




Feasibility of automated artificial intelligence screening for diabetic retinopathy in a resource-limited setting



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Background: Diabetic retinopathy (DR), a leading cause of blindness, requires effective screening, which is challenging in resource-limited settings. While artificial intelligence (AI) screening offers potential, real-world feasibility data are scarce.

Methods: In this prospective feasibility study, diabetic adults at a Cape Town public hospital endocrine clinic underwent DR screening with an autonomous AI system (LumineticsCore®) between April and July 2022. Ungradable images or AI-detected referable DR (moderate non-proliferative DR or worse) prompted ophthalmologist referral. Screening time, ungradable rates and referral burden were assessed.

Results: Sixty-two patients were screened, with a mean AI screening time of 11.7 min. Initial non-mydratic images were ungradable in 39/62 (62.9%), and 19/62 (30.6%) remained ungradable despite dilatation. Overall, 55/62 (88.7%) were referred to ophthalmology, including 36 (58.1%) for AI-referable DR and 19 (30.6%) for ungradable images. Ophthalmologist assessment found that 8/62 (12.9%) required DR treatment, corresponding to a number needed to screen (NNS) of 7.8 (95% CI, 4.2 -17.9). Cataract was the main cause of AI-ungradable images.

Conclusion: AI screening time was acceptable and identified vision-threatening DR requiring treatment at a meaningful rate (about one in eight screened). However, a high initial referral burden and many ungradable images (mainly because of cataract) could overwhelm ophthalmology services without pathway adaptation.

Contribution: This study provides feasibility data on autonomous AI screening for DR in a South African public-sector clinic. Findings highlight the need for context-specific adaptations, such as raising the referral threshold to vision-threatening DR (severe non-proliferative DR, proliferative DR and/or diabetic macular oedema) and integrating protocols for managing cataract-related ungradable images, to support sustainable implementation.

Keywords: diabetic retinopathy; non-proliferative diabetic retinopathy; proliferative diabetic retinopathy; vision-threatening diabetic retinopathy; referable diabetic retinopathy; diabetic retinopathy screening; artificial intelligence; AI screening.

Introduction

Diabetes mellitus is a significant and escalating global health issue, with a particularly concerning rise observed in low- and middle-income countries (LMICs).¹ Globally, approximately 11.1% of adults aged 20–79 years live with diabetes. Projections indicate that by 2050, one in nine adults will have diabetes, representing a 46% increase in the number of people affected. Over 80% of adults with diabetes reside in LMICs.¹

A significant complication of diabetes is diabetic retinopathy (DR). This condition affects approximately one-third of people with diabetes, and 10% of diabetic patients develop vision-threatening DR, such as proliferative diabetic retinopathy (PDR) or diabetic macular oedema (DMO).^{2,3,4} In South Africa, DR is the leading cause of blindness among the working-age population.⁵ A critical challenge is late diagnosis, as DR often remains asymptomatic until it reaches advanced stages.⁶

Screening for DR is crucial for its early detection, which facilitates timely referral to an ophthalmologist for treatment, thereby preventing permanent visual loss.⁷ While South Africa has a national screening programme, namely 'Screen for Life',⁸ implementing effective DR screening in resource-limited settings, like the nation's public health sector, faces numerous significant challenges.^{9,10,11} Services are often overburdened and hampered by a shortage of trained staff, potentially leading to inaccuracies in DR grading. Furthermore, current screening processes can

be inefficient. For instance, retinal images are typically taken with a mobile non-mydratric fundus camera and then manually graded at a central location on a different day from image capture. Subsequently, attempts to contact patients with their results frequently fail, resulting in many individuals not receiving necessary referrals for further assessment and treatment. An ideal screening process would involve efficient, accurate and immediate interpretation of fundus photographs to ensure appropriate same-day patient referral if treatment is indicated.

Artificial intelligence (AI) has shown considerable success in improving efficiency, accuracy and accessibility of DR screening programmes internationally.^{12,13} Artificial intelligence algorithms can automate the analysis of retinal images, offering diagnostic capabilities comparable to or exceeding human experts, and potentially expediting the screening process.^{14,15,16} Despite these advancements, there is limited real-world evidence on the feasibility and practical implications of implementing automated AI-based DR screening systems within resource-limited public healthcare settings, such as those in South Africa.¹⁷ The development of AI models has predominantly occurred in high-income countries, prompting essential questions regarding their performance and adaptability when implemented in LMICs.¹⁸

This study aimed to evaluate the feasibility of an autonomous AI-based diagnostic tool for DR screening in an endocrine outpatient clinic at Groote Schuur hospital, a public sector hospital in Cape Town, South Africa. The objectives were to determine if the screening process is time-efficient enough for integration into routine clinic flow, and to evaluate key performance indicators of the AI system, such as the rate of ungradable images and the proportion of AI-detected referable cases that require treatment when assessed by an ophthalmologist.

Research methods and design

Study design

This was a prospective, cross-sectional feasibility study.

