

A Wearable Device to Inform Pressure Injury Prevention Support Surfaces Selection and Design

by

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Abstract

Pressure injuries are a preventable but persistent medical challenge, with 2.5 million Americans developing pressure injuries each year. Pressure injuries are uniquely challenging to manage for wheelchair users, who have to sit for extended periods of time, up to 10-12 hours per day. Measuring the interface pressure between support surfaces and the body can assist in selecting surfaces that minimize the pressure to prevent pressure injuries from developing. However, pressure mapping systems are expensive and inaccessible for personal use outside of rehabilitation centers and hospitals. A prototype was developed to measure the interface pressure and movements of the user, using force sensing resistors and accelerometer data. Through this system, the interface pressure across surfaces can be compared to select appropriate sitting surfaces, inform repositioning habits, and prevent pressure injury development.

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1 Background

1.1 What is a pressure injury?

Pressure injuries (PIs), more commonly known as bedsores or pressure sores, are localized damage to the skin and underlying tissue that occur as a result of intense or prolonged pressure [1]. Pressure injuries are a widespread occurrence; 2.5 million people in the United States develop pressure injuries each year, and 60,000 die as a result [2]. Pressure injuries increase morbidity and mortality rates, introduce financial burdens and increase the length of hospital stays.

Pressure injuries carry a significant financial burden on the healthcare system. Pressure injuries cost about \$10,708 per patient on average, with a total cost in the US of \$26.8 billion annually [3].

Pressure injuries are most common in areas of the skin that are under pressure for extended periods of time from lying in bed, sitting in a wheelchair, or due to contact between the skin and medical devices [4].

There are a number of risk factors affecting the likelihood and severity of pressure injuries, including mobility, moisture or incontinence, level of consciousness, nutrition, and activity [5]. Pressure injuries decrease the quality of life of the patient, causing severe pain and limiting treatment options for other conditions [6].

Pressure injuries are evaluated by the degree of skin and tissue damage observed. There are four stages that range in severity from stage 1 to stage 4. For patients with Spinal Cord Injury (SCI), 25% of pressure ulcers are classified as severe (stage III or IV) [7]. The stages are outlined below [4, 8, 9].

Stage I: The area may be red and warm to the touch, or have a blue or purple tint. It may burn, hurt, or itch.

Stage II: The area looks more damaged and may have an open sore, scrape or blister. It may cause significant pain and the skin around the wound may be discolored.

Stage III: The area has a crater-like appearance due to damage below the skin's surface.

Stage IV: The area is very damaged with a large wound present. Muscle, tendons, bones, and joints may be seen. Infection is a significant risk.

Some wounds may also be classified as unstageable or as a deep tissue wound.

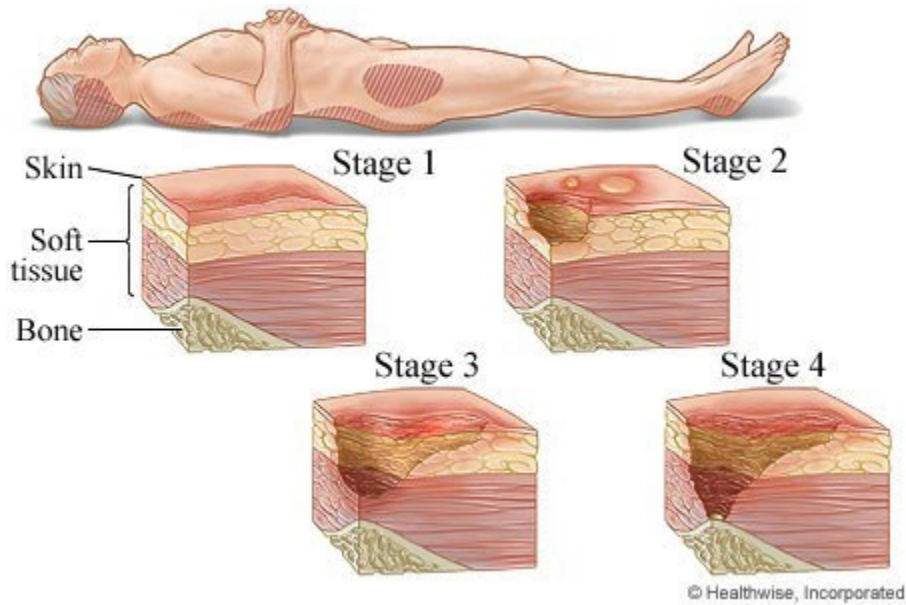


Fig. 1: The Four Stages of Pressure Injuries [1]

1.2 What causes pressure injuries?

Pressure injuries are a result of pressure in combination with shear forces, though the development is accelerated by a number of external factors. These can include microclimate, perfusion, age, health status, comorbidities, and conditions of the soft tissues [9]. Impaired mobility is also a primary contributing factor to the development of pressure injuries.

The risk factors for pressure injury development fall into two categories: mechanical boundary conditions and tolerance of individual [11]. The mechanical boundary conditions include the magnitude, time duration, and mode of action of the forces that are applied to the soft tissues as a result of contact between the skin and a solid surface. The forces can either be perpendicular to the skin (normal force), or parallel (shear force), though most of the time it is a combination of these forces. The normal force causes a pressure on the skin, which is the normal force per unit surface area. Pressure injuries develop when the blood flow to the tissues is restricted due to the pressure in the area. The tolerance of the individual is how an individual's anatomical structure is affected by the loads and pressures applied. This depends on the internal anatomy, tissue morphology, and mechanical properties of the tissues, dictating how a given level of pressure impacts the surrounding area.

The historical threshold function for safe pressure and time duration was developed by Reswick and Rogers, and demonstrates the pressure applied to the skin and duration of applied pressure [12]. However, it is inaccurate since it does not reflect the risk of tissue damage at the extremes, and a more accurate model, labeled the Gefen curve below, was developed based on animal and tissue models [13].

