Curiato

PI Connect

WHITE PAPER

Smart Surface Monitoring Platform

Sensor detection monitoring for patients at risk of pressure injury

Technology can notify a clinician via an alert: when the patient needs turning and repositioning or when the patient has experienced an incontinence event. Accurate smart dashboard data can help improve staff efficiency by reducing nurses' time spent checking patients.

Executive Summary

"Every medical device company wants to be an AI company," remarked University of Waterloo Professor Alex Wong. There has been a proliferation of sensor technologies incorporated into many emerging products. In the medical field, among the common health care acquired conditions, pressure injuries have remained one of the toughest to crack. This has attracted smart minds and data scientists. Technology's ability to accurately measure pressure injury risk factors supports nursing practice. Supplementary data generated has the potential to improve resource allocation by informing targeted pressure injury prevention strategies and decreasing unnecessary interventions. Data collection underpins the basis for artificial intelligence applications with the potential to inform clinical decision-making areas. Technology has the potential to reduce incidence of health care acquired pressure injury (HAPI) and can translate into cost savings.

This paper draws together poster presentations from Society of Advanced Wound care (SAWC) in spring 2020, Wounds Canada in fall 2020 and National Pressure Injury Advisory Panel (NPIAP) in early 2021.[†]

Meet Patty

Patty is 81 years old and was admitted to the hospital. Patty is confined to her bed, day after day, unable to care for her most basic needs, like going to the washroom. The reality is 30-60% of older people experience functional decline when hospitalized. Many of whom are unable to communicate and call for help.

Patty is not alone. Studies show that 1 in 4 people will become incontinent in their lifetime. If you are a woman older than 65, like Patty, that number soars to a 1 in 2, or 50% chance of experiencing incontinence. The reality of aging is that you or someone in your family will likely become incontinent during their lifetime.

As aging occurs the skin becomes thin and fragile. This combined with incontinence and immobility of not being able to move or reposition yourself when feeling pain can lead to serious complications such as pressure injuries - a preventable disease that claims 60,000 lives as a direct result every year in North America alone.

We live in a fast-paced world, and it may not seem possible for us to extend the kind of personal care and support the elderly deserve. With technology, we can bridge this gap, starting with pressure injury prevention and together we can change the trajectory of this silent disease. The ultimate beneficiary of this technology innovation will be patients like 81-year-old Patty. Prevention of avoidable pressure injuries can help her maintain her well-being and independence.

Influence of pressure, humidity, and temperature

Interface pressure and skin microclimate have been identified as critical risk factors in pressure injury development.[1] Interface pressure, temperature, and humidity act as a better predictor for pressure injury than pressure alone. Patient repositioning–caregiver assisted posture change–during scheduled rounds is the gold standard of care for HAPI prevention. Evidence shows that manual monitoring of patients' posture in a complex hospital environment is neither efficient nor practical.[2]

Redistribution of interface pressure where high levels are suspected is fundamental to pressure injury prevention protocols. The accurate measurement of pressure exerted in a particular area (mechanical loading) and how long a patient remains in one position can be challenging.[3] Evidence-based advice about optimal repositioning remains inconsistent.[4,5]

Excess moisture may stem from incontinence, perspiration, mucus, wound exudate, and other bodily fluids. Overhydration of the skin causes the stratum corneum to swell and stretch, weakening the connections between epidermal cells and collagen fibres, contributing to cell deformation and an increase in the coefficient of friction (COF) at the interface of mechanical load and support surface.6 Increased permeability and disruption of the normal barrier function renders the skin more susceptible to irritants and mechanical damages. Further, incontinence-associated dermatitis is an independent risk factor for pressure injury.[7,8]

Individuals with bowel and bladder incontinence and related incontinence-associated dermatitis are five times more likely (95% CI 2.62-9.50) to develop pressure injuries than those who are continent.9 Signs of skin damage can be observed within 15 minutes of exposure to moisture.[10] Monitoring skin surface moisture and temperature or microclimate in real-time can be challenging.[11] Yet, reviews of monitoring technologies show that sensor devices are associated with a substantial reduction in the risk of pressure injury.[12]

Elevated skin temperature has also been shown to be a strong predictor for pressure injury development. Although the exact mechanism remains unclear, elevated skin temperature may increase tissue metabolic demand and oxygen consumption, making the skin more vulnerable to mechanical damage.[13] In the clinical setting, skin microclimate can be modulated through repositioning to redistribute pressure, clothing and linen changes, or interventions such as dressings and the application of medical devices.[14] The skin's ability to withstand increased temperature and humidity levels can vary depending on age, comorbidities, and a host of other factors. High and low skin temperature and humidity beyond normal ranges can negatively affect the barrier function and tolerance leading to superficial skin changes.[1,14]

Clinical validation

To validate postulated solutions, Curiato undertook evaluation of a smart surface platform to measure clinical data on patient mobility and skin microclimate. The 1,407 sensor monitoring hours generated 1,101,780 frames of surface data.

