BME 261 Project Final Report

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1 Executive Summary

Background: Peripheral neuropathy is caused by damage to the peripheral nervous system, which can cause loss of sensation, movement, or autonomic control to parts of the body [1]. Those who experience peripheral neuropathy in their legs can have trouble walking and require gait aides. Currently available aides can be expensive, uncomfortable, and unreliable leaving a large area for improvement in this sector [2, 3, 4, 5].
Objectives: The goal of this project was to complete an early prototype of a revolutionary gait aide specifically made to help those with peripheral neuropathy and improve their user experience.
Methods/Outcome: To begin, research was conducted on the science behind peripheral neuropathy, patients experiences with the disease, and the currently available gait correction devices. From this, requirements and a design were set and a prototype was created. The final prototype consisted of an electrical circuit that used pressure sensors to gather plantar pressure information from four points on the user's foot. This information was then mapped to motor voltages that provided proportional feedback of the pressures by vibrating at varying intensities just below the knee. This circuit was housed in a sock. The device was then tested and found to achieve it's goal of providing directly proportional feedback to the user. The prototype was also robust enough to withstand normal day-to-day activities.
Action Recommendations: One noteworthy finding of the prototype is that deciphering the motor feedback can be challenging depending on where the motors are placed. If they are located in a region of low innervation, the user was not able to distinguish between different motor signals. Alternative design considerations such as using another feedback mechanism, placing the motors in a different location, or only giving strong alert feedback when a fall is imminent should be investigated during redesign.

2 Introduction

Peripheral neuropathy refers to a collection of conditions caused by damage to the peripheral nervous system [6]. Damage of these nerves results in numerous health effects such as involuntary movement of or loss of nerve communication to and from the extremities [6]. The list of peripheral neuropathy symptoms can range from mild to life-threatening [6]. Peripheral neuropathy is a broad disease and conditions are often classified into four different categories based on common symptoms and prognosis. These categories are: motor neuropathy (damage to the nerves controlling muscles and movement), sensory neuropathy (damage to the nerves controlling the senses), autonomic neuropathy (damage to the nerves controlling autonomic functions such as breathing), and combination neuropathy (a combination of any of the three previously listed neuropathies) [1]. For those with motor, sensory, or combination neuropathy, walking can be challenging and often require a mobility or gait aide.

Current solutions to gait abnormalities (due to motor neuropathy, strokes, multiple sclerosis etc.), include ankle-foot orthoses (AFOs), functional electrical stimulation (FES) braces, or walkers. Despite the choices, none of these solutions are ideal. AFOs can result in skin, medial malleolar, and talonavicular irritation [2], and can cost between $6 400 to $15 400 USD [3]. FES braces allow for increased ankle movement and improved comfort [4], however, surveyed users of the Odstock Dropped Foot Stimulator (a common FES brace) reported issues with the reliability of the equipment, difficulties in use, and allergic reactions [5]. FES braces are also unsafe for use around water because of their electrical components [4].

There exists a need among adult patients with motor and sensory peripheral neuropathy in

their legs for an improved corrective gait device. Traditional braces are expensive, unreliable, and uncomfortable leading to poor patient experience [2, 3, 4, 5]. An improved gait assistive device that addresses these concerns has the potential to greatly improve the lives of these patients.

3 Design

As stated in the introduction, there is much room for improvement within the medical aides available for patients suffering from peripheral neuropathy. The main goal of this project was to develop a design that would provide the user with consistent feedback on their gait thereby preventing falls. Although this was the primary objective, the team was also highly concerned with improving the user experience with this new device compared to current options.

To meet the goal of providing gait feedback, two steps are needed. First, the gait information must be collected, then the information about the gait must be translated to the patient in a useful way. Many methods for communicating the collected data to the user were considered such as displaying the information on an application, using led lights on wrist bands, etc. In the end, vibrating motors placed just above the level of the neuropathy were used as it places the feedback close to the area of interest and does not require a lot of user attention like noticing visual ques or interpreting an application. This met the design requirement of making the signals easy for the user to detect, while not severely impeding their day-to-day life.

Once the circuit of the device was designed, a method of securing the device to the patient's foot needed to be determined. This is where the goal of improving user experience was focused. Two major design requirements for user experience were set. First, the design should be comfortable for the user to wear for an extended period of time and second, the device should be inconspicuous to the public. From these requirements, it was decided that the device would be housed in a tall sock. This allowed the motors and sensors to be secured comfortably to the user's leg. Using a sock also prevents discomfort that may be caused by an ill-fitting shoe device, and draw less attention than a device that used exposed bands and wires or bulky braces.

