

# Evaluation of a Self-Administered Sensory Testing Tool to Identify Patients at Risk of Diabetes-Related Foot Problems

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**OBJECTIVE** — To study the use of a self-administered sensory testing tool designed to identify individuals at risk for diabetes-related foot problems and determine the inter-rater reliability between patient and provider sensory evaluations.

**RESEARCH DESIGN AND METHODS** — Nine centers in eight states with established foot prevention centers mailed 196 self-screening testing materials to randomly selected patients with diabetes scheduled for follow-up appointments. Patients were instructed to perform a sensory test using a 10-g nylon filament at specified sites on the foot and to complete a brief survey form before their appointment. During the follow-up appointment, providers retested patients using an identical sensory filament at the same sites and completed a provider survey.

**RESULTS** — Of the patients, 145 kept their appointments and completed the self-screening materials. There were 141 patient and 137 provider surveys that indicated the instructions were clear and easy to use. Sixty-eight percent of the patients reported self-testing without the assistance of another person. Patient and provider sensory test findings disagreed ( $P = 0.0014$ ) in 18 of 145 cases and fair inter-rater reliability was found ( $\kappa = 0.73$ ). Disagreement in sensory tests was related to patient age ( $P = 0.012$ ). Sensory loss, previously undetected by providers, was found in 23 case subjects.

**CONCLUSIONS** — Self-administered sensory tests provide patients an opportunity to share in the responsibility for preventing diabetes-related foot problems but should not replace routine foot evaluation by a provider.

In diabetes, sensory loss in the foot is considered the permissive factor that allows minor injury or repetitive stress to progress to chronic ulceration, infection, deformity, or lower-extremity amputations (1,2). Foot screening using a 5.07 monofilament (10-g bending force) has been shown to be a valuable tool in identifying patients with loss of protective sensation and at risk for diabetes-related foot problems (3–12). Sensory filaments have been shown to be stable (13) and reliable (14–16) measurement instruments. Foot complications and lower-extremity amputations have been reduced when patients

are provided with foot screens, education, proper fitting footwear, and routine care for foot problems (17–22).

Diabetes is generally a self-managed disease, with patients providing most of their own daily care (23). It has been shown that patients who are empowered with awareness of their own disease-related problems, treatment options, and tools for self-care make healthier choices in the management of their diabetes (24).

The purpose of this study was to evaluate the feasibility of a self-administered sensory testing tool designed to identify individuals at risk for diabetes-related foot

problems and to determine the inter-rater reliability between patient and foot-care provider sensory testing.

## RESEARCH DESIGN AND METHODS

Nine centers in eight states, representing a diverse socioeconomic grouping, participated in the study. The centers selected had established diabetes lower-extremity amputation prevention programs, providers trained in foot screening, and patient data programs that would identify follow-up appointments for all diabetic patients. Providers included physicians, podiatrists, registered nurses, physical therapists, and certified orthotists who received training in foot screening and monofilament testing through videotape programs (Lower Extremity Amputation Prevention [LEAP] Program, Carville, LA). Participating programs agreed to mail self-screening testing materials (in English or Spanish, as appropriate) to randomly selected patients scheduled for follow-up appointments. Patients were instructed in writing to perform the sensory test and complete a brief survey form before their appointment. Centers agreed to have providers perform an identical sensory test and complete a brief provider survey form during the appointment visit.

Patient self-testing sensory kits included an inexpensive disposable nylon-filament sensory testing tool with a 10-g bending force. The kit included easy-to-read and illustrated instructions that described how to hold the instrument, how to apply it to the skin, and where to apply it on the foot. Testing sites included the plantar aspect of the distal phalanx of the great toes and the first, third, and fifth metatarsal heads. The patients were requested to complete a survey form that included date of birth, sex, race, and five questions requiring a “yes” or “no” response (Table 1).

Providers were requested to retest patients using an identical nylon-filament instrument at the same sites on the foot and to complete a provider survey form that included type and duration of diabetes (Table 2). The patient was considered to

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Table 1—Patient responses: Patient Empowerment Program Survey

	Yes	No
The instructions for testing were clear.	141	3
The filament was easy to use.	140	4
A loss of feeling was found.	53	92
I was not aware of this loss of feeling in my feet.	34	46
The foot testing was done by the patient without assistance of another person.	99	45

Data are n.

Table 2—Provider responses: Patient Empowerment Program Survey

	Yes	No
To the best of my knowledge, this patient has not previously been tested for loss of protective sensation.	75	67
A loss of sensation was detected during this visit.	55	90
We were not previously aware of this loss of sensation.	23	54
From our discussion with the patient, the Carville filament and instructions were easily understood and used by the patient or family member.	137	8

Data are n.