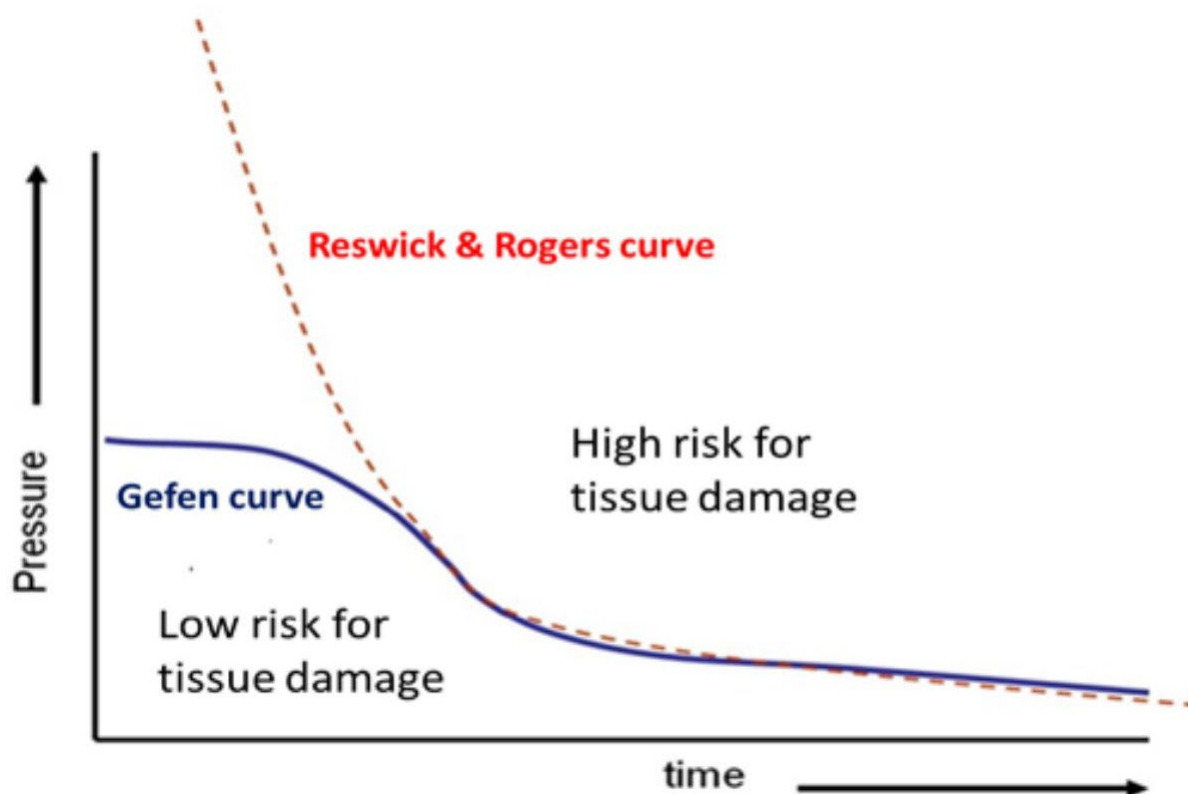


Fig. 3: The historical Reswick & Rogers curve, demonstrating the relationship between pressure and time for risk of tissue damage, as well as a newer Gefen curve developed based on animal and tissue engineered models. [9]

There are no numerical values in the graph above because it is very difficult to determine quantitative values for the pressure that will result in tissue damage. This is largely due to differences in tissue tolerances, individual anatomies and other confounding factors [13]. These include the microclimate between the skin and surface, including temperature, humidity, and airflow next to the skin surface. These factors can compromise the skin integrity and predispose tissue to pressure injury [14].

1.3 Pressure injuries in wheelchair users

3.3 million Americans use wheelchairs, primarily due to mobility disability [15]. Up to half of wheelchair users will develop a pressure injury at some point in their lifetime, with pressure injuries being one of the most common complications in disabled individuals after a SCI [16].

Wheelchair users typically spend 10-12 hours per day in a chair with limited movement, and the seated position produces larger stress than laying due to the same weight being applied over a smaller area [17]. The most common areas for pressure injury in wheelchair users are the ischial tuberosities, coccyx, and sacrum.

It is recommended that people perform pressure relief for 15 to 60 seconds every 15 to 60 minutes [18]. In interviews with staff from Spaulding Rehabilitation Hospital, it was shared that

they recommend paraplegic patients to perform pressure relief for 30 to 60 seconds every 15 minutes. For tetraplegic patients, they recommend doing a full seated tilt for 5 minutes every 15 minutes.

Immobility and lack of activity increase the risk of pressure injury in seated individuals, and the soft tissue has worse ability to tolerate pressure. Nursing home residents with higher peak interface pressures during wheelchair seating were more likely to develop pressure injuries than healthy adults [19]. Poor configuration and poor posture can increase pressure over bony prominences and is more common in nursing homes with inadequate wheelchair services.

1.4 Pressure Injury Prevention

There are numerous strategies aimed at preventing the onset and progression of pressure injuries. The aim of prevention strategies is to either reduce the magnitude or duration of the interface pressure, or the pressure between the patient and the surface.

1.4.1 Nursing Strategies

Nursing interventions for pressure injury prevention include repositioning patients and risk assessment scales.

Lying or sitting for extended periods without redistributing pressure can result in tissue damage, creating a dire need for the repositioning of patients [20]. The standard of care is for nurses and caregivers to reposition patients lying in bed every two hours, though it is recommended to determine a turning schedule based on the risk of the patient [21]. Some studies have found that turning does not always effectively relieve pressure.

Over 50 risk assessment tools have been developed to predict how likely a patient is to develop a pressure injury. The most common of these is the Braden scale, but others include the Norton, Waterlow, and Cubbin and Jackson scales. The Braden scale is most common due because it is easiest to use while also incorporates a wider range of risk factors [9]. Each of these scales relies on a series of measurements made by healthcare staff, such as activity, age, nutrition, and incontinence. Evidence indicates that the Braden scale has moderate predictive validity, which means that further tools should be developed that are easy to use but have high predictive validity to accurately assess pressure injury risk factors [22]. These risk assessment tools are used to determine the repositioning frequency as well as determine what mattress or cushions should be used for the patient.

1.4.2 Sensor Based Prevention Systems

Sensing systems have been developed to collect and display data that may be beneficial to healthcare staff. These sensors can include pressure monitoring, temperature and humidity monitoring, inertial measurement units (IMUs), and cameras [22].

