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Measurement of Plantar Pressure as a Risk Assessment Tool in Diabetic Patients to Reduce Pressure on Active Diabetic Foot Ulcers

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Abstract

Aims: *Diabetic foot ulceration is a preventable long-term complication of diabetes. In the present study, peak plantar pressures (PPP) and other characteristics were assessed in a group of 90 Egyptian patients with diabetes with or without neuropathy and foot ulcers. the aim of this study was to measure plantar pressure as a risk assessment tool in diabetic patients in order to reduce pressure on active diabetic foot ulcers.*

Methods: *A total of 90 patients having diabetes were selected. All patients had a comprehensive foot evaluation, including assessment for neuropathy using modified neuropathy disability score (MNDS). High plantar pressure is a common risk factor for diabetic foot ulcers, and patients with a history of diabetic foot ulcers often have higher plantar pressures compared to their uninjured or nondiabetic counterparts. Vertical plantar pressure is commonly assessed; however, there are studies that report shear pressures, which are smaller in magnitude and more difficult to assess than the vertical component. Currently, shear stress is often limited to barefoot assessment, while vertical plantar stress is assessed both barefoot and in shoes. Although the inside of the shoe seems to be most useful for the pressures experienced in everyday life, it still exists.*

Results*: peak pressure parameters were significantly different between the studied groups, namely, forefoot peak plantar pressure, rearfoot peak plan-tar pressure, forefoot/rearfoot ratio, forefoot peak pressure gradient rearfoot peak pressure gradient, and forefoot peak pressure gradient/rearfoot peak pressure gradient ($P < 0.05$). Research on activities of daily living in patients with diabetic peripheral neuropathy, although limited, suggests that more time is spent standing and sitting compared to walking. Such findings suggest that measuring cumulative pressure over time may be more relevant than the commonly used peak pressure parameter. Custom shoes and insoles are usually prescribed to relieve pressure on the soles of the feet. While footwear interventions are effective at offloading for the most part, results vary between individuals and are only effective when worn regularly. The provision of plantar pressure feedback provides an alternative approach and shows promising results. However, further research is required to understand the long-term effects of feedback, considering all areas of the diabetic foot.*

Conclusion: *In conclusion, persons with diabetes having neuropathy and ulcers have elevated peak plantar pressure. Risk of ulceration was highly associated with duration of diabetes, smoking, severity of neuropathy, glycemic control, and high peak pressure variables especially the forefoot peak plantar pressure, forefoot/rearfoot, and forefoot peak pressure gradient. Studies have shown that providing pressure feedback may reduce plantar pressures using emerging smart technology; however, more research is needed. To improve our understanding of the pressures leading to diabetic foot ulcers and to improve the effectiveness of interventions, further analysis of pressure is needed in all weight-bearing activities with reference to site-specific pressures.*

Keywords: Diabetic Foot Ulcers, Peripheral Neuropathy, Plantar Pressure, Pressure Feedback

1. Introduction

Currently, there are 425 million adults worldwide with diabetes, and this number is expected to rise to 629 million by 2045 [1]. Diabetes is the leading cause of non-traumatic lower extremity amputations, with up to 85% of these amputations resulting from diabetic foot ulcers (DFU) [2,

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3]. DFUs are a costly public health concern that often led to amputation or infection and are associated with reduced quality of life [4, 5]. The lifetime risk of developing a DFU is 15-25% [6, 7]. However, after an ulcer occurs, there is a high recurrence rate with 40% in the first year and up to 65% after 5 years of healing [8, 9]. Risk factors for DFU include diabetic peripheral neuropathy, foot deformity, and trauma, with diabetic peripheral neuropathy being the most significant risk factor [10, 11]. The ability to move is crucial for maintaining independence and participating in daily activities, making it a vital aspect of a person's quality of life [12]. Diabetes significantly reduces mobility, impairs lower limb function, prevents the performance of daily activities, increases physical disability, and raises the risk of death compared to individuals without diabetes. As diabetes progresses, walking performance generally declines, leading to diabetic neuropathy and, consequently, diabetic foot ulcers [13, 14]. However, there is limited research on mobility patterns in individuals with foot ulcers. The highest incidence of ulcers is in the anterior area of the foot, accounting for 71% of ulcers (13), with the most common locations being the head of the first metatarsal and the lower surface of the toe [2, 13, 15]. This review aims to investigate the role of high plantar pressure, which results from various risk factors, in predicting and preventing active DFU. The authors review different methods of evaluating plantar pressure in both barefoot and in-shoe conditions, as well as the pressure parameters analyzed in previous studies. Studies assessing plantar pressure consistently show higher pressures in people with diabetes and even higher pressures in those with ulcers. However, despite this, vertical plantar pressure alone is still considered a poor predictor of DFU in prospective studies. This review discusses the strengths and limitations of previous studies, which may have contributed to the low predictive power and correlation of previous methods with pressures experienced during real-life daily activities. With the development of new biomechanical devices in the laboratory, such as compression force plates and sensor insoles, the study of plantar pressure has become more accurate and simpler. Although sensor insoles are more challenging to calibrate, they allow for more measurements to assess pressure compared to pressure plates [16-18]. The use of these devices has become widespread in various aspects of studying plantar pressure.

