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Fabrication of a Digital Plantar Pressure Estimating Device with Internet of Things Ability

Chikwado Kingsley Onwukamuche[1], Patrick Ugochukwu Agbasi[2], Gideon Ihebuzor Nnanta Ndubuka[3], Chidi Samuel Iwuji[4], Kelechi Dorathy Kelechi[5], Innocent Chukwudi Ekuma[6]

[1]Prosthetics and Orthotics Unit, Department of Orthopaedics, Federal University Teaching Hospital, Owerri, Nigeria
[2]Prosthetics and Orthotics Department, Federal University of Technology, Owerri, Nigeria
[3,4,5]Biomedical Engineering Department, Federal University of Technology, Owerri, Nigeria
[6]Biomedical Engineering Department, Alex Ekwueme Federal University Teaching Hospital, Abakaliki, Nigeria

ABSTRACT: Digitally estimating the magnitude of the Plantar Pressures (PP) of the foot is an important aspect in the biomechanical management of diabetic foot and is not yet adopted in our clime and many low income countries mostly due to high cost and complexity of existing designs, as well as poor awareness. This study aimed to produce a cheaper, easier to use and internet of things compliant digital plantar pressure estimating device (DPPE) which should be able to detect, estimate and output in-shoe plantar pressure distribution. 10 Force Sensitive Resistor (FSR) were anatomically spread across an ambipedal insole. ESP8266 board was utilized as the microcontroller. Web applications were designed to ensure a smooth communication between the sensors, the microcontroller, the internet and the display units (Computers and Phones). The device achieved ambipedal fitting, Wi-Fi to internet signal transmissions were successful, and the sensors ability to detect and estimate pressure was achieved. The DPPE as produced in this study can help in achieving digital assessment of the PP estimation and its distribution on the foot for clinical evaluations, hence, it is an important tool in the clinical assessment of the DF managements. Use of WiFi as a mode of data transmission is ideal in a post-COVID world of ours as it supports virtual communication.

KEYWORDS: Plantar-Pressure, Diabetic-foot, Internet-of-things, smart-Insole, Force-Sensitive-Resistors

INTRODUCTION

Most low income countries have a great challenge in the availability, production and provision of technologies for the management of their citizens with different pathologies and disabilities. Possible reasons for this include lack of awareness on the part of the potential beneficiaries, their care providers and care-givers; absence of custom-made/purposive designs, financial constraints, and poor research (Tangcharoensathien et al., 2018). An example can be found in the management of the diabetic foot (DF). DF weakens the biomechanical ability of the foot to withstand the normal plantar pressures occurring between it and the floor during motion. Hence, the foot can break down, resulting into a diabetic foot ulcer (DFU) especially when these forces and their pressures (which can become elevated, or peaked) are repeated at particular plantar areas of the foot including areas where there are bony prominences (Abouaesha et al., 2001; Paltry et al., 2013).

Estimating and determining location of these areas of peak and or repeated plantar pressures is important in the management of DF and hence, DFU prevention and healing (Orlin, and McPoil, 2000). From the Harris mat to the force platforms and inshoe technologies which utilize force-sensing resistors (FSR), capacitance transducers, piezoelectric or resistive technologies, various methods of measurement have been utilized in commercial measurement devices (Orlin, and McPoil, 2000). The technology of estimating the pressure distribution on the plantar surface of the foot can help to identify and analyze various pathologies, neuromusculoskeletal anomalities, posture defects as well as efficiency of insoles and footwear designs, etc. (Jor et al., 2019). Unfortunately, most commercially existing ones are expensive (Cost can range from $20,000 to $50,000) and complicated. Hence they are not well utilized in the clinical practice, but mostly in Laboratories (Orlin, and McPoil, 2000; Thimabut et al., 2012). Also, the preference by most available commercial plantar pressure measurement/estimation devices for non-internet data transmission modules does not support the virtual medical environment where realtime information are shared across large distances, countries and continents.

These shortcomings could be responsible for the dearth of researches on the biomechanical perspective of diabetic foot management in Nigeria; considering that only a quantitative idea of how different biomechanical alterations influence the plantar pressure; could give an outcome measure analysis of the various management methods being proposed (Ogbera et al., 2005). Almost every recent study on the biomechanical features of the diabetic foot utilized plantar pressure measurement in their analysis, thus highlighting its importance. Hence, until we start adopting a quantitative estimation of Plantar Pressures (PP), outcomes of proposed methodologies for the management of diabetic foot as well as other indications will be assumptions and only qualitative.