Setting

The study was conducted at the endocrine outpatient clinic of Groote Schuur hospital, a public sector tertiary academic hospital in Cape Town, South Africa.

Study population and sampling strategy

Adults (aged ≥ 18 years) with type 1 or type 2 diabetes mellitus, consecutively attending the endocrine outpatient clinic between 21 April 2022 and 31 July 2022, were enrolled in the study.

Intervention

For each participant, a trained technician captured two 45-degree non-mydratric digital fundus images per eye

(one centred on the optic disc and one on the fovea) using a Topcon® NW400 fundus camera (Topcon, Tokyo, Japan). These images were automatically transferred to a computer with the LumineticsCore® (formerly IDx-DR®, Digital Diagnostics, Coralville, United States) AI software client. LumineticsCore® is an United States Food and Drug Administration (FDA)-approved and South African Health Products Regulatory Authority (SAHPRA)-registered, fully autonomous AI diagnostic system. The AI software performed an automated analysis, providing a real-time diagnostic report.

If initial image quality was insufficient for AI grading, pupils were pharmacologically dilated with Cyclomydril® (cyclopentolate hydrochloride 0.2%, phenylephrine hydrochloride 1%), and images were re-captured after 10 min. If images remained ungradable, the participant was referred for ophthalmological assessment.

The AI system graded DR into two main categories:

- 'Non-referable DR': This was defined as no DR, or mild non-proliferative diabetic retinopathy (mild NPDR).
- 'Referable DR': This was defined as moderate NPDR or worse.

The 'referable DR' category included a subcategory termed 'vision-threatening DR'. This was defined as severe NPDR, PDR and/or DMO.

Participants with an AI diagnosis of non-referable DR were advised to attend annual DR screening. Those with referable DR or ungradable images were scheduled for an ophthalmologist examination within 1 month of their AI screening. This examination included a dilated fundus assessment using slit-lamp biomicroscopy.

Diabetic retinopathy was graded by the ophthalmologist according to the International Clinical Diabetic Retinopathy (ICDR) severity scale as: No DR, mild NPDR, moderate NPDR, severe NPDR or PDR.¹⁹ Vision-threatening DR, when identified by the ophthalmologist, used the same definition as the AI system (severe NPDR, PDR and/or DMO) and prompted appropriate treatment, such as retinal laser photocoagulation and anti-vascular endothelial growth factor (anti-VEGF) injections.

Data collection

Before screening, baseline data including demographics, diabetes type and duration, recent glycated haemoglobin (HbA1c) and cardiovascular risk factors were collected from patient records. The AI screening time was documented, measured in minutes, from when the patient was seated at the camera until the AI diagnostic report was generated. If dilatation was required, the longer of the two AI screening times (pre- or post-dilatation) was recorded, and the dilatation time was not factored into the screening time duration. Other data collected included the number of patients requiring dilatation, the proportion of ungradable

images, ophthalmologist-determined potential causes for ungradable images, and the number of patients lost to follow-up between AI screening and the ophthalmologist appointment.

Data analysis

The data were summarised using frequencies (percentages), as well as means and standard deviations (s.d.), or medians and ranges, for normal and skewed data distributions, respectively. Data analysis was performed using RStudio (v2023.09, Posit, PBC).

Ethical considerations

This study received ethical approval from the University of Cape Town Human Research Ethics Committee on 25 February 2022 (HREC Ref: 561/2021). All participants provided informed written consent before enrolment. To ensure confidentiality, each participant was assigned a unique study number. All personal data and retinal images were securely stored on a password-protected computer accessible only to the research team.

Results

A total of 62 consecutive patients were enrolled in the study. Patient demographics and systemic risk factors for DR are summarised in Table 1. The mean age of study participants was 42 ± 15.7 years (range 21–86 years), with the majority being female (39 patients, 62.9%). The mean duration of diabetes was 14.6 ± 9.3 years (range 0.8–35 years). A high proportion of patients (58 individuals, 93.5%) had an HbA1c level of $\geq 6.5\%$, with a median HbA1c of 8.9% (range 5.6% – 16.7%). Sixty participants (96.8%) were insulin dependent, and pre-existing cardiac disease was reported in five patients (8.1%). For 23 patients (37.1%), this was their first screening for DR.

The mean AI screening time per patient was 11.7 ± 3.3 min (range 7–25 min). Of the 62 patients screened using the AI system, initial non-mydriatic images were ungradable for 39 individuals (62.9%). Despite pharmacological dilatation,

TABLE 1: Demographics and systemic risk factors for diabetic retinopathy ($N = 62$).

