An embedded wearable device for monitoring diabetic foot ulcer parameters

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ABSTRACT

Diabetic foot complication is one of the leading cause of non-traumatic lower extremity amputations. Due to diabetic complications such as neuropathy, diabetic patients do not feel any pain in their feet. Due to this they are often unaware of any ulcer or wound formed on their feet. This along with impaired healing of the wounds often escalates into lower extremity amputation affecting patient's socio-economic well-being. By monitoring different parameters of the foot and using it for predicting possible occurrence of ulcer we aim to avoid occurrence of ulcers . We developed a new hardware with accompanying software while evaluating the design to ensure it helps in taking early preventive measures for the feet and avoid the occurrence of ulcer and further complications.

CCS CONCEPTS

• **Computer systems organization** → **Embedded systems**; • **Networks** → Wireless sensors.

KEYWORDS

healthcare, diabetic foot, smart sock, wireless sensors

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1 INTRODUCTION

Diabetes is a commonly known disease with no permanent cure, all around the world. An estimated 65 million people in Europeans [17] and 300 million globally [31] will suffer from diabetes by 2025. Diabetic foot condition is caused due to effects of diabetes and often leads to amputations and in some cases to death. Diabetic foot is an umbrella term used to describe medical condition such as ulcer, ischemia, infection or other complications of the lower limb caused due to diabetes and its effects. The most common problem found in diabetic foot is advanced ulceration of the foot which often requires surgical intervention and in many cases amputation. The cause of this problem can be narrowed down to three conditions: neuropathy, impaired healing and peripheral vascular disease. Neuropathy adversely affects the ability to sense pain, causing diabetic patients to become completely unaware of the damage caused to the foot and the wound heals slowly or even stall due to the effects of diabetes. In cases when patients also suffer from peripheral vascular disease that affects blood supply available to the lower extremities of the body lead to situations where patient might loose part of their lower limb if not detected in time. Diabetic Foot Ulceration (DFU) counts for 85% of amputations in diabetic conditions, while in USA 46% of foot ulcer hospitalization cases are from diabetic condition, comprising 4% of the overall population [25]. Moreover, every 30 seconds someone looses their lower limb as an effect of diabetic foot complication [4]. In [4], authors found that around 20% of all the expenditure on diabetes is spent on diabetic feet. Survival rates after amputation do not paint an optimistic picture either. Preoperative mortality rates after amputations are 9% in Netherlands where as survival rate 3 years after amputation are just 59% in Sweden and 50% in Italy [14].

This data points towards importance of detecting ulceration at the early stages to prevented and eliminate in time the conditions that follow it, preventing the accompanying social and financial burden. Studies focus on calculating pressure and defining limits for safe and unsafe pressure values, temperature and its relevance to ulceration sites, resulting in applications that monitor these parameters to determine ulceration prone areas. However, these studies temporally monitor the parameters using pressure mats or custom made footwear, limiting the amount of time the foot parameters are observed. Also, patients have to wear specific set of shoes or walk bare-feet on specific mat, become aware of the test and try to compensate their gait to *"improve"* their results. Through this work we address these issues through researching to what extent, is it possible to continuously monitor foot ulcer indicators in an efficient, accurate, and user- friendly manner with embedding sensing and communication technologies in daily worn socks. This is achieved by researching the foot parameters used to predict incidence of DFU, functional and non-functional requirements to monitor these parameters within a smart sock, compiling a set of software and hardware requirements and design decisions for continuous monitoring and detection of foot ulcer using a smart sock. We also evaluate the accuracy and efficiency of the designed smart sock to measure the foot ulcer indicators as well as evaluating the user-friendliness and comfort of smart sock.

2 DIABETIC FOOT ULCER INDICATORS

An investigation into current literature points towards two main parameters than can be used to ulcer prediction : temperature and

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pressure. These parameters are analysed and discussed on the basis of evidence found in literature.

2.1 Temperature

For non-invasive remote monitoring of diabetic foot, temperature measurements can be used as a base parameter. Temperature of human body is the result of thermal balance between thermal energy supplied by core and energy lost to the environment [9]. Studies of dermal thermometry have suggested that variations in temperature $> 4^0 F$ ($> 2.2^0 C$) could be helpful in skin surveillance [2]. This rise in temperature can be detected up to one week before actual foot ulceration occurs [19]. However there is no reference range available as body temperature can vary widely from person to person and even within different body parts of the same individual.

