International Journal of Medical Discoveries
Volume 2, Issue 2
ISSN: 3067-7912

SCHOLARLY SUMMIT
THE ACADEMIC PUBLISHERS

# Wearable AI Technologies for Continuous Ophthalmic Monitoring: Evaluating Diagnostic Accuracy, Patient Outcomes, and Adoption Challenges in Eye Care

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**Abstract**

Vision loss and blindness caused by chronic-eye diseases such as diabetic eye disease, glaucoma and age-related macular degeneration are a major cause of irreversible vision loss. Many of these diseases progress silently without symptoms and are often diagnosed only through a thorough visual examination. With technological advancements in artificial intelligence (AI) and miniaturized, wearable sensing devices, there is now an opportunity for continuous, out-of-hospital monitoring, enabling earlier detection and intervention. This article outlines a new conceptual framework for a wearable AI-integrated solution for continuous monitoring of the eye. The framework presents its major components including system architecture, data processing pipelines, and AI inference workflows. We conducted a comprehensive literature review from 2010–2024 using MEDLINE, Embase, and IEEE Xplore, covering multiple publication types in three areas: AI-assisted diagnosis using ophthalmic images, chronic disease monitoring via wearable biosensors, and digital adoption of technology in healthcare. The information obtained allowed us to propose an artificial intelligent framework consisting of four layers: data collection, edge processing, AI inference, and clinical communication. The results support the use of deep learning for analysis of ophthalmic images and provide evidence that wearable biosensors have a role in chronic disease management. However, challenges remain including regulatory, technical, ethical, and equity issues. Strategies such as privacy-preserving AI, adaptive regulatory frameworks, and inclusive system design offer potential solutions. The application of wearable AI for continuous monitoring will evolve as a new paradigm for ophthalmic care, and the proposed framework can support future development and clinical implementation.

**Keywords:** wearable technology; artificial intelligence; ophthalmic monitoring; diabetic retinopathy; glaucoma; macular degeneration; teleophthalmology.

## 1. Introduction

Hundreds of millions of people globally are blind and visually impaired, which disproportionately exposes them to healthcare inaccessibility in addition to a low socioeconomic status. The World Health Organization (WHO) also states that about 2.2 billion individuals have some kind of visual impairment, most of which could be prevented or treated in case of early detection (Bourne et al., 2021). The most common irreversible causes of blindness include glaucoma, diabetic retinopathy (DR), and age-related macular degeneration (AMD) which are chronic and progressive conditions and tend to remain asymptomatic until advanced. In many cases, it is often too late in life when the patients notice that their vision has become blurred and seek medical care, as irreversible damage has already taken place (Tham et al., 2014; Wong et al., 2014).

Nonetheless, the existing paradigm of ophthalmic care is based on periodic, clinic visits, which are generally performed either once or twice a year. This method is inappropriate according to the dynamism and continuousness of these diseases. As an example, intraocular pressure (IOP), the main risk factor that can be altered in glaucoma is highly diurnal and short-term, and therefore, single point clinical measurements cannot be used to accurately gauge the risk factor. In the same way, retinal pathologies change over time, which may be between the visits of clinics, reducing the chances of early diagnosis and early treatment.

In the last ten years, artificial intelligence (AI) has revolutionized the process of analyzing ophthalmic images and has been able to match or even surpass the performance of trained clinicians. Deep convolutional neural networks (CNNs) have proven to be very accurate in identifying

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Received: 24-Apr-2026 Revised: 19-May-2026 Accepted: 9-Jun-2026

International Journal of Medical Discoveries
Volume 2, Issue 2
ISSN: 3067-7912

diabetic retinopathy using fundus images (Gulshan et al., 2016), and further studies have extended AI use to the domain of AMD grading, glaucomatous optic neuropathy detection, retinal vein occlusion, and diabetic macular edema. Another breakthrough was the FDA approval of the first autonomous AI diagnostic system, IDx-DR, in the U.S. in 2018 (Abramoff et al., 2018), which made the history of AI in clinical ophthalmology by establishing a regulatory precedent.

At the same time, wearable health technologies have made it possible to constantly monitor physiology without the need to visit a clinic. Smartwatch-based electrocardiogram (ECG) monitors and continuous glucose monitoring (CGM) devices have been proven to be clinically effective and acceptable to regulators in the management of chronic diseases (Turakhia et al., 2019). Such developments underscore the viability and increased adoption of wearable, real-time health monitoring systems.

The integration of AI-powered ophthalmic diagnostics with the wearable biosensor technology is a disruptive threat to the eye care industry. The paper will discuss the idea of a wearable system that would constantly gather ophthalmic data and implement real-time AI analysis and move the paradigm of episodic diagnosis to constant monitoring and active disease control. This model can support the earlier diagnosis, better patient outcomes, and fundamentally change the ophthalmic care delivery model.

There are three contributions of this study. First, it suggests a new four-layer conceptual model of an AI-assisted continuous ocular monitoring system, describing the system architecture, data flow and functional entities. Second, it summarizes the current data on the viability and clinical applicability of AI-based eye tests and wearable health devices. Third, it suggests a set of the main impediments to adoption, such as regulatory, technical, ethical, and equity barriers, and proposes possible strategies to deal with them. These contributions combined will help to establish the basis of research in the future and the creation of ophthalmic care wearable AI systems that could be clinically viable.

## 2. Background and Literature Context

### *2.1 The Global Burden of Chronic Ophthalmic Disease*

This study is based on the growing global burden of preventable blindness which is a critical foundation. Glaucoma, diabetic retinopathy (DR) and age-related macular degeneration (AMD) are chronic ophthalmic diseases that are the most common causes of irreversible vision loss, which is mainly caused by the late detection and management. The leading cause of irrevocable blindness globally is glaucoma, which has an estimated global prevalence of 76 million and is predicted to increase to 111 million by 2040 (Tham et al., 2014). It is typified by progressive optic neuropathy, in most cases accompanied by high intraocular pressure and is usually asymptomatic until in late stages. By the time symptoms will be noticed, a significant and permanent loss of vision has already taken place. Although it is important to diagnose glaucoma early, it is always reported in population-based studies that a large percentage of cases of glaucoma have not been detected. Diabetic retinopathy is a major cause of vision loss in working-age adults, with one-third of diabetic people around the world having it (Cheung et al., 2010; Leasher et al., 2016). Although the development of sight-threatening complications, such as proliferative DR and diabetic macular edema (DMO) is mostly preventable by means of prompt interventions, such as laser photocoagulation and anti-VEGF therapy, the problem of late diagnosis is a significant challenge to successful treatment. With the growing rate of diabetes worldwide, DR is becoming a growing public health issue especially in low-resource contexts. The main reason behind vision loss in people aged 50 years and above is age-related macular degeneration, which is estimated to affect 196 million individuals worldwide in 2020 with an estimated 288 million individuals affected in 2040 (Wong et al., 2014). The neovascular type of AMD may cause severe and rapid vision loss in a few weeks. Even though there are effective therapies like the anti-VEGF therapy, the success of these therapies greatly relies on early diagnosis and early start. All these circumstances draw an acute lack of communication between the course of the disease and its early detection, which is why new methods of constant monitoring and early diagnosis in ophthalmic practice are urgently needed.

