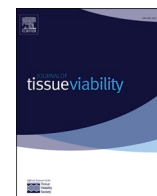




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Wearable sensors-based postural analysis and fall risk assessment among patients with diabetic foot neuropathy

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ABSTRACT

Aims: To investigate the cross-sectional association between deep and superficial diabetic neuropathy, postural impairment assessed by wearable inertial sensors, and the risk of fall among patients with diabetic foot.

Methods: Diabetic patients attending a University Podiatric Clinic were evaluated for the presence of deep and superficial peripheral neuropathy in sensory tests. Postural impairment was assessed using a wearable inertial sensor, and the evaluation of balance/gait and risk of fall was determined by the Tinetti Scale and Downton Index, respectively. Glycemic control was measured by glycated haemoglobin concentration and fasting glycaemia.

The postural parameters measured were the anteroposterior and medio-lateral sway of the center of mass (CoM) and the sway area (area traveled by the CoM per second). The results were analyzed through a logistic regression model to assess those posture variables mostly significantly associated with neuropathy and risk of fall scales.

Results: A total of 85 patients were evaluated. Spearman's rank correlation coefficients showed a strong and significant relationship ($p < 0.05$) between deep diabetic neuropathy assessed by Semmes-Weinstein monofilament, diapason and biothesiometer and postural alterations, whereas no significant correlations between superficial (painful sensitivity) neuropathy and the postural parameters. The sway path of the displacement along the anterior-posterior axis recorded during tests performed with eyes open and feet close together were significantly ($p < 0.05$) correlated with a poor glycemic (glycated haemoglobin concentration) control and each other with all diabetic neuropathy tests, fall risk scales, muscular weakness, ankle joint limitation and history of ulcers.

Conclusions: The results support the existence of a strong association between alterations of the deep somato-sensitive pathway (although depending on the tool used to measure peripheral neuropathy), glycemic control and balance impairments assessed using a wearable sensors. Wearable-based postural analysis might be part of the clinical assessment that enables the detection of balance impairments and the risk of fall in diabetic patients with diabetic peripheral neuropathy.

1. Introduction

Diabetic peripheral neuropathy (DPN) is defined as a symmetrical, length-dependent sensorimotor polyneuropathy resulting from metabolic and microvascular alterations. It affects between 20 and 40 % of individuals with type 2 diabetes, with a considerably variable reported prevalence due to different diagnostic criteria and assessment methods

[1–5]. The condition encompasses a heterogeneous group of clinical syndromes and alterations, with different patterns of neurologic involvement, course, and underlying mechanisms [1,2].

Diabetic patients with DPN typically present deep and superficial sensory impairments, reduction in ankle tendon reflexes, muscle weakness and foot deformity [6]. Among the related chronic complications, a loss of protective sensation (LOPS) or light touch-pressure

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with a distal-to-proximal symmetrical pattern is a common condition, caused by small and large nerve fiber dysfunction. LOPS leads to impaired balance and poor coordination, determining a risk of suffering from a fall-related injury 15 times greater than in a healthy person [4–7]. Postural impairments may also play an important role in contributing to other DPN-related complications, such as foot ulcerations and infections, often leading to amputations and higher mortality [7].

There is evidence that postural alterations and neuropathy are associated in patients with diabetes [8]. The analysis of postural alterations in previous studies were performed by analyzing different postural parameters with different instruments such as platforms e.g. static posturography in order to evaluate postural control [9–12] or to measure linear accelerations at the trunk and ankle levels [13] or by using dual force platform with a touch plate [14] or to evaluate center of pressure [15]. Dynamometric platform was also used to evaluate sway and dynamic balance [16]. Postural sway has been measured by using horizontal translating force platform [17] or by standing on foam rubber mat [18]. Force platform measurements (such as Kistler force plates) were used to evaluate the fluctuations of the center of pressure to identify postural sway [19–23]. Stabilogram diffusion analysis were done to examine the center of gravity sway using a motion tracker system based to analyse local and central control balance parameters [24].

Wearable inertial sensor units benefit greatly from innovative low-cost, portable, and objective measuring instruments able to quantify physical fall risk in clinical practice [25–28]. In these devices, the concomitant use of accelerometers, gyroscopes and magnetometers can provide very accurate estimates of the postural parameters, as well as the position, the acceleration, and the speed produced by the movement's balance among diabetic patients with DPN [28–33].

Despite these issues, the relationship between postural alterations assessed by wearable inertial sensors and its association with different tools aimed to evaluate both deep and superficial sensory impairments, neurological tests aimed to evaluated balance and the risk of falls (Tinetti scale and Downton index) and glycaemic control have been little investigated in diabetic foot patients.

The present study aims to verify if there is an association between postural impairment recorded by wearable-based postural analysis and deep and superficial diabetic neuropathy, and the risk of falls among patients with diabetic foot.

2. Methods

2.1. Sample

A cross-sectional study was conducted on consecutive diabetic foot patients attending the Academic podiatry clinic at the University of Bologna (IRCCS Rizzoli Orthopaedic Institute, Bologna).

The study was conducted with the approval of the Ethics Committee for Human Research (Reference: 659/2021/Sper/IOR - 2021) and all procedures were undertaken in accordance with the ethical requirements of the Helsinki Declaration.

The inclusion criteria were as follows: patients age ≥ 18 years; diagnosis of type 1 or type 2 diabetes; blood test to measure glycated haemoglobin and fasting glycaemia were performed within the last 3–4 months. Blood analysis was performed in order to analyse the association between posture parameters and glycemic control, by monitoring glycated hemoglobin concentration (HbA1c) and fasting glycaemia.

The exclusion criteria were as follows: foot or ankle surgery within the previous year; conditions causing major gait and posture disorders such as amputation, moderate/severe cognitive impairment or uncontrolled psychiatric problems; the presence of active ulcers and retinopathy in order to perform postural tests without any known confounding factor. The minimum sample size for the sample to be representative of our Clinic was calculated using the population estimation, considering a

prevalence of diabetes neuropathy about 25 % [4,5] and the total number (N = 109) of the diabetic patients fulfilling the inclusion criteria attending to the Hospital Clinic in 2021. A sample size of 80 subjects randomly selected will suffice to estimate with a 95 % confidence and a precision $\pm 5\%$ units, considering a prevalence of neuropathy in the sample to be around 25 %.

Demographic characteristics and data about comorbidities were recorded, and all the patients underwent a comprehensive assessment by two expert podiatrists and an expert nurse. A clinical assessment in terms of risk of fall, muscular strength, and ankle joint evaluation was carried out on each participant, concurrently with a postural and peripheral neuropathic assessment.

2.2. Risk of fall, muscular strength and ankle joint evaluation

The risk of fall was assessed using the Tinetti Scale and Downton Index. The Tinetti Scale has 7 items for gait assessment (with a total score of 12 points) and 9 items for balance evaluation (with a total score of 16 points). With a possible total of 28 points, a final score < 19 indicates a high risk of falls, a score between 19 and 24 indicates a moderate risk, and a score > 25 indicates a low risk of falls.

