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Application of NerveCheck Master in the Diagnosis of Diabetic Peripheral Neuropathy

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Abstract: Backgraund/Objetive: Diabetic peripheral neuropathy is a condition that affects the motor, sensory, and autonomic fibers of the peripheral nervous system, with distal polyneuropathy being its most common form. Traditional methods for diagnosing sensory loss, such as tactile assessment, temperature evaluation, and vibratory perception threshold testing, are labor intensive and time consuming. **Results**: To effectively assess thermal and vibratory sensitivity, NerveCheck Master is an affordable and portable device that uses standardized stimuli to measure sensory response. **Conclusions**: Compared to traditional methods like the infrared laser thermometer, the Rydel–Seiffer tuning fork, and the Semmes–Weinstein monofilament, this device provides definitive results regarding the severity of DPN.

Keywords: diabetes mellitus; diabetic peripheral neuropathy; diagnosis; NerveCheck Master

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1. Introduction

Diabetic peripheral neuropathy (DPN) is a significant complication associated with diabetes mellitus, characterized by the degeneration of motor, sensory, and autonomic fibers within the peripheral nervous system. Among its manifestations, distal polyneuropathy is the most common form, resulting in sensory and motor impairments that can severely affect patients' quality of life. As the disease progresses, patients may experience symptoms such as pain, tingling, numbness, and weakness in the extremities, particularly in the feet and hands. This condition not only leads to discomfort and functional impairment but also increases the risk of foot ulcers and infections, which can result in amputations if not managed effectively [1–3].

The pathophysiology of DPN is complex and multifactorial, involving metabolic, vascular, and genetic factors. Chronic hyperglycemia leads to various biochemical changes, including the accumulation of advanced glycation end-products (AGEs) and oxidative stress, which contribute to nerve damage. Furthermore, microvascular damage may impair blood flow to peripheral nerves, exacerbating neuropathic symptoms [2].

Several risk factors have been identified that contribute to the development and progression of DPN, including prolonged duration of diabetes, poor glycemic control, obesity, and coexisting medical conditions such as hypertension and dyslipidemia. It is important to note that DPN can also occur in individuals with prediabetes, highlighting the need for early intervention and monitoring in at-risk populations [3,4].

The accurate diagnosis of DPN is essential for initiating appropriate management strategies. Traditional diagnostic methods primarily involve assessing sensory loss in small and large caliber nerve fibers [3–5]. Commonly used techniques include:

This method involves the use of monofilaments, such as the Semmes–Weinstein 5.07 monofilament, to evaluate pressure sensitivity in patients. Failure to perceive the monofilament indicates a loss of protective sensation, which is a hallmark of DPN [2–4].

This assessment determines the ability to sense changes in temperature, which can be impaired in neuropathic conditions [2–4].

Utilizing tuning forks, typically set at 128 Hz, this test evaluates vibratory sensation, another critical sensory pathway affected by DPN [2–4].

Despite their widespread use, these techniques can be time-consuming and require trained personnel for accurate administration and interpretation, which may not always be feasible in clinical settings [5,6].

To address the limitations of traditional diagnostic methods, Quantitative Sensory Testing (QST) has emerged as a valuable tool for assessing vibration and thermal sensation. QST provides a more comprehensive evaluation by enabling simultaneous measurement of multiple sensory modalities. This approach enhances the efficiency of diagnosing DPN, allowing healthcare providers to obtain a more accurate picture of sensory loss without having to rely on each method individually [3–5].

NerveCheck Master (Figure 1) represents a significant advancement in the field of DPN diagnostics. As the first portable and low-cost QST device, it enables the assessment of thermal and vibratory sensitivity through standardized testing protocols. By quantifying sensory loss and vibratory perception values, this device allows clinicians to evaluate the severity of DPN more reliably [6,7].

