Received: 28 February 2025 | Revised: 26 June 2025 | Accepted: 26 August 2025 | Published online: 17 October 2025

RESEARCH ARTICLE

Artificial Intelligence and Applications
2025, Vol. 00(00) 1–14
DOI: 10.47852/bonviewAIA52025555

BON VIEW PUBLISHING

Predictive Artificial Intelligence Models in the Early Identification of Diabetic Retinopathy

Gabriel Silva-Atencio[1,*], Edwin Acuña-Acuña[1] and Maziar Lalezary[2]

[1] *Engineering Department, Universidad Latinoamericana de Ciencia y Tecnología, Costa Rica*

[2] *Doctor Retina, Beverly Hills, USA*

Abstract: This study aims to evaluate the precision of a mathematical system using Artificial Intelligence (AI) in forecasting retinal anomalies linked to Diabetic Retinopathy (DR). The study adopted a quantitative, descriptive, and exploratory approach. A standard sample of 1684 ocular fundus images was analyzed. These images were divided into two groups: Class 0 for healthy eyes and Class 1 for eyes with DR. A finite population model was used to determine the sample size, which came from a publicly available database. Experts in the field validated the results obtained to guarantee the accuracy of the findings. The study used the Vision AI solution to train and test 3,752 publicly available medical images. During the training phase, an independent set of 1,684 medical images that had not been included in the training sample was selected. The sample was then classified into two groups: (1) Class 0 for healthy eyes; and (2) Class 1 for eyes with DR. To evaluate the model's performance, a statistical analysis was conducted using key metrics such as accuracy, sensitivity, specificity, F1-score, and confusion matrix. The AI-based model demonstrated an accuracy exceeding 90%, with statistically significant findings supporting the study's hypothesis. The findings highlight the model's ability to detect and predict DR in real time, improving the accuracy of disease detection.

Keywords: Artificial intelligence, diabetic retinopathy, early detection, predictive model, retinal abnormalities

1. Introduction

Artificial intelligence (AI) is not a technology far removed from everyday life. Autonomous cars and voice-recognition assistants are already part of modern society. What futurists imagined in television shows is now part of our reality [1]. The reach and advantages of this technology extend beyond expectations, with applications that support decision-making in mission-critical systems, particularly in the healthcare sector. In this field, AI has helped address complex challenges, including cost reduction and faster response times. Danieli et al. [2] emphasize that AI-based applications allow for highly accurate and efficient detection of autoimmune diseases. This approach shortens response times and reduces human bias, leading to more timely and effective diagnoses. Al-Worafi [3] underscores the need of using emerging technologies to detect and diagnose diseases with enhanced sensitivity, specificity, robustness, and simplicity, especially in resource-constrained settings. Technology contributes to reducing human error caused by biases in knowledge, experience, or expertise in data interpretation [4].

The health industry has to deal with more complex, hard-to-treat ailments contributed by the advent of the digital age. The Pan American Health Organization (PAHO) emphasizes this by claiming a 25% increase in diabetes prevalence over the previous decade [5]. This increase shows the importance of finding new ways and instruments to quickly and accurately identify problems, especially in low-income areas where access to full ophthalmologic examinations and modern imaging equipment is limited. Moreover, there often exists a deficiency of professionals with the requisite knowledge, experience, and skill to promptly diagnose ocular illnesses [6], presenting a considerable problem for contemporary medicine.

In addition, conventional screening procedures such as direct ophthalmoscopy and fluorescein angiography typically require the pupils to be dilated, are time-consuming, and dependent on the availability of highly qualified ophthalmologists. These techniques are often not available in low- and middle-income nations because they are too expensive, the infrastructure is not good enough, or they are too far away, which leads to delayed diagnosis and more cases of blindness that might have been avoided [7]. These restrictions highlight the need for scalable, cost-effective, and automated systems that can function correctly in primary care environments without direct professional involvement.

Diabetic Retinopathy (DR) is a prevalent complication of diabetes that may result in vision loss if not properly identified and managed. Loffler et al. [8] and Wang [9] found that one-third of those with diabetes had pathological abnormalities in the retina due to changes in the blood vessels. The researchers also spoke about how hard it is to find, understand, assess, and predict this issue, which might lead to full or partial vision loss if not identified immediately.

In light of this, screening becomes an essential remedy. However, more than 80% of patients who undergo screening show no evidence of the condition, which means that a significant amount of money is spent on monitoring individuals who are actually healthy. This is further exacerbated by a shortage of professionals trained to make accurate diagnoses, underscoring the urgent need for new, effective, and

*Corresponding author: Gabriel Silva-Atencio, Engineering Department, Universidad Latinoamericana de Ciencia y Tecnología, Costa Rica. Email: gsilvaa468@ulacit.ed.cr

accessible screening tools and methods. Kawas et al. [10] and Zhang et al. [11] mention that the use of advanced techniques can improve the accuracy of ophthalmic disease diagnoses, speeding up diagnoses and reducing the likelihood of human error.

Felix et al. [12] and Fernandes et al. [13] agree that the use of algorithms based on mathematical models not only improves accuracy but also significantly reduces diagnostic costs and the need for specialized interventions. Rawat et al. [14] highlight the performance of deep convolutional neural network (CNN) models on the Vision AI platform, improving response times and accuracy. The level of processing, prediction, and decision of ophthalmologic images within the model offer superior efficiency in the detection of a pathology compared to similar results generated by a clinical analyst manually.

Likewise, Capponi et al. [15] argue in their study that if it were possible to train AI using advanced techniques for the diagnosis and treatment of ophthalmologic pathologies, it would allow for the timely prevention of diseases in real time. This creates a technical and scientific challenge related to the use of automated data management models for decision-making in mission-critical systems. In this regard, Dokeroglu et al. [16] and Wang and Naveed [17] report that the use of AI would enable the rapid and accurate detection of DR, along with other eye diseases. Therefore, given this approach, the following research question emerges and serves as the foundation of the present study: Would the use of mathematical algorithms based on AI, which process data from the retinas of ophthalmologic patients, allow the detection of positive patients with DR disease with a level of accuracy greater than 90% confidence?

