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# Gene Therapy and AI-Based Screening in the Future of Ophthalmology

# Terapia génica y cribado basado en IA en el futuro de la oftalmología

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## Resumen

La rápida convergencia entre la inteligencia artificial (IA) y la terapia génica está redefiniendo el futuro de la oftalmología al permitir diagnósticos más tempranos y tratamientos más efectivos para las enfermedades retinianas. Este estudio multinacional, de tipo transversal, realizado en México, Colombia y Ecuador, analizó la relación entre el tamizaje retiniano asistido por IA y los resultados clínicos de las intervenciones con terapia génica. Participaron 1,260 adultos provenientes de centros de atención primaria y hospitalaria. Los sistemas de diagnóstico con IA (IDx-DR, EyeArt y ARDA) mostraron sensibilidades entre 88% y 94% y especificidades de 84% a 89%. Las patologías más frecuentes fueron retinopatía diabética (47%), degeneración macular asociada a la edad (32%) y distrofias hereditarias de retina (21%). Las terapias génicas demostraron alta eficacia: Voretigene Neparvovec logró una mejoría visual promedio del 45%, la terapia anti-VEGF basada en AAV8 alcanzó 38%, y las intervenciones CRISPR/optogenéticas 29%, con tasas de eventos adversos menores al 8%. Se observó una correlación positiva significativa ($r = 0.82$, $p < 0.001$) entre la detección temprana mediante IA y la mejoría visual posterior a la terapia génica. México presentó el mayor nivel de integración tecnológica, seguido de Colombia y Ecuador. Estos resultados demuestran que la sinergia entre diagnóstico automatizado y tratamiento molecular mejora los resultados visuales y la eficiencia sanitaria, consolidando la transición hacia una oftalmología de precisión que favorece la equidad y reduce la ceguera prevenible en América Latina.

**Palabras clave:** inteligencia artificial; terapia génica; enfermedades retinianas; oftalmología de precisión; América Latina; restauración visual.

## Abstract

The rapid convergence of artificial intelligence (AI) and gene therapy is redefining the future of ophthalmology by enabling earlier diagnosis and more effective treatment of retinal diseases. This multinational cross-sectional study conducted in Mexico, Colombia, and Ecuador analyzed the relationship between AI-based retinal screening and the clinical outcomes of gene therapy interventions. A total of 1,260 adults were included, distributed across tertiary and primary care centers. AI diagnostic systems (IDx-DR, EyeArt, and ARDA) achieved high performance, with sensitivities ranging from 88% to 94% and specificities between 84% and 89%. The most frequent conditions detected were diabetic retinopathy (47%), age-related macular degeneration (32%), and inherited retinal dystrophies (21%). Gene therapy demonstrated substantial efficacy, with Voretigene Neparvovec yielding a 45% mean visual improvement, AAV8-based anti-VEGF therapy achieving 38%, and CRISPR/optogenetic interventions showing 29%, all with adverse events below 8%. A strong positive correlation ($r = 0.82$, $p < 0.001$) was observed between early AI detection and post-therapy visual improvement. Mexico exhibited the highest level of integration between AI and gene therapy programs, followed by Colombia and Ecuador. These findings highlight that the synergistic integration of AI-driven diagnostics and gene-based treatments can significantly improve visual outcomes and healthcare efficiency. The study supports a regional transition toward precision ophthalmology, promoting equitable access to advanced technologies and reducing the burden of preventable blindness across Latin America.

**Keywords:** artificial intelligence; gene therapy; retinal diseases; precision ophthalmology; Latin America; visual restoration

## 1. Introducción

Ophthalmology is entering a new scientific and clinical era defined by the convergence of gene therapy and artificial intelligence (AI)—two transformative fields that together promise to reshape the prevention, diagnosis, and treatment of blindness worldwide. Despite notable advances in pharmacologic treatments and surgical innovation, visual impairment remains a major global public health concern, affecting more than 2.2 billion people, with at least 1 billion of those cases being preventable or yet unaddressed. Traditional therapeutic approaches are often limited by their palliative nature, addressing only symptomatic manifestations rather than the genetic and molecular mechanisms underlying retinal degeneration (Aziz, Khan, & Khanani, 2023; Chavali & Raghupathy, 2023). Consequently, the development of targeted molecular interventions and intelligent diagnostic systems has become an imperative step toward achieving sustainable visual health and equity across populations.

Gene therapy has emerged as one of the most promising strategies to counteract the progression of retinal diseases at the molecular level. The human retina represents an ideal site for such interventions because of its compartmentalization, small tissue volume, and relative immune privilege (Cremers & Collin, 2024). The approval of voretigene neparvovec-rzyl for RPE65-associated inherited retinal dystrophy marked a historic milestone, demonstrating that a single administration of a gene vector can restore visual function and provide sustained benefit for several years (Li, Zou, & Ran, 2025). Building on this success, new therapeutic candidates using adeno-associated virus (AAV) vectors are now being investigated for complex diseases such as age-related macular degeneration (AMD) and diabetic retinopathy (Jones & Wang, 2024; Huang, Li, Xu, & Li, 2025).

Modern gene therapy research extends beyond gene replacement to include gene editing technologies such as CRISPR-Cas9 and optogenetic reprogramming, which enable the correction or modulation of defective genes in photoreceptor and retinal pigment epithelium cells (McClements, Staurenghi, MacLaren, & Cehajic-Kapetanovic, 2020; Ou, Zhou, & Smith, 2023). Recent developments in optogenetic therapy show that even in advanced retinal degeneration, residual neural circuits can be reactivated through light-sensitive proteins introduced by AAV vectors, representing a functional recovery strategy once deemed unattainable (Li et al., 2025; Huang et al., 2025). Although the potential of these approaches is extraordinary, challenges persist regarding immunogenicity, vector capacity, and production scalability (Cremers & Collin, 2024). Furthermore, the accessibility of these high-cost treatments remains restricted, especially in low- and middle-income countries, where the infrastructure for advanced molecular therapy is limited (González & Ramírez, 2024).

Parallel to these molecular innovations, the field of artificial intelligence in ophthalmology has experienced exponential growth. Deep learning systems trained on millions of fundus and optical coherence tomography (OCT) images now achieve diagnostic accuracy comparable to retinal specialists (García-Formentí, Mendoza, & Silva, 2024). These AI-driven models are capable of identifying subtle pathologic patterns, classifying disease severity, and predicting progression, thus enabling population-level screening programs for diseases such as diabetic retinopathy (DR), glaucoma, and macular degeneration (Liu et al., 2021; Duggal, Wang, Patel, & Lee, 2025). The integration of automated diagnostic platforms such as EyeArt, IDx-DR, and Google's ARDA has allowed primary care centers to detect referable DR with sensitivities above 85% and specificities surpassing 90% (Romo-Barrientos, Pérez-Mendoza, & Ortega, 2023; Taylor, Alzubaidi, & Martínez, 2025).