Pressure monitoring is the most common and most extensively studied sensing-based prevention technique [23]. Continuous bedside pressure mapping (CBPM) uses a pressure map where the matrix of pressure sensors is placed on top of a mattress. The pressure value of each location is then displayed. Wellsense, Tekscan, Vista-medical, Xsensor, Novel Electronics, and Sensor Products all have pressure mapping systems that can be used for CBPM [22]. The largest proven

benefit of CBPM is that healthcare staff can more effectively reposition patients to reduce peak pressure [24]. This was shown to lead to a lower incidence of PIs, demonstrating the effectiveness of pressure sensing systems at giving real time feedback to healthcare staff.

Another promising sensing system includes the use of IMU data to detect the posture of a patient in bed. The IMU data can be tracked over time and shown to the patient or nurse to encourage movement or repositioning. One system that is currently available on the market is the LEAF Patient Monitoring system, a wearable patient sensor that can give digital turn reminders to the patient and nurse. It has been shown to improve protocol adherence rates and reduce pressure injury incidence [25].

The effectiveness of these sensor-based systems shows promise that by collecting and presenting data to both patients and healthcare staff, better healthcare decisions can be made that lead to a reduction in pressure injury prevalence.

1.4.3 Support Surfaces

The National Pressure Injury Advisory Panel (NPIAP) defines support surfaces as “specialized devices for pressure redistribution designed for management of tissue loads, microclimate, and/or other therapeutic functions” [9]. Support surfaces can include mattresses, overlays, cushions, and other surfaces that aim to relieve pressure. The aim of these surfaces is to reduce either the magnitude or duration of the pressure between the patient and support surface [26].

One type of support surfaces is constant low-pressure (CLP) devices, which aim to distribute weight over a larger contact area. Another type is alternating pressure (AP) devices that vary the pressure beneath the patient mechanically. “Low-tech” CLP support surfaces include foam, gel-filled, fiber-filled, air-filled, and water-filled mattresses or cushions. “High-tech” support surfaces include alternating pressure mattresses, where the patient lies on air-filled sacs that inflate and deflate to relieve pressure at different places for short periods of time. Higher specification foam mattresses are recommended for higher risk patients. The relative benefits of CLP and AP support surfaces are unclear.

1.4.4 Cushions

Wheelchair cushions act as support surfaces to prevent pressure injuries by redistributing pressure and off-loading injury-prone bony prominences. There are four main types of static cushions – air, foam, and gel, or a combination of any of the three [27]. A common PI prevention strategy is the prescription of an appropriate wheelchair cushion. The cushion needs to have specific properties that address different aspects of PI prevention and general user comfort, such as pressure responses, microclimate, and stability and support for the wheelchair user.

A commonly prescribed air cushion is the ROHO, typically sold for around \$420 [28]. The ROHO is a static cushion that has air cells made of neoprene. The cells are all connected, but air is released from the cushion so that it is molded to the user.



Fig 4: The ROHO Cushion, an air-filled cell-based cushion [29]

There are also a few dynamic cushions on the market, such as the Ease cushion [30]. The Ease cushion has a foam base with air cells that inflate and deflate. The Ease Cushion uses alternating pressure technology to redistribute pressure and prevent skin breakdown, increasing blood flow and reducing risk of developing pressure injuries. The Ease Cushion is sold for \$649. In a study researching the effectiveness of a dynamic air cushion, it was found that the inflation/deflation sequences can redistribute pressure of the sitting area and prevent the redistribution of blood supply to underlying tissues [27]. Some studies have indicated the air cushions are better at interface pressure reduction than gel cushions, and others have indicated that gel cushions are better at reducing interface pressure than foam cushions. However, individualized evaluation of interface pressure is suggested for prescription of wheelchair cushions [31].

1.4.5 Cushion Evaluation

Cushions are evaluated on several criteria: immersion, impact damping, hysteresis, horizontal stiffness, stability, pressure mapping, 10% force deflection, and envelopment [32]. Each of these has an associated International Organization for Standardization clause related to their measurement.

Immersion (ISO 16840-2:2018 Clause 11) is the ability for the body to sink into the cushion, resulting in better pressure distribution. Impact damping (ISO 16840-13:2021) is the ability to reduce the impact loading on tissues and help maintain postural support. Hysteresis (ISO 16840-2:2018 Clause 14) is the ability to provide support during loading and unloading. Horizontal

stiffness (ISO 16840-2:2018 Annex C) is the ability of the cushion to respond to slight horizontal movements in the forward direction. Stability (ISO 16840-13:2021) is the ability of the cushion to resist lateral leaning movements. Pressure mapping (ISO 16840-6:2015 Clause 14) measures the magnitude and distribution of pressure on a loaded cushion. 10% force deflection (ISO 16840-6:2015 Clause 20) is the ability to elastically deform to produce a 10% deflection. Envelopment (ISO 16840-12:2021) is the ability for the cushion to conform to the contours of the body, resulting in a better pressure distribution. Each of these are voluntary standards that can be used by cushion manufacturers to benchmark products, as well as by healthcare staff to compare and select cushions.

1.5 Interface Pressure

When sufficient levels of pressure are transmitted to the tissue, it can stop blood flow to the area and lead to tissue breakdown, the start of pressure injuries. The internal or interstitial pressure is defined as the resultant pressure that is transmitted to the tissue from the subject-surface interface, but the measurement of this is inherently invasive. For that reason, interface pressure is the widespread parameter used as it is more easily measured in a clinical environment [33].

Variability can be introduced by the setup of the sensor and experiment, including due to subject positioning, measuring system, curvature and compliance of the subject-support surface interface, shape of the underlying bony structure, and weight being supported[34]. The subject-support surface interface also varies vastly by the individual which effects interface pressure. Prior studies show that posture and body orientation have a profound effect on the subject-surface interface pressure [33]. For that reason, it is important to ensure the positioning of subjects is the same across surfaces to ensure repeatability.

High interface pressures are a major contributing factor in the development of pressure injuries, yet a safe interface pressure is extremely difficult to determine due to variations between individuals and the number of other factors that increase risk of pressure injury. The range of interface pressures varies widely based on anatomic sites and subjects' underlying anatomy but is approximately between 60-200 mmHg. There is no consensus on the safe interface pressure, but numerous studies have determined a safe interface pressure [33].

One study found that histologic changes occur when an interface pressure of 100 mmHg or higher is applied for more than 30 minutes, or when 40-80 mmHg is applied for an hour or more [35]. This study recommended reducing the interface pressure to 45 mmHg or less.