The Downton Index is an instrument with high sensitivity for predicting risk of falls, and is grouped in five categories related to that risk: previous falls, medication, sensory deficit, mental state, and ambulation. A total score of 3 or more is a predisposing factor for falling [34–37].

Muscle strength and ankle range of motion were measured using a dynamometer and the Weight-bearing Lunge Test (WBLT) respectively [38,39]. Limited ankle dorsiflexion due to reduced extensibility of the Achilles tendon leads to increased forefoot pressure and postural impairments, which can be a key factor in instability of posture [40–43]. The muscle strength of both legs was measured by a dynamometer, and was recorded in Newtons (Lafayette Instrument Company, Kentucky). WBLT was used on each limb to evaluate the range of motion of the ankle joint in dorsiflexion. The patients stood in front of the wall and placed their feet on a measuring tape placed on the floor, starting at a distance from the wall of 10 cm (Fig. 1). At the point where the patients could touch the wall with their knee without lifting their heel from the floor, the distance (cm) between the big toe and the wall was recorded [43–45].

2.3. Postural assessment

A reliable and validated Inertial Measurement Units (IMUs) wearable posturographic sensor system (mSway, mHealth Technologies, BO, Italy) was applied to evaluate postural assessment. This sensor consists of a tri-axial accelerometer, a tri-axial gyroscope, and a magnetometer that measure sway during eight sessions lasting 30 s (eyes open/closed,



Fig. 1. Inertial measurement unit (IMU) and its location to assess posture parameters.

with foam pads and without foam, on feet held together and on opened feet). The data were collected by placing the sensor in the lumbar area at L5 level using an elastic band (Fig. 1). The patients held the position autonomously, and the assessment was always conducted under safe conditions with the presence of practitioners nearby, especially in the tests with closed eyes and feet together.

As in previous studies, the assessment procedure included a visual perturbation (eyes-open or closed) and somatosensory perception disturbances (foam surface of 4-cm thick and 35 kg/m³ dense) as shown in Fig. 2 [46–51]. After this procedure, the inertial sensor mSway sent the postural parameters collected (Table 1) to a computer via Bluetooth: the data were stored and finally analyzed.

2.4. Diabetic foot peripheral neuropathy assessment and tests

Superficial (painful sensitivity) and deep sensitivity (light touch-pressure and vibratory sensitivity) were assessed as illustrated in a recently published study [52]. The procedure in each test was explained by the practitioners before the assessment, and it was conducted as described in the literature [53–61]. Various clinical tests evaluating different nervous functions were performed due to the heterogeneity of DPN.

- Deep sensitivity was evaluated by examining the vibration perception threshold (VPT) using two instruments able to assess large-fiber function: biothesiometer Polyneuro+ (Diabetik Foot Care Pvt Limited, India) and 128-Hz Rydel-Seiffer diapason (Podoservice, Spain), and by the assessment of protective sensation light touch by -pressure 5.07 Semmes-Weinstein monofilament (10 g) [62].
- Superficial sensitivity was assessed by a painful sensitivity test through the Pin-Prick (Neuropen®) tool, able to assess small-fiber function.

The Pin-Prick test was performed at six points on the plantar surface: on the big toe, on the first and fifth metatarsal heads, on the medial and lateral arches, and finally near the ungual edge of the big toe. The sharp part of the instrument was pressed perpendicularly over the six zones, and the patient was instructed to indicate verbally or by raising their hand when they noticed the sharp stimulus [63,64]. An abnormal result for this test was considered when the sharp stimulus was not detected on the dorsal side of the big toe [65,66].

For vibratory sensitivity, both biothesiometer and diapason were placed on five bone prominences on each foot: the distal area of the big toe, the first and fifth metatarsal heads, and both malleoli [67–69]. In the case of the diapason, after hitting it, it began to vibrate at an intensity of 8 to 0 and the patient had to indicate the moment when the sensation of vibration stopped. Vibratory sensitivity was considered reduced when intensities were not noticed for values ≤ 6 in people under 60 years and

Table 1
Definitions of postural parameters collected by inertial sensors.

Name [unit of measurement]	Description
Sway Path of the displacement along the AP axis [mm]	Length of the Sway Path traveled from the Center of Mass (CoM) during the oscillation in the antero-posterior axis.
Sway Path of the displacement along the ML axis [mm]	Length of the Sway Path traveled from the Center of Mass (CoM) during the oscillation in the medio-lateral axis.
Sway Area [mm ² /s]	Area traveled by the Center of Mass (CoM) per second.

for values ≤ 4 in people over 60 [57]. In contrast, the biothesiometer was applied on the bone prominences vibrating at an initial intensity of 25 V. The intensity was increased until the patient was able to notice the stimulus or up to a maximum of 50 V. If they noticed 25 V, the intensity was reduced until they no longer noticed the stimulus. Results for vibratory sensitivity were considered abnormal when intensities above 25 V were not detected in the big toe [57–69].

The Semmes-Weinstein monofilament test was carried out at 10 sites: the dorsum coinciding with various foot dermatomes: the dorsal interdigital area of the first and second toes, the plantar surface of the third, fourth and fifth toes, the first, third and fifth metatarsal heads, the medial and lateral arches and the heel surface. The monofilament was pressed perpendicularly against the skin on each area until it folded. After removing it from each area, we waited for a second for the patient to respond, and if they did not, we registered altered sensitivity in that area [58]. The test was considered abnormal when four of the ten areas had altered sensitivity to light touch-pressure [59].

After the superficial and deep sensitivity assessment, and according to the indications of the International Working Group of the Diabetic Foot (IWGDF), the presence of sensory peripheral neuropathy was considered when the protective sensation test and vibratory sensitivity evaluated by the biothesiometer were altered [70].

2.5. Statistical analysis

Descriptive analysis for quantitative variables was reported as the mean value, the standard error mean (SEM), and range, whereas the categorical variables were described as frequencies and proportions. Data analysis was performed using IBM SPSS® 25.0, and the associations between the quantitative variables and categorical data were analyzed using the non-parametric Mann-Whitney U test or the parametric Student’s t-test, depending on the distribution of the quantitative variables in each categorical variable. Chi-square test to compare proportions in two categorical variables. Spearman’s linear correlation coefficient was used to establish the correlation between the quantitative variables. Logistic regression was performed to try to determine which variables were related to the presence of neuropathy by making a predictive model including variables that had been significant in the bivariate analysis. This technique can be used to simultaneously assess several factors presumed but necessarily related to the dependent variable, in our case presence or not of neuropathy in different assessment tools. Thus, we obtained measurements (odds ratios) of the association between each variable adjusted to all the other variables to detect possible interactions between them and the effect studied. A confidence level of 95 % was set, and statistical significance was defined as *p* < 0.05 for all analyses.