The present study therefore aimed to design, produce and test an inshoe plantar-pressure detection and estimation device which should be able to detect the in-shoe plantar pressure distribution, estimate it and project out same in a format that is digitally readable. Such a device is to have a low cost and simplicity of operation, support the Internet of Medical Things technology (IoMT) and hence enable its acceptability among diabetic foot clinicians in Nigeria and beyond.

MATERIALS AND METHODS

The present prototype considered the following components:

Sensor

10 Force Sensitive Resistor (FSR), thin Film MD30-60@50Kg were utilized as the pressure Sensors. This FSR matches the design specifications of this study as it has the following features:

- Ultra-thin, when compared with other Pressure sensors
- Waterproof as well as highly pressure sensitive
- Good durability and stable performance
- Insensitive to electromagnetic interference (EMI)
- Insensitive to electrostatic discharge (ESD)

Each FSR MD30-60@50kg comprises of 2 conductive areas separated by an adhesive spacer to prevent them from contacting each other. When the sensor is not loaded or at rest, there is maximum resistance and vice versa. The 10 FSRs were positioned at strategic anatomical positions of the foot namely the forefoot, the midfoot and the hind foot as shown below:

TI		T2		T3
F1		F2		F3
	M1		M2	
	H1		H2	

T = Toe region; F = Forefoot region; M = Midfoot region; H = Heel region

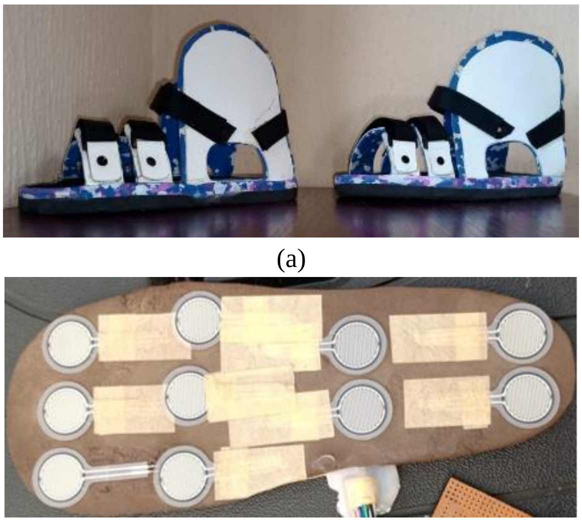
Hence, for the right foot, it is expected that the sensor readings for the T1, F1, M1 and H1 will represent the medial aspect of the foot, but for the Left foot, same reading will represent the lateral foot and vice versa.

Insole and diagnostic footwear

The pressure sensors were imprinted on the inshoe insole (Smart insole) which is in turn fitted into a special footwear fabricated for the purpose of this study. Both were made to be ambipedal and hence could be used for the left and right feet. Both were designed from the foot tracing of a normal individual. Ethylenevinyl acetate (EVA) foam (2mm thick) was used as the smart insole while 1mm thick EVA foam were used as the top and bottom layers to protect the sensors and wiring from shear stresses.

Having prepared the insoles, the sensors are affixed on the insole (Figure 1) in-line with the anatomical foot tracing done earlier and held in place with adhesive tape.

Standard shoe making tools and materials were used in making the Diagnostic Footwear.



(a)

(b)

Figure 1: (a) The Diagnostic Footwear and (b) The smart insole

Micro-Controller Unit.

Due to its support of Internet of Medical Things (IoMD), an ESP based microcontroller (ESP8266 board with 10bit Analog to Digital Converter (ADC)) was utilized for the present study. The ESP8266 board was set up as shown below in figure 2 and 3.

