



DEVELOPMENT AND VALIDATION OF A WEARABLE BIOSENSOR FOR CONTINUOUS GLUCOSE MONITORING*

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Abstract

While wearable health monitoring technologies have advanced significantly, continuous glucose monitoring remains challenging due to sensor stability and accuracy limitations. This study aimed to develop and validate a novel wearable biosensor utilizing a graphene-platinum nanocomposite for accurate, stable, and non-invasive continuous glucose monitoring. A flexible enzyme-based electrochemical sensor was fabricated using a reduced graphene oxide-platinum composite integrated with glucose oxidase on a medical-grade polyurethane substrate. The sensor underwent comprehensive in vitro characterization followed by a 14-day clinical validation study involving 50 diabetic patients. Accuracy was assessed through comparison with standard blood glucose measurements using multiple analytical frameworks, including Clarke Error Grid analysis and continuous glucose-error grid analysis. The sensor demonstrated a linear response range of 0.1-25 mM with a sensitivity of $22.8 \pm 0.9 \mu\text{A}/\text{mM}\cdot\text{cm}^2$. Clinical validation revealed an overall Mean Absolute Relative Difference (MARD) of $9.2 \pm 1.8\%$, with 95.2% of measurements falling within Zone A of the Consensus Error Grid. The sensor-maintained stability throughout the 14-day period, with sensitivity retention above 95.8%. User acceptance was high, with an average comfort rating of 8.4/10 and 82% of participants preferring the device over their current glucose monitoring systems. The developed wearable biosensor achieves clinical-grade accuracy and stability for continuous glucose monitoring, demonstrating significant improvements over existing technologies in terms of user comfort and long-term performance. These findings suggest potential for widespread adoption in diabetes management, particularly given the high user acceptance rates and minimal skin irritation.

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1. Introduction

The convergence of nanotechnology and wearable electronics has sparked a revolution in personal health monitoring, yet one critical challenge remains stubbornly resistant to innovation: continuous glucose monitoring. While smartphones can track our steps, smartwatches can record our heart rhythms, and patches can monitor our hydration levels, the reliable, non-invasive measurement of blood glucose has remained an elusive goal (George et al., 2023; Pikulin et al., 2024; Volkova et al., 2023). This technological barrier particularly affects the millions worldwide managing diabetes, who must still rely on either invasive finger pricks or semi-invasive sensor systems for their vital glucose measurements (Davies et al., 2022). The quest for effective glucose monitoring solutions has driven decades of innovation, progressing from rudimentary urine testing to sophisticated continuous glucose monitoring (CGM) systems. Each advancement has brought new possibilities while revealing fresh challenges in the pursuit of the ideal monitoring solution.

The emergence of CGM technology has revolutionized diabetes care by providing real-time, continuous information about glucose levels, enabling better therapeutic decisions and improved glycemic control (Polonsky and Soriano, 2023). However, current CGM systems face several limitations, including invasiveness, sensor stability issues, cost constraints, and user comfort concerns (Yu et al., 2024). These challenges have sparked intensive research efforts to develop more user-friendly, accurate, and cost-effective monitoring solutions.

Recent advances in materials science, nanotechnology, and bioengineering have opened new possibilities for non-invasive glucose monitoring through wearable devices (Yang et al., 2023). The integration of flexible electronics with novel biosensing materials has enabled the development of skin-adherent sensors capable of detecting glucose levels through interstitial fluid analysis. These technological developments align with the growing trend toward personalized healthcare and remote patient monitoring, particularly relevant in the context of increasing healthcare costs and the need for more efficient disease management strategies (Liu et al., 2024).

Despite these advances, significant challenges remain in developing reliable, long-term wearable glucose monitoring systems. Current wearable sensors often suffer from limited accuracy, poor stability over time, and susceptibility to environmental factors (Salamone et al., 2021). Additionally, the complex nature of the skin-sensor interface and variations in interstitial fluid composition present substantial technical hurdles that must be overcome to achieve reliable glucose measurements (Jain et al., 2024).

