Objective Fall Risk Detection in Stroke Survivors Using Wearable Sensor Technology: A Feasibility Study

Running Head: Fall Risk Detection in Stroke Survivors

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Abstract

Background: Stroke survivors often have persistent neural deficits related to motor function and sensation, which increases their risk of falling, most of which occurs at home or in community settings. The use of wearable technology to monitor fall risk and gait in stroke survivors may prove useful in enhancing recovery and/or preventing injuries.

Objective: Determine the feasibility of using wearable technology (PAMSys™) to objectively monitor fall risk and gait in home and community settings in stroke survivors.

Methods: In this feasibility study, we used the PAMSys™ to identify fall risk indicators (postural transitions: duration in seconds, and number of unsuccessful attempts), and gait (steps, speed, duration) for 48 hours during usual daily activities in stroke survivors (n=10), compared to age-matched controls (n=10). A questionnaire assessed device acceptability.

Results: Stroke survivors mean age was 70±8 years old, were mainly Caucasian (60%) women (70%), and not significantly different than the age-matched controls (all p-values > 0.20). Stroke survivors (100%) reported that the device was comfortable to wear, didn't interfere with everyday activities, and were willing to wear it for another 48 hours. None reported any difficulty with the device while sleeping, removing/putting back on for showering or changing clothes. When compared to controls, stroke survivors had significantly worse fall risk indicators and walked less (p<0.05).

Conclusion: Stroke survivors reported high acceptability of 48 hours of continuous PAMSys™

monitoring. The use of in-home wearable technology may prove useful in monitoring fall risk and gait in stroke survivors, potentially enhancing recovery.

Keywords: accidental fall risk; ambulatory monitoring**;** feasibility study; gait

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Introduction

Nearly 800,000 people sustain a stroke in the United States each year.[1] Stroke survivors often have lingering neurological deficits related to sensorimotor function, which can increase their risk of falling.[2,3] Community-dwelling stroke survivors fall up to seven times more annually, than healthy adults of a similar age.[4] Stroke survivors who fall, often fall repeatedly.[4] Falling after a stroke often results in major personal and public health losses due to hip or other fractures, loss of independence, fear of falling, activity restriction, reduced mobility and social isolation.[4-6] Since fall-related injuries represent an enormous and growing burden to all stroke survivors, their families, society, and to our health care system (direct medical costs $28.3 billion); preventing falls and fall-related injuries is critical.[7,8] The risk of falling is a persistent and serious concern regardless of the length of time post-stroke.[4]

Clinical and laboratory-based measures (e.g., timed up and go test, balance tests) have failed to predict falls or fall risk with substantial sensitivity.[9-11] Moreover, many of the existing screening tools (e.g., timed up and go test) tend to discriminate poorly between fallers and non-fallers.[12] An innovative, light weight, wearable, mobile, kinematic motion sensor (i.e., PAMSys™) for objectively monitoring fall risk (postural transition), and gait (steps, speed, duration) in naturalistic environments (i.e., home and community) has recently been developed.[13-15] Validating the use of a wearable mobile technology for objectively monitoring fall risk and gait in naturalistic environments among stroke survivors is important, yet lacking in the current scientific body of knowledge.

The goal of this study was to determine the feasibility of using a kinematic motion sensor (PAMSys™, Biosensics LLC, MA, USA) to objectively monitor fall risk and gait in naturalistic environments in community-dwelling stroke survivors. The specific aims were to: 1.) Determine the acceptability of wearing the PAMSys™ Equipment (i.e., t-shirt with velcro pocket closure for sensor) for 48 consecutive hours ascertaining both comfort and challenges; 2.) Determine fall risk indicators (postural transition) and gait parameters (steps, speed, duration); and 3.) Compare fall risk indicators and gait data obtained using the PAMSys™, with data from age-matched controls collected in a prior study among a non-frail population cohort (Clinical Trials.gov, Identifier #NCT01880229).

Methods

Design

This feasibility study used a prospective, observational approach.

