Volume 4, Issue 3, 2026

Frontier in Medical & Health Research

ISSN: (e) 3007-1607 (p) 3007-1593

DEEP LEARNING–ENABLED SCREENING OF DIABETIC RETINOPATHY USING RETINAL IMAGING DATA FROM SOUTH ASIAN POPULATIONS: EVIDENCE FROM PAKISTAN

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DOI: https://doi.org/10.5281/zenodo.21427589

Keywords
Deep Learning; Diabetic Retinopathy; Retinal Imaging; Artificial Intelligence; Automated Screening; Pakistan.

Article History
Received: 01 January 2026
Accepted: 17 March 2026
Published: 31 March 2026

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Abstract

Background: *Diabetic retinopathy (DR) is a leading cause of preventable blindness among individuals with diabetes, particularly in low- and middle-income countries such as Pakistan. Deep learning has emerged as a promising approach for automated retinal image analysis and early disease detection.*

Objective: *This study evaluated the effectiveness of deep learning-enabled retinal image analysis for automated diabetic retinopathy screening using retinal imaging data from South Asian populations, with evidence from Pakistan.*

Methods: *A quantitative cross-sectional study was conducted using retinal fundus images from* ***600 patients with diabetes*** *collected from selected hospitals in Pakistan. A deep learning model based on a Convolutional Neural Network (CNN) was developed and evaluated using standard performance metrics. Structural relationships were analyzed using PLS-SEM.*

Results: *The deep learning model achieved an overall accuracy of 95.4% and an AUC-ROC of 0.98, demonstrating excellent diagnostic performance. The findings revealed that deep learning-enabled retinal image analysis significantly improved automated detection of diabetic retinopathy, early diagnosis, clinical decision-making, and overall screening outcomes* ($p < .001$).

Conclusion: *Deep learning-enabled retinal screening is an effective and reliable approach for the early detection of diabetic retinopathy in Pakistan. Integrating AI-assisted retinal imaging into routine diabetic eye care can improve screening efficiency, facilitate timely intervention, and reduce preventable vision loss.*

INTRODUCTION

Diabetes mellitus has emerged as one of the fastest-growing chronic diseases worldwide, posing significant challenges to healthcare systems and public health. The International Diabetes Federation (IDF) estimates that more than 537 million adults are currently living with diabetes, and this number is projected to increase substantially over the coming decades, particularly in low- and middle-income countries (International Diabetes Federation [IDF], 2025). Pakistan is among the countries with the highest diabetes prevalence globally, with a rapidly increasing burden attributed to urbanization, sedentary lifestyles, unhealthy dietary habits, obesity, and population aging. The growing prevalence of diabetes has consequently increased the incidence of diabetes-related complications, including diabetic retinopathy (DR), which

Frontier in Medical & Health Research

ISSN: (e) 3007-1607 (p) 3007-1593

remains one of the leading causes of preventable blindness among working-age adults.

Diabetic retinopathy is a progressive microvascular complication of diabetes characterized by structural and functional damage to the retinal blood vessels resulting from prolonged hyperglycemia. If left undiagnosed and untreated, DR may progress from mild non-proliferative stages to proliferative diabetic retinopathy and diabetic macular edema, ultimately leading to irreversible visual impairment and blindness (Wong et al., 2024). Clinical evidence consistently demonstrates that early detection and timely treatment can prevent the majority of diabetes-related vision loss, making routine retinal screening an essential component of diabetes management.

The diagnosis of diabetic retinopathy traditionally relies on ophthalmologists' interpretation of retinal fundus photographs or dilated retinal examinations. Although these methods provide high diagnostic accuracy, they require experienced retinal specialists, advanced ophthalmic equipment, and substantial healthcare resources. In many developing countries, including Pakistan, shortages of ophthalmologists, unequal distribution of specialized eye care services, delayed referrals, and limited access to retinal screening facilities reduce the effectiveness of national diabetic retinopathy screening programs. Consequently, many patients present with advanced stages of disease when treatment options become more complex and less effective.

Recent advances in Artificial Intelligence (AI), particularly deep learning, have transformed medical image analysis by enabling automated disease detection with diagnostic performance comparable to experienced clinicians. Deep learning algorithms, especially Convolutional Neural Networks (CNNs), automatically extract complex image features from retinal fundus photographs without requiring manual feature engineering. These models have demonstrated remarkable performance in detecting diabetic retinopathy by identifying microaneurysms, retinal hemorrhages, hard exudates, cotton wool spots, neovascularization, and other pathological retinal abnormalities (Ting et al., 2019).

Deep learning-based retinal image analysis has gained considerable attention because it facilitates rapid, scalable, and cost-effective diabetic retinopathy screening. AI-enabled screening systems can analyze thousands of retinal images within a short period while maintaining high levels of diagnostic accuracy, sensitivity, and specificity. Such technologies have the potential to improve screening coverage, reduce diagnostic delays, optimize healthcare resource allocation, and support clinical decision-making, particularly in regions where retinal specialists are scarce (Topol, 2019).

The integration of digital retinal imaging, electronic health records, cloud computing, and AI-assisted clinical decision-support systems has further enhanced the capability of automated ophthalmic screening. Explainable Artificial Intelligence (XAI) techniques have also improved the transparency and interpretability of deep learning predictions by highlighting retinal regions associated with disease detection, thereby increasing clinicians' confidence in AI-assisted diagnosis (Rajpurkar et al., 2022). These technological advances are increasingly supporting ophthalmologists rather than replacing clinical expertise.

Despite substantial international progress, the implementation of AI-assisted diabetic retinopathy screening in Pakistan remains limited. Most deep learning models have been developed using retinal imaging datasets obtained from North American, European, or East Asian populations. However, retinal pigmentation, disease presentation, imaging quality, genetic diversity, diabetes progression, and healthcare infrastructure differ considerably across populations. Consequently, AI models trained on foreign datasets may not generalize optimally to South Asian populations, including Pakistani patients.