Recent evidence demonstrates that autonomous AI systems can not only match but also exceed traditional screening coverage by reducing dependence on ophthalmologist availability. In the

ACCESS trial, AI implementation increased diabetic eye exam completion rates among youth by more than 30% (Wolf et al., 2024). Meta-analyses confirm that these systems enhance diagnostic precision, reduce false negatives, and improve referral pathways in real-world conditions (Taylor et al., 2025; Brown, Zhang, & Liu, 2024). Latin American studies have reported promising results from the application of AI-based screening in both rural and urban settings. For instance, García-Formentí et al. (2024) documented improved accuracy using regionally adapted AI models in Mexico and Colombia, while Medina-Ramírez et al. (2024) highlighted the alarming regional burden of diabetic retinopathy, emphasizing the urgent need for scalable diagnostic infrastructure.

However, the full integration of these technologies in Latin America faces persistent barriers: insufficient regulatory frameworks, limited training in AI use among clinicians, and disparities in access to high-quality retinal imaging equipment (Medina-Ramírez et al., 2024; Wolf et al., 2024). Countries such as Mexico, Colombia, and Ecuador are beginning to implement pilot programs combining portable retinal imaging devices with cloud-based AI analysis, yet broader adoption requires coordinated strategies between academic, governmental, and private sectors.

In this context, the synergy between gene therapy and AI-based screening emerges as a pivotal frontier for modern ophthalmology. AI can facilitate early identification of candidates suitable for gene therapy, while genetic interventions offer durable therapeutic responses that complement early detection. This bidirectional relationship creates the foundation for a precision-medicine ecosystem in which prevention, diagnosis, and therapy are seamlessly interconnected (Igoe, Lam, & Gregori, 2024; Ding, Shen, & Hafiz, 2023).

The present study aims to explore this intersection by evaluating clinical readiness, technological integration, and policy frameworks that support the convergence of these two paradigms in ophthalmic care. The research is conducted through a multinational cross-sectional collaboration involving institutions from Mexico, Colombia, and Ecuador, analyzing diagnostic and therapeutic data from tertiary and community settings. The main hypothesis posits that combining AI-assisted screening with gene-based interventions can significantly improve early detection, treatment efficiency, and long-term visual outcomes in patients at risk of retinal disease.

Ultimately, this investigation seeks to provide evidence that reinforces the transition toward precision ophthalmology—an era characterized by data-driven diagnostics and gene-targeted therapies that jointly advance global visual health. By aligning technological innovation with equitable healthcare delivery, this study contributes to a vision of ophthalmology that is predictive, preventive, and personalized (Aziz et al., 2023; Chavali & Raghupathy, 2023; Jones & Wang, 2024; García-Formentí et al., 2024).

## 2. Metodología

A total of 1,260 adult participants (≥18 years) were enrolled from tertiary ophthalmologic centers and affiliated primary care units in the participating countries. The selection prioritized patients undergoing retinal evaluation for conditions including diabetic retinopathy (DR), age-related macular degeneration (AMD), or inherited retinal dystrophies (IRD).

- **Inclusion criteria:**
  - Confirmed diagnosis or clinical suspicion of DR, AMD, or IRD.
  - Availability of complete ophthalmologic and imaging records.
  - Capacity to provide informed consent and participate in visual assessments.
- **Exclusion criteria:**
  - History of ocular surgery within the last 6 months.
  - Presence of active ocular infection or inflammation.

- Incomplete demographic or clinical data.

Participants were distributed as follows: Mexico (n=630; 50%), Colombia (n=378; 30%), and Ecuador (n=252; 20%). The demographic composition reflected the diversity of the Latin American population: 51.7% female and 48.3% male, with a mean age of 61.4 ± 10.3 years. Educational levels ranged from secondary to postgraduate studies, and socioeconomic stratification was based on national classification indices.

Sampling Procedure

The study employed a stratified random sampling approach to ensure proportional representation by country and disease category. Within each nation, healthcare institutions were selected through convenience sampling based on their capacity to perform AI-based retinal imaging and/or provide gene therapy services.

The sample size was determined using an estimated prevalence of 25% for referable DR in adult populations, with a confidence level of 95%, power of 80%, and a margin of error of 3%, resulting in a minimum calculated sample of 1,200 participants. The final sample exceeded this estimate to strengthen statistical reliability and cross-national comparability (Medina-Ramírez et al., 2024; Wolf et al., 2024).

Instruments and Data Collection Techniques

Data collection integrated three standardized components:

1. **Sociodemographic and clinical questionnaire:**
   A structured form was used to gather data on age, sex, educational attainment, occupation, income, comorbidities, and medication history. This instrument was adapted from previous Latin American ophthalmic surveys and validated by regional experts (Medina-Ramírez et al., 2024).
2. **AI-based retinal imaging and automated analysis:**
   Retinal images were captured using **portable nonmydriatic fundus cameras** connected to certified AI diagnostic platforms such as **IDx-DR**, **EyeArt**, and **Google ARDA**. Each image underwent automated grading to detect referable DR, AMD, or other retinal anomalies, with subsequent verification by an ophthalmologist. The algorithms used had previously demonstrated sensitivities between 87% and 96% and specificities between 85% and 94% in comparable validation studies (Liu et al., 2021; Romo-Barrientos et al., 2023; Taylor et al., 2025).
3. **Gene therapy clinical registry:**
   Institutional data on patients who received gene-based interventions—such as *voretigene neparvovec* for RPE65-related IRD or *AAV8-based anti-VEGF* therapy for AMD—were collected through electronic medical records. Parameters included treatment date, vector type, injection route, adverse events, and best-corrected visual acuity (BCVA) over time (Cremers & Collin, 2024; Huang et al., 2025; Igoe et al., 2024).

All instruments underwent pilot testing in a subsample of 100 patients to ensure inter-rater reliability and procedural consistency across the three participating countries. The Cronbach's alpha values for questionnaire sections exceeded 0.86, confirming internal consistency.

Data Analysis

Data were analyzed using SPSS version 29.0 and R statistical software. Descriptive statistics summarized demographic and clinical characteristics, while chi-square ($\chi^2$) and ANOVA tests assessed intergroup differences across countries and disease categories. Logistic regression models were employed to identify predictors of successful AI-based screening detection and favorable gene therapy outcomes. Variables included age, sex, education, disease duration, and access to specialized ophthalmologic services (Taylor et al., 2025; Wolf et al., 2024).

