

THE SMART SOLE:
USING HYBRID AI ANALYSIS TO INFORM
PATIENTS ON FOOT PRESSURE
ANOMALIES FOR PERIPHERAL
NEUROPATHY

CREATED BY BASIL AMIN

ABSTRACT:

Diabetic Peripheral Neuropathy (DPN) is a disorder with a prevalence level of 50% in people with Diabetes. This Neuropathological disorder can have substantial impacts on those who suffer from it, including: ulcers, infected ulcers, foot deformities, charcot foot, irregular gait pattern etc. These said complications contribute largely to substantial consequences suffered by those who suffer from DPN such as amputation, or in severe cases, death. The primary reason this is such a significant issue is because those who suffer from DPN lose all sensation in their feet, and therefore are completely unaware of the occurrence of such complications. Moreover, the present treatment for Diabetic Peripheral Neuropathy does not provide substantial aid, being mainly physical therapy, or prescribed medication, and there is no existing cure. The reasoning behind this is because our knowledge of the pathogenesis of DPN is relatively limited, and thus it is challenging to develop treatment without this knowledge.

The aim of this project, the Smart Sole, is to implement a never before seen, noninvasive method of attempting to prevent such complications by simply informing the user when an anomaly in foot pressure data is present, attempting to replace the role of the nervous system in the foot. The system utilizes hardware to collect data from the foot, and artificial intelligence to detect behaviour and inform the user of anomalies in foot pressure data wirelessly on a device running the software. The Smart Sole also aims to provide periodic feedback, to try and mitigate risks in the long term as well, by creating a report utilizing generative ai.

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1: INTRODUCTORY

1.1 Diabetic Peripheral Neuropathy

Peripheral Neuropathy refers to the set of neurological disorders that concern damage to the Peripheral Nervous System, which is a significant neurological network that sends and receives signals from the central nervous system (the brain, and the spinal cord) to all other parts of the body. The most common and impactful sort being Diabetic Peripheral Neuropathy (chronic), affecting roughly 50% (*approx. 250 million Diabetics*) (Alam U., et al., 2017) of patients who suffer from Diabetes, as well as being associated with a poor prognosis, and a high mortality rate. Its occurrence is dependent on a multitude of factors such as: age, duration of Diabetes, glucose control and type 1 or type 2 diabetes.

Diabetic Peripheral Neuropathy typically occurs in the legs or feet, most commonly the feet. It is caused by high blood sugar which inflicts damage upon the nerves; consequently, the patient loses all sensation in their feet or legs and remains uninformed on any injury or health related occurrences in the feet, as they cannot feel pain, and experience loss or abnormal feeling of temperature (Pineda-Gutierrez, et al., 2017). Examples of damage that a patient may be unaware of includes ulcers, and deformities, which can possibly result in much required amputation.

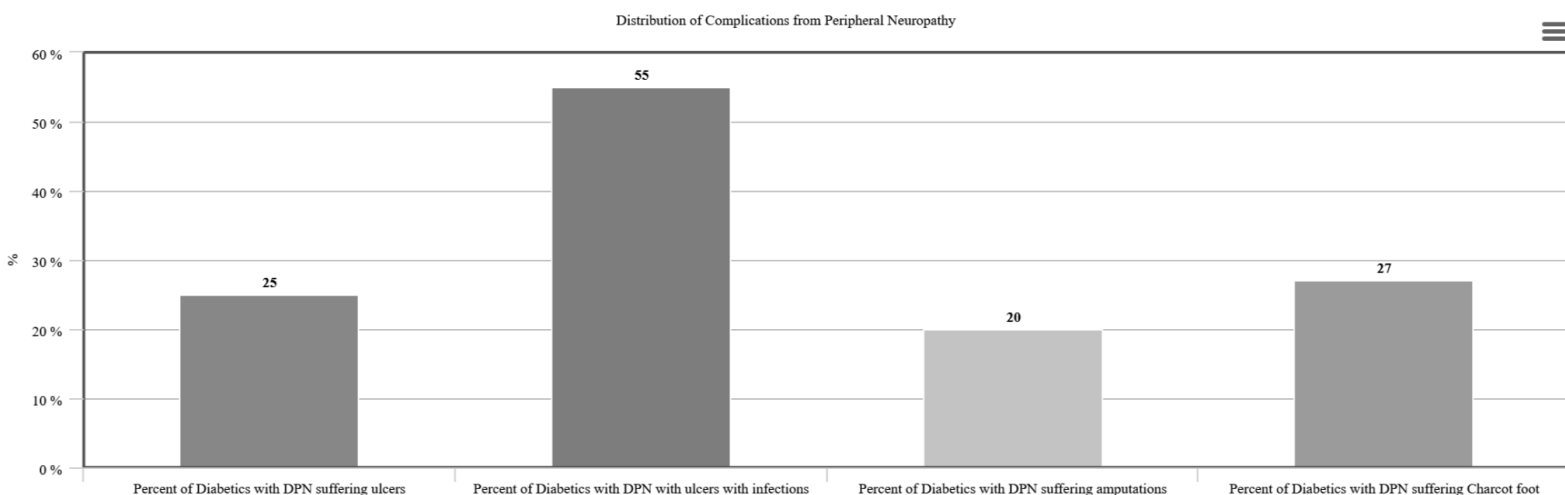


Figure: 1.A

Figure 1.A thoroughly demonstrates the distribution of complications that are typical for patients who suffer DPN (Diabetic Peripheral Neuropathy). This data, originating from published studies (Chapter 8) demonstrates the significant portions that these complications take of Diabetics with DPN. Diabetics with Diabetic Peripheral Neuropathy suffering from: Ulcers, infected ulcers, amputations and charcot foot (disfigurement). These complications all contribute to the mortality rate of patients diagnosed with Diabetic Peripheral Neuropathy, with a 2023 study (ref. 13) demonstrating that 1 in 5 of patients diagnosed with DPN, pass away due to these complications.

