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ORIGINAL ARTICLE

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Efficacy of a new microvibration sensation measurement device at detecting diabetic peripheral neuropathy using a newly devised finger method

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Abstract

To investigate the efficacy of the finger method using a new microvibration sensation measurement device in the evaluation of diabetic peripheral neuropathy (DPN). A cross-sectional study of 52 type 2 diabetic outpatients was performed. Patients were evaluated for DPN using American Diabetes Association (ADA) criteria, Michigan Neuropathy Screening Instrument, and the finger method. Patients were classified into probable DPN or non-DPN groups, according to ADA criteria. The finger method measured peripheral neuropathy vibration (PNV) score of index and middle fingers using the new device in three procedures: PNV 1, PNV 4, and PNV 8. PNV scores ranged from 1 to 30 and were compared between the two groups. The PNV scores were significantly higher in the DPN group ($P < .01$). The PNV scores for right fingers of DPN and non-DPN groups were 10.2 ± 7.4 and 3.4 ± 3.3 by PNV 1, 20 ± 4.9 and 10.7 ± 5.3 by PNV 4, and 23.2 ± 4.9 and 14.6 ± 7.8 by PNV 8. Our data suggest that the finger method performed with the new device is useful in the evaluation of DPN.

KEYWORDS

diabetes mellitus, diabetic peripheral neuropathy, finger sensation, neuropathy screening, sensory threshold

1 | INTRODUCTION

Diabetic peripheral neuropathy (DPN) is a complication of diabetes mellitus (DM). The diagnostic criteria for DPN were established by the American Diabetes Association (ADA).[1] A diagnosis of probable DPN is routinely made in medical practice, as a nerve conduction (NC) study must be performed to make a definite diagnosis of DPN (confirmed DPN), which requires significant time commitment and is expensive. In addition, NC values differ depending on a patient's background. Thus, assessment of NC abnormality is difficult. While the diagnosis of probable DPN is routinely performed in medical practice, the combination of distal sensation tests including vibration sensation tests, neurologic manifestation assessments, and ankle reflex tests that is required to identify probable DPN also has problems, including the complexity of the tests and the nonquantitative nature of the tests, which prevent the classification of severity of DPN. In Japan, it has been shown that the tests required to diagnose probable DPN were performed in only 33% of DM patients.[2]

The development and aggravation of DPN can be prevented by blood glucose control[3–7] and exercise therapy.[8] Thus, a simple

detection method for DPN in the early stages of DM is required. In addition, if both medical care staff and patients themselves could evaluate for the presence of DPN, asymptomatic DPN patients may be motivated to actively participate in DM treatment.

We developed a new quantitative microvibration sensation measurement device that is applied to the fingers. Previously, we performed a pilot study using the device in 15 diabetes patients and confirmed a significant reduction in the vibratory sensation in diabetes patients when compared to healthy subjects.[9] Using this device, we investigated the differences in the sensory threshold of index and middle fingers to compare DPN and non-DPN patients divided according to ADA diagnostic criteria.

2 | METHODS

2.1 | Subjects

A total of 52 consecutive type 2 diabetic outpatients presenting at Takamatsu Heiwa Hospital between August 17 th 2013 and March 30 th 2014 were included in the cross-sectional study.

Subjects were excluded from the study if they met any of the following criteria: peripheral arterial occlusive disease, chronic alcohol abuse, lumbar spine disorders, severe renal failure, critical liver disease, or any other cause of peripheral neuropathy.

The study was approved by the institutional ethics committee of Kagawa University (Registration number: 25–025) and Takamatsu Heiwa Hospital, and written informed consent was obtained from all subjects.

2.2 | Data collection and evaluation of DPN

Patient characteristics including age, gender, body mass index (BMI), smoking status, blood pressure, low-density lipoprotein cholesterol (LDL–C), high-density lipoprotein cholesterol (HDL–C), HbA1c, and duration of diabetes were recorded for all patients.

