International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY

Diagnostic Accuracy of EyeArt system for Detecting Referable Diabetic Retinopathy across Multiple Retinal Imaging Modalities: a Systematic Review

INPLASY202620008

doi: 10.37766/inplasy2026.2.0008

Received: 3 February 2026

Published: 3 February 2026

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202620008

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 3 February 2026 and was last updated on 3 February 2026.

INTRODUCTION

Review question / Objective PICO framework - Adults undergoing routine retinal screening (P) , Any version of EyeArt to applied to fundus, ultra-widefield photos taken on ocular camera and smart phones (I), masked grading by human trained / expert graders (C) , diagnostic accuracy tests specifically sensitivity, specificity, predictive values, accuracy
Objective : To evaluate the diagnostic accuracy of the EyeArt AI Eye Screening System for independently detecting referable diabetic retinopathy (RDR) in adults undergoing routine retinal screening, using human grading as the reference standard, across multiple imaging modalities.

Rationale Diabetic retinopathy (DR), a complication of chronic hyperglycemia, is a leading cause of preventable blindness in adults. Routine retinal screening enables timely detection and treatment, but most programs depend on specialist graders and are limited by workforce and infrastructure constraints. Autonomous artificial intelligence (AI) systems such as EyeArt® offer a point-of-care alternative for detecting referable DR. Accordingly, this review consolidates available evidence on EyeArt's diagnostic accuracy in adult DR screening, to support informed decision-making on how autonomous systems can complement or partially replace human graders.

Condition being studied The condition being studied is Diabetic retinopathy (DR) which is an eye disease caused by long-term high blood sugar in people with diabetes. It damages small blood vessels in the retina, which is the light-sensitive layer at the back of the eye, causing them to leak or bleed and reducing the oxygen supply to eye tissue. This can lead to blurred vision, dark spots, and difficulty seeing clearly, and in severe cases may result in vision loss or blindness. Good control of blood sugar and regular eye checkups can help prevent or slow its progression.

METHODS

Search strategy Databases : PUBMED, CINAHL, Cochrane, EMBASE
[diabetes mellitus[MeSH Terms] OR Diabetes OR screen* OR retinal OR (Diabetic Retinopathy)]
AND [EyeArt OR (EyeArt AI screening) OR (EyeArt system) OR (Artificial Intelligence) OR (AI assisted diagnosis)] AND (Human grad*) OR (Expert grad*) OR (scree*) OR (diabetic retinopathy) OR (grad*)
AND [(Sensitivity and Specificity[MeSH Terms]) OR (Predictive Value of Tests[MeSH Terms])) OR (ROC Curve[MeSH Terms])) OR (Retinopathy/diagnostic imaging[MeSH Major Topic])) OR (Referable Diabetic Retinopathy)) OR (Diagnostic Accuracy)) OR (Sensitivity)) OR (Specificity)) OR (ROC)) OR (Area Under the Curve)].

Participant or population Adults (≥ 18 years of age) with Diabetes undergoing routine retinal screening irrespective of race, sex, ethnicity or country of origin, at a point of care center at any level of establishment.

Intervention Artificial Intelligence (AI) based eye screening system, EyeArt, which uses fundus images taken according to specification, to classify whether a participant's diabetic retinopathy is severe enough to be referred to an eye doctor or not.

Comparator Human graders - physicians, clinicians etc., who are trained to distinguish referable DR cases because they have such expertise. This is currently considered the gold standard.

Study designs to be included Literature that included prospective, retrospective, or cross-sectional observational designs in the study of EyeArt's retinal screening abilities.

Eligibility criteria Inclusion Criteria:
- Studies published between January 1, 2012 and December 31, 2025, reflecting the period since EyeArt's initial release.
- Only English-language studies
- Adults (≥18 years) with diabetes
- Studies using the International Clinical Diabetic Retinopathy (ICDR) scale or classification systems that could be mapped to ICDR (e.g.) the UK NHS DESP
- Studies that reported real-world patient data with enough information to derive sensitivity, specificity, predictive values, accuracy, or confusion-matrix components, to ensure sufficient data for EyeArt's performance estimation.
- A minimum sample size of ≥100 retinal images (≥50 patients)

Exclusion Criteria
- Case series, narrative reviews, reports, abstracts only, conference papers
- Studies on Ai algorithm development for DR screening
- The comparator is NOT human graders.

Information sources Doctoral course material, Electronic databases, Google Scholar and Generative AI.

Main outcome(s) -Diagnostic accuracy statistics for EyeArt's performance to independently identify if a retinal image indicates a referable case or not.
- specifically - > Confusion matrix elements (True and False positives, True and False negatives, Sensitivity, Specificity, Positive and negative predictive values and accuracy.

Additional outcome(s) None.

Data management XL sheets were used to extract , compile and organize data and to compute performance accuracy statistics.

Quality assessment / Risk of bias analysis QUADAS-2 tool was used for Risk of Bias and applicability concerns in each study.

Strategy of data synthesis One of the inclusion criteria is to select only those studies that reported sensitivity and specificity and / or confusion matrix elements and predictive values so that these may be computed. It was imperative that sensitivity and specificity data was available for each study. Hence, these were calculated in the Excel sheet with outcome values if they were not mentioned in the study.
Since no meta-analysis will be performed, outcomes-based interpretations about EyeArt performance will be drawn from these statistics, such that results across studies were comparable.

Subgroup analysis No sub-group analysis was performed.

Sensitivity analysis A sensitivity analysis was performed by repeating the aggregate analysis after excluding studies judged to be at high risk of bias or methodological outliers (e.g., Tufail et al., 2017), to evaluate the robustness of the findings.

Language restriction No.

Country(ies) involved USA.

Keywords Diabetic retinopathy, Eye Screening, EyeArt, Systematic Review, Artificial Intelligence, Diagnostic test accuracy, Confusion matrix, Fundus photography, Ultra-wide field.

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