

Smart diabetic foot ulcer risk assessment and wound healing management device for chronic care patients: A comprehensive review

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Abstract:

Diabetic foot ulcer (DFU) is among the most severe chronic complications of diabetes mellitus and represents a major contributor to hospitalization, lower-limb amputation, disability, and healthcare expenditure worldwide. The increasing prevalence of diabetes has significantly raised the burden of chronic wounds, particularly among elderly individuals and patients with long-standing uncontrolled diabetes. Conventional approaches to diabetic foot monitoring primarily rely on periodic clinical examination and subjective wound assessment, which frequently delay early diagnosis and intervention. Consequently, emerging smart healthcare technologies integrating artificial intelligence (AI), Internet of Things (IoT), wearable biosensors, thermal imaging, pressure sensing, cloud computing, and telemedicine have transformed diabetic wound management from reactive treatment toward proactive prevention. Recent advances have enabled continuous monitoring of plantar pressure, skin temperature, moisture, tissue oxygenation, gait abnormalities, and wound morphology using portable and wearable smart devices. AI-driven predictive algorithms can identify patients at high risk for ulcer development, estimate wound progression, and recommend individualized treatment strategies. Smart wound dressings further enhance healing by providing controlled drug release, infection monitoring, and real-time physiological sensing

Keywords:

Diabetic foot ulcer, Artificial intelligence, Internet of Things, Wearable biosensors, Smart wound dressing, Chronic wound management, Telemedicine, Machine learning, Risk assessment, Digital healthcare.

1. Introduction:

Diabetes mellitus has emerged as one of the fastest-growing chronic diseases globally, affecting hundreds of millions of individuals and imposing a substantial socioeconomic burden on healthcare systems. One of its most debilitating complications is diabetic foot ulcer (DFU), a chronic non-healing wound resulting from the combined effects of peripheral neuropathy, peripheral arterial disease, infection, immune dysfunction, and repetitive mechanical trauma. Approximately one-third of individuals living with diabetes are expected to develop a diabetic foot ulcer during their lifetime, while recurrence rates remain exceptionally high despite appropriate treatment

Recent advances in biomedical engineering have introduced intelligent technologies capable of continuously monitoring multiple physiological parameters associated with diabetic wound progression. These include wearable plantar pressure sensors, infrared thermography, multispectral imaging, humidity sensors, electrochemical biosensors, wireless wound dressings, smartphone-based imaging systems, and artificial intelligence-assisted diagnostic platforms¹.

Smart wound dressings represent another important innovation in chronic wound management. Unlike conventional dressings that merely provide physical protection, smart dressings incorporate embedded biosensors capable of monitoring wound pH, oxygen concentration, glucose, bacterial activity, moisture, inflammatory biomarkers, and temperature. Advanced hydrogel-based dressings may simultaneously deliver

antimicrobial agents, growth factors, stem cells, or nanoparticles while continuously reporting wound status to clinicians².

Table.1: Major Risk Factors Associated with Diabetic Foot Ulcer Development

Risk Factor	Mechanism	Clinical Impact
Peripheral neuropathy	Loss of protective sensation	Repetitive unnoticed trauma
Peripheral arterial disease	Reduced tissue perfusion	Delayed healing
Poor glycemic control	Impaired immunity	Infection susceptibility
Foot deformity	Abnormal pressure distribution	Ulcer formation
Previous ulcer history	Scar tissue weakness	High recurrence
Infection	Tissue destruction	Increased amputation risk
Smoking	Reduced microcirculation	Poor wound healing
Chronic kidney disease	Impaired immunity	Severe ulcer progression

The concept of personalized chronic care has become increasingly important because diabetic wound progression varies substantially between individuals depending on glycemic control, vascular status, nutritional condition, immune response, comorbidities, and treatment adherence. AI-supported predictive analytics enable personalized risk stratification and individualized management strategies that improve treatment effectiveness while reducing unnecessary healthcare utilization³.

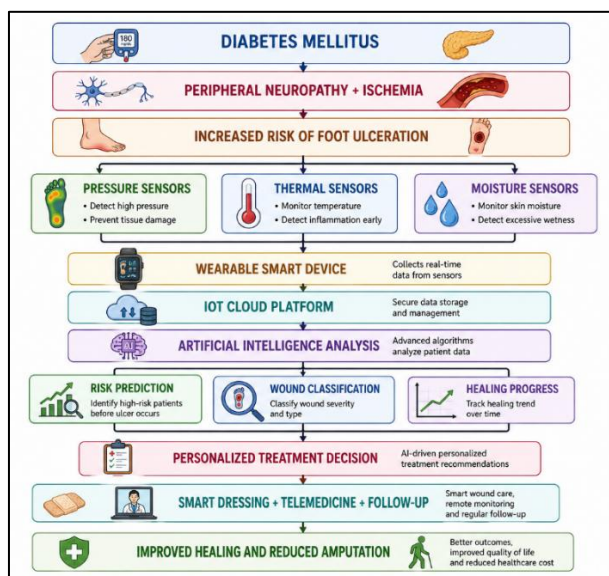


Figure.1: Conceptual Framework of a Smart Diabetic Foot Ulcer Risk Assessment and Wound Healing Management System

2. Epidemiology of diabetic foot ulcers:

Diabetic foot ulcer is recognized as one of the leading causes of disability among individuals with diabetes. The prevalence of DFU continues to rise in parallel with increasing rates of type 2 diabetes, obesity, population aging, and sedentary lifestyles. Epidemiological investigations indicate that approximately 15–34% of diabetic patients will develop at least one foot ulcer during their lifetime, while recurrence rates approach 40% within one year and nearly 65% within five years after healing⁴.

