Diabetic Foot Assessment of People With Diabetic Peripheral Neuropathy And Associated Factors To Plantar Pressure Changes.

Juliana Vallim Jorgetto (✉ julianavallim26@gmail.com)

Federal University of Sao Paulo: Universidade Federal de Sao Paulo   https://orcid.org/0000-0003-3758-5201

Daniella Silva Oggiam

UNIFESP: Universidade Federal de Sao Paulo

Monica Antar Gamba

UNIFESP: Universidade Federal de Sao Paulo

Denise Miyuki Kusahara

UNIFESP: Universidade Federal de Sao Paulo

Research Article

Abstract

Diabetic neuropathy is one of the main complications of Diabetes Mellitus, which can lead to loss of protective sensation, motor alteration, in plantar pressure, generating deformities, abnormal gait and mechanical trauma to the feet.

OBJECTIVE: to evaluate the distribution of plantar pressure, sensorimotor changes, balance and associated factors to plantar pressure changes in people with peripheral diabetic neuropathy.

METHOD: Cross-sectional study conducted with individuals registered in the municipal public health network of a city in the east of São Paulo - Brazil, with Diabetes Mellitus and Peripheral Neuropathy identified by the Michigan Screening Instrument, sensory-motor changes by the International Consensus, static and dynamic assessments of plantar pressure using Baropodometry with BaroScan and balance using the Berg scale.

RESULTS: Of the 200 individuals evaluated, 52.55% had no plantar protective sensitivity, the static evaluation did not identify changes in the peak of plantar pressure, however in the dynamics the average in the right foot was 6.08 (± 2) kgf / cm2 and 6 , 7 (± 1.62) kgf / cm2 on the left foot, the center of static pressure on the right foot was lower (10.55 ± 3.82) than on the left foot (11.97 ± 3.90), pointing hyper plantar pressure. The risk of falling was high, ranging from 8 to 56 points, with an average of 40.96 (± 10.77).

CONCLUSION: The absence of protective plantar sensitivity, increased pressure, biomechanical changes lead to loss of balance and are predictive of complications in the feet due to diabetic neuropathy.

Introduction

Among the complications of diabetes, Peripheral Diabetic Neuropathy (NDP) is the most common and comprises a set of clinical changes that affect the peripheral sensory, motor and autonomic nervous systems, in an isolated or diffuse manner, in the proximal or distal segments. It affects about 50% of people with DM over 60 years of age, and may be present before the loss of protective sensitivity is detected, resulting in greater vulnerability to trauma and greater risk of developing ulcerations [1].

The causes of NDP are multifactorial and are related to long-term hyperglycemia and ischemia of sensitive, motor and autonomic nerve fibers, leading to thickening of the vascular walls and obstruction of blood flow. Symptoms include burning pain, stinging, paresthesia, feelings of cold and heat, and hyperesthesia, which tend to exacerbate at night. Signs include reduced sensitivity to pain, vibration and temperature, hypotrophy of small interosseous muscles (claw and hammer toes), anhidrosis and distention of the dorsal veins of the feet. Autonomic dysfunction leads to an increase in arteriovenous shunts, making the foot warm and insensitive, identified as a foot at high risk for injuries [2].

NDP is the complication responsible for 40–70% of non-traumatic lower limb amputations. Approximately 20% of hospitalizations of individuals with diabetes occur due to lower limb injuries and 85% of lower limb amputations in individuals with DM are preceded by ulcerations, with the main associated factors being foot deformities and trauma [3, 4].

Sensorimotor Neuropathy, one of the manifestations of NDP, causes a gradual loss of protective pedal sensation, which makes them vulnerable to trauma. Furthermore, one of the consequences of Sensorimotor Neuropathy is the atrophy of the intrinsic muscles of the foot, causing an imbalance between flexor and extensor muscles, triggering osteoarticular deformities leads to claw and hammer toe deformities, overlapping toes, head prominences metatarsal and hallux valgus (bunion) [3]. Such deformities alter the pressure points in the plantar region, leading to overload and skin reaction with local hyperkeratosis (callus), which with continuous walking can progresses to plantar ulceration [4]. The loss of skin integrity in the situations described above constitutes an important gateway for the development of infections, which can progress to amputation [5].

In view of the magnitude of the problem and the multiple causes that favor the onset of injuries and ulcerations in the feet of people with diabetes, a thorough evaluation of the lower limbs is fundamental for the early recognition of changes that may prevent the onset of injuries.

In addition to clinical and physical examination through inspection and palpation techniques to check for possible skin, musculoskeletal and vascular changes, the baropodometry can be used to measure foot plantar pressures distribution can reveal the interface pressure between the foot plantar surface and the sole and ability of static and dynamic overload of specific structures or anatomical areas of the foot, in addition to considerations about its function and postural control.

The baropodometer is an advanced force platform that provides data with a high diagnostic value. It offers direct and indirect information about the position of the patient in the standing position, dynamic gait analysis, distribution of loads during walking, peak pressure and contact time with the ground, and detection of areas in risk on foot and helps in the production of orthotic insoles, and detection of biomechanical abnormalities of the foot mainly in pathological conditions such as NDP, the recovery of foot biomechanical function. [6].

This system also allows the identification of pressure center (COP), a parameter that represents a weighted average of the total pressure exerted on the surface in contact with the ground, where its trajectory and displacement parameters can be adopted as indicators of balance and body posture, making it fundamental tools to provide information on the postural balance of individuals with NDP [7, 8].

In this context, devices capable of detecting plantar pressures are a way to obtain objective functional parameters of the foot, presenting important clinical advantages, as they allow diagnose foot problems at an early stage for injury prevention, risk management and general wellbeing [9].

There are a variety of plantar pressure measurement systems but in general they can be classified into one of two types: platform systems and in-shoe systems. In the In-shoe systems, sensors are flexible and embedded in the shoe such that measurements reflect the interface between the foot and the shoe. The system is portable which allows a wider variety of studies with different gait tasks, footwear designs, and terrains, but present as a further limitation the fact of spatial resolution of the data is low compared to platform systems due to fewer sensors [10].

Healthy individuals, in a static situation, present plantar pressure in the posterior region of the foot of up to 6kgf / cm2, however, people with NDP may have their plantar load distribution modified with damage to the biomechanics of the feet, balance and gait, allowing increased plantar pressure in some areas of the foot to the detriment of others, predisposing them to the occurrence of injuries. Considering the relationship between the risks of foot ulceration and the increase in plantar pressure, the use of baropodometry assumes relevant clinical applicability in the prevention of these injuries [11], as well as in the evaluation of the effectiveness of interventions, conservative or surgical procedures in the feet with disorders.