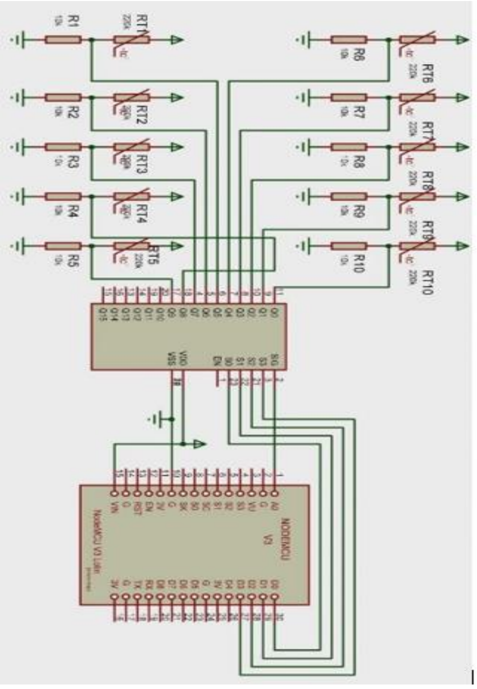


Figure 2: ESP board setup for the present study.

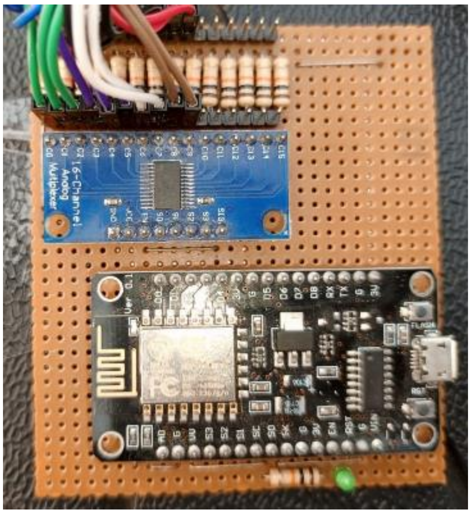


Figure 3: The ESP board

Each of the 10 FSRs were connected to 10 of the 16 ESP board channels. This connection involved a unit each of a voltage divider comprising of a fixed 10kΩ resistor connected in series with the resistance of the FSR. These were feed into the channels of the analogue to digital converter (ADC) of the ESP board from channels 1 to 10.

Display device

The display unit is to display the digital plantar pressure estimates. Computer screen and/or mobile phone were 2 major display units considered.

Software.

The softwares that will provide the instructions necessary to run the system as well as support the wireless transmission of information were designed to ensure smooth running of the device. Software tools utilized include Arduino IDE, C++, NextJs, FastAPI, SocketIO, and Linode.

Working Principle

When loading occurs on the sensing/conductive area of the Force sensing resistor, the separation between substrate layers gradually disappears as the pressure increases. This increases current to start flowing through the FSR hence, resistance reduces. Therefore the relationship between the magnitude of loading to the Resistance of the FSR, and to the current flow is as follows:

$P \propto 1/Rfsr$ equation 1

$P \propto I$ equation 2

P = Pressure magnitude

Rfsr = Resistance of the FSR

I = Current.

Each of the FSR is connected in series to the 10k ohm resistors in a voltage divider format as shown below

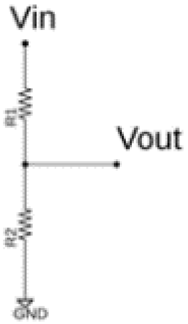


Figure 4: A typical voltage divider circuit

Hence, the output voltage obtained is as follows

$V_{out} = V_{in}\frac{R_1}{R_1+R_2}$ equation 3

Where V_{in} = Supply voltage

V_{out} = Output voltage that feeds the ESP microcontrollers Analog-Digital Converter

R_1 = 10kΩ

$R_2 = R_{FSR}$ = FSR Resistance

Based on the equation 3 above, the V_{out} will tend to increase with increasing loading of the FSR (Since increase in loading decreases the RFSR).

With the FSRs connected to the ESP board channels in the form of units of voltage dividers (as shown above in figure 4); the microcontroller's 10 bit ADC converts the sensor's analogue Voltage (V_{out}) to a digital number that ranges from 0 to 1023 (210 = 1024). ADC readings ranges from 0 - 1023 are transmitted wirelessly by the ESP's WIFI to the display device. The ADC reports an output signal which changes in proportion to a change in the input or supply voltage. Hence, the ADC assumes 5V is 1023 (maximum load); and anything less than 5V will be a ratio between 5V and 1023 as illustrated below

$\frac{ADC\ RESOLUTION}{SYSTEM\ VOLTAGE} = \frac{ADC\ READING}{ANALOG\ VOLTAGE\ MEASURED}$ equation 4

Therefore, when the ADC reading is 600, considering that

ADC Resolution = 1023

System Voltage = 5V

ADC reading = 600

The Analog voltage would have been 2.93V.

