MASSACHUSETTS MEDICAL DEVICE DEVELOPMENT CENTER (M2D2)
AND
THERATORR MEDICAL, INC. (TMI)

Pressure Redistribution Medical Mattress

Reactive Support Surface

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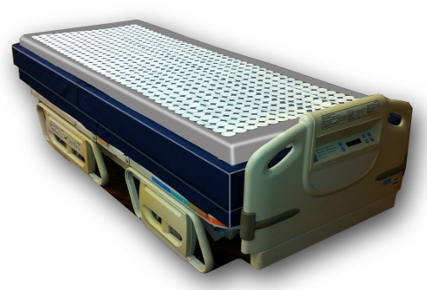

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Introduction

TheraTorr Medical, Inc. is developing a medical mattress with a reactive support surface that has the potential to prevent tissue breakdown, facilitate the healing of pressure ulcers, and improve patient comfort.

The mattress surface consists of groups of contiguous, discrete reactive support units called SensorCells™. A SensorCell is comprised of two principal components (Figure 1): an inflatable diaphragm (cell) and a specially designed support core. When the SensorCells making up the reactive surface are inflated to a uniform low pressure, they collectively support and distribute the patient's weight evenly and minimize tissue/surface pressure gradients. The University of Massachusetts Lowell, Department of Plastics Engineering, has performed a battery of tests on SensorCells made with dipped latex cells. These tests will be used as baseline data for evaluation of alternative SensorCell designs and component materials.

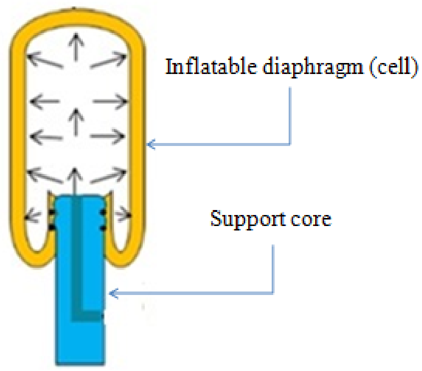

Figure 1: The SensorCell™.

Pressure Ulcers

Pressure ulcers (decubitus ulcers), commonly called "pressure sores," are skin or tissue injuries resulting from continuous, excessive tissue interface pressure (TIP) acting on localized areas of the body. If left unrelieved, excessive TIP leads to tissue breakdown and tissue necrosis, as capillaries are compressed and blood flow is restricted. Uncontrolled moisture, friction, and shear further increase the likelihood of tissue degradation and can further retard the healing process. Pressure ulcers develop most frequently on skin and tissue over bony prominences (Figure 2), where high TIP, moisture, friction, and shear are more difficult to control.

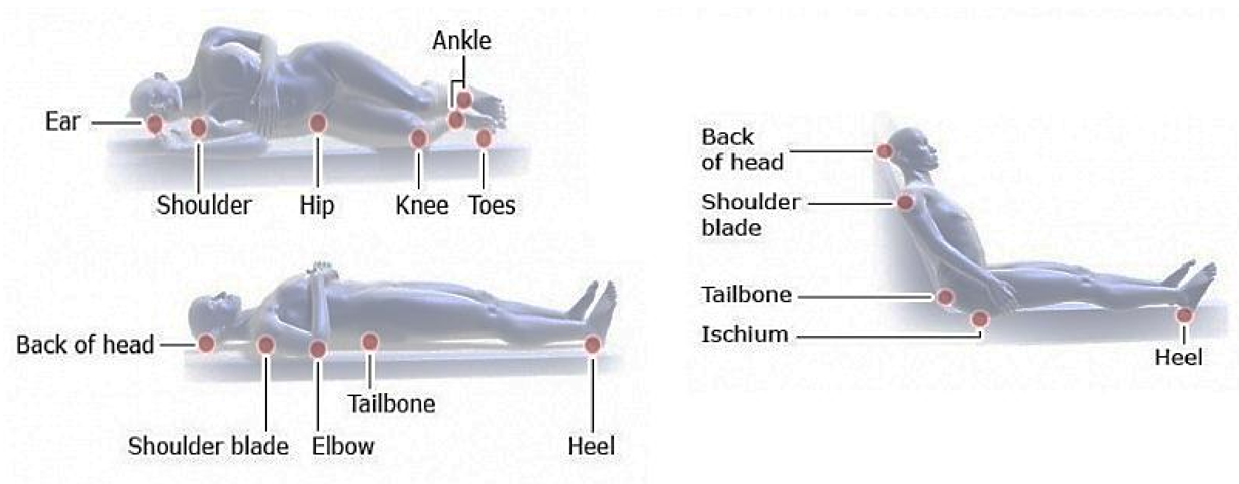

Figure 2: High risk areas for developing pressure sores.[1]