### *2.2 Limitations of Episodic Ophthalmic Care*

The limitation of traditional episodic eye care is that it relies on isolated time-limited measures to evaluate conditions that are constantly changing and developing. This conclusion has fundamental flaws, chief of them being lack of temporal density. For example, IOP is usually measured during a cursory clinic appointment as a singular point in time in a 24-hour continuous cycle. Therefore, nocturnal peaks highly related to glaucoma would not be detected. Continuous-collected data following the

Triggerfish study using a sensor embedded in contact lenses found patterns of corneoscleral flattening during sleep not typically identified by conventional method of daytime measurement (Mansouri et al 2012).

The restrictions imposed by glaucoma screening have been seen in other long-term eye diseases, such as DR. Screening Programmes such as Annual Eye Assessments do improve the likelihood that the eye condition would be diagnosed but do not pay attention to keep up with the changes in the disease between any two dates of assessment. An individual with diabetic retinopathy could experience significant changes in their vision due to severe eye conditions (severe retinopathy) as a result of uncontrolled diabetes before their next doctor's appointment. Risk Stratified screening will try to monitor more frequently individuals with higher severity of disease but will always face challenges due to costs and limited resources in the healthcare system. As such, a focus on episodic eye care will make it difficult to identify individuals at risk of vision loss/eye disease within different groups of patients at the same time.

Episodic care does not provide adequate service due to time and structural limitations on service. Globally, there are approximately 200,000 ophthalmologists for an estimated 8 billion people; this creates geographically disparate access to eye care. The ophthalmology workforce is severely lacking as demonstrated by multiple sources (Bourne et al., 2021). The lack of ophthalmologists creates a time restriction on the ability to have timely and appropriate access to eye care across the globe. The combination of both structural and time factors creates a void in health care delivery that needs to be addressed. Solutions to these problems include continuous monitoring devices that can integrate with artificial intelligence for real-time data collection and remote analysis. Continuous monitoring devices can resolve the limitations of episodic care enabling earlier detection and better disease management as well as increased access to eye care services.

### *2.3 Artificial Intelligence in Ophthalmic Diagnosis: Evidence Base*

In the last 10 years, the use of AI for diagnosing eye problems in patients has greatly expanded as there have been numerous studies that support using this technology in practice. The first major study in AI for ophthalmology was done by Gulshan et al. (2016). They found that a deep learning algorithm (CNN) could diagnose diabetic retinopathy (DR) with an accuracy level similar to or better than that of trained eye doctors by looking at more than 128,000 retina photos. This study provided good evidence that computers could use retinal images to diagnose DR, and encouraged more research on the use of AI in ophthalmology.

Since Gulshan et al. (2016), many researchers have confirmed and expanded the findings from this study. For example, Ting et al. (2017) found that the performance of deep learning systems was similar even in multi-ethnic populations and therefore generalizable beyond the original training data, which consisted mostly of Caucasian patients. This represents a major change from a simple demonstration that AI can be used for diagnostic purposes to robust use of AI in the real world. Artificial Intelligence (AI) has performed very well at analyzing Optical Coherence Tomography (OCT) scans further than just optic fundus photography. Specifically, AI has completed the segmentation of retinal layers successfully, as well as detecting pathologies such as person's fluid retention who has had Age-Related Macular Degeneration (AMD) and/or Diabetic Macular Oedema (DMO). The algorithms for these analyses have been validated on large datasets, with sufficient agreement from retinal experts, suggesting their clinical application (Kather et al., 2020). Conversely, while algorithms using OCT derived retinal nerve fibre layer and optic disc images have been successful in diagnosing glaucoma, the inherent variability of anatomical structures creates a barrier to interpreting these images for the early diagnosis of glaucoma. The development of explainable AI technologies (Gradient-weighted Class Activation Mapping (Grad-CAM), etc.), has provided a means to enhance the interpretability of AI-derived diagnostic imaging systems by indicating various regions of an image which contribute to the ultimately assigned diagnosis (Selvaraju et al., 2017). Gaining this level of trust in AI by clinicians will lead to its incorporation into clinician practice.

Wondering about the future of AI in ophthalmology? Regulatory advancements further prove that AI has reached maturity and its use has also reached a level that can be considered to be an accepted part of healthcare delivery around the world. With the initial approval by the FDA of IDx-DR, the first completely autonomous AI diagnostic system capable of generating clinical outputs without physician interpretation, this achievement puts IDx-DR at the forefront of technological progress toward achieving full implementability. Similar experiences with AI diagnostics by various global healthcare systems suggest that although regulatory pathways are still complex,

International Journal of Medical Discoveries
Volume 2, Issue 2
ISSN: 3067-7912

clinical implementation of AI-based diagnostic systems is already highly feasible and increasingly acceptable.

### *2.4 Wearable Technology in Chronic Disease Management: Analogous Precedents*

Wearable technologies for managing chronic disease have already been successfully integrated into diabetes management and heart disease management. Both of these areas serve as solid examples through which the transformative power of continuous monitoring will be demonstrated when it comes to transforming episodic monitoring (e.g. classic 2 to 3-month diabetic assessment) into a proactive approach to disease management that relies on just-immediate data.

However, the obvious exception to the above-mentioned gap is continuous glucose monitoring (CGM). The development of CGM has led to a paradigm shift in diabetic care. With the use of under-the-skin electrochemical sensors that continually monitor glucose molecules in the interstitial fluid of the subcutaneous space, CGM enables individuals with diabetes to monitor their glucose levels in real-time and see how their glucose levels are trending throughout the day. CGM is superior to standard fingersticks for measuring blood glucose in terms of glycaemic control, reduced hypoglycaemic events, and improved quality of life, based on the outcomes of randomized controlled clinical trials (Bollyky et al., 2018). The ability to create CGM has also required advances in sensor miniaturization, biocompatibility of sensors, calibration algorithms, and user-focused data interfaces, all of which mirror the development challenges associated with the design of wearable monitoring systems that would be used in ophthalmology.

