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A Novel Robotic Monofilament Test for Diabetic Neuropathy

Chumpon Wilasrusmee,[1] Jackrit Suthakorn,[2] Claire Guerineau,[2] Yuttana Itsarachaiyot,[2] Vera Sa-Ing,[2] Napaphat Proprom,[1] Panuwat Lertsithichai,[1] Sopon Jirasisrithum[1] and Dilip Kittur,[3] [1]Department of Surgery, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, [2]Center for Biomedical and Robotics Technology (BART LAB), Department of Biomedical Engineering, Faculty of Engineering, Mahidol University, Bangkok, Thailand, and [3]Department of Surgery, SUNY Upstate Medical University, Syracuse, New York, USA.

OBJECTIVE: The use of the Semmes-Weinstein (SW) monofilament test is recommended as a screening method for diabetic neuropathy. It offers an important chance to prevent further complications of diabetic foot. We aimed to develop a prototype Robotic Monofilament Inspector that can be used as a standard machine for screening of diabetic neuropathy.

METHODS: Development was divided into three parts: computer software, control box, and Robotic Monofilament Inspector. The examiner conducted the SW test (by hand and by robotic inspector), vibration perception threshold, and Toronto Clinical Scoring System without knowledge of patient information. The unpaired *t* test or Wilcoxon rank-sum test was used to determine the differences between independent groups in terms of continuous outcomes, while the χ^2 test was used to determine categorical outcomes. Agreement between the various diabetic neuropathy tests was measured using the kappa statistic.

RESULTS: The SW test and vibration perception threshold were more valid tests for neuropathy than the Toronto test. The robotic test was in excellent agreement with the two former tests and appeared to be valid (kappa statistic, 0.35–0.81). Another indirect evidence for the validity of the robotic test was the finding that diabetic patients with foot ulcers had a higher prevalence of neuropathy (77% *vs.* 38%). This might indicate that the robotic test was more valid than the manual test.

CONCLUSION: The Robotic Monofilament Inspector could be used as a simple screening machine. This prototype may be developed further for routine clinical use. [*Asian J Surg* 2010;33(4):193–8]

Key Words: diabetic foot, Semmes-Weinstein monofilament, Toronto Clinical Scoring System, vibration perception test

Introduction

Diabetic foot problems are a leading cause of hospitalization and amputation in patients with diabetes mellitus.[1] The most common cause of nontraumatic lower extremity amputation reported in many countries is diabetic foot ulcer.[2] Peripheral sensory neuropathy is a major risk factor that contributes to the development of diabetic foot ulcer.[3] According to a clinical practice guideline for diabetic foot disorders (2006 revision),[4] the Semmes-Weinstein (SW) monofilament examination has been recommend for detecting the loss of protective sensation in diabetic patients.

Diabetic neuropathy comprises a number of different syndromes ranging from subclinical to clinical.[5] It is not a well-understood complication of diabetes. The loss of sensory sensation leads to failure to sense and protect from minor trauma, altered plantar pressure, and foot

Address correspondence and reprint requests to Dr Chumpon Wilasrusmee, Department of Surgery, Faculty of Medicine, Ramathibodi Hospital, Mahidol University 270 Rama VI Road, Bangkok 10400, Thailand.
E-mail: racwl@mahidol.ac.th • Date of acceptance: 15 December 2010

deformities, leading to chronic wounds. The main group of neurological disturbances in patients with diabetes is subclinical neuropathy.[6]

The early identification of neuropathic abnormalities is crucial because it offers diabetic patients an important opportunity to prevent further foot complications.[7] Several methods are used to detect diabetic neuropathy, including the nerve conduction test, the vibration sense test, and validated questionnaires. However, one method may be valid only for one end of the disease spectrum. Although there is no agreement on a gold standard for detecting peripheral neuropathy, an accurate measurement should differ from those with and those without diabetes.[8] The vibration sense test has been used as a gold standard for detecting diabetic neuropathy.[9] A sophisticated test, such as a nerve conduction study, is rarely necessary.[4]