[1] US National Library of Medicine – National Institutes of Health

As capillary blood flow (perfusion) is reduced, the incidence and severity of pressure ulcers (PU's) increase. Traditionally, a tissue interface pressure of 32 millimeters of mercury (mmHg) was considered to be the threshold of injury, as that is the average capillary blood pressure at its arterial inflow. However, 32 mmHg is the average capillary blood pressure for a healthy individual. The threshold may indeed be lower for frail patients and those with compromised blood circulation – those patients that most frequently suffer from bed sores.

Prevalence

Three to six percent of the 36 million patients admitted to hospitals develop pressure ulcers during their hospital stay[2]. People with impaired sensation, prolonged immobility, and advanced age are at greatest risk. According to the Center for Disease Control and Prevention (CDC), 11% of nursing home patients develop pressure ulcers. The economic impact of pressure ulcers on the U.S. healthcare system is to add billions of dollars and millions of days of hospitalization for their treatment to an already overburdened system. The average additional cost for treating a pressure ulcer acquired during a hospital stay, according to CDC statistics, is $25K.[3] Not to be overlooked is the extreme discomfort caused by bed sores and their negative impact on the quality of life of chronic sufferers.

Prevention programs have relied on the use of specialty pressure relief mattresses, supplemented with periodic repositioning of bedridden patients to reduce pressure ulcer risk. The Centers for Medicare and Medicaid Services announced in 2008 that pressure ulcers are a "reasonably preventable" condition and that reimbursement would no longer be provided for the treatment of pressure ulcers acquired during a hospital stay. Though healthcare providers have focused their efforts on prevention, the rate of pressure ulcer formation does not appear to have decreased.

Research Objective

The University of Massachusetts Lowell, Department of Plastics Engineering, collaborated with TheraTorr Medical, Inc. in the design, formulation, and analysis of its principal performance component, the SensorCell. The objective was to research design options for the cell component of the SensorCell — including geometry, materials, and molding methods — to identify the best alternatives for performance, manufacturing feasibility, reliability, and cost. This paper documents the performance testing of one of the alternative SensorCell designs, made with a dipped latex cell (Kent Elastomer, Kent, OH), which established the baseline performance against which subsequent versions of SensorCells will be judged.

Origin of the Design

The SensorCell is a vertically oriented discrete element that can provide a constant tissue interface pressure over a large vertical displacement. TheraTorr's support surface consists of 500–1,000 contiguous SensorCells (depending on the chosen diameter) that form a planar surface in which the individual cells operate as discrete and independent lifting elements that conform to the shape and movement of the body, redistributing and alleviating TIP.

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[2] Allman, R., et al. Pressure sores among hospitalized patients, Ann Intern Med, 1986;105:337-41
[3] Healthcare Cost and Utilization Project, 2008 - http://www.hcup-us.ahrq.gov/reports/statbriefs/sb64.jsp

Cell Orientation

The vertical orientation is a key design feature of the SensorCell. The SensorCell behaves similarly to a pneumatic piston in that 1) the force generated by the cell is proportional to the internal air pressure and the cell diameter; 2) the cell diameter does not change as it is compressed vertically; and 3) the cell has the same force-generating potential over its entire displacement (Figure 3A, below). The more deeply the patient can sink into the surface (to the limit of the midline of the body), the more surface area is engaged in sharing the patient's weight, thus reducing the load per unit area on the surface.