3. Results

3.1. Socio-demographic and clinical characteristics of the study sample

The sample included 85 patients, 46 males and 39 females. A total of 18 patients (21.2 %) had a diagnosis of Type 1 diabetes, and 67 patients (78.8 %) had a diagnosis of Type 2. Thirty-nine patients (45.9 %) were

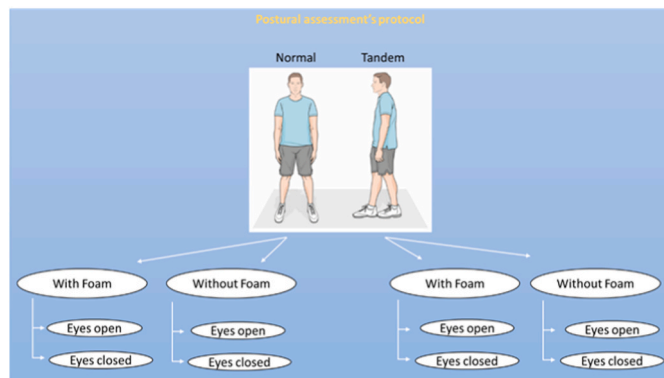


Fig. 2. Flow diagram and graphical representation of the postural assessment procedure.

taking insulin, 40 patients (47.1 %) were taking oral anti-diabetic drugs and 6 patients were not taking any medication. The participants had a mean age \pm SEM of 68.1 ± 1.3 (range, 20–87). The body-mass index (BMI) identified that 26 patients (30.6 %) had a normal weight, 39 patients (45.9 %) were overweight, and 20 patients (23.5 %) were obese. The patients' mean value of HbA1C (mmol/mol) was 52.9 ± 1.3 . The Tinetti scale identified 52.9 % of patients with a low risk of falling; 40 % had medium risk, and 7.1 % had a high risk of falling. The Downton scale scores indicated that 45.9 % of patients were at a high risk of falling (>3 points); 54.1 % were at a medium risk (1–2 points) or a low risk (0–1 points).

Altered muscle strength was recorded in 20 of 85 patients (23.5 %) and altered ankle joint mobility (lunge test <10 cm) was recorded in 62 of 85 patients (73.8 %). Six (7.1 %) patients developed ulcers in one of the feet during their diabetes, 2 (2.4 %) developed bilateral ulcers, while 77 (90.6 %) had no ulcers. 82 (96.5 %) participants had no history of amputations, and 3 (3.5 %) had experienced unilateral amputations.

Painful sensitivity assessed with the Pin-Prick test was altered in 11 of 85 patients (12.9 %). Vibratory sensitivity was altered in 33 of 85 patients (38.8 %) when evaluated through the biothesiometer and in 20 of 85 patients (23.8 %) when evaluated with a diapason. Protective

sensation assessed with the monofilament test was altered in 16 of 85 patients (18.8 %).

Data from the evaluation of sensory-motor functions and Tinetti and Downton scale were evaluated as a continuous variables and also as dichotomous variable (normal versus altered) based on the cut-off scores reported in the literature. The significant value of these group differences and Spearman's correlation with postural parameters are reported in Tables 2 and 3 respectively. In contrast, no significant association was found between postural tests performed with eyes closed and feet close together (EC_Tandem) or performed with eyes closed and feet close together and foam (EC_TF) and neuropathy value. Many patients failed to perform these types of tests during the study, and we decided to exclude these tests from the analysis of the results for this reason.

3.2. Analysis of postural parameters and clinical tests

Age was significantly associated with most of the postural parameters except the parameter EO_Foam_SP_AP_axis" and EC_SP_AP_axis that were not significantly associate with age. The most significant correlations were found for EO_SP_ML_axis ($p = 0.001$; $\rho = 0.35$), EO_Foam_SP_ML_axis ($p = 0.003$; $\rho = 0.32$), EO_Tandem_SP_AP_axis

Table 2
Associations between postural parameters and parameters of sensitivity alterations (expressed as categorized variables based on cut-off scores).

Type of test	Superficial Sensitivity	Deep Sensitivity							
	Pain sensitivity (pin-prick)	Vibration sensation (DP)	Protective sensation (monofilament)	Vibration sensation (BTM)	Osteotendinous reflexes	Digital deformities	Muscular Strength	Lunge test	Presence of sensory neuropathy
EO_SP_AP_axis	NS	p (0.021) $Z = -2.316$	p (0.006) $Z = -2.724$	NS	NS	NS	NS	NS	p (0.013) $Z = -2.482$
EO_SP_ML_axis	NS	p (0.000) $Z = -4.541$	p (0.000) $Z = -3.659$	p (0.011) $Z = -2.532$	NS	p (0.038) $Z = -2.072$	NS	NS	p (0.001) $Z = -3.451$
EO_Sway_Area	NS	p (0.004) $Z = -2.902$	p (0.007) $Z = -2.690$	NS	NS	NS	p (0.005) $Z = -2.828$	NS	p (0.009) $Z = -2.610$
EO_Foam_SP_AP_axis	NS	p (0.021) $Z = -2.305$	p (0.008) $Z = -2.655$	NS	NS	NS	NS	NS	p (0.026) $Z = -2.225$
EO_Foam_SP_ML_axis	NS	p (0.000) $Z = -3.796$	p (0.001) $Z = -3.313$	p (0.019) $Z = -2.349$	NS	NS	NS	NS	p (0.001) $Z = -3.019$
EO_Foam_Sway_Area	NS	p (0.044) $Z = -2.018$	p (0.027) $Z = -2.216$	NS	NS	NS	NS	NS	NS
EO_Tandem_SP_AP_axis	p (0.007) $Z = -2.686$	p (0.024) $Z = -2.253$	p (0.020) $Z = -2.321$	p (0.015) $Z = -2.442$	p (0.017) $Z = -2.386$	p (0.036) $Z = -2.103$	p (0.038) $Z = -2.077$	p (0.014) $Z = -2.470$	p (0.0035) $Z = -2.104$
EO_Tandem_SP_ML_axis	p (0.008) $Z = -2.659$	p (0.012) $Z = -2.506$	p (0.005) $Z = -2.837$	p (0.017) $Z = -2.386$	NS	NS	NS	NS	p (0.017) $Z = -2.396$
EO_Tandem_Sway_Area	p (0.007) $Z = -2.713$	p (0.035) $Z = -2.110$	p (0.011) $Z = -2.537$	p (0.015) $Z = -2.442$	p (0.036) $Z = -2.102$	NS	p (0.048) $Z = -1.978$	NS	p (0.018) $Z = -2.371$
EO_TF_SP_AP_axis	NS	p (0.045) $Z = -2.000$	p (0.046) $Z = -2.027$	NS	NS	p (0.021) $Z = -2.304$	NS	NS	NS
EO_TF_SP_ML_axis	NS	p (0.022) $Z = -2.297$	p (0.007) $Z = -2.717$	p (0.025) $Z = -2.245$	NS	p (0.008) $Z = -2.643$	NS	p (0.019) $Z = -2.344$	p (0.022) $Z = -2.298$
EO_TF_Sway_Area	p (0.041) $Z = -2.041$	NS	p (0.036) $Z = -2.093$	NS	NS	p (0.011) $Z = -2.533$	p (0.047) $Z = -1.989$	NS	NS
EC_SP_AP_axis	NS	p (0.001) $Z = -3.381$	p (0.006) $Z = -2.759$	NS	NS	p (0.041) $Z = -2.045$	NS	NS	p (0.013) $Z = -2.494$
EC_SP_ML_axis	p (0.021) $Z = -2.301$	p (0.000) $Z = -4.818$	p (0.000) $Z = -4.098$	p (0.001) $Z = -3.274$	NS	NS	NS	NS	p (0.000) $Z = -3.837$
EC_Sway_Area	NS	p (0.001) $Z = -3.381$	NS	NS	NS	NS	p (0.024) $Z = -2.251$	NS	p (0.005) $Z = -2.821$
EC_Foam_SP_AP_axis	p (0.026) $Z = -2.221$	p (0.000) $Z = -4.499$	p (0.002) $Z = -3.036$	p (0.028) $Z = -2.203$	NS	NS	NS	NS	p (0.006) $Z = -2.750$
EC_Foam_SP_ML_axis	NS	p (0.000) $Z = -5.148$	p (0.000) $Z = -3.521$	p (0.015) $Z = -2.423$	NS	NS	NS	NS	p (0.001) $Z = -3.218$
EC_Foam_Sway_Area	NS	p (0.000) $Z = -3.934$	p (0.019) $Z = -2.343$	NS	NS	NS	NS	NS	p (0.030) $Z = -2.166$

