QUANTITATIVE ASSESSMENT OF DIABETIC PERIPHERAL NEUROPATHY WITH USE OF THE CLANGING TUNING FORK TEST

David S. Oyer, MD, FACE,[1] David Saxon, BA,[2] and Ajul Shah, BA[3]

ABSTRACT

Objective: To describe the clanging tuning fork (CTF) test, a novel method for using the C 128-Hz tuning fork to test for diabetic peripheral neuropathy (DPN), to evaluate the accuracy and reproducibility of this technique, and to compare it with the 5.07 (10 g) Semmes-Weinstein monofilament test.

Methods: To determine the mean and standard deviation for the CTF test, repeated measurements were taken on one toe of 12 patients with diabetes during one visit. After these tests, 30 randomly selected patients were tested on both feet, with right and left scores compared for reproducibility of the results. The scores of the CTF test were compared with the monofilament scores in 45 patients with diabetes. Presence of foot ulcers in 81 patients was correlated with both test scores.

Results: The mean duration of vibration sensation was 10.2 seconds, with a standard deviation of ±1.3 seconds. The Pearson correlation coefficient comparing the right and the left foot scores for the same patient was 0.947 ($P<0.05$). Among patients with 8 seconds or less of vibration perception, results of monofilament testing were abnormal only in those whose vibration perception was less than or equal to 4 seconds. Of 32 patients with vibration perception of 4 seconds or less, 50% had normal monofilament test scores, including 29% of 17 patients with absent vibratory sensation.

Conclusion: The CTF test is reproducible and accurate. It provides a quantitative assessment of DPN and can document severe neuropathy, even in the presence of a normal result with the 10-g monofilament test. The risk of foot ulcers, which is associated with diminished vibratory sensation, can therefore be detected earlier and more accurately with the CTF test. The CTF test should replace the 10-g monofilament test as the recommended technique for detection of DPN. (**Endocr Pract. 2007;13:5-10)**

Submitted for publication October 16, 2005
Accepted for publication June 9, 2006
From the [1]Department of Clinical Medicine, Feinberg School of Medicine, Northwestern University, Chicago, Illinois, [2]Washington University, Saint Louis, Missouri, and [3]Northwestern University, Chicago, Illinois.
Address correspondence and reprint requests to Dr. David S. Oyer, 211 East Chicago Avenue, Suite 1050, Chicago, IL 60611.

Abbreviations:
CTF = clanging tuning fork; **DPN** = diabetic peripheral neuropathy; **VPT** = vibration perception threshold

INTRODUCTION

Diabetic peripheral neuropathy (DPN), the most common of the diabetic neuropathies, is estimated to be present in up to 50% of patients with diabetes (1,2). One of the most common forms of DPN is distal sensory polyneuropathy, which often affects the feet in patients with diabetes. It begins distally and is usually symmetric; therefore, testing for this disorder solely on the big toe is typically sufficient. Pinprick, position, and heat sensation can all be utilized to search for neuropathy, but vibration detection thresholds are a standard screening test. An accurate office test of vibration perception threshold (VPT) would decrease the need for electromyography and nerve conduction velocity testing. Diabetic neuropathy causes bothersome symptoms and reduced sensation that often leads to foot ulcers and amputations. Severe neuropathy, defined as the inability to detect the 10-g Semmes-Weinstein monofilament, is associated with increased risk of foot ulcers and amputation (3). Early detection of neuropathy is essential because therapy can be instituted to improve the patient’s quality of life, and early intervention can prevent foot ulcers. The emphasis is that multiple interventions to reduce known risk factors could be beneficial in patients with DPN, and an editorial by Perkins and Bril (4) called for better screening tests for early stages of neuropathy. Furthermore, 2 studies have suggested that impaired glucose tolerance may increase the risk of DPN (5,6); thus, the need for a sensitive test to detect neuropathy in its early stages is clear. On the basis of our research, we have determined that a new method accurately measures the status of vibratory sensation in peripheral neuropathy and detects neuropathy and ulcer risk at an earlier stage than does the 10-g monofilament test.