In cardiovascular medicine, there has been a parallel evolution with regard to the use of non-invasive diagnostic modalities. For example, the Apple Heart study demonstrated that smartwatch-based PPG (photo plethysmography) was a valid method of continually monitoring pulse irregularities that may indicate atrial fibrillation (AF) when validated against ECG (electrocardiography) data from a relatively large sample of subjects (Turakhia et al., 2019). A key finding from this research demonstrated the limitations associated with using continuous monitoring technologies for managing false positive alert situations. Moderately specific devices, when utilized in large numbers, produce vast quantities of alerts and generate excessive false positives. Consequently, a careful focus on achieving the appropriate balance between sensitivity and clinical utility is critical. Likewise, this issue presents significant challenges to ophthalmic wearable devices due to the burden of excessive false positive alerts on both the healthcare workflow and the patient experience.

The Triggerfish contact lens sensor represents early attempts at providing continuous data in an ophthalmic setting. The Triggerfish device is capable of continuously recording telemetrically for a 24-hour period the dimensional changes of the eye associated with the fluctuations of intraocular pressure (IOP). Clinical research has shown that the device is well tolerated, and that it can obtain meaningful data patterns by detecting changes that occur during the night, which are not detectable with conventional clinic-based assessments (Mansouri et al., 2012; De Smedt et al., 2012). Currently, as far as functioning goes, ophthalmic wearables are limited and they lack real-time diagnosing capabilities due to the lack of integrated artificial intelligence. Collectively, these two items create precedent that demonstrate both the ability to conduct continuous monitoring, as well as clinically demonstrate the merits of continuous monitoring. In addition, as a summary, they also highlight areas of design/implementation difficulties that need to be addressed before we will have fully functional (integrated, AI-enabled) wearable systems in ophthalmology.

## 3. Proposed Conceptual Framework: Four-Layer Architecture

This segment discusses the main contribution of the current study, a theoretical framework for an AI-enabled wearable system for ongoing ophthalmic observation. This conceptual framework utilizes previous information and identifies gaps within literature regarding continuous ophthalmic monitoring, such as: structural features required, data flow through the system, and how each of these structural features function together to allow for real-time evaluation of chronic eye diseases outside of traditional clinical settings. Importantly, this framework currently serves as a theoretical document; it does not represent either an operational or validated device that has been or will be created. It is expected that the framework will be used for future studies, prototype creation, or clinical validation. The architecture given has been divided into 4 different tiers that are dependent upon one another: data collection, edge processing, AI inference, and clinical communication. Each tier provides one of the necessary components for transforming abstract physiological signals into clinically applicable information. Collectively,

International Journal of Medical Discoveries
Volume 2, Issue 2
ISSN: 3067-7912

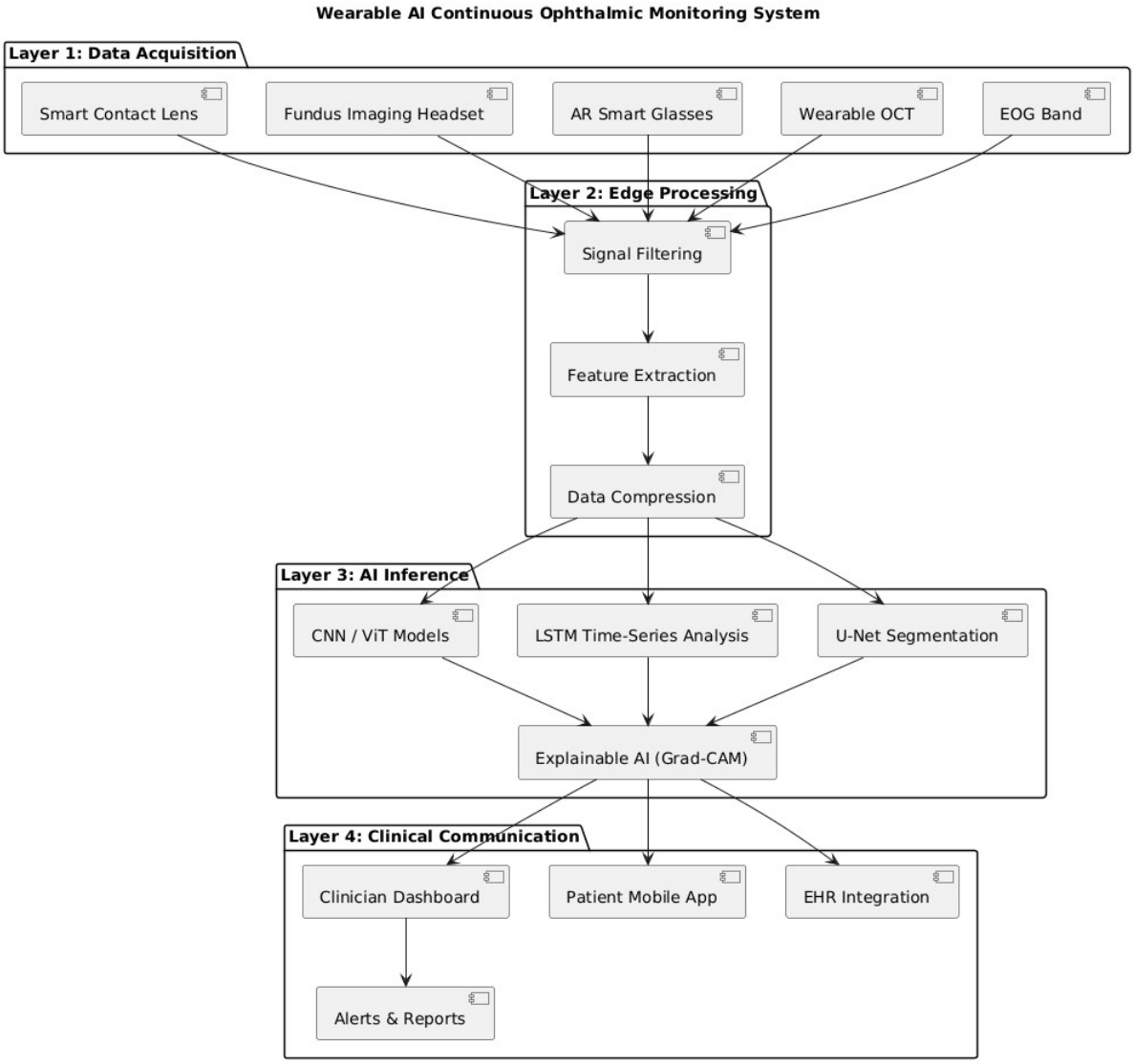


***Figure 1. Conceptual architecture of the proposed wearable AI system for continuous ophthalmic monitoring.***

the 4 tiers offer a scalable and integrative framework for wearable ophthalmic monitoring, seen in Figure 1.