Globally, diabetic foot complications account for a considerable proportion of diabetes-related healthcare expenditure. Hospital admissions associated with diabetic foot ulcers exceed those for many other diabetic complications because patients often require prolonged antibiotic therapy, repeated surgical debridement, vascular intervention, and rehabilitation. Lower-middle-income countries experience particularly high disease burdens due to delayed diagnosis, inadequate access to multidisciplinary foot care services, limited patient awareness, and insufficient preventive screening programs⁵.

3. Pathophysiology of diabetic foot ulcer:

Diabetic foot ulcer (DFU) develops through a complex interaction of metabolic abnormalities, vascular impairment, neuropathy, immune dysfunction, repetitive mechanical stress, and impaired tissue repair mechanisms. Chronic hyperglycemia initiates a cascade of biochemical alterations that progressively damage nerves, blood vessels, connective tissue, and skin integrity. Unlike acute wounds, diabetic ulcers frequently

become trapped in a prolonged inflammatory phase, preventing normal wound healing and increasing susceptibility to infection⁶.

3.1. Peripheral neuropathy:

Peripheral neuropathy is considered the principal initiating factor in most diabetic foot ulcers. Persistent hyperglycemia damages sensory, motor, and autonomic nerve fibers through oxidative stress, activation of the polyol pathway, accumulation of advanced glycation end products (AGEs), and chronic inflammation. Sensory neuropathy diminishes pain perception, allowing patients to remain unaware of repetitive trauma caused by ill-fitting footwear, foreign objects, or prolonged walking. Consequently, minor injuries often progress unnoticed until ulceration becomes clinically evident⁷.

Motor neuropathy contributes to muscle weakness and intrinsic foot muscle atrophy, leading to structural deformities such as claw toes, hammer toes, and prominent metatarsal heads. These deformities redistribute plantar pressure unevenly, creating localized areas of excessive mechanical loading that predispose to tissue breakdown. Autonomic neuropathy further impairs sweat gland function, resulting in dry, cracked skin that facilitates microbial invasion and ulcer formation⁸.

3.2. Peripheral arterial disease:

Peripheral arterial disease (PAD) significantly compromises tissue perfusion and oxygen delivery to the lower extremities. Diabetes accelerates atherosclerosis by promoting endothelial dysfunction, vascular inflammation, lipid deposition, and arterial calcification. Reduced blood flow limits nutrient supply, delays inflammatory cell recruitment, decreases angiogenesis, and impairs collagen synthesis, thereby slowing wound repair. Patients with combined neuropathy and PAD experience markedly higher rates of infection, gangrene, and lower-limb amputation compared with those without vascular disease⁹.

3.3. Hyperglycemia and cellular dysfunction:

Persistent hyperglycemia disrupts multiple cellular processes essential for wound healing. Elevated glucose concentrations impair neutrophil chemotaxis, macrophage polarization, fibroblast proliferation, keratinocyte migration, and endothelial cell function. Excessive production of reactive oxygen species (ROS) induces oxidative stress, damaging DNA, proteins, and cellular membranes. Simultaneously, accumulation of AGEs alters extracellular matrix structure and increases inflammatory cytokine production, preventing transition from the inflammatory to proliferative healing phase¹⁰.

Chronic Inflammation

Unlike acute wounds, diabetic ulcers exhibit sustained inflammation characterized by prolonged activation of neutrophils and pro-inflammatory macrophages. Elevated levels of tumor necrosis factor- α (TNF- α), interleukin-1 β (IL-1 β), interleukin-6 (IL-6), and matrix metalloproteinases (MMPs) accelerate degradation of extracellular matrix proteins and newly synthesized collagen. This inflammatory imbalance delays granulation tissue formation, angiogenesis, and epithelialization, contributing to chronic non-healing wounds¹¹.

Biofilm Formation and Infection

Bacterial infection plays a central role in delayed wound healing. Common pathogens include *Staphylococcus aureus*, methicillin-resistant *S. aureus* (MRSA), *Pseudomonas aeruginosa*, *Escherichia coli*, *Proteus* species, and anaerobic bacteria. These microorganisms often organize into biofilms, complex microbial communities embedded within a protective extracellular matrix that enhances resistance to antibiotics and host immune responses. Biofilms maintain chronic inflammation and substantially delay tissue repair¹².

3.4. Impaired angiogenesis:

Healthy wound healing requires formation of new blood vessels through angiogenesis. Diabetes suppresses vascular endothelial growth factor (VEGF), endothelial progenitor cell recruitment, nitric oxide synthesis, and endothelial cell proliferation. Consequently, diabetic wounds demonstrate reduced capillary density, poor oxygenation, and inadequate nutrient delivery, further delaying tissue regeneration¹³.

3.5. Stages of wound healing and their alteration in diabetes:

Normal wound healing proceeds through four overlapping phases: hemostasis, inflammation, proliferation, and remodeling. Diabetes disrupts each phase through metabolic and vascular abnormalities.

During hemostasis, platelet activation and clot formation generally remain intact; however, diabetic patients frequently exhibit altered platelet function and increased thrombotic tendencies that impair microcirculation. In the inflammatory phase, excessive recruitment of inflammatory cells prolongs cytokine release and tissue

destruction. During the proliferative phase, fibroblast dysfunction, reduced collagen deposition, diminished angiogenesis, and impaired keratinocyte migration delay granulation tissue formation and wound closure. Finally, in the remodeling phase, collagen maturation and extracellular matrix reorganization remain incomplete, resulting in weaker scar tissue and increased ulcer recurrence¹⁴.

Understanding these pathological alterations provides the rationale for smart monitoring systems capable of detecting early physiological changes before irreversible tissue damage occurs.