Table 3

Correlations between postural parameters and specific somato-sensitive tests (expressed as continuous variables) and Tinetti and Downton scales.

Type of test	Protective sensation (monofilament)	Pain sensitivity (Pin-prick)	Vibration sensitivity (diapason)	Vibration sensitivity (biothesiometer)	Muscular strength	Lunge test	Tinetti scale: posture	Tinetti scale: gait	Downton scale	Tinetti: total score
EO_SP_AP_axis	70 % <i>p</i> (0.002–0.049) rho = 0.14–0.33	66,67 % <i>p</i> (0.12–0.36) rho = 0.23–0.27	40 % <i>p</i> (0.023–0.030) rho = (–0.24) – (–0.25)	20 % <i>p</i> (0.030) rho = 0.24	<i>p</i> (0.007) rho = –0.29	NS	<i>p</i> (0.003) rho = –0.32	<i>p</i> (0.002) rho = –0.34	<i>p</i> (0.002) rho = –0.34	<i>p</i> (0.001) rho = –0.37
EO_SP_ML_axis	90 % <i>p</i> (0.000–0.034) rho = 0.23–0.41	66,67 % <i>p</i> (0.016–0.045) rho = 0.22–0.26	100 % <i>p</i> (0.000–0.001) rho = (–0.37) – (0.49)	100 % <i>p</i> (0.000–0.001) rho = 0.34–0.42	<i>p</i> (0.003) rho = –0.32	<i>p</i> (0.004) rho = –0.32	<i>p</i> (0.000) rho = –0.41	<i>p</i> (0.001) rho = –0.35	<i>p</i> (0.000) rho = –0.40	<i>p</i> (0.000) rho = –0.38
EO_Sway_Area	40 % <i>p</i> (0.005–0.009) rho = 0.29–0.30	NS	100 % <i>p</i> (0.002–0.013) rho = (–0.272) – (–0.33)	60 % <i>p</i> (0.015–0.029) rho = 0.240–0.26	<i>p</i> (0.001) rho = –0.36	NS	<i>p</i> (0.000) rho = –0.39	<i>p</i> (0.000) rho = –0.38	<i>p</i> (0.000) rho = –0.38	<i>p</i> (0.001) rho = –0.35
EO_Foam_SP_AP_axis	50 % <i>p</i> (0.002–0.021) rho = 0.24–0.34	16,67 % <i>p</i> (0.012) rho = 0.27	NS	NS	NS	<i>p</i> (0.031) rho = –0.24	<i>p</i> (0.001) rho = –0.35	<i>p</i> (0.002) rho = –0.33	<i>p</i> (0.000) rho = –0.42	<i>p</i> (0.001) rho = –0.37
EO_Foam_SP_ML_axis	60 % <i>p</i> (0.001–0.005) rho = 0.31–0.39	66,67 % <i>p</i> (0.007–0.047) rho = 0.22–0.29	100 % <i>p</i> (0.000) rho = (–0.38) – (–0.50)	100 % <i>p</i> (0.000–0.003) rho = 0.32–0.40	<i>p</i> (0.013) rho = –0.27	<i>p</i> (0.002) rho = –0.34	<i>p</i> (0.001) rho = –0.37	<i>p</i> (0.006) rho = –0.30	<i>p</i> (0.003) rho = –0.33	<i>p</i> (0.000) rho = –0.38
EO_Foam_Sway_Area	40 % <i>p</i> (0.005–0.031) rho = 0.24–0.30	NS	NS	NS	<i>p</i> (0.022) rho = –0.	<i>p</i> (0.050) rho = –0.22	<i>p</i> (0.000) rho = –0.48	<i>p</i> (0.000) rho = –0.45	<i>p</i> (0.000) rho = –0.38	<i>p</i> (0.000) rho = –0.47
EO_Tandem_SP_AP_axis	60 % <i>p</i> (0.001–0.047) rho = 0.22–0.37	83,33 % <i>p</i> (0.005–0.0018) rho = 0.26–0.30	100 % <i>p</i> (0.000–0.001) rho = (–0.35) – (–0.38)	100 % <i>p</i> (0.002–0.003) rho = 0.32–0.34	<i>p</i> (0.001) rho = –0.35	<i>p</i> (0.005) rho = –0.31	<i>p</i> (0.003) rho = –0.32	<i>p</i> (0.048) rho = –0.22	<i>p</i> (0.002) rho = –0.34	<i>p</i> (0.005) rho = –0.31
EO_Tandem_SP_ML_axis	60 % <i>p</i> (0.000–0.015) rho = 0.27–0.42	16,67 % <i>p</i> (0.005) rho = 0.30	100 % <i>p</i> (0.000) rho = (–0.38) – (0.42)	100 % <i>p</i> (0.000–0.002) rho = 0.34–0.42	<i>p</i> (0.032) rho = –0.24	NS	<i>p</i> (0.001) rho = –0.36	NS	<i>p</i> (0.004) rho = –0.31	<i>p</i> (0.008) rho = –0.29
EO_Tandem_Sway_Area	70 % <i>p</i> (0.000–0.045) rho = 0.22–0.39	33,33 % <i>p</i> (0.005–0.046) rho = 0.22–0.31	100 % <i>p</i> (0.001–0.003) rho = (–0.32) – (–0.35)	100 % <i>p</i> (0.000–0.003) rho = 0.33–0.38	<i>p</i> (0.006) rho = –0.30	<i>p</i> (0.038) rho = –0.23	<i>p</i> (0.001) rho = –0.37	NS	<i>p</i> (0.001) rho = –0.36	<i>p</i> (0.009) rho = –0.29
EO_TF_SP_AP_axis	20 % <i>p</i> (0.030–0.040) rho = 0.23–0.24	33,33 % <i>p</i> (0.042–0.043) rho = 0.22	80 % <i>p</i> (0.014–0.029) rho = (–0.24) – (–0.27)	20 % <i>p</i> (0.049) rho = 0.22	<i>p</i> (0.015) rho = –0.27	<i>p</i> (0.004) rho = –0.31	<i>p</i> (0.017) rho = –0.26	<i>p</i> (0.037) rho = –0.23	<i>p</i> (0.043) rho = –0.22	<i>p</i> (0.019) rho = –0.26
