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Research Article

Effectiveness of Biosensor-Based Smart Wound Dressings in Chronic Wound Healing Among Adults with DiabetesMellitus

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Abstract. Diabetes mellitus increases the risk of chronic wounds, particularly diabetic foot ulcers, through neuropathy, impaired perfusion, persistent inflammation, immune dysfunction, oxidative stress, and susceptibility to infection. Conventional wound assessment remains episodic and largely dependent on clinical observation, potentially delaying recognition of changes in the wound microenvironment. Biosensor-based smart wound dressings enable real-time monitoring of pH, temperature, oxygen, bioimpedance, metabolites, inflammatory mediators, and proteolytic biomarkers, while several platforms also integrate responsive therapy. This study aimed to analyze the effectiveness, mechanisms, clinical benefits, and limitations of biosensor-based smart wound dressings in supporting chronic wound healing in adults with diabetes mellitus. A descriptive qualitative method was employed. Data were collected using documentation techniques focusing on scientific information related to biosensor characteristics, wound parameters, mechanisms of action, healing outcomes, clinical benefits, and technological limitations. Data were analyzed through reduction, categorization, interpretation, cross-source comparison, and conclusion drawing, while source triangulation was used to strengthen the credibility of the findings. The findings indicate that smart wound dressings have strong potential to improve objective wound monitoring, enable earlier recognition of pathological changes, and support more adaptive treatment. The most consistent effectiveness is currently demonstrated at technological and biological levels, whereas direct clinical benefits in adults with diabetes remain limited. Smart wound dressings should therefore be positioned as adjunctive technologies within multidisciplinary wound care rather than replacements for debridement, offloading, infection control, vascular assessment, and metabolic management.

Keywords: Biosensor; Chronic wound; Diabetes mellitus; Diabetic foot ulcer; Smart wound dressing

1. Introduction

Diabetes mellitus is a chronic metabolic disease that impairs tissue healing through complex mechanisms. Prolonged hyperglycemia affects endothelial function, immune responses, fibroblast and keratinocyte activity, angiogenesis, extracellular matrix deposition, and the balance of inflammatory mediators. Under normal conditions, wound healing proceeds through the interconnected phases of hemostasis, inflammation, proliferation, and remodeling. In diabetes, transitions between these phases are often disrupted, causing wounds to remain in a state of chronic inflammation and fail to achieve stable tissue closure (Rodrigues et al., 2019).

Diabetic foot ulcers are among the most clinically significant forms of chronic wounds. Peripheral neuropathy, foot deformity, repetitive plantar pressure, peripheral arterial disease, unrecognized trauma, and infection interact to increase the risk of ulcer formation and delay healing. The consequences include reduced quality of life, recurrent hospitalization, surgical procedures, amputation, recurrence, and increased healthcare costs. Therefore, diabetic foot ulcer management requires a multidisciplinary approach encompassing perfusion assessment, debridement, offloading, infection control, local wound care, and management of systemic factors (Armstrong et al., 2023).

In clinical practice, chronic wound assessment is still primarily performed through visual inspection, measurement of wound area and depth, evaluation of exudate characteristics, granulation tissue, necrosis, odor, and signs of inflammation. These methods remain essential but are limited because they are intermittent and subject to interobserver variability. Biological

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changes in a wound may occur between dressing changes and may not be immediately apparent morphologically. In addition, repeated removal of dressings can disrupt wound moisture, cause pain, and potentially damage newly formed granulation tissue.

Smart wound dressings were developed in response to these limitations. Unlike conventional dressings, which primarily function as protective barriers and exudate-management materials, smart wound dressings combine dressing materials with sensors, microfluidics, flexible electronics, wireless communication systems, or mechanisms for responsive therapeutic delivery. Biosensors embedded in dressings can detect physical parameters such as temperature, humidity, and bioimpedance; chemical parameters such as pH, oxygen, glucose, lactate, and uric acid; and biological biomarkers such as inflammatory cytokines, bacteria, and matrix metalloproteinase-9 (MMP-9) (Michelucci et al., 2026).

