ABOUT THIS PAPER: This is a final report submitted to the Massachusetts Institute of Technology THINK Competition. I received funding and mentorship from THINK to construct this project. This report was filed after finishing the project. The project was awarded 1st place in the THINK Competition, was a Semi-finalist in the Regeneron Science Talent Search, and is a candidate in the National Gallery for America's Young Inventors.

A Preventative Solution to the Formation of Diabetic Foot Ulcers

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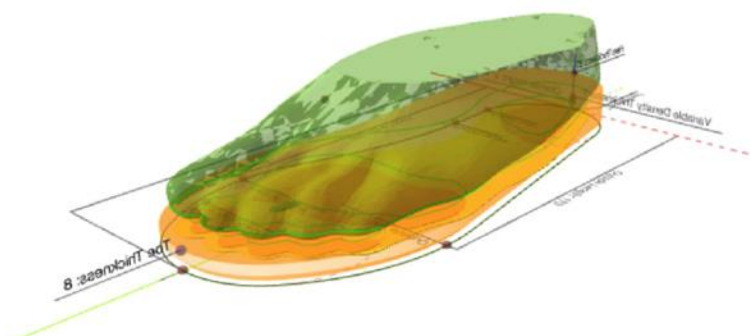

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A Preventative Solution to the Formation of Diabetic Foot Ulcers

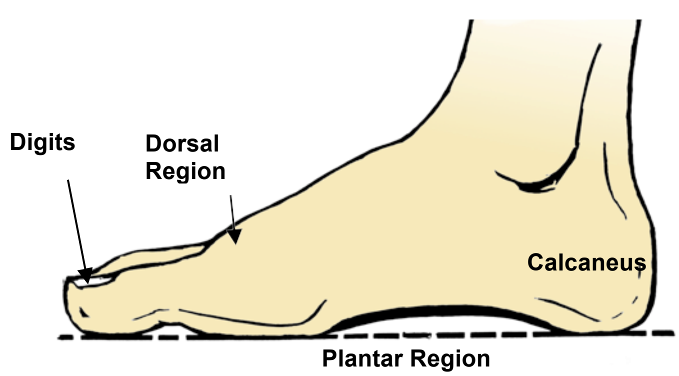
Abstract:

Diabetic polyneuropathy (DPN) is one of the most common complications of diabetes mellitus (diabetes). DPN is a disorder associated with impaired peripheral nerve function and reduced blood circulation in appendages. Even minor trauma to appendages can lead to the formation of chronic ulcers (non-healing wounds) that may require expensive medications, treatments, and even amputations. The formation of diabetic foot ulcers (DFUs) is the most prevalent consequence of DPN and results from improper foot placement and friction in shoes, which often begin unknown to the patient due to the impaired sensation. To significantly reduce the probability of forming DFUs, I developed a force-sensitive insole that could detect and correct misaligned foot positions in a user. I constructed a unique insole embedded with an array of Tekscan A301 force-sensitive resistors (FSRs). By monitoring pressure distributions across the user's foot, the insole can monitor the user's foot orientation inside of the shoe. An algorithm then analyzes the user's pressure distribution across the insole and, in the case of a potentially damage-inducing foot position, alerts the user via smartphone notification of the anatomical region of the foot currently misplaced. Data is also wirelessly logged in an external Google Spreadsheet that enables the patient and their medical advisors to observe and accurately respond to recurring trends in the user's foot placement. After calibrating and testing the prototype, it was found that the insole was highly accurate in detecting and correcting misaligned versus correctly-aligned foot positions. By developing a technology that can be integrated into everyday life, I developed a patient-friendly solution to preventing DFUs and improving the quality of life for patients with DPN.

Problem Description:

Diabetes mellitus, or more commonly referred to as diabetes, is a disorder characterized by chronic high blood sugars due to a combination of insulin deficiency and insulin resistance. Insulin is a protein-hormone secreted by beta cells located in islets of the pancreas in response to carbohydrate consumption. Failure to produce insulin (insulin deficiency) or respond appropriately to insulin (insulin resistance) over long periods of time can lead to high blood sugars that will damage the nerves and blood vessels. When such damage affects nerves, irreversible loss of nervous sensation occurs. This condition, called diabetic polyneuropathy (DPN), is seen in all forms of diabetes [1]. High blood sugar also leads to reduced blood circulation in appendages. If exposed to even mild trauma, this reduced blood circulation can lead to impaired wound healing due to the inadequate oxygenation and lack of blood plasma -- a compound necessary for wound healing.

Figure 1. General regions of the foot. Note the plantar and calcaneus.



When combined, vitiated sensation along with reduced blood flow in appendages can lead to patients unknowingly injuring themselves and developing non-healing bruises and cuts. The most common place for DPN-linked ulcers (non-healing wounds) to form is on the feet (in the plantar and inter-digital regions -- see Figure 1) due to their consistent friction with objects, such as shoes. Because these DPN patients lack sensation in their feet, they may inadvertently orient their feet so that there is undue pressure on certain points of the foot causing bruising and cuts [2]. Such wounds are likely to develop chronic non-healing infections (i.e. ulcers) requiring expensive treatments including amputation. Thus, diabetic foot ulcers (DFUs) are among the most prevalent complications of any form of diabetes for tens of millions around the globe. In the United States alone, 9.4% of all Americans have been diagnosed with some form of diabetes [3]. Of these individuals, 15-25% have contracted chronic DFUs. These patients face the risk of amputation and exorbitant medical bills. In the case of amputation, mortality rates increase significantly. One study found that the average survival time of a non-diabetic patient after the amputation of a lower extremity (such as the legs) was approximately 7.38 years while the survival rate of a diabetic patient for the same amputation was only 2.0 years [4]. In addition, the average DFU/DPN patient spent about four times as much on medical bills in 2015 ($30,755) compared to a typical diabetic patient ($6,632) in the same year [5].

Having evaluated the extent of DFUs as well as their monetary and health consequences, it is clear that a solution that can prevent DFUs is necessary. Already, a number of preventative solutions have been implemented in the medical field to help combat the formation of DFUs. Most important among these solutions is the protection of the feet. Many doctors recommend that patients wear DPN shoes. These shoes contain enlarged internal spaces with additional padding and shock-absorbing soles that can reduce the likelihood of developing DFUs. Nonetheless, patients who lack lower-body sensation can still injure themselves with such shoes if their feet become contracted or oriented in a way that can lead to increased amounts of friction and bruising. Other preventative techniques for DFUs include the frequent examination of feet (especially interdigital spaces), prudent trimming of toenails, and moisturization of the feet to prevent skin cracking and wounds [2]. Some technological solutions to DFUs have also been proposed, however few, if any, have ever been developed for commercial use. A group of scientists led by Dr. Metin Yavuz, a biomedical engineer from Fort Worth University, developed a shoe that could regulate temperatures to prevent fungi formation [6]. However, this technology was never made public. Some pressure sensing footwear has been developed for medical data logging purposes, but not for immediate patient-response mechanisms. While all of these technologies do present some benefit for patients, they fail to directly address the primary cause of DFUs: shoe-to-foot friction. DPN shoes, as mentioned earlier, do not prevent feet from taking on harmful positions. Common foot examination and care techniques can detect early trauma and ulcers but may not be able to prevent the aforementioned friction from causing DFUs. And emerging technologies, are still being developed and have been mostly used for data-logging purposes with doctors.

