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## **ORIGINAL ARTICLE**

# Exploring plantar pressure distribution in patients with newly diagnosed diabetes: Implications for foot ulcer prevention in an overweight Mexican population



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#### **KEYWORDS**

Type 2 diabetes mellitus; Plantar pressure; Body mass index; Diabetic foot ulcer; Peak plantar pressure

#### Abstract

*Introduction:* Elevated plantar pressure (PP) constitutes a risk factor for developing foot ulcers. Once present, elevated PP increases morbidity and mortality in patients with diabetes. Given the high prevalence of overweight and obesity in the Mexican population, this study aimed to describe the magnitudes and the distribution of the PP observed in a sample of newly diagnosed patients with diabetes, adjusting for body mass index (BMI) groups (normal weight, overweight, grade I obesity, and grade II and III obesity).

*Materials and methods*: A total of 250 volunteers attending a comprehensive care program for the management of type 2 diabetes received foot assessments that included vascular and neurological evaluation, the identification of musculoskeletal changes, and measurements of PP.

*Results*: Diabetic neuropathy and peripheral arterial disease were present in 21.6% and 11.2% of all participants. Musculoskeletal alterations were present in 70.8% of participants. A positive and significant correlation (p < 0.001) was observed between BMI and the peak PP of all anatomical regions assessed. After adjusting for BMI, significant differences (p < 0.001) were seen between groups. The metatarsal region, particularly under the third metatarsal head, denoted the highest magnitudes across all BMI.

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*Conclusions:* Periodic PP assessment is recommended to identify the distribution of highpressure points along the plantar surface. However, as a preventive measure, it is suggested to encourage patients with diabetes and overweight or obesity to wear appropriate footwear and pressure-relief insoles to relieve high-pressure areas – often seen in these populations – to help prevent foot complications.

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#### PALABRAS CLAVE

Diabetes tipo 2; Presión plantar; Índice de masa corporal; Úlcera diabética; Presión plantar pico

#### Resumen

*Introducción:* La presión plantar (PP) elevada constituye un factor de riesgo para desarrollar úlceras en el pie, aumento de la morbilidad y la mortalidad en los pacientes con diabetes. Dada la alta prevalencia de sobrepeso y obesidad en la población mexicana, este estudio tuvo como objetivo describir las magnitudes y la distribución de la PP observada en una muestra de pacientes recién diagnosticados con diabetes, ajustando por grupo de índice de masa corporal (IMC): normopeso, sobrepeso, obesidad grado I, y obesidad grados II y III.

*Materiales y métodos:* Asistieron 250 voluntarios a un programa de atención integral para el manejo de la diabetes tipo 2, recibieron evaluaciones de los pies que incluyeron: evaluación vascular, neurológica, de alteraciones musculoesqueléticas y de la PP.

*Resultados*: La neuropatía diabética y la enfermedad arterial periférica estuvieron presentes en el 21,6% y el 11,2% de los participantes. Las alteraciones músculoesqueléticas estuvieron presentes en el 70,8% de los participantes. Se observó una correlación positiva y significativa (p < 0,001) entre el IMC y la PP máxima de todas las regiones anatómicas evaluadas. Después de ajustar por el IMC, se observaron diferencias significativas (p < 0,001) entre los grupos. La región metatarsiana, particularmente debajo de la cabeza del tercer metatarsiano, denotó las magnitudes más altas en todas las categorías del IMC.

*Conclusiones*: Se recomienda una evaluación periódica de la PP para identificar la distribución de los puntos de alta presión plantar. Sin embargo, como medida preventiva, se sugiere alentar a los pacientes con diabetes y sobrepeso u obesidad a utilizar calzado adecuado y plantillas para descargar las zonas de alta presión para prevenir complicaciones en los pies.

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#### Introduction

Diabetic foot, a condition related to neurological, vascular, dermatological, metabolic, and musculoskeletal disorders, is defined by the World Health Organization (WHO) as a disease in which ''neuropathy, ischemia, and infection lead to tissue disruption causing morbidity and possible amputation''.<sup>1</sup> A common complication of this condition is foot ulcers, which could lead to lower limb amputations, with worldwide prevalences of 4% up to 10% and 15% up to 25%, respectively.<sup>2,3</sup> In the Mexican population, these prevalences are 7% and 1.7%, respectively.<sup>4</sup>

Peripheral arterial disease (PAD) and distal neuropathy (DN) have been identified as factors that may contribute to the development of ulcers. PAD may affect local blood perfusion, and distal neuropathy leads to the eventual loss of protective sensibility. These promote the appearance of changes to the foot morphology that contribute to the increase of plantar pressure at the forefoot.<sup>5</sup> Deformities, such as longitudinal arch collapse, hallux valgus, and hammer toes promote the exposure of the heads and increase the pressure underneath them.<sup>6,7</sup> Connective and soft tissue glycation promotes biomechanical changes that make the forefoot prone to injuries since its thickness is 36% up to 48% thinner vs the one seen in the heel.<sup>8-11</sup>