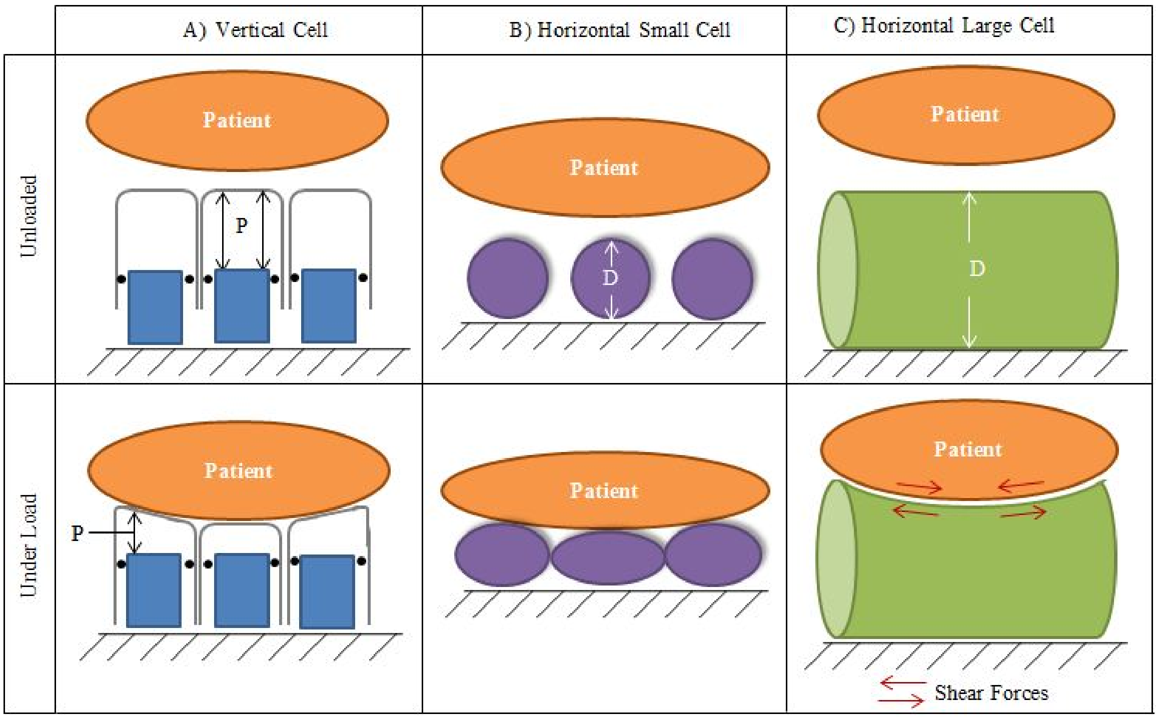
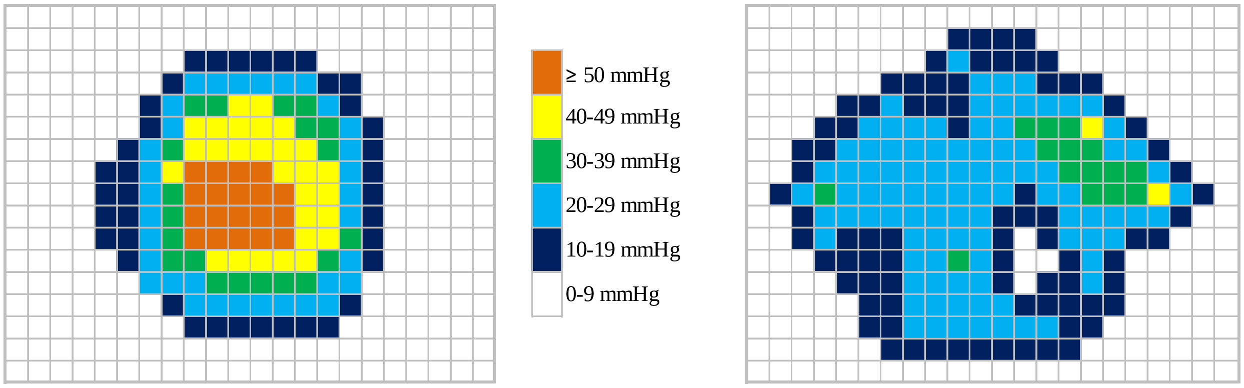


Figure 3: Comparison of vertically and horizontally oriented discrete cells.

In comparison, horizontal cell orientation — the prevailing design common to all contemporary low air-loss (LAL) surfaces — does not provide the same benefits. As seen in Figure 3B above, horizontally oriented cells with a small diameter can conform to an irregular geometry, but the maximum displacement is limited by the diameter of the cell. As the cell diameter is increased (Figure 3C), the maximum attainable depth is also increased. However, larger cells cover a significant skin surface of the patient, and such air chambers can generate significant shear forces when adapting to irregular body surfaces. In addition, horizontally oriented air chambers flatten as the patient sinks into them, increasing the contact area of each cell and generating unwanted forces as the surface material is stretched between adjoining protrusions, creating significant shear forces. Therefore, the surface as a whole cannot adequately conform to the patient's anatomy, causing pressure gradients to develop. The tendency of large skin/surface contact areas to produce pressure gradients is called "hammocking."

Discrete Elements

To minimize the TIP and shear, the TheraTorr support surface tested used a design consisting of a multiplicity of discrete elements, i.e., SensorCells. Each SensorCell can move freely in the vertical plane and conform independently to the shape of the patient, while transferring minimal force to adjoining cells.