The most common parameters measured are maximum, minimum, and average pressures. It is recommended to wear stretchy clothing and standardize the clothing worn when evaluating across different products [33]. In a study that ranked products on different groups of subjects, including SCI and elderly groups, it was found that the ranking of products is significantly different for each group [36]. Pressure injury prevention clinics that measure interface pressure on a regular basis have been shown to be effective at helping participants prevent pressure injuries by determining correct cushions and postures for the patient [37].

2 Motivation

The current method of measuring the interface pressure for wheelchair cushions is typically done using a pressure mapping device, carried out at hospitals or rehabilitation centers. These are often not available to nursing homes or for individual homes, making it difficult to make informed, data-driven decisions on which cushion might be best for the user. The motivation behind this study was to develop a low-cost wearable with pressure sensing capabilities that could be used to make individualized, informed decisions for wheelchair cushion selection. Interface pressure measurements are extremely variable between individuals, so having an accurate, consistent device on hand can make it easier to choose a cushion with a better pressure distribution. Current pressure maps are too expensive and complex for personal use.

In addition to selecting an appropriate cushion, it is recommended to offload pressure with pressure relief adjustments while seated in a wheelchair. With frequent prescribed readjustments, it may be difficult or even impossible for seated individuals to adhere to the recommendation. Previous studies have shown that monitoring movement using IMU or accelerometer data could help understand how frequently a person is moving or adhering to the readjustment recommendations. The prototype will make it easier to track movements while sitting for prolonged periods of time to understand readjustment habits and develop better readjustment strategies.

3 Prototyping Process

3.1 Engineering Requirements

Several design considerations were brainstormed with a goal of developing a prototype to measure interface pressure and understanding the readjustment frequency of seated individuals.

- I. The device needs to have pressure sensing capabilities in appropriate areas that are most likely to have the highest threshold of pressure.
- II. The presence of the system should not introduce errors that would affect the interface pressure being measured.
- III. The geometry of the device should be flexible enough to conform to the surfaces and the body to accurately measure the interface pressure.
- IV. The system should be accurate across the range of expected pressure values.
- V. The sensor system should be cost-effective so that it can be used for individual use at home or nursing homes.

3.2 Prototype Brainstorm

Using the design considerations outlined above, three main designs were considered.

Force Sensing Resistor (FSR) System

For this concept, an array of FSRs would be placed or sewn into a fabric that could be worn by the user. Each FSR would be connected to an analog pin on a microcontroller to read in the voltage, which would be calibrated and adjusted to get a pressure reading.

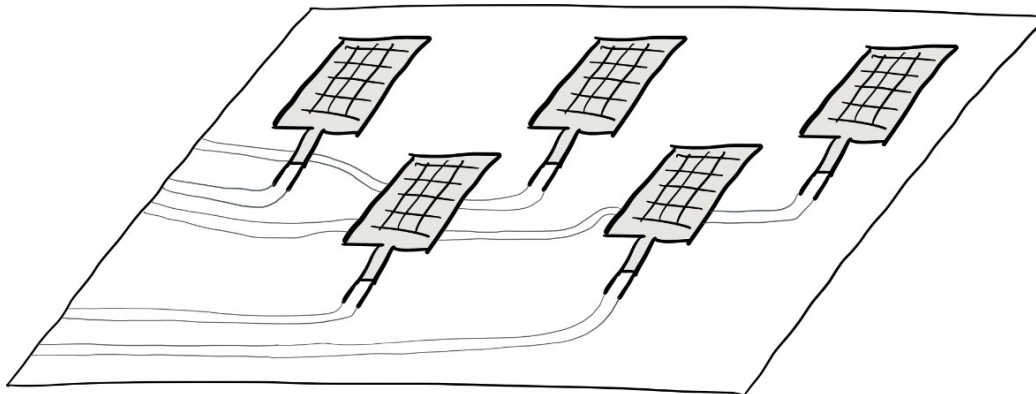


Fig. 5: A sketch depicting the FSR design considered for the prototype, with sensors sewn into a piece of fabric, and connected to the microcontroller.

Air Pocket Pressure Sensor

Another prototype idea was to place multiple tubes or pockets that would be filled with air on the surface of the fabric. Each of these pockets would be connected to an air pressure sensor that would show the interface pressure in each pocket.

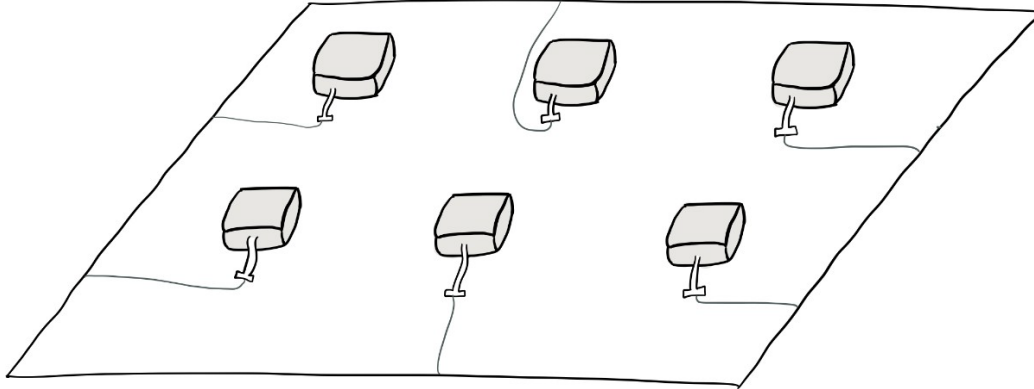


Fig. 6: A sketch depicting the air pocket design considered, showing the pockets of air that would be placed underneath the user and the connection to the air pressure sensor.

Pressure-Sensitive Conductive Plastic (Velostat/Liquistat)

Using a pressure-sensitive conductive plastic, conductive thread, and conductive fabric tape, the resistance of the plastic can be measured at each output location. This would then be sewn into a fabric that would be worn by the user to measure the interface pressure between the person and the surface they are seated on.