Since it has been described that in the diabetic foot, the highest values of plantar pressure are usually located right to the site of the ulcer, its assessment has been recommended as a valuable method to identify and reduce the risk of ulceration and subsequent amputation of the lower limb in patients with diabetes.<sup>12-14</sup> An ulceration pathway has been described through the interaction of elevated PP, constant mechanical stress in the plantar tissue, and neuropathy.<sup>15-17</sup>

In Mexico, the high prevalence of overweight (39.1%) and obesity (36.1%) has become a problem of public health<sup>4</sup> in addition to diabetes. Since people with obesity (BMI  $\geq$  30 kg/m<sup>2</sup>) frequently denote increased PP at the midfoot and metatarsal regions,<sup>18,19</sup> this study aimed to describe the PP figures adjusted by body mass index (BMI) that were present in a sample of early-diagnosed volunteers with type 2 diabetes.

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#### Materials and methods

#### Study design

We conducted a descriptive and cross-sectional study, nested in the cohort of the protocol entitled ''Validation of a comprehensive management model for patients with type 2 diabetes'' in CAIPaDi (Spanish acronym for Center for the Comprehensive Management of Patients with Diabetes) of the National Institute of Medical Sciences and Nutrition Salvador Zubirán in Mexico City. The center Ethics and Research Committees (ref 1198) approved the protocol which has been registered in ClinicalTrials.gov: NCT0283608. The multidisciplinary program includes four initial monthly visits and two annual follow-up assessments that aim to achieve metabolic control goals.<sup>20,21</sup>

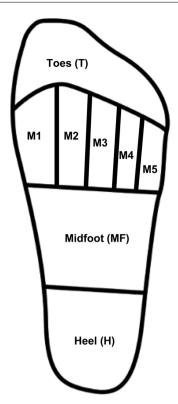
The above-mentioned program establishes the following inclusion criteria: patients with type 2 diabetes diagnosed less than five years ago, age between 18 and 70 years, nonsmoking habit, and with no disabling complications such as lower limb amputation or those that require the use of some type of support device to walk that could modify pressure measurement. During each visit, the participant is assessed by professionals from nine different disciplines: endocrinology, diabetes education, nutrition, psychology, dentistry, psychiatry, physical therapy, ophthalmology, and foot care.

Foot care intervention involves dermatological, neurological, and vascular evaluations to determine the health condition of the foot and the quantitative evaluation of the plantar pressure for the identification of abnormal pressure points, which constitutes the subject matter of this study.

#### Data collection

All patients with complete health records, glycated hemoglobin, lipid profile, and blood pressure measurements were included. Anthropometric parameters included BMI and body composition. BMI was classified as normal weight  $(18.5-24.9 \text{ kg/m}^2)$ , overweight  $(25-29.9 \text{ kg/m}^2)$ , grade I obesity  $(30-34.9 \text{ kg/m}^2)$ , and grade II and III obesity  $(35.0-44.9 \text{ kg/m}^2)$ .

A physical assessment of the skin and nails was performed on both feet. Onychomycosis, onychocryptosis, and plantar hyperkeratosis were classified as present or absent. The neurological evaluation was performed using the 128-Hz tuning fork test and the 10g Semmes-Weinstein monofilament to confirm the perception of vibration and pressure, respectively. The loss of perception to vibration (LVS) was considered if the patient stopped perceiving the stimulus in <8s. Loss of pressure sensation (LPS) was confirmed if the patient reported not perceiving the stimulus in 5 or more of the 10 evaluated anatomical points. DN was assumed when the patient tested positive to either one or the two tests.<sup>5,21</sup> The vascular condition was also evaluated using the anklebrachial index (ABI). PAD was considered with an ABI <0.9.22 Finally, musculoskeletal alterations were recorded through physical examination of both feet and legs and plantar footprint. Pes cavus, claw toes, hallux valgus, fallen plantar arch, talus valgus or varus and genu valgus or varus were evaluated.23-26



**Figure 1** Anatomical regions of the footprint considered for the analysis. *Abbreviations*: M1–M5: area comprised under the 1st through 5th metatarsal heads. This figure shows the plantar footprint subdivided into areas of interest for the analysis.

#### Plantar pressure measurements

Baropodometric techniques enable the qualitative and quantitative assessment of PP, either statically or during the gait cycle, and are useful to timely identify high-pressure zones and prevent plantar ulcer formation.<sup>17,27</sup> Assessments included peak plantar pressure (PPP) mean values for the anatomical regions of the foot (Fig. 1), which included the hallux and lesser toes (T), the area comprised under each metatarsal head (M1, M2, M3, M4, and M5), the metatarsal region as a whole (MT), the midfoot (MF), and the heel region (H). Pressure-time integral (PTI) was computed for regions with the highest PPP value. A MatScan platform and the FootMat Research software (ver. 7.00-65) by Tekscan (Boston, MA, United States) were used to acquire and analyze plantar pressure registries.

