

# Clinical Usefulness of the Two-site Semmes-Weinstein Monofilament Test for Detecting Diabetic Peripheral Neuropathy

The present study was done to validate the two-site Semmes-Weinstein (SW) monofilament test in identifying patients at risk of lower-extremity complications in clinical setting. The SW monofilament test and nerve conduction study were conducted on type 2 diabetic patients (n=37) at Pusan National University Hospital in Korea. As the duration of diabetes mellitus was longer, neuropathy identified by nerve conduction study and complications of diabetes were more severe ( $p<0.01$ ). The number of sites unable to perceive SW monofilament ( $p<0.001$ ) was larger in patients with lower-extremity neuropathy symptoms than those without symptoms. Sensitivity and specificity at two sites (the third and fifth metatarsal head sites) were 93% and 100%, respectively. In conclusion, the two-site SW monofilament test was a sensitive, specific, simple, and inexpensive screening tool for identifying diabetic peripheral neuropathy in clinical setting.

**Key Words :** Diabetes Mellitus; Diabetic Neuropathies; Diabetic Foot; Diagnosis

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## INTRODUCTION

There has been a decreasing trend in complications of diabetes such as diabetic retinopathy or nephropathy due to better treatment and understanding of the disease. However, the incidence of lower-extremity amputations resulted from diabetic foot ulceration continues to be high (1). Diabetic foot ulceration is the leading cause of lower-extremity amputations other than trauma, and the overall risk for amputation has increased in diabetes 15-fold beyond that for nondiabetic people (2). Foot ulceration results in longer days of hospitalization and higher mortality rates in diabetic patients due to complication with healing failure. It is well accepted that peripheral neuropathy is a risk factor for developing foot ulceration, thus early detection and meticulous foot care can reduce lower extremity amputation rates by about 50-80% (3-7).

Nerve conduction studies have been used as the gold standard, but can be time-consuming, expensive, and impractical to operate in a primary care clinic. The Semmes-Weinstein (SW) monofilament test is simple and inexpensive to use as a screening tool to identify patients at risk for diabetic foot complication in primary care setting. Light touch sensation was measured using SW nylon filaments, which buckle at a constant known pressure. There are three types of filaments: 4.17, 5.07 and 6.1 (1, 10 and 75-g force, respectively). Birke

et al. (8) examined all three types of the SW monofilaments in a group of 72 patients with Hansen's disease and 28 patients with diabetes mellitus, and concluded that the 5.07/10-g monofilament was the best indicator of protective sensation.

The rationale of monofilament test is to measure the patient's ability to sense a point of pressure. Inability to sense the 10-g force pressure is considered as insensate and an independent predictor for higher risk of foot ulceration (4). Unfortunately, there is no consensus on how the monofilament is to be used or the results interpreted, while conceptually simple. Number of testing sites varied from one to ten, and the criteria for determining protective sensation, specificity or sensitivity were different in each study (9-14). Thus, we conducted SW monofilament tests on ten sites, and then evaluated the impact of each site and combinations of sites for testing.

## MATERIALS AND METHODS

We studied 37 type-2 diabetic outpatients at Pusan National University Hospital. Their sex, age, duration of diabetes, fasting serum glucose, HbA1c, and presence of complications of diabetes were obtained from medical records. Examiner conducted SW monofilament test prior to asking whether patients noticed any lower-extremity neuropathy symptom (numbness,

