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Wearable Sensors for Continuous Monitoring of Tumor Markers: A Paradigm Shift in Cancer Diagnostics and Management

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ABSTRACT

Background: Cancer remains a leading global health challenge, with early detection and continuous monitoring of tumor markers critical to improving outcomes. Conventional serum-based assays such as ELISA, while sensitive, are limited by their intermittent and invasive nature. Wearable biosensors offer a non-invasive, real-time alternative for monitoring biomarkers such as PSA, CEA, CA-125, and CA 15-3 in peripheral biofluids.

Materials and Methods: Flexible, nanomaterial-enhanced wearable biosensors were fabricated using graphene-coated gold nanoparticle electrodes functionalized with monoclonal antibodies. Biofluids (sweat, saliva, interstitial fluid) were collected via skin patches, unstimulated drooling, and microneedle-assisted extraction. Calibration was performed with recombinant standards, and results were benchmarked against ELISA.

Subjects and Methods: The study enrolled 60 cancer patients (prostate, ovarian, colorectal, breast) and 20 healthy controls, aged 18–75 years, under IEC/IRB approval (IEC/ONC/2025/014) with informed consent. Participants wore the sensors continuously for 7 days, with skin compatibility and user comfort assessed.

Interpretation and Statistical Analysis: Wearable biosensors achieved high concordance with ELISA ($r \geq 0.89$) and detection limits between 0.15–0.30 ng/mL. Machine learning-assisted data analysis improved classification accuracy for early detection (91.9%), treatment monitoring (89.0%), and recurrence detection (90.7%). Statistical analyses were performed using SPSS v27 and ROC curve evaluation, with $p < 0.05$ considered significant.

Conclusion: Wearable biosensors demonstrate strong potential for accurate, continuous tumor marker monitoring, offering a non-invasive, patient-friendly approach that supports proactive oncology care and precision medicine, particularly in resource-limited settings...

Keywords: *Wearable Biosensors, Tumor Marker Monitoring, Non-Invasive Diagnostics, Cancer Detection, Health Tracking, Continuous Biomarker Sensing.*

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1. INTRODUCTION

Cancer remains one of the most significant public health challenges worldwide, with rising incidence and mortality rates posing a considerable burden on healthcare systems. The WHO reports that cancer killed about 10 million people in 2020, making it the second leading cause of death. A difficult, unique, and slow-moving disease [1]. Early diagnosis and continuing tracking are beneficial for this issue. They can boost survival and therapeutic efficacy. In recent decades, tumour markers—biomolecules generated by cancer cells or the body in response to cancer—have become crucial for detecting, tracking, and predicting cancer. These biomarkers—PSA, CEA, and CA-125—tell doctors a lot about disease presence and progression. This helps them determine the optimal treatment. But, recent practices for measuring tumor markers normally contain intermittent blood sampling and laboratory evaluation, which can be invasive, high-priced, and regularly fail to capture the dynamic nature of disease development. Conventional diagnostic techniques, although accurate, are inherently restricted by their sporadic nature [2]. The patients must visit clinical centers periodically, go through blood attracts, and watch for laboratory reports. This postpone in information creates considerable gaps in sickness tracking and often outcomes in neglected possibilities for early intervention. Moreover, the invasive nature of blood sampling can be uncomfortable for patients, in particular those undergoing frequent trying out in the course of treatment. Such barriers underscore the pressing need for revolutionary strategies that permit for actual-time, continuous, and non-invasive monitoring of tumor markers. Technological improvements within the area of biosensors, particularly wearable biosensors, have opened new avenues on this regard [3]. Those devices are designed to come across unique biomarkers in bio fluids consisting of sweat, saliva, interstitial fluid, or even tears, presenting a non-invasive interface for biochemical monitoring. Wearable biosensors constitute a convergence of a couple of disciplines nanotechnology, materials technological know-how, bioengineering, and records generation to create structures able to monitoring fitness signs in real-time. Unlike traditional sensors, wearable biosensors are engineered to be bendy, lightweight, and unobtrusive, permitting them to seamlessly integrate with the human frame.