4. Conventional methods of diabetic foot assessment:

Despite technological advances, conventional clinical assessment remains the cornerstone of diabetic foot management. Healthcare professionals evaluate ulcer characteristics, vascular status, neurological function, and infection severity using standardized clinical methods. However, these approaches are often subjective, intermittent, and dependent on clinician expertise¹⁵.

4.1. Visual examination:

Routine visual inspection identifies skin discoloration, callus formation, blisters, fissures, deformities, ulcer depth, exudate, necrotic tissue, and signs of infection. Although inexpensive and widely available, visual assessment cannot detect physiological changes preceding visible tissue injury, limiting its value for early risk prediction¹⁶.

4.2. Monofilament testing:

The 10-g Semmes–Weinstein monofilament test assesses protective sensation by applying standardized pressure at multiple plantar sites. Loss of sensation indicates peripheral neuropathy and increased ulcer risk. Although highly practical, the test detects established neuropathy rather than predicting future ulcer development¹⁷.

4.3. Vibration perception threshold:

A 128-Hz tuning fork or biothesiometer measures vibration perception, providing additional information regarding large-fiber neuropathy. Reduced vibration sensation correlates strongly with ulcer risk and progression¹⁸.

4.4. Ankle-Brachial index:

The ankle-brachial index (ABI) compares ankle and brachial systolic blood pressure to evaluate peripheral arterial disease. Values below 0.90 generally indicate arterial insufficiency. However, arterial calcification common in diabetes may falsely elevate ABI values, reducing diagnostic accuracy¹⁹.

4.5. Doppler Ultrasound:

Handheld Doppler devices evaluate arterial blood flow and vascular patency. These instruments assist clinicians in determining tissue perfusion before surgical intervention or advanced wound therapy²⁰.

4.6. Wound measurement:

Ulcer size, depth, undermining, tunneling, and tissue composition are commonly assessed using disposable rulers, sterile probes, acetate tracings, or digital photography. Manual measurements are subject to inter-observer variability and may fail to detect subtle healing changes over time²¹.

Although these conventional techniques remain clinically valuable, they provide only periodic assessments and depend heavily on patient attendance at healthcare facilities. Consequently, continuous home-based monitoring technologies have gained increasing importance in chronic diabetic care.

5. Smart wearable sensors for diabetic foot monitoring:

Rapid advances in wearable biosensor technology have transformed diabetic foot management by enabling continuous, non-invasive physiological monitoring. Wearable devices collect real-time information regarding plantar pressure, temperature, humidity, gait dynamics, oxygen saturation, and biomechanical stress, allowing early detection of tissue damage before ulcer formation becomes clinically apparent²².

5.1. Plantar pressure sensors:

Abnormally elevated plantar pressure represents one of the strongest predictors of ulcer development. Smart insoles equipped with flexible pressure sensors continuously measure pressure distribution during standing

and walking. Data are transmitted wirelessly to smartphone applications, enabling patients and clinicians to identify high-risk pressure zones. AI algorithms analyze cumulative loading patterns and recommend off-loading interventions, footwear modifications, or activity adjustments to prevent ulceration²³.

5.2. Temperature monitoring sensors:

Localized inflammation preceding ulcer formation typically produces a sustained increase in skin temperature. Wearable infrared sensors embedded in socks, insoles, or foot mats detect temperature differences between corresponding anatomical sites. Studies have demonstrated that temperature elevations of approximately 2.2°C between contralateral feet may predict ulcer development several days before visible tissue injury becomes apparent²⁴.

5.3. Humidity sensors:

Excessive moisture promotes skin maceration and microbial growth, whereas inadequate moisture contributes to fissuring and tissue breakdown. Flexible humidity sensors continuously monitor skin hydration within footwear, allowing early intervention before skin integrity deteriorates²⁵.

5.4. Motion and gait sensors:

Accelerometers, gyroscopes, and inertial measurement units evaluate walking speed, stride length, balance, gait symmetry, and physical activity. Changes in gait mechanics may indicate pain, neuropathy progression, or compensatory weight redistribution associated with developing ulcers²⁶.

5.5. Oxygen monitoring sensors:

Emerging wearable oxygen sensors estimate local tissue oxygenation using optical spectroscopy. Reduced oxygen saturation may identify ischemic tissue before ulceration and assist clinicians in evaluating vascular interventions²⁷.

6. Internet of things (IOT) architecture in smart diabetic foot care:

The Internet of Things (IoT) has become the technological foundation for modern diabetic foot monitoring systems. IoT enables seamless communication among wearable sensors, mobile applications, cloud databases, healthcare providers, and artificial intelligence platforms, creating an integrated digital ecosystem for chronic disease management.

A typical IoT architecture consists of four interconnected layers:

Sensing layer: Wearable sensors embedded within insoles, socks, wound dressings, or foot mats continuously collect physiological data such as pressure, temperature, moisture, oxygenation, and movement.

Communication layer: Bluetooth Low Energy (BLE), Wi-Fi, ZigBee, Near Field Communication (NFC), and fifth-generation (5G) wireless technologies securely transmit collected data to smartphones or cloud servers.

Cloud computing layer: Large volumes of patient data are stored, processed, and integrated with electronic health records. Cloud infrastructure enables long-term trend analysis, remote accessibility, and scalable data management.

Application layer: Artificial intelligence algorithms analyse incoming data, generate individualized risk scores, issue alerts, recommend interventions, and support telemedicine consultations.

IoT-based monitoring reduces unnecessary clinic visits while facilitating timely intervention, continuous follow-up, and personalized chronic care management²⁸.