Project Idea and Goals:

To address the issue of DFUs in DPN patients, I proposed the construction of a novel insole with two primary functions: (1) guide the user's foot into an optimal position which minimizes foot-to-shoe friction and allows it to receive the maximal protection from a DPN shoe and (2) detect and alert the user when their foot leaves the optimal position. To accomplish the former goal, 3D modeling software and later vacuum casting technology was used to create a defined impression of the contour of the user's foot on the insole. In the case that the user's foot unintentionally left its natural positioning within the impression, readings from a network of A301 FSRs strategically placed at the various locations of the insole to detect inaccuracies in the user's foot placement would trigger a microcontroller to send notifications to a smartphone and log the data into a Google Sheets spreadsheet for further analysis. The primary goal of this project was to construct and test an insole that combined the FSR-impression system and observe its potential applications to the medical field.

The Functioning of the FSR-impression System:

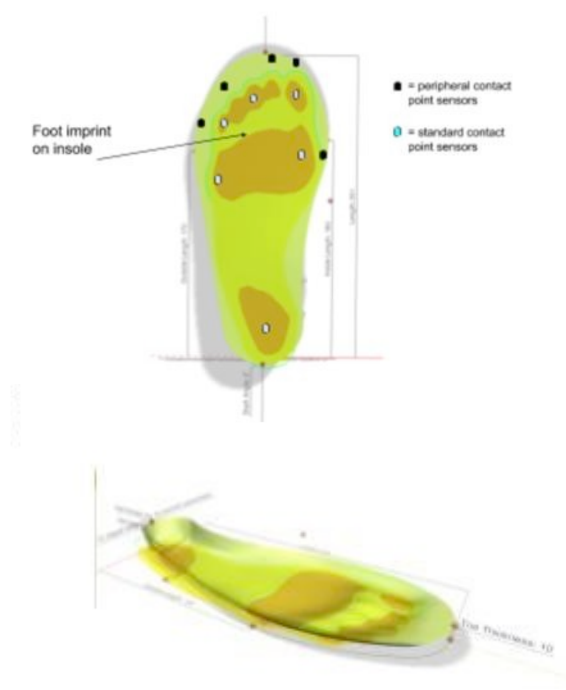
The anatomy of the human foot reveals three distinct locations where maximal contact is made between the ground and right foot (Figure 2): calcaneus (B), first metatarsal (A), and fifth metatarsal (C). The high levels of downward force that are exerted by a person during their typical stride make these regions ideal markers for where the user's foot is located in the shoe. By determining the location of the maximal pressure points, the orthotic "tripod" can be created and used to predict foot orientation [7]. For the purposes of this project, the locations of high levels of downward force will be referred to as the "standard points of contact" and will be used to detect the position of the foot. Tekscan Flexiforce A301 FSRs will be placed at the following standard points of contact: calcaneus, first metatarsal, fifth metatarsal, first toe pad ("big toe"), and fifth toe pad ("pinky toe"). We can determine whether or not a portion of the foot is in the correct position depending on the magnitude of the analog reading taken by the microcontroller. In addition to the standard points of contact, a second measurement will be taken to directly detect foot-to-shoe friction. This will consist of vertically oriented A301 FSRs located at regions of the

Figure 2. Demonstrates three points of the orthotic foot tripod (right foot): calcaneus (b), first metatarsal (a), and fifth metatarsal – on other side of foot (c)

foot most likely to experience friction with the side of a shoe. These will be defined as the intersection between the sesamoid and proximal phalanx, tips of the digits, and intersection of the metatarsal and proximal phalanx (Figures 3, 4) [8]. To help the user ensure that their foot is in the optimal position of the insole, an impression of their feet will be embedded into the insole so that it is possible for the user's foot to naturally fit into place (Figure 4). Depending on the degree of the user's sensational impairment, the user might be able to feel whether their foot is properly placed simply from the ridges and valleys of the contoured insole. Otherwise, the FSR-impression system will detect improper foot placement and alert the user via smartphone notification.

Figure 3. Regions of foot relevant to sensor placement.

Figure 4. (Top) The placement of peripheral and standard point of contact sensors. (Bottom) Insole contour using 3D model created with Gensole.



All FSRs will be wired to a small microcontroller, which will evaluate incoming data and determine whether or not to send a message to the user. In a healthy person's stride, the standard contact points will experience sudden surges in pressure for each step. If the person stands still, all sensors will detect constant pressure. And if the person sits, slight pressure will still be detected if all components of foot are in the "proper position." In a DPN patient however, if any of the standard points of contact sensors receive minimal force data for an extended period of time, this may indicate that the user's foot is out of the correct position indicated by the imprint and thus the microcontroller will send an alert to the user's smartphone telling them the following information: the foot that needs to be repositioned and the portion of the foot that is triggering the sensor. If any of the peripheral contact points are triggered for an extended period of time, indicating unwanted friction between foot and shoe, the module will similarly alert the user to re-position their feet. The "extended period of time" mentioned in the above explanations will be 60 seconds. This time limit will allow for the insole to detect and alert the user of only damage-inducing foot position, not minor foot position changes.

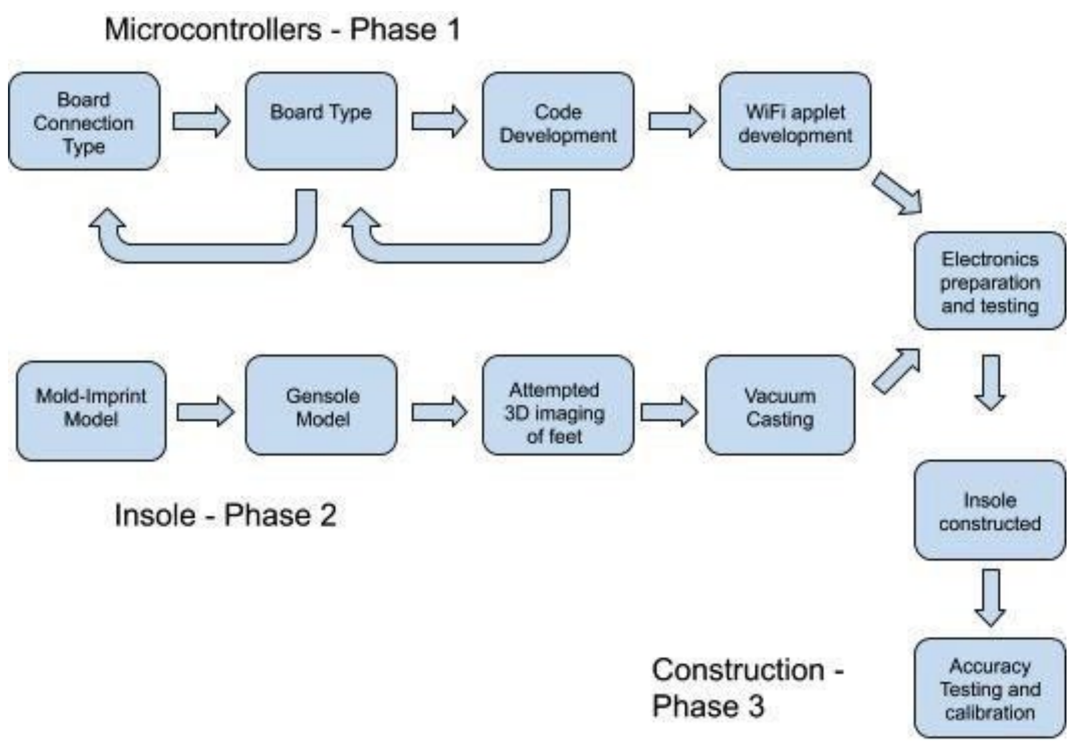
This solution is not meant to take the place of existing treatments recommended by doctors.

