A Development of Plantar Pressure Sensor for Foot Ulcer Detection in Diabetic Neuropathy Individuals – A Pilot Study

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Abstract. Diabetes mellitus is a metabolic disorder that derived from the body’s inability to attain glucose homeostasis. Further increase in glucose level in the bloodstream, if left untreated, will lead to further metabolic disorder and complication such as amputation of a lower limb that caused by a foot ulcer. Approximately, 60% of diabetic foot ulcer comes from neuropathy. Thus, an early detection of foot ulcer would benefit particularly for diabetes individuals to reduce the risk of amputation. In this research, a plantar pressure sensor system is developed by using the Flexiforce sensor with data acquisition of NI-USB6008 as an interface to gather measurement data. There are four Flexiforce sensors that are placed at the most identified points at the right foot, which are heel, mid foot, fore foot and toe. In this pilot study, the right foot was chosen to be tested with this system. Further analysis was carried out to distinguish between 3 healthy individuals and 3 individuals with diabetes based on gathered plantar pressure value. A correlation study was performed between plantar pressure data and blood glucose data at \( t = 0 \) (\( G_t \)) to further justify the result before distinguishing the metabolic state of the individual. Although results show no significant different \((p<0.05)\) between these two groups based on 4 measurement points, this research provides a promising finding as some of the pressure reading of diabetes patients are significantly higher than a normal person. Hence, early detection of a foot ulcer is a good indicator that can significantly reduce diabetes-related foot complications through early education and appropriate foot care. This early detection of a foot ulcer also could benefit a better diagnosis and reduce subsequent risk and impact on diabetes-related foot complications.

1. Introduction
Glucose homeostasis can be achieved when endogenous insulin secreted by pancreatic \( \beta \)-cell is able to regulate the level of glucose in the bloodstream. However, the inability of a human body to attain glucose homeostasis will lead to the emergence of diabetes mellitus \([1, 2]\). This diabetes mellitus is a metabolic disorder with disturbance of fat, protein metabolism and carbohydrate which resulting defects from the formation of insulin secretion and insulin action \([3]\). In Malaysia, it was estimated of about 3.3 million people who have been diagnosed with diabetes in 2015 \([4]\). Diabetes mellitus can bring effect in short term and long term \([5]\). The National Health and Morbidity Survey (NHMS) 2013 has shown that the
prevalence of diabetes in Malaysia has increased by 31.0% in the space of just 5 years, from 11.6% in 2006 to 15.2% in 2011 [6]. Characteristic symptoms such as blurring of vision, thirst and weight loss often happened to people with diabetes. One of the long-term effects of diabetes is amputation for lower limb. Major amputation is related to foot ulcer in a diabetes patient [5].

A foot ulcer is defined as gangrenes formation and loss of sensation in diabetic patients’ feet. Ulceration of foot in diabetes individuals is common. It is estimated approximately 15% of diabetic people worldwide will develop foot ulcer [7]. A further complication in foot ulcer can cost limb and life-threatening. A foot ulcer is usually related to diabetic neuropathy, which is a common complication of diabetes. Diabetic neuropathy is a condition where the nerve damage can occur in the legs and feet if the person has diabetes. Approximately, 60% of diabetic foot ulcer comes from neuropathy. Diabetic foot ulcer usually, starts off with sores or blisters on foot or lower limb [7]. Thus, an early detection of foot ulcer is essential and useful as an indicator that can reduce diabetes-related foot complications by applying appropriate foot care [8].

Various screening techniques in diagnosing the diabetic neuropathy have been proposed and are currently being used. These include the evaluation of vibration perception threshold (VPT), plantar foot pressure measurements, joint mobility, and Semmes-Weinstein monofilament (SWF) testing [9]. Both VPT and SWF focus on the assessment of sensory function and are among the preferred test to detect foot ulcer in the absence of a gold standard test. However, poor standardization of measurement limits the application of VPT and SWF in clinical practice. Both techniques define different methods varying from one testing area to another testing area on the same foot during the assessment and there is no evidence or consensus about the most appropriate threshold [10].

Thus, this pilot study proposes an alternative way to detect an early sign of foot ulcer by identifying the pattern of plantar or foot pressure for diabetes patients via LabVIEW software. A successful outcome would indicate a clear trend in denoting the metabolic state of the patient. Hence, an early detection of foot ulcer could benefit the diagnosis and reduce subsequent risk and impact.