Once the overall design was created, a more detailed prototype design was developed and built. This is described in the next section.

4 Prototype

As stated in the design section, the prototype uses pressure sensors and vibrating motors to sense and relay information to the user. To sense information, four thin film pressure sensors are installed acting as R_2 of a voltage divider into an insole in the sock. The R_1 resistors were specially chosen depending on sensor location as described in section 4.2. These force sensors are connected to four analog input pins on an Arduino Uno board. The Arduino is housed in a custom 3D printed casing secured to the ankle using a band and Velcro. When the pressure sensors are activated, the V_{out} values are sent into the Arduino where they are mapped to directly proportional voltage outputs between 0V and 5V. This voltage is then sent to the vibrating motors circuit located at the top of the sock. The vibrating motors are connected in series with an appropriately sized resistor to four digital IO pins and vibrate in accordance to the mapped value. This provides directly proportional haptic feedback to the patient and allowing them to gather information about their walking patterns for which they could not feel on their own.

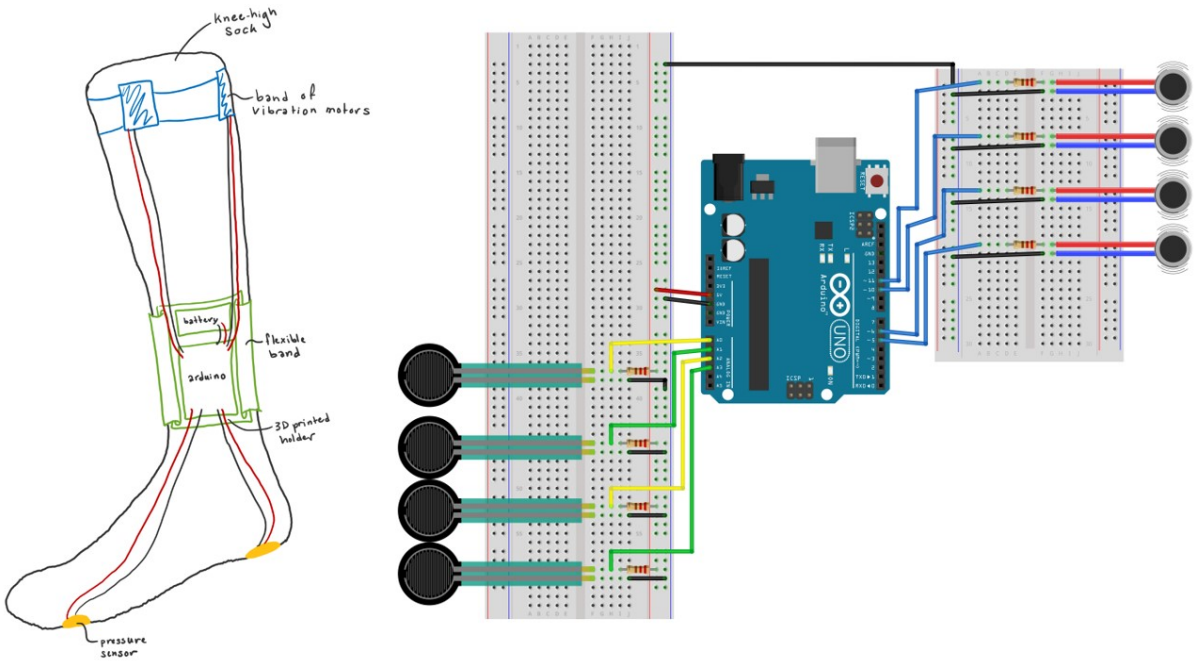

Figure 1: Design sketch and circuit schematic of full device design.

