg. The subject was given a 5-min rest while the data were recorded and the accelerometer and hand-held counters were reset.

The subject then ascended and descended two flights of stairs (step vertical rise 10 cm) with a "turnaround area" at the top, midway, and bottom of the stair flights. The observers again recorded the steps taken with the right leg using the hand-held counters. Data were recorded and all devices for counting were reset.

A fiberglass-only total contact cast (TCC) with a rubberized rockerbottom sole incorporated into the outer layer of fiberglass was then applied to the right lower leg with a technique similar to that previously described [27]. Following a 15-min curing time for the TCC, the subject allowed to acclimate to the TCC by walking on flat ground covered with hospital-grade short-nap carpet. Once a consistent gait pattern was observed, the accelerometer was programmed for a subject's cadence (average adult) and leg motion (gentle) and attached to the distal, lateral aspect of the casted right lower leg. A similar protocol to that described for the athletic-shoe condition was followed, and data were recorded for each of the walking surface conditions. The same orthotist applied all TCCs.

STATISTICAL ANALYSIS

Using interclass correlation coefficients, we calculated the reliability for the two observers who used hand-held digital counters. A two-way (footwear × step-counting device) analysis of variance (ANOVA) with repeated measures was used to analyze the data, separately, for the walking surface conditions (flat-surface, stair-climbing). Tukey's post hoc tests were used to analyze significant interaction effects. The probability level was set at 0.05.

The percentage error for the SAM was calculated as ([device count – mean observer count]/mean observer count) × 100 for each footwear condition (athletic shoe, TCC) and walking surface conditions (flat-surface, stair-climbing). A positive value indicated overcounting and a negative value denoted undercounting by the SAM. With a two-way (footwear × surface condition) ANOVA with repeated measures, we analyzed the percent error data, separately, for the walking surface conditions. Tukey's post hoc tests were selected to analyze significant interaction effects. Again, the probability level was set at 0.05.

RESULTS

The reliability between the observers using the hand-held counters was $r = 0.9999$ for both types of footwear on the flat walking surface. For stair climbing, the reliability was $r = 0.9923$ and 0.9928 for the athletic shoe and TCC, respectively.

We observed marked similarities in step counting for the hand-held digital counters and SAM, regardless of walking surface. This would suggest that the SAM is a reliable and valid device (**Tables 2** and **3**).

Subjects were observed to take significantly ($p = 0.035$ and $p = 0.040$) more steps while wearing the TCC for the flat-surface walking and stair climbing, respectively. For the right foot during flat-surface walking, each subject took an average of 561.8 steps (range = 502 – 655; standard deviation (SD) = 54.07) out of the cast and an average of 625.2 steps (range = 520 – 728; SD = 71.04) in the TCC. The TCC would appear to affect a subject's stride length, causing it to shorten. This finding was verified by the average stride length out of the cast being 1.06 steps/m (range = 0.91 – 1.24; SD =

Table 2.
Repeated measures ANOVA (counting method × footwear) for flat-surface walking.

Source	SS	df	MS	*F*	*p**
Counting Method	12.233	2	6.117	1.633	0.224
Footwear	60483.75	1	60483.75	5.171	0.035
Counting Method × Footwear	0.100	2	5.00E-02	0.019	0.981

ANOVA = analysis of variance
SS = sum of the squares
MS = mean square
df = degrees of freedom
F = *F*-ratio
*Probability level = 0.05

Table 3.
Repeated measures ANOVA (counting method × footwear) for stair climbing.

Source	SS	df	MS	F	p*
Counting Method	40.833	2	20.417	7.095	0.054
Footwear	117.600	1	117.600	4.891	0.040
Counting Method × Footwear	4.900	2	2.450	0.851	0.473

ANOVA = analysis of variance; df = degrees of freedom; MS = sum of the squares; *F* = *F*-ratio; MS = mean square; *Probability level = 0.05

Table 4.
Repeated measures ANOVA (walking surface × footwear) for SAM percent error.

Source	SS	df	MS	F	p*
Walking Surface	234.600	1	234.600	9.280	0.007
Footwear	9.791	1	9.791	0.297	0.297
Walking Surface × Footwear	11.225	1	11.225	0.444	0.514

ANOVA = analysis of variance; df = degrees of freedom; SS = sum of the squares; *F* = *F*-ratio; MS = mean square; *Probability level = 0.05

0.10) and 1.18 steps/m (range = 0.98 – 1.37; SD = 0.13) in the cast for flat-surface walking.

