Pressure Ulcer Monitoring Platform—A Prospective, Human Subject Clinical Study to Validate Patient Repositioning Monitoring Device to Prevent Pressure Ulcers

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Objective: The objective of this prospective clinical study was to validate two prototype pressure ulcer monitoring platform (PUMP) devices, (PUMP1 and PUMP2), to promote optimal bed repositioning of hospitalized patients to prevent pressure ulcers (PUs).

Approach: PUMP1 was a wearable electronic device attached to the patient gown with no skin contact. PUMP2 was a set of four identical electronic devices placed under the patient's bed wheels. A video camera recorded events in the patient room while measurements from the PUMP devices were correlated with true patient repositioning activity. The performance of these PUMP devices developed by our research team were evaluated and compared by both clinicians and engineers.

Results: Ten mobility-restricted patients were enrolled into the study. Repositioning movement was recorded by both PUMP devices for 10±2h and corroborated with video capture. One hundred thirty-seven movements in total were detected by both PUMP1 and PUMP2 over 105h of capture. Two false positives were detected by the sensors and 11 movements were missed by the sensors. PUMP1 and PUMP2 never conflicted in data collection.

Innovation: The presented study evaluated two different sensors' abilities to capture accurate patient repositioning to eventually prevent PU formation. Importantly, detection of patient motion was completed without contact to patient skin.

Conclusion: The clinical study demonstrated successful capture of patient repositioning movement by both PUMP1 and PUMP2 devices with 85% reliability, 2 false positives, and 11 missed movements. In future studies, the PUMP devices will be combined with a SMS-based mobile phone alert system to improve caregiver repositioning behavior.

Keywords: wound care, pressure ulcer, pressure ulcer monitoring, pressure ulcer prevention, clinical translation, repositioning monitoring

INTRODUCTION

MORE THAN 2.5 MILLION people in the United States develop pressure ulcers (PUs) every year.¹ These wounds are associated with pain, risk for serious infection, and increased

health care costs.¹ The Centers for Medicare and Medicaid (CMS) no longer provides additional reimbursements to hospitals for patient care if the patient has acquired a PU while under the hospital's care.²

Hospital-acquired pressure ulcers (HAPUs) are areas of localized skin and soft tissue destruction caused by prolonged pressure that typically affect nonambulatory patients.³ HAPUs are expensive to treat with a U.S. median cost at \$39,000 per patient stay.² The National Pressure Ulcer Advisory Panel (NPUAP) estimates PUs to cost the U.S. health care system \$3.6 billion per year.⁴ Determining a more precise financial burden of HAPUs in the U.S. health care system is multifaceted. Wound care is complex, and hospitals diverge across treatment pathways, based on wound severity and comorbidities.⁵ Furthermore, HAPUs consume significant nursing resources that may otherwise be directed to patient care for the primary admission diagnosis.¹

Several interventions and preventive measures are recommended to avoid HAPUs including patient repositioning, proper nutrition, pressure relieving support surfaces (*e.g.*, pneumatic mattresses), and skin care.⁶ One of the most effective preventive measures is frequent patient repositioning to avoid prolonged pressure on body surfaces.⁷ However, compliance with this nursing intervention has proven to be insufficient, especially during night shifts with less staff.¹ Moreover, there is no automatic and objective real-time documentation in the electronic medical record of repositioning events.¹ Consequently, many patients are not optimally repositioned, and documentation is inadequate, resulting in increased infection, patient morbidity, and financial liability for treating HAPUs.¹

Herein, we describe the validation of a reusable, low-cost patient repositioning monitoring solution (projected manufacturing cost of \$10–20 for Pressure Ulcer monitoring platform 1 [PUMP1] and \$40–60 per set of PUMP2) to be implemented in any health care facility with minimal disruption to existing workflow. PUMP aims to identify patient nonrotation, alert nursing staff to intervene with patient rotation protocols, and automatically document these preventive events within the electronic medical records.

CLINICAL PROBLEM ADDRESSED

Frequent patient repositioning has been shown to be effective in reducing the incidence of PUs. Nurses are the primary providers responsible for this important preventative measure; however, compliance with this intervention is often insufficient and undocumented. There is currently no standardized, automated process for patient positioning to be recorded, resulting in a lack of optimal repositioning and documentation of patient position. The prevention of this debilitating and

costly consequence can potentially be achieved by employing real-time position monitoring to increase optimal patient repositioning by nursing staff through alerts and integration with the medical records.