In 2009, Baccarin and colleagues evaluated and compared the pattern of plantar pressure distribution using sensor insoles. Their study showed that the progression of the disease does not affect the pattern of plantar pressure distribution, but a history of plantar fascia causes a change in the distribution pattern, with most forces being transferred to the middle and heel [19]. Maroli and Piccioli evaluated the pattern of plantar pressure distribution during walking in patients with neuropathic diabetes and found that these patients have a longer time interval between heel contact and toe lift compared to healthy individuals, indicating limited movement in the middle tarsal, subtalar, and wrist joints [20]. Although individuals with diabetic foot ulcers on the soles of their feet may have lost their depth sensation, their activities may still exhibit characteristics of a protected gait pattern during barefoot walking to compensate for the ulcers, potentially leading to reduced plantar pressure in the diabetic foot ulcer phase [21, 22]. This suggests the possibility of altered gait in individuals with diabetic foot ulcers, which contradicts previous findings. Based on these studies, the aim of this study was to investigate plantar pressure in the soles of the feet in diabetic patients and those with active diabetic foot ulcers during walking.

Section Snippets

2. Research Design and Methods

Study design and participants: A cross-sectional method was used in accordance with the research topic and objectives. G*Power software was utilized to estimate a minimum sample size of 90 individuals, with a statistical power of 0.8, an effect size of 0.95, and a significance level of 0.05 [20]. The statistical population consisted of individuals with type 2 diabetes and diabetic foot ulcers. The sampling method was random and accessible. The statistical sample included 30 healthy men (height: 174.46±7.21 cm; weight: 79.46±8.53 kg; BMI: 26.19±3.23 kg/m2), 30 diabetic men (height: 175.86±5.33 cm; weight: 6.3±13 cm; BMI: 27.34±3.45 kg/m2), and 30 individuals with active diabetic foot ulcers (height: 177.37±6.38 cm2; weight: 84.40±8.83 kg; BMI: 26.93±3.52 kg/m2) who were not required to undergo amputation according to their doctor's diagnosis. The inclusion criteria were confirmation of type 2 diabetes and diabetic foot ulcers, age between 55 and 75 years, not using immunosuppressant drugs such as cortisone, residing in Ardabil, being literate or having a literate family member, and having the ability and willingness to participate in the study [23, 24]. Each participant completed and signed a consent form. Exclusion criteria included a history of lower body surgery, spinal deformity, osteoporosis, fracture, or lower body disorders. Diabetic peripheral neuropathy leads to a loss of protective sensation due to abnormally high, repetitive, and undetected pressures applied to the weight-bearing plantar surface of the foot. Additionally, foot deformities such as hammertoe and small muscle wasting further contribute to increased plantar pressure, particularly in the metatarsal heads where the bony prominences are located. Other factors, including reduced ankle dorsiflexion and decreased thickness of the plantar tissue, have also been reported to play a role in increasing plantar pressure [10, 14]. High pressure on the sole of the foot results in callus thickening, which puts more pressure on the underlying soft tissue and leads to tissue breakdown and scarring [25, 26].

Current interventions for preventing diabetic foot ulcers focus on reducing these high plantar pressures. In high-risk diabetic feet, custom shoes and/or insoles are often prescribed to alleviate pressure from high-risk areas by accommodating foot deformities. When worn, these interventions have been shown to significantly reduce wound rates. However, poor adherence to footwear interventions often limits their effectiveness. Previous research supporting the association between high plantar pressure and the risk of diabetic foot ulcers has some limitations, which will be discussed in the following sections.

2.1 Instruments and Examination

Most studies examining plantar pressure in the diabetic population have utilized barefoot pressure analysis, primarily through the use of pressure platforms (Figure 1). These platforms provide a walkway that ensures proper foot placement. However, there are differences in methodology and patient characteristics among the articles (Table 1). Some studies focus on checking pressure in specific areas on the soles of the feet, with the majority focusing on the forefoot. Only a few studies analyze pressure at the site of wounds. Despite some variation, the literature generally agrees that diabetic patients, especially those with a history of DFU, have higher plantar pressures than controls [27, 28].

Figure 1: Pressure Stat (Medical Gait Technology by Emmen, the Netherlands) is Utilized for Collecting Barefoot Pressure Data

The Rs-Scan device was positioned at the center of a 15-meter walking path. A leg scanning pressure plate (Rs Scan International, Belgium, 0.5 × 0.5 × 0.02 m, 4363 sensors, 300 Hz) was clearly marked along the 15 m area. The software (Footscan1 9 Gait 2nd Generation software, Rs Scan International) automatically divided the foot into ten anatomical regions: medial heel (MH), lateral heel (LH), first to fifth metatarsals (M1-5), hallux (T1), and lesser toes (T2–5) (Figure 2).Correct walking attempts required a full foot strike in the middle of the leg scan. If the participant was unable to target the foot scan or lost balance, the walking and running tests were repeated. Plantar pressure data were collected during the standing phase of walking, defined as heel contact with the ground until toe lift. The average of three walking trials was used for statistical analysis.

The dependent variables in this study included the peak vertical ground reaction force, time to peak forces, vertical loading speed, peak pressure (N/cm2) in 10 areas of the foot, peak forces in 10 areas of the foot and middle and anterior displacement of the center of pressure (COP). In normal walking, the vertical GRF bimodal curve consists of two peaks: the first peak in heel contact (FzHC) and the second peak in the push-off phase (FzPO). There is also a dip between the two peaks (FzDF) during midstance [25]. To calculate the amount of vertical loading during walking, the slope of the connection line from the moment of heel contact to the initial peak of the vertical ground reaction force curve was calculated [26]. Vertical loading rate during running was calculated as the average slope from 20% to 80% of the vertical GRF (Fz) at the point of interest [27]. A frequency cutoff of 20 Hz was used to smooth the ground reaction force response data during walking [27]. To normalize vertical ground reaction force values, these values were divided by body mass and then multiplied by 100 [27].