4.1 Key Prototype Choice: Pressure Sensor Type

As noted in the above paragraph, the final prototype uses four individual thin-film pressure sensors on the sole of the foot. When deciding what type of sensor to use, there were 2 main considerations. Firstly, should individual sensors or an entire insole be used? Second, what should the force limit of the sensors be? Individual sensors were chosen over a set insole sensor design, as it allowed for more customization in the sensor placement and the number of sensors used. Individual sensors can be placed in the ideal location for each patient, as discussed in section 4.3 below. An added benefit of using individual sensors is that they provided four individual inputs to the Arduino, making the project code very simple and the prototype easy to troubleshoot. The force limit needed for the pressure sensors was calculated using the equations below and the smallest sensors possible for the given peak foot force were chosen to reduce cost. 10 kg thin film pressure sensors were chosen to meet these requirements and since the peak force applied was calculated to be 2.98kg, there was no expected overloading of the sensors.

$$\begin{aligned} &\textit{Max Plantar Pressure } [7] \\ &= 230kpa = 33.36psi \\ &\textit{Diameter } [8] \\ &= 0.5in^2 \end{aligned} \qquad \begin{aligned} &\textit{Area} = \pi \times r^2 \\ &= \pi \times \left(\frac{0.5}{2}\right)^2 \\ &= 0.196in^2 \end{aligned} \qquad \begin{aligned} &\textit{Total Force} = 0.196in^2 \times 33.36psi \\ &= 6.55lbs \\ &\mathbf{= 2.98kg} \end{aligned}$$

4.2 Key Prototype Choice: Voltage Divider Resistors

As noted in the first paragraph of the prototype section, the thin-film pressure sensors act as R_2 in a typical a voltage divider circuit. To accurately detect the range of pressures applied to the sensor, an adequate first resistor, R_1, must be chosen for the voltage divider. An ideal R_1 would hold the output voltage at 2.5V when a mid-range resistance was provided by the pressure sensor.

As the sensors experience more pressure (patient is applying more pressure to one part of their foot), they become less resistive and would reduce the amount of voltage that the analog input pins receive. As the sensors experience less pressure (patient is lifting their foot), they become more resistive and would increase the amount of voltage that the analog input pins receive. In addition, picking an R_1 that was too large would drop all of the voltage and there analog input pins would not receive any voltage (V_{out} would always be close to 0), and if R_1 was too small it would not cause a significant voltage drop (V_{out} would always be close to 5). It should be noted that the pressure applied to the sensor and V_{out} are inversely proportional.

To choose the best resistor, R_1, a series of trials were conducted. For each sensor, potential resistor values of 47, 100, 407, 1K, 4.7K, and 10K ohms were tested. The resistor being tested was placed into the voltage divider circuit, then the user stepped onto the insole and stood normally (applying a medium level of pressure) and the output voltage was measured. This was repeated 5 times for each of the potential resistors, and the average output voltage was graphed. The resistor that provided a reading closest to 2.5 v when the user was standing normally was chosen as the final resistor (as outlined above). This was repeated for each of the four sensors with final R_1 values chosen to be 1kΩ, 470Ω, 1kΩ, and 470Ω for the front (big toe), medial (ball of foot), back (heel), and lateral sensors respectively as shown in Figure 2.

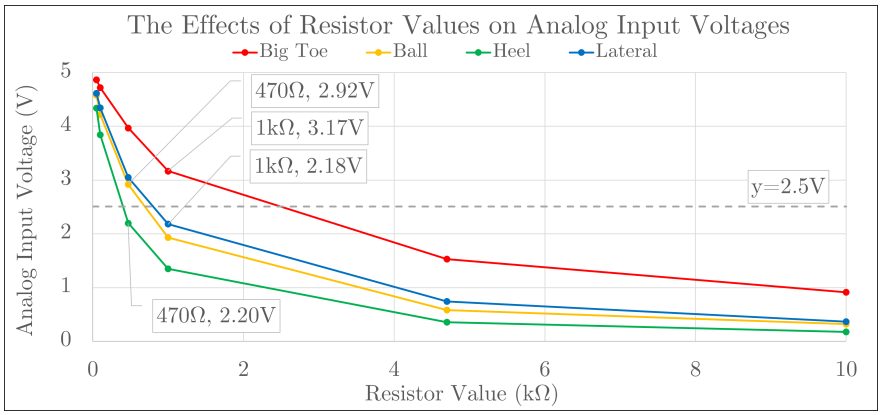

Figure 2: Graph showing the mean Vout for each of the resistors tested, and the resulting second resistor chosen for each sensor location.

