# Advances in diabetic footwear and plantar pressure distribution devices: literature review on design, efficacy, and patient outcomes DOI: 10.35530/IT.076.01.2024149

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#### ABSTRACT – REZUMAT

# Advances in diabetic footwear and plantar pressure distribution devices: literature review on design, efficacy, and patient outcomes

This literature review aims to explore the significance of diabetic footwear in managing foot-related complications associated with diabetes, especially related to diabetic neuropathy, peripheral arterial disease, and ulcerations. The goal is to synthesise key research on the design, efficacy, and impact of diabetic footwear in preventing foot ulcers, reducing pressure, and promoting healing. The review highlights recent advancements in diabetic footwear technology, including innovations such as smart sensors and other industry 4.0 advancements, while also addressing the barriers to patient compliance and the challenges in evaluating long-term outcomes. Special considerations are addressed to publications and authors in the field of diabetic research as their continuous impact drives knowledge forward and provides relevant data in improving patients' quality of life. Findings show that diabetic footwear plays a critical role in preventing foot complications, but further research is needed to standardise footwear designs and assess long-term benefits.

Keywords: diabetic footwear, neuropathy, diabetic foot, ulcers, plantar pressure offloading, footwear design

#### Progrese aduse încălțămintei pentru diabetici și a dispozitivelor de distribuție a presiunilor plantare: analiza literaturii privind designul, eficiența și impactul asupra pacientului

Această trecere în revistă a studiilor recente în domeniul încălțămintei terapeutice pentru pacientul diabetic își propune să exploreze importanța încălțămintei pentru diabetici în gestionarea complicațiilor asociate diabetului la nivelul picioarelor, în special cele legate de neuropatia diabetică, boala arterială periferică și ulcerațiile. Scopul este de a sintetiza cercetările cheie privind designul, eficiența și impactul încălțămintei pentru diabetici în prevenirea ulcerației piciorului, reducerea presiunii plantare și promovarea vindecării. Analiza evidențiază progresele recente în dezvoltarea încălțămintei pentru diabetici, inclusiv inovații precum introducerea senzorilor inteligenți și alte progrese ale industriei 4.0, abordând totodată barierele în calea asimilării de către pacienți a acestui tip de încălțăminte si provocările în evaluarea rezultatelor pe termen lung. Considerații speciale sunt adresate publicațiilor și autorilor din domeniul cercetării diabetului, deoarece impactul lor continuu dezvoltă cunoștințele și oferă date relevante pentru îmbunătățirea calității vieții pacienților. Constatările arată că încălțămintea pentru diabetici joacă un rol critic în prevenirea complicațiilor piciorului diabetic, dar sunt necesare cercetări suplimentare pentru a standardiza modelele de încălțăminte și pentru a evalua beneficiile pe termen lung.

*Cuvinte-cheie:* încălțăminte pentru diabetici, neuropatie, picior diabetic, ulcere, descărcare de presiune plantară, design și proiectare încălțăminte

#### Introduction

Diabetes is a long-term condition affecting millions worldwide, often resulting in serious complications, particularly in the lower limbs. Among these, diabetic foot complications, such as neuropathic ulcers, represent a major challenge in diabetes management. These issues frequently lead to significant morbidity and an increased risk of limb amputation. Common conditions associated with diabetes include neuropathy, peripheral arterial disease, and the development of foot ulcers. Diabetic foot ulcers, which affect up to 25% of individuals with diabetes at some point in their lives, remain a critical concern due to their contribution to the high incidence of lower limb amputations. To prevent and manage these complications, appropriate footwear and plantar pressure-relieving devices are essential in minimising strain during walking [1–5]. With a current estimate of over 300 million individuals impacted globally, projections suggest that this alarming figure could potentially double by the year 2030, thereby significantly elevating the occurrence and severity of amputations linked to advanced and untreated foot ulcers.