The recognition of the most frequent changes in the feet of people with DM by primary care professionals is a necessary condition for the reduction of injuries, as it generates information that allows directing the assessment during the care of the multidisciplinary team and in the prevention of complications.

Thus, this study aims to evaluate the foot, distribution of plantar pressure and associated factors to change of plantar pressure in individuals with NDP.

Method

Study design

Cross-sectional, descriptive study was carried out in Primary Health Care Units in the city of São João da Boa Vista - SP, in East Paulista, Brazil, between November 2018 and February 2019.

This study is part of a doctoral thesis that is being carried out at the Federal University of São Paulo, Brazil, whose main objective is to evaluate the effect of therapeutic footwear on diabetic patients with NDP and plantar changes. Thus, in this cross-sectional study, we included only patients with this involvement.

Participants were recruited when they were consulted at the Primary Health Care Units, at which time they were invited to participate in the study, and upon acceptance, signed the free and informed consent form - ICF.

Individuals with type 2 Diabetes Mellitus (DM2), registered in the municipal public network of the city, aged over 30 years, more than five years of diagnosis of DM2 and previous diagnosis of NDP, identified from screening by Michigan Screening System (MNSI) were included [11]. Exclusion criteria were

established as individuals with cognitive impairment that prevented them from meeting requests during care, preventing the complete feet assessment.

The selection of participants was determined by means of a non-probabilistic sample per cluster from a population of 2542 individuals diagnosed with DM2 and registered in the 13 Basic Public Health Units in the city. According to prevalence estimated by other studies, the sample was calculated assuming that about 50% of people with diabetes will have diabetic neuropathy over the course of the disease. Therefore, we included a sample of 200 individuals assuming a sampling error of 6.5% and the 95% confidence interval.

Outcome variables were sensorimotor changes: protective pedal sensation, Achilles reflex, vibratory sensitivity, dermatological changes, osseous deformities, muscle strength and function identified according to the International Consensus on Diabetic Foot [2]; in addition to balance changes, and changes in plantar pressure. In order to characterize the participants, demographic and clinical variables and the use of appropriate footwear were also investigated. Adequate shoes were considered those with soft material and without internal seams, height and width proportional to the size of the foot and its possible deformities with semi-flexible sole [12].

For the evaluation of the feet and identification of changes, a thorough physical examination was performed, consisting of sensory and motor evaluation. The sensory evaluation was carried out using the plantar protective sensitivity tests (Semmes-Weinstein 10 g monofilament), vibratory sensitivity (128 Hz tuning fork) and the Aquileu Reflex test, following the guidelines of the Brazilian Diabetes Society, given by the International Working Group on the Diabetic Foot (IWGM) [12].

The motor / functional evaluation of the feet consisted of muscle strength tests and functional tests in activities of daily living and biomechanics. Muscle function tests were based on the protocols established by Kendall et al. [13], which grades the muscle strength of the foot and ankle from 0 to 5, with degree zero-0 occurring in degree zero muscle strength on palpation. palpable muscle contraction, grade two-2 joint movement with elimination of gravity, grade three-3 complete joint movement against gravity, grade four-4 complete joint movement against gravity and some resistance and grade five-5 normal muscle strength against gravity and resistance.

The functional evaluation of the lower limbs was performed using tests described by Palmer and Epler [14], which use the number of repetitions of movements performed by the subject in the period of 30 seconds, in the standing and sitting positions, as the scale for data analysis. divided into 4 levels: non-functional, poorly functional, reasonably functional and functional. For inversion and eversion movements, the following repetitions are considered: 0 = non-functional, 1−2 = poorly functional, 3−4 = reasonably functional and 5−6 = functional, while for the other movements are considered: 0 non-functional, 1−4 poorly functional, 5−9 reasonably functional and 10-up as functional.

The Berg Balance Scale [15], also called Balance Scale, was used to assess the participants' balance, where the risk of falling is assessed by testing tasks related to day-to-day activities, involving static and

dynamic balance. Through this scale, scores between 54 to 56 points indicate risk of mild fall, 54 to 46 indicate moderate risk of fall and scores between 46 – 36 risk of severe fall.

The static and dynamic evaluation of the plantar pressure was performed using a baropodometer platform (BAROSCAN®, Londrina, Paraná, Brazil), which is composed of 4096 sensors with 5mm of surface of each sensor distributed in an area of 50x50cm of active surface, 10mm of thickness, frequency of acquisition of 200 Hz and resistive technology with 12-bit analog conversion coupled to a microcomputer, making it possible to perform these types of exams, as it allows to identify the foot typology, evaluate the distribution of static or dynamic plantar pressures, identify the pressure center (COP) and the points of maximum pressure, minimum and average pressure and take into account the area and time of contact of the feet with the ground (contact surface) [16].

We chose this evaluation method because platform systems are constructed from a flat, rigid array of pressure sensing elements arranged in a matrix configuration and embedded in the floor to allow normal gait and can be used for both static and dynamic studies calculating the relationship between force and pressure on a support platform composed of sensors capable of capturing, comparing and measuring pressures in different regions of the plantar surface and the pressure center [7].

In addition to formulating an index capable of evaluating the effectiveness of rehabilitation devices, such as orthoses, dynamic study of the function and the process of rolling the foot, calculating the degree of torsion the axis of the foot joint and the assessment of movement, which can show us the reliability of these parameters for such changes [17].

Patients were instructed to walk in a straight line through the examination room and when they reached the platform, step first with their right foot on the outward route, and on the return, with their left foot. The route was repeated three times by the patients to calculate the average peak pressure exerted by the feet on the platform [18]. It is noteworthy that all patients underwent a period of adaptation to the equipment, thus minimizing changes due to non-habituation to it, being accepted as a normal value up to 6 kgf / cm2 or 534 kPa, according to the platform used and according to Armstrong and Lavery (1998) [19]. For this study, a platform calibrated in kgf /cm2 was used, in addition to being a fully developed and produced equipment in Brazil.

The COP was obtained by selecting the Save Center of Force option in the platform program, with the oscillation of the pressure center registered and later quantified.