Rather, it is meant to be implemented in parallel with existing technologies, like DPN shoes, to prevent DFUs.

Procedure:

The path to achieving the desired product was by no means a linear one. The flowchart below illustrates the process by which the final product was developed. In this section, each phase of the flowchart is summarized. Materials and a circuit schematic can be found in Appendix C.

Overview of Project Procedure:



Phase 1: Hardware and Software Development

Board Connection Platform:

When this project was proposed, it was determined that a Bluetooth Low Energy (BLE) connection would be established between the insole's microcontroller and user's smartphone. This would allow for rapid, reliable data transmission between microcontroller and smartphone. As the connection would be tested on my own smartphone, an iPhone, it was determined that a BLE connection would be necessary as Apple smartphones are only able to connect to the BLE frequency. In addition, as there would be two microcontrollers (one per insole), the master/slave configuration would have to be used in order for the user to receive data from both insoles (this is because it is very difficult to pair one IOS device to multiple BLE devices). The master/slave configuration is a feature of some Bluetooth modules that allows for data to be relayed from a "slave" module to a "master" module which can connect to a user's smartphone. This allows for the user to only connect their phone to one Bluetooth device. After developing an app that could be downloaded onto user's phones to connect to the microcontroller via BLE using XCode Swift, licensing issues with Apple's Developer Program prevented the app from being able to be tested. As a result of this setback, a separate app called "Serial," which was available on the IOS App Store, was used to achieve similar results (Figure 5). However, after extensive board testing using the Adafruit Huzzah ESP32, it was determined that the master/slave configuration would likely not be possible on the board without introducing large amounts of new code which might disrupt the functioning of the current code (see Board Type and Code and Wi-Fi Development). After testing on other boards and meeting similar difficulties in establishing a reliable Bluetooth connection (and other board-specific irregularities), the BLE platform was abandoned. Instead, a Wi-Fi-based connection was successfully established on the Adafruit Huzzah ESP32 and other boards. This Wi-Fi based connection is the current method of data transmission and allows for notifications to be sent to a user's smartphone and data logging via Google Sheets (see Code and Wi-Fi Development).

Figure 5. Early Bluetooth Serial interface on iPhone.

Board Type:

As alluded to in previous sections, a variety of boards were tested to find a suitable candidate for the purposes of this project. The original board proposed was the Adafruit Huzzah ESP32 which was chosen because of its abundance of analog input pins, integrated Wi-Fi, and integrated BLE. Nonetheless, after failed attempts to establish a reliable master/slave BLE connection using the board, along with the board's tendency to overheat (which could cause damage to a wearer) and generate inaccurate analog readings due to frequent electrical noise, this board was discarded. A new type of Adafruit board, called the Bluefruit 32u4 was then purchased and tested. Attempting to use the board's integrated BLE led to similar issues as described with the Huzzah ESP32. A series of other boards were then tested, including the Arduino Nano microcontroller. This board did not have an integrated BLE module however could be connected to a HC-10 module to facilitate a BLE connection. While the board appeared to be promising as a master/slave connection was established between HC-10 modules, the board was later abandoned because of its lack of an onboard 2-pin JST port, necessary for the board to be powered by a lithium ion battery and without USB connection to a computer.

When the decision was made to pursue a Wi-Fi based connection between microcontroller and smartphone, the Arduino Rev 2 Wi-Fi was tried. This board immediately proved to be suited for our tasks and successfully transmitted data to both a Google Sheets spreadsheet and smartphone (see Code and Wi-Fi Development). Nonetheless, the board was far too large to be mounted on the insole. Thus, a similar board from Arduino, called the MKR 1010 Wi-Fi, was used. After major changes to the main code were made so that compilation could occur on this board's unique processor, the board proved to be functional. Its accurate analog readings made it the preferred board over the Huzzah ESP32. The MKR 1010 Wi-Fi is the current board in use.

Code and Wi-Fi Applet Development:

The original code developed for this project had three primary goals: receive and analyze sensor readings, determine whether readings represented a significant incorrect foot position, and alert the user via smartphone BLE if an incorrect position had occurred. Due to the large number sensors connected to the microcontroller, an object-oriented approach was taken towards code design. Using the Arduino IDE, a separate library was created that defined an FSR class. Each FSR sensor was given an object that contained instance variables representing the analog input pin and several counters (these would be used to detect and respond to only repetitive stimuli). All objects were placed into arrays corresponding to their sensor type: standard point of contact or peripheral point of contact. Several methods (or "functions" as the Arduino IDE is derived from C++) were created to evaluate each object's analog input reading. Then, if the event had occurred frequently (at least five times) in the span of one minute, an alert would be sent to the user describing the position of the foot that was misplaced in the following format: "Incorrect position at: [foot region]." This function existed to ensure that minor incorrect positions that may be not be significant were not consistently pestering the user. Each function was specific to either the standard points of contact or peripheral points of contact. Each had different pressure thresholds to account for the varying degrees of force applied at different regions of the foot. Analog readings are proportional to the amount of force exerted.

When it was decided to switch to a Wi-Fi based form of data transmission, the code was changed to allow for Internet connectivity. A series of new functions were added that connected to a local Wi-Fi network or hotspot given the correct Service Set Identifier (ssid) and password. The ability for the board to connect to a smartphone-generated hotspot allows for its use in locations without Wi-Fi connection. Due to the relatively data-efficient process of data transmission, only a few kilobytes of data are used in this process. In addition, the IFTTT network was used to create a series of "applets", or miniature programs that performed a single action

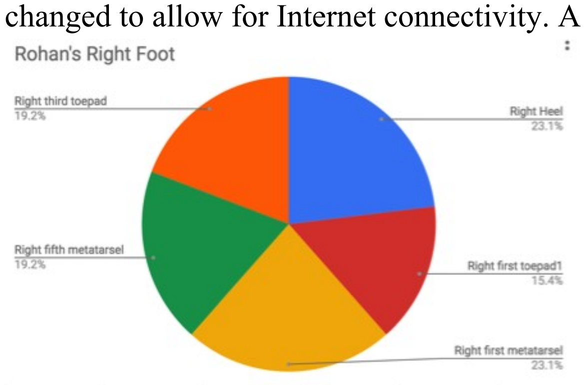


Figure 6. A Google Sheets pie graph made from sample data of my foot.

and could be called upon by a single API key. IFTTT network was created to allow for users to create applets that performed useful tasks, such as monitoring a news feed for articles that fit the tastes of the user. However, using the Webhooks program, API keys could be assigned to these actions and used in the Arduino IDE code to transmit data. Using these API keys, along with embedded JSON objects, strings or integer values could be sent from a microcontroller to data sheets and smartphones. All messages were time-stamped as well to help the user identify the time at which the incorrect position occurred.