This can usually be drawn back to the fact that patients suffering from Diabetic Peripheral Neuropathy lose sensation within their feet, which can be a significant contributor to the mortality rate, amputation rate, feet deformities such as Charcot foot and delayed diagnosis due to unawareness of early complications such as ulcers.

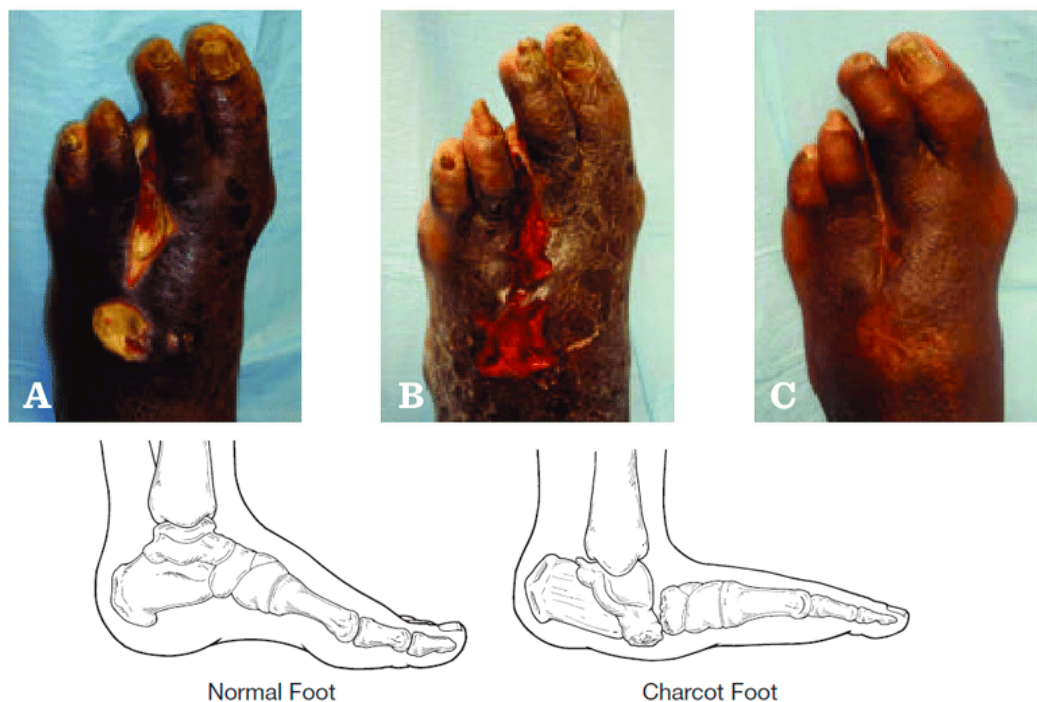


Figure 1.B

Figure 1.B (*Charcot Foot — Jason Morris, DPM, n.d.; FIGURE 3 Progression of a Diabetic Foot Ulcer from Necrotic Wound Base...*, n.d.)) Shows the development of a Diabetic foot ulcer and Charcot foot.

1.2 Current solutions, medical treatment and diagnosis

The current solutions to the consequences of Peripheral Neuropathy exist with the prime goal of reducing the progression of Diabetic Peripheral Neuropathy, reducing any inflicted nerve pain that may be a consequence of nerve damage and to manage its complications and restore function. Due to the relatively substandard knowledge of the pathogenesis of Diabetic Peripheral Neuropathy that we have, its treatment is oriented around relieving its symptoms rather than curing. There is currently **no existing cure or drug on the market** for Diabetic Peripheral Neuropathy treatment, proposing a significant problem to a significant number of people. Examples of current treatment include: Antidepressants (to depolarize neurotransmitters) , Opioids such as Oxycodon (as a front-line therapeutic agent) and Physical Therapy methods such as acupuncture. These forms of relief are primarily based on our current pathogenesis of Diabetic Peripheral Neuropathy, which is that it may interact with neurological and blood supply disorders, and is caused by insulin deficiency, insulin resistance, hyperglycemia and dyslipidemia. In addition, Orthotics attempts to aid the feet, however, it is quite strange to try to alleviate a problem after it has been caused, specifically when you know it will occur.

At current, there are 2 distinct processes to diagnosis: the conventional method, being referenced in type 2 diabetes screening, whereas in Traditional Chinese Medicine diagnosis is reliant on previous medical records of the patient, accompanied by detailed physical examination records, specifically neural examination records; the diagnosis is fully based on symptoms from clinical examination. If an

anomalistic manifestation has been observed, the patient is typically recommended to see a neurophysiologist.

It is understandable that these methods are in use, given our lack of knowledge in the pathogenesis of Diabetic Peripheral Neuropathy; however given our current technological era, as companies, research organisations and academic institutions continue to develop marvels of cyber-human engineering, such as state of the art controllable prosthetics, Neuralink brain chips, etc. It should be evident that a technological solution is the answer to accommodate a problem as simple as providing feedback to a Diabetic suffering Diabetic Peripheral Neuropathy, who is suffering significantly reduced sensation?

