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**The Use of the Semmes-Weinstein Monofilament and Other Threshold Tests
for Preventing Foot Ulceration and Amputation in Persons with Diabetes**

[Advances in Managing The Diabetic Foot: Systematic Review]

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Abstract

OBJECTIVE: To evaluate the evidence supporting the Semmes-Weinstein monofilament (SWM) and other threshold testing in preventing ulcers and amputation.

SEARCH STRATEGY: We searched the MEDLINE database using the Medical Subject Headings ("diabetic foot" or "diabetes mellitus" and ["foot ulcer" or "foot diseases"]) and ("sensory threshold" or "touch" or "vibration" or "monofilament [text word]" or "two point discrimination [text word]") restricted to studies with human subjects and published in the English language between 1985 and 2000.

DATA ABSTRACTION: The studies were abstracted by one author (J.M.) and confirmed by the second author (J.S.).

SELECTION CRITERIA: The studies had to contain original data collection and SWM or another threshold assessment method.

DATA COLLECTION/ANALYSIS: All articles were abstracted for study design, testing method, population, and results.

MAIN RESULTS: We identified 6 prospective studies using SWMs and 4 with vibration perception thresholds (VPTs), including 1 randomized controlled trial. The increased risk of ulceration ranged from an odds ratio (OR) of 2.2 to 9.99, and the risk of

amputation was a relative risk of 2.9 using the SWM and an OR of 4.38 to 7.99 for VPT. The randomized controlled trial of screening plus treatment for those with previous ulcers had no significant decrease in the number of ulcers or minor amputations but showed significantly fewer major amputations.

CONCLUSIONS: The SWM is currently the best choice for screening for clinically significant neuropathy because it is portable, inexpensive, painless, easy to administer, acceptable to patients, and provides good predictive ability for the risk of ulceration and amputation. Once the patient without protective sensation has been identified, management with protective footwear and patient education to prevent damage should be instituted but compliance is often difficult to implement.

CLINICAL QUESTION Does the use of the Semmes-Weinstein monofilament or another method of neuropathy screening reduce the outcome of ulcers and amputation in persons with diabetes?

"If I were to choose between pain and nothing, I would choose pain." - *William Faulkner*

Foot ulceration is the most common serious complication of diabetes, affecting up to 15% of all persons with diabetes during their lifetimes.¹ A key risk factor for these foot complications is peripheral neuropathy,^{2,3} which leads to altered function and physical deformity. Results from the Diabetes Control and Complications Trial⁴ suggest that strict glycemic control might prevent or delay the onset of neuropathy. Because no treatment for peripheral neuropathy is currently available, experts recommend periodic neurologic screening and, if neuropathy is detected, specific interventions of footwear and patient education.² Many experts specify the Semmes-Weinstein monofilament (SWM) as the best available screening instrument for neuropathy.

We reviewed the chain of evidence that supports the recommendations for neuroassessment in preventing ulceration and amputation. We begin our article with a brief review of neurophysiology to illuminate the challenges of neuroassessment and describe the physical properties of the SWM. We then provide a systematic review of the evidence supporting use of the monofilament and other clinical methods to detect clinically significant neuropathy. We also provide a brief review of the evidence for effective management of the neuropathic foot and conclude with recommendations for future research.

BACKGROUND

Clinical evidence of peripheral neuropathy is reported in more than 50% of persons who have had diabetes for 20 years or more.⁵ Diabetes damages nerves through vascular, autoimmune, and biochemical mechanisms.⁶ The most common form of peripheral neuropathy in diabetes is the distal symmetric polyneuropathy (DSPN), often described as a stocking-glove neuropathy,⁵ which affects the longest nerves first and progresses proximally (Figure 1). All modalities may be affected, including sensory, motor, and autonomic nerve function, but the loss of the sensory signals poses the greatest threat to the limb. The person who does not have protective sensation may not perceive the pain of stepping on a needle, the flame burning his foot, or the inflammation of a blister due to repetitive trauma from ill-fitting footwear.

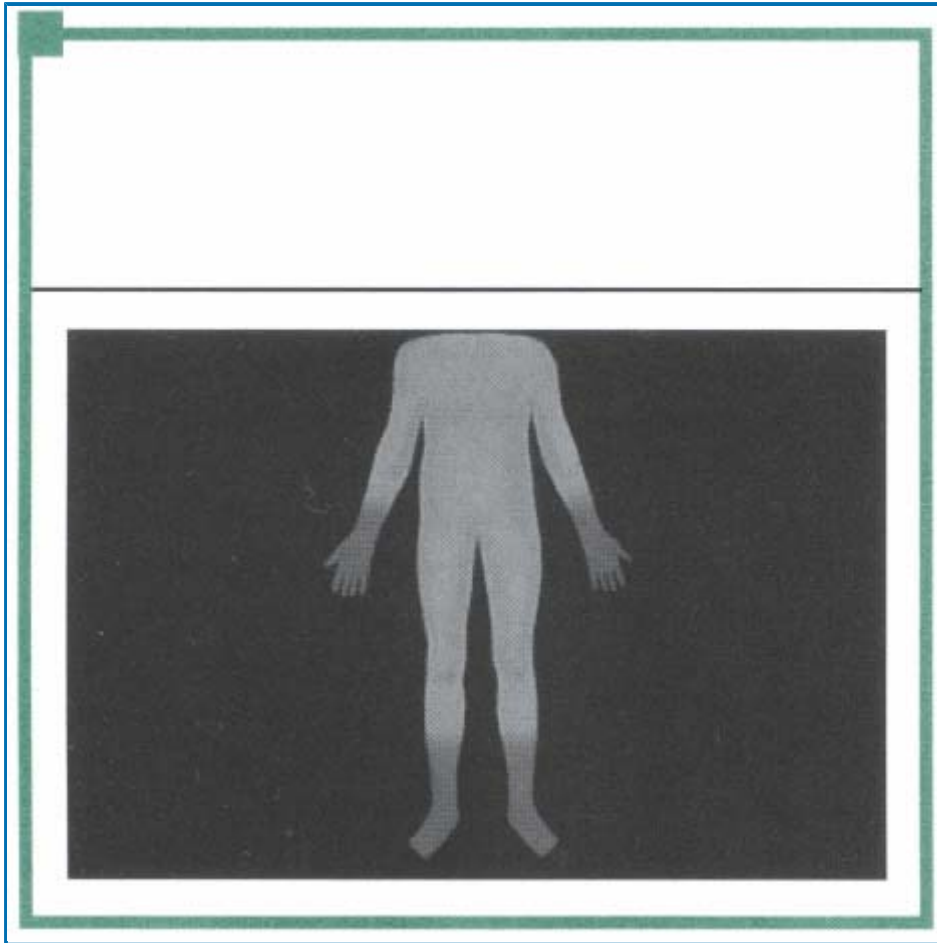


FIGURE 1 Distribution of Distal Symmetric Polyneuropathy in Diabetes

The detection of DSPN is complex because of the variety of affected nerve fibers and sensory end organs, overlapping functions that provide economy of function, and redundancy of important sensory signals. The sensory system is composed of large fibers called A-beta fibers (10-15 microns) that carry touch sensation, thinly myelinated A-delta fibers (2-5 microns) that carry sensations of sticking pain and temperature, and unmyelinated C fibers (0.5-1.5 microns) that carry burning pain.⁷ Clinical assessment of neuropathy includes function (eg, electrophysiologic tests), deep tendon reflexes, psychosomatosensory tests (eg, SMW), and sensory symptoms. Since no single modality stands out as the gold standard, a consensus conference of the American Diabetes Association and the American Academy of Neurology recommends that multiple measures be used for clinical and research purposes.⁸

Several test batteries have been developed, but they require complicated expertise, time, and expense. Many batteries include electrophysiologic testing (eg, nerve conduction studies), which provides an objective result with high sensitivity for nerve dysfunction ⁹

but very poor specificity for ulceration and amputation. The test is uncomfortable, time-consuming, requires expensive equipment and training, and is expensive (\$500-\$1500). In contrast, psychosomatosensory threshold tests provide rapid, comfortable, and inexpensive assessments of sensory function far more suitable for the primary care patient. The most commonly used threshold tests are the SWM and the vibration perception threshold (VPT).