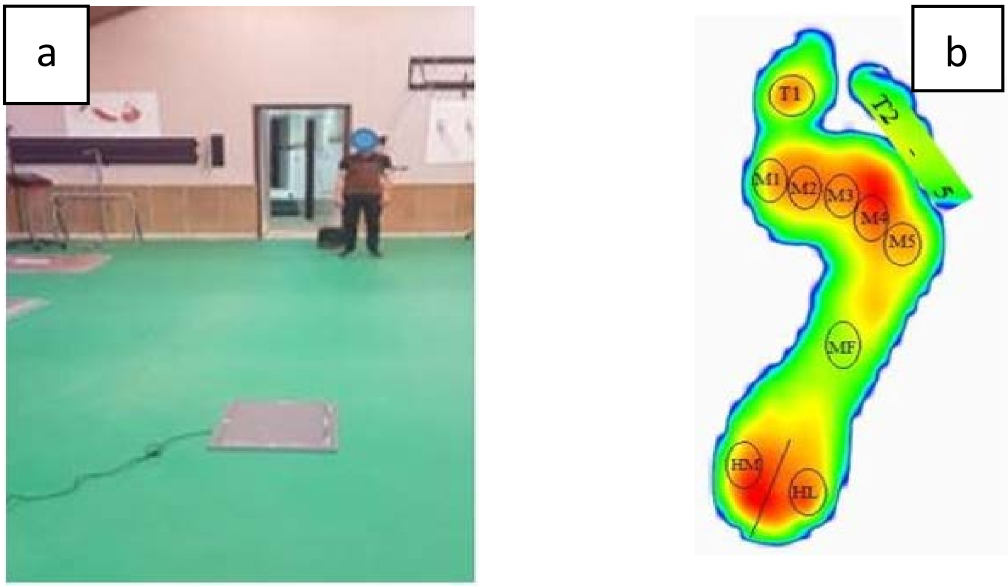

Figure 2: Walking Path and Foot Scan Machine (a), Ten-Foot Areas (b)

2.3 Statistical Analysis

First, the normality of the distribution of the variables was confirmed using the Shapiro-Wilk test. The MANOVA test was used to compare between groups. The significance level for all analyses was set at $p < 0.05$. Statistical analyses were performed using SPSS (version 24, SPSS Inc., Chicago, IL). Additionally, the effect size (d) was calculated as the ratio of the mean difference divided by the pooled standard deviation [28]. Prospective studies consistently report significantly higher peak plantar baseline pressures in diabetic participants who had ulcers during the follow-up period compared to those who remained ulcer-free (Table 1). These studies included patients with and without a history of DFU. People with a history of DFU have been reported to have significantly higher plantar pressure than those without a history of DFU. Therefore, including participants without a history of DFU in such studies may dilute the results and decrease the sensitivity of the wound predictor to low pressure. Patients with active DFUs potentially alter their gait (albeit without any sensory feedback) to avoid further damage to the active wound. Changes in gait and resulting pressures are expected to vary depending on DFU status. Therefore, the analysis should ideally group patients accordingly.

Friberg et al. also found a significantly greater peak plantar pressure for the injured group compared to the control group, which had no ulceration [29]. Unlike many whole-foot barefoot studies, Lavery et al. described recording the location of the peak pressure [30]. However, as is the case with most whole-foot barefoot studies, they did not report the location and did not perform any special local pressure analysis. A more comprehensive pressure analysis, which takes into account the effect of location on pressure and DFU, as well as more accurate grouping of patients, may improve the prediction of DFU.

3. Results

A descriptive analysis of the data obtained from the study participants showed that there were no statistical differences between the groups in terms of age, height, and weight (See Table 1). However, significant differences were found between the groups in various aspects related to the ground reaction force and walking.

Variables	Groups		
	Diabetic	DFU	Healthy
N	30	30	30
Age (years)	68.00±8.41	68.50±6.69	68.33±6.75
Mass (kg)	70.93±5.34	72.23±5.29	72.46±4.95
Height (cm)	171.93±5.27	172.63±5.04	171.80±5.10
BMI	24.08±2.62	24.33±2.69	24.62±2.30
Gender	Male	Male	Male
Range of age	55-75	55-73	56-75

Table1: Demographic Characteristics of Healthy Individuals

In the diabetic, DFU, and healthy groups, significant differences were observed in the vertical component of the ground reaction force during heel contact (≤0.001), middle position (p=0.002), moving the foot away (p=0.023), the time to reach the peak of the vertical component of the ground reaction force in the middle stance phase (p=0.001), vertical loading rate (p=0.046), center of pressure displacement in the medial-lateral component (p=0.030) and anterior-posterior component (p=0.043), and walking speed (p=0.037) (Table 2). Further analysis revealed that the vertical component of the ground reaction forces during heel contact (p≤0.001), middle position (p=0.002), leg exit phase (p=0.023), the time to reach the vertical peak of the ground reaction forces component in the middle stance phase (p≤0.001), vertical loading rate (p=0.011), and displacement of the center of pressure in the anterior-posterior component (p=0.018) were higher in the diabetic foot ulcer group compared to the diabetic group (Table 2). Additionally, the vertical component of the ground reaction forces during heel contact (p=0.030), toe-off phase (p=0.017), and the time to reach the peak of the vertical component of the ground reaction forces in the middle position (P = 0.033) in the diabetic group compared to the healthy group (Table 2). Moreover, the vertical component of the ground reaction forces during heel contact (p = 0.008), middle position (p = 0.002), vertical loading rate (p = 0.045), displacement of the center of pressure in the medial-lateral component (p = 0.010) and walking speed (p=0.003) were lower in the diabetic foot ulcer group compared to the healthy group (Table 2).