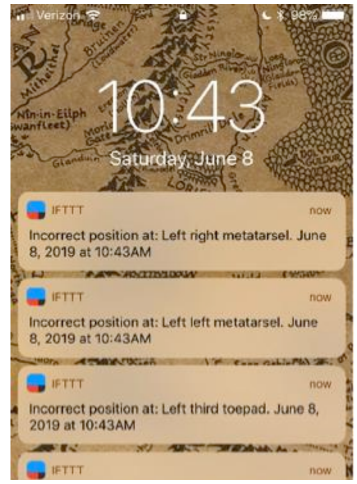


Figure 7. iPhone notifications sent via the IFTTT platform.

As C++ is not an object-oriented program, it took a great deal of time to figure out how to compile the code in the language. Nonetheless, even after compiling the code, it was found that not all board processors could run the code. Among these boards was the MKR 1010 Wi-Fi. As a result, the code was completely rewritten to eliminate object-oriented aspects. The final code still functioned similarly to the object-oriented code, and had improvements in its repetitive error detection functions, but the code was longer and more redundant. While it is not the most efficient program, it will function for this project. Examples of the smartphone notification (possible for Android and IOS devices) and spreadsheet entries are shown to the left (Figures 6, 7). Please see Appendix A to view both forms of code.

Phase 2: Insole Development

The goal of all models described below (until vacuum casting) was to obtain a 3D file of an insole with an embedded contour of the foot that could be 3D printed on silicone material. Once achieved, the 3D schematic would be printed on silicone material in the lab of Professor Paul Shepard of Cornell University at his Organic Laboratory. A graduate student of Professor Shepard named Ronald Heiser had agreed to do the printing (for free).

Mold-Imprint Model:

The mold-imprint model was the first attempt at creating an insole with an embedded contour. Unfortunately, it never reached the implementation stage as early simulations revealed major errors in the design. This model consisted of using a Generic insole design imported from the Gensole Insole 3D Modeling program and overlaying the 3D scan of a foot onto it. This was to be done on the program Fusion 360 by Adobe (Figure 8). The foot scans were of a random

Figure 8. Attempting to use the mold-imprint model on Tinker cad software.

patient and were available on the Gensole program. After overlaying the foot onto the insole, it was found that the impression would be too jagged and not ideal for the smooth contours required of the insole.

Gensole Model and Partnership with Dr. James Robison:

It was determined that another way to create the desired insole was to import a 3D scan of my feet into the Gensole platform. The "sole morph" feature could be used to generate an embedded contour in the insole. The imported files, however, had to be in the STL-ASCII format to compile. To obtain these scans, a partnership was reached with a local podiatrist at Marin Foot and Ankle: James Robison, DPM. Dr. Robison expressed interest in this project and agreed to provide free support. After a few meetings, he used a Sharp Shape Scanner (SSScanner) to take 3D images of my feet. These images were then sent to Root Laboratories Inc. where they were to be processed and the proper files sent back. Unfortunately, the lab was not able to convert them to the correct STL form, or even a similar OBJ or STL Binary form (which could be converted to STL-ASCII) due to the old scanning equipment that was used. The file form in the SCN format could not be opened even after using SCN-specific applications such as Image Scope. After speaking to representatives from Root Labs, I was put in contact with a technician at Sharp Shape, the scanner manufacturing company. He explained that the company was phasing out its SSScanners and the current files could not be converted. Dr. Robison, unfortunately did not have the new scanner yet, so this possibility was ruled out. Nonetheless, a sample insole was 3D printed on plastic to demonstrate the potential feasibility of this plan in the future, if Dr. Robison purchases the new scanners from Sharp Shape (Figure 9). The file used was from Gensole's platform and does not match the contour of my feet.

Figure 9. (Top) 3D schematic of insole. (Bottom) 3D printed insole on plastic.

Vacuum Casting:

Dr. Robison, besides being a local podiatrist, also used to work as an orthotics specialist. In his office, he has a lab space with a variety of equipment used to create custom insoles for his patients. After the 3D printing ventures failed, Dr. Robison proposed an alternative way of creating an insole: vacuum casting technology. This old technology was not generally used to create

Figure 10. (Left) Plaster casts of my feet. (Right) Bio-Foam imprints sent to Root Labs Inc.

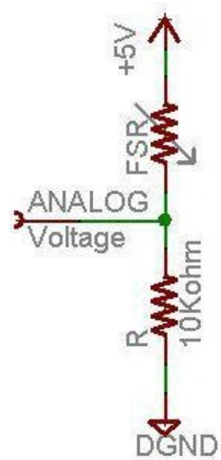
contours of a user's foot onto an insole, however the process could be altered to do so. Using Bio-Foam®, Dr. Robison obtained impressions of my feet on a foam surface (Figure 10). These pseudo-scans were sent to Root Laboratories Inc. Using a process by which a positive cast was made from the negative foot impressions in the confines of a vacuum, clay molds were made of my feet and sent back to Dr. Robison (Figure 10). These molds were then covered in a heat-moldable foam that caused them to precisely capture the contours of my feet. The foam insole was then ready to be lined with my hardware.

Phase 3: Electronics and Insole Construction

Assembly of Voltage Divider Circuits:

To connect an FSR to a microcontroller, it is necessary for a voltage divider circuit to be made. A 5V input is required for the anode of the FSR. The cathode pin must be split between an analog input lead and 10K Ohm resistor which leads to ground. The value of the resistor varies depending on the resistivity of the FSR and voltage intake limits of the microcontroller pins. The greater the value of the resistance however, the less sensitive the FSR becomes. It was decided to use a 10K Ohm resistor, as opposed to the initially proposed 1M Ohm resistor, to allow for increased sensitivity but also a strong resistor to prevent damage to the board. The 10K resistor also does not overheat when voltage is applied because it has such a high resistance value relative to the amount of voltage passing through it.

Figure 11.



The voltage divider circuits were assembled according to the schematic at the right (Figure 11). First, a female-female jumper wire was severed and soldered at a three-way junction to the 10K resistor and a long strip of PCB wire. Next, a second strip of PCB wire was soldered to the opposite end of the resistor (resistors were not polarized so position did not matter). Next, female headers were added to the ends of the resistor-PCB wire and first PCB wire. All intersections were covered with heat shrink to prevent any potential short circuits (Figure 16). This process was repeated 16 times. In addition to the soldering of the voltage divider circuits, each jumper wire connected to the anode (VCC end) of the FSR needed to be extended to span the full length of the insole.