The monofilament was developed by von Frey in the late 1800s, using horse hairs of different diameters and lengths to test pressure sensation of the skin. Semmes and Weinstein revived this technique in the late 1950s to study peripheral neuropathy in brain-injured veterans, using a nylon filament embedded in a plastic handle (Figure 2).¹⁰ The Semmes-Weinstein monofilament assesses the threshold for light touch pressure in a semiquantitative fashion.¹¹ This instrument exploits the unique physical properties of a buckling column to produce a reproducible quantifiable force despite the force applied to the handle ¹² (Figure 3). Filaments are calibrated to provide a specified force measured in grams and are identified by a number that is 10 times the log of the force in milligrams exerted at the tip of the filament (eg, the 5.07 monofilament exerts 10 g of force). The actual pressure delivered to the skin surface is the force divided by the surface area of the filament and may vary depending on the angle with the skin. Monofilaments are commercially available in sizes ranging from 1.65 to 6.65 (Appendix).

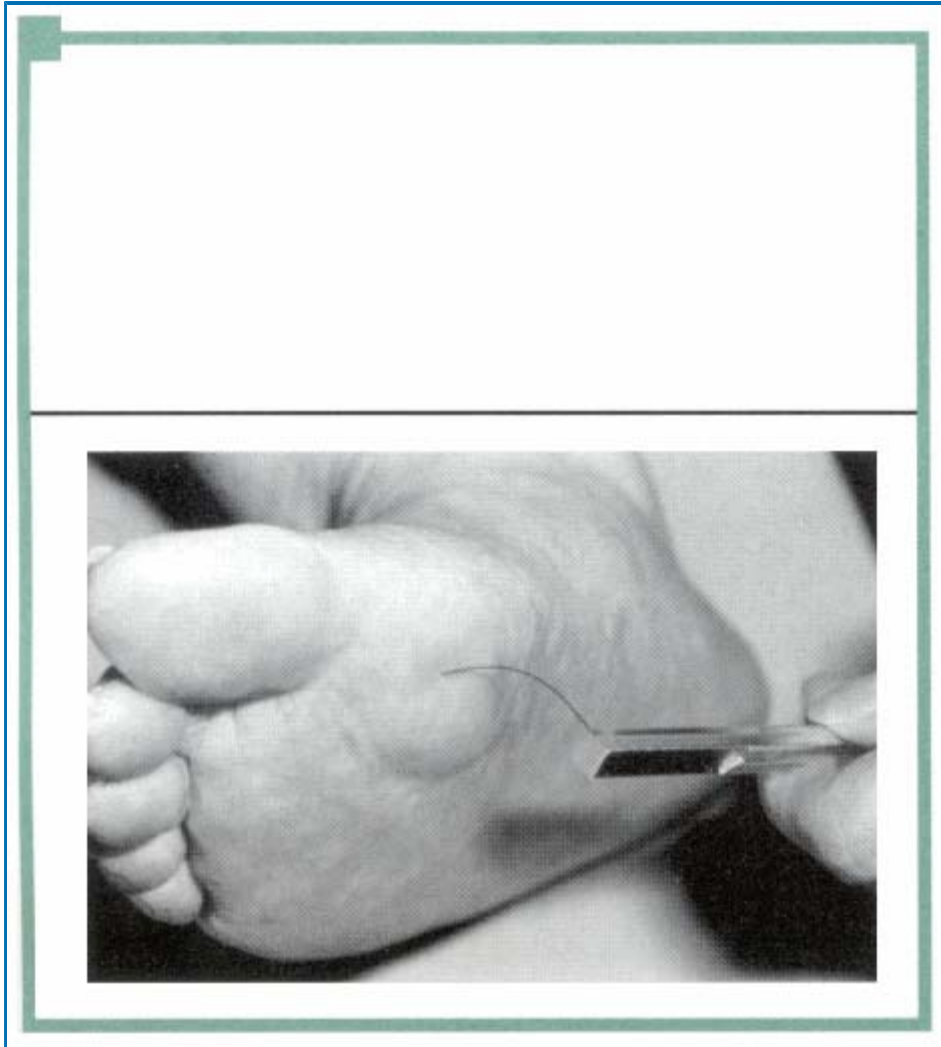


FIGURE 2 Testing method with the Semmes-Weinstein monofilament. Pressure is applied to the handle sufficient to gently bow the nylon filament.

