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Original Article

Integrative studies to design and validate wearable footwear among neuropathic patients

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ABSTRACT

Uncontrolled high blood sugar levels leads to diabetic neuropathy, which is usually develops slowly. Damaged nerves stop sending messages or may send message slowly at the wrong times. The propsed model is an insole for individuals with peripheral neuropathy conditions, where the peak plantar pressure value is measured at specified locations of the foot by means of a pressure sensor, which can be accessed via a mobile applications; Simultaneously, a stimulation is given at acupressure points of the foot to relieve pain at definite intervals of time, based on the signals from the controller. A controller is being used to perform these operations which will be transmitted to the mobile application via Bluetooth terminal.

1. Introduction

Diabetic Neuropathy is a condition in which severe nerve damage occurs and it is the most common complication of type 1 and type 2 diabetes [1]. The condition is driven by high blood glucose levels which when persist for a longer duration leads to damage of peripheral blood vessels [2]. In general, there are 4 main symptoms seen prevalent in individuals suffering from this condition: Tingling, burning sensation, loss of feeling and numbness. Each individual may experience every one of these symptoms, in correlation with the intensity of neuropathy. Based on the area of damage, Diabetic Neuropathy can be localised and categorised into 4 different types: Peripheral, Autonomic, Proximal and Focal. Comparatively, the most prominent type is Diabetic Peripheral Neuropathy [2]. The peripheral nervous system has both somatic sensory and motor nerves. The studies on conducted for understanding the physiopathology of Diabetic Neuropathy suggests that the pain experienced and severity of Neuropathy are not to be associated with each other, as they don't in most cases necessarily interact with the nerve damage. Currently, the treatments available for this condition include drugs for relieving the pain, massaging devices and physiotherapy sessions from time to time [3]. Lack of proper diagnosis and therapeutic care for the disease might lead to worst circumstances of experiencing ulcers which can cause great discomfort to the patient [4]. Thus, the disease, Diabetic Neuropathy, needs constant monitoring of the individual's severity towards neuropathy (NCV tests) and proper care or treatment to help build an untethered lifestyle for the individual suffering from it.

2. Prevalence of DPN

Accurate data on the prevalence of neuropathy have been difficult to acquire as there has been wide variability in the clinical tools used to define neuropathy and very few studies have been undertaken in population-based settings where estimates are less biased towards those with more severe disease [5]. Additionally, only a few studies have assessed neuropathy – defining the total diabetic population Ref [6]. Few studies have included a sample from the general population with normal glucose tolerance, allowing for an accurate assessment of the degree that diabetes contributes to the development of peripheral neuropathy. Estimation of the proper prevalence of DPN, there is need for more epidemiological studies [6]. Nevertheless, some accurate estimates have now been established and the impact of the main confounding factors on prevalence has been assessed.

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3. Pathways to foot complications

Although evidence is weak that foot care education reduces the risk of first ulceration, a thorough understanding of the mechanisms of ulceration is important to mitigate the incidence of foot lesions and thereby amputations. The pathways to foot ulceration are summarized, with key contributory factors also listed below [7,8].

- Distal sensorimotor peripheral neuropathy. This condition is common in 50% of geriatirc population suffering from T2DM. Small-fiber nerve dysfunction results in loss of pain and temperature perception; patients literally lose the "gift of pain" that normally protects us from tissue damage. Large-fiber dysfunction results in unsteadiness, increasing the risk of trips and falls; recurrent unnoticed minor injuries might increase the risk of Charcot neuroarthropathy. Motor neuropathy contributes to small-muscle wasting and a potential imbalance of skeletal muscles of the foot [9].
- Autonomic neuropathy. Peripheral sympathetic dysfunction results in decreased sweating (i.e., dry foot skin, increasing the risk of callus formation) and, in the absence of PAD, warm feet due to the release of vasoconstriction. Plantar callus within the neuropathic foot is related to a marked increase in ulcer risk.
- PAD. A major risk factor for foot lesions in diabetes. Neuropathy and PAD often coexist and may lead to neuro-ischemic ulceration.
- Deformity. Any deformity with different risk factors will increase ulceration risk [10]. Clawing of the toes is common, leading to increased metatarsal head pressures that, in neuropathic patients, may result in breakdown due to repetitive moderate stress to an insensate area. Other examples include Charcot deformities and hallux valgus.
- Age, sex, and duration of T2DM. The chance of ulcers and amputations will raise to two-to fourfold with each age and period of disease. In Western countries, male sex is associated with a 1.6-fold increase in foot ulcer risk.
- Ethnicity. In the United States, ulceration is more common among Hispanics, Native Americans, and individuals of African-Caribbean descent.
- Repetitive minor trauma. Such trauma can occur as a consequence of high pressures under a neuropathic foot or from an mal-fitting shoe or a unwanted materials inside a shoe.
- Past foot ulceration or amputation. Both are major risk factors. The annual incidence of ulceration may be as high as 30–50% in people with a past episodes of foot sores [11].
- Other microvascular complications. Several different conditions are noted to be related with an increased risk of foot ulceration. Visual disorder as a results of retinopathy is a longtime risk factor for foot sores [12]. Perhaps the most high-risk group for ulceration is the dialysis population. It can be safely presumed that patients with kidney disease have more risk of ulceration. Dialysis management is an important issue for foot sore [13–16].
- Transplantation. People with T2DM will be at more risk of foot lesions however after the successful kidney, pancreas, or combined pancreas-kidney transplantation.

