Development of A Novel Robotic Monofilament Probe for Diabetic Neuropathy Screening

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***Abstract*— People with diabetes are unable to produce or properly consume insulin, which is produced by pancreas. A common complication of diabetes is diabetic neuropathy which is able to affect any part of the nervous system. The diabetic peripheral neuropathy is normally detected by the physicians during the patient's examination. The physician detects the loss of sensations in diabetic foot by using a monofilament to apply onto 3 sites on each foot. This study is to introduce a new robotic monofilament probe for diabetic neuropathy screening as a section of a telemedicine for diabetes disease project. The development of the "Robotic Monofilament Probe" is able to reduce the cost and time for both patient and physician during the long term examination period. Moreover, the system is a part of telemedicine project for diabetes disease which the system will be able to transfer examination data to the physician in a remote area.**

I. Introduction

This section introduces background of our study, which includes; diabetic neuropathy, current traditional diagnosis, statement of problem and project overall.

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A. Diabetic Neuropathy

People with diabetes are unable to produce or properly consume insulin, which is produced by pancreas. Diabetes can be classified into 2 types.

Type 1 Diabetes is a failure from the body to produce insulin and to allow glucose to enter them. Generally, the failure is caused by the destruction of beta cells on pancreas. Most affected people with this type are below 20 years old. The patients need insulin replacement, and also the blood glucose level monitoring.

Type 2 Diabetes (also known as non insulin-dependent) is an insulin resistance with defective insulin secretion. This type of diabetes is the most common one with about 85% of all diabetes patients. Most affected people are at or above 40 years old, and have a history of the family antecedent with diabetes.

In 2007, according to the statistics from International Diabetes Federation (IDF), Diabetes is the fourth leading disease causing global death. There are 246 million worldwide people, and is expected to affect 380 million by 2025.

One of the most common complications of diabetes is Diabetic Neuropathy which can affect any part of the nervous system. The primary types of Diabetic Neuropathy are sensory motor and autonomic. The sensory motor neuropathy affects the nervous systems while peripheral neuropathy plays the most important role to cause of foot ulceration [1].

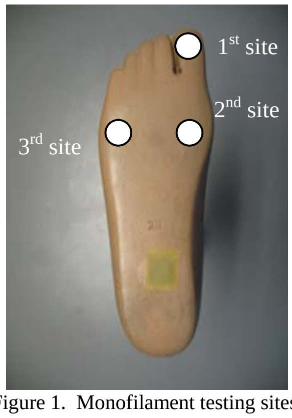

Figure 1. Monofilament testing sites.

B. *Current Traditional Diagnosis*

It is not evident for the medical staff to detect diabetic peripheral neuropathy (DPN). The interrogation and the usual clinical examination do not allow revealing symptoms or reliable enough neurological signs to predict the arisen of an ulcer by the foot. Moreover, this neuropathy is often asymptomatic. The standard neurological clinical examination (reflexes, diapason), it is too subjective and presents a too weak reproducibility. The measure of the speed of nervous conduction by electromyogram is expensive and complex, not useful examinations in primary care and their value forecast is insufficient what makes them unsuitable for the screening of the patient's diabetics at risk to ulcer's injury. To date, the only tool recommended for the screening of the sensory neuropathy for the diabetic patient is the Semmes-Weinstein monofilament.

The effectiveness of the Semmes-Weinstein monofilament examination (SWME) for DPN screening had been tested by many researchers and the results showed that it was useful and had similarity to other screening [5, 6]. However, SWME has the advantage over other screening that it is simple and inexpensive. Moreover, SWME demonstrated sufficient statistical power to differentiate non-diabetic control subjects from subjects with diabetes, as well as to differentiate subjects with diabetes with and without neuropathy [7]. SWME also shows the sufficient reproducibility for the assessment of diabetic neuropathy in daily clinical practice [8].