Moreover, Pakistan faces several healthcare challenges, including a rapidly increasing diabetes burden, limited retinal screening infrastructure, shortages of ophthalmologists, inadequate rural healthcare services, and delayed diagnosis of diabetic retinopathy. These challenges emphasize the need for locally validated AI models capable of

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ISSN: (e) 3007-1607 (p) 3007-1593

accurately detecting diabetic retinopathy using retinal imaging data from Pakistani patients.

Although deep learning has demonstrated exceptional diagnostic performance internationally, empirical evidence regarding its clinical effectiveness, diagnostic accuracy, and applicability within Pakistan remains scarce. Few studies have developed or validated deep learning models using retinal imaging datasets representative of South Asian populations. This evidence gap limits the widespread adoption of AI-assisted retinal screening within Pakistan's healthcare system.

Therefore, the present study investigates the effectiveness of deep learning-enabled diabetic retinopathy screening using retinal imaging data from South Asian populations, with particular emphasis on evidence from Pakistan. The study aims to evaluate the diagnostic performance of deep learning algorithms in detecting diabetic retinopathy while providing empirical evidence to support the integration of AI-assisted retinal screening into routine ophthalmic practice and national diabetic eye disease prevention programs.

Problem Statement

Diabetic retinopathy remains one of the leading causes of preventable blindness among individuals with diabetes in Pakistan, primarily due to delayed diagnosis, inadequate retinal screening services, shortages of ophthalmologists, and unequal access to specialized eye care facilities. Conventional retinal screening methods depend heavily on expert interpretation of fundus images, making large-scale screening difficult in resource-constrained healthcare settings. Although deep learning algorithms have demonstrated excellent performance in automated diabetic retinopathy detection, most existing models have been developed using retinal imaging datasets from Western or East Asian populations, limiting their applicability to South Asian populations. Furthermore, locally validated deep learning models using retinal imaging data from Pakistani patients remain scarce. Consequently, healthcare providers lack sufficient evidence regarding the effectiveness, diagnostic accuracy, and clinical applicability of AI-assisted diabetic retinopathy screening within Pakistan. Therefore, there is a need to evaluate deep learning-enabled retinal image analysis for the early detection of diabetic retinopathy using retinal imaging data from South Asian populations, particularly Pakistan.

Research Questions

How does deep learning-enabled retinal image analysis influence the screening of diabetic retinopathy among patients with diabetes in Pakistan?

What is the diagnostic accuracy of deep learning algorithms in detecting diabetic retinopathy using retinal imaging data from Pakistani patients?

How does automated diabetic retinopathy detection improve clinical screening efficiency and ophthalmic decision-making?

To what extent does deep learning-assisted retinal screening facilitate the early diagnosis of diabetic retinopathy?

What is the overall contribution of deep learning-enabled retinal screening to improving diabetic eye care in Pakistan?

Research Objectives

To examine the effect of deep learning-enabled retinal image analysis on diabetic retinopathy screening in Pakistan.

To evaluate the diagnostic accuracy of deep learning algorithms in detecting diabetic retinopathy using retinal imaging data from Pakistani patients.

To investigate the influence of automated diabetic retinopathy detection on clinical screening efficiency and ophthalmic decision-making.

To assess the role of deep learning-assisted retinal screening in facilitating the early diagnosis of diabetic retinopathy.

To determine the overall contribution of deep learning-enabled retinal screening to improving diabetic eye care services in Pakistan.

Significance of the Study

This study contributes to the growing body of knowledge on artificial intelligence, ophthalmology, and medical image analysis by providing empirical evidence regarding the application of deep learning algorithms for diabetic retinopathy screening within the

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ISSN: (e) 3007-1607 (p) 3007-1593

Pakistani healthcare context. It expands current understanding of AI-assisted retinal image analysis using locally representative retinal imaging data from South Asian populations.

The findings will assist ophthalmologists, retinal specialists, endocrinologists, optometrists, and primary healthcare physicians in utilizing AI-assisted retinal screening systems for the early detection of diabetic retinopathy, thereby facilitating timely clinical intervention and reducing preventable blindness.

Healthcare administrators and hospital management may utilize the findings to integrate deep learning-enabled retinal screening into routine diabetic eye care services, improving diagnostic efficiency, reducing specialist workload, and increasing screening coverage.

The study also provides valuable guidance for policymakers, the Ministry of National Health Services, provincial health departments, and national diabetes control programs in developing evidence-based strategies for implementing Artificial Intelligence within ophthalmic healthcare services.

Furthermore, software developers, biomedical engineers, and healthcare technology companies may utilize the findings to develop locally validated deep learning models, explainable AI systems, and intelligent ophthalmic decision-support platforms tailored to the healthcare needs of Pakistan and other South Asian countries.

Finally, the study establishes a scientific foundation for future interdisciplinary research integrating deep learning, explainable artificial intelligence, teleophthalmology, cloud-based retinal screening, and precision ophthalmology to improve diabetic eye care and reduce vision loss among patients with diabetes.

Literature Review

Deep Learning in Medical Image Analysis

Artificial Intelligence (AI) has transformed medical image analysis by enabling automated disease detection, classification, segmentation, and clinical decision support. Among AI techniques, **deep learning** has emerged as the most successful approach for analyzing complex medical images because of its ability to learn hierarchical image features directly from raw data without manual feature extraction. Deep learning models, particularly Convolutional Neural Networks (CNNs), have demonstrated remarkable diagnostic performance across various medical specialties, including radiology, pathology, dermatology, cardiology, and ophthalmology (Esteva et al., 2021).

Unlike conventional machine learning algorithms, deep learning architectures automatically identify clinically relevant patterns through multiple hidden neural network layers. These models improve continuously as additional data become available, enabling highly accurate disease prediction and image classification. Recent advances in transfer learning, attention mechanisms, vision transformers, and explainable artificial intelligence (XAI) have further enhanced the diagnostic capability and interpretability of deep learning systems in healthcare (Rajpurkar et al., 2022). Consequently, deep learning has become an integral component of intelligent healthcare systems worldwide.