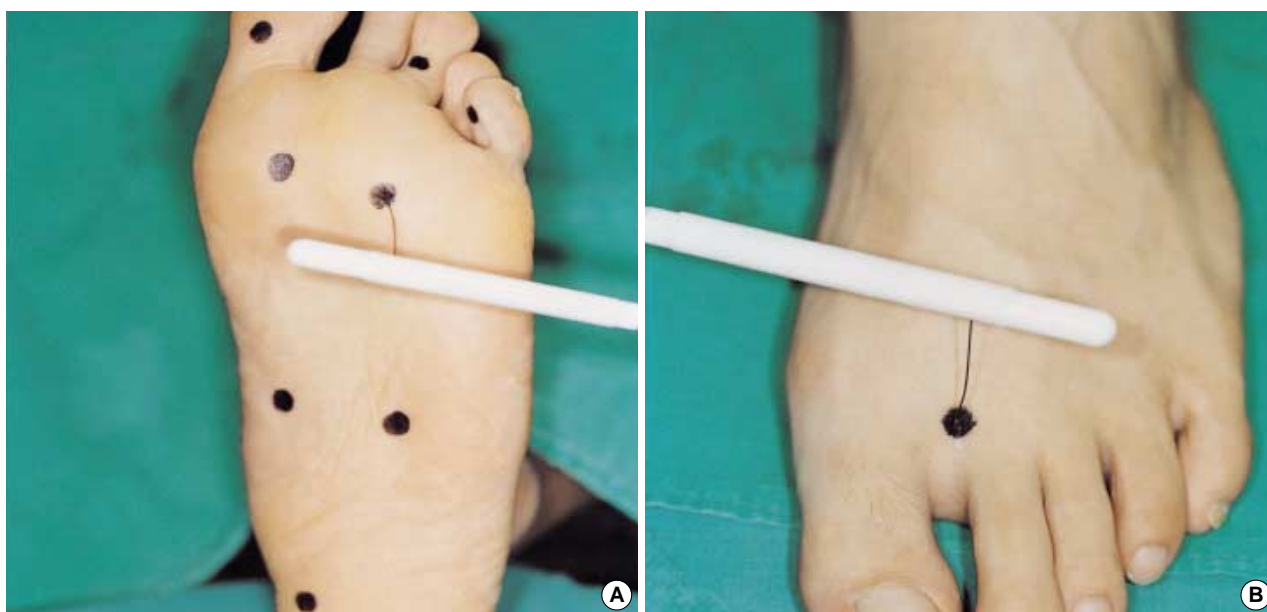


Fig. 1. The sites of Semmes-Weinstein monofilament test.

tingling sensation, burning or aching pain) to be blinded from patient's perception. Nerve conduction study was followed.

While patients were unable to observe their feet, the 10 g-force SW monofilament was used on ten sites of alcohol wiped foot (Fig. 1). We tested the dorsal surface of the foot between the base of the first and second toes, the first, third and fifth toes, the first, third and fifth metatarsal heads, the medial and lateral midfoot, and the heel in random order. Test sites were prearranged to examine not only plantar but also various peripheral nerves and dermatomes of the foot.

The SW monofilament was pressed perpendicular to the test site with enough pressure to bend the monofilament for 1 sec. Patients were asked to answer "Yes or No", when felt or did not feel the press of the monofilament, respectively. If a patient did not perceive the filament at more than 4 out of 10 sites, that individual was reported as abnormal and the site(s) was recorded.

Counterpoint MK II (Dantec, Copenhagen, Denmark) was used for nerve conduction studies in all patients. Motor conduction velocities, distal motor latencies and distal compound muscle action potential amplitudes of the peroneal and tibial nerves were studied. Additionally, sensory parameters, such as sensory conduction velocities and amplitudes of the sensory nerve action potentials of the peroneal and sural nerves were measured according to standard procedures. Room temperature was maintained at 20-25°C to avoid any environmental variation.

Data were analyzed by SPSS statistical program. Age of patients with and without symptoms was compared using a two-sample t-test. Duration of diabetes and HbA1c of patients with and without symptoms were compared using Wilcoxon's rank sum t-test. Sex, the results of SW monofilament test and nerve

conduction study, and complications of diabetes were compared using Fisher's exact test. Nerve conduction study was used as gold standard to calculate sensitivity and specificity of SW monofilament test at each site and then to evaluate the impact of each site and combinations of sites. *P* value of <0.05 was required for statistical significance.

## RESULTS

Duration of diabetes was longer among the patients with lower-extremity neuropathy symptoms than those without

Table 1. Characteristics of study subjects

Characteristics	With symptom*	Without symptom
Number	24	13
Age (yr) (Mean $\pm$ SD)	57.0 $\pm$ 9.3	62.7 $\pm$ 6.8
Sex (% male)	54.2	53.8
Duration of diabetes mellitus (yr) (Mean $\pm$ SD)	14.8 $\pm$ 6.7	8.0 $\pm$ 7.1**
HbA1c (%)	9.2 $\pm$ 2.0	9.0 $\pm$ 2.0
Semmes-Weinstein monofilament (% abnormal)	100.0 (24/24)	53.8 (7/13) <sup>†</sup>
Nerve conduction study (% neuropathy)	95.8 (23/24)	46.2 (6/13) <sup>‡</sup>
Problems complicated with diabetes (%)	83.3 (20/24)	46.2 (6/13) <sup>‡</sup>
Diabetic nephropathy	20.8 (5/24)	7.7 (1/13)
Diabetic retinopathy	0.0 (0/24)	15.4 (2/13)
Diabetic nephropathy and retinopathy	62.5 (15/24)	23.1 (3/13)

