PUP® (Patient Is Up) Smart Sock Technology Prevents Falls Among Hospital Patients With High Fall Risk in a Clinical Trial and Observational Study

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ABSTRACT

Hospital inpatient falls, especially of older adult patients, can result in injury and death and generate high costs. A new technology, PUP® (Patient Is Up) Smart Socks, combines sensors and geolocation in socks with a wireless platform. To determine whether these socks prevent falls of patients with high fall risk, we performed a clinical trial at one hospital, and an observational study at two other hospitals. In the clinical trial, patients spent 1,694 patient-days wearing the socks, reducing falls from 4 to 0 per 1,000 patient-days ($p < 0.01$). In the observational study, patients spent 2,286 patient-days wearing the socks, reducing falls from 4 to 1.3 per 1,000 patient-days ($p < 0.05$). The new technology resulted in a significant reduction in fall rates among patients with high fall risk and may greatly reduce inpatient fall-related injury and death and their associated costs. [*Journal of Gerontological Nursing, 47*(10), 37-43.]

Inpatient falls are a major adverse safety event in hospitals. Each year, 700,000 to 1,000,000 people in the United States fall in the hospital (Currie, 2008). Due to the aging population, falls and the injuries they cause are expected to increase. Based on data from the National Database of Nursing Quality Indicators (NDNQI; 2007), which included data from 1,263 hospitals across the United States, the fall rate was 4 falls per 1,000 patient-days in medical units. Injuries due to these falls occurred at 1.1 per 1,000 patient-days, and approximately 0.2% of all falls resulted in death (Bouldin et al., 2013). Apart from injuries to patients and longer hospital stays due to falls, falls also incur additional costs for hospitals. Since 2008, the Centers for Medicare & Medicaid Services (CMS) does not reimburse hospitals for certain types of traumatic injuries that occur while patients are in the hospital, such as those due to a fall (Ganz et al., 2013). Based on data from various countries, the average cost of a fall without serious injury was $1,586; a fall resulting in minor to moderate injury cost $9,996; and a fall resulting in serious injury cost $24,249 (Spetz et al., 2015). On average, an in-hospital fall incurs $13,316 in additional costs (Bouldin et al., 2013). Despite extensive nation-wide efforts to improve fall prevention, in-hospital falls were only reduced by 5% between 2014 and 2017 (Agency

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for Healthcare Research and Quality, 2019), indicating that current fall prevention methods do not have enough impact.

Most falls occur when patients are unassisted by nurses or staff, most often during toileting. Poor mobility and confusion are often contributing factors, and a major risk factor is older age, with more than one half of falls in hospitals involving people aged ≥80 years (National Patient Safety Agency, 2007). It is thought that in hospitals, approximately 30% of these falls are preventable by intervention (Cameron et al., 2012). Standard fall prevention focuses on three strategies: patient instructions; increasing nurse awareness by, for instance, assessing each patient's fall risk; and preventive measures, such as having patients wear non-skid socks or installing bed and chair pressure sensors. Bed and chair pressure sensors that warn nurses when a patient is getting out of bed are known to induce alarm fatigue due to high numbers of false alarms (16%), as well as non-directional alarms (Kosse et al., 2013). In two large randomized controlled trials, bed and chair pressure sensors did not prevent falls in hospital settings (Sahota et al., 2014; Shorr et al., 2012). Bed and chair pressure sensors are nonetheless common in U.S. hospitals.

In recent years, various technological developments have been made to improve fall prevention. These technologies include interactive devices that require long-term training (Hauer et al., 2020), various types of wearable stretch sensors (Chander et al., 2020), a wireless sensor network (Jähne-Raden et al., 2019), and video surveillance (Quigley et al., 2019). One of these newly developed technologies is based on a smart sock with wearable sensors, the PUP® (Patient Is Up) Smart Socks. This technology uses a platform built around a patented Smart Sock that documents and notifies the three closest caregivers when a patient wearing the socks is up and out of bed unattended.

In the current study, we performed a single-arm clinical trial at one hospital, as well as an observational study in two other hospitals. The objective was to determine whether the fall rate for patients with high fall risk decreases with the use of the new smart socks technology.