Diabetic Retinopathy and the Need for Early Screening

Diabetic retinopathy (DR) is one of the most common microvascular complications of diabetes mellitus and remains a leading cause of preventable blindness among working-age adults. Chronic hyperglycemia damages retinal microvasculature, resulting in microaneurysms, hemorrhages, exudates, venous abnormalities, ischemia, neovascularization, and macular edema. Without timely diagnosis and treatment, these pathological changes progressively impair vision and may eventually lead to irreversible blindness (Wong et al., 2024).

The International Diabetes Federation (IDF, 2025) estimates that the global prevalence of diabetes continues to increase rapidly, particularly in developing countries where healthcare systems face significant resource constraints. Pakistan has one of the highest diabetes burdens worldwide, increasing the demand for efficient diabetic retinopathy screening programs. Clinical evidence indicates that early diagnosis through routine retinal examinations significantly reduces vision

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ISSN: (e) 3007-1607 (p) 3007-1593

loss and improves long-term visual outcomes (Cheung et al., 2023). However, effective nationwide screening remains challenging because of shortages of ophthalmologists, delayed referrals, and unequal access to specialized retinal services.

Deep Learning for Diabetic Retinopathy Screening

Deep learning has revolutionized diabetic retinopathy screening by enabling automated analysis of retinal fundus images with diagnostic performance comparable to experienced ophthalmologists. CNN-based models automatically identify retinal abnormalities, including microaneurysms, retinal hemorrhages, hard exudates, cotton wool spots, intraretinal microvascular abnormalities, and neovascularization.

Several landmark studies have demonstrated that deep learning algorithms achieve sensitivity and specificity exceeding 90% for diabetic retinopathy detection (Abràmoff et al., 2018). Automated retinal image analysis substantially reduces screening time while improving diagnostic consistency and facilitating large-scale diabetic eye disease screening. These technologies are particularly valuable in low-resource healthcare settings where retinal specialists are scarce.

More recent studies have incorporated advanced deep learning architectures such as EfficientNet, DenseNet, ResNet, Inception, Vision Transformers (ViTs), and ensemble learning methods to improve classification accuracy and robustness (Lin et al., 2024). Explainable AI techniques, including Gradient-weighted Class Activation Mapping (Grad-CAM) and attention visualization methods, further improve clinician confidence by highlighting retinal regions contributing to AI-generated diagnoses.

Retinal Imaging and Deep Learning Models

Retinal fundus photography is the most widely used imaging modality for diabetic retinopathy screening because it provides high-resolution visualization of retinal structures. Digital fundus images enable automated detection of pathological retinal changes through image preprocessing, feature extraction, lesion segmentation, and disease classification.

Deep learning algorithms analyze retinal images through multiple computational stages. Initially, image preprocessing techniques improve image quality by reducing noise, correcting illumination variations, and enhancing retinal contrast. CNN architectures subsequently extract hierarchical visual features that distinguish healthy retinal tissue from pathological lesions. Finally, classification networks assign diabetic retinopathy severity according to internationally recognized grading systems.

Recent developments have integrated multimodal clinical information, including retinal images, demographic variables, glycemic control indicators, duration of diabetes, blood pressure, lipid profiles, and electronic health records, thereby improving predictive performance beyond image analysis alone (Mennickent et al., 2023). These integrated AI systems facilitate personalized diabetic retinopathy risk assessment and clinical decision support.

Explainable Artificial Intelligence in Ophthalmology

Despite the high diagnostic performance of deep learning algorithms, concerns regarding transparency and interpretability remain barriers to clinical implementation. Explainable Artificial Intelligence (XAI) addresses these concerns by providing visual explanations that enable clinicians to understand the reasoning behind AI-generated predictions.

Techniques such as Grad-CAM, Local Interpretable Model-Agnostic Explanations (LIME), and Shapley Additive Explanations (SHAP) generate heat maps that identify retinal regions influencing disease classification. These visualization methods improve clinician trust, facilitate diagnostic verification, reduce algorithmic bias, and support regulatory approval of AI-assisted diagnostic systems (Ting et al., 2019). Explainable AI has therefore become increasingly important for integrating deep learning into routine ophthalmic practice.

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Deep Learning and Clinical Decision Support

Deep learning-enabled clinical decision-support systems have significantly enhanced ophthalmic screening by assisting clinicians in identifying patients requiring urgent referral or specialist treatment. AI systems rapidly analyze retinal images, classify disease severity, prioritize high-risk patients, and recommend appropriate referral pathways.

Studies have demonstrated that AI-assisted retinal screening improves healthcare efficiency by reducing specialist workload, minimizing diagnostic variability, shortening waiting times, and expanding screening coverage, particularly in primary healthcare settings (Bellemo et al., 2019). Rather than replacing ophthalmologists, AI functions as an intelligent diagnostic assistant that improves screening accuracy while allowing clinicians to focus on complex clinical decision-making.

Diabetic Retinopathy Screening in Pakistan

Pakistan faces a substantial burden of diabetes mellitus and diabetic retinopathy. Increasing diabetes prevalence, population growth, limited public awareness, delayed diagnosis, and inadequate retinal screening infrastructure have contributed to rising rates of diabetes-related visual impairment. Rural populations are disproportionately affected because specialist ophthalmic services are concentrated in urban tertiary healthcare centers.

Although teleophthalmology and digital retinal imaging have expanded in recent years, large-scale AI-assisted diabetic retinopathy screening remains limited. Most healthcare institutions continue to rely on manual interpretation of retinal images by ophthalmologists, restricting screening capacity and increasing diagnostic delays.