4. Pathway to ulceration

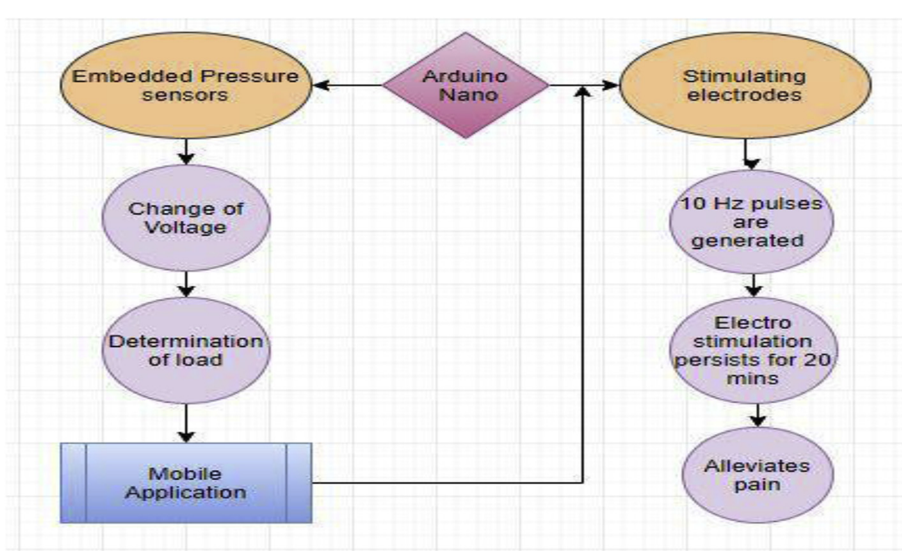
The combination of 2 or additional risk factors to ulceration. Examples include:

- Neuropathy, deformity, and trauma. Inappropriate footwear is the general outcome of trauma in Western communities .
- Neuropathy plus chemical trauma. Over use of over-the-counter corn medications on a neuropathic foot can lead to ulceration. Understanding the many risk factors that increase the chance of foot lesions developing will help to prevent many episodes of foot ulceration if the screening process is followed [17].

5. Scope and purpose of the project

To analyze the irregular plantar pressures on an individual with Diabetic Peripheral Neuropathy. This would help the patient to track and recover from the internal damage caused over the years, acquired from this condition. The pressure patterns partially help us understand how load is distributed unevenly in the foot region of an individual suffering from Diabetes for a longer duration which lead to the rise of Neuropathic conditions. As these uneven load patterns can cause severe damage to the nerves and make the flow of blood & signals more constricted; also results in a loss of feeling totally when considering the long term effects. A specified intensity of stimulation is given simultaneously causing a counteractive effect that would help balance and neutralise the damage caused by the condition after prolonged use [18].

6. Methodology



6.1. Pressure sensor

Basically, the pressure sensors act like a transducer, indicates the pressure imposed. Alternatively, it detects the forces exerted on a surface and gets it converted into an electrical signal whose strength is relative to the strength of the force. So, they can also be used to measure the force exerted. Pressure transducers hold a sensing factor on fixed area and gives output according to pressure applied in comparison to that area having thin pressure. The pressure generated move the diaphragm with the pressure transducer. The pressure difference is measured as electric output.