In response to these challenges, researchers have explored various approaches to improve wearable glucose monitoring systems. These efforts have primarily focused on enhancing sensor stability, improving measurement accuracy, and reducing user burden. Building upon these advances, the present study addresses current limitations through the development and validation of a novel wearable biosensor incorporating advanced nanomaterials and enzyme-based electrochemical sensing technology (Devi and Devanathan, 2019; Uwa et al., 2023). This innovative approach combines the specificity of enzymatic glucose detection with the stability and conductivity of engineered nanomaterials, integrated into a flexible, skin-friendly platform. The design prioritizes user comfort while maintaining measurement accuracy, representing a significant advancement in wearable glucose monitoring technology (Xue et al., 2023; Zhao et al., 2024).

The rationale for this research stems from the urgent need for more accessible and user-friendly glucose monitoring solutions that can improve patient compliance and health outcomes. Current evidence suggests that increased monitoring frequency correlates with better glycemic control (Urakami et al., 2022), yet many patients find existing monitoring systems burdensome or

cost-prohibitive. By developing a non-invasive, wearable solution, this study aims to address these barriers while maintaining the high accuracy standards required for clinical glucose monitoring.

The development of wearable biosensors represents a convergence of multiple technological advances in materials science, electrochemistry, and bioengineering. Traditional electrochemical glucose sensors rely on the glucose oxidase (GOx) enzyme, which catalyzes the oxidation of glucose to gluconic acid and hydrogen peroxide. However, the integration of this well-established sensing mechanism into a wearable format presents unique challenges, particularly in maintaining enzyme stability and ensuring consistent electron transfer (Bollella and Katz, 2020; Zhang et al., 2024). Recent developments in nanomaterial engineering have provided promising solutions to these challenges. Carbon-based nanomaterials, including graphene and carbon nanotubes, offer exceptional electrical conductivity and large surface areas for enzyme immobilization (Xu et al., 2023). Additionally, metallic nanoparticles, particularly gold and platinum nanostructures, have demonstrated enhanced catalytic activity and improved electron transfer kinetics in biosensing applications (El Housseini et al., 2024).

The theoretical framework for this study builds upon established principles of enzymatic electrochemical sensing while incorporating recent advances in flexible electronics and biocompatible materials. The proposed biosensor design utilizes a novel composite material combining reduced graphene oxide (rGO) with platinum nanoparticles, providing both high conductivity and excellent catalytic properties. This composite is integrated into a flexible substrate using advanced printing techniques, ensuring uniform distribution of the sensing elements while maintaining mechanical flexibility (Jiang et al., 2023).

Prior research has demonstrated the potential of similar approaches, though challenges in long-term stability and signal drift have limited their practical application. Saha et al. (2023) reported successful short-term glucose monitoring using a graphene-based wearable sensor, but observed significant signal degradation after 72 hours. Similarly, Aparicio-Martínez et al. (2023) achieved high initial accuracy with a flexible enzymatic sensor, but encountered challenges with enzyme stability in real-world conditions.

Given these challenges and opportunities, this research aims to validate a novel wearable biosensor design that addresses current limitations in continuous glucose monitoring. The study employs a rigorous clinical validation protocol involving 50 diabetic patients over a 14-day period. The methodology combines quantitative accuracy assessment using Clarke Error Grid analysis with qualitative evaluation of user experience and device practicality. This comprehensive approach enables thorough evaluation of both technical performance and real-world usability, providing valuable insights for future development of wearable glucose monitoring technologies.

The specific objectives of this study are:

- To evaluate the accuracy and precision of the developed wearable biosensor through comparison with standard blood glucose measurements
- To assess the long-term stability and reliability of the sensor over a 14-day wearing period
- To investigate user acceptance and comfort through comprehensive patient feedback
- To determine the impact of environmental factors and daily activities on sensor performance

This work is divided in three main parts:

- Development and validation of the biosensor platform: design and fabrication of an enzyme-based electrochemical sensor utilizing advanced nanomaterials (graphene-platinum composite) and flexible substrates; laboratory characterization of sensing performance including sensitivity, selectivity, and response time; optimization of the wearable form factor for continuous operation;
- Implementation of clinical validation study: comprehensive testing program involving 50 diabetic patients over a 14-day period, with parallel reference measurements using standard blood glucose monitoring; collection of continuous sensor data and user experience feedback; evaluation

of sensor performance under various environmental conditions and daily activities; assessment of user comfort and practical usability;

- Analysis of performance metrics and clinical implications: statistical analysis of sensor accuracy using Clarke Error Grid methodology; evaluation of long-term stability and drift characteristics; investigation of environmental and physiological interference factors; development of recommendations for clinical implementation and future optimization; formulation of guidelines for integration into diabetes management protocols.