EO_TF_SP_ML_axis	90 % <i>p</i> (0.000–0.048) rho = 0.39–0.22	16,67 % <i>p</i> (0.039) rho = 0.23	100 % <i>p</i> (0.001–0.003) rho = (–0.32) – (–0.36)	100 % <i>p</i> (0.004–0.038) rho = 0.23–0.31	<i>p</i> (0.005) rho = –0.31	<i>p</i> (0.001) rho = –0.35	<i>p</i> (0.006) rho = –0.30	<i>p</i> (0.034) rho = –0.23	<i>p</i> (0.018) rho = –0.26	<i>p</i> (0.006) rho = –0.30
EO_TF_Sway_Area	60 % <i>p</i> (0.009–0.050) rho = 0.22–0.29	33,33 % <i>p</i> (0.029–0.034) rho = 0.23–0.24	80 % <i>p</i> (0.003–0.016) rho = (–0.27) – (–0.32)	40 % <i>p</i> (0.029–0.038) rho = 0.23–0.24	<i>p</i> (0.008) rho = –0.29	<i>p</i> (0.011) rho = –0.28	<i>p</i> (0.007) rho = –0.30	NS	<i>p</i> (0.015) rho = –0.27	<i>p</i> (0.021) rho = –0.25
EC_SP_AP_axis	60 % <i>p</i> (0.004–0.017) rho = 0.26–0.32	66,67 % <i>p</i> (0.003–0.035) rho = 0.23–0.32	60 % <i>p</i> (0.011–0.023) rho = (–0.25) – (–0.28)	80 % <i>p</i> (0.008–0.023) rho = 0.25–0.29	<i>p</i> (0.046) rho = –0.22	NS	<i>p</i> (0.004) rho = –0.31	<i>p</i> (0.000) rho = –0.45	<i>p</i> (0.012) rho = –0.27	<i>p</i> (0.000) rho = –0.39
EC_SP_ML_axis	100 % <i>p</i> (0.000–0.042) rho = 0.22–0.46	100 % <i>p</i> (0.000–0.025) rho = 0.24–0.39	100 % <i>p</i> (0.000) rho = (–0.45) – (–0.51)	100 % <i>p</i> (0.000–0.000) rho = 0.45–0.49	<i>p</i> (0.010) rho = –0.28	NS	<i>p</i> (0.000) rho = –0.39	<i>p</i> (0.001) rho = –0.36	<i>p</i> (0.008) rho = –0.29	<i>p</i> (0.000) rho = –0.38
EC_Sway_Area	60 % <i>p</i> (0.000–0.003) rho = 0.33–0.39	83,33 % <i>p</i> (0.000–0.036) rho = 0.23–0.38	100 % <i>p</i> (0.000–0.011) rho = (–0.28) – (–0.39)	100 % <i>p</i> (0.001–0.027) rho = 0.24–0.34	<i>p</i> (0.044) rho = –0.22	<i>p</i> (0.048) rho = –0.22	<i>p</i> (0.002) rho = –0.33	<i>p</i> (0.000) rho = –0.41	<i>p</i> (0.013) rho = –0.27	<i>p</i> (0.001) rho = –0.37
EC_Foam_SP_AP_axis	60 % <i>p</i> (0.000–0.007) rho = 0.29–0.40	83,33 % <i>p</i> (0.001–0.018) rho = 0.26–0.35	100 % <i>p</i> (0.000–0.009) rho = (–0.29) – (–0.40)	100 % <i>p</i> (0.000–0.006) rho = 0.30–0.38	NS	NS	<i>p</i> (0.008) rho = –0.29	<i>p</i> (0.002) rho = –0.33	NS	<i>p</i> (0.004) rho = –0.31
EC_Foam_SP_ML_axis	70 % <i>p</i> (0.000–0.027) rho = 0.25–0.41	83,33 % <i>p</i> (0.002–0.044) rho = 0.22–0.33	100 % <i>p</i> (0.000–0.002) rho = (–0.034) – (–0.45)	100 % <i>p</i> (0.000–0.001) rho = 0.36–0.40	<i>p</i> (0.036) rho = –0.23	NS	<i>p</i> (0.001) rho = –0.35	<i>p</i> (0.015) rho = –0.26	<i>p</i> (0.019) rho = –0.26	<i>p</i> (0.005) rho = –0.31
EC_Foam_Sway_Area	50 % <i>p</i> (0.006–0.040) rho = 0.23–0.30	33,33 % <i>p</i> (0.009–0.036) rho = 0.23–0.26	100 % <i>p</i> (0.002–0.023) rho = (–0.25) – (–0.33)	100 % <i>p</i> (0.016–0.030) rho = 0.24–0.27	NS	NS	<i>p</i> (0.014) rho = –0.27	<i>p</i> (0.038) rho = –0.23	<i>p</i> (0.042) rho = –0.22	<i>p</i> (0.032) rho = –0.24

($p = 0.003$; $\rho = 0.32$), EO_Tandem_SP_ML_axis ($p = 0.004$; $\rho = 0.32$), EO_Tandem_Sway_Area ($p = 0.005$; $\rho = 0.31$), EC_SP_ML_axis ($p = 0.003$; $\rho = 0.32$), EC_Sway_Area ($p = 0.005$; $\rho = 0.30$). These data were confirmed by the correlations with Tinetti and Downton scales: inverse correlation between age and Tinetti balance score ($p = 0.001$, $\rho = -0.35$, the lower the score on the Tinetti test, the higher the risk of falling) and by the direct correlation with Downton index ($p = 0.005$, $\rho = 0.30$, the higher the score on the Downton index, the higher the risk of falling).

Regarding the correlation with BMI, the postural parameters most significantly correlated were EO_Sway_Area ($p = 0.001$; $\rho = 0.35$), EO_Foam_SP_AP_axis ($p = 0.004$; $\rho = 0.32$), EO_Foam_Sway_Area ($p = 0.001$; $\rho = 0.37$), EC_SP_AP_axis ($p = 0.001$; $\rho = 0.35$), EC_Sway_Area ($p = 0.0001$; $\rho = 0.38$), EC_Foam_SP_AP_axis ($p = 0.005$; $\rho = 0.31$), EC_Foam_Sway_Area ($p = 0.001$; $\rho = 0.34$). BMI was correlated with Downton index ($p = 0.23$; $\rho = 0.25$) but not Tinetti score ($p = 0.019$; $\rho = -0.13$).

