

A Novel IoT System For Patient-Centric Pressure Ulcer Prevention Using Sensor Embedded Dressings

Sachin Rangarajan*, Young Lee*, Vinith Johnson*, Kaelan Schorger*, Hanmin Lee*,
Dung Nguyen†, Mohammad H. Behfar‡, Elina Jansson†, Jari Rekilä†, Jussi Hiltunen†,
Eric Vin§, Katia Obraczka§

*Department of Surgery, University of California San Francisco, San Francisco, CA

{sachin.rangarajan, young.lee, vinith.johnson, kaelan.schorger, hanmin.lee}@ucsf.edu

†VTT Technical Research Centre of Finland Ltd. Kaitoväylä 1, Oulu, 90570, Finland

{dung.nguyen, elina.jansson, jari.rekilä, jussi.hiltunen}@vtt.fi

‡VTT Technical Research Centre of Finland Ltd. Tietotie 3, Espoo, 02150, Finland

mohammadhossein.behfar@vtt.fi

§Department of Computer Science and Engineering, University of California Santa Cruz, Santa Cruz, CA
evin@ucsc.edu, katia@soe.ucsc.edu

Abstract—Pressure ulcers/injuries (PU/Is) are localized damage to the skin and/or underlying tissue caused by prolonged pressure to an area of the body. PU/Is affect over 2.5 million individuals in the United States annually, are associated with increased morbidity and mortality, and incur a cost of approximately \$11 billion to the US healthcare system. Mitigating PU/Is continues to be a challenging task using traditional methods due to their time- and labor-intensive nature, and existing technological solutions tend to be prohibitively expensive, inefficiently implemented, or ineffective. Thus, there is a clear unmet need for a holistic, end-to-end, hospital-integrated, patient-centric system for PU/I prevention. Such a system can monitor pressure at high-risk areas and uses real-time sensor data, analysis, and visualization to guide clinicians and caregivers to perform effective preventative measures. In this paper, we describe a proof of concept of this system, which integrates: (A) a prototype "smart wound dressing" capable of detecting of changes in interface pressure and patient angle over time, including during routine patient repositioning maneuvers; and (B) an open software infrastructure that collects pressure-over-time data, stores, analyzes, and displays them to clinicians and caregivers. We present preliminary results obtained using our current prototype which uses machine learning algorithms to infer a patient's current position based on data from the pressure sensor.

Index Terms—Wearable computers, correlation and regression analysis, medical information systems.

I. INTRODUCTION AND BACKGROUND

Pressure ulcers/injuries (PU/Is) are localized damage to the skin and/or underlying tissue caused by prolonged pressure to an area of the body. PU/Is typically develop in low-mobility individuals (bedridden or wheelchair-confined), over bony prominences, such as the sacrum, ischial tuberosities, or heels [1]. Despite widespread attention and regulation, PU/Is are highly prevalent, affecting over 2.5 million individuals in the United States annually [2]. These debilitating wounds have severe downstream implications to patients and healthcare facilities, are associated with increased morbidity and mortality, and incur a cost of approximately \$11 billion to the US healthcare system [3]. Treatment of deep tissue PU/Is requires intensive wound management that can take years, leading to

major disability and increased health and economic burden for patients, caregivers, and health care facilities. Current standard practice for preventing PU/Is involve intermittent assessments by hospital and long-term care facility staff using the highly subjective Braden scale, and repeated manual repositioning of the patient; these tactics have low compliance because of their time- and labor-intensive nature. In one study, 54% of patients undergoing "standard care" are adequately turned to clinical standard, only 39% of turns reach the minimum angle threshold, and 38% of patients remain in the turned position for more than 15 minutes [4]. Even "standard turning by experienced ICU nurses does not reliably unload all areas of high skin-bed interface pressures" as found by one study, due to the presence of "triple jeopardy areas [that] remain at risk for skin breakdown and help to explain why PU/Is occur despite the implementation of standard preventive measures" [5].

Competitor technological solutions that attempt to address PU/Is include handheld skin scanners designed to identify areas at risk of pressure injury formation (which take additional time from an already busy nurse's schedule), devices to detect compliance with patient turning (which do not detect triple-jeopardy areas), pressure sensing mats (which cannot measure accumulation of skin pressure since they are placed on the bed, rather than the patient), and air-fluidized mattresses (which are noisy and prohibitively expensive). Most commonly, self-adherent soft foam dressings are used on the skin to distribute pressure to attempt to prevent pressure injury formation.

