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Development of an Active In-shoe Pneumatic System for Monitoring and Redistributing Plantar Pressures: Toward Diabetic Foot Management

Pedro Manuel de Castro Martins

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FACULDADE DE ENGENHARIA DA UNIVERSIDADE DO PORTO



**Development of an Active In-shoe Pneumatic System for
Monitoring and Redistributing Plantar Pressures:
Toward Diabetic Foot Management**

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Doctoral Program in Occupational Safety and Health

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Doctoral Program in Occupational Safety and Health

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To all my family.
To all my professors.
To all people with diabetes.

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REPÚBLICA
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Resumo

O pé diabético representa uma das complicações mais graves e onerosas da diabetes mellitus, frequentemente associada a ulcerações plantares originadas por picos de pressão local e alterações na sensibilidade cutânea protetora. A monitorização e a redistribuição eficaz da pressão plantar constituem, assim, estratégias de prevenção precoce e ações para a reabilitação e vigilância em tempo real. O presente trabalho propôs o desenvolvimento e validação de um sistema pneumático ativo integrado no calçado, designado MoonWalking®, capaz de monitorizar e redistribuir a pressão plantar de forma dinâmica, com potencial para prevenir lesões associadas ao pé diabético. O sistema conjuga uma palmilha com células pneumáticas de atuação, sensores de pressão, válvulas e um módulo de controlo eletrónico responsável pela recolha de dados, processamento e resposta ativa às variações da pressão plantar. A validação do sistema foi conduzida em várias fases. Numa primeira etapa, avaliou-se a concordância das medições da pressão plantar com um sistema de referência, confirmando a fiabilidade dos registos com níveis superiores a 91% em condições estáticas e dinâmicas. Seguidamente, testou-se a capacidade de redistribuição da pressão plantar através da ativação controlada das células pneumáticas, observando-se reduções significativas nos picos de pressão plantar e no nível de exposição à pressão em regiões críticas do pé, onde, no calcanhar, a exposição reduziu cerca de 42%. Os resultados confirmaram a eficácia do sistema na descarga da pressão localizada com base nos limiares recomendados na literatura clínica. Por fim, foi conduzido um estudo de usabilidade com o sistema instalado em calçado de segurança, com o objetivo de avaliar a perceção na perspetiva do utilizador. Os participantes reportaram níveis de conforto e estabilidade semelhantes ou superiores aos da palmilha original do sapato usado como controlo, com destaque para o aumento percebido de amortecimento e ajuste ao pé. Estes resultados reforçam a pertinência da utilização do sistema em ambiente laboral, conciliando prevenção de risco ocupacional e vigilância de saúde em trabalhadores com pé diabético ou com predisposição para lesões plantares. Em síntese, o sistema MoonWalking demonstrou viabilidade técnica, funcional e ergonómica, evidenciando potencial para evolução futura como plataforma integrada de monitorização e redistribuição plantar inteligente, com impacto significativo na prevenção do pé diabético e na promoção da saúde ocupacional.

Palavras-chave: monitorização da pressão; palmilha pneumática; pé diabético; pressão plantar; redistribuição da pressão; úlceras.

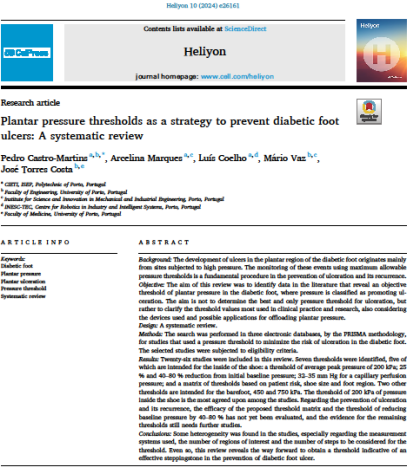
Abstract

Diabetic foot represents one of the most serious and costly complications of diabetes mellitus, often associated with plantar ulcerations caused by local pressure peaks and changes in protective skin sensitivity. The monitoring and effective redistribution of plantar pressure are therefore key strategies for early prevention and rehabilitation, as well as for real-time surveillance and management. The present work proposed the development and validation of an active pneumatic system integrated in footwear, called MoonWalking®, capable of monitoring and redistributing plantar pressure dynamically, with the potential to prevent injuries associated with diabetic foot. The system combines an insole with pneumatic action cells, pressure sensors, valves, and an electronic control module responsible for data collection, processing, and active response to variations in plantar pressure. The system's validation was conducted in several phases. In the first step, the agreement between plantar pressure measurements and a reference system was evaluated, confirming the reliability of the recordings, with levels above 91% under both static and dynamic conditions. Next, the ability to redistribute plantar pressure through the controlled activation of pneumatic cells was tested, resulting in significant reductions in plantar pressure peaks and the level of pressure exposure in critical foot regions, with heel exposure reduced by approximately 42%. The results confirmed the effectiveness of the system in offloading localized pressure based on the thresholds recommended in the clinical literature. Finally, a usability study was conducted with the system installed in safety footwear, aiming to evaluate the user's perception from their perspective. Participants reported levels of comfort and stability similar to or superior to those of the original insole of the shoe used as a control, with emphasis on the perceived increase in cushioning and fit to the foot. These results reinforce the relevance of utilizing the system in the work environment, reconciling occupational risk prevention and health surveillance in workers with diabetic foot or a predisposition to plantar lesions. In summary, the MoonWalking system demonstrated technical, functional, and ergonomic feasibility, showing potential for future evolution as an integrated platform for monitoring and intelligent plantar redistribution, with a significant impact on the prevention of diabetic foot complications and the promotion of occupational health.

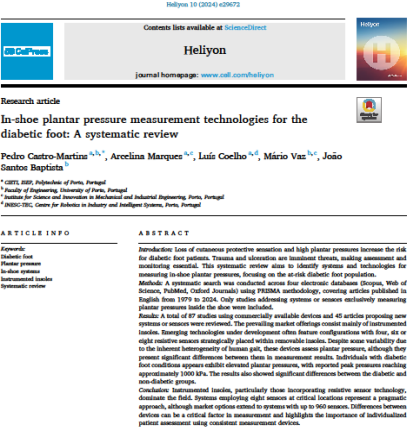
Keywords: diabetic foot; plantar pressure; pneumatic insole; pressure monitoring; pressure redistribution; ulcers.

Author's Publications

A list of scientific articles produced by the author during the research work within the scope of this thesis was published in indexed international scientific journals with peer review. These articles are included in the literature review and results sections. For other publications, visit the author's ORCID page: Pedro Castro-Martins^{ORCID} (<https://orcid.org/0000-0001-5430-0496>).



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1. Introduction
Loss of cutaneous sensation and subsequent ulceration of some regions in the feet of people with diabetes are common

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CiteScore: 8.2

Impact Factor: 3.5

Quartile: Q2

Article Status: Published on June 19, 2025

Inserted in Chapter 3 – Methods, Results, and Discussion; Section 3.3

UN Sustainable Development Goals

The United Nations Sustainable Development Goals (SDGs) provide a global framework to achieve a better and more sustainable future for all. It includes 17 goals to address the world's most pressing challenges: poverty, inequality, climate change, environmental degradation, peace, and justice.

This work was developed in accordance with the UN SDGs, specifically SDG 3, which aims to ensure access to quality healthcare and promote well-being for all. Based on SDG 3, the proposed active pneumatic system was designed to monitor and redistribute plantar pressures within the footwear to prevent foot injuries and manage diabetic foot conditions. This directly contributes to the health and well-being of at-risk populations by mitigating localized plantar pressure peaks and improving foot protection for people with diabetes and the general population.

SDG	Target	Indicator	Contribution of this work
Goal 3: Good Health and Well-being. Ensure healthy lives and promote well-being for all at all ages.	3.4	3.4.1	Contributes to the reduction of premature mortality from non-communicable diseases by improving the prevention and management of diabetes-related complications, specifically diabetic foot.
	3.8	3.8.1	It supports universal access to essential healthcare services and safe, effective, affordable medical technologies, particularly diabetic foot care.
	3.d	3.d.1	Enhances health system capacity to detect, manage, and respond to health risks, with a focus on occupational safety and health related to diabetes care and its complications.

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NOTE: This document incorporates several published articles into the text (Sections 2.2, 2.3, 3.1, and 3.3), which were developed during the course of this doctoral research. The figures contained in the incorporated articles were not individually indexed in the main List of Figures.

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List of Abbreviations and Acronyms

ADC	Analog-to-Digital Converter
BLE	Bluetooth Low Energy
CC BY	Creative Commons Attribution license
EU	European Union
FDM	Fused Deposition Modeling
GDPR	General Data Protection Regulation
PCB	Printed Circuit Board
PET	Polyethylene Terephthalate
PLA	Polylactic Acid (3D printing filament)
PTI	Pressure-Time Integral
SD	Standard Deviation
SDG	Sustainable Development Goal
SLA	Stereolithography
SWM	Semmes-Weinstein Monofilament
THT	Through-Hole Technology
UN	United Nations
USD	United States Dollar
VAS	Visual Analog Scale

Chapter 1

Introduction

This chapter aims to provide the reader with an understanding of the problem of diabetes and diabetic foot ulcers, highlighting their clinical, social, and economic relevance. The theoretical framework, the formulation of the research question and the hypotheses, as well as the objectives that guide the development of this study, are presented. Additionally, the scientific and practical relevance of this work is discussed, the organization of the thesis is described, and the main points addressed are synthesized to provide the reader with a clear and structured view of the research developed.

1.1 - Background

Diabetes mellitus is one of the most prevalent chronic diseases worldwide and one of the leading causes of morbidity and mortality when associated with macro and microvascular complications. The number of people with diabetes is estimated to continue to increase steadily in the coming decades, driven by factors such as an ageing population, changes in lifestyles, and inequalities in access to healthcare. Currently, in 2025, about 589 million adults between the ages of 20 and 79 are living with diabetes worldwide, and this is expected to increase to 853 million by the year 2050. In 2024 alone, more than three million deaths were recorded, with an estimated occurrence every nine seconds. Diabetes caused at least one trillion USD in health expenditure, a 338% increase over the last 17 years (International Diabetes Federation, 2025; van Netten, Apelqvist, et al., 2024). Figure 1.1 illustrates the global distribution and prevalence of diabetes mellitus.

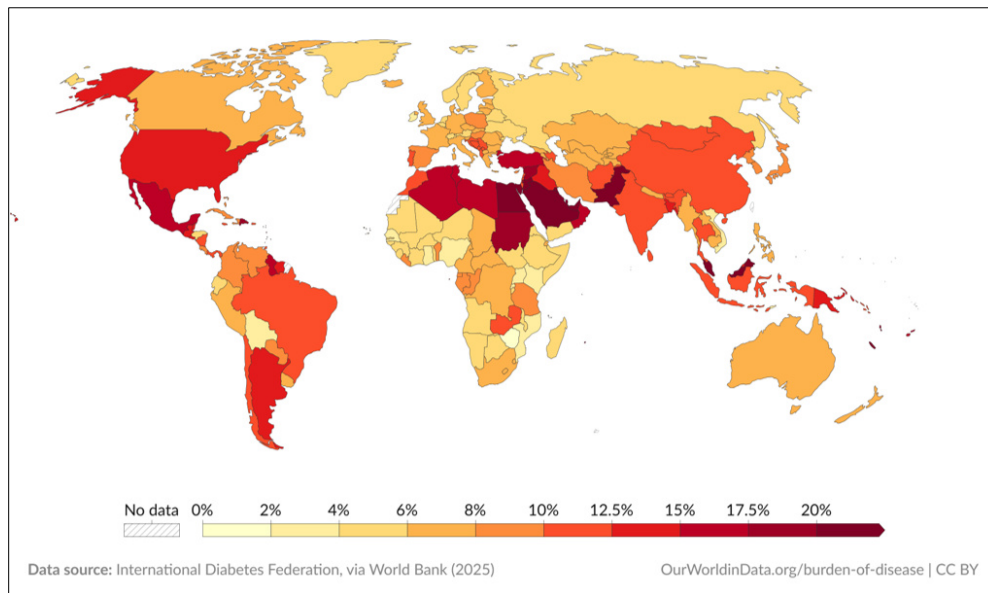


Figure 1.1 – Worldwide distribution and proportion of population aged 20–79 who have diabetes mellitus.

In addition to its systemic impact, diabetes is often associated with localized complications, especially in the lower limbs, which significantly compromise individuals' quality of life. Among these, foot ulceration, a complication known as diabetic foot (Figure 1.2), which is of clinical, social, and economic relevance, is one of the most disabling and costly complications of this disease, mainly caused by the development of peripheral diabetic neuropathy in people with diabetes mellitus (Edmonds et al., 2021; Schaper et al., 2024). The etiopathogenesis of diabetic foot ulcers is complex and multifactorial, involving mainly peripheral neuropathy, ischemia, and repetitive mechanical overload on the lower limbs. Neuropathy, through the loss of protective skin sensitivity, increases the risk of undetected injuries due to insensitivity to pain, while ischemia limits the body's ability to heal. In addition to these factors, plantar overload in specific regions of the foot (see Figure 1.2a and 1.2b: toes, more frequent in the hallux; metatarsals, with a higher incidence in the first metatarsal; lateral-midfoot; and heel), is usually associated with biomechanical changes in gait and structural deformities, which contribute to the development of recurrent lesions that are very difficult to heal (Bus et al., 2024; McDermott et al., 2023; Monteiro-Soares et al., 2024). Sometimes, amputation of the affected limb is the outcome for the ineffective treatment of lesions with frequent recurrences (Figure 1.2c), where the lifetime incidence of lower limb amputation is 20% and five-year mortality can reach 70%. Globally, it is estimated that 19% to 34% of people with diabetes develop plantar ulcers in their lifetime, which is not only a public health problem, but also a relevant challenge for the sustainability of health systems, taking into account the direct costs associated with treatment and the indirect costs related to lost productivity, absenteeism from work, and early retirement (Armstrong et al., 2017; Chou et al., 2022; Edmonds et al., 2021; McDermott et al., 2023).

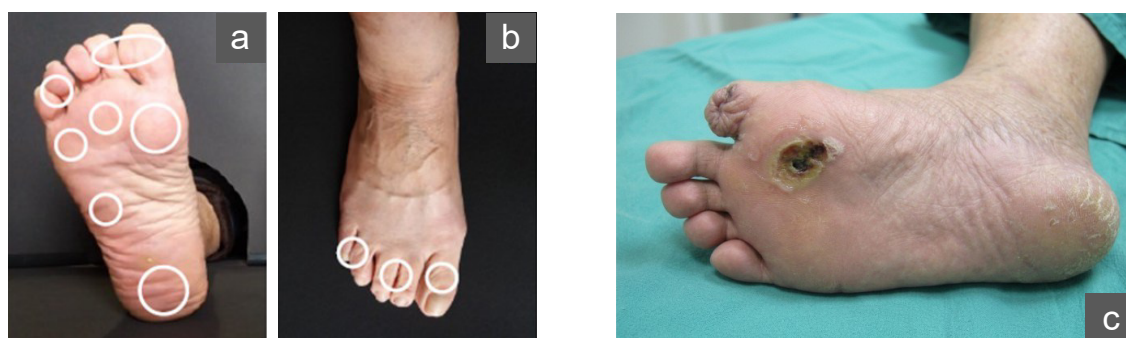


Figure 1.2 – Areas with the highest incidence of diabetic foot lesions in the plantar (a) and dorsal (b) regions. Diabetic foot with ulcer under treatment and amputated hallux (c). Source: Author's digital archive, 2025.

1.2 - Research Problem

Management of localized plantar pressure plays a crucial role in the treatment of diabetic foot disease by preventing plantar ulcers and recurrences caused by increased pressure. Given this scenario, effective monitoring and redistribution of plantar pressures are central strategies for reducing the incidence of these lesions. The use of therapeutic footwear, insoles, and customized orthotics has been one of the most recommended approaches for several decades, having demonstrated a positive impact on reducing plantar pressure peaks and mitigating the risk of ulcer recurrence (Bus et al., 2004; Collings et al., 2023; Okoduwa et al., 2024; Uccioli & Giacomozzi, 2009; Ulbrecht et al., 2014). Nevertheless, significant limitations remain: the effectiveness of insoles varies depending on the characteristics of the user's foot and the progression of neuropathy, adherence tends to be low in contexts of prolonged use, and the cost-benefit ratio of these solutions remains uncertain, especially in healthcare systems with limited resources (A. W. Jones et al., 2024; Nouman et al., 2021).

With technological advances, smart devices and sensor-equipped insoles capable of real-time monitoring of plantar pressure have emerged. These solutions, particularly when integrated with immediate feedback systems, have shown potential for reducing the incidence of ulcers by alerting the user to risky situations (Kosaji et al., 2025). However, most of these approaches remain dependent on external alerts and notifications and do not intervene directly on the redistribution of pressure, restricting their preventive effectiveness (Dragulinescu et al., 2020; Pataky et al., 2010; Ramirez-Bautista et al., 2017; Van et al., 2017; Ying et al., 2020). At the same time, computational modeling using finite elements has enabled the optimization of insole and footwear designs, offering promising prospects for customization. However, these simulations do not fully incorporate gait variability or clinical factors such as friction, which limits the immediate applicability of the models in a clinical context (Ghassemi et al., 2015; Ghazali et al., 2021; Telfer et al., 2014).

The need for active plantar pressure redistribution systems has emerged in this context. Unlike traditional solutions, active systems monitor pressures and intervene adaptively on the regions of the foot where these pressures originate. Although these proposals are few and

very recent, they include, on the one hand, devices based on magnetorheological fluids (Hemler et al., 2023) and, on the other hand, pneumatic systems (Erel et al., 2024). The latter are particularly promising, as they combine relatively low cost, greater ease of integration into footwear, and real-time responsiveness. Preliminary laboratory tests suggest significant reductions in both plantar pressure peaks and pressure-time integral (PTI), a parameter recognized as a critical marker of ulceration risk, also associated with plantar pressure thresholds recognized as inducing lesions (Cavanagh et al., 2002; Erel et al., 2024; P. Jones et al., 2021). However, the literature on active pneumatic systems remains limited despite its potential. Most existing studies are based on tests with pneumatic sensors and actuators designed for human gait recognition, without being directly intended for diabetic foot or plantar pressure redistribution (Gabrecht et al., 2023; Hayakawa et al., 2020, 2022). Additionally, there are still gaps in our knowledge regarding the impact of these technologies on prolonged use, particularly in terms of comfort, adherence, material durability, and feasibility in real-world contexts. Comparative studies examining the performance of active pneumatic systems in relation to traditional solutions for monitoring plantar pressure are also scarce, which is an essential aspect for supporting their adoption in clinical practice and occupational health. (Kosaji et al., 2025; Ramadhan et al., 2025). Such limitations compromise the translation of emerging technologies into clinical practice and occupational safety and health, where preserving mobility and preventing ulcers are crucial for maintaining quality of life and productive capacity in working populations with diabetes.

1.2.1 - Research Question and Hypotheses

Considering the scenario described above, the central question guiding this applied research work arises: To what extent can an active pneumatic system, integrated into footwear, monitor plantar pressure in real time and redistribute it effectively and safely, overcoming the limitations of conventional approaches and with a view to contributing to the prevention of diabetic foot injuries?

From this problem, the following research hypotheses are enunciated:

- i. The active pneumatic system can monitor plantar pressure in real time and detect critical threshold limits, showing significant agreement with reference systems considered the gold standard.
- ii. Pneumatic activation of air cells reduces plantar pressure peaks in critical regions of the foot when compared with passive insoles.
- iii. The dynamic redistribution of plantar pressure contributes to keeping the plantar pressure thresholds below 200 kPa (or an effective pressure reduction), as established in clinical literature, and reducing the PTI, two parameters associated with the high risk of ulceration.
- iv. The system offers functional viability and acceptable levels of comfort, essential for user acceptance, when compared with passive shoes.

1.2.2 - Objectives

The study's general objective is to develop and validate an active pneumatic system integrated into footwear, capable of monitoring and redistributing plantar pressure in real time, assessing its effectiveness and feasibility as a device to prevent diabetic foot injuries.

To achieve the general objective, the following specific objectives have been defined:

- i. Explore and define the state of the art on in-shoe devices for monitoring plantar pressure, dynamic and active pressure adjustment insoles, and threshold values for injury prevention in diabetic foot.
- ii. Design and implement a functional prototype of a pneumatic insole, integrating monitoring sensors and plantar pressure redistribution actuators adaptable to different types of footwear.
- iii. Validate the accuracy of plantar pressure monitoring by comparing system results with those of reference devices, such as the Pedar® insole system, under static and dynamic conditions.
- iv. Evaluate the effectiveness of pneumatic activation in redistributing, offloading, and reducing plantar pressure peaks in at-risk regions.
- v. Examine the impact of the system on reducing PTI and confirm its ability to record human gait patterns.
- vi. Analyze in an exploratory way the feasibility of use in terms of comfort, stability, and user acceptability.

1.3 - Study Rationale

The relevance of this research is evident on two interdependent levels. Academically, the study contributes to filling existing scientific gaps in the literature, bringing technological research closer to the clinical context and practice in occupational safety and health. Socially, it offers an innovative solution with the potential to reduce the incidence of diabetic foot ulcers, prevent amputations, improve quality of life, and ensure better conditions for inclusion and labor productivity for people with diabetes. In this sense, this work represents an original contribution to the interface between biomedical engineering and occupational safety and health, reinforcing the role of emerging technologies in protecting the health of vulnerable populations and preventing injuries with high clinical and social impact.

1.4 - Thesis Structure

This thesis comprises scientific articles published in peer-reviewed international journals during the research work, incorporating the original publications. It is organized into four main chapters. Chapter 1, Introduction, presents the context of the problem, defines the

research question, outlines the objectives, and discusses the study's relevance. Chapter 2, Literature Review, critically analyzes the state of the art on diabetic foot ulceration, monitoring, and plantar pressure redistribution, and describes emerging technologies in this area. Methodology, Results, and Discussion are integrated into Chapter 3, which describes the design, development, and validation methods of the active pneumatic system, presenting and discussing the main experimental and comparative results obtained. Limitations encountered throughout this applied research work are also discussed. Chapter 4 presents the conclusions, considering the results obtained and identifying future perspectives. Figure 1.3 illustrates the general organization of this thesis and the contribution of each previously published article.

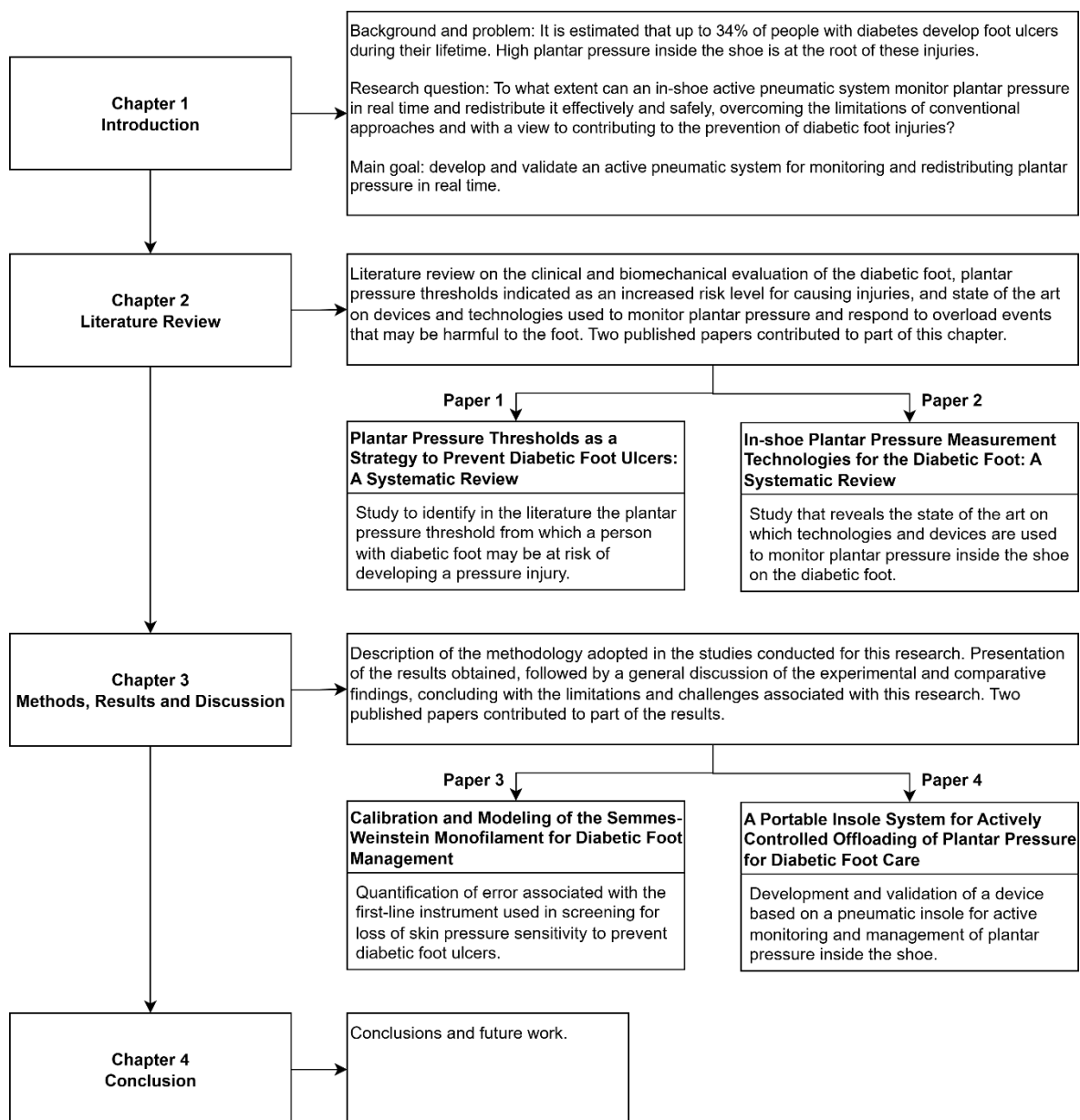


Figure 1.3 – General thesis structure and outline of the background, research question, published articles, and their contribution.

1.5 - Summary of Chapter 1

In summary, diabetic foot ulcers are a serious complication of diabetes, associated with neuropathy, ischemia, and mechanical overload, with significant clinical, social, and economic impacts. Currently available solutions, such as therapeutic footwear and customized insoles, although effective in reducing plantar pressures when regularly adjusted to the biomechanical changes in the user's foot, still have limitations regarding sustained effectiveness, prolonged adherence, and cost-effectiveness. Intelligent real-time monitoring approaches represent a significant advance, but they remain essentially warning systems, without directly intervening in the redistribution of plantar pressure. In this context, significant gaps in the state of the art have been identified (this issue will be discussed in more detail in Chapter 2), such as the absence of preliminary clinical validation for active systems or the scarcity of studies for comparisons with conventional solutions, and insufficient data on comfort, adherence, and cost-effectiveness. Thus, for the development of this applied research project, the central question is formulated as follows: To what extent can an active pneumatic system, integrated into footwear, monitor plantar pressure in real time and redistribute it effectively and safely, overcoming the limitations of conventional approaches and with a view to contributing to the prevention of diabetic foot injuries?

This research aims to develop and validate an active pneumatic system for real-time monitoring and redistribution of plantar pressure. To this end, specific objectives have been defined, including validating monitoring accuracy, evaluating the effectiveness in reducing pressure peaks, analyzing the impact on pressure-time integral, and assessing the feasibility of use in terms of comfort and acceptability. Thus, the proposed system is expected to be reliable and effective, offering significant advantages over conventional solutions. In this context, the study aims to make a twofold contribution: on the one hand, academic, by advancing the knowledge and validation of active pneumatic technologies; on the other hand, social, by proposing a solution with the potential to reduce the incidence of ulcers and amputations, improve quality of life, and promote the productive inclusion of people with diabetes.

Based on this summary, the following chapter proceeds to a literature review, which deepens theoretical concepts, empirical evidence, and technologies supporting the development of the proposed system.

Chapter 2

Literature Review

This chapter presents a critical and detailed review of the scientific literature on diabetic foot, summarizing aspects of clinical and biomechanical assessment, with a greater focus on prevention strategies through plantar pressure control and the technologies used to measure and redistribute this in-shoe pressure. Existing gaps and current research challenges are discussed to substantiate and contextualize the development of this study. Finally, the main topics are summarized, providing the reader with an integrated overview of the current state of the art in this area. The chapter also includes two scientific articles previously published within the scope of this research. Sections 2.2 and 2.3 correspond to systematic reviews of the literature developed and published in indexed international journals.

2.1 - Clinical and Biomechanical Evaluation of Diabetic Foot

Diabetic foot ulcer is one of the most serious complications of diabetes mellitus, resulting from the interaction of multiple factors that affect skin integrity and healing. Among the main determinants are peripheral neuropathy, which reduces or eliminates the protective sensitivity of the foot; peripheral arterial disease, which limits blood supply and tissue repair capacity; and local mechanical overloads, which cause chronic pressure points favorable to the formation of lesions (Bowling et al., 2022; McDermott et al., 2023). These conditions lead to relevant clinical and functional consequences, including difficulty in healing, high risk of infection, and, in advanced cases, culminate in amputation, with a clear direct impact on the individual's mobility and absenteeism from work (Chou et al., 2022; Hicks et al., 2020).

2.1.1 - Importance of Early Ulceration Risk Evaluation

Early identification of people at increased risk of plantar ulcers is a pillar of secondary and tertiary prevention in the diabetic foot setting. Systematic clinical evaluations allow risk to be stratified and guide interventions (greater health literacy, use of therapeutic footwear, and even localized plantar pressure offloading devices) to mitigate adverse events. Studies show that screening and multidisciplinary follow-up programs reduce the incidence of ulcers and amputations, which reinforces the need for accurate screening methods applicable in clinical and occupational contexts (Chan & Lo, 2020; Pérez-Panero et al., 2019; Singh et al., 2005). Within this paradigm, the combination of sensory, vascular, and biomechanical assessments provides a more robust clinical portrait of the patient's individual risk, allowing targeted interventions that preserve their functional capacity and keep them fit for their professional activity (Bus et al., 2024; Hon et al., 2024; Schaper et al., 2024).

2.1.2 - Methods of Skin Sensitivity Evaluation

Evaluating the protective sensitivity of the foot is a simple but clinically valuable procedure for stratifying the risk of ulceration. The Semmes-Weinstein monofilament (SWM) is internationally recognized as a first-line instrument for detecting loss of skin sensitivity and identifying individuals with significant sensory peripheral neuropathy (Bus et al., 2024; Schaper et al., 2024; Tan, 2010). According to international guidelines, the typical protocol recommends applying the SWM of 10 g (5.07) to standardized points on the foot until the filament makes a slight curvature. At this moment, a force of 10 gf will have been applied to the patient's skin. This method (described in more detail in Chapter 3, Section 3.1) is expected to measure the loss of sensitivity in several areas of the plantar region, mainly in the fingers, metatarsal regions, and heel. The inability to detect the force applied to one or more points is associated with an increased risk of ulcer, putting the patient in a situation of potential risk (Bus, Lavery, et al., 2020).

Although the SWM is the instrument used in the first line to assess the loss of skin sensitivity, the literature points out relevant limitations of the monofilament as an isolated test: interobserver variability; relatively low sensitivity in some population contexts; and dependence on the application protocol, such as force, contact time, and the points tested (Chikai & Ino, 2019; Wang et al., 2017). These limitations justify complementarity with other methods (vibration sensitivity with tuning fork or bioesthesiometer and thermal sensitivity tests) and a global clinical assessment (Raymond et al., 2019). It is essential to note that the calibration and physical understanding of the instrument are crucial factors for the reproducibility of results in studies and clinical practice. Thus, the article published with the theme "Calibration and Modeling of the Semmes-Weinstein Monofilament for Diabetic Foot Management", integrated in Chapter 3, Section 3.1, addresses precisely these issues, proposing calibration procedures and models that explain the behavior of the monofilament

under different application conditions. This research provides methodological support for interpreting sensory measurements with SWM and improving the reliability of screenings in clinical and occupational health settings.

2.1.3 - Plantar Pressure Monitoring

Plantar pressure monitoring is a key strategy in preventing ulcers caused by excessive pressure. Identifying peak pressure points, quantifying load distribution, and estimating parameters such as the pressure-time integral (PTI) enable the guidance of localized plantar pressure offloading interventions and the design of pressure redistribution devices. The biomechanical parameters most commonly used in the literature include plantar contact areas, a pressure threshold, peak pressure, and PTI, variables that are related to and associated with the risk of overload injury when they persist at high levels (Cavanagh et al., 2002; P. Jones et al., 2021; Lockhart et al., 2024; Sinha et al., 2020).

In clinical practice and research, the plantar pressure threshold of 200 kPa (measured inside the shoe) has often been cited as a standard objective reference for implementing pressure offloading methods. The selection and interpretation of a possible threshold must also consider individual variables (body mass, foot morphology, and presence of calluses or anatomical deformities) and the characteristics of the measurement system itself (P. Jones et al., 2021; Lockhart et al., 2024). Given the critical role of high plantar pressure, Section 2.2 provides a detailed systematic review of the plantar pressure thresholds adopted for preventing pressure ulcers in the diabetic foot and to prevent their recurrence.

It is essential to note that the choice of measurement system should consider a configuration that closely resembles the user's daily life; that is, measurements should be taken inside the shoe. Although they may be helpful in specific clinical contexts, measurements taken on barefoot pressure platforms do not accurately reflect the daily setting in which the user is typically exposed (usually wearing footwear). This approach may affect the absolute values and clinical applicability of the measurements. Systems inside the shoe, such as Pedar® insoles, among others, have high validation and repeatability for pressure measurements during gait, so they are often considered a reference for intervention studies and device validation (Parker et al., 2023; Price et al., 2016; Putti et al., 2007). Thus, considering the importance of instrumentation for plantar pressure monitoring, Section 2.3 provides a systematic review of the literature that addresses the main measurement technologies inside footwear, both devices available on the market and new approaches still in the research stage.

2.2 - Plantar Pressure Thresholds as a Strategy to Prevent Diabetic Foot Ulcers: A Systematic Review

This section is based on an open-access article published by the author under the terms and conditions of the Creative Commons Attribution (CC BY) license. This systematic review aims to identify objective plantar pressure thresholds that can be used to prevent diabetic foot ulcers, as high pressures are a key factor in the development of these lesions. Seven different pressure thresholds were identified, with 200 kPa being the most widely accepted value for use inside shoes.

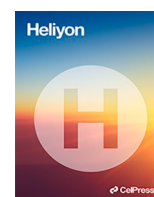
Pedro Castro-Martins, Arcelina Marques, Luís Coelho, Mário Vaz, & José Torres Costa (2024). Plantar pressure thresholds as a strategy to prevent diabetic foot ulcers: A systematic review. *Heliyon*, 10(4), e26161. <https://doi.org/10.1016/j.heliyon.2024.e26161>

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Research article

Plantar pressure thresholds as a strategy to prevent diabetic foot ulcers: A systematic review



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ABSTRACT

Background: The development of ulcers in the plantar region of the diabetic foot originates mainly from sites subjected to high pressure. The monitoring of these events using maximum allowable pressure thresholds is a fundamental procedure in the prevention of ulceration and its recurrence. **Objective:** The aim of this review was to identify data in the literature that reveal an objective threshold of plantar pressure in the diabetic foot, where pressure is classified as promoting ulceration. The aim is not to determine the best and only pressure threshold for ulceration, but rather to clarify the threshold values most used in clinical practice and research, also considering the devices used and possible applications for offloading plantar pressure.

Design: A systematic review.

Methods: The search was performed in three electronic databases, by the PRISMA methodology, for studies that used a pressure threshold to minimize the risk of ulceration in the diabetic foot. The selected studies were subjected to eligibility criteria.

Results: Twenty-six studies were included in this review. Seven thresholds were identified, five of which are intended for the inside of the shoe: a threshold of average peak pressure of 200 kPa; 25 % and 40–80 % reduction from initial baseline pressure; 32–35 mm Hg for a capillary perfusion pressure; and a matrix of thresholds based on patient risk, shoe size and foot region. Two other thresholds are intended for the barefoot, 450 and 750 kPa. The threshold of 200 kPa of pressure inside the shoe is the most agreed upon among the studies. Regarding the prevention of ulceration and its recurrence, the efficacy of the proposed threshold matrix and the threshold of reducing baseline pressure by 40–80 % has not yet been evaluated, and the evidence for the remaining thresholds still needs further studies.

Conclusions: Some heterogeneity was found in the studies, especially regarding the measurement systems used, the number of regions of interest and the number of steps to be considered for the threshold. Even so, this review reveals the way forward to obtain a threshold indicative of an effective steppingstone in the prevention of diabetic foot ulcer.

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1. Introduction

Diabetes is an incurable chronic disease with an exponential growth trend worldwide. According to the 2021 report of the International Diabetes Federation [1], about 537 million adults are living with diabetes, advancing a projected increase to 643 million people with diabetes by 2030 and 784 million by 2045. In 2021 this disease was responsible for 6.7 million deaths and caused health expenditures of 862 billion euros [1].

The diabetic patient has an increased susceptibility to develop diabetic foot, a complication that translates mainly into ulceration of some regions of the feet. This is a frequent consequence due to comorbidities such as diabetic neuropathy, peripheral vascular disease, foot deformities, and pressure injuries caused by the patient's footwear during gait [2–7]. These comorbidities are at the genesis of the loss of protective cutaneous sensitivity, which interrupts the patient's protective cutaneous feedback mechanism by drastically reducing pain sensitivity [8]. This condition makes these patients more susceptible to trauma that can precipitate an injury and easily develop into an ulcer [9–12].

Because of these complications it is expected that about 34 % of people with diabetes will develop at least one foot pressure ulcer during their working life. The level of recurrence of ulcers after healing is 40 % in the first year and increases to about 60 % in three years [13]. These lesions are highly associated with infection and limb amputation [14].

The development of diabetic foot ulcers originates mainly in places of the plantar region subject to greater pressure, such as the metatarsal heads, toes, and heel. Although less frequent, the dorsal region can also be affected by ulcers, mainly on the bony prominences of the toes [15]. For this reason, the mapping of hyperpressure sites is used to guide the manufacture of custom footwear, orthotics, and insoles adapted to each patient with the goal of reducing these pressures at a particular location on the foot. This procedure, and the use of this equipment to relieve the pressures, during a treatment phase or permanently, sometimes conditions the natural locomotion of the user [16,17].

Supervision, reduction and/or redistribution of plantar pressures are essential actions to avoid injury or accelerate ulcer healing and prevent recurrence [18,19]. For this purpose, active monitoring of these pressures, through technologies integrated into the footwear, begins to replace the traditional procedure of measuring platforms that are used only in clinical settings and with the barefoot. Sensors integrated into the footwear itself, in removable insoles or socks, are some examples [20–23]. In this sense, these monitoring systems need to know what the admissible pressure threshold for the generality of these patients, where, once exceeded, an alert is triggered by the occurrence of hyperpressure [24,25].

Some studies, including systematic reviews of the literature, address the possible effectiveness of insoles and other systems in measuring plantar pressures and gait analysis, highlighting efforts to identify pressure peaks and define preventive thresholds for diabetic foot ulcers. Despite the reported advances, there is still a need for additional studies to establish a reliable threshold [16,17, 21]. Considering this, what is novel about our systematic review is that it aims to aggregate scattered information about the most relevant plantar pressure thresholds in practice and clinical research for treatment and to avoid possible ulcerations when pressure measurement systems are used as prevention. With this information we have devised a set of plantar pressure ranges and thresholds which we have associated with specific applications and contexts, encompassing both prevention and therapeutic approaches within the scope of the diabetic foot. As far goes the authors knowledge this type of revision and information gathering was not reported in the current scientific literature.

In this systematic review, the focus was to systematically review the existing literature covering the definition of an objective threshold of plantar pressure in the diabetic foot where pressure is classified as an ulceration promoter. Within this objective we want to understand in what conditions this threshold is applied to promote an effective reduction of plantar pressure, preventing, and helping to treat ulceration or relapse, encompassing all the stages involved in diabetic foot management. This systematic literature review does not aim to determine the best and only pressure threshold for ulceration, but rather, to aggregate information with the aim of clarifying the threshold values most used in clinical practice and research and the related contexts while also considering the used devices and possible applications for offloading plantar pressure in diabetic foot.

2. Materials and methods

This systematic review was conducted and structured according to the guidelines proposed by PRISMA methodology – Preferred Reporting Items for Systematic Reviews and Meta-Analyses [26]. In this literature review, we chose to carry out only a systematic review according to the PRISMA methodology, without providing a meta-analysis.

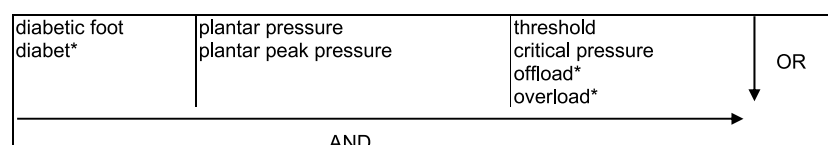


Fig. 1. Keywords used in the search performed in the electronic databases.

2.1. Research strategy

A literature search was conducted in three scientific repositories – Scopus, PubMed, and Web of Science – in December 2021 (updated in April 2023). These electronic databases were chosen because they are recognized by the scientific community and because their content is compatible with the areas under study. They were screened using keywords (Fig. 1) properly selected to restrict the data obtained to the subject of study and maximize the article identification process. The common search query for all electronic databases was: (diabetic foot OR diabet*) AND (plantar pressure OR plantar peak pressure) AND (threshold OR critical pressure OR offload* OR overload*). This query was the most consistent for all electronic databases consulted and the one that returned the best results. In addition, articles identified in the citations of the respective authors during the screening process were included, which were also subject to the eligibility criteria.

2.2. Selection and eligibility criteria

The information selection method considered published articles without any additional restrictions (date, document type, source type and language) to broaden the data mining. In a first approach, duplicate records were removed. Next, the titles and abstracts of the articles were analyzed to classify them as being on-topic, and those that did not fit the topic were rejected. Articles that addressed the topic of assessment and quantitative reduction of plantar pressure through a certain threshold, intended for people with diabetic foot or similar applications, were classified as on-topic. In the next step, the full text of the considered articles was reviewed and eligibility criteria were applied, selecting those articles that cumulatively met the following requirements: i) studies directed to diabetic patients with diabetic foot previously diagnosed by their attending physician, or classified with high probability of developing ulcers or complications by the association of comorbidities such as neuropathy (classification according to the IWGDF guidelines – International Working Group on the Diabetic Foot [3,27]); ii) focusing on the measurement of plantar pressure and using – or obtaining in their results – a quantitative threshold for plantar pressure; iii) and directed towards reducing plantar pressure and/or studying its effects by applying a given plantar pressure threshold; iv) other similar applications aimed at controlling the effects of plantar pressure on the diabetic foot according to a quantitative pressure threshold.

The study aimed to evaluate the acceptability of plantar pressure threshold values in different scenarios, using a quantitative analysis as a reference. However, to avoid bias, case reports were excluded from the review due to their purely qualitative characteristics. Furthermore, a minimum cohort size of 10 individuals was established for the intervention, with or without a control sample. Considering the large population of patients with diabetic foot, for us this minimum intervention sample was defined from the beginning as a minimum acceptable size. Randomized controlled trials (RCT), cohort and case-control studies were included. The article selection process was carried out by two independent authors, PCM and LC, with divergences regarding the inclusion or not of a

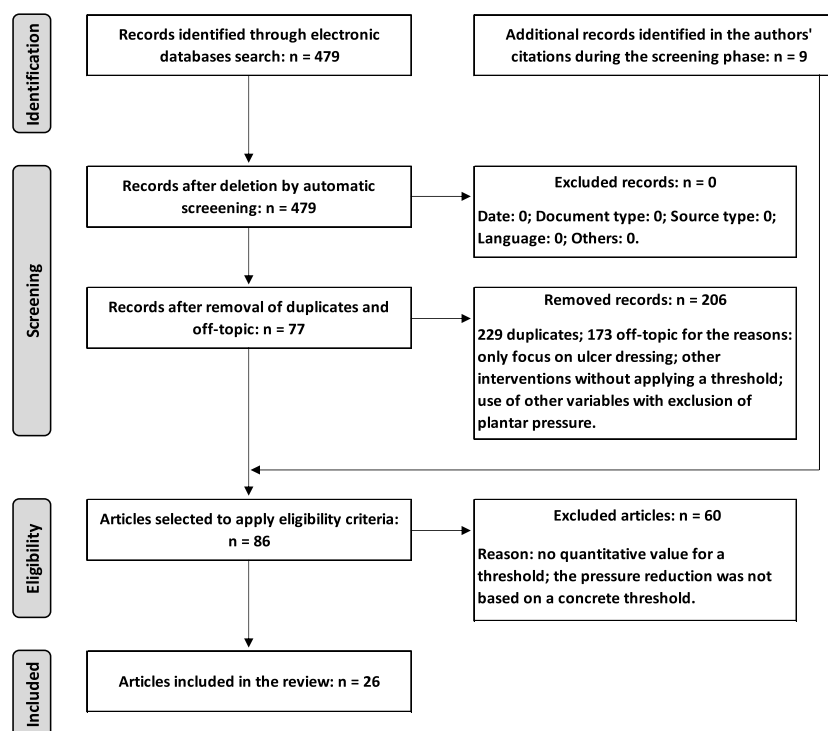


Fig. 2. PRISMA methodology flow diagram for the article selection process.

Table 1
Summary of information regarding the twenty-six studies included in the review.

Author, year	Purpose	Participants: n (M/F); age $\pm$ SD		Duration	Regions of Interest	Measuring System (method)	Pressure threshold and criteria applied
		Intervention	Control				
Maharana, 2022 [51]	Design and customization of shoe arches for dynamic offloading.	71 (–/–); 55 $\pm$ 10.9	29 (–/–); 56.1 $\pm$ 8.7	–	10 subregions distributed through the plantar region.	Pedar-X (insole)	200 kPa. Pressure value < 200 kPa used to consider effective pressure reduction and avoid injuries from prolonged high plantar pressure.
Muir, 2022 [50]	Test the effect of standard and 3D-printed diabetic insoles on reducing plantar pressure.	12 (8/4); 63.8 $\pm$ 9.2	–	–	In the place of the plantar region where the high-pressure level is presented.	Pedar-X (insole)	200 kPa. A pressure value < 200 kPa is used to consider an effective pressure reduction and 200 kPa used as the maximum threshold for injury risk to occur.
Cao, 2021 [31]	Reduce plantar pressure through appropriate footwear.	19 (10/9); 65.7 $\pm$ 3.4 17 (9/8); 65.2 $\pm$ 6.8	20 (11/9); 65.2 $\pm$ 5.4	1 session	7 sub-regions distributed over the plantar region.	Medilogic 5.8.1 (insole)	200 kPa. All measurements with pressures above 200 kPa are considered as hyperpressure.
Abbott, 2019 [32]	Reducing plantar pressure with the aid of a biofeedback monitoring system.	32 (28/4); 59.1 $\pm$ 8.5	26 (23/3); 67.1 $\pm$ 9.6	18 months	8 sub-regions distributed over the plantar region.	SurroSense RX (insole)	35 mm Hg (capillary perfusion pressure as an indirect measure of increase plantar pressure). Suggested ulceration risk for all pressures $\geq$ 35 mm Hg. If in the last 15 min of measurement 95 % or more readings are $\geq$ 35 mm Hg an alert is issued for the patient to correct gait and relieve pressure at the identified local.
Martinez-Santos, 2019 [33]	Reducing plantar pressure through a customized insole.	60 (40/20); 67.0 $\pm$ —	–	1 session	5 sub-regions distributed in the plantar forefoot.	Pedar-X (insole)	200 kPa. A pressure value < 200 kPa is used to consider an effective pressure reduction, in 20 steps.
Parker, 2019 [34]	Identify risk regions and reduce plantar pressure through orthoses.	57 (50/7); 61.4 $\pm$ 10.0	–	6 months	3 sub-regions distributed in the plantar forefoot.	Pedar (insole)	200 kPa. The risk regions were identified and classified considering plantar pressure > 200 kPa in 30 steps/foot.
Author, year	Purpose	Participants: n (M/F); age $\pm$ SD		Duration	Regions of Interest	Measuring System (method)	Pressure threshold and criteria applied
Searle, 2018 [52]	Evaluate the equinus foot and investigate any clinical effects on plantar pressure.	Intervention 104 (54/50); 73.3 $\pm$ 5.6	Control 40 (16/24); 28.8 $\pm$ 7.9	1 session	5 sub-regions distributed throughout the plantar region, with greater focus on the forefoot.	Pedar-X (insole) Tekscan HR Mat (barefoot)	In-shoe: 200 kPa. Pressures $\geq$ 200 kPa are classified as hyperpressures, in 12 steps/feet. Barefoot: 700 kPa. Pressures > 700 kPa barefoot serve to identify groups with current or recently healed ulcers.
Preece, 2017 [35]	Evaluate optimal footwear design and appropriate pressure reduction.	102 (52/50); 57.0 $\pm$ 9.0	66 (36/30); 56.0 $\pm$ 8.0	1 session	3 sub-regions distributed in the plantar forefoot.	Pedar-X (insole)	200 kPa. Footwear intended to prevent first ulceration must ensure a pressure < 200 kPa at 25 steps/foot.
Telfer, 2017 [53]	Comparing performance in pressure relief through optimized insoles.	18 (5/13); 64.4 $\pm$ 9.2	–	1 session	3 sub-regions distributed in the plantar forefoot.	Pedar-X (insole) Emed platform (barefoot)	In-shoe: 200 kPa. 200 kPa threshold used to evaluate insoles and customize them, in 12 steps/foot. Barefoot: 450 kPa. Barefoot pressure threshold of 450 kPa used to select regions of interest.
Van, 2017 [36]	Evaluating the biofeedback method	11 (–/–); —	–	Up to 6 weeks	Plantar region.	FeetMe One (insole)	40–80 % reduction. 40–80 % reduction in peak

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Table 1 (continued)

	for reducing plantar pressure.						pressures for 70 % of the total steps during walking, every 20 steps.	
Arts, 2015 [37]	Reduce plantar pressure by modifying footwear.	85 (70/15); 62.6 ± 10.2	–	15 months	8 sub-regions distributed across the forefoot and midfoot.	Pedar-X (insole)	200 kPa. Footwear modified in the area where an average peak pressure ≥200 kPa occurs, in 12 steps/foot.	
Chapman, 2014 [38]	Reduce plantar pressure through balance shoes and orthotics.	87 (–/–); —	–	1 session	Plantar region.	—(in-shoe)	200 kPa. Maximum threshold of 200 kPa used to identify an effective pressure reduction.	
Author, year	Purpose	Participants: n (M/F); age ± SD	Intervention	Control	Duration	Regions of Interest	Measuring System (method)	Pressure threshold and criteria applied
Waaijman, 2014 [39]	Identify risk factors for ulcer recurrence.	171 (141/30); 63.3 ± 10.1		–	18 months	10 sub-regions distributed over the plantar region.	Pedar-X (insole)	200 kPa. Pressure >200 kPa used to classify participants into groups above the ulceration risk threshold, in 12 steps/foot.
Bus, 2013 [40]	To evaluate the effect of wearing customized shoes on pressure reduction.	171 (140/31); 63.3 ± 10.2		–	18 months	Midfoot and forefoot.	Pedar-X (insole)	25 % reduction or 200 kPa. Shoe modifications until one of the identified thresholds is reached, whichever occurs first, in 15 steps.
Rodriguez, 2013 [41]	Evaluate biofeedback corrected walking strategy to reduce plantar pressure.	21 (12/9); 57.8 ± 2.9		–	10 days	11 sub-regions distributed over the plantar region.	Pedar-X (insole)	40–80 % reduction. The new walking strategy should reduce the base pressure in the shoe by 40–80% for 7 out of 10 steps.
Ferber, 2013 [42]	Compare instrumented insoles to determine the correlation between simultaneous measurements based on a given threshold.	10 (7/3); 27.9 ± 6.6		–	1 session	8 sub-regions distributed over the plantar region.	SurroSense RX (insole) Pedar-X (insole)	32 mm Hg (capillary perfusion pressure as an indirect measure of increase plantar pressure). Suggested ulceration risk for all pressures ≥32 mm Hg.
Giacomozzi, 2013 [43]	Validate new protocol to apply pressure thresholds customized according to the patient’s risk level.	11 (–/–); 70.2 ± 6.7	20 (–/–); 67.0 ± 7.9		4 months	4 sub-regions distributed over the plantar region.	Pedar-X (insole)	Pressure matrix (see Table 3). Different thresholds for four regions of the foot and stratified by risk level and shoe size, for every 20 steps/foot.
Lin, 2013 [44]	Evaluating the effect of customized insoles on pressure reduction.	26 (10/16); 68.0 ± 9.0		–	1 session	5 sub-regions distributed in the plantar forefoot.	Pedar-X (insole)	200 kPa. The ulceration risk site is the forefoot region where the highest average peak pressure value is > 200 kPa in 30 steps.
Arts, 2012 [45]	Evaluate pressure reduction through customized footwear.	171 (140/31); 62.8 ± 10.2		–	1 session	10 sub-regions distributed over the plantar region.	Pedar-X (insole)	200 kPa. Pressure reduction is successful if it is at levels <200 kPa, every 12 steps/foot.
Author, year	Purpose	Participants: n (M/F); age ± SD	Intervention	Control	Duration	Regions of Interest	Measuring System (method)	Pressure threshold and criteria applied
Waaijman, 2012 [46]	To evaluate the effect of wearing customized shoes on pressure reduction.	117 (–/–); 63.3 ± 10.1	32 (–/–); —		12 months	10 sub-regions distributed over the plantar region.	Pedar-X (insole)	25 % reduction or 200 kPa. Reduction of the peak pressure by 25 % or an absolute level <200 kPa Shoe modification based on the anterior location of the ulcer and/or the two sites with pressure >200 kPa, in 20 steps.
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Table 1 (continued)

Bus, 2011 [47]	To evaluate the effect of wearing customized shoes on pressure reduction.	23 (17/6); 59.1 ± 12.6	–	1 session with multiple trials	10 sub-regions distributed over the plantar region.	Pedar-X (insole)	25 % reduction or 200 kPa. Shoe personalization is successful if the pressure reduces by at least 25 % of the average peak value at that location or is < 200 kPa, in 15 steps.
Waaijman, 2011 [48]	To evaluate the effect of wearing customized shoes on pressure reduction.	58 (–/–); 62.6 ± 10.3	–	–	Plantar region.	Pedar-X (insole)	25 % reduction or 200 kPa. Shoe modifications until one of the thresholds is reached.
Pataky, 2010 [25]	Evaluate biofeedback-corrected walking strategy to reduce plantar pressure.	13 (6/7); 60.8 ± 12.3	–	Up to 10 days	Previously classified risk area in the plantar region.	Pedar (insole)	40–80 % reduction. The new walking strategy should reduce the base pressure in the shoe by 40–80 % for 7 out of 10 steps.
Owings, 2009 [49]	Measuring plantar pressures and providing information for a given threshold of ulceration prevention.	49 (38/11); 62.9 ± 10.3	–	1 session	3 sub-regions distributed in the plantar forefoot.	Pedar (insole)	200 kPa. Set a target pressure of 200 kPa to prevent ulcer recurrence, in 30 steps.
Owings, 2008 [54]	Evaluating the effect of customized insoles on pressure reduction.	20 (10/10); 63.7 ± 10.7	–	1 session	4 sub-regions distributed over the medial and forefoot.	Pedar-X (insole) Emed-D Platform (barefoot)	In-shoe: no threshold or criteria, just to measure pressure. Barefoot: 450 kPa. Barefoot pressure threshold of 450 kPa used to select regions of interest, in the first step.
Armstrong, 1998 [30]	Identify a threshold of peak forefoot plantar pressure that has a sensitivity and specificity for tracking ulceration.	70 (52/18); 52.3 ± 10.3	149 (50/99); 51.8 ± 10.4	1 session	Plantar region.	Emed platform (barefoot)	Barefoot: 700 kPa. Pressures >700 kPa barefoot serve to identify groups at higher risk of ulceration, for every 3 step/foot.

given article were resolved by a third author, AM, to guarantee objectivity in the selection of articles.