METHOD

Study Population

For the clinical trial, patients with high fall risk aged ≥18 years were included at three floors of an academic hospital in Ohio (AHO). Upon admission to the hospital, patients' fall risk scores were assessed by nurses based on the hospital's criteria. Before patients were asked to sign informed consent forms, the use of the Smart Socks and Palarum system were explained to them. Patients who lacked capacity to consent, with an anatomy or wound issue that would bar them from wearing socks, and patients for whom the sock would impede medical treatment were excluded from the study. The aim was to enroll 2,500 patients in the clinical trial. Compared to a historical fall rate of 4 per 1,000 patient-days, and assuming a dropout rate of 5%, we would have at least 70% power to detect a 25% reduction in the fall rate at alpha level 0.1 with 2,360 patients. Approval for the current study was obtained from the hospital's Institutional Review Board (IRB).

For the observational study, patients at two hospitals were included: three medical/surgical units of a hospital in South Carolina (HSC) and two medical/surgical units at a hospital in Ohio (HOH). Upon admission to the hospital, patients' fall risk scores were assessed by nurses based on the Morse Fall Risk Scale (Morse et al., 1989) at the HSC and the Hester-Davis Scale (Hester & Davis, 2013) at the HOH. Scores on the Morse Fall Risk Scale can range from 0 to 150, and patients were included in the study if they had a score ≥51 (Press Ganey Network of Care, 2020). Scores on the Hester-Davis Scale can range from 0 to 77, and patients were included in the study if they had a score ≥15 (Hester & Davis, 2013). In addition, patients could be included in the study based on clinical judgment of the attending nurse. No IRB approval was required for the observational study as the Smart Socks were added to standard care and posed no safety risks.

Technology

Palarum LLC's system consists of PUP Smart Socks (**Figure 1A**), an in-room tablet for each patient room, a local server, a monitoring device at the nurses' station, and Palarum Smart Badge notification devices worn by nurses. The PUP Smart Socks include three pressure sensors woven into the sock's fabric, which work through a Bluetooth transmitter affixed to the sock's exterior (**Figure 1B**). The sock and Bluetooth transmitter work to validate when a patient is attempting to stand through Palarum's proprietary algorithm. After a caregiver assists the patient in putting on the PUP Smart Socks, they will enter the appropriate patient data into the dedicated in-room tablet to enroll the patient in the PUP fall prevention program. When the patient gets out of bed and steps on the floor, pressure is detected by the sock sensors, which trigger an alert. This alert is displayed in the patient's room on the in-room tablet, a monitoring device located at the nursing station, and the three closest smart notification devices worn by caregivers. If a patient takes off the socks, this is detected by the system and immediately reported to nurses so the socks can be put back on.

Study Design

For the clinical trial, the study period was June 10 to June 21, 2019, and October 7, 2019 to March 17, 2020. For the observational study, the study period was May 1 to August 28, 2019 at the HSC, and July 31 to November 27, 2019 at the HOH. To introduce the use of Smart Socks, the observational study started with a 30-day introduction period, followed by

a 90-day intervention period.

All patients included in the study were provided with Smart Socks for the duration of their hospital stay. For patients included in the clinical trial, bed alarms were turned off, and for patients included in the observational study, bed alarms were used. After inclusion of patients, data were gathered in real-time through the platform. Data collected included, among other variables: department number, room number, date and time of start of Smart Socks wearing, date and time of stop of Smart Socks wearing, number of safety events, response times, the time at alarm, and patient-days. A full patient-day was defined as a 24-hour period. Falls and false alarms were reported by nurses using the hospital's Incident Report System. A *false alarm* was defined as a situation where the system reports a safety event even though the patient did not actually get out of bed. For the purposes of this study, we only looked at unique patients; therefore, if a patient was readmitted during the study, they would only count as a single patient.

Statistical Analysis

All data were automatically downloaded from the server into Microsoft Excel spreadsheets. Linear regression analyses were performed to analyze nurse response times using GraphPad Prism v8.1.2 (access https://www.graphpad.com). Chi-square analyses were performed to analyze fall rates using GraphPad's QuickCalcs (GraphPad Prism, 2020). A p value < 0.05 was considered statistically significant.