In this paper, we describe a system that addresses PU/Is without succumbing to the pitfalls mentioned above. The system integrates: (A) a prototype "smart wound dressing" capable of detecting of changes in interface pressure and patient angle over time, including during routine patient repositioning maneuvers; and (B) an open software infrastructure that collects pressure-over-time data, stores, analyzes, and displays them to clinicians and care givers in real time. As an inexpensive device that passively collects data (rather than re-

quire active interaction from nurses), and a form factor already used (wound dressing), this system can be smoothly integrated into nurses' workflow. This system, critically, can measure both accumulation of pressure directly on the patient's skin, as well as real-time pressure points (such as triple-jeopardy-points). We present preliminary results obtained using our early prototype which uses machine learning algorithms to infer a patient's current position based on data from the pressure sensor. We also discuss our future work plans to upgrade the system to provide an automated, comprehensive, individualized patient repositioning guidance for both nurses as well as non-trained care givers.

II. PROPOSED SYSTEM

This section presents our patient-centric repositioning guidance platform for PU/I prevention and its two functional components, A) the pressure sensing dressing and B) the patient monitoring IoT software infrastructure.

A. Pressure Sensor

1) System description and readout electronics: The sensing patch is comprised of an electronics engine and an array of 48 force sensing resistors (FSR). The electronics is composed of an operational amplifier (in non-inverting configuration) and two multiplexers (MUX) for scanning 48 FSRs and an acceleration sensor. The electronics core is controlled by an embedded Bluetooth-enabled microcontroller (nRF52832), which algorithmically reads each individual sensor and converts the raw value to a corresponding force measurement, which is stored in a temporary register. The data transmission between the patch and mobile/PC device is handled via BLE communication. The system function block diagram is shown in Fig. 1.

2) Patch Integration: Creation of the large area conformal patch through conventional flexible electronics manufacturing methods is challenging and uneconomical. To overcome this issue, instead of conventional PCB fabrication process, the patch was realized using printed electronics technology. The patch layout was processed with roll-to-roll screen printing line. EMS CI-1036 was the conductive ink used. The FSRs were electrically bonded to the layout using anisotropic conductive adhesive (ACA) film (3M 9703). A printing speed of 2 m/min and a drying temperature of 120°C were used. After assembly of the FSRs on the printed layout, the patch was converted using skin friendly tapes and films on both sides. On the top side, the printed tracks and FSRs were covered by a 100 um TPU film, and on the bottom side, the patch was covered using a non-woven medical tape. The stack structure diagram and the fully assembled patch are shown in Fig. 2 and Fig. 3 respectively.

3) FSR Benchtop Characterization: Several commercial FSRs were screened to select the most optimal pressure sensing element for the patch. The main selection criteria were resistance drift (over time), accuracy and repeatability of the sensors. A set of benchtop tests was conducted to extract force-resistance curves of the sensors. The characterization tests

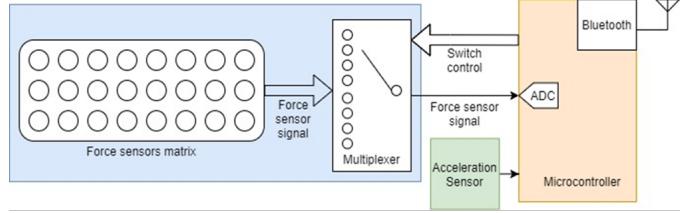


Fig. 1. Hardware system function block diagram.

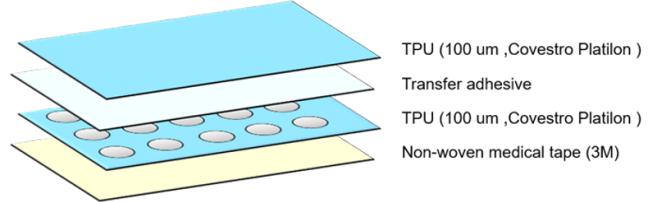


Fig. 2. Stack structure diagram.

were performed using precision reference weights (0.5-1 kg) as well as strain tester device. The sensors were sandwiched between two layers of a Mepilex Border Sacrum (Molnlycke, Sweden) wound dressing to simulate the real-life application. The characterization data suggested Ohmite FSR06 as the optimal sensor. The sensor's thickness is 0.375 mm with an active area of 14.70 mm which can detect force within the range of 1.5-50 N.

B. Patient Monitoring IoT Software Infrastructure

The data collected from the pressure sensing dressings feeds into a novel IoT patient monitoring software platform described in more detail in [6]. Our patient monitoring software system integrates and automates the basic components of the patient monitoring workflow, namely: (1) data collection from off-the-shelf and custom sensors; (2) data storage and (3) data analytics to, respectively, store and process sensor data streams and patient-specific health information; and (4) real-time data visualization mechanisms that can display to clinicians and care givers relevant information in real time. The system includes four main software components, namely: Sense, Store, Analyze, and Visualize, as illustrated in Fig. 4.