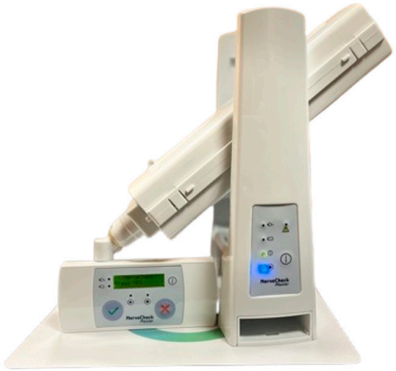

Figure 1. NerveCheck Master.

The advantages of NerveCheck Master over traditional devices include:

The device utilizes predefined stimuli to ensure consistency in testing and enhance the reliability of results [6].

Unlike singular testing methods, NerveCheck Master evaluates both vibratory and thermal sensory perception, providing a more holistic understanding of the patient's neuropathic condition [7].

Its portability and ease of use make it accessible for use in various clinical settings, promoting wider adoption among healthcare providers [6].

Timely and accurate diagnosis of DPN is crucial for effective management, which may include lifestyle modifications, pharmacological interventions, and regular monitoring. Patients diagnosed with DPN can benefit from educational programs focused on foot care, glycemic control, and the importance of routine screenings to prevent complications such as foot ulcers and infections [6,7].

2. Objective

The primary aim of this study is to compare the diagnostic capability of NerveCheck Master with traditionally employed methods to evaluate sensitivity in subjects with dia-

betes mellitus. Additionally, this study seeks to analyze the results obtained from examinations conducted with both the conventional devices and NerveCheck Master as the current diagnostic method for DPN.

3. Materials and Methods

This study is descriptive, observational, and cross-sectional, without any therapeutic intervention, aiming to determine the QST device's ability to distinguish between subjects with and without DPN. The target population includes individuals over 18 years old from the province of Seville, previously diagnosed with DM.

This study is descriptive as it describes the results of a defined population, cross-sectional because data are collected at a specific point in time, and observational because no variables are controlled during the process; they are observed, measured, and subsequently analyzed.

3.1. Population

In line with the study's objectives, the sample comprises 16 subjects diagnosed with DM, forming a single group with a mean age of 68.88 $\pm$ 9.30 years. Of these, 56.3% are women and 43.8% are men.

Fieldwork was conducted in the Clinical Podiatry Area of the University of Seville, following the prior written authorization that facilitated the development of the study within these facilities.

3.2. Inclusion Criteria

- Prior diagnosis of diabetes mellitus
- Age over 18 years

3.3. Exclusion Criteria

- Previous or current foot ulceration
- Partial or complete foot amputation
- Ankle–Brachial Index (ABI) < 0.9 or >1.3
- Neuropathy attributable to causes other than diabetes mellitus
- Current or previous Charcot joint disease
- Non-palpable dorsalis pedis and posterior tibial pulses
- Impairment of psychological and cognitive capacity

3.4. Sample Selection

In alignment with the study's objectives, the primary criterion for including a subject in the study is a prior diagnosis of either type 1 or type 2 diabetes mellitus.

Subsequently, a comprehensive medical history is conducted to determine whether the subject meets the criteria for participation in the study. Key factors include the progression and treatment of diabetes mellitus, the glycated hemoglobin (HbA1c) level from the most recent analysis, and any concomitant conditions, if present (5,8). Once a subject is included in the study, the necessary examinations are performed to determine the presence or absence of DPN.

3.5. Data Collection

The data collection process begins with gathering personal information and a detailed medical history. This includes recording personal details (name, surname, date of birth, contact phone number, sex, weight, and height) and any previous or current conditions, such as foot ulceration, prior amputations, and current or past Charcot joint disease.

For subjects previously diagnosed with DM, the duration of the disease and the treatment regimen (oral antidiabetics, diet, and/or insulin) are documented, along with the glycated hemoglobin level from the most recent blood test.

As described in the literature, it is deemed appropriate for the subject to remain in the examination area for 20 min in a seated position to minimize the influence of external factors on the examination [8,9].

Firstly, a neurological examination is conducted, which includes the assessment of tactile sensitivity using the Semmes–Weinstein 5.07 monofilament (Touch-Test/Aesthesio, UK) with a 10 g force, the evaluation of Achilles and patellar reflexes, and vibratory perception assessed using the Rydel–Seiffer 128 Hz (LuxaMed, Thomastown) tuning fork and the Horwell Neurothesiometer (PhiMed Europe). Each of these assessments is performed following current clinical guidelines.