4.3 Key Prototype Choice: Plantar Sensor Placement

To decide on the placement of the pressure sensors, it was essential to determine the locations of the foot which would receive the most pressure to provide accurate readings and map to the Cartesian directions of the motors. Since foot pressure distribution varies relative to foot arch type [9], the team first calculated the prototype user's foot arch type following the procedure set out in Imaizumi et al. The prototype user's arch height ratio was calculated by dividing the navicular bone height (measured at 6.2 cm) by the foot length (measured at 22.8 cm) to give a ratio of 0.27. This classified the prototype user's foot arch type as a high foot arch type, following the classification used by Imaizumi et al. (i.e., an arch height ratio greater than 0.25 is a high foot arch type). Once the user's foot arch type had been determined, the team considered the following foot pressure distribution (shown in Figure 3A) to determine the ideal sensor placement. In the figure, red indicates areas of the foot which receive the most pressure, while blue areas receive the least pressure. Hence, the sensors were placed on the great toe, lateral and medial metatarsals and at the heel (shown in Figure 3B). However, from the team's research, it was found that there

was significant debate surrounding the clinical significance of morphological parameters (such as foot arch type) in determining foot pressure distribution [10]. Thus, the team decided to conduct further tests to determine if the selected sensor placements (shown in Figure 3B) would be ideal for the user. In this report, only the testing for the sensor at the medial metatarsals position is included, with three other positions (shown in 3C) being tested: position A at the lower great toe, position B at the original location (medial metatarsals), position C at the middle metatarsals, and position D at the medial arch.

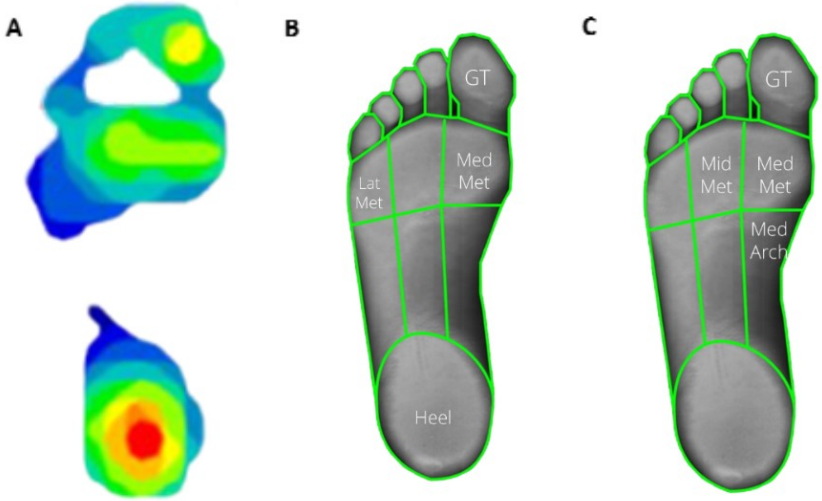

Figure 3: Images showing the foot pressure distribution (A) considered by the team to determine the ideal pressure sensor placement (B) adapted from Imaizumi et al. (C) shows the sensor testing performed to determine the ideal placement of the sensor originally placed at the medial metatarsals.

To test the sensor placement, the team laid down the sensors one at a time in the positions indicated in Figure 3C. The user was then asked to step on and then walk off the sensors to mimic a normal gait cycle. *From these voltage readings, a Q-Q plot was graphed using R, to determine if the data was normalized. The Q-Q plot for the sensor placed at position A was included in this report. As the line of best fit (showing the intersection of the quantiles calculated from the data and theoretical quantiles for a normal distribution) passes through nearly all the points, this indicates a normal distribution is a good fit for the data. Hence, as the data was shown to be normalized, an ANOVA test was then run to test for a significant difference in the mean voltage output at each sensor position. These results are summarized in Tables 1 & 2. A p-value less than 0.05 was found indicating that there was a statistically significant difference. To determine between which groups (i.e., which sensor positions) a significant difference occurs, a post-hoc Tukey test was run (results shown in Table 3). These results showed that there was a significant difference between locations B and A as well as locations B and D; however, no significant difference was found between locations B and C. The team decided to choose location B (i.e., the medial metatarsals) over location C since a location closer to the edge of the foot would provide greater accuracy in detecting the user's balance.*