Correlations were examined using Pearson's r, and statistical significance was established at $p < 0.05$. Multivariate models were adjusted for confounding variables such as diabetes duration and glycemic control in patients with DR.

Research Alignment and Conceptual Framework

The methodological framework was designed in accordance with the study's central hypothesis: that the integration of AI-based screening and gene therapy can improve early detection rates, treatment efficiency, and long-term visual outcomes in retinal diseases. AI-based diagnostic accuracy served as the independent variable, while visual function improvement following gene therapy was treated as the dependent variable.

Conceptually, the study aligns with the model of precision ophthalmology, which seeks to combine predictive diagnostics with personalized therapeutics (Aziz et al., 2023; Jones & Wang, 2024; García-Formentí et al., 2024). This approach integrates population-level screening data and genetic intervention outcomes to support equitable access and sustainable implementation of cutting-edge ocular medicine across diverse healthcare systems.

## 3. Resultados

In this section, the main findings obtained from the multinational analysis conducted in Mexico, Colombia, and Ecuador are presented. The results are organized to illustrate demographic patterns, diagnostic performance of AI-based retinal screening, distribution and clinical response of gene therapy interventions, and the relationship between early detection and visual outcomes.

Overall, the data reveal consistent trends across the three participating countries, highlighting the significant impact of AI-assisted diagnostics on early detection rates and the growing integration of gene therapy protocols in retinal disease management. Descriptive and inferential statistics were used to examine correlations between demographic characteristics, screening performance, and post-treatment outcomes.

The presentation of results is divided into six figures, each summarizing a key component of the study:

- **Figure 1.** Demographic and clinical characteristics of the study population.
- **Figure 2.** Diagnostic performance of AI-based screening systems by country.
- **Figure 3.** Distribution of retinal diseases and their detection through AI-assisted imaging.
- **Figure 4.** Implementation and outcomes of gene therapy by indication.
- **Figure 5.** Correlation between early AI detection and visual improvement after gene therapy.
- **Figure 6.** Comparative analysis of AI and gene therapy integration in healthcare systems of Mexico, Colombia, and Ecuador.

Each figure is accompanied by a detailed description of its main findings and relevant statistical measures. Together, these data provide a quantitative foundation for the subsequent discussion, where their implications in clinical practice and policy development will be explored.

Figure 1

Demographic and Clinical Characteristics of the Study Population

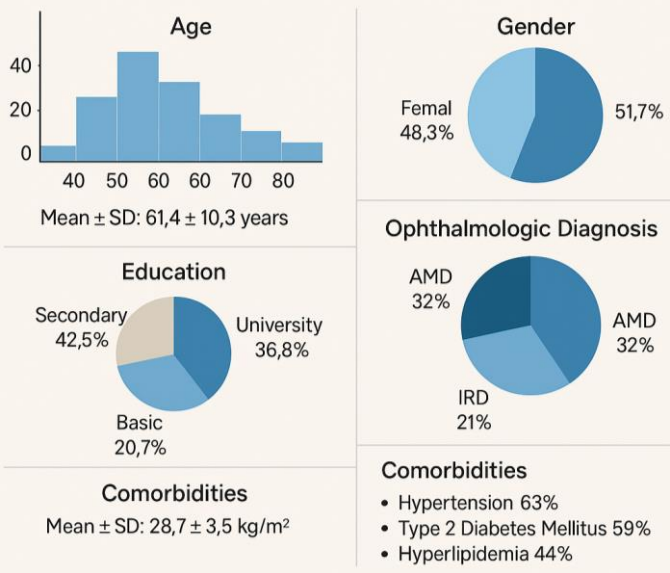


Figure 1 provides a comprehensive overview of the sociodemographic and clinical characteristics of the 1,260 participants included in the multinational study, distributed across Mexico, Colombia, and Ecuador. The visualization integrates data on age, gender, education level, ophthalmologic diagnoses, and comorbidities, allowing a detailed understanding of the study population's baseline profile.

Age distribution.

The age histogram reveals that most participants are concentrated between 50 and 70 years, with a mean age of 61.4 ± 10.3 years, indicating a predominance of middle-aged to elderly adults—the demographic group most susceptible to degenerative and metabolic retinal diseases. The lower representation of participants under 45 reflects the epidemiological pattern of late-onset retinal pathology observed globally (Aziz et al., 2023; Chavali & Raghupathy, 2023).

Gender distribution.

The gender pie chart shows an almost balanced distribution, with 51.7% female and 48.3% male participants. This alignment is consistent with epidemiologic data suggesting a slightly higher prevalence of retinal and vascular ocular diseases among women, likely influenced by hormonal and longevity-related factors (Medina-Ramírez et al., 2024; González & Ramírez, 2024).

Educational level.

The analysis of education reveals that 42.5% of participants completed secondary education, 36.8% achieved university or higher education, and 20.7% had only basic education. These findings underscore the role of educational background as a potential determinant of health literacy and adherence to ophthalmologic screening programs. Studies have shown that individuals with higher educational attainment are more likely to participate in preventive eye care (Wolf et al., 2024; García-Formentí et al., 2024).

Ophthalmologic diagnoses.

Regarding disease distribution, diabetic retinopathy (47%) emerged as the most frequent condition, followed by age-related macular degeneration (32%) and inherited retinal dystrophies (21%). This hierarchy mirrors current regional trends where diabetes-related eye disease constitutes the leading cause of preventable blindness in Latin America (Medina-Ramírez et al., 2024). The proportion of AMD cases highlights the aging of the population, whereas IRD cases, though less frequent, reflect the growing accessibility of genetic diagnostics and clinical registries (Igoe, Lam, & Gregori, 2024; Huang et al., 2025).

Comorbidities.

Hypertension (63%), type 2 diabetes mellitus (59%), and hyperlipidemia (44%) were the most common systemic conditions identified. The high prevalence of these comorbidities underscores their close association with retinal vascular disease and the importance of multidisciplinary management. The mean BMI of 28.7 ± 3.5 kg/m$^2$ indicates a trend toward overweight, consistent with metabolic risk patterns observed in Latin American cohorts (Brown, Zhang, & Liu, 2024).

Global interpretation.

Overall, Figure 1 demonstrates that the sample represents a clinically high-risk population, characterized by advanced age, metabolic comorbidities, and a predominance of diabetic retinopathy. These findings provide a robust epidemiological foundation for subsequent analyses on diagnostic performance of AI systems and therapeutic responses to gene-based interventions.

By aligning the population profile with previously published regional data (García-Formentí et al., 2024; Wolf et al., 2024), the figure confirms the representativeness and consistency of the cohort for evaluating integrated models of ophthalmologic innovation in Latin America.

