Screening Of Foot Ulceration in Diabetic Neuropathy Patients Using Flexi Force Sensor Platform

S. Krishna Priya¹, A.N.Nithyaa2, R.PremKumar3

Abstract—In this work, an experimental setup for effective screening of foot ulcer in diabetic neuropathy patients is described. Diabetes brings with it neurovascular complications, which results in development of increase in pressure among the foot regions. Patients with diabetic poly neuropathy often lose pain and temperature sensations in their feet, resulting in inadequate pressure under their feet, during walking or standing. This may cause injury in the feet; painless trauma develops and results in ulceration. So prevention of diabetic foot ulcer is needed. A circuit is proposed to measure the pressure on the foot with the help of force sensing resistor. The pressure on the foot is acquired by the sensor. For large scale data acquisition system, a graphical program environment like Lab VIEW is needed. According to the Normalized Peak Pressure (KPa) values Classification of normal and diabetic neuropathy patients was done. In this method diagnosis of foot ulceration is done in an earlier stage thereby the further ulceration is prevented.

Index Terms—Diabetic Foot Ulceration, Normalized peak pressure, Data Acquisition Unit, Lab VIEW Software, FSR.

I. INTRODUCTION

Feet provide stability support while walking, standing and running. The foot has five major functions, it is the foundation for the whole body, it can adapt to uneven ground, it acts as a shock absorber, it provides leverage for propulsion, and it absorbs transverse leg rotation. Loss of anyone of these functions can be detrimental to the patient, and is often noticed in patients with diabetes[1]. More than 50 million people in the world have diabetes the prevalence of diabetes among those over 45-65 years of age group. In India diabetic is the second most common cause of lower limb amputation. Foot ulceration is affecting 25% of patients with diabetes during lifetime and 85% proceeds to lower limb amputation[2]. Diabetes mellitus, commonly referred to as diabetes was first identified as a disease associated with "sweet urine," and excessive muscle loss. Elevated levels of blood glucose (hyperglycemia) lead to spillage of glucose into the urine, hence the term referred as sweet urine. Normally, blood glucose levels are highly controlled by insulin, a hormone produced by the pancreas. Insulin regulates the blood glucose level[3]. In patients with diabetes, the absence or insufficient production of insulin causes hyperglycemia. Diabetic foot ulcer is one of the major complications of diabetes mellitus, and probably the major component of the diabetic foot. Being a natural phenomenon, wound healing is usually taken care of by the body's innate mechanism of action that works reliably most of the time, Diabetes mellitus is one such metabolic disorder that impedes normal steps of wound healing process. Peripheral neuropathy is a most common complication of diabetes and its early detection may reduce morbidity and particularly diabetes-related foot complications through provision of education and appropriate foot care. Most common among the neuropathies are chronic sensorimotor distal symmetric polyneuropathy and the autonomic neuropathies. The lack of protective sensation from sensory neuropathy leads to repetitive trauma resulting in ulceration and is considered as one of the major initiating risk factors in the pathogenesis of diabetic foot ulceration (FU). Vibration perception threshold (VPT) using biothesiometer and pressure perception using Semmes–Weinstein monofilament, both focused on assessment of sensory function, have been proposed to identify patients at risk of FU in the absence of gold standard test. However, peripheral autonomic dysfunction may result through sweating reduction in abnormal skin conditions increasing the risk of FU [4]. Diabetes is also an important factor in accelerating the hardening and narrowing of the arteries, leading to strokes, coronary heart diseases and other blood vessel diseases[15]. This is referred to macro vascular diseases. There are 3 types of diabetics:

- Type 1 diabetics - failure to produce insulin
- Type 2 diabetics - cells fail to use insulin
- Gestational diabetics - high glucose level during pregnancy

II. DIABETIC FOOT:
Figure 1 Diabetic foot

Figure 1 Diabetic foot should be checked at every visit to the clinic[12]. It is important to make a careful examination and assessment of the feet before making any decision about treatment. The examination is performed for 3 sections by podiatrists.