Ethics in human research

The study was approved in 2018 by the institutional research ethics committee with human beings at the Federal University of São Paulo - UNIFESP and Platform Brazil (CAE 2,695,704) and conducted in accordance with national standards that govern clinical research.

Statistical analysis

All collected data were transcribed to a specific data collection form for the study and then entered electronically into a secure database. The data obtained were analyzed according to descriptive statistics through measures of frequency and central tendency, and inferential statistics through the chi-square test, with a significant value equal to or less than 0.05 (5%) being accepted, in addition to calculating the ratio prevalence.

Results

In this study, participated 200 individuals with NDP. The data regarding the sociodemographic characterization and clinical of the studied sample are shown in Table 1.

Table 1

Sociodemographic characterization and clinical of people with Diabetes Mellitus and Neuropathy, Brazil, 2018–2019. n = 200

Variables	n	%	Mean(± DP)	Min-Max
Sociodemographic				
Sex				
Female	135	67.33		
Male	65	32.66		
Age				
< 36 years	20	10.05		
36–46	28	14.07		
47–57	33	16.58		
58–68	63	31.66		
69–79	38	19.10		
> 80 years	17	8.55		
Breed				
White	118	59.30		
Parda	25	12.56		
Black	55	27.64		
Yellow	1	0.50		
Education Level				
Incomplete Elementary School				
Incomplete Elementary School	87	43.72		
Complete Higher Education	26	13.07		
Complete high school	42	21.11		
Incomplete high school	13	6.53		
Complete primary education	17	8.54		
Illiterate	9	4.52		
Incomplete Higher Education	6	3.01		
Occupation				

Variables	n	%	Mean(± DP)	Min-Max
Retired	104	52.76		
Sick leave	3	1.51		
From home	27	13.57		
Occupied	54	27.14		
Unemployed	12	6.03		
Clinical				
Diagnostic time (years)			14.06 ± 9.61	05−45
Weight (kg)			80.73 ± 18.35	45−126
Height (m)			1.63 ± 0.08	1.48−1.80
BMI (kg/cm$^{2)}$			29.15 ± 7.32	27.9−30.3
Glucose (mg/dL			176.26 ± 75.19	33−545
HbA1c (%)			5.76 ± 3.11	5.1−11.0

Among the individuals evaluated, the majority were female, with a mean age of 58.9 ± 14.5 years. About half of the participants had incomplete primary education (43.72%) and were retired (2.0%), with glycemic values above the references, glycated hemoglobin (HbA1c) with wide variation (5.1−11.0%) and overweight.

Regarding chronic complications, peripheral arterial disease was present in 49.5% of individuals, gastrointestinal disorders 32%, retinopathy 17.5%, nephropathy in 2.5%, sexual dysfunction 29%, and amputation in 3.5% of patients. Regarding comorbidities, the most frequent were systemic arterial hypertension (81.5%) and dyslipidemia (56%). As for drug treatment, 82 (41%) individuals used only insulin and 145 (72.5%) metformin and 23 (11.5%) sulfonylureas (gliclazide, glimepiride, glavos, glyphage and glibenclamide).

The results of the sensitive, dermatological and motor evaluations of the sample participants are presented below (Table 2).

Table 2
Distribution of the sensory, dermatological and motor
assessment of the feet of the sample participants. n = 200

Variables	RightFoot	Left Foot
Sensitive	n(%)	n(%)
Plantar protective sensitivity		
Present	22(11.06)	22(11.06)
Reduced	73(36.68)	73(36.68)
Absent	105(52.55)	105(52.55)
Aquileus Reflection		
Present	104(52.00)	83(41.50)
Reduced	56(28.00)	72(36.00)
Absent	23(11.50)	24(12.00)
Vibratory Sensitivity		
Present	96(48.00)	96(48.00)
Reduced	60(30.00)	56(28.00)
Absent	36(18.00)	30(15.00)
Dermatological		
Dermatological disorders	07(3.50)	05(2.50)
Pre-ulceration	04(2.00)	-
Ulceration	151(75.50)	143(71.50)
Callosity	94(47.00)	94(47.00)
Fissure	103(51.5)	89(44.50)
Edema	89(44.50)	91(45.50)
Ringworm	62(31.00)	62(31.00
Hyperpigmentation	175(87.50)	175(87.50)
Dry skin	02(1.00)	05(2.50)
Infection		
Deformities		

Variables	RightFoot	Left Foot
Bone deformities	148(74.00)	141(70.50)
Bone prominence	42(21.00)	32(16.00)
Hallux valgus	42(21.00)	48(24.00)
Claw and / or hammer fingers		

The plantar protective sensitivity was absent in 105 (52.55%) individuals, while the Achilles reflex decreased in 72 (36.18%) people, the vibratory sensitivity present in 96 (48%) of those evaluated, which shows the diversity changes in sensory sensitivity when evaluating NDP.

Regarding dermatological changes and osseous deformities, the skin was dry in most participants (87.5%), while dermatological changes as the presence of calluses was identified in 75.5% of the individuals and the osseous deformity represented by bone prominence in 74% of people.

When analyzing sensitivity and motor changes comparatively between left and right foot, it was found that they were more prevalent in the right foot, except for ringworm and infection.

The classification of strength in the ankle and foot muscles is shown in Table 3.

Table 3
Frequency and percentage of muscle responses for each ankle and foot muscle assessed.

Variables	n = 200	%	Variables	n = 200	%
Long finger flexor Right			Long finger flexor Left		
0	09	4.52	0	07	3.52
1	19	9.55	1	12	6.03
2	48	24.12	2	29	14.57
3	56	28.14	3	67	33.67
4	39	19.60	4	52	10.55
5	18	9.05	5	21	5.53
Long flexor of the hallux Right			Long flexor of the hallux Left		
0	09	4.52	0	06	3.02
1	17	8.54	1	12	6.03
2	30	15.08	2	29	14.57
3	62	31.16	3	67	33.67
4	50	25.13	4	53	26.63
5	22	11.06	5	21	10.55
Long finger extender Right			Long finger extender Left		
0	09	4.52	0	06	3.02
1	16	8.04	1	12	6.03
2	28	14.07	2	27	13.57
3	64	32.16	3	68	34.17
4	50	25.13	4	52	26.13
5	21	10.55	5	22	11.06
Long hallux extender Right			Long hallux extender Left		
0	09	4.52	0	06	3.02
1	17	8.54	1	13	6.53
2	28	14.07	2	25	12.56
3	63	31.66	3	69	34.67