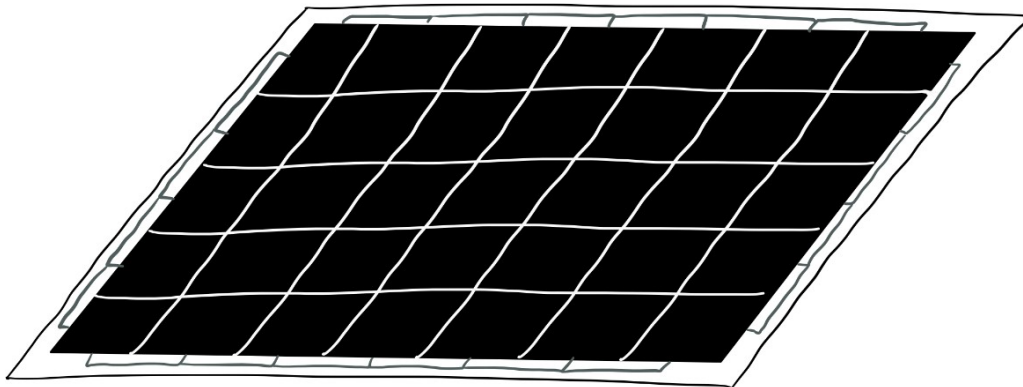


Fig. 7: A sketch depicting the pressure-sensitive conductive plastic design considered, with the lines indicating the conductive thread and tape that run across the conductive plastic fabric.

When deciding between the different brainstormed options, the design requirements were considered. A Pugh chart was developed with the following characteristics: accurate, low-cost, reliable, does not interfere with pressure reading, and conforms to existing geometry.

Features	FSR System	Air Pockets	Pressure Sensitive Plastic
Accurate	0	0	0
Low cost	0	0	+
Reliable	0	0	-
No interference with pressure reading	0	-	0
Conforms to existing geometry	0	0	-
Total	0	-1	-1

Table 1: Pugh chart comparing the three sensing systems considered.

Based on the Pugh chart and considering the different characteristics of each option, the FSR system was chosen. FSRs ave an ideal interface due to their minimal thickness and flexible construction. They have lower accuracy than other types of force sensors, but can be more suitable due to their small size, small thickness, low cost, and easy integration with textiles [38]. FSRs are useful for medical applications due to their thin and flexible construction [39].

In addition to pressure sensing, the system should also incorporate an accelerometer sensor. Prior research has demonstrated that access to accelerometer data about movement of the user can improve adherence to prescribed pressure relief adjustments, ultimately leading to a reduction in pressure injury onset [25]. For this reason, the prototype should contain an accelerometer to monitor movement and adjustments to seated position.

3.3 Prototype Design

3.3.1 Sensors

The device is constructed using 12 Interlink FSR UX 406 sensors. These sensors were chosen for their wide range of pressure sensing capabilities (0.5N to 150N), thin profile, and their use in other medical applications [38, 39].

The placement of the sensors was determined by prior pressure maps developed for seated individuals. A typical pressure map is shown below, as well as a secondary pressure map with the decided locations of the sensors for the purpose of this prototype.

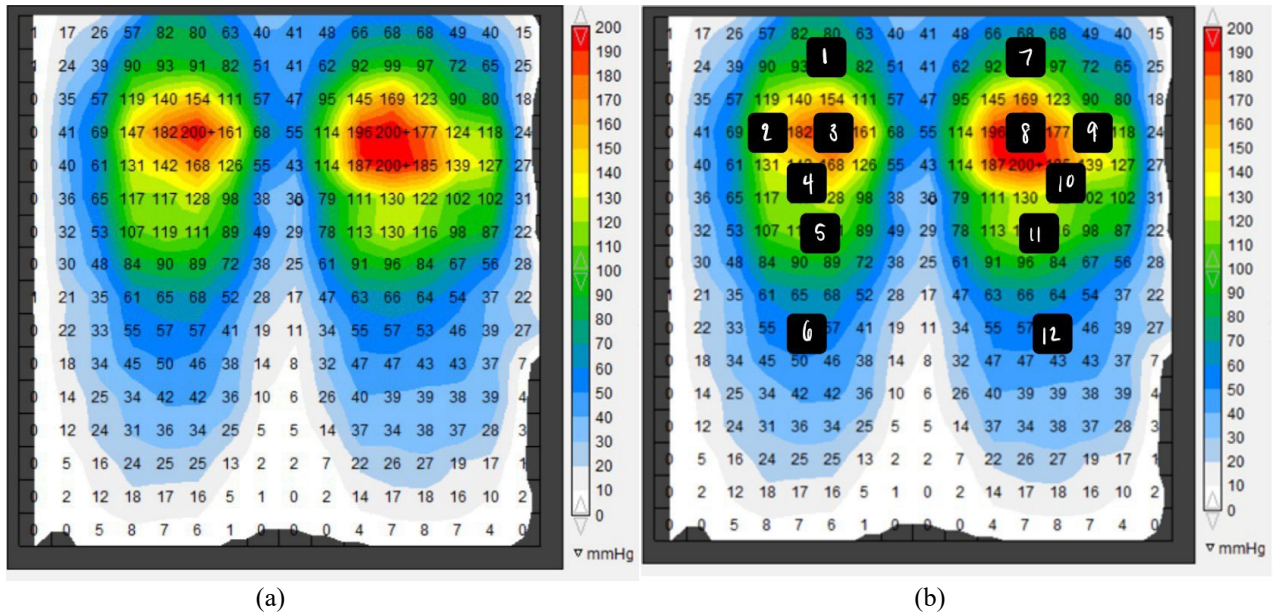


Fig. 8: (a) Demonstrates a typical pressure mapping of a seated surface, (b) demonstrates the overlay of sensors that is proposed for this prototype [40]

It is recommended to wear stretchy clothing that conforms to the shape of the body while measuring interface pressure. Because of this, the fabric for the wearable was decided to be 92% Polyester and 8% Spandex for a conforming but stretchy fit.

3.3.2 Electronics

Each of the sensors connects to a pin on a 16-Channel Digital Multiplexer CD74HC4067. The multiplexer is connected to an analog pin on the Arduino Uno, as well as four digital pins. The MPU-6050 3 Axis accelerometer sensor is also connected to the Arduino Uno through the SDA, SLA, and digital pins.

The wiring diagram is provided below.