The current level of evidence in the medical literature focuses primarily on the use of the SW monofilament test as a simple screening method to detect diabetic neuropathy.[10] Several reports have shown the effectiveness of this test.[11–14] Although it is useful, simple, reproducible, and inexpensive,[15] the examination must be performed by a physician or medical staff member on whom the loss of time and labour is incurred to patients. Interexaminer variations can reduce the accuracy of the test result. In this study, we developed a prototype, Robotic Monofilament Inspector (RMI) that might be used as a standard machine for the screening of diabetic neuropathy.

Patients and methods

Conceptual design and hypothesis

This development was divided into three parts: computer software, control box, and RMI (Figure 1). The physician could access to the patient's data either in the clinic or by remote access. The model of this system was previously published by our group.[16] A brief explanation of this system follows.

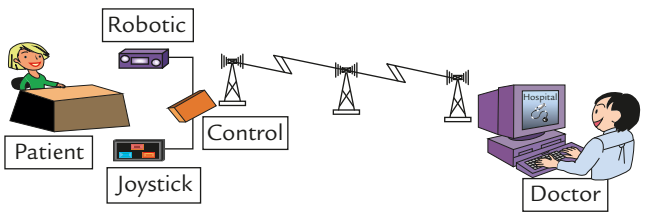

Figure 1. Diagram of the three parts, computer software, control box and the Robotic Monofilament Inspector.

Computer software

The computer software was the program that controlled the action of all parts and kept the patient demographic data and test results. This program was commanded by the doctor or health care professionals. The patient's demographic data must be added into the program before starting the operation (Figure 2).

Control box

The control box was an electronic system that was implemented with an ARM7 microcontroller (Analog Devices Inc., Norwood, MA, USA). This part received the command from the computer software and could pass the command to the monofilament robotics tester. It also worked as a receiver that got the response from the answer box (Figure 3).

RMI

The RMI was the machine that controlled the monofilament to specify test sites (patient's foot). This machine received the command from the control box and moved the monofilament with regular force and duration of touch.

There are currently some controversies on the number of testing sites.[12] In this study, the RMI was developed according to the recommendations of the International Working Group on diabetic foot.[13] The study by McGill et al[14] showed that the combination of the plantar aspects of the first and fifth metatarsals had a high sensitivity and specificity for neuropathy. They defined insensate as when patients did not feel the monofilament at either of these two sites.

The sites tested in this study were as follows (Figure 4): the great toe (site 1); the plantar aspect of the first metatarsal (site 2); the plantar aspect of the fifth metatarsal (site 3). Each site was randomly tested three times. During the examination, patients were in the sitting position and gave their response by pushing a button on an "answer box." The patients were required to respond before continuing to the next examination. If the answer was incorrect two or more times out of three examinations per site, the site was considered to be positive. If the answer was incorrect once or less, the site was considered to be negative.

Design and development

According to the working direction of the monofilament, a solenoid actuator was applied to the inspector. The model-testing machine was developed according to the