Variables	Component	Diabetic	DFU	Healthy	F	sig
Vertical ground reaction force	FzHC	1526.63±280.54*●	1940.59±231.69*♦	1717.78±378.50♦●	14.01	P≤0.001
	FzMS	1411.62±225.72*	1572.08±196.07*♦	1345.61±316.58♦	6.43	0.002
	FzPO	1455.91±255.60*●	1626.69±261.59*	1653.56±359.55●	3.93	0.023
Time to peak forces	FzHC	246.02±89.48	230.05±36.54	261.73±86.53	1.34	0.267
	FzMS	392.79±63.57*●	477.23±75.17*	443.82±109.79●	7.48	0.001
	FzPO	580.66±87.96	571.65±75.50	602.42±99.41	0.96	0.385
Loading rate	Vertical	7.03±2.89*	8.58±1.34* ♦	7.35±2.98 ♦	3.18	0.046
center of pressure displacement	Medial and lateral	32.99±11.99	38.53±12.71 ♦	30.47±10.62 ♦	3.65	0.030
	Anterior-posterior	235.70±23.85*	250.88±24.28*	237.93±26.41	3.25	0.043
Velocity		1.33±0.19	1.27±0.13 ♦	1.37±0.13 ♦	3.42	0.037

Table 2: Comparison of Values for Vertical Ground Reaction Force (Expressed as a Percentage of Body Mass), Time to Peak Forces (in Milliseconds), Vertical Loading Rate, Center of Pressure Displacement and Velocity in Three Groups: Diabetic Type 2, DFU and Healthy

* Shows a significant difference between the diabetic group and the group with diabetic foot ulcer
● Shows a significant difference between the diabetic group and the healthy group
♦ Shows a significant difference between the healthy group and the group with diabetic foot ulcer

The differences between the peak force groups in metatarsus 1 (p=0.014), metatarsus 2 (p=0.027), metatarsus 3 (p≤0.001), metatarsus 4 (p=0.006), medial (p=0.002) and lateral (p=0.003) heel, as well as the peak pressure in metatarsus 3 (p=0.001) and medial heel (p=0.010) and lateral (p=0.016) in the three groups (diabetic, DFU, and healthy) were found to be significant (Table 3). The results indicated that the peak force in metatarsal 1 (p = 0.014), metatarsal 2 (p = 0.027), metatarsal 3 (p ≥ 0.001), metatarsal 4 (p = 0.006), middle (p = 0.003) and lateral (p = 0.003) heel pressure, as well as the peak heel pressure 3 (p ≤ 0.001), medial (p = 0.004) and lateral heel (p = 0.007), were higher in the diabetic foot ulcer group compared to the diabetic group (Table 3). Furthermore, the results showed that the peak force in metatarsal 1 (p=0.006), metatarsal 3 (p=0.015), medial (p=0.023) and lateral heel (p=0.011), as well as the peak pressure in the middle area (p=0.013) and lateral heel (p=0.019) were lower in the diabetic group compared to the healthy group (Table 3).

Variables	Area	Diabetic	DFU	Healthy	F	sig
peak force	Toe 1	222.40±84.16	252.21±101.83	231.60±77.69	0.89	0.413
	Toe 2-5	80.43±31.63	98.18±52.17	81.61±43.89	1.56	0.214
	M1	233.77±64.58*●	293.18±103.12*	292.24±90.81●	4.52	0.014
	M2	188.08±59.68*	237.92±77.46*	222.62±77.52	3.76	0.027
	M3	190.02±51.48*●	269.48±67.88*	23268±78.12●	10.65	P≤0.001
	M4	148.48±43.46*	192.46±57.81*	172.81±52.58	5.50	0.006
	M5	85.15±29.79	86.27±39.50	88.15±35.22	0.05	0.946
	MF	178.62±67.88	217.94±108.56	191.24±75.00	1.64	0.199
	MH	359.62±87.77*●	471.30±137.49*	427.61±132.45●	6.45	0.002
	LH	292.69±71.28*●	372.92±94.53*	352.99±103.08●	6.37	0.003

peak pressure	Toe 1	16.61±4.77	17.31±6.15	17.12±4.16	0.15	0.859
	Toe 2-5	6.78±1.95	6.94±3.04	6.65±2.03	0.10	0.897
	M1	13.79±3.72	15.06±5.53	15.28±2.03	0.86	0.423
	M2	21.28±6.19	23.14±5.87	22.95±6.17	0.84	0.431
	M3	17.66±3.99*	21.90±4.22*	19.76±4.78	7.15	0.001
	M4	13.79±3.51*	16.04±3.76*	14.98±3.84	2.76	0.069
	M5	9.50±2.97	8.87±2.70	9.47±2.82	0.48	0.620
	MF	6.77±1.73	7.56±3.10	7.08±1.78	0.91	0.404
	MH	18.56±3.71*●	22.09±5.33*	21.40±4.74●	4.85	0.010
	LH	16.69±3.62*●	19.68±4.58*	19.20±4.38●	4.33	0.016

Table 3: Comparison of Peak Force and Peak Pressure in Ten Areas of The Foot in Three Groups: Diabetic, Diabetic Foot Ulcers and Healthy Individuals During Walking

* Demonstrates a significant difference between the group with diabetes and the group with diabetic foot ulcers.
● Demonstrates a significant difference between the group with diabetes and the healthy group.
♦ Demonstrates a significant difference between the healthy group and the group with diabetic foot ulcers.

Another proposed explanation for vertical plantar pressure being a poor predictor of DFU is the failure to consider plantar shear stress. Commercial systems have primarily focused on vertical pressure but examining shear stress could enhance understanding of plantar mechanics and their role in DFU development [32]. Research has shown that peak shear and peak vertical pressure often occur at different locations on the foot, indicating the complexity of DFU Yavuz et al. [33]. Some studies have found that peak shear stress corresponds to recently healed forefoot DFUs, while others have found DFUs at locations where both peak shear stress and peak vertical pressure are present, as well as locations with no peak parameters. This highlights the multifactorial nature of DFU Yavuz et al. [34].

