Device for Assessing Plantar Neuropathy

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***Abstract*—The prevalence of diseases, such as diabetes, has led to an increase in plantar neuropathy in less developed countries throughout the world. The resulting lack of sensation in the foot can lead to injury, infection, or even amputation. Detection of peripheral neuropathy can lead to diagnosis of an underlying disease. Advanced screening methods can be invasive and less available in these poorer areas. The use of tactile sensation testing is an effective method of screening for the development of plantar neuropathy, but these methods require professional training and lead to biased diagnosis since they are performed by hand. The objective of this project is to design an automated plantar neuropathy diagnostic device based on the Semmes-Weinstein test. A foot will be placed within a device which is capable of full adjustability in the XY plane. Monofilament applicators will be manually positioned to the correct positions underneath the foot, and the subsequent testing procedure of applying the forces to the foot is fully automated. Monofilaments with various buckling forces will be randomly applied to specific testing sites on the foot and the patient must respond when the forces are perceived. The patient's ability or inability to feel the different levels of forces correspond to different degrees of sensory loss in the foot.**

Keywords—plantar neuropathy; Semmes-Weinstein test; monofilament

I. INTRODUCTION

Peripheral neuropathy is a condition that results in numbness, tingling, or muscle weakness due to damaged peripheral nerves. Neuropathy most commonly starts in the feet and ascends up the legs as the condition progresses [1]. It is for this reason that neuropathy screenings are initially performed on the foot. Existing diagnostic methods include the Semmes-Weinstein monofilament method, vibration, nerve biopsy, skin biopsy, and nerve conduction velocity and EMG. The Semmes-Weinstein test requires a monofilament to come into contact with the skin for a short duration, and the monofilament buckles when the critical load is applied. The patient then indicates if the force is perceived. This testing is done by hand which can result in human bias regarding timing of applications and test reproducibility. However, the monofilament method is non-invasive, relatively inexpensive, and does not require laboratory analysis. It was also found to be a more effective method than vibration testing [2].

The objective of this project is to design an automated plantar neuropathy diagnostic device based on the Semmes-Weinstein test. In order to diagnose the stages of plantar neuropathy, several design requirements were created. The device needs to be adjustable along a certain range in order to accommodate varying foot sizes and geometries. Different magnitudes of tactile forces must be applied to the foot in order to test for the varying degrees of sensation loss. Additionally, randomization of the testing helps minimize the occurance of false positive [3]. Each test will output a diagnostic score depending on which force levels are perceived. This score is indicative of the degree of sensation loss.

II. METHODS AND DESIGN

A. Mechanical Components and Frame Design

Forces of 0.6, 10, 100, and 300 gram-force with a ± 5% tolerance will be applied to specific locations of the foot. These specific forces indicate various levels of sensation in the foot. These force thresholds represent diminished light touch, diminished protective sensation, loss of protective sensation, and presence of deep pressure sensation only [4]. It was determined that three testing sites would be used because testing three sites yielded the same sensitivity and specificity as the ten testing ten sites method [5]. The forces will be applied to the big toe, the first metatarsal head, and the fifth metatarsal head. Semmes-Weinstein monofilaments are used as the force applicators. These monofilaments are engineered to buckle at specific forces, resulting in a guaranteed way of delivering the force accurately.

The force application is applied through the use of stepper motors. A gear on the shaft of the stepper motor will mesh to two gear racks on either side of it. As the motor rotates in one direction, the two racks will move vertically in opposite directions, raising the monofilament to contact the foot. The motor can then reverse direction to contact the foot with another force. The device must also be able to hit three specific spots on different sized feet with these applicators, so the motors ride on

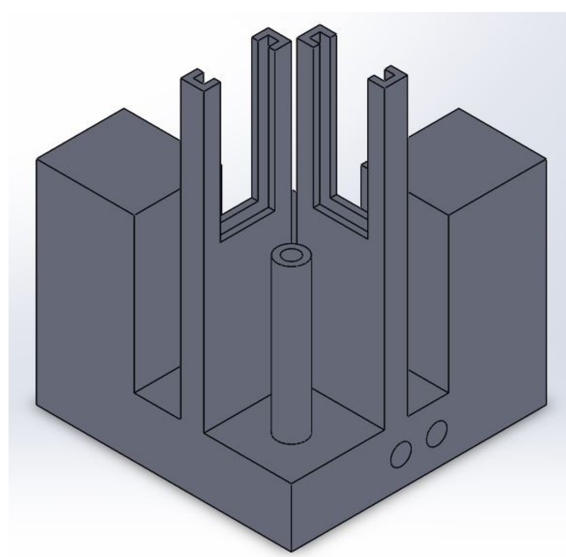

Figure 1. SolidWorks of one of the 3-D printed blocks that will hold the stepper motors and rack and pinion system.