Table.2: Comparison of Smart Technologies Used for Diabetic Foot Ulcer Monitoring

Technology	Parameters Measured	Advantages	Limitations
Smart pressure insoles	Plantar pressure	Early pressure detection	Battery dependence
Infrared thermal imaging	Skin temperature	Detects pre-ulcer inflammation	Environmental influence
Smart socks	Temperature, pressure	Continuous home monitoring	User compliance
Humidity sensors	Moisture	Prevents skin maceration	Calibration required
Optical oxygen sensors	Tissue oxygenation	Detects ischemia	High cost
Smartphone wound imaging	Wound size and colour	Remote monitoring	Image quality variability
AI-assisted image analysis	Healing prediction	High diagnostic accuracy	Requires large datasets
Smart wound dressings	pH, temperature, infection biomarkers	Continuous wound assessment	Limited commercial availability

7. Artificial intelligence in diabetic foot ulcer risk assessment:

Artificial intelligence (AI) has emerged as one of the most transformative technologies in diabetic foot ulcer (DFU) prevention and chronic wound management. Traditional wound assessment depends largely on clinician expertise and intermittent evaluations, whereas AI systems can continuously analyse complex physiological data, identify subtle abnormalities, and predict ulcer development before visible tissue damage occurs. AI enables healthcare systems to shift from reactive treatment toward predictive, preventive, and personalized care²⁹.

7.1. Machine learning algorithms:

Machine learning (ML) is a branch of artificial intelligence that enables computers to recognize patterns from historical datasets without explicit programming. In diabetic wound care, ML algorithms identify relationships between clinical variables and wound outcomes, allowing accurate prediction of ulcer formation, healing probability, recurrence, hospitalization, and amputation risk³⁰.

Commonly used supervised machine learning algorithms include:

- Logistic regression
- Decision trees
- Random forests
- Support vector machines (SVM)
- Gradient boosting algorithms
- Extreme Gradient Boosting (XG Boost)

7.2. Deep learning for wound image analysis:

Deep learning has revolutionized automated wound assessment through convolutional neural networks (CNNs). CNNs automatically extract clinically relevant image features without requiring manual feature engineering³¹.

Digital wound photographs obtained using smartphones, digital cameras, or specialized imaging systems undergo pre-processing before being analysed by deep learning algorithms. CNNs perform several important clinical functions:

- Automatic ulcer detection
- Infection detection
- Healing progression monitoring

Several studies have reported diagnostic accuracies exceeding 90% for automated wound classification, approaching the performance of experienced wound specialists.

Deep learning significantly reduces interobserver variability while enabling standardized wound documentation across healthcare institutions³².

7.3. Computer vision technologies:

Computer vision combines digital imaging with artificial intelligence to interpret visual information obtained from diabetic wounds.

Modern smartphone-based wound assessment applications employ computer vision techniques including:

- Edge detection
- Colour analysis
- Three-dimensional reconstruction
- Texture analysis
- Morphological feature extraction
- Image segmentation
- Depth estimation³³

7.4. Artificial intelligence–driven clinical decision support systems:

Clinical Decision Support Systems (CDSS) integrate AI algorithms into healthcare workflows by providing evidence-based recommendations during patient management.

Modern diabetic wound CDSS combines:

- Electronic health records
- Laboratory reports
- Sensor-derived physiological measurements
- Medical imaging

- Medication history
- Clinical guidelines
- Risk prediction models³⁴

7.5. Smart wound dressings:

Traditional wound dressings primarily provide physical protection and moisture retention. Smart wound dressings represent a major advancement by continuously monitoring wound physiology while simultaneously delivering therapeutic interventions.

These multifunctional dressings incorporate:

- Flexible biosensors
- Microelectronics
- Drug delivery systems
- Hydrogel matrices
- Conductive polymers
- Nanoparticles
- Wireless communication modules³⁵

The integration of sensing and therapeutic functions enables continuous wound assessment without repeated dressing removal, thereby minimizing tissue disruption.

7.6. Hydrogel-based smart dressings:

Hydrogels are three-dimensional polymer networks capable of retaining large quantities of water while maintaining flexibility.

Hydrogel dressings provide several therapeutic advantages:

- Moist wound environment
- Reduced pain
- Enhanced cell migration
- Improved angiogenesis
- Controlled drug release
- Protection against dehydration³⁶

7.8. Ph-sensing dressings:

Healthy skin typically maintains a mildly acidic pH between 4.5 and 5.5.

Chronic diabetic wounds frequently demonstrate elevated pH values exceeding 7.5 due to bacterial colonization and prolonged inflammation.

Smart pH-responsive dressings utilize:

- Colorimetric indicators
- Electrochemical sensors
- Optical biosensors³⁸

These systems continuously monitor wound acidity and provide early warning of infection before obvious clinical symptoms appear.

7.9. Drug-releasing smart dressings:

Advanced smart dressings provide controlled release of therapeutic agents according to wound conditions.

Commonly incorporated agents include:

- Antibiotics
- Antimicrobial peptides
- Silver nanoparticles
- Zinc oxide nanoparticles
- Copper nanoparticles³⁹

7.10. Nanotechnology in diabetic wound healing:

Nanotechnology has significantly expanded therapeutic options for chronic diabetic wounds.

Nanomaterials possess unique physicochemical characteristics including:

- Large surface area
- Enhanced drug loading
- Improved tissue penetration

- Controlled release kinetics
- Antimicrobial activity⁴⁰

7.11. Silver nanoparticles:

Silver nanoparticles exhibit broad-spectrum antimicrobial activity against Gram-positive bacteria, Gram-negative bacteria, fungi, and multidrug-resistant organisms.