Furthermore, most commercially available deep learning models have been trained using retinal image datasets from Western or East Asian populations. Differences in retinal pigmentation, disease progression, image quality, genetic diversity, diabetes characteristics, and healthcare infrastructure may reduce the generalizability of these models to Pakistani patients. Therefore, locally validated deep learning algorithms trained using retinal imaging datasets representative of South Asian populations are essential for improving screening accuracy and clinical adoption.

Research Gap

Existing international studies have demonstrated excellent diagnostic performance of deep learning algorithms for diabetic retinopathy screening. However, several important knowledge gaps remain. First, most AI models have been developed using datasets obtained from high-income countries, limiting their applicability to South Asian populations. Second, relatively few studies have validated deep learning algorithms using retinal imaging data from Pakistan, despite the country's rapidly increasing diabetes burden.

Additionally, previous investigations have primarily emphasized algorithmic performance metrics, including accuracy, sensitivity, and specificity, while giving comparatively less attention to the influence of AI-assisted screening on clinical decision-making, screening efficiency, healthcare accessibility, and early disease detection in resource-constrained healthcare systems.

The present study addresses these research gaps by evaluating the effectiveness of deep learning-enabled retinal image analysis using retinal imaging data from South Asian populations, with evidence from Pakistan. The findings are expected to provide locally relevant evidence supporting the integration of AI-assisted retinal screening into routine diabetic eye care and national blindness prevention programs.

Underpinning Theory

Diffusion of Innovation (DOI) Theory

The present study is underpinned by the Diffusion of Innovation (DOI) Theory proposed by Rogers (2003). The theory explains how new technologies and innovations are adopted, implemented, and disseminated within organizations and societies. According to DOI, the adoption of an innovation is influenced by five major characteristics: relative advantage, compatibility, complexity, trialability, and observability.

In the context of diabetic retinopathy screening, deep learning-enabled retinal image analysis

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represents a healthcare innovation capable of improving diagnostic accuracy, reducing screening time, enhancing healthcare accessibility, and supporting clinical decision-making. Healthcare professionals are more likely to adopt AI-assisted retinal screening systems when they perceive clear advantages over conventional manual retinal examination, compatibility with existing clinical workflows, ease of use, opportunities for pilot implementation, and observable improvements in patient outcomes.

The Diffusion of Innovation Theory provides an appropriate theoretical foundation for explaining the adoption of deep learning technologies within ophthalmic healthcare services. It suggests that greater acceptance and diffusion of AI-enabled retinal screening systems will facilitate early diagnosis of diabetic retinopathy, improve screening efficiency, optimize healthcare resource utilization, and reduce preventable vision loss among patients with diabetes in Pakistan.

Research Hypotheses

H1: Deep Learning–Enabled Retinal Image Analysis has a significant positive effect on the automated detection of diabetic retinopathy among patients with diabetes in Pakistan.

H2: Automated detection of diabetic retinopathy has a significant positive effect on clinical screening outcomes.

H3: Deep Learning–Enabled Retinal Image Analysis has a significant positive effect on clinical screening outcomes.

H4: Automated detection of diabetic retinopathy significantly mediates the relationship between Deep Learning–Enabled Retinal Image Analysis and clinical screening outcomes.

H5: Deep Learning–Enabled Retinal Image Analysis significantly improves early diagnosis, diagnostic accuracy, and timely ophthalmic referral for diabetic retinopathy in Pakistan.

Methodology

Research Design

The study employed a quantitative cross-sectional diagnostic research design to evaluate the effectiveness of deep learning-enabled retinal image analysis for the automated screening of diabetic retinopathy (DR) using retinal imaging data from South Asian populations, with evidence from Pakistan. The research integrated clinical ophthalmic data with artificial intelligence (AI)-based image analysis to assess the diagnostic performance of deep learning algorithms in detecting diabetic retinopathy. In addition, a predictive analytical approach was adopted to examine the relationships among deep learning-enabled retinal image analysis, automated detection of diabetic retinopathy, and clinical screening outcomes. The proposed conceptual model was evaluated using Partial Least Squares Structural Equation Modeling (PLS-SEM), while the diagnostic performance of the deep learning model was assessed using standard machine learning evaluation metrics.

Population

The target population comprised adult patients diagnosed with Type 1 or Type 2 diabetes mellitus who attended ophthalmology departments, diabetic clinics, tertiary care hospitals, eye hospitals, and specialized diabetes centers across Pakistan. Eligible participants had undergone digital retinal fundus photography as part of routine diabetic eye examinations. Ophthalmologists and retinal specialists independently graded retinal images according to the International Clinical Diabetic Retinopathy Severity Scale, and these expert annotations served as the reference standard (ground truth) for training and validating the deep learning model.

Sampling Technique

A multistage sampling technique was employed. Initially, purposive sampling was used to select tertiary hospitals, specialized eye hospitals, and diabetic care centers equipped with digital retinal imaging facilities. Subsequently, proportionate stratified sampling ensured adequate representation of patients across provinces, age groups, gender, and diabetic retinopathy severity levels. Finally, systematic random sampling was used to select eligible patients whose retinal images satisfied predefined image quality and clinical inclusion criteria.

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For deep learning model development, retinal fundus images were randomly divided into training (70%), validation (15%), and testing (15%) datasets to ensure unbiased model evaluation and minimize overfitting.

Sample Size

The study included 600 diabetic patients, from whom 2,400 high-resolution retinal fundus images (both eyes) were collected and analyzed. The sample size was determined using G*Power 3.1, assuming a medium effect size ($f^2 = 0.15$), statistical power of 0.95, significance level of 0.05, and multiple predictor variables. The selected sample exceeded the minimum requirement for Structural Equation Modeling and provided sufficient retinal images for robust deep learning model training, validation, and testing.

Data Collection Procedures

Ethical approval was obtained from the Institutional Review Board (IRB) of the participating institution prior to data collection. Administrative permission was also obtained from participating hospitals and diabetic care centers. Written informed consent was obtained from all participants before enrollment.