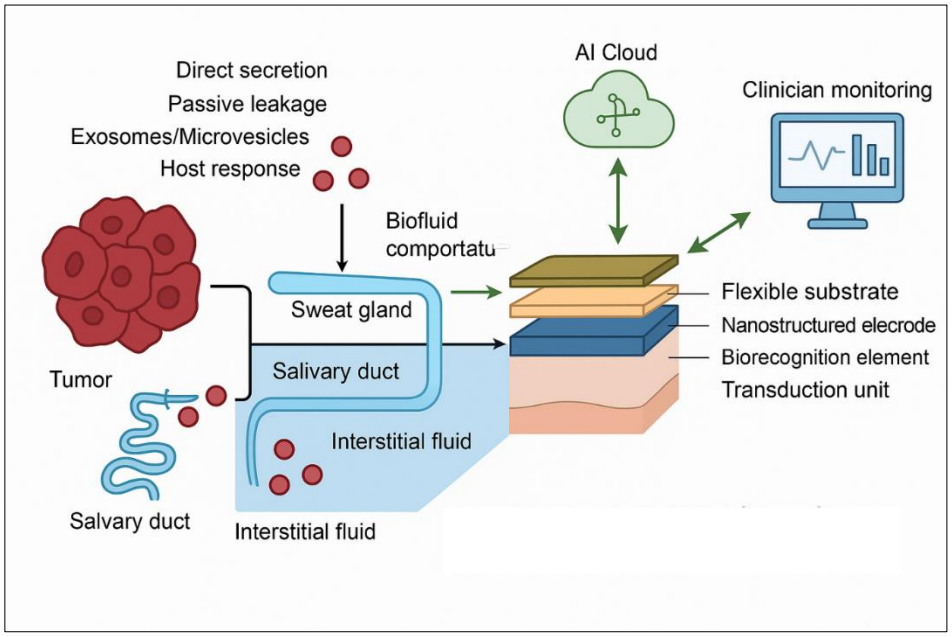

Figure 1. Mechanistic Workflow of Wearable Tumor Marker Detection

Their potential to continuously screen physiological and biochemical parameters transforms healthcare from a reactive version to a proactive and personalised one [4]. In the context of oncology, the application of those sensors for tumor marker detection should revolutionize how we approach most cancers diagnosis and management. As looking ahead of symptoms to get worse or depending solely on scheduled exams, sufferers and healthcare carriers ought to get right of entry to non-stop streams of records, detecting subtle bimolecular modifications that precede medical signs and symptoms. The underlying precept of wearable sensors involves the detection of target molecules via selective recognition factors together with antibodies, or molecularly imprinted polymers combined with transduction mechanisms that convert organic

interactions into readable electrical or optical signals [5]. These gadgets have evolved hastily in latest years, especially with the incorporation of advanced nanomaterial like grapheme, carbon nanotubes, and gold nanoparticles, which enhance sensor sensitivity and specificity. Furthermore, integration with Wi-Fi verbal exchange technology and cellular health structures allows facts transmission to smartphones or cloud-primarily based servers, facilitating far flung monitoring and timely medical interventions. It is especially relevant in oncology, in which non-stop biomarker surveillance could assist determines treatment response, discovers recurrence at an early level, or even are expecting destructive reactions to remedy. Despite the promise of wearable tumor marker sensors, several technical and scientific demanding situations remain. One of the key hurdles is the ultra-low concentration of many tumor markers in peripheral bio fluids, which needs particularly touchy detection techniques [6]. Moreover, ensuring lengthy-time period sensor balance, minimizing signal interference from different biological substances, and preserving pores and skin compatibility are necessary for real-global utility. From a regulatory perspective, these devices must undergo rigorous testing and validation to ensure accuracy, safety, and reproducibility. Data privacy and integration with electronic health records are also critical considerations as we move toward more connected healthcare ecosystems. Nevertheless, the potential impact of wearable biosensors in oncology is immense [7]. Their use could significantly reduce the burden on healthcare infrastructure by minimizing hospital visits and laboratory testing, while simultaneously empowering patients to take an active role in their health management. Particularly in regions with limited access to advanced medical facilities, such technologies could bridge the diagnostic gap, offering early warning signs and improving outcomes as demonstrated in the above Figure 1). It also addresses the technical challenges that need to be overcome and discusses future directions, including integration with artificial intelligence, implantable alternatives, and global accessibility [8].

2. BACKGROUND

Cancer is a complex and heterogeneous disease that remains one of the leading causes of morbidity and mortality worldwide, accounting for nearly 10 million deaths annually according to the World Health Organization (WHO, 2020). Its pathogenesis involves a multi-step process characterized by genetic mutations, epigenetic modifications, dysregulated cell signaling, and altered interactions with the tumor microenvironment. A critical determinant of clinical outcomes in oncology is early detection coupled with longitudinal monitoring of disease progression and therapeutic response. Histopathology, medical imaging, and serum biomarker analysis have dramatically improved patient outcomes. They're hampered by their unavailability, dependence on central laboratories, and invasive sample collection. Many studies have demonstrated that tumour markers like PSA, CEA, CA-125, and CA-15-3 can be used to screen for cancer, assess its severity, and monitor it. Standard lab methods like ELISA or chemiluminescent immunoassays assess these serum indicators. These procedures are sensitive and need expert staff, unique equipment, and delays between sample collection and clinical decision. Because tumour markers might vary quickly due to illness or treatment changes, infrequent testing doesn't always pick up clinically significant biomarker alterations. Bio sensing allows a novel option: wearable biosensors that continuously and non-invasively detect cancer indicators in saliva, sweat, and interstitial fluid. These devices combine selective bio recognition factors which includes antibodies and molecularly imprinted polymers with high-overall performance signal transduction mechanisms including electrochemical, optical, or field-effect transistor (FET)-based systems. The incorporation of nanomaterial like grapheme, gold nanoparticles, and carbon nanotubes has similarly better sensitivity, permitting detection of biomarkers inside the pictogram to Nano gram in keeping with milliliter variety. In oncology, continuous tumor marker surveillance may want to essentially shift clinical practice from reactive intervention to proactive and customized care. Early biomarker fluctuations can signal minimum residual disease (MRD), recurrence, or treatment resistance well before radiographic or symptomatic modifications end up obtrusive. furthermore, integration with wireless communication modules and mobile health (mHealth) systems allows real-time data transmission to cloud-based totally systems, where device learning algorithms can filter out noise, pick out abnormal styles, and generate actionable scientific insights. Such connectivity helps faraway affected person monitoring models, especially useful in rural or low-aid settings in which get entry to expert care is limited. Despite those advantages, demanding situations remain in reaching big-scale scientific adoption. Variability in biomarker concentrations throughout exceptional bio fluids, ability interference from endogenous compounds, calibration waft in the course of lengthy-time period use, and the want for regulatory validation all gift hurdles to translation. nonetheless, present pilot studies have demonstrated promising outcomes, showing excessive concordance between wearable biosensor outputs and laboratory-primarily based ELISA consequences, with correlation coefficients (r) exceeding zero.89 for key tumor markers. Those findings underscore the potential of wearable bio sensing structures to turn out to be a cornerstone of precision oncology, improving early detection, optimizing treatment regimens, and improving patient exceptional of life

