Too few, too many or just right?

How many sites should be tested to detect diabetic peripheral neuropathy?

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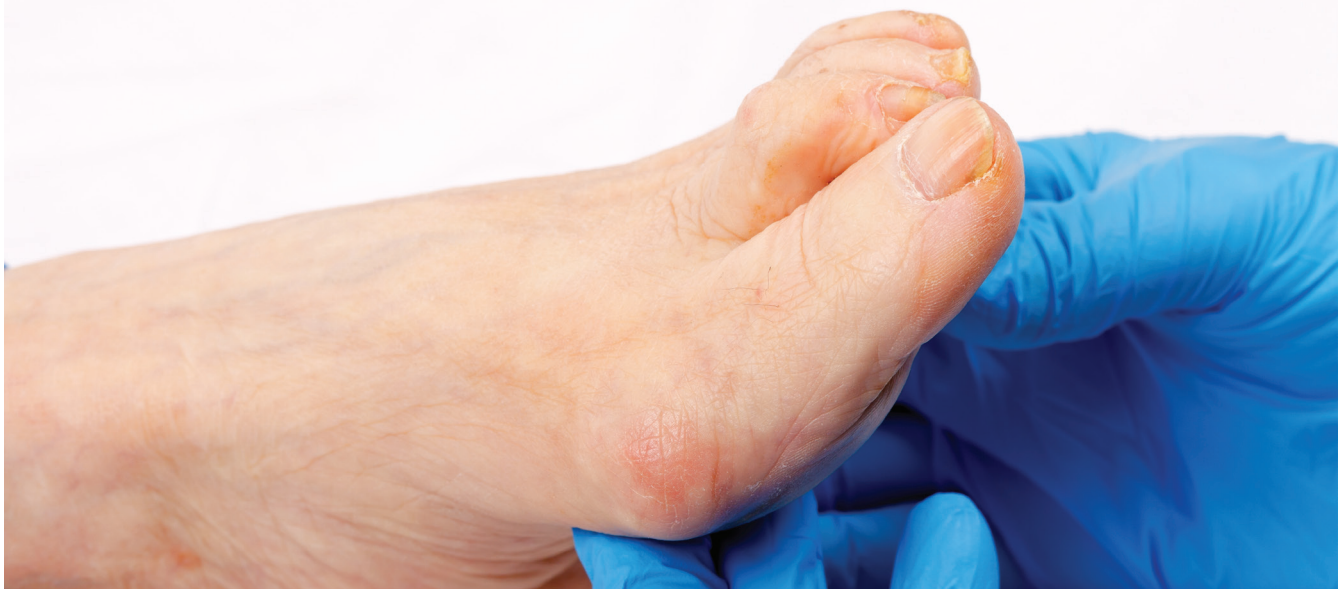
Diabetic peripheral neuropathy (DPN) is a widespread diabetes complication that affects up to 90% of individuals living with diabetes.[1] It is commonly divided in two forms based on the absence or presence of pain. It is well recognized that DPN is a powerful predictor of diabetic foot ulceration, and evidence establishes its role in the pathophysiology of new and recurring foot ulcers and lower-extremity amputations.[2-3] Early detection of DPN can help to lower the incidence of these diabetic foot complications, and health-care professionals can therefore adapt their clinical practices to patients' needs. Global management of patients with DPN should be tailored according to this condition.[4]

More than 30 years ago, the 10 g Semmes–Weinstein monofilament (SWM 10 g) testing technique was described as a good method to assess loss of protective sensation (LOPS) in the clinical setting. It is still widely used for DPN screening, because, along with the inability to sense vibrations, LOPS represents one component of DPN.[4,6] This technique is favoured by most clinicians because of its accuracy, low cost and convenience.[7-8] A recent meta-analysis demonstrates that SWM 10 g is fairly accurate in diagnosing LOPS in individuals with diabetes.[6] However, there are multiple ways to perform this test and interpret its results.[7,9-10]

Location and Number of Sites

The original SWM 10 g testing technique was designed to test 11 plantar sites: the first, third and fifth metatarsal heads and five corresponding toes, the medial and lateral midfoot and the heel.[8] The dorsal surface between the base of the first and second toes was added to provide a more complete representation of the different peripheral nerves and dermatomes of the foot.[11] Later, because clinicians needed an easy and reliable test, a 10-site technique was developed.[12] A number of studies have since demonstrated that fewer than 10 sites could allow an equivalent overall accuracy. Table 1 summarizes the evidence for 1-site, 4-site and 10-site SWM techniques.[7,9,13-15] Moreover, techniques requiring fewer than 10 sites are more practical when testing individuals with toe amputations, are less time-consuming for professionals and may extend durability (lifetime) of the SWM 10 g. It has also been reported that 4-site testing identified 90% of individuals with DPN, with one insensate forefoot site being consistent for LOPS.[7,16] The



most common testing site for all described SWM 10 g techniques is the hallux, plantar or dorsal, but there is no evidence to confirm that this is the most sensitive site for testing LOPS.[9]