In this regard, Omer [18] and Silk et al. [19] highlight in their research that the use of data management models not only optimizes diagnoses but also provides improved accessibility and efficiency in patient care. Fernandes et al. [13] argue that the use of AI applications increases disease prevention in different areas of the healthcare sector. Shu et al. [20] reinforce emerging technologies in the field of ophthalmology and their potential to significantly improve global eye health. Osto et al. [21] highlight both the practical and socioeconomic benefits of using AI in decision-making processes for diagnosing patient pathologies. All of the above establishes a valid argument supporting the viability and feasibility of the proposed study. Finally, based on the findings of the present study, the aim is to contribute to the state of the art using a model based on emerging technologies.

2. Literature Review

In the era of modern medicine, DR presents itself as one of the most important challenges to be overcome by human beings. Fernandes et al. [13] point out that the increasing global prevalence of this disease reflects a worldwide epidemic of diabetes, which affects more than 422 million people in 2023; one of the main causes is the sedentary lifestyle and inadequate diets that have contributed to the increase in the incidence of this disease, mainly in low-income countries with limitations in specialized medical care. Liu et al. [22] and Zhang et al. [23] emphasize that this situation puts considerable pressure on public health systems, as there are insufficient resources and qualified personnel to provide adequate care.

This global scenario underscores the need to adopt comprehensive strategies in the health sector that address preventive, timely, and severe complications to mitigate the impact of this disease worldwide [24] as DR is one of the diabetic diseases with greater complications, severity, and incidence, due to the progressive deterioration of blood vessels in the retina. Thus, Yuan et al. [25] describe that the first symptoms of this disease include abnormalities such as microaneurysms, which can progress to more severe conditions such as diabetic macular edema and the proliferation of new blood vessels, causing hemorrhages, retinal detachment, and blindness. For this reason, Rahmani et al. [26] highlight the importance of implementing new tools, mechanisms, or methods that allow the generation of accurate, timely, and real-time diagnoses to prevent the evolution of this pathology and its effects.

However, in modern ophthalmology, addressing this great challenge requires advanced technological tools capable of distinguishing between healthy eyes and those affected by DR. Irfan et al. [27] highlight in their findings that the use of technologies to facilitate the capture of retinal images for analysis and interpretation plays a key role in the early detection and diagnosis of ophthalmologic diseases. Therefore, this innovative approach would not only raise the standards in diagnosis but also drive earlier and more personalized interventions, thus improving the patient's quality of life.

Donniacuo et al. [28] and Fernandes et al. [13] agree that these images are essential elements, that should be considered by clinical analysts to identify the pathology of a healthy eye. According to Flaxel et al. [29], it is crucial to categorize, classify, and determine the severity of DR in order to establish appropriate therapy. The international clinical disease severity scale for DR is the scientific evidence and does not require specialized tests such as optical coherence tomography or fluorescein angiography as it facilitates communication between caregivers of diabetic patients and promotes more effective management of DR, being able to prevent more than 90% of cases of vision loss.

Meregalli Falerni et al. [30] and Wang [9] highlight in their studies the relevance of the evolution of ophthalmologic diagnosis from clinical features, using visual indicators, which facilitates an in-depth understanding of complex diseases. However, Rahmani et al. [26] emphasize the crucial role that an emerging technology such as AI could play in ocular diagnostic assessment and accuracy.

AI is undoubtedly gaining ground as a tool that enables the identification, management, analysis, and interpretation of complex data in health sciences. Likewise, Mansour et al. [31] emphasize that this technology can process large volumes of data at a low cost, in real-time, and with a reduced margin of error, which makes it a primary tool for early detection and classification of diseases without the need for invasive procedures. Bahreyni et al. [32] and Fernandes et al. [13] emphasize that the use of CNN-based models enhances the diagnostic process by enabling faster, more efficient, effective, and high-quality medical diagnoses.

However, in the field of DR, this technology represents a significant advance allowing more accessible and sustainable diagnoses in populations previously disadvantaged by the lack of specialized medical resources. Omer [18] states that the use of AI allows democratizing access to quality medical care and marks a radical change in the way eye care is approached globally, while Zheng et al. [33] state that this technology serves to obtain significant improvements in the treatment of diabetic complications; thus, raising the quality of medical care and improving patient outcomes [30].

This technological advance, such as AI technology, can contribute to the field of medical diagnostics; however, it would not be feasible without its ability to identify, interpret, and analyze medical images because it accurately determines anomalies that cannot be recognized through conventional diagnostic methods. Dorweiler et al. [34], Martínez-Gutiérrez et al. [35], and Osto et al. [21] agree that the evaluation of medical images allowed classifying different ophthalmologic pathologies with a higher level of accuracy than a clinical analyst who performs it manually; this is an aspect of special relevance in environments characterized by limited access to medical specialists and advanced technology, as AI can contribute as an innovative element to transform patient care [36].

In this context, Abulfadl et al. [37] and Fernandes et al. [13] underscore the need of a comprehensive evaluation of the structural integrity of the retina for the identification of advanced vascular anomalies. Furthermore, fundus evaluation is a crucial process that augments these methodologies by allowing direct monitoring of retinal status and fostering the swift identification of any structural or vascular alterations [29].

Osto et al. [21] and Zhu et al. [38] contend that the utilization of complementary medical diagnostic techniques would facilitate improved accessibility and early detection of DR, thereby enhancing diagnostic efficiency in contemporary clinical environments, given the limitations of traditional methods in certain clinical contexts. Doctors can easily and cheaply check the state of the retina by looking at the fundus. This makes it simpler to discover abnormalities early. This strategy is particularly useful in places where access to modern technology may be restricted. Furthermore, the use of AI overcomes traditional limitations by facilitating the expansion of fundus assessments in a more accurate, timely manner and to a wider population in real-time [39]. Therefore, the integration of traditional diagnostic techniques with technological innovations such as AI is paramount to managing various scenarios of DR-associated pathologies [40].

Additionally, Liu et al. [22] and Rahmani et al. [26] highlight that currently, traditional DR diagnostic techniques present additional challenges such as limited accessibility, high costs, and the invasive nature of the technique, which hinder the effectiveness and early detection of DR. Thus AI-based predictive models offer a more accessible, economical, and scalable detection of the disease [36].