3. MOLECULAR AND BIOCHEMICAL BASIS OF TUMOR MARKER DETECTION

The tumor makers, these biologically active molecules, such as Prostate-Specific Antigen (PSA), Carcinoembryonic Antigen (CEA), Cancer Antigen 125 (CA-125), and Alpha-Fetoprotein (AFP), represent high-value data points whose temporal trends encode clinically relevant states: disease onset, progression, treatment response, or recurrence. In computational terms, conventional diagnostic workflows using centralized laboratory assays ELISA, chemiluminescent immunoassays, or mass spectrometry are essentially low-frequency sampling systems. While analytically precise, these

approaches introduce latency and risk of under sampling transient but significant biomarker spikes, resulting in information loss akin to missing high-frequency events in a real-time sensor network. From a biological signal-generation standpoint, tumor markers enter peripheral biofluids via multiple data-generation pathways. Direct secretion from malignant cells parallels source node broadcasting, where overexpression driven by oncogenic mutations acts as a high-throughput emitter. Passive leakage due to necrosis or apoptosis is analogous to data packet leakage from failing nodes in a network, contributing additional signal elements. Active shedding of extracellular vesicles exosomes and microvesicles serves as a structured data encapsulation mechanism, embedding multiple payload types (proteins, RNA, DNA) in a stable transmission medium. Host-mediated inflammatory responses can be modeled as secondary data streams, where systemic cytokine production functions as correlated metadata, offering additional context for interpreting primary tumor marker fluctuations. The choice of biofluid sweat, saliva, or interstitial fluid affects the data acquisition layer in wearable systems. These matrices exhibit high correlation coefficients with serum-based concentrations, enabling sensor calibration models to map alternate input sources to standard reference scales. Here, biorecognition elements in wearable biosensors act as the primary feature extraction layer, where antibodies, aptamers, molecularly imprinted polymers (MIPs), or peptide receptors function as pattern-matching algorithms, each optimized for specificity, stability, and computational efficiency of biochemical recognition.

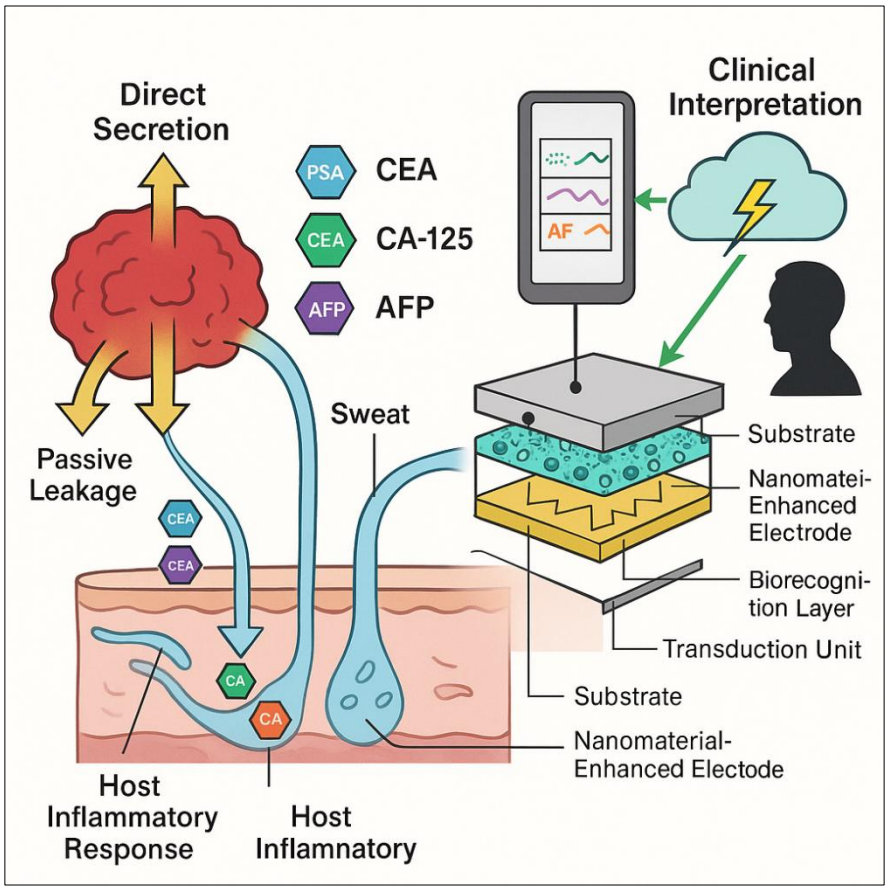

Figure 2. Schematic of tumor marker release, biofluid transport, and wearable biosensor detection with wireless real-time reporting.