Participants

Community-dwelling stroke survivors from all sex/gender and racial/ethnic groups, aged ≥ 50 years, at least 3 months post-stroke, and living in the Tucson, AZ area were targeted for study enrollment. Stroke survivors that walked with an assistive device (e.g., cane or walker) were eligible. Potential participants were recruited from multiple sources, including a list of prior study participants that agreed to be contacted for future studies, outpatient stroke rehabilitation centers, senior centers, and neurology/neurosurgery offices. For safety reasons, those not eligible for participation included stroke survivors who had a serious medical condition that would interfere with study participation (e.g., myocardial infarction or cardiac surgery in the past 3 months or active treatment for cancer). Approval to conduct the study was obtained from the Institutional Review Board at the University of Arizona. The investigation was carried out according to the principles outlined in the Declaration of Helsinki, including written informed consent from all subjects. For this feasibility study, we enrolled 10 community-dwelling stroke survivors.[16]

Procedures

All interested stroke survivors were interviewed either in person or by telephone to determine eligibility using a self-report screening questionnaire. If the study eligibility criteria were met, participants were scheduled at a convenient time for a one-hour study appointment, upon which written informed consent was obtained, prior to any data collection. Data were collected in the Interdisciplinary Consortium for Advanced Motion Performance (iCAMP) Laboratory at the University of Arizona. All participants received a map to iCAMP with parking directions.

Self-reported demographics (e.g., age, gender) and stroke history (e.g., stroke type, months post-stroke) were collected from each participant at the study appointment. The participants were instructed on the use of the PAMSys™, which they wore for 48 consecutive hours and then mailed back in a laboratory-addressed, pre-paid Fed-Ex envelope. Participants were telephoned on the third day following the study visit to determine the acceptability of the PAMSys™and assure return of the PAMSys™ Equipment. To ascertain PAMSys™ Equipment acceptability (e.g., comfort, challenges), study staff interviewed participants using an investigator-developed questionnaire (14 yes/no questions, see Appendix). Questions related to comfort of the PAMSys™ included: "Did you wear the PAMSys™ equipment (t-shirt and sensor) for the full 48 hours?"; "Would you be willing to wear the PAMSys™ equipment (t-shirt and sensor) for another 48 hours?”. Questions related to potential challenges included: “Did you have any difficulty removing the PAMSys™ to take a shower?”; “Did you have trouble sleeping while wearing the PAMSys™ equipment?” In addition, we monitored actual falls and adverse events reported by participants during the study (48 consecutive hours of wearing PAMSys™ Equipment). Upon complete data collection, the participant was thanked and a small incentive ($25 gift card) to cover the costs of participation was mailed to them.

Kinematic Motion Sensor: PAMSys™

PAMSys™ is a small (5.1x3x1.6cm), light (24g), wearable sensor technology containing a tri-axial accelerometer. The system computes various parameters associated with the participant’s movement from the data recorded by the PAMSys™ unit placed in a mid-sternal pocket located in a comfortable t-shirt (see Figure 1). The PAMSys™ technology uses validated advanced signal processing algorithms and biomechanical models of human motion to identify posture (walking, sitting, standing, lying), postural transitions (fall risk indicators: duration in seconds, and number of unsuccessful attempts) and gait (steps, speed, duration).[14,15] These parameters consist of: (a) the participant’s trunk tilt (specified in degrees, measuring the angle between the participant’s trunk axis, and the axis aligned with the gravitational force); (b) the type of the participant’s postural transitions (e.g., sit-to-stand); (c) duration of the participant’s postural transitions; (d) duration of the participant’s locomotion (number and duration of continuous walking bouts); (f) characterization of the participant’s locomotion (gait speed and number of steps); and (g) type of the participant’s postures (walking, sitting, standing, lying). The details of the algorithms to identify each posture has been described and validated previously.[13-15,17,18] Briefly, a participant’s posture is used to first detect body position, then subsequently to classify the transitions between postures, i.e., sitting-to-standing, standing-to-sitting, lying-to-sitting, and sitting-to-lying; for determining fall risk.[14,15,18,19] Lying posture is identified by measuring the trunk angle from the accelerometer data. Postural transition and duration are identified by measuring the pattern recognition of the trunk tilt. Then postural transition is classified as sitting or standing via pattern recognition of the vertical accelerometer. The PAMSys™ can quantify postural transition including number of successive postural transitions (unsuccessful attempts rising from a chair), number and duration of postural transitions, and postural transition variability. These parameters were able to distinguish between older adults at low and high risk of falling.[14] Gait parameters include the number of steps, walking speed, and amount of walking.[18] Gait speed and number of steps are detected according to the vertical accelerometer peaks satisfying pre-defined conditions. Gait speed is detected by measuring step time and intensity of the vertical and frontal accelerometers. Finally, a series of rules are applied to enhance accuracy and identify misclassification errors (e.g., walking during sitting is unlikely; leaning backward for extended period of time during standing is unlikely). The PAMSys™ has an embedded battery that allows data recording in the memory unit (2GB) with a suitable sample-rate frequency (50 Hz), for up to six days of continuous measurement. The data can be transferred to a computer via a USB reader for analysis.