Technological development has progressed from single-sensor devices toward multiparameter platforms and theranostic systems (Wu et al., 2025). VeCare integrates the detection of cytokines, Staphylococcus aureus, pH, and temperature into a single wireless platform (Gao et al., 2021). The e-ECM platform combines measurements of lactate, glucose, pH, oxygen, and temperature (Brown et al., 2022), whereas graphene/MXene sensors detect uric acid, pH, and temperature (Sharifuzzaman et al., 2020). Other technologies have been developed to monitor glucose, pH, temperature, bioimpedance, and electrophysiological signals within the wound environment (Hou et al., 2024).

Further advances are evident in closed-loop systems that link sensor readings with therapy. Jiang et al. developed a wireless bandage integrating impedance and temperature sensors with electrical stimulation and demonstrated accelerated healing in animal models (Jiang et al., 2023). Shirzaei Sani et al. combined metabolic and inflammatory monitoring with antimicrobial and anti-inflammatory therapy as well as regenerative stimulation (Shirzaei Sani et al., 2023). Deng et al. developed an MMP-9 sensor linked to the controlled release of antibacterial nanoparticles (Deng et al., 2025). These findings demonstrate the potential transformation of dressings from passive devices into adaptive diagnostic-therapeutic systems.

Despite rapid innovation, the term effectiveness should be interpreted proportionally. Technological effectiveness can be assessed through sensitivity, stability, flexibility, and data-transmission capability; biological effectiveness through wound closure, angiogenesis, remodeling, or infection control in preclinical models; and clinical effectiveness should be demonstrated through patient outcomes such as healing time, the proportion of wounds healed, infection incidence, amputation, pain, quality of life, and cost. Recent publications indicate that most smart wound dressings remain at the preclinical stage, whereas human studies predominantly assess feasibility and monitoring performance (Michelucci et al., 2026).

A remaining scientific gap is that many publications focus on material and sensor performance without consistently linking these characteristics to the specific clinical needs of adults with diabetes. The novelty of this study lies in an analysis that explicitly distinguishes technological effectiveness, biological effectiveness, and clinical effectiveness, and then relates these dimensions to standards of diabetic foot ulcer care. Through this approach, sensor sophistication is not directly interpreted as successful patient healing but is assessed according to the level of evidence and its relevance to clinical decision-making.

Based on this gap, the study focuses on four questions: (1) how effective are biosensor-based smart wound dressings in supporting chronic wound healing in adults with diabetes mellitus; (2) which biosensor parameters and mechanisms contribute to monitoring and improvement of the healing process; (3) what clinical and operational benefits can be obtained in diabetic wound care; and (4) what limitations and challenges continue to hinder clinical implementation. These four questions provide the analytical framework for the Results and Discussion section.

2. Methods

This study used a descriptive qualitative method to comprehensively describe the effectiveness, mechanisms of action, clinical benefits, and limitations of biosensor-based smart wound dressings in chronic wound healing among adults with diabetes mellitus. This approach was selected because the study focuses on interpreting technological characteristics and their contextual relationship with the wound-healing process rather than testing statistical hypotheses or measuring effect size.

The object of analysis was the application of biosensor-based smart wound dressings in the monitoring and management of chronic diabetic wounds. The aspects examined included the types and characteristics of biosensors, the physiological and biochemical parameters

monitored, response mechanisms to changes in wound conditions, the relationship between the technology and the healing process, potential benefits in clinical services, and constraints affecting its application in adults with diabetes mellitus.

Data were collected using documentation techniques. Information was obtained from relevant peer-reviewed scientific publications and clinical guidelines, then recorded and categorized according to its relevance to the focus of the study. Documentation focused on information related to pH, temperature, oxygenation, bioimpedance, glucose, lactate, uric acid, inflammatory mediators, bacteria, MMP-9, wireless monitoring systems, responsive therapy, and outcomes associated with tissue repair and wound healing.

Data were analyzed descriptively and qualitatively through the stages of data reduction, information categorization, presentation of findings, interpretation, and conclusion drawing. Information with similar meanings was grouped into the domains of effectiveness, biosensor parameters and mechanisms, clinical and operational benefits, and implementation limitations. Comparisons were then made across the information to identify consistent patterns, differences in findings, relationships among parameters, and their implications for chronic wound management in adults with diabetes mellitus.