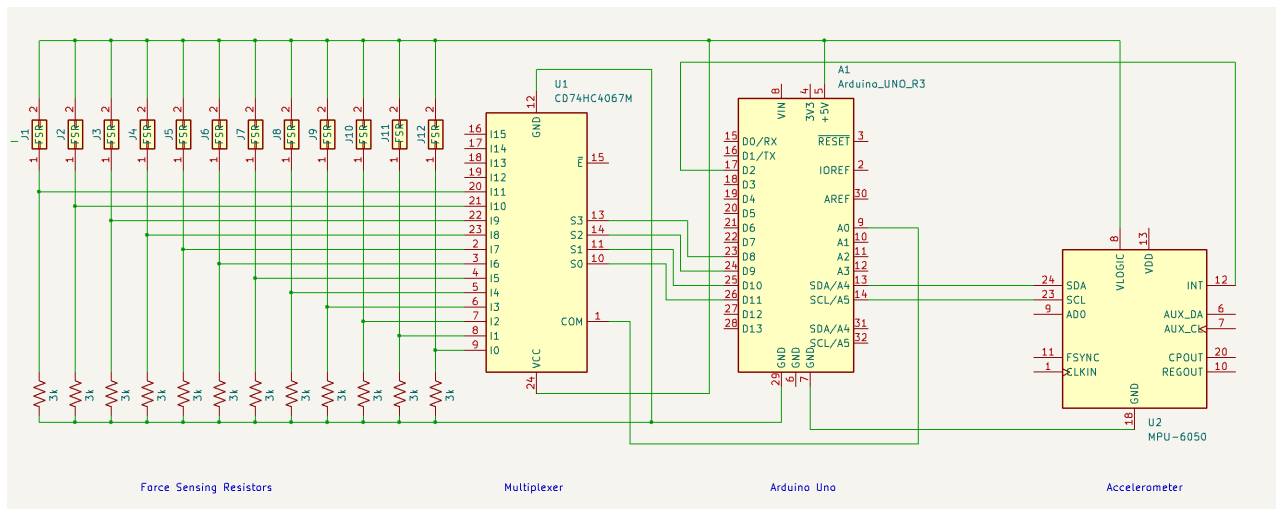


Fig. 9: Wiring diagram demonstrating the connections between the components of the prototype

The sensor data is acquired through the MATLAB Arduino Hardware Library, after which it was processed and plotted. Using the Arduino Hardware Library in MATLAB significantly slowed the sample rate to around 100 Hz, but there were benefits to the ease of live data plotting and visualization. Using serial monitor data directly, and collecting and plotting it in MATLAB resulted in a much quicker sampling rate, closer to 1 kHz.

3.3.3 Final Prototype

The final prototype consists of a pair of shorts with 12 Interlink FSR sensors sewn into it at the designated locations as shown previously, with an accelerometer sewn into the waistband. The wiring was also soldered to a protoboard for greater robustness during testing. An image of the final prototype is shown below.



Fig. 10: An image of the prototype, demonstrating the 12 FSR resistor sensor layout as well as the electronics layout.

3.4 Calibration

The reliable use of FSRs depends on proper calibration. A study was conducted calibrating an Interlink Electronics 402 FSR, which was the basis of the calibration procedure for this experiment. In a static calibration test, weights were placed on the sensor to find the relationship between the applied force, and as a result the applied pressure, and the output voltage. Each sensor was calibrated individually using this method.

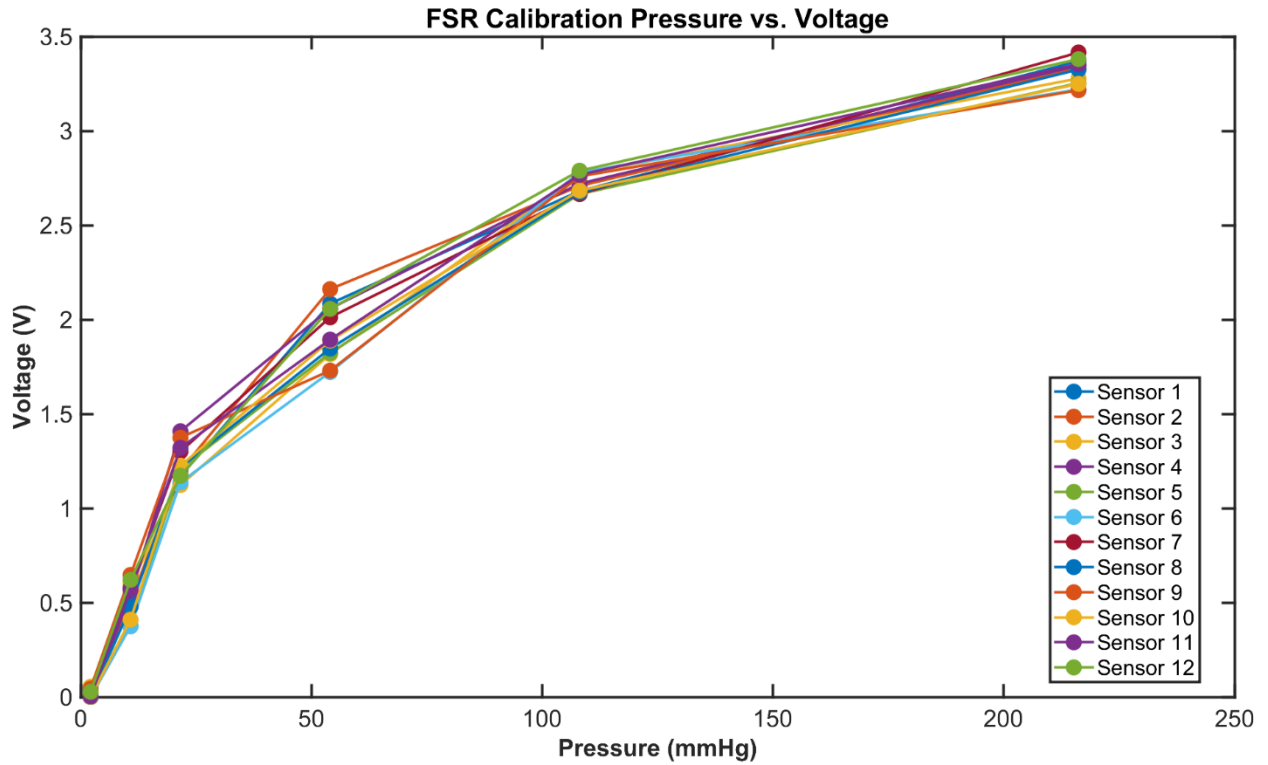


Fig. 11: A plot of the FSR pressure inputs and the voltage outputs during the calibration for each of the 12 sensors.

A line of best fit was found for each sensor, such that the voltage could be inputted and the pressure outputted, as in the experimental setup. The results are shown below in separate plots for each of the sensors.