6.2. Microcontrollers

In general, microcontrollers are computers which are embedded into other systems so that they can control the features and actions of the product. Therefore, it's otherwise called an embedded controller. These are low-power devices which are programmed to run only one program at a time. The program is pre-stored in ROM and are mostly not changed. The microcontroller consists of a dedicated input device in order to receive and process input and often a LED system to display the output value.

6.3. Stimulators

The stimulators send impulses from the electric current produced at a desired range to stimulate the nerve/muscle for given therapeutic purposes. The impulse intensity is pre-programmed by the microcontroller based on the need and requirement of the device. It helps in naturally building the ability to restore the functions occurred due to the damage as a consequence to the condition/disease. The impulses are programmed to be given at a desired interval of time. It helps in eliminating muscle spasm, muscle weakness, tingling and burning sensation particularly in the foot.

6.4. Insole

Insoles are usually referred to as foot-beds or inner soles that runs underneath and supports the bottom of the foot. Preferably, Orthotic insoles are used with adjustable size requirements. These insoles are mostly made up of silica gel or any flexible polymer with bubble like air pockets that helps the user feel at ease while using it. The insoles are to be made of breathable material that keeps the foot at the right temperature rather than putting it under pressure and making the insoles damp and sweaty after long use.

6.5. Relay

Relays are the primary protection as well as switching devices in most of the control processes or equipment. All the relays respond to one or more electrical quantities like voltage or current such that they open or close the contacts or circuits. A relay is a switching device as it works to isolate or change the state of an electric circuit from one state to another.

6.6. Power supply

Two 9 V batteries are used to provide electricity for both the insoles. The supply network is individual and separate for both the insoles. The batteries come with a snap connector cap which when connected switches on the network and when taken off switches off the network entirely.

6.7. Mobile application

An application is required to constantly monitor the pressure value and switch on and off the stimulators. The readings are received by the application via the Bluetooth module to the app which is in the form of volts. The values are displayed for each sensor separately with commands for both the left and the right insole.

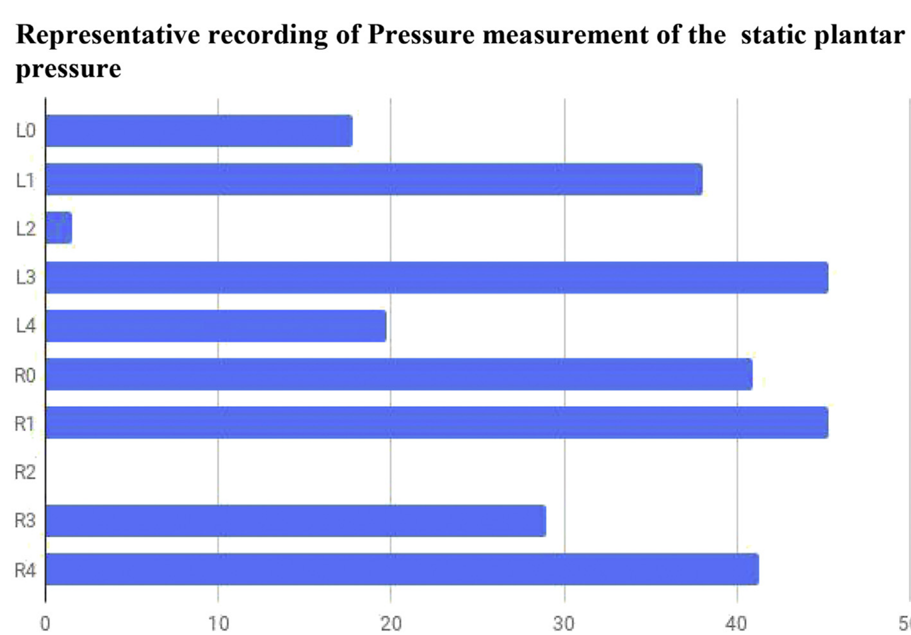


Fig. 1. The measurement was made on left foot (L) and Right foot (R) during static (sitting posture) during 20 mins. The sensor recoded the measurement every 5 mins (0, 1,2,3,4) zero being at the start of the experiment and after every 5 mins the pressure is measured for next 20 mins and at the end of the 20 mins and average pressure recorded for all thirty patients is represented in the above graph for each time point.