Variables	n = 200	%	Variables	n = 200	%
4	50	25.13	4	54	27.14
5	22	11.06	5	20	10.05
Lumbrical Right			Lumbrical Left		
0	09	4.52	0	06	3.02
1	17	8.54	1	11	5.53
2	26	13.07	2	27	13,.57
3	64	32.16	3	70	35.18
4	52	26.13	4	53	26.63
5	20	10.05	5	21	10.55
Interosseous Right			Interosseous Left		
0	09	4.55	0	06	3.02
1	14	7.04	1	10	5.03
2	33	16.58	2	27	13.57
3	61	30.65	3	72	36.18
4	51	25.63	4	52	26.18
5	21	10.55	5	21	10.55
Tibialis anterior Right			Tibialis anterior Left		
0	09	4,.52	0	06	3.02
1	13	6.53	1	09	4.52
2	32	16.08	2	26	13.07
3	56	28.14	3	66	33.17
4	59	29.65	4	60	30.15
5	20	10.05	5	20	10.05
Triceps surae Right			Triceps surae Left		
0	09	4.54	0	06	3.02
1	13	6.53	1	09	4.52
2	32	16.08	2	27	13.57

Variables	n = 200	%	Variables	n = 200	%
3	57	28.64	3	67	33.67
4	58	29.15	4	59	29.65
5	20	10.05	5	20	10.05

It can be seen from Table 3 that the degrees of strength 2, 3 and 4 were the most present for all muscles, however there is an expressive frequency of individuals who already manifest diabetic motor neuropathy, with weakening of the intrinsic muscles of the foot, more marked on the right foot.

In Fig. 1, it is possible to observe the categorization of the functional analysis of the movements of the feet and ankle in the studied sample.

Regarding the functionality of the movements using the Palmer and Epler test [14], the extension of the toes was the most functional of the movements, with more than 90% of representativeness among the study participants. The minimum number of repetitions was zero, as out of the 200 evaluated, 10 were unable to perform the movements due to other pathological processes affected, such as ankle fracture, visual impairment and ulceration.

The baropodometric variables evaluated in this study were the plantar pressure and average, maximum and minimum dynamic plantar pressure, as well as the COP and contact surface area. Regarding the static evaluation, it can be observed that no individual had peak plantar pressure, that is, the mean static plantar pressure in the right foot was 2.72 ($\pm$) kgf /cm^2, with a maximum of 5.22 and a minimum of 0.96, and on the left foot, the average of 2.52 ($\pm$) kgf /cm^2 with a maximum of 5.61 and a minimum of 0.7.

As for the dynamic assessment of plantar pressure, the average plantar pressure on the right foot was 6.08 ($\pm$ 2) kgf /cm^2, with a maximum of 8.83 and a minimum of 1.64, while on the left foot the average was 6,7 ($\pm$ 1.62) kgf /cm^2 with a maximum of 13.28 and a minimum of 2.21. On the right foot, 35 (17.5%) individuals had peak plantar pressure above 6 kgf /cm^2 and 44 (22%) on the left foot, representing a high risk for possible ulcerations, since the general average of plantar pressure was already found. if above the reference values considered normal for this variable.

The description of the values of plantar pressures, second right and left foot, static and dynamic evaluation are shown in Fig. 2.

The mean of the static COP on the right foot was 10.55 ($\pm$ 3.82) and on the left foot 11.97 ($\pm$ 3.90). This analysis explains why the change in postural balance in the study was considered of severe intensity for the risk of falling.

Regarding the contact surface, it can be called the contact area for each foot during the walk, where statically the average on the right foot was 111.15 ($\pm$ 57.68) and on the left foot 105, 33 ($\pm$ 32.9), while in

the dynamic examination on the right foot it was 605.92 (± 193.4) and on the left foot 507.08 (± 69.27).

Table 4 shows the factors associated with changes in plantar pressure raised in the study.

Table 4 - Correlation between sensory, dermatological and motor changes and plantar pressure in the feet of the sample participants.

Variables	With change in plantar pressure n(%)	No change in plantar pressure n(%)	Prevalence Ratio	Confidence Interval	p-value
Sensitive					
Plantar protective sensitivity					
Present					
Yes	1	21			
No	27	150			
Total	28	171	0,3	[0,04; 2,09]	0,173
Reduced					
Yes	8	65			
No	20	106			
Total	28	171	0,69	[0,32; 1,49]	0,336
Absent					
Yes	19	78			
No	9	93			
Total	28	171	2,22	[1,06; 4,67]	**0,029**
Aquileus Reflection					
Present					
Yes	17	95			
No	11	76			
Total	28	171	1,2	[0,59; 2,43]	0,609
Reduced					
Yes	4	52			
No	24	119			
Total	28	171	0,43	[0,15; 1,17]	0,078
Absent					
Yes	7	16			
No	21	155			
Total	28	171	2,55	[1,22; 5,33]	**0,016**
Vibratory sensitivy					
Present					
Yes	14	82			
No	14	89			
Total	28	171	1,07	[0,54; 2,13]	0,841
Reduced					
Yes	4	56			
No	24	115			
Total	28	171	0,39	[0,14; 1,06]	**0,048**
Absent					
Yes	10	26	2,52	[1,27; 4,98]	**0,009**
No	18	145			
Total	28	171			
Dermatological disorders					
Pre-ulceration R	3				
Yes	47	9			
No	50	140			
Total	149		1,87	[0,66;5,32]	0,261
Pre-ulceration L					
Yes	1	14			
No	49	135			
Total	50	149	0,94	[0,22;3,94]	0,932
Ulceration R					
Yes	2	2			
No	48	147			
Total	50	149			
Ulceration L					
Yes	2	8			
No	48	141			
Total	50	149	1,53	[0,34;6,82]	0,58
Callosity R					
Yes	32	119			
No	18	30			
Total	50	149	8,58	[1,2; 61,5]	**0,006**
Callosity L					
Yes	32	109			
No	18	40			
Total	50	149	11,11	[1,55; 79,83]	**0,001**
Deformities					
Osseous deformities					
Bone prominence R					
Yes					
No	28	120			
Total	0	51			
Bone prominence L	28	171			
Yes					
No	19	120			
Total	9	51			
Hallux valgus R	28	171	0,91	[0,44;1,90]	0,804
Yes					
No	12	30			
Total	16	141			**0,002**
Hallux valgus L	28	171	2,8	[1,44; 5,46]	
Yes					
No	10	22			
Total	18	149			**0,002**
Claw and / or hammer fingers R	28	171	2,9	[1,48; 5,69]	
Yes	6	36	1,02		
No	22	135			0,964
Total	28	171	1,02	[0,44; 2,35]	
Claw and / or hammer fingers L					
Yes	8	40			
No	20	131			0,553
Total	28	171	1,26	[0,59; 2,67]	

A statistically significant association was identified between changes in plantar pressure and the absence of protective plantar sensitivity (p = 0.029), absent aquilus reflection (p = 0.016), reduced vibratory sensitivity (p = 0.048) and absent (p = 0.009), presence of calluses on right foot (p = 0.006) and left foot (p = 0.001) and hallux valgus on right foot (p = 0.002) and left foot (p = 0.002).