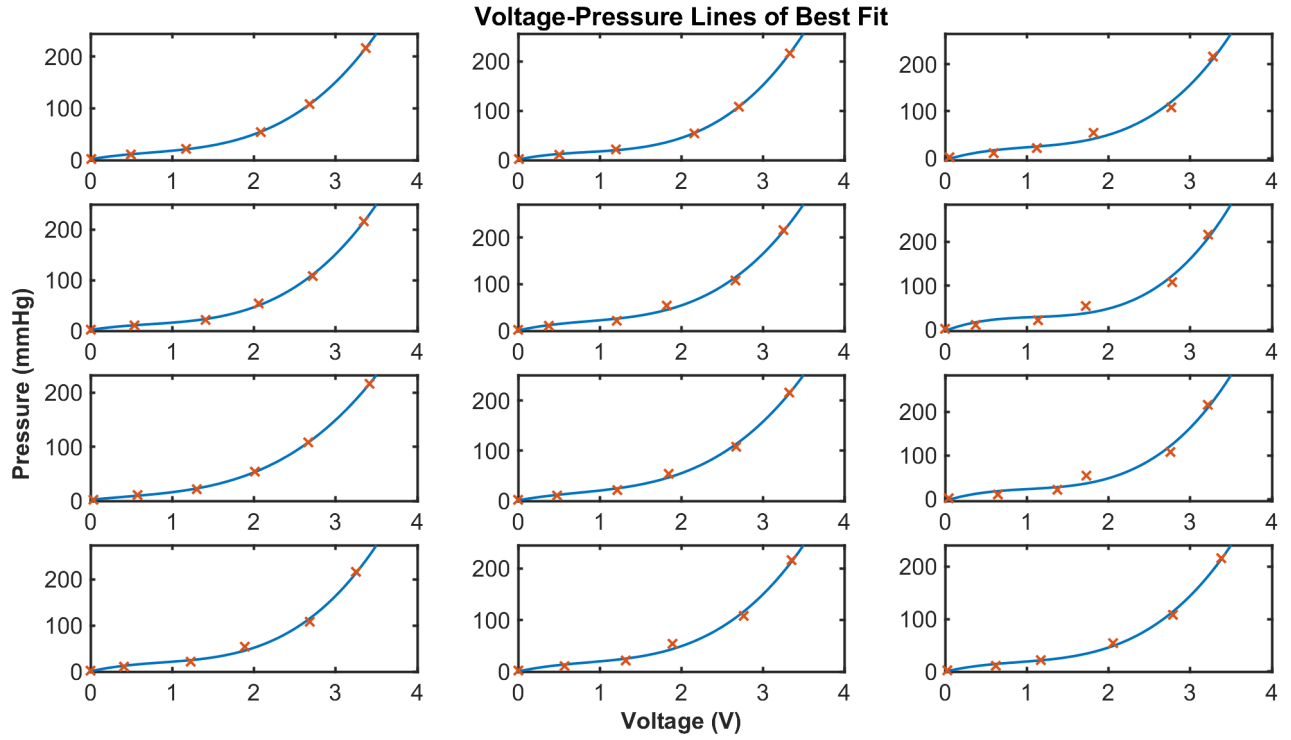


Fig. 12: Plots of each of the voltage-pressure curves and lines of best fit for each of the FSR sensors.

Using these curves, the pressure was calculated from the voltage reading of each of the sensors while testing the prototype.

4 Testing

The device was tested while worn on four surfaces – a wooden chair, a plastic chair, a ROHO cushion, and a foam cushion. The results are shown in a color map below.