### *3.1 Overview of the Architecture*

The proposed framework for the development of a wearable AI-based ophthalmic monitoring system uses a vertically integrated pipeline whereby continuously gathered ocular data goes through sequential processing stages, yielding clinically-actionable outputs (Table 1). A systematic methodology transforms raw physiological signals into useful diagnostic insights. The architecture includes four interdependent layers (1) Data Acquisition Layer, where continuous physiological & imaging data are collected from the ocular region using wearable devices; (2) Edge Processing Layer to preprocess, filter and convert raw data into structured features for subsequent analysis. The third phase, AI Inference Layer uses machine learning algorithms to evaluate the features of the given data, allowing for determination of diagnosis based on detection, classification or prediction of disease present. The last phase is known as the Clinical Communication Layer, which assists with decision making for health care professionals by converting model outputs into clinically relevant information, as well as providing appropriate patient-facing feedback. Together these layers create a comprehensive and scalable continuous ophthalmic monitoring framework that is AI-enabled.

International Journal of Medical Discoveries
Volume 2, Issue 2
ISSN: 3067-7912

*Table 1. Proposed Four-Layer Architecture for Wearable AI Continuous Ophthalmic Monitoring*

| WEARABLE AI CONTINUOUS OPHTHALMIC MONITORING SYSTEM PROPOSED FRAMEWORK | |
|---|---|
| ***LAYER 1***<br>Data Acquisition | Wearable Sensor Platform: Smart contact lenses (IOP-related corneoscleral strain, tear biomarkers), portable fundus imaging headsets, AR smart glasses (retinal camera), portable OCT units, EOG sensors. Raw data acquisition from all sensor modalities and continuous transmission to the microcontroller embedded within the sensor platform. |
| ***LAYER 2***<br>Edge Processing | Low Power Microprocessor for device (ARM Class or similar):<br>Processing of signals (noise removal, artifact rejection, baseline correction), extraction of features (intraocular pressure waveform characteristics, retinal image quality, blink parameters, OCT layer demarcation). Compressed feature vector transferred over encrypted connection via BLE/Wi-Fi to inference engine. |
| ***LAYER 3***<br>AI Inference | Cloud-based or hybrid AI engine: Disease-specific deep learning algorithms (CNN for classification of fundus images, LSTM for analysis of IOP time series, U-Net for segmentation of OCT images, Vision Transformer for detection of multiple diseases), federated learning framework for privacy-preserving model updates, explanation component (Grad-CAM attention maps). |
| ***LAYER 4***<br>Clinical Communication | Clinical dashboard security: Real-time alerts to ophthalmologist with explanation visualizations, mobile phone application for patients providing personalized feedback and compliance reminders, HL7 FHIR-compliant electronic health record integration, population-based surveillance, appointment scheduling reminders. |

### *3.2 Data Acquisition Layer*

#### *3.2.1 Smart Contact Lenses*

Smart contact lenses represent the most invasive and possibly most clinically important ophthalmic monitoring system, which provides the closest interaction with the surface of the eye and its surroundings. The best-known and clinically investigated smart contact lens sensor is the Triggerfish contact lens sensor made by Sensimed AG. It includes a micro-engineered strain gauge incorporated into a soft contact lens, which can monitor the deformation of the corneosclera, which is proportional to the changes in IOP as mention in table 2 and transmit the telemetric signal continuously for up to 24 hours of wear. Studies on this device have shown its feasibility and the importance of monitoring continuous IOP-related parameters in glaucoma patients, especially at night, using telemetric monitoring (Mansouri et al., 2012).

The smart contact lenses of tomorrow will include other sensing capabilities, including glucose, lactate, and cytokine measurements in tears, which may be achieved through electrochemical sensors embedded in the material of the lenses themselves. Anterior segment optics can also be recorded by incorporating miniaturized photodetectors and imaging components into the contact lens itself. The technical difficulties associated with sensors in contact lenses include the ability to transmit electrical power safely and wirelessly, while adhering to regulatory guidelines on electromagnetic exposure. Data transmission and sensor stability over time, without compromising the optical qualities necessary for clear vision, also pose significant technical barriers.

#### *3.2.2 Fundus Imaging Headsets and AR Smart Glasses*

Fundus imaging systems, which allow capture of images of the posterior segment of the eye, are the most suitable sensor technology for DR and AMD screening based on the substantial body of scientific literature supporting the use of AI analysis of fundus and OCT images, as mention in table 2. There already exist several portable hand-held non-mydriatic fundus cameras, which prove that the level of optical performance required for AI analysable fundus imaging can be achieved away from the slit lamp setting of the clinic. The next stage would be the miniaturization and integration of this optical imaging equipment into head-worn wearable systems. AR-based smart glasses, including the Meta-Rayban glasses, Microsoft HoloLens, and medical-grade variants, are equipped with high-resolution cameras pointed outward

to take videos at real-time rates. Incorporation of the said platforms into retinal imaging will require installation of suitable illumination devices and optics for focusing on the fundus as well as the ability to take images at the necessary rate using software control for AI evaluation. The added benefit offered by AR goggles in incorporating gaze tracking is the ability to carry out an ambulatory visual field test based on pupil stability and fixation.

*3.2.3 Wearable OCT Modules*

Optical coherence tomography has the most significant resolution for retinal structures of all available technologies, which makes it possible to examine the retina at the micrometre level in cross-sections, which is necessary for quantitative assessment of retinal nerve fibre layer thickness in glaucoma and accumulation of fluid in DMO and neovascular AMD, mention in table 2. Miniaturisation of OCT systems to wearable head-mounted devices using swept-source lasers, photonic integrated circuits, and microelectromechanical system scanners is currently a topic of technological development. Despite the lack of commercially available wearable OCT systems used in clinical practice, there are publications demonstrating the feasibility of miniaturising OCT systems for use outside of clinics, indicating the feasibility of this component (Ronneberger et al., 2015 – considering segmentation algorithms that could be used for these systems).

*3.2.4 Electrooculography Bands*

EOG records the electrochemical potential difference between the cornea and the retina, which varies according to the position and motion of the eyes and can be applied for monitoring blink behavior, eye movement activity, and other factors related to the ocular surface. Worn on a forehead band or an orbital band with electrodes, EOG continuously tracks the blink frequency, blink duration between consecutive blinks, blink closure adequacy, and spontaneous eye movements, told in table 2. The importance of this technology lies in its clinical significance with regards to measuring the severity of dry eye disease, monitoring neurodegenerative disorders that affect eye movement, and ocular fatigue detection.