A study conducted by Yavuz et al. compared shear stress and vertical plantar pressure values between diabetic participants with and without a history of DFU. Both peak shear stress and vertical plantar shear stress were higher in the DFU group, but only shear stress was statistically significant. The study may have been underpowered to detect a significant difference in peak vertical pressure, but the authors believed the result was clinically meaningful. It is important to note that these studies measured shear stress while barefoot, so the results may not reflect the shear stress exerted in a shoe, which can vary depending on the shoe type. Further research is needed to fully understand the role of shear stress in DFU development, but currently, there are only a limited number of commercially available devices capable of measuring in-shoe shear stress. Nevertheless, existing research suggests that measuring plantar shear and vertical pressure, along with other risk factors, can improve the understanding and prediction of DFU. However, more ecologically valid research is necessary before plantar pressure can be disregarded as the sole predictor of DFU.

3.1 Analysis of Barefoot Pressure Specific to the Wound Site

To the authors' knowledge, there have only been two studies evaluating barefoot pressure at the site of a previous wound. Although different in study design, the results suggest that wound location is related to the amount of pressure at that particular site. In a prospective study, barefoot pressure was evaluated using a pressure platform at the site of a previous wound, using methods similar to those previously discussed. Patients who re-ulcerated at the same site during the follow-up period had significantly higher pressures than patients who did not re-ulcerate at that site or did elsewhere [31]. While this study provides interesting insight into the specific pressure at the wound site, it lacks data on any specific site on the sole of the foot or comparison with a control group. A recent cross-sectional study addressed these limitations and identified a site-specific relationship in the hallux. Barefoot pressure in the hallux, measured using the Pressure Stat footprint map, was higher for diabetic patients with previous hallux DFU compared to a group of diabetic patients with ulcers in another location and a group of non-diabetic individuals. Pressure Stat, a semi-quantitative footprint map, is an easy and inexpensive way to highlight specific areas of pressure on the sole of the foot by comparing the gray scale of the footprint with a calibration card. However, its subjective nature, along with the general limitations of barefoot analysis, necessitates further research using less subjective analysis to confirm site-specific relationships between plantar pressure and DFUs.

Disaggregating plantar pressure analysis into zones may provide more detailed information, but barefoot analysis may be criticized as patients with diabetic neuropathy are advised to avoid walking barefoot due to the risk of injury. Additionally, barefoot pressure analysis may not accurately reflect the pressures experienced on a daily basis that ultimately lead to ulcers. Nevertheless, barefoot analysis provides a "baseline" measure of plantar pressures without the potential confounding effects of shoe or orthosis pressure and may therefore be informative for certain purposes. Since most daily activities are performed while wearing shoes for patients with diabetic neuropathy, it is suggested that a more ecologically valid approach to analyzing plantar pressure in everyday life is to do so in shod conditions.

3.2 In-Shoe Pressure Analysis

People with diabetic neuropathy are advised to always wear shoes during daily activities to reduce pressure and the risk of foot injury. However, patients who follow these guidelines still develop ulcers. Therefore, insole pressure analysis is an important aspect discussed in the literature. Figure 1 shows an example of a vertical pressure sensor inside a shoe. However, developing sensors to measure shear stress inside a shoe has proven to be more challenging [35]. Although there have been advancements in measuring in-foot shear stress, studies examining its relation to DFU (Diabetic Foot Ulcer) are relatively rare [36].

Studies generally indicate that vertical plantar pressures experienced in shoes are lower than those experienced while barefoot. However, individuals who develop ulcers still have higher in-shoe vertical pressures compared to groups that remain ulcer-free. The advantages and disadvantages of barefoot and in-shoe pressure analysis are outlined in Table 3. In in-shoe pressure studies, a threshold of 200 kPa for vertical plantar pressure has been suggested to identify individuals at risk of DFU. Azad had pressure levels above this threshold, while some individuals with ulcers had pressure levels below it. Additionally, one study reported that 36% of patients without ulcers and 51% of patients with ulcers had pressures above the threshold.

Assessment type	Advantages	Disadvantages
Barefoot	• Easy to use • Durable • Embedded in floor to allow normal gait • Allows assessment of base plantar pressure development without footwear	• Restricted to laboratories • Requires familiarisation to ensure natural gait • Can be limited by patient's ability to make contact with the platform • Requires multiple trials • Walking barefoot presents a risk to diabetic neuropathy patients • Does not account for pressure-reducing nature of footwear
In-shoe	• Portable system • Allows multiple footsteps per trial • Less risk to the diabetic foot • Allows assessment of pressure-reducing nature of footwear	• Majority of systems involve the participant being tethered by cables • Possibility of sensor slipping and becoming damaged

Table 4: Advantages and Disadvantages of Barefoot and In-shoe Pressure Assessment Methods`

Studies that assess in-shoe pressure primarily focus on specific areas. Some studies have examined in-shoe pressure at the sites of previous diabetic foot ulcers (DFUs), and these studies have yielded similar results to barefoot analysis. However, more research is needed in this field. To the authors' knowledge, only one study has analyzed pressure separately at previous DFU locations. This study found that the composite pressure at the wound sites was higher than the pressure at the same site in non-wounded patients. However, the study did not conduct any statistical analysis to compare the pressure data. When examining the data by location, the hallux and heel, which had the highest rate of DFU with metatarsals, had lower peak plantar pressures than the non-ulcerated group. However, peak plantar pressures for ulcerated metatarsals were higher. Additionally, a higher baseline peak pressure was only significantly associated with an increased risk of DFU in the metatarsals, potentially indicating a location-specific connection solely in the metatarsals. However, it is important to note that this study only analyzed five strides per foot, whereas Arts and Bus suggest that twelve strides are necessary to ensure reliable and valid in-shoe pressure data [37]. Furthermore, 50% of the entire group and 19% of the non-neuropathic wound group had neuropathy, which is a major risk factor for DFU. The inclusion of non-neuropathic patients in the study raises the possibility that some DFUs are not neuropathic plantar ulcers and may have developed through a different pathway unrelated to plantar pressure, potentially affecting the results. Therefore, further analysis is required to confirm whether there is a location-specific and wound pressure relationship for neuropathic DFUs.