Pressure Map of a Spherical Test Mannequin
Low Air-Loss Surface
138 units of area

Pressure Map of a Spherical Test Mannequin
SensorCell Support Surface
193 units of area

Figure 4: Pressure distributions for common air mattress (left) and SensorCell support surface (right).

Figure 4 compares the pressure distribution for a low air-loss (LAL) surface commonly found in healthcare facilities with the pressure distribution of the SensorCell support surface.[4] As shown by the orange and yellow areas on the pressure map at left (Figure 4), the LAL surface clearly has less contact area and more areas of high localized pressure when compared to the TheraTorr support surface.

The independent SensorCells allow the patient to sink into the support surface until the contact area increases sufficiently to involve enough independent cells to fully support and stabilize the body (Figure 5). Since the cells provide a large maximum displacement [127 mm (5 in.) for the SensorCells tested], they can conform to bony protrusions and other irregular anatomical features without bottoming out. The SensorCells also minimize shear forces, as the cells act independently. Tensile stresses are not transmitted within the plane of the sensing surface because the cells are free to separate from one another. Minimal lateral forces can be supported without buckling the cells. Therefore, the independent motion of each SensorCell limits the shear forces exerted on the patient.

Minimum Flotation Requirements

The SensorCell support cores are connected to a manifold that pressurizes the cells and equalizes the system pressure to the connected cells. Decreasing the system pressure reduces the TIP exerted by all the SensorCells attached to that manifold. This results in a softer surface, allowing the body to sink into the mattress until it is in contact with a sufficient number of cells to support its weight and achieve equilibrium. Conversely, temporarily increasing the system pressure results in a firmer surface, which allows greater patient mobility and easier patient repositioning by care providers but increases the TIP.

[4] The pressure mapping data for this illustration were obtained using a spherical test mannequin. The LAL surface and the SensorCell surface were both set at the minimum pressure settings for optimal flotation. Both surfaces were covered with a single, thin layer of cloth sheeting.

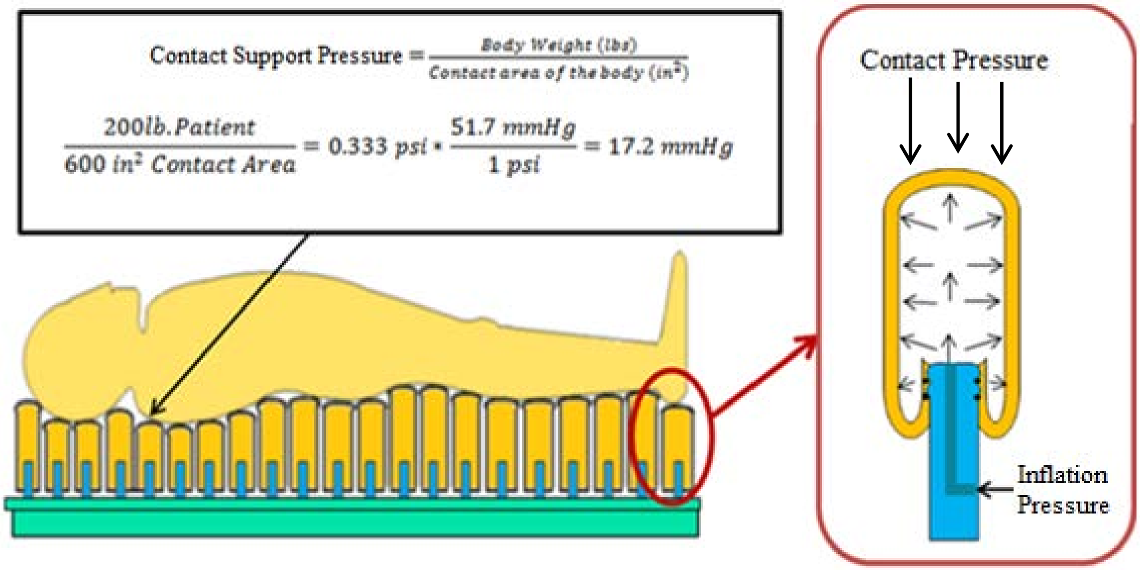


Figure 5: Required contact pressure to float a patient below capillary closing pressure.

In summary, a support surface made from discrete SensorCells more evenly conforms to the patient's anatomy and distributes the patient's weight more evenly over a broader surface, thus minimizing shear and friction forces and reducing the TIP.