Regarding gender differences, significant differences were observed for the following postural parameters EO_Sway_Area ($p = 0.019$; $Z = -2.354$), EO_Foam_SP_AP_axis ($p = 0.033$; $Z = -2.130$), EO_Tandem_SP_AP_axis ($p = 0.029$; $Z = -2.185$), EO_Tandem_SP_ML_axis ($p = 0.028$; $Z = -2.194$), EO_Tandem_Sway_Area ($p = 0.036$; $Z = -2.093$).

We evaluated the effect of age, BMI and gender potential contributors to the presence or not of neuropathy in logistic regression analyses aimed to determine which postural parameters were related to different impairments and clinical tests (see Results section 3.5.).

A history of ulcers was significantly associated with all the postural parameters analyzed (p values < 0.05 – 0.01) except for sway area recorded with eyes open with foam, eyes closed with foam and eyes closed (EO_Foam_Sway_Area, EC_Sway_Area and EC_Foam_Sway_Area). The validated scales that assessed the risk of falls (Tinetti and Downton) were significantly ($p < 0.05$) associated with postural parameters (Sway area and Sway Path of the displacement along the antero-posterior (AP) and medio-lateral (ML)) recorded during the test performed with eyes open and eyes open with foam. In particular, the Tinetti score and the Downton index were significantly ($p < 0.05$) associated with all types of postural tests and parameters (Table 3). Although the total Tinetti score and the Downton index were correlated with each other and with postural parameters, our results support the validity of wearable sensors for measuring balance impairments and risk of falls in DPN patients.

Muscular strength and the Lunge test were significantly ($p < 0.05$) correlated with almost all parameters and types of tests, confirming that postural balance is highly dependent on muscle strength and the limited range of motion of the ankle joint. P values for the significant differences/correlations between postural parameters and clinical tests described above are shown in Tables 2 and 3.

3.3. Analysis of postural parameters and DPN

In the relationships between postural parameters and superficial sensitivity measured by Pin-Prick test, only 6 of the 18 parameters analyzed were significantly associated with reduced pain sensitivity (EO_Tandem_SP_AP_axis: $p = 0.007$; EO_Tandem_SP_ML_axis: $p = 0.008$; EO_Tandem_Sway_Area: $p = 0.007$; EO_TF_Sway_Area: $p = 0.041$; EC_SP_ML_axis: $p = 0.021$; EC_Foam_SP_AP_axis: $p = 0.026$, Mann-Whitney test). No significant associations were observed for the other postural parameters ($p > 0.05$ in all cases).

As for deep sensitivity, light touch-pressure measured by monofilament was significantly associated with all postural parameters ($0.000 < p < 0.046$) except one, the EC_Sway_Area ($p > 0.05$). Vibratory sensitivity was also associated with all postural parameters ($0.000 < p < 0.035$) except EO_TF_Sway_Area ($p > 0.05$) when it was measured by a tuning fork, whereas when it was measured by the biothesiometer, 9 of the 18 parameters were significantly associated with vibratory sensation (OA_SP_ML_axis: $p = 0.000$; OA_Foam_SP_ML_axis: $p = 0.000$;

OA_Tandem_SP_AP_axis: $p = 0.024$; OA_Tandem_SP_ML_axis: $p = 0.012$; OA_Tandem_Sway_Area: $p = 0.035$; OA_TF_SP_ML_axis: $p = 0.022$; OC_SP_ML_axis: $p = 0.000$; OC_Foam_SP_AP_axis: $p = 0.000$; OC_Foam_SP_ML_axis: $p = 0.000$, Mann-Whitney test). All postural parameters were therefore significantly associated with the deep sensitivity pathway, either with altered light touch-pressure, altered vibratory sensation or both, as occurs in most parameters. However, altered vibratory sensitivity measured by a biothesiometer was not significantly associated with as many postural parameters as the tuning fork test.

The presence of sensory neuropathy (altered monofilament, Pin-Prick, diapason and biothesiometer tests) was significantly associated with all postural parameters ($0.0001 < p < 0.035$) except EO_Foam_Sway_Area, EO_TF_SP_AP_axis, EO_TF_Sway_Area ($p > 0.05$ in all cases) (see Tables 2 and 3).

3.4. Analysis of the relationship between postural parameters and glycosylated hemoglobin

There were significant and positive correlations between glycosylated hemoglobin and two postural parameters e.g. Sway Path of the displacement along the AP axis recorded during the test performed with eyes open and feet close together ($\rho = 0.24$, $p = 0.043$, Spearman's tests) and during Test performed with eyes open, with feet close together and foam ($\rho = 0.25$, $p = 0.034$, Spearman's tests) (Fig. 3). No significant correlations were observed between glycaemia and postural parameters ($p > 0.05$).

3.5. Variables of posture associated with the presence of neuropathy: logistic regression analysis

To determine how much the presence of neuropathy (assessed with different tools used to evaluate deep sensitivity) was influenced by the variables found to be significantly associated in bivariate analyses to the presence of neuropathy, a multiple logistic regression model was applied. Starting with the variables that were significant in the previous analyses, we analyzed the parameters of posture found previously significantly associated, age, gender and BMI to explain and predict the presence of neuropathy. Thus, a backward statistical procedure was applied, with the initial model taking the multiple logistic regression model (that included the main effects of all the explanatory variables) as input and also including presence or not of neuropathy as a response variable. Eight posture parameters, BMI and gender significantly ($p > 0.05$) predict the presence of neuropathy based on vibration sensitivity (measured with the diapason) (Table 4). In contrast the variable "EO_SP_ML_axis" and gender were the variables that significantly ($p > 0.05$) predict the presence of neuropathy based on vibration sensitivity (measured with the biothesiometer). The presence of neuropathy based on protective sensation assessed with the (monofilament) was significantly ($p < 0.05$) predicted by "EO_Foam_SP_ML_axis" and gender. The presence of neuropathy based on the International Working Group of the Diabetic Foot (IWGDF) (considering protective sensation test and vibratory sensitivity evaluated by the biothesiometer) was significantly ($p < 0.05$) predicted by the posture parameter "OA_SP_ML_axis" and gender (Table 4).

4. Discussion

Postural impairments may play an important role in DPN complications, but dedicated screening methods and treatment strategies are still lacking. There is therefore an urgent need to identify the most accurate early postural biomarker of nerve damage for improved diagnosis of DPN in the clinical care of patients, and to enable an accurate evaluation of future therapies in clinical trials.