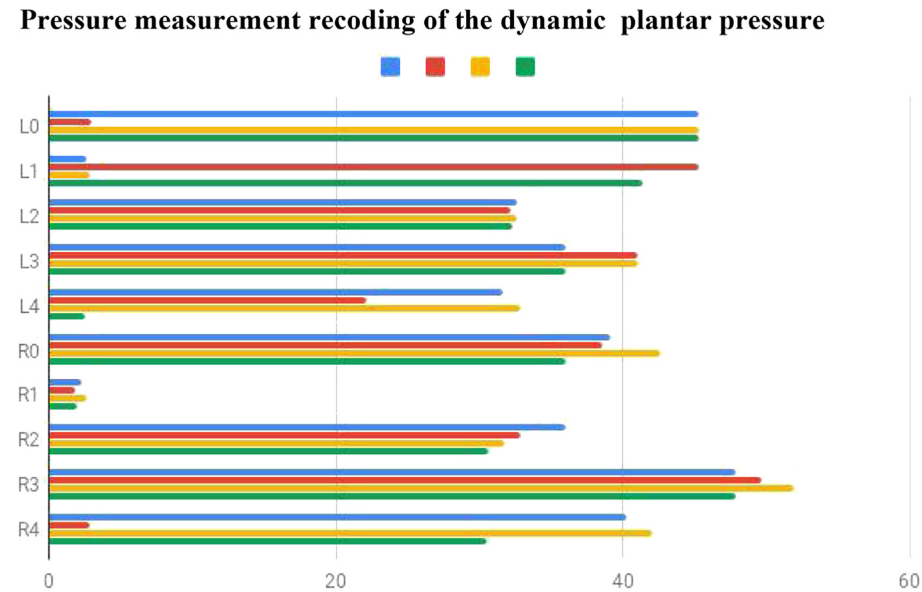


Fig. 2. The measurement was made on left foot (L) and Right foot (R) during dynamic (walking and standing) during 20 mins. The sensor recoded the measurement every 5 mins (0, 1,2,3,4) zero being at the start of the experiment and after every 5 mins the pressure is measured for next 20 mins and at the end of the 20 mins and average pressure recorded for all thirty patients is represented in the above graph for each time point. Since during the dynamic phase the pressure exerted differentially on the different part of the foot, the pressure exerted is measured separately and is color coded (color blue denotes Sole region, Yellow: medial fore foot, green lateral fore foot and red is mid foot).

7. Research setup & data collection

For the conduction of this experiment, the data has been collected from thirty Diabetic Neuropathy patients. This study population is over-40-year-old patients with type II diabetes, who do not shown no foot ulcerations or deformities and who were able to walk without the need for support or assistance. The individuals included in the study who are allowed to wear the footwear, underwent plantar pressure measurement, statically and dynamically performed. The patients are allowed to wear the footwear for a period of 20 min. Dataset has been collected from the mobile application which would record the plantar pressure of the patients. Then, the same procedure were repeated with the other patients. similarly, stimulators are employed at the peak pressure points of the patient to relieve pain and provide symptomatic relief.

8. Results

The group of thirty patients were over their 40 years of age, ranging from 41 to 72 years. Participants had T2DM for more than 5 years. The study evaluated statis and dynamic measurements of plantar pressure. Participants showed decline in plantar pressure upon wearing our diabetic shoe verses normal shoe. Around 45.31 kilopascal pressure was the average maximum measured plantar pressure of all thirty patients and average from both foot. the diabetic footwear reduced 17% in ehe measured peak plantar pressure values, thus reaching 24 kiopascal on average Fig. 1.

Around 51.93 kilopascal on average was the maximum dyanmic pressure measured. the diabetic shoe was able to showreduction of 21% of the maximum dynamic pressure, thus reaching 30.325 kilopascal. the pressure was the maximum on the soles (blue in the Fig. 2) , and reduction was seenon all the regions and mainly on the sole after the diabetic footwear use.

9. Conclusion

Footwear is beneficial among geriatric patients with T2DM to reduce neuropahty coplications. However, diabetic shoe was more effective in reducing the pain due to neuropahty compared to regular footwear. it is also useful for predicting or peventing the risk of ulcers in diabetics and thus can mitigate the risk of amputation. it also provides therapeutic effect to the patients who are suffereing from diabetic neuropathy. However, clincial studies are required to validate furtehr that our hypothesis of reducing the peak plantar pressures can prevent plantar lesions and follow up clinical studies are required to evaluate role of plantar pressure in reducing the incidence of foot ulcers.

Conflicts of interest

The present study does not have any Conflict of Interest.

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