There is great variability in the methodologies of these studies, including population selection and sample sizes, that limits internal and external validity to choose the best technique.[7,9,13-15] However, some studies—such as Baraz et al. 2014, Lee et al. 2003, Perkins et al. 2001/2010, Rayman et al. 2011, Zhang et al. 2017 and Brown et al. 2017—have fewer methodological flaws according to potential risk of bias assessment in a meta-analysis.[9] Their internal validity is thus considered to be at a higher level.

Three different patient responding techniques were used in all the studies in Table 1:

- yes/no technique
- forced-choice technique
- yes/no combined with site identification technique

The yes/no technique is simple: ask the patient whether they feel pressure applied. The forced-choice technique consists of asking the patient to identify whether contact with the SWM 10 g is

Diabetes Canada Guidelines: Recommendations on How to Perform 10 g Semmes–Weinstein Monofilament Resting[5]

1. Apply the SWM 10 g on patient's hand so that he or she knows what to expect. Encourage patient during testing by giving positive feedback.
2. The patient must not be able to see whether or where the examiner applies the SWM 10 g. Apply the SWM 10 g perpendicular to the skin surface and apply sufficient force to cause the filament to bend or buckle. The total duration of contact, from initial skin contact to removal of the SWM 10 g, should be approximately 2 seconds.
3. Apply the SWM 10 g along the perimeter of, not on, an ulcer site, callus, scar or necrotic tissue. Do not allow the SWM 10 g to slide across the skin or make a repetitive contact at the test site.
4. Press the SWM 10 g to the skin and ask the patient whether they feel pressure applied ('yes'/'no') and where they feel the pressure ('left foot'/'right foot').
5. Repeat contact twice at the same site, but alternate this with at least one 'mock' contact in which no filament is applied (for total of 3 questions per site).

Protective sensation is present at each site if the patient correctly answers 2 out of 3 contacts. There is a LOPS with 2 out of 3 incorrect answers. The patient is then considered to be at risk of diabetic foot ulceration.

Table 1: Evidence for 1-Site, 4-Site and 10-Site SWM Techniques

Studies	Number of Sites Tested per Foot	Number of Sites Insensitive to Represent LOPS	Sensitivity (%)	Specificity (%)
1-site Technique				
Kumar et al. 1991	Plantar hallux	1/1	100	78
Pham et al. 2000	Dorsal hallux	1/1	91	34
Perkins et al. 2001	Dorsal hallux (repeated 4 times)	a. 2/8 b. ≥ 5/8	c. 41 d. 77	e. 68 f. 96
Olaleye et al. 2001	Dorsal hallux (repeated 4 times)	a. 2/8 b. 3/8 c. 4/8 d. 5/8	a. 62 b. 58 c. 35 d. 30	a. 84 b. 92 c. 97 d. 97
Perkins et al. 2010*	Dorsal hallux (repeated 4 times)	Both feet 5/8	72	64
Najafi et al. 2014	Dorsal hallux (repeated 10 times)	3/10	17	87
Pambianco et al. 2011	Dorsal hallux (repeated 10 times)	3/10	20	98
Brown et al. 2017	Dorsal hallux	1/1	47	73
4-site Technique				
Miranda-Palma et al. 2005	Plantar hallux; metatarsal head 1, 3, 5	1/8	86	58
Jayaprakash et al. 2011	Plantar hallux; metatarsal base 1, 3, 5	Both feet 1/8	63	93
Rayman et al. 2011	Tips of toes 1, 3, 5 dorsal hallux	Both feet 5/8	81	91
Bedi et al. 2012	Plantar hallux; metatarsal base 1, 3, 5	Both feet 1/8	49	48
Baraz et al. 2014**	Plantar hallux; metatarsal head 1, 3, 5	Both feet a. 1/8 b. 2/8 c. 4/8	 a. 51 b. 46 c. 38	 a. 73 b. 75 c. 87
Zhang et al. 2017	Plantar hallux; metatarsal head 1,3, 5	1/4	19	96
10-site Technique				
Armstrong et al. 1998	Dorsal between base toe 1–2; plantar toe 1,3,5; metatarsal head 1,3,5; plantar medial and lateral midfoot; plantar heel	4/10	> 90	80
Lee et al. 2003	Dorsal between base toe 1–2; plantar toe 1,3,5; metatarsal head 1,3,5; plantar medial and lateral midfoot; plantar heel	≥ 5/10	93	100
Zhang et al. 2017	Dorsal between base toe 1–2; plantar toe 1,3,5; metatarsal head 1,3,5; plantar medial and lateral midfoot; plantar heel	1/10	22	94