There was a difference in the prevalence of changes in both exposed and unexposed limbs by the chi-square test at 5% significance for: sensitivity plantar protector absent, absent aquilus reflection, reducend and absent vibratory sensitivity, callosity on right foot and left foot and hallux valgus on right foot and left foot.

Protective plantar sensitivity was 2.2 times more prevalent than having plantar alteration in both limbs of those who had decreased plantar protective sensitivity.

For the participants who had absent Aquilus reflection, the prevalence of presenting plantar alteration in both limbs was 2.5 times than in those who had this diminished reflex.

For those individuals who presented decreased vibratory sensitivity, the prevalence is 61% lower of having plantar alteration in both limbs in relation to those who presented this type of intact sensitivity, and for the absent vibratory sensitivity, it is 2.5 times more prevalent of having plantar alteration. of both members that who owns or owns in a diminished way.

Participants who presented calluses on their right feet have almost 8.6 times more prevalence of having changes in both limbs than those who do not have calluses on their right limbs. On the other hand, this prevalence increases to 11.1 for individuals with left foot calluses.

In relation to individuals who presented hallux valgus on the right foot, they have almost 3 times more prevalence of having plantar alteration in both limbs of those who did not present hallux valgus in the right limb. The same is true for hallux valgus on the left foot.

In the assessment of the participants' balance, an average of 40.96 ± 10.77 points was obtained on the Berg Balance Scale, with 06 (3%) individuals presenting a low risk of falling, 68 (34%) moderate risk and 115 (57.5%) serious risk of falling.

When analyzing the type of shoes used by the participants, 92 (46%) used appropriate shoes, with orthopedic sandals being the most prevalent 53 (26.5%).

Upon palpation of the peripheral pulses, 25% had an absent anterior and posterior tibial pulse, while the popliteal pulse was present in 76.66% and in 38.33% the pedicle pulse was absent.

Discussion

Among the total number of individuals evaluated in this study, there was a statically significant difference between individuals with and without changes in the plantar pressure according to the absence of plantar

protective sensitivity, achilles reflex and vibratory sensitivity, as well as presence of calluses on the right and left foot and hallux valgus in the right foot and left foot.

The plantar protective sensitivity was absent in more than 50% of them and decreased by 36.68%. There was a high percentage of individuals with muscular and dermatological alterations, being more evident in the right foot. More than half of the patients showed balance changes with moderate and increased risk of falling, with just under half wearing appropriate footwear. It was also possible to identify an increase in plantar pressure, above the values considered normal in the healthy population, especially in the individuals' left foot.

These findings are worrisome since the dermatological and muscular alterations cause the displacement of support and pressure areas in a contralateral way during the walk. Thus, in their presence, there may be an increase in the contact of the foot with the ground in some areas and a decrease in this contact in opposite areas of the plantar surface. These changes associated with loss of protective sensitivity compromise the biomechanics of the feet, altering gait and balance and increasing the risk for the development of plantar ulcers in individuals with NDP.

According to Fawzy et al. (2014) [20], diabetic neuropathy can be identified as one of the main risk factors for ulceration and, consequently, amputation of the foot, since the lack of protective sensation from sensory neuropathy leads to repetitive trauma in a high pressure area.

Motor neuropathy leads to atrophic changes in the musculature of the foot that can cause foot deformity and decreased joint mobility, and these problems subsequently lead to an area of increased plantar pressure in the foot that can result in ulceration [21].

According to the American Diabetes Association and Mendonça et al. (2011) [22], there are several factors that contribute to the injury in the diabetic foot, which may result from two or more associated risk factors, triggered by both extrinsic as well as intrinsic traumas associated with peripheral neuropathy, peripheral vascular disease and biomechanical alteration.

In the study by Silva et al. (2014 [23], the authors report that biomechanical changes are associated with risk factors for complications of diabetic foot and appearance of ulcers, such as the absence of plantar and vibratory sensitivities, an achilles reflex, in addition to the presence of bone deformities such as calluses and hallux valgus.

In NDP, the impairment of fine fibers of type Aδ and C [24], cause a decrease in plantar protective sensitivity, especially regarding the tactile, thermal, pressure and proprioception perception, and the absence of the latter leads to the loss of deep tendon reflexes [25]. Thus, neuropathy leads to insensitivity, and subsequently to foot deformity, with the possibility of developing abnormal gait [26]. Still, due to the lack of a painful response, NDP favors the repetition of trauma in the tissue, and dermatological and bone changes such as calluses and bone prominence [27].

In addition, when there is damage to the peripheral nervous system, a significant deficit in muscle strength can be evidenced, which can lead to losses in the strategies necessary to maintain the stability and balance of the human body during gait, leading to serious future losses, such as ulcerations [28].

Maintaining the balance of the human body depends on the intrinsic coordination of the vestibular system, vision and tactile and proprioceptive information. These components work in an integrated and complementary way and any change in one or more of these systems results in postural instability and, consequently, increases the risk of falls, skin lesions, fractures and prolonged immobilizations [29]. In the present study, 57.5% had a serious risk of falling due to changes in balance, showing that sensory deficit is one of the main causes of postural instability in people with diabetic neuropathy.

Thus, it is evident that the patients included in this study have favorable conditions for the development of plantar injuries and that they would benefit from the implementation of systematic assessment strategies and early interventions to prevent complications resulting from the conditions imposed by the underlying disease.

The evaluation of plantar pressure in order to identify the increase in plantar pressure in vulnerable areas in the feet of people with NDP, has been widely used, as demonstrated by Arts et al (2012) [30] and Waaijman et al (2012) [31], to enable changes in patients' shoes and insoles to obtain adequate footwear, with reductions in peak plantar pressure and decreased risk of pre-ulcerations and ulcerations in these individuals [17, 32].

