ABSTRACT

Pressure ulcers are localized wounds characterized by the breakdown of skin and underlying tissue. On average, annual treatments cost upwards of $55 billion. In particular, there is an increased susceptibility to pressure ulcer development among individuals with spinal cord injuries (SCI) due to muscle atrophy and loss of sensation.
in their lower body. Current pressure mapping devices lack portability, typically cost $5000-$6000, and are generally only utilized within clinics, making pressure mapping usage limited and very expensive. Our project’s objective was to address these needs by developing an affordable, portable take-home device that can provide a continuous pressure map of the individual’s seat-buttocks interface and also aid in developing healthy pressure relieving habits. Our solution to this objective was designing a device made of inexpensive smart materials that can provide real-time pressure feedback via a smartphone app. This invention would help prevent the risk of pressure ulcer development by providing an easy way for the user to interpret simple data and make the proper modifications.

**INTRODUCTION/BACKGROUND**
The development of pressure ulcers is a concerning issue for individuals with SCI. In addition to their increased susceptibility due to muscle atrophy, the loss of sensation in the lower body can lead these individuals to become inattentive to periods of high pressure on certain areas of their lower bodies. Pressure mapping devices have been developed for clinicians to assess optimal seating positions and cushions for these individuals. However, no inexpensive and conventional pressure mapping devices have yet been developed to be used by individuals with SCI as take-home devices outside of the clinic. Also, no such devices have had informative features focusing on the development of routine pressure relieving habits.

Our goal was to design a pressure mapping external garment that can not only display a visual pressure map, but also be a portable, ergonomic, shape-conforming, and affordable learning tool for persons with SCI to use throughout daily activities. The product would be made of breathable material with a belt buckle for a fixed adherence to the individual’s body. The pressure sensors would be thin, inexpensive, and strategically positioned for optimal accuracy of pressure outputs. Lastly, the device would provide real-time cues for pressure alleviation and record time intervals of pressure alleviation or high pressure buildup.

**PROBLEM STATEMENT**
Due to muscle atrophy, loss of sensation, and a sedentary lifestyle, individuals with SCI are commonly prone to pressure ulcer development. Therefore, our team’s goal is to design an effective and portable pressure sensing system that can develop healthy pressure relieving habits and be affordable to all individuals with SCI.

**DESIGN AND DEVELOPMENT**
Pressure Sensor Material
The material used for our pressure sensing material is fabricated from highly resistive material, conductive thread, and nonconductive material. Several layers of velostat, which is the highly resistive material, are set between two layers of neoprene, which is the nonconductive material. Cross-sections of the conductive thread woven into both layers can detect changes in voltage when under compression. An increase in compression results in more of a voltage drop between the power supply thread and the bottom conductive thread. These conductive threads then that act as leads which transmit these voltage outputs to the microcontroller.

The positional layout of the sensors is based on anatomical regions that experience the highest amounts of pressure when sitting. Refer to Figure 1 below for this layout.

The conductive thread leads are run through the top neoprene material and into an 8-pin adapter on the exterior of the side of the device. Refer to Figure 2 for a diagram of these leads.
**Power**

A 9V battery supplies the power to the microcontroller, which can output a 5V power supply. From there, a conductive thread will run across the bottom layer of neoprene and cross patterns with the each sensor’s conductive threads, located within the top layer. Figure 2 below displays the layout of the power supply in red.

![Diagram](image)

**Circuit Board / Microcontroller**

Copper wires from the 8-pin adapter are surrounded by an insulated conduit and transmit the inputs from the conductive threads to the circuit board, where a voltage divider converts these inputs in readable signals. After the operational amplifier buffers these signals, the inputs travel to the microcontroller, an Arduino Leonardo, where the data is then processed into pressure values. This Arduino has an attached shield with Wi-Fi capabilities that can wirelessly transfer the output pressure values to the software of the user’s iPad or iPhone.
Software
An iOS app compatible with the user’s ipad or smartphone has been designed using xCode software. The app interface displays a real-time pressure map of the pressure sensors and their designated areas. A color scheme visually indicates to the user levels of pressure, with red denoting high levels and blue denoting low levels.

The app also logs pressure alleviations when all sensors detect extremely low levels of pressure for a pre-set duration (e.g. 10 seconds). A text box specifies the elapsed time since the last pressure alleviation occurred.

The app also features an audible cue that sounds when dangerous levels of pressure are detected for a certain pre-determined period of time (e.g. 20 minutes), informing the patient that they should alleviate and redistribute their pressure. This alarm feature has the option to be deactivated. The app also features customizable properties for pressure alleviations that can be modified on an individual basis.
Figure 4: App interface displaying high pressure values

Figure 5: App interface displaying various pressure values and time elapsed since last pressure alleviation
External Material
A breathable wicking material (40% polyester, 60% nylon) covers the internal pressure sensor material. An adjustable belt buckle is attached to the sides of the device on the proximal end, providing a fixed adherence to the user’s body.