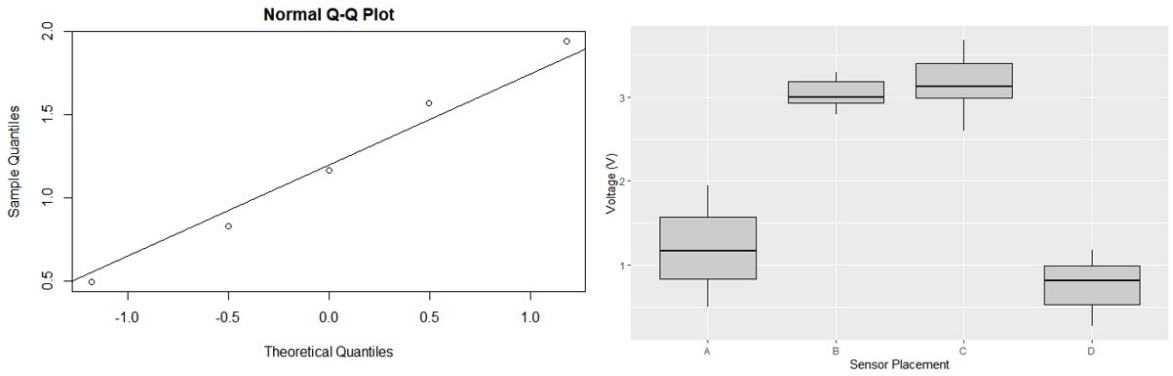

Figure 4: Q-Q plot for sensor placed at position A, illustrating that the data is normalized. The boxplot of the voltage readings taken at each position is shown on the left, to illustrate the difference in voltage readings at different positions.

TABLE 1: SUMMARY

Groups	*Count*	*Sum*	*Average*	*Variance*
A	5	6.005859	1.201172	0.329554
B	5	15.20508	3.041016	0.040798
C	5	15.78613	3.157227	0.168045
D	5	3.774414	0.754883	0.129099

TABLE 2: ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Between Groups	23.02689	3	7.67563	45.99658	4.32E-08	3.238872
Within Groups	2.669983	16	0.166874			
Total	25.69687	19				

TABLE 3: POST-HOC TUKEY TEST RESULTS

Treatment Pairs	***Tukey HSD p-value***	***Tukey HSD inference***
Position A vs B	0.0010053	Significant
Position B vs C	0.8999947	Insignificant
Position B vs D	0.0010053	Significant

5 Analysis

5.1 Design Choice Analysis: Motor Feedback

To evaluate the design choice of using motors to provide haptic feedback, user testing was conducted. A team member wore the device and was asked to identify what motor was vibrating on each trial. The user's ability to identify the vibrating motors was tested at 3 stimulus levels: low (1V sent to motors), medium (3V), and high (5V). Each level had 16 trials, 4 trails per motor, in a randomized order. The number of correct identifications for the motors at the three levels is shown in Figure 5.

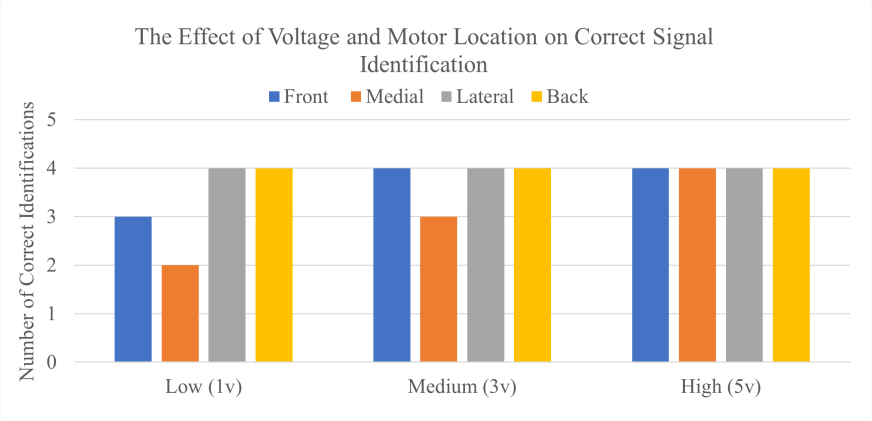

Figure 5: Graph showing the number of correct identification per motor for 3 different stimulus levels. A score or 4 means that all of the signals for that motor were identified correctly.

In Figure 5 it can be seen that the lateral and back motors were always properly identified when the user was asked to state which motor was on. However, the medial and front motors were not always correctly identified. For trials at the lower stimulus levels, the user sometimes stated that the front motor was on when the medial motor was on and vice versa.