Subjects were evaluated for the presence of DPN using the Michigan Neuropathy Screening Instrument[10] (MNSI), ADA criteria, and the finger method. Examinations and collection of all variables were performed on the same day. Subjects were classified into the DPN group (DM patients with probable DPN) or non-DPN group (DM patients without probable DPN) according to the ADA criteria.[1] Probable DPN was defined as the presence of a combination of symptoms and signs of neuropathy including any two or more of neuropathic symptoms, decreased distal sensation, or decreased or absent ankle reflexes.

The neuropathic symptoms were identified using the MNSI.[10] The MNSI consists of two parts. The first part of MNSI, the MNSI–Questionnaire (MNSI-Q), estimates the severity of neuropathic symptoms using a self-administered questionnaire consisting of 15 "yes or no" questions. The questionnaire has a maximum score of 13 points, and a higher score is indicative of more neuropathic symptoms.

The second part of the MNSI, the MNSI–examination (MNSI-E), consists of a brief physical examination that involves (i) the inspection of feet for deformities, dry skin, hair or nail abnormalities, and the presence of calluses or infection; (ii) the semiquantitative assessment of vibration sensation at the dorsum of the great toe; (iii) the grading of ankle reflexes; and (iv) monofilament testing. Patients were scored on a 10-point scale, and those patients that screened positive on the MNSI–examination with a score greater than two were considered to be neuropathic.

Decreased distal sensation was defined as decreased or absent perception of vibration sensation in both great toes using the timed method.

Vibration sensation was performed with the great toe unsupported and was tested bilaterally using a 128 Hz tuning fork placed over the dorsum of the great toe on the bony prominence of the distal interphalangeal joint. Subjects underwent the test with eyes closed and were asked to indicate when they could no longer sense the vibration from the vibrating tuning fork.

The examiner should feel vibration from the handheld tuning fork for 5 seconds longer on his distal forefinger than a normal subject at the great toe. A trial using a nonvibrating tuning fork was performed to ensure that the patient responded to vibration and not pressure. Vibration was scored as (i) present, if the examiner sensed the vibration on his or her finger for < 10 seconds;(ii) reduced, if vibration was sensed for 10 seconds; or (iii) absent, if no vibration was detected.

2.3 | Design of a quantitative microvibration sensation measurement device

A new quantitative microvibration sensation measurement device was used that was composed of microvibration actuators arranged in two straight lines, on which the subject placed his or her index and middle fingers to measure the threshold of the perception of tactile sensation against vibratory tactile stimuli. Eight vibration pins were placed so that all the pins contacted a finger cushion from the tip of the finger to the second joint (Figure 1A).

A shape memory alloy (SMA) wire was employed to generate the physical vibratory stimuli from the vibration actuator. The SMA was formed into a thin wire, which resulted in the SMA being able to contract in length at a particular temperature. The SMA wire (Toki Corp., BioMetal, BMF75; Tokyo, Japan) was selected to make the compact actuator for tactile presentation. When the temperature of the SMA wire was increased above 69°C, the wire began to shrink until the temperature was over 72°C. When the temperature of the SMA wire was lowered back to 72°C, the wire began to expand back to the initial length until the temperature was below 69°C. The contraction and the return to the initial length of the SMA wire were controlled by an electric pulse current to the body. The alloy has an electrical resistance of 0.6 ohms per 1 mm and accepts an electrical current to heat its body. Through the application of a pulse current to the SMA wire, the temperature of the wire instantly rose as a result of the generation of heat and shrank up to 95% of its initial length during the on-pulse state. During the off-pulse, the wire instantly cooled down as a result of heat radiating into the air and returned to its initial length. The process of shrinkage and expansion of the SMA wire was synchronized with the ON/OFF pulse current. To control the magnitude of the vibration, the amplitude of pulse signals H and the duty ratio W/L were determined from calories exchanged. To amplify