Subsequently, a vascular examination is carried out, involving the palpation of the dorsalis pedis and posterior tibial pulses in both feet and the measurement of the Ankle-Brachial Index (ABI), which takes into account the systolic blood pressure in both the arm and the ankle. Additionally, a thermal assessment is performed using an infrared laser thermometer and a temperature sensor scale.

Finally, a neurological examination is conducted using NerveCheck Master (NerveCheck®). This test (Figure 2) is performed while the subject is seated, with the knees flexed and the soles of the feet resting on a flat surface parallel to the ground.

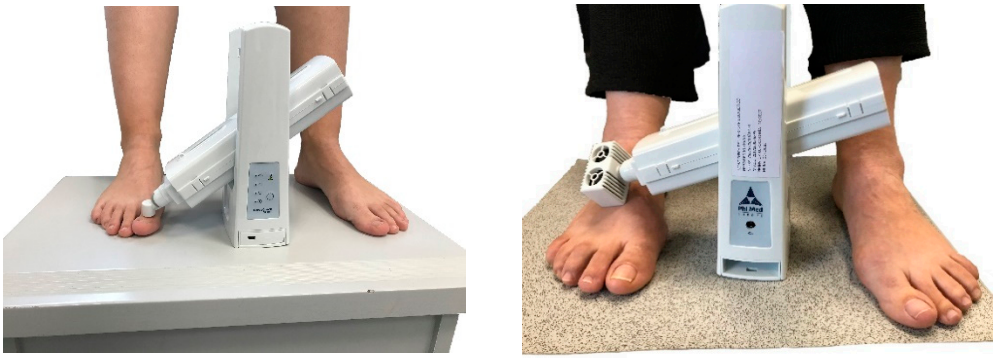

Figure 2. Assessment of vibratory and thermal sensitivity with NerveCheck Master.

The examination consists of a series of 4 tests categorized into vibration, cold, heat, and heat pain.

With the subject seated and the soles of their feet resting on a flat surface parallel to the ground, the vibratory head of NerveCheck Master is placed on the eponychium of the first or second toe, as these are the most sensitive areas to vibration. The subject's ability to perceive the vibratory stimuli is assessed and recorded.

At the other end of the device, the thermode is placed on the dorsal aspect of the foot. NerveCheck Master delivers a total of 5 cold stimuli at varying intensities (from 15 to 25 °C). The subject is asked to indicate when they feel the stimulus and when they do not. Results are recorded and categorized as normal or abnormal based on the subject's responses.

Similar to the cold test, the thermode is positioned on the dorsal aspect of the foot. After delivering five stimuli at different temperatures (ranging from 40 to 46 °C), the subject reports their thermal perception. The results are evaluated and classified as normal or abnormal depending on the subject's ability to detect the stimuli.

For this final test, the thermode is placed in the same position as for the cold and heat tests. NerveCheck Master gradually increases the temperature from 32 °C to 49 °C, and the subject must indicate to the examiner when they first perceive the heat stimulus. Results

are assessed and categorized as normal or abnormal based on the subject's reported onset of sensation.

These tests provide a comprehensive evaluation of the subject's sensory functions related to vibration, cold, heat, and heat pain, enabling accurate assessment of diabetic peripheral neuropathy [10].

3.6. Ethical Considerations

In accordance with the Helsinki Declaration [11], Decree 139-2010, and Law 14/2007 on biomedical research, an informed consent model was implemented prior to the study. This study was registered with ClinicalTrials.gov under registration number NCT06485362. The Bioethics Research Committee of the Virgen Macarena-Virgen del Rocío University Hospitals was obtained. University of Seville. Approval code: INV06-19 Approval date: 8 May 2019.

Informed consent was provided to participants both verbally and in writing, adhering to general bioethical principles and professional ethics [12,13].