The use of AI-based predictive models for clinical diagnosis of DR builds on the use of DL-based techniques because they facilitate the analysis of large volumes of data (medical images) for accurate identification of pathological patterns [10, 32]. This gives accurate diagnoses in remote areas and reduces the incidence of serious complications by 30% [41].

Among the techniques contained in DL, the ResNet50 architecture stands out, which is a platform designed from the deep CNN model, for the classification of ophthalmological images. Because it has a structure with residual connections, for the training of models of great depth, this makes the gradients that flow directly through the layers. Thus addressing the challenge of gradient fading in deeper networks, which contributes to optimizing both the sensitivity and specificity of the diagnosis and treatment strategy [17, 40, 42].

Kawas et al. [10] and Kumawat and Chawla [43] highlight among the potential benefits of the platform its ability to manage cases individually for patients, which enables adaptation to their needs, given the possible limitations of resources, tools, or materials. This manages to establish a synergy between clinical analysts and ResNet50 to establish a solid foundation in clinical decision-making processes based on evidence and informed data [19].

The level of precision used by the ResNet50 architecture is essential to facilitate early interventions and prevent the progression of DR; for this reason, its structure is composed of a set of mathematical models and statistical analysis to identify, analyze, and categorize medical images for classification. Capponi et al. [15], Chiaramonti and Testa [40], and Nam et al. [44] argue that the level of accuracy in automated systems for data management is crucial, as these systems enable early intervention in chronic and progressive eye diseases, thereby helping to prevent severe and permanent visual damage. The ResNet50 design has been demonstrated to be superior in finding DR, which makes diagnoses more accurate and has a large effect on clinical results.

Recent advancements in computer vision have resulted in novel architectures that surpass traditional CNNs in both precision and comprehensibility. The recognition Transformer (DETR) model [45], for instance, doesn't need hand-crafted anchors for object identification, which makes it suitable for hard tasks like exudates and hemorrhages in retinal diseases. Vision Transformers (ViT) and Swin Transformers [46] have shown state-of-the-art efficacy in medical image processing via the use of global self-attention mechanisms that enhance feature representation across spatial contexts. Researchers have also studied multi-modal Transformer models, like MedFuse and TransMed, to find how they might combine retinal pictures with clinical data (such as patient age and glucose levels) to improve the accuracy of diagnosis [47].

This study uses ResNet50 because it strikes a good balance between speed and accuracy in diagnosis. However, the proposed Vision AI model is designed to be modular, which means that Transformer-based architectures can be added in the future. This will make it scalable and retains its relevance as the field continues to evolve.

Finally, although AI-based predictions show a high level of confidence, it is paramount to complement these results with additional assessments with clinical analysts [12] because this validation process not only verifies the accuracy of AI diagnoses but also establishes regular follow-up and comprehensive evaluations by eye care experts [43]. Moreover, integrating these emerging technologies with traditional clinical expertise highlights their essential value in improving eye care [48]. Integrating AI into everyday medical processes represents a great challenge, as it is crucial to take into consideration complementary aspects such as minimizing the risks of diagnostic errors, data privacy, system adaptability, collaboration between the parties involved, and establishing new regulations to optimize these advances and ensure that AI improves eye health care.

Despite the availability of several FDA-approved systems like EyeArt, IDx-DR, and Retmarker, many of these tools require costly infrastructure, are limited to specific imaging devices, or depend on centralized, specialist-based environments [49]. In contrast, the Vision AI model proposed in this study offers key differentiators:

1) Scalability, by being adaptable to various clinical settings and regional constraints.
2) Accessibility, particularly in low-resource environments, as it operates efficiently without needing invasive equipment or specialist supervision.
3) Implementation simplicity, through a lightweight algorithmic structure that can be embedded into existing diagnostic workflows with minimal cost.
4) Cross-platform compatibility, allowing the model to analyze retinal images from diverse fundus cameras, thus avoiding bias or dependence on a specific device manufacturer.

These characteristics position Vision AI as an innovative, practical, and clinically reliable alternative that expands the reach of early DR detection, especially in underserved populations [50]. Unlike existing commercial tools, this model was validated using real-world multicenter datasets and supports decentralized diagnostic implementation, making it highly relevant for public health deployment.

3. Methodology

The study adopted a quantitative approach evaluating the following hypothesis: Would the use of mathematical algorithms based on AI, which process data from the retinal images, allow the detection of DR with a level of accuracy greater than 90% confidence? Based on statistical analysis, patterns of behavior will be established and this theory will be proven [51]. In addition, the study sought to develop the object of research, identifying regularities and relationships between the components of the study [52]. Additionally, the study identified the properties and characteristics of the phenomenon related to the main strategies for the early detection of DR [53]. Then, an exploration was conducted to model the factors to be considered in strategies for the correct use of AI-based models for early prediction of ocular pathology [54].

Initially, 5436 retinal images were classified by retina specialists into two categories: 1) healthy eyes (Class 0) and 2) Eyes with DR (Class 1). This allowed the feasibility of the research and the testing of the proposed hypothesis. Additionally, the validation process used the expert judgment of specialists to reduce the error in the classification of the images. Next, training, validation, and testing of the data management model were conducted based on deep CNN algorithms within the Vision AI platform.

In the statistical analysis stage, the ResNet50 architecture, thanks to its ability to learn through residual functions, allowed the input layers to be adjusted for residual mapping, achieving the stacking of residual blocks within a 50-layer network, with the aim of optimizing the training process, reducing loss and data preprocessing [55–58].

Figure 1 illustrates the processing of a block (image) within the ResNet architecture. Here, the stacking of the layers usually finds ideal weights and biases, resulting in the best network performance, through successive forward passes, error calculations, and backpropagation. By adding the input back to the output, this architecture prevents gradients from vanishing too quickly. The goal is the introduction of residual blocks containing an identity shortcut connection that skips one or more layers.

A complete ResNet50 architecture is illustrated in Figure 2, where the convolution kernel size, output channel size, and stride size (default is 1) are displayed, similarly for the grouping layers.