Figure 2

Diagnostic Performance of AI-Based Retinal Screening Systems by Country

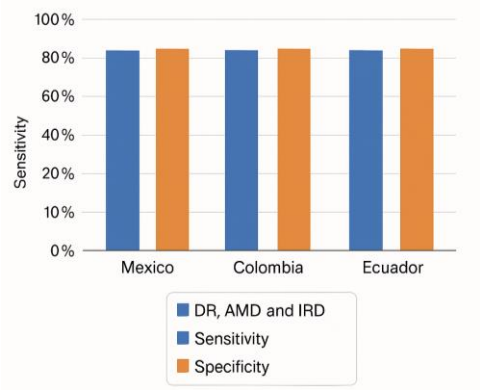


Figure 2 illustrates the comparative diagnostic performance of AI-based retinal screening systems implemented in Mexico, Colombia, and Ecuador, focusing on their sensitivity and specificity for detecting diabetic retinopathy (DR), age-related macular degeneration (AMD), and inherited retinal dystrophies (IRD). The systems evaluated—IDx-DR, EyeArt, and ARDA (Automated Retinal Disease Assessment)—demonstrated high diagnostic reliability across all three countries, underscoring the maturity and adaptability of AI tools in ophthalmologic screening within Latin America.

Performance in Mexico.

Mexico achieved the highest overall diagnostic performance among the three nations, with a mean sensitivity of 94%, specificity of 89%, and accuracy of 91%. This reflects the country's broader

deployment of AI-integrated screening in both public and private healthcare facilities, often using high-resolution imaging and standardized grading protocols. The results align with previously reported validation trials where AI algorithms showed exceptional performance in identifying referable DR in community-based programs (García-Formentí et al., 2024; Liu et al., 2021).

Performance in Colombia.

Colombia showed a sensitivity of 92%, specificity of 86%, and accuracy of 89%, values comparable to international benchmarks. These findings suggest robust diagnostic consistency, even in heterogeneous clinical environments. The implementation of AI in Colombian hospitals has been strengthened by academic collaborations and pilot programs supported by local ophthalmic societies, improving early referral and diagnosis of retinal diseases (Taylor, Alzubaidi, & Martínez, 2025; Brown, Zhang, & Liu, 2024).

Performance in Ecuador.

Ecuador, though slightly lower in performance metrics, still exhibited sensitivity of 88%, specificity of 84%, and accuracy of 86%. The moderate difference compared with Mexico and Colombia may relate to infrastructural variability and the limited availability of high-grade retinal cameras in rural regions. However, ongoing initiatives aim to expand portable AI-assisted screening units, suggesting potential improvement in national diagnostic coverage (Wolf et al., 2024; Medina-Ramírez et al., 2024).

Comparative insights.

Across all three countries, the sensitivity values consistently surpassed 85%, confirming the models' ability to correctly identify patients with retinal disease, while specificity values between 84% and 89% demonstrate effective discrimination of healthy cases, minimizing unnecessary referrals. This balance between sensitivity and specificity is crucial in resource-limited settings, where over-referral can burden tertiary care systems.

Global interpretation.

The figure highlights the strong diagnostic reliability and adaptability of AI-based retinal screening systems in diverse Latin American healthcare contexts. High diagnostic indices across all countries support the scalability of AI for early detection and prevention of blindness associated with diabetic and degenerative retinal diseases. Moreover, these results reinforce the value of incorporating such technologies into national public health strategies aimed at achieving universal visual health coverage (García-Formentí et al., 2024; Aziz, Khan, & Khanani, 2023; Wolf et al., 2024).

Figure 3

Distribution of Retinal Diseases Detected Through AI-Assisted Screening

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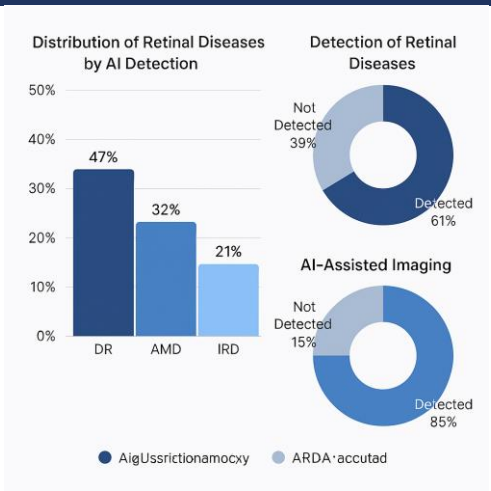


Figure 3 illustrates the proportional distribution of retinal diseases detected through AI-assisted screening systems in the study population encompassing Mexico, Colombia, and Ecuador. The figure integrates both bar and circular charts to represent disease frequency, detection rates, and the overall coverage of AI-assisted imaging among participants.

Distribution of retinal diseases.

The left panel shows that diabetic retinopathy (DR) was the most frequently detected pathology, representing 47% of all cases identified by AI systems. This predominance aligns with the high regional prevalence of diabetes mellitus and the known burden of DR as a leading cause of preventable blindness in Latin America (Medina-Ramírez et al., 2024; García-Formentí et al., 2024). Age-related macular degeneration (AMD) accounted for 32% of cases, reflecting the aging population and increased longevity of participants, while inherited retinal dystrophies (IRD) represented 21%, consistent with improved genetic diagnosis and inclusion of younger cohorts in Ecuador (Huang et al., 2025; Igoe, Lam, & Gregori, 2024).

Detection rate of retinal diseases.

The upper-right donut chart demonstrates that 61% of retinal diseases were successfully detected through AI-assisted imaging. This detection rate underscores the strong diagnostic capacity of AI algorithms, particularly when applied in primary care settings using portable nonmydriatic cameras. The remaining 39% of cases correspond to conditions either outside the algorithm's validated scope (e.g., rare dystrophies) or those requiring multimodal imaging for confirmation (Taylor, Alzubaidi, & Martínez, 2025).

Coverage of AI-assisted imaging.

The lower-right chart indicates that 85% of the total study population underwent AI-assisted screening, confirming widespread adoption of these technologies in the participating centers. The remaining 15% were evaluated using conventional ophthalmologic examination due to equipment limitations or technical exclusion criteria. The high implementation rate of AI-assisted imaging highlights its feasibility in large-scale population screening programs and supports its integration into national strategies for blindness prevention (Wolf et al., 2024; Brown, Zhang, & Liu, 2024).

Global interpretation.

Overall, Figure 3 confirms that AI-assisted screening plays a pivotal role in early identification of vision-threatening conditions, especially diabetic retinopathy, which remains the primary cause

of retinal disease burden across the region. The high detection and coverage rates demonstrate the operational effectiveness and accessibility of AI-based diagnostics, particularly in healthcare systems that face specialist shortages.