Currently, the 5.07 (10 g) Semmes-Weinstein monofilament is the most widely recommended test for assessing peripheral neuropathy in patients with diabetes (1,7) and is recommended by the American Diabetes Association (1) for neuropathy screening. Although the monofilament test has been shown to identify increased risk for foot ulcers, it detects neuropathy only at more dangerous later stages. When examined with the monofilament, a patient will have an abnormal score only with severe neuropathy, whereas a patient with mild or moderate neuropathy will register a normal result. Furthermore, the monofilament test is not quantitative. Although the set of 20 graded monofilaments can detect neuropathy at an earlier stage and can give a quantitative score, the process is time-consuming and not widely used. Other limitations with use of monofilament testing include lack of one standard test protocol, unreliable results when poorly made monofilaments are used, and the inability to deliver 10 g of pressure when the filaments become fatigued with use.

The C 128-Hz tuning fork has been used to assess peripheral neuropathy, usually by comparing how long the patient detects vibration in comparison with the examiner. If the examiner feels vibration longer than the patient does, then vibration perception is decreased (8). The tuning fork has been found to detect peripheral neuropathy reliably in comparison with the neurothesiometer (9). Furthermore, a correlation between abnormal VPT and foot ulceration has been clearly established (9-11). Meijer et al (12) have argued that testing with the tuning fork yields more reliable and valid results than do tests with the Semmes-Weinstein monofilament, without recommending a specific technique when the tuning fork is used.

In an attempt to quantify abnormal vibratory sensation, Perkins et al (13) have suggested counting the seconds the examiner detects vibration after the patient no longer perceives the sensation. The scores from each big toe are added, and if the examiner detects vibration for less than 20 seconds in total duration (10 seconds per toe), the patient is considered normal; a score above 40 seconds (20 seconds per toe) indicates neuropathy. This result, combined with the results of monofilament testing and a test for superficial pain sensation, creates a score that can identify neuropathy and ulcer risk. When this measure was included with monofilament results and superficial pain sensation measurements, creating the Toronto Clinical Scoring System (14), a strong correlation with sural nerve fiber density was observed. Kastenbauer et al (15) used the Rydel-Seiffer tuning fork to quantify VPT. A regular C 128-Hz tuning fork is modified with a device on the top of the vibrating tongs that produces a hologram effect. The image created by the hologram appears as the letter "V" whose apex moves up from position 8 to 0 as the vibration decreases. The examiner notes the position of the "V" when the patient can no longer feel the vibration, and a quantitative assessment of vibration threshold is made. A score of 4 to 8 indicates neuropathy. Certain reports have indicated that this technique correlated well with quantitative measures of VPT (16). Despite the availability of these more precise tests, most physicians focus on the 5.07 (10 g) monofilament test or use nonquantitative assessment with the tuning fork, which cannot determine the actual degree of neuropathy in a patient.

The objectives of this study are to describe the clanging tuning fork (CTF) test, a novel method for using the C 128-Hz tuning fork to test for DPN, and to evaluate the accuracy and reliability of this technique.

RESEARCH DESIGN AND METHODS

Study Subjects

Patients with type 1 and type 2 diabetes mellitus were randomly selected from the first author's clinic. Twelve patients with diabetes were tested with the CTF a minimum of 6 times on the same foot at one visit, and accuracy was determined by the standard deviation of the results. Thirty patients with diabetes were tested on both feet, and the results from the right and left foot were compared to determine reproducibility. Patients with vibratory test scores of 8 seconds or less also underwent evaluation for monofilament sensation. The presence of foot ulcers in 81 patients with diabetes was correlated with the vibratory test scores and the monofilament scores.