CNNs use convolutional parameter layers to iteratively learn to transform input images into hierarchical feature maps [57].

The ResNet50 architecture was selected due to its balance between depth, training efficiency, and accuracy. Unlike older models like VGG16, which contains more parameters and lacks residual connections, ResNet50 avoids the vanishing gradient problem and improves learning in deep networks. Although newer models such as EfficientNet and Vision Transformers show promise, they require more computational resources or larger datasets. Therefore, ResNet50 offered a robust and practical solution for this clinical imaging task.

Figure 1
Processing a residual block

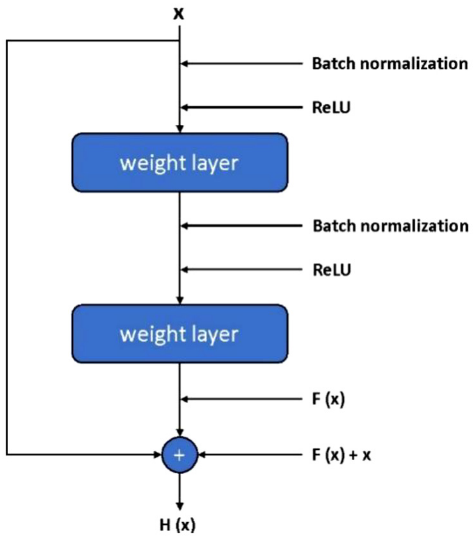
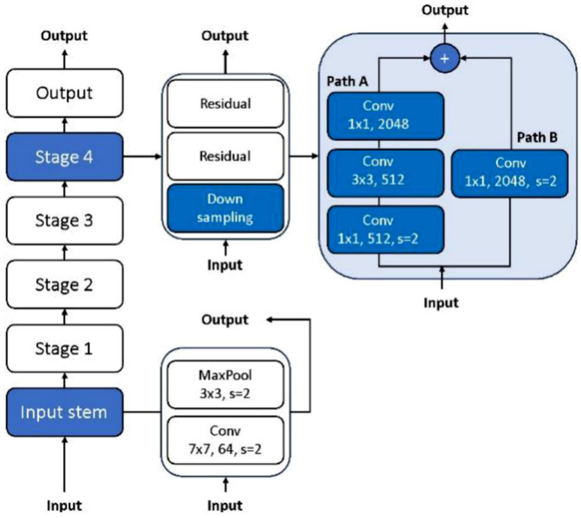


Figure 2
ResNet50 architecture



The ResNet50 architecture demonstrated reliable performance in medical image recognition, enabling more accurate results through the use and analysis of confusion matrices. Compared to VGG16, ResNet50 is more efficient; and while EfficientNet or Vision Transformers offer better accuracy in large datasets, they demand higher computational cost and complex tuning, which was not ideal for the project scope.

The CNN network used the following parameters for its training:

1. The input corresponding to the training dataset consisted of 3752 images, each labeled with a category (Class 0 and Class 1).
2. Next, the training dataset used a classifier to learn the structure of each of the classes.
3. Subsequently, the quality of the classifier was evaluated by asking it to predict a label for a new set of images that it had never seen before.
4. Finally, the comparison of the actual labels with those estimated (predicted) by the classifier was performed.

The ResNet50 architecture was selected for its balance in depth, efficiency, and precision in training and testing data models in deep networks, avoiding the problem of gradient disappearance. Although technologies such as VGG16, EfficientNet, and Vision Transformers exist, they require greater computing power and a larger data sample for use, which made their use impossible.

The pre-trained Vision AI model was adapted to the dataset using a fine-tuned method to optimize the learning rate. Once this stage was completed, the training process began with a new random input layer for the first epoch to ensure optimal performance with the selected dataset. Subsequently, the remaining dataset, resized to 448 × 448 pixels was trained for 50 epochs, where the weights of the later layers were updated more rapidly than the previous layers.

To mitigate overfitting and overconfidence, label smoothing was applied as a regularization technique, enhancing model performance and reducing overfitting. Once the training stage was complete, testing was carried out on the Vision AI platform, where pre-established labels were compared with unlabeled data. The parameters used to verify the accuracy of the results were sensitivity, specificity, and F1 score.

The Vision AI platform uses TensorFlow and Keras algorithms for data contrast and validation, while OpenCV and Numpy algorithms are used for data processing.

The ResNet50 input layer required the retinal fundus images to be 224 × 224 pixels in size. OpenCV and NumPy were used to preprocess the data, which included normalizing the RGB channels to a range of [0, 1]. During training, the study applied many data augmentation strategies to make the model more general and reduce overfitting. These adjustments included flipping the photographs both horizontally and vertically, rotating them randomly by up to 15°, zooming them in by up to 10%, and changing the brightness slightly. The research made these improvements using Keras's ImageDataGenerator module. The mean and standard deviation of each pixel from the training dataset were also used to normalize the images. This method made sure that the data was consistent and contributed to the dataset's diversity without affecting how useful it was for therapeutic purposes.

Finally, the study evaluated the concept that AI-based arithmetic algorithms might discover DR in positive cases with more than 90% accuracy. The Vision AI platform's confusion matrix showed that the model was quite reliable in making predictions.

4. Results

These findings show that the approaches utilized worked well and provided a lot of information about how the data were used to train, verify, and test the models. The distribution of the data and the accuracy of the classifications are crucial to ensure reliable and timely diagnoses. The following tables and figures highlight the characteristics of the datasets, the effectiveness of the applied AI tools, and the validation of the proposed models; thus demonstrating the solutions obtained in this study.

Table 1 shows the distribution of the dataset used for training, validation, and testing, with 80% allocated for training and validation, and 20% reserved for mathematical model testing minimizing the risk of overfitting [60].

Table 2 shows the distribution of the images used for each class (3752 images for each class) through oversampling [59].

The training process involved classifying 3752 images of healthy eyes and 3752 eyes with DR. For validation, 938 healthy eyes and 409 DR eyes were used, while 1173 healthy and 511 DR eyes were reserved for model testing. The sample size was determined using the finite population model based on a known database of participating patients collected in 2022 through open data and available in Latin America, North America, Asia, and Europe, ensuring both geographic variability and demographic variability [34, 44].