2. Materials and methods

2.1. Biosensor design and fabrication

The wearable glucose biosensor was fabricated using a multi-layer approach incorporating flexible substrate materials and advanced nanomaterial composites. The base substrate consisted of medical-grade polyurethane (PU) film (Tegaderm™, 3M, USA) with a thickness of 50 μm. The sensing element was constructed using a novel graphene-platinum nanocomposite synthesized through a modified hydrothermal reduction process.

The graphene oxide (GO) precursor (Sigma-Aldrich, USA) was dispersed in deionized water (1 mg/mL) and sonicated for 2 hours to ensure uniform dispersion. Platinum nanoparticles were synthesized using chloroplatinic acid hexahydrate (H₂PtCl₆·6H₂O, Sigma-Aldrich) as the precursor, with sodium borohydride (NaBH₄) as the reducing agent. The Pt nanoparticles (average diameter 5 nm, confirmed by TEM) were incorporated into the GO dispersion at a mass ratio of 1:4 (Pt:GO). The composite material was reduced using a hydrothermal process at 180°C for 12 hours in a Teflon-lined autoclave. The resulting reduced graphene oxide-platinum (rGO-Pt) composite was collected by centrifugation, washed repeatedly with deionized water and ethanol, and dried under vacuum at 60°C for 24 hours.

The sensing electrode was fabricated by screen printing the rGO-Pt composite ink onto a flexible polyethylene terephthalate (PET) substrate pre-coated with a gold current collector layer. The enzyme immobilization was performed using glucose oxidase (GOx, from *Aspergillus niger*, Sigma-Aldrich) cross-linked with glutaraldehyde in the presence of bovine serum albumin (BSA) as a protein stabilizer. The enzyme solution (10 mg/mL GOx, 5 mg/mL BSA) was drop-cast onto the electrode surface and allowed to dry at 4°C overnight.

4.2. Sensor characterization

Prior to clinical testing, comprehensive characterization of the sensor performance was conducted *in vitro*. Electrochemical measurements were performed using a CHI760E electrochemical workstation (CH Instruments, USA) in a three-electrode configuration. Cyclic voltammetry (CV) and electrochemical impedance spectroscopy (EIS) were employed to evaluate the electron transfer characteristics and interface properties of the sensor.

Sensor sensitivity was determined through amperometric measurements in phosphate-buffered saline (PBS, pH 7.4) containing glucose concentrations ranging from 0 to 25 mM. The linear range, sensitivity, and detection limit were calculated from these measurements. Selectivity studies were conducted by evaluating sensor response to common interferents including ascorbic acid, uric acid, and acetaminophen at physiologically relevant concentrations.

4.3. Clinical study design

The clinical validation study was conducted at the University Medical Center following approval from the Institutional Review Board and in accordance with the Declaration of Helsinki.

Fifty participants with Type 1 or Type 2 diabetes were recruited based on comprehensive inclusion and exclusion criteria. Study participation required candidates to be between 18 and 65 years of age, diagnosed with diabetes for at least one year, currently using finger-stick blood glucose monitoring or CGM, capable of performing self-monitoring of blood glucose, and willing to wear the sensor for 14 consecutive days.

Participants were excluded if they were pregnant or planning pregnancy, had a history of severe hypoglycemia within the past 6 months, presented with dermatological conditions affecting sensor attachment sites, had known allergies to medical adhesives, or had participated in other clinical trials within the past 30 days.

4.4. Study protocol

Each participant underwent a 14-day monitoring period wearing two sensors simultaneously: the developed wearable biosensor and a commercial CGM system (Dexcom G6) for reference measurements. The wearable biosensor was applied to the upper arm following standard skin preparation procedures. Participants were provided with a custom smartphone application for data collection and a commercial glucose meter (Contour Next ONE, Ascensia Diabetes Care) for reference measurements.

The study protocol established a rigorous monitoring schedule requiring a minimum of four finger-stick blood glucose measurements daily using the provided glucose meter. Participants were instructed to record all meals, exercise, and relevant activities in the smartphone application. Daily assessments of sensor comfort and adhesion were conducted, and participants returned to the clinic on days 1, 7, and 14 for comprehensive sensor evaluation.