This literature review explores recent research on diabetic footwear and advancements in plantar devices by providing valuable insight into a variety of biomechanical and neurological disorders. It assesses the effectiveness of these innovations in reducing plantar pressure, preventing ulcerations, and enhancing mobility for individuals with diabetes-related lower limb issues. By reviewing the latest studies. the objective is to highlight current healthcare practices and guide future advancements in the design and prescription of diabetic footwear. The findings emphasise the overall success of modern therapeutic footwear technologies for diabetic patients with various foot deformities. Additionally, extensive clinical trials have shown significant improvements in muscle tone supporting the arches, enhanced trophic nutrition in the feet, and a more balanced foot-loading structure [6-12]. All of these factors contribute positively to the functional capabilities of the footwear and, consequently, to the well-being of diabetic patients. According to recent studies, the use of custom plantar devices has been shown to reduce the risk of foot ulcers by up to 85%, and the recurrence rate of ulcers can drop by 50% when appropriate footwear is used in combination with other preventative measures. Additionally, patient satisfaction with adapted footwear devices is high, with over 90% reporting improved comfort and mobility. The advancements in this area represent a significant step forward in improving the quality of life for individuals suffering from diabetic foot conditions, ensuring better mobility and reduced complications arising from improper footwear [13-27].

To guide readers effectively, the paper is structured as follows:

# Introduction

• Overview of the prevalence and challenges of diabetic foot complications, the significance of diabetic footwear, and the objectives of the manuscript.

### Methodology

Description of the literature search strategy and inclusion criteria.

#### Specific demands on the diabetic foot

 Analysis of the clinical and biomechanical challenges posed by diabetes on foot health.

# Structural analysis of diabetic footwear

• Evaluation of footwear design innovations, material performance, and the role of advanced tech-

nologies in addressing diabetic foot complications

### **Customised Smart footwear solutions**

 Exploration of intelligent footwear designs incorporating adaptive technologies to optimise therapeutic outcomes

### Contributions to the literature review

 Summary of key advancements and their implications for future research and clinical applications.

# METHODOLOGY: LITERATURE SEARCH STRATEGY

The literature search used reputable databases such as Web of Science, PubMed, Scopus, and Google Scholar. The primary focus was on key terms related to diabetic footwear and innovations while also including diabetes-related foot complications and the overall quality of life for affected individuals. Key search terms included "diabetic footwear", "neuropathy", "foot ulcers", "pressure offloading", "diabetic foot care" and "footwear design". This strategy was designed to gather a broad and comprehensive selection of studies examining diabetic footwear and its effectiveness in preventing foot-related complications.

Over 60 relevant articles and conference papers were identified across scientific databases, confirming the significance of diabetic footwear as a topic of interest in numerous studies and research groups. However, not all articles were included in this review. The inclusion criteria were limited to peer-reviewed studies published within the past five years, with a focus on clinical trials, meta-analyses, and systematic reviews. Only research that specifically addressed foot complications and the role of diabetic footwear was retained, resulting in 45 peer-reviewed articles. Studies that were not peer-reviewed or unavailable in English were excluded. Additionally, a selection process considered the impact factor and citation count of the relevant papers (figure 1).

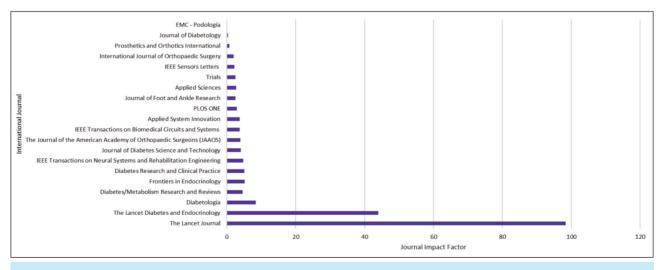


Fig. 1. Impact factor for journals and online publications in the field of diabetic footwear

# SPECIFIC DEMANDS ON THE DIABETIC FOOT

According to analysis and projections of the general impact of diabetic foot complications, these represent a formidable challenge in the holistic management of diabetes, imposing substantial health burdens and economic strains on patients and healthcare systems alike [15]. Diabetes mellitus encompasses a range of conditions that predispose individuals to foot ulcerations and potential limb loss. The pathophysiology is further complicated by vascular and neuropathic damage, present in both type 1 and type 2 diabetes, which significantly increases the risk of severe complications such as infections and, in advanced cases, amputations. Chronic hyperglycemia, along with factors like excessive pressure and thermal dysregulation at the skin interface, exacerbates these risks. The combination of poor circulation and impaired wound healing is a critical factor in the development of diabetic foot complications. Vascular insufficiency not only hinders the body's natural healing processes but also significantly increases the risk of deep infections, necrosis, and osteomyelitis. As a result, foot ulcerations become dangerous entry points for infections, heightening the risk of a cascade of severe outcomes [28-31].