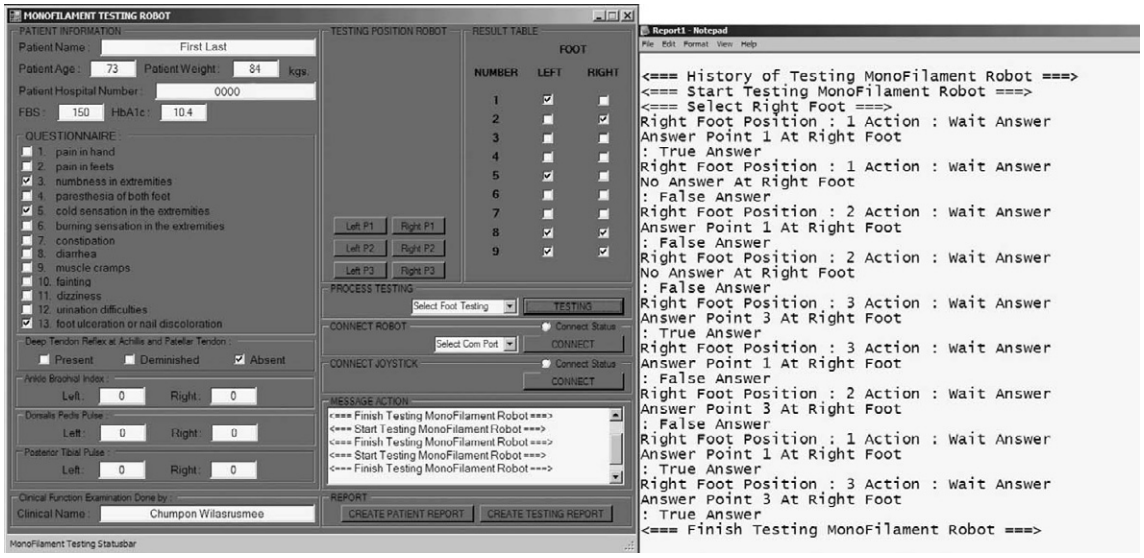

Figure 2. Graphical user interface in the computer software.

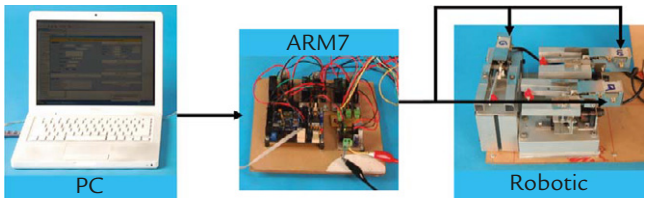

Figure 3. Control box with ARM7 microcontroller.

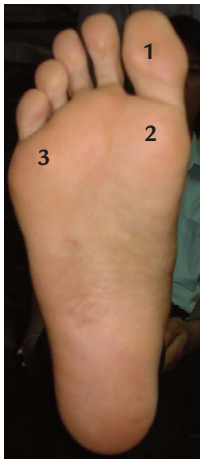

Figure 4. Sites to be tested with the monofilament.

tested sites. The first part of the model was tested at the great toe plantar site. This part had no movement, so the base was fixed. The second part of the model was tested at the plantar aspect of the first metatarsal. This part had one direction of movement on the Y axis. The tested point could be adjusted manually by moving the slider in and out. The third part of the model was tested at the plantar aspect of the fifth metatarsal. This part had two directions of movements on the X and Y axes. The tested point could be adjusted manually to fit different feet sizes.

The RMI was tested randomly either before or after the examination by hand. The testing steps were as follows:

(1) The examiner commanded the computer software to test the patient.
(2) The program sent the action command to the control box.
(3) The control box processed the command and sent it to the RMI.
(4) The RMI acted as a command from the control box.
(5) The control box waited for the answer from the patient. The response from the answer box was passed to the control box and sent to the program.
(6) The program kept the answer.
(7) The step was iterated from Steps 2 to 6 until the total testing number was met.
(8) The program created the report for consideration of the result.

Patients

A total of 71 individuals who provided their informed consent participated in this study. There were 40 participants who were diagnosed with diabetes and 31 participants who had normal blood sugar levels. The sex, age, duration of diabetes, fasting serum glucose, HbA1c, and presence of diabetic complications were recorded. The examiner conducted the SW test (by hand and by robotic

inspector), vibration perception threshold (VPT), and Toronto Clinical Scoring System (CSS) without knowledge of the patients' lower-extremity neuropathy symptoms so as to be blinded from the patients' perceptions. The controls were recruited from an outpatient surgical clinic. They received regular follow-up for at least three years for other diseases such as hernia, breast mass, and haemorrhoid. They had no underlying disease and were healthy.