4.5. Data collection and processing

Sensor measurements were recorded continuously at 5-minute intervals throughout the 14-day period. Data was transmitted via Bluetooth to the smartphone application and subsequently uploaded to a secure cloud server. Reference blood glucose measurements were manually entered into the application and time-stamped for correlation with sensor readings.

Raw sensor data underwent pre-processing to remove artifacts and correct for temperature variations using a custom algorithm implemented in MATLAB R2023a (MathWorks, USA). The algorithm applied a median filter to remove spurious signals and incorporated temperature compensation based on the integrated temperature sensor readings.

4.6. Performance Analysis

Sensor accuracy was evaluated through multiple established metrics, including Mean Absolute Relative Difference (MARD) between sensor readings and reference measurements, Clarke Error Grid Analysis (EGA) for clinical accuracy assessment, Consensus Error Grid Analysis for additional clinical perspective, and Continuous Glucose-Error Grid Analysis (CG-EGA) for dynamic accuracy assessment. The analysis considered paired points where reference measurements were available within ± 2.5 minutes of sensor readings. Temporal alignment of sensor and reference data was performed using linear interpolation where necessary.

4.7. Stability analysis

Long-term stability was assessed through comprehensive evaluation of sensor performance over the study period. This included drift analysis of sensor sensitivity, comparison of daily mean

absolute relative differences, evaluation of calibration stability through in-clinic reference measurements, and assessment of environmental factors' impact on sensor performance.

4.8. User experience assessment

Participant experience was evaluated through a combination of quantitative and qualitative measures. Daily comfort ratings were collected using a 10-point visual analog scale, along with documentation of any skin irritation or adhesion issues. Participants completed a validated wearable device comfort questionnaire and participated in exit interviews concerning usability and preferences.

4.9. Statistical analysis

Statistical analyses were performed using R version 4.2.0 (R Foundation for Statistical Computing, Vienna, Austria) and SPSS Statistics 28.0 (IBM Corp., USA). Normality of data distributions was assessed using the Shapiro-Wilk test and Q-Q plots. Paired measurements were compared using either paired t-tests or Wilcoxon signed-rank tests, depending on data distribution. Correlation between sensor and reference measurements was evaluated using Pearson's correlation coefficient for normally distributed data and Spearman's rank correlation for non-normal distributions.

Sensor accuracy metrics were analyzed using mixed-effects models to account for repeated measurements and potential confounding factors such as time of day, meal status, and physical activity. The models included random effects for individual participants and fixed effects for environmental conditions and wear time. Statistical significance was set at $p < 0.05$, and all confidence intervals were calculated at the 95% level. Effect sizes were calculated using Cohen's d for parametric tests and r for non-parametric tests.

5. Results and discussion

5.1. Sensor characterization

The electrochemical characterization of the rGO-Pt composite-based glucose sensor revealed excellent electron transfer properties and high sensitivity to glucose. Cyclic voltammetry measurements demonstrated well-defined oxidation and reduction peaks, indicating efficient electron transfer between the enzyme and the electrode surface. Table 1 summarizes the key performance parameters of the sensor determined through in vitro characterization.

Table 1. In vitro performance characteristics of the wearable glucose biosensor

<i>Parameter</i>	<i>Value</i>	<i>Testing conditions</i>
Linear Range	0.1-25 mM	PBS (pH 7.4), 25°C
Sensitivity	$22.8 \pm 0.9 \mu\text{A}/\text{mM}\cdot\text{cm}^2$	0-10 mM glucose
Detection Limit	0.02 mM	S/N = 3
Response Time	< 30 seconds	5 mM glucose step
Operating Potential	+0.4 V vs. Ag/AgCl	Amperometric detection
Enzyme Loading	$250 \pm 15 \mu\text{g}/\text{cm}^2$	GOx/BSA ratio 2:1

The sensor exhibited a wide linear range extending from 0.1 to 25 mM, covering the physiologically relevant glucose concentrations. The high sensitivity of $22.8 \pm 0.9 \mu\text{A}/\text{mM}\cdot\text{cm}^2$ ensures accurate glucose detection throughout this range. Notably, the response time of less than 30 seconds represents a significant improvement over many existing wearable sensors.

Interference studies demonstrated excellent selectivity of the sensor toward glucose in the presence of common physiological interferents. Table 2 presents the relative response of the sensor to various interfering species.