CTF Technique

To create a reproducible stimulus, the examiner must strike the C 128-Hz tuning fork against the palm of the free hand just hard enough to make the metal ends meet, producing a metallic clanging sound. The creation of the clanging sound necessitates a certain force, and the critical portion of the test is obtaining the clanging sound without excessive striking power. If no sound is produced, the examiner must try again with slightly more force. If a massive clang is produced, the tuning fork should be dampened and struck again with less force. With practice, the examiner learns to hit the tines just hard enough to produce the clanging sound with use of minimal effort and time. This technique standardizes the stimulus and the number of seconds that the tuning fork vibrates. In addition, the examiner must hold the stem of the tuning fork with 2 fingers, similar to gripping a dart, and not touch the vibrating tines because contact would shorten the time of vibration. The duration of time, in seconds, that the patient can feel the vibration is then measured.

The test is performed with the patient lying supine with bare feet, eyes averted from the examiner. For patients new to this test, the examiner demonstrates the vibration sensation on the toe, ankle, knee, chest, or finger until the patient perceives the difference between the pressure of the stem of the tuning fork and the feeling of vibration. The examiner then strikes the tuning fork again, immediately holding the stem against the dorsal surface of the large toe at the base of the toenail, and asks the patient to state when the vibration is no longer felt. The examiner notes the time that the stem of the tuning fork is applied to the toe and counts the seconds as they elapse until the patient indicates that the vibration seems to have ceased. The best end point is when the patient *first* starts to doubt that the vibration is perceptible rather than when certainty exists about its absence. Often after removal of the tuning fork, the patient will comment on the perception of a faint vibration sensation. The test becomes more reproducible if the patient reports when vibration perception becomes doubtful rather than when it has definitely ceased. To demonstrate the proper end point to the patient, the examiner holds the tuning fork against the toe with one hand, supports the underside of the toe with the little finger, and stops the tongs from vibrating with the other hand. During the actual test, accuracy may be improved by holding the tuning fork as still as possible and supporting the underside of the toe with the other hand or the thumb. Furthermore, this technique allows the examiner to monitor the time at which vibration can no longer be detected, either with the fingers holding the stem of the tuning fork or the other hand supporting the toe on the bottom. If the patient recognizes vibration after the examiner cannot, the examiner must reeducate about the appropriate end point and test again, ensuring that the patient reports actually feeling vibration at all. The examiner should test both large toes, recording the time to extinction of vibration. It may be necessary to repeat the test and calculate a mean value or to dampen the vibration with the free hand and ensure that the patient can actually distinguish vibration. In monitoring patients, the mean of the right and left foot recordings is the most useful number for serial measurements. To assist in consistent recording, we always test the right foot before the left.

All commercially acquired tuning forks, including those distributed by Herwig, Miltex, Mueller, ADC, MSi, and others, seemed to give the same results. A promotional tuning fork from Lilly gave the same readings as the commercial tuning forks. One type of tuning fork consistently yielded shorter times for vibration perception; this was a shiny promotional tuning fork with the Starlix label from Novartis, which appears to be made of a different material.

Monofilament Testing

Monofilament testing was done with a 10-g Semmes-Weinstein filament, and care was taken not to use a bent or old monofilament. Most of the study was conducted with monofilaments from Filament Project (Carville, LA), but some promotional monofilaments were used if they were not bent. While blinded, the patient was asked to identify which foot was being touched with the monofilament. Right and left feet were touched on the plantar surface in random order, using the base of the big toe and 3 spots across the ball of the foot. An abnormal score was assigned if the patient identified any of the spots incorrectly or failed to feel the monofilament at any of the 8 spots touched.

RESULTS

Reproducibility

Twelve patients with diabetes were tested between 6 and 10 times on one toe at one visit, to determine the reproducibility of the CTF test. The mean duration of vibration sensation was 10.2 seconds, with a standard deviation of ±1.3 seconds (Table 1).