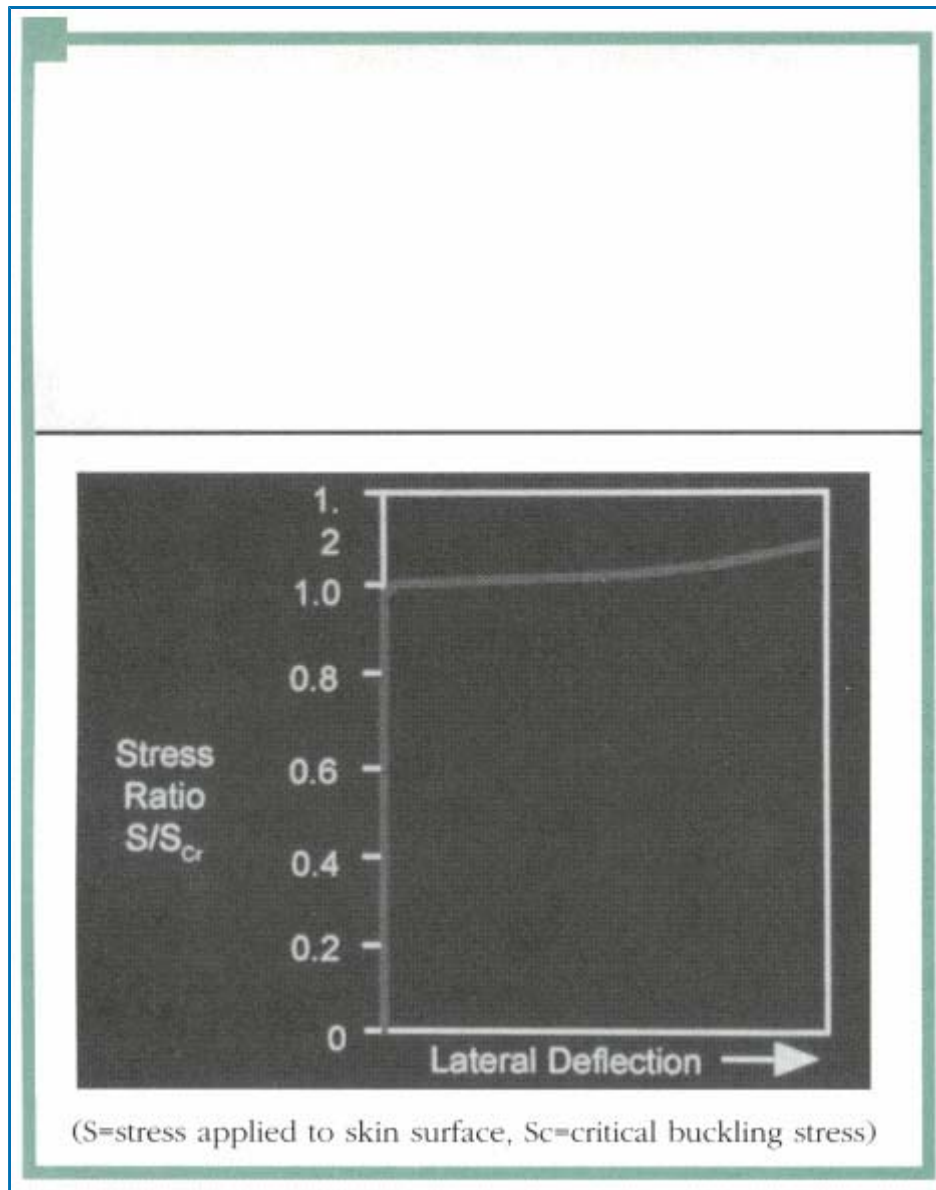


FIGURE 3 Lateral deflection relationship to stress ratio. Note that the stress ratio remains constant over a wide range of lateral deflection.

The monofilament was first advocated for diabetic neuropathy screening by a missionary physician named Brand. While in India he observed that persons with leprosy repeatedly injured themselves without any complaint of pain. Once a wound occurred the patient continued to use the injured limb, preventing healing and often extending the damage. After careful observation he realized

that these patients had peripheral neuropathy rather than "bad flesh" as was traditionally taught, and he found that those protected by a plaster cast would heal. Patients with insensate limbs were taught various strategies to protect the limb from harm with astonishing success. His management of insensate limbs revolutionized care for persons with leprosy around the world.

In 1965 Brand came to Carville, Louisiana, to head the leprosarium of the US Public Health Service and to continue his research on the insensate limb. While attending medical meetings he noticed that persons with diabetes had injuries and complications similar to those of persons with leprosy. He reasoned that both suffered a loss of protective sensation that allowed trauma to occur and continue without uncomfortable warning signals. Again he challenged the medical dogma of the day and successfully applied his approach of identification and protection of the insensate limb to persons with diabetes. His book "Pain: the Gift Nobody Wants"¹³ chronicles his simple observations in India that led to his innovative approaches to the diagnosis and treatment of peripheral neuropathy.

METHODS

Search Strategy

The Medical Subject Heading "diabetic foot" was established in 1994 to replace "diabetic foot ulcer" and the combination of "diabetes mellitus" and "foot diseases." We searched the MEDLINE database in July 2000 using the Medical Subject Headings in the following search strategy: "diabetic foot" *or* "diabetes mellitus" *and* ("foot ulcer" *or* "foot diseases"). We then searched for "sensory threshold" *or* "touch" *or* "vibration" *or* "monofilament (text word)" *or* "two point discrimination (text word)." The results of these 2 searches were combined using "and" and were restricted to articles that used human subjects and were published in the English language between 1985 and 2000. Abstracts were reviewed to determine if the article represented original data collection and included the SWM or another neuropathy assessment method that could be readily conducted in a primary care setting. Also, all references from the articles and clinical reviews obtained from the search were scanned for other articles that may have been missed with this strategy. One additional publication was located that had been missed in the original search because it was coded as "leg ulcer" rather than "foot ulcer" *or* "diabetic foot ulcer." A search using "leg ulcer" *and* "diabetes mellitus (exploded)" *and* "diabetic neuropathies (classification, complications, physiopathology, diagnosis)" with the same restrictions yielded another 15 publications, but no additional publications were identified that met our criteria. We also added an article published in May 2000 in a major diabetes journal that was not yet indexed.¹⁴

Inclusion Criteria and Assessment of Study Quality

We adopted the standard criteria for assessing diagnostic evaluations.^{15,16} Articles were restricted to those with a reference standard of foot ulceration or amputation. Although foot ulceration in the neuropathic foot may not cause pain or functional limitation initially, the presence of an ulcer imposes a very high risk of subsequent amputation, with severe repercussions on function, survival, and costs. Each study was assessed for:

- Study design
- Patient population characteristics and potential for selection bias
- The degree that the examiners were blinded to the results of the other test
- Application of the test and the reference standard to all the subjects
- Test characteristics-likelihood ratios or sensitivity, specificity, and predictive value
- Reproducibility-intrarater and interrater reliability and factors affecting reproducibility

A few articles that did not assess ulcers or amputations but provided information on technical aspects or reproducibility are included in the text but not presented in the tables.

The studies were abstracted by one author (J.M.) and confirmed by the second author (J.S.).

RESULTS

We identified 6 prospective studies and 10 comparative or observational studies that evaluated the association of the SWM with ulceration. We also identified 7 observational studies and 4 prospective studies linking VPTs to ulcers or amputation. The articles, study design, study population, testing methods, and results are listed in [Table 1](#) and [Table 2](#). We also included information on other types of threshold tests, including temperature threshold and 2-point discrimination if included in the study. Several studies appear to report data from the same population. The publications by McNeely, Boyko, and Adler report on the same Seattle veteran population, while the Lavery, Armstrong, Frykberg, and Pham publications appear to include the same San Antonio podiatric population.