Before PP assessment, the equipment was calibrated with the patient's weight following the manufacturer's instructions. Afterwards, the participants were asked to walk barefoot and at a self-selected speed through the gait pathway to become familiar with the procedure before being measured. A mean of five footprints for each foot was considered for analysis.

#### Statistical analysis

The sociodemographic variables were expressed as mean and standard deviation or median and range or prevalence. The normality of data was assessed using the

Table 1	Demographic characteristics and biochemical markers of	participants.
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Variable	Mean $\pm$ SD/median (range)
n	250
Age (years)	$\textbf{52.2} \pm \textbf{10.1}$
Sex (male/female)	132/118
Diabetes duration (years)	1 (0-5)
Weight (kg)	$\textbf{76.87} \pm \textbf{15.75}$
Height (m)	1.61 (1.37–1.89)
BMI $(kg/m^2)$	<b>29.1</b> ± <b>4.45</b>
Fasting blood glucose (mmol/mol)	6.59 (3.44–16.37)
HbA1c (%)	$7.1\pm1.65$ (54 mmol/mol)
Blood pressure (mmHg)	
Systolic	123.4±15
Diastolic	75.7±7.6
Total cholesterol (mmol/L)	9.0±2
HDL (mmol/L)	$2.3\pm0.6$
LDL (mmol/L)	6.0±2.0
No HDL (mmol/L)	$8.5 \pm 2.4$
Triglycerides (mmol/L)	88.8 (2.7-40.7)

BMI, body mass index; HbA1c, glycosylated hemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

Kolmogorov–Smirnov test. The mean values of the variables of interest were compared using a one-way ANOVA test. Post hoc analysis was conducted with Fisher's least significant difference (LSD) when significant differences were observed, and the Student *t* tests was used for comparison purposes. The Pearson correlation test was used to assess the association between continuous variables and the chi square test was used to investigate the association among discrete variables. Statistical significance was assumed at p < 0.05. Data analysis was performed with the SPSS statistical package (IBM, version 21).

#### Data and resource availability

The data and resources are available upon request to the corresponding author.

#### Results

From February 2015 through January 2016, a sample of 250 patients (500 feet) was recruited: 132 women and 118 men, with a mean age of  $52 \pm 0.1$  years and a median history of diabetes of 1 year (0–5). The sociodemographic data and biochemical characteristics of the participants are shown in Table 1.

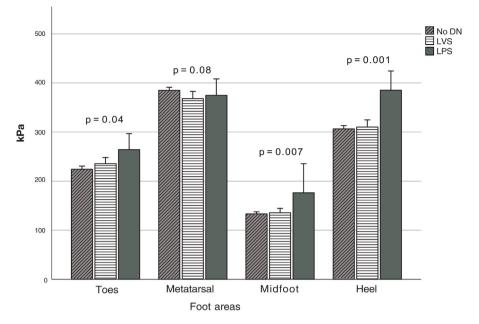
Based on the physical examination of both feet, these were the prevalences of the following conditions: DN (21.6%), musculoskeletal alterations (at least one of the following: hallux valgus, flat foot, claw toes, pes cavus, talus valgus/varus, heel spur, genu valgus/varus) (70.8%), PAD (9.5%), and hyperkeratosis (45.2%). Furthermore, to identify an association between the latter and the increment of PPP, hyperkeratosis interquartile prevalence was determined resulting as follows: 1st quartile 38.7% (n = 124), 2nd quartile 38.6% (n = 114), 3rd quartile 46.7% (n = 122) and 4th

quartile 47.5% (n = 120) (p = 0.319). The presence of ulcers or amputation of foot segments was not reported.

Fig. 2 depicts the PPP stratified based on the type of DN when detected, which was observed at the anatomical regions (Fig. 1). Significant differences were seen in the MF (p = 0.007), T (p = 0.04), and H (p = 0.001) zones. Based on the Fisher's LSD test, post hoc analysis revealed that the LPS group showed significantly higher PPP values in the heel region with a mean of 385.5 kPa (p = 0.001 and p < 0.001, vs the LVS and no DN group, respectively), followed by the region comprising the hallux and lesser toes with 264.4 kPa. It differed significantly from the group without DN (p = 0.04) but not from the LVS group. Furthermore, elevated figures of up to 176.4 kPa were reported in the midfoot region, which was statistically different from those with LVS (p = 0.004) and no DN (p = 0.002). The MT region (M1–M5 considered simultaneously) denoted the highest PPP magnitudes in 80% of all cases, but no statistical differences were seen in the group (p = 0.08). The computed mean PTI observed at this anatomical region (MT) in participants with no DN was  $93.4 \pm 24.2$  kPa/s, while in those with LVS and LPS, it was  $93.1 \pm 31.5$  kPa/s and  $90.8 \pm 34.8$  kPa/s, respectively. No statistical differences were found between these figures (p = 0.94).

When adjusting for BMI, the highest magnitudes of the mean PPP were also found in the MT (M1–M5) region at the following rates: 83.7% in the normal-weight group, 85.0% in the overweight group, 77.3% in the grade I obesity group, and 77.7% in the grade II obesity group (Table 2). The third metatarsal head consistently presented the highest values, exceeding 300 kPa in the four groups.