3.3 Influence of Daily Activity on DFU Development

Research has shown that the development of a DFU is influenced by both plantar pressure and repeated loading. The amount of activity a person engages in is often used to estimate the cumulative pressure exerted on the soles of the feet. It has been suggested that individuals with diabetic neuropathy have a higher cumulative pressure exerted and a greater risk of ulceration. This is also true for most studies that evaluate activity. Studies often record the number of steps per day as an indicator of weight-bearing physical activity. However, studies have shown that patients with a history of DFU walk significantly fewer steps per day compared to people without a history of DFU and healthy people [38, 39, 40]. This contradicts the belief that increased cumulative load leads to DFU. An accelerometer is regularly used to measure activity, but data collected over a short period of time may not adequately represent the activity levels of diabetic patients at risk of DFU, which can vary [38]. Additionally, Le Master et al. used questionnaires to record self-reported activities of the past 24 hours [39]. Unlike previous studies, this study included all weight-bearing activities, including standing and sitting, which likely contribute to the cumulative pressure exerted on the plantar sole and associated DFU risk. However, there was limited analysis of different types of activity, apart from baseline, where patients with previous DFU spent more hours sitting than walking.

Furthermore, Le Master et al. reported no significant difference in weight-bearing activity between participants who developed an ulcer at follow-up and those who did not [41]. In fact, a higher activity level reduced ulcer risk, contradicting previous theories. Additionally, participants with neuropathy were slightly less active than those with intact sensation. However, such differences were not significant. Although activities other than walking were considered, activity in the previous 24 hours remained constant between questionnaires during each 17-week time period. In addition, the questionnaire was reported to have strong validity with step-activity monitoring. However, the sensitivity of this measure may be questionable in terms of distinguishing between different types of weight-bearing activity. A more sensitive method for detecting types of activities than questionnaires is the triaxial accelerometer, as reported by Najafi et al. initially [41]. However, the results were not compared with the control group and the analysis was only performed during 48 hours. In addition, no previous foot deformities or DFUs were noted, suggesting that participants may be at lower risk than previously studied groups, which was also indicated by higher step counts. Nevertheless, such results are promising and highlight the importance of future studies measuring a variety of weight-bearing activities, as all ultimately contribute to the cumulative stress and load applied to the plantar foot and the associated DFU risk. Future studies should compare the activity of high-risk patients with control subjects with accelerometers worn for longer periods of time.

3.4 Relevance of Cumulative Pressure Data for DFU Risk

Although further research is necessary, previous studies suggest that diabetic patients who are at risk of ulcers tend to spend more time standing and sitting rather than walking [41, 42]. However, it is important to note that individuals are still at risk of ulceration during such weight-bearing activities. Assessment of pressure in the diabetic population has been limited to walking. Compared to walking, other weight-bearing activities such as standing usually have lower peak pressures. However, this pressure is applied for a longer period of time. Prolonged pressure increases the duration of blood occlusion and ischemia of plantar tissue, thereby increasing the risk of DFU. It may be more indicative of DFU risk than peak pressure. However, such an analysis only exists for walking. Integral pressure-time data are sometimes reported alongside the parameter of choice, peak pressure, with conflicting views on whether it adds any benefit [63]. Most studies reporting both parameters found no difference between them, essentially no results, or a significant pattern has been reported. For the peak pressure, there was also a pressure-time integral. The few studies that found differences, perhaps indicating a benefit of reporting both, had some limitations. Differences were evident only in the heel, possibly due to its greater variability during stance compared to other regions. Furthermore, other studies that showed differences between parameters did not standardize walking speed. Walking speed affects the pressure-time integral more than peak pressure, and differences are expected to be minimal if standardized. In addition, integrated pressure-time data along with steps per day were used to estimate cumulative plantar pressure. While this may provide a more accurate estimate of cumulative pressure compared to using either measurement alone, again, the only activity assessed was walking. More research is needed on the stress parameters of all weight-bearing activities in daily life. Peak integral pressure, pressure-time, and cumulative pressure data may be best suited for various weight-bearing activities. However, until such an analysis is performed in the diabetic cohort, no conclusions can be drawn.

3.5 Planter Offloading Interventions for Active Foot Ulcers

In clinical practice, offloading interventions such as shoes and insoles are commonly prescribed to reduce pressure on the sole of the foot in an attempt to improve or prevent diabetic foot ulcers (DFUs). The primary goal of these interventions is to reduce plantar pressure on active DFUs or areas at risk of developing a DFU by transferring pressure to other areas of the foot or drainage system. As discussed in previous sections, plantar pressure in shoes is lower than in barefoot conditions. Therefore, custom-made therapeutic shoes are usually prescribed to alleviate ulcers and drain affected areas of the foot. However, it is still possible to develop sores while wearing these shoes. Although the main goal of shoe prescription is to relieve high plantar pressures, the measurement of plantar pressure often does not play a role in shoe design and manufacture. Instead, clinical judgment and the shape of the foot are taken into account, resulting in varying methods and materials used. It is more of an art than a science [43, 44, 45].