Their therapeutic benefits include:

- Biofilm inhibition
- Reduced bacterial burden
- Anti-inflammatory effects
- Promotion of epithelialization
- Accelerated collagen synthesis

Silver nanoparticle dressings have become widely used in infected diabetic wounds.⁴¹

7.12. Zinc oxide nanoparticles:

Zinc is essential for:

- DNA synthesis
- Protein synthesis
- Cell proliferation
- Enzyme activation
- Immune regulation

Zinc oxide nanoparticles stimulate fibroblast proliferation while enhancing collagen deposition and angiogenesis⁴².

8. Telemedicine and remote wound monitoring:

Telemedicine has become increasingly important in chronic diabetic care, particularly following the rapid expansion of digital healthcare services.

Patients can securely transmit:

- Smartphone wound photographs
- Sensor data
- Blood glucose readings
- Medication adherence
- Physical activity
- Temperature measurements⁴³

8.1. Smartphone applications:

Modern diabetic wound applications provide numerous patient-centered functions:

- Daily wound photography
- Automated wound measurement
- Medication reminders
- Blood glucose recording
- Foot care education

9. Clinical outcomes of smart diabetic foot technologies:

Clinical investigations evaluating intelligent diabetic wound management systems consistently demonstrate encouraging outcomes.

Reported benefits include:

- Earlier ulcer detection
- Reduced wound progression
- Improved healing rates
- Decreased infection incidence
- Lower hospitalization rates⁴⁴

10. Challenges and limitations of smart diabetic foot ulcer management devices:

Although smart diabetic foot ulcer (DFU) risk assessment devices have shown significant promise in improving early diagnosis and chronic wound management, several technological, clinical, economic, and

regulatory challenges continue to limit their widespread implementation. Addressing these barriers is essential before these devices can become standard components of routine diabetic care⁴⁵.

10.1. Clinical Validation:

Many wearable monitoring systems and artificial intelligence (AI)-based diagnostic tools have demonstrated excellent performance under controlled research conditions. However, relatively few devices have undergone large-scale multicentre clinical trials involving diverse patient populations. Variations in ethnicity, skin pigmentation, ulcer severity, environmental conditions, comorbidities, and healthcare infrastructure may influence device performance.

Furthermore, many published studies include relatively small sample sizes, limiting generalizability. Long-term clinical validation is necessary to determine whether smart technologies consistently reduce ulcer incidence, accelerate healing, decrease amputations, and improve patient survival in real-world clinical settings⁴⁶.

10.2. Accuracy and reliability:

Continuous physiological monitoring depends on accurate sensor performance. Several factors may affect measurement reliability, including:

- Sensor drift over time
- Calibration errors
- Mechanical damage
- Battery depletion
- Sweat accumulation
- Improper device positioning⁴⁷

10.3. Patient compliance:

The effectiveness of wearable monitoring devices depends largely on consistent patient use. Elderly individuals, who constitute a substantial proportion of diabetic patients, may experience difficulties related to:

- Limited digital literacy
- Poor vision
- Reduced manual dexterity
- Cognitive impairment
- Device discomfort
- Frequent charging requirements
- Forgetfulness

10.4. Cost and accessibility:

Although technological innovations continue to reduce manufacturing costs, many advanced monitoring systems remain expensive.

High costs arise from:

- Flexible biosensors
- Wireless communication modules
- Artificial intelligence software
- Cloud computing infrastructure
- Medical-grade electronics

10.5. Data privacy and cybersecurity:

Smart healthcare devices continuously collect sensitive patient information including:

- Blood glucose levels
- Wound photographs
- Physiological sensor data
- Geographic location
- Electronic medical records
- Medication history
- Multi-factor authentication⁴⁸
- Secure cloud architecture
- Role-based access control

- Blockchain-supported data integrity
- Regular security updates
- Intrusion detection systems

Compliance with national and international data protection regulations remains an essential requirement for digital healthcare implementation⁴⁹.

10.6. Regulatory challenges:

Medical devices incorporating artificial intelligence require comprehensive regulatory evaluation before commercialization.

Regulatory agencies evaluate:

- Clinical safety
- Diagnostic accuracy
- Software reliability
- Manufacturing quality
- Risk management
- Cybersecurity

11. Ethical considerations:

The integration of artificial intelligence into healthcare introduces important ethical considerations requiring careful attention⁵⁰.

11.1. Algorithmic bias:

Artificial intelligence models are trained using historical datasets.

If these datasets inadequately represent certain populations, algorithmic bias may occur.

Potential sources include:

- Ethnic imbalance
- Age imbalance
- Sex differences
- Skin pigmentation variability
- Socioeconomic disparities⁵¹

11.2. Explainable artificial intelligence:

Many deep learning algorithms function as "black boxes," producing predictions without explaining the underlying reasoning.

Healthcare professionals generally prefer transparent AI systems capable of providing interpretable clinical explanations.

Explainable AI improves:

- Clinician confidence
- Patient trust
- Regulatory acceptance
- Clinical accountability

11.3. Informed Consent:

Patients should receive comprehensive information regarding:

- Data collection
- Artificial intelligence analysis
- Cloud storage
- Information sharing
- Potential risks
- Privacy protection

Obtaining informed consent remains fundamental to ethical digital healthcare⁵².

12. Emerging innovations and future perspectives:

Rapid advances in biomedical engineering, nanotechnology, artificial intelligence, and digital health continue to reshape diabetic wound management.

Several emerging technologies are expected to further improve chronic diabetic care over the coming decade.

12.1. Digital twin technology:

Digital twins create personalized virtual representations of individual patients by integrating:

- Clinical history
- Laboratory investigations
- Imaging studies
- Wearable sensor data
- Lifestyle information
- Genetic profiles

These virtual models simulate disease progression and predict treatment outcomes before clinical interventions are implemented⁵³.