2. Methodology

2.1. Participant Data
Volunteered participants were recruited to undergo this pilot study. Participants were aged between 24 and 63 years old. Three of the participants already diagnosed with diabetes and the other three are healthy. Each participant underwent a blood glucose test using the glucometer (Accu Check Advantage®, Roche) before going for the plantar pressure diagnosis test.

2.2. Plantar pressure Diagnosis Set-up
The prototype of the plantar pressure sensor is developed and conducted in the university lab as shown in Fig 1. The data collection was obtained from the National Instruments (NI) system. The type of DAQ hardware applied in this study is NI USB-6008 multifunction I/O device. It interfaces with the computer through a USB connector. This DAQ module is chosen based on its simplicity and easy to plug in into the computer slot. In this study, four of the Flexiforce sensors ranges from 0-100 lbs are being selected to measure the plantar pressure of the participants. A few concerns have been considered in choosing this sensor such good sensitivity, simple construction, long-term stability and linearly responsive with applied pressure. The active sensing area of the Flexiforce sensor is at the end of the sensor. This characteristic is compatible with the insole of the foot as placements of these sensors are distributed at specific points that potentially have higher pressure. Furthermore, the sensor material type is polyester and has a good flexibility.

In this pilot study, four Flexiforce sensors are used and connect to DAQ device. Every sensor is placed
at an identified location at the insole of the right foot and directly connected to DAQ. The four locations of the foot are identified as heel, mid foot, fore foot and toe. The output voltage then connected to the DAQ analog input as shown in Fig 1. Each sensor is connected in the form of a voltage divider circuit.

Figure 1. The experimental set-up of the plantar pressure sensor.

Participant then will be asked to step on his or her right foot on the plantar pressure set-up. The pressure and voltage reading were recorded for further analysis. The results of each of the identified points on the person’s right foot are displayed on the front panel of the LabVIEW system. The front panel as shown in Fig 2 allows the user to see the result of the individual foot, whether he or she has potentially a risky foot ulcer or not. The light emitting diode (LED) on the front panel act as an indicator for each of the four identified point located on the plantar pressure. The LED for risky foot ulcer will be light up when the pressure exceeds 62kPa [1]. If the pressure obtained less than 62kPa, LED for normal foot will be light up.
2.3. System Operation

Figure 3 illustrates the flowchart of the system operation. The system starts by initializing all four sensors. All four Flexiforce sensors are reset to 0V during the initialization process. If the initializing process runs well, then the participant will step his or her right foot on the Flexiforce sensor that has been set up for the plantar pressure experiment. Then, the LabVIEW program will start receiving data from all four Flexiforce sensors via the NI DAQ system. This LabVIEW program will identify the metabolic status of ulcer or non-ulcer foot based on the data obtained by the DAQ. The reading obtained will be correlated with the blood glucose reading in mmol/ml (fasting BG). Both results from the experiment set up and blood glucose reading will be compared at the end of the experiment.
Start

Initialize flexi sensor

Initializing sensor?

YES

Patient steps/stands on flexi sensor

LabVIEW receive data from flexi sensor through DAQ

Identify metabolic state ulcer or non-ulcer through data gathered from LabVIEW

Correlate with blood glucose reading in mmol/ml (fasting BG)

Result from blood glucose = result from developed system?

YES

End

NO

Figure 3. Flowchart of plantar-pressure study.

2.4. Calibration

A method used to find the relation between input and output related to the actual unit is called as calibration. In this experiment, input is pressure and the output is voltage, so an experimental calibration is completed. In order to calibrate the sensor, a known uniform weight is applied to the sensing area of the
Flexiforce sensor using a “puck” test. This “puck” test is used to make sure all of the weight from the weightage is focused on the sensing area only. This process is repeated with different weights from 100g-500g to get a range of measurements. Then, a linear interpolation graph between the load (g) and voltage (V) is plotted as shown in Figure 4.