This difficulty can be overcome by comparing one part of the body with it's symmetrical counter part since under normal circumstances they are considered to be comparable [9, 15]. Clinical studies on the home monitoring of plantar foot temperature have shown that frequent temperature assessment, and, treatment in the case of temperature differences greater than $2.2^0 C$ between same regions of both foot, can prevent diabetic foot complications [20].

2.2 Pressure

There is significant literature available that looks into the increased foot pressure and its correlation with ulcer formation. In a paper presented by [8], authors inspected the pressure measurements using static and dynamic measurement techniques. Static techniques measure pressure when person is standing still where as dynamic measurements are done when person is moving (e.g. walking). It is well established that abnormally high pressure points are common with severe neuropathic conditions or in patients with prior ulcer history[8] and this is supported by numerous studies found in the literature [3, 5, 7, 16].

Study by [16] showed that elevated pressure doubles risk of ulceration. Generally pressure greater than 6 kg/cm^2 is considered as high pressure site with risk of ulceration. However different studies use different value as threshold. In addition to this difference of measurement setups, methods and units makes choosing universal threshold difficult. [5] overcome this issue by taking ratio of forefoot to rear-foot pressure (F/R) of the same foot. This approach offers some advantages: since it is a ratio, it is absolute value that is independent of measurement unit. Also since both pressure measurements are taken from the same foot, external factors involved are common making it fairly independent of external factors. Their study has shown that F/R value of 2 or more can predict ulceration risk with the same specificity as a peak pressure of 6 kg/cm^2.

3 STATE OF THE ART

Although there are several parameters available for prediction of diabetic ulcer, majority of commercial systems focuses on pressure measurement. [24] present comparison and evaluation of three commercial insole systems available in the market. These commercial insole systems are expensive, with prices ranging from 10,000£ to 14,000£ , due to high sensor density, high sampling frequency and comprehensive software provided for analysis. However such systems are focused on research and lab use. Home monitoring has less restrains in terms of all the features provided in the table such as sensor density and sampling rate but the cost of the system must be reasonable.

Similar to commercial systems, most of the literature is targeted towards pressure measurement. These literature refer to platform systems as standard measurement devices used in laboratories that offer simple measuring systems in which sensors are arranged in matrix format on flat surface mostly focusing on pressure measurements. Such set-ups are only suitable in research laboratories and rigorous tests across different surfaces reflecting real life scenarios are difficult to conduct [29]. Since this is a special set up, patient needs time to familiarize with the setup to reproduce the natural gait. Also these systems are bulky and usage is restricted to non continuous indoor measurements.

Due to limitations imposed by platform systems, researchers are targeting in-shoe systems. Such insole system made up from carbon embedded peizo-resistive material sandwiched between two layers of conducting electrodes [29]. The horizontal electrode layer consists of 15 elements whereas vertical electrode layer consists 5 elements resulting in total 75 sensing nodes. The data is sampled at 13Hz sampling frequency and transmitted to PC wirelessly via Arduino+Bluetooth setup. WalkinSense [11] consists of eight pressure sensors and data acquisition system. Authors compared this system with commercial F-Scan system by Tekscan®, study has reported some inconsistencies in readings and advised further investigation with large sample size. A fabric sensing array based insole design by [28] is based on carbon black based silicon which is developed by author's research group. This sensor can be used to measure pressures from 10 Pa upto 800 kPa. Insole design consists six of such fabric sensing array sensors and wireless transmission circuit, providing 100 Hz sampling frequency with 2kPa resoultion and ±5% accuracy. A sock design [21] measures temperature, pressure and toe angle for diabetic foot risk uses very thin (<0.3 mm) fiber optical sensors based on Fiber Bragg Gratings (FBGs) at five locations for all the measurements, providing advantages such as electrical insulation, chemical resistance, elimination of frequent calibration and temperature independence. Smart socks using piezo-resistive and conductive fabric [23] measures pressure at eight different locations to find patient specific information, because pressure measurements are dependent on the foot anatomy and hence they can vary from person to person. RFID tag harvests radio frequency energy and powers a sock consisting of four, fabric made piezoelectric force sensor for plantar pressure measurements [18]. However the response of the sensor is highly non-linear and battery limitation allows only 40-80 readings. A wireless insole monitoring system [12] of three pressure sensors, accelerometer and gyroscope, Bluetooth module and battery introduces new capabilities for seamless wireless charging and over the air update. A multi-modal skin sensing system for diabetic foot [6], use acclerometer, humidity, force, temperature, galvanic skin response and bio-impedance to define skin condition built with Arduino and Raspberry pi sampling at 20Hz.

