

Next Generation Footwear for Diabetic Neuropathy: A Narrative Review on Biomechanical Innovations and Smart Technologies for Ulcer Prevention

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ABSTRACT

Diabetic Neuropathy (DN) significantly alters foot biomechanics, leading to abnormal pressure distribution, impaired gait patterns, and a heightened risk of foot ulcers, which often precede lower-limb amputations. Traditional diabetic footwear focuses on static pressure relief but lacks real-time adaptability to biomechanical changes. Recent advancements in smart sensor technology, Artificial Intelligence (AI), and 3D printing offer a dynamic approach to ulcer prevention and mobility enhancement. This narrative review explores emerging innovations in diabetic footwear that integrate biomechanical adaptations and smart technologies to optimise pressure redistribution, improve gait stability, and reduce ulcer risk in individuals with DN. A comprehensive literature review was conducted using PubMed, SCOPUS, Web of Science, and PEDro databases. Studies focusing on pressure-sensing insoles, AI-assisted gait analysis, thermal ulcer detection, and 3D-printed orthotics were analysed. The impact of these technology on plantar pressure offloading, gait mechanics, and ulcer prevention was evaluated. Recent findings indicate that smart footwear incorporating pressure sensors can reduce peak plantar pressures by up to 35%, thereby significantly lowering the risk of ulcer formation. AI-driven wearable technologies enables early detection of abnormal gait patterns, allowing real-time interventions to help prevent diabetic foot complications. Additionally, 3D-printed footwear offers personalised pressure redistribution, surpassing traditional diabetic shoes in providing customised foot support. Integrating biomechanical principles with sensor technology shows considerable potential for improving mobility and foot health in diabetic patients. Future research should focus on large-scale clinical trials, cost-effectiveness, and practical implementation to ensure widespread accessibility in diabetic foot care.

Keywords: Adaptive technology, Biomechanics, Gait analysis, Pressure offloading, Smart footwear, 3D-printed orthotics

INTRODUCTION

The DN is a prevalent condition characterised by symptoms of peripheral nerve dysfunction in patients with Diabetes Mellitus (DM), after excluding other potential causes of peripheral nerve dysfunction [1]. The primary risk factor for the development of plantar foot ulcers is Diabetic Peripheral Neuropathy (DPN). DPN can affect the motor, sensory, and autonomic nervous systems. The protective feedback loop involving touch and pain is disrupted by sensory neuropathy. In addition to reducing strength and impairing muscle innervation, motor neuropathy leads to reduced muscle strength, impaired innervation, decreased joint movement and the development of foot deformities. These abnormalities may result in increased plantar foot pressures, particularly in the forefoot may result from various abnormalities [2].

The prevalence of DM is higher in India (4.3%) than in the West (1-2%) [3]. Diabetes increases an individual's lifetime risk of developing foot ulcers by 12-25% [4]. Diabetes-related foot ulcers are prevalent, incapacitating, and often result in leg amputation [5]. Diabetic sensory, motor, and autonomic neuropathy lead to Diabetic Foot Ulcers (DFU). Autonomic neuropathy results in viscoelastic changes in the skin, such as dryness; motor neuropathy produces foot deformities and biomechanical irregularities, and sensory neuropathy results in loss of protective sense [6].

The gold standard for treating DFUs consists of offloading the ulcer, managing any infection, debridement of the lesion, and revascularisation techniques where necessary [7]. Plantar ulcer healing is greatly dependent on effective offloading, as previous studies have demonstrated that increased plantar pressures play a major role in diabetic patients developing plantar ulcers in individuals

with diabetes [8]. The importance of ulcer offloading is growing since it has been noted that improper offloading of the foot (in the high-pressure areas increases the likelihood of a healed foot ulcer recurring, even after the ulcer has healed [9].