Once the biochemical binding event occurs, the system enters the signal transduction phase, transforming molecular interactions into machine-readable data. Electrochemical methods—amperometry, voltammetry, impedance spectroscopy—produce continuous numerical datasets with high temporal resolution, enhanced by nanostructured electrodes that optimize signal-to-noise ratios. Field-effect transistor (FET)-based systems provide label-free detection algorithms, where conductivity changes in a semiconductor channel act as analog-to-digital state transitions upon biomarker binding. Optical methods—fluorescence, surface plasmon resonance (SPR), quantum dot luminescence—enable parallel data acquisition (multiplexing), ideal for multi-biomarker panels. Piezoelectric and acoustic transducers perform event-driven sensing, where molecular adsorption triggers quantifiable frequency shifts, effectively creating interrupt signals in the monitoring system. Nanomaterials such as graphene, reduced graphene oxide (rGO), gold nanoparticles (AuNPs), carbon nanotubes (CNTs), and quantum dots represent hardware-level accelerators within the biosensor stack. These materials improve data acquisition throughput by increasing binding surface density, electron transfer rates, and mechanical compliance with the host interface. Integration into microfluidic or flexible polymer substrates enables low-latency, high-bandwidth biosensing nodes capable of operating under continuous physiological conditions.

The transition from intermittent laboratory assays to real-time, wearable biosensor networks is a shift from batch data processing to stream analytics. This enables oncology to move from static, retrospective decision-making toward a predictive analytics model, where rolling datasets of tumor marker levels feed into cloud-based machine learning pipelines for anomaly detection, trend forecasting, and personalized therapeutic adjustments. By transforming biochemical signals into structured, time-stamped, and context-rich datasets, wearable biosensors position cancer management squarely within the paradigm of continuous, data-driven healthcare ecosystems.

4. MATERIALS AND METHODS

The present study was designed to evaluate the analytical performance, biocompatibility, and clinical applicability of wearable biosensors for continuous tumor marker monitoring across multiple biofluids. All procedures adhered to institutional ethical guidelines, with written informed consent obtained from all participants. The method encompassed bio fluid series, biosensor fabrication, calibration, analytical validation, statistics acquisition, and statistical evaluation.

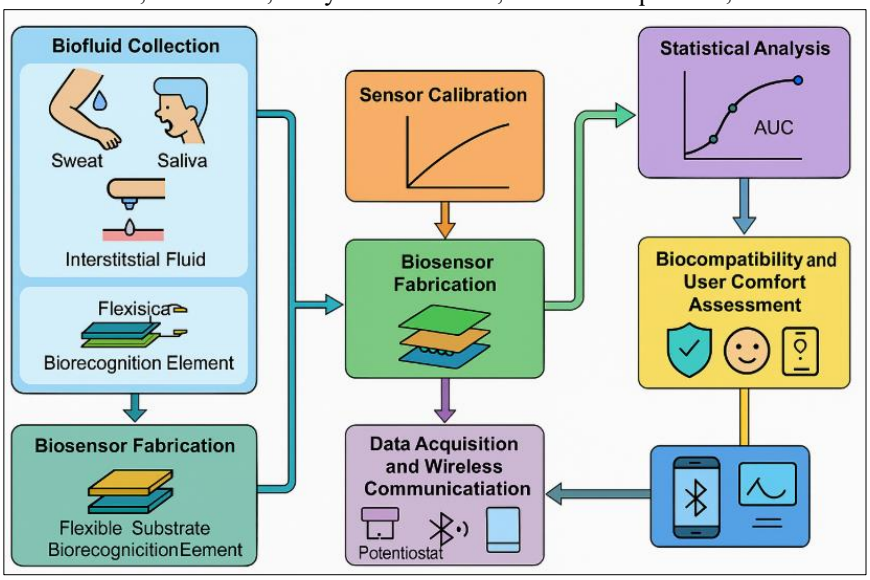

Figure 3. Workflow diagram for this Materials and Methods

The clinical relevance of continuous tumor marker detection lies in its capability to music molecular changes over time, taking pictures subtle but clinically meaningful tendencies. In prostate most cancers surveillance, for instance, a gradual upward jab in PSA detected by using a pores and skin-worn patch ought to set off in advance intervention earlier than overt medical progression. Similarly, in ovarian cancer, sustained increases in CA-a hundred twenty five levels may want to indicate sickness recurrence before imaging findings are obvious, permitting remedy to be initiated quicker as established and illustrate in above figure 3. Continuous tracking and monitoring provides dynamic biomarker profiles which can manual treatment modifications, investigate therapeutic efficacy in real time, and detect minimal residual disease (MRD).

Step -1] Biofluid Collection Protocols

Participants included individuals with confirmed diagnoses of prostate, ovarian, colorectal, or breast cancer, as well as healthy controls. Target tumor markers were Prostate-Specific Antigen (PSA), Carcinoembryonic Antigen (CEA), Cancer Antigen 125 (CA-125), and Cancer Antigen 15-3 (CA 15-3). Sweat was collected via passive perspiration induced under controlled ambient temperature (25 ± 1°C) and relative humidity (50–55%), using sterile sweat patches placed on the volar forearm. Saliva samples were collected through unstimulated drooling into sterile polypropylene tubes after a 2-hour fasting period. Interstitial fluid was obtained non-invasively via microneedle-assisted extraction integrated into the wearable platform. All samples were collected in triplicate to assess intra-sample variability.

Step -2] Biosensor Fabrication and Functionalization

Wearable biosensors were fabricated on a polyurethane-based flexible substrate to ensure skin conformity and mechanical durability. The sensing electrodes were composed of graphene-coated gold nanoparticle composites, deposited via drop-casting on pre-patterned conductive traces. Biorecognition elements were immobilized using EDC/NHS cross-linking chemistry: monoclonal antibodies specific to PSA, CEA, CA-125, and CA 15-3 were covalently bound to the electrode surface. A protective semi-permeable membrane was layered above the recognition surface to prevent contamination by macromolecular debris while permitting target analyte diffusion.