Current preventative solutions aimed at reducing PU development are often based on staff experience and are difficult to incorporate into the clinical setting. Evaluating the efficacy of a low-cost automatic sensor to detect patient repositioning is a critical step toward determining how to minimize efforts needed by clinical staff to effectively reduce PU formation through optimal repositioning. Current solutions include mattress-based, loadcell-based technologies and wearable sensors to detect and confirm repositioning (*e.g.*, earlysense, LEAF).^{8–14} Although the reported detection accuracy is high, most of these systems have been validated only with predefined movements performed by healthy subjects in a lab environment. Our study validates two monitoring systems (PUMP1 and PUMP2) in hospital rooms with immobile patients over a period of 10 ± 2 h. One of the systems is a wearable sensor, and the other is a loadcell-based system. We did not study a mattress-based system as this type of system contains an array of piezoelectric sensors or optical fibers that increase the cost. Different from existing chest-worn devices, our wearable sensor is attached to the patient's gown, not the skin, which is more comfortable for the patient and eliminates the possibility of causing an ulcer. The presented trial validates the performance of our monitoring systems (PUMP) in detecting repositioning activities.

MATERIALS AND METHODS

Sensors

PUMP consists of two different sensor devices: PUMP1 and PUMP2. Both sensors are designed and developed by our team to never have direct contact with patient skin. PUMP1, a wearable sensor that conveniently fits on a patient gown or clothing near the chest, directly monitors patient rotation. PUMP1 (Fig. 1) contains a microprocessor, a rechargeable lithium-ion battery, a microSD card for storing the measured data, and several sensors. The sensors include an accelerometer (3D acceleration measurement), gyroscope (3D angular velocity), magnetometer (direction), light sensor (luminance measurement), and a thermometer (ambient temperature).

PUMP1 contains a circuit board (Fig. 1A) within a small box (Fig. 1B) that was attached to the patient's gown using a clip (Fig. 1C). By attaching

Figure 1. Wearable device for PUMP1. (A) Macroscopic view of the circuit board. (B) Constructed prototype consisting of the small box in which the sensor and circuit board was placed. (C) Clip used to attach PUMP1 to patient gown. PUMP, pressure ulcer monitoring platform.

directly to the patient gown, PUMP1 measures body movement. Patient rotation was detected from nine output channels produced by the accelerometer, gyroscope, and magnetometer within the inertial measurement unit.

PUMP2 is a bed sensor system consisting of four sensor pads (each 12×4 inches) placed under the four wheels of a hospital bed to measure changes in body weight distribution. PUMP2 measures patient in-bed movement. The entire bed sensor system is shown in Fig. 2 consisting of sensor pads and a controller. The system is powered by plugging into a power socket, thus the system does not require recharging.

Each sensor pad in PUMP2 sandwiches four components (Fig. 2): First, the top plate (black areas in Fig. 2B) is made from an alloy metal, divided in two opposite sections; it is a high-performance “spring” metal that, when under pressure at the opening between the two sections, yields into a “V” shape, holding the bed wheel in place. Second, the surface of the top plate in the V-shaped region is covered by aluminum oxide sand paper to increase holding friction. Third, below the top plate, there is a rubber sheet (shown in red in Fig. 2B) to prevent the top plate from over-extension and to dampen bed oscillation. Fourth, the next layer of PUMP2 is a polycarbonate plate (shown in white in Fig. 2B) to form the base of the sensor, supporting the top layers and hosts four load cells, which is the last layer of the system. Polycarbonate is a very strong material, not electrically conductive, allowing us to

Figure 2. Bed sensors used for PUMP2 consisting of four sensor pads (outside corners) and the controller (center). (A) Bird's eye view of the four sensor pads and controller prototype. (B) Design of the sensor.

embed within it four load cells to reduce the total device thickness. The sum of the outputs from the four load cells is sent to the controller unit located at the center of the four pads as shown in Fig. 2A. The controller receives signals from the four pads and transmits them using a wireless communication link. Total weight that can be withstood by PUMP2 (patient and bed combined) is 1,320 kg.

Clinical trial

The prospective, experimental, single-blinded human subject study was reviewed and approved by the University of Pittsburgh Institutional Review Board (IRB)—PRO15110149 (ClinicalTrials.gov identifier NCT09252664).