Hence, increase in sensor pressure, decreases Sensor resistance, increases voltage, increases the ADC output.

Below is the block diagram of the present device (figure 5) showing the flow of the design.

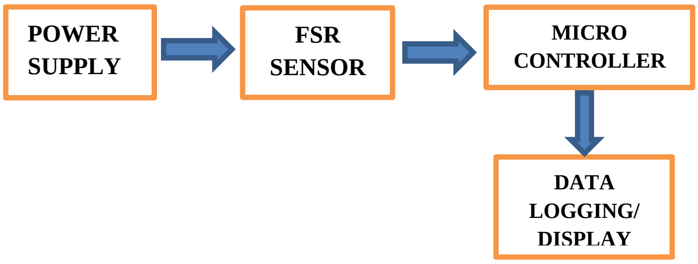


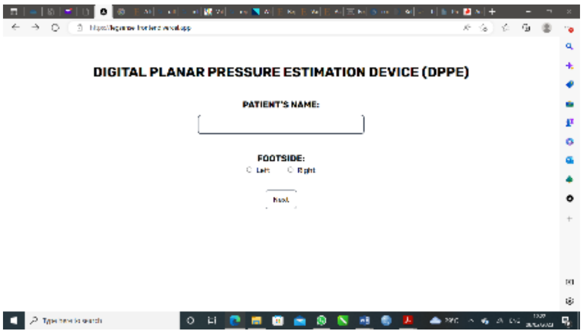
Figure 5: Block diagram of the DPPE

Method of structuring the Display

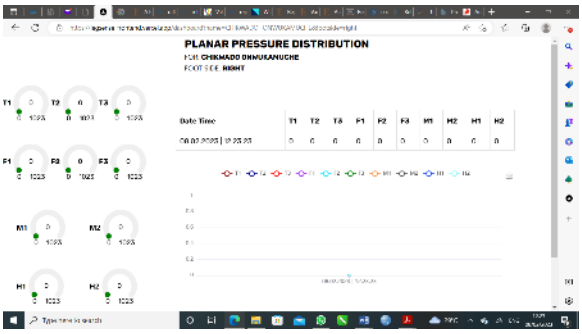
The website for the web-based software display was created at https://legsense-frontend.vercel.app. Figure 6 (a)-(d) below shows the displays and effects of clicking on the control buttons. The display had 2 platforms. The first platform was a welcome page requesting the name of the client, side of the foot affected, and the "Next" button. Clicking the "Next" button is expected to load the next page as shown in the figure 6 (a)-(d) below.

The second platform has the Start/Stop buttons which will Start the process or end it. The Refresh button returns the page to a zero state (Refresh). The Done button assumes completion of task and returns the user to the first platform in preparation for another client.

The Table on the right contains seconds by seconds logging of the pressure distributions on each of the sensors. The line chart shows a dynamic graphical pressure fluctuations on each sensors. The Summary Statistics becomes activated after each test is concluded by clicking on "STOP" button. The summary statistics table shows the average Plantar Pressure on each sensor after Time (t) in seconds. It also shows the Peak (Maximum) plantar pressure estimate on each sensor after Time (t).



(a)



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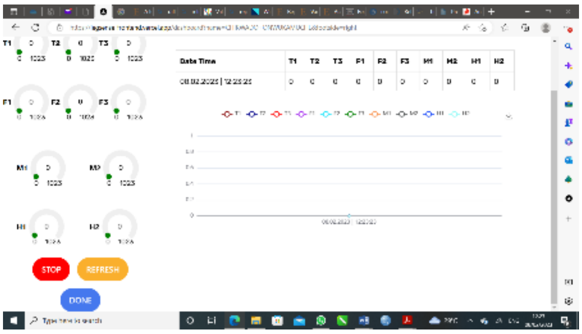