2.3. Data extraction

Once the selection process of eligible articles was completed, the following data were collected: i) identification of the authors, year of publication and title; ii) research topic and objectives; iii) methodology applied; iv) results obtained and conclusions. The data extracted were useful to answer a set of questions and to perform an objective synthesis of the information, relating the different approaches and criteria to establish an objective plantar pressure threshold. Data extraction was performed by PCM and was subsequently reviewed and validated by LC. Additionally, and carried out by the same authors, the quality of studies included in this systematic review was assessed using the Newcastle-Ottawa Quality Assessment Scale [28] for cohort and case-control studies. Studies with Newcastle-Ottawa scores of 0–3, 4–6 and 7–9 were considered as poor, fair, and good quality, respectively. For RCT studies the Jadad Scale [29] was used, where a score of 0–2 points is considered poor quality and a score of 3–5 points is considered good quality.

3. Results

The search and selection process, illustrated in Fig. 2, initially identified a total of 479 records (Scopus: 172; PubMed: 135; Web of Science: 172), spanning a time window from 1989 to 2022. Of these, 229 duplicates and 173 classified as off-topic were excluded. After this screening, 86 articles remained (with inclusion of 9 articles identified in the authors' citations) for application of the eligibility criteria. In the end, 26 studies were effectively included in this review.

3.1. Description of included studies

The information collected revealed the plantar pressure thresholds currently used to promote pressure reduction and aid in the treatment and prevention of diabetic foot ulceration. Most studies were conducted from 2008 to 2022, only one study [30] is older, conducted in 1998. Twenty-two studies [25,31–51] focus on reducing plantar pressure by applying pressure thresholds on the foot solely inside the shoe. One study [30] presents only pressure thresholds for the barefoot foot with emphasis on identifying regions of interest in the foot or classifying risk groups. Three other studies [52–54] expose a hybrid methodology, in addition to making pressure measurements inside the shoe, they also indicate thresholds for barefoot pressure. A summary of the information from the studies included in this systematic review can be seen in Table 1.

Regarding the quality assessment of the studies included in this systematic review, according to the Newcastle-Ottawa Quality

Table 2
Scores of the Newcastle-Ottawa Quality Assessment Scale (cohort and case-control) and Jadad Scale (RCT) for the included studies.

Newcastle-Ottawa scale items:										Score		
Case-control	Selection		Comparability		Exposure/Outcome		Non-response		Follow-up of cohorts	0 - 9		
	Adequacy of case definition	Representativeness of the cases	Selection of controls	Definition of controls	Ascertainment of exposure	Same method	Non-response rate					
Case-control	Maharana, 2022 [51]	*	*	*	*	*	----	----	7			
	Cao, 2021 [31]	*	*	*	*	*	----	----	8			
	Giacomozzi, 2013 [43]	*	*	*	*	*	----	----	9			
	Armstrong, 1998 [30]	*	*	*	*	*	----	----	7			
Cohort	Representativeness		Non-exposed cohort		Ascertainment of exposure		Outcome was not present		Comparability of cohorts		5	
	Muir, 2022 [50]	*	----	*	*	*	----	----	----	----		
	Martinez-Santos, 2019 [33]	*	----	*	*	*	----	----	----	----		
	Searle, 2018 [52]	*	*	*	*	*	----	----	----	----		
	Preece, 2017 [35]	*	*	*	*	*	----	----	----	----		
	Telfer, 2017 [53]	*	----	*	*	*	----	----	----	----		
	Van, 2017 [36]	*	----	*	*	*	----	----	----	----		
	Arts, 2015 [37]	*	----	*	*	*	----	----	----	----		
	Chapman, 2014 [38]	*	----	*	*	*	----	----	----	----		
	Waaljman, 2014 [39]	*	----	*	*	*	----	----	----	----		
	Rodriguez, 2013 [41]	*	----	*	*	*	----	----	----	----		
	Ferber, 2013 [42]	*	----	*	*	*	----	----	----	----		
	Lin, 2013 [44]	*	----	*	*	*	----	----	----	----		
	Arts, 2012 [45]	*	----	*	*	*	----	----	----	----		
	Waaljman, 2012 [46]	*	*	*	*	*	----	----	----	----		
	Bus, 2011 [47]	*	----	*	*	*	----	----	----	----		
	Waaljman, 2011 [48]	*	----	*	*	*	----	----	----	----		
	Pataky, 2010 [25]	*	----	*	*	*	----	----	----	----		
	Owings, 2009 [49]	*	----	*	*	*	----	----	----	----		
	Owings, 2008 [54]	*	----	*	*	*	----	----	----	----		
Jadad scale items:										0 - 5		
RCT	Randomization		Blinding		Dropouts						3	
	Abbott, 2019 [32]	2	0	1	1	1	----	----	----	----		
	Parker, 2019 [34]	2	1	1	1	1	----	----	----	----		
Bus, 2013 [40]										2		4
Newcastle-Ottawa quality score: 0 – 3, poor (red); 4 – 6, fair (yellow); 7 – 9, good (green). Jadad quality score: 0 – 2, poor (red); 3 – 5, good (green).												

Assessment Scale for cohort and case-control studies, 7 studies received high score (7–9, representing good quality and low risk of bias) and 16 studies received a moderate score (4–6, fair quality with the possibility of presenting some risk of bias). For the RCT studies, using the Jadad Scale, all 3 studies were classified as good quality, which implies a low risk of bias. The quality assessment scores can be consulted in Table 2.

Geographical distribution. The selected studies are mainly concentrated in Europe (75 %), and to a lesser extent in North America (12.5 %), Asia (8.3 %) and Oceania (4.2 %).

Participants and demographics. The studies included groups of participants for intervention and control that, in total, ranged from 10 [42] to 219 [30] people. The target population mainly comprised diabetic patients for the intervention groups, but also healthy people for some control groups. The intervention groups are heterogeneous from study to study, consisting of diabetics with/without neuropathy, with/without history of ulceration, and with/without foot deformity. The age of the participants, when provided, including healthy people for the control groups, is between 27.9 ± 6.6 [42] and 73.3 ± 5.6 [52] years. The gender ratio, when provided, showed male participation ranging from 5 [53] to 141 [39] persons, and female from 3 [42] to 117 [30].

Purpose of the studies. The studies' approaches were always expected to reduce plantar pressure based on a certain threshold. Some studies proposed to assess the ability to reduce plantar pressure by: wearing custom footwear [31,35,37,38,40,45–48,52]; custom insoles [33,44,50,51,53,54]; orthotics [34,38]; and through a biofeedback alert for the user to adopt a gait pattern capable of relieving pressure in the risk region indicated by the system [25,32,36,41]. One study compared the ability of two insole systems for pressure measurement to detect a low capillary perfusion pressure, as an indirect measure of plantar pressure threshold [42]. Other studies were based on identifying ulceration risk factors and regions associated with pressure level and suggesting appropriate thresholds to prevent ulceration [30,39,43,49,52].

3.2. Pressure measurement systems

Different systems of plantar pressure measurement were identified. For measurements inside the shoe, instrumented insoles with sensors distributed across the plantar region have been used [25,31–37,39–49,52–54]. Barefoot measurements were performed using pressure platforms [30,52–54]. Fig. 3 presents a distribution between the systems used to measure plantar pressure and the number of studies that used them. This provides an overview of the most used systems for plantar pressure assessment and the various applications for diabetic foot management.

Instrumented insoles. The Pedar system, based on an instrumented insole for insertion inside the shoe, has been the most widely used and considered the gold standard system for this type of application [25,33–35,37,39–41,43–49,52–54]. It consists of a thin structure to couple inside the shoe and contains 99 sensors in the plantar region that can be subdivided into regions of interest. Other similar systems have also been used, such as the Medilogic insoles [31], SurroSense [32,42] and FeetMe [36]. The SurroSense (with 8 sensors) and FeetMe insoles, in addition to measuring the reduction of maximum peak pressure, were also used in a gait adaptation strategy through a biofeedback hyperpressure alert, indicating to the user the region at risk for him to compensate his gait pattern and relieve the pressure in that area of the foot [32,36].

Pressure platforms. For the barefoot measurements Tekscan HR Mat pressure measurement platforms were used [52] and Emed [30,53,54]. They are usually only used in a controlled clinical or laboratory setting. The procedure consisted in locomotion of the patient with bare feet on the platform surface and, at this moment, the pressures exerted by the plantar region of the feet on the platform were recorded, also enabling the identification of potential regions of study interest [30,52–54].

Table 3

Matrix of pressure thresholds for the plantar region stratified by risk level and European (EU) shoe size [43,55]. Risk level: (0) low - no neuropathy, no history of ulceration or foot deformity; (1) medium - with neuropathy, but no history of ulceration or foot deformity; (2) high - with neuropathy and foot deformity, but no history of ulceration; (3) very high - with neuropathy, foot deformation, and history of ulceration.

Risk Level	EU shoe size	Pressure threshold (kPa)			
		Rearfoot	Midfoot	Forefoot	Toes
0–1	36/37	230	100	270	160
	38/39	200	90	240	150
	40/41	180	80	220	130
	42/43	160	70	200	120
	44/45	150	70	180	110
2	36/37	210	60	240	140
	38/39	180	60	220	130
	40/41	160	60	200	120
	42/43	140	60	180	110
	44/45	130	60	160	100
3	36/37	180	60	220	130
	38/39	160	60	190	120
	40/41	140	60	180	100
	42/43	130	60	160	100
	44/45	120	60	140	90

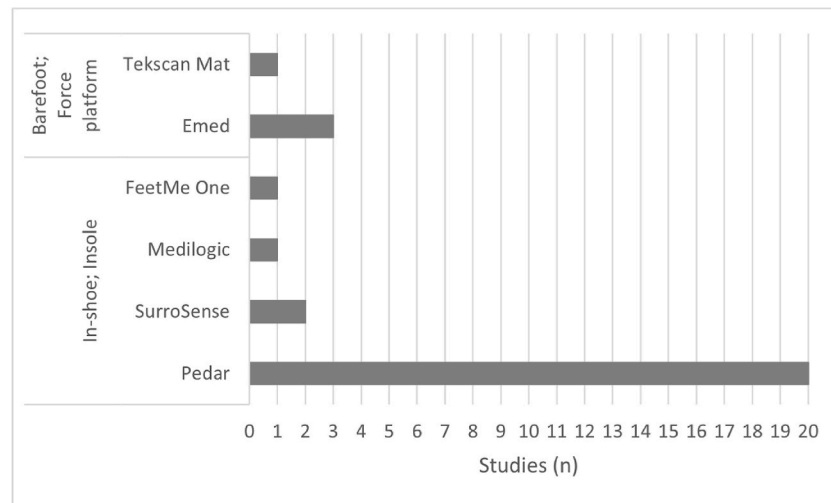


Fig. 3. Distribution of studies according to the plantar pressure measurement systems used, grouped by in-shoe and barefoot scenarios. Studies that used more than one measurement system were counted in the respective system groups.

3.3. Regions of interest

The plantar region of the feet was the focus of the studies, however, this was divided into 3 areas: rearfoot, midfoot, and forefoot. Within these, the authors defined regions of interest that ranged from 3 [34,35,49,53] up to 11 [41] subregions, distributed in one of these areas or across the entire plantar region. These subregions comprised the heel, the lateral and medial midfoot, the heads of the five metatarsals, and the toes. These are sites where the highest pressure events occur or, the previous sites of ulceration to prevent their recurrence [45–48].

3.4. Pressure thresholds inside the shoe

Five different thresholds for managing plantar foot pressure inside the shoe have been identified. The authors use them as target thresholds for an effective and successful pressure reduction to avoid injury and ulceration. Fig. 4 presents a distribution between the thresholds applied in the management of plantar pressure and the number of studies that used them, both for applications inside shoes and with the barefoot. This provides an overview of the most used thresholds for plantar pressure management and the various research applications on ways to offloading plantar pressure in the diabetic foot.

Threshold of 200 kPa. Of the thresholds identified, the threshold of 200 kPa mean peak pressure was the most widely used and cut

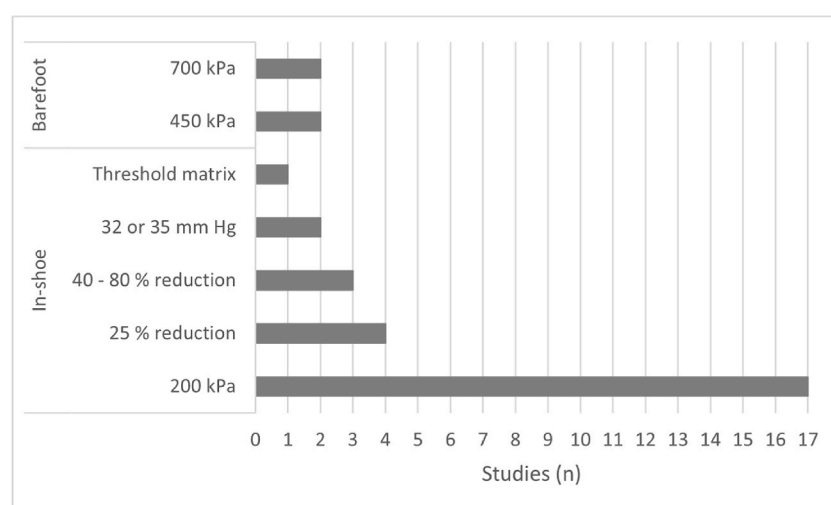


Fig. 4. Distribution of studies according to pressure thresholds, grouped by in-shoe and barefoot scenarios. Studies that used more than one threshold were counted in the respective threshold groups.

across the majority (about 67 %) of studies. This threshold is applied to the set of measurements taken during a walk for every 12 steps per foot [37,39,45,52,53] up to 30 steps per foot [34] or, from 15 [40,47] up to 30 common steps [44,49]. The authors of the studies used the 200 kPa ceiling of plantar pressure to: monitor the previous ulcer site and determine risk factors (pressure) for recurrence [39, 49]; identify regions of interest where hyperpressures occur [34]; customize or evaluate footwear [31,35,37,40,45–48], insoles [33,44, 53] and orthotics [34,38] with the aim of promoting foot pressure reduction; and to evaluate the limitations imposed by the equinus foot condition in diabetic patients and its repercussion on the increase of plantar pressure [52].

Pressure reduction by 25 %. In addition to the established threshold of 200 kPa, four studies also propose a second alternative, suggesting a 25 % reduction in the baseline pressure characteristic of a given patient [40,46–48]. This alternative arises because it was considered to have clinical relevance due to some participants having pressures below the threshold of 200 kPa but were still at risk of developing or had developed an ulcer. Others, with pressures above the threshold did not develop an ulcer [47,48]. This may have been a factor in considering the threshold of 200 kPa or an effective reduction by 25 % of baseline pressure, whichever occurs first [40].

Pressure reduction by 40 - 80 %. A more ambitious threshold reduction is proposed by three studies and consists of lowering the initial baseline pressure by 40–80 % [25,36,41]. The proposed reduction is based, after a prior alert by biofeedback, on learning and adapting the gait pattern with the aim of relieving pressure in a certain region of the foot, properly signaled in this alert. This reduction interval is monitored and calculated during the gait for every 7 of 10 steps [25,41] or for every 14 of 20 steps [36].

Threshold of 32 or 35 mm Hg. These values in millimeters of mercury correspond to approximately 4.3 and 4.7 kPa of pressure, respectively, and relate to capillary arterial pressure (capillary perfusion pressure) in the plantar region of the foot. This is a threshold used as an indirect measure to assess the increase in plantar pressure caused by supporting a person's body weight in their daily activities. The use of this threshold is supported by the fact that even very low external plantar pressures occlude perfusion of the capillary bed into the soft tissues of the foot, significantly impairing the neurovascular response of patients with diabetic foot ulcers compared to patients without ulcers [32,42]. Ferber et al. [42] used a threshold of 32 mm Hg to test and compare two insole-based pressure measurement systems, one that detects vertical plantar pressure (Pedar-X) and the other capillary perfusion pressure (SurroSense RX) and are intended to support the management and treatment of pressure ulcers. In this study, they detected plantar pressure exceeding capillary perfusion pressure (>32 mm Hg), considering this threshold as the minimum pressure that over a 15-min period can lead to minor superficial skin damage [42]. However, in a more recent study, with the same measurement system (SurroSense RX), Abbott et al. [32] found that during 15 min of measurement if 95 % or more of the readings are ≥ 35 mm Hg capillary perfusion pressure, there is effectively a strong likelihood of ulceration. When these conditions are present an audiovisual and vibratory alert is issued for the patient to correct their gait or posture [32].

Stratified threshold matrix. This concept is suggested by Giacomozzi et al. [43]. It consists of a matrix that assigns a certain stratified threshold based on the patient's risk level, shoe size and foot region. The thresholds were based on reference pressures capable of minimizing the risk of ulceration through measurements inside the shoe every 20 steps per foot [43]. The risk level was previously assigned using the protocol proposed by Uccioli et al. [55], which follows the following classification: 0, low risk - no neuropathy, no history of ulceration or foot deformity; 1, medium risk - with neuropathy, but no history of ulceration or foot deformation; 2, high risk - with neuropathy and foot deformation, but no history of ulceration; 3, very high risk - with neuropathy, foot deformation and history of ulceration [55]. Table 3 shows the respective matrix with proposed thresholds.

3.5. Barefoot pressure thresholds

The proposed thresholds are generally indicated for pressures originating inside the shoe. However, and although this approach is the most realistic [49], as it translates the daily life of any patient, four studies have been identified that indicate a pressure threshold with the barefoot [30,52–54]. Barefoot pressure assessment is performed only in a clinical setting and using a pressure platform. This assessment can serve to select regions of interest [53,54] and to classify eventual patients into risk groups [30,52]. As previously described, in Fig. 4 it is possible to consult the distribution between the thresholds applied in the management of plantar pressure and the number of studies that used them, both for applications inside shoes and with the barefoot.

Threshold of 700 kPa. An older study by Armstrong et al. [30], revealed that pressures greater than 700 kPa for regions of the plantar forefoot have specificity and sensitivity for screening and identifying groups at higher risk of ulceration. Measurements were performed for 3 steps per foot [30]. More recently, Searle et al. [52], in evaluating the effects of equinus foot condition on plantar pressure in diabetic patients, used the 700 kPa threshold to identify groups with current or recently healed ulcers. This threshold was applied for every 12 steps per foot [52].

Threshold of 450 kPa. Telfer et al. [53] and Owings et al. [54] used a threshold of 450 kPa pressure to select the regions of interest that exceeded this threshold. The threshold was applied for the first step [54] or for every 12 steps per foot [53].

3.6. Summary of study results

The use of objective thresholds to reduce plantar pressure to lower values has revealed in some studies an apparent relationship between pressure reduction and a minimization of ulceration risk [25,32,37,41,43–49]. However, clear evidence of the effectiveness of these pressure thresholds in footwear was more pronounced in four studies [32,39,40,49].

Within footwear, pressure reduction to a threshold of 200 kPa has been achieved by using custom therapeutic footwear, custom insoles, or by modifying their structures to accentuate the reduction in a particular region of interest. For example, Arts et al. [45], using customized footwear, found effective reduction in 61 % of all feet with deformity and specifically in 81 % of feet with midfoot deformity, 44 % of feet with forefoot deformity, and in 62 % of anterior ulcer sites. Using insoles optimized by numerical simulation,

Telfer et al. [53] obtained lower plantar pressure peaks in 88 % of the regions of interest compared to devices based on a mold. Generically all shoe modifications significantly reduced the peak pressure at the target locations compared to pre-modification levels [33,37,45,47,48,53]. In particular cases, the metatarsal heads were the most targeted regions in reducing pressure [37].

According to the review conducted, Owings et al. [49] was the precursor of the 200 kPa threshold. In their study, which aimed to measure plantar pressures at the anterior ulcer site and provide information for a given threshold for ulceration prevention, they evaluated 49 participants who wore a Pedar pressure-measuring insole inside extra-deep shoes with custom insoles. The average peak pressure in the shoe at this location averaged 207 kPa while walking for 30 steps. This value was rounded to 200 kPa to provide a target average peak pressure in the shoe [49]. Using this same threshold, Waaijman et al. [39] in a study of 171 participants with diabetes, recently healed ulcer and neuropathy, wearing customized shoes for more than 80 % of the hours of the day reduced the pressure below the 200 kPa threshold, thus leading to a decreased risk of ulcer recurrence [39].

For the threshold of 200 kPa or a reduction by 25 % of the baseline pressure, Bus et al. [40] showed evidence for the 200 kPa threshold using customized shoes. For a participant group of 171 people (apparently the same group used by Waaijman et al. [39]), they were able to decrease ulceration recurrence by 46 % after an evaluation over 18 months. However, the results for the 25 % threshold of reduction in base pressure in the footwear proved to be non-significant in decreasing the relative risk of ulcer recurrence, with the exception that if there is effective adherence to wearing the prescribed footwear for 80 % or more of all steps during the wearer's daily locomotion [40]. Other studies that used this 25 % pressure reduction threshold, as the main objective was to evaluate the ability to optimize and customize shoes, considering the number of modifications required to achieve this end, did not evaluate the effect on ulceration [46–48].

The 40–80 % reduction in initial shoe pressure was based on strategies of gait pattern adaptation through biofeedback prompts and recommendations. Effectively, the participants in these studies were able to correct their posture while walking and thereby reduce the pressures in the places identified as having the highest pressures and classified at risk by the measuring system. Van et al. [36] found that 50 % of the steps for all participants in their study were below the proposed maximum pressure threshold [36], however, these studies did not assess ulcer recurrence rates [25,36,41].

On the proposed threshold for a maximum capillary perfusion pressure (as an indirect measure of plantar pressure threshold) of 32 or 35 mm Hg, and further on the strategy of gait pattern correction by biofeedback prompts, the study by Abbott et al. [32] resulted in a 71 % reduction in the risk of relapse in the intervention group compared to the control group, suggesting that a pressure greater than 35 mm Hg in the shoe for 95 % of the previous 15 min increases the risk of ulceration [32]. Whereas for the 32 mm Hg threshold, Ferber et al. [42] when comparing two measurement systems in insole format, SurroSense vs. Pedar-X, only found good to very good correlations for six of the eight SurroSense sensors and a poor correlation in two sensors, analyzing the number of sites that recorded above 32 mm Hg, without assessing their effect on ulceration [42].

The thresholds indicated in the matrix suggested by Giacomozzi et al. [43], for the rearfoot, midfoot, forefoot and toes, also considering the risk level (according to the classification model of Uccioli et al. [55]) of the patient and the size of the shoe worn, have not yet been evaluated in relation to ulceration rates. However, it should be emphasized that after 4 months of wearing the prescribed footwear with application of the proposed thresholds, none of the patients developed plantar ulcers or signs of plantar tissue damage. This protocol may have general validity, however, its application can only be done reliably if the test is performed with the same calibrated measurement system (Pedar) and with the insoles of sizes 36–45 [43].

In the studies where the 450 and 700 kPa barefoot thresholds were used, they showed ability to identify regions of interest and classify risk groups. For the 450 kPa threshold it was possible to identify regions of interest where this value was exceeded [53,54]. At the 700 kPa threshold, it was possible to classify risk groups [30,52]. For example, Searle et al. [52] when evaluating adult diabetic participants with the equinus foot condition, found that they had a significantly higher peak pressure with barefoot than the control group without equinus foot [52] and, Armstrong et al. [30] verified with clear evidence that the peak plantar pressure was significantly higher for patients with ulcers compared to the control group [30].

4. Discussion

The studies included in this review presented different objectives and different applications for adopting a certain plantar pressure threshold. Some have focused on outcomes research to prove the effectiveness of reducing pressure by changing the design of custom shoes and insoles. Others were concerned with evaluating whether reducing pressure beyond a certain threshold would have a positive impact on the appearance or treatment of pressure ulcers. Despite the disparate objectives, a common objective was to consider a threshold that was favorable and that would reduce pressure to a safe level for the integrity of the foot. Even so, some studies have revealed objective data on recommended thresholds for plantar pressure, some of which are based on the prevention of ulceration and its recurrence, both for the barefoot (although fewer) and inside the shoe. However, it is reinforced that it is more realistic to measure and monitor plantar pressure inside the shoe [49], as it reflects the daily life of any patient and is an environment conducive to greater pressure and injuries caused by the additional pressure imposed by the shoe.

As for the systems for measuring pressure inside the footwear, due to the high heterogeneity of the systems available on the market, each with its own characteristics (number of sensors, measuring range, sampling rate, etc.), it makes it difficult to select which system is the best and, above all, to make comparisons of the results obtained with this measurement systems [56].

In the studies included in this review, there was considerable variation in the number of regions of interest that the authors considered for analysis, as well as in the number of steps over which the 200 kPa threshold is evaluated. In the literature there are recommendations of a minimum number of 12 steps per foot required to obtain statistically reliable data [57]. It is also important to emphasize the importance of other variables that may increase the risk of injury and influence the pressure inside the shoe. The

temperature and humidity inside the shoe can be factors that increase the risk of ulceration [58,59].

The threshold of 200 kPa is the most widely agreed upon among studies, and is the threshold proposed by international guidelines for diabetic foot care, when pressure measurements are taken with a sensor of 2 cm² [3]. However, more evidence is needed to confirm this value and whether dynamic pressure peaks contribute more to ulceration than low sustained pressures within the shoes. The low static pressures in the foot [32], when the patient with diabetic foot adopts a prolonged (1–2 h) and certain posture, may be inducing small irreversible lesions in the foot tissues, such as injuries caused by bedsores in bedridden patients [60].

The heterogeneity of the methodologies adopted by the studies and their broad objectives were also an obstacle to carrying out a meta-analysis. On the other hand, a high number of studies with fair quality, which may present some potential risk of bias, do not allow us to state with evidence about which pressure thresholds are most effective in preventing ulceration, despite the International Working Group on Diabetic Foot [3] admit that the 200 kPa pressure threshold is the most recommended to prevent and accelerate the treatment of possible diabetic foot ulcers. From our perspective, the threshold matrix proposed by Giacomozzi et al. [43] could be a sensible and more easily customizable approach for each patient. This matrix considers the level of risk of the disease (presence or not of neuropathy, ulcers, and anatomical deformities in the foot), the size of the shoe/foot and four regions of interest on the foot, proposing a specific threshold for each situation. However, this approach still needs additional studies to clarify its evidence. On the other hand, we must also highlight those important studies, mainly RCTs and case-control classified with good quality, addressed the proposal of thresholds for 200 kPa or a 25 % pressure reduction.

5. Strengths and limitations

A strength is the comprehensive systematic review of the literature using a rigorous methodology according to the PRISMA protocol. This allowed us to have a broader view of the pressure thresholds most used to promote an adequate plantar pressure reduction in diabetic foot. Limitations include the small number of electronic databases that were screened, Scopus, PubMed, and Web of Science. This fact may have excluded some articles, although the selected databases are highly recognized by the scientific community and have a wide multidisciplinary spectrum. An additional limitation was the obstacle created to carrying out a meta-analysis due to the heterogeneity of the methodologies adopted in the studies and the type of applications that implied different objectives in the adoption of pressure thresholds.

6. Conclusion

In this systematic review, seven thresholds were identified that are used for the purpose of reducing the risk of diabetic foot ulceration or identifying regions of clinical interest. Five of which are intended for the inside of the shoe: a threshold of average peak pressure of 200 kPa; 25 % and 40–80 % reduction from initial baseline pressure; 32–35 mm Hg for capillary perfusion pressure (as an indirect measure of plantar pressure threshold); and a matrix of thresholds based on patient risk, shoe size and foot region. Two others are intended for the barefoot, 450 and 750 kPa. While measurement inside the shoe is more pertinent and realistic, the thresholds for the barefoot can be useful for identifying regions of interest and classifying the patient into a given level of risk.

The threshold of 200 kPa of pressure inside the shoe is the most consensual among the studies. About the prevention of ulceration or its recurrence, the effectiveness of the proposed threshold matrix and the threshold of reducing baseline pressure by 40–80 % has not yet been evaluated, and the evidence for the remaining thresholds needs further study. Further tests should be considered to prove the effect on ulceration of low static pressures on the foot when prolonged over time compared with dynamic pressures.

Despite some heterogeneity in the methodologies adopted, especially about the measurement systems used, the number of regions of interest to be studied, and the number of steps to be considered for threshold application, this review reveals the path to follow to obtain an objective threshold that is indicative of an effective threshold for diabetic foot ulcer prevention. Furthermore, it is important to highlight the need for a next stage in research, which could focus on additional refinements, such as determining specific thresholds based on the most critical locations in the plantar region while considering foot anatomy variations (such as size, type, deformities, among others). This additional step could be an important contribution to a more precise approach to preventing diabetic foot ulcers based on a certain threshold.

What is already known

- Plantar pressure monitoring is used to minimize the risk of diabetic foot ulceration and customize footwear suitable for diabetic people, as well as to assist nurses in the management of this condition;
- In practice, a specific plantar pressure threshold is not yet used by the medical community to prevent ulceration and its recurrence, although there are many clinical studies indicating favorable thresholds in certain situations.

What this paper adds

- It is important to add the information available in the literature to make known the most relevant measurable pressure thresholds to identify the risk of plantar ulceration in diabetic people;
- We provided a systematic review of the literature which reveals the most promising and objective plantar pressure thresholds to be applied in the prevention of diabetic foot ulceration;

- The healthcare professional, physician or nurse, can find a suitable threshold for their diabetic patients or clinical case studies for pressures originating from inside the shoe or with the barefoot.

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Data availability statement

This work is a systematic literature review based on searches in the previously mentioned electronic databases, therefore, the data supporting this study were not stored in any other repository. All additional data and information are available upon request from the corresponding author.

CRedit authorship contribution statement

Pedro Castro-Martins: Writing – review & editing, Writing – original draft, Validation, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Arcelina Marques:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Luís Coelho:** Writing – review & editing, Methodology, Conceptualization. **Mário Vaz:** Validation, Supervision, Conceptualization. **José Torres Costa:** Validation, Supervision, Conceptualization.

Declaration of competing interest

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

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2.3 - In-shoe Plantar Pressure Measurement Technologies for the Diabetic Foot: A Systematic Review

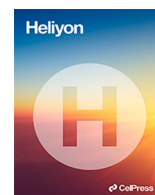
This section is based on an open-access article published by the author under the terms and conditions of the Creative Commons Attribution (CC BY) license. This systematic review examines technologies for measuring plantar pressure within footwear, with a focus on the diabetic foot population at risk of ulcers and trauma due to loss of protective skin sensitivity and high plantar pressures. Commercial systems and proposals for new sensors were identified, with a focus on insoles equipped with resistive sensors, the most common technology on the market. The review also found significant differences in measurement results between devices, highlighting the importance of using consistent devices in individual patient assessments.

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Research article

In-shoe plantar pressure measurement technologies for the diabetic foot: A systematic review

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ABSTRACT

Introduction: Loss of cutaneous protective sensation and high plantar pressures increase the risk for diabetic foot patients. Trauma and ulceration are imminent threats, making assessment and monitoring essential. This systematic review aims to identify systems and technologies for measuring in-shoe plantar pressures, focusing on the at-risk diabetic foot population.

Methods: A systematic search was conducted across four electronic databases (Scopus, Web of Science, PubMed, Oxford Journals) using PRISMA methodology, covering articles published in English from 1979 to 2024. Only studies addressing systems or sensors exclusively measuring plantar pressures inside the shoe were included.

Results: A total of 87 studies using commercially available devices and 45 articles proposing new systems or sensors were reviewed. The prevailing market offerings consist mainly of instrumented insoles. Emerging technologies under development often feature configurations with four, six or eight resistive sensors strategically placed within removable insoles. Despite some variability due to the inherent heterogeneity of human gait, these devices assess plantar pressure, although they present significant differences between them in measurement results. Individuals with diabetic foot conditions appear to exhibit elevated plantar pressures, with reported peak pressures reaching approximately 1000 kPa. The results also showed significant differences between the diabetic and non-diabetic groups.

Conclusion: Instrumented insoles, particularly those incorporating resistive sensor technology, dominate the field. Systems employing eight sensors at critical locations represent a pragmatic approach, although market options extend to systems with up to 960 sensors. Differences between devices can be a critical factor in measurement and highlights the importance of individualized patient assessment using consistent measurement devices.

1. Introduction

Loss of cutaneous sensation and subsequent ulceration of some regions in the feet of people with diabetes are common

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consequences of the disease, attributed to complications such as peripheral neuropathy, peripheral vascular disease, decreased joint mobility and high pressure injuries [1–7]. Diabetic neuropathy disrupts the patient’s protective cutaneous feedback mechanism, significantly reducing sensitivity to touch and pain [8]. As a result of these complications, it is estimated that approximately 34% of people with diabetes will develop a foot pressure ulcer during their lifetime [9]. These lesions are highly prone to infection, and in severe cases, may necessitate amputation, making diabetic foot ulcers a leading cause of nontraumatic lower limb amputation [10].

Following the decrease or loss of protective skin sensitivity, the integrity of the skin and the patient’s perception of painful stimuli are compromised, rendering them susceptible to traumatic ulceration, a complication commonly termed diabetic foot [11–14]. These diabetic foot ulcers predominantly occur in the plantar region of the forefoot [15,16], corresponding to regions where high pressures typically occur between the foot and the patient’s footwear during gait [17]. However, the midfoot and plantar rearfoot regions are also affected [18,19] and, less frequently, the dorsal region [17]. Consequently, mapping high plantar pressures zones is employed to guide the manufacture of footwear and insoles adapted to offload pressure in these critical regions [20–22].

Supervision of patients and reduction of plantar pressures are essential actions to accelerate ulcer healing and prevent recurrence [23,24]. Currently, plantar pressure monitoring through footwear-integrated technologies is beginning to replace the traditional procedure of measuring platforms, which are typically only used in clinical and barefoot settings. Examples include sensors integrated into the body of footwear, insoles, or socks [25–28].

To better understand and address plantar pressures within footwear in individuals with diabetic foot, it is essential to explore available measuring devices, the results they yield, and their application conditions. In this context, this review seeks to employ systematic methods to identify all the measuring devices used in these conditions, systematically highlight and compare the characteristics of their technologies and application methodologies, and additionally, establish a synthesis of current technologies and those in the research and development phase serving this purpose. The objective is to provide a comprehensive and comparative overview of various plantar pressure measurement technologies used inside shoes, presenting their characteristics and some associated plantar pressure measurement results.

2. Methods

This systematic review was conducted and structured according to the guidelines proposed by the PRISMA methodology – Preferred Reporting Items for Systematic Reviews and Meta-Analysis [29]. A meta-analysis is not included in this systematic review.

2.1. Research strategy

This work focuses exclusively on in-shoe devices intended for diabetic foot conditions from both clinical and occupational health and safety perspectives. To develop an objective research question, the PICO concept was employed: Population, in-shoe plantar pressure devices; Interest, technologies used to assess in-shoe diabetic foot plantar pressure; Comparison, variability in technology characteristics; Outcomes, results offered by the technologies. This approach led to the following research question: In the context of existing in-shoe plantar pressure measuring devices (P), what are the technologies and methodologies used for measuring diabetic foot plantar pressure (I), how do the distinct characteristics of these devices compare (C) and what are the measurement results (O) obtained? This research question aims to provide a comprehensive overview and comparison of various plantar pressure measuring devices, their technologies, features and the results they offer, thereby informing researchers, doctors and others healthcare professionals about the available options.

In December 2022 (updated in February 2024), four electronic databases (Scopus, Web of Science, PubMed, Oxford Journals) were screened using selected keywords (see Fig. 1) to capture relevant literature on the topic. The search query used, with the combination of keywords to search all databases, was: (“diabetic foot” OR “neuropathy”) AND (“plantar pressure” OR “foot ulcer” OR “injury prevention”) AND (“measurement system” OR “measurement sensors” OR “instrumented insole” OR “instrumented shoe” OR “instrumented footwear” OR “in-shoe system” OR “smart socks”). The records obtained through the database search were managed using Mendeley software. However, the article selection process was conducted manually, with Mendeley assisting only in identifying duplicate records, which were subsequently validated and removed based on the authors’ decision.

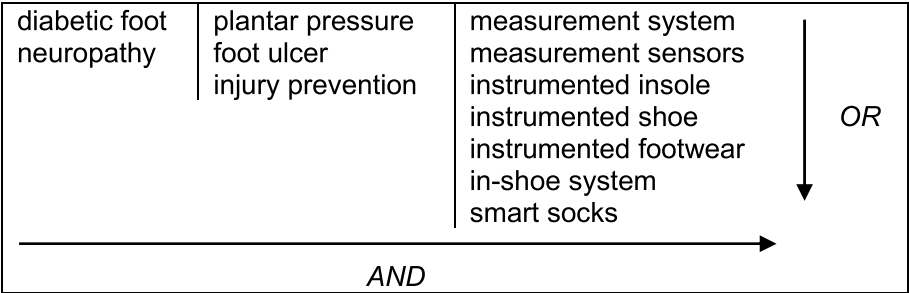


Fig. 1. Keywords used in the search for the selection of articles in the databases.

2.2. Selection and eligibility criteria

The main information included in this systematic review was derived from articles (document type) published in journals (source type). The review covered articles published in the English language without date restrictions. The initial review process consisted of two main steps: abstract-level screening and full-text review. During the abstract-level screening, the titles and abstracts of the articles were analyzed to classify them as on-topic or not, based on the proposed eligibility criteria outlined below. Articles that clearly did not fit the topic were rejected at this stage. In the subsequent step, the full text of the remaining articles was thoroughly reviewed and eligibility criteria were applied. Articles were selected if they met the following cumulative requirements: i) utilization of systems for plantar pressure measurement or development of new systems and/or sensors; ii) inclusion of systems and/or sensors incorporated into the footwear and/or removable devices insertable into footwear; iii) with applicability in the context of diabetic foot pathology for monitoring plantar pressures. The article selection process was conducted independently by two authors, PCM and AM. Any discrepancies regarding the inclusion of a particular article were resolved by a third author, LC, to ensure objectivity in the article selection process.

The articles included considered studies that proposed new sensors or systems still under research or development, which served as the main source of information. Additionally, articles utilizing measurement systems already available on the market were included to identify the standard system and the usage rates. Studies that did not use systems or sensors attached to the inside of the shoe or that could be inserted, such as insoles or other removable methods, to measure plantar pressures were excluded. Similarly, articles reporting studies of plantar pressure assessment conducted barefoot, i.e., without any footwear, were also excluded. Furthermore, the reference lists of eligible articles cited by the authors were analyzed to identify further relevant information, which was subject to the same eligibility criteria. This analysis was conducted only once and the same selection method mentioned earlier was followed, with any discrepancies resolved by a third author.

The scope of this review covered information pertaining to devices specifically designed to measure in-shoe high plantar pressures, distinct from other plantar pressure measurement systems used barefoot in clinical setting. We considered this approach more appropriate as it mirrors the daily life experience of individuals with diabetes, whether diagnosed with diabetic foot or at high risk of developing it, as they typically wear shoes, including shoes customized to reduce plantar pressure.

2.3. Data extraction

Once the selection process of eligible articles was completed, the following data were collected: i) identification of the authors, year of publication and title; ii) research subject and objectives; iii) methodology applied, including the equipment used or type of device developed and/or proposed sensors, object of measurement, technology used, number of sensors and their locations, operating conditions and target and control sample (if applicable); iv) results obtained and conclusions. These extracted data were essential in addressing a set of predefined questions outlined in the results section and facilitated an objective synthesis of the most relevant information. Additionally, data was aggregated concerning the measurement of plantar pressure in individuals with diabetes and

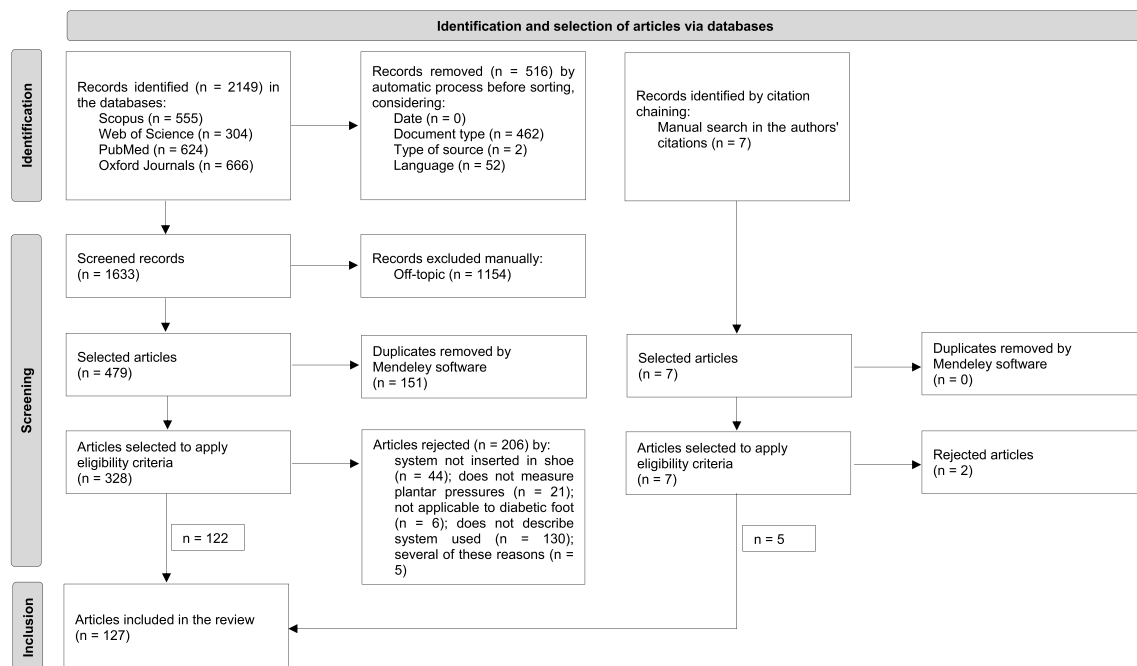


Fig. 2. Flow diagram of the selection of articles according to the PRISMA methodology.

Table 1
Summary of the characteristics of the devices available on the market to measure and evaluate plantar pressures inside the shoe. (a) considering the number of publications resulting from research whose authors use these devices in their studies.

Device and manufacturer	Number of publications	Publication references	Utilization rate (a)	Device features					Acquisition rate	Usage cycles
				Application type	Number of pressure sensors	Technology	Other sensors	Battery life		
F-Scan TekScan, USA [31]	42	[35,36,47,48, 72,86,87,94], [96–129]	44.7%	Insole	960 (variable with insole number)	Resistive	–	2 h	100 Hz	5 to 15 (with intense activity)
Pedar insole novel GmbH, Germany [32]	35	[96,97, 130–162]	37.2%	Insole	99	Piezoelectric or capacitive	–	4.5 h	50 or 100 Hz	–
Biofoot Biofoot IBV, Spain [163]	1	[85]	1.1%	Insole	64	Piezoelectric	–	–	750 Hz	–
RS Scan Rs Scan, Belgium [164]	1	[165]	1.1%	Insole	356 or 900	Capacitive	–	–	–	–
SurroSense RX or Sensory Insole Orpyx Medical Technologies [166]	6	[130,167–171]	6.4%	Insole	8 or 37	–	Temperature	8–12 h	100 Hz	–
Sensoria Socks Sensoria Inc., USA [91]	2	[73,170]	2.1%	Sock	3	Piezoresistive textile	–	–	Bluetooth	–
paroTec Paromed, Australia [172]	3	[110,173,174]	3.2%	Insole	24	Piezoresistive	–	–	SD memory card	–
Medilogic Medilogic GmbH, Germany [90]	1	[139]	1.1%	Insole	240	Resistive	–	16 h	Wireless (no detail)	100 or 300 Hz
Walkasins Rx Function, USA [175]	1	[176]	1.1%	Orthosis/ Insole	–	–	–	–	Wireless (no detail)	–
WalkinSense Tomorrow Options Microelectronics [177]	2	[177,178]	2.1%	Insole	8	Piezoresistive	–	–	Wireless (no detail)	–

Table 2
Summary of the characteristics of devices under development to measure and evaluate plantar pressures inside the shoe.

