PULCE Pad: Pressure Ulcer Detection System

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Executive Summary

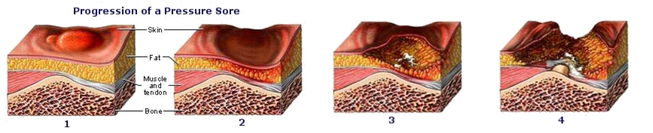
Pressure ulcers, more commonly known as bedsores, develop due to local pressures that are in excess of what the localized region can withstand. Blood vessels are obstructed, and thus the area is not provided with sufficient nutrients and begins to deteriorate. Hospital conditions in the US are such that an estimated 2.5 million cases of pressure ulcers are reported each year with a projected total additional cost of $8.5 billion in hospital bills [1]. Typical preventative measures for pressure ulcers include using a qualitative scale to evaluate patient risk for pressure ulcers and the occasional repositioning of patients by caregivers, but the large time demands on caregivers prevent this from being an effective method of detection.

PULCE uses temperature and pressure changes associated with pressure ulcers to detect its formation early without the need for frequent attention from the caregiving staff. Temperature and pressure are continuously monitored so that risk areas can be identified. Once a region presents a risk, the caregiver is notified via pager to call their attention to the patient. This objective method for continuously monitoring pressure ulcer risk is more reliable than older methods and will lead to a more efficient and bedsore free hospital.

What is a Pressure Ulcer?

Pressure ulcers are skin lesions caused by concentrated and prolonged pressure in an area of body. They form when pressure impedes blood flow, leading to tissue necrosis . Moist skin, shear force, and friction increase pressure ulcer occurrence. Indicators of pressure ulcer formation are a change in temperature and high pressure in a localized area.

When a pressure ulcer forms. there is usually a 1-2°F increase in temperature due to inflammation brought about by tissue damage due to higher pressure in that area. There are four stages of pressure ulcer formation (Fig. 1).



Stage I: Blanching and inflammation, leading to an increase in temperature → **Stage II**: Early stage of lesion formation: red, serum filled → **Stage III**: Total tissue loss, fat visible → **Stage IV**: Exposed bone, muscle, or tissue through wound

Fig. 1: Four stages of pressure ulcer formation [2]

Pressure ulcers often occur in areas where weight is concentrated lying down, such as the coccyx and buttocks. Groups at high risk of developing pressure ulcers include bedridden and limited mobility patients.

Clinical Need

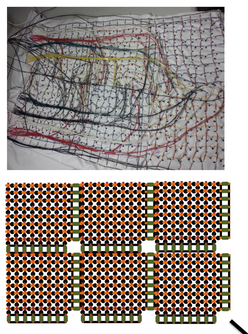
- Current detection methods rely on a subjective nurse assessment of patient using the Braden scale
- Nurses need to attend to patients every 2 hours and redistribute the weight
- Pressure-alternating mattresses do not prevent pressure ulcers
- No objective pressure ulcer detection system exists to continuously monitor patient for pressure ulcers
- Pressure ulcers can lengthen hospital stays by 3.5-5 times [3]

Description of Market

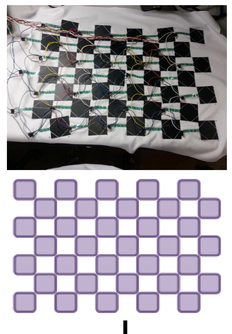
- Number of bedridden patients is at 1.4 million in nursing homes and an additional 250,000 in long term care hospitals
- Home health care and hospice patients will also benefit from a pressure ulcer detection device
- Pressure-redistributing support mattresses can be used to lower occurrence of pressure ulcers but do not prevent their development

Description of Design

Temperature Monitoring
Voltage is applied to an array of temperature sensitive resistors (thermistors). Different resistances across rows and columns change the voltage, which is measured and correlated to temperature.



Pressure monitoring
Voltage is applied to a pressure sensitive resistor array. Different resistance across each resistor change the voltage across the test resistor, which is measured and correlated to pressure.



Important Characteristics:
- 1 ft x1.5 ft – large enough to accommodate the body region which is at greatest risk for most patients
- Wicking fabric – prevents moisture build-up, which can be a contributor to pressure ulcer development.
- Easy to interpret output- heat map style output is simple and intuitive
- Real-time data – continuously updated
- Notify caregiver

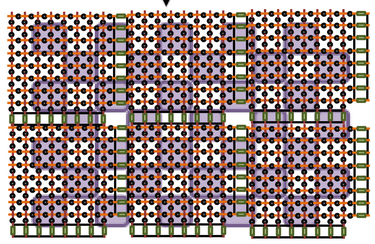


Fig. 2: PULCE Pad components

The PULCE pad (Fig. 2) uses only relative temperatures and pressures to diagnose pressure ulcers. Relative temperature is used because a typical body temperature will vary from person to person and relative temperature still allows us to still monitor small differences in temperature. Similarly, the critical pressure required to incite a pressure ulcer is not the same from person to person – it is more important to measure relative pressure. This allows us to keep costs low while providing a useful system.