NDP is a factor that is related to the increase in plantar pressure mainly in the anterior region of the feet (metatarsal head), and these values of peak plantar pressure expressed in kgf /cm^2 or kPa, correspond to the average of the pressure values occurred by region of the sole of the foot (hindfoot, midfoot and forefoot) during dynamic baropodometry, showing the influence that foot deformities have on peak plantar pressure values [10]. Therefore, it appears that in our study there was an increase in plantar pressure in the dynamic examination due to the presence of these deformities.

The center of pressure shows the distance between the center of pressure of each foot in relation to the center of body pressure during the path traveled between the support and balance phase, occurring the point of application of the vector of the vertical force of the reaction to the ground [11], which may suggest inappropriate postural attitudes over time, thus favoring changes in plantar pressure in individuals with diabetic neuropathy. These changes can cause limitations and possible plantar ulcerations, justifying the need for preventive clinical intervention.

According to Armstrong, Boulton and Bus (2017) [30] it is likely that there is a relationship between these variables, mean peak plantar pressure, pressure center and contact surface, because with the increase in the time of diagnosis of diabetes, there is an increase in plantar pressure and a greater oscillation of these individuals. Therefore, understanding this process would optimize the physiotherapeutic assessment and treatment procedures, as well as providing early action in the prevention of falls and ulceration.

Footwear considered appropriate must have a thick sole, sufficient width and depth to accommodate a sock and the foot comfortably, the inside of the footwear must be soft and seamless, adjustable with laces or velcro, offering total protection to the toes (round or square toe), sole up to three centimeters, and made with soft raw material [7, 19, 34]. It should be noted that the use of inappropriate shoes has been described in the literature as a relevant factor for the development of the risk of ulceration and peak plantar pressure [18, 35–38].

According to Luna et al (2020) [39], the use of inadequate footwear increases the repetitive local mechanical efforts on the foot in patients with DM and NDP, and the accurate measurement of the foot and shoe length is necessary to ensure a correct fit, avoiding the risk of foot ulcer.

According to Collings et al (2019) [40] and Jarls et al (2020) [41], therapeutic / suitable footwear is often used to reduce high tissue pressures associated with the risk of foot ulceration, therefore, guidelines for the care of the feet of people with diabetes recommend the use of therapeutic shoes or personalized insoles in the preventive management of people at risk of foot ulceration, as defined by the National Institute for Health and Care Excellence [38].

Discharge devices such as suitable footwear reduce peak plantar pressure by 14–76% compared to plantar pressure in the bare feet of individuals with NDP [39], which means that adherence to the use of this device is an important contributor to reducing the foot load [45]. Thus, plantar pressure, weight-bearing activity and adherence play a role in the foot load [46].

The findings on plantar pressure and device adherence confirm the importance of providing people with diabetic foot disease with pressure-reducing interventions and ensuring adherence to their use [47]. In addition, the findings emphasize that, to determine foot load, it is important to look beyond a single foot load factor, as single foot load factors are likely to be insufficient to understand treatment progress [48–50].

In this study, evaluations were performed only in patients with already diagnosed diabetic peripheral neuropathy. Diabetic patients without neuropathy were not evaluated. Although this is a limitation, the simple description of the occurrence and types of changes in the feet of patients with neuropathy already constitutes an alert factor for physiotherapists and other health professionals who care for individuals with this pathology.

Conclusion

Among the total number of individuals evaluated in this study, plantar protective sensitivity was absent or decreased in most of them. Furthermore, a high percentage of individuals with muscular and dermatological alterations were identified, being more evident in the right foot. More than half of the patients had balance changes with a moderate and increased risk of falling, with slightly less than half wearing appropriate shoes. Furthermore, it was possible to identify an increase in plantar pressure, above the values considered normal in the healthy population, especially in the individuals' left foot. These

results showed the magnitude of changes that can compromise the biomechanics of diabetic individuals and predispose them to injuries. Thus, in view of the increase in the number of cases of diabetes and consequently of Peripheral Diabetic Neuropathy, it is evident the importance of knowing the profile of this population, as well as their current health situation so that it can be traced to outline strategies for actions directed to the specific needs of this population and the prevention of injuries.

Abbreviations

COP: Pressure center

DM: Diabetes Mellitus

DM2: Type 2 Diabetes Mellitus

HbA1c: Glycated hemoglobin

ICF: Informed Consent Form

MMSI: Michigan Screening System

DPN: Peripheral Diabetic Neuropathy

UBS: Basic Health Unit

UNIFESP: Federal University of São Paulo

Declarations

ACKNOWLEDGEMENTS

AUTHORS 'CONTRIBUTIONS

JVJ, DSO, MAG, and DMK were involved in the design of the study. JVJ and DMK were involved in data collection, data analysis and interpretation of results. JVJ, MAG, and DMK wrote the manuscript. All authors read and approved the final version.

FUNDING

AVAILABILITY OF DATA AND MATERIALS

Requests for further detail on the data collected in this study, or data sharing arrangements, can be submitted to Juliana Jorgetto (julianavallim26@gmail.com).

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This project was approved by the Federal University of São Paulo and Plataforma Brasil (protocol number CAE 2,695,704). Informed consent was provided by all participants.

CONSENT FOR PUBLICATION

Not applicable.

COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHOR DETAILS

[1]Physiotherapist, PhD student of the Postgraduate Program in Nursing at the Federal University of São Paulo, UNIFFESP, Brazil. .

[2]Nurse, Associate Professor at the Department of Nursing in Public Health at Escola Paulista de Enfermagem, Universidade Federal de São Paulo, UNIFFESP, Brazil..

[3]Nurse, Adjunct Professor, Department of Pediatric Nursing, Escola Paulista de Enfermagem, Universidade Federal de São Paulo, UNIFFESP, Brazil.

References

1- Santos AL et al. Complicações microvasculares em diabéticos Tipo 2 e fatores associados: inquérito telefônico de morbidade autorreferida. Ciênc. saúde coletiva vol.20 no.3 Rio de Janeiro mar. 2015.

2- International Working Group on the Diabetic Foot. International Consensus on the Diabetic Foot. International Diabetes Federation; 2019.

3- Sociedade Brasileira de Diabetes. Diretrizes da Sociedade Brasileira de Diabetes: 2015-2016.São Paulo: Ac farmacêutica; 2016.