Among the various shoe designs available, shoes with rocker soles designed to compensate for minimal motion at the foot and ankle joints and maximize foot contact have consistently been shown to reduce forefoot stress. Other designs have shown inconsistent results [46, 47, 48]. To further facilitate plantar unloading, the use of an insole is a critical component of therapeutic footwear and has been shown to significantly reduce plantar pressure compared to footwear alone. Custom insoles are preferred over off-the-shelf alternatives. However, the addition of barefoot pressure assessment to the design process has significantly improved drainage capabilities and reduced recurrence of DFU. Barefoot pressure analysis helps identify areas of high pressure to guide insole design. While this approach has been successful in most cases, there is evidence of inter-individual variation, with some individuals showing no benefit from additional barefoot pressure input. This variation may be due to the shoe's impact on the pressure profile of the sole. Studies that modified insoles based on in-shoe pressure reported significant reductions in plantar pressure after modifications. However, poor adherence to the shoe by some patients affected the results. When non-adherent patients were excluded from the analysis, a significant reduction in DFUs was observed. Continuous unloading is necessary to prevent relapse, and while customized therapeutic shoes,

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particularly insoles designed using plantar pressure data, have been effective, results vary between individuals. More research is needed to establish standardized and reliable protocols for designing and maintaining modifications over time.

The aim of this study was to investigate plantar pressure in diabetic patients with active foot ulcers while walking. The results showed that the vertical component of the ground reaction forces in the heel contact phase middle position, and toe-off phase, as well as the time taken to reach the peak of the vertical component of the ground reaction forces in the middle stance phase, and the magnitude of vertical loading, were higher in diabetic foot ulcers compared to the diabetic group. Additionally, the vertical component of the ground reaction forces in the heel contact phase, middle stance phase, and vertical loading speed were higher in the diabetic foot ulcer group compared to the healthy group. In this study, we did not control for walking speed because previous research has shown that diabetics walk more cautiously than the healthy group, indicating longer standing time in patients with diabetic foot ulcers [29]. However, previous studies have shown that walking speed can significantly affect the distribution and magnitude of plantar pressures and ground reaction forces [29, 30]. A faster walking speed, indicated by a shorter stride duration, has been found to increase the force exerted on the heel contact, mid stance, toe-off, and little toes (T2-5), while decreasing plantar pressure in the front medial and lateral positions [31]. It is important to note that these results were compared with those of healthy individuals, and comparing them with patients with diabetic foot ulcers may yield different results [29]. Additionally, the vertical component of the ground reaction forces during the heel contact phase and mid-stance was higher in the diabetic foot ulcer group than in the healthy group. Before developing a diabetic foot ulcer, individuals typically experience diabetic neuropathy, which causes numbness in the legs and impaired proprioception. This leads to improper weight distribution and increased pressure on the legs, resulting in ulceration in areas that bear the most pressure. Ko et al. (2012) found that several factors, including the severity of diabetic neuropathy, foot deformities, overweight, and altered walking patterns, contribute to the increased ground reaction forces observed in individuals with diabetic foot ulcers.

In their study on patients with diabetes, Viswanathan et al. (2003) discovered that the incidence of restricted joint movement and the force and pressure applied in these individuals were higher compared to healthy individuals [49]. They also demonstrated that patients with diabetic neuropathy and a history of diabetic foot ulcers had more joint movements and plantar pressure than diabetic patients without neuropathy [49]. They further stated that high pressure on the soles of the feet and joint restrictions contribute to ulceration in individuals with neuropathic diabetes [49]. Meroli and Occioli examined plantar pressure in neuropathic diabetic patients and found that walking time was longer in these patients compared to healthy individuals (20, 50, 51). Increased ground reaction force in patients with diabetic foot ulcers may be associated with the severity of diabetic neuropathy, foot deformities, overweight, and changes in walking patterns. Baren et al. (2015) identified local deformities such as toe and toe deformities as the main factors contributing to increased dynamic plantar pressure in their population. Fernando et al. (2016) also found higher ground reaction forces in diabetic foot patients compared to the healthy group, suggesting that individuals with diabetic foot ulcers experience greater mechanical stress while walking. Furthermore, Fernando et al. (2016) revealed that shear force is also higher in the diabetic foot ulcer group compared to the healthy group. Altered gait is likely a contributing factor to elevated plantar pressures due to changes in motion. This suggests that the higher ground reaction forces experienced by individuals with active DFUs are likely due, at least in part, to altered kinematics. Therefore, the gait characteristics of individuals with DFUs, particularly changes in motion and kinetic changes in ground reaction force, likely contribute to increased plantar pressure.

Additionally, the results showed that the amount of vertical loading was higher in the diabetic foot ulcer group than in the healthy group. Various studies have shown that the vertical loading rate has a direct relationship with the vertical component of the ground reaction force. The loading speed is obtained by dividing the first peak in the image of the ground reaction force in the perpendicular direction by the time it takes to reach the same peak [52]. Increased loading rates above 70 N/kg have been reported to be associated with an increased risk of stress fractures as well as patellar pain [53]. It has also been reported that people with loading rates greater than 100 N/kg have compression fractures in the lower leg [54]. The amount of vertical loading is a measure of the impact that is transmitted to the body during the contact phase with the heel and is associated with various injuries [55]. There was an increase in the diabetic foot ulcer group compared to the healthy group. Additionally, the results of the present study showed that the displacement of the center of pressure in the medial-lateral component in the diabetic foot ulcer group was greater than in the healthy group, and in the anterior-posterior component, it was greater than in the diabetic group. This shows that patients with diabetic foot ulcers have more imbalance than the diabetic and healthy groups, which can lead to many risks [56, 57]. Functional balance control, or the ability to maintain a stable position during daily functional activities of life, requires an efficient and dynamic interaction between three factors: the person, the performance being performed, and the environment. All human beings have to perform different tasks in different environments due to the needs of daily life. From an individual point of view, what distinguishes patients with diabetic foot ulcers from others and endangers their health is the destruction of the sensory and motor nerves in this lower limb. This reduces the accuracy and efficiency of reactive strategies that control balance, such as ankle, hip, and gait motor strategies, which may cause a person to lose balance if they are unable to regain their posture and lead to falling [58, 59]. The findings of previous studies show a significant reduction in basic variables of balance such as postural oscillation speed, anterior-posterior postural oscillation speed dispersion, amplitude of oscillations,