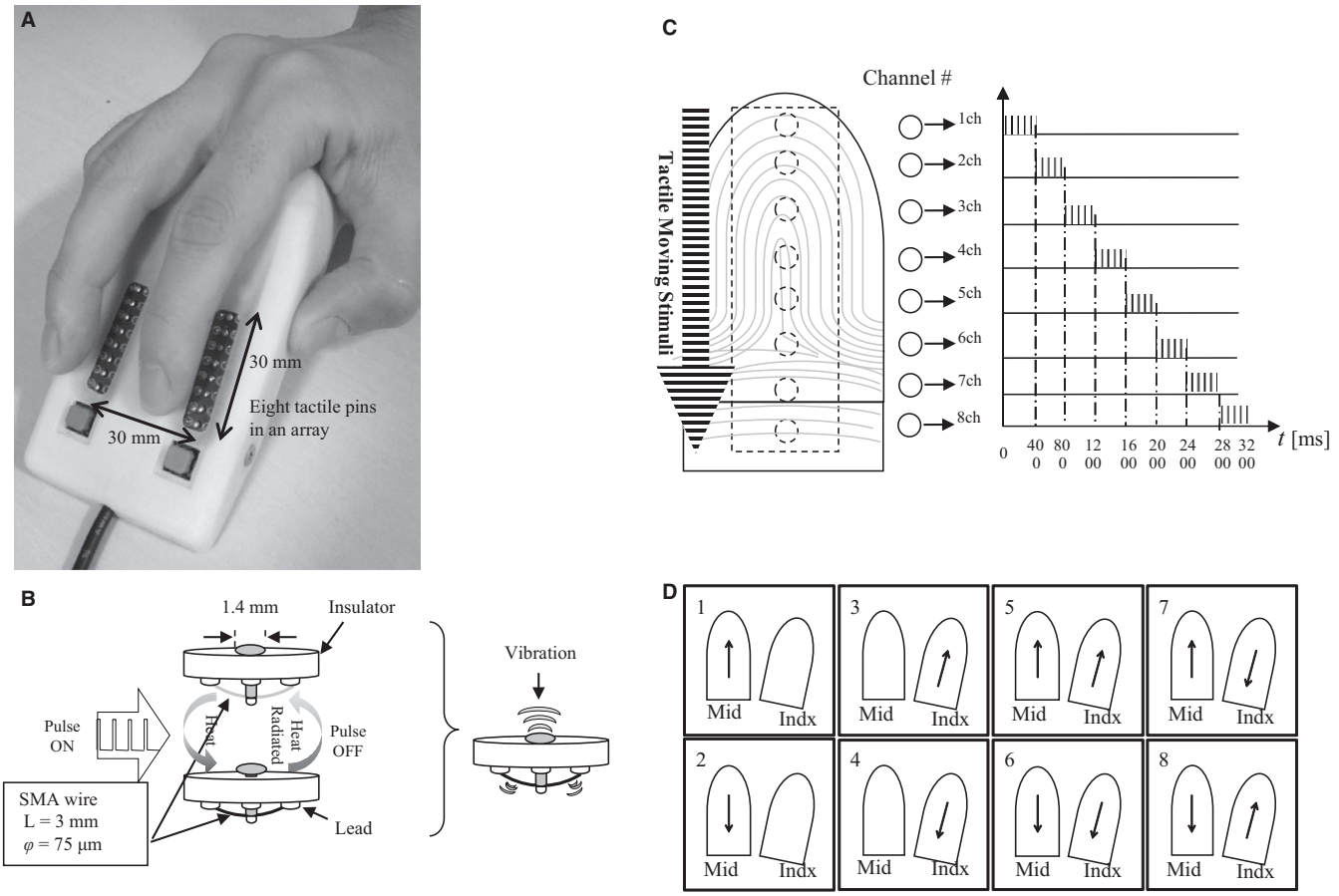

FIGURE 1 New quantitative microvibration sensation measurement device. (A) Structure of the vibration actuator; (B) presentation of the tactile vibratory stimuli; (C) the eight patterns of moving directions for tactile stimuli. Mid, middle finger; Indx, index finger

the microvibration generated by the SMA wire to make the vibration actuator usable as a tactile actuator in the tactile measurement device, we employed a round-head pin that was fixed to the middle of the SMA wire, to transform the movement of the SMA wire to the vibration of the pin-head. The structure of the vibration actuator, which consisted of a 75 μm in diameter and 3 mm in length SMA wire and a 1.4 mm in diameter and 3 mm in length round-head pin, is shown in Figure 1B.