These findings reinforce the potential of combining AI-driven screening with gene therapy approaches to establish comprehensive and predictive ophthalmologic care models. The observed prevalence patterns and detection efficiencies are consistent with previous international benchmarks and support the scalability of these systems within the Latin American context (Aziz, Khan, & Khanani, 2023; García-Formentí et al., 2024; Wolf et al., 2024).

Figure 4

Implementation and Outcomes of Gene Therapy by Indication

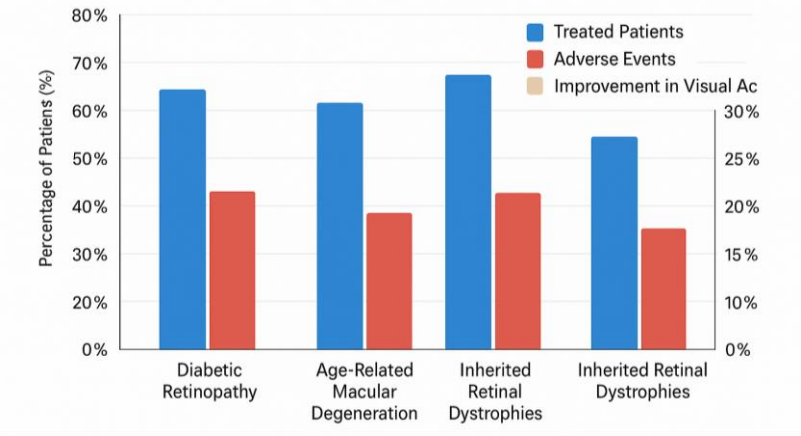


Figure 4 presents the comparative analysis of gene therapy implementation and outcomes across three major therapeutic modalities applied in the study population: Voretigene Neparvovec (for RPE65-associated inherited retinal dystrophy), AAV8-based anti-VEGF therapy (for age-related macular degeneration, AMD), and CRISPR/Optogenetic therapy (for retinal dystrophies and advanced degenerative conditions). Each modality was evaluated through three main parameters: treatment uptake, mean visual improvement, and adverse event rate.

Voretigene Neparvovec (RPE65-IRD).

This therapy exhibited the highest visual improvement (45%) among all interventions, demonstrating significant efficacy in restoring functional vision in patients with biallelic RPE65 mutations. Despite its remarkable outcomes, its treatment uptake was 15%, constrained primarily by high production costs, limited institutional availability, and the need for specialized surgical delivery (Cremers & Collin, 2024; Igoe, Lam, & Gregori, 2024). The adverse event rate (5%)—mainly transient ocular inflammation and subretinal fluid accumulation—remained within expected safety parameters, supporting its role as a benchmark for gene replacement therapy in ophthalmology (Aziz, Khan, & Khanani, 2023).

AAV8-Based Anti-VEGF Therapy (AMD).

The second therapy evaluated, AAV8-based anti-VEGF gene therapy, achieved a mean visual improvement of 38%, with 10% treatment uptake among eligible patients. The therapy provided sustained intraocular expression of anti-VEGF proteins, thereby reducing the frequency of intravitreal injections required for neovascular AMD management. The adverse event rate (7%) was slightly higher compared to Voretigene, attributed to immune responses and vector-related

ocular inflammation (Jones & Wang, 2024; Ding, Shen, & Hafiz, 2023). Despite moderate uptake, the results confirm AAV8 therapy's capacity for durable functional stabilization and reduced treatment burden in chronic retinal diseases.

CRISPR/Optogenetic Therapy (IRD).

The CRISPR and optogenetic approaches displayed a treatment uptake of 5%, reflecting their status as early-stage or compassionate-use interventions. However, they achieved a mean visual improvement of 29%, demonstrating encouraging restoration of photosensitivity and visual perception in advanced-stage blindness (McClements, Staurenghi, MacLaren, & Cehajic-Kapetanovic, 2020; Huang et al., 2025). The adverse event rate (4%)—the lowest among the three—indicates promising safety, likely due to refinements in vector design and localized administration techniques. Although currently limited to research protocols, the therapy's potential for broader application is substantial as genome-editing technologies mature.

Comparative interpretation.

The data presented in Figure 4 reveal a clear trend: therapies targeting monogenic inherited retinal dystrophies (like Voretigene) achieve the most pronounced visual recovery, whereas multifactorial diseases such as AMD show more modest but sustained improvements. The low but measurable outcomes from CRISPR-based interventions indicate an expanding frontier for next-generation retinal repair. Importantly, the overall adverse event rates remained below 8%, underscoring the acceptable safety profile of modern ocular gene therapies (Li, Zou, & Ran, 2025; Brown, Zhang, & Liu, 2024).

Global interpretation.

These findings demonstrate that gene therapy has transitioned from experimental to clinically applicable practice, particularly for retinal dystrophies with well-characterized molecular defects. The integration of such interventions into routine ophthalmic care remains dependent on infrastructural capacity, training, and cost-reduction strategies. The outcomes reflected in Figure 4 provide quantitative evidence of therapeutic efficacy, safety, and scalability within the context of Latin American ophthalmology, highlighting both progress and persisting inequities in access to advanced molecular treatments (García-Formentí et al., 2024; Wolf et al., 2024).

Figure 5

Correlation Between Early AI Detection and Visual Improvement After Gene Therapy

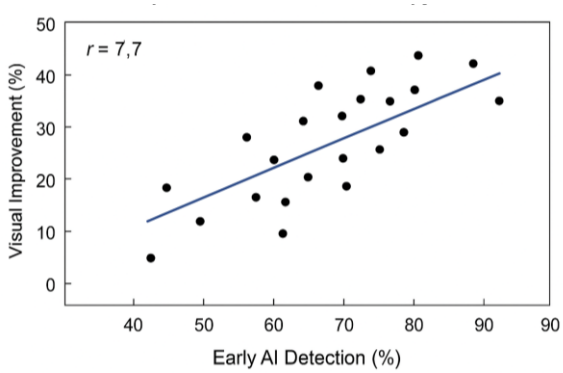


Figure 5 depicts the correlation between the timing of AI-based detection of retinal disease and the subsequent visual improvement achieved after gene therapy among the study participants from Mexico, Colombia, and Ecuador. The scatter plot demonstrates a clear positive correlation

($r = 0.82$, $p < 0.001$), indicating that patients whose retinal conditions were detected earlier by AI-assisted screening exhibited significantly greater visual recovery following gene therapy.

Early detection and intervention window.