***Table 2. Proposed Wearable Device Categories: Monitoring Targets, Sensing Mechanisms, and Key Engineering Challenges***

| **Device Category** | **Main Sensing Object** | **Sensing Technology** | **Main Engineering Challenges** |
|---|---|---|---|
| Smart Contact Lens | IOP, Tear Biomarkers | Strain gauges, electrochemical sensors | Wireless power supply<br>Biocompatibility<br>Long-term reliability of sensors<br>Maintaining optical properties |
| Fundus Imaging Headset | Structure of retina (DR, AMD) | Miniaturised non-mydriatic optics, CMOS camera | Quality of image without mydriasis<br>Device weight<br>Moving from professional cameras<br>Uniform lighting |
| AR Smart Glasses | Retinal imaging, visual field | Cameras, eye-gaze detection | Optical modifications for fundus imaging<br>Wearable comfort<br>Coaxial illumination |
| Wearable OCT Module | Retinal layer thickness, fluid analysis | Swept-source OCT, MEMS | Miniaturisation of swept-source OCT<br>Motion correction<br>Batteries lifetime |
| Electrooculography Band | Blink dynamics, ocular surface condition, eye movements | Electrocorticography on the surface of the face | Consistent contact between electrode and skin<br>Facial artefacts of electrocardiogram signal<br>Comfort when wearing |

*Notably, this table shows an abstract categorization of wearable devices that have been recommended under the proposed framework. All devices in the table are conceptual engineering designs based on literature, but no performance data is provided regarding the overall wearable AI system.*

International Journal of Medical Discoveries
Volume 2, Issue 2
ISSN: 3067-7912

### *3.3 Edge Processing Layer*

The Edge Processing Layer acts as a critical bridge or intermediary point between the raw data from wearable sensors and the structured, high quality data for downstream AI analysis. Because of the limitations of wearable devices with respect to their computational capabilities, bandwidth, and energy use, this layer must carefully manage two competing demands - i.e., performing robust signal processing and minimizing resource use.

As part of this process, the Edge Processing Layer will perform signal conditioning, quality evaluation, feature extraction and data compression directly on the device. Signal conditioning includes applying modality-specific noise reduction techniques that improve the reliability of the data. For instance, we smooth the IOP time series data by applying either a moving average or a Kalman filter, and applying frequency domain filtering to the EOG signals, and spatial filtering to the image data to increase its visual fidelity. At the same time there are mechanisms in place for evaluating the signals, as well as for eliminating any unreliable/corrupted signal data that have been recorded due to motion artifacts, pixel displacement or environmental interference. The basic functions of these processes include (but are not limited to) "quality gating," where we filter out any data that does not meet certain predetermined thresholds (e.g., an adequate amount of light, being in-focus, being within the field of view) prior to any other type of analysis being performed. Moreover, using feature extraction, we further reduce the amount of the data by converting the original signals into compact representations that contain a high degree of information. One example of how to summarize IOP data is by calculating the mean, diurnal variation, nocturnal peaks, and rate of change. Intermediate feature sets that have been created using previously trained Convolutional Neural Networks provide a means by which image data can be efficiently represented, which facilitates accurate analysis without having to transmit full-resolution images. Collectively, this layer provides the transition between the data acquisition layer (first layer) and the intelligent inference layer (third layer), and represents the highest level of data fidelity possible while maximizing the overall performance of the system.

### *3.4 AI Inference Layer*

The AI Inference Layer serves as the analytical foundation of our entire system because processed data are converted into clinically interpretable results at this layer. In addition to utilizing advancements in AI application to the field of ophthalmology, this layer leverages pre-trained machine learning models for each of the various methods/dataset types (image analysis, etc.) used to make the diagnosis. To perform image analysis, we use a type of deep learning model — specifically deep convolutional neural networks (CNNs) — to detect and classify various conditions (diabetic retinopathy, age-related macular degeneration) based on the images provided. These models have been developed based on large datasets (e.g., EyePACS, MESSIDOR-2, UK Biobank) and are now being used for wearable device data. The challenge here is the difference in quality and acquisition of images for the various standard devices that cause what is known as domain shift. Our approach will incorporate domain adaptation methods to enable the models to perform reliably across all of the sites included in our analysis. Long short-term memory (LSTM) networks are being used to model the dynamic patterns of temporal data, specifically intraocular pressure (IOP), for clinical purposes. The ultimate goal of these models is to find clinically meaningful characteristics, including nocturnal peaks, long-term increases, and abnormal variability associated with the risk of developing glaucoma. In order to address data privacy concerns and scalability issues, federated learning has been incorporated into this layer, allowing for decentralized model training across devices without transferring patient data. This allows continuous improvement to occur without compromising the privacy of patient data. Finally, this layer incorporates techniques such as Grad-CAM and methods for feature attribution to provide transparency regarding the decision-making process of clinicians. These techniques assist in establishing clinician trust in the results and thereby facilitate the implementation of the findings into clinical practice.

### *3.5 Clinical Communication Layer*

The AI-generated communications layer transforms outputs into actionable information for key stakeholders, including clinicians, patients, and public/public health organizations. The effectiveness of the overall system is based not only on analytical accuracy but also on how the insights created are communicated and acted upon. Therefore, this layer is vital to achieve real-world clinical impact. For clinicians, this layer is a secure, role-based dashboard only for the purposes of supporting decision-making when compared to raw data interpretation. The information displayed is done so with application

of principles derived from human factors engineering (e.g., clinical-related alert systems). Alerts provided are prioritized by urgency and include several pieces of contextual information, such as explanations of how an alert was created (i.e., heat maps), segments of relevant data, and longitudinal trends. Careful calibration of the alert thresholds is necessary to achieve a balance between sensitivity and specificity, in order to reduce the occurrence of alert fatigue (i.e., annoying, incorrect alerts, etc.) while avoiding missing clinically significant events. Patients receive communication about their health via a mobile app designed to encourage them to participate in their own care management decisionsProviding tailored feedback will help patients better understand their disease state and motivate them to continue monitoring their condition by responding quickly when alerted. The interface must be designed to support varying levels of both health and digital literacy, particularly for those with vision impairments. At a system level, integrating continuous monitoring data into a patient's electronic health record (EHR) would allow for continuous monitoring data to be included as part of the patient's longitudinal medical record through interoperability standards (e.g., HL7 FHIR). This allows for coordinated patient care, helps support clinical audits and research opportunities. Also, aggregate, de-identified continuous monitoring data can assist with the creation of public health strategies, resource utilization, and tracking of disease outbreaks.