The important rules by the International Working Group on the Diabetic Foot (IWGDF) and the American Diabetes Association have evolved after decades of advising against weight-bearing activities in individuals with diabetes-related neuropathy, current guidelines now encourage a gradual increase in physical activity, provided that appropriate shoe and comprehensive foot care are ensured [10,11]. Smart shoe design has been significantly influenced by wearable technology and the Internet of Things (IoT), which have increasingly permeated the footwear industry in recent years [12]. Three-dimensional (3D) printing, also referred to as Additive Manufacturing (AM), is one of the most significant innovations in this field. AM is capable of producing intricate structures that are not achievable using traditional manufacturing techniques [13]. Various technologies and devices that become boon for patients with DFUs include custom insoles, 3D-printed orthotics that allow the creation of patient-specific orthotics that precisely match foot anatomy, footwear with wide and deep toe boxes to accommodate foot deformities, sensor-embedded footwear, temperature-monitoring devices, IoT technology that allows for continuous remote monitoring of foot health, and 3D scanning technologies facilitate precise fitting [13-19].

By eliminating biomechanical stressors and providing preventive support, footwear is essential for preventing ulcers. The design and functionality of footwear for diabetic people have been completely transformed by recent developments in biomechanical engineering

and smart technology. With an emphasis on biomechanical advancements and smart technologies for ulcer prevention, this literature review attempts to investigate the present status of research on next-generation footwear.

Literature Search

The literature search was conducted using electronic databases, including PubMed, Scopus, Web of Science, and Google Scholar. Keywords and phrases used included “DN footwear,” “biomechanical innovations in diabetic shoes,” “smart footwear for ulcer prevention,” “pressure redistribution in diabetic footwear,” “wearable technology for diabetic foot care,” “sensor-based footwear for diabetes,” “3D-printed orthotics for DN,” and “gait analysis in diabetic foot care.” To gather all relevant information on the topic and reduce the possibility of bias in the review process, systematic reviews, narrative reviews, comprehensive reviews, original research articles, and case reports were included.

Biomechanical Innovations in Diabetic Footwear

The integration of biomechanics with emerging smart technologies in diabetic footwear represents a paradigm shift in the prevention and management of foot ulcers in individuals with DN. Traditional offloading strategies have primarily focused on redistributing plantar pressure through static insoles and therapeutic shoes; however, these approaches often fail to accommodate real-time biomechanical variations and dynamic gait adaptations [10]. Recent advancements in sensor technology, AI, and 3D printing have facilitated the development of next-generation footwear capable of continuous monitoring, adaptive pressure redistribution, and personalised gait optimisation [20]. By leveraging these innovations, smart diabetic footwear not only mitigates peak plantar pressures but also enhances mobility and reduces the incidence of ulcer formation, thereby addressing a critical gap in diabetic foot care.

Biomechanical modifications in next-generation shoes primarily focus on redistributing plantar pressure and improving gait stability. Traditionally, prefabricated diabetic footwear provided generic pressure relief; however, 3D-printed insoles and AI-driven interventions are now offering personalised solutions [17].

3D-printed orthotics for pressure redistribution: A 3D-printed insole customised based on individual foot morphology provide superior plantar pressure redistribution [17]. These insoles effectively reduce peak plantar pressures by up to 35%, thereby lowering the risk of ulceration in diabetic patients [17]. These insoles target high-pressure areas such as metatarsal heads and heels, which are particularly prone to ulcers [21]. Studies show that diabetic patients using 3D-printed insoles experience better gait stability and lower ulcer recurrence rates compared to standard orthotics [17].

Personalised insoles improve shock absorption and weight distribution, reducing mechanical stress on the foot [22]. These insoles are commonly fabricated from thermoplastic polyurethane (TPU) and flexible polymer blends, enhancing durability, breathability, and comfort [23]. Integration with plantar pressure mapping ensures real-time adjustments to achieve optimal offloading [24]. Despite promising results, large-scale clinical trials are needed to confirm their long-term effectiveness and cost-efficiency [17]. Future advancements may include real-time pressure sensors and AI-driven monitoring for improved foot ulcer prevention [17].