Author, Year	Reference Standard	Populations*	Testing Method	Results
Comparative Studies				
Birke, 1986 ¹⁷	Current ulcer	28 patients, 72 leprosy patients (no diabetes)	SWM: 4.17, 5.07, 6.10 tested next to ulcer calibrated	No patient with ulcer felt less than SWM 6.10
Holewski, 1988 ¹⁸	Recent or previous ulcer	20 patients with recent or previous ulcers, 20 patients with neuropathy, 20 patients with no ulcers or neuropathy, 20 patient controls without diabetes	SWM: 3.22, 3.61, 4.31, 5.07, 6.10, 6.45 + test ≥3 of 6 plantar sites on forefoot	SWM 5.07: sensitivity 100%, specificity 100%
Liniger, 1990 ¹⁶	Current or healed ulcers	26 foot clinic patients with ulcers; 58 outpatient diabetes clinic; 108 inpatients	Rydel-Seiffer tuning fork + test ≤4.0	95% of patients with ulcers
Kumar, 1991 ¹¹	Current ulcer	Convenience sample at national patient meeting, 171 without ulcers; 11 with current ulcers	SWM: 4.17, 5.07, 6.10 1 site on great toe VPT—plantar surface, big toe, VPT >35 volts=insensate calibrated	SWM 5.07: sensitivity 100% specificity 77.7% 78.6% sensitivity 93.4% specificity
Mueller, et al 1996 ¹⁹	Current ulcer	23 with ulcer; 23 without ulcer; 24 controls, no diabetes	SWM: 4.17, 5.07, 6.10 + test=failed >20% of 10 trials at 6 sites	All patients with ulcer failed to feel SWM 5.07
Vileikyte, 1997 ²⁰	Current ulcer	Manchester Diabetes Center or Diabetic Foot Clinic; 37 with ulcer, 95 without ulcer	Tactile circumferential discriminator + test ≥6 SWM 5.07 VPT >35 V	sensitivity 100%, specificity 58.3% sensitivity 91.9%, specificity 76.0% sensitivity 86.5% specificity 79.2%
Cross-sectional Studies				
Sosenko, 1990 ²¹	Ulcer current or past	314 type 2 clinic patients; 91 had ulcer or ulcer hospitalization (convenience sample)	SWM:-1.65 6.16 plantar surface: hallux, 1, 2, 5 mtp result=mean of ast 3 correct and last 3 incorrect responses, excluding highest and lowest values, calibrated VPT >25 V great toe + test=5.6 units Temperature perception Cold: change of 2.4 °C above reference. Hot: change of 3.1 °C above reference	SWM 4.21: sensitivity 84%, specificity 96%, PPV 76% sensitivity 83% specificity 87%, PPV 49% Cold: sensitivity 81% specificity 74%, PPV 32% Heat: sensitivity 85% specificity 74%, PPV 33%

TABLE 1 Observational Studies Noting the Association of the Semmes-Weinstein Monofilament or Vibration Perception Threshold with

Ulceration

Author, Year	Reference Standard	Populations* Testing	Method	Results
Frykberg, 1998 [†]	Ulcer current or past	251 patients, 99 with ulcer present or past recruited from 3 foot care clinics (Boston, San Antonio, San Francisco) may have included patients reported in Armstrong or Lavery	SWM 5.07; 2 of 3 sites (great toe, metatarsal head, heel) VPT ≥25 V great toe	OR=9.6 (95% CI, 5.02-18.5) OR=4.1 (95% CI, 1.89-8.87) adjusted for age, sex, race, duration OR=11.7 (95% CI, 7.4-18.4) OR=4.4 (95% CI, 2.58-7.54) adjusted for age, sex, race, duration
Case Control Studies				
Boulton, 1986 ^{††}	Current ulcer	University diabetes clinic, Miami, Florida, 86 with foot ulcers 46 without foot ulcer hospitalization	VPT >25 V, mean of 3 readings on each great toe	OR=10.77 (95% CI, 4.59-25.73)
Olmos, 1995 ^{††}	Current ulcer	Teaching hospital clinic recruits, Columbus, Ohio, 168 without ulcer hospitalization, 14 with ulcer in last year	SWM 5.07; great toe tip, 1,5 mtp plantar surface, number of insensate sites from each foot added (R + L)	≥2 of 6 sites=sensitivity 85.7%, specificity 84.0%, ≥1 of 6 sites=sensitivity 85.7%, specificity 81.9%
McNeely, 1995 ^{††}	Current ulcer	Veterans (men), Seattle Veterans Affairs: 46 with ulcers; 322 without ulcers; (same population as Boyko, see Table 2)	SWM 5.07; + test ≥1 of 9 sites	OR=18.4 (95% CI, 3.83-88.47) controlled for Achilles reflex and transcutaneous carbon dioxide pressure
Armstrong, 1998 ^{††}	Current or recent ulcer	Podiatry clinic University of Texas Health Sciences Center at San Antonio, 30 with ulcers, 85 without ulcers, age-matched	SWM 5.07; + test ≥4 of 10 sites VPT >25 V great toe SWM 5.07; ≥4 sites insensate AND vibration threshold >25 V	95% sensitivity 82% specificity† 80% sensitivity, 85% specificity† 88% sensitivity 88% specificity 100% sensivity, 76% specificity
Lavery, 1998 ^{††}	Current or recent ulcer	Texas Diabetes Institute patients (may have included patients reported in Armstrong, see above): 76 with ulcers, 149 controls without ulcers, age-matched	SWM 5.07; ≥4 sites insensate OR vibration threshold >25 V VPT >25 V great toe	Univariate OR=32.5, P < .001; multivariate model: OR=15.2, P < .001, controlled for prior amputation, elevated plantar pressure, symptoms of neuropathy, bony deformity, poor control of diabetes, duration of diabetes, and male sex.

*Patients with diabetes unless otherwise specified.
†Interpolated from graph.
††SWM denotes Semmes Weinstein monofilament; VPT, vibration perception threshold; OR, odds ratio; RR, relative risk; CI, confidence interval; mtp, metatarsal phalangeal joint; V, volts; PPV, positive predictive value.

TABLE 1 continued

Author, date	Follow-up	Population	Test Method	Outcome Risk Estimate
Cohort Studies				
Rith-Najarian et al, 1992 ²⁷	2.5 years	358 Native Americans	SWM 5.07; + test ≥ 1 site of 8 sites on plantar surface, calibrated	Ulcers: RR=9.99 (95% CI, 4.8-21.0); amputation: RR=17 (95% CI, 4.5-95.0)
Litzelman et al, 1997 ²⁸	1 year	352 obese indigent urban patients in RCT of care, mainly African Americans	SWM 5.07; + tests ≥ 1 of 3 sites on toes Thermal sensitivity, $>2.04^\circ$ above 25°C =warm $>1.58^\circ$ below 25°C =cold	Ulcers: OR=5.46 (95% CI, 2.39-12.45) Ulcers: OR=3.04 (95% CI, 1.17-7.88)
Young et al, 1994 ²⁴	3-4 years	469 consecutive clinic patients, United Kingdom, excluded prior ulcers and vascular disease	VPT $>25\text{ V}$	Ulcers: OR=7.99 (95% CI, 3.65-17.5)
Coppini et al, 1998 ²⁶	10 years	405 diabetes clinic patients without ulcer	VPT, abnormal age-adjusted values Abnormal clinical examination=1 or more; ankle jerks, tuning fork, cotton wool sensation	Ulcers: OR=4.38 (95% CI, 1.11-17.26); (95% CI, 1.11-17.26); sensitivity 70% specificity 70% Ulcers: OR=2.3 (95% CI, 1.00-5.20); sensitivity 55%, specificity 72%
Boyko et al, 1999 ²⁵	mean 3.7 years	749 veterans without current foot ulcer	SWM 5.07; + test >1 of 9 sites	Ulcers: RR=3.37 (95% CI, 2.45-4.63); RR=2.2 (95% CI, 1.5-3.1) adjusted for history of amputation or ulcer, Charcot deformity, TcPo ₂ , body weight, AAI, and orthostatic blood pressure
Adler et al, 1999 ²⁷	3.7 years	776 male veterans (same populations as Boyko)	SWM 5.07; + test >1 of 9 sites	Amputation: RR=2.9 (95% CI, 1.1-7.88), adjusted for hospitalization of ulcer, insulin, TcPo ₂
Pham et al, 2000 ²⁴	mean 30 months	248 patients from 3 diabetic foot clinics	SWM 5.07; + test at great toe VPT $>25\text{ V}$	Ulcers: OR=5.4 (95% CI, 2.6-11.6); sensitivity 91%, specificity 34% Ulcers: OR=8.2 (95% CI, 7.4-18.4)
Randomized Controlled Trial				
Klenerman et al, 1996 ²⁹ , McCabe	RCT	1001 screened, 192 at risk treated;	Deficit in any of the following: SWM 5.07 VPT,	Treatment vs controls: ulcers:

TABLE 2 Prospective Studies Predicting Ulceration or Amputation with Semmes-Weinstein Monofilament and/or Vibratory Perception Threshold

In general the comparative studies used small convenience samples. Although the cross-sectional studies were larger, no mention was made of the representativeness of the sample. The observational studies were generally performed on patients with ulcers, so blinding was not possible (however, the examiners in the prospective studies were obviously blinded). Two of the prospective cohort studies were restricted to subjects without an ulcer history, and the others made no mention of blinding the examiner to the ulcer history.

Which Size Monofilament Should Be Used?

The first publication using the SWM came from Carville,¹⁷ reporting the results from patients with Hansen's disease or diabetes using the 4.17, 5.07, and 6.10 monofilaments. No patient with a neuropathic ulcer could sense the 5.07 monofilament, so Carville and colleagues suggested that this level provided the best discrimination. Three observational studies¹⁷⁻¹⁹ found that the 5.07 SWM (10 g) correlated best with the presence or history of an ulcer, while 2 other observational studies suggested that the 4.21 (1 g) was a better discriminator.^{20,21} All 6 of the prospective studies evaluating the SWM used the 5.07 SWM.^{14,22-26}

What Sites Should Be Tested?

Conflicting recommendations have been published on the proper sites for testing. Publications from Carville²⁷ have specified 10 sites distributed over the plantar surface of the toes, metatarsal heads, insole, and heel, and the dorsum of the foot. Evaluations of 2 small cohorts of normal persons without neuropathy reported that the skin with hair (ie, the dorsum of the foot) was 10-fold more sensitive than the sole, and the heel was 10-fold less sensitive than the plantar surface of the forefoot.^{18,28} In the diabetic foot, the plantar aspect of the forefoot provides the best discrimination between those who did and did not have ulcers, while the heel provides essentially no discrimination.¹⁸ A study of 304 patients that specifically addressed this question²⁹ found that 4 plantar sites on the forefoot (great toe and the metatarsal heads of the first, third, and fifth ray) identified 95% of the patients who had 1 or more absent sensation sites when 8 plantar sites were tested (Figure 4).

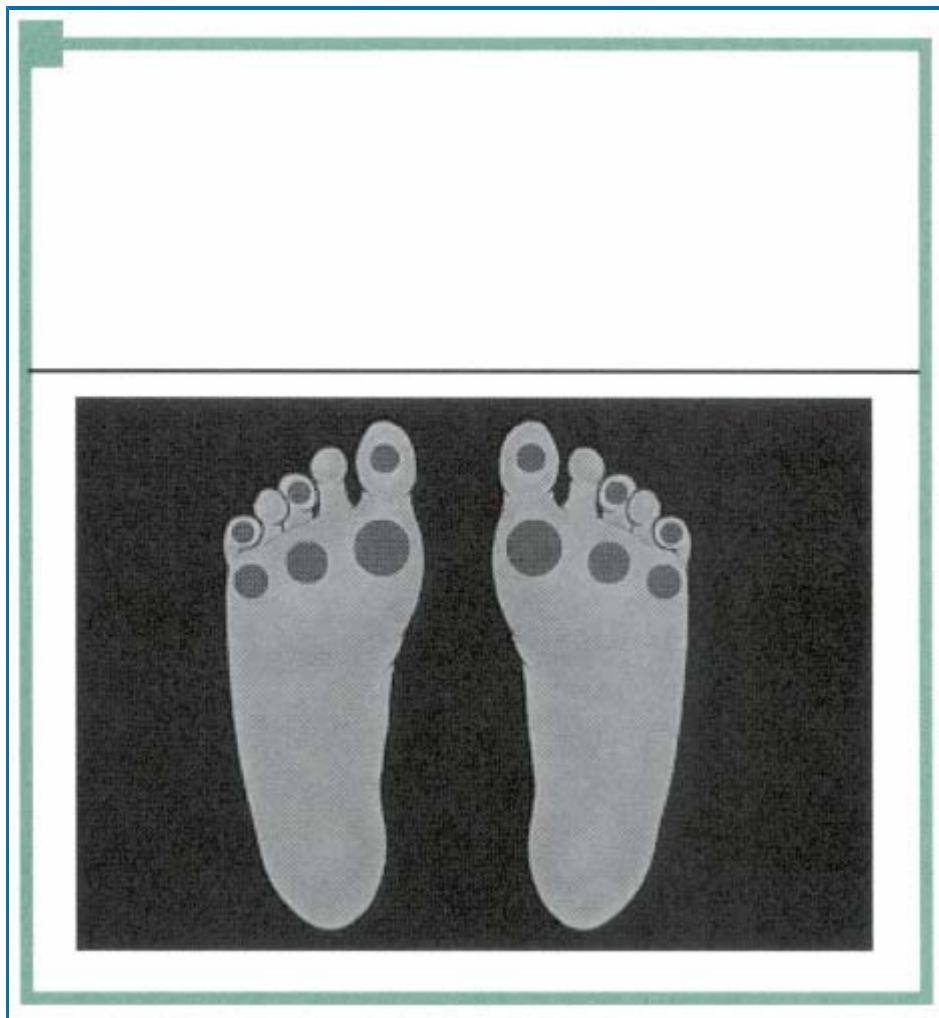


FIGURE 4 Recommended testing sites for the Semmes-Weinstein monofilament. Sites on the forefoot are the most informative.

How Many Sites Should Be Tested?

The number of insensate sites required to define an insensate foot has also been debated. The proposed cutoffs for defining an insensitive foot range from 1 to 4 sites.¹⁸ All 6 prospective studies used 1 or more insensate site to define a person as insensate.^{14,22-26}

Predictive Ability of the Monofilament

The observational studies assessed the sensation in persons with diabetes who had and did not have a current ulcer or history of

an ulcer.^{18,30,31} Four prospective studies from very different populations demonstrate the predictive ability of the monofilament for ulcers and amputation. Rith-Najarian and colleagues²² tested 358 patients with type 2 diabetes in a population of Native Americans and found that 70 (19%) patients were insensate at one or more sites. The insensitive area was retested twice to confirm the classification. Over the next 2 years 37 of the 92 persons with insensate feet developed ulcerations, compared with only 4 of 266 persons who had intact sensation (relative risk [RR] = 9.9; 95% confidence interval [CI], 4.8-21) The risk of amputation also increased in the group who did not have sensation (odds ratio [OR] = 17; 95% CI, 4.5-95, [Figure 5](#)). The second study was conducted with indigent inner-city persons, mainly of African American race with type 2 diabetes.²³ The population was recruited for a randomized controlled trial of foot care but was analyzed as a prospective cohort for this study. After controlling for the effects of intervention, the monofilament predicted a foot ulcer with an OR of 2.75 (95% CI, 1.55-4.88) over 1 year of follow-up. The third prospective study came from a longitudinal study of veterans with diabetes,²⁴ primarily of older men with type 2 diabetes. A cohort study from the same population found that the monofilament was associated with an RR of 2.2 (95% CI, 1.5-3.1) for ulceration, controlled for several other risk factors. The fourth study combined patients from podiatric clinics in 3 cities: Boston, Massachusetts; San Antonio, Texas; and San Francisco, California.¹⁴ Persons insensate to the 5.07 SWM had an OR of 5.4 (95% CI, 2.66-11.6) for the development of ulcers.