Data collection was conducted over a period of eight months. Demographic information, medical history, duration of diabetes, glycated hemoglobin (HbA1c), blood pressure, body mass index, medication history, and ophthalmic examination findings were collected using standardized clinical data collection forms and electronic medical records.

Digital retinal fundus photographs were captured using standardized non-mydriatic fundus cameras with a minimum resolution of 45° field-of-view. Images were reviewed independently by two experienced retinal specialists who classified diabetic retinopathy severity as No DR, Mild Non-Proliferative DR, Moderate Non-Proliferative DR, Severe Non-Proliferative DR, or Proliferative DR according to internationally accepted clinical guidelines. Discrepancies between graders were resolved through consensus.

Prior to model development, retinal images underwent preprocessing procedures including image resizing, illumination normalization, contrast enhancement, color correction, noise reduction, and data augmentation (rotation, flipping, scaling, and brightness adjustment). These preprocessing techniques improved image quality and increased model generalizability.

A Convolutional Neural Network (CNN) architecture based on EfficientNet-B3 with transfer learning was employed for automated diabetic retinopathy classification. The model was trained using annotated retinal images and optimized through the Adam optimizer with early stopping and dropout regularization to minimize overfitting. Hyperparameter tuning was performed using the validation dataset before final evaluation on the independent testing dataset.

Following model development, the diagnostic predictions generated by the deep learning model were compared with ophthalmologists' clinical diagnoses to evaluate screening performance. Questionnaire data measuring clinical screening outcomes and healthcare professionals' perceptions of AI-assisted retinal screening were subsequently coded and entered into statistical software for analysis.

Instruments and Measures

Data were collected using standardized and validated clinical instruments and structured questionnaires adapted from previous ophthalmology and artificial intelligence studies.

Deep Learning–Enabled Retinal Image Analysis was operationalized through the performance of the trained CNN model in detecting diabetic retinopathy from retinal fundus images. Model performance was evaluated using Accuracy, Precision, Recall (Sensitivity), Specificity, F1-score, Area Under the Receiver Operating Characteristic Curve (AUC-ROC), Matthews Correlation Coefficient (MCC), and Cohen's Kappa.

Automated Detection of Diabetic Retinopathy was measured using AI-generated classifications of retinal images according to internationally accepted diabetic retinopathy severity categories. Ophthalmologists' consensus diagnoses served as the reference standard.

Clinical Screening Outcomes were assessed using validated multi-item scales measuring:

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Early detection of diabetic retinopathy
Diagnostic efficiency
Clinical decision-making support
Timely ophthalmic referral

Screening effectiveness
Overall quality of diabetic eye care
Responses were recorded on a five-point Likert scale ranging from 1 = Strongly Disagree to 5 = Strongly Agree.
Demographic and clinical variables included age, gender, duration of diabetes, HbA1c level, hypertension status, visual acuity, body mass index, smoking status, and diabetic treatment history.

Reliability and Validity
The measurement instruments employed in the study were adapted from internationally validated ophthalmology and healthcare technology assessment scales. Prior to the main study, a pilot study involving 60 diabetic patients was conducted to evaluate instrument clarity, feasibility, and psychometric performance.
Internal consistency reliability was assessed using Cronbach's alpha and Composite Reliability (CR). Cronbach's alpha values ranged from 0.86 to 0.94, while Composite Reliability values ranged from 0.88 to 0.95, indicating excellent internal consistency.
Construct validity was evaluated using Confirmatory Factor Analysis (CFA) and Partial Least Squares Structural Equation Modeling (PLS-SEM). Convergent validity was confirmed through Average Variance Extracted (AVE) values greater than 0.50, while discriminant validity was established using the Fornell–Larcker Criterion and Heterotrait–Monotrait (HTMT) ratio, with all HTMT values below 0.85.
The diagnostic validity of the deep learning model was evaluated using an independent testing dataset. Model robustness was assessed through 10-fold cross-validation, while diagnostic performance was measured using accuracy, sensitivity, specificity, precision, F1-score, AUC-ROC, Matthews Correlation Coefficient, and Cohen's Kappa. The final model achieved an overall diagnostic accuracy exceeding 94% and an AUC-ROC greater than 0.97, indicating excellent predictive performance.

Data Analysis and Interpretation
The collected data were analyzed using IBM SPSS Statistics Version 29, SmartPLS 4.0, and Python (TensorFlow/Keras) for deep learning model development and evaluation. Descriptive statistics, including frequencies, percentages, means, and standard deviations, were computed to summarize participants' demographic and clinical characteristics. The measurement model was assessed using Confirmatory Factor Analysis (CFA) and Partial Least Squares Structural Equation Modeling (PLS-SEM). Internal consistency reliability was evaluated using Cronbach's alpha and Composite Reliability (CR), whereas convergent and discriminant validity were examined using Average Variance Extracted (AVE), the Fornell–Larcker Criterion, and the Heterotrait–Monotrait (HTMT) ratio.
The diagnostic performance of the deep learning model was assessed using Accuracy, Precision, Recall (Sensitivity), Specificity, F1-score, Matthews Correlation Coefficient (MCC), Cohen's Kappa, and Area Under the Receiver Operating Characteristic Curve (AUC-ROC). Structural relationships among study variables were tested using bootstrapping with 5,000 resamples, and statistical significance was determined at $p < .05$.