## 4. System Workflow Execution

The suggested four-layer framework is a continuous and end-to-end data processing pipeline that converts raw ophthalmic signals into clinical actionable information. Whereas Section 3 outlines the structural constituents of the system, this section outlines the interaction between the structural constituents in a dynamic manner during the operation of the system in the real world. The workflow starts with the stage of data acquisition due to the continuous informatization of wearable devices in which multimodal ophthalmic data, such as intraocular pressure signals, retina images, OCT scans, and eye movement patterns, are registered. The idea of constant physiological monitoring using wearable sensors has been popular in the healthcare field to allow real-time data recording beyond the clinical setting (Patel et al., 2012). During the edge processing phase, raw data are preprocessed, such as noise filtering, artifact removal, and quality assessment. The feature extraction is then done to produce small and meaningful representations of the data, which minimizes the transmission burden and maintains clinically pertinent data. The capability to minimize the latency and bandwidth demands has been discovered to make edge computing one of the important enablers of real-time processing in wearable healthcare systems (Shi et al., 2016). The processed data are subsequently relayed to AI inference layer, with the specific machine learning models processing the received signals. Convolutional neural networks are used to process image-based data and sequence-based models like LSTM networks are used to process temporal physiological signals. The application of deep learning methods has also proven to be very accurate in the process of ophthalmic diagnosis, especially when it comes to classifying retinal images and identifying diseases (Gulshan et al., 2016). After the analysis, the system does decision support and alert generation in which risk scores are calculated and contrasted against pre-defined thresholds. AI-based clinical decision support systems have demonstrated the possibility of enhancing diagnostic efficiency and time to intervention (Topol, 2019). Lastly, during the clinical communication phase, the outcomes are sent to healthcare providers with the help of secure dashboards and to the patients with the help of mobile applications. This will guarantee timely clinical intervention and continuous engagement of patients which are key elements of modern digital health ecosystems (Steinhubl et al., 2015).

## 5. Use Case Scenarios for Continuous Ophthalmic Monitoring

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International Journal of Medical Discoveries
Volume 2, Issue 2
ISSN: 3067-7912

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## 6. Theoretical Basis for Clinical Value

### *6.1 Enhanced Temporal Resolution of Disease Monitoring*

Continuous monitoring of the eyes provides a key advantage over episodic clinical data due to its ability to utilize continuous data instead of limited episodic data. This shift in data collection will not only increase how often we observe the data but will also change how disease is assessed, moving from intermittent snapshots to a continuous view of physiological processes over time. Continuous monitoring provides the ability to collect normal fluctuations, including those times when patients are not being observed, across a full 24-hour interval. This series of tests is not only valuable for documenting diurnal cycles in medication adherence but is also valuable documentation from other disciplines in medicine. Four examples are hypertension, where 24-hour monitoring outside a clinical setting serves to either characterize or predict the risk of developing cardiovascular disease, intraocular pressure (IOP) in glaucoma patients, and improvements in patient care due to continuous monitoring via emerging wearable technology. In the case of hypertension, 24-hour blood pressure monitoring outside the clinic has been shown to predict the development of cardiovascular disease better than measurements taken in a clinic setting due to their ability to document variability. Increases in the range of IOP experienced in patients with glaucoma demonstrate that fluctuations in IOP occur at different times of the day and night and can lead to the progression of the disease if they are not properly documented (Weinreb et al., 2014); however, single measurements may provide insufficient information to detect a potentially diseased eye. Therefore, wearable technology for continuous monitoring allows health care professionals to have access to more accurate information regarding the progression of disease, allowing for more reliable detection of pathological patterns, and improving clinical decision-making.

### *6.2 Early Detection and Therapeutic Window*

The window of opportunity to prevent or limit irreversible damage caused by the disease process and/or to initiate timely treatment based on the identification of the disease process is referred to as the "therapeutic window." This has been established as a concept for serious and chronic ocular diseases such as glaucoma, diabetic retinopathy, and age-related macular degeneration. Unfortunately, many patients are diagnosed at a late stage of their disease because of delayed diagnosis associated with episodic care. One example is glaucoma, where the optic nerve is irreversibly damaged. Treating elevated intraocular pressure (IOP) slows down progression of the disease if the patient is treated prior to significant loss of retinal ganglion cells (RGCs). Therefore, continuous monitoring of both IOP and the variability in IOP aids in the earlier detection of pathological changes associated with glaucoma and allows for sooner initiation of treatment. In the case of DR, earlier stages of DR provide the opportunity for improved glycaemic control and the option of preventive treatment (for example, laser photocoagulation). Fixed screening intervals may fail to detect rapidly progressing disease before it becomes advanced. Continuous monitoring systems incorporating AI can detect retinal changes earlier, allowing timely intervention. In neovascular age-related macular degeneration, disease progression can occur over a short period, often days to weeks. Early detection of retinal changes or symptoms such as metamorphosis

allows prompt initiation of treatment, improving visual outcomes. Overall, continuous monitoring systems have the potential to detect diseases earlier in their progression, maximizing the effectiveness of available treatments and improving patient outcomes.

### *6.3 Personalised Monitoring and Adaptive Care*

Continuous monitoring (which provide more density of data and therefore greater resolution for analyzing longitudinally over time), it will be possible to identify individual patterns, trends, and responses to treatment. This allows for a movement away from population-based healthcare models towards a patient-specific model of treatment. At present, the effectiveness of treatment is determined by measuring patients at long intervals, with variability and delay impacting the utility of those measurements. However, through the use of continuous measurement methods and collection of data in near real time, the ability to evaluate the effectiveness of treatment is accelerated, allowing for adjustments to individual care plans to be made much more rapidly than in the current system. The AI (artificial intelligence) systems developed for use with the above described continuous measurements will analyze longitudinal trends for the individual over time. Rather than relying on established thresholds for entire populations, individual baselines will be established; any deviations from those baseline measurements will be identified, thereby providing the ability to recognize clinically significant changes that would not otherwise be recognized when making comparisons based on entire population groups. A patient-centered approach to monitoring allows for better identification of when to intervene with the patient, to implement rapid intervention strategies and to achieve improved long-term outcomes and support the evolution towards precision-based ophthalmic care models, as illustrated in figure 2.