Diabetic Peripheral Neuropathy is normally detected by a doctor during a patient's examination. A doctor detects the loss of sensations in diabetic foot by using a monofilament to apply perpendicularly onto 3 sites on each foot (See Figure 1) and an application of the monofilament is shown (See Figure 2).

C. *Statement of Problem*

The cost of treating these feet complications is an important part of the cost of diabetes (about 25%). Moreover, the patient identification at risk of foot ulceration can help in prevention in such patients. The neuropathies associated with diabetes represent insidious and progressive processes for which a disconnection exists between pathological severity and the development of symptoms [2]. Strict glycemic control and good daily foot care is the key to prevent complications of diabetic neuropathy [3]. The subjects, who are elder, have longer duration of diabetes, higher fasting plasma glucose (FPG), high triglyceride level and under insulin treatment, have a higher prevalence of positive Semmes-Weinstein Monofilament Test (SWMT) [4]. So it is important to take care of these kinds of patients.

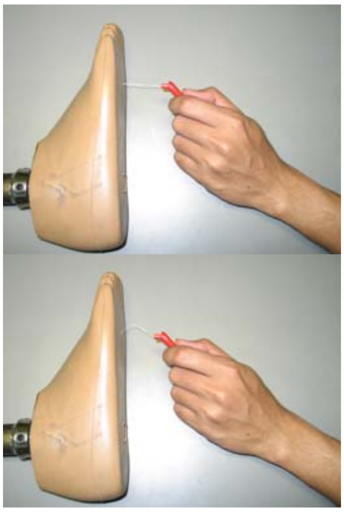

Figure. 2. Applying a monofilament perpendicular to the skin's surface.

D. *Project Overall*

This study is a part of Diabetic Neuropathy Telemedicine Project. The project can be divided into 4 phases; 1) pre-clinical study phase, 2) development of the first prototype phase, 3) pre-pilot test for device improvement, and 4) full-scale clinical trial phase. This paper presents the 2nd phase of developing the first prototyped device for diabetic neuropathy screening. The robotic monofilament problem is developed to examine by using the similar method that physicians perform manually. This probe allows either healthcare staffs or patients to perform regular testing without doctor's attending. Another advantage, the system can transfer the tested data to doctors in the remote area, which means that the doctor can diagnose the disease in the distant place that also known as "Telemedicine".

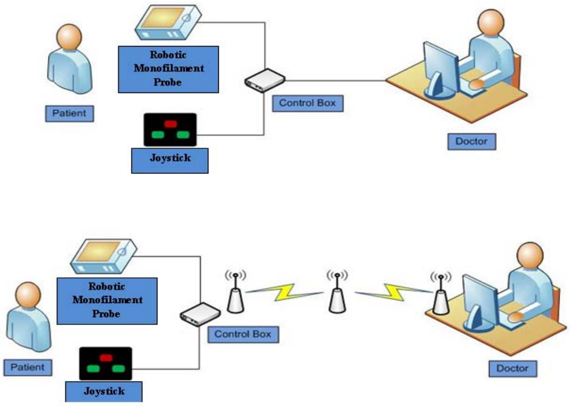

Figure. 3. System diagram: GUI and Controller Command, Control box, and Robotic Monofilament Probe.

II. PROTOTYPE SYSTEM

A. Diagnosis System

Our system is basically divided into three parts which are GUI and Controller Command, Control Box, and Robotic Monofilament Probe. To understand a connection of each part in the system, the diagrams are made for illustrating a whole picture of the system as shown in Figure 3 which has two diagrams with a small difference in the data transfer. The upper diagram illustrates the system that a doctor/user is with a patient in a clinical room, while the lower one illustrates the system that a doctor/user is in a remote area but can pull up a result or data through wireless device. Figure 4 illustrates the schematic control of the diagnosis system which includes; 1) system control PC, 2) control box, 3) robotic monofilament probe and 4) interaction pad (joystick).