The recent research trend is shifting from shoe based system towards socks based systems. There are few sock designs targeted towards diabetic foot monitoring parameters. Sock design is preferred to shoe or insole design as it can cover more use-case scenarios

Table 1: Available literature on foot parameter moitoring

Work	Sensorsr				Nr. Sensor	Communication	Noteworthy
	P	Acc	T	Gyr			
[29]	✓				75	Bluetooth	Custom peizo-resistive sensor grid
[11]	✓				8	-	Comparison with commercially availble F-scan System
[28]	✓				6	Bluetooth	Custom fabric sensor, weight calculation
[21]	✓		✓		5	Wired	Fiber Bragg Gratings (FBG) based optical sensors, toe angle
[23]	✓				8	Bluetooth	Custom Piezo-resistive fabric sensor, internal strain-stress calculation
[12]	✓	✓		✓	4	Bluetooth	Wireless charging, Over the air update focused design
[27]	✓				6	-	Custom Pressure sensitive conductive rubber (PSCR) sensors
[26]			✓		6	Bluetooth	Washable sock design using neurofabric sensors

P=pressure, Acc=Accelerometer, Gyr=Gyroscope, T=temperature

both indoor and outdoors. [30] demonstrated the use of temperature for ulcer prediction. [21] designed a sock that monitors foot pressure and temperature using Fiber Bragg Grating but the design is not comfortable and continuous monitoring is not possible. Although there are few examples of commercial socks, only Siren and Alpha-fit socks are capable of detecting abnormal changes in temperature or pressure respectively. These socks just target one parameter each. Moreover, none of these products give any information about number of sensors, spatial resolution, measurement range and accuracy of the system. Furthermore, out of these socks only Siren Socks are available in the US on doctor's prescription.

4 TECHNOLOGY INVESTIGATION & SELECTION

Our methodology and rationale behind designing the functional requirements for smart sock takes into the consideration the following factors: Able to continuously monitor the required parameters, functional and ergonomic for daily usage, ensuring a constant readings not affected by the normal bio-mechanics of the foot. The sensors must be calibrated with errors within a specific range and low energy consumption to allow long term monitoring and data logging. Non-functional requirements regards the safety, considering the sock targets neuropathy patients, with little or no sensation of pain, the sock must not cause any damage to the foot. Also must be lightweight, fit different sizes and be washable and reusable.

The following sensor technologies are considered and their capabilities are assessed: pressure sensors, temperature sensors, accelerometer sensors, heart-rate sensors.

4.1 Pressure sensors

Pressure sensors come in different forms: Capacitive force sensors, when force is applied distance between two conductive plates, separated by dielectric, is reduced thereby increasing capacitance, that is translated to applied force using conditioning circuits [10]. Optical sensor consists of LED light transmitted through the thin fiber and detected by a photo-diode on the other end, measuresing the light intensity as result of the exerted force [10]. Force Sensitive Resisters (FSR) are piezo-resistive devices linearly decreasing the resistance as the force applied on them increases.

Considering the above pressure sensing technologies and the commercially available sensors. FSRs are selected for further process as they offer :

- Thin and flexible design (0.2mm thickness).
- should measure required range of pressure/Force (upto 4448N).
- Easy to integrate.
- Linear output with simple conditioning circuit.
- Suitable for low power design.
- Such sensors are widely used and characterised in different studies in literature marking their suitability for foot pressure measurement.