Peripheral vascular disease in individuals with diabetes presents a challenging scenario characterised by reduced blood flow and subsequent risk of numerous complications. This vascular insufficiency, coupled with neuropathic changes in the extremities, creates a vulnerable condition for those affected. The development of ischemic conditions, further complicated by the unique anatomical structure of the foot, underscores the urgent need for targeted interventions. Notably, strategies such as compression therapy, advanced wound care techniques, and the use of specialised therapeutic footwear aim to improve circulation and reduce the risk of lesion formation [28, 31]. Both clinicians and patients must recognise that impaired vascular health may necessitate changes in mobility strategies to help maintain functional activity while protecting the locomotor system. This highlights the importance of regular vascular assessments, as even in the presence of neuropathy, poor blood flow can lead to severe ischemic events if not properly managed. Thus, a comprehensive and proactive approach to evaluating vascular health is essential for effectively managing diabetic foot complications [32-37].

Peripheral artery disease (PAD), often a consequence of atherosclerosis, poses a significant challenge in diabetic foot care due to its impact on circulation in the lower limbs. As arterial plaque builds up, blood flow becomes restricted, depriving tissues of vital nutrients – a critical issue for individuals at risk of diabetic foot ulcers. The gradual progression of atherosclerosis often goes unnoticed, but in severe cases of PAD, patients may experience debilitating foot pain or ulceration due to ischemia. To reduce the risk of diabetic foot ulcers, patients must maintain strict glycaemic control and eliminate smoking, both of which contribute to vascular damage. Preventive strategies should focus on those at high clinical risk, emphasising the incorporation of functional foot orthoses into treatment plans. These measures aim to enhance circulation and alleviate pressure on vulnerable areas of the foot, reducing the likelihood of ulcer formation [34–40]. Orthotic interventions designed to align the foot with the specific geometry of a patient's footwear promote an even distribution of plantar pressure. This biomechanical adjustment not only enhances propulsion dynamics but also reduces excessive forces that could otherwise jeopardise sensitive areas of the diabetic foot.

Additionally, specialised footwear aims to minimise high-impact stress, ensuring that energy generated during the push-off phase is efficiently transferred to the ground rather than absorbed by the foot. Given that diabetes-related foot infections are a leading cause of hospitalisation among this population, concerns arise regarding the adequacy of educational efforts aimed at informing high-risk individuals about the importance of foot protection and preventive care strategies. The high prevalence of ulcer formation in diabetic patients underscores the need for greater awareness and proactive management to prevent these complications [41, 42].

The formation of ulcers within the diabetic population represents a significant challenge, characterised by a notably high prevalence of foot ulceration, estimated to be between 15 and 25% over a lifetime in diabetic communities. This statistic is particularly significant when considered in the context of the broader landscape of diabetes prevalence in Europe and beyond, revealing a substantial overall number of individuals affected [1, 43]. When examining the multifaceted factors contributing to foot ulceration in diabetic patients, it becomes clear that the condition results from a complex interplay of influences. The relationship between cause and effect is rarely simple. For instance, abnormal foot pressures, often stemming from reduced pain sensation, can lead to altered gait patterns. Sensory neuropathy, particularly the loss of protective sensation, has long been recognised as a major factor in the development of foot ulcers. Current understanding suggests that the formation of plantar foot ulcers arises from the interaction of various factors, with elevated plantar pressure being a significant contributor. The diabetic foot exemplifies this intricate interplay, where diabetes directly impacts both the microvascular and macrovascular systems. The duration of diabetes further amplifies these effects. The range of contributing issues includes peripheral neuropathy, autonomic dysfunction, peripheral arterial disease, foot deformities, poorly fitting footwear, fragile and dry skin, reduced transcutaneous oxygen levels, a history of previous foot ulcers, and the presence of structural deformities such as hammer toes. This complex combination of factors highlights the need for comprehensive management strategies to prevent the onset of foot ulcers in diabetic patients [44-47].

# STRUCTURAL ANALYSIS OF DIABETIC FOOTWEAR

The design of footwear for individuals with diabetes represents a crucial interdisciplinary field of study situated at the intersection of healthcare and innovation. To gain a comprehensive understanding of this field, it is essential to go through a thorough examination of relevant patents and empirical studies, as well as relevant articles. Authors like Bus et al. [2, 6] and Hemler et al. [48] have investigated the multifaceted considerations that shape the creation of functional footwear tailored for individuals with diabetes, as interpreted by medical professionals, industry stakeholders, and design experts. The findings highlight the numerous factors that influence the design, manufacturing, and distribution of these products. A conceptual framework is proposed in their work, illustrating the evolving recognition of the diabetic consumer seament, which begins with personalised clinical solutions, progresses through adaptive manufacturing techniques, and ultimately encompasses prospective diagnostic advancements and cutting-edge technological innovations [49-52].