![Graph of load VS voltage](image)

**Figure 4.** Graph of load VS voltage.

From the calibration process, it can be concluded that the voltage is inversely proportionally to the load. As a result, the voltage to pressure equation is determined as in equation (1). The equation is expressed from the linear equation, \( y = mx + c \). From the voltage value obtained it then converted to kPa unit by dividing the \( x \) (in g) by area of the sensor sensing area and then divided it by 1000 to convert g to kg. Then, divided the value to 101.97 to change it into kPa unit as shown in equation (2).

\[
x \text{ (load)} = \frac{y \text{ (voltage)} - c \text{ (interpolation)}}{m \text{ (slope)}} \tag{1}
\]

\[
1 \text{ kPa} = \frac{101.97}{m^2} \tag{2}
\]

3. Results and Discussions
Diabetes frequently affiliates with gait conditions assessed with plantar measurement equipment. This is because elevated pressures are convincingly considering as a contributing major risk factor of foot
ulceration in diabetic neuropathy feet with deformities [9, 11, 12]. Thus, understanding the magnitude and dynamic of foot pressure plays a key role in the formation of an ulcer in the diabetic neuropathic patient.

Previous studies had shown interest in developing methods to identify and differentiate between normal and neuropathic individuals [11,12]. Prior study had proposed Normalized Peak Pressure (NPP) and Pressure Contact Ratio (PCR) techniques to understand the pressure distribution pattern under the soles of diabetic neuropathic feet patient that is possible to have foot ulcer [13].

In this pilot study, the plantar pressure set up is developed to distinguish the early sign of foot ulcer in diabetes patients by monitoring the pressure on the foot based on the developed LabVIEW system. Table 1 shows the pressure and voltage reading for each participant obtained from each of the pressure sensors that located at the four identified points of the foot.

| Participant | Age | Weight (kg) | Glucose (mmol/ml) | Years of Diabetes | Sensor Placement on Foot |
|-------------|-----|-------------|-------------------|------------------|------------------------|
| 1           | 49  | 82          | 9.3               | 3 years          | Heel (1): 50kPa, 30kPa, 10kPa, 40kPa, Mid foot (2): 3.1V, 3.3V, 3.5V, 3.2V, Fore foot (3): 50kPa, 20kPa, 50kPa, 30kPa, Toe (4): 3.1V, 3.4V, 3.2V, 3.3V |
| 2           | 52  | 84          | 12.8              | 6 years          | Heel (1): 50kPa, Mid foot (2): 3.4V, 3.2V, Fore foot (3): 50kPa, 20kPa, 50kPa, Toe (4): 3.5V, 3.4V, 3.2V, 3.3V |
| 3           | 24  | 45          | 8.7               | 4 years          | Heel (1): 50kPa, Mid foot (2): 50kPa, 20kPa, 50kPa, Fore foot (3): 50kPa, 10kPa, 20kPa, Toe (4): 3.1V, 3.4V, 3.2V, 3.3V |
| 4           | 51  | 83          | 6.3               | Nil              | Heel (1): 50kPa, Mid foot (2): 50kPa, 20kPa, 50kPa, Fore foot (3): 50kPa, 10kPa, 20kPa, Toe (4): 3.1V, 3.4V, 3.2V, 3.3V |
| 5           | 63  | 69          | 5.4               | Nil              | Heel (1): 20kPa, Mid foot (2): 20kPa, 8kPa, 10kPa, Fore foot (3): 20kPa, 10kPa, 20kPa, Toe (4): 3.3V, 3.5V, 3.3V, 3.5V |
| 6           | 47  | 85          | 6.1               | Nil              | Heel (1): 40kPa, Mid foot (2): 40kPa, 9kPa, 20kPa, Fore foot (3): 40kPa, 9kPa, 20kPa, Toe (4): 3.2V, 3.5V, 3.4V, 3.5V |

The results show that all of the diabetes participants have a higher reading of the pressure sensor at toe point with the highest value of 40kPa compared to the healthy participant with a lowest reading of 6kPa. This proves that this developed plantar pressure system is able to detect the possibility of the foot ulcer in diabetic patient.

Figure 5 shows the front panel of the LabVIEW system which the indicator turns green when the system identified that points of the participant’s foot are normal and have no foot ulcer. However, if the pressure is more than 62 kPa, then the indicator will turn to a red color.