4.1.1 Sensor Readings With Conditioning Circuit.

Simple voltage divider network used for previous testing does not provide linear output. A signal conditioning circuit as shown in Figure 2 is also designed to drive FSR. The op-amp circuit shown is a simple inverting op-amp configuration with reference voltage provided at non-inverting terminal. Due to virtual ground, both terminals of the op amp will try to be at the same voltage. This means op-amp will try to make voltage at inverting terminal equal to V_{ref}. Since op-amp does not draw any input current, the voltage at inverting terminal is essentially voltage across FSR. This allows to see feedback circuit as voltage divider network.

4.2 Temperature sensors

We identified the following temperature sensors technologies: Thermocouples, Resistor Temperature Detector (RTDs),Semiconductor temperature sensor ICs (ST-ICs), Thermistors. **Thermocouple** works on the Seebeck effect principle where two dissimilar conducting metals connected together forming an electrical junction allowing the Seebeck effect to be observed where a small voltage is generated across this electrical junction being a function of the temperature. **RTDs** utilize the change of material resistance when their temperature changes, exhibiting high degree of linearity ie. resistance is directly proportional to temperature. RTDs are highly precise and repeatable, but react slowly to temperature changes. **Thermistors** work on same principle as RTDs but with a different construction. Each thermistor has temperature co-efficient indicating the degree of change in resistance for change of temperature. **ST-ICs** exist in two flavors (local and remote digital temperature sensor) differing in the sensor position inside or outside the chip: Local temperature

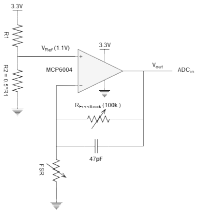
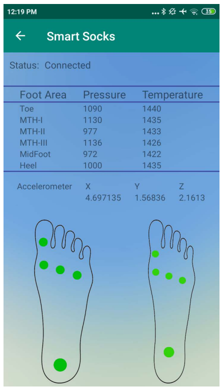


Figure 1: Sensor conditioning circuit.



Status: Connected

Foot Area	Pressure	Temperature
Toe	1090	1440
MTH-I	1130	1435
MTH-II	977	1433
MTH-III	1136	1426
MidFoot	972	1422
Heel	1000	1435

Accelerometer	X	Y	Z
	4.697135	1.56836	2.1613

Figure 2: Data logging and visualization.

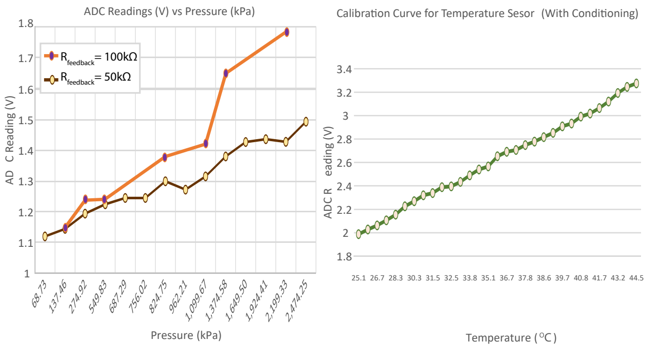


Figure 3: FSR ADC Rfeedback= 50kΩ/100kΩ and Temperature calibration with Condition circuit

sensors measure their own die temperature or the ambient temperature around it [13]. Remote digital temperature sensors measure the temperature of an external transistor.

Table 2: Requirements for sensors to be used

	Sensors			
	Pressure	**Acceleromet**	**Thermometer**	**Heart-rate**
1	Range 0-1000 kPa	14 bit resolution	Accuracy: ±0.5°C	SpO2 cappable
2	Linear response	Output data rates 1.56 to 800 Hz	Range: 25 to 45°C	
3	Flexibile woven	Flexible woven	Flexible woven	Flexible woven
4	Low Power	Low power	Low power	Low power
5	Min 5*5mm	I^2C digital interface		
6		dynamic range ±2 to ±8 g		

4.3 Accelerometer sensor

Pressure information alone can be insufficient to detect abnormal foot condition, because the pressure happens for a multitude of certain posture or physical activity. Enhancing that information with gait and stride information acquired by the accelerometer sensors is favorable. Nowadays cheap MEMS accelerometer provide enough information to calculate gait patterns.