3-D printed ABS plastic blocks as exampled in Figure 1. These various blocks were created in SolidWorks and will slide along metal rods to allow for full adjustability in the XY plane. This rail system will be attached to a frame along with two heel cup holders in a configuration that will allow for testing on both feet.

B. Electrical Components and Scoring Algorithm

The device is required to apply the tactile forces to the foot automatically and in a randomized fashion. In order to achieve this, an Arduino Mega, six NEMA 11 stepper motors, and six Big Easy stepper motor drivers were used. To control the stepper motors, the programmed Arduino is connected to the motor drivers which are then connected to and activate the stepper motors. A diagram of this is shown in Figure 2. The Arduino is programmed to allow for application of the monofilaments at randomized time intervals between 2 to 5 seconds after each force application [6]. In addition, the Arduino was programmed to randomize the testing sites and the force levels to be applied. The randomization of the time intervals, testing sites, and force levels is required in order to reduce subject predictability of the force applications. While the device is running, the subject presses the handheld button when a force is perceived. The handheld button is wired to the Arduino in order to record user input. The algorithm written uses the user input to calculate a diagnostic output score. The flowchart shown in Figure 3 gives an overview of how the algorithm works for calculating the output score. The final score is the maximum out of the scores from each of the testing sites and is outputted on a 7-segment display.

III. CONCLUSION

The intended goal of this device is to diagnose plantar neuropathy effectively while being non-invasive, relatively inexpensive, and unbiased. After the initial adjustment in order to fit the foot, the test is performed automatically. The hardware is programmed to randomize the forces in order to eliminate predictability. The algorithm used for diagnosis uses an industry standard for diagnosis in order to accurately quantify symptom severity consistently. These factors are intended to make the device an effective and reliable diagnostic tool for assessing neuropathy that is suitable for underdeveloped countries.

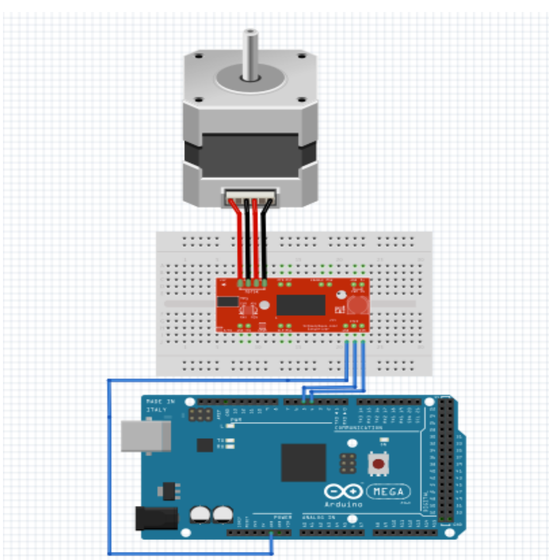

Figure 2. Diagram showing the connections between the Arduino Mega, motor driver, and a stepper motor.

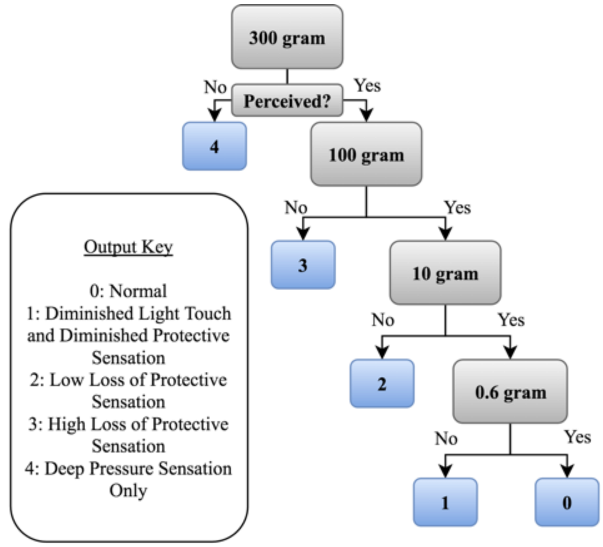

Figure 3. Flowchart illustrating the output score based on the force perceived or not perceived.

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