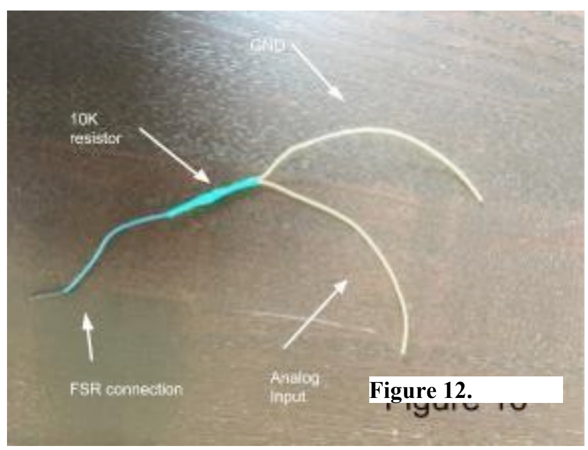


Figure 12.

Board Connections:

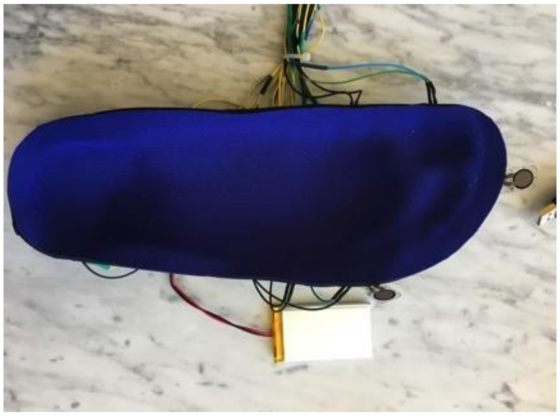
A variety of challenges were encountered throughout the hardware construction process. A major challenge was that the MKR 1010 Wi-Fi did not have the same number of analog inputs as the Adafruit Huzzah ESP32 did. As a result, the number of sensors per insole had to be reduced to just seven. Nonetheless, with advice from Dr. Robison, these sensors were placed at strategic locations that would allow the detection of improper foot position. Currently, the sensors in the insole are placed at the following standard points of contact: calcaneus, first metatarsal, fifth metatarsal, first toe pad, and fifth toe pad. Peripheral sensors are placed at the intersection of the metatarsal and proximal phalanx along with the front of the third toe. These areas are the most likely to experience foot-to-shoe friction in diabetics, according to Dr. Robison.

A second problem that was encountered was the presence of only one ground and one VCC pin the MKR 1010 Wi-Fi. Thus, it became necessary to split the pin to power all seven FSRs. As there is no easy way to split the pin without the use of a breadboard, a unique approach was taken using microcontroller pin headers and copper metal sheets. Using extra pin headers from the many boards that were not used, four eight-pin strips were made. Next, for each strip, a 1mm wide band of copper metal was cut to the length of the eight pin-strip and soldered into place, creating a makeshift terminal. The bottom of the headers was covered in electrical tape to prevent short circuits. After running several trials each individual sensor and then the entire group of sensors, it was determined that the reduction in power per sensor did not appreciably affect their performance or accuracy. By adjusting the pressure thresholds in the main code, I could account for any lower values caused reduced power to each sensor.

Insole Construction:

The insole itself was constructed at Dr. Robison's office in his lab-space. Using a heat gun and a strong adhesive known as "Barge," the standard point of contact sensors were adhered to their appropriate positions on the foam insole. Then, a layer of neoprene (which is often used to construct DPN shoes) was adhered to the insole to cover the sensors and foam insole to prevent damage to the FSRs. The peripheral sensors were then added to their appropriate locations. All leads were threaded under the foam insole and tied together into a single bundle of wires that travelled up through the shoelaces and to the microcontroller located outside of the shoe.

It should be noted that an important issue that arose was the accessibility of the microcontroller during the testing process. Because the microcontroller was originally meant to be enclosed in the insole, it was difficult to manipulate wire connections and sensor positions as the insole was being tested. For this reason, the microcontroller and all sensor leads are located outside of the shoe for greater accessibility until the insole has been completely calibrated. This allows for greater accessibility to the microcontroller. The images below show the completed right-foot insole (Figures 13). The insole runs by simply plugging in the lithium-ion battery.



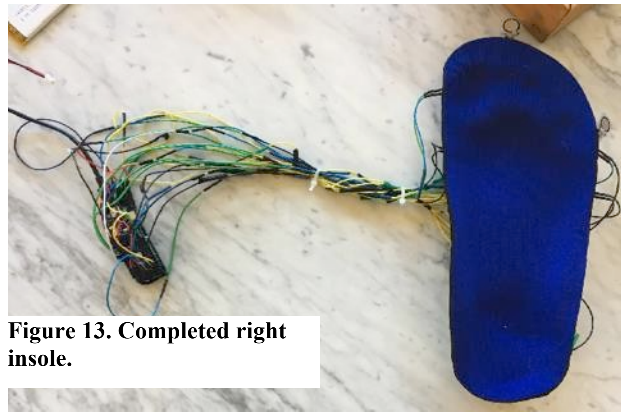


Figure 13. Completed right insole.

Project Timeline:

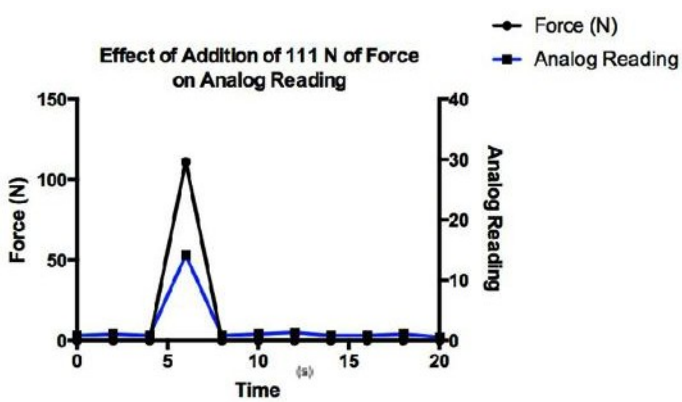
It should be noted that due to a variety of setbacks, the timeline for the completion of this project was extended significantly passed the estimated completion time of early May. The final project was completed in the first week of June.

Results and Testing:

The primary purpose of this experiment was to test the hypothesis that the FSR-impression system accurately measures the orientation of the user's foot in a shoe. Thus, calibration was a large part of the testing process. In this section, I discuss the process of calibrating the insole. I calibrated the insole to my feet.