RESULTS

Patients and Safety Events

In the single-arm clinical trial at the AHO, 567 high fall risk patients were included. In total, these patients wore the Smart Socks for 1,693.8 patient-days. The Smart Socks recorded a total of 5,078 safety events at the AHO (**Table 1**). In the observational study, 670 patients were included at the HSC and 279 patients at the HOH. These patients wore the Smart Socks for 2,100 and 809 patient-days, respectively. A total of 5,359 safety events were recorded at the HSC, and 1,488 at the HOH (**Table 1**). No adverse events were observed that were due to wearing the Smart Socks.

Fall Rates in the Clinical Trial and Observational Studies

In the clinical trial, one fall was reported that occurred during a medical procedure with a nurse present; therefore, this fall was excluded from the analyses. No other falls were reported during the study period. During the clinical trial, 1,694 patient-days were recorded, amounting to 0 falls per 1,000 patient-days (**Table 1**).

During the observational study, three falls were reported during the training period and three during the intervention period, while in those periods 623 and 2,286 patient-days were recorded, respectively. This amounts to 4.8 falls (3/623) per 1,000 patient-days during the training period and 1.3 falls (3/2,286) per 1,000 patient-days during the intervention period (**Table 1**).

Because historical fall rates as falls per 1,000 patient-days were not available for two of the three locations, we compared the observed fall rates to the known NDNQI fall rate of 4 falls per 1,000 patient-days for hospitals in the United States (Bouldin et al., 2013). A χ^2 analysis reveals that during the training period of the observational study, the observed fall rate (3 falls in 623 patient-days) was not significantly different from the expected fall rate ($\chi^2[1, N = 623] = 0.104$, $p > 0.05$). A χ^2 analysis reveals that during the intervention periods of the clinical trial and observational studies, the number of observed falls (3 falls in 3,980 patient-days) was significantly lower than the expected number of 4 falls per 1,000 patient-days ($\chi^2[1, N = 3{,}980] = 10.527$, $p < 0.002$). In addition, when analyzed separately, the intervention period fall rates of the clinical trial and observational study were significantly lower than the expected numbers ($\chi^2[1, N = 1{,}694] = 6.827$, $p < 0.01$ and ($\chi^2[1, N = 2{,}286] = 4.145$, $p < 0.05$, respectively).

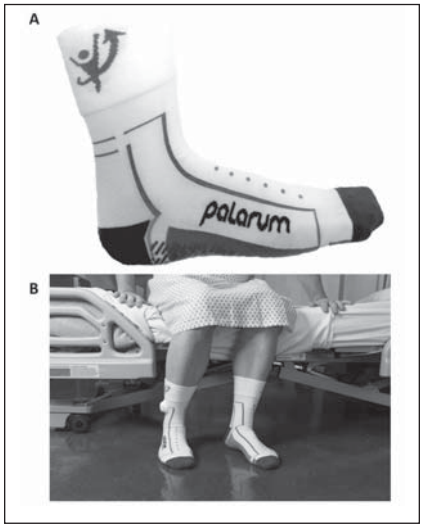

Figure 1. (A) PUP® (Patient Is Up) Smart Sock and (B) Smart Socks in use.

Nurse Response Times and False Alarms in the Clinical Trial

In the clinical trial, 5,078 safety events were reported with an average response time of 54 seconds (275,540 seconds/5,078 events), with a median of 23 seconds and a range of 0 to 1,673 seconds. Linear regression analyses of response times showed that the response times declined slightly (slope –0.4373, F[1, 5,076] = 6.257, $p < 0.02$, $R^2 = 0.001231$). Only 11 of the 5,078 alarms were false alarms, where the patient was not found standing; therefore, in 99.8% of cases the system was correctly detecting a standing position.

Nurse Response Times to Alarms During Observational Study

The average nurse response time at the HSC for the entire 120-day period was 93 seconds (497,593 seconds/5,359 safety events), with a median of 39 seconds and a range of 0 to 1,295 seconds. Response time was 84 seconds (113,763 seconds/1,361 safety events) during the 30-day training period and 96 seconds (383,830 seconds/3,998 safety events) during the 90-day intervention period. The average nurse response time at

TABLE 1

Alarms and Falls During the Clinical Trial and Observational Study

	n		
	Clinical Trial	Observational Study	
Variable	6-Month Intervention	30-Day Training	90-Day Intervention
Patient-days	1,694	623	2,286
Alarms	5,078	1,848	4,999
Alarms per 1,000 patient-days	2,998	5,580	4,076
Falls	0	3	3
Falls per 1,000 patient-days	0	4.8	1.3

the HOH for the entire 120-day period was 111 seconds (164,831 seconds/1,488 safety events), with a median of 54 seconds and a range of 0 to 1,443 seconds. Response time was 78 seconds (37,986 seconds/487 safety events) during the 30-day training period and 127 seconds (126,845 seconds/1,001 safety events) during the 90-day intervention period.