The validity of PAMSys™ has been demonstrated in four separate pilot studies among both community dwelling and hospitalized older adults (n=66, mean age=75 years), by benchmarking the results with an independent analysis using an optical motion system (sensitivity=99% for postural transition duration; sensitivity/specificity ≥87% for change in postural transition).[15,18] Such detection of postural transitions represents a tremendous technologic leap over what is currently available to objectively monitor fall risk, and gait in stroke survivors in naturalistic environments during everyday life.

Data Analysis

To determine the acceptability of wearing the PAMSys™ Equipment (i.e., t-shirt and sensor) for 48 consecutive hours, we used descriptive statistics to assess both comfort and challenges. The PAMSys™ data is complex and provides time stamps for each participant's data. The data were extracted and then analyzed using IBM® SPSS® for Windows, Version 20.0 (IBM Corp). To determine fall risk indicators (postural transition), and gait (steps, speed, duration) among stroke survivors using the PAMSys™ we used descriptive statistics. We used independent t-tests, to compare fall risk and gait parameters with PAMSys™ data from age-matched controls collected in a prior study.

Results

Stroke survivors were on average 70 years old and 3.5 years post-stroke. The majority were retired, college-educated, Caucasian women, reporting an ischemic stroke with hemiparesis. The majority of the age-matched controls were Caucasian women, similar to the stroke survivors. There were no significant differences between the stroke survivors and controls participants according to age, ethnicity, or gender (Table 1).

Stroke survivors (100%) reported that the PAMSys™ was comfortable to wear for the full 48 hours, did not interfere with normal everyday activities and were willing to wear it for another 48 hours. A total of 6 stroke survivors reported removing the PAMSys™ to take a shower (mean time off=31 minutes); while 4 stroke survivors reported removing the PAMSys™

to change clothes (mean time off=11 minutes). None reported any difficulty with the PAMSys™ while sleeping, removing or putting back on for showering or changing clothes or that it became wet or dirty (Table 2). When these stroke survivors were asked what they would like to tell the next participant to expect and share their experience, all (100%) commented that the PAMSys™ was comfortable, lightweight, enjoyable, and easy to wear. There were no falls or adverse events reported during the study (48 consecutive hours of wearing PAMSys™). Compared to controls, stroke survivors had significantly worse fall risk indicators ($p<0.05$), needing on average more than 4 seconds to change their posture (e.g., sit-to-stand) and had on average over 10 failed sit-to-stand attempts per day. In addition, compared to controls, stroke survivors took fewer steps (on average 4337 steps/day) and spent less time walking ($p<0.05$) during the 48-hours of continuous monitoring (Table 3).

Discussion

Few studies have evaluated body-worn sensors among older adults in home and community settings.[20,21] To our knowledge, this is the first study conducted in community-dwelling stroke survivors, which has objectively monitored fall risk indicators and gait in home and community settings using a kinematic motion sensor (PAMSys™).

One of the issues surrounding the acceptability of body-worn sensors among older adults, reported in the literature, is the potential discomfort of wearing the device for a prolonged period of time (>24 hours).[22] In our feasibility study, all stroke survivors reported that the PAMSys™ was comfortable to wear for the full 48 hours, did not interfere with normal everyday activities and were willing to wear it for another 48 hours. None of these stroke survivors reported any difficulty with the PAMSys™ while sleeping, removing/putting back on for showering/changing clothes or that it became wet/dirty. Results from our study are similar to findings reported by Bloch and colleagues[23] examining the acceptability of wearing a body-worn sensor for an extended period of time (>24 hours) among older adults. Thus, objective cross-sectional monitoring using this kinematic motion sensor is feasible and acceptable.