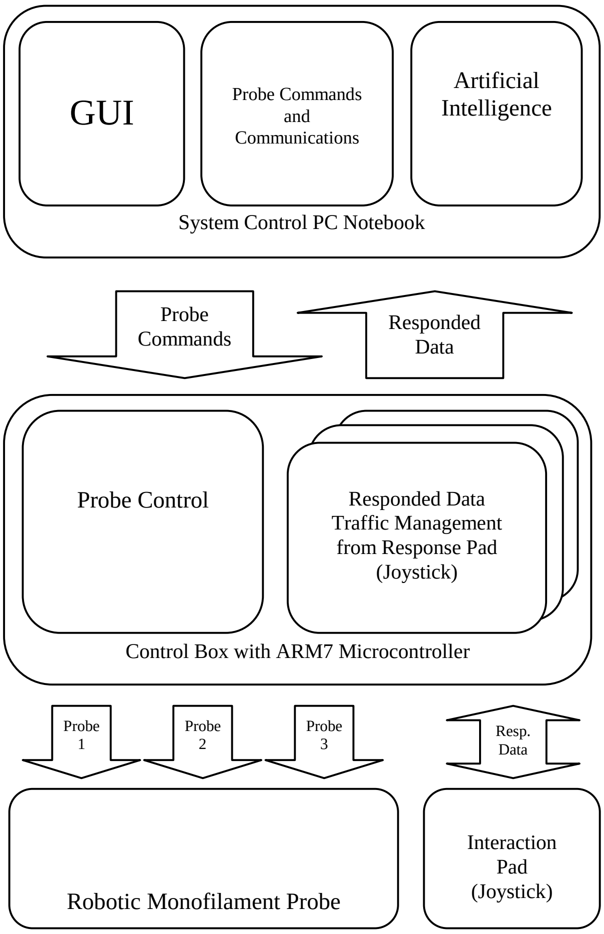

Figure. 4. Schematic control of the diagnosis system includes; system control PC, control box, robotic monofilament probe and interaction pad.

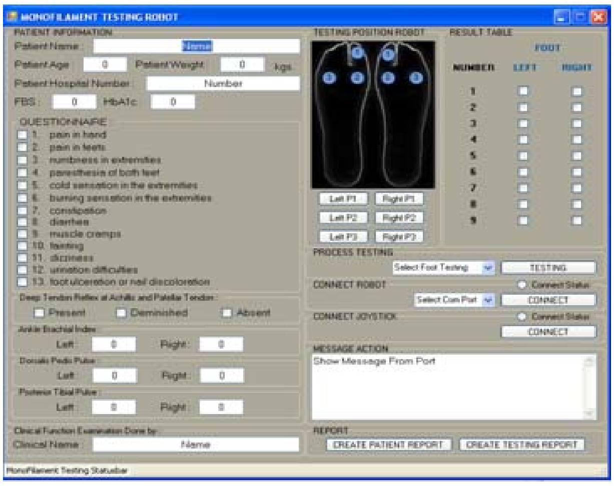

Figure. 5. Graphical User Interface (GUI) for command and control Robotic Monofilament Probe, and also collect patient's information and test result.

1) GUI and Controller Command

Graphical User Interface (GUI) and Controller Command are computer programs to command and control Robotic Monofilament Probe by sending all commands through Control Box, to receive an answer from patient through a joystick consisting of four buttons which compose of three ones that refer to three testing sites and one button that refers to no feeling, and to collect patient's information and test result as well. The illustration of GUI is shown in Figure 5 divided into two sections; which are patient's information containing patient name, age, weight, hospital ID number, and questionnaire about other symptom of patient according to doctor's suggestion such as pain in hand, diarrhea, and fainting and another section is the testing section containing a picture of testing sites, a command button to connect Robotic Monofilament Probe and a joystick, and test result.

2) Control Box

A command from Graphical User Interface (GUI) is sent to Control Box (see Figure 6) which is processed by ARM7 microcontroller and Command Box then sends a command to control an action of Robotic Monofilament Probe.