\*Symptoms of peripheral neuropathy, \*\**p*=0.005 by Wilcoxon's rank sum test, <sup>†</sup>*p*<0.001 by Fisher's exact test, <sup>‡</sup>*p*<0.01 by Fisher's exact test.

**Table 2.** Sensitivity and specificity of using the 10-g monofilament at each site

Sites*	Nerve conduction study		Sensitivity (95% confidence interval)	Specificity (95% confidence interval)
	Positive (n=29)	Negative (n=8)		
No.1			20.7 (6.0-35.4)	100.0 (100.0-100.0)
Abnormal <sup>†</sup>	6	0		
Normal	23	8		
No.2			34.4 (17.2-51.8)	100.0 (100.0-100.0)
Abnormal	10	0		
Normal	19	8		
No.3			31.0 (14.2-47.9)	87.5 (64.6-110.4)
Abnormal	9	1		
Normal	20	7		
No.4			44.8 (26.7-62.9)	100.0 (100.0-100.0)
Abnormal	13	0		
Normal	16	8		
No.5			86.2 (73.7-98.8)	100.0 (100.0-100.0)
Abnormal	25	0		
Normal	4	8		
No.6			69.0 (52.1-85.8)	100.0 (100.0-100.0)
Abnormal	20	0		
Normal	9	8		
No.7			65.5 (48.2-82.8)	100.0 (100.0-100.0)
Abnormal	19	0		
Normal	10	8		
No.8			65.5 (44.4-79.7)	100.0 (100.0-100.0)
Abnormal	19	0		
Normal	10	8		
No.9			62.1 (44.4-79.7)	87.5 (64.6-110.4)
Abnormal	18	1		
Normal	11	7		
No.10			0.0 (0.0- 0.9)	100.0 (100.0-100.0)
Abnormal	0	0		
Normal	29	8		

\*1. first toe; 2. third toe; 3. fifth toe; 4. first metatarsal head; 5. third metatarsal head; 6. fifth metatarsal head; 7. medial midfoot; 8. lateral midfoot; 9. Heel; 10. dorsal surface of foot between the base of the first and second toes. <sup>†</sup>Abnormal if patient was unable to perceive the monofilament at each site (See Fig. 1).

**Table 3.** Sensitivity and specificity of using 5.07/10-g monofilament at 10 sites

10 Sites*	Nerve conduction study	
	Positive (n=29)	Negative (n=8)
Abnormal*	27	0
Normal	2	8

\*Abnormal if patient was unable to perceive the monofilament at more than four of 10 sites. Sensitivity (95% confidence interval): 93.1 (83.9-102.3). Specificity (95% confidence interval): 100.0 (100.0-100.0).

symptoms (Table 1). Abnormal SW monofilament results were observed in 100% of the patients with symptoms, while in 53.8% of patients without symptoms (Table 1). There were more complications of diabetes among patients with symptoms than those without ( $p<0.01$ ) (Table 1). Patients with symptoms also had more neuropathy identified by nerve conduction study than those without symptoms ( $p<0.01$ ) (Table 1).

Specificity of SW monofilament test was similar (87.5-100

**Table 4.** Sensitivity and specificity of the 5.07/10 monofilament test at two sites

10 Sites*	Nerve conduction study	
	Positive (n=29)	Negative (n=8)
Abnormal*	27	0
Normal	2	8

\*Abnormal if patient was unable to perceive monofilament at any of two (third and fifth metatarsal heads) sites. Sensitivity (95% confidence interval): 93.1 (83.9-102.3). Specificity (95% confidence interval): 100.0 (100.0-100.0).