Recent evidence underscores the growing utility of 3D-printed insoles in addressing biomechanical issues in individuals with DN, particularly for offloading high-risk plantar regions and enhancing comfort. Studies have shown that 3D-printed insoles are as effective, if not superior to, conventional methods in redistributing plantar pressure and improving user comfort in individuals with diabetic feet at risk of ulceration, flexible flat feet, and plantar fasciitis [25-27].

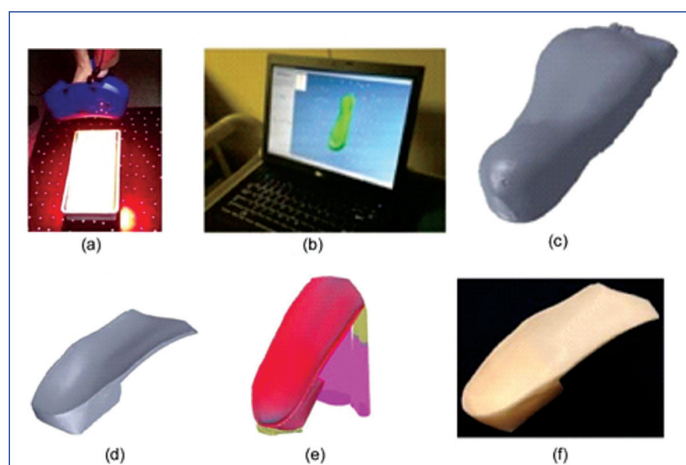
Several factors contribute to their effectiveness. First, improvements in shape acquisition through digital scanning have enhanced the

accuracy of capturing foot morphology compared to traditional manual methods [28]. Second, shape acquisition using an impression foam box under weight-bearing conditions allows for more reliable and convenient replication of plantar contours than traditional plaster casting in non weight-bearing positions [25,26]. Third, computer-aided design enables precise customisation of insole features, such as height, relief areas, and reinforcement zones, before fabrication [29]. Collectively, these innovations make 3D-printed orthotics a promising tool for ulcer prevention in DN by facilitating individualised pressure offloading and improved gait biomechanics.

AI-Powered Gait Analysis for Early Risk Detection

AI-based gait analysis systems offer significant potential for the early detection of DFU risks by continuously monitoring critical gait parameters, including step length, cadence, and weight distribution [20]. Advanced machine-learning algorithms, such as Convolutional Neural Networks (CNNs) and Long Short-Term Memory (LSTM) networks, have been shown to have accuracy in detecting gait asymmetries and abnormal foot-pressure distribution, leading to a reduction in DFU recurrence rates by as much as 40% [20]. The integration of AI-driven smart insoles allows for the early identification of plantar-pressure irregularities and allows prediction of potential ulcer formation 14-21 days before onset, thereby enabling timely intervention and personalised gait recommendations [12]. Furthermore, AI-powered motion-analysis techniques have demonstrated efficacy in distinguishing individuals at high-risk of DFU from those at low-risk, thus enhancing the accuracy of DFU risk assessments [25].

In addition to gait-based methods, AI technologies such as thermal imaging and smartphone-based diagnostic tools have demonstrated high sensitivity and specificity in detecting DFU risks [26,27]. Remote monitoring of foot temperature, coupled with AI-enhanced screening tools, further bolster DFU prevention efforts by allowing for continuous, real-time surveillance [28,29]. The stages in 3D scanning and printing process is shown in [Table-Fig-1] [30]. Thermal imaging has proven to be particularly sensitive in identifying hidden neuropathies and vascular abnormalities—both precursors to ulceration, enabling early interventions [31]. Moreover, hyperspectral imaging has exhibited remarkable sensitivity (95%) and specificity (80%) in predicting tissue at risk for ulceration, often identifying potential damage an average of 58 days before visible lesions appear [32].