Design Validation

To validate the functionality of the design, SensorCells consisting of dipped latex cells were tested at a range of system pressures. Latex has a relatively low modulus and is flexible enough to permit repeated rolling without any permanent deformation. The exterior of the cells were coated with a urethane material to improve durability.

Testing

SensorCells were tested individually using an Instron Universal Testing Machine (Model #4481) at inflation pressures ranging from 13 to 104 mmHg (0.25 to 2 psi) at 13 mmHg (0.25 psi) increments. Nine latex cells were tested at each inflation pressure. Each latex cell was mounted on a support core that duplicated those used in the mattress. Prior to the start of testing, each SensorCell was inflated to 52 mmHg (1 psi) and five exercise cycles were performed to the maximum displacement of 127mm. The SensorCell was then inflated to the required internal air pressure, which was maintained and monitored throughout the test. The crosshead of the machine was lowered, compressing the SensorCell at a rate of 50.8 mm/min to a maximum displacement of 127mm. The resulting load vs. displacement data were recorded. The diameter of the top of each cell was used to calculate the contact area, which was subsequently used to convert the recorded load data to contact pressure data.

Characteristic contact pressure vs. displacement results are shown in Figure 6. The rigidity of the SensorCell, which is a function of both the material and the design, is observed in the initial linear region of the curve, labeled ❶ on the diagram. Folding of the cell's lower edge and the initiation of the rolling action occurs at ❷, which is the maximum contact pressure observed during each test. Once the cell wall is rolling, the contact pressure drops and remains nearly constant for the remainder of the loading curve, labeled ❸. Unloading begins at ❹. The unloading curve closely resembles the loading curve, but is offset downward due to frictional losses. For ideal behavior (optimal pressure redistribution) in a clinical setting, the majority of the loading-unloading curve should be between the minimum pressure required to support a patient (estimated at 17 mmHg for a 200-lb body) and the pressure at which restriction of blood flow in capillaries starts to occur (32 mmHg for healthy patients).

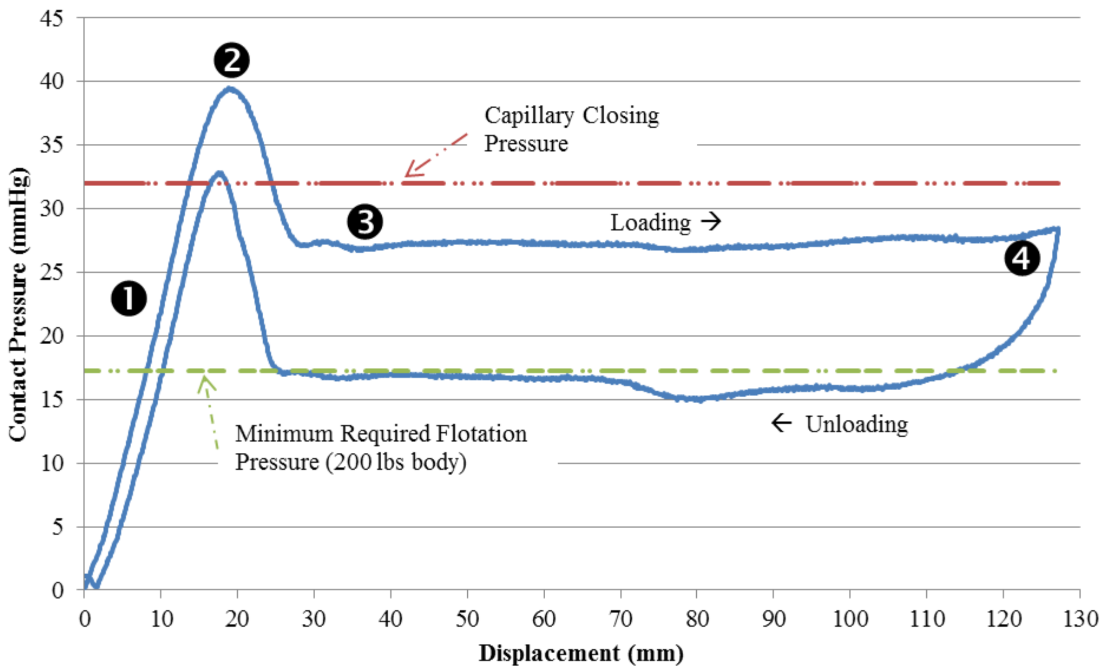


Figure 6: Average contact pressure vs. displacement for cells tested at 26 mmHg (0.5 psi).