In this feasibility study, when compared to age-matched controls, stroke survivors had significantly worse fall risk indicators and walked less. These findings are consistent with findings reported by others,[24-27] that stroke survivors are relatively sedentary when compared to same-aged adults with/without a chronic disease. Our results further highlight the utility of using objective kinematic motion sensors to monitor fall risk and gait in community-dwelling stroke survivors—so that strategies can be implemented early on, to reduce the risk of falling in this vulnerable population. For example, one underutilized strategy is for healthcare providers to provide counseling on increasing physical activity participation and/or recommending a variety of suitable exercise programs, such as Tai Chi or SilverSneakers®, to reduce the risk of falling.[28-30]

Study Limitations

As with any feasibility study, the small sample limits generalizability of the results. We monitored fall risk indicators and gait parameters for 48 hours only, so our results may not be representative of other stroke survivors. However, these stroke survivors reported their willingness to wear the PAMSys™ for another 48 hours indicating acceptability, there were no reported challenges (e.g., no trouble sleeping with device on) indicating successful implementation, with ease of use (e.g., able to remove and put back on after showering) indicating practicality.

Conclusion

Falls and fall risk are major concerns for stroke survivors. Since the majority of fall-related events occur at home or in community settings, the use of wearable mobile technology in stroke survivors may be useful to monitor fall risk and gait in these settings, which could further enhance recovery and/or prevent injuries. We have demonstrated the utility of the PAMSys™ system for incorporation into cross-sectional monitoring of fall risk and gait assessment, with the potential for rehabilitation outcome assessment. As sensor algorithms become increasingly more predictive with less obtrusive applications, the potential for continuous monitoring of those at high risk for falling will develop into practical solutions for home and community settings.

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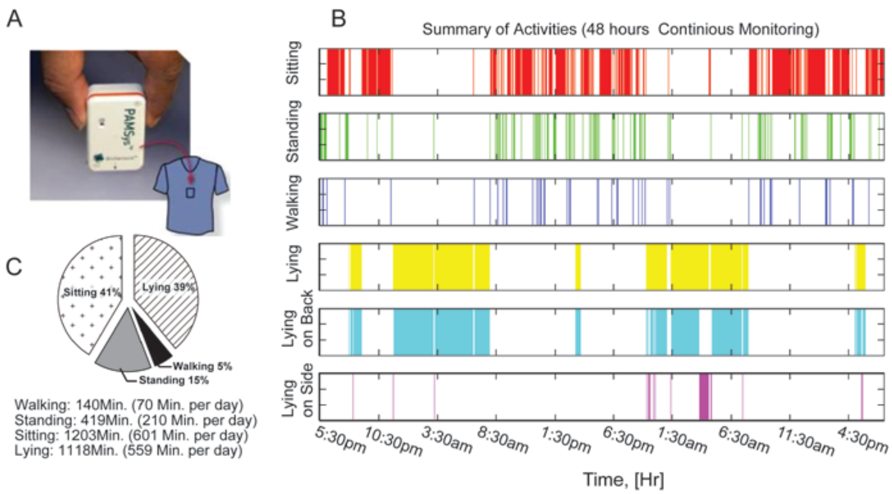
Figure Legend

Figure 1: PAMSys™ Wearable Sensor Technology

Figure Caption

(A) PAMSys™ equipment (t-shirt and sensor).
(B) Summary of activities for a typical participant during 48 hours.
(C) Same data reported as the percentage of time (in minutes).