However, despite the advancements in therapeutic footwear, significant challenges persist in the applied design and design of diabetic footwear and plantar pressure relief devices. The study by Tiwari et al. [53] elucidates the intricacies of diabetic neuropathy and its ramifications for foot biomechanics and plantar pressure distribution innovations. The heterogeneous nature of diabetic neuropathy complicates the standardisation of interventions and makes it difficult to predict outcomes reliably. This underscores the importance of a personalised approach to diabetic foot care involving a multidisciplinary team that includes podiatrists, orthotic specialists, technicians, and other relevant healthcare professionals.

Additionally, patient non-compliance with prescribed footwear devices and inserts, which are designed to correct and relieve plantar pressures, poses a significant challenge. Many patients seek immediate results and struggle to adapt to these devices longterm, limiting the potential therapeutic benefits. Addressing this issue requires not only tailoring interventions but also enhancing patient education and support to improve adherence and ensure sustained outcomes [54–56].

Given these challenges, proposals have emerged for the development of intelligent footwear solutions that can manage plantar pressures on an individualised basis. Traditional load-relieving orthotics often lack the flexibility to adapt to dynamically changing plantar pressure patterns, which vary depending on factors like gait speed, foot contact surface, and body support surface. This limitation highlights the need for smart footwear capable of adjusting in real time to the varying demands of different gait stages. Such adaptive footwear could provide more effective pressure relief, enhancing both comfort and therapeutic outcomes for diabetic patients [48, 53, 57–60].

# Performance of insole materials for diabetic footwear

A consensus has been reached among podiatric specialists engaged in the study and analysis of treatment conditions associated with diabetic neuropathy and foot ulceration. The consensus pertains to strategies for addressing footwear solutions. The primary objective is to reduce maximum plantar pressures to mitigate the risk of diabetic foot ulcerations or to facilitate the healing and prevention of existing ulcerations. As it is noted in studies by authors such as Haris et al. [60], the impact of factors such as changes in walking speed and changes in the materials used in the manufacture of shoe uppers on plantar pressures is significant. The authors determined that slower walking speeds (approximately 4 km/h) are more suitable for individuals with complications of diabetes mellitus. Ethylene vinyl acetate (EVA) gill material was the most commonly used, and it was also the most effective in reducing maximum plantar pressures in the forefoot area. Moreover, customised multi-density gills comprising multiple densities, softer materials in the hindfoot (EVA), augmented support for the longitudinal arch of the foot, and shock-absorbing support in the metatarsal area demonstrated favourable outcomes in reducing plantar pressures and preventing ulcer recurrence, as evidenced in research by Ahmed et al. and Hemler et al. [13, 48, 61]. In the reviewed literature, it is emphasised that regardless of the route chosen to reduce foot pressures, it is essential to consider patient comfort, the patient's ability to adhere to specialist recommendations, and individual foot characteristics when selecting insole and ankle materials designed to optimise therapeutic benefits.

Papers presented at Conferences in the field of advanced medical and therapeutical footwear such as International Conference on Computer, Control and Robotics (ICCCR) [62], IEEE International Biomedical Instrumentation and Technology Conference (IBITeC) [63], International Conference on Applied Smart Systems (ICASS) [64] and 8<sup>th</sup> International Conference on Modeling Simulation and Applied Optimization (ICMSAO) [65] have presented a hard focus on insole design and construction highlighting the increased significance of footwear components in the overall product.

# CUSTOMISED SMART FOOTWEAR SOLUTIONS

In current articles in the field of diabetic footwear, many researchers have directed their attention to smart and intelligent technologies, integrating industry 4.0 concepts, making footwear advancements that will turn the products easy to accept and integrate into daily life by their prospective users. In their 2023 paper, Hemler et al. [48] introduce a novel approach to diabetic foot care: the development of smart footwear designed to relieve plantar pressures during walking. This innovative technology employs the integration of sensors within the modular footwear's modular insole, facilitating real-time monitoring and adjustment of plantar pressure distribution. This optimises the therapeutic efficacy and patient comfort.