The mean percent error for the SAM for flat-surface walking was 0.136 and 0.206 percent for the athletic shoe and TCC, respectively. For stair climbing, the mean percent error was observed to be –3.648 and –5.697 percent for the athletic shoe and TCC, respectively. A repeated measures (walking surface × footwear) ANOVA (**Table 4**) demonstrated significance ($p = 0.007$) for walking surface. Thus, the SAM undercounted the number of steps taken by the subject during stair climbing while wearing either type of footwear.

DISCUSSION

The SAM is an accurate device for recording activity level. This accelerometer not only is reliable and valid when walking surface conditions change but also is accurate when a TCC is applied. This device can be used to assess the results of treatments intended to make patients more mobile or assess the effects of the number of loading events on other clinical phenomena. In particular, the device is thought to be ideal to investigate the potential relationship between the effects of repetitive trauma or activity level on rates of foot-ulcer healing, particularly for those patients treated with a TCC.

The greatest limitation to our study involves the use of healthy subjects. However, we observed that the healthy subjects reacted similarly to patient populations who wear TCCs. Subjects took more steps for a given distance walked, suggesting that they used a shortened stride length [1,3,28]. Consequently, we believe the data from the SAM can be used reliably to monitor activity level in a patient population treated with a TCC.

Although the pedometer has been used in the past to record activity level, its accuracy has been shown to vary considerably in a healthy population and is even more questionable for use in subjects with gait disorders [10,15,22,24]. Movement style and walking speed of the subject, mode and location of attachment, and the amount of soft tissue at the attachment site all affect its accuracy [21]. The SAM, however, has the capability to be calibrated for a subject's unique cadence and leg motion, as we showed by the accuracy it maintained even with the application of a TCC. The clinicians' observation that the walking speed of a subject wearing a TCC becomes slower as the stride length shortens was confirmed by the SAM, which proved adept at adjusting to these changes. Finally, the SAM was not affected by its attachment location—against the lower leg or on the outside of the TCC.

Short-term measures of gait and lower-limb functionality have been reported in the literature with limited benefit. However, long-term monitoring of activity level, although recognized as a means of evaluating factors influencing physical function or treatment efficacy, has not been adequately reported [21]. Devices used previously to monitor activity levels over extended periods of time are characterized by the limitation of providing only a "lump sum," overall measure of the activity level for a given monitoring period [21,24]. Further analysis of an individual's activity requires that he or she maintains a daily log or record the step count; both of which could influence one's natural activity pattern. Other devices are able to provide a time-based breakdown of data and record changing patterns of activity [21,29] but the unit of measure provided is difficult to equate directly with gait functionality. The SAM can provide hourly and daily records of activity level without the individual's awareness and also can monitor activity patterns for up to

4 weeks. It also correlates accurately with gait functionality. In the patient population with a diabetic foot ulcer, the clinician can now monitor and regulate a patient's activity level affecting the rate of ulcer healing.

The SAM showed a tendency to undercount when the subjects were climbing stairs (mean percent error = –4.67 percent). Undercounting increased slightly (–5.70 percent) with the application of a TCC. During data collection, we observed that two of the subjects in the TCC used a "step-to-gait" pattern versus the more conventional "step-through" pattern to climb stairs. They did this to promote stability. Although this altered gait pattern increased the percent error for the SAM, the increment in error is not considered clinically important because patients who wear lower-limb casts typically avoid stair climbing generally.

Only one other study, thus far, has evaluated the use of the SAM in monitoring activity level. Shepherd et al. compared the SAM to a known pedometer while healthy subjects walked over flat ground (400 m) and navigated a single flight of stairs while wearing regular footwear [10]. They concluded that the SAM demonstrated greater accuracy in all activities tested compared to the pedometer and was not affected by a subject's weight, body mass index, age, or gender. Supporting Shepherd et al. [10], we did not observe the accuracy of the SAM to be affected by body mass index for either type of footwear or walking surface.

The clinical implications for the SAM are intriguing. We now have an accurate device to measure activity level in patient populations after treatment that putatively improves mobility and in those with disease processes likely affected by repetitive loading. In the diabetic patient population, the ability to accurately monitor a patient's activity level even while the patient is immobilized will greatly enhance the clinician's overall understanding concerning extrinsic factors that influence foot-ulcer healing.

CONCLUSIONS

The SAM is a reliable and valid custom-designed accelerometer that can accurately monitor activity level over varying ground surface conditions and for varying lengths of time. The device has also been shown to be highly accurate for use with cast immobilization of the lower leg. Although variations in gait may affect the accuracy of the SAM, the percent error is considered small and the device is likely to give excellent reporting of actual step events of patients during or following treatment for a number of lower-limb pathologies.

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