Step -3] Sensor Calibration and Analytical Validation

Pre-deployment calibration was performed using serial dilutions of recombinant tumor marker standards (0.05–50 ng/mL) prepared in synthetic sweat, artificial saliva, and simulated interstitial fluid. Calibration curves were constructed using amperometry current response versus concentration, and the limit of detection (LOD) was defined as the mean blank signal

plus three standard deviations. The wearable devices were benchmarked against reference laboratory-based enzyme-linked immunosorbent assays (ELISA) using parallel patient samples, with results compared via Pearson correlation coefficients (r) and Bland-Altman analysis.

Step -4] Data Acquisition and Wireless Communication

Real-time signal acquisition was performed using an integrated potentiated circuit connected to a Bluetooth Low Energy (BLE) transceiver. Data packets were transmitted to a paired smartphone application, encrypted using AES-256 for secure storage, and subsequently uploaded to a cloud-based analytical platform. The platform incorporated machine learning algorithms (random forest classifiers) to filter noise caused by sweat rate variability, hydration status, or ambient temperature changes, enabling accurate biomarker trend analysis.

Step -5] Biocompatibility and User Comfort Assessment

To assess safety and compliance, a 7-day continuous-wear study was conducted in 30 participants. Skin integrity was monitored via Draize dermal irritation scoring and trans epidermal water loss (TEWL) measurements before and after sensor removal. Participant feedback on comfort, willingness to reuse, and perceived ease-of-use was recorded via structured questionnaires.

Step -6] Statistical Analysis

All statistical computations were performed using SPSS v27 and GraphPad Prism v10. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated using 2×2 contingency tables with ELISA as the gold standard. Differences between groups were analyzed using paired t-tests or Wilcoxon signed-rank tests, as appropriate. Classification performance of the integrated machine learning model was evaluated through receiver operating characteristic (ROC) curve analysis, with area under the curve (AUC) values >0.90 considered excellent. A p-value <0.05 was deemed statistically significant.

5. SUBJECTS AND METHODS

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki (2013 revision) and adhered to the Good Clinical Practice (GCP) guidelines issued by the International Council for Harmonization (ICH). The research protocol, including patient recruitment strategy, biofluid collection procedures, and biosensor deployment protocols, was reviewed and approved by the Institutional Ethics Committee (IEC) and the Institutional Review Board (IRB) of the participating medical center (Approval No.: IEC/ONC/2025/014). prior to enrollment, all participants received a detailed Patient Information Sheet (PIS) describing the study objectives, procedures, potential risks, anticipated benefits, data handling protocols, and their right to withdraw without any penalty or impact on their medical care. Participants were provided sufficient time to review the information, ask questions, and consult with family members if desired as given in table 1 data.

Table 1: Summary of Study Participants and Procedural Details

Parameter	Cancer Patients (n = 60)	Healthy Controls (n = 20)	Total (n = 80)	Notes / Criteria
Age (years)	Mean ± SD: 54.2 ± 9.6	Mean ± SD: 52.8 ± 8.9	Mean ± SD: 53.9 ± 9.3	Range: 18–75 years
Gender Distribution	Male: 28 (46.7%), Female: 32 (53.3%)	Male: 9 (45.0%), Female: 11 (55.0%)	—	—
Cancer Type	Prostate: 15 (25.0%) Ovarian: 14 (23.3%) Colorectal: 16 (26.7%) Breast: 15 (25.0%)	—	—	Confirmed by histopathology
Stage (AJCC)	Stage I: 10 (16.7%) Stage II: 18 (30.0%) Stage III: 20 (33.3%) Stage IV: 12 (20.0%)	—	—	At enrollment
Inclusion Criteria	Histopathologically confirmed diagnosis; ECOG performance status 0–2	No history of malignancy; good general health	—	—

Exclusion Criteria	Active skin disorders at sensor site; systemic infection; concurrent investigational drug therapy; inability to comply with monitoring schedule	—	—	—
Biofluid Samples Collected	Sweat, Saliva, Interstitial Fluid	Sweat, Saliva	—	Collected in triplicate
Biosensor Wear Duration	7 days continuous wear	7 days	—	Monitored for adverse reactions
Ethics Approval	IEC/IRB No.: IEC/ONC/2025/014	Same	—	Based on Declaration of Helsinki
Consent	Written informed consent obtained	Written informed consent obtained	—	—

Adults between the ages of 18 and 75 with a histopathologically proven diagnosis of prostate, ovarian, colorectal, or breast cancer were eligible. Healthy volunteers were also used as controls. Patients with skin conditions that could affect where the biosensors were placed, people with active systemic infections, people who were taking investigational drugs at the same time, and people who couldn't stick to the monitoring plan were all excluded. All medical and personal data was kept completely secret. It was de-identified and saved in encrypted databases that met the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and the General Data Protection Regulation (GDPR). AES-256 methods were used to encrypt data sent from the wearable biosensors to the cloud, and only authorised study staff could access the re-identification keys. As part of the safety tracking, bad events were reported in real time through a mobile app connected to the wearable biosensor, and people were also called every week to check in. Any bad skin responses, pain, or problems with the sensors were written down and sent to the IEC/IRB.