DPN and LOPS are the most common manifestations of diabetes, and affect all sensory modalities of pain and thermal sensation (small

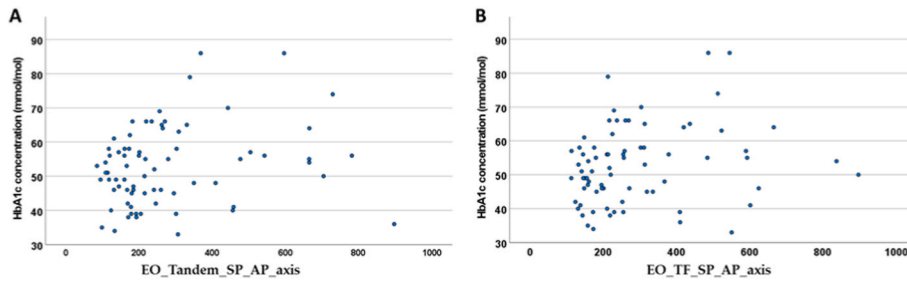


Fig. 3. (A) Correlation analysis between the HbA1c score and Sway Path of the displacement along the AP axis recorded during tests performed with eyes open and feet close together; (B) Correlation analysis between the HbA1c score and Sway Path of the displacement along the AP axis recorded during tests performed with eyes open, feet close together and foam.

Table 4

Final logistic regression model: variables associated with the presence of neuropathy.

Presence of neuropathy based on vibration sensitivity (diapason)				
Variables	p-value	Exp(B)	95 % C.I. EXP (B) LL	95 % C.I. EXP(B) UL
EO_SP_AP_axis	0.009	0.95	0.91	0.99
EO_SP_ML_axis	0.001	1.11	1.04	1.18
EO_Tandem_SP_AP_axis	0.020	1.03	1.01	1.06
EO_Tandem_Sway_Area	0.013	0.95	0.92	0.99
EO_TF_SP_ML_axis	0.048	1.01	1.00	1.02
EC_SP_AP_axis	0.041	1.03	1.00	1.06
EC_Sway_Area	0.009	0.73	0.57	0.92
EC_Foam_Sway_Area	0.016	1.29	1.05	1.58
BMI	0.037	0.64	0.42	0.97
Gender	0.003	392.66	7.42	20783.78
Presence of neuropathy based on vibration sensitivity (biothesiometer)				
EO_SP_ML_axis	0.019	1.02	1.004	1.044
Gender	0.041	2.95	1.05	8.31
Presence of neuropathy based on protective sensitivity (monofilament)				
EO_Foam_SP_ML_axis	0.002	1.07	1.02	1.11
Gender	0.018	7.89	1.43	43.66
Presence of neuropathy based on the International Working Group of the Diabetic Foot (IWGDF) (considering protective sensation test and vibratory sensitivity evaluated by the biothesiometer)				
EO_SP_ML_axis	0.001	1.05	1.02	1.07
Gender	0.010	10.55	1.75	63.66
Categorized Tinetti scale score (medium/high versus low fall risk)				
EC_SP_ML_axis	0.002	1.03	1.01	1.04
Categorized Downton index score (high versus low fall risk)				
EO_Foam_SP_AP_axis	0.017	1.01	1.00	1.03
EO_Tandem_Sway_Area	0.021	1.01	1.00	1.02

LL: lower limit; UL: upper limit; Exp(B): or the odds ratio, is the predicted change in odds for a unit increase in the predictor. The “exp” refers to the exponential value of B. When Exp(B) is less than 1, increasing values of the variable correspond to decreasing odds of the event’s occurrence, when Exp(B) is more than 1 is the opposite.

unmyelinated C fibers and small myelinated Aδ fibers), vibration, and touch (large myelinated Aβ fibers).

Diabetic polyneuropathy primarily involves C unmyelinated nerve fibers, poorly myelinated Aδ fibers, and myelinated AB fibers. Aδ and C fibers collect thermal and pain information (in particular, Aδ fibers convey sensations related to cold and C fibers sensations related to heat), while Aβ are large fibers and convey tactile and vibratory sensitivity [71, 72]. Distal sensory neuropathy is considered a mixed small- and large-fiber neuropathy and in clinical practice, it is diagnosed by a symmetrical reduction of distal sensation in both feet. Sensory impairment in small nerve fibers (unmyelinated C- and Aδ-fibers) are determined by pinprick testing, whereas sensory impairment in large nerve fibers (Aβ and Aα-fibers) that convey vibratory and light touch-pressure sensation is assessed using tuning forks or quantitative vibration meters such as a biothesiometer [71,72].

Neuropathy progression affects nerve fibers **heterogeneously**,

meaning that different neurophysiological tests are required to identify dysfunction in patients with diabetes. Several studies have assessed postural stability and fall risk in individuals with diabetic neuropathy, and dynamic postural stability has been shown to be impaired in these patients. In fact, subjects with diabetic sensory neuropathy show larger root mean square values for the center of pressure displacement in both anteroposterior and mediolateral directions [73–76]. In order to determine which postural parameters are most affected and correlated with neuropathy, we compared the main diabetic somatosensory screening tests (for the deep and superficial sensitivity) with a wearable-based postural analysis.

Impairment of vibration sensation is associated with balance and walking function, but there is a lack of information regarding the link between screening tests for DPN and the risk of falling among patients with diabetic foot [77–84].

Interestingly, although vibration sensation can be clinically assessed using a tuning fork or, more accurately, by using a biothesiometer to determine vibration perception thresholds [85,86], in our study, the alterations observed in vibratory sensitivity measured by a biothesiometer were less significantly associated than tuning fork test with several postural parameters. A previous study [86] demonstrated that tuning fork is a useful tool in assessing the specific sensory modality of vibratory sensitivity, particularly in people over 50 years of age (being most of the patients involved in the present study aged more than 50 years old), at the hallux and the thumb nail fold because it did not consistently change with age, as found with the assessment with the biothesiometer. These differences between the two instruments used to measure vibratory sensitivity might be explained by the thicker and variable subcutaneous tissue thickness in the explored foot surfaces in fact in our study overweight/obesity reduce the evaluation of neuropathy only when it was assessed by the diapason (see Table 4).

Regarding the lack of relevant correlations of Pinprick test and postural parameters, this could be due this test relies on application of controlled pressure by the clinician and this can lead to high variability during measurements thus, in turn, leading to different values compared to other DPN tests [87]. In addition, many patients are likely to be missed if they report unimpaired subjective perception of pinprick sensation [88] or/and that small-fiber neuropathy was too small in our patients to be detected with this test. This fact support the use of multimodal testing is recommended in clinically suspected cases to positively rule out small fiber neuropathy.

We compared the association between some DPN tests and a wearable-based postural analysis in order to understand which postural parameters and clinical tests are more predictive for detecting a diabetic person with postural impairments and risk of falling. As for clinical variables, a “previous history of foot ulcers” was strongly associated with all postural parameters recorded, as well as muscular strength and the Lunge test. Postural investigation using wearable inertial sensors enables identification of balance abnormalities that may also adversely affect foot ulceration.

Although several studies previously agreed that people with diabetes

present higher levels of postural sway than people without diabetes, to our knowledge, the present study is the first to apply wearable inertial sensors to investigate at the same time DPN with several DPN tests, muscle weakness, risk of fall scales, foot deformities, Achilles tendon extensibility, osteotendinous reflexes and postural impairments [83].

We selected nine postural parameters and eight tests performed under different conditions: eyes open (EO) and eyes closed (EC) with or without somatosensory perception disturbances (foam) and with or without feet close together, for a duration of at least 30 s which gave a detailed analysis of postural parameters.