1.3 The Smart Sole

The Smart Sole is a never-before seen method aiming to virtually inform Diabetics who suffer from Diabetic Peripheral Neuropathy, since they suffer loss of sensation in their feet, preventing the previously said complications from occurring. It uses a structured method to do this, utilizing physical hardware to collect data, wireless transmission using BLE (Bluetooth Low Energy) and various data processing, machine learning algorithms and artificial intelligence models to provide detailed scheduled feedback and real time feedback to the user.

PROJECT HYPOTHESIS: Using AI to analyse foot pressure data can enable a system to provide feedback to Diabetics suffering from Diabetic Peripheral Neuropathy of anomalous foot movements, thereby reducing the risk of complications associated with this condition.

2: SCIENTIFIC METHODOLOGY

2.1 Objectives

The three primary aims of this project are:

- To Alert the user in real time of foot-pressure anomalies that may cause harm, such as wounds.
 - To distinguish between what is normal and what is abnormal, first I will program a behaviour classification model to detect user activity to define what exactly is “regular” data and “irregular” data.
 - To be capable of differentiating between normal and abnormal, I will then program another model to detect whether or not the given data is normal or abnormal
 - Finally, if the input is abnormal, an alert is sent. Otherwise, the next data input is examined.
- Provide detailed interpretable feedback to users, periodically, so that they are able to improve upon the feedback given to them, and track their progression.
 - Take many samples of data over a given time period
 - Store these data samples

- Feed the samples from the current and last period as well as input questions to a language model
- Receive and display a natural language output to the user

2.2 Materials and software

ELECTRONICS:

--XIAO *ESP32-S3* MCU BOARD

-x2 *LiPo Battery 3.7v, 400mAh*

-X2 402 *UX FSRs*

-408 *UX FSR 100mm*

-BLE Antenna

-X3 10K Ω resistors

-X2 LiPo Battery ports

-Jumper Wires

-5V Linear Voltage Regulator

-Computer

OTHER PHYSICAL PARTS

-(generic) Insole

-3D printed battery packs

SOFTWARE:

- PlatformIO development platform

-Llama 3.2 1B LLM

-MS Excel (data analysis)

-KiCAD

2.3 Methodology

First and foremost, before developing any software or programs, data is required to

- Identify the key factors and relationships in data features that allow distinction of behaviour
- Train models
- Create an accurate expectation to hold capability to identify if there is an error e.g. hardware problem

To collect data, I initially modelled a prototype electronics system in KiCAD and then a breadboard (Figure 2.A). This was done to identify any errors that may occur early on in the hardware before wiring and soldering together parts and potentially wasting them. The aim of this prototype was to simply transmit sensor data (force sensitive resistors) through Bluetooth or BLE (Bluetooth Low energy) to a connected device running a Python script to display all the received data.

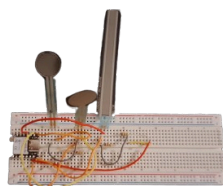


FIGURE 2.A

Figure 2.A is the initial breadboard prototype made to detect errors. It features the same components found in the final model, (Electronics, section 2.3) and uses wiring through connected terminals to send power and signals.

The reasoning behind placing the force sensitive resistors in this configuration, is because the main pressure points when a foot makes contact with a surface is in these locations (Figure 2.B)

After validating and testing the hardware, I built, wired and soldered a number of insole models that are capable of transmitting data wirelessly. Then I organized data collection sessions for students and staff in my school as well as members of my family. In each session, each participant would wear the insole, complete a dynamic or stationary activity, and their data would be collected. The regular activities included:

- Walking
- Standing
- Sitting

Additionally, anomalous activities based on common irregular gait patterns and foot pressure positions that are commonly present in those who suffer from Diabetic Peripheral Neuropathy were also completed and included:

- Limping
- Heel avoidance (stationary)
- Heel avoidance (dynamic)
- Lateral Arch pressure (stationary)
- Lateral Arch pressure (dynamic)

Dynamic meaning that this irregularity takes place while the patient is walking and stationary meaning this irregularity takes place when the patient is standing still or sitting.

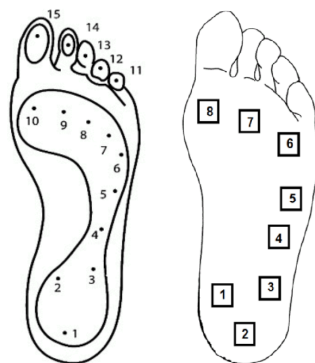


Figure 2.B

Figure 2.B (*Pineda-Gutierrez et al. 2019*) conveys the main pressure points when the foot makes contact with a flat surface. The points (1, 2, 3) surround the heel, points (4, 5, 6, 7) are on the Lateral Arch and points (10, 9) are on the Medial Metatarsal.

When this data was collected, in its raw format, was simply hundreds of lines of input strings, where each line contains the 3 labelled input features and their current data values in the form of 12-bit ADC (Analog to digital converter). I then plotted some session behaviours to compare the differences and similarities in each behaviour's data (example Figure 2.C).