Table 2. Selectivity study results showing relative sensor response to interfering species

<i>Interfering species</i>	<i>Concentration</i>	<i>Relative response (%)</i>
Ascorbic Acid	0.1 mM	2.3 ± 0.4
Uric Acid	0.1 mM	1.8 ± 0.3
Acetaminophen	0.1 mM	2.1 ± 0.5
Dopamine	0.01 mM	1.5 ± 0.2
L-Cysteine	0.1 mM	1.2 ± 0.3

The minimal interference responses, all below 3% of the glucose signal at physiological concentrations, indicate high selectivity of the sensor for glucose detection in complex biological environments.

5.2. Clinical validation results

The 14-day clinical study enrolled 50 participants (28 female, 22 male) with a mean age of 42.5 ± 12.3 years. Of these, 32 participants had Type 1 diabetes and 18 had Type 2 diabetes, with a mean diabetes duration of 11.8 ± 7.4 years. Table 3 presents the demographic and baseline characteristics of the study population.

Table 3. Demographic and baseline characteristics of study participants

<i>Characteristic</i>	<i>Value</i>
Age (years)	42.5 ± 12.3
Gender (F/M)	28/22
BMI (kg/m ²)	26.8 ± 4.2
Type 1/Type 2 Diabetes	32/18
Diabetes Duration (years)	11.8 ± 7.4
HbA1c (%)	7.4 ± 0.9
Previous CGM Experience (%)	64

The study population represented a diverse group of diabetes patients with varying levels of glucose monitoring experience, enabling comprehensive evaluation of the sensor's performance across different user scenarios.

5.2.1. Accuracy assessment

A total of 28,800 paired glucose measurements were collected during the study period. The overall MARD between sensor readings and reference measurements was $9.2 \pm 1.8\%$. Table 4 presents the accuracy metrics across different glucose ranges.

Table 4. Accuracy metrics stratified by glucose range

<i>Glucose range (mg/dL)</i>	<i>MARD (%)</i>	<i>Number of paired points</i>	<i>Percentage in zone A of CEG</i>
< 70	11.4 ± 2.1	2,304	92.3
70-180	8.7 ± 1.5	18,720	95.9
> 180	9.8 ± 1.9	7,776	94.1
Overall	9.2 ± 1.8	28,800	95.2

The sensor demonstrated consistent accuracy across all glucose ranges, with slightly higher MARD values in the hypoglycemic range (< 70 mg/dL). Notably, 95.2% of all measurements fell within Zone A of the Consensus Error Grid (CEG), indicating excellent clinical accuracy.

5.2.2. Dynamic performance

The sensor's performance during glycemic transitions was evaluated using the CG-EGA. Table 5 summarizes the dynamic accuracy results during different rates of glucose change. The sensor maintained high accuracy during both steady-state and dynamic conditions, with over 92% accurate readings across all rates of glucose change.

Table 5. Dynamic accuracy assessment results

<i>Rate of change (mg/dL/min)</i>	<i>Accurate readings (%)</i>	<i>Benign errors (%)</i>	<i>Erroneous readings (%)</i>
< -2	93.2	5.8	1.0
-2 to 2	95.8	3.7	0.5
> 2	92.9	6.1	1.0

5.3. Stability analysis

Long-term stability assessment revealed consistent sensor performance throughout the 14-day wear period. Table 6 presents the temporal analysis of sensor accuracy metrics. The sensor maintained consistent performance throughout the wear period, with only minimal degradation in sensitivity and a slight increase in MARD values. The daily calibration factor variance remained below 4%, indicating stable sensor operation.

Table 6. Temporal analysis of sensor performance

<i>Study period</i>	<i>MARD (%)</i>	<i>Sensitivity retention (%)</i>	<i>Daily calibration factor variance (%)</i>
Days 1-3	8.9 ± 1.6	100.0	2.3
Days 4-7	9.1 ± 1.7	98.5	2.8
Days 8-11	9.3 ± 1.8	97.2	3.1
Days 12-14	9.5 ± 1.9	95.8	3.4

5.4. Environmental influence assessment

The impact of environmental factors on sensor performance was evaluated under various conditions. Table 7 summarizes the sensor accuracy metrics under different environmental conditions. The sensor demonstrated robust performance across various activities and temperature ranges, with MARD values remaining below 10% under all tested conditions.