4- International Diabetes Federation. Diabetes and Cardiovascular Disease. 2009.

5- International Diabetes Federation (IDF). International Working Group on the Diabetic Foot Prevention and Management of Foot Problems in Diabetes Guidance Documents and Recommendations; 2017.

6- Ochoa-Vigo K, Torquato Mtcg, Silvério Ias, Queiroz Fa, De-La-Torre-Ugarte-Guanilo Mc, Pace A. Caracterização de pessoas com diabetes em unidades de atenção primária e secundária em relação a

fatores desencadeantes do pé diabético. Acta Paul Enferm. 2006; 19(3): 296-303.

7- Boulton AJ. The diabetic foot: grand overview, epidemiology and pathogenesis. Diabetes Metab Res Rev. 2008;24 Suppl 1:S3-6.

8- Van Netten JJ, Price PE, Lavery LA, Monteiro-Soares M, Rasmussen A, Jubiz Y, Bus SA. Prevention of foot ulcers in the at-risk patient with diabetes: a systematic review. Diabetes Metab Res Rev. 2016;32(Suppl 1):84–98. 2.

9- Baumfeld D et al. "Reliabitiy of baropodometry on the Evaluation of plantar load distribution: A tranversal study". BioM. Res. Inter, vol. 2017

10- Razak AH, Zayegh A, Begg RK, Wahab Y. Foot plantar pressure measurement system: a review. Sensors (Basel). 2012;12(7):9884-912. doi: 10.3390/s120709884. Epub 2012 Jul 23. PMID: 23012576; PMCID: PMC3444133.

11- Robinson CC. Baropodometria em indivíduos diabéticos e pré-diabéticos com e sem neuropatia. Universidade federal do Rio Grande do Sul. Programa de Pós-Graduação em Neurociências (Dissertação de Mestrado), 2011.

12- Sociedade Brasileira de Diabetes. Diretrizes da Sociedade Brasileira de Diabetes: 2018-2019.São Paulo: Ac farmacêutica; 2019.

13- Kendall FP, Mccreary EK, Provance PG. Músculos: provas e funções. 4ª ed. São Paulo (SP): Manole; 1995.

14- Palmer L, Epler ME. Princípios das Técnicas de Exame. In: Palmer L, Epler ME, editors. Fundamentos das técnicas de avaliação musculoesquelética. 2ª ed. Rio de Jneiro: Guanabara Koogan; 2000. p. 7-33.

15- Berg K, Maki B, Williams J. Clinical and laboratory measures of postural balance in an elderly population. Arch Phys Med Rehabil. 1992; 73: 1073–80.

16- BaroScan- Manual de Instruções. HS techonology. Londrina, 2010.

17- Filippin NT, Sacco ICN, Costa PHL. Plantar pressure distribution: definition, characterization and applications in the study of the human movement Physiotherapy Brazil - Volume 9 - Number 2 - March / April 2008.

18- Teles JCMA et al. Baropodometria como um método de avaliação do equilíbrio em pacientes diabéticos: revisão sistemática. Revista Varia Scientia – Ciências da Saúde. 2015; 1(2):156-166.

19- Armstrong DG, Lavery LA: Plantar pressures are higher in diabetic patients following partial foot amputation. Ostomy Wound Manage 44:30–32, 34, 36 passim, 1998.

20- Fawzy AO et al. Plantar Pressure as a risk assessment tool for diabetic Foot Ulceration in egyptian Patients with diabetes. Clinical Medicine Insights: Endocrinology and Diabetes 2014:7 31–39 doi:10.4137/CMed.s17088.

21- Periyasamy R, Anand S, Ammini AC. Prevalence of standing plantar pressure distribution variation in north Asian Indian patients with diabetes mellitus. Proc Inst Mech Eng H. 2013; 227 (2): 181–9.

22- Mendonça, S. S., Morais, J. S., & Moura, M. C. G. G. (2011). Proposal for a physiotherapy assessment protocol for diabetic feet. Physiotherapy in Motion, 24 (2), 285-298.

23- Silva CAM et al. Pé diabético e avaliação do risco de ulceração. Ver. Enf. Ref.; Série IV - n.° 1 - Fev./Mar. 2014, 153-161.

24- Boulton A., Pedrosa HC. Abordagem diagnóstica, terapêutica e preventiva da neuropatia periférica. In: VILAR, L. Endocrinologia clínica. 3 ed. Rio de Janeiro: Guanabara Koogan, 2006. p.126 - 144.

25- Dutra et al. RESEARCH Is it possible to substitute the monofilament test for the Ipswich Touch Test in screening for peripheral diabetic neuropathy? Diabetol Metab Syndr (2020) 12:27.

26- Ministério da Saúde. Cadernos de Atenção Básica: Estratégias para o Cuidado da Pessoa com Doença Crônica (Diabetes Mellitus). Brasília- DF; 2016.

27- Hinchliffe, RJ et al. Guidelines on diagnosis, prognosis, and management of peripheral artery disease in patients with foot ulcers and diabetes (IWGDF 2019 update). Diabetes Metab Res Rev. 2020;36(S1):e3276.

28- Lipsky BA, Senneville É, Abbas ZG, et al. Guidelines on the diagnosis and treatment of foot infection in persons with diabetes (IWGDF 2019 update). Diabetes Metab Res Rev. 2020;36(S1):e3280.

29- Sales KLS, Souza LA, Cardoso VS. Equilíbrio estático de indivíduos com neuropatia periférica diabética. Fisioter. Pesqui. vol.19 no.2 São Paulo Apr./June 2012.

30- Arts ML, Waaijman R, de Haart M, et al. Offloading effect of therapeutic footwear in patients with diabetic neuropathy at high risk for plantar foot ulceration. Diabet Med 2012;29:1534–41.

31- Waaijman R, Arts ML, Haspels R, et al. Pressure-reduction and preservation in custom-made footwear of patients with diabetes and a history of plantar ulceration. Diabet Med 2012;29:1542–9.

32- Collings R, Freeman JA,Latour J, et al. INSoles To Ease Pressure (INSTEP) Study:

a multicentre, randomized controlled feasibility study to compare the effectiveness of a novel instant optimised insole with a standard insole for people with diabetic neuropathy: a study protocol. BMJ Open 2019;0:e029185.

33- Armstrong DG, Boulton AJM, Bus SA. Diabetic foot ulcers and their recurrence. N Engl J Med. 2017;376:2367–75.