The SMA actuators were driven by a pulse-width modulated (PWM) rectangular wave signal with arbitrary frequency, amplitude, and duty ratio. Variable frequencies of up to 300 Hz and variable voltage amplitude were obtained through the current control of the amplifier.

2.4 | The finger method

The microvibration measurement device was constructed through the arrangement of eight tactile-pin actuators. The presentation of vibratory stimuli generated by the tactile pins was made using tactile higher-level perceptual processes.[11,12] When the pins in an array were driven by pulse current signals with time delays (Figure 1C), the subject perceived that a vibratory object continuously moved from Ch. 1 (fingertip) to Ch. 8 (second joint of a finger), due to the effects of tactile apparent movement perception. In this manner, moving tactile stimuli were presented from different directions, according to the time delay among tactile pins.

Tactile presentation using apparent movement perception was measured using microvibration sensation measurement device at different frequencies and amplitudes. The amplitude of the vibration was divided into 30 steps from 1, with the lowest amplitude being difficult for healthy people with normal tactile sensitivity to perceive movement, to 30, which is the greatest amplitude and is perceived by a subject with severely damaged tactile sensation.

To examine the lowest threshold of tactile sensitivity of the index and middle fingers, we proposed the peripheral neuropathy vibration (PNV) score. The subject placed his/her index and middle fingers on the pin arrays and was presented with tactile stimuli at different vibration frequencies and amplitudes in random directions. Through "yes" or "no" responses to questions about tactile perception, the system allowed for the measurement of threshold of tactile presentation, which was related to the severity of DPN. This sensory threshold measurement method was defined as the finger method.

2.5 | Experimental procedures using the finger method

We performed three different procedures using the finger method to examine the performance of the device at reflecting the level of DPN symptoms. The first procedure presented tactile stimuli simultaneously

to both fingers in one direction starting at the fingertips (Pattern 6 in Figure 1D) and asked subjects whether they perceived the presented stimuli. This procedure, known as the PNV 1 direction test (PNV 1), examined the perception of tactile stimuli of two fingers. The second procedure was to present one moving stimulus to one of the two fingers in a random direction and required the subject to identify the finger and direction to which the tactile stimulus was presented. This procedure, known as the PNV 4 directions test (PNV4), required the subject to identify the tactile perception as one of four patterns (patterns 1, 2, 3, and 4 in Figure 1D). The third procedure, known as the PNV 8 directions test (PNV8), stimulated one or both fingers with moving stimuli in random directions. The subject was required to identify the finger(s) and the direction of movement from the eight patterns presented in Figure 1D.

In each procedure, the examination started with the least vibratory amplitude and the amplitude was increased in a stepwise manners until the subject recognized the vibratory stimulus. If the subject answered correctly at least twice for three stimuli of the same amplitude, the amplitude was increased one step. This was continued until the subject failed to correctly answer twice, then the previous step stimulus, which was the lowest threshold of tactile sensitivity, was recorded as the PNV score.

To assess PNV score reproducibility, intra- and interexaminer agreement tests were performed on 10 healthy volunteers. To evaluate for interexaminer reproducibility, the volunteers underwent the three finger method procedures twice, with the procedures being performed by two separate examiners on the same day. To evaluate for intra-examiner reproducibility, the volunteers underwent the three finger method procedures performed twice by the same examiner at 4- week intervals. Intra- and interrater agreements were determined using Spearman's rank correlation coefficient between tests.

2.6 | Statistical analysis

Statistical methods used included chi-square tests and Fisher's exact tests for nominal variables and Mann–Whitney U-tests for ordered categorical variables to compare groups. All statistical analyses were performed using SPSS version 22.0 (Tokyo, Japan). A *P*-value of < .05 was considered to be statistically significant.

Missing results were excluded from analysis.