Author, year	Device (typology)	Measurement object	Technology	Number of sensors	Sensor locations	Operational conditions				Measuring range	Sensitivity and Resolution	Temperature and Humidity	Usage cycles
						Communication	Battery life or capacity	Acquisition rate					
Amemiya et al., 2016, 2020 [46, 81]	Plantar system	Plantar pressure and shear force	Triaxial piezoelectric sensor (Shokac Chip, Touchence, Japan)	6	Two sensors in each location: 1st, 2nd and 5th metatarsal head	Bluetooth (with control unit attached to the user's leg)	Yes (no details)	100 Hz	Tests with normal pressure at 510 kPa and shear at 127 kPa	-	-	-	-
Anas, 2014 [42]	Insole	Plantar pressure/force and dorsiflexion	Resistive force sensor (FSR 402, Interlink electronics) + flexible resistive strain gauge (FBS FLX-01, Spectra Symbol)	4 + 1	FLX sensor: longitudinal of the sole of the foot; FSR sensor: hallux, 1st and 5th metatarsal heads, and heel	Wired	Yes (no details)	10 Hz	Author presents measurements with patients up to 80 N force and dorsiflexion angle up to 50°	-	-	-	-
Aqueveque et al., 2018 [41]	Insole	Plantar pressure	Capacitive sensor	8	Hallux, between the 4th and 5th toes, three on the metatarsal heads, lateral and medial midfoot and heel	Bluetooth	500 mAh	100 Hz	-	-	-	-	-
Atlas et al., 2008 [56]	Plantar system	Plantar pressure	Resistive force sensor (Flexiforce, Tekscan)	-	Heel	Wired (control unit on the user's belt)	-	-	-	-	-	-	-
Brown et al., 2004 [58]	Plantar system (using specific diabetic footwear soles)	Plantar pressure	Resistive force sensor (FSR, Interlink electronics)	7	Hallux, heel, base of the 5th metatarsal, heads of the 1st, 2nd, 3rd/4th and 5th metatarsals	Wired	-	60 Hz	-	-	-	-	-
Dabiri et al., 2008 [57]	Plantar system	Plantar pressure	Resistive force sensor (Flexiforce, Tekscan)	5	1st, 3rd and 5th metatarsal heads, lateral midfoot and heel	Zigbee or Bluetooth	Yes (no details)	-	-	-	-	-	-
Darwich et al.,	Insole	Plantar pressure	Resistive force sensor (FSR)	7	Hallux, 1st and 5th metatarsal	Wireless (no details)	-	200 Hz	-	-	-	-	-

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Table 2 (continued)

Author, year	Device (typology)	Measurement object	Technology	Number of sensors	Sensor locations	Operational conditions					Sensitivity and Resolution	Temperature and Humidity	Usage cycles	
						Communication	Battery life or capacity	Acquisition rate	Measuring range					
2023 [61]			402, Interlink Electronics)		heads, medial and lateral midfoot and two on the heel									
Du et al., 2015 [51]	Sensor	Plantar pressure and shear force	Triaxial inductive sensor	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Normal force: 0–800 N; Shear: 0–130 N	1 N	–	–	–	–
	Plantar system for attaching to the shoe	Plantar pressure	Resistive force sensor (FSR, Interlink Electronics)	6	Hallux, 1st, 3rd and 5th metatarsal heads and medial and lateral heel	Wired	–	100 Hz	0–1.2 MPa	0.1–10 kg cm ^{−2} ±0.5% of total applied force	–30 to 170 °C	–	–	–
Gerlach et al., 2015 [82]	Insole	Plantar pressure	Piezoresistive sensor	6	Hallux, three on the metatarsal heads, lateral midfoot and heel	Wired	–	100 Hz	–	–	–	–	–	–
Ghazi et al., 2024 [62]	Insole	Plantar pressure	Resistive force sensor (FSR, Flexiforce)	5	1st and 5th metatarsal heads and three on the heel	Wi-Fi, with smartphone app	AAA battery (2 un.)	0.2 Hz	–	–	–	–	–	–
Guignier et al., 2019 [71]	sock	Plantar pressure	Fiber optic sensor (POF, Geniomer)	3	Metatarsus, midfoot and heel	Wired	–	–	Tests between 3 and 120 kPa	–	–	–	–	–
Hamatani et al., 2016 [36]	Hybrid insole (integration of F-Scan insole and uniaxial and biaxial shear sensors)	Plantar pressure and shear force	F-Scan: resistive; Uniaxial and biaxial shear sensor: no details	F-Scan: 954 (variable with insole number); Uniaxial: 3; Biaxial: 1	F-Scan: the entire plantar region; Uniaxial: 1st, 2nd and 5th metatarsal heads; Biaxial: heel	Wired	–	50 Hz	F-Scan: up to 862 kPa; Sensors: no details	F-Scan: 3.9 sensors per cm ² (spatial resolution) Sensors: no details	–	–	F-Scan: 5 to 15; Sensors: no details	–
Hu et al., 2024 [64]	Insole	Plantar pressure	Resistive force sensor (based on Velostat polymer film; Adafruit Industries)	174	The entire plantar region	Bluetooth	3.7 V, 230 mAh; up to 3 h	50 Hz	–	–	–	–	–	–
Klimiec et al.,	Insole	Plantar pressure	Piezoelectric sensor (PVDF)	8	Hallux, 4th toe, 1st, 3rd and 5th	Wi-Fi or Bluetooth	720 mAh	–	–	–	–	Up to 85 °C	–	–

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Table 2 (continued)

Author, year	Device (typology)	Measurement object	Technology	Number of sensors	Sensor locations	Operational conditions				Sensitivity and Resolution	Temperature and Humidity	Usage cycles
						Communication	Battery life or capacity	Acquisition rate	Measuring range			
2014 [39]					metatarsal heads, lateral and medial midfoot and heel							
Laaralbi et al., 2023 [63]	Insole	Plantar pressure	Resistive force sensor (based on Velostat polymer film; 3 M's Electronics)	6	Hallux, 1st and 5th metatarsal heads and two on the heel	-	-	-	-	-	-	-
Leal-Junior et al., 2018 [69]	Insole	Plantar pressure	Fiber optic sensor (POF)	4	Medial and lateral forefoot, lateral midfoot and heel	Wired (to control unit fixed on the back of the shoe)	9 V	-	-	0.009 N ⁻¹	-	-
Li et al., 2023 [65]	Insole	Plantar pressure	Resistive force sensor (based on conductive carbon film)	104	The entire plantar region	Wi-Fi, with computer	Yes (no details); up to 3 h	28 Hz	0–1600 kPa	0.01 kPa ⁻¹ in the range 500–1600 kPa	-15 to 40 °C	3000 times at ≈ 850 kPa
Liang et al., 2016 [67]	Plantar system	Plantar pressure	Fiber optic sensor (FBG)	6	1st, 2nd, and 3rd metatarsal heads, lateral and medial midfoot and heel	Wired	-	-	-	-	No temperature influence	-
Lin et al., 2017 [75]	sock	Plantar pressure	Piezoresistive textile sensor	4	1st, 3rd and 5th metatarsal head and heel	RF 866 MHz	Battery-free (RF energy harvested, with RFID)	-	Up to 1 MPa	Up to 400 kPa, 10 kPa resolution; 400 kPa–1000 kPa, 60 kPa resolution	-	-
Lord et al., 2000 [47]	Hybrid footwear-coupled plantar system (combination of F-Scan insole and biaxial shear sensors)	Plantar pressure and shear force	F-Scan: resistive; Biaxial shear sensor; magneto-resistive	F-Scan: 954 (variable with insole number); Biaxial: 3	F-Scan: the entire plantar region; Biaxial: heel, 1st (or 2nd) and 3rd (or 4th) metatarsal head	Wired	-	F-Scan: 100 Hz; Sensors: 400 Hz	F-Scan: up to 862 kPa; Sensors: no details	F-Scan: 3.9 sensors per cm ² (spatial resolution) Sensors: no details	-	F-Scan: 5 a 15; Sensors: no details
Luna-Perejón	Insole	Plantar pressure	Capacitive sensor (with	12	Seven in the forefoot, three	Bluetooth	Two LiPo battery	10–25 Hz	-	0.46–0.76 pF kPa	-	-

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Table 2 (continued)

Author, year	Device (typology)	Measurement object	Technology	Number of sensors	Sensor locations	Operational conditions				Temperature and Humidity	Usage cycles	
						Communication	Battery life or capacity	Acquisition rate	Measuring range			
et al., 2023 [66] Mahmud et al., 2023 [72]	Insole (two models, I and II)	Plantar pressure and temperature	PMDS dielectric) Model I: fiber optic (FBO); Model II: resistive force sensor (FSR) and negative temperature coefficient thermistors (NTC)	Model I: 15 sensing units for pressure and 5 for temperature; Model II: 16 FSR and 8 NTC	in the midfoot area and two in the heel Model I: at approx. the same location as model II; Model II: nine FSR in the forefoot, four in the midfoot area and three in the heel; five NTC in the forefoot, two in the midfoot area and one in the heel	Model I: wired with USB serial; Model II: Bluetooth	Model I: not applicable; Model II: no details	Model I: 40–100 Hz; Model II: 40 Hz	Model I: up to ≈64.6 kg and ≈252.2 °C; Model II: ≈690–1380 kPa and –30 to 90 °C	Model I: resolution of 0.1 °C and 1 με for strain; Model II: ≈ resolution of 0.5% of the applied pressure	–	–
Mori et al., 2012 [35]	Hybrid insole (integration of F-Scan insole and uniaxial and biaxial shear sensors)	Plantar pressure and shear force	F-Scan: resistive; Uniaxial and biaxial shear sensor; magnetic variation (Keisoku Support Ltd., Hiroshima)	F-Scan: 960 (variable with insole number); Uniaxial: 2; Biaxial: 1	F-Scan: the entire plantar region; Uniaxial: 2nd and 5th metatarsal heads; Biaxial: heel	Wired	–	F-Scan: 50 Hz; Sensors: 500 Hz	F-Scan: up to 862 kPa; Sensors: uniaxial up to 10 kgf and biaxial up to 8 kgf	F-Scan: 3.9 sensors per cm ² (spatial resolution) Sensors: 0.1 kgf	–	F-Scan: 5 a 15; Sensors: no details
Morley et al., 2001 [93]	Multisensor system	Plantar pressure, temperature and humidity	Pressure sensor: resistive (Paromed); Temperature sensor: Resistive RTD (Paromed); Humidity sensor: no details (Honeywell HIH series)	4 + 2 + 1	Pressure: heel and three metatarsal heads; Temperature: under the 3rd metatarsal head and on the heel; Humidity: toe cap of the insole	Wired	Yes (no details)	Pressure: 30 Hz; Temp. and humidity: 1 reading per min.	–	–	Stability up to 35 °C and up to 95% humidity	Some days with 8 h of daily use
Ostadabas et al., 2012 [44]	Insole	Plantar pressure	Resistive force sensor (Flexiforce, Tekscan)	5	Hallux, heel and 1st, 2nd and 3rd/5th	Wired	–	250 Hz	–	–	–	–

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Table 2 (continued)

Author, year	Device (typology)	Measurement object	Technology	Number of sensors	Sensor locations	Operational conditions				Sensitivity and Resolution	Temperature and Humidity	Usage cycles
						Communication	Battery life or capacity	Acquisition rate	Measuring range			
Pataky et al., 2000 [54]	Plantar system for attaching to the shoe	Plantar pressure	Resistive force sensor (FSR 174, International Electronics)	4	metatarsal heads 1st, 3rd and 5th metatarsal head and heel	Wired, up to control unit on user's belt	4 LR6 1.5 V batteries; up to 8 days or 60,000 gait cycles	96 Hz	—	—	—	$\approx 10^7$
Pataky et al., 2003, 2005 [59, 60]	Plantar system	Plantar pressure	Resistive force sensor (FSR 174, International Electronics)	5	Hallux, on the 1st, 3rd and 5th metatarsal heads and heel	Wired	—	96 Hz	—	—	—	—
Perrier et al., 2014 [74]	sock	Plantar pressure	Piezoresistive knitted textile	8	Hallux, four on the metatarsal heads, lateral midfoot, and medial and lateral heel	Bluetooth	Yes (no details)	—	—	—	—	—
Rajala et al., 2017 [40]	Insole	Plantar pressure	Piezoelectric sensor (PVDF)	8	Hallux, two on the 1st metatarsal head, 2nd, 3rd, 4th and 5th metatarsal head and heel	Wired	—	—	Author presents measurements with patients up to ≈ 500 kPa	28.5 ± 1.0 pC.N ⁻¹	10–40 °C	—
Raviglione et al., 2017 [73]	Wearable system	Plantar pressure	Piezoresistive textile sensor	1	Plantar region (to be placed on the area of interest)	Bluetooth	—	—	0–845.5 kPa	—	—	—
Suresh et al., 2014 [70]	Footwear-coupled plantar system	Plantar pressure	Fiber optic sensor (FBG)	2	Forefoot and heel	Wired	—	200 Hz	Author presents measurements with patients up to ≈ 700 kPa	1.3 pm.kPa ⁻¹ 0.8 kPa	—	—
Suresh et al., 2015 [38]	Insole	Plantar pressure	Fiber optic sensor (FBG)	4	1st and 5th metatarsal head, medial and lateral heel	Wired	—	—	Author presents measurements with patients up to ≈ 1400 kPa	1.2 pm.kPa ⁻¹ ≈ 0.8 kPa	—	—

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Table 2 (continued)

Author, year	Device (typology)	Measurement object	Technology	Number of sensors	Sensor locations	Operational conditions				Usage cycles		
						Communication	Battery life or capacity	Acquisition rate	Measuring range		Sensitivity and Resolution	Temperature and Humidity
Takano et al., 2014 [48]	Hybrid footwear-coupled plantar system (combination of F-Scan insole and uniaxial shear sensors)	Plantar pressure and shear force	F-Scan: resistive; Uniaxial shear sensor: Magnetic variation (Keisoku Support Ltd., Hiroshima)	F-Scan: 954 (variable with insole number); Uniaxial: 2	F-Scan: the entire plantar region; Uniaxial: 1st and 2nd metatarsal head	Wired	–	F-Scan: 50 Hz; Sensors: 500 Hz	F-Scan: up to 862 kPa; Sensors: up to 200 N	F-Scan: 3.9 sensors per cm ² (spatial resolution) Sensors: 6.1 × 10 ^{−4} kgf	–	F-Scan: 5 a 15; Sensors: no details
Tan et al., 2021 [45]	Insole	Plantar pressure	Piezoresistive textile sensor	6	Hallux, 1st and 4th metatarsal head, lateral midfoot, and medial and lateral heel	Bluetooth	Yes (no details)	–	Up to 800 kPa (0–100 kPa stability guarantee)	3.96 kPa ^{−1} in the range 0–36 kPa ^{−1} (0.49 kPa ^{−1} for upper range)	–	1000
Tang et al., 2023 [52]	Insole	Plantar pressure and shear force	Capacitive sensor	4	Hallux, 1st and 5th metatarsal heads and heel	Wireless (no details)	Yes (no details)	100 Hz	–	–	–	–
Wang et al., 2005 [50]	Sensor	Plantar pressure and shear force	Fiber optic (no detail)	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	–	Detection limit for shear: 2.2 N	–	–
Wang et al., 2008 [68]	Sensor	Plantar pressure	Fiber optic (PMDs)	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Up to 500 kPa	0.1% 0.027 N	–	–
Wang et al., 2020a [37]	Insole (control system integrated in the sole of the shoe)	Plantar pressure	Flexible piezoresistive sensor	8	Hallux, 1st, 2nd/3rd and 4th/5th metatarsal heads, medial and lateral midfoot, medial and lateral heel	Bluetooth	3.7 V, 450 mAh; up to 20 h	20 Hz	0–45 N or 0–600 kPa	0.0105 N ^{−1}	–	Up to 10 ⁵
Wang et al., 2020b [49]	Sensor	Plantar pressure and shear force	Triaxial inductive sensor	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Shear (x, y): −160 to 160 kPa; Vertical pressure (z): 0–1047 kPa	x: 489.1 nH mm ^{−1} y: 494.6 nH mm ^{−1} z: 187.1–1210 nH mm ^{−1}	–	–
Wertsch et al.,	Plantar system for	Plantar pressure	Resistive force sensor (FSR,	8	Hallux, 1st, 2nd, 4th and	Wired	–	35 Hz	–	–	–	–

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Table 2 (continued)

Author, year	Device (typology)	Measurement object	Technology	Number of sensors	Sensor locations	Operational conditions				Sensitivity and Resolution	Temperature and Humidity	Usage cycles
						Communication	Battery life or capacity	Acquisition rate	Measuring range			
1995 [53]	attaching to the shoe		Interlink Electronics)		5th metatarsal heads, medial and lateral midfoot and heel							
Zhu et al., 1991 [43]	Insole	Plantar pressure	Resistive force sensor (based on conductive polymer pressure sensor; FSR Interlink Electronics)	7	Four on the metatarsal heads, hallux and posterior and anterior heel	Wired (system in a backpack on the user's back)	Yes (no details)	20 Hz	Author presents measurements with patients up to 657 kPa	-	Sensors calibrated at 36 °C	-
Zhu et al., 1993 [80]	Insole	Plantar pressure	Resistive force sensor (based on conductive polymer pressure sensor; FSR, Interlink Electronics)	7	Four on the metatarsal heads, hallux and posterior and anterior heel	Wired (system in a backpack on the user's back)	Yes (no details)	35 Hz	0–1.2 MPa	0.3–30 mV kPa ⁻¹	Sensors calibrated at 36 °C	-

healthy. This involved synthesizing the results of studies presenting data on average plantar pressure in critical areas such as the hallux toe, metatarsal heads, lateral midfoot and heel, as reported in the analyzed studies. It is important to note that no additional processing was conducted on these data, only a Mann-Whitney test was performed to assess whether differences are statistically significant in plantar pressure patterns in different groups of individuals, including those with diabetes and healthy individuals, with measurements performed by some of the devices and technologies identified in this review. For the Mann-Whitney test, a confidence level of 99% was applied, corresponding to a significance level (α) of 0.01. Results with P value < 0.01 were considered to indicate a statistically significant difference between the comparison groups.

3. Results

The search and selection process, depicted in Fig. 2, initially identified a total of 2149 articles, spanning from 1979 to February 2024. From this process, eligible articles ($n = 127$) were categorized into two groups: i) 87 studies using commercially available plantar pressure measurement systems; and ii) 45 research articles focused on the development of new systems and/or sensors for measuring plantar pressures inside the shoe or capable of attachment. It's noteworthy that some authors addressed the use of multiple models, including hybrid models combining existing systems available on the market with new sensors under development. Consequently, these articles were counted in both groups.

For the first group of 87 articles, only an informative summary is provided to identify each system used. In this group, authors do not detailed descriptions of the characteristics and utility of the devices employed. Instead, their focus lies solely on the variables measured in each group of volunteer patients. The analysis only consisted of identifying the device used, its applicability, the respective utilization rate and the values obtained in plantar pressure measurements. The studies belonging to the second group of 45 articles were included in this systematic review for a more detailed analysis. These articles present the most recent advances in technology for monitoring plantar pressures inside footwear suitable for the diabetic foot conditions. The information collected from both groups provided important insights into the current state of technology and its evolutionary trend. A summary of the information collected characterizing the first and second groups is presented in Tables 1 and 2, respectively.

The assessment of data quality from the studies was not conducted due to several reasons. Firstly, the great diversity among the identified studies, coupled with the lack of a universal methodology and specific guidelines (particularly in studies at the intersection of engineering and health disciplines), made it challenging to establish a standardized approach. Additionally, some studies lacked a defined target sample and objective classification of the study type. This diversity not only prevented the assessment of study quality but also rendered the conduct of a meta-analysis unfeasible.

3.1. What is the typology of the devices and what can they measure?

Systems available on the market. The market offers some products intended for both users and healthcare professionals, all aimed at measuring and evaluating plantar pressures. These products primarily consist of systems intended to be inserted inside shoes, typically in the form of insoles or socks (although socks are less common compared to insoles). Despite their shared purpose of measuring plantar pressures, these systems vary in their technological characteristics [30]. Table 1 provides a comparative summary of the technology used by each system and their distinctive features, with complementary information taken from manufacturers' websites.

Among these systems, the F-Scan systems [31] and Pedar insole [32], both in the insole format for insertion into shoes, stand out as the most widely used for assessing plantar pressures, 44.7% and 37.2% respectively. Of all the devices available, the Pedar insole system is considered the gold standard and one of the most established insole-based plantar pressure measurement systems on the market [26].

Many of the devices can pair and communicate with smartphones through mobile applications to register the data collected in the measurements and access other features. These applications enhance user interaction by presenting data in the form of graphs and colorful mappings indicating areas of plantar pressure, while also issuing alerts for potential occurrences of high pressures. However, it's worth noting that most of these applications are primarily aimed at the sports market, focusing on data collection for athlete performance analysis rather than on preventing high pressure injuries in diabetic foot conditions. Nonetheless, there are also some applications available in this field [22,26,30,33].

Systems and sensors under development. Although some equipment is already available on the market for measuring pressure inside the shoe, the development of new technologies is essential. Solutions with new sensors, wearables and telehealth approaches capable of remotely monitoring a wider set of variables representing the main risk factors of patients with foot pathology are increasingly sought [34].

The evolution of developed equipment shows that the concept of an insole to assess plantar pressures is predominant [35–45]. While systems for measure plantar pressures are prevalent, it's noteworthy that some authors advocate for a hybrid model, simultaneously measuring shear forces in the horizontal plane along with vertical pressures on the shoe insole [35,36,46–52]. Shear results from friction of the foot with the insole itself, which may indicate potential overheating of the skin and an increased risk of injury [35, 36].

These devices require a control unit to process the acquired data. In recent developments, proposals for system concepts that are fully integrated into the structure of the shoe have emerged. The entire technology, especially its control unit, is now embedded in the sole of the shoe, giving the appearance of a conventional shoe [37]. For a more comprehensive analysis, Table 2 presents a comparative summary of the characteristics of the systems under development.

3.2. What technology is used?

This review identified several types of technology integrated into the proposed measurement systems, including resistive technology [44,53–65], piezoelectric [39,40,46], capacitive [41,52,66], inductive [49,51], fiber optics [38,50,67–72] and textile technology with piezoresistive features [73–75]. In Fig. 3A, the graph depicts the most prevalent technology used, along with its associated percentage.

Currently there is a wide variety of sensors to measure the forces and pressures between the foot and the interior of the shoe, including those used for monitoring the human gait. The most used sensors that can be incorporated into pressure measuring devices in footwear are classified into the following categories based on their operating principle:

- resistive sensors: this is the most widely used type of sensor in various applications. They consist of an active area filled with a conductive polymer or ink with conductive properties. When pressure is applied to this area, the material's resistance decreases with increasing pressure. The behavior of these sensors is well known and exhibits an almost linear and predictable response within a certain range of pressure values and operating temperatures [26,30,76–78]. The resistive sensors used are mostly force-sensing resistors (FSRs) [61,62], although other applications use Velostat, a polymeric film that follows the same behaviour as this type of sensor [63–65];
- piezoresistive sensors: like resistive sensors, the entire body of these sensor is typically made of piezoresistive material. They are designed to react when the material is stretched, resulting in a variation in electrical resistance. This resistance is measured and converted into a corresponding pressure value [26,30,77];
- piezoelectric sensors: these sensors utilize the piezoelectric effect, generating an electrical voltage from applied mechanical pressure. They convert mechanical action into an electrical charge, which is measured and converted into a pressure value. The active area can be produced using polyvinylidene difluoride (PVDF), a type of thermoplastic fluoropolymer [26,30,77,78];
- capacitive sensors: comprising two conductive plates with an insulating material between them, capacitive sensors exhibit a decrease in distance between the plates when pressure is applied. This compression of the insulating material leads to a variation in sensor capacitance and consequently its electrical voltage, representing a pressure value [26,30,77,78];
- inductive sensors: these sensors generate a variable electromagnetic field through a coil. When a metallic material enters this field, eddy currents are induced, altering the coil's inductance value. This change corresponds to the observed deformation resulting from applied pressure [49];
- textile sensors: utilizing conductive inks combined with textile material or integrated conductive wires within the textile matrix. A textile matrix can incorporate a large number of sensors. However, they may exhibit non-linearity and sometimes a significant hysteresis [26,30];
- fiber optic sensors: typically produced in a polymer (POF, Polymer Optical Fiber; PMDS, Polydimethylsiloxane), fiber optic sensors consist of a light emitter and a light receiver with a specific wavelength. When the fiber is pressed, the Fiber Bragg Gratings (FBG) sensor measures deformation by varying the photo-elastic constant of the fiber and a change in microstructure period, resulting in a change in Bragg wavelength [38,50,67–72].

3.3. What is the configuration and number of sensors?

Typically, pressure sensors for measuring plantar pressures on a patient's foot are positioned on the inner base of the shoe, either incorporated in the insole itself or within a secondary removable insole [77]. These sensors can be employed individually to obtain

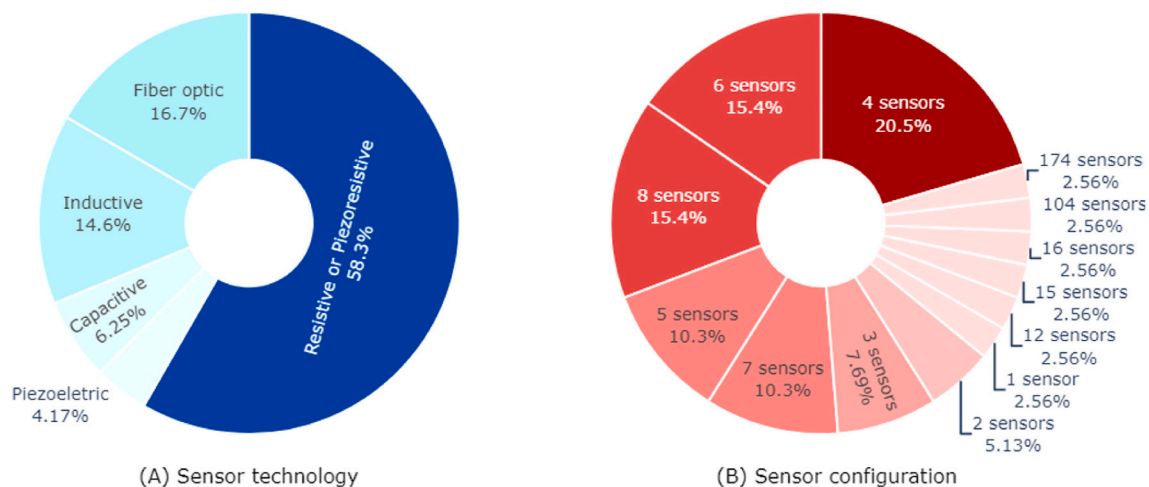


Fig. 3. Predominant sensor technologies (A) and distribution of the most commonly used sensor configurations (B).

discrete measurements of specific region of clinical interest or arranged in an array for higher spatial resolution and sensor density. In the latter configuration, greater resolution is achieved by distributing sensors across the intended skin region for evaluation [79]. These sensors are usually placed at strategic points, which are well-defined in the literature as areas where high pressures commonly occur, considering various foot types such as normal, planus and cavus foot [2]. Some authors propose systems with one until eight measurement points in the plantar region [37,54,55]. However, configurations with four (20.5%), six (15.4%) or eight (15.4%) measurement points/sensors are more prevalent [37,39–41,43,58], as they cover the key points considered clinically relevant for assess plantar high pressures [2]. In Fig. 3B, the graph illustrates the most used sensor configuration along with the corresponding percentage.

The critical points where sensors are typically positioned include the plantar region of the hallux, the heads of the first, second/third and fourth/fifth metatarsals, the medial and lateral midfoot, and the medial and lateral heel [37,54,55]. Some commercially available devices offer more comprehensive foot mapping, such as the F-Scan insole, which can feature a spatial distribution of approximately 960 sensors [31].

The measurement area covered by each sensor in a given configuration and arrangement in the plantar region depends on the sensor density and desired spatial resolution. In the most common model, with FSR sensors (31.1%) distributed at discrete points across the plantar region, the standard diameter of the sensor's active area is approximately 15 mm [42,43,53–55,58,59,80]. However, in other configurations, authors choose for smaller diameters, ranging from 4 to 10 mm, considering different technologies used and systems [35–37,44,46–48,56,57,81]. There are other configurations with greater spatial resolution of sensors, achieved through a matrix produced with Velostat film, which can reach a hundred square sensors measuring 5 mm on each side [63–65].

3.4. What are the operating conditions?

All systems require an additional external unit for acquisition, processing, and power supply, which is sometimes included in the external unit's box. Most systems, as reported by Refs. [41,46,47,55,81,82], have an acquisition rate around 100 Hz. This external unit is typically attached to the patient's leg or waist and connected with wires to the measuring device inside the shoe [43,46,54,56,80].

Some authors propose systems with a wireless communication-enabled control unit to enhance patient mobility and utility outside of the clinical environment. For example, systems with Bluetooth or Wi-Fi connectivity [37,39,41,45,57,73,74], powering by battery, but with varying levels of autonomy, ranging from a few hours to several days, depending on usage cycles [39,41,54,69,83].

These devices are subject to operating conditions imposed by the individual characteristics of each user's foot. The upper limit of measurement can vary from approximately 500 kPa to 1.4 MPa, as reported by Refs. [37,45,49,55,68,73,75,80]. Information regarding the sensitivity, resolution of measurement amplitude, tolerated temperatures, humidity limits and number of usage cycles is scarce. Some authors only guarantee sensor stability for about 1000 usage cycles [45] or up to 100,000 cycles [37] for singular sensors placed in specific insole locations. In other cases, they guarantee stability for only five to 15 usage cycles with intense activity, such as the F-Scan insoles [31], sometimes combined in a hybrid model with other sensors [35,36,47,48].

Table 3

Average values (rounded to the unit) of plantar pressure measured in different studies with diabetic and non-diabetic (healthy) participants. Abbreviations: MH 1 - first metatarsal head, MH 2/3 - second/third metatarsal heads, MH 4/5 - fourth/fifth metatarsal heads, ML - midfoot lateral.

Author, year	Target Sample	Used device	Average plantar pressure values (kPa)					
			Hallux 1	MH 2/3	MH 4/5	ML	Heel	
Amemyia et al., 2016 [46]	3 non-diabetics	Plantar system with triaxial pressure sensors (system developed by the author)	–	172	319	158	–	–
Ledoux et al., 2013 [127]	596 diabetics with: ulceration potential & with ulcer	F-Scan [31]	200 &	242 &	308 &	177 &	141 &	266 &
Lung et al., 2016 [94]	8 non-diabetics & 19 diabetics	F-Scan [31]	172 297 &	383 320 &	362 400 &	220 – &	267 – &	241 280 &
Martinez et al., 2008 [85]	45 non-diabetics	BioFoot [163]	489 178	510 359	390 585	– 159	– –	280 –
Ostadabbas et al., 2012 [44]	11 non-diabetics	Insole with FSR sensors (system developed by the author)	124	95	114	68	–	185
Pataky et al., 2005 [60]	15 non-diabetics & 15 diabetics (right foot)	Insole with FSR sensors (system developed by the author)	101 & 205	160 & 137	221 & 205	97 & 160	– & –	321 & 187
Pataky et al., 2005 [60]	15 non-diabetics & 15 diabetics (left foot)	Insole with FSR sensors (system developed by the author)	104 & 165	146 & 140	220 & 179	91 & 174	– & –	298 & 184
Reints et al., 2017 [136]	30 non-diabetics	Pedar insole [32]	139	98	108	91	25	130

3.5. What results do these technologies offer?

When a patient uses a certain device, either on their own initiative or on the advice of the attending physician, the goal is to objectively measure the plantar pressures involved between the foot and the shoe used. Disparities in plantar pressure values are found in the literature, which are intrinsically linked to factors such as the type of footwear used (model, material, lacing method), the chosen measurement system, the method of device insertion and accommodation within the footwear and the characteristic anatomy of each patient [44,84–87]. Table 3 demonstrates the average plantar pressure measurements obtained in studies conducted with diabetic and non-diabetic (healthy) volunteer participants.

Each patient has a pressure threshold, above which they may be at risk. With the help of these measurement technologies, it is possible to determine the generally advised maximum thresholds over time. According to sources [2,88,89], reducing plantar pressure to values below 200 kPa may be crucial for favorable ulcer treatment and prevention of ulcer recurrence. A reduction $\geq 30\%$ in peak pressure during walking (compared to current therapeutic footwear for patients with diabetes) is advised to ensure relief of plantar pressure at high pressure sites [2,88,89]. Thus, evaluating plantar pressure values below 200 kPa ($200 \text{ kPa} \cong 2 \text{ kgf. cm}^{-2}$) with a validated and properly calibrated system with a measurement sensor with an active area of 2 cm^2 is recommended [2].

These systems are widely used in sports and clinical settings to assess human gait and foot-related disorders. Analyzing plantar high pressures can provide important insights into various clinically relevant parameters, including plantar pressure at discrete points, whole foot average pressure, critical peak pressures, center of pressure, displacement and velocity metrics, balance and human gait [30]. The results obtained are fundamental not only for detecting gait and foot-related abnormalities but also for monitoring various pathologies, such as the risk of ulceration from loss of sensation in the feet resulting from diabetic neuropathy [22,25,30].

Following the utilization of these measurement technologies to assess plantar pressures and their clinical implications, it becomes essential to visually examine the distribution of average plantar pressure data among different patient groups and device types. Figs. 4 and 5 present detailed representations of the average plantar pressure measurements, derived directly from the data presented in Table 3. These data were extracted from studies conducted by respective authors without additional processing, only a classification by groups was made and the sample size of each study was considered for subsequent statistical analysis. Fig. 4A shows the distribution of average plantar pressures between the non-diabetic and diabetic population through measurements with all devices. The data represented in Fig. 4B are between groups of author-devices and market-devices with measurements from the entire participant population. Fig. 5A shows the distribution of average plantar pressures for the non-diabetic population, and in Fig. 5B for the diabetic population, both through measurements with author-devices and those available on the market. These graphical depictions serve as important tools for further analysis and interpretation of the obtained data, clarifying possible disparities and trends in plantar pressure distribution across various conditions and measurement modalities. Additionally, Table 4 presents the results of the Mann-Whitney test for comparing plantar pressures between non-diabetic and diabetic patient groups, as well as between market-devices and author-devices based on plantar pressure measurement locations. Some variables are not reported due to missing data, as not all authors measure pressures with sensors in the same positions. A significance level (α) of 0.01 was applied and results with a P value < 0.01 indicate a statistically significant difference between the comparison groups.

4. Discussion

The aim of this systematic review was to identify devices for measuring plantar pressure exclusively inserted, or able to be inserted and removed, within footwear suitable for patients with diabetic foot. Of the devices identified and available on the market, instrumented insoles for insertion into footwear are dominant. The same is true for new technologies under development, with insoles being the most widely studied and used concept.

Most of the devices have the advantage of enabling wireless data communication and possibility of pairing with a smartphone via an app. They make it possible to acquire values in real time while the user is performing his normal movements. It also gives the user the possibility to view some instant results of interest and receive alerts in case of plantar high pressure [37,39,73,74,90,91]. On the

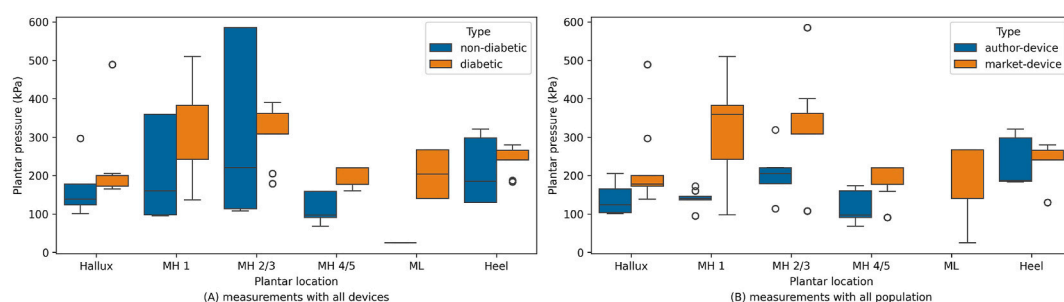


Fig. 4. Distribution of average plantar pressures between the non-diabetic and diabetic population through measurements with all devices (A) and between the group of author and market available devices with measurements from all participants (B). The studies do not present sufficient data for ML plantar location to compare author-devices vs. market-devices. Abbreviations: MH 1 - first metatarsal head, MH 2/3 - second/third metatarsal heads, MH 4/5 - fourth/fifth metatarsal heads, ML - midfoot lateral.

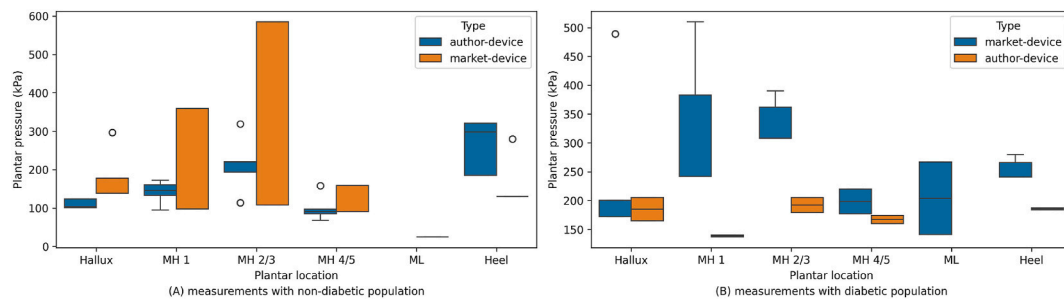


Fig. 5. Distribution of average plantar pressures of the non-diabetic population (A) and the diabetic population (B) both through measurements with author devices and those available on the market. The studies do not present sufficient data for ML plantar location to compare author-devices vs. market-devices. Abbreviations: MH 1 - first metatarsal head, MH 2/3 - second/third metatarsal heads, MH 4/5 - fourth/fifth metatarsal heads, ML - midfoot lateral.

Table 4

Results of the Mann-Whitney test ($\alpha = 0.01$) for comparison of plantar pressures between non-diabetic and diabetic patient groups, as well as between market-devices and author-devices. Abbreviations: MH 1 - first metatarsal head, MH 2/3 - second/third metatarsal heads, MH 4/5 - fourth/fifth metatarsal heads, ML - midfoot lateral, NA - not applicable values due to lack of data to compare. Only underlined *P* values do not represent statistically significant differences in plantar pressures between groups.

Mann-Whitney test	<i>P</i> value					
	Hallux	MH 1	MH 2/3	MH 4/5	ML	Heel
non-diabetic vs. diabetic (all devices)	<0.0001	<0.0001	0.0081	<0.0001	<0.0001	<u>0.5504</u>
market-device vs. author-device (all population)	<0.0001	<0.0001	<0.0001	<0.0001	NA	<u>0.0457</u>
market-device vs. author-device (non-diabetic population)	<0.0001	<0.0001	0.0082	<0.0001	NA	<0.0001
market-device vs. author-device (diabetic population)	<u>0.8679</u>	<0.0001	<0.0001	<0.0001	NA	<0.0001

other hand, a disadvantage common to almost all devices are that their control unit and data storage is usually fixed on the leg or waist of the user, which can become a nuisance and even induce small changes in human gait [43,46,54,56,80]. Recent developments are exploring new approaches to fully integrate the control unit into the sole of the shoe, aiming to provide a more natural user experience [37].

Two factors to consider, given that this equipment is intended for daily use rather than solely in a clinical environment, are battery autonomy and the number of allowed usage cycles to ensure data quality. Some systems [31,32] claim to have features for high-performance activities, such as sports or more dynamic human gait, however, in the case of commercial F-Scan insoles, their durability does not go beyond 15 uses [31]. As such, in other systems, the durability of the sensors should also be considered, because due to the flexion of the shoe during walking and the friction of the foot itself, they will be subject to a high wear [79].

Another additional factor to consider is the insertion of any plantar pressure measuring system inside the shoe. The available space of the shoe must be balanced with the space taken up by the device [79]. As referred to by the international guidelines [2] on the assessment of the diabetic foot and recommendations on the appropriate footwear to be worn, consideration must be given to the internal structure of the footwear or any foreign body that may add relief. Due to the patient losing protective skin sensitivity and pain sensation being compromised [2], anybody that adds relief inside the shoe can lead to trauma, thus becoming a problem in these cases [79]. For this reason, sensors incorporated within the insole itself or under the insole are the most effective solution [37]. The insertion of the equipment inside the shoe must not increase the risk of injury, and the presence of the device must be as unobtrusive as possible to avoid inducing forced changes in human gait [92,111,112,114,116,117,129–131,134,137,138,142,148,149].

The most established technologies for integrating these systems, which have been used for years, are resistive sensors. For their simplicity and knowledge of their behavior, these sensors are commonly selected for instrumented removable insole solutions or systems integrated into the shoe [42,44,53–60]. Other technologies such as fiber optic sensors, used in more recent approaches, are beginning to show some results, but still have some difficulties in sensor calibration and characterization. The control unit, which needs a light emission source, is also still a constraint because of its dimensions [50]. New inductive sensors in plantar systems are being developed, and besides measuring plantar pressure, they also measure the shear forces inherent to the friction between the foot and the inside of the shoe. This concern in evaluating the shear forces is pertinent because through friction there is an increase in the temperature of the cutaneous region and it may trigger an ulcer [49,51].

The approach with discrete sensors is the simplest, even from the point of view of control electronics. The configuration with eight sensors located in the hallux, metatarsal heads, midfoot and heel proves to be the most pragmatic decision because it covers the crucial points where high pressures occur [37,40,41,53,74]. The advantage of this type of configuration over a sensor array with higher spatial resolution is the high sampling frequency in signal acquisition (typically 100–200 Hz or higher) since the number of sensors used is smaller and makes possible a faster reading of the entire measurement system [35,41,44,46,47,55,70,81,82].

Although several studies fail to adequately communicate the characteristics of the product and it is not possible to effectively

compare their capabilities, the results obtained using these technologies still show that it is possible to measure and evaluate plantar pressures. However, average values of plantar pressure, like those presented in Table 3, may depend on the anatomical characteristics of the foot of each patient, the type of footwear and other conditions. Nevertheless, the plantar pressure peaks may occur in a wider range of values. For example, some authors [44,85–87] recorded values from 100 kPa up to 500 kPa for the hallux region, up to approximately 700 kPa for the first metatarsal head and values exceeding 950 kPa for the second metatarsal head [44,85–87]. There seems to be a slight tendency for the group of people with diabetes with greater susceptibility to ulceration in a certain plantar region to be those who have higher pressure values compared to healthy people. Even so, there are healthy people with high pressure values, for example, in the heel [94]. This reveals the characteristics of human gait that vary from person to person, which requires adapting a certain pressure threshold case-by-case basis as a strategy to avoid ulcerations [95].

After analyzing Table 4, which presents the results of the Mann-Whitney test comparing plantar pressures between groups of people with diabetes and non-diabetic, as well as between market-devices and author-devices based on the locations of plantar pressure measurements, it is observed that there are statistically significant differences in practically all locations, except for two locations in three different comparison tests. Specifically for the heel, in comparisons between non-diabetic patients and diabetics with all devices, and when comparing market-devices vs. author-devices across the entire population, *P* values of 0.5504 and 0.0457 were obtained, respectively. These suggest the absence of a statistically significant difference between these groups at this location. Similarly, when comparing market-devices vs. author-devices for the diabetic population, no statistically significant difference was found for the hallux, with a *P* value of 0.8679. However, the most *P* values (<0.0001) suggest a significant difference in certain measurement locations between the groups evaluated. It is important to highlight that some variables do not present values due to lack of data, as not all authors measure pressures with sensors in the same positions.

Although we made efforts to produce a rigorous systematic review, it is important to recognize some limitations that may have impacted our analysis. The diversity of studies included in the review may have influenced the consistency of our approach and the interpretation of results, due to variations in the methodology each used, target sample and classification of studies. This diversity also made it impossible to assess the quality of studies, including carrying out a meta-analysis, due to the lack of a universal methodology with specific guidelines for this type of studies. Although with a smaller impact, it is important to mention some aspects that can be considered as limitations during the research and article selection process. Screening restricted to English only, document and source type may have resulted in the loss of some relevant studies. Although we explored four databases (some multidisciplinary) recognized by the scientific community, it is possible that other sources of literature were not considered. These considerations highlight the necessary prudence in interpreting results and suggest that, particularly for studies using plantar pressure measurement technologies, a universal methodology with its own guidelines is necessary.

5. Conclusion

This systematic review highlighted the abundance of equipment available on the market and the ongoing trend of new developments. It has also revealed insufficient technical data, making it difficult to make a comprehensive comparison of device and sensor characteristics, particularly regarding operating conditions, sensitivity, resolution, temperature and humidity tolerance and the number of admissible usage cycles.

Tactically placed sensors at points associated with high-risk areas of peak plantar pressure are widely used, enabling the calculation of peak or average plantar pressures in these regions. The frequent use of plantar pressure analysis to customize insoles and footwear tailored to individual patient needs may effectively relieve plantar pressure in patients with diabetic foot. Resistive sensor technology emerges as the most practical choice for integration into devices due to its widespread use and ease of implementation. The use of these technologies with the different techniques is recommended to try to assess and predict risk situations.

The analysis of average plantar pressure values, comparing patients with diabetes and potential complications with healthy individuals, suggests a trend in which it is possible to differentiate the two groups by plantar pressure level in some areas of the foot. This statement may be partially supported due to the significant differences obtained in the comparison tests. Recognizing the limitations of the studies' data sample, it is important to highlight that statistically significant differences between different types of devices are also suggested. This can be a critical factor and highlights the importance of individualized patient assessment using consistent measuring devices. By evaluating each patient with the same type of device, clinicians may be able to minimize measurement error and obtain more objective data to characterize plantar pressure patterns and assess the progression of injury risk over time.

Although it was not the focus of this review, the synthesis of the information collected allows considering that the approaches used to assess the shear forces are relevant [49,51], since the friction of the foot inside the shoe during gait is extremely important due to the overheating of the skin and the imminent risk of injury [133]. Another aspect excluded from the focus of this review, but currently with increasing importance, refers to the patient's adherence to these technologies for daily use when prescribed by your attending physician. Poor adherence appears to be common in offloading strategies for a variety of reasons.

Protocol and registration

The protocol of this systematic review was not registered.

Ethics approval

Not applicable within the scope of this systematic review.

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Data availability statement

This work is a systematic literature review based on searches in the previously mentioned electronic databases, therefore, the data supporting this study were not stored in any other repository. All additional data and information are available upon request from the corresponding author.

CRediT authorship contribution statement

Pedro Castro-Martins: Writing – review & editing, Writing – original draft, Visualization, Validation, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Arcelina Marques:** Writing – review & editing, Writing – original draft, Validation, Supervision, Methodology, Data curation, Conceptualization, Funding acquisition. **Luís Coelho:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Mário Vaz:** Writing – original draft, Validation, Supervision, Funding acquisition, Conceptualization. **João Santos Baptista:** Writing – original draft, Visualization, Validation, Supervision, Project administration, Conceptualization.

Declaration of competing interest

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

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2.4 - Active Plantar Pressure Redistribution Systems in Footwear

Plantar pressure redistribution has traditionally been addressed through passive solutions such as custom orthotics, insoles, and therapeutic footwear. Although these interventions have shown some efficacy in reducing pressure peaks in individuals with diabetic foot (Bus, Zwaferink, et al., 2020; Lazzarini et al., 2020), its action remains static and limited by the absence of dynamic adaptation to the biomechanical variations that occur during walking or other prolonged activities. In this context, active plantar pressure redistribution systems are beginning to be considered and emerging as an innovative approach, initially based on the development and integration of sensors, actuators, and control algorithms to record human gait patterns (Castro-Martins et al., 2023; Hayakawa et al., 2020; Low et al., 2015). Although these approaches are still very incipient and are still in the research plan, the experiments that are under development are basically distinguished into: (i) solutions based on intelligent materials, such as magnetorheological fluids, which alter rheological properties under the action of a given magnetic field (Grivon et al., 2015, 2016; Hemler et al., 2023; Ntella et al., 2020, 2022); and (ii) pneumatic solutions, which use controllable air cells to modulate local pressure (Baousi et al., 2017; Castro-Martins et al., 2023; Erel et al., 2024; Gabrecht et al., 2023; Hayakawa et al., 2020; Low et al., 2015).

2.4.1 - Magnetorheological Systems

Magnetorheological fluids have ferromagnetic particles suspended on a liquid substrate, whose viscosity can be changed almost immediately by the application of an external magnetic field (Osial et al., 2023). When applied to orthopedic devices, especially in prototypes of shoes for adaptive cushioning, they allow modulating the stiffness and mechanical response of the insole, adapting to the needs of redistribution in different phases of gait (Grivon et al., 2015). Important advantages of this approach include the high response speed and the ability to fine-tune the resistance. However, there are still highly relevant limitations that increase the complexity of the design, such as the difficulty of creating a portable device due to the need for a power source with a large capacity to generate powerful magnetic fields, energy consumption, and weight, which culminates in the difficulty of integration into everyday footwear (Grivon et al., 2015; Hemler et al., 2023; Ntella et al., 2020, 2022). To date, experimental evidence applied to diabetic foot is still limited, with most work limited to laboratory prototypes and computer simulations (Hemler et al., 2023; Tiwari et al., 2024).

2.4.2 - Pneumatic Systems

Pneumatic systems consist of insoles with interconnected air chambers, where the internal pressure can be dynamically controlled. This technology enables the redistribution of plantar pressures by selectively filling and emptying chambers, thereby adjusting to the specific

conditions of each user. Therefore, pneumatic systems emerge as a promising alternative due to their potential for scalability, potentially lower cost, and ease of modularity, when compared to approaches that integrate magnetorheological fluids (Castro-Martins et al., 2023; Erel et al., 2024; Grivon et al., 2016; Haris et al., 2023). The main advantages of these systems include design flexibility, customizability, and relative simplicity of manufacture compared to magnetorheological systems. However, these devices also face technical challenges, such as miniaturizing pneumatic control components, achieving energy autonomy (particularly in portable systems), and resisting mechanical wear. Although scarce, recent preliminary studies have shown that cyclical variations of internal pressure in insoles with interconnected air chambers can reduce peaks and modify pressure patterns during different phases of human gait (Erel et al., 2024; Haris et al., 2023, 2024).

2.5 - Literature Gaps and Research Challenges

The state-of-the-art analysis reveals significant advances in understanding the biomechanics of diabetic foot and the development of technologies for monitoring and redistributing plantar pressure. However, several critical gaps persist, particularly regarding active systems, which limit the practical application of these advances in the clinical setting. These gaps can be grouped into two main levels: technological and clinical.

Despite recent progress, active systems for monitoring and redistributing plantar pressure still face some technical obstacles on the technological front. Miniaturization and integration of sensors and actuators without compromising user comfort remain significant challenges, while limited energy autonomy compromises application in portable devices. Added to this is the scarcity of cross-validation studies that allow comparing different measurement systems and protocols (especially in the field of pressure monitoring), including comparative validations with gold-standard systems such as the Pedar® measuring insole (Amaro et al., 2025; Putti et al., 2007). Another critical point is that many current active pressure redistribution solutions do not perform monitoring based on specific plantar pressure thresholds, limiting their adaptive response capacity to the user's real needs at a given time. For example, pneumatic systems proposed so far operate with a timed cyclic transition of air between several pressure cells (a behavior like an anti-bedsore mattress) in an insole inserted in a sandal, without the ability to react dynamically to pressure thresholds defined for the diabetic foot (Erel et al., 2024).

In the clinical context, it is observed that most studies with active devices for managing plantar pressure focus on small and heterogeneous samples, often restricted to experimental contexts, which compromises the generalization of the results. In addition, the lack of clinical trials evaluating the long-term efficacy of interventions represents a relevant limitation for substantiating recommendations based on solid evidence. The insufficiency of direct comparisons between passive and active interventions is also noteworthy, making it

challenging to establish standardized clinical guidelines incorporating active redistribution technologies. Thus, even with the promising technologies being developed, translation to clinical practice still has a way to go. On the other hand, there are still difficulties related to patient adherence, which include aspects such as comfort and aesthetic standards, once associated with passive devices, such as shoes and orthoses (Bus et al., 2012; Bus, Zwaferink, et al., 2020; Park et al., 2023; Van Netten et al., 2016; van Netten et al., 2019; Waaijman et al., 2013).

Given these gaps, priority research challenges emerge that should guide future studies. Multicenter clinical trials with representative samples are crucial for validating the effectiveness of technologies. However, at an early stage, it is still necessary to expand the development of hybrid systems, which combine continuous monitoring with active and adaptive response based on real-time pressure thresholds to overcome current limitations. Assessing the economic impact and cost-effectiveness of technological solutions is also crucial for enabling their integration into healthcare systems. Additionally, it is essential to investigate further factors related to usability and patient adherence, both of which are equally crucial for clinical success. Finally, the creation of standardized validation protocols will allow direct comparisons between different technologies, facilitating progress in this area (Lockhart et al., 2024; Ng et al., 2024; Ramadhan et al., 2025; Tiwari et al., 2024).

2.6 - Summary of Chapter 2

In this chapter, a critical review of the literature on the clinical and biomechanical assessment of diabetic foot, plantar pressure monitoring, and redistribution strategies was presented, with emphasis on pressure thresholds and emerging technologies. Systematic review articles already published were also integrated, making significant contributions to the state of the art in plantar monitoring, in-shoe pressure thresholds, and their use as a preventive strategy.

The detailed analysis of active plantar pressure redistribution systems highlighted the potential of magnetorheological and pneumatic approaches, while also identifying technological limitations and a lack of robust clinical evidence. Research gaps and challenges were identified, highlighting the need to develop autonomous and efficient technologies that are validated using standard measurement systems. This necessitates the subsequent realization of longitudinal studies and multicenter validations to integrate these technologies into clinical practice and the field of occupational safety and health.

This chapter thus provides the conceptual and critical basis that supports the research developed in the following chapters, particularly regarding the development and validation of a portable pneumatic active system for monitoring and redistributing plantar pressure.

Chapter 3

Methods, Results, and Discussion

This chapter presents the methods, results, and discussion regarding the development and validation of an active pneumatic system for monitoring and redistributing plantar pressure. Before proceeding to the details of the proposed system's development, the limitations of SWM, a widely used instrument for assessing loss of skin sensitivity in the foot in people with diabetes, are explored. Given that pain insensitivity is a determining factor in injury risk, characterizing SWM behavior during the patient assessment procedure is particularly important to highlight the method's weaknesses and reinforce the need for additional and complementary strategies, such as monitoring plantar pressure within certain thresholds, which serves as an early warning mechanism for potentially in-shoe harmful events. Later, this chapter details the conceptual and technical fundamentals of the active in-shoe pneumatic system, culminating in the implementation of a functional prototype. The parameters used to assess plantar pressure, as well as the preliminary results of an exploratory usability study, are also presented. This study gathers both quantitative and qualitative evidence regarding the device's performance and user acceptance, with a focus on occupational safety and health. Finally, the overall discussion frames the results obtained, considering the literature, and highlights their contributions, limitations, and practical implications.

This chapter includes two scientific articles previously published within the scope of this research. Sections 3.1 and 3.3 correspond to articles that present results obtained in the evaluation of SWM and in the implementation and validation of the developed prototype, respectively. During the evolution of the prototype creation, it became possible to register

two trademarks (MoonWalking® and MoonWalking® - Pneumatic Insole System); therefore, in Section 3.5, the developed system is referred to as MoonWalking.

3.1 - Calibration and Modeling of the Semmes-Weinstein Monofilament for Diabetic Foot Management

This section is based on an open-access article published by the author under the terms and conditions of the Creative Commons Attribution (CC BY) license. This scientific article highlights the significance of accurate calibration of the SWM, which is used to assess loss of sensitivity in the feet of patients with diabetes, and proposes a new device for automating the metrological evaluation of this instrument. The results highlight the significant errors in a set of monofilaments tested relative to the nominal value of 10 gf, underscoring the need for frequent calibration to enhance diagnostic accuracy and reliability. The study aims to raise awareness of the impact of inadequate instrument calibration on clinical decisions and improve diabetic foot management, thereby reinforcing the need for complementary alternatives to prevent diabetic foot injuries.

Pedro Castro-Martins, Luís Pinto-Coelho, & Raul D. S. G. Campilho (2024). Calibration and Modeling of the Semmes-Weinstein Monofilament for Diabetic Foot Management. *Bioengineering*, 11(9), 886. <https://doi.org/10.3390/bioengineering11090886>
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Article

Calibration and Modeling of the Semmes–Weinstein Monofilament for Diabetic Foot Management

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Abstract: Diabetic foot is a serious complication that poses significant risks for diabetic patients. The resulting reduction in protective sensitivity in the plantar region requires early detection to prevent ulceration and ultimately amputation. The primary method employed for evaluating this sensitivity loss is the 10 gf Semmes–Weinstein monofilament test, commonly used as a first-line procedure. However, the lack of calibration in existing devices often introduces decision errors due to unreliable feedback. In this article, the mechanical behavior of a monofilament was analytically modeled, seeking to promote awareness of the impact of different factors on clinical decisions. Furthermore, a new device for the automation of the metrological evaluation of the monofilament is described. Specific testing methodologies, used for the proposed equipment, are also described, creating a solid base for the establishment of future calibration guidelines. The obtained results showed that the tested monofilaments had a very high error compared to the 10 gf declared by the manufacturers. To improve the precision and reliability of assessing the sensitivity loss, the frequent metrological calibration of the monofilament is crucial. The integration of automated verification, simulation capabilities, and precise measurements shows great promise for diabetic patients, reducing the likelihood of adverse outcomes.