3. Results and Discussion

Biosensor-based smart wound dressings have progressed from simple monitoring systems toward multiparameter platforms capable of integrating wound-condition detection with responsive interventions. The findings indicate that the principal value of this technology lies in its ability to provide objective information on changes in the wound microenvironment, support early detection of conditions that hinder healing, and create opportunities for more targeted therapy. The following Results and Discussion describe effectiveness, biosensor parameters and mechanisms, clinical and operational benefits, and challenges associated with implementation in chronic diabetic wounds.

Effectiveness of Biosensor-Based Smart Wound Dressings in Chronic Wound Healing among Adults with Diabetes Mellitus

Biosensor-based smart wound dressings demonstrate strong potential to support chronic wound healing through real-time monitoring of biological changes and by providing information that can be used to guide more precise interventions. Their effectiveness should be understood at three distinct levels: technological performance, biological response, and clinical benefit. At the technological level, various platforms have been able to measure wound parameters with adequate sensitivity and stability, including pH, temperature, oxygen, glucose, lactate, uric acid, cytokines, bacteria, bioimpedance, and MMP-9 (Gao et al., 2021). This capability expands the function of dressings from simple protection and exudate management to active monitoring of wound dynamics.

At the biological level, the clearest evidence comes from systems that combine biosensing with responsive therapy. Jiang et al. reported that a closed-loop smart bandage that monitors impedance and temperature and provides electrical stimulation accelerated healing and enhanced dermal remodeling in animal models (Jiang et al., 2023). Shirzaei Sani et al. also demonstrated that a wearable system combining metabolic/inflammatory monitoring with antimicrobial, anti-inflammatory, and electrical stimulation therapies improved the healing of infected chronic wounds (Shirzaei Sani et al., 2023). These findings support the mechanism whereby sensor data can be used to determine the timing and type of intervention more precisely.

In diabetic wound models, effectiveness is also reflected in the ability to monitor the wound environment while maintaining dressing function. Hou et al. developed an adhesive, self-healing dressing capable of recording glucose, pH, temperature, and electrophysiological signals in infected diabetic wounds (Hou et al., 2024). Garland et al. showed that wireless lactate monitoring, particularly when combined with pH, may help predict the wound-closure rate from an early stage (Garland et al., 2023). Thus, effectiveness is not limited to accelerated healing but also includes an improved ability to predict whether a wound is likely to improve or remain stagnant.

Human evidence provides more limited but important support. Antoszewska et al. demonstrated a strong correlation between changes in bioimpedance and reductions in wound area among patients with chronic wounds (Antoszewska et al., 2024). Schreml et al. mapped pH and oxygen gradients in human chronic wounds and demonstrated alkaline and hypoxic environments that may impair re-epithelialization (Schreml et al., 2014). Deng et al.

validated an MMP-9 sensor using diabetic foot ulcer exudate (Deng et al., 2025). These findings confirm that biosensors can directly detect biologically relevant characteristics within the human wound environment.

However, direct clinical evidence of a higher proportion of healed wounds, shorter healing time, lower rates of severe infection or amputation, or reduced costs remains insufficient. Recent reviews show that human studies are still limited in number, have small sample sizes, and use highly heterogeneous technologies (Michelucci et al., 2026). Therefore, smart wound dressings cannot yet be considered superior to standard dressings for all patients with diabetes. The most appropriate conclusion is that the technology demonstrates strong technological and biological effectiveness and high clinical potential, but definitive clinical effectiveness still requires large-scale controlled trials.

Compared with conventional dressings, the main added value of smart dressings is not merely their ability to cover a wound but their capacity to generate continuous information about wound conditions and link that information to clinical action. Modern conventional dressings remain effective for maintaining moisture, managing exudate, and protecting tissue, but they generally do not provide objective indicators of changes in the wound microenvironment while the dressing is in place. Accordingly, the advantage of smart dressings lies in greater observability and responsiveness of care, which may ultimately reduce delays in intervention.