Between the BMI groups/categories, significant differences were observed in all the plantar pressure variables studied, and positive, moderate, and significant correlations (p < 0.001) were found between the mean PPP of all analyzed regions of the foot and the BMI (Table 2). No statistical differences were found among study variables



**Figure 2** Peak PP distribution based on the type of diabetic neuropathy. *Abbreviations*: No DN, nondiabetic neuropathy present; LVS, loss of vibration sensation; LPS, loss of pressure sensation; MT, metatarsal region; MF, midfoot region. The figure shows the PPP values at the four indicated regions when each type of neuropathy is present.

when gender was used for comparison purposes within BMI groups.

Finally, PPP denoted its highest values along the entire plantar surface when these alignment conditions were found: ankle varus (369.0 kPa), ankle valgus (387.8 kPa), and genu valgum (388.0 kPa). Similarly, PTI reached its highest figures when claw toes (99.2 kPa/s), pes cavus (98.0 kPa/s), or ankle varus (95.9 kPa/s) were observed.

### Discussion

In Mexico, the prevalence of overweight, obesity, and diabetes has reached a level of national concern. Diabetes often appears concomitantly with one of these first two conditions. Since it has been reported that the presence of high PP values may be associated with ulceration, especially when distal neuropathy is present, we considered it relevant to describe the magnitudes and distribution pattern of the PP present across BMI categories in a sample of volunteers with diabetes.

Previous studies have reported increased PP scores as body weight increases.<sup>28</sup> In a population of older adults, body weight was a significant and independent predictor of most plantar load variables and could account for up to 16% of the variance of the PPP. Additionally, out of a sample of patients with obesity,<sup>18,28</sup> some authors reported that the midfoot area reported statistically significantly higher PPP when compared with normal body weight figures. They attributed this to the collapse of the longitudinal arch due to the sustained and increased impact forces associated with excessive weight. Our results were consistent with these findings, and a significant increase was detected between normal and obese participants in the midfoot (MF) area (p < 0.001). Arnold et al. simulated overweight in the study population by adding 10 and 15 kg to each participant's body weight.<sup>19</sup> They demonstrated a significant increase (p < 0.01) in the PPP below the calcaneal region and the 2nd through 5th metatarsal heads for each loading condition.<sup>19</sup> Our study observed a significant increment underneath the five metatarsal heads between these groups (normal and overweight). An increasing trend persists throughout the rest of the groups (obesity grade I and grade II or more) as supported by the positive and significant correlation (p < 0.001) observed.

Alternatively, and to complement the findings described above, Robinson et al. reported that volunteers with prediabetes and diabetes were prone to show significantly higher pressure levels (p = 0.01) and augmented PTI values (p < 0.001) in the metatarsal region vs those participants without diabetes.<sup>29</sup> In our study, PTI was not computed for each anatomical region. However, global PTI denoted a slight but positive correlation as weight increased (r = 0.25, p < 0.001) and was significantly higher in those participants with obesity.

A prevalent concern among clinicians is determining an ulceration cut-off point regarding PP figures. Some ulceration risk cut-off points have already been proposed, but a consensus has not yet been reached. Reported PPP figures may range from 348.6 up to 821.0 kPa from volunteers who walk barefoot and with ulcers. However, in a more comprehensive approach, Fawzy et al. suggested a cut-off point of 355 kPa in the mean PPP of the forefoot to indicate a high risk for ulceration.<sup>16</sup> They further clarify that this proposed figure validity may be strengthened when used along with other contributing risk factors, such as the duration of diabetes, smoking habit, blood glucose levels, degree of foot deformity, and the presence of peripheral neuropathy.