Before providing informed consent, subjects were made aware of the intervention, including the placement of the video camera in the room to correlate the monitoring device output with the video-captured real-time data of actual subject repositioning events.

Screening and eligibility determination included a review of medical records to ensure that the participants were immobile and unable to independently reposition themselves. Eligibility criteria included the following: is 18 years of age or older, able to provide

informed consent, immobile or mobility-restricted, requires assistance to reposition self while lying in bed (e.g., inpatient standard of care documentation ordered for patient repositioning). Exclusion criteria included the following: being less than 18 years of age, unable to provide informed consent, able to ambulate independent of support person, able to get out of bed independent of support person, not required to have repositioning by clinical staff as part of the standard patient care, and pregnancy.

Research activities were three-fold: (1) Placement of PUMP1 on the participant's gown with no direct skin contact; (2) Placement of PUMP2 under the wheels of each hospital bed; and (3) Placement of video camera in participant hospital room to capture actual repositioning and corroborate with PUMP1 and PUMP2. No audio was collected. Duration of data capture was set to be 10 ± 2 h to ensure change in at least one nurse shift. The devices were removed and movement data plus video-captured data were collected. Raw data collected by both PUMP1 and PUMP2 for each subject can be found in Supplementary Figure S1.

Repositioning events recorded by the PUMP1 and 2 devices and the video camera were immediately uploaded to the team's internal server and abstracted. The data between the monitoring device and video capture were compared and analyzed by watching the video to detect whether there were conflicts between the number of events captured by the PUMP devices and true repositioning events, to validate PUMP performance in the clinical setting. PUMP data were analyzed by evaluating thresholds of each detected movement obtained from the sensors, including data from the accelerometers, gyroscopes, magnetometers, and light sensors. Then, detected movements from the sensors were compared to the video footage to confirm whether or not a true movement occurred.

The industry standard of practice for turning and repositioning a patient at risk for PUs is every 2 h. "Repositioning" was defined as a rotation of the patient's core body while lying in bed, to include adjusting individual limbs for cleaning purposes and/or comfort measures. This practice of "repositioning" is conducted to redistribute pressure, especially at bony prominences on the patient's body to decrease pressure against the skin that may interfere with tissue perfusion.¹⁰

Results are presented as average $\pm$ standard deviation.

RESULTS

Over a 5-month period, 10 human subjects were enrolled into the study (3 male, 7 female) at an

average age of 60.0 ± 17.2 years and weight of 76.1 ± 27.2 kg at screening. Movement was recorded by both PUMP1 and PUMP2 for 10 ± 2 h and corroborated with video capture. A total of 105 h of data were captured. One hundred thirty-seven movements were collectively detected between PUMP1 and PUMP2. An average of 6.5 ± 1.9 movements per subject were detected by PUMP1 (gown sensor) and an average 7.2 ± 1.9 movements per subject were detected by PUMP2 (under-bed sensors). Eleven movements were missed by PUMP1 (wearable gown sensor) and seven movements were missed by PUMP2 (bed sensor). Two false positives were detected by PUMP1 and 1 by PUMP2, which was the same event. PUMP1 detected a total of eight more movements than PUMP2.

The two subjects with sensor-missed movements were the only two subjects enrolled in the study with tracheostomy tubes and required almost continuous care by the nurses. Missed movements captured by video camera include repositioning movements, such as a nurse rearranging the subject's arms, lifting the subject's legs, and cleaning the subject. Video capture of a separate, third subject confirms a nurse dressing the subject and getting the subject out of bed, which is a true movement for PU prevention; however, the sensors could not detect significant signals in regular forms, indicating a missed movement. The one false positive detected during monitoring of one of the subjects with the tracheostomy tube was due to the nurse leaning on the bed, triggering the sensor, but not touching the subject for clinical care.

DISCUSSION

The clinical trial demonstrated successful capture of movement by both PUMP1 and PUMP2 devices with 21 incorrect detections from a total of 137—indicating an 85% reliability of the PUMP system detecting patient repositioning. Importantly, detection of motion was completed with zero contact with patient skin to ensure no additional ulcers were developed due to the devices. In future studies, the patients will be monitored and correlated with a short text message-based mobile phone alert system for nursing staff to validate patient repositioning.