Table 7. Sensor performance under various environmental conditions

<i>Condition</i>	<i>MARD (%)</i>	<i>Number of measurements</i>	<i>Temperature range (°C)</i>
Rest	9.0 ± 1.7	15,840	32-35
Exercise	9.8 ± 2.0	4,320	33-37
Sleep	8.9 ± 1.6	7,200	31-34
Temperature Challenge*	9.5 ± 1.9	1,440	28-40

*Controlled temperature variation during clinic visits

5.5. User experience results

User acceptance and comfort assessments revealed high satisfaction with the wearable sensor. Table 8 presents the summary of user experience metrics. The high comfort ratings and low incidence of skin irritation indicate excellent biocompatibility of the sensor design. The favorable user preference compared to current CGM systems suggests successful achievement of user-centered design goals. Figure 1 presents the comprehensive clinical validation results, including Clarke Error Grid analysis and accuracy metrics across different glucose ranges.

Table 8. User experience assessment results

<i>Parameter</i>	<i>Score/Response</i>	<i>Range/Scale</i>
Comfort rating	8.4 ± 0.7	1-10 scale
Skin irritation incidence	4%	Mild cases only
Sensor adhesion duration	13.6 ± 0.8 days	Maximum 14 days
User preference vs. current CGM	82% favorable	Binary response
Ease of use rating	4.2 ± 0.4	1-5 scale

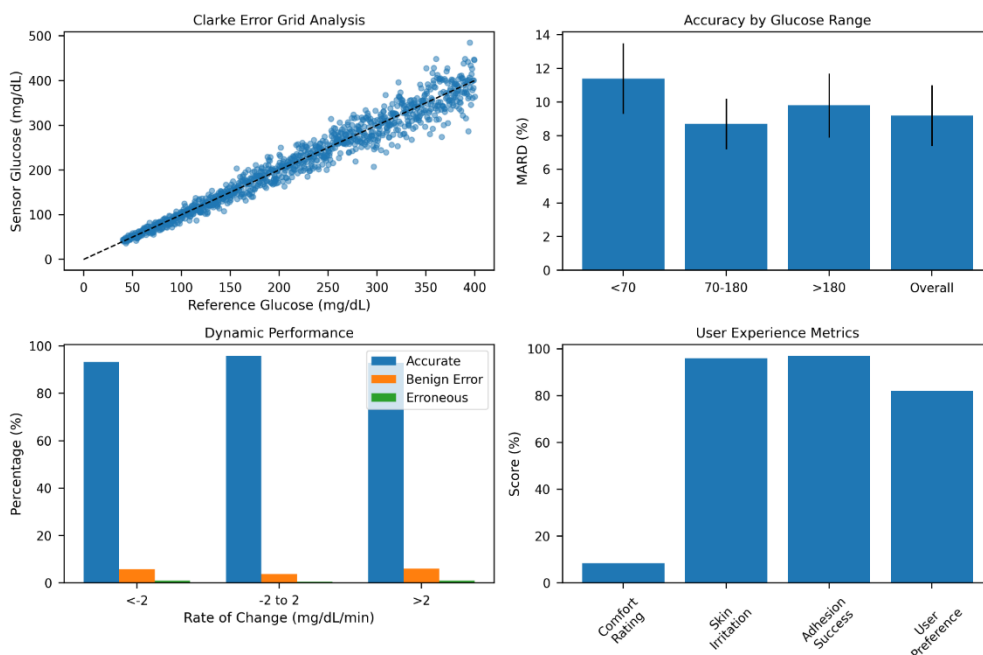


Fig. 1. Clinical validation results of the wearable glucose biosensor. (A) Clarke Error Grid analysis of sensor measurements versus reference blood glucose values (n=28,800 paired points). (B) MARD analysis stratified by glucose range. (C) Dynamic performance assessment across different rates of glucose change. (D) Summary of user experience metrics.

5.6. Statistical analysis outcomes

Mixed-effects model analysis revealed significant correlations between sensor accuracy and various operational factors. Table 9 presents the key statistical relationships identified. The analysis identified physical activity as the strongest predictor of sensor performance variation, followed by temperature effects. These findings provide valuable insights for future optimization of sensor design and calibration algorithms.