The findings obtained through the AI models were compiled through the Vision AI application. Figure 3 shows descriptive information on the efficacy of the application in ophthalmologic screening for the classification of a healthy eye in an accurate and timely manner.

Figure 3 illustrates the results of the Vision AI application of a healthy eye, with a confidence level of 97.6%; the left frame (Quadrant 1) shows the representation of the healthy fundus; the right frame (Quadrant 2) shows the heat map of the healthy eye, where Vision AI can assess the optic nerve region (1), which is an important characteristic for the early detection of ocular pathology [37], and the foveal region (2), which facilitates the central vision and the detection of diseases such as macular degeneration [32], and the macula of the retina region (3), allowing to corroborate the state of retinal health [11]. Descriptive information on the efficacy of Vision AI for the classification of an eye with DR is shown in Figure 4.

Figure 4 illustrates the results of an eye with DR with a confidence level of 96.5%; in the left frame (Quadrant 1), the color fundus image can be appreciated; and in the right frame (Quadrant 2), the heat map, where Vision AI can recognize the optic nerve region (1) and macular region (2) that suggest a high activity in this region, indicating the presence of microaneurysms and exudates, characteristic symptoms of DR [29, 36]. In addition, areas in the periphery of the retina stand out (3); where other signs of DR could be present that complement the screening due to the size, morphology, and compartment of the peripheral zone [17]. Table 3 summarizes the results obtained through the Vision AI application.

The study also got more findings from the mathematical models by using Vision AI (see Table 4).

This evidence demonstrates that the results are representative, exceeding the 90% confidence level established for the health sciences sector [65]. This reaffirms the reliability and robustness of Vision AI for the detection of DR as a clinical screening tool.

The objective of the research was to determine the diagnostic accuracy for identifying DR in positive patients and to validate the proposed hypothesis using a confusion matrix. According to Weng et al. [41], the confusion matrix is a mathematical tool that provides insights into accuracy and efficiency in identifying DR from fundus images. In this study, the matrix was used to accurately predict different ocular condition classes, with a focus on highlighting specific areas indicative of symptoms related to DR.

Fernandes et al. [13] and Irfan et al. [27] highlight that this mathematical model predicts each category from a comparative analysis of an image that has been previously classified, giving it predictive capabilities by training. However, if the model is unable to recognize the category to be evaluated, it assumes the status of unclassifiable category to be considered in a subsequent training. Figure 5 shows the descriptive information of the efficiency obtained by the confusion matrix used in Vision AI for the classification of the different types of eyes in the selected sample.

Moreover, to assess the model's learning behavior over time, the training and validation accuracy and loss were monitored throughout the 50 training epochs. The results showed stable convergence without significant overfitting, indicating that the model generalized well to new images. These trends confirm the robustness of the training strategy and support the model's reliability in clinical applications.

To make the results easier to understand, a comparison bar chart was also made. It showed the final performance metrics for both classes: accuracy, precision, recall, and F1-score. These images show clearly how well the model can diagnose both healthy and sick individuals, which is in line with existing standards for AI-based medical imaging.

Table 5 analyzes 1,684 images using a confusion matrix, obtaining an accuracy of over 90% in the results. Additionally, the receiver operating characteristic under the curve (ROC-AUC) was 0.96, confirming a high level of accuracy in findings, with categorized and unlabeled images.

Table 5 shows that the accuracy level in detecting healthy eyes was 95.35% (1128/1183), while the DR group was 91.02% (456/501); in both scenarios, the results exceeded 90% accuracy.

Izah et al. [66] emphasize that in medical research, maintaining a confidence level above 90% is important to ensure the accuracy and reliability of the findings. A high confidence level is associated with narrower confidence intervals, which in turn reduces the likelihood of Type I errors (false positives) and Type II errors (false negatives). Field-Richards et al. [67] and Lee et al. [68] emphasize that strong statistical analyses and high confidence levels are essential for directing evidence-based behaviors. Vaajoki et al. [69] add that the use of complementary statistical parameters enhances a study's sensitivity, which ensures the detection of true, valid, and applicable effects in real clinical settings.

By applying AI-based mathematical algorithms and statistical methods to retinal data from ophthalmologic patients, the model

Table 1
Characteristics of training, validation (80%), and test (20%) datasets

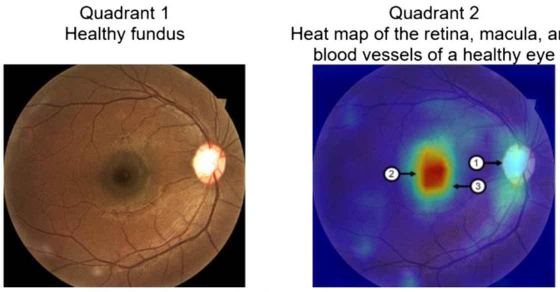
Dataset	Training and Validation						Test					
Sources	**Eyepac 7622 / 88 702**	**ODIR-5K 3517 / 9568**	**1000 Images 887 / 1000**	**REFUGE 597 / 1200**	**Cataracts 495 / 601**	**IDRID 235 / 516**	**ODIR-5K 1361 / 9568**	**EyePac 995 / 88 702**	**REFUGE 115 / 1200**	**IDRID 115 / 516**	**1000 Images 56 / 1000**	**Cataracts 33 601**
Classify as Normal	2747 / 7622	1378 / 3517	67 / 887	590 / 597	303 / 495	77 / 175	411 / 1361	225 / 995	11 / 115	5 / 115	17 / 56	ene 33
Classify as Diabetic Retinopathy	1333 / 7622	253 / 3517	136 / 887	6 / 597	3 / 495	116 / 175	341 / 1361	229 / 995	8 / 115	89 / 115	may 56	0 / 33
Classify as Other Retinopathy	1010 / 7622	968 / 3517	549 / 887	0 / 597	144 / 495	0 / 175	315 / 1361	199 / 995	82 / 115	14 / 115	26 / 56	25 / 33
Classify as Not classifiable	2532 / 7622	918 / 3517	135 / 887	1 / 597	45 / 495	30 / 175	294 / 1361	340 / 995	14 / 115	7 / 115	ago 56	jul 33
Examinations or Patients		5000					5000					
Age range, years		Mean = 57.85 Std = 11.7					Mean = 57.85 Std = 11.7					
Sex		Male 54% Female 46%					Male 54% Female 46%					
Ethnicity and race, or from the country	USA	CHINA	CHINA	CHINA		INDIA	CHINA	USA	CHINA	INDIA	CHINA	
Provided by	EyePACS	Shang Gong Medical Technology Co., Ltd	Joint Shantou International Eye Centre (JSIEC), China.	Zhongshan Ophthalmic Center		Eye Clinic located in Nanded, India	Shang Gong Medical Technology Co., Ltd	EyePACS	Zhongshan Ophtalmic Center	Eye Clinic located in Nanded, India	Joint Shantou International Eye Centre (JSIEC), China.	
Retinal camera		Cannon, Zeiss and Kowa				Kowa VX-10a digital fundus camera with 50-degree field of view	Cannon, Zeiss and Kowa			Kowa VX-10a digital fundus camera with 50-degree field of view		