To determine what causes this misidentification, analysis of the innervation of the lower human leg was conducted using Complete Anatomy software. Shown in Figure 6, this analysis found that the areas of front and medial sensors were both innervated by medial crural cutaneous branched of the saphenous nerve. Since both of these signals are being picked up by branches of the same main saphenous nerve and carried towards the central nervous system, the confusion in differentiation when stimulus is light makes sense. However, this discovery has serious implications. Depending on the patient's level of neuropathy, the motors may need to be placed at different heights on their leg. The level of innervation at this location, combined with the possibility of lower nerve sensitivity caused by their neuropathy may make the patient unable to differentiate between motor vibrations. If they are unable to do obtain the proper information, they will miss critical stimulus and be at risk of a fall.

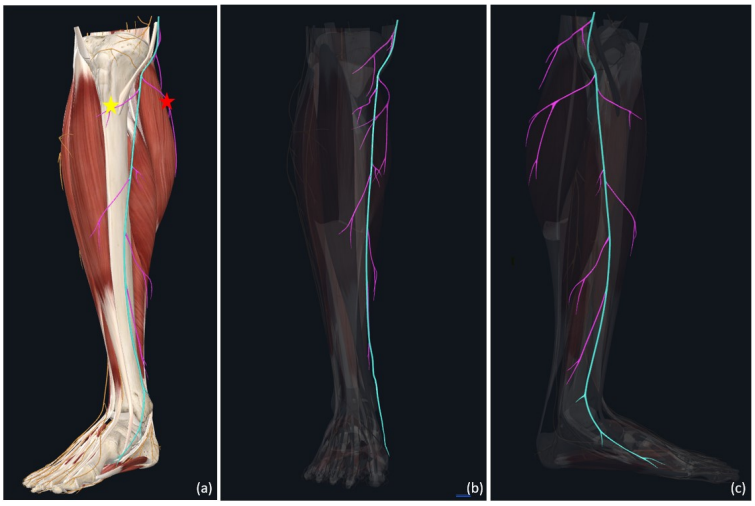

Figure 6: Analysis of innervation of human lower leg ins Complete Anatomy (a) diagram showing innervation of the lower leg, the yellow and red stars shows the approximate locations of the front and medial motors respectively (b) front view and (c) side view of the saphenous nerve that innervates the front and medial lower leg.

One redeeming factor found through the analysis is that the user was able to correctly identify the signalling motor at high stimulus levels 100% of the time. Identifying signals when there is high levels of stimulus is important as it indicates an improper pressure distribution, that may lead to a fall. If the user can reliably identify high motor feedback, this means that the device is good at performing it's primary goal and alerting the user to a problem with their gait. If this goal is achieved, the misidentification of specific motors at lower stimulus levels, may be overlooked in determining this early prototype's level of success.

Overall the analysis found that, although vibrating motors can provide adequate haptic feedback for some users and were proven to be reliable for high stimulus levels, they may not be the optimal feedback mechanism for all patients. Other design alternatives that would improve reliability and ease of identification should be considered in future designs.

6 Example Results

Figure 7: Final prototype on patient from the front and side.

As shown in Figures 7 & 8, and attached videos (uploaded separately to Dropbox), the device works as intended and is able to be worn while performing normal day-to-day tasks and moderate exercise.

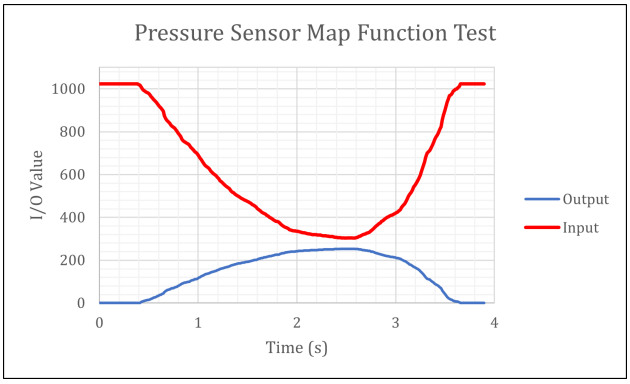

Figure 8: Graph showing the input readings from one pressure sensor and the output to the corresponding vibrating motor over 1 step. It should be noted that input lowers as the pressure increases because of the functioning of the thin-film pressure sensors. The analog read (sensor input) has a range of 300 - 1023 (the viable pressure range that can be applied by the foot) and the analog write (motor output) has a range of 0-255.

As shown in Figure 8, the sensors detect pressure variations throughout a step and proportionally relay this information to the motors that vibrate at varying intensities to convey accurate step information.