The SW test

All participants were tested by robotic inspector and by hand following the practical guidelines on the management and prevention of diabetic foot.[13] The SW monofilament examination was conducted by hand at three noncallused sites on each foot (Figure 4): (1) great toe, (2) plantar aspect of the first metatarsal head, and (3) plantar aspect of the fifth metatarsal head using 5.47/10 g monofilament. The monofilament was pressed perpendicular to the test site with enough pressure to bend the monofilament for 1 second. The patients were asked if they felt anything touching their skin and whether it was on the left or right foot. The examinations were repeated three times for each site and included at least one fake examination. If the answers were incorrect two or more times out of three examinations per site, the site was considered to be positive. If the answer was incorrect once or less, the site was considered to be negative. The examinations were conducted at all six sites in a random order each time.

Clinical stratification assessment

The neuropathy severity grading was constructed according to the simplified Toronto CSS.[15] The symptom score was graded as present = 1 and absent = 0 (numbness or tingling of the toes and feet). Reflex scores were graded as absent = 2, reduced = 1, and normal = 0 for each side. Sensory test scores was graded as abnormal = 1 and normal = 0. The sensory test was performed on the toes. All symptoms and signs were combined for a total of 19 points. If the combined scores were between 0 and 5, the participants were classified as negative for neuropathy. On the other hand, if the combined scores were more than 5, the participants were classified as positive for neuropathy.

VPT

The VPT was assessed on both sides of the upper and lower limb lateral condyles using a C64 quantitative tuning fork (Takano Manufacturing, Nagoya, Japan) and applied perpendicularly.[17] Participants were requested to respond when they first lost the vibratory sensation. The vibration disappearance threshold was estimated as the intersection of the two virtual triangles that moved on a scale from 0 to 8. An average threshold below 4 was considered to be abnormal.

Statistical analyses

Continuous data were summarized as mean (SD) or median (range) as appropriate. Categorical data were summarized as counts and percentage. The unpaired *t* test or Wilcoxon rank-sum test was used to determine the differences between independent groups in terms of continuous outcomes, while the χ^2 test was used to determine categorical outcomes. Agreement between the various diabetic neuropathy tests was measured using the kappa statistic. Statistical significance was defined as a p-value of 0.05 or less. Stata Statistical software version 9 (StataCorp, College Station, TX, USA) was used for all statistical analyses.

Results

The participants included 40 diabetic patients, 13 (33%) of whom had foot ulcers, and 31 controls with normal blood sugar and no foot ulcers. A total of 78% of the diabetic group had a clinical neuropathy score of more than five. In the nondiabetic group, there were no cases of symptomatic neuropathy and the clinical score of neuropathy was less than five. The clinical characteristics of the participants are presented in Table 1.

According to the various neuropathy tests, the prevalence of neuropathy in the two groups are presented in Table 2. The highest prevalence of diabetic neuropathy was found when using the clinical score. The agreement between the robotic test, the manual SW test, and other neuropathy tests in terms of the kappa statistic is given in Table 3. The clinical score had the lowest agreement. The prevalence of neuropathy in diabetic patients with or without foot ulcers according to various neuropathy tests are given in Table 4. The lowest prevalence of neuropathy in diabetic foot ulcer was found in the manual SW test.

Discussion

The principle behind the use of the SW monofilament test is calibration to buckling when a force is exerted.

Table 1. Clinical characteristics of participants

Characteristic	DM group ($n=40$)	Non-DM group ($n=31$)	p
Age (yr): mean (SD)	62.8 (9.7)	59.3 (7.7)	0.112
Gender (male): *n* (%)	20 (50%)	7 (23%)	0.018
FBS (mg, %): median (range)	130 (85–285)	83 (72–108)	<0.001
Foot ulcer (yes): *n* (%)	13 (33%)	0	NA
HbA1c: mean (SD)	7.56 (1.56)	–	NA

DM = diabetes melliteus; FBS = fasting blood sugar; NA = not applicable.