Appendix: PAMSys™ Acceptability Questionnaire



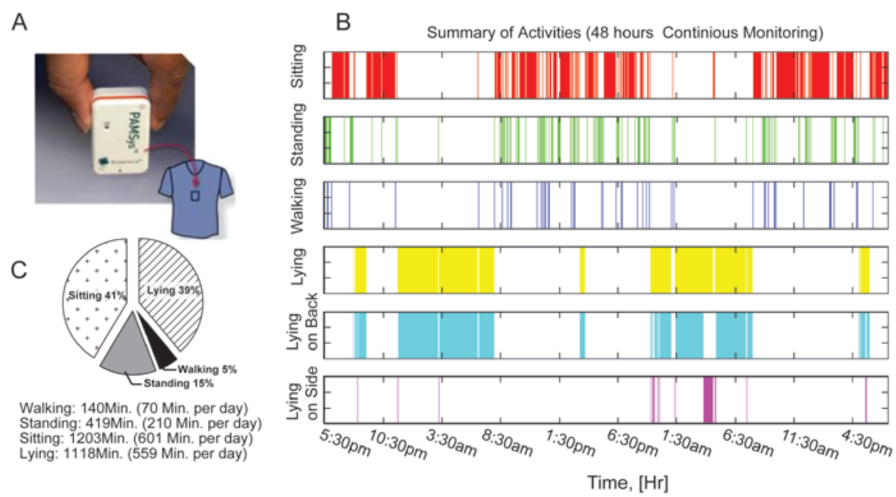

A
B
Summary of Activities (48 hours Continious Monitoring)
Sitting
Standing
Walking
Lying
Lying on Back
Lying on Side
5:30pm 10:30pm 3:30am 8:30am 1:30pm 6:30pm 1:30am 6:30am 11:30am 4:30pm
Time, [Hr]
C
Sitting 41%
Lying 39%
Walking 5%
Standing 15%
Walking: 140Min. (70 Min. per day)
Standing: 419Min. (210 Min. per day)
Sitting: 1203Min. (601 Min. per day)
Lying: 1118Min. (559 Min. per day)

Table 1: Characteristics of Community-dwelling Stroke Survivors and Healthy Controls*

	Stroke Survivors, n=10	Controls, n=10	p-value#
Demographics			
Age, mean ± SD	70 ± 8	74 ± 7	0.216
Women, %	70	89	0.228
Caucasian, %	60†	78	0.258
Married, %	50	---	---
College graduate, %	70	---	---
Retired, %	80	---	---
Stroke-related Characteristics			
Months post-stroke, mean ± SD	42 ± 25	---	---
Ischemic stroke, %	60	---	---
Hemorrhagic stroke, %	40	---	---
Hemiparesis, %	70	---	---
First stroke, %	70	---	---

*self-reported, # based on t-test or chi-square tests, † other ethnicities included African-American (n=3, 30%), and Mexican-American (n=1, 10%)

Table 2: PAMSys™ Acceptability among Community-dwelling Stroke Survivors

PAMSys™ Equipment (i.e., t-shirt and sensor)	n=10
Comfort	
Worn for the full 48 hours, %	100
Comfortable to wear for 48 hours, %	100
Willing to wear for another 48 hours, %	100
Challenges	
Interfered with normal everyday activities, %	0
Trouble sleeping while wearing, %	0
Difficulty removing to take shower/change clothes, %	0
Difficulty putting back on, %	0
PAMSys™ t-shirt become wet/dirty, %	0

Table 3: PAMSys™ Data Comparing Stroke Survivors with Age-Matched Controls

PAMSys™ 48-hour Data	Stroke Survivors, n=10	Controls, n=10
Fall Risk		
PT Duration (in seconds), mean ± SD	4.3±0.9*	3.6±0.3
High Fall Risk= > 4 seconds		
Aborted PT Attempts (number per day), mean ± SD	11.5±4.9*	0
High Fall Risk= > 10 aborted attempts/day		
Gait		
Steps (number), mean ± SD	8,674±4,863*	12,600±2,937
Speed (meters per second), mean ± SD	0.98±0.06	1.0±.19
Duration (% of total activity), mean ± SD	6.6±3.6*	9.4±1.8

PT=postural transition; *significantly worse, $p<0.05$

Appendix: PAMSys™ Acceptability Questionnaire

	Yes	No
1. Did you wear the PAMSys™ equipment (t-shirt and sensor) for the full 48 hours?		
2. Was the PAMSys™ equipment (t-shirt and sensor) comfortable to wear for 48 hours?		
3. Did you have trouble sleeping while wearing the PAMSys™ equipment (t-shirt and sensor)?		
4. Did the PAMSys™ equipment interfere with your normal everyday activities?		
5. Did the PAMSys™ t-shirt become dirty during this time?		
6. Did the PAMSys™ t-shirt become wet during this time?		
7. Did you use any body lotion while you were wearing the PAMSys™ equipment?		
8. Did you remove the PAMSys™ equipment to take a shower/change clothes?		
8.a. Did you have any difficulty removing the PAMSys™ equipment?		
8.b. Did you have any difficulty putting the PAMSys™ equipment back on?		
9. Did you return the t-shirt because it got dirty?		
10. Did you return the t-shirt because it got wet?		
11. Would you be willing to wear the PAMSys™ equipment (t-shirt and sensor) for another 48 hours?		
12. Did you have any problems related to wearing the PAMSys™ equipment (t-shirt or sensor)? If yes, please explain____		
13. What would you like to tell the next participant about what to expect while wearing the PAMSys™ equipment (t-shirt and sensor)? Answer____		
14. Is there anything else you would like to tell us about your experience wearing the PAMSys™ equipment? If yes, please explain____		