Linear regression analyses of response times over the 120-day period showed that at the HSC, response times increased slightly (slope +2.187, F[1, 5,357] = 22.17, $p < 0.0001$, $R^2 = 0.004122$), whereas at the HOH a more substantial increase in response times was observed (slope +7.021, F[1, 1,486] = 64.57, $p < 0.0001$, $R^2 = 0.04164$).

Compliance

To improve awareness of the study, nurses were asked to fill out two checklists per unit per day during the study. Questions ranged from number of patients enrolled to number of nurses. During the clinical trial, compliance with filling out the checklists varied from 76.4% to 100% per month. Average compliance was high, at 96.4% over the entire study period (**Table 2**). During the observational study, compliance with filling out the checklists varied from 83% to 95% per month at the HSC, with an average of 89.9%. At the HOH, compliance varied from 92% to 100% per month, with an average of 96.7%. At the HSC, compliance decreased during the intervention period, whereas at the HOH it increased (**Table 2**).

DISCUSSION

We performed a single-arm clinical trial and an observational study with the objective of determining whether use of the PUP Smart Sock technology leads to a reduction of in-hospital falls among patients with high risk of falling. We found that fall rates were significantly reduced in both studies.

We set out to determine in a clinical trial whether Smart Sock technology would reduce in-hospital fall rates. Due to the COVID-19 outbreak, we were unfortunately forced to stop the study mid-March 2020, which meant we were unable to include the 2,500 patients we aimed for in the study protocol. However, the number of falls was reduced to such an extent that we were nonetheless able to detect a statistically significant reduction of fall rates, to 0 falls per 1,000 patient-days.

The clinical trial was performed in an academic hospital and included intensive guidance. In addition, an observational study was performed at two non-academic hospitals where the Smart Sock technology was used without additional guidance. In this study, the use of the Smart Sock technology also led to a significant reduction of falls among patients with high fall risk.

We only analyzed falls and fall rates among patients with high fall risk; however, the NDNQI data from the 1,263 hospitals across the United States are based on all patients (Bouldin et al., 2013). The NDNQI fall rates would have been higher if they were also solely based on patients with high fall risk. Nonetheless, the Smart Socks significantly reduced fall rates, although the difference could have been more pronounced when only comparing against fall rates of patients with high fall risk. During the training period of the observational study, fall rates were higher than during the actual intervention period (during the training period preceding the clinical trial, data were not collected). This finding illustrates the importance of allowing staff time to get used to the new fall prevention system and for potential start-up problems to be resolved.

Bed and chair pressure sensors are the most widely used type of fall prevention in hospitals; however, these types of sensors have no effect on fall reduction. One study showed that active promotion of the use of bed alarms increased the number of alarms 36-fold ($p = 0.004$) but did not reduce fall rate (risk ratio = 1.09, 95% confidence interval [CI] [0.85, 1.53]) (Shorr et al., 2012). Another study found that bed and chair pressure sensors combined with radio pagers also did not reduce fall rate (rate ratio = 0.90, 95% CI [0.66, 1.22]) (Sahota et al., 2014). In addition, a systematic review on the effects of bed and chair sensors did not find a significant effect on fall rate (Cameron et al., 2018). Compared to the effect

of bed and chair pressure sensors, the Smart Sock technology is much better, as it reduced fall rates, not only in the clinical setting but also in the real-life setting of regular hospitals.

Several other wearable sensor devices have been developed to prevent falls that are attached to the ankles, wrists, and chest, or the upper leg, or integrated in a singlet (Ferrari et al., 2012; Jähne-Raden et al., 2019; Visvanathan et al., 2019). These wearable devices appear promising but have been tested in only zero to five individuals and have not been shown to reduce falls yet (Ferrari et al., 2012; Jähne-Raden et al., 2019; Visvanathan et al., 2019), whereas we tested the Smart Socks in 1,516 unique patients.