The incorporation of self-adjusting soles and insoles, along with adaptive design features, represents a significant advancement in the preventive care of diabetic feet affected by neuropathy. These innovative footwear designs continuously redistribute plantar pressure, shifting the load from the forefoot and midfoot regions to the posterior heel area. Early evaluations have shown promising results in terms of both pressure relief effectiveness and positive user feedback. However, further research is necessary to evaluate the long-term efficacy, durability, and cost-effectiveness of these smart footwear solutions in real-world clinical settings to determine their viability as a standard intervention.

Ahmed Saved, in collaboration with numerous other researchers, is another of the most prolific authors in the field of diabetic footwear. His articles offer valuable insights into the design characteristics and efficacy of customised insoles for diabetic patients, as well as footwear design features that can reduce the risk of neuropathic foot ulceration. One of the studies conducted [13] emphasises the importance of individualised footwear and insole design features that are specifically tailored to each individual user. This is a crucial aspect to be considered to address specific foot pathologies and various biomechanical abnormalities. The use of customised insoles made from multi-density materials, soft protective cushions in the metatarsophalangeal area and rocker sole footwear designs has been demonstrated to result in significant reductions in plantar pressure and diabetic foot ulcer recurrence rates. However, the technological process is a challenging one, as there is a lack of standardisation in footwear dimensions, and issues such as variability in design parameters and patient adherence to wearing recommendations must be addressed to optimise treatment outcomes. The author also entered into the area of Al-supported technologies. The design principles suggested are universal and address the practical challenges faced by practitioners in creating personalised footwear and insoles for individuals at moderate to high risk of plantar forefoot ulceration. These principles include guidelines for designing and modifying both fully custom-made and prefabricated medical-grade footwear (Pedorthic footwear). Additionally, they emphasise tailoring modifications to ensure affordability, suit specific activities, and improve patient adherence [66].

Other relevant studies refer to authors such as Wang et al., who investigated the efficacy of wearable sensor systems to monitor plantar loading in the assessment of diabetic foot ulcers. The objective was to give readers a comprehensive overview of recent advancements in plantar pressure and stress sensing while also highlighting future needs in this important area of healthcare [67].

According to the research of D'Amico et al. and Deselnicu et al., the CAD-CAM approach delivers superior offloading performance compared to traditional shape-based methods of insole construction. The method enables comprehensive analysis of the entire plantar surface without relying on predetermined anatomical masking. It allows for a detailed evaluation of how and where custom-made insoles redistribute underfoot pressure about the Foot Impression, making the technology particularly valuable in the design phase, guiding modifications needed to optimise insole offloading performance [68, 69].

### CONTRIBUTIONS TO THE LITERATURE REVIEW

This paper has focused on work published since 2019. Several papers have continued to contribute to research on diabetic footwear, focusing on improving the design, off-loading techniques and patient adherence. Notable articles and reference works that reflect the principles of continuous improvement in the design and features of diabetic patient footwear are listed below in table 1.

LIST OF RELEVANT ARTICLES CONSIDERED FOR THE REVIEW						
Reference	Journal	Article	Publication Year	Journal Impact Factor	Article Citations	
Hellstrand et al. [14]	Prosthetics and Orthotics International	Clinical guidelines recommending prosthetics and orthotics in Sweden: Agreement between national and regional guidelines	2024	0.8	Data not available	
Tiwari et al. [53]	Applied System Innovation	A Tunable Self-Offloading Module for Plantar Pressure Regulation in Diabetic Patients	2024	3.8	1	
Thimabut et al. [10]	IEEE Transactions on Neural Systems and Rehabilitation Engineering	Novel Vibrating Foot Orthoses for Improving Tactile Sensation in Type 2 Diabetes with Peripheral Neuropathy	2024	4.8	Data not available	
Ramstrand et al. [70]	Journal of Foot and Ankle Research	Exploring potential risk factors for lower limb amputation in people with diabetes – A national observational cohort study in Sweden	2024	2.5	Data not available	