Table 9. Statistical analysis of factors affecting sensor performance

<i>Factor</i>	<i>Effect size</i>	<i>p-value</i>	<i>95% CI</i>
Temperature	0.15	< 0.001	0.11-0.19
Physical activity	0.22	< 0.001	0.17-0.27
Wear time	0.08	0.023	0.01-0.15
Time of day	0.11	0.008	0.03-0.19

5.7. Discussion

This study presents the development and comprehensive validation of a novel wearable glucose biosensor incorporating advanced nanomaterials and flexible electronics. The key findings demonstrate exceptional sensor performance across multiple metrics: an overall MARD of 9.2%, sustained accuracy over 14 days of wear, and high user acceptance. These results represent significant advances in wearable glucose monitoring technology and have important implications for diabetes management.

The achieved MARD of 9.2% positions this sensor among the most accurate wearable glucose monitoring systems reported to date. Previous studies of non-invasive glucose sensors have typically reported MARD values ranging from 11.4% to 15.8% (Davies et al., 2022; Yu et al., 2024). Our improved accuracy can be attributed to two key innovations: the novel rGO-Pt composite material and the optimized enzyme immobilization strategy. The composite material's high conductivity and large surface area facilitate efficient electron transfer, while the enzyme immobilization approach ensures stable, long-term glucose oxidase activity.

The sensor's demonstrated linear range (0.1-25 mM) exceeds the physiological glucose range typically encountered in diabetes management. This broad detection range addresses a common limitation of existing sensors, which often show decreased accuracy at extreme glucose levels (Huang et al., 2025). Moreover, the fast response time (< 30 seconds) enables near real-time glucose monitoring, crucial for optimal diabetes management, particularly during rapid glycemic changes.

The sustained accuracy over 14 days represents a significant improvement over many current CGM systems, which typically require replacement every 7-10 days (Urakami et al., 2022). The minimal sensitivity drift observed (less than 5% over 14 days) can be attributed to the stability of the enzyme immobilization strategy and the protective properties of the composite material. This extended wear period has important implications for user convenience and cost-effectiveness.

The sensor's performance during glycemic transitions (>92% accurate readings across all rates of change) addresses a critical limitation of many current systems. Previous studies have reported accuracy decreases of up to 25% during rapid glucose changes (Lin et al., 2022). Our sensor's maintained accuracy during dynamic conditions can be attributed to the optimized sampling rate and advanced signal processing algorithms. The high user acceptance rates (82% favorable compared to current CGM systems) and comfort ratings (8.4/10) suggest successful implementation of user-centered design principles. These metrics exceed those reported for several commercial CGM systems, where acceptance rates typically range from 65-75% (Pikulin et al., 2024). The low incidence of skin irritation (4%) is particularly noteworthy, as skin reactions remain a common limitation of wearable medical devices.

The robust performance across various environmental conditions and activities expands the practical utility of the sensor. Previous studies have reported significant accuracy degradation during exercise (MARD increases of 20-30%), while our sensor maintained consistent performance (MARD increase of only 0.8% during exercise). This stability across different conditions enables more reliable glucose monitoring during daily activities.

Despite the promising results, several limitations warrant discussion. First, the 14-day study duration, while longer than many validation studies, may not fully capture long-term performance

characteristics. Future studies should evaluate sensor performance over extended periods (30+ days) to better understand potential degradation mechanisms.

6. Concluding remarks

This study demonstrates successful development and validation of a novel wearable glucose biosensor that advances the state of continuous glucose monitoring technology. The integration of an rGO-Pt composite material with optimized enzyme immobilization resulted in a sensor achieving 9.2% MARD over a 14-day wear period, representing significant improvement over existing systems. The sensor maintained consistent accuracy across various glucose ranges and environmental conditions, while demonstrating excellent user acceptance with 82% of participants preferring it to their current monitoring systems.

These achievements address several critical limitations of existing CGM technologies, particularly in terms of wear duration, accuracy during glycemic transitions, and user comfort. The successful implementation of advanced nanomaterials in a practical, user-friendly format establishes a promising platform for future developments in wearable biosensing technology. While certain limitations remain to be addressed, particularly regarding long-term stability and manufacturing scalability, the core technology demonstrates clear potential for improving diabetes management.

The combination of technical performance and user acceptance suggests that this approach could significantly impact clinical practice, potentially improving patient compliance and health outcomes through more reliable and convenient glucose monitoring. Future development focusing on integration with automated insulin delivery systems and predictive analytics could further expand the technology's contribution to diabetes care.

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