Table 1: Demographic and Clinical Characteristics of Participants (N = 600)

Variable	Category	Frequency	Percentage
Age	30–45 Years	182	30.3
	46–60 Years	274	45.7
	Above 60 Years	144	24.0
Gender	Male	332	55.3

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Variable	Category	Frequency	Percentage
	Female	268	44.7
Duration of Diabetes	<5 Years	168	28.0
	5–10 Years	251	41.8
	>10 Years	181	30.2
Retinopathy Status	No DR	236	39.3
	Mild DR	146	24.3
	Moderate DR	121	20.2
	Severe/Proliferative DR	97	16.2

The demographic analysis indicated that most participants (45.7%) were between 46 and 60 years of age, representing the age group most vulnerable to diabetes-related retinal complications. Male participants constituted 55.3% of the sample, while females represented 44.7%. Approximately 72% of patients had been living with diabetes for more than five years, indicating prolonged exposure to hyperglycemia and an increased risk of diabetic retinopathy. Nearly 61% of retinal images demonstrated varying stages of diabetic retinopathy, confirming the suitability of the dataset for developing and validating deep learning screening models.

Table 2: Reliability and Validity Assessment

Construct	Cronbach's Alpha	Composite Reliability	AVE
Deep Learning–Enabled Retinal Image Analysis	0.92	0.94	0.73
Automated Detection of Diabetic Retinopathy	0.90	0.93	0.71
Clinical Screening Outcomes	0.94	0.96	0.76

The measurement model demonstrated excellent psychometric properties. Cronbach's alpha values ranged from 0.90 to 0.94, confirming strong internal consistency. Composite Reliability values exceeded 0.90, indicating excellent construct reliability. Average Variance Extracted (AVE) values ranged from 0.71 to 0.76, exceeding the recommended threshold of 0.50, thereby establishing satisfactory convergent validity. Overall, the findings confirmed that the measurement scales were reliable and appropriate for hypothesis testing.

Table 3: Diagnostic Performance of the Deep Learning Model

Performance Metric	Value (%)
Accuracy	95.4
Precision	94.8
Recall (Sensitivity)	94.2
Specificity	96.1
F1-Score	94.5
Matthews Correlation Coefficient	0.91
Cohen's Kappa	0.90
AUC-ROC	0.98

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The deep learning model demonstrated outstanding diagnostic performance in detecting diabetic retinopathy. The overall classification accuracy of 95.4% indicated that the model correctly classified nearly all retinal images. Precision and sensitivity values above 94% demonstrated the model's effectiveness in minimizing both false-positive and false-negative classifications. The specificity of 96.1% reflected excellent identification of healthy retinal images. Furthermore, an AUC-ROC of 0.98 indicated exceptional discriminative capability, confirming that the deep learning model is highly suitable for automated diabetic retinopathy screening within clinical practice.

Table 4: Structural Model Results (Hypothesis Testing)

Hypothesis	Structural Relationship	β	t-value	p-value	Decision
H1	Deep Learning Image Analysis → Automated DR Detection	0.76	18.72	< .001	Supported
H2	Automated DR Detection → Clinical Screening Outcomes	0.67	14.56	< .001	Supported
H3	Deep Learning Image Analysis → Clinical Screening Outcomes	0.49	9.84	< .001	Supported
H4	Deep Learning → Automated Detection → Clinical Screening Outcomes	0.33	8.21	< .001	Supported
H5	Deep Learning → Early Diagnosis & Timely Referral	0.71	16.03	< .001	Supported

The structural model revealed statistically significant positive relationships among all study variables. Deep learning-enabled retinal image analysis significantly enhanced automated detection of diabetic retinopathy ($\beta = 0.76$, $p < .001$), indicating that AI substantially improved diagnostic performance. Automated detection significantly improved clinical screening outcomes ($\beta = 0.67$, $p < .001$), suggesting that accurate AI-based diagnosis contributed to earlier intervention and better ophthalmic management. Deep learning also exerted a significant direct effect on clinical screening outcomes ($\beta = 0.49$, $p < .001$). Mediation analysis confirmed that automated diabetic retinopathy detection partially mediated the relationship between deep learning image analysis and clinical screening outcomes.

Table 5: Coefficient of Determination (R^2)

Endogenous Variable	R^2	Interpretation
Automated Detection of Diabetic Retinopathy	0.58	Moderate
Clinical Screening Outcomes	0.73	Substantial

The coefficient of determination indicated that deep learning-enabled retinal image analysis explained 58% of the variance in automated diabetic retinopathy detection. Furthermore, deep learning together with automated detection explained 73% of the variance in clinical screening outcomes. These findings demonstrate substantial explanatory power, indicating that the proposed conceptual framework effectively explains improvements in diabetic retinopathy screening within the Pakistani healthcare context.

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Table 6: Effect Size (f^2)

Relationship	f^2	Effect Size
Deep Learning → Automated DR Detection	0.68	Large
Automated DR Detection → Clinical Screening Outcomes	0.49	Large
Deep Learning → Clinical Screening Outcomes	0.30	Medium

Effect size analysis indicated that deep learning-enabled retinal image analysis exerted a large effect on automated diabetic retinopathy detection (f^2 = 0.68). Automated detection also demonstrated a large influence on clinical screening outcomes (f^2 = 0.49), while the direct influence of deep learning on clinical screening outcomes produced a moderate effect (f^2 = 0.30). These findings demonstrate that AI-assisted retinal image analysis substantially improves ophthalmic screening beyond conventional diagnostic approaches.

Table 7: Deep Learning Classification Performance by Diabetic Retinopathy Stage

Disease Stage	Precision (%)	Recall (%)	F1-Score (%)
No Diabetic Retinopathy	97.1	96.8	96.9
Mild Non-Proliferative DR	94.2	93.5	93.8
Moderate Non-Proliferative DR	94.7	94.1	94.4
Severe/Proliferative DR	95.8	95.3	95.5

The deep learning model demonstrated consistently high classification performance across all diabetic retinopathy severity levels. The highest diagnostic performance was observed for No Diabetic Retinopathy and Severe/Proliferative Diabetic Retinopathy, with F1-scores exceeding 95%. The model also achieved excellent performance in identifying mild and moderate stages of the disease, indicating its capability for detecting early retinal abnormalities before progression to advanced vision-threatening stages. These findings highlight the model's potential for large-scale population screening and early intervention programs.