Keywords: diabetic foot; monofilament; metrological verification; buckling force



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1. Introduction

Diabetes, a chronic disease, is witnessing a great surge in global incidence, particularly in most developed countries. Every year, around 1.5 million deaths worldwide are directly attributed to diabetes [1]. Middle East and North Africa areas are particularly affected, as can be observed in Figure 1 [2]. The disease can present several complications, and when coexisting with other comorbidities, serious problems arise for the patient, as is the case of the diabetic foot. This condition manifests as lower limb complications, predominantly in the plantar region, whose evolution can have devastating effects and with a high probability of compromising part of the affected limb [3]. Although it is possible to minimize the occurrence of ulcers by carefully monitoring the feet and using appropriate footwear [4,5], as a preventive measure, clinical tests must be periodically conducted to assess the loss of skin sensitivity to pressure on the foot, aiming to preclude imminent injuries. The 10 gf Semmes–Weinstein monofilament (SWM) test is the most used first-line instrument in the assessment of the loss of protective sensitivity in the diabetic foot, with well-established international recommendations for its widespread use [3,6].

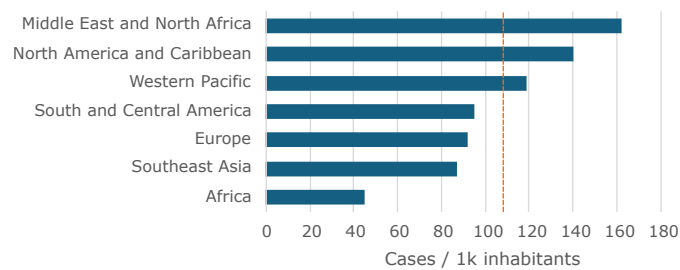


Figure 1. Worldwide prevalence of diabetes per region. Average is represented by the vertical dashed line.

The SWM is a widely used diagnostic tool designed to assess and quantify sensory loss, particularly in individuals with conditions such as diabetes, peripheral neuropathy, or Hansen’s disease (leprosy). The tool consists of a set of monofilaments of varying thicknesses, made of nylon (or analogous flexible plastic material, sometimes unspecified), each estimated to bend when a specific amount of force is applied. During a sensory test, a clinician applies the monofilament perpendicular to the skin until it bends, holding it in place for about one to two seconds. This procedure is repeated at several locations, on the foot or other relevant areas of the body, to assess sensory perception. This design allows healthcare providers to evaluate a patient’s ability to perceive light touch at different thresholds, which is crucial in detecting and monitoring sensory deficits. The test helps to determine the smallest force a patient can feel, which in turn classifies the degree of sensory loss. For example, a person who can only perceive thicker filaments, which require more force to bend, has greater sensory impairment than someone who can detect thinner filaments [7]. In the particular case of the diabetic foot, a single 10 gf monofilament is used, and the test locations are on the plantar area, as depicted in Figure 2 (though some additional locations on the foot dorsum can be covered as part of the screening process).

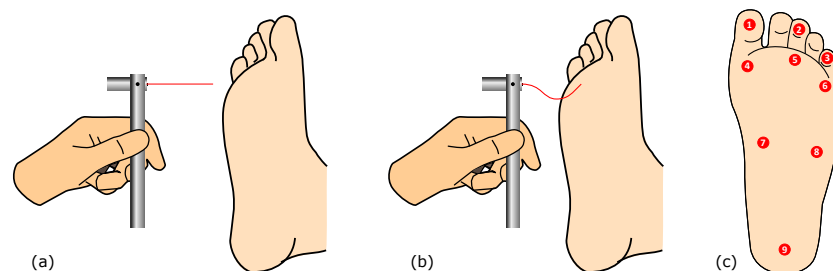


Figure 2. Plantar sensitivity assessment using the monofilament, showing (a) the approaching stage; (b) the contact stage, with visible buckling; and (c) the related evaluation points, for the left foot.

Traditionally, this assessment is conducted manually by experienced healthcare professionals, although automation through collaborative robotic systems is also emerging as a viable alternative [8,9]. Despite the wide usage of this test, its qualitative nature lacks the capability to provide numerical data, posing a challenge for objective comparison among screening tests. Additionally, given the lack of accuracy of these devices, considering the same patient, it may be possible to obtain different plantar sensitivity responses when using two different monofilaments [10].

Moreover, the inherent limitations of the SWM test extend to its uncertainty concerning measurement errors, hindering its utility as a decision-making support tool. Despite the literature advocating for quantitative assessments of sensory loss severity in diabetic foot cases, the SWM test fails to provide definitive insights. Consequently, some scholars express reservations regarding the reliability of the force applied by the SWM on the patient’s skin during sensitivity screening tests [11–14]. In fact, in a systematic review

with meta-analysis [10], it is reported that monofilament tests have limited sensitivity for screening diabetic peripheral neuropathy and that their clinical use in the evaluation of diabetic peripheral neuropathy could not be encouraged. This reinforces the present study indicating the use of the monofilament can be encouraged as long as the operation characteristics of the monofilament are known and monitored, as is the case with other medical devices.

Concerning the monofilament operating principle, one issue to consider is that the compressive force decreases with the number of successive uses, resulting in a significant change in its initial elastic characteristics. This phenomenon introduces potential inaccuracies in subsequent assessments, which is critically reinforced by the uncertainty surrounding the threshold at which such errors become significant [12]. Furthermore, environmental factors such as temperature and relative humidity can exert considerable influence on the compression force, dimensions, and the subsequent deformation of the SWM. Laboratory tests conducted under varying environmental conditions, including controlled temperature and humidity levels of up to 37 °C and 80%, demonstrated a progressive decrease in the force exerted by the monofilament by approximately 40% [15]. If a nylon product absorbs moisture, dimensional changes will occur with increasing moisture content [16]. This effect is directly proportional to the exposed surface area, as occurs in monofilaments. However, moisture-related variations are small in controlled environments such as most healthcare facilities, making this a negligible effect for the current study.

The evaluation of the SWM performance, as a clinical tool, is still rather unexplored, despite its impact on medical decisions. Nevertheless, this technique is widely used due to its simplicity, practicality, and low cost. As a routine screening device, it is used to select diabetics who still have protective sensitivity from those who do not [3,7,17], guiding the definition of the follow-up processes. However, there are guidelines that warn healthcare professionals about the possible loss of flexion strength of the monofilament over time and that this deterioration can result in inconsistent force application, deviating from the manufacturer's specified standards [17]. Consequently, healthcare providers are urged to have access to equipment that enables them to monitor whether a given monofilament maintains the required force levels for diabetic foot screening (and also for other clinical applications where this instrument is used).

The main contributions of this article are highlighted in the following points:

- An analytical model for the mechanical behavior of the SWM is presented. This helps to understand the individual impact of each variable on the behavior of the monofilament during its use. On the other hand, it allows for establishing operational ranges for the parameters of the usage environment in order to maintain the measurement characteristics.
- A new metrological testing device is described, expanding a previous version [18], which aims to evaluate the behavior of a given monofilament. This equipment's main functionalities are quantifying the deviation of an SWM in relation to the 10 gf standard, and carrying out fatigue tests. There is also the possibility of carrying out other types of studies.
- A testing methodology for monofilaments is also presented, establishing a possible reference procedure for the creation of international guidelines regarding their metrological behavior.

The rest of this paper is organized as follows: The modeling of the monofilament behavior under plantar sensitivity test conditions is first presented. This helps to understand the critical parameters to observe during usage and during the devices' calibration. Then, a new device is thoroughly described, designed to evaluate the SWM in terms of its real compression force and, with this, to provide information to healthcare professionals about the force range for a monofilament. Several tests are then performed with a sample group of monofilaments. The obtained results are presented and widely discussed. Finally, the main aspects of the study are highlighted as well as some prospects for future work.

2. An Analytical Model of the Semmes–Weinstein Monofilament

When performing the diabetic foot plantar sensitivity test using a monofilament, it is recommended to use monofilaments with specific characteristics to ensure consistent and standardized results. The SWM test is commonly used for this purpose, and it is commercially available in a set of distinct target force values with specific characteristics. These devices consist of nylon filaments that can have different diameters and lengths to apply a specific force to the skin when they are pressed and buckling. Usually referred to in grams by the medical community, the most commonly used target levels in the SWM test include 0.07 g, 0.16 g, 0.4 g, 0.6 g, 1 g, 2 g, 4 g, 10 g, and 300 g [19,20]. These target levels allow for the evaluation of different levels of tactile sensitivity, with a 10 g monofilament being recommended for the evaluation of the diabetic foot [21].

Each monofilament is usually labeled with a number (during manufacturing) representing the force required for buckling to occur. These numbers range from 1.65 to 6.65 (evaluator size, a dimensionless scale) and indicate different standardized pressure values to be applied; the higher the number, the greater the force required for the buckling of the monofilament and therefore the greater the pressure exerted on the skin. For example, the evaluator size of 5.07 concerns a 10 g monofilament and, as such, the manufacturer states that a force of 10 gf is required for its buckling [19]. If this monofilament is applied to a specific point on the foot, and the patient cannot feel the pressure, this may indicate a loss of sensitivity in that region [21].

2.1. Materials

The monofilament is generally made of nylon, which is a generic designation for a family of synthetic polymers composed of polyamides. To specifically understand how the material behaves mechanically during operation and use, it is necessary to have particular knowledge about it.

Concerning the material's properties, the most relevant to consider is Young's Modulus. This property represents the stiffness of the nylon fiber, and it affects its resistance to buckling, with a higher Young's modulus indicating greater stiffness, hence resisting buckling. The Yield stress and Poisson's ratio can also be considered. These represent the ability to withstand deformation before experiencing permanent damage or failure and a measure of the material's lateral contraction when subjected to axial loading, respectively.

Extruded Nylon 6.6 (extruded polyamide 6.6) is the most common type, which is known for its high strength, stiffness, and excellent resistance to wear. However, it can be affected by moisture absorption, causing slight changes in its mechanical properties, including Young's modulus. Nylon 6, an alternative also widely used, has good mechanical strength, toughness, and abrasion resistance, being generally less affected by humidity compared to other types of nylon. Humidity absorption by nylon fibers can cause changes in the material's ability to resist compression or deflection. The relationship between humidity and Young's modulus can be described using the following empirical equation [22]:

$$E(H) = E_0 \cdot (1 - \beta \cdot (H - H_0)) \quad (1)$$

where $E(H)$ is Young's modulus at humidity H , E_0 is the reference Young's modulus at a reference humidity H_0 , and β is the humidity coefficient. The humidity coefficient (β) represents the rate at which Young's modulus changes with humidity and is typically provided by the material manufacturer, varying for different types of nylon. Humidity acts as a plasticizer in nylon and therefore reduces strength and stiffness properties but increases elongation and toughness. In general, as humidity content rises, significant increases occur in impact strength and other energy-absorbing characteristics of the material.

The Young's modulus of a material usually decreases as temperature increases. This inverse relationship can be modeled using the following equation:

$$E(T) = E_0 \cdot (1 - \alpha \cdot (T - T_0)) \quad (2)$$

where $E(T)$ is Young's modulus at temperature T , E_0 is the reference Young's modulus at a reference temperature T_0 , and α is the temperature coefficient of the material. The temperature coefficient (α) represents the rate at which Young's modulus changes with temperature. Like humidity, it can vary for different types of nylon and is typically provided by the material manufacturer.

Besides material factors, geometry also plays a role. Length and diameter, or more specifically the length-to-diameter ratio of the fiber, is a critical geometric factor affecting buckling behavior. Longer fibers or fibers with smaller diameters are more prone to buckling. In addition, imperfections such as bends, eccentricities, or deviations from a perfect straight form, can amplify the tendency for buckling. Imperfections act as localized stress concentrations and can initiate buckling at lower loads. Imperfections can be a result of the manufacturing process but also a consequence of monofilament misuse (for example, when objects inadvertently cause permanent plastic deformations due to placing the monofilament device in a clothing pocket exposed to keys, a pen, or others). The boundary conditions imposed on the fiber ends can also significantly influence buckling [23]. In most cases, a fixed at one edge and pinned at the other (fixed–pinned) coupling is considered, but different skin stiffness can alter this behavior, leading to variations in buckling modes and critical buckling loads.

Finally, loading conditions must also be taken into account. The magnitude and direction of the applied compressive load directly influence the buckling behavior, with higher compressive loads increasing the risk of buckling. The rate at which the load is applied can also affect buckling behavior. Rapid loading or dynamic loading conditions may lead to different buckling responses compared to static loading [24].

It is important to note that the abovementioned variables are interconnected, and their combined effects need to be considered in evaluating column buckling in a nylon fiber. Analytical methods, such as Euler's buckling theory or finite element analysis, can be employed to assess the influence of these variables and predict both the critical buckling load and mode of failure for a specific nylon fiber column. Experimental testing can also provide valuable insights into the buckling behavior by considering these variables in a real-world scenario. In Table 1 a summary of which material characteristics can affect the monofilament measurement performance is presented.

Table 1. Summary of factors that impact the operation characteristics of monofilament.

Material	Geometry	Loading Conditions	Environment
Young's Modulus	Length and diameter	Compressive load	Temperature
Yield stress	End conditions	Load distribution	Moisture
Poisson's ratio	Imperfections	Loading rate	

2.2. Buckling

In practice, it is observed that 10 gf monofilaments are commercially available with a wide range of diameters and small variations in length. Most of the time, no information is given about the material from which it is produced. These characteristics can strongly impact the behavior of the monofilament when in operation, as will be shown in the following sections of this study.

The buckling equation [25], also known as Euler's buckling equation, allows for the estimation of the force that leads to the initial buckling. It is given as follows:

$$F_c = \frac{\pi^2 \cdot E \cdot I}{L_e^2} \quad (3)$$

where F_c is the critical buckling force, E is the Young's modulus of the material, I is the 2nd moment of inertia of the cross-sectional area, and L_e is the effective length of the filament. The effective length is calculated as $L_e = k \cdot L$, where k is defined taking into account the boundary conditions, and L is the real length of the monofilament. The end near the handle

of the monofilament will always be clamped, while for the free end, two possibilities can be considered. The first case will correspond to the most common situation in which the point of contact with the skin has no slippage and which, due to the small diameter of the filament, can be considered a hinged–pinned connection. When the skin surface at the contact point does not guarantee sufficient friction (due to oil, dryness, sweat dirt, or other factors), then there will be a hinged connection with sliding. For the clamped–pinned case, a theoretical $k = 0.7$ was defined, and for the clamped–(pinned and sliding) case, $k = 2.0$ was the reference (clamped means rotation, and translation-fixed, pinned, and sliding means rotation and translation-free) [26].

To calculate the second moment of inertia (I) for a circular cross-sectional area, the following formula is used:

$$I = \frac{\pi \cdot d^4}{64} \quad (4)$$

where d is the diameter of the filament.

Hence, defining the monofilament material, length, and diameter allows us to estimate its critical buckling force. On the other hand, if the critical force is known, as well as the geometrical dimensions, then Young’s modulus for an unknown material can be estimated.

2.3. Deflection

During the evaluation of plantar sensitivity, the monofilament is positioned horizontally to move perpendicularly toward the patient’s foot. In this position, the nylon filament behaves like a cantilever beam subjected to distributed load, corresponding to its own weight, that will cause the deflection of the free extremity.

When a beam is not flexed or deflected, the applied load is mainly an axial load, meaning a force that acts along the longitudinal axis of the beam. The material of the beam is more efficient in supporting this type of load, as it is designed to resist compression and tension forces along its length. In this case, the load is transmitted directly to the supporting base, making the structure more stable and resistant.

On the other hand, when a beam is bent or flexed, it encounters extra forces known as bending moment and shear. This bending action causes the particles within the beam’s material to move relative to each other, creating internal stresses. These internal stresses, if excessive or repeated, have the potential to weaken the structure. The bending moment is a specific type of force during this bending process, which includes both a bending force (the force bending the beam) and torque (a twisting force). Over time, these combined forces from the bending moment can lead to deformation and, ultimately, material failure. In simpler terms, when a beam bends, it experiences forces that can strain its material and gradually compromise its strength and shape. Additionally, shear, which is a cutting force perpendicular to the axis of the beam, can also affect the load-carrying capacity of the structure.

In this context, let us estimate the deflexion of the monofilament due to its weight. Considering a linear elastic deformation and a small deflection ($<1/10$ of span), the displacement of the monofilament-free extremity can be calculated from the general elastic equation [26], which is as follows:

$$\frac{d^2y(x)}{dx^2} = \frac{M}{E \cdot I} \quad (5)$$

where the x axis is defined along the length L of the monofilament, M is the bending momentum, E is Young’s modulus, and I is the moment of inertia (Equation (4)). The monofilament weight is given as follows:

$$w = V \cdot \rho \cdot g \quad (6)$$

where V is the volume of the monofilament, ρ the material’s density, and g is the gravity. In the present case, the load is distributed along the monofilament, and it can be expressed

as $q = w/L$. In these conditions, the monofilament elastic deflection in the free extremity $y(L) = \delta$ can be written as follows:

$$\delta = \frac{w \cdot L^4}{8 \cdot E \cdot I} \quad (7)$$

3. Monofilament Calibration Equipment

Medical device calibration holds significant importance within the healthcare industry for several compelling reasons. Firstly, calibration ensures the provision of accurate and reliable measurements by medical devices. This precision is paramount for diagnosing medical conditions, determining suitable treatment options, and effectively monitoring patient health. By establishing consistency and accuracy in readings, calibration contributes to the overall quality of healthcare delivery. Secondly, the major concern of patient safety is intricately linked to medical device calibration. An incorrectly calibrated device can lead to erroneous readings, potentially resulting in misdiagnosis, inappropriate treatment, or patient harm. Regular calibration practices serve as a crucial mechanism to identify and rectify any deviations or inaccuracies, thus minimizing the risk of adverse events and fostering patient well-being [27]. Moreover, compliance with regulatory standards and guidelines is of utmost importance in the healthcare domain. Calibration is an indispensable component in meeting these requirements, as regulatory bodies, such as the Food and Drug Administration (FDA), often mandate regular calibration of medical devices to ensure both patient safety and device performance. Failure to comply with these regulations can result in severe consequences such as penalties, legal ramifications, and reputational damage for healthcare institutions [28].

Calibration serves as an integral part of quality control programs, ensuring that medical devices consistently adhere to established standards and specifications. By systematically calibrating devices at appropriate intervals, healthcare organizations can promptly identify and rectify any deviations or discrepancies in device performance. This proactive approach significantly contributes to maintaining the overall quality and reliability of diagnostic and therapeutic procedures, thereby fortifying the foundations of healthcare provision. In addition, calibration plays a pivotal role in preserving data integrity within healthcare settings. Numerous medical devices are seamlessly integrated with electronic health record (EHR) systems or employed for clinical research purposes. Calibration practices ensure the accuracy and reliability of the data generated by these devices, thereby bolstering the credibility of data analysis, research outcomes, and evidence-based decision-making within the medical community [29].

Another notable aspect lies in the extended lifespan and enhanced performance of medical devices due to regular calibration. By effectively detecting and rectifying any inaccuracies or signs of wear and tear, calibration mitigates the risk of premature device failures. Consequently, this practice reduces equipment downtime, minimizes repair costs, and optimizes operational efficiency within healthcare facilities, facilitating seamless healthcare delivery [29,30].

Lastly, calibration contributes to traceability and standardization within the healthcare sector. The process involves comparing measurements obtained from a medical device against a traceable reference standard, establishing a chain of traceability that ensures consistent measurements across different devices and locations. This standardization facilitates effective communication, collaboration, and data sharing among healthcare providers and institutions, promoting a cohesive healthcare ecosystem [30].

In conclusion, medical device calibration holds a pivotal position in healthcare, warranting attention due to its role in enabling accurate measurements, ensuring patient safety, maintaining regulatory compliance, supporting quality control initiatives, preserving data integrity, optimizing device longevity, and fostering traceability and standardization. As such, calibration practices are instrumental in delivering effective healthcare and promoting favorable patient outcomes [31].

3.1. Equipment Architecture

The proposed device consists of two elements that can work together or independently. First, it is a force sensor system that can measure and display the applied force. The other is an accurate linear displacement system for simulating various SWM application scenarios. The various components of the developed device and their interactions are shown in the diagram in Figure 3. The equipment should be interfaced with a computer to allow for better equipment operation, for the observation of evaluation charts, data persistence, and statistics, among other functionalities. During development, preference was given to standard components already tested and available on the market. Where this was not possible, specific parts were designed from scratch and designed and simulated using 3D modeling software (Solidworks 2023) to ensure all project requirements and desired properties were met. Prototypes were then printed with 3D printing technology using PLA (a type of organic biodegradable thermoplastic polymer), tested, and improved when necessary. The produced parts proved to have good mechanical resistance and operational reliability in the desired operation conditions, thus exhibiting excellent performance for their intended purpose.

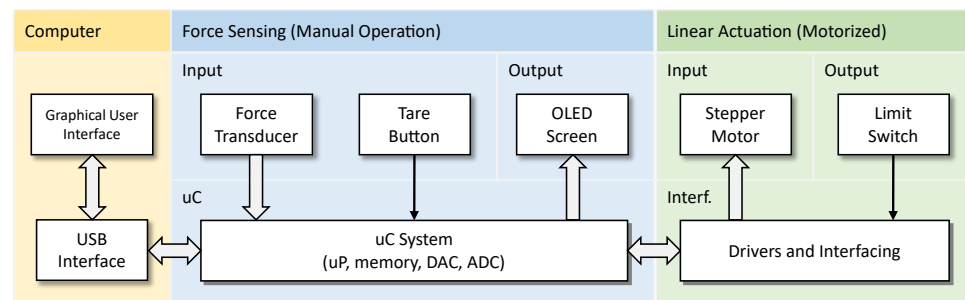


Figure 3. Main equipment components and their interaction: uC—microcontroller, uP—microprocessor, DAC—digital to analog converter, ADC—analogue to digital converter, Interf.—interface.

3.2. Force Sensing System

This is a portable element and can be operated alone to carry out measurements with manual application of the monofilament and take measurements, thereby sensing the value of the applied force. However, it can also be coupled with the precision linear displacement system (PLDS) (described next) and work together as a single mechanism in automatic mode. The force sensing system (FSS) (see Figure 4), in summary, is equipped with an OLED screen, a force transducer, a button to carry out the tare measurement, a connector for power input, and a USB Mini-B input for communication with a computer. Finally, an electronic controller (composed of a microprocessor, memory, and digital converters), based on the IC ATmega328, is responsible for carrying out all the programmed operations and executing the commands that will be sent through a computer application. When in automatic mode, the computer fully controls the equipment, i.e., when the FSS is coupled with the PLDS. The fundamental element consists of a force measurement platform, shaped similarly to the morphology of the plantar region of a human foot, which, in turn, is coupled to the force transducer. The surface of the platform has an ethylene–vinyl acetate coating with a texture and hardness chosen to be similar to what is observed with real biological tissues. It will be on this platform that the monofilament under evaluation will apply its strength, in a movement similar to the technique used in the sensitivity evaluation of the diabetic foot. Through this measurement process, it is possible to obtain the respective inherent value of the buckling force applied by the SWM.

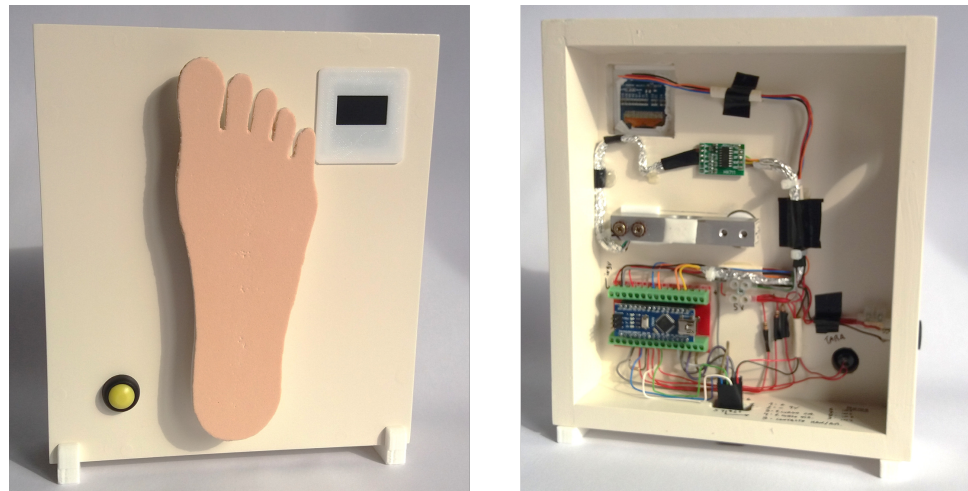


Figure 4. Force sensing system and its measurement platform are shaped similarly to the plantar region of the foot: external view of the module for manual measurement (**left**) and inner hardware components (**right**).

3.3. Precision Linear Displacement System

This PLDS mechanism is responsible for the motorized application of the SWM. Therefore, for this mechanism to operate, it has to be coupled to the force sensing component, since, in turn, this is what contains all the control electronics and computer interfacing (through a dedicated application) and is responsible for measuring the buckling force of the monofilaments that will be subject to metrological verification. The PLDS element is composed of a stepper motor, a v-shaped sliding guide, a trolley with bearings, and a fixation support for the SWM. This set of components will carry out the movements to apply the strength of the monofilaments, simulating the technique used by health professionals on the diabetic foot assessment. In Figure 5, the full equipment can be observed in detail. The PLDS, depicted in a lower position, has visible slots for the rods connecting the visible tray with the motorized mechanism, hidden below. The top clamp, mounted on the tray, is used to robustly fixate the SWM, as shown in the figure. It allows us to adjust pitch and yaw incidence angles, creating the possibility for different testing conditions. Finally, in the rightmost area, the FSS platform (already described) can be observed, which in this case is operating as an integrated system with the PLDS.

The hidden stepper motor is responsible for moving a reinforced rubber belt, connected to a guided chariot. With this setup, it is capable of performing precise linear movements. It basically consists of the movement of the visible tray that follows with the SWM attached and simulates the technique of applying the monofilament to the patient's foot. The monofilament is then moved and comes into contact with the measurement platform, where the applied force is measured, as this platform is coupled to the force transducer. These displacement movements of the monofilament fixation support are provided by the gantry and v-shaped sliding guide. The motion is supported by a transmission belt that is engaged in a pulley coupled to the stepper motor shaft, ensuring the desired precision. The displacement is electronically controlled and can be performed in linear and continuous movements, forwards and backwards, with end-of-course control or the number of steps taken.

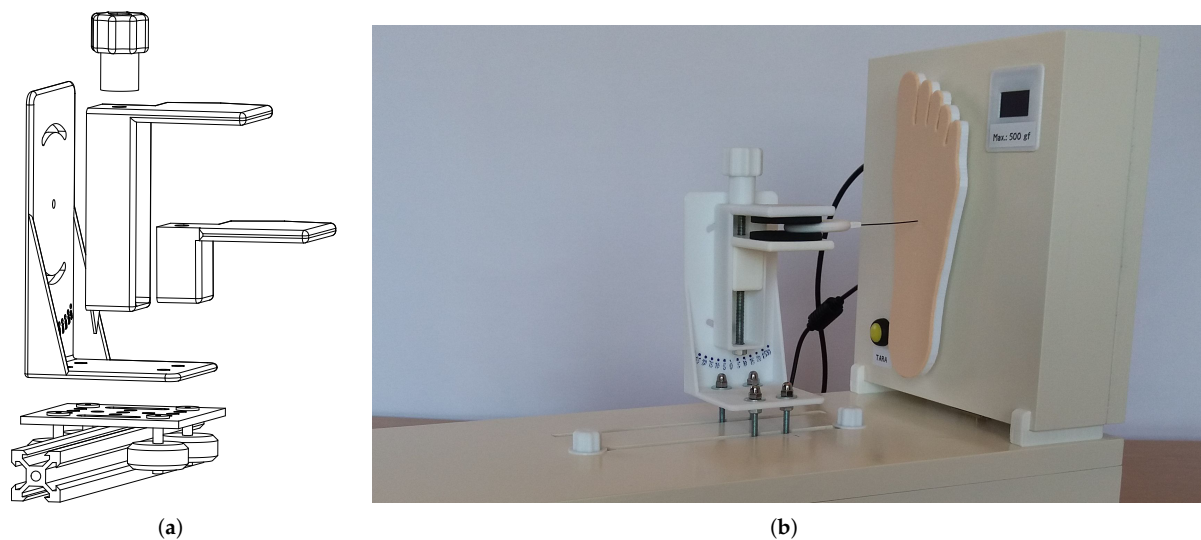


Figure 5. Proposed equipment, with a detailed view of the precision linear displacement system integrated with the force sensing system platform: (a) CAD drawing of the PLDS system with expanded components; (b) photographic image of the implementation of the PLDS and FSS.

3.4. Equipment Technical Specifications

Since the proposed equipment is intended to serve as a measurement system, it is important to consider the inherent accuracy and precision characteristics of force transducers, the components that convert physical quantities into corresponding electrical signals. To ensure that the equipment transmits quality estimates of the applied forces, it was subjected to a calibration process using a compression machine (Multitest 10-i, MecMesin, West Sussex, UK) with a load cell. This compression machine is approved to carry out calibration tests, and its main characteristics are detailed in Table 2. This step allowed for adjustments to the proposed equipment's measurement algorithm to ensure precise and accurate measurements in a range of 0.1 gf to 500 gf.

Table 2. Technical specifications of the compression testing machine—MecMesin Multitest 10-i.

Specification	Value/Description
Load cell ref.	ILC 10 N
Range (N)	0 to 10
Resolution (N)	>0.0001 (1:6500)
Precision (N)	± 0.01 (0.1% fs)
Acquisition rate (Hz)	10
Displacement velocity (mm s^{-1})	0.08 (a)

(a) Velocity can be controlled.

Although the developed equipment has the capacity to carry out accurate measurements in a wider measurement range, for safety reasons, the force transducer was limited to 500 gf of maximum admissible load, which is within the expected SWM test values. This step ensures the integrity of the equipment and makes it possible to adapt it to other assessments with monofilaments of a caliber greater than 10 gf (there are calibers of up to 300 gf on the market, more commonly used to assess deep sensitivity). If 500 gf is exceeded, all system operation is aborted, and an error message appears on the screen, instructing the user to remove the load and reset the equipment. The internal resolution of the sensing stage is high (the integrated analog-to-digital conversion offers a 10-bit resolution with $\pm 2\text{LSB}$ accuracy), allowing us to obtain a high number of decimal places. During development, a balance must be found between information accuracy and usefulness. Hence, it

should be noted that, although the measuring equipment is capable of operating with a higher resolution, the measured values in the range 0 gf to 99.9 gf are presented rounded to a single decimal place. In the hundreds range, from 100 gf to 500 gf, the measured values are rounded to the nearest unit. This procedure guarantees a balanced rounding and speeds up the comparison of the values obtained in the measurements with the values declared by the monofilament manufacturers. The same approach can be used to evaluate other monofilament calibers.

The PLDS is intended to perform high-precision movements. For this, a stepper motor, powered by a ULN2003A-based electronic driver, and a toothed belt drive are used. This setup is capable of making minimum increments of 0.08 mm in the displacement steps at the time of a given measurement. Still, regarding the characteristics of the linear displacement component, a total space of approximately 140 mm can be covered, enough to manipulate the various models of monofilaments available on the market. Table 3 shows the most relevant technical specifications of the proposed equipment. The measurement range, resolution, precision, and accuracy were obtained through the calibration process with the MecMesin Multitest machine.

Table 3. Detailed equipment specifications.

Specification	Value/Description
Range (gf)	(a) 0.1 to 99.9 and (b) 100 to 500
Resolution (gf)	(a) 0.1 and (b) 1
Precision (gf)	(a) ± 0.03 and (b) ± 0.25
Accuracy (%)	(a) ± 0.36 and (b) ± 0.68
Displacement resolution (mm)	0.08
Power supply (V DC)	9
Computer interface	USB mini-B connector; Specific Windows app
Modes	Linear by limit switch and by number of steps

(a) Rounds the measurement value to a single decimal place; (b) rounds the measurement value to unity.

When the equipment is operated in automatic mode, it is necessary to connect it to a computer through a USB Mini-B communication cable. This communication, through a specific computer application developed for this purpose, allows us to operate the equipment and receive all the information related to each monofilament evaluation. As for the energy source of this equipment, it is powered by an external source of 9 V DC.

4. Methods, Results, and Discussion

Analyzing the literature reveals that there is still uncertainty about the effective accuracy and precision of monofilaments in their use to test the loss of sensitivity in the diabetic foot. Therefore, the methodology applied in the present study was organized with the aim of obtaining a concrete answer, performing a rigorous metrological verification of fourteen SWM of 10 gf (from different manufacturers) most used by the medical community in general. For this verification, equipment capable of simulating the conventional procedure used by healthcare professionals was developed (previously described). This procedure registers the behavior of the nylon filament until it deforms with the recommended curvature, at which point the force declared by its manufacturer will have been applied. The equipment will also be able to perform fatigue tests to assess performance after several repetitions.

In the following subsections, a set of different scenarios that were used to explore the proposed calibration equipment, as well as the analytical model of the monofilament, will be presented.

4.1. Equipment Validation

To evaluate the measurement performance of the proposed equipment, it was submitted to a series of validation procedures through controlled tests with a MecMesin compression machine. This machine, with a valid calibration certificate from a national

metrological institution, is able to produce a controlled pre-determined force with a precision of ± 0.01 N. The MecMesin machine can also provide information about the force that was produced with a resolution of ± 0.0001 N (in other words, the actuation control system is not able to achieve the same resolution as the measuring system). The test protocol consisted of compressing the FSS of the proposed equipment into several measurement points plus a random increase of $\leq 25\%$, in rounds of thirty measurements for each. The mean compressive force values of each set and the respective standard deviation obtained by the MecMesin machine and the proposed equipment were recorded. The obtained results can be observed in Table 4. It should be noted that the standard deviation (SD) values indicated by the MecMesin machine were deliberately provoked to verify whether the FSS equipment followed the same behavior.

Table 4. Mean force and related standard deviation ($\pm$ SD) from the MecMesin and FSS equipment. The MecMesin row shows the mean and standard deviation the generated forces, and the FSS row shows the measured forces' related statistics. For each reference point, a series of thirty measures were obtained at a room temperature of 20 °C.

Reference Point	6 gf	10 gf	15 gf	20 gf	50 gf	300 gf
MecMesin	6.4 $\pm$ 0.5	11.3 $\pm$ 0.1	16.7 $\pm$ 0.1	22.2 $\pm$ 0.6	80.0 $\pm$ 3.7	344.3 $\pm$ 26.2
FSS	6.4 $\pm$ 0.5	11.3 $\pm$ 0.1	16.7 $\pm$ 0.1	22.3 $\pm$ 0.6	80.0 $\pm$ 3.9	345.6 $\pm$ 26.3

In addition, the obtained results were plotted using Bland–Altman plots [32]. This type of representation provides a valuable visual representation to observe the agreement between two measuring instruments. It allows for a quick assessment of comparability or discrepancies between the instruments. The plot displays the mean difference between the measurements obtained from the two instruments as a horizontal line, which, if close to zero, indicates little to no systematic bias. Moreover, the limits of agreement (corresponding to ± 1.96 standard deviations, or a 95% confidence interval), represented by two horizontal dashed lines above and below the mean difference line, offer insight into the range within which most of the differences lie. Any deviation from a consistent distribution of points around the mean difference line may suggest proportional bias, wherein differences vary with measurement magnitude. Outliers in the plot are easily identifiable and can highlight potential measurement errors or instances where one instrument performs exceptionally well or poorly.

In Figure 6 the very good performance of the proposed equipment can be observed, either in the 10 gf monofilament operation range (Figure 6a) but also near its operational limits (Figure 6b). Near the 350 gf reference point, it can be observed that the values' differences are higher and always positive. This is due to the combination of numerical rounding in the MecMesin system and also in the proposed system. This aspect does not have relevance for the specific purposes of this study, whose operational range is near 10 gf, for which excellent metrological properties were observed.

The obtained results showed that the FSS equipment presented very precise and consistent measurements, which is a positive indication of the performance of the proposed equipment. The comparison of the values obtained by the FSS equipment with the values measured by the MecMesin machine verified the reliability of the measurements carried out by the FSS. The very similar standard deviation values between the two devices indicate that the FSS measurements are consistent and demonstrate that the proposed equipment has a good repeatability capability in its measurements. It should be noted that the mean relative error, calculated on all tests of the various measurement ranges, was approximately 0.28%. These results also show that the FSS equipment is able to perform the SWM buckling force measurement tests with accurate and reliable results. If the analysis interval is the force range that is often used for diabetic foot-related procedures, the proposed system can achieve the highest measuring performance.

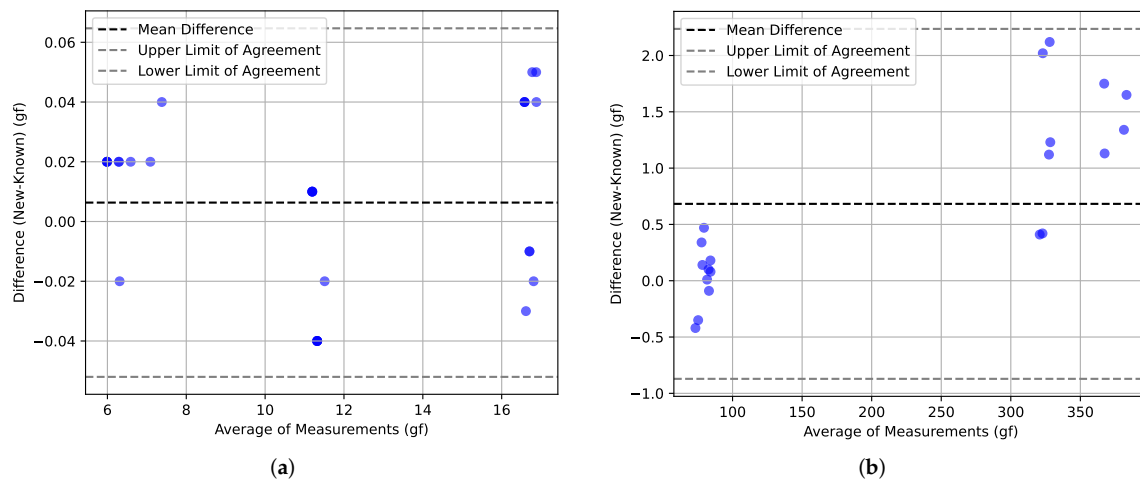


Figure 6. Bland–Altman plots comparing a reference device (MecMesin) and the proposed equipment (FSS): (a) for reference forces near the 10 gf monofilament operation range; (b) for reference forces near the operational range limit of the proposed equipment.

4.2. Monofilament Axial Compression

After ensuring the optimal accuracy and consistency of the calibration equipment, a set of tests was performed with monofilament devices used for the plantar sensitivity test. Fourteen monofilaments, with a force threshold of 10 gf, were carefully chosen from diverse manufacturers. All the devices were in new condition, and none had information besides the critical force. All tests were conducted at a stable room temperature of 20 °C to minimize environmental influences on the results. The monofilament, clamped in the PLDS and starting from a reference position, was longitudinally displaced towards the FSS, by 10 mm (necessary displacement to make the buckling curvature recommended), applying force in a perpendicular direction in relation to the platform. This setup mirrored real-life scenarios and facilitated precise plantar sensitivity evaluations. To assess the impact of different monofilament progression speeds on plantar sensitivity, two values were used: 4 mm s^{−1} and 8 mm s^{−1}. Again, these speed choices were chosen with the purpose of mimicking the human-made procedure. It should be noted that the tests with different speeds were performed with a difference of 24 h between them to minimize potential fatigue or memory effects on the monofilament.

Figure 7 illustrates the force–displacement charts obtained from the experimental data. Upon compression initiation, two distinct regimes become apparent: a linear regime before reaching the critical force F_c , and a buckling regime that follows thereafter. The force contours of the tested devices can be categorized into two groups. The first group exhibits an incremental force rise up to its critical value, maintaining relative stability throughout the entire displacement range. In contrast, the second group demonstrates an overshooting phenomenon, with the critical force slowly decaying during buckling. This behavior may arise from the utilization of monofilament material, which offers superior resistance to compression compared to deflection. By comparing the two charts, it can be observed that, when the displacement speed is higher, this effect is less visible. Looking at the final values, it can be observed that all monofilaments provided a force that is different from the expected 10 gf, and many of them exerted a force twice the expected value. A smaller diversity of behaviors for the 8 mm s^{−1} scenario can also be observed.

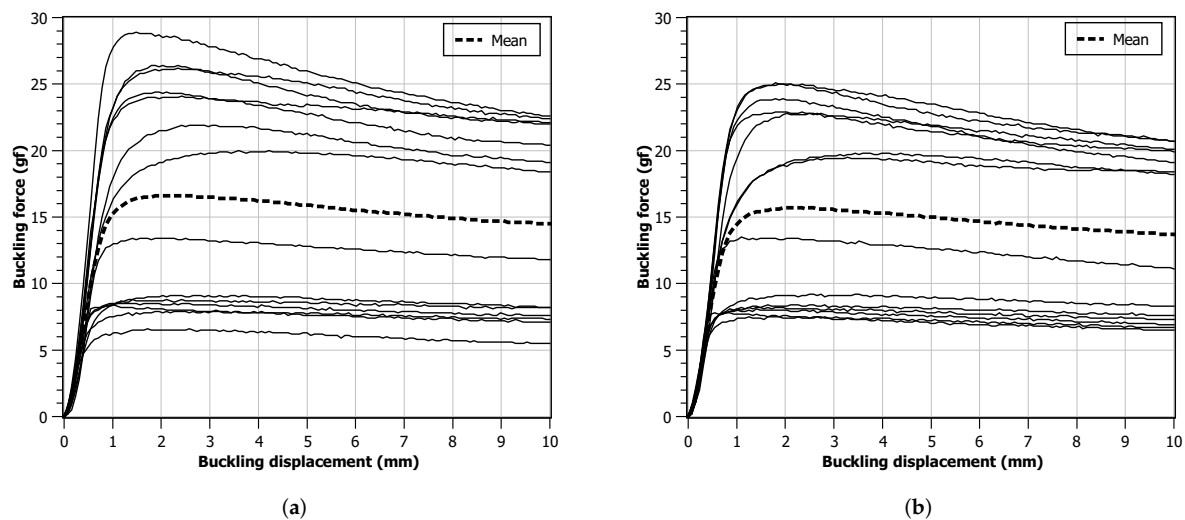


Figure 7. Force values measured with the FSS as a function of monofilament displacement. Each line represents one monofilament. The dashed line is calculated as the mean value of the other lines: (a) progression speed of 4 mm s^{-1} ; (b) progression speed of 8 mm s^{-1} .

4.3. Monofilament Stress Tests

Utilizing a monofilament in isolation for testing purposes may not fully represent the real-world conditions in which the device is intended to be used. To better simulate actual usage scenarios, it was decided to investigate the behavior of each of the fourteen monofilaments through a sequence of 20 consecutive compression cycles, with a time interval of 3 s between consecutive compressions. The experiments were conducted at a room temperature of 20°C and at two distinct displacement speeds, as in the previous test. Again, tests with different speeds were performed with a difference of 24 h between them to minimize possible effects of memory or fatigue on the monofilament.

Figure 8 presents charts for the critical force measurements obtained for each monofilament across the 20 cycles. It can be observed that all monofilaments have a higher critical force in the first compression trial that starts to decay with repeated compressions. On average, this effect is slower and smaller when a lower displacement speed is used. For the higher displacement speed, most monofilaments reach a force plateau after the second compression. It can also be observed that, in both scenarios, the average value is above the expected 10 gf, being around 15 gf for the 4 mm s^{-1} and around 13 gf for the 8 mm s^{-1} case. In the faster displacement scenario, it can be observed that two monofilaments do not provide a contour pattern compatible with all the others. This may point to geometrical defects during manufacturing or non-homogeneous material distribution.

Figure 9 shows the charts for the critical force values for each monofilament independently. Two groups (1 to 6 and 7 to 12), showing to share similar behavior during the experiments, can clearly be observed. In general, due to the observed repeatability, it was found that the monofilament device can be reliable for repeated usage but a stable high-precision manufacturing process is necessary.

The above-presented experiments and the reported results provide valuable insights into the monofilament's performance under repeated compression, reflecting its ability to withstand continuous usage and offering a more comprehensive understanding of its behavior in practical applications, since these instruments, after disinfection, can be used several times a day in several patients.

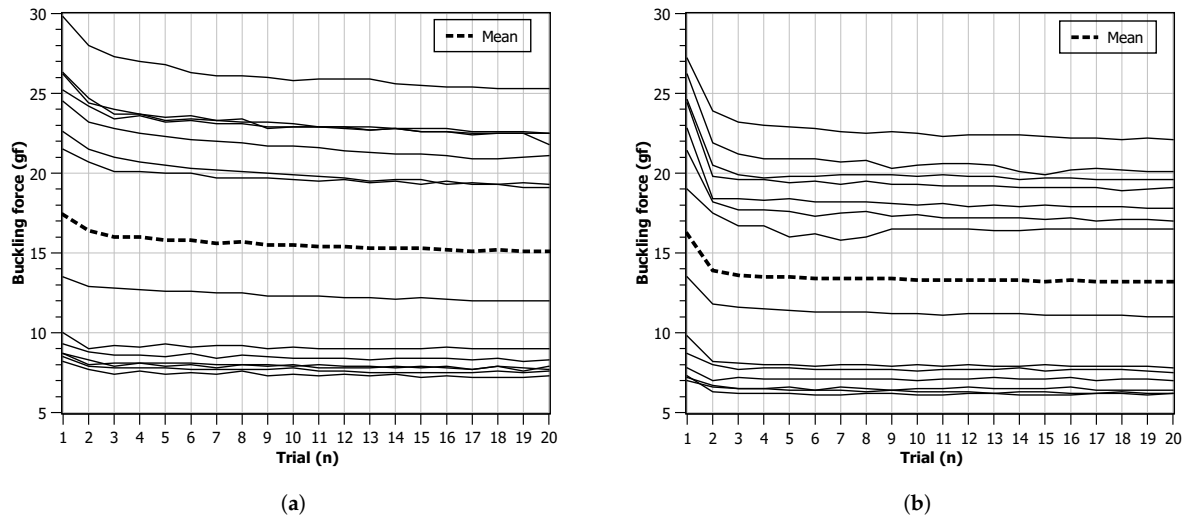


Figure 8. Critical force values during 20 trials. Each line represents one monofilament. The series mean value is calculated and represented as a dashed line: (a) progression speed of 4 mm s^{-1} ; (b) progression speed of 8 mm s^{-1} .

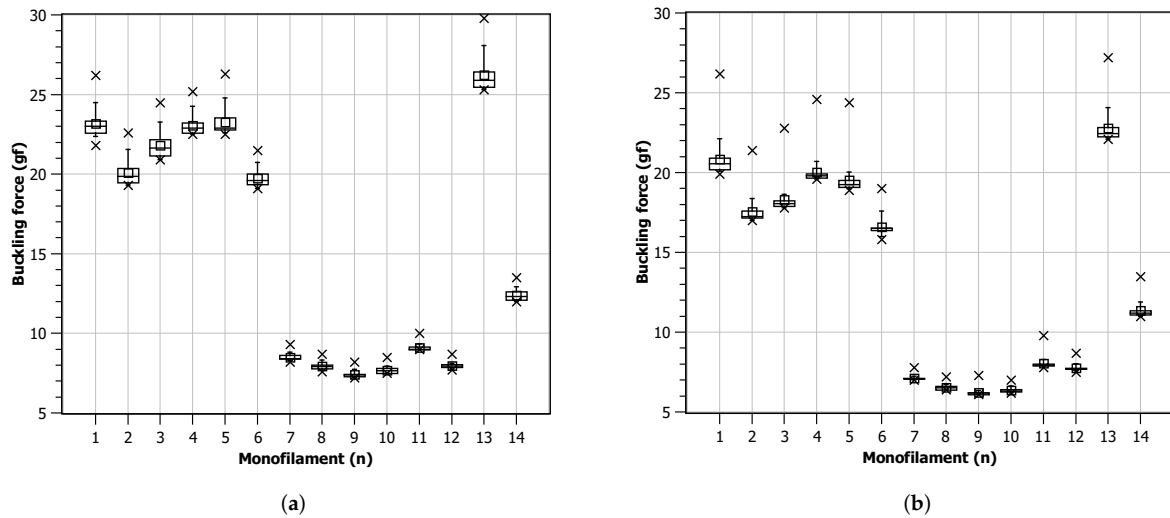


Figure 9. Critical force values after 20 trials: (a) progression speed of 4 mm s^{-1} ; (b) progression speed of 8 mm s^{-1} .

4.4. Theoretical Value of Critical Force

By substituting the measured values of a 10gf monofilament sample

$$d = 0.61 \text{ mm} = 0.00061 \text{ m}$$

into Equation (4), we can compute

$$I = \frac{\pi \cdot (0.00061)^4}{64}$$

To calculate the effective length ($L_{\text{effective}}$), the boundary conditions must be considered. For a clamped-free condition, the effective length is considered to be 0.7 times the actual length. Therefore,

$$L = 38 \text{ mm} = 0.038 \text{ m}$$

$$L_{\text{effective}} = 0.7 \cdot 0.038 = 0.02660 \text{ m}$$

Now, the Young's modulus (E) of the nylon material must be defined. For the purpose of this example, a typical value for nylon was assumed, being approximately 2 GPa (2×10^9 Pa). All the values in Euler's buckling equation can be replaced (3):

$$F_{\text{critical}} = \frac{\pi^2 \cdot (2 \times 10^9) \cdot \left(\frac{\pi \cdot 0.00061^4}{64} \right)}{0.02660^2}$$

Simplifying the equation, the following is obtained:

$$F_{\text{critical}} \approx \pi^2 \cdot (2 \times 10^9) \cdot \left(\frac{\pi \cdot 0.00061^4}{64} \right) \cdot \left(\frac{1}{0.02660^2} \right) \approx 0.18961 \text{ N}$$

The resulting value will be in units of force, such as newtons (N). To make a direct comparison with the target values of the monofilaments possible, it should be converted to the mass unit as follows:

$$m = \frac{F}{a} = \frac{0.18961}{9.80665} = 0.01933 \text{ kg} = 19.33 \text{ g}$$

Therefore, this monofilament has a critical buckling force of approximately 19.33 gf, well above the 10 gf declared by the manufacturer but compatible with some of the obtained test results, as shown in Figure 7. However, it should be noted that these calculations assume linear elastic behavior and neglect any other factors that may affect the buckling behavior, such as imperfections or other deformation complexities. Additionally, the actual buckling behavior of a nylon filament may also depend on other factors like temperature, moisture, and manufacturing tolerances, as previously mentioned.

4.5. Material and Geometry Variations

Using the measures obtained during the monofilaments tests (in Section 4.2), the material's Young's modulus E was estimated for each device, as seen in Table 5. Considering all tested devices, the average value for Young's modulus is 2.74 GPa, which is within the expected value range for a nylon polymer. These values were then used to calculate how the monofilament behaves when there is slippage of the free extremity, as shown in the rightmost column. The effective length L_e of the monofilament is a quadratic parameter in Equation (3), showing that inadequate friction conditions between the monofilament and the skin surface will have a very significant impact on the result and quality of the SWM test.

Table 5. Monofilament properties for four distinct devices. The materials' Young's moduli E was estimated from previously obtained geometrical dimensions (diameter d , length L , and critical force measures F_c , considering clamped–pinned boundary conditions $k = 0.7$, corresponding to the device calibration procedure setup conditions). Using E , a new critical force was calculated considering clamped–sliding boundary conditions $k = 2.0$. (First column represents a number attributed to a given monofilament device for reference purposes.)