Note: All classifications have been performed by ophthalmologist specialists in retina serving as Ainnova Tech's advisors. Additionally, the images used for this study were obtained through open data and cameras mentioned in this table, allowing us to obtain a variety of cameras avoiding a bias or dependency on a specific brand.

Table 2
Data used for model training

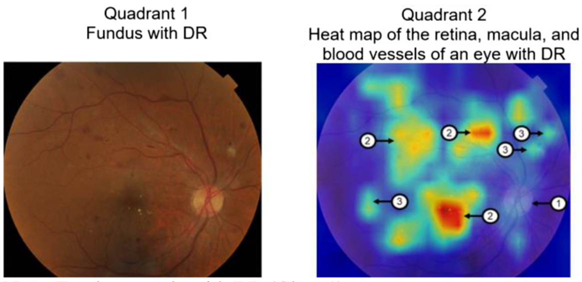
Categories	Number of data for training with oversampling	Number of data for validation	Number of test data
Actual healthy (Class 0)	3752	938	1173
Actual DR (Class 1)	3752	409	511

Figure 3
Using Vision AI platform to classify healthy retinas



Note: Healthy fundus sample (Class 0).

Figure 4
Using the Vision AI platform and classification of eyes with DR



Note: Fundus sample with DR (Class 1).

achieved a diagnostic accuracy of 91.02% in identifying positive cases of DR. This level of accuracy shows that the AI model is strong and dependable enough for mission-critical use in healthcare settings. This supports the acceptance of the alternative hypothesis and the rejection of the null hypothesis.

5. Discussion

DR is a microvascular consequence of diabetes mellitus that affects the retinal blood vessels and may result in partial or total vision loss in advanced stages. Recent studies indicate that DR is a primary cause of avoidable blindness among working-age people, particularly impacting those with inadequate metabolic management of diabetes [70]. After 20 years of having diabetes, over 60% of those with type 2 diabetes and practically all people with type 1 diabetes are thought to have some level of retinopathy [71].

Detecting DR in its early stages is crucial to prevent serious complications. Studies such as the Early Treatment Diabetic Retinopathy Study (ETDRS) have shown that early interventions such as intensive glycemic control and laser photocoagulation significantly reduce the risk of visual impairment [72]. The advent of anti-Vascular Endothelial Growth Factor (anti-VEGF) therapy and surgical techniques has revolutionized treatment outcomes in DR; however, undetected disease remains a burden despite excellent treatment options [73]. Advances in AI-based tools have improved the quality and access to early detection [74].

A summary of the comparative analysis between the optimizations applied is presented in Table 6.

Undoubtedly, hypothesis testing ratifies the results and provides evidence that the use of AI demonstrates robustness, reliability, and accuracy in the detection of DR. In this regard, Kumar et al. [75] highlight that the accuracy of DR grading found an error rate of 49% among internists, diabetologists, and resident physicians in overlooking the diagnosis of Proliferative Diabetic Retinopathy (PDR). Meanwhile, Sarantakos et al. [39] highlight the importance of adopting AI technologies in modern medicine to improve accuracy and efficiency in medical diagnostics on a global scale, along with the benefits of cost savings, speed, efficiency, and effectiveness in outcomes towards the patient.

Early and accurate diagnosis of DR is essential to prevent progression to advanced stages that can be blinding. Traditional screening and diagnostic techniques for DR include ophthalmoscopy and fluorescein angiography [76]. Although these techniques are effective, they have several limitations. For instance, ophthalmoscopy requires dilation of the pupils which is time-consuming, uncomfortable, and temporarily debilitating for patients. Fluorescein angiography is invasive by way of intravenous injection of a contrast medium which can cause severe adverse reactions [77].

The high cost of traditional screening poses a significant barrier to care especially in populations and regions with limited resources [78]. The reliance on the clinical judgment of the specialist can yield inconsistent diagnoses and significant interobserver variability [79]. These limitations have motivated the development of technologies, such as AI-based systems, which aim to improve diagnostic accuracy and facilitate early detection [80].

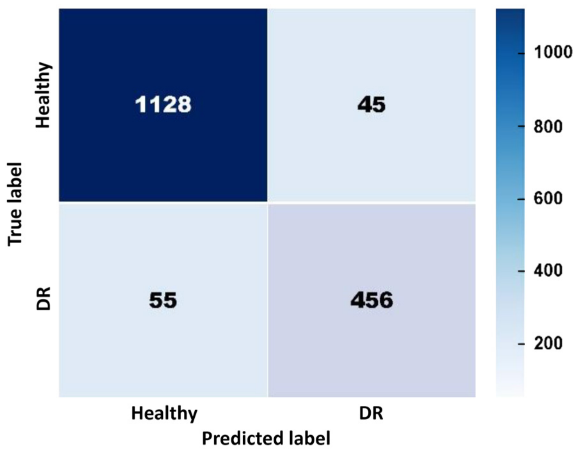
Table 3
Retinal image classification results via Vision AI

Study	Dice Parameter	ADF (mm)	Jaccard Index	Acc %
Normal	Normal	97.6%	High accuracy in identifying normal images is crucial to avoid false positives. The model accurately confirmed the absence of pathologies.	Boldrin et al. [61].
DR	DR	96.5%	High accuracy in detecting DR is essential for early and effective interventions. The model detected clear signs of DR such as microaneurysms and hard exudates.	Flaxel et al. [29]; Martínez-Gutiérrez et al. [35].