These data were compared with simultaneously scheduled nursing observations in line with clinical protocols. Further analysis can then demonstrate the accuracy of such a system designed to monitor the position of patients or urination events. To do this a prospective trial was conducted, following ethics approval, at a single tertiary care facility in a large urban centre in Canada. All staff on the study units received training in recruitment and study protocols. The eligible population was recruited from complex continuing care and post-acute care rehabilitation settings. Inclusion criteria were adults, hospitalized for > 18 hours, at risk of pressure injuries, as defined by the InterRAI Pressure Injury Risk Assessment Scale with or without a current pressure injury.

The study results are summarized in Table 1 and described in more detail in the original posters. A manuscript is being prepared for submission to a peer reviewed journal.

Table 1 *Overview of trial results. All tests produced P-values of less than .05. A total of 104-patients met the inclusion criteria with mean age was 59 years (range 21-92, ± 19.15)*

Interface pressure visualization	Number of times nurses recorded patient posture n = 600	Number of times smart surface platform data postures correlated n = 552	IRR 92.0% (95% CI=(89%,94%))
Humidity	Number of times nurses recorded bladder incontinence events n = 132	Number of times smart surface platform data bladder incontinence correlated n = 125	IRR 94.7% (95% CI=(89%,98%))
Temperature	Number of times nurses recorded temperature n = 132	Number of events identified using sensor temperature data n = 115	IRR 87.1% (95% CI=(80%,92%))

PI-Connect shown in Figure 1 comprises an array of sensors embedded in a thin, flexible surface placed underneath the bedding and not in direct contact with the patient. The sensors gathered data from the subject's bedding surface in the form of interface pressure (mmHg), temperature (Celsius) and humidity (0-100% RH) at 4-second intervals. For the initial analysis, data related to mobility/activity status were extracted from the head-to-toe assessment forms.

A comparative statistical analysis was conducted between the two datasets. To establish of interface pressure data, classifications of sensor data by three independent raters were compared to patient position(s) recorded by nurses. Sensor-generated humidity and temperature data corresponding to each bladder incontinence-related moisture comment were input independently into a smart surface platform model. The model had been previously trained on a small set of bladder incontinence sensor data to classify whether the data at a particular timestamp represents an incontinence event or non-incontinence event.