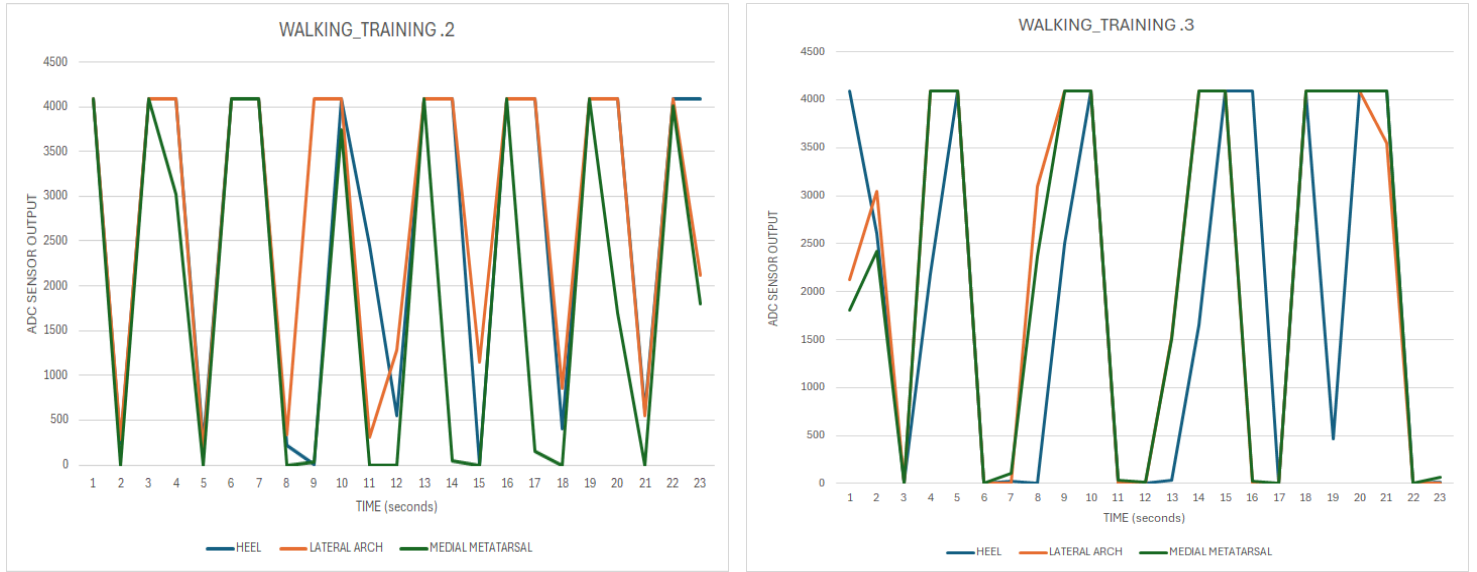


Figure 2.C

Figure 2.C shows 2 examples of the plotted data in the form of trend graphs, where the y axis represents the current ADC value and the x axis represents time in seconds. The current activity being executed in both of these sessions are walking, being a regular behaviour. The swing is apparent when the values spike down and the stomp is seen when the value spikes up. The rest of this data is found in the project Github repository linked at the end of this paper.

Then, I worked on trying to refine the formfactor of the hardware (figure 2.D) by cleaning up the wiring, and creating a quick and easy way to plug in the power supply. Similar to the data collection session models, this one worked well, however was more directed to refining user aspects. The schematic for this model (figure 2.D) was also made to test any modifications if necessary.

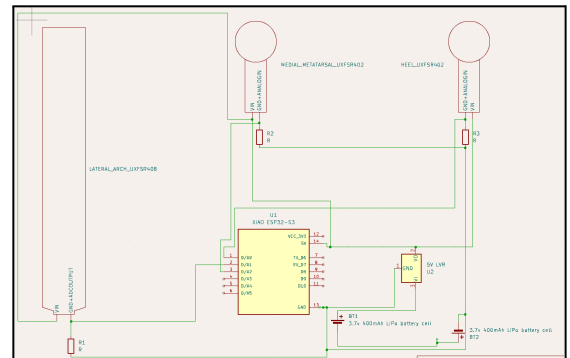
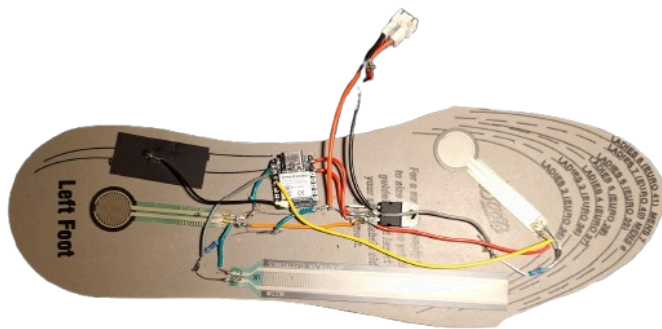


Figure 2.D

Figure 2.D shows the hardware on the bottom of the Smare Sole model. The side with the electronics is inserted downwards facing the sole. The 3 FSRs are sensing foot pressure data and the XIAO ESP32-S3 is receiving and transmitting it. The FSRs are in a $10K\Omega$ resistor voltage divider circuit configuration. A Bluetooth antenna and a Lithium Polymer battery port are connected to the MCU.

Then, I began developing computer programs in an iterative manner, with the aim of detecting the user's behaviour from foot pressure data, detecting if there is an irregularity in this data or selected behaviour and then alerting the user.

I started by creating a piece of computer software that is capable of receiving a stream of data via Bluetooth and then displaying it on a computer terminal where each line is a string of the data from each of the 3 pressure points, receiving this data at a rate of 1 line per second. Then, to find irregularity in the data, the system must first identify what the current behaviour of the user is.

To do this, I developed a Deep feedforward neural network behaviour detection model also known as a multilayer perceptron to take in an input matrix containing each of the pressure points in the form:

$$\begin{bmatrix} x, x_1, x_2, \dots, x_{10} \\ y, y_1, y_2, \dots, y_{10} \\ z, z_1, z_2, \dots, z_{10} \end{bmatrix}$$

Where x is the Heel input value, y is the Lateral Arch input value and z is the Medial Metatarsal input value. The input string also contains the time T in seconds, however, is not necessary for the neural network output.

I wrote a data parser to take the input string and then preprocess the data to this format for the behaviour detection model.