Table 2 PPP	distributed by ¿	anatomical reg	Table 2 PPP distributed by anatomical region and stratified based on BMI	ied based on B	.IMI						
BMI	*ddd	PTI*	*_	MT*	MT1*	MT2*	MT3*	MT4*	MT5*	MF*	H*
	(kPa)	(kPa/s)	(kPa)	(kPa)	(kPa)	(kPa)	(kPa)	(kPa)	(kPa)	(kPa)	(kPa)
Normal weight	$357.6 \pm 72.3$ $84.6 \pm 27.7$	$84.6 \pm 27.7$	$209.1 \pm 53.2$	$357.4 \pm 69.2$	$189\pm 62.6$	$250.1 \pm 71.7$ $330.3 \pm 79$	$330.3 \pm 79$	$253.9 \pm 59.1$	$140.1\pm 66.7$	$140.1\pm 66.7  118.2\pm 55.5  304\pm 73.9$	$304 \pm 73.9$
n = 98	(343.1-372.1) (79.1-90.2)	(79.1–90.2)	(198.4-219.8)	(343.6-371)	(176.4-201.5)	(176.4–201.5) (235.7–264.4) (314.5–324.3) (242–265.7)	(314.5-324.3)	(242-265.7)	(126.7-153.5)	(126.7-153.5) (107.1-129.4) (289.1-318.8)	(289.1–318.8)
Overweight	$356.3 \pm 62.4$ $90.8 \pm 22.3$	$90.8 \pm 22.3$	$225.4 \pm 60$	$372.1 \pm 62.7$	$195.1 \pm 67.5$	$269.8 \pm 69.9$	$334.6 \pm 73.4$ $269.3 \pm 71.7$	$269.3 \pm 71.7$	$143.7 \pm 61.0$	$143.7\pm 61.0  124.5\pm 31.9  293.5\pm 67$	$293.5 \pm 67$
<i>n</i> = 198	(356.5-374.0) (87.7-93.9)	(87.7–93.9)	(217-233.8)	(363.4-380.9) (	(185.7–204.6)	(185.7–204.6) (260.0–279.6) (324.4–344.9) (259.3–279.6) (135.1–152.2) (120.0–128.9) (284.1–302.9)	(324.4-344.9)	(259.3-279.6)	(135.1-152.2)	(120.0-128.9)	(284.1-302.9)
Obesity grade I	$393\pm59$	$97.4 \pm 25.4$	$232.8 \pm 68.9$	$379.0 \pm 58.7$	$209.2 \pm 74.7$	$292.5 \pm 71.7$	$357.6 \pm 74.4$	$357.6 \pm 74.4  288.2 \pm 65.9  163.9 \pm 69$	$163.9 \pm 69$	$144.6\pm43$	$316.9 \pm 65.5$
<i>n</i> = 150	(398.5-402.5) (93.3-101.5)	(93.3-101.5)	(221.7-243.9)	(387.6-406.5)	(387.6-406.5) (197.1-221.2) (280.9-304)	(280.9–304)	(354.6-369.6)	(354.6–369.6) (277.5–298.8) (152.7–175.0) (137.9–151.6) (306.3–227.4)	(152.7-175.0)	(137.9–151.6)	(306.3-227.4)
Obesity grade II	$406.1\pm53.9  107.2\pm29.7$	$107.2 \pm 29.7$	$252.5 \pm 70.3$	$414.2 \pm 63.9$	$249.9 \pm 66.1$	$317.8 \pm 72.7$	$372.2 \pm 74.2$	$372.2 \pm 74.2$ $327.9 \pm 66.4$	$203.1 \pm 64.6$	$174.2 \pm 39.2$	$350.9 \pm 74.8$
or more	(388.6-423.5)	(99.1-115.3)	(388.6-423.5) (99.1-115.3) (233.3-271.7)	(396.8-431.7)	(231.9-267.9)	(396.8-431.7) (231.9-267.9) (298.0-337.7) (352.0-392.5) (309.8-346.1) (185.5-220.7) (163.5-184.8) (330.5-371.3)	(352.0-392.5)	(309.8-346.1)	(185.5-220.7)	(163.5-184.8)	(330.5-371.3)
n = 54											
Pearson's	0.293	0.285	0.204	0.307	0.255	0.323	0.214	0.307	0.270	0.397	0.215
correlation	(<0.001)	(<0.001)	(<0.001)	(<0.001)	(<0.001)	(<0.001)	(<0.001)	(<0.001)	(<0.001)	(<0.001)	(<0.001)
(p value)											
Values expresse	d as mean $\pm$ SD	(95% confidenc	ce interval). PPP	3, absolute peak	c plantar pressu	ire; PTI, pressui	re-time integr	al; MT, metatar	sal region; MT1	-MT5, areas co	Values expressed as mean ± SD (95% confidence interval). PPP, absolute peak plantar pressure; PTI, pressure-time integral; MT, metatarsal region; MT1-MT5, areas comprised beneath
1st-5th metatai	rsal heads; MF, n	nidfoot region;	<pre>lst-5th metatarsal heads; MF, midfoot region; H, heel region;</pre>	Pearson's corre	elation denotes	Pearson's correlation denotes the association between pressure and BMI of each one. Significance level: $p < 0.05$ .	between press	sure and BMI of	each one. Signi	ficance level: $p$	< 0.05.
* Significant di	ifferences observing	ved between B.	Significant differences observed between BMI categories (on	one-way ANOVA: p < 0.001)	<i>p</i> < 0.001).						

Although we must be cautious when generalizing the above results to other populations, in our study, the overall mean PPP was 376.5 kPa, placing it at the lower limit of the above range. It must be outstated that the studied population did not present positive smoking habits and mainly stood within the metabolic control goal.

In our study, the mean PPP observed (376.5 kPa) was above the proposed cut-off point, even in volunteers without DN (384.6 kPa) and in those within the normal weight range (357.4 kPa). However, the low prevalence of DN observed, the short evolution of diabetes, and the absence of smoking habits in our study population should be pointed out and may contribute to our findings.