Table 4
Complementary results of Vision AI statistical models

Measure	Normal	DR	Goal
Sensitivity level	96.16%	90.2%	Represents the level of accuracy to correctly detect true positives and negatives [62].
Level of specificity	90.2%	96.16%	It represents the probability that the results of a test will be negative if you do not have the disease [63].
F1-score	95.75%	90.1%	It represents the evaluation that combines precision and sensitivity in a single harmonic metric, offering a balance between both [64].

Figure 5
Confusion matrix results for a sample of 1684 eyes



Vision AI has several advantages over other modern tools in the market. For instance, Eyenuk's EyeArt system, which also uses AI, has demonstrated 91.3% accuracy in DR detection but requires more specialized equipment and is not as accessible due to the high cost of acquisition [81]. The retinalyze system, while effective, is less accurate and more costly as it requires specialized equipment and highly trained personnel [82]. Similar to EyeArt, IDx-DR requires expensive technology and trained personnel to operate, which poses implementation challenges in places with little resources [83]. Retmarker is another program used to monitor the progression of DR; however, it requires significant manual input and is costly to maintain [84]. In addition, it demonstrates lower accuracy compared to Vision AI.

In summary, Vision AI is great at finding DR, with a high accuracy and sensitivity rate of 96.16% for healthy eyes and 90.2% for DR. It is a good and useful option due to its ease of access and low operational costs. This is particularly true in remote places or areas with limited access to resources. Vision AI is a better option than previous procedures as it is non-invasive, quick, and highly automated. Previous methods are typically intrusive, costly, and depend on experts. This

Table 5
Results of the confusion matrix prediction model

Categories	Number of patients predicted to be healthy	Cumulative percentage of patients predicted as healthy (%)	Number of patients predicted with DR	Cumulative percentage of patients predicted with DR (%)
Actual healthy (Class 0)	1128	95.35%	45	8.98%
Actual DR (Class 1)	55	4.65%	456	91.02%
Total	**1183**		**501**	

Table 6
Comparative analysis of the predictive model of retinal images through Vision AI and traditional techniques

Features	Vision AI	Traditional screening
Invasiveness	Non-invasive	Invasive; pupil dilation, angiography
Cost	Lower operating cost	High; equipment, personnel
Accessibility	**HIGHLY ACCESSIBLE** in remote areas	**LIMITED**; requires specialized infrastructure
Processing time	**RAPID AQUISITION** (<3 sec.)	Slow; requires preparation and processing time
Need for specialists	Reduced, high automation	High; dependent on specialist expertise
Early detection capacity	High precision and sensitivity	Variable; some techniques do not effectively detect early changes, because it is done manually by the clinical analyst.
Accuracy rate	96.16% (healthy) and 90.2% (DR)	Variable; usually lower without AI

makes it less dependent on a qualified operator or specialist knowledge, making it easier to detect problems early with great accuracy.

Omer [18] and Zeng et al. [85] highlight that Vision AI improves DR detection by analyzing a wide range of parameters in depth. This is very important for protecting eye health. Abegaz et al. [86] and Rapach et al. [87] also show that the approach works well in finding vascular adverse events by giving clear examples of real positive cases. Combining AI-based systems with tools like the confusion matrix is very important for informed decision-making in mission-critical applications extending beyond healthcare.

Rapach et al. [87] contend that this approach facilitates the acquisition of diagnostic accuracy regarding biomarkers present in high-risk patients to enhance their quality of life. Outside of healthcare, Bagheri et al. [88] improved complicated design processes in engineering models by employing systems and simulations that were evaluated using a confusion matrix. An et al. [89] obtained more accurate and efficient risk assessment in sustainable development environments, resulting in cost savings, reduced execution times, and positive environmental impact. In education, Chiang et al. [90] activated self-monitoring to help teachers improve pedagogical strategies, and Premeaux et al. [91] demonstrated the role of AI in automating construction processes and improving business decision-making. These findings emphasize the importance of AI-based technologies in establishing new principles, standards, and policies to drive innovation while ensuring efficiency.

As society enters the 5th Industrial Revolution, where automation and AI will dominate, particularly in healthcare, it is crucial to develop guidelines for certifying and accrediting emerging technologies. Agencies like the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) must expedite approvals to make advanced technologies more accessible, cost-effective, and impactful in improving quality of life. This study underscores how AI-based systems can effectively detect DR, showcasing their ability to improve accuracy, sensitivity, and specificity in retinal image classification, along with the ability to safeguard the confidentiality, integrity, and availability of patient data in a connected world.

Despite its advantages, Vision AI faces limitations, particularly its reliance on input image quality. Issues such as lens opacities, insufficient illumination, or patient movements, can compromise diagnostic accuracy [92]. This challenge is not unique to Vision AI. It underscores the need for improved algorithms to handle challenges and ensure accurate diagnoses in all conditions [93].

While Vision AI is highly accurate in detecting DR, some other technologies offer complementary strengths. For instance, Retmarker offers detailed tracking of DR progression, which is a crucial metric for monitoring treatment outcomes over time [94]. Emerging multimodal technologies that combine AI with biomarkers or genetic data provide an even more comprehensive assessment of ocular health status and risk of DR progression, outperforming Vision AI in certain clinical scenarios [95]. Nevertheless, Vision AI remains an invaluable tool, particularly in resource-limited settings, where its low cost and high accuracy enable timely diagnosis, addressing the growing global burden of diabetes and its complications [96].

The confusion matrix has been instrumental in validating Vision AI's performance, highlighting its ability to reduce misdiagnosis and preserve resources. In ophthalmology, where early detection is critical, AI's ability to identify disease states is transformative. Vision AI democratizes access to high-quality diagnostics, making advanced healthcare more accessible worldwide.