The Behavioural detection model is made up of 4 layers in total, with 2 hidden layers consisting of 128 neurons (Figure 2.E)

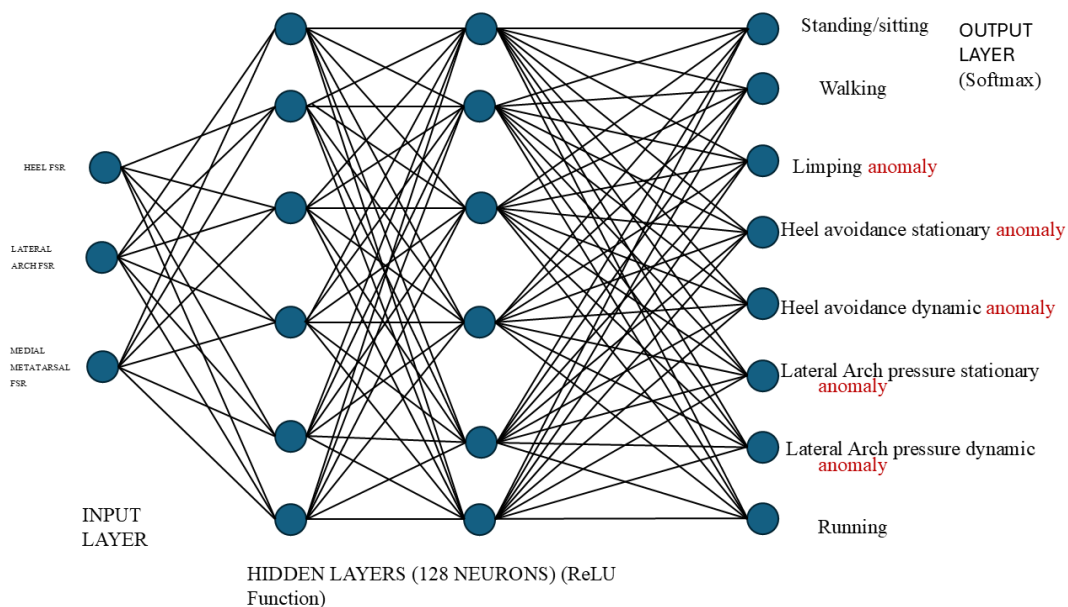


Figure 2.E

Figure 2.E shows the structure of the Multilayer perceptron, with 3 input features in the Input layer, 128 neurons in the hidden layers, and 8 labels in the output layers. These labels have been selected since these are the most common behaviours in people with DPN in gait patterns, etc.

This model then must be trained in order to output accurate labels in accordance to the input data. I then created csv files of each session and behaviour, and then trained the model on each of these datasets as well as my own datasets that I myself have collected, to allow it to accurately output predictions for the behaviour. There are some preset anomalous labels for common irregular movements and positions that those who suffer DPN do.

Then, to specifically detect anomalies, I applied a machine learning algorithm known as Isolation Forest that specifically aims to detect irregular values in datasets. To accurately find all anomalies, the behaviour is given to a function that aims to select a dataset from a group of datasets that contain regular data relative to the behaviour. If an anomalistic behaviour was selected, this step is skipped.

The selected regular dataset is then appended to the input dataset given from the sensors. This was added to the software to try and standardize the values in the dataset so that the Isolation Forest Algorithm can accurately distinguish between anomalies and regular values. I sampled these regular datasets from training data from the behavioural detection model. Then, I tested the system in a run once configuration. When applied however, this should run continuously until the connection via Bluetooth has disconnected, meaning the device was turned off. I decided to test each system individually before using them all together to make error detection easier.

I then tested the accuracy of the model by creating a testing dataset, and another test dataset to examine the accuracy of the Isolation Forest Model.

Then, I programmed a GUI to display the system metrics. This consisted of a graph displaying the current value of each sensor Input, a string output displaying the current behaviour, then a boolean statement as to whether or not the behaviour or data is anomalous.

THE FOLLOWING SECTION OF THE METHODOLOGY IS STILL IN PROGRESS AT THE TIME OF THE WRITING OF THIS PAPER.

PROPOSED METHOD:

Then, for tracking the user's progress, providing them with detailed feedback, and ultimately allowing them to improve in the long term, I will start by taking the Llama 3.2 1B parameter model. I will start by making a suitable input format that can be given to the Language model. This format will be JSON (JavaScript Object Notation). This input should consist of sampled anomalous data collected throughout the week. A csv file will store these files, from being extracted after processing in the real time feedback process. Then, I will write paired sample outputs, one from the current period, and one from the previous period. They will be tagged so that the Language model can differ between time periods.

Then, I will put this data and tokenize it then pass it through the model for training. It will then be trained and capable of providing periodic feedback.

3: RESULTS

The highly beneficial results of this project include:

- An accurate behaviour detection neural network model
- A system capable of informing the user when an anomaly is present
- An attempt at preventing future potential complications
- A system overall that can provide behaviour based feedback based on pressure in the user's feet.

The results of this project start from the hardware.