Being consistent with other studies, the PTI was recorded. No significant differences were observed regarding the PTI between the groups with and without DN (p=0.93). Various findings have been made surrounding the PTI. In a meta-analysis, Fernando et al. reported that in patients with diabetic peripheral neuropathy, the PTI was higher when ulceration was present.<sup>30</sup> In a systematic review, Bus et al. stated that this parameter would not be more effective than PPP in predicting the appearance of ulcers.<sup>31</sup>

Although our results were not significant (p = 0.18), they reported higher PPP figures in patients with altered sensitivity. No significant differences were seen in the PTI between the groups with and without DN (p = 0.94). However, a growing trend was observed in those groups with altered sensitivity. In a recent study by Bartolo et al., when evaluating PPP and PTI in groups of patients without DN, with DN, and with a history or current neuropathic ulcer, minimal significant changes were seen in the PPP between the ulcerated and non-ulcerated groups. However, the PTI values increased significantly in the ulcerated groups in all regions of plantar ulceration.<sup>32</sup> Logistic regression testing demonstrated that as PTIs under the hallux increase, the likelihood that an individual living with DN will develop ulceration increases.<sup>32</sup> This study proposes the PTI as a clinical tool for evaluating high-risk diabetic foot, so it could be important to pay attention to this parameter in patients with higher BMI since, according to our own results, the PTI is higher in overweight and obesity groups.

Studies that subdivided the footprint into delimited anatomical regions for analysis report that the area most often denotes the highest PPP values can be found under the 3rd metatarsal head.<sup>18,33</sup> Our findings were consistent with former reports: mean PPP values were persistently elevated in the metatarsal region and particularly underneath the 3rd metatarsal head across all BMI categories (330.3–372.2 kPa). From grade I obesity onwards, the values at the abovementioned site exceeded the value proposed by Fawzy et al. as a cut-off point for ulceration risk (355 kPa).<sup>16</sup>

Finally, although not statistically significant, in this study an upward trend in the prevalence of hyperkeratosis was seen as the magnitude of PPP increased; however, a significant and positive correlation of PP with BMI was identified. Recently, in a systematic review and meta-analyses in which hyperkeratosis was classified as a pre-ulcerative sign, van Netten et al. reported that if treated (callus removal), a slight but immediate reduction of in-shoe and barefoot PP may be attained. This group of researchers also pointed out that the use of pressure-optimized therapeutic

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footwear/insoles vs standard therapeutic footwear/insoles might reduce the risk of plantar ulceration.<sup>33</sup> These facts are relevant to health care professionals in the sense that an assessment of the presence of hyperkeratosis at the foot and of the type of footwear a patient uses can easily be performed without the need for sophisticated technology.

According to our findings, a recommendation for clinicians is to pay special attention to individuals with early-diagnosed diabetes who are presently in the range of overweight or obesity, regardless of their metabolic control. Management of elevated pressure at the studied sites can be done via the recommendation of adequate footwear (wide and square-shaped tip) and customized and total-contactadapted insoles. Early management of hyper-pressure points in the central forefoot region and midfoot may prevent future foot complications, especially in individuals with neuropathy.

A limitation of this study is that the reported PP figures should be taken with caution as a reference to extrapolate to other populations that may not have such a short duration of diabetes, a positive smoking habit, or adequate metabolic control. These were distinctive characteristics of our sample. As Fawzy et al. proposed, these, among other factors, may increase ulceration risk.<sup>16</sup> Another limitation of our study is that the foot size of the participants was not considered for the analysis, given that foot size commonly determines plantar area, which may affect PP. Also, in this study the presence, or not, of hyperkeratosis was registered, but when present, its location was not described. This knowledge is relevant in the sense that hyperkeratosis implies a noticeable punctual increase in pressure.

Future lines of research should include the study of the association between the presence and distribution of hyperkeratosis with pressure, as a potential factor in triggering the appearance of ulcers. Additionally, more prospective and survival analysis studies evaluating plantar pressure over time are needed to accurately determine cut-off points that can alert clinicians about the presence of high-risk pressure levels that may lead to the development of plantar ulcers, given the presence of other factors.

This study is an initial effort to evaluate baropodometric data in a large number of Mexican patients recently diagnosed with type 2 diabetes and describes its PP distribution pattern. These findings may be useful to health care workers who assist people with diabetes to pay special attention to those who are within the BMI ranges of obesity and overweight, to implement rigorous foot care measures and recommend to them the use of appropriate footwear/pressure-relief insoles that helps reduce the risk of ulceration.

## Conclusions

This study included a population with a low prevalence of diabetic neuropathy and peripheral arterial disease, with a relatively short course of the disease. The PP variables studied denoted a generalized increase in the different anatomical regions of the foot as the BMI increased. The highest pressure levels recorded were consistently present in the central forefoot (3rd metatarsal head). In patients with overweight and obesity, pressure approached or exceeded the levels proposed as safe to avoid ulceration. However, they did not present aggregate factors (evolution time, smoking) that may contribute to increased ulceration risk. Based on these findings, early intervention to raise awareness – especially in patients with overweight and obesity – about the use of appropriate footwear and insoles to manage high-pressure points would be advisable to reduce the risk of foot ulcers.