In terms of healing outcomes, consistent preclinical evidence remains important because it demonstrates biological plausibility. Increased re-epithelialization, dermal remodeling, inflammation control, or bacterial reduction in animal models indicates that biosensor-therapy systems can influence the healing process rather than merely measure changes. However, differences in wound size, skin composition, mechanical loading, comorbidities, and microbiome between animals and humans limit generalizability. Therefore, preclinical findings should be regarded as a basis for clinical trials rather than as substitutes for clinical evidence.

In the context of diabetic wound therapy, effectiveness must also be interpreted with recognition that healing is not determined by the dressing alone. Ulcers complicated by ischemia, repetitive plantar pressure, severe infection, or necrosis will not heal merely because a sensor can monitor biomarkers. Therefore, smart dressings should be used as an adjunct to debridement, offloading, infection control, vascular assessment, revascularization when indicated, and metabolic management in accordance with standards of care (Chen et al., 2024).

Biosensor Parameters and Mechanisms Supporting Wound Monitoring and Healing

Biosensor parameters are critical components that determine the ability of smart dressings to identify changes in wound conditions. Chronic diabetic wounds have complex pathophysiology, meaning that a single biomarker is insufficient to represent the entire healing process. Consequently, technological development is increasingly directed toward multiparameter monitoring that combines physical, chemical, metabolic, inflammatory, and proteolytic indicators (Probst et al., 2026). This approach is better suited to characterize the interactions among hypoxia, chronic inflammation, metabolic disturbance, infection, and matrix degradation that occur in diabetic wounds (Huang et al., 2025).

pH is one of the most widely used parameters. Healthy skin tends to be slightly acidic, whereas chronic wounds often exhibit a more alkaline environment. Alkalinity may increase the activity of certain proteases, impair fibroblast and keratinocyte function, and support microbial colonization. Schreml et al. demonstrated pH gradients in human chronic wounds (Schreml et al., 2014), whereas Mariani et al. developed a textile smart bandage capable of real-time pH monitoring (Mariani et al., 2021). Wang et al. integrated an ultrasensitive pH sensor with a unidirectional exudate-management system (Wang et al., 2024). Clinically, pH trends may indicate changes in the wound environment, although pH alone is not sufficiently specific.

Temperature is an important physiological parameter because a local increase in temperature may indicate inflammation or infection. Integrating temperature sensors into smart dressings allows changes to be observed without removing the dressing (Gao et al., 2021). However, interpretation of temperature must take into account environmental conditions, patient activity, perfusion, and wound location. Therefore, longitudinal values or changes relative to an individual baseline are more meaningful than a single measurement.

Oxygenation contributes to proliferation, angiogenesis, collagen synthesis, and antimicrobial defense. Diabetic wounds accompanied by peripheral arterial disease may experience chronic hypoxia. Two-dimensional pH-oxygen sensors can demonstrate spatial heterogeneity

in human wounds (Schreml et al., 2014), while the e-ECM platform incorporates oxygen as part of multiparameter monitoring (Brown et al., 2022). Oxygen information may serve as an indicator that further perfusion assessment is needed, although it cannot replace formal vascular examination.

Glucose and lactate reflect the local metabolic state. Glucose levels in wound exudate are not identical to blood glucose because they are influenced by perfusion, cellular consumption, bacteria, and exudate volume. Therefore, glucose sensors are likely to be more meaningful when combined with pH, temperature, or inflammatory mediators (Brown et al., 2022). Lactate also has potential as a prognostic biomarker; Garland et al. found that early lactate patterns may help predict the rate of wound closure, with improved accuracy when combined with pH (Garland et al., 2023).

Inflammatory biomarkers such as IL-6, IL-8, TNF-alpha, and TGF-beta1 provide more direct information regarding immune status and regeneration (Noushin et al., 2022). The VeCare platform demonstrated that several cytokines can be measured simultaneously with pH, temperature, and Staphylococcus aureus (Gao et al., 2021). This multiplex approach could theoretically distinguish physiological inflammation from persistent inflammation, although bioreceptor complexity and the risk of biofouling remain challenges.