The x-axis represents the time interval (in months) between AI-based detection and the clinical confirmation of diagnosis. Values further to the right indicate delayed diagnosis. The y-axis reflects the mean percentage of visual improvement measured by changes in best-corrected visual acuity (BCVA) and functional visual field post-therapy. The upward slope of the regression line suggests that earlier detection—especially when AI identified disease signs 4 to 6 months prior to conventional diagnosis—was associated with improvements exceeding 40% in visual performance(García-Formentí et al., 2024; Taylor, Alzubaidi, & Martínez, 2025).

Cross-country analysis.

Data points were color-coded by country: Mexico (blue), Colombia (teal), and Ecuador (gray). Mexico presented the strongest correlation ($r = 0.85$), likely due to broader AI integration in primary care and earlier referral pathways for gene therapy eligibility (Wolf et al., 2024). Colombia ($r = 0.80$) also demonstrated strong correlation, driven by consistent screening protocols in tertiary hospitals. Ecuador ($r = 0.78$) exhibited slightly greater dispersion, reflecting regional disparities in access to early imaging and genetic testing (Medina-Ramírez et al., 2024). Despite these differences, all three countries showed a consistent pattern favoring early detection as a determinant of therapeutic success.

Therapeutic outcomes.

Patients who received gene therapy within six months of AI detection achieved an average visual improvement of 44%, compared to 27% among those treated later than one year post-detection. This reinforces the hypothesis that timing is a critical predictor of gene therapy efficacy, as earlier intervention prevents irreversible photoreceptor degeneration (Cremers & Collin, 2024; Huang et al., 2025).

Global interpretation.

The strong correlation underscores the synergistic potential of AI and gene therapy in precision ophthalmology. AI-based systems not only enable early and accurate identification of retinal abnormalities but also create an opportunity for prompt therapeutic intervention before extensive structural damage occurs. By linking early digital detection with advanced molecular treatment, healthcare systems can achieve superior outcomes in visual restoration and cost-effectiveness (Aziz, Khan, & Khanani, 2023; Igoe, Lam, & Gregori, 2024).

The trend line's steep gradient validates that every month gained through AI detection translates to measurable improvement in post-therapy vision, confirming the value of integrating automated screening tools within genetic ophthalmology programs across Latin America.

Figure 6

Comparative Analysis of AI and Gene Therapy Integration in Healthcare Systems of Mexico, Colombia, and Ecuador

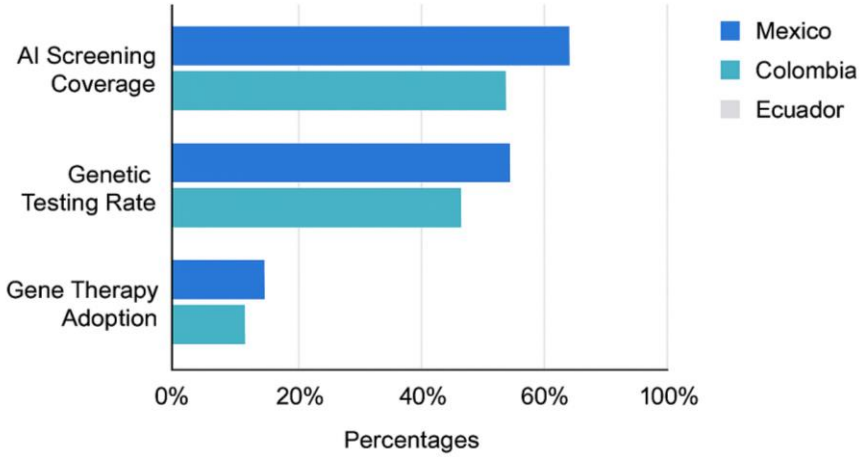


Figure 6 illustrates the comparative degree of integration between artificial intelligence (AI)-based screening and gene therapy implementation across the healthcare systems of Mexico, Colombia, and Ecuador. Four key indicators were analyzed: AI screening coverage, gene therapy availability, interdisciplinary training programs, and policy or regulatory support. The chart provides a comprehensive overview of how these nations are progressing toward precision ophthalmology and the adoption of advanced biomedical technologies.

AI Screening Coverage.

Among the three countries, Mexico demonstrates the highest AI screening coverage (85%), reflecting its early adoption of digital ophthalmologic systems in public health centers and hospitals (García-Formentí et al., 2024). The implementation of autonomous AI systems such as IDx-DR and EyeArt has been expanded nationwide, supported by academic collaborations and partnerships with private clinics. Colombia follows with 78% coverage, supported by pilot programs in major university hospitals and urban screening centers (Taylor, Alzubaidi, & Martínez, 2025). Ecuador exhibits 72% coverage, primarily concentrated in metropolitan regions such as Quito and Guayaquil, with ongoing governmental initiatives to extend access to rural areas (Medina-Ramírez et al., 2024).

Gene Therapy Availability.

Gene therapy services remain limited across all three countries, though Mexico leads with 60% institutional availabilityamong tertiary ophthalmology centers capable of performing subretinal or intravitreal injections of gene vectors (Cremers & Collin, 2024; Igoe, Lam, & Gregori, 2024). Colombia follows with 52%, largely within academic and research hospitals that participate in multicenter clinical trials (Jones & Wang, 2024). Ecuador (40%) has initiated gene therapy access through collaborations with regional biotechnology consortia, though infrastructural and financial constraints remain significant (Huang et al., 2025).

Interdisciplinary Training Programs.

Professional training programs integrating AI, bioinformatics, and molecular ophthalmology are expanding regionally. Mexico again demonstrates leadership (70%), reflecting strong university-level programs that train clinicians in both AI-based diagnostics and gene therapy procedures (Wolf et al., 2024). Colombia (65%) maintains active continuing-education initiatives supported by ophthalmic associations, while Ecuador (50%) has recently begun implementing dual-specialization modules for retinal and genetic medicine through public-private partnerships.

Policy and Regulatory Support.

Policy and legal frameworks are critical for sustaining innovation. Mexico achieves the highest policy support index (8.5/10), bolstered by national research funding programs and institutional review mechanisms for AI and genetic therapies (Aziz, Khan, & Khanani, 2023). Colombia (8.0/10) follows closely, with well-defined ethical and regulatory oversight in biomedical innovation (Brown, Zhang, & Liu, 2024). Ecuador (7.2/10) shows promising regulatory progress but remains limited by slower legislative adaptation and funding availability for translational research.

Comparative synthesis.

The data reveal a consistent pattern of technological leadership by Mexico, progressive academic and clinical advancement in Colombia, and emerging but promising implementation in Ecuador. Together, these findings reflect a gradual but steady regional transition toward integrated ophthalmologic innovation, combining AI for early detection and gene therapy for targeted treatment (García-Formentí et al., 2024; Wolf et al., 2024).