Keeping this in mind a short survey of accelerometers is conducted, chosing the MMA8451 with following characteristics:

- 14 bit resolution.
- Output data rates (ODR) from 1.56 Hz to 800 Hz.
- $\pm 2g$ / $\pm 4g/\pm 8g$ selectable dynamic range.
- Low power operation (1.95-3.6 V supply voltage)
- I^2C digital output interface.

4.4 Heart-rate monitoring

Heart rate monitors can provide information about pulse and oxygen saturation (SpO2) of the blood that are used to extract foot perfusion information and evaluate the effective blood flow of the foot. They work by shining light to the skin and measuring the light scattered due to the blood flow changes, such as pulse rate or change in blood volume. The intensity of the reflected light will change accordingly, allowing to estimate the pulse rate or oxygen saturation. The pulse can be detected in two specific areas of the foot and we tested those sites with a MAX30102 low power heart-rate and SpO2 monitor. We found that sensor provided inconsistent results, because of the following causes and decided not to use for integration in the sock design:

- Heart-Rate sensor is very sensitive to any movement of the sensor from the skin surface, resulting in erroneous readings.
- Difficult to point the sensor to the arteries within the sock.
- The use of accerlrometer to compensate for the movement of the sensor is a tedious task.

4.5 Communication Protocol Selection

Transferring the data to the back-end should be performed wirelessly. Wired protocols such as UART provide simple and reliable data transfer but require a physical connection between two ends limiting the range of motion and affecting the safe movemenet of the subject. Wireless protocols provide better way to connect to different type of end devices as Bluetooth and WiFi capabilities become more commonplace. We explored five different wireless technologies suitable for data transfer. **Zigbee** is a wireless technology for integrating sensor network applications into the IOT, built on the universal IEEE 802.15.4 standard and addresses the requirement for low power consumption, low data-rates, and is highly secure and reliable. **ANT** stands for "Advanced and Adaptive Network Technology" targeting collection and transfer of sensor data with high degree of inter-operability. Nodes in the ANT network can act as transmitters, receivers, or transceivers to route traffic to other nodes. **Bluetooth Low Energy (BLE)** caters to the needs of a wide range of applications aiming to provide an extended communication range at reduced cost and power consumption based on 2.4 GHz radios. Software Development Kits (SDKs) and reference designs are available which makes easier to work with BLE enabled SoCs. **WiFi** is designed for large data transfer using high speed throughput, based on IEEE 802.11,but not suitable for low power operation. **Near Field Communication (NFC)** is the wireless sensor technology designed for short range communication. It operates in the 13.56 MHz ISM band providing data-rates upto 424 Kbits/sec with a maximum range of 10 cm.

Table 3: Comparison of different wireless technologies. (Adopted from [1, 22])

Parameter	Bluetooth	WiFi	Zigbee	ANT	NFC
Range	100	150	100	30	10 cm
Throughput	1 Mb/sec	11 Mb/sec	250 kb/sec	20 kb/s	424kb/sec
Latency	2.5ms	1.5 ms	20ms	Nil*	NA
Power	30mA	-	30mA	-	50mA
Security	AES-128	AES	AES-128	AES	none

4.6 Sensor Conditioning and Calibration

Once sensor technology is selected and sensors are finalized it is important to characterize these sensors before integrating into the system. This is done by using calibration setups for both temperature and pressure shown in Figure 4.

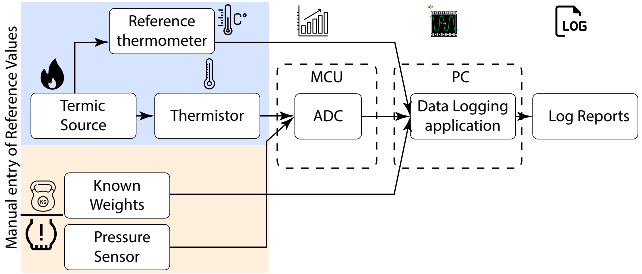


Figure 4: Diagram of calibration setup

Depending on the type of sensor and range of changes in sensor values, conditioning circuit is designed. Use of conditioning circuit helps to linearize the sensor output and allows to take full advantage of available voltage range to provide better resolution. Figure 2 shows an example of conditioning circuit used for pressure sensor. It is found that R_{feedback} resistor of $100k\Omega$ provides better sensitivity within range of interest and shown in the Figure 3 Pressure Temperature verses voltage readings plot is shown in Figure 3 Temperature.

