

Choosing a Vibratory Test to Pair With Semmes Weinstein Monofilament Testing for Evaluating Lower Extremity Sensation in Patients With Diabetes: A Comparison of Three Vibratory Methodologies

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Abstract

Background: Numerous guidelines recommend pairing Semmes-Weinstein monofilament (SWM) testing with a secondary clinical test when screening for diabetic peripheral neuropathy, yet time is very limited in clinical practice. This study compared the time to complete and the diagnostic agreement of three vibratory sensation tests.

Methods: Sixty-five individuals (42% male; aged: 61 ± 12 years) were recruited. A single investigator administered the following tests bilaterally: 10-site SWM, traditional tuning fork (TTF), electronic tuning fork (ETF), and vibration perception threshold (VPT) via biothesiometer. Times to physically administer the tests were compared with a one-way repeated measures ANOVA. Cochran's Q test was used to compare the varied tests' diagnostic agreement.

Results: The ANOVA indicated there were significant ($P < .001$, partial eta squared = .442) differences in time to complete the varied tests. Sidak post hoc comparisons indicated the VPT (21.2 ± 14.3) testing took an intermediate time to complete, while the ETF (9.7 ± 6.5) and TTF (10.1 ± 7.5) tests took the least amount of time, and the SWM (28.6 ± 8.4) test took the longest time. There were also numerous significant differences ($P \leq .001$) between the different tests in regards to neuropathy diagnoses.

Conclusions: Tuning fork methods required 11 seconds less to administer than VPT testing. Although that may seem trivial, it is worth noting peripheral neuropathy screening often fails to occur in the precious few minutes clinicians are allotted per patient. Considering ETF's intrinsic control of stimulus amplitude and its ease of use with an embedded timer, the ETF is recommended over the TTF. Clinicians should also be mindful that different tests yield different diagnostic conclusions.

Keywords

diabetic peripheral neuropathy, tuning fork, vibration perception threshold, screening

One of the most common complications secondary to diabetes is diabetic peripheral neuropathy (DPN), which affects the autonomic, motor, and sensory nerves of the peripheral nervous system.^{1,2} DPN is “the presence of symptoms and/or signs of peripheral nerve dysfunction in patients with diabetes after excluding other causes.”³ Diabetic peripheral neuropathy has been reported to affect at least 20% of people with type 1 diabetes after 20 years of disease duration and 50% of people with type 2 after 10 years of disease duration.¹

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The loss of protective sensation secondary to DPN puts the patient at an increased risk for foot ulcerations and associated complications such as infections and amputations that cause significant morbidity and mortality.^{4,5} Diagnosing DPN in a timely and cost-effective manner allows for preventative measures to be implemented prior to individuals developing an initial or primary ulcer.

Nerve conduction velocity assessment is considered the gold standard for diagnosing DPN, however, it is expensive, time consuming, and may require separate visits.⁶ There are a number simple clinical means of screening for DPN. The American Diabetes Association's "Standards of Medical Care in Diabetes" call for DPN screening during physical examination on an annual basis by 5.07/10 g Semmes Weinstein monofilament (SWM) test *and* temperature, pinprick sensation or vibration.^{2,7} In contrast to temperature and pinprick evaluations, there are currently a number of technologies to clinically test vibratory sensation. Some of these include the 128-Hz traditional tuning fork (TTF), 128-Hz electronic tuning fork (ETF), and a biothesiometer.

The traditional 128-Hz TTF is widely used to assess individuals' ability to perceive a vibratory stimulus. However, a large variety of testing protocols are described in the literature. The various methods reported generally fall under two types of testing: on-off or timed assessments. On-off methods dichotomize responses to whether patients can simply perceive a vibratory stimulus imparted to the test site via the tuning fork.⁸⁻¹² Timed assessments are based upon the fact that the amplitude of stimulus decreases over time and take into consideration how long a patient perceives the tuning fork vibrating. The outcome may simply be the absolute duration during which the participant can feel it,¹³ how long the patient can feel the vibration relative to how long the tester can feel it,^{8,14} or in the special case of a graduated tuning fork- the number indicated on the fork at the time sensation of vibration stops.¹⁵

The ETF is also capable of conducting both on-off and timed assessments of vibratory sensation.^{16,17} In addition to vibrating at the same frequency as the 128-Hz TTF, the 128-Hz ETF also has the same vibratory decay rate as the TTF. In contrast to the TTF, the ETF initiates each test with a fixed amplitude of stimulus as opposed to the TTF's amplitude which varies in response to the striking force manually imparted by the test administrator. An additional feature of the ETF is the inclusion of an integrated timer that simplifies the process of conducting timed assessments.