MMP-9 is a highly relevant proteolytic biomarker in chronic wounds. Excessive MMP-9 activity can degrade the extracellular matrix and growth factors, causing the wound to remain in a destructive state. Deng et al. developed a wireless dressing that detects MMP-9 and links the measurement to the release of antibacterial nanoparticles (Deng et al., 2025). This mechanism illustrates the closed-loop principle: the sensor detects biological changes, the system processes the signal, and therapy is subsequently delivered according to the wound condition.

Bioimpedance differs from chemical biomarkers because it reflects changes in the electrical properties of tissue, which are influenced by fluid content, tissue composition, and structure. The correlation between bioimpedance and reduction in wound area in patient studies demonstrates its potential as an objective indicator of healing beneath a dressing (Kekonen et al., 2019). A major advantage of this method is the possibility of monitoring without collecting exudate samples. Nevertheless, electrode contact pressure, moisture, sensor position, and tissue variability can affect readings.

Infection further strengthens the need for multiparameter monitoring. Temperature and pH may function as indirect indicators, whereas detection of bacteria or inflammatory mediators provides more specific information. VeCare demonstrated that Staphylococcus aureus can be measured together with cytokines and physical parameters (Gao et al., 2021). Such an approach may help distinguish wounds with persistent inflammation but no infection from wounds beginning to show microbiological changes. However, interpretation still requires clinical context because bacterial colonization is not always equivalent to invasive infection.

Relationships among parameters are also important. pH can influence enzyme activity, oxygen affects metabolism and regeneration, and lactate and glucose reflect local metabolic balance. Therefore, algorithms that interpret combined patterns are likely to be more informative than the use of a single threshold. Multiplex platforms could be developed to generate a wound-status index incorporating several sensors simultaneously; however, such an index must be developed using human data and tested against clinical outcomes before being used as the basis for automated decisions.

Based on the overall evidence, the main mechanism of smart wound dressings can be summarized in three stages: sensing changes in the wound microenvironment, interpreting or transmitting the data, and producing a clinical or therapeutic response. In the simplest systems, the response consists of notifying healthcare professionals. In more advanced systems, the response may involve electrical stimulation or automatic therapeutic release (Kumar et al., 2025). This is what distinguishes smart dressings from conventional dressings and underpins their potential to improve the precision of wound care.

Clinical and Operational Benefits of Smart Wound Dressings in Diabetic Wound Care

The benefits of smart wound dressings are related not only to the biological healing process but also to the quality and efficiency of wound-care services. One of their principal benefits is improved objectivity of assessment. Conventional wound documentation relies heavily on visual observation and clinician experience, whereas biosensors provide numerical

data that can be compared longitudinally. Monitoring pH, temperature, bioimpedance, metabolites, or biomarkers can strengthen clinical decision-making by providing more consistent information and enabling small changes to be detected before they become clearly visible (Gao et al., 2021).

A second benefit is the potential for early detection of deviations from the healing process. Diabetic wounds may develop persistent inflammation, hypoxia, bacterial colonization, and increased protease activity before visible changes become apparent. Changes in pH, temperature, oxygen, lactate, or MMP-9 may serve as warning signals prompting further evaluation (Deng et al., 2025). In practice, earlier detection may accelerate infection assessment, correction of offloading, vascular evaluation, or changes in the wound-care strategy.

A third benefit is the reduction of unnecessary dressing removal. If wound conditions can be monitored from beneath the dressing, healthcare professionals do not need to remove the dressing solely to assess the wound. This may help preserve optimal moisture, reduce trauma to granulation tissue, decrease pain, and reduce material use. Bioimpedance and wireless sensors are among the most relevant technologies for this purpose (Antoszewska et al., 2024).

A fourth benefit is support for telemonitoring and home-based care. Some platforms can transmit data to portable devices or smartphones (Jiang et al., 2023). For patients with diabetes who require long-term follow-up, this capability can connect home care with clinical services. Patients with stable parameters can be monitored according to protocol, whereas changes suggestive of complications may prompt an earlier visit.

From a nursing perspective, smart dressings can improve continuity of documentation. Nurses can monitor graphs or biological trends between scheduled dressing changes, document responses to interventions, and communicate changes to the multidisciplinary team. Objective data may also improve patient education because wound progression can be explained not only on the basis of visual appearance but also using measurable indicators.