#	d (mm)	L (mm)	E (GPa)	I (m ⁴)	F_c (k = 0.7) (gf)	F_c (k = 2.0) (gf)
1	0.61	38	2.99	6.797×10^{-15}	28.91	3.54
2	0.46	41	3.65	2.198×10^{-15}	9.80	1.20
3	0.71	38	1.68	12.474×10^{-15}	29.81	3.65
4	0.52	38	2.65	3.589×10^{-15}	13.50	1.65

From Equation (3) it can be observed that, while Young's modulus appears as a linear coefficient, the (monofilament's) length is squared, being more relevant for the force's

final value. In Equation (4), a linear factor in Equation (3), it can be observed that d has a fourth-order exponent, causing small variations in the variable to have a high impact on the results.

Figure 10 shows the critical force as a function of monofilament length and diameter, for two distinct Young's moduli. The effect of increased length and reduced diameter (for example considering a 10% manufacturing tolerance) can lead to a severe difference in the critical force. By observing the contour lines' orientation, the importance of diameter variations can be identified as highly relevant to the devices' performance (as expressed in Equation (4)). The correct choice of material is also an important factor to consider for manufacturing purposes, as a lower Young's modulus value allows for a higher dimensional tolerance.

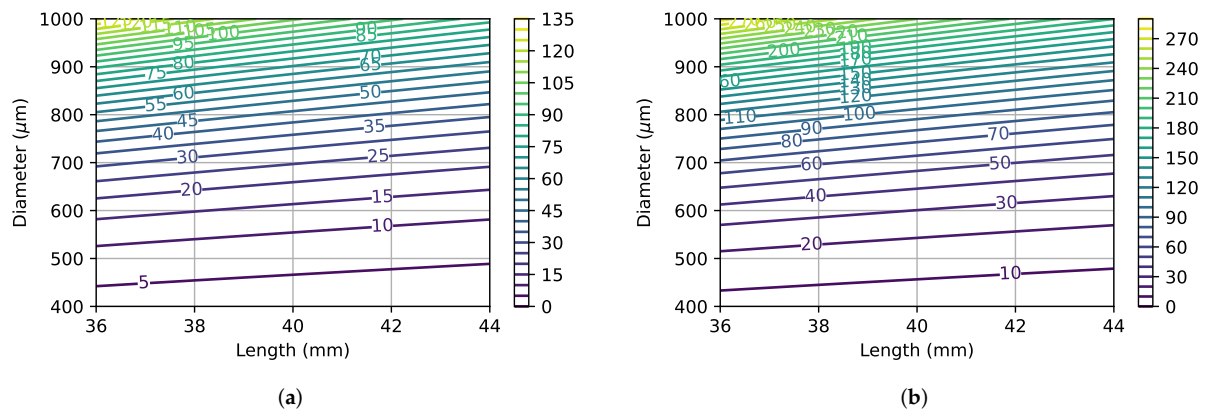


Figure 10. Critical force as a function of the monofilament length L and diameter d . Values are in gf. Young's moduli correspond to the minimum and maximum values that were estimated during calibration tests. (a) $E = 1.68$ GPa. (b) $E = 3.65$ GPa.

Deflection due to the monofilament weight can have a major impact on the device performance since, as seen in Figure 7, there are two distinct regimes during compression, mediated by the occurrence of the critical buckling force. When the monofilament has a higher length and smaller diameter, assuming equal material properties, then the deflection will be higher, and the transition between the two observed regimes does not present an overshoot.

In the center of Table 6 (in bold typeface), the deflection value δ is shown, due to its own weight, for the longest ($L = 41$ mm) and thinnest ($d = 0.46$ mm) monofilament of the experimental test set. For this case, the relative deflection in relation to its diameter $\delta(\%d)$ was 17.8%. This monofilament (and others in the test set with similar properties) shows no overshoot in the force–displacement contours of Figure 7 (the monofilament group whose curves are shown lower in the chart). For the shortest ($L = 38$ mm) and thickest ($d = 0.71$ mm) monofilament (not shown in Table 6), the deflection was $\delta = 55$ μm , corresponding to 7.8% of its diameter.

From Equations (4) and (7), it can be seen that both diameter d and length L have a high impact on the monofilament deflection behavior, as can be observed in the variations presented in Table 6. The highest relative deflection $\delta(\%)$ was obtained for a 10% increase in the monofilament length and a 10% decrease in its diameter, leading to a deflection increase of 81%.

Table 6. Deflection of the devices' free extremity due to their own weight, considering 10% variations (increase or decrease) in the monofilament length L and diameter d . Absolute values δ are in μm . Relative deflection $\delta(\%)$ values have the 10 gf monofilament deflection (center, bold typeface) as reference. Relative deflection $\delta(\%d)$ values have the diameter of each monofilament as reference. The reference monofilament has length $L = 41 \text{ mm}$, diameter $d = 0.46 \text{ mm}$, Young's modulus $E = 3.65 \text{ GPa}$, and density 1100 Kg m^{-3} .

$d \backslash L$	$L(-10\%)$			$L(0\%)$			$L(+10\%)$		
	$\delta (\mu\text{m})$	$\delta (\%)$	$\delta (\%d)$	$\delta (\mu\text{m})$	$\delta (\%)$	$\delta (\%d)$	$\delta (\mu\text{m})$	$\delta (\%)$	$\delta (\%d)$
$d (-10\%)$	66.26	−19%	16.0%	100.99	23%	24.4%	147.87	81%	35.7%
$d (0\%)$	53.67	−34%	11.7%	81.81	0%	17.8%	119.77	46%	26.0%
$d (+10\%)$	44.36	−46%	8.8%	67.61	−17%	13.4%	98.98	21%	19.6%

5. Conclusions

In this article, a novel equipment designed for the automatic metrological evaluation of SW monofilaments was introduced, providing a valuable tool for both objective assessment and training of health professionals in the SWM test procedure. The present study demonstrates the system's capability to automatically evaluate monofilaments, yielding detailed and precise displacement vs. force contours that characterize the behavior of each individual device.

5.1. Key Contributions

While some studies have consistently recommended the use of monofilament as a fast and cost-effective tool for assessing diabetic neuropathy [3], concerns have been raised about the reliability of the measurements obtained with this device, contradictorily not encouraging its usage [10]. The current paper introduces a solution to resolve this conflict, eliminating the main limiting factor in the use of monofilament. The proposed equipment allows users to benefit from the advantages of the monofilament while enhancing confidence in its usage, thereby supporting more accurate clinical decisions and improving healthcare outcomes.

Notably, the presented findings reveal that the forces applied by the monofilaments may deviate from the manufacturers' specifications, highlighting the importance of accurate calibration and testing parameters for reliable clinical assessments. Understanding these discrepancies contributes to the refinement of neurological diagnosis and rehabilitation strategies, enabling more effective treatment decisions.

In addition to presenting a new device for the automatic metrological evaluation of SW monofilaments, this study encompasses the development of analytical models to comprehend the influence of each variable on the critical buckling force during monofilament compression. These analytical models serve as valuable tools to investigate and dissect the complex behavior of monofilaments under compression, allowing us to gain deeper insights into the factors that significantly impact the critical buckling force. By employing these analytical models, it was possible to discern the interplay between various parameters, shedding light on their individual contributions to the overall behavior of the monofilaments during the compression process.

Using this calibration equipment and the analytical model, various tests were conducted on a range of commercially available monofilament devices. The combination of experimental results and analytical modeling provides deeper insights into their operational characteristics and allows us to estimate the potential errors during its use. With this knowledge, healthcare professionals can make more informed decisions when interpreting results and devising adequate follow-up routines and treatment plans for patients based on accurate and precise data.

5.2. Challenges and Constraints

The primary objective of the proposed device is to offer regular calibration of the monofilament within a clinical setting, ensuring consistent accuracy in patient assessments. The prototype presented here was meticulously designed to be both robust and user-friendly. However, to fully validate its effectiveness, it is crucial to gather usage data from a diverse pool of users. This step, which remains to be undertaken, will provide valuable insights for refining the device. User feedback, collected during routine clinical use, will be instrumental in guiding further enhancements to both the hardware and software, allowing the authors to optimize the device's performance and usability.

The integration of the proposed device into a clinical setting requires the development and implementation of new procedures as part of routine operations. Key aspects such as the timing and frequency of calibrations, as well as the assignment of responsibilities, must be clearly defined. It is also crucial to outline the implications of the calibration results, considering all variables that could impact the device's performance. Furthermore, comprehensive training sessions will be necessary, and it is essential to address the expectations and concerns of all stakeholders. These aspects present significant challenges that must be carefully managed, and only by addressing them can the objectives that motivated the development of the proposed device be fully achieved.

Regarding the materials used in the construction of the monofilament, while a broader range of materials could have been explored, our focus was on those most commonly cited in the literature. This choice was made to align with established clinical practices and ensure the device's immediate applicability in real-world settings.

5.3. Future Directions

The equipment is planned to be implemented within a real clinical practice setting, specifically in a service dedicated to diabetic foot monitoring. It is important to evaluate the level of error associated with ongoing assessments, taking into account the operational practices of the service and the procedures for utilizing monofilaments. Understanding these error margins will be crucial in improving the accuracy of diabetic foot assessments. Additionally, it is important to evaluate the user experience with the software that was developed for operating the proposed equipment. Only an easy-to-use system can ensure the adequate integration of the system, thus achieving its purpose.

Furthermore, efforts are being made to develop comprehensive training initiatives for healthcare professionals who administer the Semmes–Weinstein test. The goal is to heighten their awareness and sensitivity to significant variations in the force applied by the monofilaments during testing. According to the literature [33,34], the tactile sensitivity of an operator when applying force is approximately 10 gf, which is comparable to the force required for the monofilament test. However, there is potential to enhance this sensitivity further by employing neurofeedback techniques, which could improve the responsiveness of skin mechanoreceptors [35]. This training can be essential in identifying defective devices and improving diagnostic consistency.

5.4. Study Impact and Outlook

In summary, this study not only advances the reliability and practical application of monofilament-based diabetic neuropathy assessments but raises awareness for the continued improvement in clinical tools. The proposed calibration device and analytical model enhances the knowledge and precision of current methodologies. Furthermore, it promotes a more robust and precise usage of SW monofilaments, ultimately contributing to improvement in clinical practices and decision-making processes.

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3.2 - Plantar Pressure Monitoring and Redistributing In-shoe System

The proposed system is based on the development of an active device integrated into the shoe, designed to monitor and redistribute plantar pressure in real time. The overall concept includes four main components: (i) a sensor module for the acquisition of plantar pressure data; (ii) a module of pneumatic actuators responsible for active pressure redistribution; (iii) a central unit for pneumatic control and data communication; and (iv) the physical integration of a pneumatic insole, composed of four air cells, into a shoe adapted for the diabetic foot, as well as in safety footwear. These four air cells, which comprise the insole, are located in the plantar regions targeted for monitoring and action, including the most relevant areas of the foot for the development of ulcers in the context of diabetic foot: toes, metatarsals, lateral-midfoot, and heel (see Figure 3.1). These areas were selected based on their clinical and biomechanical relevance (Schaper et al., 2024; van Netten, Bus, et al., 2024), corresponding to critical areas in plantar pressure distribution during gait. The prototype integrates pressure sensors, automation algorithms, and pneumatic control to stabilize, redistribute, and apply localized offloading pressure in a specific area of the foot. This approach aims to offer a functional solution that combines continuous monitoring with immediate intervention mechanisms on plantar pressure. A high-level diagram is presented in Figure 3.1, illustrating the overall system architecture and the interactions between the different modules.

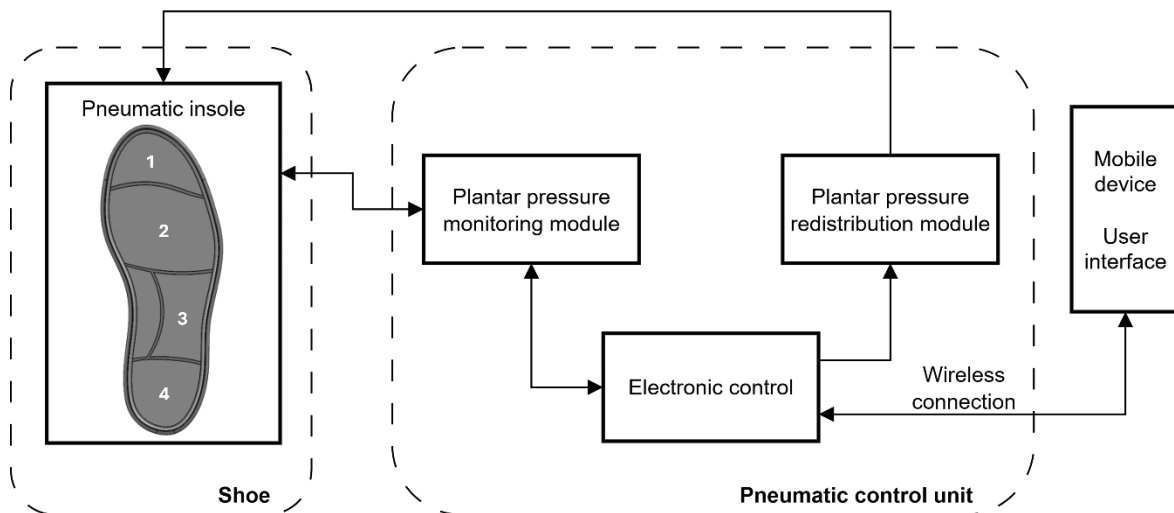


Figure 3.1 – System architecture overview.

For a better understanding of the system's functionalities, it is essential to clarify some terminology that will be frequently used, as follows:

Stabilization of plantar pressure: This procedure involves initial stabilization of pressure when the user puts on the shoe. The system distributes pressure across all four air cells of

the pneumatic insole, adapting the insole's structure to the user's foot morphology. This pressure stabilization and the consequent adjustment of the insole structure occur when all air cells are interconnected via a pneumatic circuit, promoting the distribution of air between cells to adjust according to the plantar morphology of the foot.

Plantar pressure redistribution: Occurs when the system acts to regulate plantar pressure in a specific intervention area (one of the four air cells in the insole) and promotes a change in the contact area of the plantar region, causing a redistribution of plantar pressure.

Localized plantar pressure offload: With this procedure, it becomes possible to offload plantar pressure in a specific intervention area by draining air from the respective cell, which naturally leads to a redistribution of plantar pressure.

Plantar pressure threshold: The predefined value (or a pressure pattern based on the threshold), above which the user may be at risk of injury, such as the thresholds previously addressed in the literature, with the threshold of 200 kPa being the most consensual value among the scientific and medical community (P. Jones et al., 2021; Schaper et al., 2019). However, the system allows this threshold value to be changed and adjusted according to user needs.

Real-time monitoring and response: The system is designed to operate in real time, as the process of monitoring plantar pressure occurs approximately every 0.067 seconds. This frequency corresponds to a sampling rate of 15 Hz per cell/zone, resulting in 60 measurements per second for the four plantar zones. The detection of the established pressure pattern, based on the predefined pressure threshold value, triggers the localized offloading action, which must occur within an interval of up to 100 ms after the event is detected. This process can be repeated successively until the threshold is reached or the minimum operational air volume of the target cell/zone of intervention is achieved.

Active system: A system that uses an algorithm to collect data in real time and, based on the data collected, triggers automatic (or user-controlled) response actions to manage plantar pressure inside the shoe.

Next, the methodology used to create and operate the various modules that comprise the system is presented, starting with the monitoring of plantar pressure, followed by the pneumatic control unit and activation for pressure redistribution, and finally, the design of the pneumatic insole that will be inserted inside the shoe. Subsequently, in Section 3.3, the various steps and procedures for assembling and creating the functional prototype, as well as integrating all components, are presented in detail, along with the results obtained from operability and validation tests of the developed device.

3.2.1 - Method for Real-Time Plantar Pressure Monitoring

Continuous monitoring of plantar pressure is an essential requirement for preventing ulcers in individuals with diabetic foot disease, allowing the identification of areas of mechanical overload and triggering corrective actions in real time (Patry et al., 2013). In this context,

two distinct approaches were explored for the development of a module for monitoring plantar pressure inside the shoe: (i) the use of a textile insole with piezoresistive pressure sensors printed by screen-printing method; and (ii) the design of a pneumatic rubber insole, equipped with air cells, which allows the indirect measurement of plantar pressure through principles of pressure transmission in fluids.

In the first approach, piezoresistive sensors were printed on textile substrates using the screen-printing technique. This method enabled the integration of flexible sensors directly into an insole, resulting in a lightweight, discreet, and adaptable solution that conforms to the morphology of the human foot. The screen-printing technique was used to deposit conductive and piezoresistive inks on textile substrates (for example, polyester coated with a polyurethane film, or others), forming electrodes with interdigitations and intermediate layers of a functional piezoresistive ink. Piezoresistive sensors operate on the principle of varying electrical resistance in response to mechanical deformation caused by the application of pressure to their active area. Each sensor is made up of three fundamental elements: (i) a layer of conductive electrodes, printed with conductive ink (Sink01NP®, Nanopaint) on the textile substrate and responsible for transmitting voltage and electrical signals; (ii) piezoresistive intermediate layer, based on a functional ink (PR2NP®, Nanopaint) whose resistance varies depending on the pressure applied; (iii) external textile substrate layer on the top and bottom, which ensures mechanical stability by providing support and protection to the sensors. Figure 3.2 presents an illustration of the configuration of the elements that comprise a piezoresistive sensor, along with a sample of one of the insoles produced using this technique.

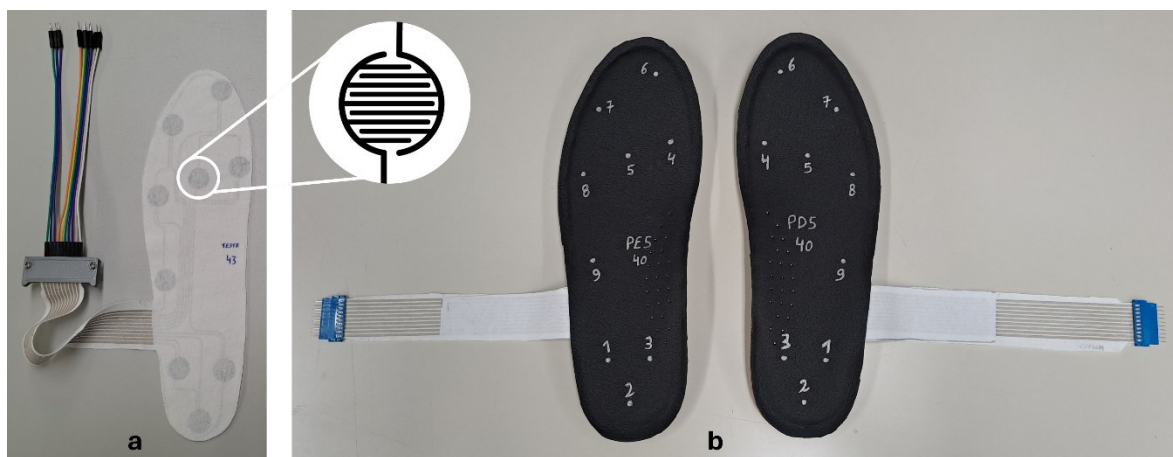


Figure 3.2 – Piezoresistive sensor elements printed on textile substrate using screen printing technique (a), and a sample of a pair of insoles with piezoresistive sensors (b).

From a functional perspective, each piezoresistive sensor responds to pressure variations by changing its electrical resistance, which is then converted into a digital signal for further processing (see Figure 3.3). Regarding the electronics, data acquisition was carried out through a signal conditioning circuit based on voltage dividers, followed by an analog-to-

digital converter (ADC) with 12-bit resolution (see Figure 3.3), which allowed data collection to determine the operating curve of the sensors and their operational measurement range. Given that the relationship between applied pressure and electrical resistance is not always linear, it was necessary to implement calibration methods capable of mapping the electrical response in applied pressure values. This calibration was conducted using certified measurement platforms, ensuring a correct correlation between the measured values and the signals obtained. The methodology used and the results obtained in tests with sensors of this nature are presented in Appendix A, where a scientific article published within the scope of this research work provides preliminary results on the behavior of these sensors during the calibration and characterization phase.

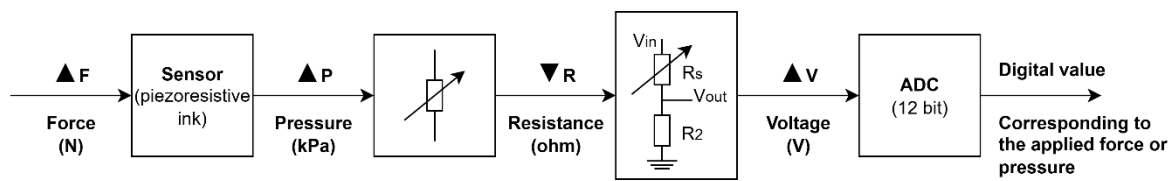


Figure 3.3 – Operating method of piezoresistive sensors printed on a textile substrate and their electrical signal conditioning circuit.

Although this approach has advantages such as flexibility, ergonomic integration capacity, and the implementation of a simple electronic circuit, some significant limitations have been empirically observed, namely, the degradation of performance after repeated cycles of load and unload, some variation of electrical resistance as a function of temperature variation, signal drift over time, and some hysteresis that requires periodic recalibrations. In summary, this solution demonstrated the feasibility of using printed sensors in biomedical applications, mainly due to their ability to integrate discreetly into footwear. However, it should only be recommended for use that does not require great precision. However, the challenges associated with the sensors' characteristics, which led to instability in their behavior and required periodic calibrations, motivated the exploration of a second approach, based on pneumatic principles, designed during the study of how to create an active system inside the shoe to offload plantar pressure.

The second approach consisted of designing a rubber insole equipped with four pneumatic cells (method discussed in Subsection 3.2.4), distributed in the previously defined critical plantar regions (toes, metatarsals, lateral-midfoot, and heel). Each cell functions simultaneously as a sensory element and an actuator element. The operating principle is based on the uniform transmission of pressure applied to a fluid confined in a compartment, as established by Pascal's Principle, which states that the pressure applied to a fluid at rest is transmitted uniformly and with equal intensity in all directions. In this system, when one of the plantar zones is compressed by the user's weight, the pressure exerted is transmitted to the air contained in the corresponding cell, raising the internal pressure of the pneumatic circuit. The internal pressure variation is then measured by pneumatic pressure sensors, thus

providing an indirect measure of the pressure exerted on the plantar region. An illustration of this method of operation is shown in Figure 3.4.

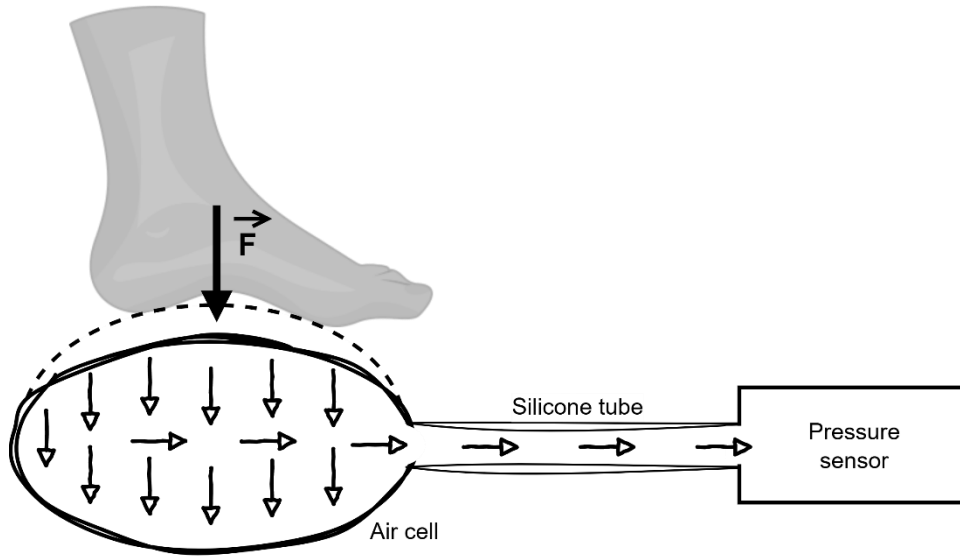


Figure 3.4 – Plantar pressure measurement method through air cell compression.

Although the system uses ambient air as the working fluid and is technically compressible, it is considered that for the expected operating pressure range, the compressibility effects are negligible and do not compromise functional performance. According to Pascal's Principle, a force (F) applied to a fluid confined under a given area (A) is transmitted uniformly in all directions and translates into a magnitude of pressure (P), which can be calculated by Equation 3.1:

$$P = \frac{F}{A} \quad (3.1)$$

Under conditions close to atmospheric pressure and up to a few times its value, the compressibility factor (Z) of the air remains very close to the unit ($Z \approx 1$), which indicates almost optimal behavior and almost instantaneous pressure transmission (Elliott et al., 2023). The calculation to obtain the compressibility factor of the air can be performed by Equation 3.2, where P is the pressure, V is the actual volume, n is the number of moles, R is the constant of the gases, and T is the temperature:

$$Z = \frac{P \cdot V}{n \cdot R \cdot T} \quad (3.2)$$

According to experimental data and classic literature (Elliott et al., 2023; Green & Perry, 2007), the Z value for air is typically between 0.9911 and 1.0004 under pressure conditions that can vary from 1 bar to 10 bar, and temperature conditions from ≈ 250 K (-23.15 °C) to ≈ 350 K (76.85 °C), which confirms, under these conditions, its proximity to the behavior of

an ideal gas. Thus, the practical application of Pascal's Principle remains valid, allowing us to assume that the pressure exerted by the foot on each air cell is transmitted uniformly and effectively to the pneumatic circuit, without relevant losses or delays that compromise real-time monitoring. The use of reduced volumes of air inside the cells and operation in moderate pressure ranges additionally contributes to mitigating any dynamic damping effects associated with compressibility. Any residual deviations related to leaks or thermal changes in rapid cycles were experimentally evaluated, but no events were identified that could compromise the reliability of the monitoring system.

At this stage, it was already predictable that this strategy could offer several advantages, namely mechanical robustness, greater fatigue resistance from prolonged use, immunity to environmental variations, and the possibility of direct integration with the active plantar pressure redistribution module (discussed in Subsection 3.2.2). Additionally, the use of pneumatic pressure monitoring enables the same elements responsible for actuation (insole air cells) to also serve as pressure measurement sensors, simplifying the overall system design and reducing the need for discrete electronic sensors. This integration represents an innovative step towards the design of active plantar pressure offload devices, with strong potential to increase reliability and facilitate the integration of the two devices within the shoe, including the monitoring element and the active element for pressure redistribution.

3.2.2 - Method for Active Redistribution of Plantar Pressure

Active redistribution of plantar pressure is the second key pillar of the proposed solution and a primary innovative aspect. It is not enough to detect overloads, but it is also necessary to act on them to mitigate potential injuries. In the developed prototype, redistribution is achieved through air cells integrated into the insole, allowing for local adjustment of internal pressure based on real-time plantar pressure data. This strategy allows for relieving areas where the pressure threshold has been reached and redirecting the load to more tolerant adjacent areas.

The operation of the redistribution module is based on the principle of controlled air exhaustion (emptying) and/or air injection (insufflation) of pneumatic cells integrated into the shoe insole, located in four specific plantar regions (toes, metatarsals, lateral-midfoot, and heel), to reduce local pressure in those regions. Each cell is connected to the pneumatic control unit by silicone tubes, where valves are operated that control the flow of air into or out of the cells. Localized pressure reduction interventions occur according to these steps:

- i. Each air cell is compressed by the area of the plantar region of the user's foot during walking or in static mode, and pressure sensors monitor and collect data from that pressure at a rate of 15 Hz for each cell.
- ii. Pressure sensors detect that a zone has exceeded the configured threshold, for example, a predefined pressure pattern based on the 200 kPa threshold.

- iii. The pneumatic control unit sends a command to the opening of the exhaust valve corresponding to the overloaded cell, draining part of the air. This event occurs within a fraction of a second, approximately 100 ms.
- iv. The system repeats adjustment cycles until the cell pressure approaches the set threshold or until the minimum operating air volume of the cell is reached.
- v. If necessary, a mini pneumatic pump can inject air into the cells to maintain sustained pressure or restore some operating air volume.

Pressure redistribution does not occur as an isolated event, but as part of a control cycle. The pressure sensors provide readings at 15 Hz per cell. The algorithm compares these readings with the preset threshold, decides which cells to act on, and sends commands to the pneumatic control unit to actuate the valves and/or pump. This cycle is continuous and adaptive, adjusting to the user's walking pattern. Figure 3.5 illustrates the architecture of the pneumatic circuit, which includes pressure sensors to monitor plantar pressure, an air pump, and valves that control the offload and redistribution of plantar pressure.

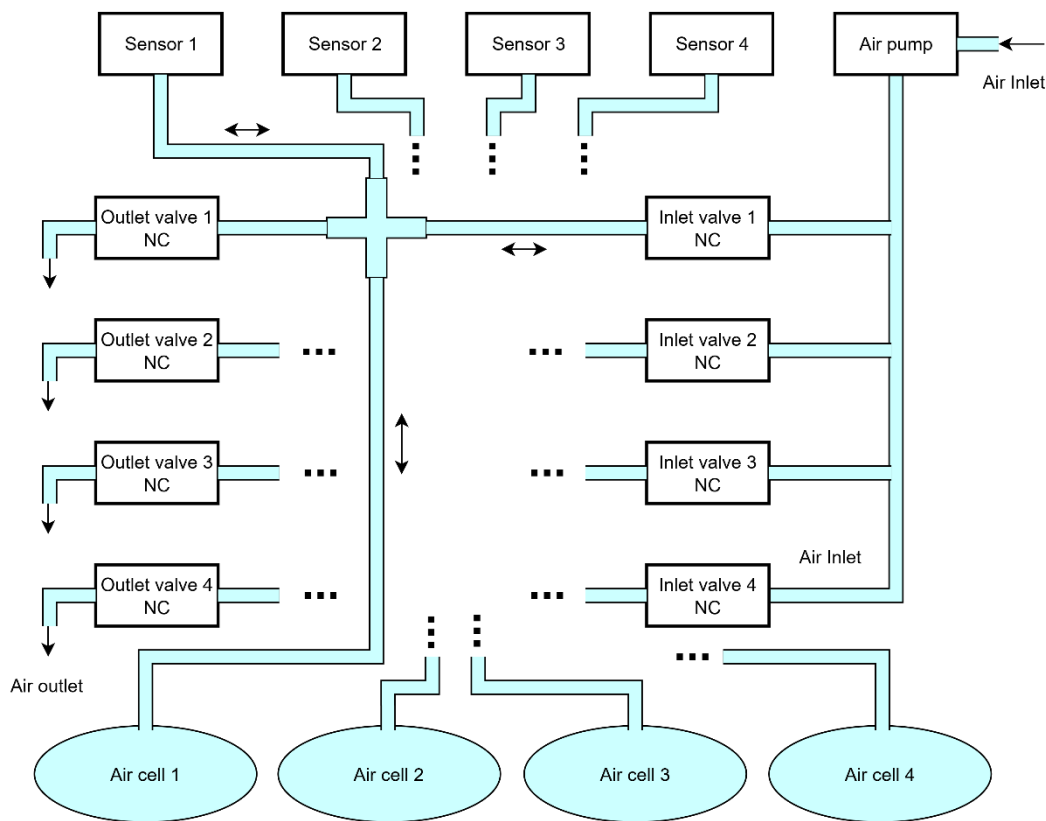


Figure 3.5 – Pneumatic circuit architecture and valve mechanism for controlling offload and redistribution of plantar pressure. NC, normally closed valve.

For safety and efficiency, maximum and minimum volumes of air in each cell have been defined to prevent structural collapse, loss of cushioning, compromise of insole comfort, or override of sensor monitoring functionality. For example, cells cannot be emptied, as it would lead to the sinking of the compartment and a consequent failure to record plantar pressure values correctly. Each cell has a maximum number of discharges that it can perform,

considering its internal pressure and air volume. Another important feature of the system is related to the procedure of offloading plantar pressure in a specific area, an action that consequently causes a dynamic redistribution of this pressure. When a cell is relieved, other adjacent areas absorb some of the dissipated load. The control algorithm is programmed to evaluate the pressure increase in neighboring cells and prevent the generation of new overloads, thereby constituting an intelligent redistribution rather than a simple unilateral offload. However, in certain situations, it may be necessary to trigger the pressure stabilization process, as described above, which involves distributing the pressure across all four air cells, thereby promoting adaptation of the insole structure to the user's foot morphology. This pressure stabilization occurs when all air cells are interconnected through the pneumatic circuit with the opening of the air inlet valves. This action promotes the distribution of air between cells to adjust the insole structure according to the plantar morphology of the foot. In summary, the proposed active redistribution method combines measurement, control logic, and actuation, allowing a response to plantar overloads from the perspective of preventing diabetic foot injuries and in the context of occupational safety and health.

3.2.3 - Electropneumatic Control and Automation Unit

The control unit constitutes the central core of the proposed system, integrating the components responsible for data acquisition, signal processing, decision-making, and the activation of pneumatic elements. In addition to housing pressure sensors, valves used to control air flow, and a mini pneumatic pump, this unit also ensures wireless communication with external devices.

To ensure the coordinated operation of all subsystems, a customized electronic printed circuit board (PCB) has been developed. The PCB design (see Appendix B) was conceived in such a way as to allow the integration of all necessary modules for the operation of the device: a central microcontroller, responsible for processing data from the sensors and executing the control algorithms; four pneumatic pressure sensors, connected via pneumatic circuit to each air cell in the insole for real-time measuring of plantar pressure variations; and power circuits for the activation of the valves and the mini-pump for exhaust and air injection.

Communication between the control unit and external devices, such as smartphones or laptops, was implemented through Bluetooth Low Energy (BLE), a technology chosen for its low energy consumption and broad compatibility with mobile platforms. This protocol ensures continuous monitoring through the real-time transmission of plantar pressure data at an update rate compatible with the frequency of data acquisition. Remote communication with the system also enables the configuration of parameters, including the definition of plantar pressure thresholds and pressure redistribution strategies, while ensuring the secure local storage and synchronization of data on the user's device. The use of BLE also enhances

future compatibility with mobile applications for remote clinical monitoring, thereby reinforcing the system's practical application in real-world scenarios, such as diabetic foot monitoring or as a preventive strategy in occupational safety.

The control unit is housed in a compact box, produced using a 3D printer with fused deposition modeling (FDM) technology and PLA (polylactic acid) filament. It will be attached to the user's waist and connected to the shoe through silicone tubes. The detailed design and wiring diagram of the PCB is available in Appendix B. Section 3.3 presents the timing of the design and assembly of the control unit in the final prototype.

3.2.4 - Pneumatic Insole Manufacturing Method

The development of pneumatic insoles required the exploration of different manufacturing approaches to simultaneously achieve a design adapted to the shape of the foot, mechanical flexibility, and air tightness. At an early stage, additive manufacturing processes using 3D printing with flexible resins were tested, due to the advantage of allowing rapid prototyping and the direct creation of complex geometries, including the cavities for the inner air cells of the insole. Despite these advantages of the 3D printing method, the tests carried out revealed significant limitations. The low mechanical resistance of the thin walls, the fragility of the bonds between layers of material, and the air permeability observed in some resin formulations prevented the obtaining of functional parts for repeated use in a dynamic environment. Various geometries and printing parameters were tested, but the prototypes consistently exhibited small air leaks or structural flaws after the resin curing process or even after a few load cycles. Figure 3.6 presents some examples of insole components created with liquid resin (BASF-FL60, Ultracur3D) using the stereolithography technique (SLA), but these proved to be non-functional.

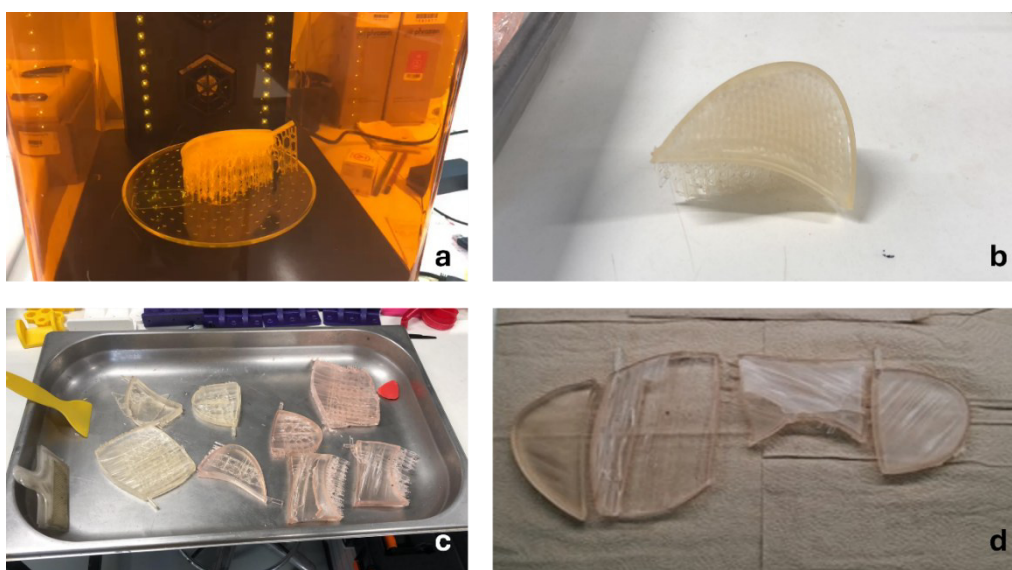


Figure 3.6 – Examples of non-functional insole parts produced by SLA: curing process of parts already printed by SLA (a), part corresponding to the air cell for the toes region (b), several parts that make up the pneumatic insole (c), and a complete but non-functional pneumatic insole with several defects (d).

Due to these limitations, a strategy based on molding has been advanced for manufacturing. Rigid molds were designed based on the negative of the insole configuration and 3D printed using high-strength PLA material, allowing for the injection of liquid rubber. This approach enabled greater control over the dimensions of the air cell cavities and ensured that the continuous internal walls were completely airtight. The design of the molds has been optimized to allow the pouring or injection of the rubber in a liquid state, ensuring the uniform formation of pneumatic cells and providing resilience and flexibility to the insole. Figure 3.7 illustrates the molds used for pouring and injecting liquid rubber.

In this final solution, a semi-industrial-grade liquid urethane rubber (Vytaflex™ 40, Smooth-On) was used, selected for its high elasticity, resistance to mechanical fatigue, and impermeability to air. The choice of this material proved decisive in ensuring the insole's durability in repeated loading and unloading cycles, as well as its ergonomic adaptation to the human foot. The manufacturing process involved applying liquid rubber to molds that had been previously prepared with a release spray (Ease Release 400, Mann™ Release Technologies) to ensure complete filling of the wall cavities corresponding to the air cells and facilitate subsequent demolding. After the pouring and injection stage, the rubber was subjected to a curing process with a controlled temperature at 23 °C (for 24 hours), ensuring proper vulcanization and obtaining stable mechanical properties. Once solidified, the part was carefully removed from the mold and subjected to manual finishing to eliminate burrs and ensure the tightness of the pneumatic circuit.

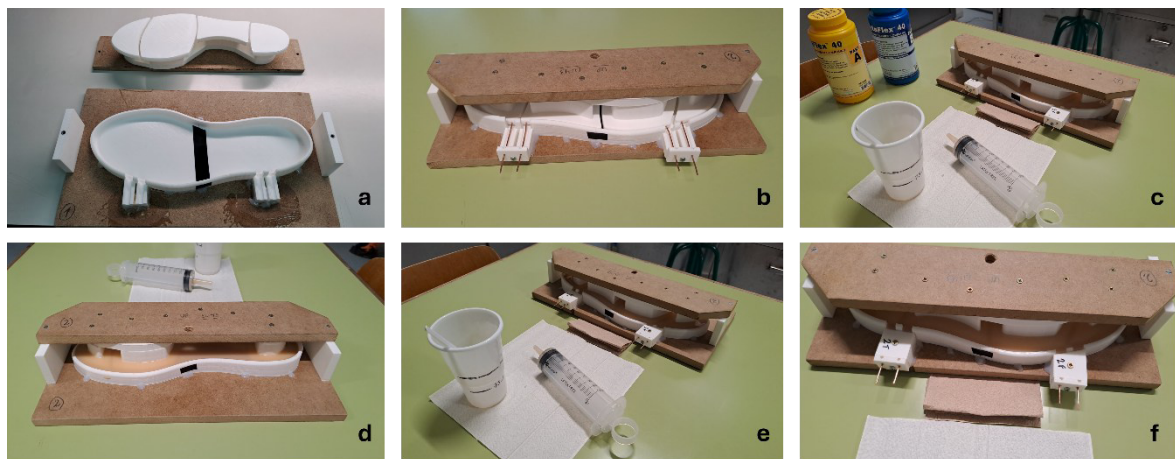


Figure 3.7 – Molds used to produce insoles with pouring and injection of liquid urethane rubber: lower and upper parts of the mold created by 3D printing with PLA (a), assembled mold (b), mold prepared for rubber injection (c), injected liquid rubber (d), and mold stabilization and resting during the curing process (e, f).

The insole has been designed into two distinct parts, corresponding to the top and bottom sections of the set, with the bottom part accommodating the air cell cavities. To ensure the permanent union of these parts, the contact faces were previously subjected to a chemical aggression with acetone ($\geq 99\%$) for about two minutes, to promote surface activation and improve adhesion. The bonding was carried out using the same liquid urethane rubber used

in the manufacture of the parts, applied as a bonding and vulcanization layer between the previously activated surfaces, which had been treated with acetone. After joining, the set remained at rest for 24 hours to ensure complete curing and structural cohesion of the insole. Figure 3.8 illustrates the two constituent parts of the insole that undergo the bonding process.

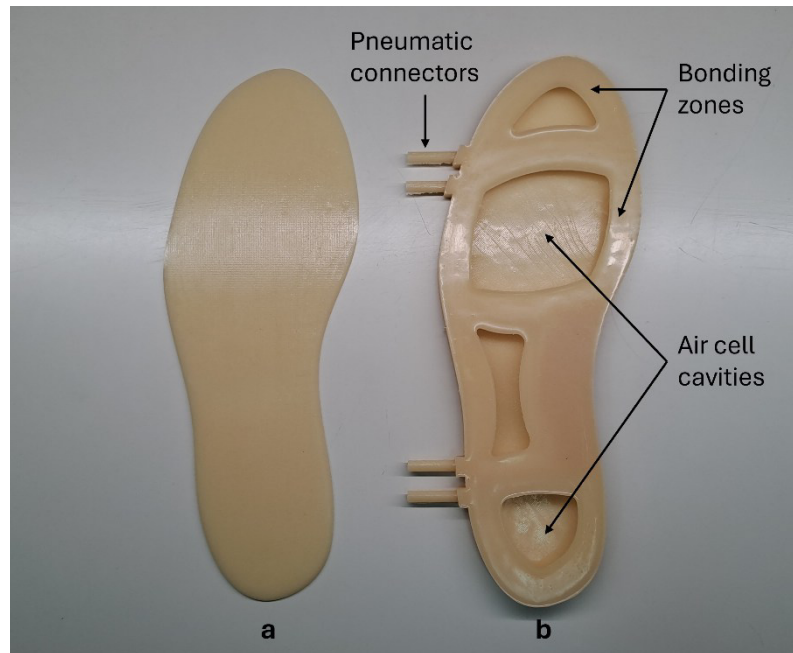


Figure 3.8 – Parts of the insole before bonding: top (a) and bottom (b).

This methodology overcame the limitations of the initial tests with flexible resin using SLA. Although this second approach involved a manual process, it was possible to obtain a functional and robust pneumatic insole with mechanical characteristics compatible with prolonged use in real-world conditions. Additional details on the technical aspects of the pneumatic insole's dimensions and the assembly process in the shoe, including a description of the liquid rubber's characteristics, are presented in Section 3.3, allowing the manufacturing method to be contextualized within the scope of the functional prototype developed.

3.3 - A Portable Insole System for Actively Controlled Offloading of Plantar Pressure for Diabetic Foot Care

This section is based on an open-access article published by the author under the terms and conditions of the Creative Commons Attribution (CC BY) license. This published study validates the principles described in Section 3.2, describes the entire development of the active pneumatic system for monitoring and redistributing plantar pressures, and presents results obtained in tests that confirm the system's operability.

Pedro Castro-Martins, Arcelina Marques, Luís Pinto-Coelho, Pedro Fonseca, & Mário Vaz (2025). A Portable Insole System for Actively Controlled Offloading of Plantar Pressure for Diabetic Foot Care. *Sensors*, 25(12), 3820. <https://doi.org/10.3390/s25123820>
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Article

A Portable Insole System for Actively Controlled Offloading of Plantar Pressure for Diabetic Foot Care

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Highlights

What are the main findings?

- The pneumatic insole can monitor, stabilize and offload plantar pressure in real time.
- Over 91% of measurements are reliable, with up to about 42% pressure reduction.

What is the implication of the main finding?

- Strong potential to support foot injury prevention strategies in at-risk populations.

Abstract: Plantar pressure monitoring is decisive in injury prevention, especially in at-risk populations such as people with diabetic foot. In this context, innovative solutions such as pneumatic insoles can be essential in plantar pressure management. This study describes the development of a variable pressure system that promotes the monitoring, stabilization, and offloading of plantar pressure through a pneumatic insole. This research was also intended to evaluate its ability to redistribute plantar pressure, reduce peak pressure in both static and dynamic conditions, and validate its pressure measurements by comparing the results with those obtained from a pedar[®] insole. Tests were carried out under both static and dynamic conditions, before and after the pressure stabilization process by air cells and the subsequent pressure offloading. During the validation process, methods were used to evaluate the agreement between measurements obtained by the two systems. The results of the static test showed that pressure stabilization reduced pressure on the heel by 32.43%, distributing it to the metatarsals and toes. After heel pressure offloading, the reduction reached 42.72%. In the dynamic test, despite natural dispersion of the measurements, a trend to reduce the peak pressure in the heel, metatarsals, and toes was observed. Agreement analysis recorded 96.32% in the static test and 94.02% in the dynamic test. The pneumatic insole proved effective in redistributing and reducing plantar pressure, with more evident effects in the static test. Its agreement with the pedar[®] system reinforces its reliability as a tool for measuring and managing plantar pressure, representing a promising solution for preventing plantar lesions.

Keywords: diabetic foot; health and safety; offloading; plantar pressure; pneumatic insole; ulcers; wearable sensors



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1. Introduction

The foot is a complex and essential structure of the human body that plays an important role in locomotion and balance, supporting the total weight of the body during daily activities [1]. While walking, forces equivalent to about one and a half times a person's body weight are transmitted through each step [2], thus making the feet susceptible to a series of problems, especially when imbalances occur in the distribution of plantar pressure. Therefore, foot health is essential for general well-being, and any change that generates plantar overload can lead to injury situations [1,2]. This topic is particularly important in the population living with diabetes mellitus, which currently affects about 536.6 million people worldwide and is forecast to affect 642.7 million by the year 2030. One of the most debilitating complications of this disease is the development of diabetic foot, a condition associated with an increased risk of ulceration and amputation in the lower limbs [3].

Several key differences between healthy and diabetic groups underscore the necessity of tailored interventions for individuals with diabetic foot. Healthy individuals typically possess normal skin sensitivity in their feet, enabling them to perceive pain, pressure, and temperature changes effectively. In the diabetic population, peripheral neuropathy, a common condition in this group, leads to a significant reduction in foot skin sensitivity, making patients unable to detect excessive pressures that would normally cause pain. As a result, pressure ulcers form, often in areas of increased plantar pressure, such as the heel and metatarsal areas [4]. According to several studies [5,6], the inability to properly redistribute plantar pressure in the feet exponentially increases the risk of severe ulcerations and subsequent infections, compromising not only immediate health, but also patients' quality of life over time [5–7]. Furthermore, individuals with diabetic foot pathology exhibit significant differences in foot biomechanics and plantar pressure distribution compared to healthy individuals. The loss of protective sensation caused by peripheral neuropathy often leads to altered gait patterns and an inability to detect excessive pressure or impending injury. These changes result in prolonged and uneven plantar loading, particularly in areas such as the heel and metatarsal heads, thereby increasing the risk of skin lesions, ulceration, and infection. Additionally, structural deformities, reduced joint mobility, and impaired microcirculation further compromise foot function and healing capacity. In contrast, healthy individuals retain intact sensory feedback, normal gait mechanics, and effective plantar pressure redistribution during locomotion and standing, which helps prevent tissue damage. These biomechanical and physiological disparities underscore the need for targeted interventions, such as pressure-redistributing insoles, specifically designed for at-risk populations [8,9].

Despite the regular monitoring that can be performed in people with diabetes [10,11], the risk of developing a pressure ulcer in the foot during their active life has a probability that can reach up to 34%, and the level of ulcer recurrence between the first and third year after cure is expected to be 40% and 60%, respectively [12]. Due to these factors, among others, predictions have been made that indicate that worldwide, there is an amputation every 20 s in patients with diabetic foot [13]. This implies a progressive degradation of the patient's quality of life, as well as imposing an important economic and financial burden on their families and society in general [3].

To mitigate the problems described, this work proposed the development of a system based on an innovative pneumatic insole. The primary aim is to develop and validate a pneumatic insole system capable of monitoring, stabilizing, and offloading plantar pressure, thereby addressing key limitations of existing solutions. To achieve this, the work focuses on four main technical goals: (i) the development of a plantar pressure data acquisition system; (ii) the implementation of a continuous monitoring mechanism that compares real-time pressure values against predefined thresholds; (iii) the design of a closed-loop control

strategy for plantar pressure regulation; and (iv) the creation of an active pneumatic insole capable of adjusting its internal pressure in real-time. Additionally, the work further aims to describe the design and fabrication processes of the insole and its electropneumatic control system, evaluate its effectiveness in redistributing and offloading plantar pressures through laboratory-based experimental testing under static and dynamic conditions, and critically analyze the results to identify current limitations and propose future improvements.

This document details the proposed system in Section 3. Here, the methodologies used in the development and manufacturing stages of the pneumatic insole are described, as well as the operation of the electropneumatic control system. In Section 4, to demonstrate the operation of the insole intervention when it is requested to act in the pressure offloading, a set of experimental laboratory tests was developed. The obtained results are described and partially discussed. Section 5 provides an overall discussion and highlights some of the identified limitations. Finally, Section 6 presents the main conclusions and discusses future work.

2. Related Work

One of the most debated solutions in the field of pressure ulcer prevention is the use of therapeutic and personalized footwear. Although user-adapted footwear design has advanced significantly in recent decades, many of the models available are passive, meaning they do not actively respond to changes in plantar loads that occur throughout the day [14]. As far as the authors' knowledge goes, the state of the art on active insoles is scarce. Very recently, system-level approaches have been proposed to regulate plantar pressure distribution according to clinically recommended thresholds, usually based on the most consensual threshold of 200 kPa [5] for the maximum permissible pressure in each area of the foot. These systems are based on magnetorheological fluids [15] and air-powered pneumatic mechanisms [16,17] to control the pressure offloading in cells distributed in an insole or directly on the sole of the user's shoe [15–17].

The work by Hemler et al. [15] presents the development of a plantar pressure relief system integrated into adaptive footwear, designed to prevent ulcers in patients with diabetes. This system uses sensors to continuously monitor pressures and a mechanism with modules containing magnetorheological fluids. When an exciting magnetic field is applied to the fluid, the modules change their stiffness to relieve plantar pressure. However, this system does not act on the toes or midfoot areas [15]. A more recent work by Erel et al. [16], as far as the authors are aware, is the only published work that shares similarities with the solution proposed here; it describes an insole designed to cyclically relieve plantar pressure for patients with diabetic foot. The insole is made of seven air cells distributed throughout the plantar region, four of which alternate controlled inflation and deflation, providing periodic pressure relief in specific areas. This system behaves similarly to an anti-bedsore mattress and aims to mitigate the repetitive stress and excessive load that contributes to the development of plantar ulcers in individuals with diabetic neuropathy [16]. In our previous study [17], we proposed a preliminary concept of an active in-shoe pneumatic insole intended for the prevention of plantar injuries. The findings suggested that an insole with four air-inflated cells (in the toes, metatarsals, lateral-midfoot, and heel regions) would be a viable solution, with air being the most suitable fluid to manage the volume of each cell to redistribute and offload plantar pressure [17]. Although the system proposed by Erel et al. [16] introduces an important approach to pressure relief through cyclic inflation and deflation of air cells, it presents several key limitations. First, the insole was tested in an open-toe sandal, which may compromise accurate pressure measurements, particularly in the forefoot area. This concern has been noted by the authors themselves, who recommend further studies using regular shoes. Second, the study lacks

detailed information regarding the pneumatic control unit, including its components, portability, and overall architecture. This omission makes it difficult to fully understand the system's design or replicate its functionality. Third, the system developed by Erel et al. provides only pre-programmed and uncontrolled cyclic inflation/deflation of the air cells, without incorporating any feedback mechanism or adaptive control. As such, it operates as a passive device, unable to respond to real-time plantar pressure data or clinical risk thresholds. This limits its capacity to deliver targeted, patient-specific pressure relief in dynamically changing conditions.