4.7 Gateway

A smart-mobile device like the smartphone is the most optimal choice given the capabilities and range of Bluetooth availability. Android smartphone is chosen as end-device application platform given its portability, ease of connection and operation. An android application ,called 'smart-socks', is developed with two goals in mind: data logging and data visualization. The app is used for temperature, pressure, accelerometer data acquisition. The app is capable to registers itself for automatic parameter updates from the sock, on connection. Log the acquired data with respective timestamp to a csv file for further investigation. Visualize the parameters for different regions of the foot.

5 TEST AND EVALUATION

For evaluation of socks and its suitability of desired application, following tests are performed:

- Pressure and Accelerometer Test
- Temperature Test

5.1 Pressure Test and Accelerometer Test

For this test, leg was kept in different positions for around 20 seconds each. These postures are:

(1) Standing still
(2) Pressure on Heel
(3) Pressure on Toe
(4) Foot in the air

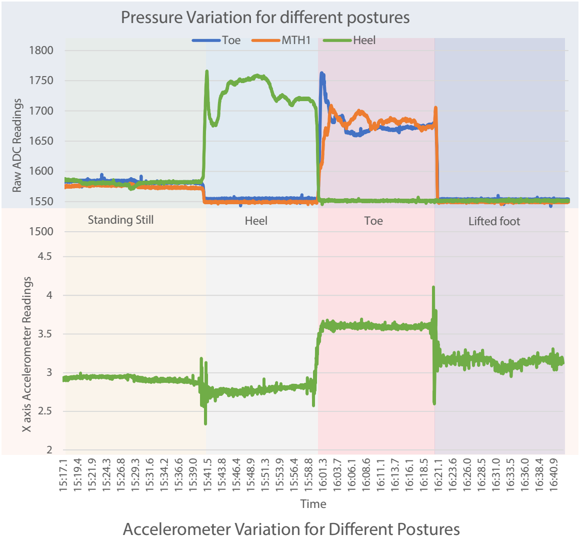


Figure 5: Different postures Pressure (toe, MTH1, heel) and acceleration readings.

The obtained test results are shown in Figure 5. It can be observed that for standing still, almost all of the sensors show similar pressure indicating similar pressure distribution. When all of the pressure is put on heel by lifting toe up, FSR at heel position (green line in Figure 5 pressure graph) shows high pressure readings where as toe sensors show no load reading. Opposite behaviour is observed when heel is lifted high instead of toe. Finally when foot is lifted completely and kept in the air, all the sensors give no-load reading confirming proper functioning of sensors.

Accelerometer readings are also analysed and result for x-axis change, accelerometer is positioned at the back of the foot above the heel, with X-axis aligned with vertical movement of the foot. So its movement should correlate with heel movement. This behaviour can be confirmed from the plot in Fig. 5 demonstrating proper functioning of sensor.

5.2 Measuring foot temperature variations

Accuracy of temperature sensor is already established in sensor characterization with just 1% error. This test is performed to test how well the sock can responds to changes in temperature. To check this, foot is exposed to a heat source for few minutes and then taken away and placed in open air. To reflect such behaviour temperature readings should show increment for sometime and then shows decrement afterwards corresponding to the processes of exposing to and getting away from heat source. Plot of the temperature readings of this test are shown in Figure 6. Similar to earlier test this test also conforms to the expected behaviour.

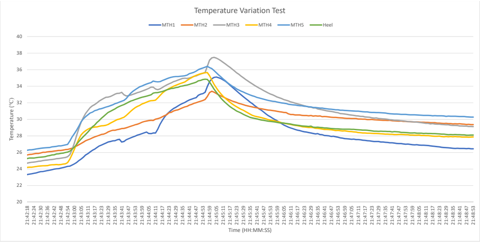


Figure 6: Temperature readings for different areas of the foot when foot is subjected to varying temperature using heat source.