Finding the Range of Analog Values for Large Force

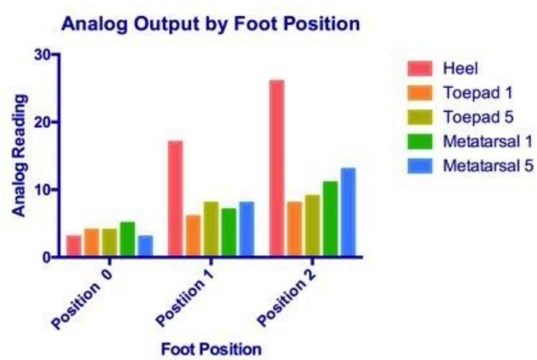
To begin the calibration process, it was imperative to understand the full range of analog values that could be generated from varying levels of force applied to the FSR sensors. The process began by running all 14 FSR sensors that would be used across both insoles and testing the effect of the addition of 25 lb. weight or 111 N of downward force on the analog reading (no units). The graph below represents the effect of the addition of the force on analog readings for one FSR tested when weight was added at the sixth second.



The purpose of this experiment was to establish a range of maximum and minimum values for the FSR from a concentrated force-source. In the insole, the addition of neoprene will absorb and dissipate foot-impact force so the user's full weight will never be exerted on any FSR. From this experiment, it was found that the maximal analog reading for the sensors was 123. The minimal reading was 0. The relatively small readings picked up by the microcontroller's analog pins when 0 N of force was added were likely due to static electricity.

Finding the Range of Analog Values for the Insole

Having established a range of potential values, all five standard-point-of-contact FSRs on the insole were then tested. A short program that displayed only the analog readings from all seven FSRs was written and its results are shown below. As there was no quantitative way to measure the exact force exerted by my feet, three positions were tested: no foot (position 0), one foot on insole and one foot off insole (position 1), and standing on one foot on insole (position 2). These weights correlate to approximately (0 N, 311 N, and 511N, although the neoprene likely caused less than a third of the exerted force to be detected by the FSR). Three trials were completed and their average results shown in the graph (below).

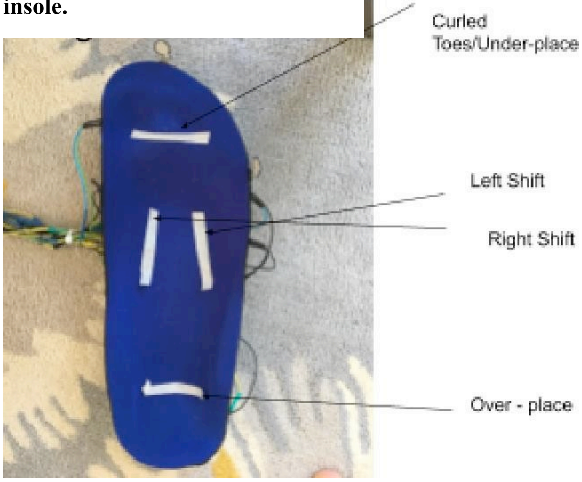


The results of this experiment demonstrated that (1) the range of analog values was in fact only from 0 to approximately 26 and (2) differing regions of the feet exerted vastly different analog readings. Again, the fluctuations shown in the graph when no force was added likely are caused by small amounts of static electricity detected by the microcontroller analog input pins. As long as all threshold values are above the maximum value observed from the 0 N readings (5), the insole should remain accurate. Based on these findings, it was decided to divide the standard points of contact FSRs into three groups, each with separate threshold values: calcaneus, metatarsals, and toes.

Determining the Threshold Values for Each of the Three Standard Point of Contact FSR Groups

At this point, I could begin testing minimum threshold analog values for the detection of the user's foot. To evaluate the accuracy of the current threshold values, six-foot positions were tested (Figure 15). The error notifications generated by each position were compared with the expected error notifications (shown in the table below), and the total number of inaccurate notifications was displayed. As the expected error notifications for each position were decided only off which sensors would be physically covered by a foot based on the given foot position, it was possible that other sensors other than the expected sensors may detect force if some pressure was being dissipated to them based on the current position. For this reason, if an observed error that was not an expected error occurred in all three tests, it was not counted as an error. Each set of calibration values was tested three times and the frequency of each error notification was recorded. For a threshold value to be deemed sufficient, it had to receive the correct expected values for all positions and generate fewer than three total errors (deviations from expected values). To ensure that the foot placement for each position was consistent for each trial, small strips of tape were placed on the insole to define the angle of rotation or distance to move the foot forwards or backwards (Figure 14). As shown in Figure 14, the over-place strip was placed 5 cm from the bottom edge of the insole. The left-shifted strip was placed 3.5 cm from the right edge (measured from the tape's center). The right-shifted strip was placed 3.5 cm from the left edge (measured from the tape's center). The under-placed strip, which also served as the toe-curling strip, was located 5 cm from the top tip of the insole. Because the insole was tested outside of the shoe, peripheral sensors could not be directly activated so their calibration has been delayed until the insoles are finalized -- see below. The data below refers only to the calibration of the standard point of contact FSRs.

Figure 14. Testing positioning of insole.



Foot Position	**Expected Values**
Normal Placement (A)	None
Curled Toes (B)	1st toepad, 1st metatarsal, 5th toepad, 5th metatarsal
Over - placed (C)	Calcaneus
Left - shifted (D)	5th toepad, 5th metatarsal
Right - shifted (E)	1st toepad, 1st metatarsal

Error Message Abbreviations

Error Message	Abbreviation
Calcaneus	C
1st Metatarsal	M1
5th Metatarsal	M5
1st Toe pad	T1
5th Toe pad	T5

Figure 15. Foot positioning.

Under - placed (F)	1st toepad, 1st metatarsal, 5th toepad, 5th metatarsal

Below is a sample data set generated from the following the calibration values currently in use. For images of each trial and a screenshot of the images that appeared on the screen, see Appendix B. Abbreviations are shown in the table above.

Calibration Values

Region	**Analog Value**
Calcaneus	10
Toes	7
Metatarsals	8

Right Insole Calibration -- Test 5

Position (see figure)	Expected	Trial 1	Trial 2	Trial 3	Error Count
No foot (Neg. control)	T1, T5, M1, M5, C	T1, T5, M1, M5, C	T1, T5, M1, M5, C	T1, T5, M1, M5, C	0
A	None	None	None	None	0
B	T1, T5, M1, M5	T1, T5, M1, M5	T1, T5, M1, M5	T1, T5, M1, M5	0
C	C	C	C	C	0
D	T5, M5	M5, M1, T5	T5, M1, T5	T5, M1, T5	0
E	T1, M1	M1, T1, M5	M5 ,M1, __	M1, M5 , __	2*
F	T1, M1, T5, M5	T1, M1, T5, M5	T1, M1, T5, M5	T1, M1, T5, M5	0
Total					2

*Deviations from expected value are highlighted. If same deviation occurs in all three trials, it is not counted in the "Total Error" column

Highlighted values represent deviations from expected values. The number of errors is tallied in the far-right column. There is one exception however. As explained above, if a repeated deviation occurs in all trials, it is not countered as an error. The reason for this is that despite certain sensors being physically covered by the foot, force may not be being detected by the FSRs if the foot is not in the correct valley of the embedded contour. In an incorrect position, the user's foot will be dissipating great amounts of force due to the valleys of the surrounding contours and thus will not trigger the FSRs below their feet. This is not a design flaw, rather a highly accurate representation of the positioning of a user's foot. As shown in the table for both positions D and E, some repetitive deviations were generated, but for the aforementioned reasons, they were not counted as errors.