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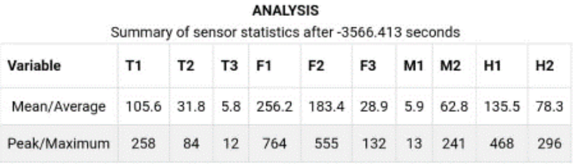

ANALYSIS

Summary of sensor statistics after -3566.413 seconds

Variable	T1	T2	T3	F1	F2	F3	M1	M2	H1	H2
Mean/Average	105.6	31.8	5.8	256.2	183.4	28.9	5.9	62.8	135.5	78.3
Peak/Maximum	258	84	12	764	555	132	13	241	468	296

(d)

Figure 6 Sample of the Display on the output. a: The introductory page; b: Page showing the gauges, the data log table and the chart area; c: Scrolled down page showing the Start/Stop, Refresh and Done buttons; d: Sample of the Analysis table. This table is logged at the completion of the screening after clicking on STOP button.

Calibration

Since the objective of the device was to detect the distribution of pressure on the foot as well an estimate of its quantity, the device calibration was done based on the digital value of the output of each FSR (Bits). It has been stated earlier that the Analog Digital Converter (ADC) values ranges from 0-1023. Observation of the unloaded state of the device displayed a reading of 0-12 bits. The Guage display widget on the software was used to create a calibration of the device based on the following:

0-12	No load
12-400	Green
401-600	Blue
601-800	Purple
801-900	Pink
>900	Red.

The colour changes of the gauges therefore gave an idea of the magnitude of the pressure estimate and its variations on each of the sensors with time. Calibration of the device to read-out in Paschals will be done in future studies.

Tests

The device was tested to determine if the objectives of the study were met. The following tests were conducted on the device

Test for bilateral conformity of the insole

The insole was fitted on the right and left plantar foot to determine if the outlines of the feet were covered by it. This is to confirm the ability of the device to be used for either the left or the right foot.

WIFI/Internet data transmission test.

The ability of the device to transmit wirelessly using WIFI was also tested. The device was powered on, WIFI connection were established. Slight pressure was applied on the sensors to confirm transmission of data

Test of the sensing ability of the sensors. Gradually increasing pressure the first was applied on the sensing area of each sensor to know if the sensor value will vary with each increasing or decreasing force.

RESULT

Bilateral conformity of the insole

From Figure 7 (a) and (b) below, the test insole fitted well on both the left and right foot to estimate plantar pressure distribution on the foot.

Figure 7a: Insole test of fit for the right foot showing the medial and lateral views

Figure 7b: Insole test of fit for the left foot showing the medial and lateral views

Test running of the DPPE device (Test of WIFI data transmission)

The device was powered on with a power bank and the network router was activated, the ESP WIFI connected successfully and was detected by the Hotspot of the Android phone used for internet connection.

Figure 8a: Test running the DPPE device and WIFI connection: Loading of the forefoot area;

Figure 8b: Test running the DPPE device and WIFI connection: Loading of the

The figure 8 (a) and (b) above shows that not only was the device coupled successfully, WIFI connection was also successful and automatically connects to the android phones hotspot easily. Upon loading of individual sensor or group of sensor, the transmission of the plantar pressure estimate to the display device was successful. Data logging on the table and Chart were found to be done every 3 to 6 seconds on a real-time basis depending on the network signal strength. The colour change designed for the bits gauge was also found to be working as specified. This is shown in the gauge readings shown on the computer corresponding to the sensors pressed down on the insole.

Test of the sensing ability of the sensors

The Figure 8(a) above also shows that the sensors at a resting/unloaded state were reading from 4 to 12 bits depending on network strength. Upon loading with the thumb, the reading at the sensors (F1) started increasing with increase in the thumb depression up to 600bits. Also, the colour of the Gauge widget changed from green to blue as the thumb pressure increased toward the maximum force detectable by the sensor.

DISCUSSION

The role of digital technologies like the DPPE devices in the assessment and treatment of various pathologies including neuromusculoskeletal anomalies cannot be over-emphasized. The method of relying only on assumption and/or clinician's experience is not only subjective and hence unscientific; but also a setback to standardization and researching (Totah et al., 2017). The present study is therefore a rise–up to the challenge of not only contributing to the body of knowledge in this area; but also an embrace to the use of digital technologies in clinical process including orthotic interventions. If studies like the present one is embarked upon frequently in our clime, digitization of clinical interventions will not only become well accepted, but will also be available for clinicians to utilize at cheaper price.