34- Kelson Luiz da Silva SalesI; Leonardo Alves de SouzaI; Vinicius Saura CardosoII. Equilíbrio estático de indivíduos com neuropatia periférica diabética. Fisioter. Pesqui. vol.19 no.2 São Paulo Apr./June 2012.

35- Mehmood MK, Parkar AZ, Mustafa NT, Mustafa SS, Makin MA, Alawadi F, et al. Diabetic foot self-care: awareness and practice among type 2 diabetic patients in primary healthcare centers, Dubai Health Authority. Int J Community Med Public Health 2019;6:1-7.

36- Conners RT et al. Impact of Underwater Treadmill Training on Glycemic Control, Blood Lipids, and Health-Related Fitness in Adults With Type 2 Diabetes. Clinical Diabetes Journal, 2018.

37- Larry W Kraiss et al. Association of Vascular Surgery Board of the American Board of Surgery Examination Performance With Clinical Outcomes: Experience Matters Article in Journal of Vascular Surgery · September 2018.

38- Perdomoa CR, Romero AP, Vélez MR. Conocimientos y prácticas para la prevención del pie diabético Rev Gaúcha Enferm. 2019;40:e20180161.

39- Luna EC et al. Fit for purpose? Footwear for patients with and without diabetic peripheral neuropathy: A cross-sectional study. Primary care Diabetes. August 27, 2020.

40- Collings R, Freeman J, Latour JM, Paton J. Footwear and insole design features for offloading the diabetic at risk foot—A systematic review and metaanalyses. Endocrinol Diab Metab. 2020.

41- Jarls G et al. Predictors of adherence to wearing therapeutic footwear among people with diabetes Journal of Foot and Ankle Research (2020) 13:45 Page 2 of 9.

42- Ehrmann D, Spengler M, Jahn M, Niebuhr D, Haak T, Kulzer B, Hermanns N. Adherence over time: the course of adherence to customized diabetic insoles as objectively assessed by a temperature sensor. J Diabetes Sci Technol. 2018;12(3):695–700.

43- Chatwin, K.E.; Abbott, C.A.; Boulton, A.J.M.; Bowling, F.L.; Reeves, N.D. The role of foot pressure measurement in the prediction and prevention of diabetic foot ulceration—A comprehensive review. Diabetes Metab. Res. Rev. 2019, 36, 1–14.

44- National Institute for Health and Care Excellence. Diabetic Foot problems: prevention and management. (NICE Guideline 19). 2018.

45- Lazzarini, P.A.; Crews, R.T.; van Netten, J.J.; Bus, S.A.; Fernando, M.E.; Chadwick, P.J.; Najafi, B. Measuring Plantar Tissue Stress in People With Diabetic Peripheral Neuropathy: A Critical Concept in Diabetic Foot Management. J. Diabetes Sci. Technol. 2019, 13, 869–880.

46- Cavanagh, P.R.; Bus, S.A. Off-loading the diabetic foot for ulcer prevention and healing. J. Vasc. Surg. 2010, 52, 37S–43.
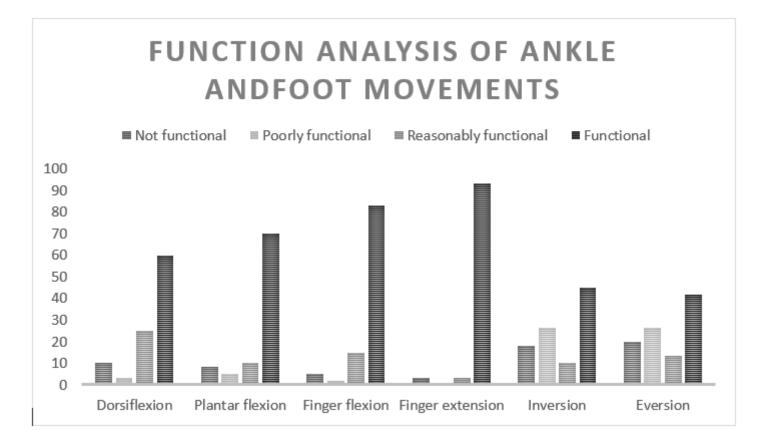
47- Schaper, NC; van Netten, JJ; Apelqvist, J .; Ônibus, SA; Hinchliffe, RJ; Lipsky, BA Practical Guidelines on the prevention and management of diabetic foot disease (IWGDF 2019 update). Diabetes Metab. Res. Rev. 2020 , 36 , e3266.

48- Huslof CM , van Netten JJ, Pijnappels M, Sicco A. Bus. The Role of Foot-Loading Factors and Their Associations with Ulcer Development and Ulcer Healing in People with Diabetes: A Systematic Review. J. Clin. Med. 2020, 9, 3591.

49- Chatwin, K.E.; Abbott, C.A.; Boulton, A.J.M.; Bowling, F.L.; Reeves, N.D. The role of foot pressure measurement in the prediction and prevention of diabetic foot ulceration—A comprehensive review. Diabetes Metab. Res. Rev. 2019, 36, 1–14.
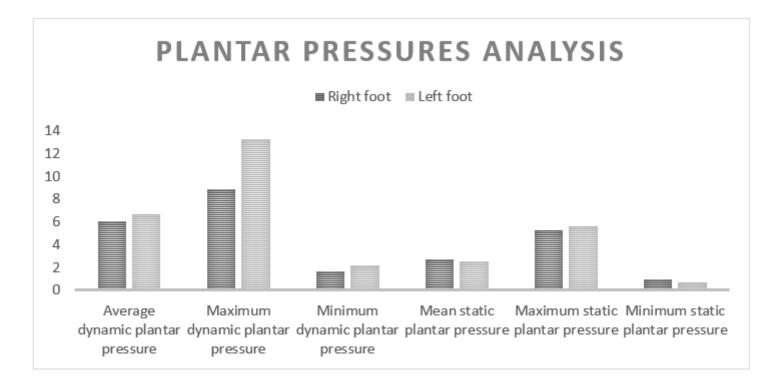
50- Teles JCMA et al. Baropodometria como um método de avaliação do equilíbrio em pacientes diabéticos: revisão sistemática. Revista Varia Scientia – Ciências da Saúde. 2015; 1(2):156-166.

Figures

Figure 1

Functional scale of the functional tests of the sample participants.

Figure 2

Static and dynamic distribution of plantar pressure (Kgf/cm2) of the study participants.