Inertial Measurement Units (IMUs) are increasingly being used in posturography, but wearable sensors have not yet become a standard in posturography in terms of the gold standard of the force platform. Force platforms are expensive and heavy to transport, making them impractical in clinical settings, unlike wearable sensors that provide a cheap and accessible means to efficiently collect and process large amounts of balance data in an unconstrained environment. IMUs systems have good reliability and repeatability compared to gold standard (optoelectronic measurement system). A study found that the repeated measurements with the accelerometer located on the lower back to acquire medio-lateral (M-L) and anterior-posterior (A-P) accelerations display an intraclass correlation coefficients from good to excellent (with values ranging from .736 to .972 for trial-to-trial and from 0.760 to 0.954 for block-to-block) [89] and good during measurements of static and dynamic postural adjustment of the body [90]. In people with diabetes, Najafi et al. observed a good correlation ($r = 0.92$) between center of mass (COM) measured using a wearable inertial sensor and center of pressure (COP) measured using the pressure platform [30]. In addition, these devices provide a cheap and accessible means to efficiently collect large amounts of human balance data in clinical environment compared to force platform, electromyography and motion capture systems that require costly equipment and trained engineers only available in a movement analysis research laboratories [91]. It is important to acknowledge that the use of wearable sensors to assess postural balance is an area of research that is still developing, despite the large number of papers focusing on this topic.

Deep diabetic neuropathy tests were more closely related to balance measures than superficial diabetic sensitivity tests, suggesting that not all DPN tests can be considered reliable for detecting patients with a risk of falling. No correlation was found between DPN and postural tests performed with eyes closed with feet closed together or performed with eyes closed and feet together and foam. This result was probably due to the difficulty in performing this test reported by many patients during the study. Deep sensitivity pathway impairment seems to have a significant implication in balance alterations, as evidenced by the fact that the score on the Tinetti scale and Downton index was significantly associated with the wearable-based postural analysis. This result suggests that the data collected are useful, as they show how a sensorized analysis of posture in diabetic patients can correlate with validated scales when investigating the risk of falling.

Most postural parameters detected by wearable inertial sensors were significantly associated with the deep sensitivity measurements either with altered light touch-pressure, altered vibratory sensation or both, suggesting they can be useful for detecting patients with balance impairments and risk of fall in bivariate analyses. Multivariate analyses revealed that some of the posture parameters can predict the presence of peripheral neuropathy with some differences depending on the methods used to measure neuropathy. The best parameter that appear predicting the presence of neuropathy is the sway path of the displacement along the ML axis as it predicted the presence of neuropathy in all tests used to analyse neuropathy in deep sensitivity pathway e.g. vibration sensitivity (with either diapason and biothesiometer), protective sensation (monofilament) and presence of neuropathy based on the International Working Group of the Diabetic Foot. The same posture variable associated with neuropathy in the deep sensitivity tests had also a significant effect upon Tinetti score dichotomizing individuals with medium/high

risk versus low risk of falls, whereas with the dichotomized Downton index score, the parameters sway area and antero-posterior sway pathway are the strongest significant association. Assessment of postural control during upright stance has shown that patients with diabetes and peripheral neuropathy may sway more than those without peripheral neuropathy [19,22,75,92,93]. We have found that men had higher odds to have neuropathy compared to women confirming previous results on gender differences [92,93]. These gender differences may also be attributed the onset of diabetic neuropathy, with males developing earlier than females [94,95] to proposed gender differences in lifestyle with men's lifestyles being more hazardous (stressful jobs, smoking habits, alcohol and drug use, lower compliance with treatment) than women's [96]. The finding of a larger sway in men than in women is consistent with previous reports showing that men may exhibit more spontaneous sway than women, and this difference may increase when there is no visual input [97,98].

Diabetic patients with a poor glycemic control, muscular weakness, a reduced range of motion of ankle, history of ulcers, impaired peripheral sensory neuropathy and risk of falling can be expected to magnify in particular, the sway path of the displacement along the AP axis recorded during the test performed with eyes open and feet close together. Further clarification of the relationship between this postural parameter and these important risk factors for people with diabetes is obviously needed, but if these relationships and interacting mechanisms are confirmed, some postural parameters recorded with a wearable sensor will play a key role in the diagnosis, prognosis and clinical management of DPN. It is important to note that our study had some limitations. Firstly, the relatively small sample size of our sample that was representative for the diabetic foot patients attending during one year the Academic podiatry clinic at the University of Bologna (IRCCS Rizzoli Orthopaedic Institute, Bologna) so our findings may not represent the population of individuals with diabetes". Second due to reduced number of diabetes type I the comparison with type II diabetes in the outcomes of the study can be underestimated. In addition, the use of neurological tests with different specificity and sensitivity can influence the strength of significant results, that why the need of more objective quantitative data such as those obtained with the sensors. Using different neurological tests such as Tinetti and Downton scale can reduce the pitfall in detecting significant differences, especially when sensitivity or specificity of neurological test are moderate (50–70 %). Probably a set of quantitative measures (composite score) including data from sensor analysis, neurological tests and clinical data could be useful mainly for older adults in order to avoid ceiling and floor effects that are commonly encountered.

Studies with a larger sample are required to clarify the course of nerve fiber impairment in DPN and to increase knowledge of the influence of this damage on posture. All the results suggested the feasibility and the importance of using wearable platforms to quantify balance performance during diabetic foot screening practices, but consensus on the assessment protocols and parameters is still lacking, and future research should focus on standardizing the measurement setup and selecting the most informative postural parameters and types of tests. The results provided in this study can be used to gain a thorough understanding of the existing wearable sensor technologies, and to improve future wearable devices developed for fall risk assessment in people with DPN.

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Credit authorship contribution statement

Conceptualization: LB; MSB; AM; EA; IJR; OC Methodology: LB; MSB Software: MS-B; OC Validation: LB Formal analysis: LB; MS-B; AM; EA;

IJ-R; OC Investigation: LB; MSB Resources: LB; MS-B; AM; EA; IJ-R; OC Data curation: LB; MS-B; AM; EA; IJ-R; OC Writing: Original Draft: LB Writing: Review and Editing: LB; MS-B; AM; EA; IJ-R; OC Visualization: LB; MS-B; AM; EA; IJ-R; OC Supervision: OC Project administration: OC; IJR Funding acquisition: N/A.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Abbreviations

- EO* =: Test performed with eyes open
EO Foam =: Test performed with eyes open and foam
EO Tandem =: Test performed with eyes open and feet close together
EO TF =: Test performed with eyes open, feet close together and foam
EC =: Test performed with eyes closed
EC Foam =: Test performed with eyes closed and foam
**foam* =: foam surface of 4-cm thick and 35 kg/m³ dense
SP_{AP} axis =: Sway Path of the displacement along the AP axis (mm)
SP_{ML} axis =: Sway Path of the displacement along the ML axis (mm)
Sway Area =: Sway Area (mm × 2)