Table 2. Prevalence of neuropathy in the participants according to various tests

Neuropathy test	DM group ($n=40$)	Non-DM group ($n=31$)	p
Robotic monofilament test (positive)	26 (65%)	2 (6%)	<0.001
Manual SW test (positive)	21 (53%)	1 (3%)	<0.001
VPT (<4)	25 (63%)	3 (10%)	<0.001
Toronto CSS (>5)	31 (78%)	4 (13%)	<0.001

SW = Semmes-Weinstein monofilament examination; VPT = vibration perception threshold; CSS = clinical scoring system.

Table 3. Agreement between pairs of neuropathy tests

Pair of neuropathy tests	Kappa statistic (SE)
Robotic and SW	0.816 (0.117)
Robotic and VPT	0.941 (0.119)
Robotic and Toronto CSS	0.350 (0.116)
SW and VPT	0.755 (0.117)
SW and Toronto CSS	0.292 (0.110)
VPT and Toronto CSS	0.294 (0.116)

SE = standard error; SW = Semmes-Weinstein monofilament examination; VPT = vibration perception threshold; CSS = clinical scoring system.

If the patient cannot feel the pressure, the foot is considered to be insensate.[18] Although conceptually simple, there is no universally accepted guideline on how the monofilament is to be used or how the results are interpreted.[19] Variations in the use of the monofilament lead to significant differences in the diagnosis and prevalence of diabetic neuropathy, which affect the workload requirements and educational and treatment programs of patients.[20]

Because there is no accepted gold standard method of diagnosing diabetic neuropathy, a new method of testing must be compared with currently established methods. In the present study, the robotic monofilament test was shown to agree well with the established SW monofilament method (Table 3). Both methods agreed well with the vibration perception test, but not so well with the Toronto CSS. The vibration perception test also did not agree well with the Toronto CSS. The latter method yielded a higher prevalence of neuropathy, even in the control (nondiabetic) group, in which the occurrence of neuropathy was not expected (Table 2). The Toronto CSS was probably oversensitive in detecting neuropathy because the multi-item questionnaire, with items that are difficult to reliably elicit, might be prone to false positive findings.

Given that the SW test and VPT might be more valid tests for neuropathy than the Toronto CSS, the present finding that the robotic test was in excellent agreement with the two former tests would seem to indicate that the robotic test is also valid. Another indirect evidence for the validity of the robotic test was that, according to the test, diabetic patients with foot ulcers had a higher prevalence of neuropathy, as might be expected (Table 4). In contrast, the manual SW test indicated that neuropathy was more prevalent in diabetics with no foot ulcers (Table 4). This might indicate that the robotic test was even more valid than the SW test.

One limitation of the present study was that the reliability of the robotic test was not systematically determined. Preliminary experience with the robotic test seemed to indicate that the test was highly reproducible, as designed, yielding identical results almost every time. The current model of the robotic monofilament test is simple to implement, but it requires some training to achieve reliable results. Future modifications may further

Table 4. Prevalence of neuropathy in diabetic patients with or without foot ulcers

Test	With foot ulcer ($n = 13$)	No foot ulcer ($n = 27$)	p
Robotic	10 (77%)	16 (59%)	0.273
SW	5 (38%)	16 (59%)	0.217
VPT	9 (69%)	16 (59%)	0.542
Toronto CSS	7 (54%)	24 (89%)	0.013

SW = Semmes-Weinstein monofilament examination; VPT = vibration perception threshold; CSS = clinical scoring system.

simplify the setup and increase its acceptability among clinicians. A standardized approach should make the monofilament test less prone to measurement bias.

The result of this study demonstrated that an RMI could be used as a simple screening machine. The validity of this novel test should be comparable to the manual SW monofilament test, and perhaps more so. This prototype may be developed further for routine clinical use.

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