## Key findings

- Different changes evaluated in the feet of patients with newly diagnosed type 2 diabetes turn out to be prevalent, mainly deformities and plantar hyperkeratosis.
- The area that denotes the highest plantar pressure values during the gait cycle is below the metatarsal region.
- Higher figures of plantar pressures were recorded on the third metatarsals and heel region in people with overweight and obesity.

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## **Conflicts of interest**

None declared.

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## References

- Home P. Prevention of diabetes mellitus by WHO study group. WHO technical report series 844. World Health Organization, Geneva, 1994. No. of pages 100. Price CHF 15.00. Diabet Med. 1996;13:392, http://dx.doi.org/10. 1002/(sici)1096-9136(199604)13:4<392::aid-dia81>3.0.co;2-x.
- Singh N. Preventing foot ulcers in patients with diabetes. JAMA. 2005;293:217, http://dx.doi.org/10.1001/jama.293.2.217.
- 3. Gregg EW, Sorlie P, Paulose-Ram R, Gu Q, Eberhardt MS, Wolz M, et al. Prevalence of lower-extremity disease in the US adult population  $\geq$ 40 years of age with

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and without diabetes: 1999–2000 national health and nutrition examination survey. Diabetes Care. 2004;27:1591–7, http://dx.doi.org/10.2337/diacare.27.7.1591.

- Instituto Nacional de Salud Pública. Encuesta Nacional de Salud y Nutrición de Medio Camino 2016 Informe Final de Resultados. Available from: https://www.gob.mx/ cms/uploads/attachment/file/209093/ENSANUT.pdf.
- Bus SA, Lavery LA, Monteiro-Soares M, Rasmussen A, Raspovic A, Sacco IC, et al. Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2019 update). Diabetes Metab Res Rev. 2020;36(S1), http://dx.doi.org/10.1002/dmrr.3269.
- Ledoux WR, Shofer JB, Cowley MS, Ahroni JH, Cohen V, Boyko EJ. Diabetic foot ulcer incidence in relation to plantar pressure magnitude and measurement location. J Diabetes Complications. 2013;27:621–6, http://dx.doi.org/ 10.1016/j.jdiacomp.2013.07.004.
- Bus SA, Maas M, de Lange A, Michels RPJ, Levi M. Elevated plantar pressures in neuropathic diabetic patients with claw/hammer toe deformity. J Biomech. 2005;38:1918–25, http://dx.doi.org/10.1016/j.jbiomech.2004.07.034.
- Kravitz SR, McGuire J, Shanahan SD. Physical assessment of the diabetic foot. Adv Skin Wound Care. 2003;16:75–7, http://dx.doi.org/10.1097/00129334-200303000-00008.
- Jan Y-K, Lung C-W, Cuaderes E, Rong D, Boyce K. Effect of viscoelastic properties of plantar soft tissues on plantar pressures at the first metatarsal head in diabetics with peripheral neuropathy. Physiol Meas. 2013;34:53–66, http://dx.doi.org/10.1088/0967-3334/34/1/53.
- Lung C-W, Hsiao-Wecksler ET, Burns S, Lin F, Jan Y-K. Quantifying dynamic changes in plantar pressure gradient in diabetics with peripheral neuropathy. Front Bioeng Biotechnol. 2016;4:54, http://dx.doi.org/10.3389/fbioe.2016.00054.
- 11. Mueller MJ, Zou D, Lott DJ. ''Pressure gradient'' as an indicator of plantar skin injury. Diabetes Care. 2005;28:2908–12, http://dx.doi.org/10.2337/diacare.28.12.2908.
- Armstrong DG, Peters EJ, Athanasiou KA, Lavery LA. Is there a critical level of plantar foot pressure to identify patients at risk for neuropathic foot ulceration? J Foot Ankle Surg. 1998;37:303-7, http://dx.doi. org/10.1016/s1067-2516(98)80066-5.
- Boulton AJ, Hardisty CA, Betts RP, Franks CI, Worth RC, Ward JD, et al. Dynamic foot pressure and other studies as diagnostic and management aids in diabetic neuropathy. Diabetes Care. 1983;6:26–33, http://dx.doi.org/10.2337/diacare.6.1.26.
- 14. Stokes IA, Faris IB, Hutton WC. The neuropathic ulcer and loads on the foot in diabetic patients. Acta Orthop Scand. 1975;46:839–47, http://dx.doi.org/ 10.3109/17453677508989271.
- 15. Fernando M, Crowther R, Lazzarini P, Sangla K, Cunningham M, Buttner P, et al. Biomechanical characteristics of peripheral diabetic neuropathy: a systematic review and meta-analysis of findings from the gait cycle, muscle activity, and dynamic barefoot plantar pressure. Clin Biomech (Bristol, Avon). 2013;28:831–45, http://dx.doi.org/ 10.1016/j.clinbiomech.2013.08.004.
- 16. Fawzy OA, Arafa AI, El Wakeel MA, Abdul Kareem SH. Plantar pressure as a risk assessment tool for diabetic foot ulceration in Egyptian patients with diabetes. Clin Med Insights Endocrinol Diabetes. 2014;7:31–9, http://dx.doi. org/10.4137/CMED.S17088.
- Veves A, Murray HJ, Young MJ, Boulton AJ. The risk of foot ulceration in diabetic patients with high foot pressure: a prospective study. Diabetologia. 1992;35:660–3, http://dx.doi.org/10.1007/bf00400259.
- Hills AP, Hennig EM, McDonald M, Bar-Or O. Plantar pressure differences between obese and non-obese adults: a biomechanical analysis. Int J Obes Relat Metab Disord. 2001;25:1674–9, http://dx.doi.org/10.1038/sj.ijo.0801785.