The following table summarizes all of the trials done in this experiment by describing the total number of errors for each calibration setting. After 5 trials, I reached a set of threshold values that could accurately determine position of a user's foot in the shoe, demonstrating that the FSR-impression system was a feasible solution for monitoring user foot position. 15 for all threshold values was chosen arbitrarily as a starting point.

Analog Threshold Values vs. Total Number of Deviations from Expected Values

Total Errors	Test 1			Test 2			Test 3			Test 4			Test 5		
	Met.	Toe	Heel	Met.	Toe	Heel	Met.	Toe	Heel	Met.	Toe	Heel	Met.	Toe	Heel
	15	15	15	10	9	13	9	8	12	8	7	11	8	7	10
	12			10			8			5			2		

By Test 5, the total number of errors generated had decreased to two, enough to satisfy the criteria stated above.

Throughout the calibration process, the testing was conducted outside of the shoe for a variety of reasons. First, in order to ensure that the foot was performing the correct testing position, it was vital to be able to observe the foot. Secondly, several small modifications are being made to the insole currently, such as the trimming of the neoprene and rounding of the insole edges that prevented us from fitting the insole into a shoe. As a result, the peripheral points of contact FSRs could not be tested, as they detect foot-to-shoe friction. The determined calibration values are the same for both insoles.

NOTE: At the times that this paper was written, the left insole was still being built and for this reason, it is not shown or mentioned in this PDF.

Discussion:

The results of this project have demonstrated the potential the FSR-impression system has for the monitoring of foot position, mitigation of foot-to-shoe friction, and possible prevention of the formation of DFUs. In addition to its ability to detect dangerous foot positioning, the insole itself can generate valuable data about user foot placement patterns over long periods of time. This data can be easily analyzed on the spreadsheet and used to facilitate informed patient-doctor interactions. Despite successfully meeting a variety of project milestones, there is still much more that can be done to increase the accuracy and value of the insole in the medical field.

An advantage of the insole wirelessly logging data into a spreadsheet is that it provides a large data set that can be used to train a machine-learning algorithm to provide answers to common patient questions. Using a structured neural network, it would be possible to identify complex patterns of foot misplacement that are occurring in a patient's stride, and suggest new types of shoes or inserts to be used. If combined with existing data sets describing the age, BMI, blood sugar levels, and DFU location of other patients, algorithms could predict the likelihood of an ulcer developing in their own foot. I have already spoken with professionals involved in medical based machine learning and am currently working on a way to implement a structured neural network into this project.

A second point of growth arises from one of the original project goals: condensing the hardware to fit inside of the insole. By using a printed circuit board, it would be possible to dramatically reduce the size of the microcontroller and its assortment of jumper wires. Additionally, designing a custom made FSR network with Tekscan would eliminate the need for separate jumper wires to be wired to each sensor. This integrated FSR matrix would allow for greater durability of the insole as well. Currently, it is possible to design such FSR matrices with Tekscan, however it is likely a more expensive process than buying and wiring each FSR individually.

Lastly, it would be imperative to conduct patient testing with the insole, assuming all legal responsibilities can be resolved. By testing this insole with at-risk DFU patients, a direct correlation could be proved between the FSR-impression system and reduced DFU formation rates. Additionally, this would allow for an even greater data set for which to train a possible neural network.

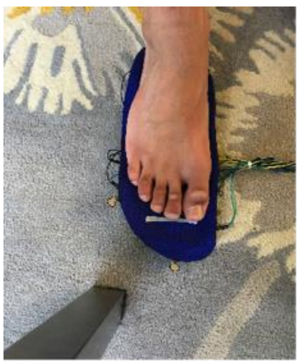
In conclusion, this project demonstrated the potential an FSR-impression based insole can have in the prevention of DFUs in DPN patients.

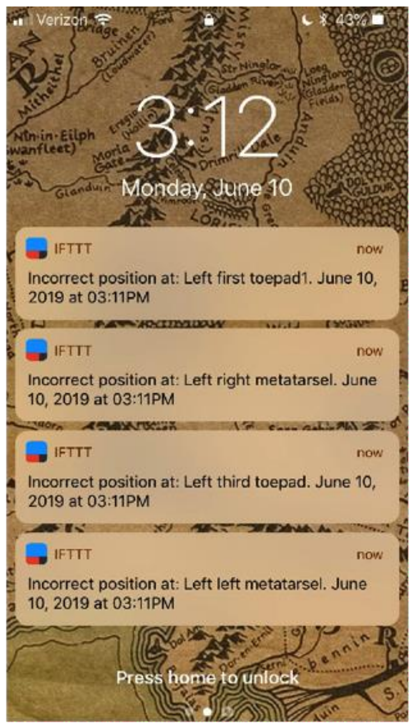
Acknowledgement:

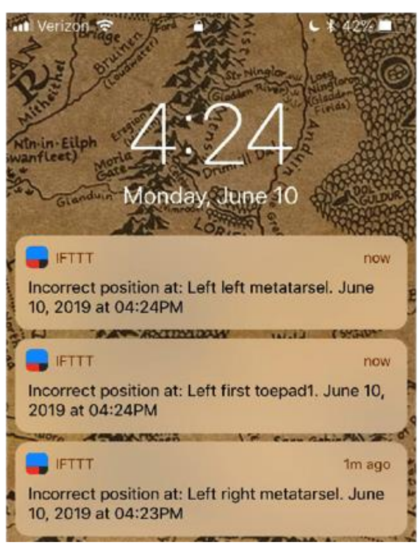
I would like to acknowledge the contributions of Dr. James Robison to this project. Without his insight, experience, and willingness to support this project free of charge, the completion of the DPN insoles would not have been possible. Dr. Robison has agreed to continue working on this project after the completion of the THINK Program as I pursue the improvement of the insole and development of a neural network. I would also like to thank Root Laboratories Inc. for helping Dr. Robison and I obtain foot scans and the plaster molds.

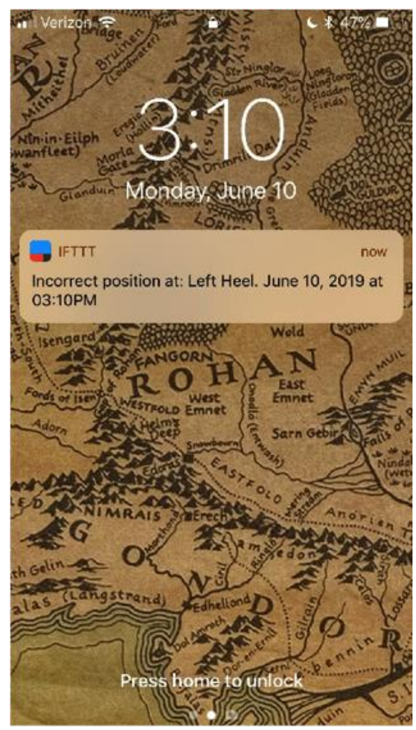
Appendix A:
Link to GitHub: https://github.com/Treebeard7/Insole-Code
Object Oriented Code is in all files except that labelled "Alternate Insole Code." This file represents the non-object-oriented code.