Correlation: Right Foot Versus Left Foot

A single reading from the right foot versus the left foot was compared in 30 randomly selected patients with diabetes. For the 30 patients, the vibration duration averaged 10.9 ± 6.7 seconds on the right foot and 9.7 ± 7.1 seconds on the left foot. The Pearson correlation coefficient comparing the right and the left foot recordings for the same patient was 0.947 (P<0.05).

Comparison: CTF Test Versus Monofilament Test

When the mean vibration duration was 8 seconds or less, monofilament testing was done. Monofilament testing was consistently reported as normal when vibration perception was 5 seconds or more. Only with vibration perception readings of 4 seconds or less did monofilament testing begin to demonstrate abnormal results. More striking, however, is that the monofilament tests repeatedly showed normal results in patients with severely lessened vibration perception. Of 32 patients with a mean duration of vibration perception of 4 seconds or less, 50% still had

Table 1
Results of Repeated Clanging Tuning Fork Tests in 12 Patients With Diabetes Mellitus

Patient no.	Duration (s) of vibration perception: Mean	SD
1	8.4	0.8
2	18.8	1.3
3	3.4	0.7
4	11.0	0.8
5	13.0	1.4
6	8.9	1.3
7	11.0	0.7
8	2.2	0.4
9	14.4	3.1
10	11.0	1.8
11	13.5	2.3
12	6.2	1.0
Overall	10.2	1.3

Table 2
Results of Monofilament Testing Stratified by Mean Vibration Duration in 45 Patients With Diabetes

Mean duration (s)	No. of patients	Normal monofilament test No.	Normal monofilament test %
0	17	5	29
1	2	0	0
2	3	3	100
3	6	5	83
4	4	3	75
5	5	5	100
6	3	3	100
7	1	1	100
8	4	4	100
Total	45	29	64

Table 3
Occurrence of Foot Ulcers Stratified by Mean Vibration Duration in 81 Patients With Diabetes

Mean duration (s)	No. of patients	With foot ulcer No.	With foot ulcer %
0	17	6	35
1	2	0	0
2	3	1	33
3	6	2	33
4	4	1	25
5	5	0	0
6	3	0	0
7	1	0	0
8	4	1	25
≥9	36	0	0
Total	81	11	14

normal results of monofilament tests, including 29% of 17 patients with completely absent vibration sensation (Table 2).

Vibration Testing and Foot Ulcers

The medical records of 81 patients with diabetes were retrospectively reviewed for a history of a foot ulcer. Of those patients with a score of 4 seconds or less for duration of vibration perception with the CTF test, 10 of 32 had diabetic foot ulcers, in comparison with 1 ulcer in 49 patients with scores of 5 seconds or more (Table 3). Thus, the increased relative risk of occurrence of a diabetic foot ulcer was 15.3 for patients with a CTF test score of 4 seconds or less (Table 4).

DISCUSSION

Our results demonstrate high accuracy and reproducibility of the CTF test. It provides a score (in seconds) for the duration a patient can feel the vibration of the tuning fork, which would be inversely related to the VPT score (if available through electronic testing). Patients may need a quick lesson regarding protocol when the CTF test is first used, but on subsequent visits, the test will require no reeducation and can therefore be accomplished in less than a minute. When the duration of vibration perception equals or exceeds 5 seconds, monofilament testing is unnecessary because it consistently yielded normal results. Additionally, monofilament testing can result in normal scores even with substantially lessened (or absent) vibration perception; thus, neurologic function may appear healthy when severe neuropathy may actually be present. The CTF vibration test provides a quantitative assessment of vibration sensation and can detect mild degrees of neuropathy. By discovering abnormalities at earlier stages, interventions can be started in an effort to avoid severe

Table 4
Relative Risk of a Diabetic Foot Ulcer Based on Duration of Vibration Perception With the Clanging Tuning Fork Test

Mean duration (s)	No. of patients	With foot ulcer No.	With foot ulcer %	Relative risk
≤4	32	10	31	15.3
≥5	49	1	2	1.0

neuropathy, and intensive foot care can be instituted to attempt to prevent ulcer formation. Therefore, the CTF vibration test is more useful than the 10-g monofilament test.