A biothesiometer is an electromechanical instrument that is used to identify individuals' vibration perception thresholds (VPT).¹⁸ Biothesiometers apply a vibratory stimulus to the testing site (commonly distal end of hallux) via a hand-held probe. The test administrator manually increases or decreases the amplitude of the vibration in order to identify the lowest system voltage at which the patient reports perception of the vibratory stimulus. A VPT value $>25V$ in at least one foot places an individual at high risk for developing a diabetic foot ulceration.¹⁸

In considering the American Diabetes Association's recommendation to pair SWM with a secondary clinical assessment of DPN, the additional time needed to conduct a secondary test is likely to be a concern for many clinicians. In fact, many clinicians currently fail to routinely conduct any testing for DPN.¹⁹⁻²² Time is presently an extremely limited commodity for physicians. A recent international study regarding primary physician consultation time in 67 countries found the time to be five minutes or less for 18 countries representing approximately 50% of the global population and the maximum value was only 22.5 minutes in Sweden.²³ Without providing specific data, Perkins et al reported SWM, pain sensation testing and vibration testing by the on-off method each required <60 seconds to perform.⁸ In contrast, Perkins et al reported vibration testing by the timed method took over one minute. With such limited time for clinicians to spend with patients, even seconds matter. Yet we are unaware of any previous studies to directly compare the time required to perform varied clinical assessments for DPN. The purpose of this study was to determine the time taken to administer the SWM test as well as three different methods of vibratory sensation tests (TTF, ETF, and biothesiometer). A secondary intent was to compare the diagnostic agreement between the four tests.

Methods

Study Design and Subjects

A convenience sample of 65 individuals with diabetes was recruited from a podiatric clinic and a free diabetes health and wellness exposition held in a large US city. All participants read and freely signed a local IRB approved informed consent form prior to participating. Study inclusion criteria included: being 18 years of age or older, having type 1 or type 2 diabetes, and willingness to participate in all testing procedures. Potential participants were excluded if impaired cognitive function precluded them from completing all the assessments. A brief study intake form captured participant demographics and diabetes history information (Table 1). The participants were generally older adults (60.7 ± 12.0 years), mostly female (58%), predominantly Caucasian (52%) or African American (45%), most had type 2 diabetes (91%), and the average duration of having been diagnosed as having diabetes was 15.1 ± 12.3 years. A single examiner (BR) performed all the tests. The examiner was a second year doctor of podiatric medicine student. Prior to initiating subject recruitment, the student received extensive one on one training regarding the conduct of the testing paradigms by a diabetic limb salvage fellowship trained podiatrist (SCW) whom had been in practice for 15 years. Tests were performed bilaterally on all participants (none of the participants had a unilateral amputation) while they were in a seated position with their eyes closed. As described in further detail in this manuscript's procedures sections, the time required to physically administer each test was measured. Instructional

Table 1. Participant Demographics.

Age	60.7 ± 12.0 years			
Sex	Male = 27 (42%)	Female = 38 (58%)		
Race	AA = 29 (45%)	Asian = 2 (3%)	Caucasian = 34 (52%)	
Ethnicity	Hispanic = 12 (18%)	Non-Hispanic = (82%)		
Diabetes	Type 1 = 6 (9%)	Type 2 = 59 (91%)		
Diabetes medication	Diet and exercise = 8 (12.3%)	Oral = 30 (46.2%)	Insulin = 9 (13.8%)	Insulin and oral = 18 (27.7%)
Diabetes duration	15.1 ± 12.3 years			

Continuous data presented as mean ± standard deviation; categorical data presented as frequency count followed by percentage in parentheses.

time was not monitored as it was expected to be highly variable due to a variety of variables associated with both the examiner and the patients (eg, patients' past experience with exams or possible hearing loss), whereas test administration time should be highly consistent as the same physical routine is repeated with each exam.