* Forced-choice technique
** Yes/no technique and identification of the site

perceived at time "A" or "B"—which may be inadequate, because the response can be guessed correctly with a probability of 50%. Therefore, the yes/no technique is expected to be more reliable and less time-consuming than the forced-choice technique.[7]

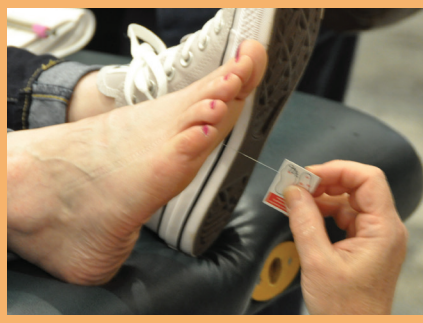
A recent study comparing SWM 10 g sensitivity using 3, 4 and 10 sites demonstrated that every technique was equally effective for screening DPN and showed a good level of intra-observer agreement and reproductivity with the yes/no technique.[10]

Interpretation

There is no clear answer on how many insensate sites suggest a patient is at risk of diabetic foot ulceration when using SWM 10 g testing. Thus, most studies used conservative approaches that, when adequately performed, were indicative of an at-risk foot in the presence of one insensate site. When the number of insensate sites increases, the test sensitivity remains similar or decreases, while the specificity increases.[12,17] To date, there is no controlled clinical trial available investigating the prognostic and predictive values of SWM 10 g testing to guide clinical decision making and to improve patient outcome such as diabetic foot ulcerations and lower extremity amputations.[7]

Accuracy and Durability of Semmes–Weinstein Monofilaments

Commercially available SWM 10 g have significant variability within and between devices, and their real bending force varies widely from the initial targeted value of 10 g. For this reason, they have a short service life and should not be used when they have lost 10% or more of their initial bending force.[20-21] It has been demonstrated that some monofilaments, excluding single-use products, can evaluate up to 70 to 90 patients for a 10-site testing each.[20] After testing 10 patients, monofilaments need a recovery time of 24 hours before further use.[21] The Canadian BPR suggests that SWM 10 g should be rested for two hours following 100 applications (20 sites per patient for a total of five evaluations).[18] Selecting a high-quality instrument and replacing it at regular intervals are important in maintaining testing accuracy.[20] Proper disinfection of the instrument must be performed between patients, and disposable SWM 10 g should be used for only one patient.



Recommendations

In general, practice guidelines conclude that two different clinical evaluations should be performed for better test sensitivity to diagnose LOPS.[4,18] The International Working Group on the Diabetic Foot (IWGDF) guidelines suggest testing LOPS with pressure and vibration.[4] The same recommendation is made in the Diabetes Canada (DC) guidelines, and they propose the same three testing sites, the plantar hallux, and first and fifth metatarsal heads of

According to the studies listed in Table 1, here is how one should perform SWM 10 g testing with a conservative interpretation for maximum accuracy with a yes/no technique:

- **1 site** tested on the dorsal surface of the hallux (repeated four times): both feet with ≥ 5/8 insensitive sites indicates LOPS.
- **4 sites** tested on the plantar surface of the hallux and first, third and fifth metatarsal heads: one foot with ≥ 1/4 insensitive site indicates LOPS.
- **10 sites** tested, including one dorsal site between the base of first and second toe, and nine plantar sites on first, third and fifth toes, first, third and fifth metatarsal heads, medial and lateral midfoot and heel: ≥ 5/10 insensitive sites indicates LOPS.

both feet in high-risk (for ulceration) feet.[5] Wounds Canada's Best Practice Recommendations (BPR) for the Prevention and Management of Diabetic Foot Ulcers advocates a 10-site testing technique.[18] Practical guidelines from the Registered Nurses' Association of Ontario support a 4-site testing technique that includes the plantar hallux and first, third and fifth metatarsal heads.[19]

Conclusion

Evidence supports 1-, 4- or 10-site SWM 10 g testing for LOPS, and practice guidelines from various national and international expert groups reflect this diversity. According to research results, 4- and 10-site techniques were as effective for screening DPN as the 3-site technique recommended by the IWGDF and the DC. They all demonstrate a good level of reproductivity and should be favoured in the clinical setting. Therefore, whether a 3-, 4- or 10-site SWM 10 g testing technique is chosen, clinicians should be aware of material limitations and interpretation pitfalls, and be consistent in the way they perform clinical testing and identify DPN to ensure accuracy, reproductivity and adequate interpretation.

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