Since maximum error in temperature readings is 0.2^0 C, maximum error in difference of temperature between left and right leg would be 0.4^0 C. This is within acceptable limit as we are interested in finding out difference of more than 2.2^0C between same region of right and left foot.

6 SHOE EVALUATION

Diabetic patients with high ulceration risk are advised to use custom footwear, produced similar to foot casting, to offload the pressure from sensitive areas. There is no definitive way to quantify the effectiveness of footwear, however, the sock designed for ulcer prediction can be used for footwear characterisation. A test is conducted to evaluate the use of sock for footwear performance, for two shoes(one sport shoe and one high-heel shoe) worn by a female participant, by putting both shoes sequentially and recording pressure readings for normal standing position. Because high-heel shoe is considered unhealthy for back as well as foot since it creates uneven pressure distribution on the foot, the Figure 7 illustrates this increase in pressure. Also,with high-heels, the toe and mid-foot area experience increased pressure, while pressure is reduced for Meta-tarsal (MTH) I,II,III. This indicates that this particular high-heel shoe forces foot to become arched between toe to mid-foot area causing unnatural distribution of pressure, affecting natural functioning of foot and back.

6.1 Usability test

Washability and usability are the practical parameters outlined in the non-functional requirements section. Since sock is developed to measure foot parameters of diabetic patients, it should be comfortable to wear and walk. To assess this, sock was provided to seven participants (three female, four male) and questioned about the usability for: .

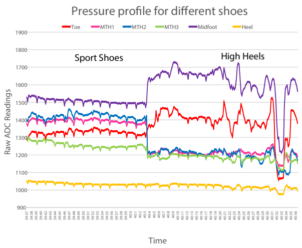


Figure 7: Pressure readings with different shoe.

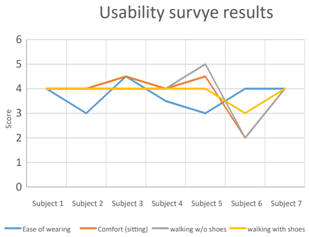


Figure 8: Comfortability test different users.

The feedback, Figure 8 form provided following questions scored 1 to 5: (1) Easy of wearing, (2) Comfort while sitting, (3) Comfort to walk with sock & shoes, (4) Comfort to walk w/o shoes, (5) Usefulness (Y/N). The overall experience results are positive. Apart from this, users were asked to provide suggestions regarding improvement in the sock design, three suggestions were provided : padding near sensor connection area of the sock, reduction in PCB size, change in sensor connectors on the PCB.

7 OPEN DISCUSSION

In order to continuously monitor the right foot parameters to predict incidence of diabetic foot ulcer, a smart sock woven with different sensors can be an optimal solution. During the conducted research we identified which foot parameters can be monitored to predict ulceration of diabetic foot. Concluding that: Static and dynamic pressure can be used to measure pressure distribution of the foot under different conditions. Persistent temperature difference of 2.2°C or more between one region of the foot and same region on the contralateral foot is an strong indicator for ulceration. In addition to this, Heart-rate can be used to check foot perfusion indicating state of blood supply of the foot is also an important and neglected parameter, mostly due to sensor placement. Based on compiled functional requirements we built a smart sock that monitor required foot parameters continuously, designed to be worn in day to day life and not affecting the normal bio-mechanics of the foot causing errors in the readings. Sensors data is reproducible and repeatable and continuous readings for long duration. Errors in sensor readings are cept to specified limits. Pressure and temperature sensors were calibrated to meet accuracy requirement. For example, sock targets to measure temperature difference of 2°C or more, whereas designed sock provides accuracy of 0.15°C thereby meeting design requirement. An Accelerometer is added to aid the correct interpretation of acquired pressure sensor readings. Feedback from users provided overall positive experience such as intuitive app design among others mentioned previously. Because this sock design is still in preliminary stage and many avenues are available for improvement in both design and functionality of the sock. Energy harvesting can be integrated with the current sock design to completely eliminate or reduce the the battery usage. Special materials which are capable of determining pressure and temperature values can be used, flexible PCBs or fabric printed PCBs can be used. A model can be trained to analyse the received sensor data on the end-point device to provide real time evaluation of the foot.

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