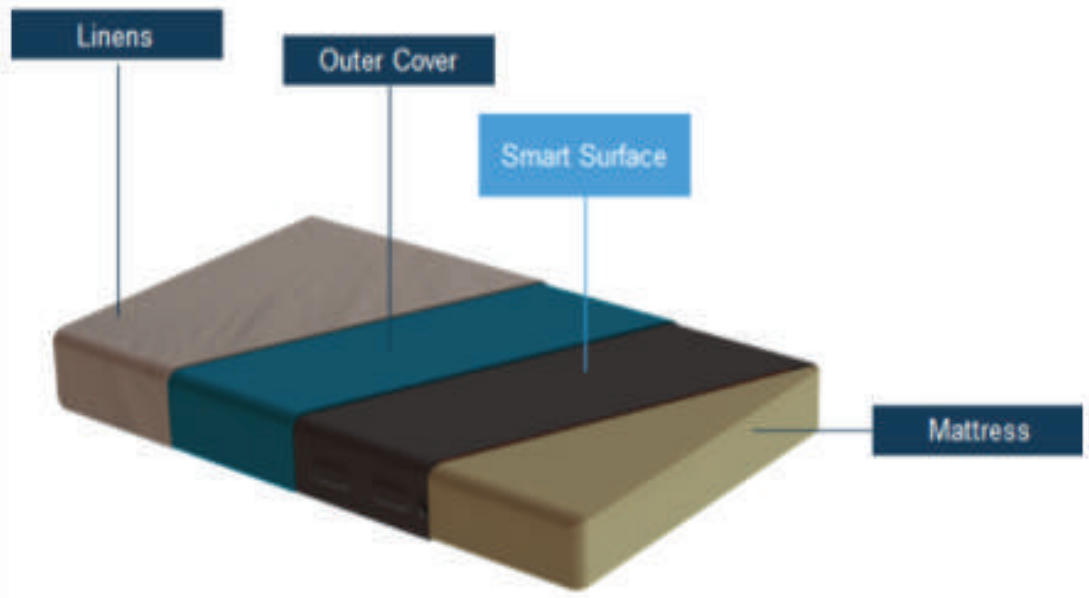
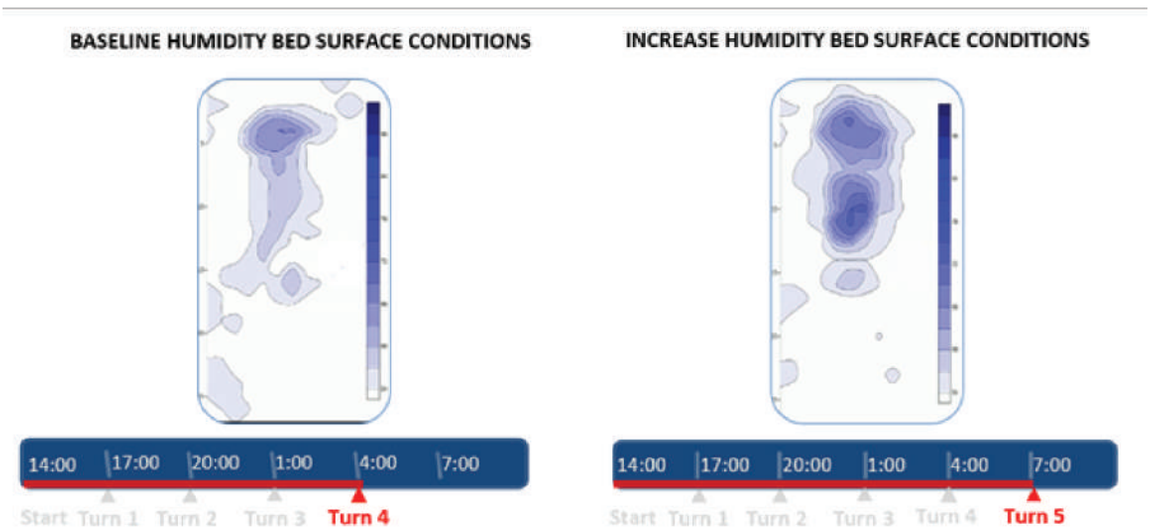


Figure 1 *A cross-sectional view of PI-Connect installed over a mattress. PI-Connect comprises an array of sensors embedded in a thin, flexible surface placed underneath the bedsheet. It is not in direct contact with the patient*

The high levels of accuracy by PI-Connect is demonstrated in detecting patient repositioning compared to observations made by nurses. This demonstrates the feasibility and potential for an intelligent system to continuously monitor patients' position changes. Detecting and recording the patient's position may help caregivers intervene more efficiently and reduce the risk of developing HAPIs. In a similar way, the potential value for using the sensor to continuously monitor moisture associated with incontinence, has the potential to mitigate risk for moisture associated skin damage. Continuous monitoring of moisture associated with incontinence by the sensor can trigger an alert to need for intervention, shown in Figure 2.

Figure 2 *Shows a timeline of each turn event with respect to nursing assessments around bladder incontinence status. A screen shot of PI-Connect sensor data from the bed surface humidity conditions (left), when the patient had no exposure to bladder incontinence, and an increase in humidity (right) after exposure to bladder incontinence are visualized. Screens shots of the gradient of average surface relative humidity levels from the bed surface are visualized from least (light blue) to greatest (dark blue) via percentage. PI-Connect data screen shots were taken at exact time points of the nursing assessments*