- Classification
- Staging
- Taking control

a. Classification

The classification allocated depends on the detection of neuropathy or neuroischaemia. The foot with a combination of neuropathy and ischaemia is called neuroischaemic foot. Neuropathy means injury present in the plantar surface of foot. ischaemic present in the border or edges of the foot [11].

b. Staging of diabetic foot

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
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<tbody>
<tr>
<td>Stage 1</td>
<td>Low risk foot</td>
</tr>
<tr>
<td>Stage 2</td>
<td>High risk foot</td>
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<tr>
<td>Stage 3</td>
<td>Ulcered foot</td>
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<tr>
<td>Stage 4</td>
<td>Infected foot</td>
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<td>Stage 5</td>
<td>Necrotic foot</td>
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<tr>
<td>Stage 5</td>
<td>Major amputation</td>
</tr>
</tbody>
</table>

c. Managing control

There are 6 different aspects of management and taking control

- Mechanical control
- Metabolic control
- Microbiological control
- Vascular control
- Wound control
- Educational control

Pressure plays an important role in diabetic patients. Pressure can cause damage to the diabetic foot in three ways[12]:

- High pressure may cause trauma
- Intermittent pressure may cause inflammation, cumulative tissue damage
- Continuous pressure, even at low level, may prevent circulation of blood to affected tissue.

III. DIAGNOSTIC PROCEDURES

a. Blood Pressure

This is the first test in the diagnosis of diabetic foot ulcer. Sphygmomanometer is the instrument to measure blood pressure. The variation between systolic pressure of both right and left leg is an indication of abnormalities in foot.

b. Monofilament test

It is a simple test for sensitive evaluation, in which a thin piece of plastic fiber is touched against the various parts of the sole of your foot and ability to feel varying pressure.

c. Sensitometer Vibration Pressure Threshold

VPT technique is used to measure the sense of vibration in the foot. The threshold value is the vibration in which the patient can feel.

d. Doppler test

Doppler test is performed to check whether there is a blood flow in foot region. In this technique gel is made to spread on the foot area. Then the device is made to move on that area and the blood flow is recognized by a sound.

IV. LITERATURE SURVEY

The new SUDOSCAN™ device is designed to perform a precise evaluation of sweat gland function based on sweat chloride concentrations using reverse iontophoresis and chronamperometry [10]. Measurements are performed where sweat glands are most numerous on the palms of the hands, soles of the feet and forehead. Large area nickel electrodes are used alternatively as an anode or a cathode and a direct current (DC) incremental voltage 4 volts is applied on the anode. This DC iontophoresis induces a voltage on the cathode and generates a current. The intensity of about 0.2 mA are obtained between the anode and the cathode, related to chloride concentration. The electrochemical phenomena are measured by two active electrodes (the anode and the cathode) successively in the three regions, while the four other passive electrodes allow retrieval of the body potential.

Walking foot pressures are found to be affected by the weight of the person and their walking velocity. It is also found that both the magnitude and duration of the dynamic foot pressures are important in the formation of ulcer in neuropathic feet of diabetic patients. Therefore, foot pressure measurements are made on a long optical pedobarograph which could accommodate at least two steps. The foot pressure analysis is done using two new parameters: Normalized Peak Pressure, NPP and Pressure Contact Ratio, PCR, which take into consideration the weight of the person. Walking velocity and magnitude and duration of the peak foot pressure acting in ten areas of the foot [5].

The traditional orthotic insole by taking ink impression is not sufficient to correct the orthotic problems like misalignments and stability. Foot orthosis is used to alter foot biomechanics and associated dysfunction [6]. Planter foot pressure studies, in patients with diabetic neuropathy indicated relationship between excessive pressure and ulceration [7]. Appropriate color intensities are used to indicate different pressure distribution of foot [8]. An attempt has been to study the pedographs of left and right in normal and pathological subjects during bipedal standing. Percentage pressure profiles were plotted to see the distribution of loading on the plantar
surface of the foot[9]. Therefore, it is essential to detect the foot at risk of plantar ulceration, at an early stage of sensation loss, so as to prevent complications and amputation. It is found that the foot pressure parameters are functions of the material properties of foot sole soft tissue and also different levels of sensation loss [10].

This paper the threshold is set in the voltage form and used for the diagnosis of foot ulcer[14]. Here the input is taken from 6 regions. So accuracy of that is less.

In order to improve the accuracy level of the signal, foot regions are taken into account can be increased by 10 for each leg. This paper presents the results of the study undertaken on 10 feet of normal and 4 feet of diabetic subjects, to find the relationship between the foot pressures characterized by the parameter known as NPP at different levels of pressure responsible for causing foot ulcer.