The initial result is that there is an electronics system that returns and transmits pressure data wirelessly from the main pressure points in the foot, using firmware programmed to transmit FSR data via BLE

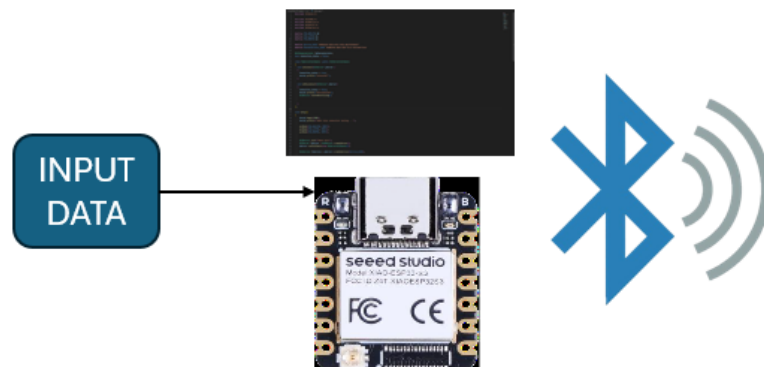


Figure 3.A

Figure 3.A shows the transmission of BLE, where the input sensor data goes through an MCU running firmware.

It is capable of sending a string in the following format:

```
bytearray(b'HEEL 0, LATERAL ARCH 0, MEDIAL METATARSAL 0, TIME 0')
```

When this is picked up, the data is first preprocessed before given to the model. It is parsed into the format: `[[1238 4095 995 4095 4095 3691 4095 4095 3885 0 3981 0 0`

```
2735
0 8 4095 81 4095 4095 4095 4095 4095 4095 4095 2092 0
3519 0]]
```

This is a 1D array, converted from the original matrix format, by flattening it before input.

Then, the Behaviour detection model received this data, and upon initial testing, gave poor results, with accuracy of 25% and a loss of 3.0760. This is not suitable for implementation, and thus, I created a greater dataset for training and testing, where I created a greater distribution of data among all behaviours, shuffled them into patterns to allow the model to recognize transition between behaviours, and modified the model architecture, adding 5 layers, 1 being hidden, the rest being for data normalization, dropout and flattening. The extra hidden layer is 32 neurons, and should overall be better for the task.

```
Behavioural_classification_model = Sequential([
    layers.Input(shape=(30,)),
    layers.BatchNormalization(),
    layers.Dense(64, activation='relu', kernel_regularizer=tf.keras.regularizers.l2(0.01)),
    layers.Dropout(0.3),
    layers.Dense(32, activation='relu', kernel_regularizer=tf.keras.regularizers.l2(0.01)),
    layers.Flatten(),
    layers.Dense(32, activation='relu', kernel_regularizer=tf.keras.regularizers.l2(0.01)),
    layers.Dropout(0.2),
    layers.Dense(len(LABELS), activation='softmax')
])
```

The total volume of the data consisted of 14,400 data points, with 600 lines with 3 features creating 1,800 data points per behaviour. These were all collected in sessions of 10 minutes per behaviour with the Smart Sole collecting data. Additionally, sitting and standing were separated movements and running was removed. The format of the data was:

```
4095,4095,3824,4095,4095,3772,4095,4095,3565,4095,4095,3607,4095,4095,3573,4095,4095,3552,4095,4095,3641,4095,4095,3930,4095,4095,3389,4095,4095,3273,6
```

(Example taken from: Heel avoidance dynamic)

The last value is the referral to the label.

Then, in order to expand the dataset, increase variability, I wrote a computer program to sample the training and test data in random batches, that made sense in real world application (Example: Walking for 2 minutes, stop and stand for 30 seconds, limp for 2 minutes etc.) and did this by creating maximum and minimum batch sizes. This led to a relatively substantial increase, leading to an accuracy level of roughly 76.3% after cross examination with multiple datasets that derive from the same file samples as the training data .

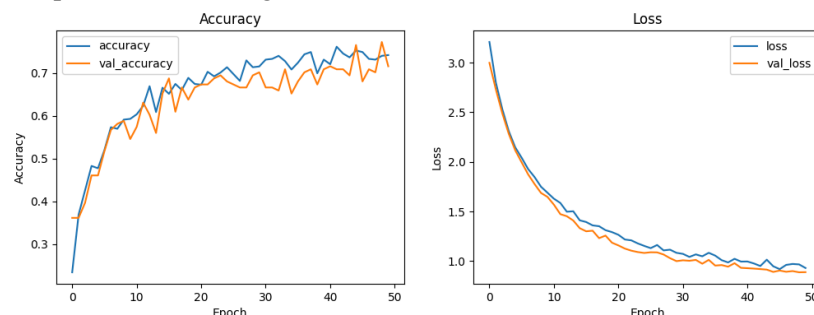


Figure 3.B

Figure 3.B demonstrates the development in accuracy of the improved training method, and the decrease in loss value as the number of Epochs (maximum capacity 50) increases. This was then repeated with an extended testing and training set, with over 50,000 data points. The testing data had roughly 27,000 data points. The model accuracy then increased to approximately 87% after cross testing.

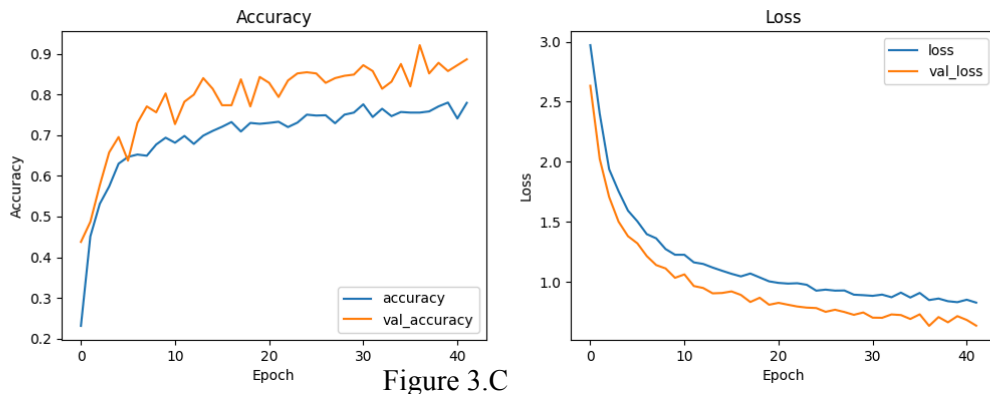


Figure 3.C

Figure 3.C shows the accuracy of the model, per epoch increased. The second graph to the right hand side demonstrates the loss value per epoch.