Materials

A 5.07/10-gram Semmes-Weinstein Monofilament (Promp Touch 5.07/10 g disposable, Quinta Edge Inc, Barrington, IL, USA) was used to test for loss of protective sensation. Vibratory sensation was tested via a traditional 128-Hz aluminum alloy TTF (Prestige Medical, Inc, Northridge, CA, USA), a 128-ETF (O'Brien Medical, LLC, model ETF128-01, Orono, ME, USA), and a biothesiometer (Diabetica Vibration Perception Threshold Biothesiometer, Xilas Medical Inc, San Antonio, TX, USA).

Procedures

Semmes-Weinstein Monofilament (SWM). Demonstration of SWM test was first performed on patients' hands to confirm participants were able to correctly perceive the sensation. The monofilament was pressed on the dorsal aspect of a participant's hand until it buckled in response to it being loaded with 10 g of force. Participants were asked to confirm whether they felt the monofilament on their hand. After familiarizing participants with the SWM, testing at the feet commenced. Ten sites were assessed on each foot (Figure 1).²⁴ Participants were instructed to keep their eyes closed throughout the examination and verbally say "yes" when they felt the monofilament being applied to their foot. A manual timer was started once the monofilament first touched the foot and the timer was stopped after all 10-sites of a foot were tested. Each foot was given a score of 0-10 corresponding to the number of sites at which participants perceived application of the SWM.

Traditional Tuning Fork (TTF). While being held at its proximal end by one hand of the examiner, the distal end of a 128-Hz TTF was forcefully struck against the palm of the examiner's other hand. The examiner attempted to strike the TTF with consistent force for each examination. Once the fork was struck it was placed onto the dorsal aspect of the distal



Figure 1. Sites of SWM testing. The nine plantar locations and one dorsal location of testing are marked with circles.

phalanx of the great toe (hallux), just proximal to the nail bed.²⁵ Prior to applying the TTF the participant was instructed to give a verbal response of "yes" if/when they could initially feel the vibration. Secondly, participants were instructed to state "now" when they ceased to feel the vibration after providing a "yes" response when they first felt a vibratory sensation. The time elapsed between application of the TTF and a subsequent "now" response was measured via a stopwatch. If participants were unable to feel vibratory sensation upon initial contact of the TTF, the duration of examination was recorded as zero.

Electronic Tuning Fork (ETF). The descending mode (high-to-low vibration amplitude progression) was used for the 128-Hz ETF testing.¹⁷ The ETF testing was conducted at the same location as the TTF and participants were advised to provide the same responses as were to be given during the TTF testing. Once the ETF was placed on a participant's foot, the examiner would press start on the device, simultaneously

causing the ETF to vibrate and the built-in timer to begin counting. Once a participant indicated the cessation of vibratory sensation by saying “now,” the examiner would release the start button, which simultaneously stopped the vibration and timer. If participants were unable to feel vibratory sensation upon initial contact of the ETF, the duration of examination was recorded as zero.

Biothesiometer Vibratory Peripheral Threshold (VPT). All VPT exams were first performed on a bony prominence on the dorsal aspect of the participant’s hand prior to examining the feet. After placing the probe on the hand the vibratory stimulus was alternately turned off and on and the participant was asked to discriminate the difference between vibratory and pressure sensation. The actual VPT assessment of the feet began once the participant gained familiarity with vibratory sensation on the hand. Manual timing of the assessment began once the device made initial contact with the foot. The head of the probe was placed over the bony prominence at the distal pulp of the hallux.²⁵ Voltage began at zero and was manually increased until the patient said “yes,” confirming that they could sense the vibration. Subjects were instructed to keep their eyes closed throughout the entire assessment of each modality. In cases where the hallux or any portion of the foot was not accessible, the testing device was placed at the next most proximal osseous prominence location of the foot that was available. This process was repeated twice and the average amplitude (voltage) and time to conduct the test (seconds) was recorded.