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Table 1

				Table 1 (	(continuation)
Reference	Journal	Article	Publication Year	Journal Impact Factor	Article Citations
Kim et al. [71]	Journal of Foot and Ankle Research	The effect of ankle-foot orthoses on gait characteristics in people with Charcot-Marie- Footh disease: A systematic review and meta-analysis	2024	2.5	Data not available
Jeffcoate et al. [28]	The Lancet Diabetes and Endocrinology	Causes, prevention, and management of diabetes-related foot ulcers	2024	44	3
Tiwari et al. [72]	IEEE Sensors Letters	A Polyester–Nylon Blend Plantar Pressure Sensing Insole for Person with Diabetes	2024	2.2	Data not available
Ahmed et al. [66]	arXiv	Al-Driven Personalised Offloading Device Prescriptions: A Cutting-Edge Approach to Preventing Diabetes-Related Plantar Forefoot Ulcers and Complications	2023	Data not available	Data not available
Bus et al. [33]	Diabetes/Metabolism Research and Reviews	Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2023 update)	2023	4.6	26
Hemler et al. [48]	Frontiers in Endocrinology	Intelligent plantar pressure offloading for the prevention of diabetic foot ulcers and amputations	2023	5.2	6
Paavana et al. [73]	International Journal of Orthopaedic Surgery	Diabetic foot: Footwear in a management programme	2023	2.05	Data not available
Withers et al. [74]	Journal of Foot and Ankle Research	Offloading effects of a removable cast walker with and without modification for diabetes-related foot ulceration: a plantar pressure study	2023	2.5	5
López-Moral et al. [75]	The International Journal of Lower Extremity Wounds	Usability of Different Methods to Assess and Improve Adherence to Therapeutic Footwear in Persons with the Diabetic Foot in Remission. A Systematic Review	2023	1.5	1
An et al. [76]	The Journal of the American Academy of Orthopaedic Surgeons (JAAOS)	Orthotic Devices for the Foot and Ankle	2023	4	2
Ong et al. [15]	The Lancet Journal	Global, regional, and national burden of diabetes from 1990 to 2021, with projections of prevalence to 2050: a systematic analysis for the Global Burden of Disease Study 2021	2023	98.4	493
Barbara and Horton [77]	Canadian Journal of Health Technologies	Custom-Made Foot Orthotics for People with Lower Limb Conditions: CADTH Health Technology Review	2022	Data not available	Data not available
Jarl et al. [78]	Journal of Diabetes Science and Technology	Personalized Offloading Treatments for Healing Plantar Diabetic Foot Ulcers	2022	4.1	6
Ntella et al. [79]	25th International Conference on Electrical Machines and Systems (ICEMS)	Pressure Offloading Device for Diabetic Footwear Based on Magnetorheological Fluids	2022	Data not available	1
Chertenko et al. [17]	Communications in Development and Assembling of Textile Products	Developing lasts with removable toe parts for customized footwear	2022	Data not available	Data not available
López-Moral et al. [80]	Diabetes Research and Clinical Practice	Effects of wear and tear of therapeutic footwear in patients remission. A 5-year follow-up study	2022	5.1	6
Gonggryp et al. [81]	EMC – Podología	Tratamiento podológico del pie diabético	2022	0.042	Data not available