V. SYSTEM COMPONENTS

a. Sensor

Different types of pressure sensor such as strain gauge, piezoelectric force sensor, optical force sensor and FSR are available. The ultra thin force sensor [13] is used for measurement of foot pressure. The flexi force sensor is made up of two layers of substrate (polyester/polyamide) film. On each layer, a conductive material silver is applied which is a layer of pressure sensitive link. Different part number is used of range (0-2.2lbs) and active areas of each part number is differ.

<table>
<thead>
<tr>
<th>Part number</th>
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<tbody>
<tr>
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</tr>
<tr>
<td>402</td>
<td>0.5”</td>
</tr>
<tr>
<td>406</td>
<td>1.5”</td>
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</table>

Characteristics

![Figure 2 Resistances vs. Force](http://interelectronics.com)

Laboratory Virtual Instrument Engineering Workbench is a graphically based programming language developed by National Instruments. Its graphically nature makes it ideal for Test and Measurements, Automation, instrumentation control, Data acquisition and data analysis applications [15]. The front panel contains a knob for indicating the pressure variation and also a LED and Buzzer which is used to alert the professionals whether the patients are having normal and abnormal foot pressure. The array which is representation of abnormal pressure points in voltage. The input from patients is interfaced to lab view with help of data logger. It is an electronic device, which has several channels. In this work 20 channels are need to acquire the signals. So the data logger model Agilent 48790A is used.

b. Amplification Unit

The Amplification unit designed by using LM324 opamp. The gain of the amplifier unit is 500db.

c. Lab VIEW

Lab VIEW, as a programming language, is a powerful tool that can be used to help achieve goals. Lab VIEW is a graphically based programming language developed by national instruments. Its graphically nature makes it ideal for Test and Measurements, Automation, instrumentation control, Data acquisition and data analysis applications [15]. The front panel contains a knob for indicating the pressure variation and also a LED and Buzzer which is used to alert the professionals whether the patients are having normal and abnormal foot pressure. The array which is representation of abnormal pressure points in voltage.

The block diagram of plantar measurement system is shown in figure 4. The sensors are placed on a rubber insole. It is a thin material especially manufactured by diabetic patients, and then all the sensors are connected by amplifier unit. These amplified signals are interfaced by PC using Lab VIEW.
VI. HARDWARE SETUP

The experimental setup which is designed for acquisition of foot pressure signal is shown in the figure 6. The power supply unit consists of step down transformer230v-12v-5v. The sensor which has the input of 12 v. The amplification circuit is used to amplify the foot pressure signal using LM324 op-amp. The pressure is obtained by voltage. The voltage can be converted pressure unit. In normal person peak pressure value is 625 KPa, but in abnormal person the peak pressure value is greater than 625 KPa. The NPP value are calculated by the person weight according to the pressure given by them. Thus the signals are interfaced to PC with help of DAQ device.

![Figure 6: Hardware Design](image)

VII. RESULTS AND DISCUSSIONS

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<tr>
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<th>2nd metatarsal(1)</th>
<th>3rd metatarsal(2)</th>
<th>4th metatarsal(3)</th>
<th>Mid.Foot 1(4)</th>
<th>Mid.Foot 2(5)</th>
<th>Mid.Foot 3(6)</th>
<th>Fore Foot(7)</th>
<th>Heel1(8)</th>
<th>Heel2(9)</th>
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Table 1 represents variation of mean NPP values in 10 areas of the foot using millimeter. The pressure is obtained by the each sensor for both normal and abnormal person. The pressure can be calculated by its voltage, the peak voltage indicates abnormal which is pressure obtained in that area is large. It indicates that there is possibility of foot ulcer in that area. The signal analysis is done by using Lab VIEW for the normal and diabetic neuropathy patients. The result shown in figure 7 is abnormal patient signal. A LED which indicates red is abnormal.
VIII. CONCLUSION

The experimental study of foot pressure parameter NPP for various class of diabetic patients and the mean value for both normal and abnormal foot pressure values are compared. Mainly 10 points are taken for pressure measurement, There will be an increase in pressure if there is possibility for getting foot ulcer in a particular area. So any variation in foot pressure which indicates of early detection of foot ulcer. This is very helpful to the Physician for the detection of foot ulcer in earlier stage and also reduces foot amputation possibilities.

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