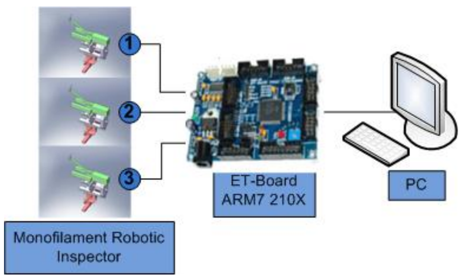

Figure. 6. Control Box to control an action of Robotic Monofilament Probe.

3) Robotic Monofilament Probe

Robotic Monofilament Probe is a device to press monofilament to touch a patient's foot at specific site. This device is actuated by the command from the control box.

According to the fact that the testing sites of the foot there is no universally accepted guideline on how the monofilament is to be used and on determining testing sites [9]. The number of testing sites that researchers used to determine are various between 1 to 10 sites. Nevertheless, for the conception of the "Robotic Monofilament Probe" we will follow the recommendation of the International Working Group on the Diabetic Foot. The sites are as following:

- The great toe (1st site)
- The plantar aspect of the first metatarsal (2nd site)
- The plantar aspect of the fifth metatarsal (3rd site)

In addition the study of McGill et al. [10] showed that the combination of the plantar aspects of the first and fifth metatarsal had a high sensitivity and specificity and they defined insensate when patients did not feel the monofilament at either of these two sites.

According to doctor's suggestion in examination each site is tested randomly in 3 times. Moreover, false tests are used to evaluate this device. A patient is in a sitting position during the examination. When a test is started, a patient answers by pushing a button on joystick. The patient needs to give a response before continuing to next examination.

B. Probe Design and Development

Due to method to apply a monofilament that it is pressed only one direction, thus the device uses electric solenoid actuator for applying monofilament.

The first part of model is in the position of great toe as shown. This part has no movement so the base was fixed.

The second part of model is in the position of plantar aspect of the first metatarsal. This part has one direction movement along foot's length. We can manually change a position of monofilament by adjusting a position of solenoid actuator for facilitating any size of patient's foot.

The third part of model is in the position of the plantar aspect of the fifth metatarsal. This part has two direction movements along and against foot's length. We can also manually change a position of monofilament by adjusting a position of solenoid actuator.

A protocol to test a patient follows these steps:

Step 1: A doctor or any medical staff commands the device through GUI and Controller Command to test a patient.

Step 2: GUI and Controller Command send an action command to Control Box.

Step 3: Control box processes a command and then sends a command to Robotic Monofilament Probe.

Step 4: Robotic Monofilament Probe is actuated by command from Control Box.

Step 5: GUI and Controller Command wait for an answer from patient response through joystick.

Step 6: GUI and Controller Command collect an answer.

Step 7: The step will be iterated from step 2 to step 6 until total testing number is met.

Step 8: GUI and Controller Command create a report of testing result.

CAD Model

To demonstrate our design, we show the CAD design in below (See Figure 7).

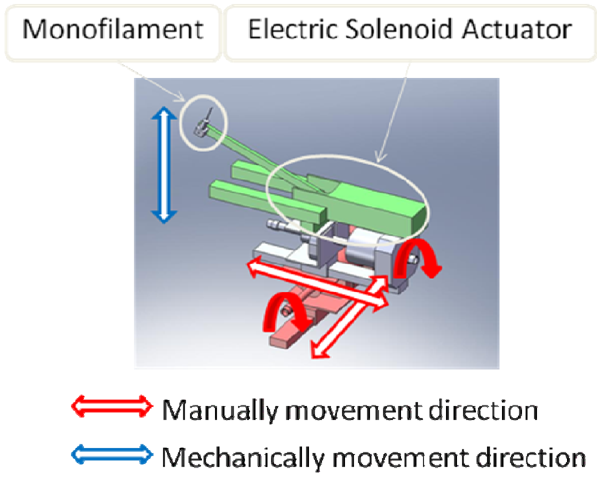

Figure. 7. The model for the plantar aspect of the fifth metatarsal position.