The challenge, therefore, lies in developing footwear solutions that not only provide greater comfort and reduce peak plantar pressure but also actively monitor and compensate for pressure during gait, thereby mitigating the risk of injury. According to recent research [15–17], footwear solutions with dynamic pressure redistribution systems can represent a promising advance in the prevention of diabetic foot injuries. The reported developments are motivated by the understanding that continuous and repetitive loading, particularly high peak pressure, is a major causal factor for foot ulcers, especially in individuals with diabetic neuropathy who may lack protective pain sensation. The aim is to relieve elevated pressures and minimize repetitive stress. The varied efficacy and limitations of existing interventions underscore the need for advanced, dynamic solutions that can actively manage pressure distribution. These efforts to develop active, adaptive, and potentially more user-friendly insoles or footwear clearly indicate a significant trend in research and development aimed at improving prevention strategies.

In addition to the benefits for patients with diabetes in particular, footwear equipped with active plantar pressure offloading systems can bring important advantages in the field of occupational safety and health. Workers who remain on their feet for long periods or who perform repetitive activities are particularly vulnerable to injuries from continuous stress, which not only affects their health but also compromises productivity due to higher absenteeism [18–20]. The development of footwear solutions that dynamically offload plantar pressure with real-time monitoring could be a solution to significantly reduce fatigue, increase comfort, and prevent musculoskeletal conditions.

In summary, the field of pressure ulcer prevention is increasingly focusing on the development of therapeutic and personalized footwear that can actively respond to changes in plantar loads. Recent advancements include dynamic pressure redistribution systems, such as air-powered pneumatic mechanisms and magnetorheological fluids, which aim to regulate plantar pressure to recommended thresholds. These systems, integrated into adaptive footwear or insoles, show promise in preventing diabetic foot injuries and mitigating repetitive stress for both patients with diabetes and workers who stand for extended periods. However, the current state of the art is still limited, and further research is needed to fully realize the potential of these active footwear solutions in reducing peak plantar pressure, enhancing comfort, and preventing injuries.

3. System Description and Manufacturing Process

To address the above-identified limitations, a novel solution is here proposed: a pneumatic insole system, with active offloading, integrated into a therapeutic shoe certified for diabetic foot care, and designed for both clinical and real-world use.

In this section, the methodology and manufacturing process of the all pneumatic insole system are described, starting with expected requirements (Section 3.1), followed by an overview of the system layout (Section 3.2), the pneumatic insole manufacturing process (Section 3.3), the methodology used for the pneumatic control unit (Section 3.4), and finally, the description of the system operation and interface (Section 3.5).

3.1. System Requirements

During the initial design stage, a set of requirements was defined to ensure the effectiveness and performance of the proposed variable pressure system. This is a crucial stage that ensures that operational characteristics cover both the technical specifications and the operating conditions of the device. Table 1 summarizes the most important prerequisites that were considered in the construction and implementation of the prototype of this system, ranging from quantitative to qualitative aspects. The selection of prerequisites was based on information obtained in other studies [4,13,15–17] in which various concepts for offloading plantar pressure in the diabetic foot are addressed, including systematic literature reviews [5,6,21], debates with health professionals specialized in diabetic foot pathology, and professionals in the footwear sector.

Table 1. Prerequisites for manufacturing the variable pressure system.

Prerequisite	Description
Uniform redistribution of plantar pressure	The system must be able to monitor plantar pressure in real-time and, based on this data and at a certain threshold, actively redistribute pressure to prevent injuries, improve comfort, and help with rehabilitation, especially in cases of diabetic foot ¹.
Maximum pressure threshold	A maximum pressure threshold of 200 kPa is the most consensual value described in the literature to avoid plantar overloads and injuries in people with diabetic foot [5,21]. The system must ensure, through a dedicated algorithm, that a certain pressure pattern above this threshold must activate the plantar pressure redistribution system. This threshold can also be customized and defined according to the user's needs and under the instructions of their attending physician [5] ¹.
Pressure adjustment mechanism	- The system must include a pneumatic mechanism capable of actively actuating and redistributing plantar pressure in response to measurements taken, through air cells in an insole made of deformable rubber materials ^{1,2}. - The pressure redistribution mechanism must respond to the algorithm conditions and the pre-established pressure threshold [5,21].
Technical specifications	- Coverage areas of the plantar region: heel, lateral-midfoot, metatarsals, and toes [4,13]. - Pressure range: 1 kPa to 1000 kPa [5,13]. - Resolution: 1 kPa ¹. - Pneumatic control: pressure sensors and solenoid valves [15–17]. - Autonomy: battery with minimum autonomy for 8 h of continuous use [6] ¹. - Interface and data collection: smartphone app [6] ¹. - Connectivity: Bluetooth Low Energy (BLE) [6].
Usability	- Portability: the pneumatic control unit must be portable so that it can be used throughout the day. Its attachment to the waist, for example, must not interfere with the user's mobility ¹. - Comfort and integration: the insole must be comfortable, flexible enough, and, if possible, able to be attached to different types of footwear, without compromising the effectiveness of the system ². - Ergonomics: the integration of the system into the footwear must be ergonomic, without compromising the comfort or functionality of the foot while walking ^{1,2}. - Safety: the system must be safe for the user, with protection against electrical failures and with emergency mechanisms that allow it to be switched off ^{1,2}.
Stability and durability	The materials used, such as pneumatic tubes, air cell structures, and other mechanisms, must be strong and durable enough to withstand the pressure involved ².
User interface	It should be carried out through a mobile application with a simple and intuitive interface so that the user (or physician) can monitor the conditions of the system and adjust parameters without technical complications. However, at this stage of prototyping, a basic commercial application already available can be used to record the measurements obtained. Later, the data analysis can be carried out [6] ¹.

¹ Also based on health professionals; ² also based on footwear experts.

3.2. Variable Pressure System Overview

The variable pressure system detailed in this study presents itself as an innovative solution for the active management of plantar pressure, integrating pressure sensors with real-time monitoring and pneumatic control. In summary, the system consists of a pneumatic insole equipped with four air cells and a pneumatic control unit, which includes a microcontroller with control electronics, an air pump, a set of pressure sensors, and solenoid valves. User interaction with the system is carried out via a graphical interface with wireless communication based on Bluetooth Low Energy (BLE). Figure 1 shows the representative scheme of the proposed variable pressure system.

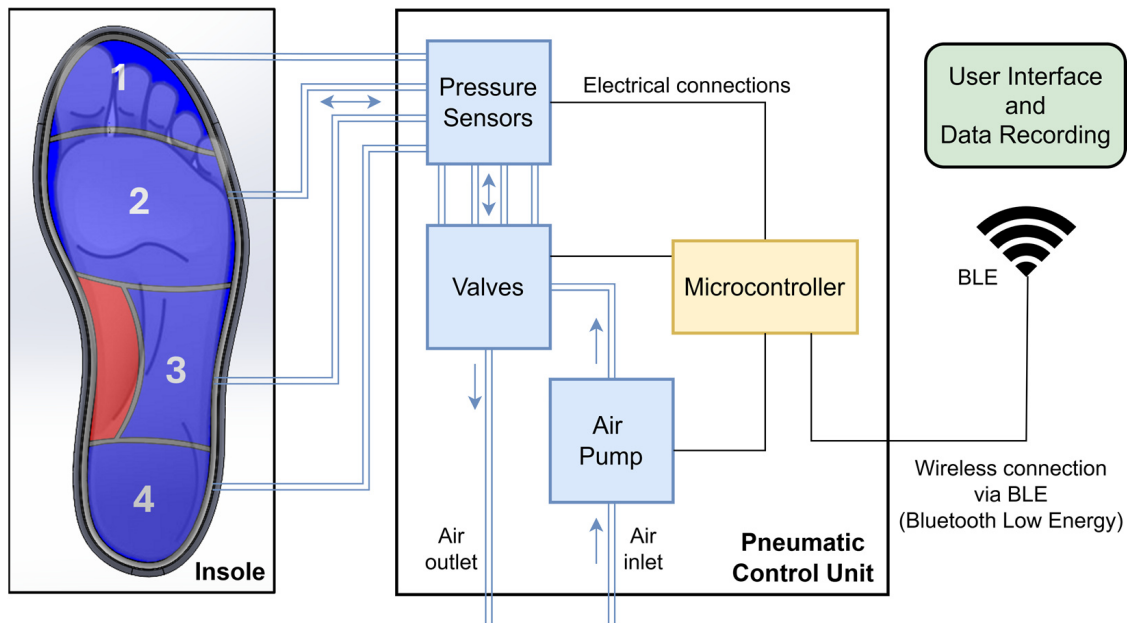


Figure 1. Representative scheme of the variable pressure system. Configuration of the insole air cells in the plantar region of the foot: 1—toes (cell 1); 2—metatarsals (cell 2); 3—lateral-midfoot (cell 3); 4—heel (cell 4); red zone—medial-midfoot (without cell).

The operating principle of the system is based on measuring the return air pressure from the cells to the sensors when the air cells are subject to compression by the areas of the foot they support, as illustrated in Figure 1. Pneumatic pressure sensors constantly measure the pressures applied to the plantar region of the foot during gait and, when pressure levels exceed the previously established threshold, a critical value for the appearance of plantar lesions, the system activates an automatic redistribution mechanism, actuating the solenoid valves to drain and adjust the air pressure in the different cells. An air pump can also be triggered to adjust the volume of air in each of the cells separately when needed. This continuous monitoring and adjustment process ensures that pressure is evenly distributed across the plantar region of the foot, reducing the likelihood of critical pressure points forming.

3.3. Insole Design and Manufacturing

The design of the pneumatic insole was developed with 3D modeling tools using computer-aided design (CAD) in SolidWorks (2024-SP5.0, Dassault Systèmes) software. The design process began with the general sizing of the insole, based on the design of a shoe sole designed for a foot size EU44 (Figure 2A). From this model, the insertion zones of the inflatable cells were created. The boundaries of each cell were created as a

function of the division of the plantar region of the foot by critical areas of greater clinical interest for plantar pressures and ulcer development [22]: cell 1, toes; cell 2, metatarsals; cell 3, lateral-midfoot; cell 4, heel. Additionally, and considering that the majority of the population has a normal foot type without abnormalities [23], in the medial-midfoot region, an area of the foot less stressed on impact during gait [24], a zone without air cell (red zone, Figures 1 and 2A) was created that serves as an intermediate support zone, providing stability and assisting as a point for additional load distribution. Each cell has been individually designed, with specific dimensions to ensure uniform redistribution of plantar pressure and to meet the biomechanical needs of the foot, with a compromise between the shape of the insole, the anatomical specificities of the foot, and comfort and flexibility. The configuration of the air cells distributed in the plantar region is illustrated in Figures 1 and 2A.

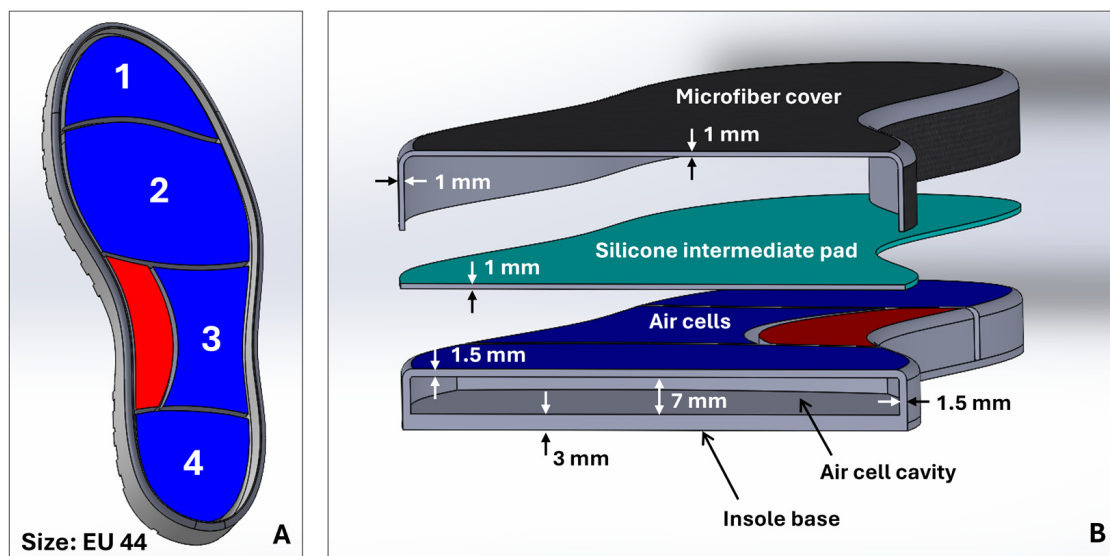


Figure 2. (A) Sole concept with layout of the air cells (numbered 1 to 4); (B) geometric characteristics of the air cell walls of the insole, silicone intermediate pad, and microfiber upper lining.

The structure that holds the insole's air cells was manufactured using a liquid rubber injection-molding process. Figure 2A,B show the concept view for the complete sole with the layout of the air cells and their main geometric features, respectively. It should be noted that the complete insole consists of three components (see Figure 2B): the structure with the air cell cavities, at the base of the insole; a silicone intermediate pad; and a microfiber top coating.

The upper lining of the insole is made of microfiber (onSteam®, Grupo Móron, Arnedo, Spain), which, like synthetic leather, is highly breathable and has the capacity to absorb up to eight times its weight in water. This microfiber, in addition to giving a soft finish to the insole, is also an element that promotes stability and prevents the foot from slipping. The silicone intermediate pad, added just below the microfiber, acts as an impact-absorbing layer and minimizes the potential risk of high-pressure points being generated at the locations of the walls that divide the air cells. This element was produced using a liquid silicone pouring mold (Ecoflex™ 00-50, Smooth-On, Macungie, PA, USA), a material that, once cured, is certified as skin safe. Finally, the structure that sits at the base of the insole and accommodates the air cells was produced using a low-pressure liquid rubber (VytaFlex™ 40, Smooth-On, Macungie, PA, USA) injection-molding process. For this process, molds were previously created by a high-resolution fused deposition modeling (FDM) 3D printing

technique, after which the liquid rubber was injected, and the respective curing process began. Table 2 provides details of the main characteristics of the liquid rubber and silicone used in the molding processes. Figure 3 shows the pneumatic insole produced and the shoe (Ortomedical, Doctor Karl, Vila do Conde, Portugal) into which it will be inserted. This shoe is certified as a medical device for diabetic foot, including, its inner lining and the upper coating (onSteam[®] microfiber, Grupo Mórón, Arnedo, Spain) of the insole are treated with silver ions, elements that give it antibacterial properties and minimize the possibility of odors inside the shoe.

Table 2. Characteristics of the materials used in the molding process to produce the insole structure.

Structure	Intermediate Pad	Insole with Air Cells
Material	Liquid silicone, Ecoflex [™] 00-50, Smooth-On	Liquid urethane rubber, VytaFlex [™] 40, Smooth-On
Application technique	Pouring	Pouring and low-pressure injection
Shore hardness scale ¹	00-50	40 A
Tensile strength ²	≈2.2 MPa	≈3.6 MPa
Elongation to break ²	980%	660%

¹ ASTM D2240 standard; ² ASTM D412 standard.

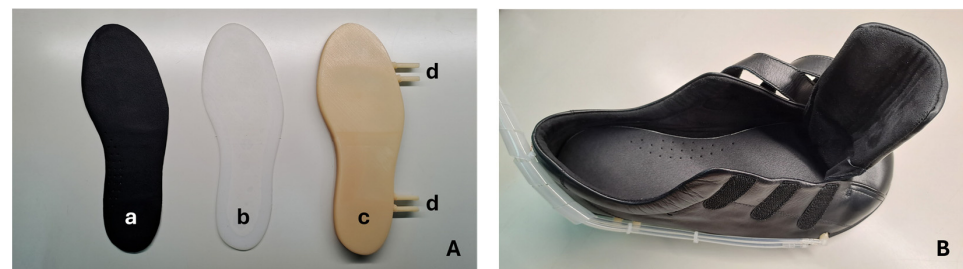


Figure 3. (A) Components that make up the pneumatic insole: (a) microfiber, (b) silicone intermediate pad, (c) rubber structure with air cells, and (d) connection points to pneumatic tubes; (B) pneumatic insole already inserted into a shoe (Ortomedical, Doctor Karl, EU44) and with the pneumatic connections.

3.4. Pneumatic Control Unit

The pneumatic control unit is divided into two parts that operate together: the control electronics, and the electropneumatic element. At the core of the electropneumatic element are the solenoid valves (0520D; 12 V DC; normally closed; FSPump), responsible for controlling the air inlet and outlet of each cell individually. The four inflatable air cells, individually connected to the control unit by 4 mm diameter silicone tubes, are managed by the control electronics, which automatically regulate the internal pressure by opening and closing the solenoid valves. These solenoid valves, together with pneumatic pressure sensors (XGZP6847D001MPG; 1 MPa; CFSensor) and a mini air pump (3202PM; 12 V DC; Makeblock), allow continuous monitoring and dynamic adjustment of the pressure, ensuring effective redistribution of air through the various areas of the insole. Although the pressure sensors come pre-calibrated from the factory, their measurements were further evaluated through a gauging process. Compressed air was applied, in various pressure ranges, and compared with the reference values of a precision pressure gauge. This process made it possible to confirm the quality of the measurements obtained and ensure reliability within the manufacturer's stated error margin ($\pm 2.5\%$ FSS). Additionally, the pressure sensors used in the system also measure temperature. This functionality allows to estimate the approximate temperature of the foot plantar region, which may be useful for complementary thermal monitoring, by measuring the temperature of the air returning from the inflatable air cells to the sensor.

A printed circuit board (PCB) was specifically designed for the system's control electronics (Figure 4). In addition to securely housing the pressure sensors, this PCB integrates three key components: a microcontroller (based on the ATmega328 chip), a power transistor module (ULN2803A), and a BLE wireless communication module (JDY34). The microcontroller operates the system's algorithm, which is responsible for processing the readings from the pressure sensors and sending commands to the higher-power peripheral elements through the transistor module, such as the mini-pump and the solenoid valves. Wireless communication via the BLE module facilitates interaction between the system and the user, which is carried out via a mobile application (Serial Bluetooth Terminal, version 1.48) on a smartphone, allowing the user to monitor and intervene with the system in real time. Additionally, an inertial measurement unit (IMU) (MPU6050) was integrated into the PCB to provide acceleration and orientation measurements. This additional information helps the microcontroller determine optimal timing for system adjustments, such as modifying air volume in the cells when the user pauses momentarily while walking. Together, these components ensure coordinated and efficient operation of the system, ensuring active redistribution of plantar pressure to minimize high-pressure events and increase safety.

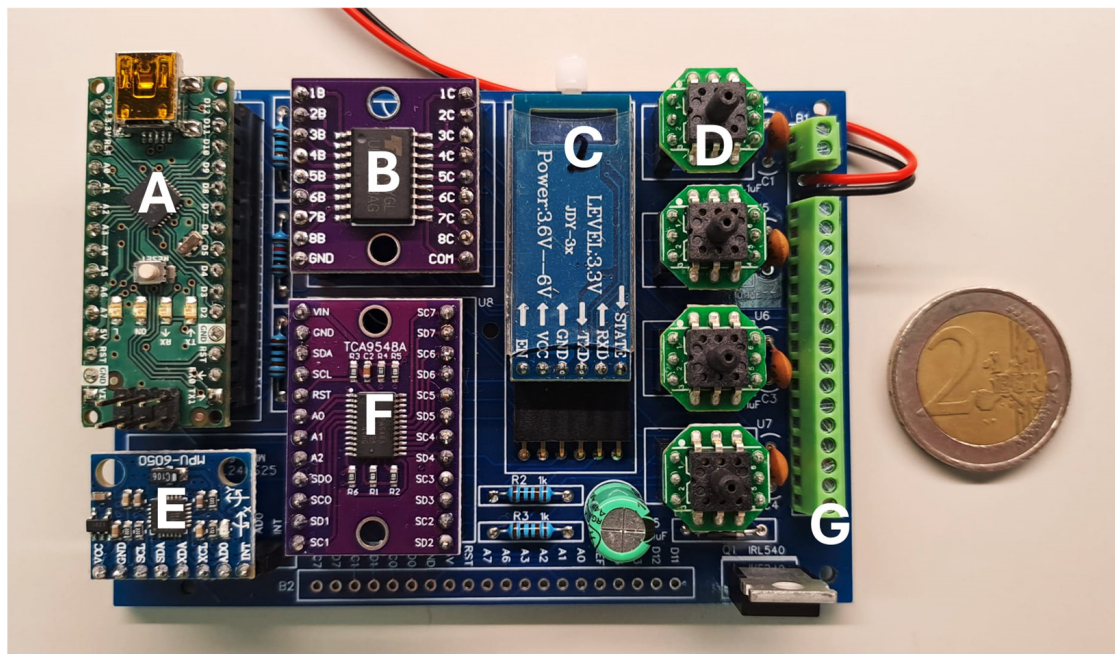


Figure 4. Printed circuit board for control electronics, consisting of: (A) microcontroller; (B) integrated circuit with power transistors; (C) BLE module; (D) pressure sensors; (E) IMU module; (F) I2C multiplexer for communication with peripherals; (G) connector bar.

Figure 5 shows the different phases of the pneumatic control unit assembly process, using the components mentioned above and through 3D printing processes. To ensure portability, this unit can be powered by a battery (12 V DC; 18650 Li-ion; 3S1P; 9900 mAh). The control unit's support box was 3D printed (in PLA by the FDM process) and designed so that it can be easily carried on the user's waist. Once attached to the waist, the silicone tubes go down the leg to the shoe, where they connect to the insole. This design, although still preliminary, facilitates access to electronic and pneumatic components, without compromising the user's natural mobility to carry out any gait tests.

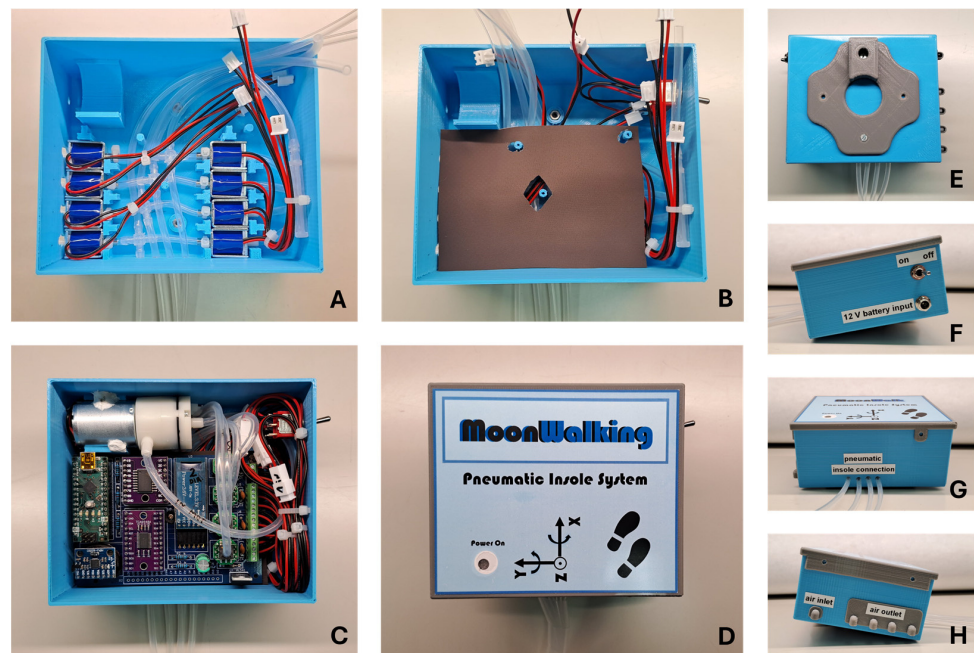


Figure 5. Assembly process of the pneumatic control unit: (A) Solenoid valves with derivations and connection to silicone tubes; (B) insulation between PCB and solenoid valves; (C) PCB, air pump and connections; (D) front view of the closed box; (E) rear view with waist fastening clip; (F) right side view with battery connector and switch; (G) lower view with connecting tubes to the insole; (H) left side view with one inlet and four air outlets.

3.5. Operation and Interface

The proposed variable pressure system is prepared to operate in an automated way, based on a dedicated algorithm that responds in real-time to changes in plantar pressures throughout the gait. Pneumatic pressure sensors continuously monitor and record measurements of pressure values with a frequency of 15 Hz. The algorithm processes these measurements and, based on a predefined pressure threshold, sends commands to the exhaust solenoid valves to adjust the volume of air in the inflatable cells. This real-time response is based on the plantar pressure monitoring process, whereby simultaneous measurements are acquired from all four cells in the plantar region with a sampling rate of 15 Hz; that is, the system records 60 samples per second (15 for each cell/region per second). Using this data, and based on the programmed algorithm, the pneumatic control system acts to regulate the pressure in the air cells. This process can take up to 100 ms (from pressure threshold detection to offloading response) and can be executed as many times as necessary until the desired threshold is reached, or until the air volume of a given cell reaches the minimum level for it to remain functional. This method aims to redistribute pressure through the four strategic zones of the insole (heel, lateral-midfoot, metatarsals, and toes) whenever a pressure pattern higher than the 200 kPa threshold (or other pre-configured) is identified, known as the critical point of overload for the appearance of plantar lesions in people with diabetic foot [5,21].

The objective is that the pressure redistribution promotes the offloading at points where high-pressure peaks originate, thus standardizing the pressure throughout the plantar region. However, if it is impossible for the system to offload pressure below 200 kPa, other approaches can be used. For example, the pressure in the regions where the highest-pressure peaks originate can be reduced by 25% [21], an alternative also used in plantar pressure reduction strategies in diabetic foot. It is worth mentioning that there

are healthy people without risk of injury who sometimes register plantar pressure values above the 200 kPa threshold [5]. In any case, so that the variable pressure system can be as comprehensive as possible, the pressure threshold can be configured and adapted to the user's real needs. For example, in the case of diabetic foot, setting a certain threshold may be recommended by the patient's attending physician. Figure 6 shows a flowchart that illustrates the mode of operation of the algorithm for the 200 kPa threshold, the most consensual, although other thresholds can be configured.

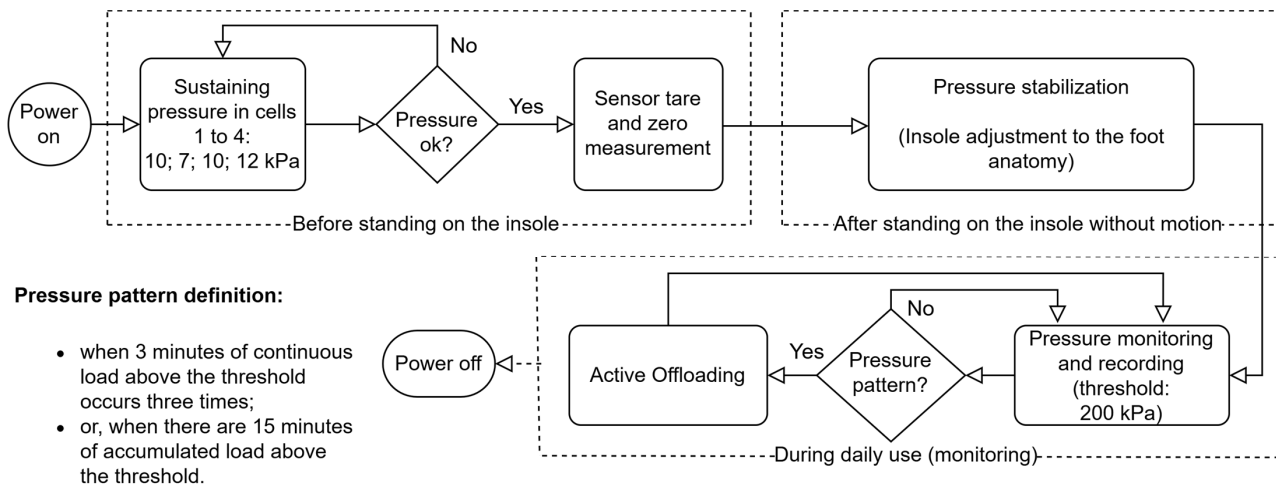


Figure 6. Variable pressure system operation algorithm based on a critical pressure threshold.

As shown in Figure 6, one of the key functionalities is the initial pressure adjustment process to inflate each cell of the insole. When the system is turned on, each cell is pressurized with an adequate sustaining pressure: toes, 10 kPa; metatarsals, 7 kPa; lateral-midfoot, 10 kPa; heel, 12 kPa. These values were obtained for a user with a mass of 79 kg, based on empirical tests, and are adequate to avoid the total sinking of the cells. Comfort and some cushioning, air volume and area of each cell (shoe size EU44: toes, 28 cm²; metatarsals, 74 cm²; lateral-midfoot, 36 cm²; heel, 34 cm²) were also considered, as well as an approximation of the distribution of body weight across the different zones of a normal foot when static (toes, 10%; metatarsals, 30%; midfoot, 10%; heel, 50% [25]).

After the initial phase of adjusting the sustaining pressure of the cells, the measurement zero for the sensors is recorded. Once the user is standing on the shoe, the system performs a pressure stabilization process to ensure an even distribution of air in the four inflatable cells of the insole. This adjustment aims to adapt the system to the specific anatomy of the user's foot while they are still standing on the insole, before starting to walk. This step allows any high-pressure points to be dissipated, maintaining a balanced redistribution of pressures throughout the plantar region of the user's foot. During this process, the air inlet solenoid valves open, bringing the four cells into communication, causing the user's body weight to promote airflow and the volume in each cell to be automatically adjusted. This initial balance promotes adaptation to the anatomy of the foot and ensures that no area suffers an overload or excessive pressure, preventing potential discomfort and injury.

The pressure offloading process in each air cell is carried out by the exhaust solenoid valves, which drain small fractions of the volume of air present in the inflatable cells in a controlled manner until a pressure value is reached as close as possible to the recommended level. On the other hand, the air pump acts when it is necessary to inject air to restore pressure in a certain cell. This dynamic adjustment happens without direct user intervention, which makes the system autonomous and responsive. Redistribution (pressure offloading

from a given region) occurs whenever the system detects a pattern of abnormal pressures (based on the algorithm in Figure 6), ensuring that air is relocated in a way that minimizes high-pressure points that can lead to the development of pressure ulcers or other injuries. However, for pressure corrections that require it, for example due to the user's accelerated speed, the system can alert the user to stop walking so it can more accurately correct the air volume of the cells. This procedure is only possible with the support of the data provided by the IMU, which will indicate the user's state of movement; that is, whether the user is stationary and standing in the same position as during the initial moment of pressure stabilization. It should be noted that the capacity for pressure offload is limited by the volume of air inside each cell. When it is not possible to drain more air (each cell needs a quantity of residual air so that they do not sink and for the sensor to be operational), it will also not be possible to relieve more pressure in that region of the foot. In these cases, the system records this event and issues an alert to inform the user. In summary, our approach enables the real-time definition and monitoring of clinically established pressure thresholds, facilitating targeted offloading in specific plantar regions while concurrently tracking potential pressure increases in adjacent areas. This dynamic regulation ensures a balanced and controlled redistribution of plantar pressure, minimizing the risk of new overload points. This pressure management sub-strategy is illustrated in Figure 7 and represents a subroutine of the "Active Offloading" event shown in Figure 6.

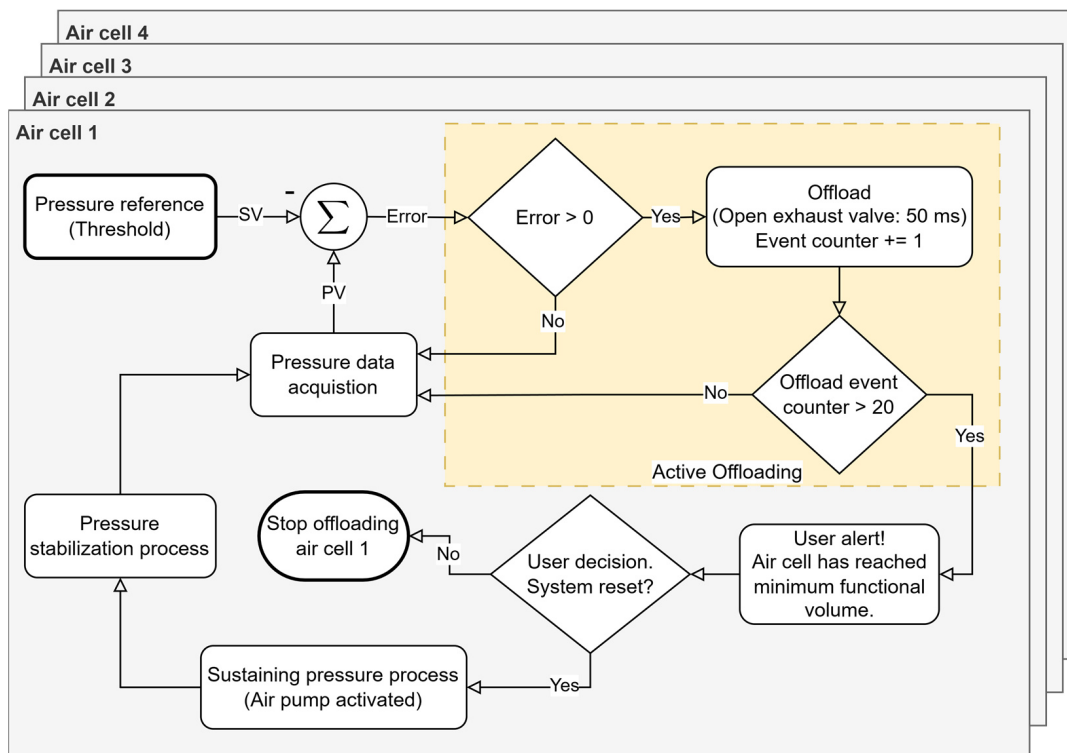


Figure 7. Independent control loop for each air cell pressure regulation (represented by overlaid squares). The pressure reference is based on clinical guidelines, but it can be independently adjusted and personalized for each foot or patient condition. SV, setpoint value; PV, process value.

In addition to the algorithm handling the data in real-time for its decision-making, it is possible to interact with the system to collect and record data. This is carried out through a mobile application (Serial Bluetooth Terminal, version 1.48) for smartphones, which communicates through BLE. This application allows the user to follow the measurements

in real-time and adjust some basic system settings, such as small adjustments in the volume of air in the cells for better comfort, as well as turning the system on and off. As described earlier, the pneumatic control unit will be attached to the user's waist, with the silicone tubes being connected to the insole that is inserted into the shoe. Figure 8 shows a user equipped with the system.



Figure 8. User equipped with the variable pressure system: (A) pneumatic control unit attached to the waist; (B) final appearance of the shoe (Ortomedical, Doctor Karl, EU44) with pneumatic insole.

4. Experimental Tests

In this section, the methodology used in the experimental tests (Section 4.1) and in the statistical analysis of the data obtained (Section 4.2) is described. Finally, in Section 4.3, the results obtained in the static and dynamic tests and in the pneumatic insole validation are presented.

4.1. Test Protocol

The preliminary tests involved a healthy participant (male, 79 kg) wearing a pair of shoes (Ortomedical, Doctor Karl, EU44) equipped with the pneumatic insole on the right foot (see Figure 8). In these tests, only the right foot was evaluated. However, to provide stability to the participant, a similar pneumatic insole, pressurized and sealed with the pre-established sustaining pressure for each cell (the same for both feet, as indicated in Section 3.5. Operation and Interface) was added to the left shoe. To validate the measurements obtained by the pneumatic insole, the pressures at the interface with the foot were obtained through a commercial system considered the gold standard for the measurement of in-shoe plantar pressure (pedar[®] insole; sampling rate of 100 Hz; measuring range from 15 kPa to 600 kPa). The variable pressure system collected pressure data from the pneumatic insole at a sampling rate of 15 Hz, with the pressure values rounded to the unit and a measurement uncertainty of ± 1 kPa. Its measuring range is from 1 kPa to 1000 kPa with a resolution of 1 kPa.

To measure the participant's plantar pressure, the pedar[®] insole was superimposed on the pneumatic insole and both were inserted into the shoe. As the pedar[®] insole consists of 99 sensors, and to record the pressure for each area of the foot corresponding to each air cell of the pneumatic insole, a division of the sensors was carried out by each of the four regions of the foot. Figure 9 illustrates the correspondence between the measurement areas of both systems.

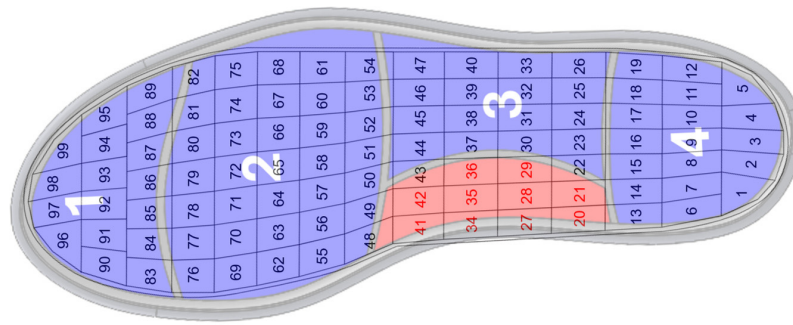


Figure 9. Layout of the pedar® insole sensors superimposed on the pneumatic insole and corresponding to the regions of the foot defined by the air cells. Toes (zone 1): sensors 83 to 99; metatarsals (zone 2): sensors 48 to 82; lateral-midfoot (zone 3): sensors 22 to 26, 30 to 33, 37 to 40, and 43 to 47; Heel (zone 4): sensors 1 to 19.

The participant was evaluated under two test conditions: static and dynamic. For the static tests, the individual remained standing with the shoes on, in a natural way, and with both feet on a rigid surface (laboratory floor), flat and level, for one minute. During this period, plantar pressure data were collected. This procedure was performed with and without pressure stabilization, as previously described in Section 3.5. Operation and Interface. For the dynamic tests, the conditions were like the static tests, although in this case, the participant walked on a level treadmill at a constant speed of 3 km/h for one minute. Additionally, in both test conditions, a simulation of the heel pressure offloading was performed (without considering any specific threshold) with a command sent to the system to trigger the event in the respective air cell. It should be considered that, in both types of tests, time intervals were selected as reasonable time frames for data collection and to verify the effects of plantar pressure; however, these periods have no direct relevance to any clinical requirements. Likewise, the speed selected for the dynamic tests was only chosen to ensure a smooth and paused gait, like a regular walk.

4.2. Data Analysis and Statistics

During the analysis of the data obtained, the following terminology was considered to classify some parameters under study: interface pressure (IP): for each air cell of the pneumatic insole, the interface pressure for each region of the foot is measured by the pedar® insole and calculated based on its sensors corresponding to the area of each selected air cell (see Figure 9), summing the pressure data of all sensors and dividing by the number of sensors; average interface pressure (AIP): due to the natural variation of the IP at each measurement instant during the gait cycle and in static mode (although much smaller), the AIP for a given measurement period can be obtained by taking the average of the IP values that are recorded at each instant; peak pressure (PP): The highest reading of a given pressure sensor for each area of the pneumatic insole is designated as the peak pressure of that area.

Non-parametric tests were selected for the statistical analysis to compare paired samples. The Wilcoxon test was used to determine the statistical difference in the pressure data of the interface (pedar® insole) before and after the pressure stabilization procedure in the pneumatic insole, as well as before and after the pressure offloading, during the static and dynamic tests. To ensure a 99% confidence level, a p -value < 0.01 was considered statistically significant. The collected data was processed and organized in Excel files, and all statistical analysis was developed in Python (version 3.10).

The conducted tests also aimed to validate the variable pressure system as a viable alternative to existing plantar pressure measurement devices. For this purpose, and consid-

ering the pedar[®] insole as the gold standard in the market, the Bland–Altman method was used to evaluate the level of agreement and equivalence of the pneumatic insole results to assess if it is reliable. For a correct comparison of the two measurement systems, and due to the difference in the sampling rate, a downsampling of the pedar[®] insole was performed; that is, each measurement obtained by the pneumatic insole corresponds to an average of seven samples of the pedar[®] insole.

4.3. Results

4.3.1. Static Tests

The IP and AIP values were analyzed for each region of the pneumatic insole during the tests in static mode. Table 3 presents the AIP values recorded, comparing them under different conditions, before and after the pressure stabilization process, and before and after the heel pressure offloading process. This last pressure offloading procedure was only performed once, and also because the heel is the region identified as the foot area supporting the greatest body weight and, consequently, the region with the greatest pressure. Variations in plantar pressure after the activation of the pressure stabilization and offloading procedures were analyzed. Figure 10 shows an illustration of the evolution of pressure values obtained by the pedar[®] insole before and after the different interventions of the pneumatic insole under the various test conditions.

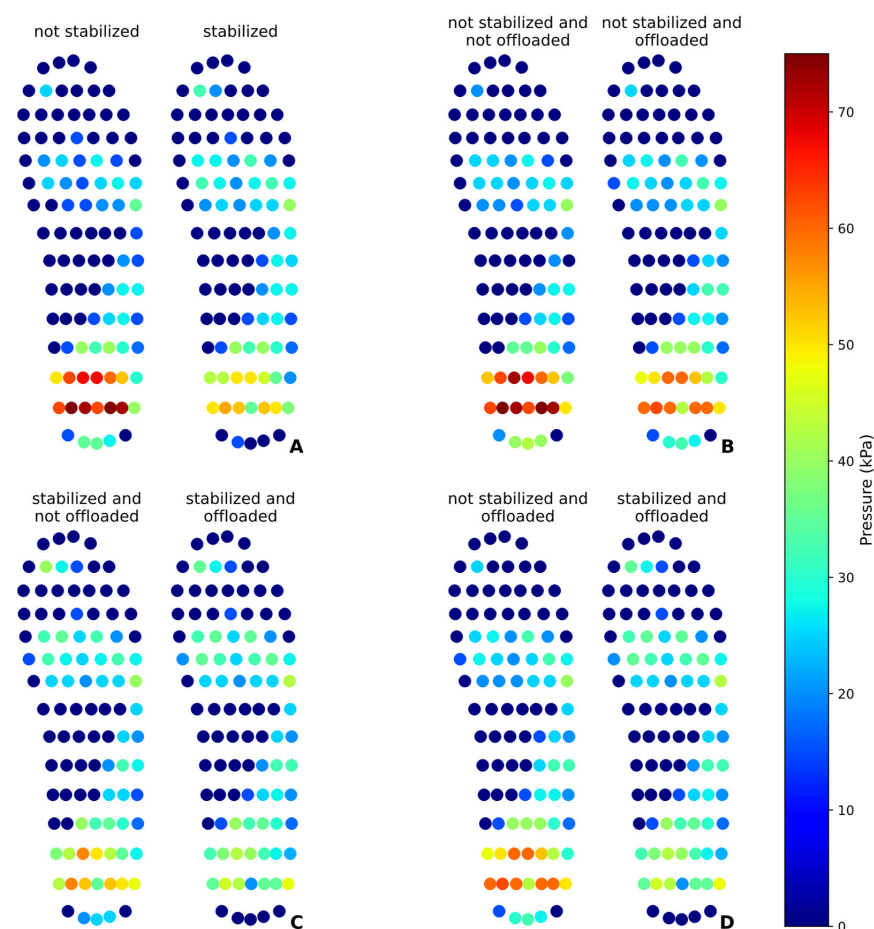


Figure 10. Interface pressure (IP) maps at a time before and after each intervention of the pneumatic insole in the heel region in static mode: (A) effect of pressure stabilization; (B) effect of pressure offloading without stabilization; (C) effect of pressure offloading, previously stabilized; (D) effect of stabilization on the pressure offloading process.

Table 3. Average interface pressure (AIP) recorded by the pedar[®] insole in the static tests before and after the pneumatic insole interventions. The pressure stabilization process was carried out for all regions of the foot, and the offloading only at the heel.

Effect	Status		Foot Zones	Average Interface Pressure AIP $\pm$ SD (kPa)		Variation Before vs. After		<i>p</i> -Value
	Before	After		Before	After	(kPa)	(%)	
Stabilize	Not stabilized	Stabilized	Heel:	49.58 $\pm$ 3.99	33.50 $\pm$ 0.76	−16.08	−32.43	<0.001
			Midfoot:	20.48 $\pm$ 2.47	21.09 $\pm$ 0.52	0.61	3.00	<0.001
			Metatarsals:	11.39 $\pm$ 1.56	14.52 $\pm$ 0.29	3.13	27.53	<0.001
			Toes:	2.51 $\pm$ 0.37	3.69 $\pm$ 0.46	1.18	46.98	<0.001
Offload	Not stabilized	Not stabilized and offloaded	Heel:	52.81 $\pm$ 0.90	45.36 $\pm$ 1.06	−7.45	−14.10	<0.001
			Midfoot:	18.88 $\pm$ 0.57	22.07 $\pm$ 0.88	3.18	16.86	<0.001
			Metatarsals:	12.23 $\pm$ 0.38	13.36 $\pm$ 0.42	1.13	9.22	<0.001
			Toes:	1.28 $\pm$ 0.14	1.36 $\pm$ 0.15	0.08	6.44	<0.001
Offload	Stabilized	Stabilized and offloaded	Heel:	36.79 $\pm$ 0.91	26.20 $\pm$ 1.67	−10.19	−27.69	<0.001
			Midfoot:	19.92 $\pm$ 0.49	21.28 $\pm$ 0.57	1.36	6.81	<0.001
			Metatarsals:	15.31 $\pm$ 0.32	16.87 $\pm$ 0.64	1.56	10.18	<0.001
			Toes:	4.86 $\pm$ 0.29	5.01 $\pm$ 0.59	0.15	3.08	<0.001
Stabilize and offload	Not stabilized and offloaded ¹	Stabilized and offloaded ¹	Heel:	45.36 $\pm$ 1.06	25.98 $\pm$ 1.16	−19.38	−42.72	<0.001
			Midfoot:	22.07 $\pm$ 0.88	21.25 $\pm$ 0.63	−0.81	−3.69	<0.001
			Metatarsals:	13.36 $\pm$ 0.42	17.11 $\pm$ 0.55	3.75	28.07	<0.001
			Toes:	1.36 $\pm$ 0.15	5.15 $\pm$ 0.65	3.79	278.11	<0.001

¹ Additional test to verify if stabilization process influences pressure offloading. Note: negative values indicate a reduction.

Analyzing the data in Table 3, it is possible to observe that all results were considered statistically significant (p -value < 0.01), proving that there is an evident difference in the AIP before and after the intervention of the pneumatic insole. The pressure stabilization process proved to be effective as a mechanism for redistributing plantar pressure as a function of foot morphology, while reducing pressure in areas of higher concentration and distributing a portion to other areas. After this process, it was found that the heel (area of higher-pressure concentration) pressure reduced by about 32.43%, and the areas that supported the effect of this reduction were mainly toes and metatarsals, where there was a compensatory increase in pressure. This is an expected behavior, as the body weight is constant and only the pressure is redistributed throughout the plantar region, minimizing any critical points of pressure accumulation. The results obtained are also promising for the pressure offloading procedure, demonstrating effective reduction in AIP following heel pressure offloading intervention, regardless of whether the initial pressure stabilization was performed. When the data is compared without any action having been taken beforehand and after the initial stabilization of the pressure and subsequent offloading, the reduction in pressure on the heel is also very evident. Under these conditions (additional test, marked with ¹ in Table 3), the reduction came to about 42.72%, where, naturally, the toes and metatarsals once again absorbed part of this portion of reduction. Figure 10 illustrates the pressure reduction results across various test conditions, with the recording of the IP values immediately before and after the respective interventions.

4.3.2. Dynamic Tests

In the dynamic tests, plantar pressure values were recorded with the participant walking on a leveled treadmill at a constant speed of 3 km/h. During walking, the interface pressure was recorded and analyzed for each region of the foot. As this is a dynamic gait test, and as the aim is to evaluate plantar pressures, this analysis only considered the stance phase, not considering the swing phase (foot raised) in which no pressure value is recorded or is very close to zero. Table 4 summarizes the AIP values, highlighting the differences before and after the activation of the pressure offloading mechanism, and its effect was

evaluated without and with the action of the initial pressure stabilization by the four air cells of the pneumatic insole. Like the static tests, and for the same reasons, the pressure offloading intervention was only performed once in the heel area.

Table 4. Average interface pressure (AIP) recorded by the pedar[®] insole in the dynamic tests before and after the pneumatic insole interventions. The pressure stabilization process was carried out for all regions of the foot, and the offloading only at the heel.

Effect	Status		Foot Zones	Average Interface Pressure AIP $\pm$ SD (kPa)		Variation Before vs. After		<i>p</i> -Value
	Before	After		Before	After	(kPa)	(%)	
Offload	Not stabilized	Not stabilized and offloaded	Heel:	77.11 $\pm$ 32.19	75.56 $\pm$ 26.25	−1.55	−2.00	<0.001
			Midfoot:	37.93 $\pm$ 9.56	41.41 $\pm$ 9.37	3.48	9.18	<0.001
			Metatarsals:	44.07 $\pm$ 19.30	43.89 $\pm$ 18.49	−0.18	−0.40	0.7055 ¹
			Toes:	42.69 $\pm$ 15.74	38.53 $\pm$ 16.17	−4.16	−9.74	<0.001
Offload	Stabilized	Stabilized and offloaded	Heel:	91.49 $\pm$ 28.36	68.86 $\pm$ 32.42	−22.62	−24.73	<0.001
			Midfoot:	43.31 $\pm$ 9.47	42.33 $\pm$ 12.70	−0.97	−2.24	0.1343 ¹
			Metatarsals:	39.36 $\pm$ 19.60	53.57 $\pm$ 17.44	14.21	36.10	<0.001
			Toes:	38.87 $\pm$ 20.42	51.65 $\pm$ 17.82	12.77	32.86	<0.001

¹ Not significant, *p*-value > 0.01. Note: negative values indicate a reduction.

The data in Table 4 reveal a heterogeneous nature intrinsic to the different phases of human gait movement. The large standard deviation, indicating substantial dispersion in the measurements, reflects the varying plantar pressure amplitudes that occur during different impact and stress moments across foot regions throughout the participant's walking cycle. Although the test data indicate a trend towards reduced pressure in the intervention area (heel), not all changes recorded in the other areas were considered statistically significant. However, it is important to highlight that the intervention to reduce pressure in the heel produced an effect, especially in the conditions in which the pressure stabilization procedure was performed prior to the pressure offloading event. In this situation, the heel region was offloaded to approximately 24.73% of its previous pressure. This reveals that the stabilization process can be an important factor for better pressure offloading.

Naturally, and due to its characteristics, during the movement of human gait, plantar pressure measurements are very dispersed. Thus, in this dynamic mode, it may also be important to assess whether the peak pressure decreased in intensity after the pressure offloading event. Figure 11 reveals this, indicating that there was indeed a reduction in the intensity of the peak pressure in the heel area where the intervention was carried out. In addition to the heel, there was also a reduction in the metatarsal and toe areas. In the midfoot region, there was an increase in peak pressure, and this zone was the one that absorbed the effect of the peak pressure reduction caused in the other regions in the dynamic tests.

4.3.3. Pneumatic Insole Validation

To validate the pneumatic insole and evaluate its level of reliability in plantar pressure measurements, with a confidence level of 95%, both in static and dynamic conditions, Bland–Altman graphs were produced comparing the pressure values measured by the two systems (pedar[®] insole vs. pneumatic insole). Figures 12 and 13 present the results obtained in the static and dynamic tests, respectively, for the different regions of the foot, allowing us to verify the level of agreement and the presence of any systematic biases. With the level of confidence conferred by the Bland–Altman method, both in the static and dynamic tests, it can be stated that the pneumatic insole (all of the variable pressure system) shows over 90% agreement with the pedar[®] insole. Considering all regions of the foot, an overall agreement of 96.32% and 94.02% is obtained for the static and dynamic tests,

respectively. For a better interpretation of the graphs, it is important to consider that if the difference between measurements is positive, it means that the pedar[®] insole has measured pressure values higher than those measured by the pneumatic insole. If the difference is negative, it means that the pedar[®] insole has measured values lower than those recorded by the pneumatic insole.