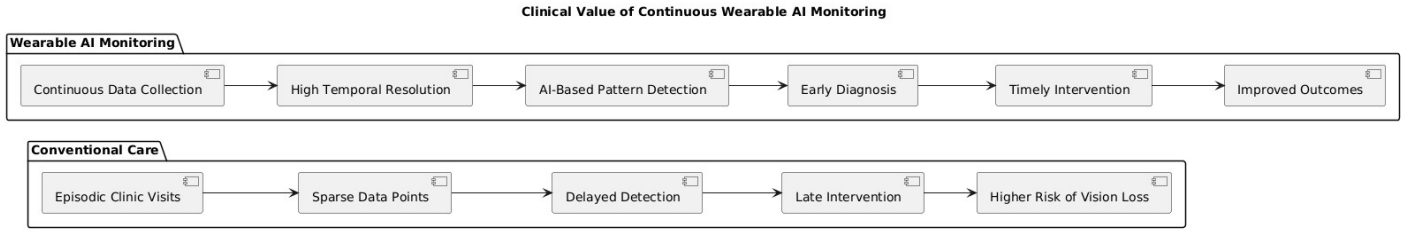


***Figure 2. Conceptual comparison between conventional episodic ophthalmic care and continuous wearable AI–based monitoring.***

## 7. Adoption Challenges and Mitigation Strategies

### *7.1 Regulatory Pathways for Continuously Learning AI Diagnostics*

The current regulatory landscape surrounding AI-based medical devices does not entirely address the unique qualities of continuous learning and real-time diagnosis using AI wearables. Several regulatory bodies, such as the Food and Drug Administration, the European Medicines Agency (EMA), and the United Kingdom's MHRA, have published guidelines regarding Software as a Medical Device (SaMD) and Artificial Intelligence/Machine Learning–based medical devices, as described in table 4 which offer a good base to work from; however, there are some qualities of our proposed wearable AI-based ophthalmic system that pose challenges to these guidelines (Matheny et al., 2019; FDA, 2021). The most critical regulatory challenge comes from continuously learning AI – an AI whose model parameters are adjusted in real-time through continued exposure to new patient information, as opposed to being "locked" once trained and validated. Regulatory evaluation typically entails the analysis of an already completed product; hence, a continuously learning AI's behaviour in use may differ from what is observable during pre-market evaluation. It will be necessary to identify criteria for ongoing surveillance, as well as triggers that would necessitate additional review. This is recognized within the FDA's Action Plan for AI/ML-Based Software as a Medical Device(Table4) (FDA, 2021). However, how this may be applied to continuous ophthalmic monitoring applications remains unclear. The problem of liability apportionment is another challenge. If a wearable AI monitor issues a diagnosis warning and no action is taken, leading to patient harm, the allocation of responsibility between the manufacturer, developer, physician, and healthcare provider remains unresolved. While guidelines exist, the issue of liability remains largely unanswered (Matheny et al., 2019).

### *7.2 Data Privacy, Security, and Governance*

The unique class of data generated by continuous, wearable ophthalmic monitoring creates data protection obligations (Matheny et al., 2019). Retinal fundus

International Journal of Medical Discoveries
Volume 2, Issue 2
ISSN: 3067-7912

photos may have unique vascular patterns, which make them biometric identifiers and are therefore protected by regulations such as the GDPR. The federated learning model architecture contained in this framework addresses privacy concerns as outlined in table 4. Specifically, federated learning greatly reduces exposure to risk compared to centralised systems because it requires that the raw patient data stays on the patient's device (discrete from the organisational infrastructure). Additionally, since model updates can be shared with others without sharing the actual raw data, it is possible to employ differential privacy techniques to provide additional protection from risks such as membership inference attacks (McMahan et al., 2017). All of these aspects should be evaluated as part of data protection impact assessments. Another major area of concern related to these systems is cybersecurity. Wearable devices or cloud-based AI systems could be targeted by cybercriminals with the intention of disrupting operations, altering diagnostic outcomes, or stealing sensitive data, all of which may lead to misdiagnosis or reduced trust in the system after such attacks. Security-by-design must be included in all of the aforementioned systems and techniques (Kruse et al., 2017). Security-by-design measures include encryption, authentication, a secure boot process, and periodic security audits.

### *7.3 Technical and Engineering Constraints*

Before health professionals can use this system as an aid in their practice, a number of technical and engineering issues will have to be resolved. Power management is an important issue for the development of the proposed system because wearable devices have limited energy sources. For the proposed system to work properly, intraocular pressure measurements need to be stable; therefore, calibration of sensors used for this purpose is very important. Intraocular pressure measurement sensors lose accuracy over time; therefore, continual reassessing of the accuracy is critical. Recalibration issues can be addressed by optimizing the materials used to construct the sensors and using algorithms to correct for drift, as well as establishing acceptable thresholds for accuracy based upon the application. In order to provide a high-quality image using the proposed wearable fundus imaging devices, several technical barriers must be addressed. The ability to produce good quality images through non-mydriatic imaging systems is affected by factors such as, but not limited to, the alignment of the pupil and the size of the pupil, as well as the amount of light used to illuminate the fundus. In addition to the above mentioned factors, variability in image quality will negatively impact the performance of AI models that utilize these images as an input, therefore, image quality will have to be taken into consideration during the validation process (Gulshan et al., 2016).

### *7.4 Clinician Acceptance and Workflow Integration*

The acceptance of Clinicians is an important component of the successful adoption of new technology in healthcare. This means that even when systems are very functional, they will not be utilized successfully unless they become part of the workflow process for the Clinician and the Clinician trusts the outputs of the system (Topol, 2019). The design of the proposed system includes components that promote clinician acceptance. The explainability element provides access to attention heat maps and visualizations of feature importance to promote transparency of AI-based decisions. Alert stratification establishes a mechanism for managing high alert volume by identifying urgent alerts versus routine informational alerts. Integration of monitoring data with the electronic health record system using HL7 FHIR standards enables access to monitoring data via existing systems. Co-design with Clinicians in the development of the user interface is highly recommended to ensure the proposed system is usable (see Table 4). Clinicians who actually practice Ophthalmology should participate in both the design and evaluation of the user interface; this will aid in increasing the likelihood of successful adoption. Human factors assessment of the prototype user interfaces should also be performed during the development of the user interfaces.

### *7.5 Health Equity and Equitable Access*

One key ethical issue is whether the use of Wearable AI Monitoring Systems will primarily be of value to wealthy people, and therefore be out of reach for underserved communities (Matheny et al 2019). Many people affected by eye disease live in areas with little access to ophthalmic services, including large geographic areas of the world including much of Africa, parts of Asia and much of Latin America (Leasher et al 2016). Equity-focused design will need to take into account both the technical and policy aspects associated with the overall design framework. At a technical level, systems should support offline capability and not require constant access to the Internet. It is also important for the design of the device to be appropriate for low-resource settings and

have compatible power sources, as indicated in Table 4. At the policy level, equitable access will likely necessitate the provision of financial support from government or healthcare organisations to ensure equitable availability of these technologies.