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enclosed area between the postural oscillation wave pattern and muscle electrical activity during disturbances in patients with diabetic neuropathy [60-62], which can increase in patients with diabetic foot ulcers due to the increase in diabetic neuropathy. Qanawati et al. (2009) showed that the ability of functional balance in patients with diabetic neuropathy in general and the ability to transfer controlled weight and move both the center of gravity and their level of support in more detail suffer a significant drop, which worsens complications [63]. One of the important reasons for the increase in peak force and peak pressure in patients with diabetic foot ulcers can be due to changes in walking due to severe peripheral neuropathy [31].

The results of the present study showed that the peak force in the first to fourth metatarsals (M1-4), medial heel, and lateral heel in the diabetic foot ulcer group was higher than in the diabetic group. The peak pressure in metatarsus M3, M4, medial heel, and lateral heel was higher in the diabetic foot ulcer group than in the diabetic group. One possible reason for increased pressure and force in these areas can be a decrease in walking speed in patients with diabetic foot ulcers [31]. The difference between the groups showed that the walking speed in the active leg ulcer group was higher than in the two control groups. A local increase in pressure and shear force in the sole of the foot is the most important mechanical risk factor for non-traumatic foot ulcers in diabetic patients [64]. Studies have shown that there is a direct relationship between ulcers and increased foot pressure and that unbalanced pressure distribution in the sole of the foot and reproducibility in a part of the foot cause diabetic foot ulcers [65, 66]. Peak pressure in the buttock, metatarsal, and hallux (T1) has been reported in diabetic patients [67]. Studies have shown that most injuries occur in the hips, metatarsals, and hallux [68]. The results showed that any change in walking parameters and changes in the pattern of muscle activity can lead to an increase in pressure on the soles of the feet [69]. Therefore, it is possible that peak pressure and peak force in people with DFU occur during walking due to altered walking patterns. To assess the pathological condition, it seems reasonable to first have detailed information on the structure, function, and normal movement of the foot, and then introduce the major deviation.

4. Conclusions and Future Directions

Diabetic foot ulcers (DFU) are a significant public health concern due to their high recurrence rates and potential for amputation. One common risk factor for DFU is high plantar pressure. Individuals with a history of DFU often have higher plantar pressures compared to non-injured or non-diabetic individuals. While vertical plantar pressure is commonly assessed, there are studies that report shear pressures, which are lower in magnitude and more difficult to measure than the vertical component. Currently, shear stress is primarily assessed when barefoot, while vertical plantar stress is assessed both barefoot and in shoes. Although in-shoe assessments are more relevant to everyday life, they still have limitations. Current stress assessments are mainly conducted in laboratories and only analyze walking, which limits their ecological validity. Limited research on daily activities in patients with diabetic peripheral neuropathy suggests that more time is spent standing and sitting than walking. These findings suggest that measuring cumulative pressure over time may be more relevant than the commonly used peak pressure parameter. Custom shoes and insoles are commonly prescribed to relieve pressure on the soles of the feet, but further research is needed to develop standard protocols for shoe design and modification based on pressure. Additionally, the effectiveness of shoe interventions varies between individuals and relies on regular use. Providing plantar pressure feedback offers a promising alternative approach, but more research is needed to understand the long-term effects of feedback, considering all areas of the diabetic foot. The introduction of smart technology, which allows continuous monitoring and feedback, shows promise based on the positive results from a randomized proof-of-concept trial. Other limitations and considerations in previous pressure assessment methods may explain the low wound prediction scores. Further pressure analysis, considering both vertical and shear components, during daily activities and all weight-bearing activities, is necessary to improve our understanding of plantar pressures that are prone to ulceration. Furthermore, research is needed to investigate whether providing feedback can lead to long-term beneficial effects, ultimately reducing plantar pressure and the occurrence of DFU.

According to the results of the present study, it can be concluded that peak plantar pressures (PPPs), peak force, and vertical loading rate increase at different stages of walking on the soles of the feet in diabetic patients with a history of neuropathic foot ulcers (DFU). These findings provide valuable information to specialists, enabling them to design medical insoles and effective exercises to reduce pressure and force in various areas of the feet. By doing so, they can take a significant step towards improving the condition of patients with diabetic foot ulcers. Standardized protocols can be developed for this purpose. While shoe interventions are generally effective in preventing ulcers, their results vary among individuals and are only effective if worn regularly. An alternative approach is to provide plantar pressure feedback, which has shown promising results. However, more research is needed to understand the long-term effects of feedback, considering all aspects of the diabetic foot. Introducing smart technology that continuously monitors pressure and provides feedback is a promising method to address these deficiencies. Positive results have been observed in a randomized proof-of-concept trial. Previous pressure assessment methods have limitations and considerations that may explain the low wound prediction scores. To improve our understanding of the pressures on the soles prone to ulceration, further stress analysis is needed. This analysis should consider both vertical and shear components and occur outside the laboratory during daily activities and all weight-bearing activities. Furthermore, research is needed to investigate whether providing feedback can lead to long-term beneficial effects, ultimately reducing plantar pressure and the occurrence of DFU.

Conflict of Interest

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Author Contributions

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