Digital twins may eventually enable highly individualized diabetic wound management.

12.2. Edge artificial intelligence:

Traditional AI systems often rely on cloud computing.

Edge AI performs data analysis directly on wearable devices, providing several advantages:

- Faster decision-making
- Reduced internet dependence
- Improved privacy
- Lower communication costs
- Reduced cloud processing requirements

Edge computing is particularly beneficial in remote healthcare environments with limited internet connectivity⁵⁴.

12.3. Flexible electronics:

Recent developments in flexible electronics have enabled sensors that conform closely to human skin.

Future smart dressings may incorporate:

- Stretchable circuits
- Printable electronics
- Flexible batteries
- Wireless charging
- Self-healing polymers

These technologies improve patient comfort during long-term monitoring⁵⁵.

12.4. Three-dimensional bioprinting:

Three-dimensional (3D) bioprinting enables fabrication of customized tissue constructs using:

- Stem cells
- Biomaterials
- Growth factors
- Extracellular matrix components

Future personalized wound patches may accelerate regeneration of complex diabetic wounds⁵⁶.

12.5. Stem cell therapy:

Stem cells possess regenerative properties including:

- Angiogenesis promotion
- Collagen synthesis
- Immune modulation
- Tissue regeneration

Combining stem cells with smart hydrogel dressings and biosensor technologies may substantially improve healing outcomes⁵⁷.

12.6. Nanorobotics:

Future nanorobotic systems may perform highly targeted therapeutic functions including:

- Infection detection
- Drug delivery

- Biofilm disruption
- Tissue repair
- Microvascular regeneration

Although currently experimental, nanorobotics represents a promising frontier in chronic wound management⁵⁸.

12.7. Blockchain technology:

Blockchain provides decentralized storage of medical information while ensuring:

- Data integrity
- Secure information sharing
- Audit trails
- Patient ownership of health records

Blockchain may improve interoperability among hospitals, wearable devices, and telemedicine platforms⁵⁹.

13. Research gaps:

Despite encouraging progress, several important research priorities remain.

Future investigations should focus on:

- Large multicenter randomized controlled trials evaluating smart monitoring devices.
- Standardized protocols for wearable sensor validation and calibration.
- Development of low-cost monitoring technologies suitable for resource-limited settings.
- Long-term evaluation of AI-supported wound management in routine clinical practice.
- Integration of wearable devices with national electronic health record systems.
- Improved explainability and transparency of deep learning algorithms.
- Development of universal interoperability standards for smart healthcare ecosystems.
- Comparative effectiveness studies evaluating combinations of wearable sensors, telemedicine, and smart wound dressings.
- Cost-effectiveness analyses to inform reimbursement and healthcare policy.
- Environmental sustainability of disposable sensors and electronic medical devices.

Addressing these research gaps will facilitate translation of innovative technologies from experimental settings into routine clinical practice⁶⁰.

14. Conclusion:

Diabetic foot ulcer (DFU) remains one of the most serious and costly complications of diabetes mellitus, contributing substantially to morbidity, mortality, reduced quality of life, prolonged hospitalization, and lower-limb amputation worldwide. The multifactorial pathophysiology of DFU, involving peripheral neuropathy, peripheral arterial disease, chronic inflammation, impaired angiogenesis, infection, and metabolic dysfunction, makes early detection and timely intervention essential for successful management. Conventional approaches to diabetic foot assessment, although clinically valuable, are largely dependent on periodic examinations and subjective clinical judgment, which may delay the identification of early tissue damage and compromise treatment outcomes.

Recent advances in digital health technologies have transformed diabetic wound management from a reactive treatment model to a predictive and preventive care approach. Smart diabetic foot ulcer risk assessment devices equipped with wearable pressure sensors, temperature sensors, humidity sensors, motion detectors, and tissue oxygen monitoring systems provide continuous, real-time monitoring of physiological parameters associated with ulcer development. Integration of these devices with Internet of Things (IoT) platforms enables seamless transmission of patient data to cloud-based systems, facilitating remote surveillance, personalized risk stratification, and timely clinical intervention.

Artificial intelligence (AI) and machine learning have further enhanced the capability of smart wound management systems by enabling automated wound image analysis, tissue classification, ulcer segmentation, healing prediction, infection detection, and individualized treatment recommendations. Deep learning algorithms have demonstrated high diagnostic accuracy comparable to expert clinicians, reducing observer variability while improving the speed and consistency of wound assessment. AI-driven clinical decision support systems also assist healthcare professionals in selecting appropriate treatment strategies based on comprehensive patient-specific data, thereby supporting precision medicine and evidence-based clinical practice.

Innovations in smart wound dressings represent another major advancement in chronic wound care. Modern intelligent dressings not only maintain an optimal healing environment but also incorporate biosensors capable of continuously monitoring wound temperature, pH, moisture, glucose levels, oxygen concentration, and inflammatory biomarkers. In addition, nanotechnology-based dressings utilizing silver nanoparticles, zinc oxide nanoparticles, hydrogels, and controlled drug delivery systems have demonstrated promising antimicrobial and regenerative properties that accelerate tissue repair while minimizing infection risk