EVALUATION
Evaluation of our device was based on accuracy, ergonomics, comfort, durability, efficacy, and safety. The circuit board resistance and number of velostat layers were optimized during testing in order to achieve the most accurate output readings and a sufficient output range. Ergonomics was assessed by meeting with potential clients and addressing their inputs on desired features, as well as suggested avoidances. Durability has been repeatedly tested through multiple prototype testing trials and no deterioration has been observed. Efficacy was addressed in the design process by evaluating client and clinician feedback and incorporating our assessments into our final design. This was further assessed through testing and client evaluation of the prototype. Safety was assessed by minimizing any of the device’s protrusions and completely insulating all areas of electrical conduction.

Further evaluation was performed when the functionalities of pressure sensor prototypes were demonstrated to our capstone advisors and fellow biomedical engineering students. Overall, continuous alterations were made to our design based on this feedback, testing, and client evaluation.

COST
As detailed in Table 1 below, the estimated cost of the prototype is approximately $157.24. In comparison to current pressure mapping devices that cost at least $5,000, the cost of materials for our device is approximately 3% of what conventional pressure mapping devices are sold for. Clearly, we our objective to fabricate an inexpensive alternative device was completed.

<table>
<thead>
<tr>
<th>Product</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conductive Thread</td>
<td>10.95</td>
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<tr>
<td>Arduino Leonardo</td>
<td>24.95</td>
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<tr>
<td>Mux Shield II</td>
<td>24.95</td>
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<tr>
<td>microSD Shield</td>
<td>16.95</td>
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<tr>
<td>Neoprene &amp; Exterior Fabric</td>
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<tr>
<td>Electrical/Wiring</td>
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<tr>
<td>Components and Battery</td>
<td>37.94</td>
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<tr>
<td>TOTAL</td>
<td>154.24</td>
</tr>
</tbody>
</table>
Table 1: Estimated Cost of Parts

**DISCUSSION AND CONCLUSIONS**

After evaluation of our device, we can confirm that it consists of the following planned features:

- Inexpensive
- Safe
- Portable
- Durable
- Accurate pressure readouts at seven prominent anatomical regions
- Feedback on progress of healthy pressure relieving habits
- Customizable on individual basis

The first major decision of our design was whether it would utilize conventional piezoelectric sensors or if we would use smart materials to detect pressure changes. After thorough research, the smart material approach was chosen for its affordability, its sufficient accuracy, and for its ease of integration into a shape-conforming garment.

Throughout the design process, the greatest difficulties came from optimizing the sensors when applying various weights. Since conventional pressure mapping devices display pressure outputs with ranges of up to 200mmHg, our goal was to achieve this range while also maintaining accurate readouts. Through much trial and error by varying the resistances, a range limit of 192mmHg was eventually reached by increasing the layers of velostat and decreasing the resistances in circuit.

Many conceptual ideas were also modified after performing clinical surveys. Our initial design was a garment worn interior to the user’s outerwear. However, from feedback we deduced that an external garment that buckles around the individual’s waist would be more aesthetic and would also maintain the shape-conformation and adherence. Additionally, the incorporation of a smartphone app with a user-friendly interface that features simple quadrants with color schemes was heavily advocated. From this feedback we were able to discern that we needed to stress making a reliable app with a simple interface.

At the beginning of our project, we faced much adversity in determining how we could improve upon expensive pressure mapping devices that already have high resolutions and efficient readouts. The most invaluable lesson was learned when we met with
potential clients and clinicians. From this feedback, we learned that many individuals with SCI had difficulty in remembering to routinely alleviate pressure by temporarily leaning or lifting off their seat. This brought us to the realization that there was actually a widespread need for the overall development of healthy pressure relieving habits, and not necessarily for more improved resolutions. Through our investigation, we discovered a hole in the healthcare market that has yet to be filled. Furthermore, after the results of our testing and receiving feedback, we believe we have met our goal and designed a product that has the potential to have a significant impact on the quality of life of up to 1.4 million individuals as well as the $55 billion industry for pressure ulcer treatment.

In order to make this potential become a reality in the future, sensors that are more optimized could make the device more accurate. A carrying case could make the device more portable and durable. Optional features could be added to the app for more statistical evaluations. Lastly, more sensors could increase the resolution. These are all possibilities in the future, but as of right now, we have a product ready to aid its first clients in developing healthy pressure alleviating habits. Treating pressure ulcers is financially cumbersome and temporal. Developing habits with our device is inexpensive, and the impacts can last for a lifetime.

ACKNOWLEDGEMENTS
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Benjamin Siderits
siderits.2@osu.edu