[Table/Fig-1]: Stages in the 3D scanning and printing process.

a) Scanning the foot using a handheld 3D scanner; b) Displaying the scanned data on a computer; c-e) Processing and modifying the 3D model for customisation; and f) Final 3D printed orthosis.

(Reproduced from Chhikara K, Singh G, Gupta S, Chanda A. Progress of additive manufacturing in fabrication of foot orthoses for diabetic patients: A review. *Ann 3D Print Med*. 2022 Oct;8:100085. <https://doi.org/10.1016/j.jstim.2022.100085>. Licensed under CC BY 4.0.) [30]

While AI-based approaches hold considerable promise for improving DFU risk detection and preventive care, it is essential to conduct

further research to validate these technologies across diverse patient populations and clinical environments. Such studies are crucial for ensuring the effective integration of AI-driven solutions into healthcare systems and optimising their utility in real-world applications [33].

Smart Sensor Technologies for Foot Ulcer Prevention

Smart sensor technologies for foot-ulcer prevention have advanced considerably through the development of pressure-sensitive insoles and thermal-monitoring systems. Traditional diabetic footwear lacks adaptability; however, smart insoles equipped with piezoelectric and capacitive sensors enable continuous plantar-pressure monitoring, detect high-pressure zones, and provide real-time alerts [12]. A study by Brooks et al., found that smart insole systems reduced DFU recurrence by 52% [33].

Thermal monitoring also crucial, as temperature imbalances signal early inflammation. Remote Foot Temperature Monitoring (RFTM) using infrared thermography has been shown to reduce ulcer occurrence by up to 91% and to save approximately USD 8,027 per patient annually by preventing hospitalisations [33]. Early detection of inflammation allows for timely clinical interventions, reducing tissue damage and reducing healthcare costs [34]. The integration of AI with smart temperature-monitoring systems can further enhance predictive accuracy for ulcer risk detection [20].

Clinical Challenges and Future Research Directions

Despite significant technological advancements, several barriers hinder the widespread adoption of AI-driven footwear. Patients often struggle with comfort and usability concerns, which could be addressed through ergonomic design improvements and AI-powered mobile coaching apps to enhance compliance [12,20]. Additionally, the high production costs associated with AI-integrated footwear and 3D-printed insoles limit accessibility, particularly in low-income settings, highlighting the need for research into scalable manufacturing processes and cost alternative materials [17].

Although preliminary studies show high efficacy, large-scale randomised controlled trials are needed to validate long-term clinical benefits [10]. Next-generation diabetic footwear integrates biomechanical principles, AI, smart sensors, and real-time temperature monitoring to prevent ulcers and enhance mobility with the potential to reduce ulcer recurrence, improve quality of life, lower healthcare costs by minimising hospital admissions, and enhance mobility and gait stability and overall mobility [10,20,33]. Future research should focus on cost-effectiveness analyses, large-scale validation studies, and patient acceptability to maximise clinical adoption [10].

CONCLUSION(S)

The integration of biomechanical principles, 3D printing, AI-powered gait analysis, and smart sensor technologies has revolutionised diabetic foot management. These innovations offer personalised solutions for ulcer prevention, early detection, and enhanced foot care. However, challenges such as cost, accessibility, and clinical validation must be addressed to facilitate their practicality widespread adoption. Future research should focus on refining these technologies, ensuring their feasibility in clinical settings, and improving patient adherence to advanced monitoring solutions.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Mar 10, 2025
- Manual Googling: Oct 27, 2025
- iTenticate Software: Oct 29, 2025 (7%)

ETYMOLOGY: Author Origin

EMENDATIONS: 6

AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was informed consent obtained from the subjects involved in the study? NA
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: Feb 28, 2025

Date of Peer Review: Mar 28, 2025

Date of Acceptance: Oct 31, 2025

Date of Publishing: Mar 01, 2026