Results

As the system pressure within the SensorCell is increased, the resulting contact pressure increases proportionally. Figure 7 shows the averaged results for tests performed at inflation pressures between 13 and 52 mmHg. The results at every inflation pressure up to 52 mmHg demonstrate the SensorCell's ability to maintain a constant contact pressure over a large displacement. Higher inflation pressures caused a slight expansion of the cell; this expansion increased at pressures beyond 52 mmHg. Specifically, the average diameter increased from 54.3 to 55.2 mm when the pressure was increased from 13 to 52 mmHg respectively. The slight increase in diameter helped initiate the rolling behavior and decreased the friction in the rolling section. Therefore, increasing the system pressure 1) reduced the magnitude of the initial peak relative to the linear portion of the curve, 2) minimized the observed pressure difference between the loading and unloading curves, and 3) improved the uniformity of the flat portion of the curve.

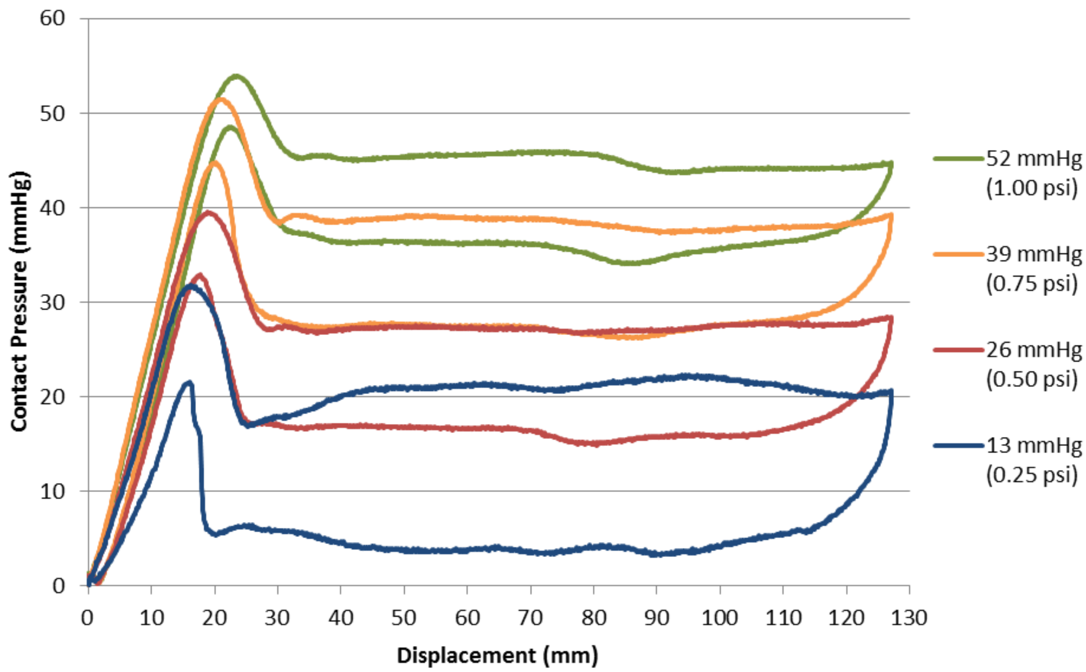


Figure 7: Average contact pressure vs. displacement at inflation pressures of 13 - 52 mmHg (0.25-1.0 psi).

There was considerable variability in the wall thicknesses of the cells received from the supplier. Although the effect of wall thickness was not specifically investigated, it was found to be a significant factor affecting the loading / unloading behavior. Prior to testing, the thickness of each SensorCell was measured at multiple locations around the circumference and along the length. Figure 8 shows how the cells with the maximum and minimum wall thickness compare to the average data taken at 26 mmHg (0.5 psi). The thickest cell had an average wall thickness of 1.13 mm (SD 0.05 mm), while the thinnest cell had an average wall thickness of 0.90 mm (SD 0.04 mm), and had an overall average measured thickness of 0.98 mm (SD 0.09 mm). As wall thickness increases, the SensorCell becomes more rigid, which inhibits the desired rolling behavior. Once rolling is initiated, there are greater frictional losses corresponding to variability in the flat portion of the curve and greater separation between the loading and unloading curves (Figure 8). Samples with the minimum wall thickness provided the best results at any given pressure.