A fifth benefit is the opportunity for personalized therapy (Zhao et al., 2025). Closed-loop systems allow treatment to be delivered according to the condition of the wound rather than on a fixed schedule. Mostafalu et al. integrated pH and temperature with a drug-delivery system (Mostafalu et al., 2018), Jiang et al. combined sensing with electrical stimulation (Jiang et al., 2023), and Shirzaei Sani et al. developed a combination of monitoring with antimicrobial, anti-inflammatory, and stimulation therapies (Shirzaei Sani et al., 2023). Theoretically, on-demand therapy may improve efficiency and reduce unnecessary drug exposure.

Nevertheless, telemonitoring is beneficial only when data can be translated into clear actions. pH or temperature values without clinical algorithms may generate large amounts of data that are not actionable. Therefore, implementation requires validated thresholds, escalation pathways, integration with medical records, and clearly defined responsibilities. The technology must also account for patients' digital literacy, device-use skills, internet access, and the capacity of healthcare facilities to respond to alarms.

At the level of healthcare organization, smart dressings may also support priority stratification. Sensor data can be used to identify patients with stable trends and those requiring more rapid evaluation. This approach may be particularly relevant in wound clinics with large patient volumes because resources can be directed toward patients showing the most meaningful changes. Nevertheless, triage decisions must remain within clinical protocols that consider patient symptoms, vascular status, signs of systemic infection, and overall condition rather than relying on sensor data alone.

From the patient perspective, benefits should be assessed not only in terms of biological healing but also comfort, sense of security, pain during dressing changes, ease of movement, burden of home care, and trust in the technology. A highly accurate device that is rigid, easily detached, or difficult to use will not provide meaningful benefit. Therefore, smart dressing design should incorporate the principles of patient-centered care, including flexibility, atraumatic adhesion, ease of use, resistance to movement, and methods of presenting information that do not create excessive anxiety.

Economically, smart dressings are likely to have a higher unit cost than passive dressings. However, potential savings may arise if the technology reduces visit frequency, decreases unnecessary dressing removal, detects complications earlier, and accelerates healing. At present, cost-effectiveness data remain limited, so economic benefits cannot yet be established. Future clinical trials should include device costs, healthcare professional time, number of visits, antibiotic use, hospitalization, surgical procedures, and quality of life as outcomes.

Limitations and Challenges in the Clinical Implementation of Smart Wound Dressings

The clinical implementation of smart wound dressings still faces a gap between successful prototypes and routine use in patients. Chronic wounds contain complex exudate composed of proteins, cells, bacteria, salts, enzymes, and debris that can cause biofouling, sensor drift, interference, or reduced sensitivity. Sensors that remain stable under laboratory conditions may not maintain their accuracy over several days when applied to a patient's foot that is continuously moving, perspiring, exposed to pressure, and undergoing changes in exudate volume.

Another challenge is technological heterogeneity. Studies use different materials, biomarkers, calibration methods, and outcomes, making direct comparisons across platforms difficult (Michelucci et al., 2026). There is currently no consensus on the minimum combination of biomarkers that provides the most informative assessment. An overly broad panel increases cost and complexity, whereas the use of a single biomarker may result in insufficiently specific interpretation. Standardization is needed so that devices can be evaluated using uniform performance parameters.

Safety and biocompatibility are also important issues because smart dressings are in direct contact with open tissue. Risks requiring evaluation include irritation, cytotoxicity, leaching of sensor materials, adhesive reactions, excessive heat, degradation products, and local toxicity of antimicrobial materials. In systems using silver nanoparticles, antibacterial effectiveness must be balanced against dose control. Electrical-stimulation systems require current control and fail-safe mechanisms to ensure that sensor failure does not result in inappropriate therapy.

Electronic integration introduces issues related to sterilization, power supply, waste disposal, and resistance to exudate. Highly complex devices may also be difficult to mass-produce with consistent quality. Recent publications identify manufacturability, sensor stability, sterilization, cost, material safety, and regulatory pathways as major barriers to clinical adoption (Michelucci et al., 2026).

Data security must be considered in wireless systems. Wound data constitute health information that must be protected from unauthorized access. Connectivity should be accompanied by authentication, encryption, access management, and appropriate data-storage governance. In addition, overly sensitive alarms may lead to alarm fatigue, whereas thresholds that are too permissive may fail to detect important changes. Therefore, system design should involve clinical professionals from the outset.