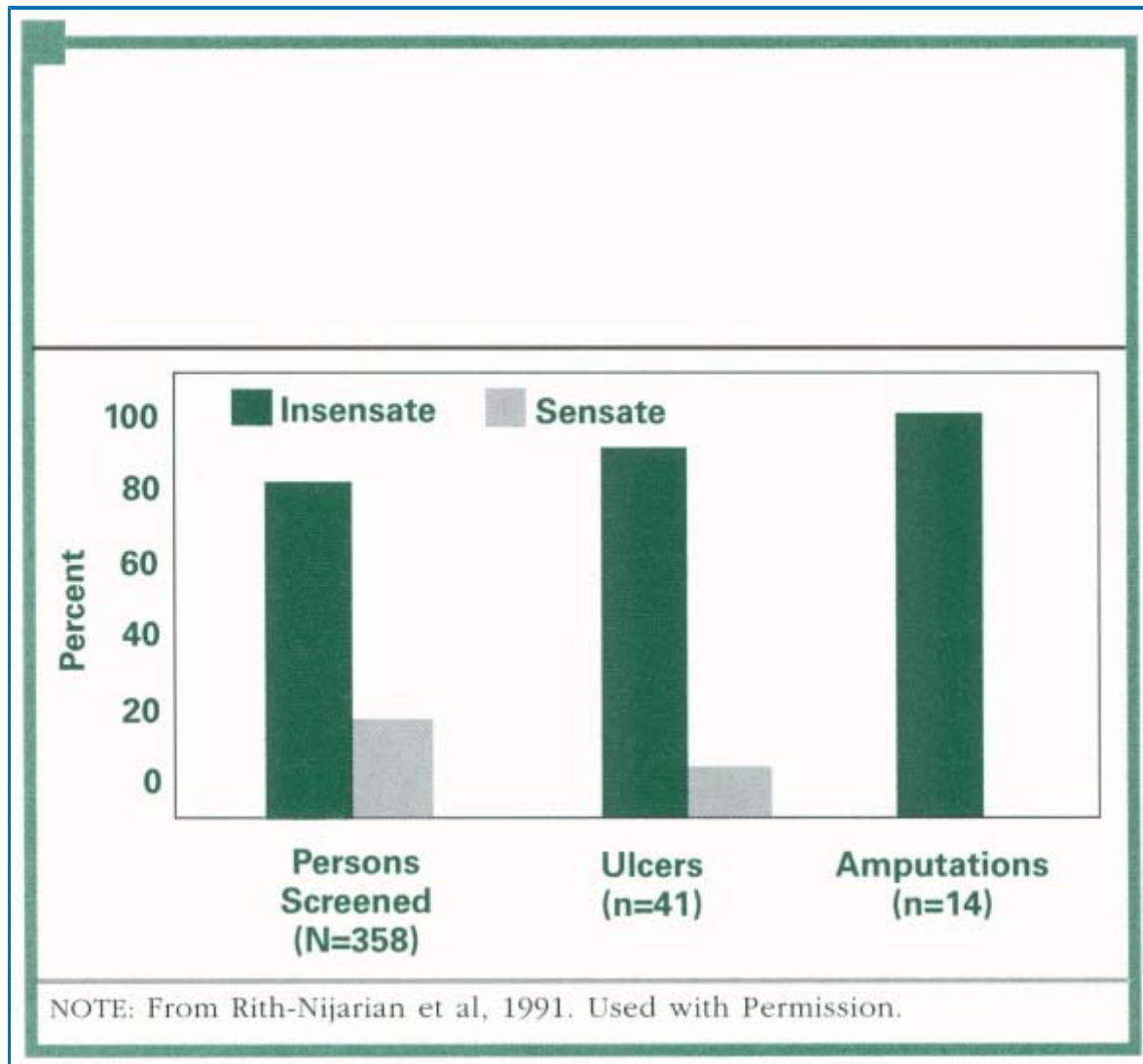


FIGURE 5 Prediction for subsequent ulcers and amputation for persons with one or more sites insensate to the 5.07 (10 g) monofilament.

How Reproducible Is the Monofilament?

The monofilament provides moderate interrater and intrarater agreement. An assessment of 304 patients from 10 university clinics noted that the SWM examination of the forefoot had moderate reproducibility ($[\kappa]=0.38-0.54$), while the arches, heel, and dorsum had only fair reproducibility ($[\kappa]=0.22-0.38$).²⁹

The method of testing with the monofilament may influence the accuracy and reproducibility of the results. Psychophysical somatosensory threshold tests require an alert, cooperative, and responsive patient for accurate results. The procedure should be explained to the patient and demonstrated on the forearm or hand. The foot should be hidden from the patient's view. The tip of the nylon fiber is applied gently to the skin surface, and pressure is applied to the handle sufficient to bow the monofilament for 1 second, then released. Patient anticipation and bias may be minimized by testing sites in a random sequence. Patient bias may be further minimized by using a forced 2-choice option technique.³² Patients are asked whether they can feel the monofilament during time 1 or time 2, with the filament applied during only one of the time intervals. If a patient provides an incorrect response, the area is retested a short time later. If the patient provides an incorrect response again or cannot feel the monofilament at either time, that site is considered insensate. However, the yes/no method of testing provides similar results and is quicker to conduct.^{32,33} Threshold testing using a range of SWM is time-consuming and is rarely used in clinical settings.³² The test is unreliable in patients who are confused, delirious, or unable to communicate. False-positives (ie, insensate) may also occur in the presence of pedal edema, ulcer, callus, or very cold limbs.

The physical properties of the monofilament also affect its accuracy and reproducibility. Two recent evaluations of monofilaments noted significant deviation from the label designation.^{34,35} Monofilaments from several different manufacturers deviated more than 10% from the labeled force in a significant proportion of tested monofilaments.³⁵ Also, the maximum force declined rapidly over the first 3 compressions and again after 100 compressions of monofilaments from all manufacturers. The investigators recommended that filaments be compressed twice before testing the first patient of the day and put at rest for 24 hours after 100 compressions (approximately 10 patients if 10 sites are tested). Monofilaments that are bowed, twisted, or kinked should be replaced to ensure accuracy. Only 3 of the studies in our review reported calibration of the monofilament.^{17,21,22} Failure to calibrate the monofilaments may have caused some of the variation in results among the studies.

How Often Should Monofilament Examination Be Repeated?