When watching video 1 (uploaded separately to Dropbox, please view with sound) it can be observed that as pressure is applied to the sensors the readings on the serial output change, and the motors on the cup can be heard vibrating at an increasing volume. This shows that the sensor-motor circuit performs its primary goal of providing proportional haptic feedback to the user.

The same outcome can be observed in video 2 (uploaded separately to Dropbox, please view). In this video, a team member can be seen wearing the device. At the end of the video, they stand stationary and lean in the four Cartesian directions applying pressure to the different sensors and pointing to the motor they can feel vibrating. This video also demonstrates that the device works as intended providing direct feedback from the sensors to the motors when pressure is applied.

Video 3 (uploaded separately to Dropbox, please view) shows a team member wearing the device while completing light exercise such as walking, stair climbing, balancing, etc. The goal of this video is to show that the prototype is robust and secure enough to be worn in everyday tasks. The bands and sock device housing keep all electrical components secure, prevent dangling wires, and keep the sensors and motors in their proper places. This prototype would be robust enough for light user testing with real patients.

7 Redesign

First, the device should be designed to allow for more variability. As stated in the "detailed sensor placement" section, the pressure sensors were placed in the ideal location for the prototype's user. However, individual's feet differ significantly and so would the ideal sensor location. In the current design, sensors cannot be moved easily to account for this. Therefore, it will be important to consider variability and patient customization in future iterations.

As stated by Dr. Dittmer in his opening presentation, patients are less likely to use their medical aide if it is detectable to the public [11]. Although the prototype cannot be seen under long pants, it is still highly detectable when the user is wearing shorts or tighter fitting clothing. Ideally in the final design, the aide would look no different from an average long-length sock. In future iterations of the design, the black box around the ankle that contains the Arduino would be replaced with small custom PCBs installed into the body of the sock. The sock would also be longer to fully cover the motors at the top. With these changes, the design would better meet the requirement of being undetectable to the public.

Currently, the circuit is not removable from the sock housing. This poses a problem as there is no way to wash or change the sock. Continuing to wear a dirty or damp sock can encourage fungal and bacterial growth leading to skin irritation, wounds, and infections that can be life-threatening [12]. In future iterations, the ability to remove the electrical components to wash and replace the sock housing should be considered. One way to achieve this is to make the device communicate wirelessly. By having one PCB and power source in the insole with the sensors and a second on a band at the top of the sock with the motors, they could use Bluetooth to relay information wirelessly. Placing these independent circuits on removable pieces (an insole that can be removed from foot of sock and a band containing the motors and PCB that can be removed from top of the sock) would allow for the sock to be washed and reused.

Currently, the device provides continuous direct proportional feedback from the sensors to the motors. Although this provides the user with accurate information about their steps, this repetitive continual stimulation may become ignored by the user over time as their brain diverts attentional resources to more pertinent stimuli [13]. In addition, the analysis above showed that motors may not be ideal and signals may get confused depending on their placement. Motor feedback may cause users to miss key information causing them to fall. In future iterations, the design choice of continual feedback vs feedback only when early fall signs are recognized and alternative feedback mechanisms should be investigated.

8 Discussion

The prototype created does address the requirements set at the beginning of the design process. It collects sensor data from the user's gait and informs them of this information using haptic feedback to prevent falls (as demonstrated in the Example Results section). This approach makes sense and works well under the contexts tested on the user for whom the device was customized. When comparing this device to other medical aides, there are benefits and drawbacks. This device uses a sock, so it is more comfortable and inconspicuous than an AFO and FES [2][5]. However, where an AFO can support those with motor neuropathy by controlling the lift of their foot [2], this haptic device cannot. The same can be said when comparing this device to FES braces that use electrical stimulation to create foot [5]. The prototype would only be a viable option for those with sensory neuropathy and not those with motor neuropathy who experience foot drop[6]. In addition, the prototype relies on a high level of innervation where the motors are placed, which may be a boundary depending on the patient's neuropathy. It is also not safe for use around water as it has exposed electrical components much like an FES but unlike an AFO [4]. There are benefits and drawbacks to each kind of gait assistive device, however, the prototype may prove useful for patients who find bulky AFOs uncomfortable and are worried about the electrical stimulation of an FES. In conclusion, this prototype presents a great opportunity to build upon and one day add to the repertoire of available gait aides for those suffering from peripheral neuropathy.

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