The personal data of the subjects included in the study were kept confidential, in compliance with Law 15/1999 on Personal Data Protection, as published in BOE 298 on 14 December 1999.

4. Results

The final sample of the study consists of a total of 16 subjects (Table 1) previously diagnosed with DM, grouped together. Of these, nine are women (56.2%) and seven are men (43.8%), with ages ranging from 51 to 79 years and a mean age of 68.88 ± 9.30 years.

Descriptive data for the quantitative variables of the study are outlined in the following table (Table 1):

Table 1. Descriptive statistics for quantitative variables.

	Mean	Standard Deviation	Minimum	Maximum
Diabetes Mellitus Duration	13.94	16.98	1	93
HbA1c	7.33	0.99	6	10
Systolic Blood Pressure Left Arm	136.28	11.99	120	160
Systolic Blood Pressure Right Arm	138.75	13.60	120	170
Systolic Blood Pressure Left Ankle	160.62	21.43	120	190
Systolic Blood Pressure Right Ankle	160.62	25.95	100	200
Ankle-Brachial Index Left Arm	1.20	0.11	1	1.46
Ankle-Brachial Index Right Arm	1.17	0.17	0.77	1.53
Temperature Dorsum Left Foot	29.85	3.29	22	28.12
Temperature Dorsum Right Foot	30.18	3.41	21.5	35.2
Temperature Forefoot Left Foot	29.13	2.83	25.3	35.3
Temperature Forefoot Right Foot	28.79	2.60	24.1	34.3
Temperature Midfoot Left Foot	28.32	2.04	25.3	33.2
Temperature Midfoot Right Foot	28.16	2.57	24.2	34.3
Average Temperature Left Foot	28.61	2.17	25.4	33.7
Average Temperature Right Foot	29.06	2.24	24.8	34

Temperature (Table 2) was assessed bilaterally using an infrared thermometer, measuring the dorsum of the foot, forefoot, and midfoot. The maximum temperature difference recorded was 2.8 °C, which indicates the presence of diabetic peripheral neuropathy (DPN).

Table 2. Temperature values for the forefoot, midfoot, and hindfoot.

	Minimum Left Foot	Maximum Left Foot	Minimum Right Foot	Maximum Right Foot
Dorsum	22	33.3	21.5	35.2
Forefoot	25.3	35.3	24.1	34.3
Midfoot	25.3	33.2	24.2	33.6

Regarding Body Mass Index (hereinafter, BMI) (Table 3), an average result of 29.92 ± 5.58 was obtained, with the minimum value found being 22.80 kg/m^2 and the maximum value being 45.20 kg/m^2.

Table 3. Descriptive statistics for age (years), weight (kg), height (meters), and BMI (kg/m^2).

	MINIMUM	MAXIMUM	STANDARD DEVIATION	MEAN
Age	51	79	9.301	68.88
Weight	60	110	15.005	81.10
Height	1.54	1.87	0.098	1.65
BMI	22.80	45.20	5.576	29.91

The variables age, weight, height, and BMI were analyzed in relation to each other to understand their interrelationships. To this end, three subjects were excluded, as they exhibited abnormal results in the 128 Hz Diapason NerveCheck Master tests (Table 4).

Table 4. Relationship between the Rydel–Seiffer 128Hz tuning fork and NerveCheck Master.

		Diapason			
		Normal		Abnormal	
		N	%	N	%
NerveCheck	Normal	10	90.9	2	40.0
	Abnormal	1	9.1	3	60.0

For subsequent analyses, only subjects who showed consistent results in both tests were considered, resulting in 13 subjects.

4.1. Analysis by Sex

It was concluded that sex does not influence the results of normalcy obtained using the 128 Hz tuning fork and NerveCheck Master tests (Tables 5 and 6).

Table 5. Analysis of subjects by sex using the Rydel–Seiffer 128 Hz tuning fork and NerveCheck Master.

	Woman		Man		
	N	%	N	%	*p*-Valor
Normal	4	57.1	6	100.0	0.122
Abnormal	3	42.9	0	0.0	

Table 6. Analysis of midfoot temperature by sex.