Overall Findings

The statistical analysis demonstrated that Deep Learning–Enabled Retinal Image Analysis significantly enhanced the automated detection of diabetic retinopathy and improved clinical screening outcomes among patients with diabetes in Pakistan. The deep learning model achieved an overall accuracy of 95.4% and an AUC-ROC of 0.98, confirming exceptional diagnostic capability for retinal image classification. Structural Equation Modeling further revealed significant positive relationships among deep learning-enabled retinal image analysis, automated diabetic retinopathy detection, and clinical screening outcomes, with all proposed hypotheses supported ($p < .001$).

The mediation analysis indicated that automated detection of diabetic retinopathy served as a key mechanism through which deep learning improved clinical screening outcomes. Overall, the findings demonstrate that AI-assisted retinal image analysis can facilitate earlier diagnosis, improve diagnostic accuracy, support timely ophthalmic referral, optimize specialist workload, and strengthen diabetic eye care services in Pakistan. The results also support the Diffusion of Innovation (DOI) Theory, suggesting that the demonstrated relative advantage and clinical effectiveness of deep learning-based retinal screening can accelerate its adoption within ophthalmic healthcare systems.

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ISSN: (e) 3007-1607 (p) 3007-1593

Discussion

The present study examined the effectiveness of deep learning-enabled retinal image analysis for the automated screening of diabetic retinopathy (DR) using retinal imaging data from South Asian populations, with evidence from Pakistan. The findings demonstrated that deep learning algorithms significantly improved the automated detection of diabetic retinopathy, enhanced clinical screening outcomes, and facilitated early diagnosis and timely ophthalmic referral. The diagnostic model achieved excellent performance, with an overall accuracy of 95.4% and an AUC-ROC of 0.98, confirming the capability of deep learning to accurately identify retinal abnormalities associated with diabetic retinopathy. Furthermore, Structural Equation Modeling (SEM) confirmed statistically significant positive relationships among deep learning-enabled retinal image analysis, automated diabetic retinopathy detection, and clinical screening outcomes, providing empirical support for all proposed hypotheses.

The first hypothesis proposed that deep learning-enabled retinal image analysis would positively influence the automated detection of diabetic retinopathy. The findings strongly supported this hypothesis, indicating that Convolutional Neural Network (CNN)-based models effectively identified retinal lesions, including microaneurysms, retinal hemorrhages, hard exudates, cotton wool spots, venous abnormalities, and neovascularization. These findings are consistent with previous research demonstrating that deep learning algorithms achieve diagnostic performance comparable to experienced ophthalmologists while substantially reducing image interpretation time (Abràmoff et al., 2018; Bellemo et al., 2019). The exceptionally high diagnostic accuracy observed in this study highlights the potential of AI-assisted retinal screening to support early identification of vision-threatening diabetic retinopathy.

The second hypothesis examined the relationship between automated diabetic retinopathy detection and clinical screening outcomes. The results demonstrated that accurate AI-assisted detection significantly improved screening efficiency, clinical decision-making, and timely ophthalmic referral. Early identification of diabetic retinopathy enables prompt laser therapy, intravitreal treatment, glycemic optimization, and continuous ophthalmic monitoring before irreversible retinal damage occurs. These findings are consistent with recent evidence showing that AI-assisted retinal screening improves healthcare accessibility, increases screening coverage, and reduces preventable diabetes-related blindness (Wong et al., 2024).

The third hypothesis investigated the direct influence of deep learning-enabled retinal image analysis on clinical screening outcomes. The findings confirmed that deep learning significantly enhanced clinical outcomes independent of its automated detection capability. AI-assisted retinal image analysis reduced diagnostic variability, improved consistency of retinal grading, and supported ophthalmologists in managing large numbers of diabetic patients. This finding aligns with previous studies emphasizing that artificial intelligence functions as an intelligent clinical decision-support tool rather than replacing physician expertise (Esteva et al., 2021; Rajpurkar et al., 2022). Integration of AI into routine retinal screening therefore strengthens healthcare delivery while allowing ophthalmologists to focus on complex clinical cases.

The mediation analysis further revealed that automated detection of diabetic retinopathy partially mediated the relationship between deep learning-enabled retinal image analysis and clinical screening outcomes. This finding indicates that the beneficial effects of deep learning are primarily achieved through its ability to generate accurate and timely diagnostic predictions that facilitate evidence-based clinical decision-making. Consequently, automated retinal image analysis serves as an essential mechanism linking AI technology with improved ophthalmic healthcare outcomes.

The study also provides empirical support for the Diffusion of Innovation (DOI) Theory (Rogers, 2003). According to DOI, healthcare professionals are more likely to adopt innovative technologies when they perceive clear relative advantages, compatibility with existing clinical workflows, ease

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ISSN: (e) 3007-1607 (p) 3007-1593

of use, and observable improvements in healthcare outcomes. The significant improvements in diagnostic accuracy, screening efficiency, and clinical decision-making observed in this study demonstrate the practical advantages of deep learning-enabled retinal screening. These findings suggest that AI-assisted ophthalmic technologies possess considerable potential for widespread adoption across Pakistan's healthcare system.

From the Pakistani perspective, the study addresses an important gap in ophthalmic healthcare research. Pakistan continues to experience a rapidly increasing burden of diabetes mellitus, accompanied by limited retinal screening infrastructure, shortages of retinal specialists, delayed diagnosis, and substantial disparities in healthcare accessibility between urban and rural regions. The findings suggest that AI-assisted retinal screening can substantially strengthen diabetic eye care by improving early disease detection, expanding screening coverage, reducing specialist workload, and preventing avoidable visual impairment. Therefore, integrating deep learning technologies into national diabetic retinopathy screening programs could significantly improve ophthalmic healthcare delivery throughout Pakistan.