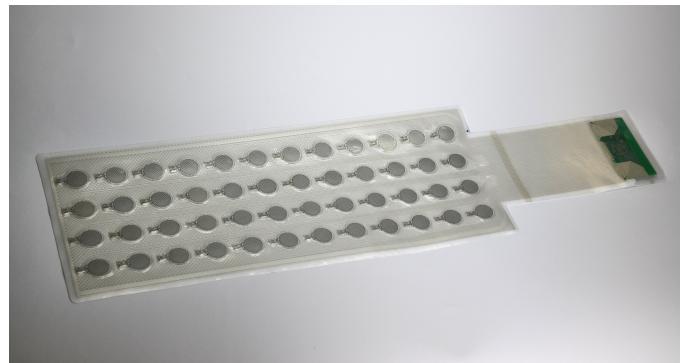


Fig. 3. Fully assembled patch.

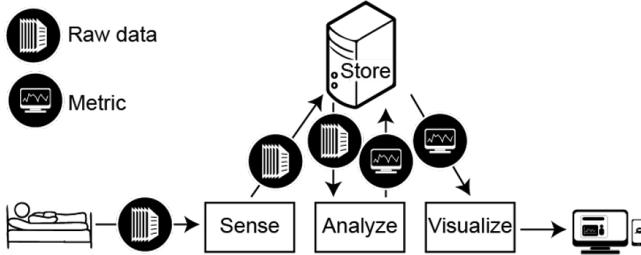


Fig. 4. Software components of the IoT patient monitoring system.

Through its ability to collect, analyze, and visualize patient-generated data, the software monitoring system aims to guide repositioning protocols objectively and effectively. It can also continuously assess and display a patient's risk of developing PU/Is in real-time and alert healthcare staff when patients need to be repositioned. In addition, the system's design allows for deployment in various settings and configurations e.g., local, edge, and cloud-based setups that can support hospital, long-term, and home care applications. For this study, the system was tailored to incorporate pressure and accelerometer data gathered from the pressure sensing dressings in order to better understand patient positioning and eventually be used to monitor patient turning effectiveness.

III. EXPERIMENTAL METHODOLOGY

A. Volunteer Study Design

We performed a preliminary observational, descriptive, healthy-volunteer study with 5 volunteers at a tertiary care, university-affiliated hospital. After obtaining Institutional Review Board (IRB) approval, adult volunteer subjects were recruited with informed consent. An experienced ICU nurse and nurse educator performed all turning procedures following standard-of-care protocol.

B. Study Protocol

All volunteers donned gowns used by patients at the hospital. The lower back and sacral area of each volunteer was padded with 3 adjacent Mepilex silicone-adherent foam dressings. On top of this layer, the pressure sensor was attached using medical adhesive tape, with the printed circuit board (PCB) containing the accelerometer and Bluetooth transmitter consistently attached to the left hip of each volunteer.

Each volunteer was placed supine on a Hill-Rom ICU bed with head of bed at 0 degrees, and with a pillow placed under the head and each arm, as standard-of-care for ICU patients. At the beginning of data collection, the volunteer remained supine for 2 minutes. After 2 minutes had passed, the ICU nurse and an assistant turned the volunteer using the standard ICU protocol of tilting the volunteer to the left and wedging pillows under the right side of the volunteer. This left position was maintained for 2 minutes. After 2 minutes had passed, the volunteer then turned to the right side using the same ICU turning technique. Lastly, the volunteer was returned to the supine position. The head of bed was then raised to 30 degrees,

and the supine, left, and right repositioning cycle was repeated for 2 minutes in each position. Pressure and accelerometer data were continuously collected from placement of the patch through removal of the patch.

C. Data Analysis Methodology

The data gathered from the experiments described above were analyzed with the goal of identifying patient position, again in the three discrete categories, namely supine, left lateral decubitus, and right lateral decubitus. This preliminary analysis was done using a simple logistic regression model trained on the volunteer data.

To prevent biased results, model training and evaluation was performed the same number of times as there are volunteers, i.e., for each iteration, a volunteer was selected as the “validation” volunteer and their data were excluded from the training data set. Furthermore, all remaining volunteers had 20% of their samples, selected at random, excluded as “test” data. The remaining data, the “train” data, were used to train the model. The performance was then evaluated on all sets of data. The “test” and “train” datasets allow us to see whether the model can fit the data and whether it is over-training to the noise in the data. “Validation” data allows us to infer how the model would perform in the field, i.e., for patients whose data had never been seen by the model. This is important since it will determine whether the model can be generalized for practical use.