Table 3—Patient demographics

	n
Race	
African-American	24
Hispanic	26
White	94
Sex	
Male	81
Female	63
Average age (years)	57 ± 14
Duration of diabetes (years)	13 ± 10

Data are n and means ± SD.

Table 4—Patient sex and ability to self-test

	Male	Female
Patient tested self	55	39
Patient required assistance	23	21

Data are n.

Table 5—Agreement of foot sensation present

	Provider no	Provider yes
Patient no	45	8
Patient yes	10	82

Data are n.  $\chi^2 = 10.205$ .  $P = 0.0014$ .  $\kappa = 0.73$ .

have loss of protective sensation if the nylon filament was not felt at any of the four sites on either foot. A paired  $\chi^2$  (McNemar test) and  $\kappa$  statistic were used to analyze the difference in agreement between patient and provider for loss of protective sensation. A  $\chi^2$  test and  $t$  test were used to analyze group differences.

**RESULTS** — One hundred and ninety-six self-screening kits were sent to patients. Self-screening materials were completed and returned by 145 individuals who kept their appointments. Of the individuals, 12 declined to participate in the survey, 16 did not complete the screening materials, and 23 did not keep their appointments. There were 141 patient and 137 provider surveys that indicated the instructions were clear and easy to use. Ninety-nine of the patients reported they tested themselves without the assistance of another person. There was no difference in sex (Table 4) among patients who reported to have self-tested compared with those who received assis-

Table 6—Patient sex and patient and provider sensory test agreement

	Male	Female
Sensory tests agreed	67	57
Sensory test disagreed	12	6

Data are n.  $\chi^2 = 1.017$ .  $P = 0.313$ .

tance from another person. There was no difference ( $t = 0.245$ ,  $P = 0.807$ ) between the ages of patients who reported to have tested their own feet ( $57.7 \pm 14.8$  years) and patients who received assistance from another person ( $58.4 \pm 13.8$  years). Further study is needed to determine whether patients can actually perform sensory testing without assistance.

Patient and provider sensory tests disagreed ( $\chi^2 = 10.205$ ,  $P = 0.0014$ ) in 18 of 145 cases and a fair inter-rater reliability ( $\kappa = 0.73$ ) was found (Table 5). There was no sex difference (Table 6) or difference in reported ability to self-test (Table 7) between patients who agreed or disagreed with provider sensory tests. Patients who disagreed with provider tests were older ( $65.4 \pm 10.3$  years) than those who agreed ( $56.4 \pm 14.5$  years,  $t = 2.544$ ,  $P = 0.012$ ). Sensory loss, previously unidentified by providers, was found in 23 case subjects, of whom 16 had received a previous foot screen by their provider.

**CONCLUSIONS** — Of the self-screening forms mailed to patients in the study, 145 (74%) were returned completed. This response indicates a strong patient interest in sharing in the evaluation of their feet as well as the usability of the testing instrument by patients.

The finding of a difference in agreement between patient and provider sensory tests was expected. We find it notable, however, that patient and provider sensory tests agreed in 87% of the cases (Table 5). There is a danger that patients may falsely find no loss of protective sensation during self-testing and not obtain preventive foot care. In this study, assuming that provider

Table 7—Patient ability to self-test and patient and provider sensory test agreement

	Patient tested self	Patient required assistance
Sensory tests agreed	87	37
Sensory tests disagreed	9	9

Data are n.  $\chi^2 = 2.917$ .  $P = 0.09$ .

tests were correct, there were ten false-negative sensory self-tests. False-negative tests are a serious limiting factor for patient self-tests not followed up by a provider.

Of particular interest was the finding that sensory loss, previously undetected, was found in 23 case subjects. This detection of unidentified sensory loss underscores the value of patients becoming empowered to share in the evaluation of their feet. If patients are able to use a sensory testing tool and share in the evaluation of their feet, providers must be knowledgeable about sensory testing and the appropriateness and availability of preventive foot care services.

The results of this study showed that the majority of patients with diabetes could accurately test their feet without assistance from another person. Age was found to influence the accuracy of self-testing. This finding is in agreement with a previous study that found that 86% of elderly subjects ( $\geq 65$  years of age) were unable to inspect and remove a simulated lesion spot on their foot because of joint immobility, obesity, or poor vision (25).

Self-administered sensory tests may be useful for providing patients an opportunity to share in the responsibility for preventing diabetes-related foot problems but, because of the risk of false negatives, should not be used as a replacement for routine foot evaluation by a provider.

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