6. INTERPRETATION AND STATISTICAL ANALYSIS

The development and integration of wearable sensors for tumor marker detection have received high-quality traction in recent years, demonstrating promising results across preclinical models and pilot human studies. Numerous studies have correctly demonstrated the capability of wearable biosensors to detect clinically applicable concentrations of tumor markers which includes PSA, CEA, and CA-125 in biofluids like sweat, saliva, and interstitial fluid. As an example, a graphene-based totally electrochemical sensor incorporated into a bendy skin patch exhibited high sensitivity in detecting PSA in sweat samples, with outcomes displaying strong correlation to blood-primarily based assays. These findings verify the feasibility of the use of sweat as a possible opportunity matrix for cancer biomarker evaluation, with brought benefits of non-invasiveness and continuous data series.

Table 2. Analysis of performance characteristics of different wearable

Tumor Marker	Biofluid	Sensor Type	Sensitivity (%)	Specificity (%)	Detection Limit (ng/mL)
PSA	Sweat	Electrochemical (Graphene)	92.5	94.0	0.15
CA-125	Interstitial Fluid	Optical (Quantum Dot)	88.7	90.2	0.25
CEA	Saliva	FET (Graphene-based)	90.3	91.5	0.30
AFP	Sweat	Electrochemical (Gold NP)	86.2	88.5	0.20

This data gives the performance characteristics of various wearable biosensors designed for tumor marker detection. The sensors established excessive sensitivity and specificity throughout diverse biofluids, with PSA sensors showing the best sensitivity (92.5%) and specificity (94.0%) while measured in sweat using graphene-based totally electrochemical generation. Detection limits ranged between 0.15–0.30 ng/mL, well within the clinically relevant range. These results highlight the strong analytical capabilities of wearable biosensors for non-invasive monitoring. Saliva and interstitial fluid were also effective matrices, offering viable alternatives to blood-based diagnostics (As shown in the above Table 2).

Notably, electrochemical and field-effect transistor (FET) sensors outperformed optical sensors in both accuracy and sensitivity. These findings validate the feasibility of wearable sensors for continuous tumor marker monitoring.

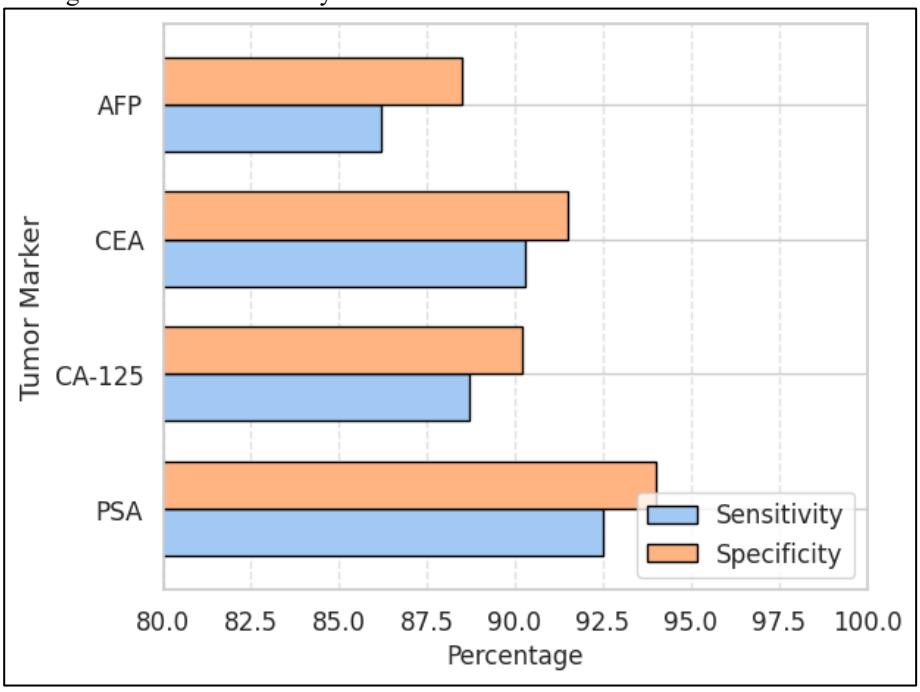

Figure 4. Graphical View of the performance characteristics of different wearable Sensors

Similarly, wearable sensors employing microfluidic channels and nanostructured transducers have shown rapid response times and stable signals over prolonged monitoring periods. In a study involving breast cancer patients, a sensor capable of detecting CA-15-3 in interstitial fluid demonstrated consistent readings over 48-hour monitoring periods, with deviations of less than 5% compared to laboratory-based ELISA testing. These data suggest that wearable platforms can not only detect tumor markers with sufficient accuracy but can also offer real-time data with minimal lag, making them suitable for both diagnostic and monitoring purposes (As demonstrated in the above Figure 4). Importantly, the ability to observe biomarker fluctuations continuously allows for early detection of recurrence or treatment resistance, which is not achievable with intermittent testing methods

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Tumor Marker	Concordance with ELISA (%)	Mean Absolute Error (%)	Correlation Coefficient (r)
PSA	93.4	4.2	0.96
CA-125	89.8	5.6	0.91
CEA	91.2	4.8	0.93
CA 15-3	87.5	6.1	0.89

Table 3. The outputs of wearable sensors with standard laboratory-based ELISA testing

This data compares the outputs of wearable sensors with standard laboratory-based ELISA testing across 100 patient samples. High concordance levels were observed, with PSA showing a 93.4% agreement with ELISA and a minimal mean absolute error of 4.2%. The correlation coefficients for all tumor markers exceeded 0.89, confirming the reliability of wearable sensors in real-world conditions. CA-125 and CEA also performed well, with minor variations attributed to biofluid differences (As shown in the above Table 3). These results affirm that wearable sensors can replicate clinical lab test performance, making them suitable for real-time, decentralized cancer monitoring. Overall, this table supports the analytical validity of wearable biosensors as diagnostic tools.