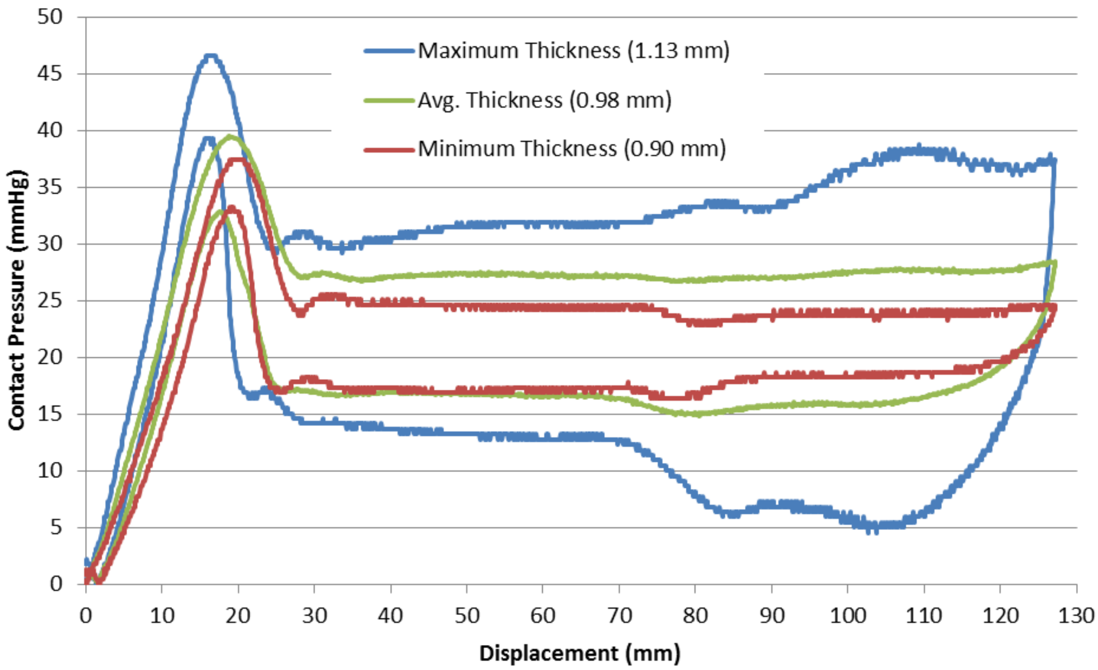


Figure 8: Effect of wall thickness on contact pressure vs. displacement at 26 mmHg (0.5 psi).

It should also be noted that thickness variations caused some samples to buckle at low pressures (13-26 mmHg) or balloon at high pressures (91-104 mmHg). These samples did not exhibit the characteristic rolling behavior, were discarded, and were excluded from the results.

Further Development

The design validation shows that SensorCell performance is improved when rolling friction is minimized. Ongoing research and development efforts are focused on optimizing the material selection for the SensorCell and selecting a manufacturing process that is both consistent and cost-effective.

Figure 9 shows how SensorCells made with dipped latex cells perform compared to dipped synthetic rubber cells and blow-molded polyolefin cells. While these three cells have slightly different geometries and the materials are significantly different, the overall performance demonstrates the feasibility of manufacturing SensorCells using a blow-molding or a dipping process.

The best performance is observed for the synthetic rubber-dipped cell. The material exhibits very low resistance to rolling friction. Therefore, the contact pressures for loading and unloading are more similar, and the initial peak that is typically observed as rolling is initiated is minimized. Figure 10 shows the pressure map for a patient lying on his back on a SensorCell support surface made from dipped synthetic rubber cells.

From our experience testing various cell designs and different manufacturing processes, we conclude that there are a number of satisfactory material and geometric options available to optimize performance and economic considerations for a product line of support surfaces. Ultimately, the ideal surface may consist of a variety of geometries and materials to suit clinical needs, functional requirements, and cost and durability objectives.