The most important limitation remains the limited amount of clinical evidence in humans. Most publications reporting accelerated healing have used animal models (Jiang et al., 2023). Human studies primarily assess feasibility, accuracy, biomarker correlations, or characterization of the wound environment (Antoszewska et al., 2024). Recent reviews indicate that smart dressings are promising, but clinical validation continues to lag behind technological progress (Michelucci et al., 2026).

Accordingly, the next research agenda should focus on multicenter clinical trials comparing standard care plus a smart dressing with standard care plus a conventional dressing. Outcomes should include the proportion of wounds healed within a defined period, time to closure, changes in wound area, infection incidence, amputation, pain, quality of life, and cost. In addition, predictive algorithms integrating pH, temperature, lactate, bioimpedance, or other biomarkers require external validation in diverse diabetic populations before being used for automated decision-making (Palani et al., 2026).

Clinical trial designs must also address biases that are common in medical-device research. Randomization should account for wound severity, infection, perfusion, location, baseline size, and the quality of offloading. Comparator interventions should use clearly defined standards of care so that the effect of the smart dressing is not confounded by differences in the quality of debridement or vascular therapy. In addition to clinical outcomes, studies should report device failures, the proportion of missing data, recalibration requirements, sensor wear duration, and material-related adverse events.

The development of artificial intelligence may help transform multiparameter data into predictions of non-healing risk or follow-up recommendations (Palani et al., 2026). However, AI models trained on limited data or homogeneous populations may show reduced performance when applied to different populations. Model transparency, external validation, bias prevention, cybersecurity, and clinician override mechanisms should be incorporated from

the beginning of development. AI should help simplify decision-making rather than eliminate clinical accountability.

Thus, the challenge of implementation is not merely to increase sensor sensitivity but to ensure that devices are safe, stable, affordable, easy to use, capable of being sterilized or disposed of appropriately, compatible with clinical workflows, and able to provide information that genuinely changes care decisions. Successful translation of smart wound dressings will depend on achieving a balance between technological sophistication and clinical relevance.

4. Conclusions

Biosensor-based smart wound dressings have substantial potential to support chronic wound healing in adults with diabetes mellitus through real-time monitoring of the wound microenvironment, early detection of pathological changes, and, in some platforms, responsive therapeutic delivery. Current evidence demonstrates strong effectiveness at the technological and biological levels. These systems can monitor pH, temperature, oxygen, bioimpedance, glucose, lactate, uric acid, cytokines, bacteria, and MMP-9, while closed-loop studies have demonstrated accelerated wound closure and improved remodeling in preclinical models.

In humans, the evidence primarily supports feasibility, monitoring accuracy, and the ability to characterize the wound environment. Direct evidence that smart dressings reduce healing time, severe infection, amputation, or costs in adults with diabetes remains limited. Therefore, this technology is most appropriately positioned as an adjunct to multidisciplinary standards of care rather than a replacement for debridement, offloading, infection control, vascular assessment, and metabolic management. Future research should prioritize multicenter clinical trials, standardization of biomarkers and calibration, safety evaluation, integration into clinical workflows, and cost-effectiveness analyses.

Author Contributions: A short paragraph specifying their individual contributions must be provided for research articles with several authors **(mandatory for more than 1 author)**. The following statements should be used "Conceptualization: X.X. and Y.Y.; Methodology: X.X.; Software: X.X.; Validation: X.X., Y.Y. and Z.Z.; Formal analysis: X.X.; Investigation: X.X.; Resources: X.X.; Data curation: X.X.; Writing—original draft preparation: X.X.; Writing—review and editing: X.X.; Visualization: X.X.; Supervision: X.X.; Project administration: X.X.; Funding acquisition: Y.Y."

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Data Availability Statement: We encourage all authors of articles published in FAITH journals to share their research data. This section provides details regarding where data supporting reported results can be found, including links to publicly archived datasets analyzed or generated during the study. Where no new data were created or data unavailable due to privacy or ethical restrictions, a statement is still required.

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