The interquartile value from the four points heel (1), mid foot (2), fore foot (3) and toe (4) for both groups are calculated as shown in Table 2. Hypothetically, patients that suffer from diabetes mellitus have higher pressure compare to normal people on the measured point observed at the insole of the foot. The results also show that the pressure on the toe is higher for the diabetes mellitus group as compared to the normal group.

Table 3 shows the result of the p-value for all the four identified points. Pressure distribution for all part of the foot shows significantly different (p > 0.05) between these two groups of diabetes mellitus and normal. This significantly different is probably due to the lack of number samples (N=3) for both groups. Furthermore, the tested subjects are having different sizes of the foot which results in the sensors cannot be placed in the right position to be measured.
Figure 5. The front panel of the LabVIEW system shows that the participant is normal and has no foot ulcer.

Table 2. The interquartile value for both groups for all the four identified points of the foot.

| Sensor placement | Interquartile value for diabetes mellitus group | Interquartile value for normal group |
|------------------|-----------------------------------------------|-------------------------------------|
|                  | Q1                                            | Q1                                  |
|                  | Q2                                            | Q2                                  |
|                  | Q3                                            | Q3                                  |
| Heel (1)         | 50                                            | 30                                  |
| Mid foot (2)     | 20                                            | 20                                  |
| Fore foot (3)    | 25                                            | 35                                  |
| Toe (4)          | 15                                            | 8                                   |
|                  | 15                                            | 10                                  |
|                  | 15                                            | 15                                  |
|                  | 25                                            | 15                                  |
From the results tabulated in Table 3, it shows that the p-value on toes indicates better measurement compare to the other three points in order to distinguish between diabetes and normal foot. Thus, these results show promising findings that relate to the hypothesis that has been made. This is proven when all points for diabetes mellitus participants developed higher pressure than normal participants.

Table 3. The result of p-value for all the four identified points on the foot.

|          | Heel (1) | Midfoot (2) | Fore Foot (3) | Toe (4) |
|----------|----------|-------------|---------------|---------|
| p-value  | 0.205    | 0.331       | 0.834         | 0.064   |

4. Summary
This study has successfully developed a foot pressure measurement setup using the Flexiforce sensor and distinguish between normal and abnormal foot based on gathered pressure. From the result obtained, this study shows a significant result where the diabetes mellitus participant produced higher foot pressure, especially at the toe as compared to the normal participant. Thus, this simple and low-cost pilot study opens a new venture in the early detection of foot ulcer in diabetic patients. For future work, the system can be further by increasing the number of samples and varying the foot size so that different sizes of the foot can obtain the perfect measurement.

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References
[1] Alberti K G M M and Zimmet P F 1998 Provisional report of a WHO consultation, Diabetic medicine 15 539-53
[2] American Diabetes Association 2014 Diagnosis and Classification of Diabetes Mellitus Diabetes Care 37 S81-S90
[3] Othman N A 2015 Analysis and Optimisation of Model-Based Insulin Sensitivity and Secretion Tests (PHD Thesis, University of Canterbury, New Zealand)
[4] Whiting D R, Guariguata L, Weil C and Shaw J 2011 Diabetes research and clinical practice 94 311-21
[5] Khanna A K and Tiwary S K 2016 Ulcers of the lower extremity (New York: Springer)
[6] Lewis V A 2011 Diabetes Spectrum 24 4-5
[7] Farzanfar B, Nazari R and Bayanollahi G 2013 Diabetic foot ulcer Gangrene management-New advancements and current trends ed A Vitin (London: InTech)
[8] Priya S K, Nithyaa A and PremKumar R 2014 Int. J. Sci. Eng. Res. 5 87-92
[9] Pham H, Armstrong D G, Harvey C, Harkless L B, Giurini J M and Veves A 2000 Diabetes Care 23 606-11
[10] Dros J, Wewerinke A, Bindels P J and van Weert H C 2009 The Annals of Family Medicine 7 555-8
[11] Bus S A, Maas M, de Lange A, Michels R P and Levi M 2005 J. Biomech. 38 1918-25
[12] Lavery L A, Armstrong D G, Wunderlich R P, Tredwell J and Boulton A J 2003 Diabetes Care 26 1069-73
[13] Patil M, Bhat V V, Bhatia M, Parivalavan R, Narayananmurthy V and Ganesan V 1997 Proc. of the 19th Annual Int. Conf. of the IEEE 1826-8