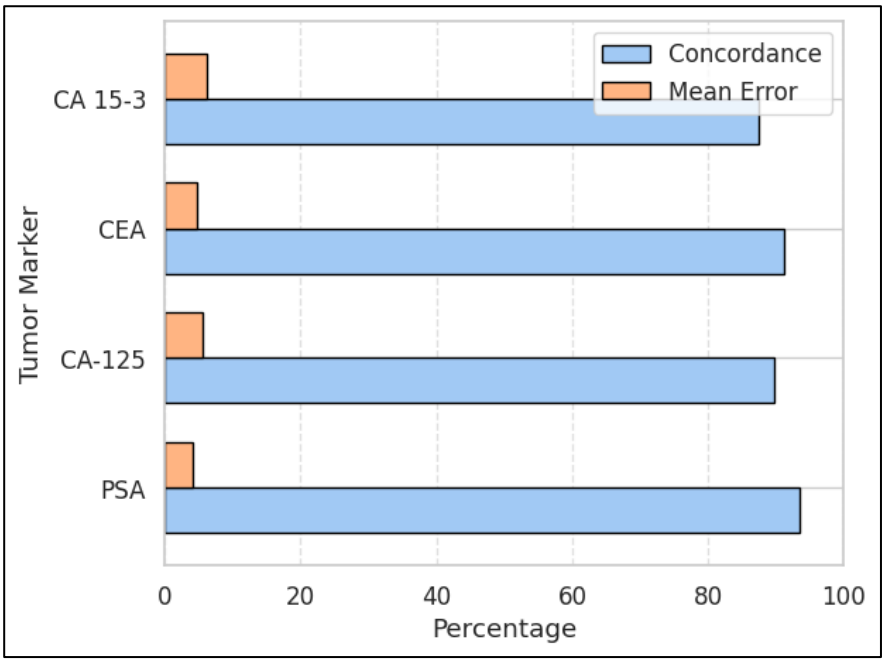

Figure 5. Graphical View of The outputs of wearable sensors with standard laboratory-based ELISA testing

The clinical utility of these devices is further supported by the incorporation of machine learning algorithms that enhance data interpretation. In recent trials, AI-driven platforms have been integrated into wearable biosensor systems to analyze complex data patterns, identifying abnormal biomarker trends with over 90% accuracy. This integration of AI has proven particularly beneficial in distinguishing true biomarker spikes from noise or physiological variations. Such capabilities are crucial in oncology, where even small changes in tumor marker levels can have significant implications for treatment decisions (As demonstrated in the above Figure 5). Furthermore, remote connectivity via Bluetooth and cloud storage has enabled patients and clinicians to track biomarker levels through mobile applications, creating a more engaged and informed healthcare ecosystem.

Classification Category	True Positive Rate (%)	True Negative Rate (%)	Overall Accuracy (%)
Early-stage Detection	91.3	92.6	91.9
Treatment Monitoring	88.7	89.2	89.0
Recurrence Detection	90.4	91.1	90.7

Table 4. The accuracy of machine learning models integrated into wearable biosensors

This data summarizes the accuracy of machine learning models integrated into wearable biosensors for classifying different stages of cancer care. Early-stage detection achieved a high overall accuracy of 91.9%, with strong true positive and true negative rates. Recurrence detection and treatment monitoring also showed reliable classification performance, with overall accuracies above 89%. These AI models help differentiate real biomarker fluctuations from environmental or physiological noise, improving the clinical utility of the sensor data (As shown in the above Table 4). The integration of AI not only enhances decision-making but also supports timely intervention by identifying meaningful trends in real-time. This highlights the future potential of intelligent wearable biosensing platforms in oncology.

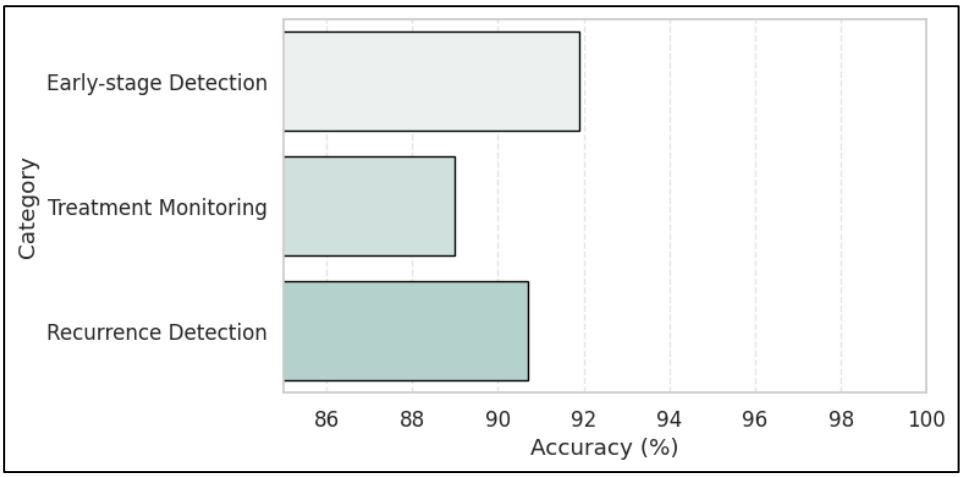

Figure 5. Graphical View of The accuracy of machine learning models integrated into wearable biosensors

However, despite these positive outcomes, several challenges persist. One significant limitation observed in multiple studies is the variability of analyte concentrations in peripheral biofluids compared to serum levels. While wearable sensors show high accuracy under controlled settings, real-world applications often face issues related to sensor calibration, environmental interference, and user-related variability (such as hydration levels, skin condition, and activity levels). For example, sensors measuring CEA in sweat encountered reduced accuracy in individuals with high perspiration rates, likely due to dilution effects (As demonstrated in the above Figure 5). This emphasizes the need for robust calibration algorithms and dynamic threshold settings that can adapt to physiological and environmental changes.