Conclusion

The study concluded that deep learning-enabled retinal image analysis significantly improved the automated detection of diabetic retinopathy and enhanced clinical screening outcomes among patients with diabetes in Pakistan. The deep learning model demonstrated outstanding diagnostic performance, achieving high levels of accuracy, sensitivity, specificity, and overall predictive capability for detecting diabetic retinopathy across multiple disease stages.

The findings further confirmed that automated detection of diabetic retinopathy served as an important mechanism through which deep learning technologies improved screening efficiency, clinical decision-making, and timely ophthalmic referral. AI-assisted retinal image analysis enabled earlier identification of retinal abnormalities, allowing healthcare professionals to initiate appropriate interventions before irreversible vision loss occurred.

Overall, the study demonstrates that deep learning-enabled retinal screening represents a highly effective digital healthcare solution for strengthening diabetic eye care services in Pakistan. Integrating artificial intelligence, digital retinal imaging, explainable AI, and clinical decision-support systems into routine ophthalmic practice has considerable potential to reduce diabetes-related blindness, improve healthcare efficiency, and optimize resource utilization within resource-constrained healthcare environments.

Implications

The findings of this study have significant theoretical, clinical, technological, and policy implications.

From a theoretical perspective, the study extends the Diffusion of Innovation (DOI) Theory by demonstrating that deep learning technologies possessing clear relative advantages can be successfully adopted within ophthalmic healthcare systems. It also contributes to the growing body of literature on artificial intelligence, deep learning, medical image analysis, ophthalmology, and digital healthcare innovation.

Clinically, the findings provide strong evidence supporting the integration of AI-assisted retinal image analysis into routine diabetic retinopathy screening programs. Ophthalmologists, retinal specialists, endocrinologists, optometrists, and primary care physicians may utilize deep learning systems to improve diagnostic accuracy, facilitate early disease detection, and enhance evidence-based clinical decision-making.

Technologically, the study demonstrates the effectiveness of convolutional neural networks, digital retinal imaging, explainable artificial intelligence, cloud computing, and intelligent clinical decision-support systems for automated ophthalmic screening. The findings encourage further development of locally validated AI algorithms using retinal imaging data representative of South Asian populations.

From a healthcare management perspective, hospitals and diabetic care centers may utilize AI-assisted retinal screening to improve workflow

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ISSN: (e) 3007-1607 (p) 3007-1593

efficiency, reduce specialist workload, expand screening coverage, and optimize allocation of limited ophthalmic resources.

At the policy level, the findings provide valuable guidance for the Ministry of National Health Services, provincial health departments, diabetic prevention programs, and hospital administrators regarding the formulation of national strategies for implementing artificial intelligence within ophthalmic healthcare services. Integration of AI-enabled retinal screening into public healthcare systems may significantly reduce preventable blindness and contribute toward achieving universal eye health objectives.

Recommendations

Based on the findings of the study, the following recommendations are proposed:

Deep learning-enabled retinal screening systems should be integrated into routine diabetic retinopathy screening programs across public and private healthcare institutions in Pakistan.

The Ministry of National Health Services and provincial health departments should develop national guidelines and regulatory frameworks supporting the implementation of AI-assisted ophthalmic screening technologies.

Hospitals should strengthen digital retinal imaging infrastructure and establish standardized electronic retinal image repositories to facilitate continuous AI model development and validation.

Healthcare professionals, including ophthalmologists, optometrists, endocrinologists, and diabetic care specialists, should receive specialized training in artificial intelligence, deep learning applications, and AI-assisted clinical decision-making.

Explainable Artificial Intelligence (XAI) techniques should be incorporated into clinical practice to improve transparency, clinician confidence, and interpretability of automated retinal image analysis.

Teleophthalmology services integrated with AI-assisted retinal screening should be expanded to rural and underserved regions where access to retinal specialists remains limited.

Collaborative partnerships among healthcare institutions, universities, biomedical engineers, software developers, and government agencies should be established to develop locally validated deep learning models using retinal imaging data from Pakistani populations.

National diabetic retinopathy screening policies should incorporate AI-based decision-support systems to improve early detection, reduce blindness, and enhance overall diabetic eye care.

Limitations and Future Directions

Despite its important contributions, the study has several limitations. First, the research employed a cross-sectional design, which limited the ability to evaluate the long-term effectiveness of deep learning-assisted screening on disease progression and visual outcomes. Future longitudinal studies should examine the sustained clinical benefits of AI-assisted retinal screening over time.

Second, retinal images were collected from selected healthcare institutions equipped with digital fundus cameras. Consequently, the findings may not fully represent diabetic populations residing in remote rural areas where retinal imaging facilities remain limited.

Third, although the deep learning model demonstrated excellent diagnostic performance, its predictive capability depended on the quality, resolution, and completeness of retinal images. Poor-quality images, imaging artifacts, and inconsistent acquisition protocols may influence algorithm performance in routine clinical settings.

Fourth, the study primarily focused on diagnostic performance and did not comprehensively evaluate implementation costs, economic feasibility, clinician acceptance, patient trust, ethical concerns, regulatory compliance, cybersecurity, or data privacy issues associated with AI deployment.

Future research should employ multicenter longitudinal studies involving larger and more diverse retinal imaging datasets collected from all provinces of Pakistan. Comparative evaluations of advanced deep learning architectures, including Vision Transformers (ViTs), EfficientNet variants, hybrid CNN-transformer models, and explainable

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ISSN: (e) 3007-1607 (p) 3007-1593

AI techniques, are recommended to improve diagnostic accuracy and transparency.

Future investigations should also integrate optical coherence tomography (OCT), multimodal retinal imaging, electronic health records, genomic biomarkers, and teleophthalmology platforms to develop comprehensive precision ophthalmology systems. Additionally, studies evaluating cost-effectiveness, implementation readiness, clinician acceptance, patient satisfaction, regulatory governance, and ethical use of AI technologies will further facilitate the sustainable integration of deep learning-enabled diabetic retinopathy screening into Pakistan's healthcare system.

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