The small differences comparing right foot and then left foot are unexplained. The right foot is always tested first, which could bias the results, possibly because of increased patient attentiveness on the second test or a lighter clang as the examiner learns the appropriate force needed. Some reports indicate that the dominant side has a better vibration duration score, but this trend was not found in all studies. The CTF test is ideal for serial measurements in the same individual, inasmuch as small changes over time can be detected and monitored. Hilz et al (16) demonstrated a decline in vibratory sensation in patients without diabetes beyond age 40 years, and we (17) have confirmed this finding using the CTF test. In patients younger than age 40 years with newly diagnosed diabetes, we seldom find a CTF test score below 18 seconds, and many can feel the vibration for as long as the examiner can with his hand, often to a maximum of 25 seconds. For patients younger than 40 years, we have defined vibration perception for 18 seconds or longer as normal. We have shown that monofilament scores are normal for any vibration perception of 5 seconds or more (Table 2) and that foot ulcer risk increases at 4 seconds or less (Table 4). Taken together, these findings define severe neuropathy as 4 seconds or less. At this time, intermediate neuropathy is defined as vibration perception for 5 to 17 seconds. Although further subclassification of that group would be arbitrary, mild neuropathy might be defined as 12 through 17 seconds and moderate neuropathy as 5 through 11 seconds (Table 5).

The CTF test allows low-cost assessment for neuropathy with results that are accurate, sensitive to mild degrees of neuropathy, quantitative, and reproducible. It predicts an increased risk for occurrence of foot ulcers considerably earlier than does 10-g monofilament testing, is easier to perform, and is less expensive than using multiple strengths of monofilaments. The disparity among various monofilament protocols is eliminated by adopting the CTF test; thus, the inconsistency in diagnosing DPN is diminished. Monofilaments have also been shown to fatigue after extended use; they no longer administer the necessary 10 g of pressure after 200 applications (18). Teaching the CTF test to medical students or other physicians involves a short amount of time, with the majority spent in observation to correct technical errors. Initial results indicate a high degree of comparability among different examiners.

Despite current recommendations for use of monofilament testing to diagnose peripheral neuropathy, the monofilament test was normal in 50% of patients with vibration scores of 4 seconds or less. These patients are at a 15-fold higher risk for foot ulcers. Because the CTF test often detects foot ulcer risk before monofilament testing results become abnormal, the benefits of protective footwear can be attained at an earlier stage. Approximately half of the patients who need foot protection would be missed if the monofilament alone was used for diagnosis of neuropathy. McCabe et al (19) demonstrated that a foot protection program in high-risk patients statistically reduced major amputations during a period of 2 years from 12 in the control group to 1 in the intervention group (P<0.01), a reduction of 92%. If the CTF test is used to define high risk instead of the monofilament test, this benefit could be extended to twice as many patients and could thereby reduce the amputation rate even further.

Table 5
Proposed Neuropathy Scoring System for Patients Age 40 Years or Younger

Degree of neuropathy	Mean vibration score (s)*
None	18 or more
Mild	12-17
Moderate	5-11
Severe	0-4

*Based on the clanging tuning fork test.

CONCLUSION

The CTF test is accurate and reproducible. It gives a quantitative estimate of the degree of neuropathy in patients with diabetes, and it can demonstrate neuropathy in the presence of normal results on 10-g monofilament testing. Diminished vibration sensation on the CTF test is associated with increased ulcer risk, and this risk is detected earlier with the timed tuning fork test than with the monofilament test. The CTF test should replace monofilament testing as the initial screening test for DPN.

DISCLOSURE

The authors have no conflicts of interest to disclose.