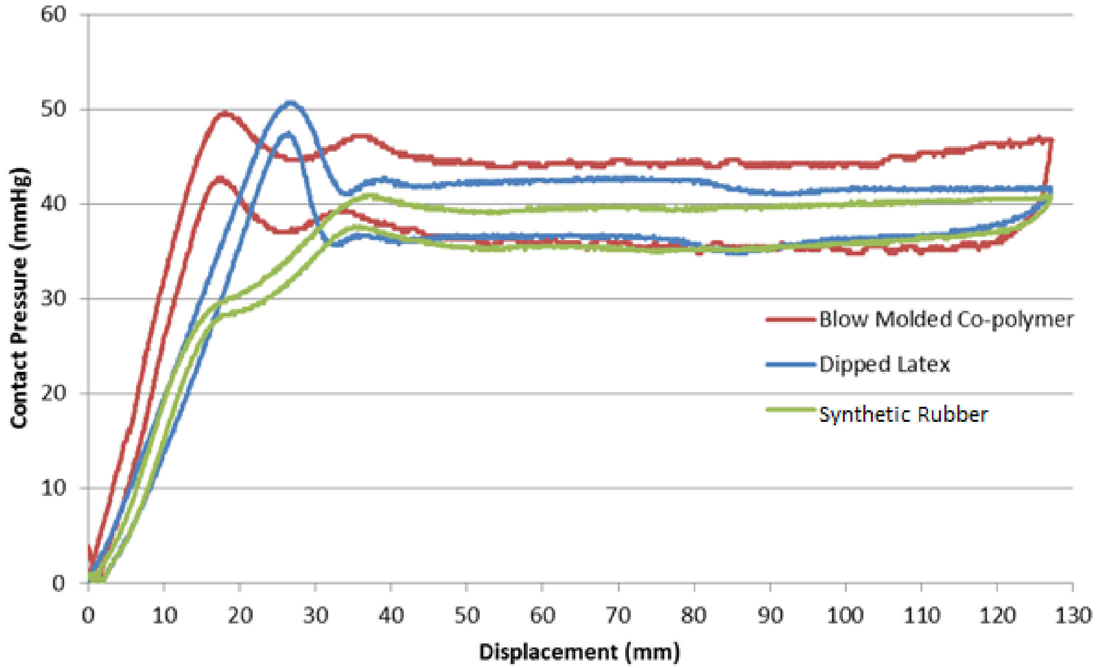


Figure 9: Comparison of blow-molded co-polymer, dipped latex, and dipped synthetic rubber cells.

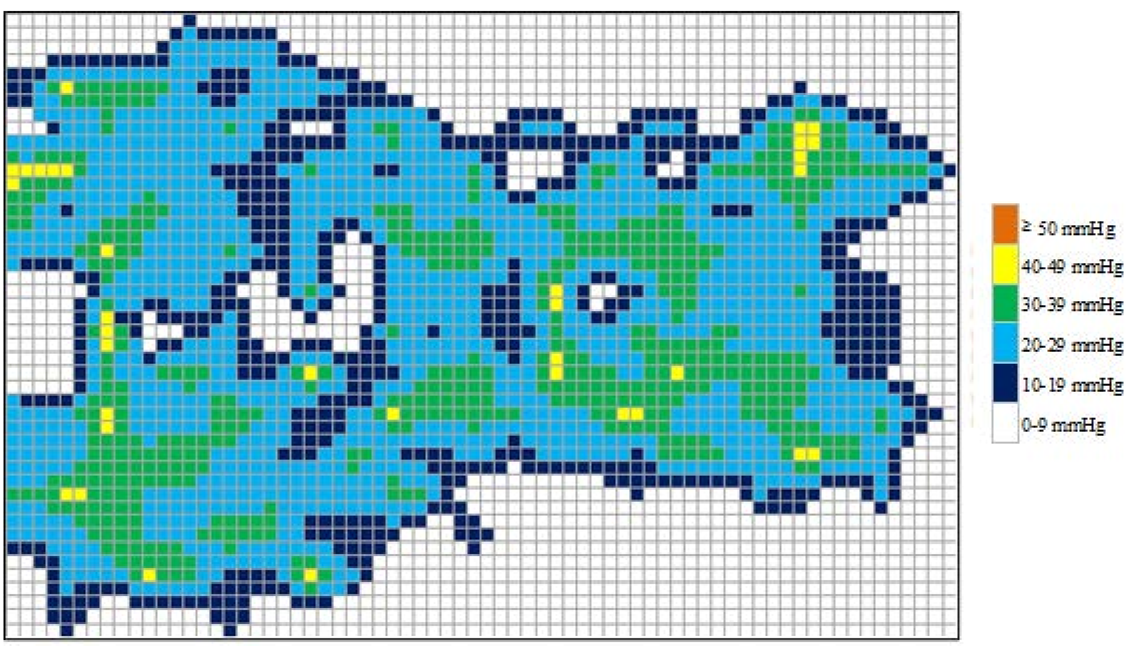


Figure 10: Pressure distribution for patient laying on dipped synthetic rubber SensorCell support surface.

Conclusion

A reactive support surface of SensorCells offers a new approach to powered pressure redistribution medical mattresses. The testing demonstrated the ability of the SensorCells to deliver uniform contact pressure over a range of system pressures. The lower end pressures, such as 13 and 26 mmHg (0.25 and 0.5 psi), perform well below the capillary closing pressure. If a reactive support surface comprised of SensorCells can operate within a system pressure of 13 – 26 mmHg, a clinician should be able to comfortably float a patient while promoting healthy blood profusion.