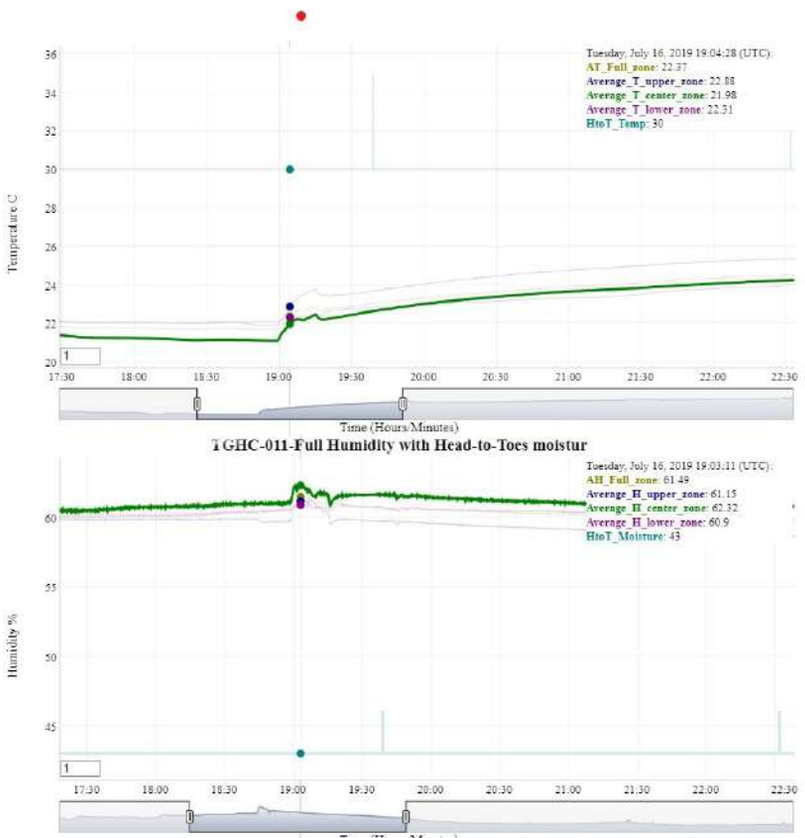


The sensors can be used to assist nursing with incontinence management by accurately detecting just-in-time increase in skin moisture thereby reducing unnecessary nurses' time spent checking a patient's incontinence status at the bedside and reduce the risk of developing pressure injuries.

Decreasing exposure time (the duration from the bladder incontinence moisture event to when a brief or wicking product is replaced) is an important aspect of incontinence-associated dermatitis and pressure injury prevention. Average surface moisture and temperature values over the period shown in Figure 3 were impacted by the presence of bladder incontinence.

Figure 3 *The two graphs below show PI-Connect sensor data for average surface temperature oC (top) and average surface relative humidity (bottom) over a period of 18 hours. Average values for both surface temperature and surface relative humidity values were segmented based on the section of the bed surface.*

Average values were segmented into upper, centre, and lower bed regions. The centre of the bed surface was highlighted given the analysis was targeted for bladder incontinence events.



Monitoring and redistributing interface pressure from segments of the body where high levels are suspected are fundamental to pressure injury prevention protocols. However, accurately measuring how much pressure is being exerted in a particular area (positioning) and how long a patient remains in one position (mobility) can be difficult, particularly in patients with limited sensation or communication skills. Visual inspection is challenging as it is not possible to observe an at risk area while a patient is lying on it. Additionally, visual observation is not a reliable measure of changes taking place under the skin. By the time a patient has been moved, tissue damage may already have occurred. Peterson et al. (2010) suggest that standard turning, even by experienced nurses, may not adequately unload all areas of high skin-bed interface pressure.15 Further confounding this issue, frequent turning has been linked to detrimental physical and psychological impacts for patients and increased risk of musculoskeletal injury for care providers. Evidence shows that HAPIs impact patient outcomes, length of stay, and hospital costs.

Envisioning a Future

Jake Tran, President & CEO of Toronto Grace Health Centre (TGHC), discusses the hospital's partnership with Curiato and the difference it has made with regards to the level of care provided at the hospital.

"As a health system, we need to be proactive in preventing skin injuries. Modern technologies allow us to be innovative in preventing skin injuries and better quality of life especially in our growing aging population. The smart bed itself allows staff to be able to make changes to patient positioning or changes as a result of pressure, moisture or temperature as they need to. And this is important because the current standard is to turn the patient every two to four hours. The technology allows staff to be able to turn the patients when they need to. Through our partnership with Curiato, we have an opportunity to create a centre of excellence. We started with little [wound care] knowledge and today our staff are engaged in education for wound care and preventive measures. And it means from a systems perspective, the interaction between Curiato and us allows us to discharge our patients faster and drive a better quality of life for our patients."