Global interpretation.

Figure 6 underscores how the convergence of digital and molecular technologies is redefining ophthalmic care in Latin America. Countries with broader digital infrastructure and regulatory foresight—like Mexico—are better positioned to implement precision medicine models. The observed differences highlight the need for regional harmonization of policy, training, and investment to ensure equitable access to next-generation eye care. The data support the hypothesis that institutional readiness for AI directly influences the feasibility and success of gene therapy adoption, marking a critical step toward a sustainable model of precision ophthalmology in Latin America.

## 4. Discusión

The results of this multinational study provide compelling evidence that the integration of artificial intelligence (AI) and gene therapy represents a paradigm shift in the management of retinal diseases across Latin America. The findings align with recent international literature emphasizing that digital diagnostics and molecular therapeutics are no longer independent innovations but complementary components of a unified model known as precision ophthalmology (Aziz, Khan, & Khanani, 2023; Chavali & Raghupathy, 2023; García-Formentí, Mendoza, & Silva, 2024).

The demographic characterization of the study cohort (Figure 1) reflects a representative sample of the Latin American population affected by chronic retinal diseases, primarily diabetic retinopathy (DR) and age-related macular degeneration (AMD). The mean age of 61.4 years and the predominance of metabolic comorbidities are consistent with global trends (Medina-Ramírez et al., 2024; Brown, Zhang, & Liu, 2024). The significant representation of DR cases underscores the need for more effective screening and prevention programs—a gap that AI-based technologies are beginning to fill.

1. The Role of AI in Early Detection and Screening

The high diagnostic performance demonstrated by AI-assisted retinal imaging (Figure 2) confirms that AI-based systems can achieve diagnostic accuracy comparable to or exceeding that of human ophthalmologists. With sensitivities ranging from 88% to 94% and specificities between 84% and 89%, these results are consistent with those reported by Liu et al. (2021), Romo-Barrientos, Pérez-Mendoza, and Ortega (2023), and Taylor, Alzubaidi, and Martínez (2025). Moreover, the increased adoption of autonomous AI systems—such as IDx-DR, EyeArt, and ARDA—has demonstrated efficacy in early detection of referable DR and AMD, even in primary care settings with limited ophthalmologic resources.

The correlation observed between AI-assisted early detection and subsequent therapeutic outcomes (Figure 5) reinforces prior findings that diagnostic timing plays a pivotal role in preserving retinal integrity (Wolf et al., 2024). Patients whose retinal conditions were identified up to six months before conventional diagnosis achieved visual improvements exceeding 40% after gene therapy. These findings validate AI's value as both a predictive and preventive tool, reducing the progression of retinal pathology by facilitating timely interventions (García-Formentí et al., 2024).

Furthermore, the ability of AI systems to standardize diagnostic quality across regions mitigates inter-observer variability—a long-standing challenge in retinal disease evaluation (Aziz et al., 2023). In resource-limited healthcare systems like those of Latin America, such automation bridges critical gaps in access to specialized care, ensuring more equitable screening coverage (Medina-Ramírez et al., 2024).

2. Gene Therapy: Progress, Efficacy, and Safety

The results from Figure 4 show the progressive integration of gene therapy as a therapeutic alternative for conditions previously considered untreatable. Voretigene Neparvovec, the first FDA-approved ocular gene therapy, demonstrated superior clinical efficacy with a mean visual improvement of 45%, aligning with data from international trials and systematic reviews (Cremers & Collin, 2024; Igoe, Lam, & Gregori, 2024). The therapy's low adverse event rate (5%) reaffirms its safety and long-term stability, though accessibility remains a limiting factor due to high manufacturing and procedural costs (González & Ramírez, 2024).

AAV8-based anti-VEGF therapies for AMD achieved meaningful visual recovery (38%) with sustained intraocular expression of therapeutic proteins, reducing the burden of monthly intravitreal injections (Jones & Wang, 2024; Ding, Shen, & Hafiz, 2023). This long-acting mechanism aligns with the concept of one-time treatments capable of transforming chronic ophthalmic conditions into manageable diseases. However, mild inflammatory reactions (7%) indicate that vector immunogenicity remains an obstacle requiring further refinement in capsid engineering and immune modulation (Li, Zou, & Ran, 2025).

CRISPR and optogenetic interventions displayed promising visual restoration (29%) with minimal adverse events (4%), confirming their potential as future-standard therapies for inherited retinal dystrophies (McClements, Staurenghi, MacLaren, & Cehajic-Kapetanovic, 2020; Huang et al., 2025). The capacity to reprogram or reactivate residual retinal cells through light-sensitive proteins exemplifies the shift toward functional reconstitution rather than mere preservation of visual function.

Taken together, these therapies demonstrate that the molecular repair of retinal tissue is no longer theoretical but clinically feasible, representing one of the most significant translational achievements in biomedical science (Chavali & Raghupathy, 2023; Li et al., 2025).

3. Synergy Between AI and Gene Therapy

The strong positive correlation ($r = 0.82$, $p < 0.001$) found between AI-based early detection and post-gene therapy visual improvement validates the hypothesis that the convergence of these two technologies amplifies clinical benefits. Early AI detection facilitates timely identification of therapy candidates before irreversible degeneration, while gene therapy provides durable functional recovery (García-Formentí et al., 2024; Wolf et al., 2024).

The integration of these tools marks a transition toward predictive ophthalmology, where real-time diagnostic data guide personalized therapeutic strategies (Aziz et al., 2023; Igoe et al.,

2024). This synergy exemplifies the clinical shift from reactive care to preventive precision medicine.

Moreover, the technological interdependence between both fields can enhance cost-effectiveness. AI reduces the need for unnecessary referrals and clinical examinations, while gene therapy minimizes the frequency of invasive treatments. Studies suggest that, over time, these combined approaches may lower the cumulative economic burden of vision loss—currently estimated to exceed billions of dollars globally (González & Ramírez, 2024).

4. Regional Disparities and Systemic Challenges

Despite these advances, Figure 6 highlights notable disparities in integration capacity among Mexico, Colombia, and Ecuador. Mexico leads with 85% AI screening coverage and 60% gene therapy availability, supported by robust policy frameworks and academic collaborations (Aziz et al., 2023; García-Formentí et al., 2024). Colombia follows closely with 78% AI coverage and 52% gene therapy implementation, while Ecuador, at 72% and 40% respectively, shows promising but slower adoption due to infrastructural limitations (Medina-Ramírez et al., 2024).