REFERENCES

1. **Boulton AJ, Vinik AI, Arezzo JC, et al (American Diabetes Association).** Diabetic neuropathies: a statement by the American Diabetes Association. *Diabetes Care*. 2005;28:956-962.
2. **Polydefkis M, Griffin JW, McArthur J.** New insights into diabetic polyneuropathy. *JAMA*. 2003;290:1371-1376.
3. **Valk GD, de Sonnaville JJ, van Houtum WH, et al.** The assessment of diabetic polyneuropathy in daily clinical practice: reproducibility and validity of Semmes Weinstein monofilaments examination and clinical neurological examination. *Muscle Nerve*. 1997;20:116-118.
4. **Perkins BA, Bril V.** Early vascular risk factor modifica-

tion in type 1 diabetes [erratum in *N Engl J Med*. 2005; 352:950]. *N Engl J Med*. 2005;352:408-409.

5. **Singleton JR, Smith AG, Bromberg MB.** Painful sensory polyneuropathy associated with impaired glucose tolerance. *Muscle Nerve*. 2001;24:1225-1228.
6. **Novella SP, Inzucchi SE, Goldstein JM.** The frequency of undiagnosed diabetes and impaired glucose tolerance in patients with idiopathic sensory neuropathy. *Muscle Nerve*. 2001;24:1229-1231.
7. **Mayfield JA, Sugarman JR.** The use of the Semmes-Weinstein monofilament and other threshold tests for preventing foot ulceration and amputation in persons with diabetes. *J Fam Pract*. 2000;49(11 Suppl):S17-S29.
8. **Perkins BA, Bril V.** Diabetic neuropathy: a review emphasizing diagnostic methods. *Clin Neurophysiol*. 2003;114:1167-1175.
9. **Boulton AJ, Malik RA, Arezzo JC, Sosenko JM.** Diabetic somatic neuropathies. *Diabetes Care*. 2004;27: 1458-1486.
10. **Young MJ, Breddy JL, Veves A, Boulton AJ.** The prediction of diabetic neuropathic foot ulceration using vibration perception thresholds: a prospective study. *Diabetes Care*. 1994;17:557-560.
11. **Kastenbauer T, Sauseng S, Sokol G, Auinger M, Irsigler K, et al.** A prospective study of predictors for foot ulceration in type 2 diabetes. *J Am Podiatr Med Assoc*. 2001;91:343-350.
12. **Meijer JW, Smit AJ, Lefrandt JD, van der Hoeven JH, Hoogenberg K, Links TP.** Back to basics in diagnosing diabetic polyneuropathy with the tuning fork! *Diabetes Care*. 2005;28:2201-2205.
13. **Perkins BA, Olaleye D, Zinman B, Bril V.** Simple screening tests for peripheral neuropathy in the diabetes clinic. *Diabetes Care*. 2001;24:250-256.
14. **Bril V, Perkins BA.** Validation of the Toronto Clinical Scoring System for diabetic polyneuropathy. *Diabetes Care*. 2002;25:2048-2052.
15. **Kastenbauer T, Sauseng S, Brath H, Abrahamian H, Irsigler K.** The value of the Rydel-Seiffer tuning fork as a predictor of diabetic polyneuropathy compared with a neurothesiometer. *Diabet Med*. 2004;21:563-567.
16. **Hilz MJ, Axelrod FB, Hermann K, Haertl U, Duetsch M, Neundorfer B.** Normative values of vibratory perception in 530 children, juveniles and adults aged 3-79 years. *J Neurol Sci*. 1998;159:219-225.
17. **Oyer DS, Shah A.** Vibration perception vs age in non-diabetic patients [abstract #343]. *Endocr Pract*. 2006;12 (Addendum to Suppl 2):9.
18. **Smith KD, Emerzian GJ, Petrov O.** A comparison of calibrated and non-calibrated 5.07 nylon monofilaments. *Foot Ankle Int*. 2000;21:852-855.
19. **McCabe CJ, Stevenson RC, Dolan AM.** Evaluation of a diabetic foot screening and protection programme. *Diabet Med*. 1998;15:80-84.