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				Table 1 (	(continuation)
Reference	Journal	Article	Publication Year	Journal Impact Factor	Article Citations
McDonogh et al. [82]	Journal of Foot and Ankle Research	Does in-shoe pressure analysis to assess and modify medical grade footwear improve patient adherence and understanding? A mixed methods study	2022	2.5	3
Ahmed et al. [13]	Trials	Footwear and insole design parameters to prevent occurrence and recurrence of neuropathic plantar forefoot ulcers in patients with diabetes: a series of N-of-1 trial study protocol	2022	2.5	1
lacopi et al. [83]	The International Journal of Lower Extremity Wounds	The Weakness of the Strong Sex: Differences Between Men and Women Affected by Diabetic Foot Disease	2021	1.5	Data not available
Pradipta et al. [63]	IEEE International Biomedical Instrumentation and Technology Conference (IBITeC)	Optimization of Insole Shoe for Diabetic Mellitus Type 2 Using Finite Element Analysis	2021	Data not available	2
Chen et al. [62]	International Conference on Computer, Control and Robotics (ICCCR)	A Novel Porous Structural Design of the Orthotic Insole for Diabetic Foot	2021	Data not available	2
Haris et al. [60]	Applied Sciences	A Review of the Plantar Pressure Distribution Effects from Insole Materials and at Different Walking Speeds	2021	2.7	13
D'Amico et al. [68]	PLOS ONE	Data-driven CAD-CAM vs traditional total contact custom insoles: A novel quantitative- statistical framework for the evaluation of insoles offloading performance in diabetic foot	2021	2.9	6
Wang et al. [84]	IEEE Transactions on Biomedical Circuits and Systems	A Novel Low-Cost Wireless Footwear System for Monitoring Diabetic Foot Patients	2021	3.8	36
Van Netten et al. [44]	Diabetes/Metabolism Research and Reviews	Definitions and criteria for diabetic foot disease	2020	4.6	206
Lazzarini et al. [85]	Diabetes/Metabolism Research and Reviews	Effectiveness of offloading interventions to heal foot ulcers in persons with diabetes: a systematic review	2020	4.6	72
Monteiro- Soares et al. [86]	Diabetes/Metabolism Research and Reviews	Guidelines on the classification of diabetic foot ulcers (IWGDF 2019)	2020	4.6	145
Bus et al. [13, 41]	Diabetes/Metabolism Research and Reviews	Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2019 update)	2020	4.6	263
Schaper et al. [1]	Diabetes/Metabolism Research and Reviews	Practical Guidelines on the prevention and management of diabetic foot disease (IWGDF 2019 update)	2020	4.6	473
Sinha et al. [87]	Journal of Diabetology	Plantar pressure analysis and customized insoles in diabetic foot ulcer management: Case series	2020	0.4	1
Ahmed et al. [61]	Journal of Foot and Ankle Research	Footwear and insole design features that reduce neuropathic plantar forefoot ulcer risk in people with diabetes: a systematic literature review	2020	2.5	49
Zwaferink et al. [88]	PLOS ONE	Optimizing footwear for the diabetic foot: Data-driven custom-made footwear concepts and their effect on pressure relief to prevent diabetic foot ulceration	2020	2.9	28

Table 1 (continuation)
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Reference	Journal	Article	Publication Year	Journal Impact Factor	Article Citations	
Hobabagabo et al. [43]	The Lancet Diabetes and Endocrinology	Forced migration and foot care in people with diabetes	2020	44	3	
Wang et al. [67]	IEEE Transactions on Biomedical Engineering	A Review of Wearable Sensor Systems to Monitor Plantar Loading in the Assessment of Diabetic Foot Ulcers	2020	Data not available	38	
Albathi et al. [65]	2019 8 <sup>th</sup> International Conference on Modeling Simulation and Applied Optimization (ICMSAO)	Design of a smart in-sole to model and control the pressure under diabetic patients' feet	2019	Data not available	2	
Bus et al. [89]	Diabetes/Metabolism Research and Reviews	Guidelines on offloading foot ulcers in persons with diabetes (IWGDF 2019 update)	2019	4.6	132	
Bus et al. [90]	Diabetes/Metabolism Research and Reviews	State of the art design protocol for custom made footwear for people with diabetes and peripheral neuropathy	2019	4.6	34	
Chatwin et al. [91]	Diabetes/Metabolism Research and Reviews	The role of foot pressure measurement in the prediction and prevention of diabetic foot ulceration – A comprehensive review	2019	4.6	74	
Crawford et al. [45]	Diabetologia	Preventing foot ulceration in diabetes: systematic review and meta-analyses of RCT data	2019	8.4	40	
Bencheikh et al. [64]	2018 International Conference on Applied Smart Systems (ICASS)	A low Cost Smart Insole for Diabetic Foot Prevention	2018	0.71	6	

# CONCLUSIONS

The findings from this study indicate that diabetic foot disorders are of critical significance, not only due to the substantial financial resources allocated to managing this condition but also because effective foot care measures can largely prevent its onset and mitigate the risks associated with this serious health issue. Identifying individuals at risk for foot ulcers and implementing timely and appropriate corrective actions can significantly reduce the incidence of serious complications, including amputations that are frequently associated with this ailment. Moreover, the ramifications extend far beyond the profound personal impact on patients and their families, translating into considerable economic savings by avoiding complex complications and ensuring that adequate and proper care is provided for those already affected by diabetic foot problems and their associated challenges. In five years, the number of severe cases and amputations caused by untreated foot ulcers could double compared to the present. Furthermore, individuals afflicted by this condition are likely to face a deteriorating quality of life following amputations, which correlates with a heightened incidence of severe comorbidities that could detrimentally influence their overall health and well-being, creating a vicious cycle that is difficult to break and affect not just the patients, but also places an enormous burden on healthcare systems worldwide. For the benefit of the afflicted individual, continued research and interdisciplinary collaboration are essential to further refine these interventions and improve outcomes for people with diabetes.

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