Although no study has specifically examined this question, the slow natural history suggests that an annual examination with the monofilament should be sufficiently frequent to detect neuropathy. Another question that remains uninvestigated is the value of repeated monofilament testing once a patient has had neuropathy confirmed. Many foot care specialists believe that repeated testing emphasizes the importance of neuropathy to patients. The current recommendations are that patients with neuropathic feet should undergo a visual examination for breaks in the cutaneous barrier at every visit, but this recommendation has not been formally assessed.

How Does the Monofilament Compare with Other Clinical Tests of Neuropathy, Including Vibration?

Symptoms are often included in diagnostic algorithms and would seem to be a logical method to assess sensory neuropathy. Tingling, burning, hyperesthesia, and other uncomfortable sensations affect more than 40% of persons with diabetes at some time

after diagnosis.^{36,37} Although pain is associated with measures of small-fiber neuropathy,³⁸ pain symptoms have poor correlation for foot ulceration ^{39,40} and do not appear to presage painless neuropathy.⁴¹ Awareness of numbness correlates poorly with current or past ulcers.²⁰ Thus, the family physician must find means other than symptoms to identify the patient at risk for ulceration.

The traditional clinical assessment of peripheral neurologic function (eg, pinprick, vibration with a tuning fork, and light touch to cotton wisp) are highly subjective and thus have poor interobserver reproducibility ($[\kappa] < 0.50$).^{29,42} Ankle jerks have slightly better reproducibility if dichotomized into normal versus abnormal ($[\kappa]=0.38-0.59$) but are poor predictors of ulceration.^{24,29,42}

The VPT can also be quantified using a biothesiometer (Biomedical Instruments, Newbury, Ohio), consisting of a probe that vibrates at 100 Hz with the amplitude varied from 0 to 50 volts. The normal range for VPT has been established in persons who do not have diabetes or known a neurologic disease.⁴³ A decrease in vibratory perception with a threshold of more than 25 volts is highly predictive of subsequent ulceration in prospective studies.^{14,44,45} The biothesiometer costs several hundred dollars and takes at least 5 to 10 minutes to use.

VPTs can also be evaluated in a semiquantitative fashion using a graduated tuning fork (Rydel and Seiffer, Firma Martin, Germany). This 64-Hz tuning fork is calibrated on an arbitrary scale of 0 to 8 by moving weights at the extremities of the prongs.^{46,47}

The graduated tuning fork is highly correlated with the other measures of vibration, and was moderately reproducible, even in the hands of inexperienced examiners. The tuning fork can be carried in a pocket, is easy and painless to use, and costs approximately \$100. No prospective data have been published using this instrument.

Another psychosomatosensory threshold test recently applied to the diabetic foot is 2-point discrimination, using a small portable disc with 8 protruding rods spaced 12.5 to 40 mm apart.⁴⁸ This method was more sensitive than either SWM or VPT for assessment of a current ulcer but was much less specific. No prospective data are available on this method. Threshold tests for temperature ^{20,23} and pain ⁴⁹ are cumbersome, irritating, and correlate less well with the risk of ulceration.

Treatment of the Insensate Foot

Currently there are no means of reversing neuropathy once it is identified. Although it cannot be reversed, management strategies can modify the risk of ulceration and amputation. The key concepts of neuropathy management are protective footwear and education to encourage patients to substitute for pain other methods of monitoring for danger signals in the feet. The evidence for these strategies comes primarily from pre- and postintervention studies of persons with leprosy and of patients seen in multidisciplinary diabetic foot care clinics who demonstrated a 50% to 80% reduction in ulcers and amputation. These have recently been supplemented with several randomized controlled trials that have shown the benefit of foot care education,⁵⁰ an organized foot care and education program,⁵¹ and special footwear.⁵² Usually several treatment modalities are provided simultaneously to patients

with multiple risk factors, making it difficult to assess the impact of specific interventions for just neuropathy.

Patient adherence to foot care recommendations and footwear is notoriously poor. A recent study [53](#) explored the home use of the monofilament by patients to detect the loss of protective sensation as a means to convince, motivate, and empower them. Although laudable, the study design and conduct limited the value of the findings. Almost half of the patients had already been tested by a provider and knew their sensation status. No data on the change in behaviors were collected, so it is unknown whether self-testing at home increased adherence. Self-administration of the test introduces the possibility of patient expectations and may bias the results. The rudimentary quality of the monofilaments may have provided false results inappropriately reassuring or alarming patients, but this was not tested. Finally, foot examination by the family physician provides an opportunity for focused education on foot care and footwear that would not be readily available at home.

The Value of Screening and Treatment

We identified only one randomized controlled study that combined screening for neuropathy with treatment. The authors randomized 2001 patients (from a general diabetes clinic in Royal Liverpool Hospital in England between 1989 and 1993) to screening plus treatment for high-risk patients versus those receiving usual care. The 1001 treatment patients were screened using the 5.07 SWM, VPT, and pedal pulses. The 259 patients with one or more abnormalities were asked to return for a repeat screening, and 37 of the 239 retested were found to be not at risk. The SWM provided the best reproducibility, with 85% agreement between the first and second screening. Overall, 128 patients were identified as high risk, which was defined as a history of a previous foot ulcer or foot deformity. Of these, 111 were already identified as high risk from either a history of ulceration or foot deformities; thus the neuropathy and vascular screening identified only another 17 patients. The 128 high-risk patients were invited to attend a weekly high-risk foot care clinic (as was any patient in the control group with a foot ulcer). At 2 years all patients were contacted for a follow-up examination. Follow-up appointments were not kept by 531 control patients and 323 treatment patients. Hospital records were reviewed to identify any other ulceration or amputation for those that did not attend the follow-up examination.

The frequencies of visits, ulcerations, and amputations were identified from a survey at the end of the 2-year period of observation. At follow-up there were 24 ulcers in the study group (the initial control patients with ulcers were excluded) and 35 ulcers in the control group ($P > .14$). At follow-up there were 7 amputations in the treatment group (1 major and 6 minor) compared with 23 (12 major and 13 minor)* in the control group. The difference in major amputations was statistically significant ($P > .01$) but was not significant for minor amputation ($P > .15$). Protective footwear was provided to 127 patients in the intervention group (unknown number in the control group), but only 36% of the patients reported that they used the footwear at all times, and 27% reported that they never wore the footwear. The study group was more likely to report regular podiatry than were controls (47% vs 36%).

DISCUSSION

The role of neuropathy in the development of foot ulcerations and amputation is well established and documented through extensive literature on neurologic testing. However, the evidence supporting simple clinical examinations for detecting clinically significant peripheral neuropathy is much less robust. Part of the reason for the paucity of data is the complexity and variation of the neurologic modalities affected and the poor reproducibility of the traditional clinical examination. At this time the SWM provides the best means to identify the loss of protective sensation, leading to ulceration and amputation, in the family physician's office. Five prospective studies have documented the ability of the SWM to identify persons at increased risk for ulcers and amputation, and 3 prospective studies assessed the predictive ability of VPT.