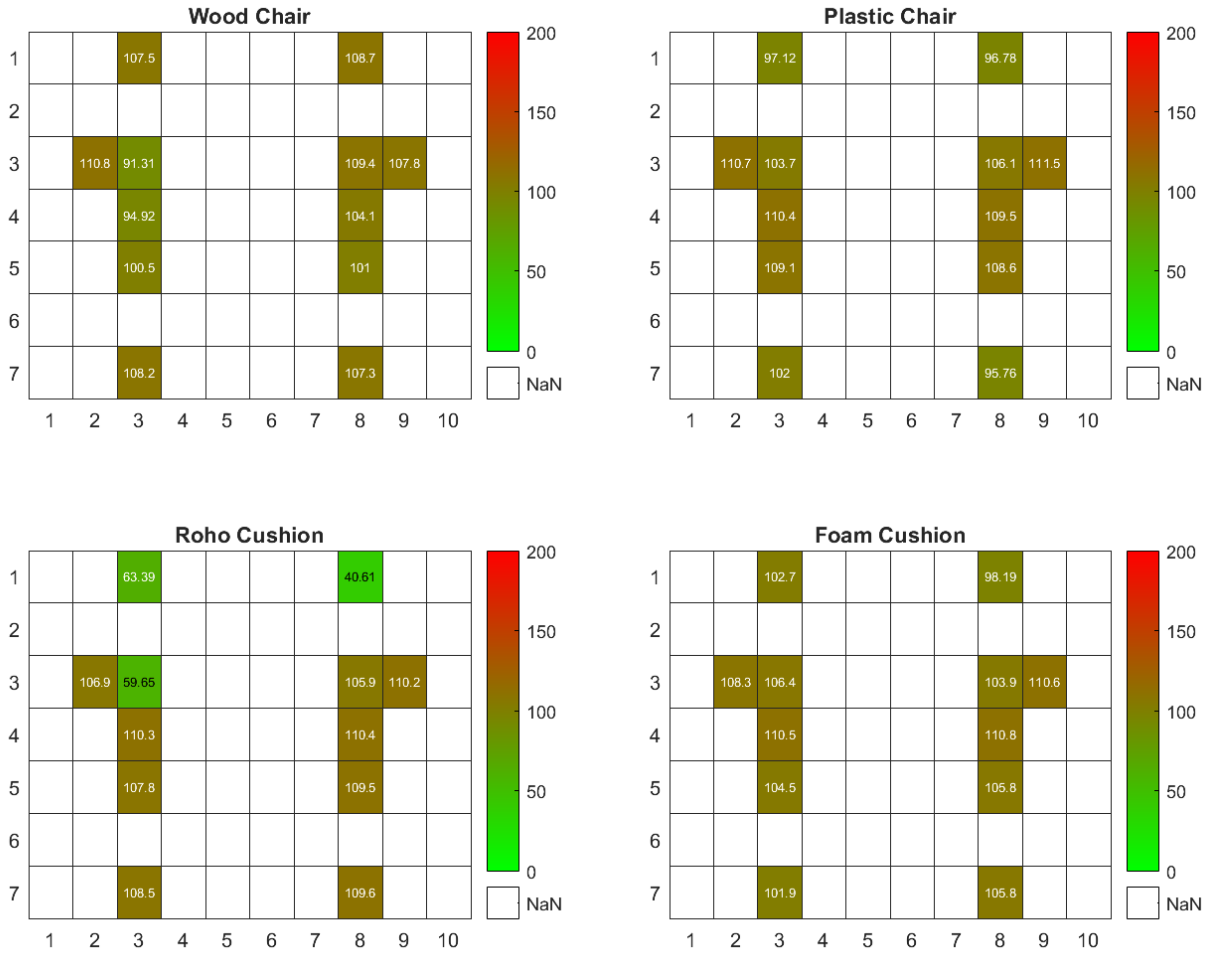


Fig. 13: Results of the pressure readings on each of the four surfaces tested, a wooden chair, plastic chair, ROHO cushion, and foam cushion.

The results are in the expected range of values as shown in previous studies, with the sensing outputs relatively consistent between trials.

In addition to plotting the values, the minimum, maximum, and average pressure for each surface were extracted and are shown below.

Surface	Minimum Pressure (mmHg)	Maximum Pressure (mmHg)	Average Pressure (mmHg)
Wooden chair	91.3	110.8	104.3
Plastic chair	89.2	111.5	103.2
ROHO cushion	40.6	110.4	95.7
Foam cushion	89.5	110.8	103.6

Table 2: Minimum, maximum, and average pressure (mmHg) shown for each surface tested.

The ROHO cushion had the lowest minimum pressure and the lowest average pressure. The results were relatively similar across all four surfaces.

Additionally, data from the accelerometer sensor was collected and processed. The data is shown in its raw form below over a period of 60 seconds with two movements.

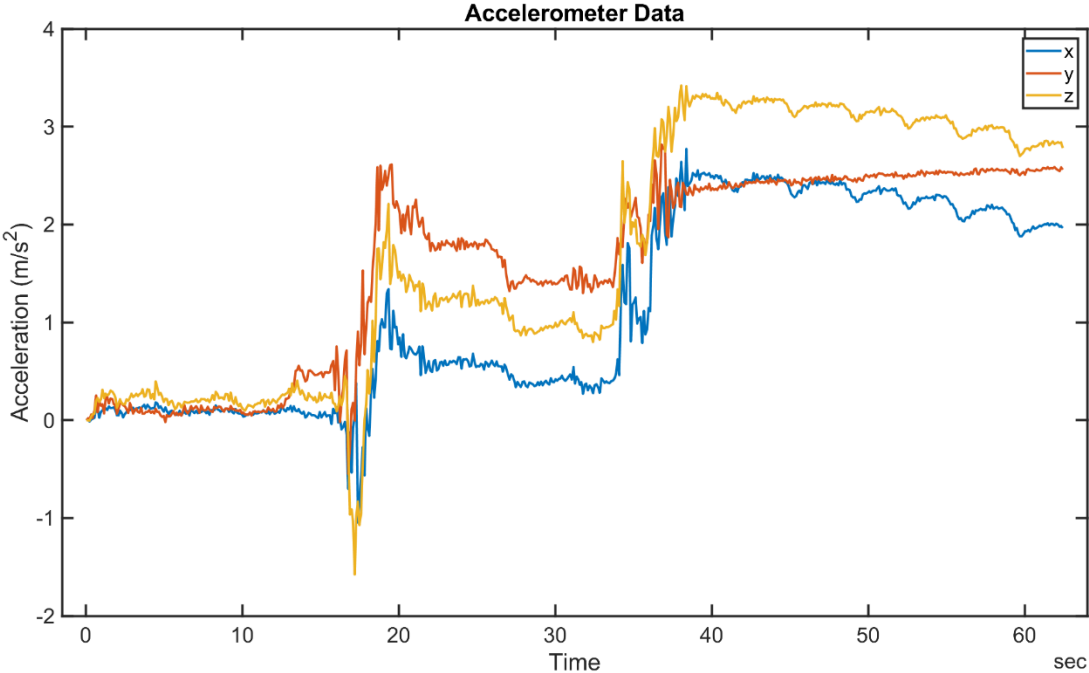


Fig. 14: Accelerometer data shown over a period of 60 seconds, with two adjustments recorded, as shown by the spikes in the accelerations.

The accelerometer data could be used to measure the number of movements or adjustments made over a given period of time, and an algorithm can be developed to automate this process by looking at the change in values a given time, with a threshold of change over a period of time signaling a movement. Moving average filters may also be helpful at smoothing out inconsistencies in the accelerometer data to filter the movements.

5 Conclusions and Future Work

This study demonstrated the prototype development of a pressure sensing wearable system as a method of pressure injury prevention. The prototype was successful, reading pressure values that were similar to values found in literature from other pressure mapping systems. This system was much less expensive than a pressure mapping system, on the order of \$100 compared to \$1,000-10,000 for a robust pressure mapping system used in rehabilitation hospital settings. The system was also able to conform to the shape of the wearer.

The system was created as a wearable in an attempt to eliminate inconsistencies such as posture changes or shifts, but there was still variation due to these factors. Future iterations should explore how to better control variations in posture and shifts in weight. It may also be easier to develop this system as a flat pressure mat that can be placed underneath the person if those inconsistencies can be eliminated.

There needs to be further work to determine the accuracy of the pressure sensing system. It would be useful to validate the readings and further calibrate using a pressure mapping system and compare the readings between the two devices. In future studies, it may also be useful to try different pressure sensors of different shapes, sizes, and types, to compare the accuracy and ease of use against one another.

Future work should explore various methods of making the system more robust. Using a form of wireless communication, such as Bluetooth or WiFi, would make it easier to wear the system and move around with it on. Finding new ways to present the live data, such as over an software app, would make it easier to see the readings in real time to adjust posture or relieve pressure.

Similar devices could be developed for other areas of the body for pressure injury prevention on mattresses, such as the heels or shoulder blades, which are both areas prone to pressure injuries. It would also be helpful for the sensors to be built into the support surfaces themselves.

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