Experimental Results

Initial tests were conducted to verify that the pressure and temperature sensors functioned correctly. A test subject sat on the PULCE pad. A colorimetric graph was used to display changes in pressure and temperature (Fig. 2)

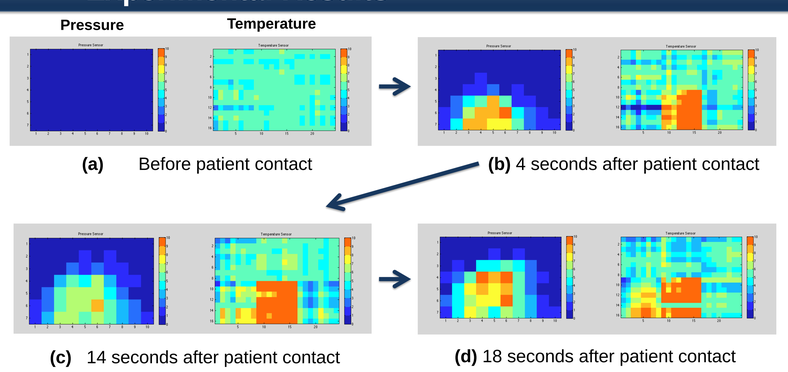


Fig. 2. Sample output illustrating changes in temperature and pressure over time. Warmer colors correspond to higher output voltages which indicate higher pressure and temperature. **(a)** Baseline output **(b)** 4 seconds after contact with PUCLE pad. Pressure and temperature changes were detected immediately after initial contact. **(c)** 14 seconds after patient contact. Temperature increases as patient warms up pad. Variations in pressure due to patient shifting. **(d)** 18 seconds after patient contact.

Tests analyzing sensitivity of temperature sensors

A thermocouple attached to metal weight was placed on PULCE Pad. Subject sat on metal disk to allow for slow heat transmission through metal. Temperature data was collected until 3°F difference was achieved from starting temperature of disk (Fig 3).

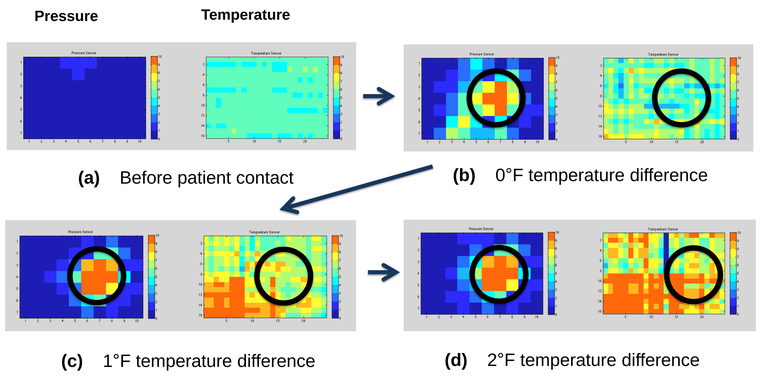


Fig. 3 Colorimetric graphs illustrating pressure and temperature changes. **(a)** Baseline output **(b)** 1 second after contact with disk on PULCE Pad. Black circle represents where disk was placed and where subject sat on. Orange indicates subject weight on disk. Initial temperature was uniform at 79.4°F. **(c)** 3 minutes after contact. Pressure changes confined to disk area because subject stopped shifting. Temperature under metal was at 81.4°F. Lower left higher in temperature due to residual heat from subject's leg immediately above (but not in direct contact). Temperature data inconclusive due to noise. **(d)** 6 minutes after contact. Area under disk was at 82.4°F. Pressure changes were confined to the disk area. Temperature was less noisy, indicating better results for greater temperature differences.

Novelty

- PULCE Pad incorporates both continuous temperature and pressure sensing in an external, non-invasive device
- It predicts the formation of a pressure ulcer by analyzing changes in temperature and pressure
- No automated detection system in the form of a pad exists
- Comparable in price to pressure-alternating mattresses which do not detect pressure ulcer formation

Estimated Product Costs

Component	Qty	Unit Cost	Cost of 1 pad ($)	Bulk Cost ($)
Moisture wicking fabric	2x1 yards	12.99	25.98	3500
Thermistors	786	0.11	86.46	86460
Pressure Sensors	35	7.00	244.94	171500
Resistors	131	0.02	2.62	13.10
Arduino Mega (microcontroller)	1	38.20	38.20	800
Solid Core Wires	20 yards	0.339	6.78	2000
Solder	--	27.43/lb	27.43	4250
Thread	--	4.39/400yd	4.39	200
		Total Cost		268711
		Unit Cost	530.01	268.71

Estimated costs for one 1.5 x 1 foot pressure ulcer detection pad were based on the material costs for building the final prototype. Bulk costs were estimated assuming 1000 pads would be manufactured. The product costs do not include labor costs for small scale production or automated machinery costs for the large scale production.

Anticipated regulatory pathway

501 (k)
- Class I
- Physical Medicine Diagnostic Device
- Approved temperature and pressure monitors exist as separate devices, but have never before been combined

Future Steps

- Improve durability and sensitivity of temperature sensing component as thermistor legs were prone to breakage
- Detect absolute pressures for a better prediction of ulcers
- Incorporate into hospital communication system to notify caregivers
- Test on patients at risk for pressure ulcers
- Implement wireless data transmission
- Open-source software for data processing
- Research methods to automate production process

Acknowledgements

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References

[1] Kuhn, BA, and Coulter, SJ. Balancing the pressure ulcer cost and quality equation. Nurs Econ. 1992 Sep-Oct;10(5):353-9

[2] http://www.spinal-injury.net/pressure-sores-sci.htm

[3] Maklebust, J. and Sieggreen, M. *Pressure Ulcers: Guidelines for Prevention and Management*. 3rd ed. 2000 Springhouse