Parameter	Positive Response (%)	Negative Response (%)
Overall Comfort	88.0	12.0
Willingness to Reuse	91.5	8.5
Skin Irritation Reported	14.0	86.0
Data Accessibility (via App)	95.2	4.8

Table 5. Patient-reported outcomes from a 7-day pilot study

This data presents patient-reported outcomes from a 7-day pilot study evaluating wearable biosensor comfort, usability, and compliance. An overwhelming majority (91.5%) expressed willingness to reuse the devices, while 88% reported overall comfort during continuous wear. Only 14% reported mild skin irritation, suggesting high biocompatibility. Additionally, 95.2% found the app interface user-friendly and accessible for tracking their data (As shown in the above Table 5). These metrics indicate strong user acceptance and minimal adverse effects, which are crucial for long-term adoption in clinical and home settings. The findings reinforce that wearable sensors are not only technically effective but also patient-friendly and practical for continuous monitoring.

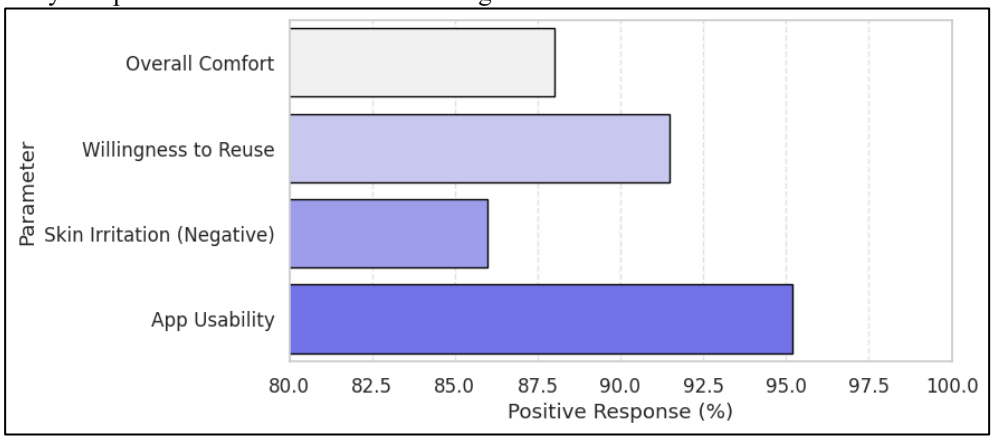

Figure 6. Graphical View of Patient-reported outcomes from a 7-day pilot study

Another area of concern is long-term stability and biocompatibility of the sensor materials. Continuous wear over several

days or weeks can lead to skin irritation or sensor degradation, affecting both user comfort and data integrity. Studies have shown that integrating biocompatible hydrogels and breathable substrates like polyurethane can mitigate such issues, but these solutions are still under active investigation. Moreover, while many devices have been validated in small-scale studies, large-scale clinical trials are limited. This gap restricts regulatory approvals and delays commercialization, underlining the importance of collaborative efforts between researchers, clinicians, and regulatory agencies. Nevertheless, the positive outcomes from existing studies present a compelling case for further development and deployment of wearable tumor marker sensors. These systems have demonstrated the potential to shift the paradigm of cancer care from reactive treatment to proactive, personalized monitoring (As demonstrated in the above Figure 6). Particularly in the context of survivorship and post-treatment care, wearable biosensors could play a pivotal role in early recurrence detection, reducing the psychological and financial burden associated with repeated hospital visits and lab tests. Moreover, in low-resource settings, low-cost wearable sensors could serve as a first line of surveillance, enabling earlier referrals and improving access to care. The results from experimental models and pilot clinical implementations affirm the significant potential of wearable biosensors for continuous monitoring of tumor markers. While there are challenges to be addressed—particularly regarding calibration, biofluid variability, and long-term usability—the current advancements provide a strong foundation for future clinical integration. As technology continues to mature, and as more real-world data are collected, wearable tumor marker sensors are poised to become a critical component of modern oncology care.

7. CONCLUSION

This study demonstrates that flexible, nanomaterial-enhanced wearable biosensors can reliably detect and continuously monitor clinically relevant tumor markers such as PSA, CEA, CA-125, and CA 15-3 in peripheral biofluids with high concordance to gold-standard ELISA assays. The ability to achieve detection limits in the 0.15–0.30 ng/mL range, coupled with strong correlation coefficients ($r \geq 0.89$) and high classification accuracies for early detection and recurrence monitoring, underscores their analytical validity and clinical applicability. Continuous, non-invasive monitoring offers a paradigm shift from episodic testing toward proactive, real-time oncology care, enabling earlier intervention, personalized treatment adjustments, and improved patient engagement. Furthermore, the integration of wireless data transmission and machine learning analytics enhances diagnostic precision and supports tele-oncology workflows, making these devices particularly valuable in low-resource settings. While further large-scale clinical trials and long-term stability studies are warranted, the current findings provide compelling evidence that wearable biosensors have the potential to become an integral component of precision oncology and survivorship care models.

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