15. References:

- (1) Armstrong DG, Boulton AJM, Bus SA. Diabetic foot ulcers and their recurrence. *N Engl J Med*. 2017;376(24):2367–75.
- (2) Bus SA, Lavery LA, Monteiro-Soares M, Rasmussen A, Raspovic A, Sacco ICN, et al. Guidelines on the prevention of foot ulcers in persons with diabetes. *Diabetes Metab Res Rev*. 2023;39(S1):e3647.
- (3) Schaper NC, van Netten JJ, Apelqvist J, Lipsky BA, Bus SA, Hinchliffe RJ, et al. Practical guidelines on the prevention and management of diabetes-related foot disease. *Diabetes Metab Res Rev*. 2024;40(S1):e3805.
- (4) Boulton AJM, Armstrong DG, Albert SF, Frykberg RG, Hellman R, Kirkman MS, et al. Comprehensive foot examination and risk assessment. *Diabetes Care*. 2008;31(8):1679–85.
- (5) Hinchliffe RJ, Forsythe RO, Apelqvist J, Boyko EJ, Fitridge R, Hong JP, et al. Guidelines on diagnosis, prognosis and management of peripheral artery disease in patients with a foot ulcer and diabetes. *Diabetes Metab Res Rev*. 2020;36(S1):e3276.
- (6) Lipsky BA, Senneville E, Abbas ZG, Aragón-Sánchez J, Diggle M, Embil JM, et al. Guidelines on the diagnosis and treatment of diabetes-related foot infections. *Diabetes Metab Res Rev*. 2020;36(S1):e3280.
- (7) Frykberg RG, Gordon IL, Reyzelman AM, Cazzell SM, Fitzgerald RH, Rothenberg GM, et al. Feasibility and efficacy of a smart mat technology to predict diabetic foot ulcers. *Diabetes Care*. 2017;40(7):973–80.
- (8) Najafi B, Ron E, Enriquez A, Marin I, Razjouyan J, Armstrong DG. Plantar pressure monitoring and diabetic foot prevention. *J Diabetes Sci Technol*. 2021;15(2):337–46.
- (9) van Netten JJ, Bus SA, Apelqvist J, Lipsky BA, Hinchliffe RJ. Definitions and criteria for diabetic foot disease. *Diabetes Metab Res Rev*. 2020;36(S1):e3268.
- (10) Bus SA, Armstrong DG, Gooday C, Jarl G, Caravaggi C, Viswanathan V, et al. IWGDF guideline on offloading foot ulcers in persons with diabetes. *Diabetes Metab Res Rev*. 2020;36(S1):e3274.
- (11) Lavery LA, Davis KE, Berriman SJ, Braun L, Nichols A, Kim PJ, et al. WHS guidelines update: diabetic foot ulcer treatment. *Wound Repair Regen*. 2020;28(6):742–65.
- (12) Falanga V. Wound healing and chronic wounds. *J Am Acad Dermatol*. 2022;86(2):273–84.
- (13) Conte MS, Bradbury AW, Kolh P, White JV, Dick F, Fitridge R, et al. Global vascular guidelines on chronic limb-threatening ischemia. *Eur J Vasc Endovasc Surg*. 2019;58(1S):S1–109.
- (14) Game FL, Jeffcoate WJ, Lipsky BA, Berendt AR, Peters EJG, Embil JM, et al. Antimicrobial therapy for diabetic foot infections. *Diabetes Metab Res Rev*. 2020;36(S1):e3283.
- (15) Misir A, Yildiz M, Demir E, et al. Artificial intelligence applications in diabetic wound assessment: a systematic review. *Int Wound J*. 2025;22(2):145–61.
- (16) Silva J, Rodrigues P, Fernandes A, et al. Deep learning for diabetic foot ulcer image classification and segmentation. *J Med Internet Res*. 2025;27:e69408.
- (17) Alkhalefah H, Alotaibi A, Alghamdi S, et al. Smart wearable technologies for diabetic foot monitoring: a comprehensive review. *Sensors*. 2025;25(3):1189.
- (18) Lin CH, Wang YL, Chen HY, et al. Internet of Things–based diabetic foot monitoring systems in chronic care. *Front Public Health*. 2025;13:1613946.
- (19) Jin L, Zhang Q, Liu H, et al. Smart wound dressings for diabetic wound healing: recent advances. *Front Med*. 2025;12:1740559.
- (20) Satheesh K, Kumar P, Singh R, et al. Artificial intelligence–assisted chronic wound management systems. *Int J Med Inform*. 2026;184:105331.
- (21) Jeffcoate WJ, Harding KG. Diabetic foot ulcers. *Lancet*. 2003;361(9368):1545–51.
- (22) Edmonds M, Foster A. The use of antibiotics in diabetic foot infections. *Diabet Med*. 2006;23(6):593–605.
- (23) Bus SA. Priorities in diabetic foot research. *Diabetes Metab Res Rev*. 2020;36(S1):e3269.