The SWM and VPT are similar, which should be of no surprise. Both test phenomena that are affected by the same nerve end organs and travel on large myelinated fibers. The vibration threshold provides continuous values of pressure assessment, while the monofilament provides a semiquantitative value similar to the relationship between semiquantitative urine dipstick tests and quantitative protein assessment. A study that evaluated both SWM and VPT thresholds [21](#) reported the mean VPT for the 4.17 SWM as 10.6 ± 6.7 V, for the 5.07 SWM 22.8 ± 12.7 V, and for the 6.10 SWM 32 ± 14.3 V. What is somewhat nonintuitive is that light touch and vibration assessment provide a more accurate prediction for the risk of ulceration and amputation than tests of small-fiber function; pain and temperature, which seem more likely to involve danger to the limb; or of symptoms. This paradox is unexplained.

Brand's recognition of diabetic neuropathy and the transfer of diagnostic and treatment methods for a third-world disease to a first-world disease is an amazing story that underscores the value of thoughtful clinical observation over clinical tradition and dogma. However, the uncritical transfer of the approach has proved confusing and unwieldy. The recommendations of 10 sites for assessment are appropriate for leprosy. *Mycobacterium leprae* prefer the cooler temperatures and thus affect nerves located in superficial tissue, resulting in sensation loss in specific cutaneous nerve distributions. In contrast, DSPN in diabetes does not follow any dermatome or specific peripheral nerve cutaneous distribution but affects all nerves, with the longest and most distal nerves affected first. If the distal sites are sensate, proximal sites are unlikely to provide additional information. In the multicenter trial, the 4 sites on the forefoot took only 39 seconds for testing, compared with 165 seconds for all 10 sites. It is hoped that evidence will finally influence expert recommendations.

Identifying a risk factor is only the first step in changing outcomes, however. After the high-risk condition is identified, effective management should be provided. Unfortunately, few studies have directly addressed the effectiveness of footwear and patient education in ameliorating the risks of neuropathy alone. There are several reasons for the paucity of evidence for treatment. Persons with neuropathy often have other risk-factors. Most of the studies assessing the effectiveness of footwear or education have included patients with one or more high risk conditions, making it difficult to identify the relationship between treatment and specific risk factors. In addition, the management is difficult to implement. The randomized controlled trial conducted more than 10 years ago in the United Kingdom provided care only to those who already had foot ulcers or bony deformities. Almost everyone in this high-risk group was given footwear, but one third never wore the shoes, highlighting the difficulty in changing behavior. Only one third

reported that they wore the shoes at all times. Furthermore, this is the group considered at the very highest risk, and they may not benefit greatly from interventions. Thus, it was not surprising that no significant difference in ulcers and minor amputations was noted. It is possible that the lower rates of major amputation noted in the study resulted from better wound care and more conservative surgical management.

A superficial reading of Klenerman and McCabe [26](#) might also lead some to suggest that screening is of no benefit and that treatment strategies should be reserved for those who develop ulcers. Actually, that is exactly what happened in that study, because persons with neuropathy were not offered treatment until they developed an ulcer. A number of epidemiologic studies have shown that both ulceration and a history of ulceration impart an independent increased risk of amputation beyond the risk factors of neuropathy, increased pressure, and peripheral vascular disease. A healed wound is only 70% as strong as normal skin,[54](#) which undoubtedly contributes to subsequent breakdown.

RECOMMENDATIONS FOR FUTURE RESEARCH

The paucity of data on simple screening tools for the primary care setting to detect clinically significant neuropathy would, at first glance, invite further research. The increasing prevalence of diabetes and foot ulcers coupled with the economic and personal burden of treating ulcers and amputations are compelling reasons for further investigation. However, studies in this area are increasingly difficult to design. The few published studies that have suggested a benefit from protective footwear and patient education make it more ethically difficult not to provide this care to the control population. If these treatments are as effective as promoted, the apparent effectiveness of screening instruments to detect adverse ulcers and amputations will appear less convincing. Also, foot screening and treatment have already been incorporated into national guidelines and quality of care assessments and may even drive physician reimbursement at some point in the near future. Thus, there will be few diabetic populations that will not undergo screening and management that can be used for comparison. Better research on motivating patients to adopt clumsy-appearing footwear and to alter foot care practices in the absence of the motivation of pain is greatly needed. And more research into the value of screening and treating persons before a foot ulcer develops is needed.

Some research efforts are currently focused on effective prevention strategies through glycemic control or dietary manipulations. Documentation of an easy and effective means to prevent neuropathy would be the ideal method of avoiding ulcers and amputations. Other research currently under way is seeking compounds that could reverse neuronal damage before significant damage occurs. Clinical trials with a variety of aldose reductase inhibitors have failed to show a significant difference in clinical neuropathy measures, suggesting that we do not have an effective medication yet, are studying people already too damaged, or our measures are too crude to identify early damage. Other treatments including the administration of exogenous nerve growth factor, gamma linolenic acid, and vitamin E currently show some promise.[55](#) However, identifying patients with early subclinical neuropathy who may respond to these compounds will require different methods of measurement that will be difficult to link to the gross clinical outcomes

of ulcers and amputations.

CONCLUSIONS

The loss of protective sensation is a significant risk factor for ulceration and amputation. Screening for the loss of protective sensation using the SWM can be readily performed in the family physician's office. The test is inexpensive, painless, easy to administer, acceptable to patients, and provides excellent predictive ability to identify the patients at risk for ulceration and amputation. Annual screening of persons who do not have risk factors should be sufficient to identify the onset of clinically significant neuropathy. Once the patient lacking protective sensation has been identified, management with protective footwear and patient education to prevent damage should be instituted, and the foot surface should be examined visually at each visit. The value of repeated tests once neuropathy is diagnosed is unknown.

RECOMMENDATIONS FOR CLINICAL PRACTICE

There is good evidence supporting the predictive ability of the SWM to identify patients with diabetes at increased risk of foot ulceration and amputation. The test is easy to administer, inexpensive, acceptable to patients, and provides more information than the history or standard neurologic exam. At this time, the test appears to provide the easiest and most acceptable means to identify patients at risk. Once neuropathy is identified, management using patient education and footwear should be instituted. The role of repeated monofilament testing once clinically significant neuropathy has been identified has not been evaluated.

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*The data are presented as they were given in the original paper. [\[Context Link\]](#)

APPENDIX

The following is a list of organizations that sell and distribute the 5.07/10-gram monofilament. This list is not exhaustive. There may be other sources for this device.

Lower Extremity Amputation Prevention Program (LEAP)

Bureau of Primary Health Care, Division of Programs for Special Populations, 4350 East West Highway, 9th floor; Bethesda, MD 20814; (301) 594-4424

Center for Specialized Diabetic Foot Care

405 Hayden Street; PO Box 373; Belzoni, MS 39038; (800) 543-9055

Connecticut Bioinstruments Inc.

39-B Mill Plain Road; Danbury, CT 06811; (800) 336-1935

North Coast Medical, Inc.

187 Stauffer Boulevard; San Jose, CA 95125; (800) 821-9319

Ortho-McNell Pharmaceutical, Inc.

(888) REGRANEX; www.regranex.com

Sensory Testing Systems

1815 Dallas Drive; Suite 11-A; Baton Rouge, LA 70806; (888) 289-9293

Smith & Nephew, Inc.

PO Box 1005; Germantown, WI 53022; (800) 558-8633 [\[Context Link\]](#)

KEY WORDS: Diabetes mellitus; diabetic foot; amputation; primary health care

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