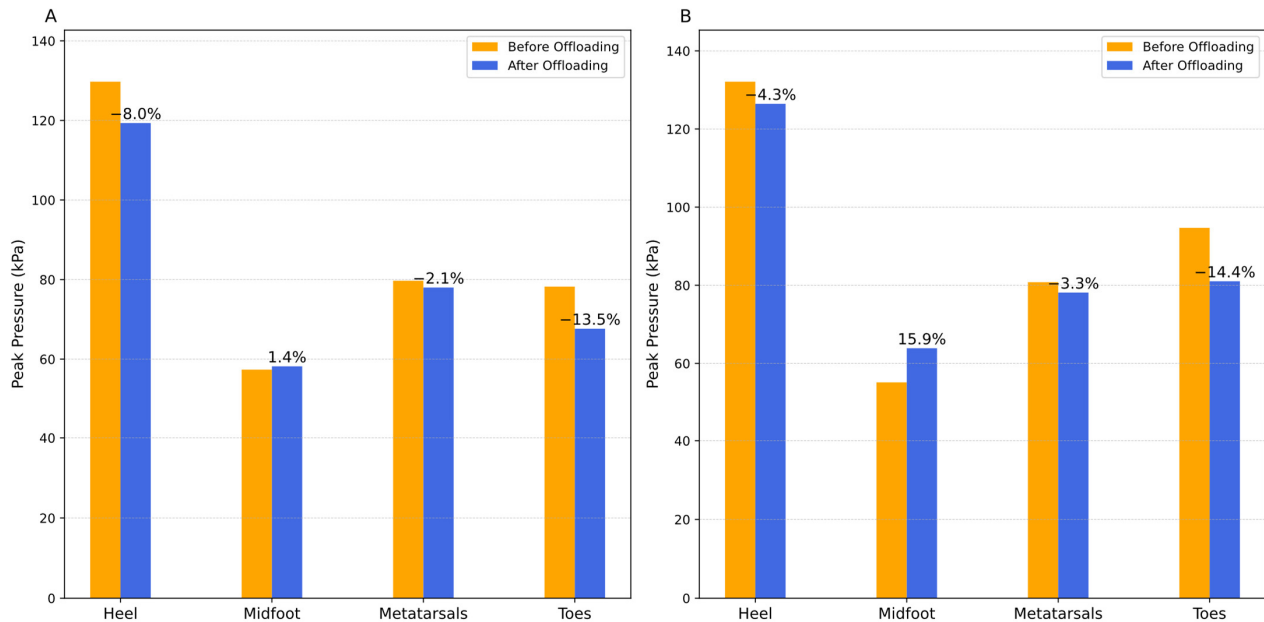


Figure 11. Intensity of plantar peak pressures before and after the heel pressure offloading event, with the percentage recording of their effect on the different regions of the foot in the dynamic test: (A) without prior stabilization procedure; (B) with prior stabilization.

For the static test (Figure 12), it is observed that some zones, such as the metatarsals, the midfoot, and the heel, present a particular pattern with several diagonal data bands. Although most of the data are within the limits of agreement, this type of pattern in some zones may indicate that the differences between measurements present a systematic bias dependent on the magnitude of the pressure value; however, the same trend is not always revealed. For example, if at a given time a measurement system tends to overestimate high values and underestimate low values, or vice versa, for the same average value of a given measurement, it can result in differences that do not follow the same trend, increasing or decreasing. It should be noted that in this static test, all the average bias lines present negative values, which indicates that, on average, the pedar[®] insole measured lower values than the pneumatic insole. However, the lower and upper limits are very close, which is a good indicator. Still analyzing the validation of the pneumatic insole during the static test, it is observed that the toes graph appears to have few data points. In fact, measurements in this region of the foot show very low-pressure values and practically no variation in the two measurement systems, resulting in several equal average values. It is also verified that the higher the pressure value, the greater the difference, with a negative trend, which indicates that the values measured by the pedar[®] insole are lower than those measured by the pneumatic insole. This is because, effectively, the pedar[®] insole only measures pressure from 15 kPa, and as the range of measurements in this region of the foot in static mode are mostly below that magnitude, a large proportion of the error is associated with the limited measurement range of the pedar[®] insole for lower pressures.

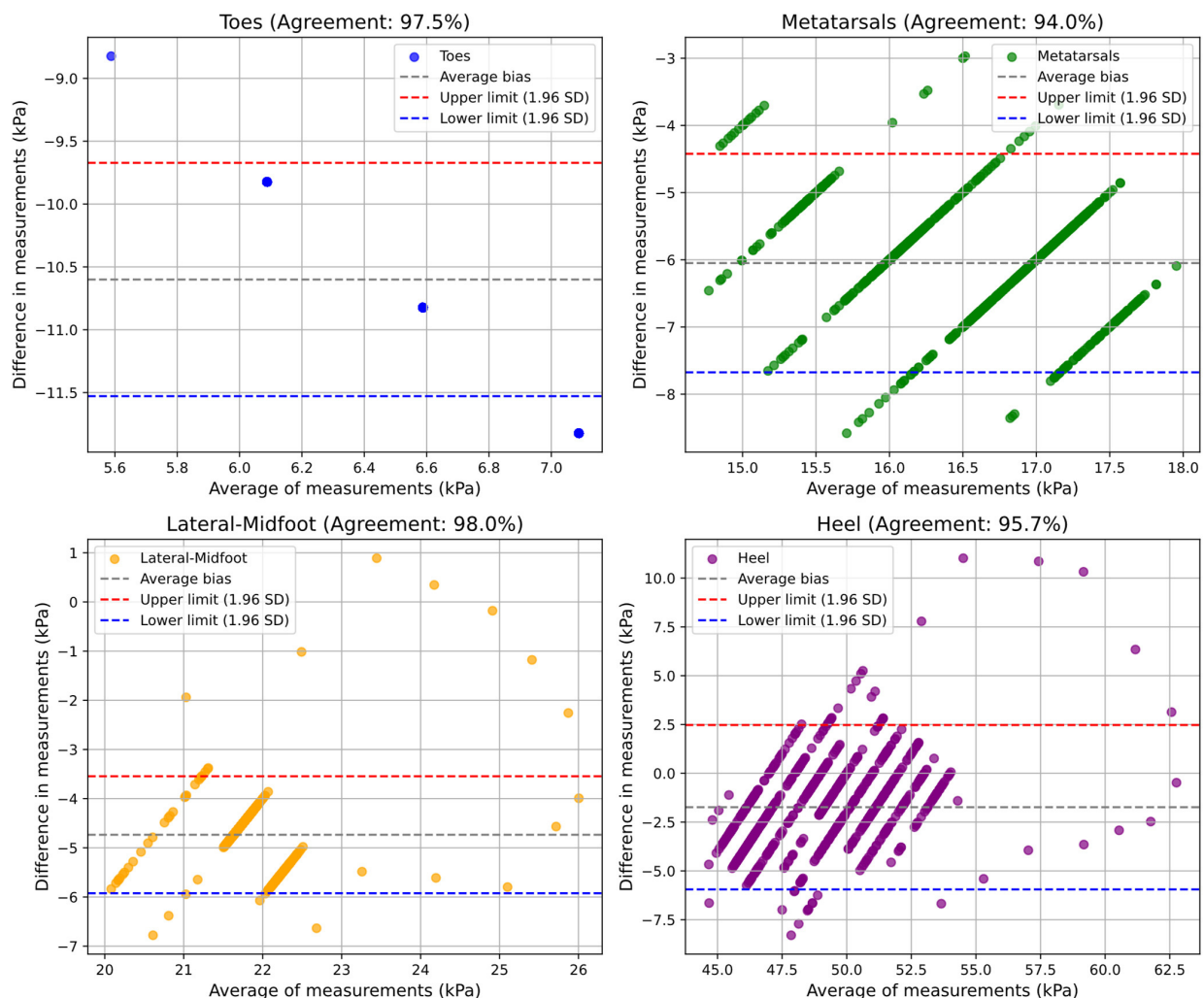


Figure 12. Agreement level evaluation of plantar pressure measurements obtained with the pneumatic insole (pedar® vs. pneumatic insole) during the static test conditions.

For the dynamic test (Figure 13), it was observed that for all regions of the foot, except for the metatarsals, with the increase in the pressure value, the difference in measurements tends to be positive, meaning that under these conditions, the pedar® insole registered higher values than the pneumatic insole. Even so, the lower and upper limits are close, and the average bias is very close to zero for all regions of the foot, which confers excellent levels of agreement: 91.2% for the toes region, 93.4% for the metatarsals, 94.9% for the heel, and 96.6% in the lateral-midfoot region. A closer analysis of these results shows that in some regions, evident clusters of values are formed for pressures at the extremes, sometimes for lower pressures, sometimes for higher pressures. This characteristic is more evident in the lateral-midfoot region, and the formation of these two clusters is due to moments of load transition during gait. For example, the cluster for the highest pressure is mainly formed at the body weight first impact instance in that air cell, or in the propulsion phase (for example, in the toes region). This sequence of events, which begins at the heel, is then propagated through all the plantar regions of the foot, although with different pressure magnitudes. The cluster for lower pressures is mainly formed during the plantar support phase, where the pressures are distributed and the intensity, which could be concentrated in a single region, is now starting to be reduced due to the pressure redistribution throughout

the plantar region. For this cluster, there is also the contribution of the drastic reduction in pressure when the foot is in the lift-off at the moment of load transition between the two feet during gait.

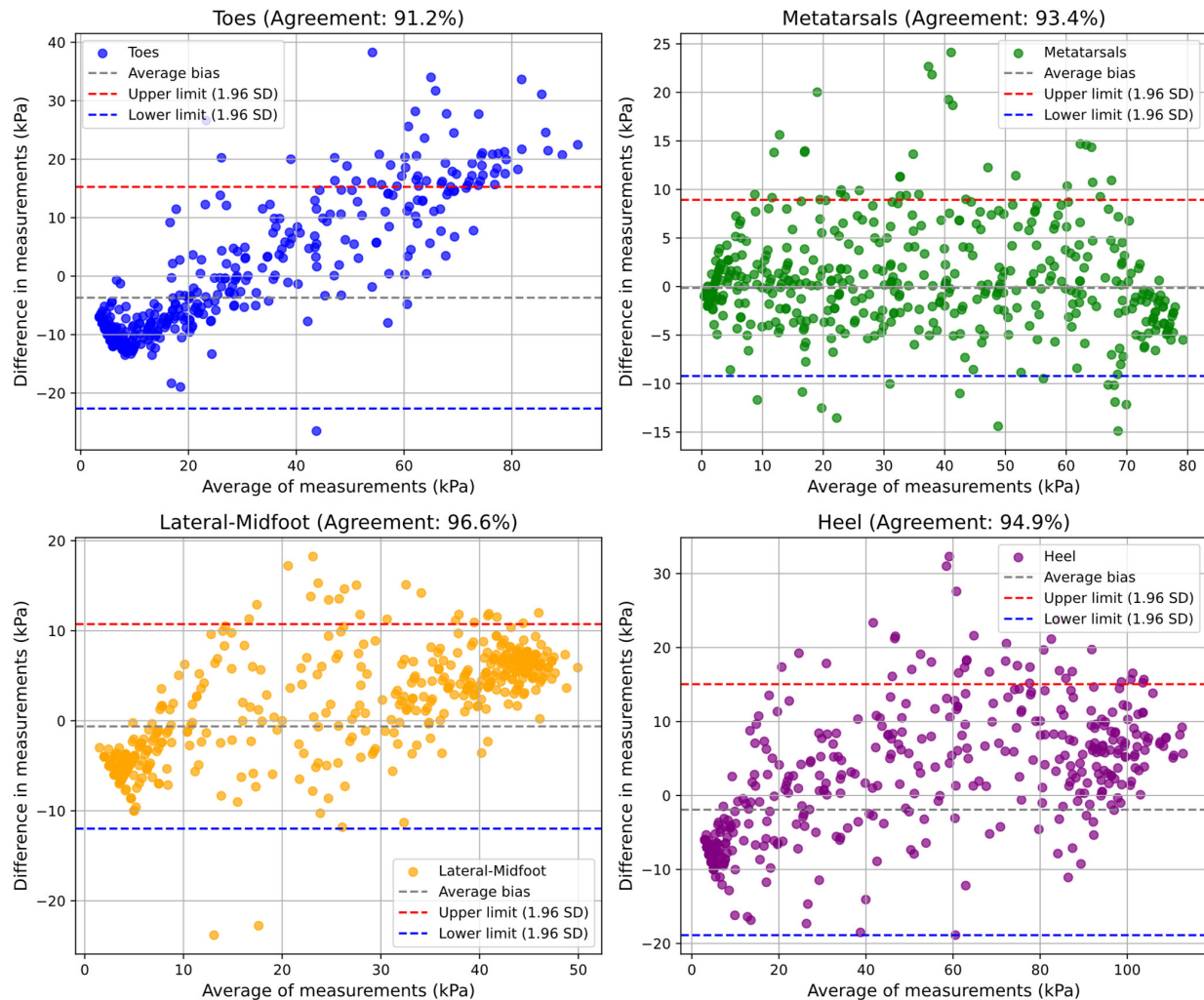


Figure 13. Agreement level evaluation of plantar pressure measurements obtained with pneumatic insole (pedar® vs. pneumatic insole) during the dynamic test conditions.

5. Discussion

The results obtained in static and dynamic tests demonstrate the effectiveness of the pneumatic insole in the redistribution and plantar pressure offloading and the feasibility of the proposed solution. The statistical analysis revealed significant differences between the test conditions, proving the ability of the variable pressure system to modify the distribution of plantar pressures. In the static test, it was found that the pressure stabilization mechanism acted by redistributing the pressures, significantly reducing the pressure on the heel (32.43%) and redistributing part of this load to the toes and metatarsals. This result is consistent with what was expected, as the pressure distribution is limited by total body weight and can only be redistributed between different regions of the foot. The pressure offloading intervention proved to be even more effective, achieving a reduction of up to 42.72% in the heel when preceded by the initial pressure stabilization. This indicates that initial stabilization improves the effectiveness of the offloading by preparing a more

homogeneous distribution of pressure before its reduction directed to a given region under static conditions.

In dynamic tests, the nature of the gait resulted in greater data variability, as evidenced by the high standard deviations. The pressure offloading at the heel achieved less significant reductions than in the static test when the stabilization process is not performed. When stabilization is performed, preceded by the offloading event, the pressure reduction can reach 24.73%. The data suggests that initial pressure stabilization may be a relevant factor, although in dynamic mode, the impact of walking may mask the effect of pressure redistribution.

The evaluation of the peak pressures confirmed that the intervention of the pneumatic insole not only reduced the peak pressure in the heel but also decreased the intensity of the peaks in other regions, such as metatarsals and toes, demonstrating an overall effect in reducing excessive pressures. However, the increased pressure in the midfoot region indicates that this area has absorbed part of the redistributed load, which may be a relevant factor in preventing injuries in regions more prone to overload, such as the heel and metatarsals. It should be noted that the pressure offloading intervention was only carried out in a single moment, and, in any daily use of the insole, this procedure can be performed several times until the desired pressure level is reached, without impairing the appropriate pressure pattern of the other regions of the foot. It is also worth mentioning that this procedure can only be performed until the air cell reaches the minimum air volume limit so that it remains operational and can make accurate pressure measurements.

The validation of the pneumatic insole using the Bland–Altman method demonstrated a high agreement (from 91% to 98%, minimum and maximum) between the values measured by the pedar® and the pneumatic insole, in both tests and for all plantar regions. The results indicate that the pneumatic insole has a performance very close to that of the pedar® insole, considered as the reference measurement system in the market. However, some systematic bias patterns have been observed, particularly at times of low pressure, where the pedar® insole has limitations in the measurement of values lower than 15 kPa. In the dynamic test, the formation of clusters in the graphs indicates a direct relationship between the moments of gait transition and the variations in plantar pressure, reinforcing the importance of considering the gait cycle in the analysis of plantar pressure.

When compared with the study by Erel et al. [16], our approach introduces several benefits. In the existing study, an insole composed of a set of air cells that operate through inflation and deflation cycles was reported, in an approach inspired by anti-bedsore mattresses, with the aim of relieving plantar pressure. Although this concept allows localized pressure relief through alternating support, it has some limitations. In particular, it does not have real-time response or control based on clinical thresholds (such as the value of 200 kPa or 25% baseline pressure reduction [5]), often associated with an increased risk of ulceration in diabetic foot pathology. Additionally, the system proposed by Erel et al. was tested on open-toe sandals, which do not reflect real walking conditions or the typical load support of closed footwear. This limitation may compromise the external validity of the results and restrict the practical applicability of the solution for everyday use, a weakness recognized by the authors themselves. In contrast, the pneumatic insole developed in the present study was tested fully integrated into a shoe certified as a medical device, commonly used daily by people with diabetic foot, ensuring greater proximity to the user's real conditions. This solution is prepared to operate continuously and autonomously, as it is configured as a portable device. It monitors plantar pressure in real-time and actively triggers air volume modulation in response to a predefined threshold, allowing dynamic, adaptive, and personalized pressure redistribution for each user. In our tests, both static and dynamic, it was possible to quantitatively demonstrate (Tables 3 and 4) that pressure offloading

(simulated event in the heel cell) resulted in pressure reductions of approximately 25% or more during the stabilization and offloading events.

Unlike Erel's solution, which works by periodically circulating air without relying on continuous measurements of localized pressure, our system avoids unnecessary actions that may occur when a cell is unnecessarily depressurized, possibly ignoring areas where there is overpressure. Our approach allows simultaneous monitoring of the offload and eventual pressure increase in other cells, maintaining a balanced and controlled redistribution pattern, with the aim of preventing the creation of new overload points. This is evident in the results presented in Tables 3 and 4, where the simulated pressure offloading event in the heel led to a redistribution of plantar pressure, resulting in a more uniform pressure distribution across all cells. Our system demonstrated a significant pressure reduction in the intervened regions, both in static and dynamic conditions. These design features, combined with the high accuracy of the measurements obtained, reinforce the potential of our solution as an effective tool for active monitoring and intelligent management of plantar pressure. Together, these features represent a significant advancement in the development of intelligent offloading systems tailored to the needs of high-risk patients.

Challenges and Constraints

Despite the advances achieved with the development of this variable pressure system, some limitations and constraints inherent to this study must be considered. One of the main limitations is that the pedar[®] system only measures pressures above 15 kPa, which can have some impact on the accuracy of measurements in regions where pressures are typically lower, such as the toes region in static mode. Thus, some type of error may be introduced in the measurements obtained, even if small. One constraint, although it has been easily overcome, is due to the acquisition rate of the two measurement systems used. The pedar[®] system operates with a frequency of 100 Hz, while the pneumatic insole has an acquisition rate of 15 Hz, which requires the downsampling process to align the data obtained by the two systems at each time instant.

The reliance of this study on data obtained from a single participant also represents a limitation. Although this approach is acceptable for this stage of prototype development, it should be noted that not all findings can be generalized. Although the system's accuracy and its pressure monitoring performance capacity have been demonstrated, it should be considered that the results of the pressure redistribution process and the reduction in peak plantar pressure may be influenced by user-specific factors, such as body weight, gait, or foot type.

Regarding the physical properties of the pneumatic insole material, no experimental tests have been carried out to evaluate its long-term elasticity, resistance, or deformation. However, the values provided by the manufacturers suggest that the materials used are suitable to withstand the intended usage conditions. Finally, a significant constraint of this study was the reliance on insole manual fabrication rather than industrial manufacturing processes. Implementation of pressurized injection molding techniques in a factory setting would enhance product quality, uniformity, and replicability. However, the time and costs associated with the preparation of an industrial production process were not compatible with the current developmental stage. Future iterations should prioritize transitioning to standardized manufacturing methods to ensure consistent performance across all produced insoles, while covering different sizes or shape adaptations.

6. Conclusions

In this study, a novel variable pressure system for monitoring and redistributing plantar pressure inside the shoe is presented, differing from conventional approaches. The

central innovation of this variable pressure system, and in particular of the pneumatic insole, lies in its real-time monitoring capability, which allows a dynamic adjustment during the user's daily activity. This is particularly important because, as identified in the literature, many of the existing solutions for ulcer prevention are passive and unable to adapt to changes in plantar pressures during the user's daily occupations. Furthermore, the proposed system, by monitoring and responding automatically, ensures greater comfort and safety both for populations at higher risk, such as people with diabetes, but also for workers subject to high plantar stress and in physically exhausting environments.

In summary, the results of this study demonstrated quantitatively that the pneumatic insole was effective in redistributing plantar pressure, reducing excessive loads, and mitigating plantar peak pressures in critical areas under both static and dynamic conditions. Additionally, the validation of the system with the gold standard showed that the pneumatic insole is a reliable and suitable device for applications in the analysis of plantar pressure. The device shows potential for real-time monitoring and targeted interventions across clinical settings, athletic performance optimization, and preventive occupational health applications, offering a versatile, cost-effective solution where precise pressure management is crucial. Moreover, its portability and modularity make it a suitable platform for future research in the field of smart footwear and plantar pressure modulation. The system also demonstrates immediate applicability in clinical settings, particularly for ulcer prevention, due to the possibility of responding to personalized thresholds for pressure relief in diabetic foot care.

Future Directions

Considering the results obtained in this study, there are several future research directions that can be explored to optimize and expand the applicability of the developed variable pressure system. One promising possibility is its integration into safety footwear, where it could contribute to improving the occupational safety and health conditions of workers subjected to long-standing periods or high levels of plantar loading. In addition, more comprehensive tests will be carried out to validate the effectiveness of the system in different population groups with a larger sample size and investigate its applicability in the prevention of plantar complications. Long-term fatigue analysis and deformation tests of the pneumatic insole materials will also be considered. These studies will consolidate the potential of the proposed system as an innovative and functional alternative for plantar pressure management, and also confirm its viability for daily use.

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Abbreviations

The following abbreviations are used in this manuscript:

AIP	Average interface pressure
BLE	Bluetooth Low Energy
CAD	Computer-aided design
FDM	Fused deposition modeling
FSS	Full Scale Span
IMU	Inertial measurement unit
IP	Interface pressure
PCB	Printed circuit board
PLA	Polylactic Acid
PP	Peak pressure
PV	Process value
SD	Standard deviation
SV	Setpoint value

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3.4 - Complementary Biomechanical Analysis of Gait and Plantar Pressure

In Section 3.3, the main results obtained with the developed prototype were presented, including the system's ability to stabilize and redistribute plantar pressure, perform localized offloading in overload regions, reduce pressure peaks, and validate its reliability of pressure measurement through agreement with a reference gold-standard system. These results demonstrate the effectiveness of the device in fulfilling the main objective of monitoring and intervening in real time on plantar pressure. However, in addition to immediate functional validation, it is important to explore the potential of the system as a biomechanical analysis tool in a complementary way. Continuous real-time monitoring of plantar pressure enables not only the detection of risk zones but also the extraction of additional parameters that characterize the foot's mechanical behavior during walking. In this sense, this section addresses two complementary dimensions of analysis: (i) the calculation of the pressure-time integral, a parameter that relates the magnitude of the pressure with its duration and which is a relevant indicator in the assessment of the ulceration risk; (ii) and the ability of the device to collect data that can be used to characterize the gait pattern, which provides complementary clinical and biomechanical information about the user's mobility. The analysis of these indicators will not only consolidate the robustness of the developed system but also demonstrate its applicability in broader scenarios of clinical and preventive monitoring, reinforcing the added value of the solution in the context of diabetic foot management and the functional assessment of human gait.

3.4.1 - Pressure-Time Integral

The pressure-time integral (PTI) is a central biomechanical parameter for evaluating plantar pressure, reflecting simultaneously the magnitude of the pressure applied and the duration of time during which this pressure is applied to a specific region of the foot. This metric is of high clinical relevance in the context of diabetic foot, given that moderate intensity pressures, maintained for prolonged periods, can be as or more harmful than short-term pressure peaks (Bartolo et al., 2023; Bus & Waaijman, 2013).

Mathematically, the PTI is defined as the integral of the pressure as a function of time, and can be expressed by Equation 3.3:

$$PTI = \int_{t_0}^{t_f} P(t) dt \quad (3.3)$$

where $P(t)$ corresponds to the instantaneous value of plantar pressure in each region during a time interval $[t_0, t_f]$. In practical applications, the PTI is calculated from a discrete

approximation through the sum of the pressure values acquired over the period under analysis, as expressed in Equation 3.4:

$$PTI \approx \sum_{i=1}^n P_i \cdot \Delta t \quad (3.4)$$

where P_i is the pressure recorded in each sample, Δt is the time interval between measurement acquisitions, and n is the total number of samples collected.

In the context of the present work, the calculation of the PTI was performed using data obtained during the experimental study described in Section 3.3. To ensure comparability, the same experimental methodology and data analysis were employed. The value of the PTI in each region was obtained by calculating Equation 3.4, which performs a discrete sum of the instantaneous pressures multiplied by the acquisition interval ($\Delta t \approx 0.067$ s). This approach allowed the comparison of results obtained by the system with and without the redistribution mechanism activated. The procedure involved simulating an overpressure event in which a localized pressure offload was triggered, specifically in the heel region, as this area consistently experienced higher pressure magnitudes during the tests, as expected. The comparison allowed not only to validate the prototype's ability to monitor plantar pressure and act in its management, but also to record the accumulated load patterns over time, fundamental to understanding the evolution of the risk of plantar ulceration. However, it was expected that the PTI value with the use of the pneumatic insole and the redistribution mechanism activated would be lower than when the mechanism was deactivated. This was what happened, and the data presented in Figure 3.9 reveal that the active mechanism of the insole promotes less exposure to pressure over time for a given intervened region.

By analyzing the graph in Figure 3.9, it is evident that when the actuation system is activated, the intervened zone becomes less exposed to pressure over time, confirming the statistical significance of this finding through the analysis carried out. Although intervention in a specific area causes a redistribution of pressure to adjacent areas (midfoot and metatarsals), the results showed that these increases were not pronounced, and even in the metatarsal zone, statistical analysis proved to be not significant. This demonstrates the insole's ability to promote localized intervention without compromising pressure levels in adjacent areas.

Continuous monitoring of the PTI opens the possibility of integrating this parameter into the decision algorithms of the active system, allowing localized offloads to be triggered not only based on instantaneous pressure peaks above clinical thresholds, but also on accumulated loads above a certain pressure exposure threshold over time. This approach represents a significant advance over systems that only consider maximum pressure values, aligning with recent clinical recommendations (Bartolo et al., 2023) that emphasize the importance of cumulative pressure as a predictor of ulceration. This functionality is particularly relevant in the working context, where the handling of heavy objects can

significantly aggravate plantar overload, increasing the risk of ulceration in workers with diabetic foot or causing musculoskeletal injuries.

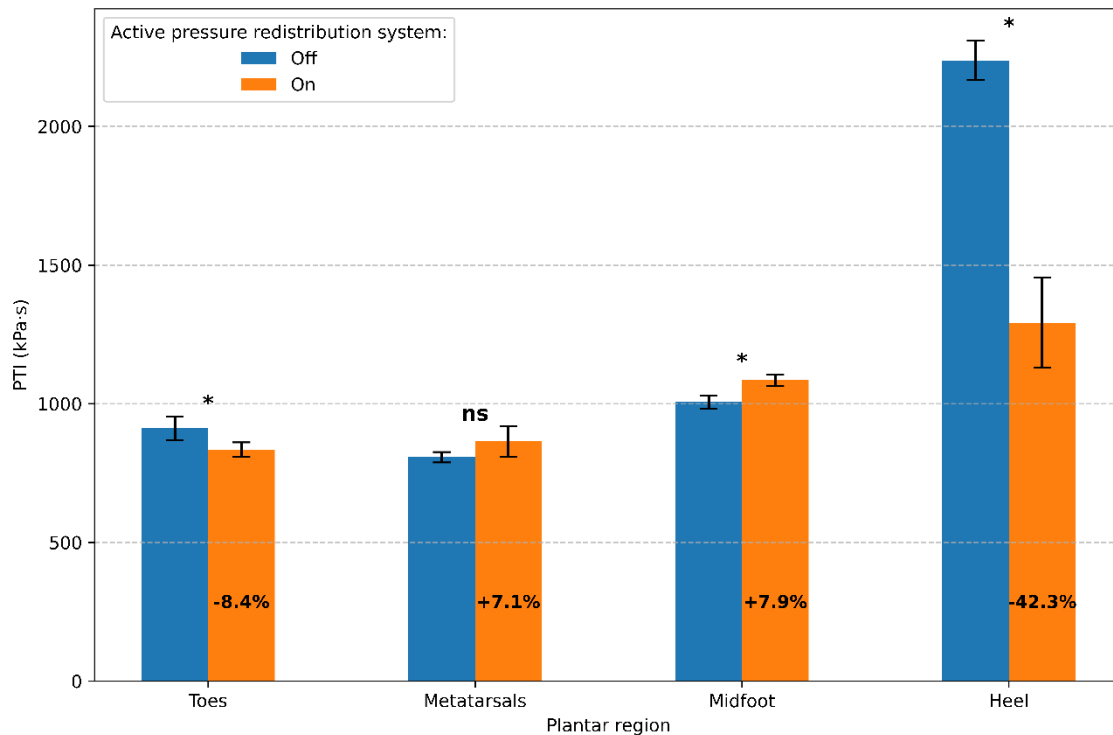


Figure 3.9 – Pressure exposure level by analysis of the pressure-time integral during 60 s of walking at 3 km/h with a simulated high-pressure event at the heel, with and without the pressure redistribution system activated. Statistical significance (* $p < 0.01$; ns: not significant) was obtained with the Wilcoxon test.

3.4.2 - Human Gait Pattern

In addition to the ability to monitor plantar pressure and identify accumulated pressure patterns, it is essential to evaluate whether the developed system can also monitor dynamic parameters related to human gait. The analysis of gait patterns is an essential tool in the functional characterization of mobility, enabling the identification of changes in the stance phase, asymmetries between limbs, and early indicators of motor dysfunction. This aspect is of clinical interest in at-risk populations, such as older adults and people in rehabilitation, where small temporal changes or asymmetries can have a significant impact on the prevention of falls and the planning of appropriate interventions (Burnfield et al., 2004).

Following the methodology adopted in the study presented in Section 3.3 and through continuous recording of pressure variations over time during gait, the system allowed the recording of the plantar contact pattern during multiple gait cycles. The typical stance sequence (initial heel contact, midfoot transition, and propulsion phase in the forefoot) was clearly identifiable in the data series obtained. Figure 3.10 shows a gait period during which a typical pattern of human gait can be observed.

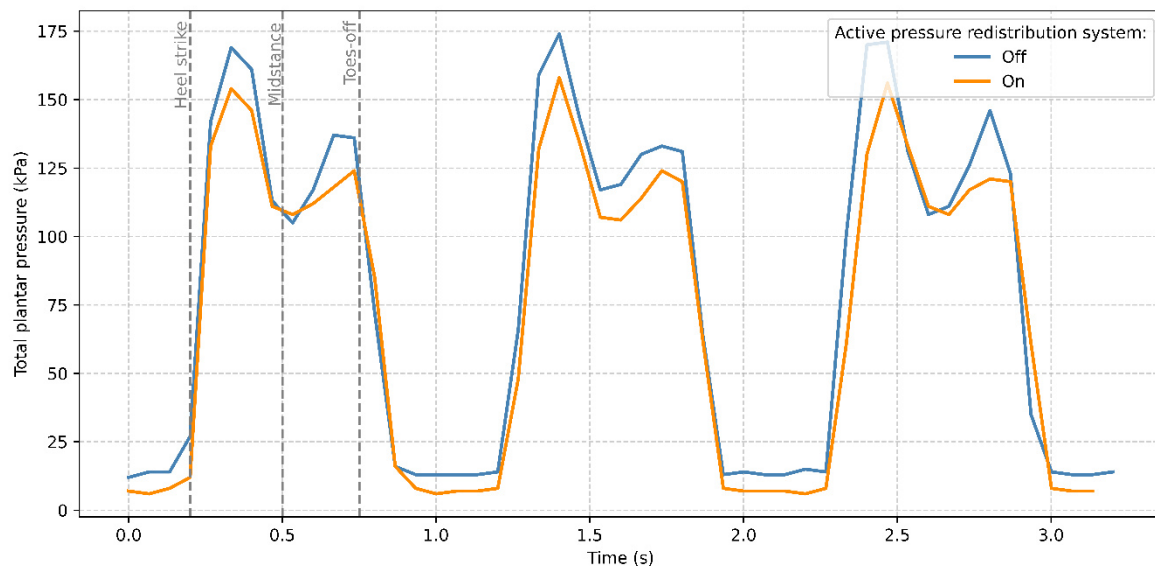


Figure 3.10 – Analysis of a period of the gait cycle (three cycles, right foot) at 3 km/h with a simulated high-pressure event at the heel, with and without the pressure redistribution system activated.

In addition to the mere qualitative characterization of the participant's gait pattern, the data collected by the system allowed for the recording of the different phases of foot support on the ground during gait, including heel impact, the intermediate support phase, and the moment of impulse immediately before lifting the foot off the ground. These parameters offer complementary information about the locomotor pattern, and it is possible to infer other quantitative metrics that can be used in clinical and ergonomic applications. In summary, the results demonstrate that the system not only reproduced the gait pattern but also reduced the magnitude of total pressure involved during gait through its active plantar pressure redistribution system. The integration of this pressure redistribution functionality extends the system's reach, positioning it as a platform for continuous monitoring and active pressure offload in both laboratory and real-world contexts.

3.5 - MoonWalking® System Usability Study

This section presents the results of the usability study conducted for the MoonWalking system, a trademark registered for the active pneumatic system developed in this work, based on the pneumatic insole design. The study aimed to evaluate the perception of comfort and functionality associated with its use when integrated into safety footwear, compared to the original manufacturer's insole.

3.5.1 - Rationale and Methodology

Usability assessment is a crucial step in the development cycle of technological solutions, enabling the collection of both qualitative and quantitative data on user comfort, functionality, and overall perception. In this context, an experimental and exploratory

observational study was conducted to evaluate the usability of the integrated MoonWalking pneumatic insole in safety footwear. The primary purpose of this study was to collect preliminary indicators on the perceived comfort and functionality associated with plantar pressure management, in comparison with safety footwear equipped with the manufacturer's original insole. At this stage, the choice of safety footwear as a test platform for the MoonWalking pneumatic insole is justified by its relevance in the occupational context, where workers are required to remain standing for extended periods or are subject to repetitive efforts. This type of footwear, although essential for foot protection, is often associated with reduced comfort levels, sole stiffness, and limited cushioning capacity, factors that can contribute to fatigue, plantar pain, and lower productivity (Arceri et al., 2024). Thus, the introduction of an insole with dynamic pneumatic control in this type of footwear presents an opportunity to evaluate the impact of perceived comfort and functionality in conditions similar to those of real use. Usability assessment in this context is therefore crucial for verifying the suitability of the solution, identifying potential acceptance barriers, and guiding future improvements in the design and integration of the insole in work applications.

The study adopted a crossover design, in which each participant experienced two conditions: (i) use of safety shoes with the manufacturer's original insole (control), and (ii) use of safety shoes with the MoonWalking pneumatic insole, at different times and with a random test order. This approach allowed each participant to act as their own control, thereby reducing inter-individual variability and increasing the robustness of comparisons, even with a small sample size. In each condition, participants wore their respective pair of shoes for approximately one hour, performing their usual work activities in a controlled context, including periods of walking, standing, sitting, and other events related to the user's work environment. At the end of each experimental period, they answered the same set of questionnaires, allowing for a direct comparison between the two conditions. The exploratory nature of the study stems from the fact that there is currently no previous data on the use of this pneumatic insole in a real-world context. This study aims to identify trends and initial perceptions that will serve as a basis for future research in broader work contexts.

The participants' perception was assessed using validated and standardized instruments, namely the adapted Visual Analogue Scale (VAS) (Couper et al., 2006), which assigns scores from 0 to 10 points for parameters of global comfort, cushioning, walking stability, foot fit, temperature, and fatigue. Binary questions (Yes or No) were used to assess perceptions of ergonomics and acceptance, including potential restrictions on movement, localized discomforts, and intentions to use in the future. Additionally, a dynamic functionality questionnaire was administered after an additional test with the MoonWalking insole, allowing for the evaluation of perception of stabilization, offload, and pressure redistribution actions in each plantar region. This study obtained ethical approval (registration no. CE0077F) from the Ethics Committee of the School of Health of the

Polytechnic of Porto. Further details on the study registration, questionnaires applied, and full experimental protocol are available in Appendix C.

3.5.2 - Usability Study Results

The sample consisted of 11 adult participants aged between 24 and 65 years, recruited for convenience from members of the academic community and workers accustomed to using safety footwear and personal protective equipment in their work activities. The predefined inclusion and exclusion criteria were respected, ensuring the homogeneity of the sample in parameters such as foot size (EU 43/44, corresponding to the insole tested after being inserted into the safety footwear), absence of injuries or deformities in the feet, and absence of musculoskeletal, neurological or vascular pathologies that could interfere with the performance of the test and the safety of the participants. All participants provided informed consent, in accordance with the ethical principles of scientific research and the General Data Protection Regulation (GDPR, Regulation (EU) 2016/679). Table 3.1 shows a summary of the demographic data and characteristics of the participants.

Table 3.1 – Demographic data and characteristics of study participants.

Sample (n)	Sex		Age range (years)	Weight range (kg)	Height range (cm)	Foot/shoe size (EU size)
	M	F				
11	9	2	24–65	60–89	167–185	43/44

The safety footwear used in the tests belongs to the X-COM line, model X-506 of the TOWORKFOR® brand. It is an S3 ESD SRC category safety shoe, featuring a non-slip and anti-perforating sole that provides impact resistance and electrostatic dissipation. This model was selected because it represents safety footwear commonly used in industrial and work settings, ensuring uniformity and comparability across test conditions. Figure 3.11 illustrates the safety shoe model used and a participant wearing it during one of the usability trials.



Figure 3.11 – Safety shoe (TOWORKFOR®, X-506) used in the usability study equipped with the pneumatic insole system (a), and participant wearing it during one of the tests (b).

Using the VAS scale, each participant assigned a score from 0 (minimum) to 10 points (maximum) for the following categories: overall comfort, cushioning, walking stability, foot fit, temperature, and fatigue at the end of use. Table 3.2 presents the mean values and standard deviations obtained for each parameter, comparing the two experimental conditions: safety footwear with the original insole and safety footwear with the MoonWalking insole. The mean difference observed between these two conditions and the general trend in participants' perception is also indicated.

Table 3.2 – Mean VAS scale (0 to 10) results. Statistical significance (* $p < 0.01$) comparing the two conditions (A and B) was obtained by the Wilcoxon test.

Parameter (perceived)	Original insole (A) (VAS $\pm$ SD)	MoonWalking insole (B) (VAS $\pm$ SD)	Mean difference (B - A)	p-value	Observed trend
Cushioning	5.5 $\pm$ 1.4	8.7 $\pm$ 0.6	+3.2	0.0009*	Increased perceived cushioning
Foot fit	7.0 $\pm$ 1.3	8.7 $\pm$ 0.9	+1.7	0.0039*	Increased perceived foot fit
Walking stability	8.0 $\pm$ 0.8	8.2 $\pm$ 1.6	+0.2	0.4375	Similar perceived stability
Temperature	6.0 $\pm$ 1.6	6.1 $\pm$ 1.9	+0.1	1.0000	Similar perceived temperature
Fatigue	6.3 $\pm$ 1.8	5.3 $\pm$ 1.8	-1.0	0.0937	Decreased perceived fatigue, not significant
Overall comfort	7.3 $\pm$ 0.6	7.9 $\pm$ 1.1	+0.6	0.1367	Similar perceived comfort

Among the parameters evaluated, statistically significant improvements were observed in perceived cushioning ($p = 0.0009$) and foot fit ($p = 0.0039$), demonstrating that the characteristics and behavior of the pneumatic insole contribute to better cushioning and a feeling of adaptation to the foot during gait, with a rating of 8.7 VAS points for both parameters. The remaining parameters (overall comfort, walking stability, and increased/decreased perceived temperature) did not show statistically significant differences between the two conditions, remaining within a perception similar to that of the conventional insole. On the other hand, perceived fatigue showed a mean reduction trend (-1.0 VAS point) during the use of the MoonWalking insole, although without reaching the desired statistical significance.

In addition to the assessment through the VAS scale, participants answered brief binary questions (Yes/No) about their perceived ergonomics, aimed at identifying perceptions related to movement restrictions, the presence of localized discomfort, and their intention to use the MoonWalking system in the future. Table 3.3 shows the percentage distribution of responses to each question.

Table 3.3 – Percentage distribution of responses (“Yes”) to questions about perceived ergonomics.

Questions about ergonomics	Original insole “Yes” (%)	MoonWalking insole “Yes” (%)
Have you noticed any limitations of movement?	0.00	0.00
Have you noticed any localized pain?	0.00	0.00
Would you wear these shoes again with this insole?	90.91	81.82

Regarding the ergonomic issues associated with shoe use in the two conditions, the results reinforce the absence of adverse effects, as none of the participants reported limitations in movement or localized pain in any of the conditions tested. Additionally, 81.82% of the participants stated that they would use the shoe with the MoonWalking insole again, a value slightly lower than that of the control condition (90.91%) but still reflecting a high acceptance and overall tolerance of the system in its current prototype configuration. It is important to note that in a sample with a small number of participants, as in this case, a single negative response from one person has a greater influence on the outcome.

After the usability test in gait, the participants answered the functionality questionnaire, aimed at assessing the subjective perception of the mechanical actions of the pneumatic system, such as stabilization, which consists of a better adaptation of the insole to the morphology of the foot, and the localized offload pressure that causes a redistribution of plantar pressure in the different areas of the foot. Table 3.4 shows the percentage of positive responses (“Yes”) obtained for each action and respective plantar zone.

Table 3.4 – Functionality perception (“Yes” responses per plantar zone) of the MoonWalking insole when the pressure stabilization or offload function is activated.

Plantar zone	Perceived pressure stabilization “Yes” (%)	Perceived pressure offload “Yes” (%)
Toes	100	100
Metatarsals	100	100
Lateral-midfoot	100	100
Heel	100	100

The functional assessment of the MoonWalking system revealed a consistent perception of stabilization and pressure offload in all plantar regions analyzed, with 100% positive responses in both dimensions evaluated. These results indicate that users were able to clearly identify stabilization (which also involves pressure redistribution) and pressure offload actions induced by the system, confirming that pneumatic behavior is perceptible from the user's perspective.

At the end of the experimental protocol, participants were asked to submit spontaneous observations about their experience of use. The responses were analyzed qualitatively and grouped into thematic categories, allowing the identification of common trends and perceptions. Overall, the participants' comments were consistent with the perceptions recorded in the questionnaires. Regarding the use of safety footwear with the original insole, it was noted that this type of footwear tends to be less comfortable than conventional footwear, mainly because it is heavier and becomes slightly warmer during use, characteristics inherent to its protective function. In the condition with the MoonWalking insole, some of these aspects were mentioned again by the participants, since the shoe model used was the same. However, there were occasional comparative observations between the two conditions that reported a slight increase in the total weight of the shoe, justified by the incorporation of the pneumatic insole. These comments were considered aspirations for future improvements to the system.

3.6 - Global Discussion

The present research enabled the consolidation and validation of an integrated system for monitoring and actively controlling plantar pressure, designed for application in injury prevention and diabetic foot management contexts. The approach adopted combined the development of a pneumatic insole with active pressure redistribution and a compact control unit, which is responsible for operating sensors, pneumatic valves, and wireless communication. The results obtained throughout the different experimental stages demonstrated that the system meets the established design objectives, presenting reliable performance in monitoring plantar pressure, automatically redistributing these pressures, and reproducing the typical pattern of human gait. Additionally, it was possible to study the behavior of the Semmes-Weinstein monofilament, one of the first-line instruments used by the medical community to screen for loss of cutaneous sensitivity to pressure in the diabetic foot. This complication compromises the integrity of the foot tissues and increases the risk of injuries due to the absence of pain perception.

Regarding the results of the study published in Section 3.1, this work made relevant contributions to the measurement of the metrological reliability of the skin sensitivity test using 10-gf monofilament. It was found that most of the monofilaments evaluated had substantial errors from the nominal value declared by the manufacturers, exhibiting deviations in both applied force and repeatability over repeated use cycles. These factors compromise the accuracy of the clinical assessment, given that an instrument supposedly calibrated to apply 10 gf to the patient's skin recorded values ranging approximately between 6 gf and 29 gf, with a mean of nearly 16 gf (for a deflection velocity of 4 mm/s). This magnitude of error, significantly higher than the nominal value, highlights the intrinsic variability of these devices. The analysis also showed that the performance of monofilaments

decreases with repeated use due to fatigue, and suggested that environmental variables, such as temperature and humidity, can introduce additional variations in buckling forces. These results corroborate observations reported in other studies (Chikai & Ino, 2019). The relevance of this study in the overall context of the thesis is manifested in two main aspects. Firstly, it confirms that apparently simple instruments, such as the 10-gf monofilament, are subject to systematic errors and variations over time, which reinforces the importance of adopting more objective and calibrated devices with continuous monitoring of their reliability. Secondly, it highlights the need to integrate complementary measures for the assessment and prevention of diabetic foot, namely the monitoring of plantar pressure within footwear based on clinically defined risk thresholds.

Regarding the developed prototype, the comparative analysis carried out in Section 3.3 confirmed the validity and agreement of the pressure values obtained against the reference system, considered the gold standard, with levels of agreement ranging from 91.2% to 98%. This experimental validation reinforced the robustness of the sensor calibration and the reliability of the pneumatic circuit in detecting plantar pressure variations under static and dynamic conditions. In addition to the pressure measurement, the effectiveness of the redistribution mechanism was demonstrated, enabling the reduction of pressure peaks during gait and the stabilization of plantar pressure distribution during static stance. These results suggest the potential clinical applicability of the device, specifically in mitigating the risk factors associated with plantar ulceration in individuals with peripheral neuropathy. The further analysis developed in Section 3.4 reinforced these conclusions by introducing a more comprehensive assessment of the biomechanical parameters extracted from the pressure data recorded by the prototype. Through the calculation of the PTI, it was demonstrated that the system, when operating in the active redistribution mode, significantly reduced the value of the PTI in the critical regions of the foot where it acted (a reduction of 42.3% in the heel), evidencing less cumulative exposure to plantar pressure without compromising the adjacent areas. This result is particularly relevant from a clinical point of view, given that PTI is directly correlated with the probability of formation of lesions due to prolonged overload (Bartolo et al., 2023). Thus, the dynamic control provided by the insole not only reduces instantaneous pressure peaks but also attenuates the cumulative effect of the load, thereby contributing to more effective protection of the tissues in the plantar region. Additionally, the reconstruction of the gait pattern based on the real-time data evidenced the system's ability to identify the different phases of the gait cycle. This functionality expands the device's potential application in mobility monitoring, motor rehabilitation, and functional assessment contexts, representing a significant advantage over conventional systems of instrumented insoles that are limited to passive measurement of plantar pressure.

The usability study of the MoonWalking system, integrated into safety footwear, complemented the experimental results obtained in the previous stages of the research, offering a user-centered perspective on the comfort, functionality, and overall perception of

the system. While biomechanical and plantar pressure analyses provided objective evidence of the insole's ability to redistribute load and reduce pressure exposure, the usability study revealed that these characteristics consistently translate into a subjective perception of greater cushioning, better foot fit, and reduced fatigue. The results showed that, although the system is still in a prototype stage, participants reported acceptable levels for the evaluated parameters, with no recorded pain events or movement restrictions. These findings are particularly relevant in the context of safety footwear, where protective characteristics often compromise shoe comfort (Arceri et al., 2024). The fact that the MoonWalking insole has maintained (in some parameters, it even improved) the perception of comfort compared to the original insole indicates that the system maintains ergonomics compatible with a possible use in occupational safety contexts, for example, and may represent an added value for workers subject to long periods of standing or handling loads.

The significant improvement observed in perception of cushioning and foot fit, as evidenced by the VAS score, reinforces the role of pneumatic modulation in achieving uniformity of plantar pressure. The redistribution of plantar pressure appears to be intuitively perceived by users, as demonstrated in the functional assessment moment, where all participants identified stabilization and offloading actions in all plantar regions tested. This conscious perception of the system's functioning is a significant indicator. However, although the difference in overall comfort did not reach statistical significance, the observed improvement trend is consistent with the other metrics. It may be due to the short duration of the experimental sessions or the absence of prolonged adaptation to the system. Future long-term studies may clarify whether the continuous use of the pneumatic insole produces more expressive cumulative effects on the perception of comfort and plantar fatigue. Even so, and despite being quite acceptable, there was a slight decrease in the percentage of participants who said they would wear shoes with the MoonWalking insole again (81.82% compared to 90.91% in the control). This decision may be related to the general comments made by some participants, which refer to some less positive aspects of safety footwear in general, considering it to be less comfortable and heavier than daily footwear. Nevertheless, two aspects need to be considered: (i) the test units were still a validation prototype, and (ii) a single negative response in a small sample size can significantly influence the result. Since incorporating the MoonWalking insole adds extra weight (for EU 44 size, per shoe: regular shoe $\approx$ 450 g; safety shoe $\approx$ 750 g; safety shoe + MoonWalking $\approx$ 930 g), this may be one of the reasons for the slight decrease in the intention to use this shoe again with the pneumatic system. In a production version, by removing material from the original sole to integrate the MoonWalking insole during manufacturing, the weight of the shoe with the pneumatic system should match that of the original shoe. In this respect, the authors believe that several details regarding comfort and aesthetics could be improved (without compromising the desired functionality), and the "wear it again" indicator could be improved.

3.6.1 - Limitations

Some of the limitations inherent to the development of this work are already described in the published articles that constitute Sections 2.2, 2.3, 3.1, and 3.3. However, other limitations can be recognized in the context of this thesis. The use of only one unilateral prototype, installed in the right shoe, is noteworthy, implying that the results reflected only the contribution of one plantar support. Although this methodological limitation has been adequately considered in the analyses carried out, assuming proportionality between the two feet, bilateral instrumentation will allow, in future studies, a more complete characterization of the variables that can be studied regarding the dynamics of human gait. Another limitation is related to the production of only one size of insole (EU 43/44), a consequence of the restrictions inherent in small-scale manufacturing and the associated costs of molding and injecting rubber into an academic environment. This limitation prevented the studies from being extended to a broader population that wore other shoe sizes. For example, in the usability study, the fact that only a single shoe size was available also limited the sample (initially planned for 20 participants), particularly among female participants, who typically wear smaller shoe sizes. This also limited the amount of time the shoes could be worn during the usability study. Despite this, the modular design of the insole facilitates future adaptation to different sizes, with minimal modifications to the molds and with minor adjustments to the manufacturing parameters.

Chapter 4

Conclusion

The present research enabled the development, validation, and evaluation of an innovative system for monitoring and actively controlling plantar pressure. This prototype was designed to contribute to the prevention of injuries and the management of diabetic foot, as well as to improve the occupational safety and health of individuals with diabetic foot who are more exposed to adversity in their work activities.

This work integrated several complementary steps, from the metrological characterization of conventional clinical instruments for screening loss of skin sensitivity in the foot, to the development, calibration, and experimental testing of a functional prototype of a pneumatic insole capable of dynamically redistributing plantar pressure. The initial study using Semmes-Weinstein monofilaments revealed significant errors in applied force compared to the declared nominal value, as well as performance reductions associated with repeated use and varying conditions of use, reinforcing the importance of objective and continuous monitorable approaches. This was a principle that guided the subsequent development of the MoonWalking system.

The development process followed an iterative and multidisciplinary approach, initially exploring the integration of piezoresistive sensors into flexible insoles for plantar pressure monitoring. While this first approach offered simplicity and low cost, it revealed limitations related to signal hysteresis and reduced repeatability after some use. These constraints highlighted the need for a more stable and robust solution, leading to the adoption of a pneumatic approach. The pneumatic architecture provided excellent metrological consistency, along with the added advantage of allowing both pressure measurement and active redistribution via controlled air cells. This technological transition marked a decisive

step in the evolution of the MoonWalking system, creating the foundation for the successful implementation of the active pneumatic insole prototype.