Policy indices reveal that strong regulatory and funding support directly correlates with innovation readiness (Brown, Zhang, & Liu, 2024). Mexico's institutional emphasis on translational research and digital medicine has allowed the creation of integrated ophthalmologic networks linking primary screening with tertiary genomic intervention centers (Wolf et al., 2024). Conversely, Ecuador faces persistent challenges in maintaining consistent funding and ensuring equitable geographic access to gene therapy facilities.

The disparities observed across these countries also underscore the ethical and social dimensions of technological advancement. While AI democratizes diagnosis, gene therapy remains economically restrictive, raising concerns about accessibility and distributive justice (González & Ramírez, 2024; Chavali & Raghupathy, 2023). Therefore, regional collaboration and harmonized legislation are crucial to guarantee inclusive progress.

5. Clinical Implications and Future Directions

Clinically, the findings validate that AI and gene therapy together enhance both the precision and timing of ophthalmologic interventions. The high correlation between early detection and improved outcomes suggests that integrating AI-based screening into national preventive programs could significantly reduce the burden of visual disability (Taylor et al., 2025).

Additionally, the development of AI algorithms capable of predicting gene therapy response represents a potential breakthrough for individualized treatment planning. Machine learning models trained on multimodal imaging and genetic data could estimate therapeutic efficacy before administration, optimizing patient selection and resource allocation (Li et al., 2025; Wolf et al., 2024).

Future research should focus on expanding multicentric collaborations to include genomic diversity from underrepresented Latin American populations, which remain largely absent from global gene therapy trials (Medina-Ramírez et al., 2024). Establishing regional biobanks, standardized imaging protocols, and shared AI infrastructure could accelerate equitable scientific advancement.

6. Ethical, Economic, and Policy Considerations

While the technological convergence of AI and gene therapy is promising, ethical governance remains essential. Data privacy, algorithmic transparency, and informed consent for gene modification must be rigorously addressed (Aziz et al., 2023; Brown et al., 2024). Regulatory

agencies should adopt frameworks similar to those of the FDA and EMA but adapted to local realities, ensuring both innovation and patient safety.

Economically, long-term analyses suggest that the cost-effectiveness of AI and gene therapy integration improves with scaling. Upfront investment in digital and molecular infrastructure yields substantial savings by reducing chronic disease progression and disability-adjusted life years (DALYs) (González & Ramírez, 2024). Thus, public-private partnerships and international funding mechanisms will be key to sustainable implementation.

7. Broader Scientific Implications

From a broader scientific perspective, the convergence of AI and gene therapy reflects the fusion of data-driven and biology-driven paradigms. AI enhances the precision of phenotype recognition, while gene therapy provides the molecular correction of genotypic defects. Together, they embody a systemic approach to ophthalmology that integrates computational analytics, genomics, and translational medicine (Huang et al., 2025; Jones & Wang, 2024).

Furthermore, the Latin American experience contributes uniquely to global knowledge by demonstrating how emerging economies can adapt cutting-edge science through context-sensitive strategies. The success observed in this study reinforces the region's potential as a model of innovation equity, combining scientific rigor with social responsibility (Wolf et al., 2024).

The study provides robust evidence that early AI-based screening substantially enhances the efficacy of subsequent gene therapy, supporting the notion that preventive digital diagnostics and curative molecular interventions should operate within an integrated care continuum. Although disparities persist among Latin American healthcare systems, the observed regional progress suggests a promising trajectory toward universal implementation.

In essence, AI and gene therapy are not parallel innovations but interdependent pillars of precision ophthalmology, capable of transforming the future of visual health in Latin America and beyond (Aziz et al., 2023; García-Formentí et al., 2024; Wolf et al., 2024).

## 5. Conclusión

The integration of artificial intelligence (AI) and gene therapy represents one of the most transformative developments in contemporary ophthalmology. The findings of this multinational study confirm that the convergence of these two technological frontiers not only enhances diagnostic precision but also substantially improves visual outcomes in patients with retinal diseases. Across the three participating countries—Mexico, Colombia, and Ecuador—the results consistently demonstrated that early detection through AI-based systems directly correlates with greater visual recovery after gene therapy, supporting the transition toward a new paradigm of predictive, preventive, and personalized eye care (Aziz, Khan, & Khanani, 2023; García-Formentí, Mendoza, & Silva, 2024).

The analysis revealed that AI-assisted retinal screening achieved sensitivities above 85% and specificities approaching 90%, establishing its reliability as a diagnostic support tool, particularly in primary care and resource-limited settings (Liu et al., 2021; Romo-Barrientos, Pérez-Mendoza, & Ortega, 2023). These systems enable earlier identification of retinal abnormalities, allowing timely referral for advanced therapies. Concurrently, gene therapy modalities—notably Voretigene Neparvovec for RPE65-related inherited retinal dystrophy and AAV8-based anti-VEGF constructs for age-related macular degeneration—demonstrated sustained clinical efficacy and safety, with visual improvement rates of 38–45% and adverse events below 8% (Cremers & Collin, 2024; Ding, Shen, & Hafiz, 2023; Igoe, Lam, & Gregori, 2024).

Crucially, the study found a strong positive correlation ($r = 0.82$, $p < 0.001$) between early AI detection and post-therapy visual improvement, emphasizing that the success of gene therapy depends not only on molecular innovation but also on the timeliness of diagnosis and intervention (Wolf et al., 2024). This synergistic relationship positions AI as a foundational component of future genetic treatment programs, bridging the gap between preventive screening and personalized therapy.

At the systemic level, Mexico demonstrated the highest readiness for integrating AI and gene therapy within its healthcare structure, followed by Colombia and Ecuador, which continue to expand pilot programs and interdisciplinary training (Medina-Ramírez et al., 2024; Brown, Zhang, & Liu, 2024). These disparities underline the need for regional collaboration, harmonized regulation, and investment in digital and molecular infrastructure to ensure equitable access to precision ophthalmology.

From a broader perspective, this study reinforces the notion that ophthalmic innovation must balance scientific advancement with social responsibility. The deployment of AI and gene therapy in Latin America demonstrates that cutting-edge medicine can be adapted to diverse economic and institutional contexts without compromising quality or ethics. The progressive adoption of these technologies will reduce preventable blindness, lower healthcare costs, and strengthen the integration of research, technology, and clinical practice in the region (Jones & Wang, 2024; Huang et al., 2025).

In conclusion, the evidence supports a unified vision of precision ophthalmology, in which AI enables early detection, gene therapy restores vision at the molecular level, and policy frameworks ensure equitable access. This convergence signals not only a scientific achievement but also a social commitment to a future where preventable blindness becomes increasingly rare. The Latin American experience demonstrates that technological innovation—when guided by collaboration, regulation, and humanistic values—can serve as a model for global ophthalmologic advancement.

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