Midfoot Temperature	N	MEAN	SD	*p*-Valor
Woman	7	29.17	3.19	0.217
Man	6	27.18	2.05	

Given the results, the midfoot temperature variable also does not differ by sex among the subjects.

4.2. Analysis by Age

Since the tuning fork or vibration variables using NerveCheck Master do not meet the parametric criteria for the age variable, the Mann–Whitney U test was used to assess the relationships between the variables. With a *p*-value greater than 0.05, it cannot be concluded that age influences the results obtained when applying the 128 Hz tuning fork test or NerveCheck Master (Table 7).

Table 7. Mann–Whitney U test for independent samples.

Age	N	MEAN	SD	*p*-Value
Normal	10	70.10	9.21	0.161
Abnormal	3	62.67	8.15	

There is also no relationship between age and midfoot temperature, with a *p*-value of 0.784.

4.3. Analysis by Body Mass Index

According to the results in the table above (Table 8), it was observed that subjects with a higher BMI tend to achieve abnormal results, and these results are statistically significant with a *p*-value of 0.027.

Table 8. Pearson correlation between right foot midfoot temperature and BMI.

		Body Mass Index
Midfoot Temperature of the Right Foot	**Pearson Correlation**	0.249
	Sig. (two-tailed)	0.412
	N	13

According to the table above, no relationship was found between BMI and midfoot temperature, as the *p*-value is greater than 0.05.

Subsequently, variable cross-tabulations were performed among the study's own variables (Table 9):

Table 9. T-test for independent samples.

Midfoot Temperature	N	MEAN	SD	*p*-Value
Normal	10	27.39	2.25	0.036
Abnormal	3	31.13	2.90	

Midfoot temperature is higher in cases of abnormality, which is statistically significant with a *p*-value of 0.036.

5. Discussion

NPD (Neuropathic Pain Disease) is defined as a condition characterized by the degeneration of motor, sensory, and autonomic fibers of the peripheral nervous system. For its identification, nerve conduction studies can be used as the gold standard; however, due to their high cost and challenging application, devices such as the MF S—W 5.07, Rydel–Seiffer graduated tuning fork, biotensiometer, and infrared thermometer have been used to date [14]. Conversely, both sensory loss and sensory threshold values can also be measured using QST (Quantitative Sensory Testing), which provides standardized stimuli and quantifies the level of response. NerveCheck Master is a new device that assesses sensory impairment in NPD through the execution of four tests: vibration, cold, heat, and heat pain [3,6,7].

According to the literature, the appropriate instrument for assessing NPD (Neuropathic Pain Disease) is one that provides accurate and objective results, is reliable, and is easy to use. Statistically, this is summarized as a validated instrument with high sensitivity and specificity [15].

The literature indicates that pain sensitivity should be evaluated using an instrument called Pinprick, which is based on discriminating the stimulus applied through pressure via the corresponding nociceptors.

The study by Perkins et al. (2001) supports this test as the most suitable for screening subjects with NPD (Neuropathic Pain Disease), given that it is a non-invasive, low-cost, and easy-to-use instrument. Furthermore, Perkins et al. suggest that the best area of the foot for examination is the dorsal aspect of the first toe at the level of the interphalangeal joint or the nail fold [16,17].

Regarding the assessment of pain sensitivity using NerveCheck Master, it was found that it cannot be compared with the previously mentioned instrument. The traditional method involves a slight puncture, which provides a diagnosis of puncture pain due to the involvement of mechanoreceptors. In contrast, NerveCheck Master performs a heat pain test, which evaluates the results corresponding to free nerve endings [10].

The examination area is also different, as NerveCheck Master applies the thermode to the dorsal part of the foot [10,17].

Regarding the thermal sensitivity of different instruments used for measuring temperature in the foot, the infrared thermometer is the most commonly used by most authors due to its ease of use and low cost [18–20].

Thermal results vary when comparing those obtained with the QST device and the thermometer. In both devices, the examination area is the same; as with NerveCheck, the thermode is placed on the dorsal part of the foot, similar to the thermometer, which is positioned a few centimeters from the dorsal foot without making direct contact with the skin [19,20].