3 | RESULTS

The probable DPN and non-DPN group had few significant differences in clinical characteristics, with only HDL-C and duration of diabetes differing significantly between the two groups (Table 1). Significant differences were observed for all items of the neuropathy examinations, including neuropathic symptoms, MNSI scores, and PNV scores for the fingers (Table 2). No significant laterality was observed in PNV score for any of the three procedures.

In the DPN group, PNV score measured by the finger method using the new device was significantly higher than in the non-DPN group regardless of the three procedures. Similarly, MNSI scores, which are the conventional DPN evaluation method, were higher in the DPN group than in the non-DPN group, with a higher score indicating more neuropathic symptoms.

Receiver operating characteristic (ROC) curves were depicted for comparison of the diagnostic capability for DPN among the three testing methods (Figure 2). When the right fingers were tested, the area under the curve (AUC) was 0.794, 0.896, and 0.823 for PNV1, PNV4, and PNV8, respectively (Figure 2A). When the left fingers were tested, the AUC was 0.734, 0.875, and 0.828 for PNV1, PNV4, and PNV8, respectively (Figure 2B). Thus, PNV4 resulted in the largest AUC among the three testing methods using any of the right and left fingers.

To determine interexaminer reproducibility between two examiners, Spearman's rank correlation coefficients for PNV 1 left, PNV 1 right, PNV 4 left, PNV 4 right, PNV 8 left, and PNV 8 right were 0.80, 0.92, 0.89, 0.99, 0.98, and 0.98, respectively. Similarly, in the evaluation of intratester reproducibility between tests, Spearman's rank

TABLE 1 Characteristics of diabetes mellitus patients classified into probable DPN and non-DPN groups

	Non-DPN Group (N = 21)	Probable DPN Group (N = 31)	*P*-value
Age (years)	63.4 ± 10.1	68.7 ± 8.1	.128*
Gender (male/female)	13/8	22/9	.494[a]
Body mass index (kg/m^2)	25 ± 4.4	28.5 ± 7.5	.111*
Current smokers (%)	4 (19%)	7 (22.6%)	.521[b]
Blood pressure (mm Hg)			
Systolic	126 ± 13	127 ± 18	.918*
Diastolic	74 ± 10	72 ± 11	.396*
LDL-C (mg/dL)	108 ± 28	99 ± 22	.381*
HDL-C (mg/dL)	58 ± 13	50 ± 14	.024*
HbA1c (%)	6.9 ± 1	7 ± 0.6	.250*
Duration of diabetes (years)	7.4 ± 1.1	13.3 ± 7.7	.003*

Data are presented as mean ± standard deviation or as N (%). *P*-values were calculated using *Mann-Whitney U-test, [a]χ2 test, or [b]Fisher's exact test.
N, number; DPN, diabetic peripheral neuropathy.

TABLE 2 Results of neuropathy examinations

	Non-DPN Group (N = 21)	Probable DPN Group (N = 31)	*P*-value
Neuropathic symptoms (%)	2 (9.5%)	15 (48.4%)	.003[a]
MNSI–Q Score	1 ± 0.8	2.1 ± 2	.017*
MNSI-E Score	1 ± 0.5	2.9 ± 1.3	<.001*
Abnormal MNSI score (%)	0 (0%)	20 (64.5%)	
PNV score			
PNV 1 Left	4.1 ± 5	9.7 ± 7.2	<.001*
PNV 1 Right	3.4 ± 3.3	10.2 ± 7.4	.004*
PNV 4 Left	12.6 ± 6.3	20.4 ± 4.8	<.001*
PNV 4 Right	10.7 ± 5.3	20 ± 4.9	<.001*
PNV 8 Left	16 ± 7.3 (n = 19)	25.1 ± 3.9 (n = 30)	<.001*
PNV 8 Right	14.6 ± 7.8 (n = 19)	23.2 ± 4.9 (n = 30)	<.001*

Data are presented as mean ± standard deviation or as N (%). *P*-values were calculated using *Mann-Whitney U-test and [a]$\chi 2$ test.
N, number; DPN, diabetic peripheral neuropathy. MNSI-Q, Michigan Neuropathy Screening Instrument Questionnaire; MNSI-E, Michigan Neuropathy Screening Instrument Examination; PNV, peripheral neuropathy vibration.