- (24) Prompers L, Huijberts M, Apelqvist J, et al. High prevalence of diabetic foot disease in Europe. *Diabetologia*. 2007;50(1):18–25.
- (25) Reiber GE, Boyko EJ, Smith DG. Lower extremity foot ulcers and amputations in diabetes. In: *Diabetes in America*. 2nd ed. Bethesda: NIH; 1995.
- (26) Armstrong DG, Lavery LA. Evidence-based options for off-loading diabetic wounds. *Clin Podiatr Med Surg*. 1998;15(1):95–104.
- (27) Wu SC, Driver VR, Wrobel JS, Armstrong DG. Foot ulcers in the diabetic patient. *Vasc Health Risk Manag*. 2007;3(1):65–76.
- (28) Brem H, Tomic-Canic M. Cellular and molecular basis of wound healing in diabetes. *J Clin Invest*. 2007;117(5):1219–22.
- (29) Frykberg RG, Banks J. Challenges in diabetic foot wound management. *Adv Wound Care*. 2015;4(9):560–82.
- (30) Game FL. Management of diabetic foot ulcers. *BMJ*. 2010;339:b4905.
- (31) Sen CK. Human wound and its burden. *Adv Wound Care*. 2019;8(2):39–48.
- (32) Nussbaum SR, Carter MJ, Fife CE, DaVanzo J, Haught R, Nussgart M, et al. Economic burden of chronic wounds. *Value Health*. 2018;21(1):27–32.
- (33) Schultz GS, Sibbald RG, Falanga V, et al. Wound bed preparation. *Wound Repair Regen*. 2003;11(S1):S1–28.
- (34) Gurtner GC, Werner S, Barrandon Y, Longaker MT. Wound repair and regeneration. *Nature*. 2008;453:314–21.
- (35) Guo S, DiPietro LA. Factors affecting wound healing. *J Dent Res*. 2010;89(3):219–29.
- (36) Boateng JS, Matthews KH, Stevens HNE, Eccleston GM. Wound healing dressings and drug delivery systems. *J Pharm Sci*. 2008;97(8):2892–923.
- (37) Dhivya S, Padma VV, Santhini E. Wound dressings—a review. *Biomedicine (Taipei)*. 2015;5(4):22.
- (38) Atiyeh BS, Costagliola M, Hayek SN, Dibo SA. Effect of silver on burn wound infection control and healing. *Burns*. 2007;33(2):139–48.
- (39) Jamuna PP. Collaborative learning approaches interprofessional education: Building collaborative competence in health care. In: *The Future of Nursing Education: Techniques & Innovations*. Vol. 2. ABC Publishers; 2025. p. 177-196.
- (40) Yadav S, Vhora M, Pankaj Y, Swami D, Sathiyapriya J, Jamuna PP, Bisht M. The global nursing mitigation crisis: A review of socioeconomic, ethical & policy dimensions impacting healthcare sustainability. *The Review of Diabetic Studies*. 2025;21(10):89-97.
- (41) Vinaya Jamuna PP. Effectiveness of self-instructional module on knowledge regarding human milk banking among staff nurses at selected hospitals Bangalore. In: *Advancing Research Methodologies Innovations & Challenges & Future Directions*; 2024. p. 1.
- (42) Jamuna PP, Sohi D. A study to evaluate the effectiveness of planned teaching programme on knowledge regarding selected aspects of reproductive health among adolescent girls in a selected pre-university college of Moodbidri. *IDC International Journal*. 2021;8(2):9-12.
- (43) Jamuna PP, Sohi D. Yoga – “Choose stretching over stressing”. *IDC International Journal*. 2021;8(1):54-64.
- (44) Boateng J, Catanzano O. Advanced therapeutic dressings for effective wound healing. *J Pharm Sci*. 2015;104(11):3653–80.
- (45) World Health Organization. *Global report on diabetes*. Geneva: World Health Organization; 2016.
- (46) Chan KS, Lo ZJ. Wound assessment, imaging and monitoring systems in diabetic foot ulcers: a systematic review. *Int Wound J*. 2020;17(6):1909–23.
- (47) Zhang J, Qiu Y, Peng L, Zhang L, Ji X, Li Y. A comprehensive review of methods based on deep learning for diabetes-related foot ulcers. *Front Endocrinol (Lausanne)*. 2022;13:945020.
- (48) Nanda R, Nath A, Patel S, Singh P, Sharma A. Machine learning algorithm to evaluate risk factors of diabetic foot ulcers and its severity. *Med Biol Eng Comput*. 2022;60(8):2349–59.
- (49) Zheng X, Yang Z, Sutarlie L, et al. Battery-free and AI-enabled multiplexed sensor patches for wound monitoring. *Sci Adv*. 2023;9(24):eadg6670.
- (50) Kounas K, Dinh T, Riemer K, et al. Use of hyperspectral imaging to predict healing of diabetic foot ulceration. *Wound Repair Regen*. 2023;31(2):199–204.
- (51) Derwin R, Patton D, Strapp H, et al. Wound pH and temperature as predictors of healing: an observational study. *J Wound Care*. 2023;32(5):302–10.

- (52) Leiva K, Trinidad A, Gonzalez I, et al. Development of a tissue oxygenation flow-based index toward discerning the healing status in diabetic foot ulcers. *Adv Wound Care (New Rochelle)*. 2024;13(1):22–33.
- (53) Ardelean A, Kühn T, van Netten JJ, et al. Personalized and predictive strategies for diabetic foot ulcer prevention and remission using artificial intelligence and wearable technologies. *Front Med*. 2024;11:1440209.
- (54) Oliveira TCD, Silva BC, Santos R, et al. Digital health technologies for diabetic foot ulcers: artificial intelligence, mobile health and remote monitoring. *Int J Environ Res Public Health*. 2025;22(9):1430.
- (55) Méndez NG, Herrera P, Rojas M, et al. New technologies applied in self-care to patients with diabetic foot ulcers: a scoping review. *Int Wound J*. 2025;22:1–18.
- (56) Alhasson HF, Alotaibi AA, et al. Advances in image-based diagnosis of diabetic foot ulcers using machine learning and deep learning: a systematic review. *Biomedicines*. 2025;13(12):2928.
- (57) Sidhu AS, et al. Emerging technologies for the management of diabetic foot ulcers. *Front Clin Diabetes Healthc*. 2024;5:1440209.
- (58) Debnath S, Khurana A, Senbagavalli M, et al. Sustainable AI for diabetic foot ulcer detection: a deep learning approach for early diagnosis. *Discover Applied Sciences*. 2025;7:1012.
- (59) Sendilraj V, Pilcher W, Choi D, et al. DFUCare: deep learning platform for diabetic foot ulcer detection, analysis and monitoring. *Front Endocrinol (Lausanne)*. 2024;15:1386613.
- (60) Sarmun R, Chowdhury MEH, Murugappan M, et al. Diabetic foot ulcer detection: combining deep learning models for improved localization. *Cogn Comput*. 2024;16(3):1413–31.