After increasing the Behavioural Detection models training data to nearly 100,000 data points and the testing data to 83,000 data points, where each data point is 1 feature per input dataset, by utilizing random batch sampling for both the testing and training data, the model shows an accuracy of 93.4% accuracy, even levelling with industry and medical level wearable Behaviour detection technology, of roughly 93.8% (Weizman et al., 2023).

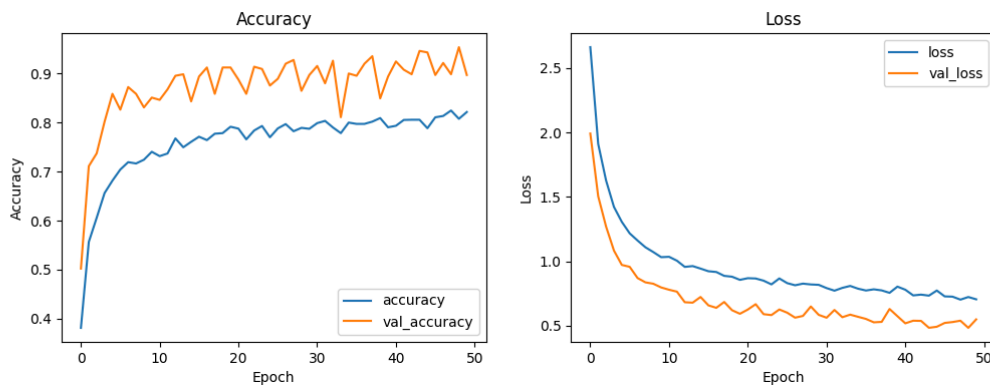


Figure 3.D

Figure 3.4 shows the highest accuracy measurement from the Smart Sole Behavioural detection model to date, showing accuracy levels of 93.4%. The graph on the left showing accuracy per epoch and the graph on the right showing loss value per epoch. As a result, using a deep feedforward neural network to detect Behaviour from foot pressure data, can be accurate in accordance to the industry standard.

Additionally, the Smart Sole's anomaly detection system, that examines the input data and appends it with data regular for the current behaviour, is successfully capable of taking the MLP's output, and selecting a sample dataset to append the input with. Upon initial testing, I found that the dataset was too small, thus I applied the same method I did to the MLP, and sampled data from my Training set, to behaviour specific files.

Then, I tested the model a number of times, with different data from different datasets. For instance, (Figure 3.E) I tested the limping data with walking data, to see if the machine learning algorithm can accurately detect the input dataset (limping) in the regular dataset (walking) and it was able to accurately determine this data was anomalous. This was tested again among other sets (Figure 3.F) to

examine validity. Due to the large size of the dataset, the model was accurately able to detect the anomalous dataset.

```
0.07478101 0.74812808 0.748980791 0.88793889 0.7811
Added Dataset (Row 251): [ 111 4095 60 523 4095 15
2283 4095 4095 2747 4095 4095 2301 4095 4095 2419 4095
4095 0]
Is the added dataset an anomaly? Yes
Anomaly Score of the added dataset: -0.6001937343227337
```

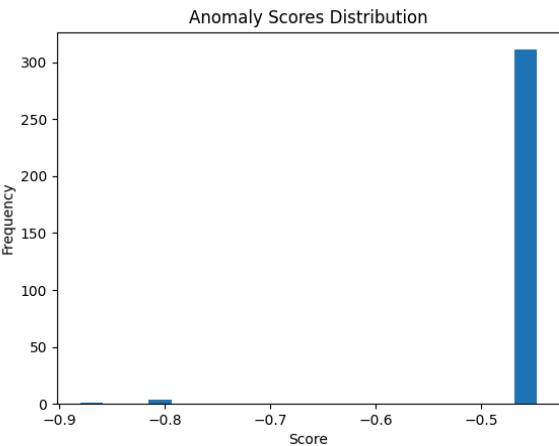


FIGURE 3.E

Figure 3.E shows the validation output of the computer program to examine the metrics of the algorithmic output, as well as a graph produced to show the anomaly scores distribution. In this special case, the regular data is standing and the input data is limping, thus leading to a huge skew in the anomaly scores distribution. The contamination value for the model at this time was 0.0316.

```
Added Dataset (Row 315): [ 15 4095 521 1171 4095 1913 4095 4095 4095 971 4095 8 925 3951
20 4095 4095 4095 4079 4095 4095 3976 4095 4095 4095 4095 4095 2827
4095 72]
Is the added dataset an anomaly? Yes
Anomaly Score of the added dataset: -0.8804265187368546
```

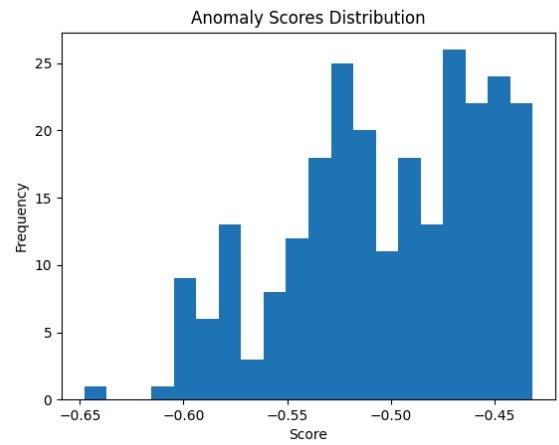


FIGURE 3.F

Figure 3.F shows the validation output of the computer program to examine the metrics of the algorithmic output, as well as a graph produced to show the anomaly scores distribution. The special case here is that this input set, in theory, should be more difficult to detect as an anomaly, because the walking data is constantly changing with the swing and stop, and there may be a near alignment with some of the regular values and the anomalous input value. However, it was still successfully detected.