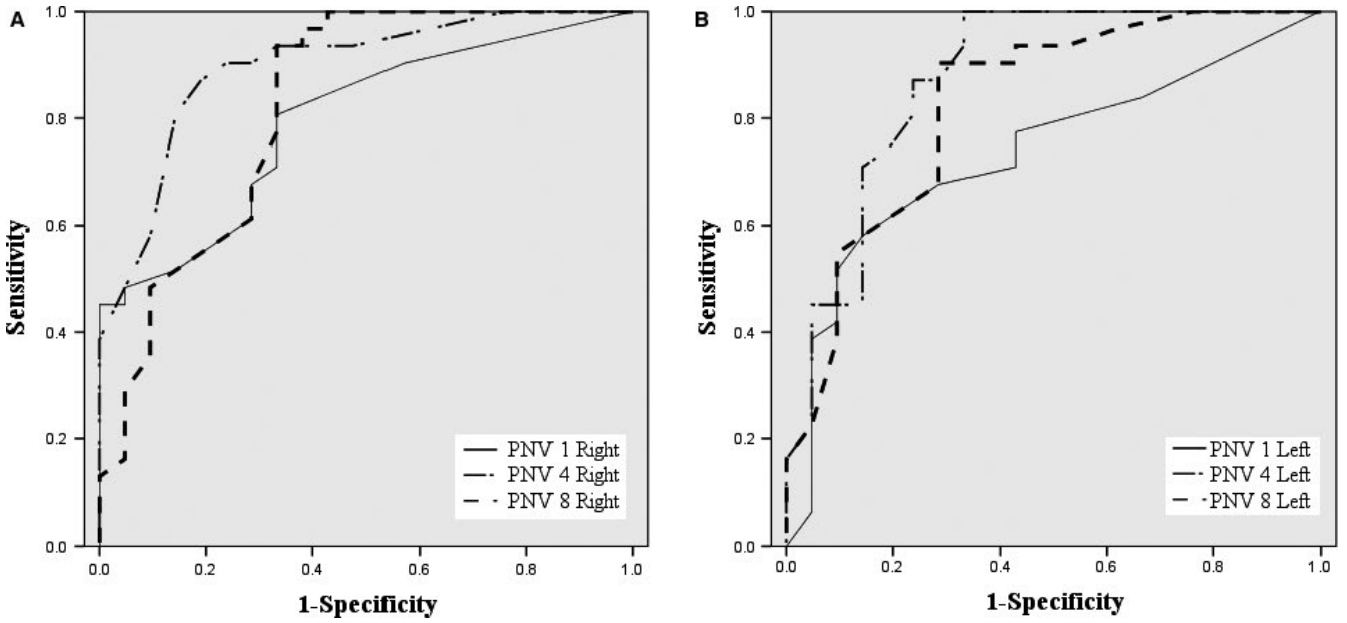

FIGURE 2 Receiver operating characteristicROC curves comparing peripheral neuropathy vibrationPNV 1 direction test, PNV 4 direction test, and PNV 8 direction test for prediction of diabetic peripheral neuropathy. (A) In right fingers, (B) In left fingers

correlation coefficients for each test procedure were 0.99, 0.81, 0.99, 0.99, 0.99, and 0.98, respectively.

4 | DISCUSSION

Using a microvibration sensation measurement device on DPN and non-DPN diabetes mellitus patients, we showed that PNV scores measured by the finger method in the DPN group were significantly higher than in the non-DPN group, with all three procedures tested. Of the finger method procedures tested, the PNV 4 directions test was suggested to be the most useful at identifying DPN.