The training data were transformed into several features before being used for training purposes. As we used a logistic regression model [7], the choice of features was critical for expressing nonlinear relationships between the data and the result. It also served the dual purpose of combating over-fitting of the model to noise patterns present in each patient's data. As the ratio of volume of data to number of volunteers was quite high, with just raw training data or poorly chosen features over-fitting quickly impacts performance of the validation step. Some choices of features for the pressure data include Objective Mobility [8] and normalized mean pressure along a three-way horizontal split of the bandage. For the acceleration data, feature selection was not needed as the data were much more condensed already (three x,y,z acceleration values versus 48 pressure values). We also added a metadata feature which provided the patients height and weight, something which would be readily available in clinical use.

While the training data was labeled during the experiments, it contained a significant amount of noise around transition points when the patient was turned. To this end, we explored the unsupervised “cleaning” of the training data to remove extraneous samples. We used an approach based on Isolation Forest model [7] for data cleaning. To prevent bias, no data cleaning was done to “test” or “validation” data in each iteration, only to “train” data.

IV. PRELIMINARY RESULTS AND ANALYSIS

To evaluate the choice of hyper-parameters for a model, such as choice of training features and whether to clean train-

ing data, we considered the mean of all “validation” accuracies for that model. We believe that this is the most adequate metric representing the model’s expected performance in clinical use. We performed a grid search over all combinations of hyperparameters, and we were able to achieve mean validation accuracies of 55% and test and train accuracies of 95%-99% (though test and train accuracies are not necessarily indicative of performance in real world settings) using raw acceleration and patient metadata. Validation accuracy of 53% was attained using raw acceleration data, patient metadata, and pressure data after data cleaning. While it may be surprising that the addition of pressure data reduced accuracy, we believe this is merely due to limited training data availability and the model overfitting to the pressure data as a result. We expect that, as we acquire additional training data from different subjects, the model will be able to detect patterns in the pressure data that will enable more accurate predictions. More importantly, this indicates that even with minimal data we are still able to make somewhat accurate patient position predictions. The data cleaning pre-processing step produced noticeable accuracy improvements for certain feature choices, further indicating that more data is required to generalize the model and produce higher accuracy predictions.

V. CONCLUSION AND FUTURE DIRECTION

The significant human and financial costs associated with pressure ulcers and the current inefficiencies and hurdles in implementing successful prevention tactics make this area an ideal target for improvement using pervasive computing and IoT principles. In this paper, we introduce a holistic, end-to-end IoT system that uses pressure sensor and accelerometer enhanced wound dressings to objectively evaluate the efficacy of repositioning efforts in redistributing pressure. This has the potential to greatly improve clinical outcomes in pressure ulcer care and prevention. The novel IoT-based approach to patient monitoring demonstrated in this paper integrates (A) off-the-shelf sensors consolidated into a form factor adequate for clinical use with (B) a software platform that continuously and autonomously collects, stores, analyzes, and displays sensor data in real time can be easily incorporated into the clinical workflow without causing risk to the patient or increasing the burden on the clinician. We demonstrate how printed electronics can be used to create a wearable patch that can easily be attached to existing clinical wound dressings. The patch is able to measure pressure and accelerometer data across five volunteers in a clinical setting, providing real-time continuous data. This data was collected by our patient monitoring software, stored, and analyzed. We have demonstrated that even with a small sample size, a simple model can be generated to predict a patient’s position using pressure and accelerometer data. We anticipate that the accuracy of this model will increase as more volunteer data are collected.

In the future, this real-time data can not only be used to further train the model, but also to provide clinicians valuable visualization of the patient’s pressure profiles and to better guide repositioning efforts in ensuring pressure is

adequately relieved. As more data are collected, we expect the posture detection model to more accurately characterize an unknown patient’s position. While the initial goal of this model is to help clinicians determine whether a patient has been turned according to the clinical standard of 30 degrees for an adequate duration, data collected from the pressure sensors on volunteers undergoing “perfect” turns by a trained ICU nurse can be used to train a model for “ideal patient turning.” We intend to generate a large data set of pressure profiles collected from volunteers undergoing these “ideal” turns to characterize whether an unknown patient undergoing repositioning fits within the parameters of these “ideal” turns, or if the repositioning effort needs to be modified.

Ultimately, we envision a system that derives a pressure injury prevention protocol unique to each patient by using objective factors that include real-time sensor data, labs and vitals, and the patient’s medical history. This system can continuously monitor a patient’s risk of pressure injury within the hospital, at long-term care facilities, and at home. This continuous monitoring in conjunction with objective clinical risk factors can be used to provide actionable information, which in turn enables caregivers to intelligently and effectively prevent pressure injuries from occurring altogether.

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