%) at each site, but the sensitivity was varied (20.7-86.2%) (Table 2). Since 27 out of 29 neuropathy patients identified as “abnormal” by nerve conduction study had abnormal SW monofilament test, sensitivity of the test at 10 sites was 93.1% (Table 3). Diabetic patients without neuropathy symptoms identified by nerve conduction study also had normal SW monofilament test, thus specificity of the test at 10 sites was 100% (Table 3). Sensitivity and specificity at two sites (the

third and fifth metatarsal head sites) were 93.1 and 100%, same as at 10 sites (Table 4).

## DISCUSSION

The present study was done to validate the SW monofilament test in identifying patients with severe neuropathy to be at risk of neuropathic ulceration. Nerve conduction test is used as the gold standard, which is expensive and difficult to operate in a primary care clinic. Thus, the 5.07/10 g SW monofilament is recommended by the International Diabetes Federation and the World Health Organization as a device that can be used to identify patients at risk of diabetic foot ulceration, as feasible by health care professionals at every level. However, there is no guideline on determining testing sites and criteria for determining protective sensation. Mueller (9), McNeely *et al.* (4) tested 9 sites, Klenerman *et al.* (10) used 6, McGill *et al.* (11) and Pham *et al.* (12) studied 5 sites. Holleski *et al.* (13), Olmos *et al.* (14), Nagai *et al.* (15), and Valk *et al.* (16) used 3 sites. Kumar *et al.* (17) and Perkins *et al.* (18) tested only one site, while Duffy *et al.* (19), Rith-Najarian *et al.* (20), and Sosenko *et al.* (21) suggested 10 sites. Nagai *et al.* (15) tested on the first toe, and the first and the fifth metatarsal heads using 2, 4, and 10 g monofilaments. They found that the sensitivity and specificity of the 4 g monofilament in the detection of diabetic peripheral neuropathy, 85% and 73%, respectively, were quite close those for the 10 g monofilament (88% and 68%, respectively) (15). In the present study, sensitivity and specificity were 93.1% and 100%, respectively based on the definition of insensate as an inability to sense four or more out of ten sites tested. McGill *et al.* (11) recommended a combination of the plantar aspects of the first and fifth metatarsal because this combination had a sensitivity of 80% and specificity of 86%. They defined "insensate" when patients did not feel the monofilament at either of above two sites (11). The sensitivity and specificity were lower than ours. We found that sensitivity and specificity of the third and fifth metatarsal heads were higher (93.1% and 100%, respectively) than other studies. Holleski *et al.* (13) reported that specificity was high on the toes and metatarsal heads, and low on the dorsal surface and the heel. McGill *et al.* (11) reported low sensitivity of the first toe and medial midfoot, while we found that sensitivity of toes and the heel was low.

Diabetes ranks the seventh among ten primary chronic diseases in Korea. Every year, 2.2-5.9% of patients with diabetes mellitus in industrialized nations develop a diabetic foot ulcer. Diabetic foot ulceration is the key factor that may accelerate a cascade of events leading to lower-extremity amputation. Numerous factors can cause diabetic foot ulceration, but peripheral sensory neuropathy is responsible for the most foot ulcerations.

As many as 40 to 50% of diabetic patients have neuropathy, which usually occurs in a stocking-glove distribution, with initial symptoms beginning with paresthesia or dysesthesia and progressing to complete loss of sensation (24). About 25% of patients with diabetes for more than 10 yr developed neuropathy and it reached 50% among individuals with more than 20 yr of duration (25). Incidence of diabetic neuropathy is positively related with age, duration, and hyperglycemia. Neuropathy can be a fatal problem in diabetic patients and economic impact of foot ulceration is staggering. Thus, identification of patient at risk for foot problem at the early stage is necessary in preventive intervention. The SW monofilament test has limitation in quantitative measurement of neuropathy, but is simple, cost-effective, and practical for detecting peripheral neuropathy. Only one patient with lower-extremity neuropathy symptoms had normal nerve conduction study and abnormal SW mono-filament test because monofilament is not the perfect tool to detect all patients at risk of developing neuropathic ulcer.

We found that the SW monofilament test was very sensitive and highly specific. Sensitivity and specificity at the third and fifth metatarsal head sites were comparable to those of 10 sites together. It is likely that the two-site SW monofilament test is useful clinically as a screening device for diabetic neuropathy as well as 10-site test. However, since this was done on small sample of Korean patients with type 2 diabetes, larger studies are warranted.

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