III. PROTOTYPE DEVICE

Figure below show the different view of the prototype and the image when laying a foot on the robotic probe. (See Figure 8-11).

The prototype of 'Robotic Monofilament Probe' is implemented, and is tested for its functioning by developers and volunteers. After a number of testing, the system is presented to an expert in neuropathy disease for system approving. The overall comment from the expert is positive. The force and motion of monofilaments are quite similar to the hand-testing. The GUI is understandable and very easy to use. The system is scheduled for a series of clinical trials in this coming summer.

Figure. 8. Monofilament when being as a part of the Robotic Monofilament Probe.

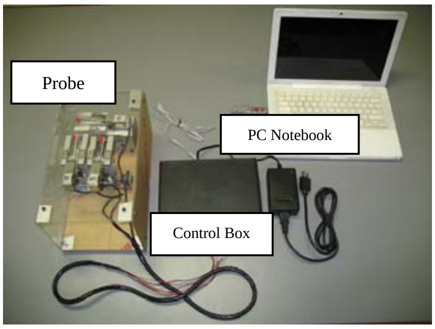

Figure.9. System of the prototype “Robotic Monofilament Probe”

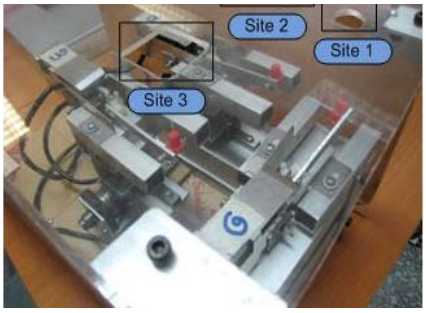

Figure. 10. Close view of the prototype“Robotic Monofilament Probe”.

Figure. 11. Image when laying a foot on Robotic Monofilament Probe.

IV. Preliminary Experimental Results and Analysis

To evaluate Robotic Monofilament Probe functions, the system was tested with four diabetic patients compared to conventional method by monofilament hand-testing. The results are shown in Table I.

TABLE I
RESULTS FROM HAND-TEST COMPARED TO ROBOTIC MONOFILAMENT PROBE

BY HAND		By Robotic Monofilament Probe	
Patient 1		Patient 1	
Site 1	Y	Site 1	Y
Site 2	N	Site 2	N
Site 3	N	Site 3	N
Patient 2		Patient 2	
Site 1	Y	Site 1	Y
Site 2	Y	Site 2	Y
Site 3	Y	Site 3	Y
Patient 3		Patient 3	
Site 1	N	Site 1	N
Site 2	N	Site 2	N
Site 3	N	Site 3	N
Patient 4		Patient 4	
Site 1	N	Site 1	N
Site 2	Y	Site 2	N
Site 3	Y	Site 3	Y

Y = Patient is able to sense the monofilament.

N = Patient is unable to sense the monofilament.

The experiments demonstrate good outcome compare to hand-testing method, except the last result from ‘patient 4’. The incorrect result for ‘patient 4’ is different at ‘Site 2,’ which is caused by improper adjustment.

V. Conclusion and Future Work

The development of a new robotic monofilament probe for diabetic neuropathy screening was reported. The development was based on traditional examination, monofilament hand-testing by physician. The diagnosis system consists of 3 parts; GUI software, control box and robotic monofilament probe. The system was designed and implemented, while it was tested for its functioning. Medical experts for diabetic neuropathy disease were preliminary testing the system, and were approving the system for a series of clinical trials. The system is scheduled for a series of clinical trials during the summer of 2009.

The diagnosis system is a part of telemedicine project for diabetes disease. The final system is capable to transfer the examination data to the physician in a remote area. The future work includes fine adjustment for its shape and surface to fit with various types of patients. The healthcare staffs that perform experiments are needed to be properly trained to reduce a number of improper uses.

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