Statistical Analyses

For statistical analyses, each foot was considered as an individual “subject” thus tests were conducted with an $N = 130$. All statistical analyses of data were done with IBM SPSS Statistics Version 25.0 software. For all analyses a P value $< .05$ was considered statistically significant. Times to administer the different tests were compared via a one-way repeated measures ANOVA. A Sidak post hoc test was used for making pairwise comparisons administration times. A backward stepwise linear regression model was run for each testing method to identify potential predictors of time to complete the exams. Age, duration of diabetes, and medication(s) used to control patients’ diabetes were evaluated for inclusion in each regression model. In order to incorporate diabetic medications dummy variables were created for “oral,” “insulin,” and “oral and insulin” that were respectively contrasted with diet and exercise alone.

The diagnostic agreement between the different tests was compared via a Cochran’s Q test to compare the repeated binary outcome of a positive or negative diagnosis for neuropathy. A Bonferroni correction for multiple tests was applied to pairwise comparisons of diagnostic agreement. In recognition of the varied administration and interpretation techniques associated with the varied tests, a liberal and a

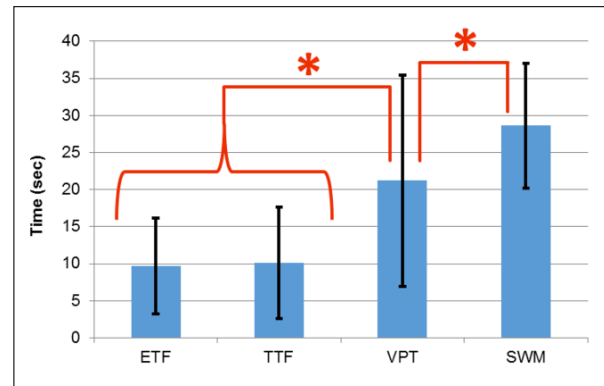


Figure 2. Comparison of time to complete sensation tests. Bars represent the mean time to complete each test for a single foot, and error bars represent the standard deviation. *Indicates a significant difference in time to complete tests.

conservative means of diagnosing peripheral neuropathy was utilized with the SWM, ETF, and TTF tests. In the case of SWM the liberal criterion for diagnosing peripheral neuropathy required failure to detect the SWM at only one of the ten locations and the conservative criterion used was a failure in at least four of the ten locations.²⁴ In the case of TTF and ETF the liberal criterion for diagnosing peripheral neuropathy was the failure to sense the vibratory stimulus for at least 9 seconds, a cutoff previously identified for use with the ETF.¹⁷ The conservative criterion for TTF and ETF was based on the “on/off” principle and failure to sense any vibration stimulus at initial application of the devices was considered indicative of peripheral neuropathy.

Results

Time to Complete

The ANOVA indicated there were significant ($P < .001$, partial eta squared = .442) differences in time to complete the varied tests. The Sidak post hoc comparisons indicated the VPT testing took an intermediate time to complete (21.2 ± 14.3), while the ETF (9.7 ± 6.5) and TTF (10.1 ± 7.5) tests took the least amount of time, and the SWM test (28.6 ± 8.4) took the longest time (Figure 2).

Time-to-Complete Predictors

The final regression model (Table 2) for predicting SWM completion time only maintained use of “insulin and oral” medications for diabetes control as a significant predictor ($R^2 = .042$, $P = .019$). The final regression model (Table 2) for predicting TTF completion time included age and use of “oral” medication ($R^2 = .111$, $P = .001$). The final regression model (Table 2) for predicting ETF completion time included age, use of “oral” medication and use of “insulin

Table 2. Regression Models for Predicting Time to Administer Tests.

	Unstandardized coefficients		Standardized coefficients	Sig.
	β	Std. error	β	
SWM test				
(Constant)	27.55	0.855		.000
Med = insulin and oral	3.86	1.624	.205	.019
TTF test				
(Constant)	16.99	3.34		.000
Age	-0.141	0.053	-.222	.009
Med = oral	3.67	1.26	.243	.004
ETF test				
(Constant)	15.711	2.964		.000
Age	-0.109	0.044	-.200	.014
Med = oral	3.183	1.269	.245	.013
Med = insulin and oral	-3.141	1.423	-.217	.029
VPT test				
(Constant)	4.297	6.385		.502
Age	0.239	0.101	.200	.020
Med = insulin and oral	8.624	2.687	.272	.002

and oral” medications ($R^2 = .200$, $P = .000$). The final regression model (Table 2) for predicting VPT completion time included age and use of “insulin and oral” medications ($R^2 = .101$, $P = .001$).