Alarm systems at hospitals do not only include alarm systems for patients getting out of bed, but also alarms from various medical devices. Due to the high number of false alarms from these various alarm systems, caregivers can get "alarm fatigue" (The Joint Commission, 2013). To avoid alarm fatigue and ensure that a caregiver responds to each alarm of a patient getting out of bed, it is essential that the alarm system produces a low number of false alarms. We found that the Smart Sock system resulted in only 0.22% false alarms, which is extremely low. For bed and chair pressure sensors, false alarms were reported to be 16% in a systematic review (Kosse et al., 2013) and 37.9% in the most recent study of bed pressure sensors (Balaguera et al., 2017). Compared to rates of false alarms by pressure sensors, the Smart Socks are a great improvement.

Nurse response times decreased slightly during the clinical trial, whereas during the observational study they increased. Nurse response times did not appear to be influenced by awareness of the study, as measured by compliance to fill out the study checklists. Compliance was high and increased in the clinical trial and at the HOH location, whereas it was low and decreased at the HSC location. Nurse response times, however, appeared to have no effect on fall rates, as at the HOH, which had the highest response time, the fall rate was reduced to zero, as in the clinical trial.

TABLE 2
Compliance With Filling in Daily Checklists

	n		
Variable	AHO	HSC	HOH
Study days	178	120	120
Number of checklists	1,068	720	480
Checklists filled in	1,030	647	464
Compliance (%)	96.4	89.9	96.7

Note. AHO = academic hospital in Ohio; HSC = hospital in South Carolina; HOH = hospital in Ohio.

In our clinical trial, many patients were included, and although these patients could be located anywhere on large wards, the average response time was only 54 seconds. In the observational study, average response times were 83 and 111 seconds. Our studies reflect real-life situations at busy wards, with many patients with high fall risk located anywhere on the ward. Only one small pilot study where patients with high fall risk were placed next to the nursing station reported response times to bed pressure sensors (Balaguera et al., 2017). More data are available on response times to call lights, and these range from approximately 4 to 6 minutes (Deitrick et al., 2006; Kalisch et al., 2013; Tzeng, 2010). On average, nurses spend 10,000 minutes per month (166 hours) responding to patient call lights (Studer Group, 2005), which places a huge burden on their time. An important function of the call light is to prevent falls when patients want to get out of bed, but when patients are frustrated by long response times to call lights (Deitrick et al., 2006), they are more likely to get out of bed by themselves, resulting in high risk of falling.

An important difference between the clinical trial and the observational study was that during the clinical study the Smart Sock system was used instead of bed alarms, whereas in the observational study, Smart Socks were used in addition to bed alarms. This difference resulted in a substantial reduction of total alarms at the clinical study site, which may have reduced alarm fatigue and resulted in shorter response times, whereas this was not the case at the observational study sites. This difference may explain the longer response times during the observational study compared with the clinical trial.

STRENGTHS AND LIMITATIONS

Many promising results of clinical trials, often performed in tightly controlled settings, do not translate well to clinical practice (Lenfant, 2003). A strength of our study was that results from the clinical trial were validated in real-life settings at regular hospitals. One of the limitations of the study was lack of control groups. However, a blinded, controlled study is difficult to perform with such obvious items as wearable technology. A limitation specific to the clinical trial was that patients who lacked the capacity to sign a consent form were excluded from the study, which excluded patients with delirium or patients with dementia who are known to be at high fall risk and may thus have affected

the observed fall rate. In the observational studies, however, these types of patients were not excluded as consent forms were not required and fall rates were also significantly reduced.

In future studies, it would be valuable to determine, at each study location, historical fall rates in patients with high fall risk, instead of in all patients. In addition, it is important that future studies also determine the effect of Smart Socks on fall rates in nursing homes and rehabilitation hospitals where there may be even more patients with high fall risk. In those settings, it may even be possible to randomize units with patients at similar fall risk to the use of Smart Socks versus standard fall prevention.

CONCLUSION

Our studies show that the use of the Smart Socks significantly reduced fall rates among patients with high fall risk in hospitals. The use of the Smart Sock technology to prevent falls will, as a result, also reduce fall-related injuries, deaths, and extended hospital stays, as well as the additional costs that are incurred by these falls.

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