The increased PNV score measured by the finger method in the DPN group may be reflective of impaired vibration sense in the fingers of DPN patients when compared to the vibration sense of non-DPN patients. DPN is normally evaluated using qualitative tests of the lower limbs, including the ankle reflex test, lower limb vibration sensation test, monofilament test, and external appearance evaluation of the feet. However, typical DPN is a chronic, symmetrical, length-dependent sensorimotor polyneuropathy[1] with a stocking-glove distribution. Thus, the application of the microvibration sensation measurement device to the fingers may also be appropriate for the evaluation of DPN. Specifically, it may be useful for patients in whom evaluation is difficult as a result of nondiabetic lower limb neuropathy complications such as

lumbar disk herniation. In addition, nerve conductive studies are appropriate for the evaluation of DPN because nerve conductive studies are quantitative and increased nerve conductive values for the upper limbs are associated with the progression of DPN.[13,14.]

The finger method evaluated in this study is superior to established test of the lower limbs, as the finger method is both quantitative and simple. The tests of the lower limbs are established tests, although preparation is required. Examinees are required to remove their shoes and socks to undergo lower limb tests. In addition, examinees are required to kneel when undergoing the ankle reflex test. In contrast, little preparation is required for the finger method. The PNV 1 direction test alone takes approximately one minute to perform. The PNV 4 directions test requires several minutes to perform; however, when compared to the amount of time required to perform a quantitative nerve conduction study, the PNV 4 directions test requires minimal time to perform. Thus, the finger method may be useful as a DPN screening test.

In the present study, the PNV4 testing method resulted in the largest AUC among the three methods using any of the right and left fingers. PNV4 is thus considered an optimal DPN screening method among the three evaluated in this study. To determine an optimal cut-off level for PNV4, we calculated the level with highest sensitivity and specificity from the ROC curves. When the cut-off level for PNV4 was set at 17, the highest sum total of sensitivity and specificity was recorded for both the tests with the right and left fingers. The test with the right fingers had sensitivity 87.1% and specificity 81%, while the test with the left fingers had sensitivity 100% and specificity 67.3%. We therefore recommend setting the PNV4 cut-off level at 17 when the finger method is used as a DPN screening test. Subjects recording values of 18 or higher with PNV4 should be suspected of having DPN and receive additional detailed evaluation.

A limitation of the finger method is that examiners are unable to confirm whether or not the examinees can feel the applied vibration. It is possible that examinees may report sensing a vibration level lower than they can actually sense. However, this is also a limitation of the established vibration sensation test that uses a tuning folk.

The finger method could be useful in the diagnosis of DPN, as it is a quantitative test that could be performed by diabetic patients themselves. Thus, it may be useful for the early detection of, improvement of, or aggravation of DPN through the periodic assessment of the vibration threshold by peripheral neuropathy patients. When PNV score is increased in the absence of symptoms, it would allow for the opportunity to perform detailed examinations or intensive therapy. In addition, the finger method may be used as a simple DPN screening test for patients with mild diabetes and abnormal glucose tolerance.

There were several limitations to this study. First, the diagnosis of diabetic neuropathy was probable DPN and not confirmed DPN, as it is difficult to diagnose confirmed DPN due to the requirement of NC abnormality. It is difficult to assess NC abnormality because NC values vary depending on a patient's characteristics, including age, height, and weight.[15] It is difficult to set normal NC values depending on the patient's backgrounds and normal deviation. For instance, one criterion for NC normality is Σ 5 NC normal deviation <95th percentile.[1,16] Second, this study was a cross-sectional study of outpatients under treatment with a limited number of patients. As a result, items that have previously been reported to be DPN risk factors, including body mass index, smoking status, blood pressure, LDL-C, and HbA1c, may not have differed between the DPN and non-DPN group. Significant differences were identified between the DPN and non-DPN for duration of diabetes and HDL cholesterol because these factors are not readily improved by treatment. Finally, the correlation coefficient for intra- and interexaminer reproducibility was favorable; however, it was only confirmed in a limited number of subjects.

5 | CONCLUSIONS

We showed that the sensory threshold of index and middle fingers was significantly higher in the DPN group than in the non-DPN group when measured using our new microvibration sensation measurement device. In addition, the PNV 4 directions test was the most useful of the three finger method procedures examined. As the finger method is a simple quantitative test method that could be performed by patients themselves and takes only several minutes, the finger method may be useful for the screening and periodic evaluation of DPN.

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CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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