According to the study by Ponirakis et al. (2017), NerveCheck Master performs the examination with greater precision than the traditionally used thermometer, based on the fact that the latter does not show sufficient temperature increases or decreases to produce a noticeable difference. In contrast, the QST device provides controlled thermal ramps through a heating–cooling process that results in gradual temperature changes, with the goal of reaching a pre-established value in the subject [6,7,10].

More recently, NerveCheck Master has been used in detecting post-COVID neurological sequelae. Odriozola et al. (2021) reported on 4 subjects with diabetes mellitus and severe SARS-CoV-2 who required non-invasive ventilation. Over a prolonged period, they underwent clinical, laboratory, and radiological evaluations and a detailed assessment of neuropathic symptoms, including neurological evaluation and QST on the dorsal foot and face, using NerveCheck Master for taste and smell assessment. The results indicated

that all four subjects developed neuropathic symptoms characterized by foot numbness with preserved reflexes. QST confirmed symmetrical abnormalities in vibration and thermal thresholds in both lower extremities in all participants, and an abnormal heat pain threshold in the face of two participants, in addition to altered taste and smell senses [21].

Ponirakis et al. (2024) evaluated the development of sensory neuropathy in subjects with severe COVID-19, assessing neuropathic symptoms, tendon reflexes, and quantitative sensory testing to measure thresholds for vibration, cold, heat, and heat pain between 1 and 3 weeks after hospital admission and 1 year later. This study included 32 participants with severe COVID-19, aged 68.6 $\pm$ 12.4 years (18.8% with diabetes). At the start of the study, 56.3% and 43.8% of participants had numbness and neuropathic pain, respectively. In the feet, 81.3% had abnormal thresholds for vibration, heat, and heat pain at the first, third week, and at one year; moreover, 50.0% had abnormal cold perception thresholds, and 12.5% had abnormalities in the face. At the 1-year follow-up, the prevalence of abnormal vibration perception thresholds was 81.3% compared to 50.0% ($p < 0.01$), the prevalence of abnormal heat perception thresholds was 81.3% compared to 43.8% ($p < 0.01$), and the assessment of heat pain over time (1 and 3 weeks, and at one year) was 81.3% compared to 50.0% ($p < 0.01$). However, there was a decrease with no changes in cold perception thresholds ($p = 0.21$) in the feet or heat pain assessment over time (1 and 3 weeks, and at one year) in the face ($p = 1.0$). Only participants without diabetes mellitus recovered from abnormal thresholds for vibration, cold, and heat perception. Participants with prolonged COVID-19 (37.5%) had baseline thresholds for vibration, cold, and heat perception comparable to those without prolonged COVID-19 ($p = 0.07$–0.69) [22].

One limitation of this study is the small sample size. A larger population sample might have shown greater concordance between NerveCheck Master and other traditional tests.

Based on the data obtained in the study, even though the reviewed literature indicates that the Horwell neurothensiometer is more specific than the Rydel–Seiffer 128 Hz tuning fork for diagnosing NPD, the latter has shown the greatest concordance with the NerveCheck Master device.

6. Conclusions

NerveCheck Master is a QST medical device used for the detection of NPD (Neuropathic Pain Disease) and requires some improvements in its performance. To achieve better results, it would be necessary to correct the operational errors, as they do not ensure adequate levels of effectiveness and efficiency for the early detection of NPD.

NerveCheck Master is not as straightforward to use compared to traditionally used instruments for diagnosing NPD. It is an excessively sensitive device that operates at low thresholds to detect any type of stimulus. As a result, the findings from examinations using the QST do not align with data from tests using the MF S—W 5.07, Rydel–Seiffer 128 Hz tuning fork, and infrared thermometer.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Review Board of Bioethics Research Committee of the Virgen Macarena-Virgen del Rocío University Hospitals was obtained. University of Seville. Approval code: INV06-19 Approval date: May 8.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Not available by decision of the authors.

Conflicts of Interest: The authors declare no conflicts of interest.

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