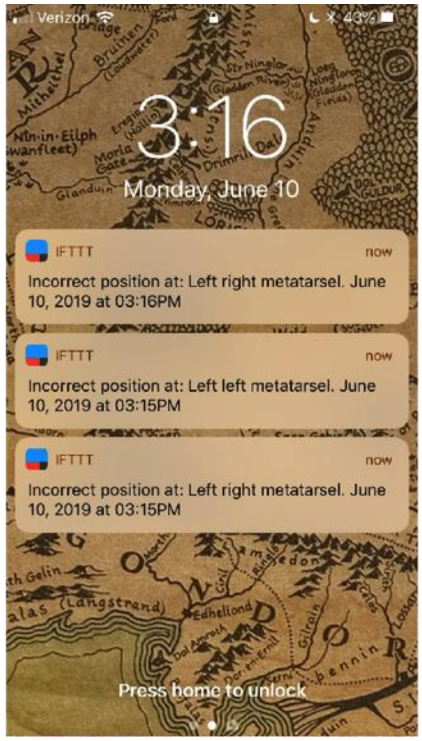
Appendix B:
Below are the photographs of the foot position and corresponding screen shot used for the data set shown in the main report. Please note that the messages refer to the "Left foot." This is a mistake as the program was not adjusted for use on the right insole. In addition, many statements contain the phrase "third toe pad." This statement was mistakenly not updated from the old code when a third toe pad was being measured. It should refer to the "fifth toe pad."

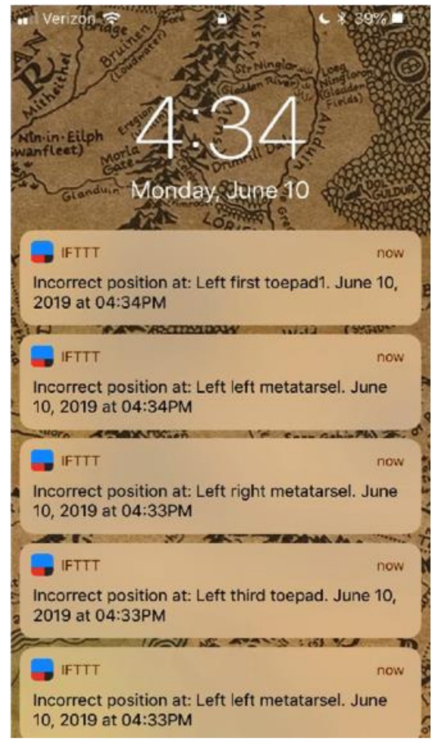












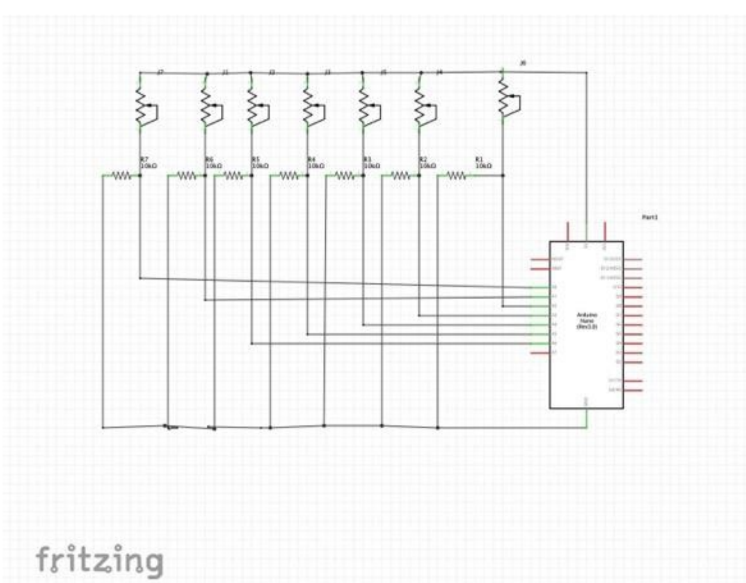
No image is shown for the standard position as it contained no notifications.

Appendix C:

Materials: Relevant to constructing the final version of the insole. Failed boards, equipment purchases, and the materials supplied by Root Laboratories and Dr. Robison are not included.

Item	Vendor	Amount
16 x Flexiforce sensors	Tekscan	223.92
Heat Shrink Coverings	Amazon	19.99
16 x 1 M OHM Resistors	Amazon	5.98
PCB Wiring	Amazon	11.99
Non toxic solder	Amazon	16.04
PCB Wiring (22 gauge)	Amazon	16.99
2 Lithium ion battery	Amazon	30
Electrical tape	Amazon	4.27
2 MKR 1010 Boards	Arduino	75.48
		404.66

Circuit Schematic:



Works Cited

1. Diabetes. (2018, August 08). Retrieved from https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444

2. Iraj, B., Khorvash, F., Ebneshahidi, A., & Askari, G. (2013). Prevention of diabetic foot ulcer. *International journal of preventive medicine*,*4*(3), 373-6.

3. New CDC Report: More than 100 million Americans have diabetes or prediabetes. (2017, July 18). Retrieved from https://www.cdc.gov/media/releases/2017/p0718-diabetes-report.html

4. Inderbitzi, R., Buettiker, M., & Enzler, M. (2003). The long-term mobility and mortality of patients with peripheral arterial disease following bilateral amputation. *European Journal of Vascular and Endovascular Surgery,26*(1), 59-64. doi:10.1053/ejvs.2002.1868

5. Juster-Switlyk, K., & Smith, A. G. (2016). Updates in diabetic peripheral neuropathy. *F1000Research*,*5*,F1000 Faculty Rev-738. doi:10.12688/f1000research.7898.1

6. Ersen, A., ADAMS, L. S., MYERS, R. T., HIRSCHMAN, G. B., LAVERY, L. A., & Yavuz, M. (2018, July 01). Temperature Regulating Shoes for Prevention of Diabetic Foot Ulcers. Retrieved from http://diabetes.diabetesjournals.org/content/67/Supplement_1/41-LB

7. James. (2018, November 07). The Foot Tripod. Retrieved from https://www.fixflatfeet.com/foot-tripod/

8. Anatomy of the Foot. (n.d.). Retrieved from https://www.arthritis.org/about-arthritis/where-it-hurts/foot-heel-and-toe-pain/foot-anatomy.php

Images:

Adafruit. (n.d.). Retrieved from https://learn.adafruit.com/assets/435

Foot Problems Checklist. (n.d.). Retrieved from https://myhealth.alberta.ca/Health/Pages/conditions.aspx?hwid=aa20138

San Antonio Plantar Fasciitis | Foot Pain | Heel Pain | Arch Support. (n.d.). Retrieved from https://www.goodfeet.com/san-antonio/

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