Diagnostic Agreement

The proportion of feet classified by each of the testing and the varied cut off criteria within individual tests are presented in Figure 3. Cochran’s Q test indicated there were significant differences between the tests. A review of all the pairwise comparisons is provided in Table 3. Many of the pairings indicated significant differences in the diagnoses of peripheral neuropathy.

Discussion

Time-to-Complete

The mean time to complete the SWM testing and each of the vibration tests for a single foot was below 30 seconds in the present study, which is similar to reporting by Perkins et al.⁸ Although no actual timing data were provided, Perkins et al reported that bilateral assessments of SWM and TTF by an “on-off method” (assessed perception of application of TTF stimulus and subsequent dampening of TTF stimulus) both required less than 60 seconds to perform. Perkins et al did claim TTF using a “timed method”

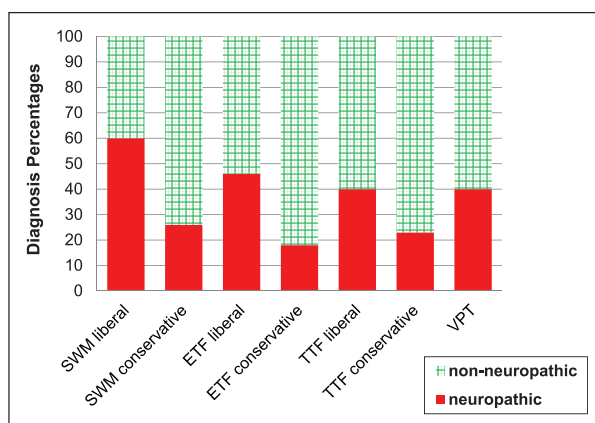


Figure 3. Proportion of feet classified as neuropathic by varied tests and varied diagnosis cut points.

did take longer “depending on the degree of normalcy” ($p = .254$). However, it should be noted that the TTF “timed method” they employed consisted of measuring how long patients could perceive stimulation at their first toe and then secondarily measuring how long the examiner could perceive TTF stimulation of their thumb. The timed TTF methodology utilized in the present study (“conservative TTF”) did not incorporate any evaluations of the examiners. Although completion times of all of the tests in the present study averaged less than 1 minute, significant differences were identified in time to complete the varied clinical screenings for peripheral neuropathy. In regards to vibration testing, the tuning fork methods required 11 seconds less per foot than measuring with the VPT.

Although a difference of 22 seconds for bilateral assessments may be considered trivial within the context of many clinical settings, the fact that ~50% of the global population spends 5 minutes or less with their primary care physicians does suggest seconds matter for many providers.²³ This is especially true in light of the fact that diabetic foot exams are routinely not performed during physician visits. The lack of regular foot exams is a problem that is not unique to any particular practice setting. Studies concerning primary-care physicians,²¹ outpatient internal medicine clinics,²² and a Veterans Affairs health system¹⁹ have all reported major deficiencies in diabetic foot screenings. Deficiencies in diabetic foot screenings have even been noted in clinics specifically dedicated to diabetes care. A study of an urban diabetes care clinic with approximately 700 patient visits per month found that only 13% of patients annually received a complete foot exam per American Diabetes Association guidelines.²⁰ SWM and other neurological exams (vibration using 128-Hz, tuning fork, pinprick sensation, ankle reflexes, vibration perception threshold) were the most commonly missed components of foot exams with only 35% and 27% of foot exams including these assessments.

Table 3. P Values for Pairwise Comparisons of Neuropathy Diagnosis by Varied Tests and Varied Diagnosis Cut Points.