Any device which can give a digital data representation of how pressure is distributed at the plantar surface of the foot is an important assessment tool in the management of many neuromusculoskeletal conditions like the diabetic foot. This work therefore joins similar studies (Jor et al., 2019; Klimiec et al., 2014; Sneha et al., 2021; Thai et al., 2018; Thimabut et al., 2014) in producing cheaper and easier Plantar pressure analysis devices for use in medical treatment of foot conditions.

Use of WiFi and Internet as opposed to Bluetooth for data transmission

While there have been similar studies on design and fabrication of plantar pressure measurement devices, the present activity utilized Wi-Fi and Internet as data transmission module unlike other studies that did not utilize internet of things technology ((Jor et al., 2019; Klimiec et al., 2014; Sneha et al., 2021; Thai et al., 2018; Thimabut et al., 2014). The advantage Wi-Fi (Wireless Fidelity) includes higher data rate, ability to connect to the internet, ability to allow more numbers of devices to connect (Pothuganti and Chitneni, 2014). The ability of Wi-Fi to connect to the internet and allow for more multiple users to connect is important in this era of virtual environment, especially for a multidisciplinary team like that needed for the management of DF. Therefore, the patient wearing the smart insole in the Diagnostic footwear does not need to be in the same space with the entre management team, yet each member of the team can visualize the plantar pressure distribution pattern of the patient across distances and then make their informed decision from it. Bluetooth and the other methods of transmission cannot connect to the internet and hence cannot have this feature.

The present study also went further to fabricate a pair of Diagnostic footwear to provide a flat surface for the sensors. This was to mimic the flat environment of a normal walking environment for the foot. The author believes that a footwear that is contoured has already biased the sensing ability of the sensors to detect the effect of a treatment design. For instance in a potential study that is evaluating the effect of varying the heights of the medial arch support on the PP. such a study should require a platform or surface that is flat in order not to over or under-exaggerate the height of the medial arch support. Hence, the medial arch support specimen being studied will be positioned appropriately on the inner sole of the footwear, then the smart insole will be put in place before the device is don on the patient for analysis to begin. The Diagnostic footwear fabricated for the present study was not only light, but was also rigid enough to avoid deformation of the sensors from bending stresses.

The need for a cost effective, easy to operate and locally available and producible plantar pressure estimating device motivated this work as well as other previous studies (Jor et al., 2019; Klimiec et al., 2014; Sneha et al., 2021; Thai et al., 2018; Thimabut et al., 2014). Our work presents a better method of strapping the device to the body in that the device is strapped to the footwear directly and the footwear to the foot. This is similar to the work of Klimiec et al., (2014) and Sneha et al., (2021). Thimabut et al., (2014) presented a more complex strapping method above the ankle, knee and hip.

The present study utilized a total of 10 sensors which can be used for the left or right feet. The more the sensors of the insole, the better the resolution of the device (Orlin and McPoil, 2000). 10 sensors for either side of the foot is more than the 3 pressure sensors employed by Sneha et al., (2021) and the 8 sensors for each foot employed by Klimiec et al., (2014) and Thai et al., (2018). There is still opportunity to increase the sensors to 16 or more with modifications in the circuitry.

CONCLUSION

The use of Wi-Fi and hence Internet of Medical Things, has many advantages over other data transmission modules, Bluetooth inclusive. Of a more potential importance is the ability to connect multiple devices, across distances, to have access to the real-time visualization of the readings of the DPPE. This importance will be beneficial to a medical multidisciplinary team like that of a typical Diabetic Foot Management Team. While the readings obtained from this DPPE device were estimates of Plantar pressure in bits and can serve as a good plantar pressure distribution estimator;

qualifying areas with and without high plantar pressures, it cannot be used to confirm plantar pressures quantity in paschal or other pressure units. Hence, there will be need to further develop this work and calibrate it to readout in pressure units. Also, there will be need to compare the output of this work with ones that have already being accepted as good standards. This is another area for further research on this work.

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