*Table 4. Summary of Adoption Challenges, Evidence-Based Barriers, and Proposed Mitigation Strategies*

| Challenge Domain | Main barrier | Proposed Mitigation Strategy |
|---|---|---|
| Regulatory | - Lack of a specific regulatory framework for continuously learning AI diagnostics in wearables<br>- Liability uncertainty of/for autonomous alerts | - Engage proactively with the FDA/MHRA AI/ML SaMD guidance<br>- Create predetermined change control plans<br>- Encourage/propose the development of guidance about liability for professional bodies |
| Data Privacy | - The sensitive biometric nature of retinal data<br>- The risk posed by centralized cloud inference processes<br>- The requirements to be compliant with the GDPR/HIPAA | - Develop a federated learning architecture<br>- Encrypt data end-to-end<br>- Implement differential privacy mechanisms<br>- Complete a data protection impact assessment |
| Technical Engineering | - Power limitations<br>- Sensor drift<br>- Variable quality of image collected from being worn<br>- Miniaturization constraints | - Research into energy harvesting technologies<br>- Develop adaptive calibration algorithms<br>- Develop gating of image quality using AI<br>- Prototype photonic integrated circuit OCT |
| Clinician Acceptance | - Distrust in AI outputs that are opaque<br>- Burden of alerts<br>- Disruption of workflow<br>- Uncertainty related to liability | - Use of explainable AI through Grad-CAM type visualisations<br>- Stratification of alerts<br>- EHR Integration<br>- Co-design/iterative clinician input<br>- Conduct human factors evaluation |
| Health Equity | - Cost barrier to devices for low-income populations<br>- Variation of digital literacy<br>- Need for connectivity<br>- Language and cultural barriers | - Offline capable edge-inference<br>- Low resource device variants<br>- Multilingual, low literacy devices<br>- Advocate for public subsidy policies |

## 8. Discussion

First, the proposed framework represents a reconstruction of ophthalmology care delivery that results from thorough evaluation of the problems posed by the current episodic paradigm, and the possibilities of modern and future technologies in overcoming them. The theoretical consistency of the framework emerges from congruence of the addressed clinical problem (inability to monitor continuously and dynamically diseases characterized by dynamic progress and high value of longitudinal monitoring) and the proposed solution (dense, continuous, AI-analyzed monitoring outside the clinic). The most significant intellectual innovation offered by the proposed framework lies in its synthesis of two areas of knowledge, which, to this point, have evolved almost independently: on the one hand, the rapidly expanding and maturing area of research focused on artificial intelligence-based analysis of ophthalmological images; and on the other hand, nascent but promising research in the field of continuous monitoring of chronic diseases using wearable devices. Such a synthesis creates a foundation for building an architectural system that will evolve into a future integrated platform for ophthalmological care, where existing and yet-to-be-developed technologies can converge and interact seamlessly. When compared against the progress in development of

International Journal of Medical Discoveries
Volume 2, Issue 2
ISSN: 3067-7912

other analogous technologies such as continuous glucose measurement systems for the management of diabetes, and the development of ambulatory ECG recording in cardiovascular disease, useful insights into the timelines of development and challenges that may be expected for wearable devices in ophthalmology can be gained. Each of these technologies took about twenty years from proof of concept to implementation in widespread clinical practice. This process involved iterations of engineering, clinical testing, regulatory assessment, economic and clinician education. Development in ophthalmology is still in its infancy when compared to these technologies and the approach outlined herein is best viewed as a research program over many years. The inclusion of these adoption barriers, especially health equity, in the framework is an indication that the framework is being developed in such a way that ensures that its transformative power will not be reserved only for those populations that have been well-supported through traditional ophthalmology. These are the very populations that have the highest level of unmet needs in terms of continuous ophthalmology surveillance and are also the populations where there is an increase in diabetic retinopathy due to diabetes. This population is also the one whose access to ophthalmology services is highly limited, thus making them better candidates for a decentralized and AI-enabled diagnosis service. It is critical to point out several significant drawbacks inherent in this approach. In its essence, this model builds on the implicit assumption that the properties of currently tested, clinically validated ophthalmologic artificial intelligence systems can successfully be transferred to the wearables format provided there are adequate engineering solutions and corresponding algorithm modifications made. While this is a well-founded idea in theory, it definitely requires empirical verification in practice, which would be achieved via prototyping and further testing. The technical difficulties related to providing sufficient energy sources for smart contact lenses, miniaturization of the wearable OCT, and the quality of non-mydriatic imaging under field conditions cannot be easily solved and require significant time. At least, based on the current scientific knowledge, there is no definite timeframe when these problems could be effectively addressed. Areas of future research that are highly prioritised in this framework are: engineering research into the design of miniaturised ophthalmic sensor systems within each proposed category of device; domain adaptation research evaluating the performance of current ophthalmic AI models on new data gathered from wearable prototypes; federated learning research on multi-site ophthalmic data sources; human factor and qualitative research investigating clinicians' and patients' views of wearable AI monitoring devices; regulatory science research addressing the development of regulatory frameworks around continuously learning diagnostic SaMDs in ophthalmology; and finally, economic analysis research looking at whether wearables can be cost-effective for various healthcare system settings.

## 9. Conclusion

This paper presented a new conceptual framework for a four-layer approach to continuous wearable AI-driven ophthalmic monitoring, based on a synthesis of extant literature related to AI-assisted ophthalmology diagnosis, wearable sensors, and chronic disease management. The paper described a clear vision of the system architecture needed to create a clinically useful solution for continuous monitoring of patients with chronic eye conditions. There are several sound theoretical justifications for the value of continuous wearable ophthalmic monitoring as applied in practice. In particular, the argument made in this paper regarding the inherent limitation in using an episodic and clinic-centric approach to diagnose chronic diseases can be considered well founded. The fact that continuous monitoring can help close this gap in many different ways (diagnosis timing, monitoring progression, personalized treatment plans, and service accessibility) can serve as a solid foundatiosn for further empirical research in the field. No attempts were made to empirically validate the ideas presented in this paper. Each of the above issues presents its own set of challenges that are complex and multifaceted in nature. However, they are not problems that are unique to this technology; indeed, similar problems were encountered in developing related wearable monitoring devices used in the field of cardiology and diabetic treatment. The journey to develop such a device is long and difficult, but not without precedent. The global burden of avoidable blindness caused by chronic eye diseases is more than enough reason to make that journey once more.

## Ethics approval and consent to participate

Not applicable

## Availability of data and material

All the data have been provide in this manuscript

**Conflicts of Interest**

Authors declare no conflict of interest

**Funding**

None

**Authors' contributions**

All authors have equally contributed to this manuscript

**Acknowledgements**

none

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