The practical implications of this research extend beyond healthcare, illustrating how emerging technologies can revolutionize various fields. The integration of AI, the Internet of Things (IoT), and Big Data can improve health systems, predict public health challenges, and drive resilient digital ecosystems [97]. This study provides a roadmap for stakeholders to leverage AI for data-driven decision-making, fostering innovation in both academic and industrial domains. Further research will continue to explore multidisciplinary applications of AI, from bioengineering to ethical considerations, paving the way for groundbreaking advancements in human health [97–100]. In conclusion, the deployment of Vision AI for early DR detection represents a significant advancement in clinical ophthalmology, particularly for underserved regions. Its low-cost, high-accuracy, and non-invasive features make it an ideal solution for rural areas and health systems with limited access to specialists [101]. Integrating this AI-based tool into national visual health programs could enhance population-level screening efforts, reduce preventable blindness, and inform data-driven public health strategies. Policymakers are encouraged to consider such technologies in the formulation of equitable, efficient, and scalable healthcare solutions.

6. Conclusions

This study conclusively illustrates how the implementation of an advanced AI model, based on the ResNet50 neural network architecture, is marking a turning point in the detection and management of DR, a severe complication of diabetes that can result in blindness. The results obtained are not only significant but also highlight the ability of the AI model to increase accuracy, sensitivity, and specificity in the classification of retinal images, whether normal or pathological.

In Latin America, it is estimated that over 45% of diabetic patients do not undergo regular ophthalmologic screenings due to the shortage of specialists, especially in rural and underserved areas [102]. In Costa Rica, for example, regions outside the Greater Metropolitan Area report fewer than one ophthalmologist per 100,000 inhabitants, significantly limiting access to early detection of DR [103]. This disparity underscores the urgent need for automated, accessible, and accurate screening tools that can support early diagnosis and intervention, even in resource-constrained healthcare settings.

The application of the confusion matrix as an evaluative tool has been crucial in this process, providing a thorough and meticulous validation of the model's efficacy. This technique has allowed verification of the model's high accuracy rate in correctly identifying and classifying ocular conditions and has impressively highlighted its potential to drastically reduce misdiagnosis and unnecessary treatment. This advantage is of paramount importance in ophthalmology, where early detection can effectively prevent the progression of DR to complete vision loss.

The findings underscore the crucial importance of incorporating advanced AI technologies into ophthalmic care. The ResNet50 model has emerged as an exceptionally promising tool for clinicians, offering a diagnostic method that is faster, less invasive, and more accessible than traditional methods. This tool becomes even more valuable in settings where access to specialists and advanced technology may be limited.

Furthermore, the integration of this model can democratize access to high-quality diagnostics, promoting fairer and more equitable detection and treatment worldwide. This approach not only improves diagnostic efficiency but also facilitates more timely and targeted interventions, essential to prevent irreversible damage to patients and significantly improve standards of eye care worldwide.

Additionally, recent findings by Vij and Arora [7] reinforce the clinical viability of ResNet-based architectures in DR diagnosis. Their study implemented a deep inductive transfer learning approach for multiclass classification of DR severity using the IDRiD dataset. Among five evaluated models, the optimized Xception network achieved an AUC-ROC of 0.9902 and precision above 0.98 across all severity stages. These results confirm that, when enhanced with fine-tuned parameters and robust preprocessing, models like ResNet50 remain highly competitive in clinical settings, particularly due to their scalability, adaptability, and strong performance in image-based diagnostics.

To push the area of AI-assisted ophthalmology forward, a number of important research paths are suggested. These suggestions are meant to fix the problems that are now present and look at how this technology may have a bigger effect:

1) Multicenter validation: To ensure the applicability and robustness of the ResNet50 model, it is essential to conduct multicenter validation studies that include diverse populations and clinical settings. This will help determine the efficacy of the model in different demographic and geographic contexts, and ensure its adaptability and scalability.
2) Integration of new technologies: Merging the AI model with other new technologies, such Optical Coherence Tomography (OCT) and fluorescein angiography, might help us learn more about DR and other retinal diseases. Looking at how these technologies can work together might lead to big improvements in how accurate diagnoses are.
3) Development of composite predictive models: Look into how to make composite models that can not only find DR but also guess how the illness will become worse. This might lead to more tailored and timely treatments, which could lead to better treatment results.
4) Research on the economic and social effects: Do research that look at how using AI to diagnose DR would affect the economy and society. These research might provide us useful information on how to lower costs, make things easier to get to, and how they affect a patient's quality of life.
5) Ethics and data privacy: Do further study on how employing AI in health affects privacy and ethics. Develop regulatory and policy frameworks that ensure the security and privacy of patient data, while fostering innovation in AI technologies.

Conclusively, this study not only validates the efficacy of AI models in ophthalmology but also lays a solid foundation for future research that could expand and improve the detection and management of eye diseases worldwide.

Acknowledgment

The authors would like to thank all those involved in the work who made it possible to achieve the objectives of the research study.

Ethical Statement

This study did not require formal ethical approval because the analysis was conducted exclusively on publicly available, anonymized retinal image datasets. This exemption is based on the institutional policy of the Universidad Latinoamericana de Ciencia y Tecnología (ULACIT), Costa Rica, regarding the use of pre-existing, de-identified data for secondary research purposes, as well as in accordance with Costa Rican national regulations for non-interventional, retrospective data studies.

Data Availability Statement

Data sharing does not apply to this article as no new data were created or analyzed in this study.

Conflicts of Interest

The authors declare that they have no conflict of interest to this work.

Author Contribution Statement

Gabriel Silva-Atencio: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Writing – review & editing, Visualization, Supervision, Project administration. **Edwin Acuña-Acuña:** Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Writing – review & editing, Visualization, Supervision, Project administration. **Maziar Lalezar:** Writing - review & editing, Visualization, Supervision, Project administration.

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How to Cite: Silva-Atencio, G., Acuña-Acuña, E., & Lalezary, M. (2025). Predictive Artificial Intelligence Models in the Early Identification of Diabetic Retinopathy. *Artificial Intelligence and Applications*. https://doi.org/10.47852/bonviewAIA52025555