Effective repositioning behavior is imperative within inpatient environments and skilled nursing facilities to ensure prevention of PUs acquired due to prolonged pressure on body surfaces. Current clinical practice involves shift-based care staff to reposition patients using schedules and reminders without objective and automated patient rotation

confirmation. Consequently, patient repositioning is performed sporadically and leads to avoidable PU development. Alternative solutions to PUMP that are in development include mattress-based technologies to detect and confirm repositioning. However, these solutions are likely to be prohibitively expensive. For example, pressure pad-based devices typically use an array of pressure sensors, which is costly compared to only four load cells that are used in PUMP2. There exist alternative under-bed load cells to PUMP2; however, these solutions are only validated by predefined movements among healthy subjects in a lab environment^{11–14} with accuracy ranges 74.9–97%. Furthermore, existing chest-worn devices come into direct contact with patient skin opposed to the PUMP1 device that does not come into patient skin contact.

PUMP will eventually incorporate a text-based mobile phone system to alert nursing staff to perform patient rotation, reducing human error in following repositioning schedules. Additionally, we plan for PUMP automatic real-time documentation of repositioning events into patient electronic medical records. This combination of current and future PUMP functionality has the potential to significantly reduce PU development.

Certain limitations exist in the study design and PUMP sensors. As a proof of concept clinical study, we had a small sample size of 10 enrolled subjects.

Another limitation of the study was the occurrence of missed movements for subjects due to tracheostomy tubes. Future PUMP systems will allow for customization of patient care needs by adjusting sensor sensitivity to each patient... Additionally, in future studies, we will conduct analyses to identify the different changes corresponding to different types of movement.

Without a cost-effective solution to reliably monitor and detect patient repositioning, millions of PUs are acquired while under hospital care. This unmet clinical need is financially burdensome and harmful to patients. In the presented clinical trial, both PUMP1 and PUMP2 sensors were proven to effectively detect patient repositioning. Importantly, neither device comes into direct contact with patient skin. Both are cost effective and low maintenance for hospital staff. Future PUMP systems to include a text-based mobile phone notification system to nursing staff will be tested on a larger sample size. PUMP provides a promising solution to reduce the occurrence of hospital-acquired PUs.

KEY FINDINGS

- Successful validation of PUMP1 and PUMP2 prototypes with 85% reliability in a 10-subject clinical trial;
- The entire PUMP system is effective with zero patient skin contact;
- Future studies will involve a sleeker design of PUMP1 and PUMP2, and a PUMP3 SMS-text messaging alert notification system to nursing staff, in addition to enrolling a larger sample size.

INNOVATION

Patient repositioning to avoid prolonged pressure on body surfaces is a critical method to reduce hospital-acquired PUs; however, the current state of the PU prevention field does not present a cost-effective solution to eliminate human error in repositioning. Current solutions include expensive mattress-based technologies.

The PUMP system, comprising of PUMP1 (wearable gown sensor) and PUMP2 (bed sensor) are low cost (a projected manufacturing cost of \$10–\$20 for PUMP1 and \$40–\$60 per set of PUMP2 devices) and have successfully determined body rotations of patients without significant technical difficulties and without disrupting the clinical workflow.

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The presented study was approved by the University of Pittsburgh Institutional Review Board on November 04, 2016 as IRB No. PRO15110149. The approved protocol was adhered to and zero unanticipated events occurred. The presented study was funded by the Pittsburgh Health Data Alliance Center for Commercial Applications in June 2015.

AUTHOR DISCLOSURE AND GHOSTWRITING

No competing financial interests exist for any author. The content of this article was expressly written by the authors listed. No ghostwriters were used to write this article. No conflicts of interests exist for any author. No commercial associations exist that may create a conflict of interest in connection with the submitted article.

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development of PUMP and conducting day-to-day setup for clinical execution. **Mingui Sun, PhD**, was Co-Investigator and served as chief engineer. He is Professor of Neurosurgery, Electrical Engineering, and Bioengineering, and Director of Center for Computational Neuroscience. **J. Peter Rubin, MD, FACS**, served as Principle Investigator. He is Chair of Department of Plastic Surgery, Chair of Executive Steering Committee on Wound Care Services. He works with the chief quality officer of UPMC to improve wound care services and prevention.

SUPPLEMENTARY MATERIAL

Supplementary Fig. S1

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Abbreviations and Acronyms

CMS = Centers for Medicare and Medicaid
 HAPUs = hospital-acquired pressure ulcers
 IRB = Institutional Review Board
 PU = pressure ulcer
 PUMP = pressure ulcer monitoring platform
 SMS = short message service