The developed prototype demonstrated high reliability and consistency in the plantar pressure data, presenting levels of agreement ranging from 91.2% to 98% compared to the reference system, considered the gold standard. These data confirmed the first research hypothesis, regarding the system's ability to monitor plantar pressure in real time with accuracy comparable to reference systems, thereby evidencing the robustness of the calibration and the reliability of pneumatic sensors. Additionally, the system demonstrated its effectiveness in actively redistributing plantar pressure, resulting in significant reductions in PTI in the critical regions where the system acted, specifically a 42.3% reduction in exposure to heel pressure, which evidences its potential in mitigating the risk factors associated with plantar ulceration. These results corroborate the second and third hypotheses, which postulated the efficacy of pneumatic redistribution in reducing peaks and exposure to plantar pressure. Furthermore, the complementary biomechanical analysis demonstrated the system's ability to detect and interpret the phases of the gait cycle, revealing its value as a functional monitoring tool.

The results of the usability study on the MoonWalking system integrated into safety footwear indicated a significant improvement in the perception of cushioning and foot fit, without compromising stability or overall comfort. The absence of movement restrictions or localized pain, combined with a positive perception of the system's stabilization and pressure offloading functions, confirmed its acceptability and potential for practical application. However, it is essential to note that some of the most common qualitative comments from participants indicate that the weight of the shoe (although it is generally a cross-cutting feature of safety footwear) is an aspect to consider in the future optimization of integrating the MoonWalking system into footwear of this nature.

The usability study complemented the technical evaluation with a user-centered perspective, and the information obtained confirmed the fourth research hypothesis, regarding the acceptance and comfort perceived by users, which was corroborated by the results that indicated a positive user experience. The integration of the system in safety footwear is particularly relevant in the field of occupational safety and health, as many diabetic workers are also subject to the same conditions as healthy workers, such as prolonged standing or exposure to repetitive loads and localized pressures in the plantar region. These conditions may constitute increased risk factors for individuals with a predisposition to peripheral neuropathy or diabetic foot. Thus, the integration of the MoonWalking system into safety footwear represents a more holistic approach to worker safety and health.

Overall, the research fully achieved the proposed objectives, including defining plantar pressure thresholds and developing a functional prototype capable of effectively integrating the functions of monitoring, controlling, and actively redistributing plantar pressure in a

single device. This integration represents a significant advancement over existing passive solutions, providing a robust technological basis for the development of intelligent systems for personalized prevention, with potential applications in both clinical and occupational contexts. The guiding research question was also comprehensively answered by the results obtained throughout this work, demonstrating the progressive and integrated fulfillment of the objectives, from the conception and development of the prototype to its experimental validation and usability evaluation.

4.1 - Future Directions

The continuation of this work should focus on the technological improvement and clinical validation of the MoonWalking system. These steps are essential to consolidate its potential as a monitoring and prevention tool in real contexts of use. In the first stage, the development of bilateral versions of the prototype is planned, allowing the simultaneous instrumentation of both feet for complete monitoring and characterization of the symmetry and dynamics of the gait. In parallel, it will be essential to promote extensive clinical trials in populations with diabetic neuropathy to validate the effectiveness of the system in preventing ulceration. These studies should also simultaneously assess the impact of prolonged system use on perceptions of comfort, safety, and adherence levels.

From an engineering perspective, the following challenges will focus on creating molds for different insole sizes, miniaturizing the control electronics, and integrating the entire system into the shoe sole. This last step will have to be part of the manufacturing process during the production of the shoe. These developments aim to transform the system into a versatile platform for biomechanical assessment and personalized prevention, aligned with the principles of digital health and preventive medicine.

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NOTE: This document incorporates several published articles into the text (Sections 2.2, 2.3, 3.1, and 3.3), which were developed during the course of this doctoral research. The references contained in the incorporated articles were not indexed in this main list of References.

Appendices

Appendix A – Preliminary Tests with Screen-Printed Piezoresistive Pressure Sensors on PET and Textile Substrates

This appendix presents a published article detailing preliminary tests with piezoresistive pressure sensors screen-printed on polyethylene terephthalate (PET) and textile substrates. This work, presented at the IEEE FLEPS 2022 conference, explores the feasibility and initial performance of these flexible sensors for possible integration into insoles.

P. Martins, C. Silva, J. Oliveira and A. Marques, "Preliminary Tests with Screen-Printed Piezoresistive Pressure Sensors on PET and Textile Substrates," 2022 IEEE International Conference on Flexible and Printable Sensors and Systems (FLEPS), Vienna, Austria, 2022, pp. 1–4, doi: 10.1109/FLEPS53764.2022.9781579.

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Preliminary Tests with Screen-Printed Piezoresistive Pressure Sensors on PET and Textile Substrates

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Abstract—The search for more practical and economically advantageous solutions to produce flexible and printable pressure sensors, is giving rise to new approaches with promising results. The production of conductive and piezoresistive inks for application on flexible and stretchable substrates is a sign of this evolution. In this paper, we propose to analyze the results of some calibration tests, performed with pressure-sensitive piezoresistive sensors screen-printed on PET and textile substrates. The results showed that these sensors generally follow a trend with a strong approximation to the linear model. The textile sensor is the most linear ($R^2 = 0.99$), and PET sensor (S1) has a higher sensitivity (40.4 mV/kPa) than the other sensors. Results obtained are, in general, within the expected behavior for the piezoresistive ink used and allowed for comparing between sensors printed in PET and textile substrates. A positive factor to consider lies in the possibility of using the screen-printing technology on different substrates, preferably in textile fabric.

Keywords—calibration; flexible sensors; piezoresistive ink; pressure sensors; screen-printed sensors

I. INTRODUCTION

In the last decade, the constant search for more practical and economically advantageous solutions to produce sensors, has given rise to new approaches with promising results. Wearable electronics has aroused great interest in micro-electromechanical systems (MEMS), whose technology integrates small electromechanical elements on a single chip, to measure and quantify physical stimulus. Among them, piezoresistive sensors stand out, and have been extensively investigated due to their excellent sensitivity, simple construction, and durability [1]. At the same time, innovative developments were observed in the fabrication of conductive inks for printed circuits and flexible substrates applications [2]–[5]. Among the most sought characteristics in these inks is the possibility of being stretchable, pressure sensitive, admitting a wide range of operating temperature and humidity, easy application with conventional techniques, among others [3], [4], [6]. The main sensor types that can be produced, based on the use of these inks are: pressure sensors; temperature; humidity; and biosensors [6]–[11]. Pressure sensors are of great interest for various applications. Its use is transversal, with large-scale applicability in industry, in domestic systems and solutions in the area of biomedical engineering and healthcare context [2], [3], [6], [7], [11], [12].

In the development of pressure sensors printed using piezoresistive inks, different manufacturing processes are used. The best printing process depends on the materials used and the application [6]. The do-it-yourself concept, expanding the production model of low-cost devices on flexible substrates (paper, fabric, and plastic film), has also been explored for chemical, environmental and biological microsensors. This concept proposes the use of conventional laser jet printers [13].

Screen printing is a widely used printing technique, as it is a relatively simple and robust, has a low cost, and can be implemented on a large scale even for sensors of different dimensions [6], [14]–[16]. In this process of printing piezoresistive sensors, in addition to the ink composition, the substrate properties must also be considered. Thermoplastic polymer substrates, such as polyethylene terephthalate (PET), are the most often used, however, substrates in textile fabrics have been the target of interesting applications, for example, in the monitoring of biomedical signals [17], [18].

In the healthcare area, especially in insole or upper shoe solutions to monitor pressures in patients with foot pathologies, piezoresistive pressure sensors are the most sought after technology to measure and monitor possible hyper-pressures inside the shoe [19], [20]. For this concept, there are a set of measurement systems based on force-sensing resistors (FSR) with a PET housing or another type of thermoplastic polymer [21]. However, research and development have advanced towards creating sensors capable of being integrated with greater ease and reliability into textile substrates, making them more flexible, washable, and with greater freedom of integration into the desired solution [3], [5], when compared to commercial FSR sensors from TekscanTM [22] or Interlink Electronics[®] [23] manufactured in PET, for example.

In this paper, we propose to analyze the results of some preliminary tests carried out with piezoresistive pressure sensors (supplied by the company Nanopaint¹) printed on a PET and textile substrates. The main objective was to perform a simple calibration and identify the behavior of these sensors, regarding their linearity, in response to a given load applied under specific conditions. This study is part of a trial to assess the feasibility of sensing an insole and upper shoe to detect pressures in patients with foot pathologies, like diabetic foot.

¹ Nanopaint – Functional Inks: <https://nanopaint-tech.com>

II. MATERIALS AND METHODS

A. Piezoresistive sensors printing process

In the production of the sensors used in this work, the piezoresistive ink (PR2NP®) and silver stretchable conductive ink (Sink01NP®) were acquired from Nanopaint, Lda. A 0.05 cm and 0.1 cm spacing between interdigitated silver pattern with compression area of 1.12 cm² were designed to obtain single PET piezoresistive sensors. To evaluate the behavior of a piezoresistive array, a 5 × 4 textile matrix was also printed. Fig. 1 shows the single sensors printed on Melinex (PET based) and the sensor array printed on Polyester (PES) textile substrate, comprising the screen-printed piezoresistive and silver electrode layers. For the three prototypes, silver electrodes were also screen-printed, with a polyester mesh from Sefar AG with 100 threads/cm using stretchable silver conductive nanoparticle ink (Nanopaint Sink01NP). After printing the electrodes, the film was heated to 120 °C for half an hour to cure the ink. The piezoresistive layers (with Nanopaint PR2NP ink) were screen-printed with a polyester mesh from Sefar AG with 65 threads/cm and the films were heated to 80 °C during 10 minutes to cure the ink. The piezoresistive film was printed with two layers and the final thickness was around 30 µm, and the conductive silver layers had an average thickness of 12 µm. The sensors used in this work (Fig. 1) are pressure sensitive and are composed of two ink layers and different interdigitated conductors. Table I presents the general characteristics of these sensors.

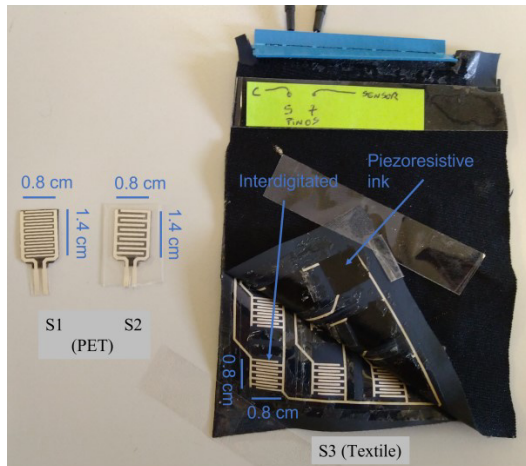


Fig. 1. Piezoresistive sensors tested in this work.

TABLE I. GENERAL CHARACTERISTICS OF SENSORS

#Sensor	S1	S2	S3
Substrate type	PET	PET	Textile
Spacing between Interdigitated	normal (0.05 cm)	large (0.1 cm)	normal (0.05 cm)
PET or Textile layers (n)	2	2	2
Piezoresistive ink layers (n)	2	2	2
Total active area (cm ²)	1.12	1.12	0.64

B. Calibration method

The calibration process consists of an operation that establishes, under specified conditions, a relationship between the values read by the measurement system (in this case, output voltage) and the known values of the applied load (pressure values) [24]. Our method consists on applying a constant pressure under specified conditions and measure the sensor response through an appropriate conditioning circuit.

To develop this procedure, the sensor was placed on a rigid base of an electronic weighing scale (KERN PLB 1000-2) with a resolution of 0.01 gf, as shown in Fig. 2. The load was applied using a handmade platform with a worm rod and contact support (see Fig. 2) sized for the area of each sensor to distribute the load over their active area. The experimental protocol for calibrating the sensors (sensor and its conditioning circuit) was designed considering the sensor being subjected to a progressive increment of 50 gf, up to a maximum value of 1 kgf (maximum value allowed by this scale).

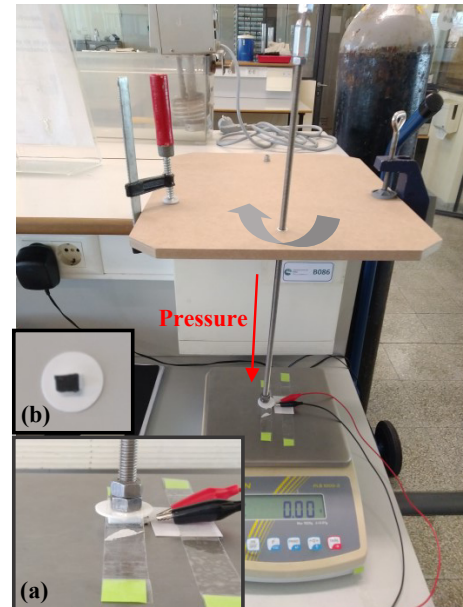


Fig. 2. Sensor calibration method. Electronic scale with a rigid base (a) and contact support for the sensor's active area (b).

The values measured by the electronic scale and the sensors measurement system were recorded to determine the calibration curve, representative of the sensor's behavior to the applied load. The sensors response was acquired using a conditioning circuit (see Fig. 3) based on a voltage divider and a microcontroller (Arduino® UNO) with a 10-bit analog-to-digital converter (ADC) operating at 5 V. Pull-down resistors with different values were used to not exceed the operating range of the ADC measurement, as indicated in Fig. 3. This setting was chosen so that the output voltage (V_{out}) increases when pressure is applied to the sensor. When the sensor is not pressed (its resistance is very high) the output voltage should be zero or very close to this value.

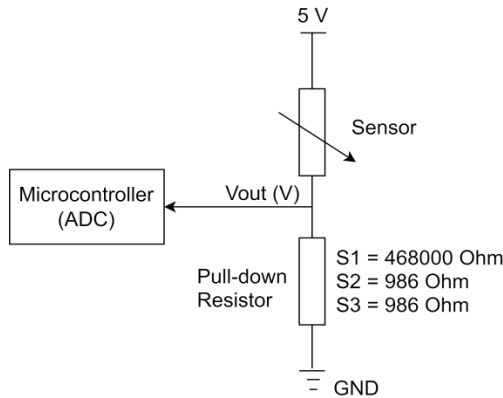


Fig. 3. Signal conditioning circuit: voltage divider with pull-down resistor.

III. RESULTS AND DISCUSSION

The calibration process was performed on all sensor samples. Fig. 4, presents the calibration curves obtained (set of sensor and circuit), showing the output voltage vs. pressure (applied in the sensor). Analyzing Fig. 4, one can verify that these sensors, generally, follow a trend with a strong approximation to the linear model, being sensor S3 the most linear. Comparing the PET sensors and observing the slope of the calibration curve (Fig. 4), sensor S1 has a higher sensitivity than S2, as S1 has a much smaller interdigitated spacing, thus increasing the contact area. In these conditions, the sensitivity values (and the corresponding uncertainties) are 40.4 ± 1.6 mV/kPa, 12.6 ± 0.4 mV/kPa and 2.4 ± 0.1 mV/kPa, for S1, S2 and S3 sensors, respectively.

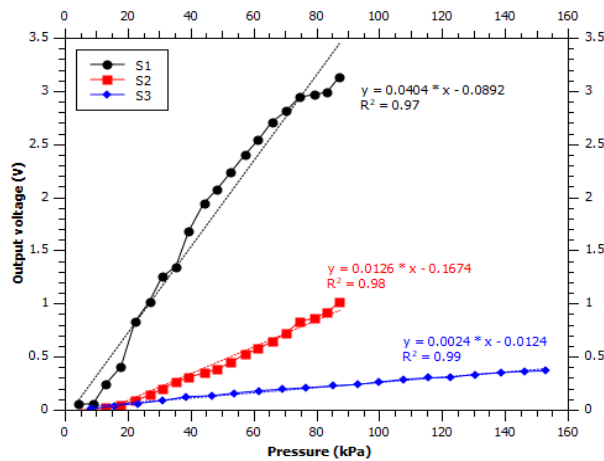


Fig. 4. Conditioning circuit sensor calibration curves.

Analyzing the sensors response according to their characteristics (Table I), sensors S1 and S2 are similar but with different interdigitated patterns and pull-down resistor. Analyzing both sensitivities, one can notice that it is higher for the sensor with a normal interdigitated pattern (S1) than the large interdigitated sensor (S2). Additionally, this sensitivity

can be also influenced by the pull-down resistor. Sensors S1 and S3 have equal interdigitated, although, these sensors have different areas and pull-down resistors, but the force is applied uniformly over their active area, so, it will not affect their response. In this way, the sensitivity is only influenced by their substrates and pull-down resistors. Some authors [25]–[27], describe that textile sensors have the disadvantage of not being always linear. In our tests, and in the case of sensor S3 (textile), although its calibration curve does not present a very high sensitivity, this sensor is the one with the greatest linearity, in the measurements range, a feature much appreciated for future applications, such as in wearable systems [20], [26].

In the tests carried out, a measurement range of 1 kgf was defined, which corresponds to different pressures in each sensor because of their active area, with S1 and S2 subjected to a maximum pressure value of about 87 kPa and S3 to a value close to 153 kPa. Looking into the possibility of integrating these sensors in an insole for measuring plantar pressures, a greater operating range is required, typically up to 500 kPa [28]. In this approach, we present a more targeted operating range for upper shoe pressures, that can go up to 60 kPa [29].

Considering that piezoresistive ink-based sensors normally exhibit a nonlinear response for wider force ranges, more tests will be needed to verify their linear response in a wide operating range suitable for insole applications. Nevertheless, after establishing their wider range response, it is possible to divide any non-linear response into two or even more linear sub-ranges.

IV. CONCLUSION

The results obtained in the calibration tests of these sensors, are within the expectations for this piezoresistive ink (Nanopaint, PR2NP®). A positive factor to consider lies in the possibility of using this technology on different substrates, preferably as textile fabric. The textile fabric being a flexible and malleable material, is much easily integrated and therefore suitable for several types of applications, like instrumented insoles and upper-shoe sensing. The use of this piezoresistive ink technology allows greater freedom in choosing the sensitivity and size of the sensor according to the intended application. For future work and to a better understanding of this specific piezoresistive ink, more sensors samples and tests with a larger load range are needed.

ACKNOWLEDGMENT

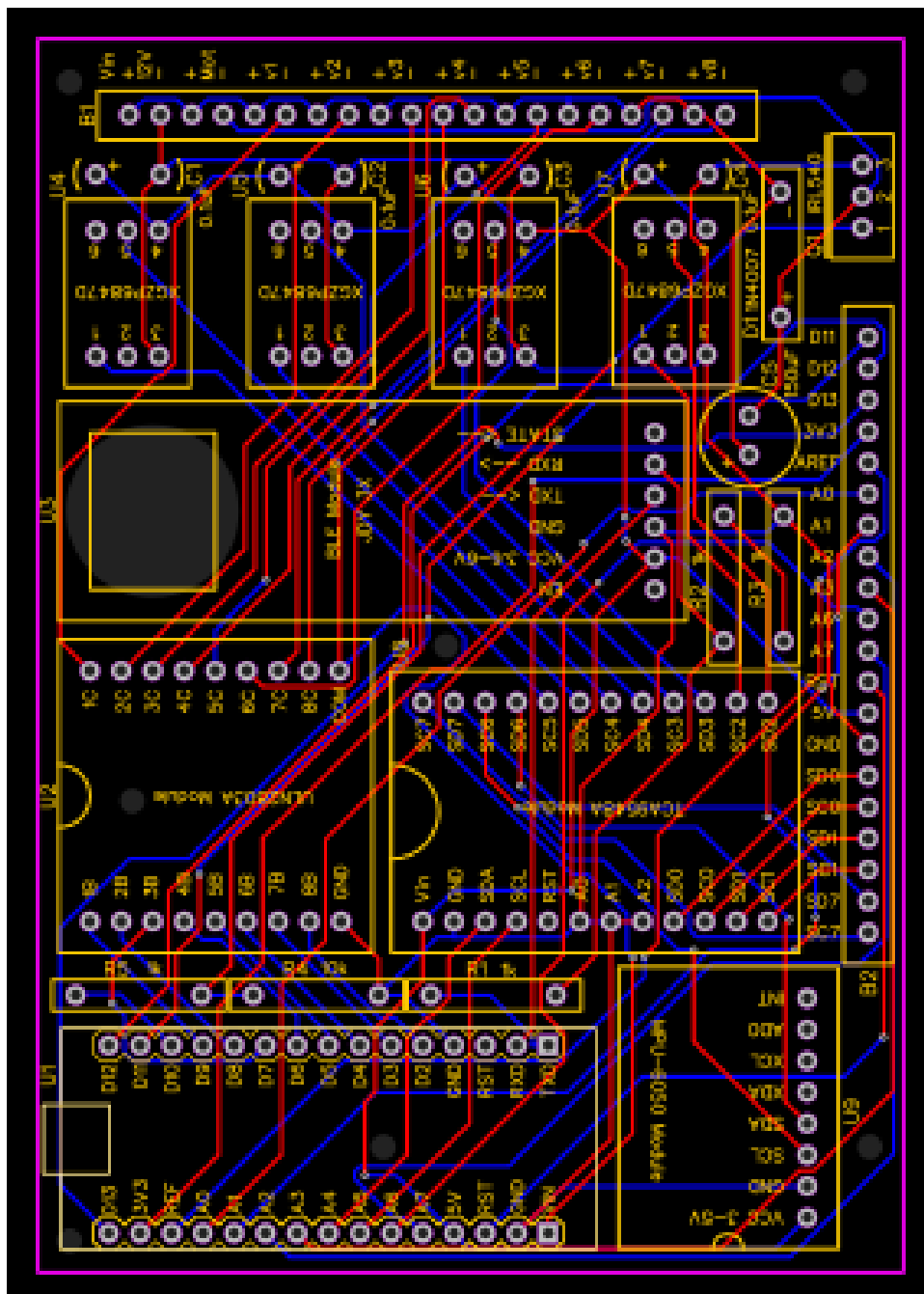
This work was developed in the scope of the “SMART-HEALTH-4-ALL – Smart medical technologies for better health and care” project (POCI-01-0247-FEDER-046115; LISBOA-01-0247-FEDER-046115), which was co-financed by Portugal 2020, under the Operational Program for Competitiveness and Internationalization (COMPETE 2020) through the European Regional Development Fund (ERDF). PM's contribution to this work was within the scope of a PhD grant (UI/BD/151285/2021) financed by the Portuguese Foundation for Science and Technology (FCT, Portugal). A special thanks to the company Nanopaint, Lda for providing the sensor samples used in this work.

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Appendix B – Technical design and electrical circuit diagram of the PCB for the electropneumatic control and automation unit.

PCB Technical Design Excerpt.



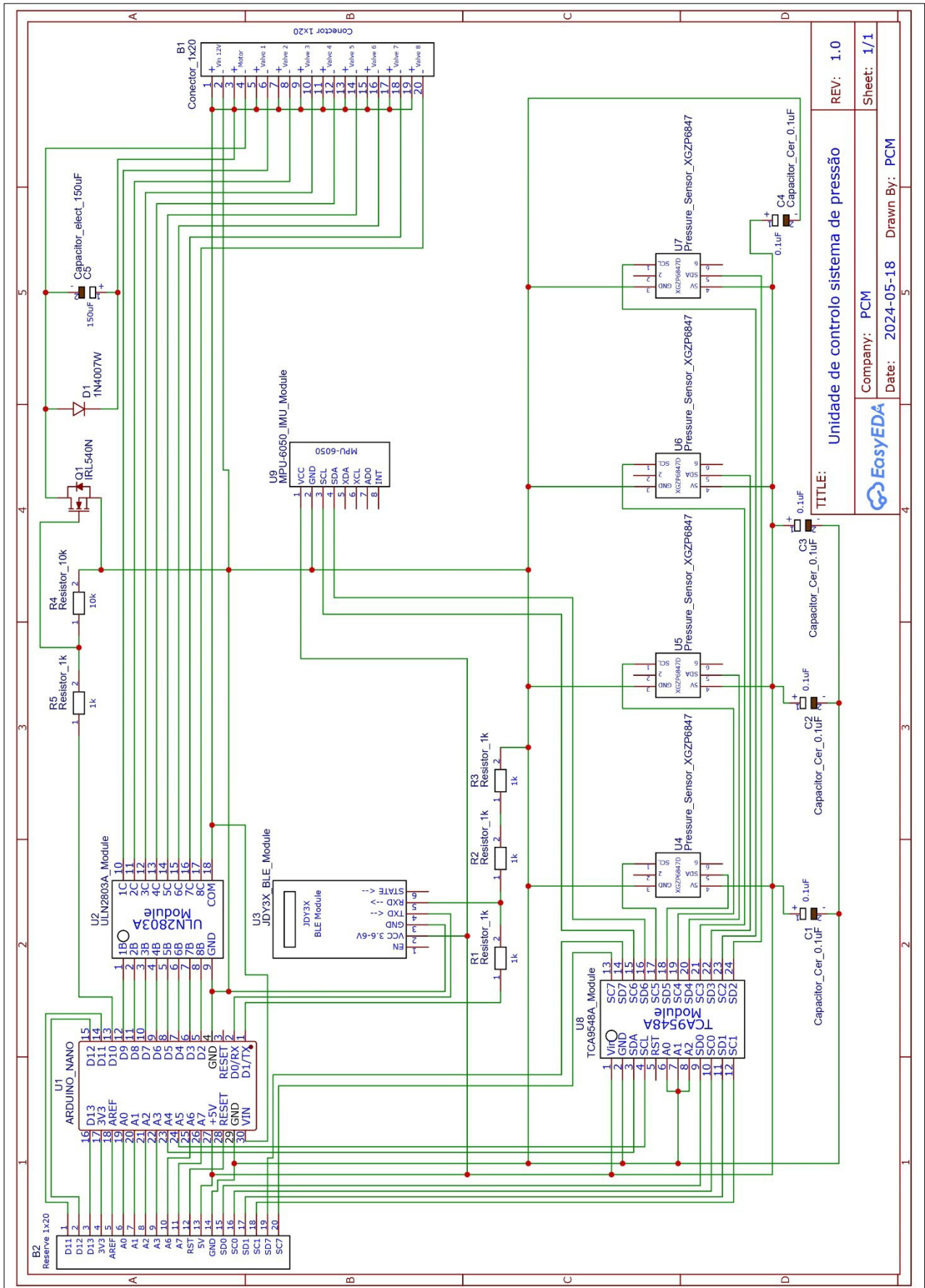
PCB dimensions: 10 × 7 cm

Supply voltage: 12 V DC

Operating voltage: 3.3–5 V DC

Other characteristics: double-sided PCB assembly with through-hole technology (THT)

Electrical Circuit Diagram.



Appendix C – Approval by the Ethics Committee and protocol for the usability study of the pneumatic insole system (MoonWalking®).



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PARECER DA COMISSÃO DE ÉTICA

Número de Registo da Comissão de Ética: CE0077F Data receção do Documento: 27/06/2025 Existência de entradas anteriores: Não

TÍTULO DO TRABALHO:
Avaliação exploratória de usabilidade da palmilha pneumática MoonWalking equipada em calçado de segurança

INVESTIGADOR RESPONSÁVEL: Pedro Manuel de Castro Martins

DATA PREVISTA PARA A REALIZAÇÃO DO TRABALHO: Início 01/09/2025 | Fim 30/10/2025

RESUMO DO ESTUDO

OBJETIVOS:
Nada a referir.

AMOSTRA:
A amostra deste estudo será composta por 20 participantes adultos recrutados de forma não probabilística por conveniência, dentro da comunidade académica e/ou de trabalhadores que utilizam regularmente calçado de segurança.
Modo de contacto e recrutamento:
Os participantes serão recrutados através de contacto direto, divulgação por email institucional e/ou afixação de cartazes informativos em locais estratégicos das instituições e/ou empresas parceiras. O objetivo será garantir a participação de indivíduos que normalmente utilizem calçado de segurança durante a sua atividade laboral ou que se enquadrem no perfil-alvo da palmilha a testar.
População-alvo:
A população-alvo inclui pessoas adultas entre os 18 e os 60 anos, com experiência de uso de calçado de segurança durante a sua atividade laboral (mínimo de 4 horas por dia).

FORMULÁRIO DE DADOS A RECOLHER:
Todos os dados serão codificados através da atribuição de um número ou código de participante, de forma a garantir o anonimato total. Não será recolhida qualquer informação identificável (como nome, número de documento de identificação, ou similar), como tal, não será possível associar a pessoa aos dados recolhidos. O conjunto de dados recolhidos são: idade, sexo, peso, altura, profissão/atividade, respostas dos questionários e registos do valor da pressão plantar. Alguém com acesso a estes dados nunca os conseguirá associar ao participante.

MATERIAL:
Não aplicável.

MÉTODOS:
Nada a referir.

RISCOS:
Refere a não existência de riscos

CONSENTIMENTO INFORMADO:
Nada a referir.

AUTORIZAÇÃO PELOS RESPONSÁVEIS LOCAIS:
Nada a referir.



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APRECIÇÃO DA COMISSÃO DE ÉTICA:

Apresenta todos os documentos, incluindo os questionários, encontrando-se o processo bem instruído.

PARECER FINAL DA COMISSÃO DE ÉTICA

De acordo com os dados analisados, o parecer é favorável desde que cumpridas todas as diretrizes submetidas a esta Comissão, recomendando-se que a decisão seja suspensa caso haja algum incumprimento grave.

Assinado por: **Pedro Manuel Ribeiro da Rocha**
Monteiro

Num. de Identificação: 09132856

Data: 2025.07.19 08:59:32 +0100

16/07/2025

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FOLHA DE ROSTO DO ESTUDO DE INVESTIGAÇÃO E DESENHO DO PROJETO

UTILIZAÇÃO OBRIGATÓRIA

TÍTULO: Avaliação exploratória de usabilidade da palmilha pneumática MoonWalking equipada em calçado de segurança

CLASSIFICAÇÃO: Estudo observacional experimental e exploratório de usabilidade com desenho cruzado (crossover)

☐ TRABALHO EM PARCERIA COM OUTRO INVESTIGADOR: ☐ NÃO ☐ SIM. SE SIM, NOME DO INVESTIGADOR:

☐ TRABALHO ACADÉMICO DE INVESTIGAÇÃO: ☐ NÃO CONFERIDOR DE GRAU ☐ CONFERIDOR DE GRAU:

☐ LICENCIATURA ☐ MESTRADO ☐ DOUTORAMENTO

☐ PROJETO DE INVESTIGAÇÃO ☐ ENSAIO CLÍNICO

☐ MEDICAMENTOS | ☐ DISPOSITIVOS MÉDICOS

☒ OUTROS Parte de trabalho académico de investigação no âmbito do Programa Doutoral em Segurança e Saúde Ocupacionais

VERSÃO: ☒ NOVO ☐ PROLONGAMENTO ☐ MODIFICAÇÃO/ADENDA (O investigador deverá apenas preencher os campos do formulário sujeitas a alteração e/ou apresentar a documentação).

CALENDARIZAÇÃO: DATA DE INÍCIO 01/09/2025 DATA DE CONCLUSÃO 30/10/2025

INVESTIGADORES
(É fundamental o e-mail, já que este constituirá a forma preferencial de contacto com os investigadores)

INVESTIGADOR RESPONSÁVEL PELA SUBMISSÃO À COMISSÃO DE ÉTICA

NOME: Pedro Manuel de Castro Martins
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ORIENTADOR

NOME: Maria Arcelina Marques
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EQUIPA DE INVESTIGAÇÃO

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ESS.004.MO.312.03

NOME 3: **Luis Filipe Martins Pinto Coelho**

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ELO DE LIGAÇÃO DA ESS|P.PORTO

NOME: **Não aplicável**

INSTITUIÇÃO | SERVIÇO | GRUPO PROFISSIONAL: **Não aplicável**

CONTACTOS (E-MAIL | TELEFONE | TELEMÓVEL): **Não aplicável**

INSTITUIÇÕES E SERVIÇOS

UNIDADES, DEPARTAMENTOS E SERVIÇOS DA ESS|P.PORTO (de entre as indicadas, mencione qual é a proponente):

Não aplicável

OUTRAS INSTITUIÇÕES INTERVENIENTES (Indique outras Instituições, Unidades, Departamentos e Serviços):

ISEP – Instituto Superior de Engenharia do Porto

CIETI – Centro de Inovação em Engenharia e Tecnologia Industrial (proponente)

FEUP – Faculdade de Engenharia da Universidade do Porto

CARACTERÍSTICAS DO ESTUDO

I. FUNDAMENTAÇÃO TEÓRICA (até 2000 caracteres (inclui espaços)):

A pressão plantar excessiva é um fator de risco bem documentado para o desenvolvimento de lesões nos pés, particularmente em pessoas com a doença da diabetes ou em populações que permanecem elevado tempo em pé, como é o caso dos trabalhadores que utilizam calçado de segurança. O desenvolvimento de soluções inovadoras para a gestão da pressão plantar tem sido objeto de investigação crescente, especialmente no âmbito da prevenção de lesões e melhoria do conforto durante atividades prolongadas.

As palmilhas pneumáticas surgem como uma alternativa promissora aos materiais ou métodos convencionais, permitindo uma redistribuição dinâmica da pressão exercida sobre a região plantar. A palmilha MoonWalking, objeto deste estudo, foi concebida com o objetivo de otimizar essa redistribuição através de células pneumáticas internas, promovendo a adaptação à morfologia plantar e aos padrões de carga ao longo do dia. Estas células de ar têm um controlo independente e estão localizadas nas principais zonas do pé que suportam o peso corporal: calcanhar; mediopé-lateral; metatarsos; e dedos. A aplicação prática de uma palmilha desta natureza no contexto de utilização de calçado de segurança poderá representar uma solução relevante na promoção da segurança e saúde ocupacionais.

A eficácia de uma solução tecnológica deste tipo deve ser avaliada não apenas por métodos laboratoriais objetivos, mas também pela experiência e perceção do utilizador. A avaliação da usabilidade, referente ao conforto e funcionalidade percebida, é crucial nas fases iniciais de desenvolvimento, fornecendo dados relevantes sobre a aceitação e aplicabilidade da solução em contexto real.

II. OBJETIVO (até 2000 caracteres (inclui espaços)):

Este estudo centra-se na avaliação exploratória da palmilha MoonWalking integrada em calçado de segurança, com o propósito de recolher dados preliminares sobre a perceção de conforto e funcionalidade para a gestão da pressão plantar. O uso de um desenho cruzado (crossover) permite que cada participante atue como o seu próprio controlo (com e sem palmilha pneumática), aumentando a robustez dos dados recolhidos mesmo com uma amostra mais reduzida. Os objetivos deste estudo são avaliar, de forma exploratória, (1) a perceção de conforto e da (2) funcionalidade associada à utilização da palmilha pneumática MoonWalking para a gestão da pressão plantar, quando equipada em calçado de segurança, em comparação com o mesmo calçado apenas com a palmilha original. Pretende-se recolher dados subjetivos dos participantes, em contexto de uso real, por meio de escalas de avaliação validadas, para analisar o impacto da palmilha na experiência de utilização.

Sendo um estudo observacional experimental de usabilidade com natureza exploratória, a presente investigação permitirá identificar tendências, limitações e potencial de melhoria do produto, fornecendo uma base sólida para estudos futuros com maior dimensão, em populações e setores laborais alvo.

III. Riscos inerentes à Investigação: ☐ SIM ☒ NÃO (Se sim, descrever como acautelar/resolver esses riscos)

IV. CRONOGRAMA

Tarefas a realizar	1 set. a 10 set. (10 dias)	11 set. a 10 out. (30 dias)	11 out. a 30 out. (20 dias)
Recrutamento de participantes			
Ensaio com o calçado de segurança com a palmilha original			
Ensaio com o calçado de segurança equipado com a palmilha pneumática			
Tratamento e análise de dados			

V. METODOLOGIA

1) Tipo de Estudo (classificar o estudo justificando)

Este é um estudo observacional experimental e exploratório de usabilidade com desenho cruzado (crossover).

A classificação como observacional justifica-se pelo facto de o estudo não envolver variáveis independentes no sentido clínico tradicional, mas sim a observação e comparação da percepção dos participantes em duas condições de uso (com e sem a palmilha pneumática). No entanto, incorpora também um carácter experimental, dado que há uma intervenção controlada (a utilização de uma palmilha inovadora) e uma recolha sistemática de dados sobre a percepção do utilizador.

A natureza exploratória do estudo deve-se ao facto de ainda não existirem dados prévios suficientes sobre a utilização desta palmilha em contexto real, sendo este um ensaio preliminar que visa obter indicadores iniciais sobre conforto e funcionalidade percebida pelo utilizador. Como tal, não se pretende fazer generalizações estatísticas para uma população, mas sim identificar tendências e avaliar a viabilidade da solução proposta.

Optou-se por um desenho cruzado (crossover), no qual cada participante experimenta ambas as condições: uso de calçado de segurança com e sem a palmilha pneumática MoonWalking em momentos distintos. Esta abordagem permite a comparação intraparticipante. Esta abordagem reduz a variabilidade individual e aumenta a robustez dos dados, sendo especialmente útil em estudos com amostras pequenas.

Por fim, a classificação como estudo de usabilidade enquadra-se no objetivo principal: avaliar a percepção subjetiva dos utilizadores relativamente ao conforto e funcionalidade da palmilha inovadora no uso com calçado de segurança.

2) Amostra e participantes (modo de contato/recrutamento, critérios de inclusão/exclusão, população alvo)

Amostra:

A amostra deste estudo será composta por 20 participantes adultos recrutados de forma não probabilística por conveniência, dentro da comunidade académica e/ou de trabalhadores que utilizam regularmente calçado de segurança.

Modo de contacto e recrutamento:

Os participantes serão recrutados através de contacto direto, divulgação por email institucional e/ou afixação de cartazes informativos em locais estratégicos das instituições e/ou empresas parceiras. O objetivo será garantir a participação de indivíduos que normalmente utilizem calçado de segurança durante a sua atividade laboral ou que se enquadrem no perfil-alvo da palmilha a testar.

População-alvo:

A população-alvo inclui pessoas adultas entre os 18 e os 60 anos, com experiência de uso de calçado de segurança durante a sua atividade laboral (mínimo de 4 horas por dia).

Critérios de inclusão:

- Idade entre 18 e 60 anos (sexo masculino e/ou feminino);
- Utilização regular de calçado de segurança durante, pelo menos, 4 horas consecutivas por dia;
- Tamanho do pé correspondente ao número europeu 44 (EU44), por ser o único disponível da palmilha em teste;
- Capacidade de caminhar autonomamente e sem qualquer auxílio;
- Disponibilidade para cumprir o protocolo completo do estudo, incluindo os períodos de teste com e sem palmilha;
- Concordância em participar e assinatura do termo de consentimento informado.

Critérios de exclusão:

- Lesões ativas, infeções ou outras complicações nos pés ou membros inferiores;
- Alterações significativas da morfologia do pé (ex.: pé cavo ou pé plano acentuado);
- Cirurgias aos pés ou membros inferiores nos últimos 12 meses;
- Qualquer patologia musculoesquelética, neurológica ou vascular nos membros inferiores;
- Contra-indicação médica para caminhada leve a moderada;
- Contra-indicação para o uso de calçado de segurança genérico;
- Utilização habitual de palmilhas ortopédicas personalizadas;
- Massa corporal superior a 120 kg;
- Gravidez;
- Qualquer condição física, cognitiva ou comunicacional que, segundo o investigador ou o próprio participante, impeça a participação segura e esclarecida no estudo, mesmo após fornecimento de informação adequada.

- 3) Procedimentos de recolha de dados (descrever todos os passos inerentes à recolha de dados e respetivos materiais)

A recolha de dados será realizada em contexto controlado, em instalações das instituições parceiras ou em local previamente autorizado (por ex., em ambiente laboral) e adequado à realização dos testes com calçado de segurança.

O estudo terá um desenho cruzado (crossover), no qual cada participante testará duas condições experimentais:

1. Calçado de segurança com palmilha original do fabricante (controlo);
2. Calçado de segurança com palmilha pneumática MoonWalking.

A ordem das condições será aleatória para minimizar o efeito da ordem e possíveis enviesamentos.

Fases do Procedimento:

1. Sessão de acolhimento e consentimento informado
 - Explicação dos objetivos do estudo, procedimentos e duração;
 - Esclarecimento de dúvidas;
 - Assinatura do termo de consentimento informado.
2. Avaliação prévia
 - Registo dos dados demográficos (idade, sexo, peso, altura, profissão/atividade);
 - Verificação dos critérios de inclusão/exclusão;
 - Confirmação do número de calçado (EU44);
 - Atribuição aleatória da ordem de uso das palmilhas (original vs. pneumática).

3. Teste com a palmilha original do sapato (ordem atribuída no procedimento 2)

O participante calça os sapatos de segurança com a palmilha original e realiza a sua atividade laboral normal durante um período de uma hora. No final deste período o participante deve preencher um questionário de conforto (consultar a secção VI, ponto 2), cujas respostas são baseadas numa escala VAS (Visual Analogue Scale). Adicionalmente, seguem-se algumas questões de resposta direta (sim/não) para avaliar a funcionalidade da palmilha percebida pelo utilizador.

4. Intervalo de descanso

- Pausa de 10 a 15 minutos.

5. Teste com a palmilha pneumática MoonWalking (ordem atribuída no procedimento 2)

O procedimento segue a mesma metodologia da outra condição (consoante a ordem sorteada no procedimento 2), mas agora o participante calça os sapatos de segurança equipados com a palmilha pneumática. No final do ensaio, o participante responde ao mesmo questionário (consultar a secção VI, ponto 2) com os mesmos instrumentos de avaliação, embora direcionado para a palmilha pneumática.

6. Teste adicional de funcionalidade da palmilha pneumática MoonWalking

Este teste visa avaliar, segundo a percepção do utilizador, as funções dinâmicas da palmilha pneumática MoonWalking: estabilizar, descarregar e redistribuir a pressão plantar. Para isso, e para comprovar que estas ações foram executadas, durante estes procedimentos o sistema pneumático de medição e monitorização da pressão plantar estará ativo.

O procedimento deste teste adicional tem a seguinte ordem:

- a) O participante utilizará novamente o calçado de segurança;
- b) Um sapato conterá a palmilha pneumática MoonWalking ligada à unidade de controlo pneumático (esta unidade é acoplada na cintura do participante);
- c) O outro sapato conterá uma palmilha pneumática selada (pressurizada e vedada da pressão atmosférica), servindo como controlo passivo;
- d) Apenas o pé direito do participante estará conectado à unidade de controlo pneumático (por limitações do protótipo atual, contudo, o outro pé servirá de controlo);
- e) O participante deverá permanecer de pé, estático e com os dois pés posicionados em solo regular;
- f) O investigador realizará procedimentos simulados de modulação da pressão (consultar a secção VI, ponto 1.1) nas quatro regiões anatómicas da palmilha: calcanhar, mediopé-lateral, metatarsos e dedos;
- g) Em cada região, será feita uma sequência de "estabilização" (uniformização da pressão à morfologia do pé) e depois uma sequência de "descarga" (redução ativa da pressão);
- h) Após cada intervenção, o investigador interroga o participante com base num questionário específico de funcionalidade percebida (consultar a secção VI, ponto 2) para cada região plantar.

7. Comentário final

- Possibilidade de registo de percepção global do participante e comentários livres;
- Registo de qualquer ocorrência adversa ou dificuldade durante os ensaios.

4) Procedimentos de tratamento dos dados (descrever forma de armazenamento, tratamento e eliminação dos dados)

Todos os dados recolhidos ao longo do estudo serão tratados de forma confidencial e em conformidade com o Regulamento Geral sobre a Proteção de Dados (RGPD – Regulamento (UE) 2016/679).

Armazenamento e segurança dos dados:

Os dados recolhidos serão inicialmente registados em fichas individuais em suporte físico (papel) ou digital (tablet/computador). Posteriormente, serão inseridos numa base de dados eletrónica local, armazenada em ambiente digital seguro, com acesso restrito ao investigador responsável e protegido por palavra-passe. Todos os dados serão codificados através da atribuição de um número ou código de participante, de forma a garantir o anonimato total. Não será recolhida qualquer informação identificável (como nome, número de documento de identificação, ou similar), como tal, não será possível associar a pessoa aos dados recolhidos. O conjunto de dados recolhidos são: idade, sexo, peso, altura, profissão/atividade, respostas dos questionários e registos do valor da pressão plantar. Alguém com acesso a estes dados nunca os conseguirá associar ao participante.

Tratamento e análise dos dados:

Os dados quantitativos recolhidos (por ex., valores de pressão plantar) serão organizados numa folha de cálculo (por ex., Excel) e posteriormente analisados com recurso a software estatístico apropriado (por ex., em Python, R, SPSS ou equivalente). Serão realizadas análises estatísticas descritivas (média, desvio-padrão, mínimo e máximo) e comparações entre condições (por ex., testes não paramétricos como o teste de Wilcoxon para dados pareados). Os dados qualitativos (por ex., respostas diretas e os comentários dos participantes) serão analisados por categorização temática simples, com o objetivo de identificar padrões de percepção.

Eliminação dos dados:

Todos os dados brutos que sejam previamente armazenados em formato físico serão transcritos para formato digital e guardados como anteriormente descrito. Porém, os ficheiros físicos serão guardados por um período máximo de dois meses após a conclusão do estudo, exclusivamente para fins de conversão em formato digital. Após esse período, todos os dados em suporte físico serão destruídos (tritutados) de forma a garantir a sua ilegibilidade. Uma vez em formato digital, todos os dados serão processados e realizada a sua análise estatística. Após este processamento, os dados brutos serão mantidos por um período de 24 meses, findo o qual, os dados serão eliminados digitalmente de forma segura.

Prevê-se que os dados processados (anonimizados e armazenados digitalmente) venham a ser utilizados para fins científicos.

Importa realçar que, apesar destes procedimentos de destruição dos ficheiros físicos e digitais, todos os dados obtidos são anonimizados desde o início do registo, uma vez que nenhuma informação pessoal dos participantes é recolhida nem é possível obtê-la de forma reversa.

VI. INSTRUMENTOS DE RECOLHA DE DADOS

1) Equipamentos

Para a realização do estudo serão utilizados os seguintes equipamentos:

- Calçado de segurança genérico (EU44): modelo padrão (igual para todos os participantes) de calçado de segurança disponível no mercado compatível com a inserção de diferentes palmilhas, garantindo as mesmas condições de proteção e suporte entre as condições testadas;
- Palmilhas padrão do calçado de segurança: palmilhas originais fornecidas com o calçado de segurança, utilizadas como controlo;
- Palmilhas pneumáticas MoonWalking: palmilhas inovadoras com um sistema de gestão de pressão plantar dinâmico, projetadas para redistribuir a pressão durante a marcha. Foram desenvolvidas especificamente para este estudo e estão adaptadas ao tamanho EU44;
- Unidade de controlo pneumático: sistema compacto (L x A x P; 10 x 12 x 5 cm) acoplado na cintura do participante para o teste adicional de funcionalidade da palmilha pneumática;
- Ambiente laboral (área de ação): área com piso regular e demarcada para garantir uniformidade no esforço e nos contextos de teste;
- Cronómetro ou aplicação de controlo de tempo: para monitorizar a duração de cada condição de teste e dos intervalos de descanso;
- Balança: para registo da massa corporal do participante;
- Ficha de registo individual do participante (totalmente anonimizada): para recolher dados genéricos dos participantes, ordem da condição testada, e eventuais comentários ou ocorrências. A cada participante será atribuído um código numérico de participação sem qualquer outro registo que permita identificar a pessoa posteriormente;
- Computador, tablet ou smartphone para resposta digital aos questionários de avaliação aplicados.

1.1) Sistema MoonWalking e modo de operação

O sistema MoonWalking compreende uma palmilha pneumática e uma unidade de controlo pneumático. A palmilha (tamanho EU44) é produzida em borracha e silicone (skin safe) com uma espessura de 14 mm e é constituída por quatro células de ar localizadas nas regiões do calcanhar, mediopé-lateral, metatarsos e dedos. A unidade de controlo pneumático, que fica acoplada na cintura do utilizador e conectada à palmilha através de quatro tubos de silicone de Ø 4 mm, é portátil, alimentada a bateria e acomoda toda a eletrónica numa estrutura compacta (L x A x P; 10 x 12 x 5 cm).

O princípio de funcionamento desta palmilha baseia-se na pressão do peso corporal do utilizador que é suportada pelos pés na região plantar. Em síntese, o utilizador ao usar um sapato equipado com esta palmilha pressiona as células de ar e, através de sensores de pressão pneumática, é monitorizada a pressão que retorna das células, sendo assim possível obter o valor de pressão plantar em cada região do pé. A medição dos valores de pressão é realizada com uma frequência de 15 Hz e o controlo das eletroválvulas e da minibomba pneumática para regular o volume de ar é operado por um algoritmo programado na unidade de processamento. Adicionalmente, com uma aplicação móvel para smartphone que comunica com o sistema através de Bluetooth, é possível interagir com a palmilha para gerir os níveis de pressão e registar os valores medidos.

As ações que podem ser executadas no sistema MoonWalking são:

- Estabilizar/uniformizar a pressão plantar: este evento consiste em uniformizar a pressão plantar, ou seja, ajustar a palmilha à morfologia do pé, anulando eventuais zonas com picos de pressão localizados;
- Descarregar a pressão localizada: este evento permite drenar ar de uma determinada célula de ar para reduzir a pressão naquela zona;
- Redistribuir a pressão: esta ação tem por base os dois eventos anteriores (estabilizar e descarregar), que, ao serem executados, estão a promover uma redistribuição da pressão plantar. A pressão plantar exercida pelo peso corporal não pode ser anulada, mas a sua distribuição por toda a região plantar pode ser otimizada.

2) Questionários

Para avaliar o conforto e a funcionalidade da palmilha em estudo, através de questionários aplicados aos participantes no final de cada intervenção, serão aplicados os seguintes instrumentos de avaliação:

1. Escala Visual Analógica (VAS - Visual Analogue Scale) de conforto global

Escala de pontuação quantitativa de 0 a 10 onde o participante assinala o seu nível de conforto global, com ancoragem nos extremos: "Desconforto extremo" (0) e "Conforto máximo" (10).

2. Questões de usabilidade funcional

Conjunto de perguntas de resposta simples (sim/não) sobre a perceção funcional do calçado.

3. Comentários livres

Espaço aberto no final de cada intervenção/questionário onde os participantes podem deixar comentários, sensações, ou outras observações adicionais sobre o desempenho das palmilhas.

Questionário para as fases de teste com as palmilhas no calçado de segurança: palmilha original e pneumática MoonWalking

Atribua uma classificação de 0 a 10 valores, para:

Conforto geral

Muito reduzido 0 1 2 3 4 5 6 7 8 9 10 Muito elevado

Nível de amortecimento

Muito reduzido 0 1 2 3 4 5 6 7 8 9 10 Muito elevado

Estabilidade ao caminhar

Muito reduzida 0 1 2 3 4 5 6 7 8 9 10 Muito elevada

Adaptação da palmilha ao pé

Muito reduzida 0 1 2 3 4 5 6 7 8 9 10 Muito elevada

Temperatura do pé

Muito frio 0 1 2 3 4 5 6 7 8 9 10 Muito quente

Nível de fadiga no final da atividade

Muito reduzido 0 1 2 3 4 5 6 7 8 9 10 Muito elevado

Responda às questões assinalando com "x":

Notou alguma limitação dos seus movimentos?

Sim [] Não []

Notou alguma dor, desconforto ou pressão excessiva numa zona específica?

Sim [] Não []

Voltaria a usar este calçado com esta palmilha em contexto laboral?

Sim [] Não []

Sugestões ou comentários adicionais:

Questionário para a fase de teste adicional de funcionalidade da palmilha pneumática MoonWalking

Responda às questões assinalando com "x":

Após o evento de estabilizar/uniformizar a pressão, sentiu a palmilha mais bem adaptada ao pé?

Sim [] Não []

Quando o descarregamento da pressão foi atuado, sentiu uma redução da pressão na zona alvo?

Zona 1, dedos: Sim [] Não []

Zona 2, metatarsos: Sim [] Não []

Zona 3, mediopé: Sim [] Não []

Zona 4, calcanhar: Sim [] Não []

Notou alguma dor, desconforto ou pressão excessiva numa zona específica?

Sim [] Não []

Sugestões ou comentários adicionais:

Development of an Active In-shoe Pneumatic System for Monitoring and Redistributing Plantar Pressures: Toward Diabetic Foot Management

Pedro Manuel de Castro Martins

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