	ETF liberal	TTF liberal	VPT	SWM conservative	TTF Conservative	ETF Conservative
SWM liberal	.093	<.001	.001	<.001	<.001	<.001
ETF liberal		1.000	1.000	<.001	<.001	<.001
TTF liberal			1.000	.093	.009	<.001
VPT				.055	.005	<.001
SWM conservative					1.000	1.000
TTF Conservative						1.000

Statistically significant P values (<0.05) are presented in bold.

Time-to-Complete Predictors

The fact that age was predictive of vibratory exams' time-to-complete is consistent with the literature. Several previous publications have noted increases in age are associated with poorer performance in clinical neuropathy tests.^{15,26,27} In the present study the VPT test, which has a positive association between time to complete and severity of neuropathy, was positively correlated with age. Conversely the vibratory tests in the present study for which poorer performance would be associated with a shorter time to complete (tuning fork exams) had completion times that were negatively correlated with age.

Considering the association between the various vibratory tests' time to completion and severity of disease, the medication associations identified in the present study may be reflective of worsening disease progression being associated with worse performance on the neuropathy tests. The timing data generally indicated individuals that were taking both oral medication and insulin to control their diabetes had poorer neuropathy test outcomes while those only taking oral medication had better test outcomes.

Limitations

Unfortunately, true sensitivity and specificity calculations were not possible in the present study due to the lack of inclusion of peripheral neuropathy screening via a "gold standard" such as nerve conduction velocity or nerve biopsy. However, it was possible to assess the agreement amongst the various clinical exams conducted. As expected, the use of "liberal" cut points for SWM, ETF, and TTF all resulted in significantly higher percentages of feet being classified as neuropathic in contrast to the conservative cut points for the exams. With 60% of feet being classified as neuropathic, the liberal SWM criterion (failure to feel SWM at $\geq 1/10$ sites) resulted in the highest proportion of feet being deemed neuropathic. In contrast, using the conservative criterion for the ETF test (failure to sense any vibration stimulus at initial ETF application) resulted in 18% of feet being classified as neuropathic which was the lowest proportion identified by the various screening tests.

The failure to record the time required to provide instructions to participants is a limitation of the present study. As alluded to in the methods section, during the design of the study there was an expectation that there would be a large amount of subject to subject variability in instructional time, thus any mean values would likely be of limited value. It was also expected individual patients' testing times would fluctuate over time in actual clinical practice, as returning patients become familiarized with the testing paradigms over repeated visits. Therefore the decision was made to focus solely on the time required to physically administer the test, which was believed to be a more reliable metric.

Another methodological limitation of the study was the documentation of ETF and TTF times as being zero seconds in cases where the stimulation was never perceived. The only times traditionally recorded in association with these tests is the duration for which a patient is able to feel the stimulus. Thus trials in which a patient failed to feel the stimulus were recorded as having a time of zero seconds. However, the stimulus must have been applied for at least a fraction of second to establish a patient did not feel the initial application of stimulus.

Conclusion

Identification of diabetic peripheral neuropathy is key to implementing strategies to prevent the occurrence of diabetic foot ulcers. Yet there is no universally acknowledged gold standard reference method for clinically diagnosing DPN,²⁸ therefore, utilizing multiple tools for assessing DPN is still considered the most appropriate method of testing for DPN. The American Diabetes Association calls for patients to be clinically screened via SWM as well as a secondary assessment.^{2,7} This study compared the time to administer and diagnostic agreement amongst three common vibratory clinical tests for peripheral neuropathy. Both the TTF and ETF required less time to conduct than VPT testing. Based upon the more objective nature of the ETF (initial vibratory stimulus strength is controlled by device in contrast to TTF) and simplicity of timing patients' duration of vibration sensation via the embedded digital timer, the ETF is recommended over the TTF. Numerous criteria have been reported in the

literature for how to interpret clinical assessments of peripheral neuropathy, clinicians should be aware that these varying criteria lead to significant differences in the diagnosed prevalence of peripheral neuropathy.

Abbreviations

AA = African American; DPN, diabetic peripheral neuropathy; ETF, electronic tuning fork; SWM, Semmes-Weinstein monofilament; TTF, traditional tuning fork; VPT, vibration perception threshold

Declaration of Conflicting Interests

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