- Arnold JB, Causby R, Pod GD, Jones S. The impact of increasing body mass on peak and mean plantar pressure in asymptomatic adult subjects during walking. Diabet Foot Ankle. 2010;1:5518, http://dx.doi.org/10.3402/dfa.v1i0.5518.
- Hernández-Jiménez S, García-Ulloa C, Mehta R, Aguilar-Salinas C, Kershenobich-Stalnikowitz D. Innovative models for the empowerment of patients with type 2 diabetes: the CAIPaDi program. Recent Pat Endocr Metab Immune Drug Discov. 2014;8:1, http://dx.doi.org/10.2174/1872214808666141110160147.
- Hernández-Jiménez S, García-Ulloa AC, Bello-Chavolla OY, Aguilar-Salinas CA, Kershenobich-Stalnikowitz D, Group of Study CAIPaDi. Long-term effectiveness of a type 2 diabetes comprehensive care program. The CAIPaDi model. Diabetes Res Clin Pract. 2019;151:128–37, http://dx.doi. org/10.1016/j.diabres.2019.04.009.
- 22. Aboyans V, Criqui MH, Abraham P, Allison MA, Creager MA, Diehm C, et al. Measurement and interpretation of the ankle-brachial index: a scientific statement from the American Heart Association. Circulation. 2012;126:2890-909, http://dx.doi.org/10.1161/CIR.0b013e318276fbcb.
- Bus SA, Sacco ICN, Monteiro-Soares M, Raspovic A, Paton J, Rasmussen A, et al. Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2023 update). Diabetes Metab Res Rev. 2023;40(3):e3651, http://dx.doi.org/10.1002/dmrr.3651.
- Larrosa Padró M, Mas Moliné S. Alteraciones de la bóveda plantar. Rev Esp Reumatol. 2003;30(9):489–98.
- Rao S, Riskowski JL, Hannan MT. Musculoskeletal conditions of the foot and ankle: assessments and treatment options. Best Pract Res Clin Rheumatol. 2012;26:345–68, http://dx.doi.org/10.1016/j.berh.2012.05.009.
- 26. Derscheid GL, Malone TR. Knee disorders. Phys Ther. 1980;60:1582-9, http://dx.doi.org/10.1093/ptj/60.12.1582.
- Fernando ME, Crowther RG, Lazzarini PA, Yogakanthi S, Sangla KS, Buttner P, et al. Plantar pressures are elevated in people with longstanding diabetes-related foot ulcers during follow-up. PLoS One. 2017;12:e0181916, http://dx.doi.org/10.1371/journal.pone.0181916.
- Birtane M, Tuna H. The evaluation of plantar pressure distribution in obese and non-obese adults. Clin Biomech (Bristol, Avon). 2004;19:1055–9, http://dx.doi.org/10.1016/j.clinbiomech.2004.07.008.
- Robinson CC, Balbinot LF, Silva MF, Achaval M, Zaro MA. Plantar pressure distribution patterns of individuals with prediabetes in comparison with healthy individuals and individuals with diabetes. J Diabetes Sci Technol. 2013;7:1113-21, http://dx.doi.org/10.1177/193229681300700503.
- Fernando ME, Crowther RG, Pappas E, Lazzarini PA, Cunningham M, Sangla KS, et al. Plantar pressure in diabetic peripheral neuropathy patients with active foot ulceration, previous ulceration and no history of ulceration: a metaanalysis of observational studies. PLoS One. 2014;9:e99050, http://dx.doi.org/10.1371/journal.pone.0099050.
- 31. Bus SA, Waaijman R. The value of reporting pressure-time integral data in addition to peak pressure data in studies on the diabetic foot: a systematic review. Clin Biomech (Bristol, Avon). 2013;28:117-21, http://dx.doi.org/10.1016/j.clinbiomech.2012.12.002.
- 32. Bartolo E, Giacomozzi C, Coppini DV, Gatt A. The pressure time integral: an underused, clinically significant parameter as a determinant of neuropathic ulceration in diabetes. Gait Posture. 2023;100:210-5, http://dx.doi.org/10.1016/j.gaitpost.2022.12.018.
- 33. van Netten JJ, Raspovic A, Lavery LA, Monteiro-Soares M, Paton J, Rasmussen A, et al. Prevention of foot ulcers in persons with diabetes at risk of ulceration: a systematic review and meta-analysis. Diabetes Metab Res Rev. 2024;40:e3652, http://dx.doi.org/10.1002/dmrr.3652.

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