Similarly, I wanted to see if I had given a regular dataset its own “regular” data, would it still detect it as an output?

After testing this, I found that they were not detected as anomalies. And thus the model is accurate enough to detect that a dataset is not regular compared to regular datasets to that behaviour.

As a result, a system with the capability of detecting behaviour, and providing feedback based on this detected behaviour to aid those who suffer from DPN by informing them on foot pressure anomalies to try and reduce complications in creating and functioning.

4: CONCLUSION AND DISCUSSION

4.1 Comparison to criteria

The original criteria for this project was:

- To Alert the user in real time of foot-pressure anomalies that may cause harm, such as wounds.
 - To distinguish between what is normal and what is abnormal, first I will program a behaviour classification model to detect user activity to define what exactly is “regular” data and “irregular” data.
 - To be capable of differentiating between normal and abnormal, I will then program another model to detect whether or not the given data is normal or abnormal
 - Finally, if the input is abnormal, an alert is sent. Otherwise, the next data input is examined.

When compared to the original criteria, the initial, and most important point in the criteria has been fulfilled. The second part is still in development. The system is able to classify behaviour, define what is abnormal and normal and return feedback to the user. The method that is used to do this is relatively accurate, and after individually testing the systems and gathering results, it is fair to determine that this method proves the initial project hypothesis.

5: IMPACT AND IMPORTANCE

5.1 Diabetic Peripheral Neuropathy increase

As more and more people begin to suffer from Diabetes, with an expected 783 million to have Diabetes by 2045 according to the International Diabetes Federation, there will be a substantial increase in the population of those who have Diabetic Peripheral Neuropathy, given it's prevalence level of 50%.

This means more and more people will suffer from Diabetic Peripheral Neuropathy complications, and consequently face severe consequences, such as amputation. The Smart Sole is a method to try and stop these complications before they happen. The current treatment of Orthotics, medication and physical therapy, aims to try and aid these complications after they occur, which is an unorthodox approach to such a problem. However, this is understandable because our understanding of the disorder is limited.

5.2 Widespread significance

Additionally, this will allow patients to know when they are getting anomalies, in real time, serving as a “virtual nervous system”, by alerting them. The Smart Sole (once added) will also be able to help with long term feedback to try and mitigate complications in the long term.

It is also important to note that fundamentally, this is a system that detects behaviour and examines if data is regular for a given behaviour. This has widespread application! This can be applied to the elderly to detect and alert for falls, those who suffer from mental disorders, etc.

6: RELATED WORK

Kim, M.-J., Han, J.-H., Shin, W.-C., & Hong, Y.-S. (2024). Gait Pattern Identification Using Gait Features. *Electronics*, 13(10), Article 10. <https://doi.org/10.3390/electronics13101956>

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7: APPENDICES

PROJECT GITHUB REPOSITORY:



DATA COLLECTION FORM:

SMART SOLE TRIAL. DATA COLLECTION TERMS AND CONDITIONS.

FULL NAME :

DATA COLLECTION PROCESS AND DATA PROCESSING

The data collection process for the Smart Sole project, spanning over a week, will consist of 3 participants a day, taking part in movement activities, while wearing an insole which collects their foot pressure data. This data will then be transmitted to the participants mobile device via BLE (Bluetooth Low Energy) through a Bluetooth Terminal (created by Innovator's Den) while simultaneously being screen-recorded, for each specific activity. The hardware in the insole has been flashed with firmware specifically to connect to both Android and Apple devices. These activities will take place over lunch, where participants will meet Basil Amin in "Insert location". You will each be assigned a day, in which you will partake in the data collection process. After the data collection process is complete for that day, each participant will share the screen recording file (.MP4, .MP3, etc.) with Basil Amin, and this will be your data collection process finished.

Your contribution of data will be purposed to train artificial intelligence models, which will improve their ability to detect common foot-pressure anomalies through behavioural recognition, and provide progressive feedback on potentially damaging habits, and preventative measures to complications that occur commonly with Diabetic Peripheral Neuropathy . This will allow Diabetics who suffer from Diabetic Peripheral Neuropathy, an opportunity to potentially increase their lifespan and lessen the risks of complications (ulcers, infected ulcers, deformities, amputation etc.) by keeping them aware virtually, since they are unable to feel pain in their feet.

TERMS AND CONDITIONS:

- I Shall not disclose any information that I have learned about the Smart Sole project from participating in the data collection process to any organisation, public bodies, or people.
- I Fully agree to partake in the data collection process, and follow all instructions, given above in this form.
- I agree to delete all recordings of data collection after they have been sent, and confirmed to be interpretable (not corrupted, correct filetype etc.) and to not send any data from the Smart Sole data collection process to any organisation, public bodies or people.
- I understand that there is a risk or possibility for problems to occur with LiPo batteries catching fire if they are damaged during the session or prior session and that Basil Amin is not liable for such an occurrence.
- By signing this form, I agree to all Terms and Conditions, and am happy to proceed with the data collection process.

NAME

SIGNATURE.....

DATE.....

8: CITATIONS

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