Work by the team at TGHC and Curiato shows statistically significant accuracy levels when comparing sensor-generated data of patient mobility to nurses' intermittent physical assessments. While manual repositioning and head-to-toe skin assessment remains the gold standard it is time consuming. This has important implications as manual repositioning and visual inspection of skin require resources, especially time, that may be limited due to high patient acuity and competing demands. Technology can assist the health care practitioner from learning whether and when a patient has effectively repositioned (self-turn). Simultaneous measure of interface pressure, humidity, and temperature in real-time is new. Technology can save caregiver time by streamlining communication and prioritizing resource allocation.

PI-Connect's capability to continuously and accurately monitor patient mobility and moisture offers the potential to decrease unnecessary interventions, inform targeted management strategies and improve the allocation of limited nursing resources. Machine learning & artificial intelligence allow us to process health data to provide a

Patient Case History

In September of 2018, Michael was admitted to St. Michael's Hospital (SMH) suffering from atrial fibrillation. After an examination, the health care team at SMH also diagnosed Michael with cellulitis (serious bacterial skin infection) in the lower part of his right leg. This condition was complicated by septic shock. The treatment of all of these conditions necessitated a prolonged stay in the ICU for Michael. The health care team in the ICU stabilized Michael's infection. Soon afterward, he began to receive limited physiotherapy (bed exercises) since at the time he had almost no ability to move his legs. He required the assistance of the nurses to help with his activities of daily living and the use of a lift to transfer to a wheelchair. At 500 pounds, pressure injuries had developed that made transfers especially painful. Michael was transferred to The Salvation Army Toronto Grace Health Centre since its complex continuing care program had an excellent wound care program and a post-acute care rehabilitation program, designed to help bariatric patients lose weight. The TGHC interprofessional health care team determined that he had three pressure injuries located at the sacrum, right hip, and right heel. Michael started his rehabilitation which included dietary management. After about a month of rehabilitation, he could transition with assistance from his bed to his wheelchair. Michael participated in the study described here evaluating PI-Connect. By early November 2019 Michael's pressure injuries were completely healed. He regained most of his independence and was using a rollator walker to remain mobile. Michael was discharged a month later weighing 260 pounds. TGHC congratulated Michael for remaining focused and attaining his goals0

'Michael, A Successful Rehab Journey' by Gerry Condotta, June 25, 2021 http://www.torontograce.org/patient-stories/michael-a-successful-rehab-journey. Reproduced with permission from The Salvation Army Toronto Grace Health Centre.

Community of Practice

Curiato is facilitating a Community of Practice on Innovations in Pressure Injuries. Among the sessions so far have included discussions centred around the following topics.

- Frank Aviles shared his experience on how the interprofessional team can harness technology to impact pressure injury.
- Virginia Capasso, PhD, guided the group through the research at Massachu setts General Hospital on Pressure Injury Development, Mitigation, and Outcomes in Patients Manually Proned for ARDS due to COVID-.19
- Kim LeBlanc, PhD, and Kevin Woo, PhD, guided the group through the aspi rations for the new Canadian Pressure Injury Advisory Panel (CPIAP).
- Laura Teague guided the group through the subject of her PhD thesis, Surgical repair of pelvic pressure injuries in persons with spinal cord injury: cost, case identification, health care utilization and risk factors for complications.
- Corey Heerschap guided the group through exploring technology and wound healing to set the scene for future discussions.

"CABHI is proud to have supported Curiato through our Industry Innovation Partnership Program, which helps fund validations studies such as this one at Toronto Grace Health Centre, analyzing how AI-based sensor devices aid injury prevention and reduction," says Mel Barsky, Director, Business Development, Centre for Aging, Brain Health Innovation (CABHI). "We look forward to continuing our work with Curiato as they scale and grow through, in part, their participation this year in our Mentorship, Capital, and Continuation accelerator program with Berkeley SkyDeck."

The most recent study collected data for 96 hours. During the first 48 hours, the system recorded in the background and in the second 48 hours, the dashboard was visible to the care staff with the same patient. "The two-week study at TGHC proved a tremendous learning experience for everyone involved in behavioural science on how to operationalize a system in a health care setting during COVID," commented co-founder Matthew Sefati. "It allowed us to witness how nurses responded to the dashboard and how it could impact interprofessional practice."

Keywords: pressure injury, incontinence-associated dermatitis, wound microclimate, sensor technology, artificial intelligence, machine learning, pressure injury, posture detection, repositioning, sensor technology, artificial intelligence, machine learning.

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