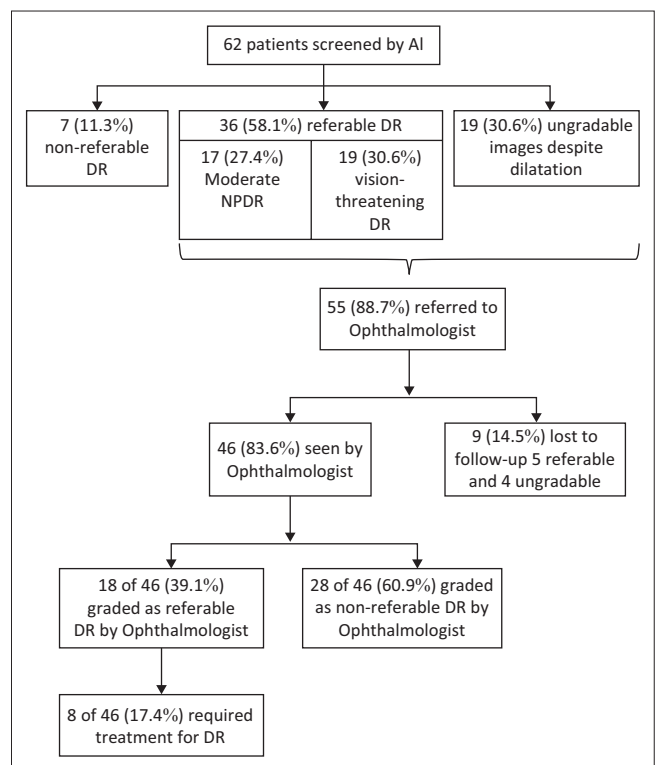
Characteristic	<i>n</i>	%	Mean	s.d.	Median	Range
Age (years)	-	-	42.0	15.7	-	21–86
Gender	-	-	-	-	-	-
Male	23	37.1	-	-	-	-
Female	39	62.9	-	-	-	-
Diagnosis	-	-	-	-	-	-
Type 1 Diabetes mellitus	32	51.6	-	-	-	-
Type 2 Diabetes mellitus	30	48.4	-	-	-	-
Insulin dependent	60	96.8	-	-	-	-
Duration of diabetes (years)	-	-	14.6	9.33	-	0.8–35.0
HbA1c (%)	-	-	-	-	8.9	5.6–16.7
Hypertension	27	43.5	-	-	-	-
Hypercholesterolaemia	24	38.7	-	-	-	-
Smoking	23	37.1	-	-	-	-
Cardiac disease	5	8.1	-	-	-	-

s.d., standard deviation; HbA1c, glycated haemoglobin.

images for 19 of these patients (30.6% of the total cohort) remained ungradable. The automated AI system graded 7 patients (11.3%) as non-referable DR and 36 patients (58.1%) as referable DR. In the referable category, 19 patients (30.6% of the total cohort) were graded as the subcategory of vision-threatening DR. Thus, a total of 55 patients (88.7%) were referred to ophthalmology, because of either a referable DR grading by the AI or ungradable images (see Figure 1).

Nine of the 55 referred patients (16.4%) were lost to follow-up between their AI screening and the subsequent ophthalmology appointment. The ophthalmologist was able to grade the DR in all the referred patients. Among the 46 patients examined by the ophthalmologist, human grading classified 28 (60.9%) as non-referable (no DR or mild NPDR) and 18 (39.1%) as referable (moderate NPDR or worse). A comparison between AI grading and human grading by the ophthalmologist is detailed in Table 2. Of the 14 patients identified by AI with vision-threatening DR who attended the ophthalmology assessment, 7 (50.0% of this subgroup) were confirmed by human grading as having vision-threatening DR (severe NPDR, PDR, or DMO); one was graded as referable but not vision-threatening (moderate NPDR) and 6 (42.9% of this subgroup) were graded as non-referable (no DR or mild DR).

Based on the ophthalmologist's assessment, 8 patients (8 of 46, 17.4% of patients seen by the ophthalmologist; 8 of 62, 12.9% of the total study participants) received treatment for their DR. All eight of these individuals had severe NPDR or PDR and were treated with panretinal photocoagulation. Two of this group also received



DR, diabetic retinopathy; NPDR, non-proliferative diabetic retinopathy; AI, artificial intelligence.

FIGURE 1: Patient grading and referral flow.

intravitreal anti-VEGF injections for associated DMO. The number needed to screen to detect one case of vision-threatening DR (severe NPDR, PDR, or DMO) requiring treatment was 7.8 (95% confidence interval [CI], 4.2–17.9).

Regarding the causes of ungradable images, cataracts were a significant factor (see Table 3). Of the 46 patients assessed by the ophthalmologist, 17 (37.0%) had associated cataracts. Among the 15 patients with ungradable images who were seen by the ophthalmologist, 10 (66.7%) had cataracts identified as the most likely cause.

Discussion

This study evaluated the real-world feasibility of utilising an autonomous AI system for DR screening within a resource-limited public sector endocrine clinic in Cape Town, South Africa. Our findings suggest that while AI screening is highly effective with a low number needed to screen and appears operationally feasible in terms of the time taken per screening, the resultant high referral burden and a significant rate of ungradable images present considerable challenges to sustainable implementation in this context.

Low number needed to screen

In this study, the number needed to screen to identify treatable, vision-threatening DR was 7.8 (95% CI, 4.2–17.9), indicating that one in every eight patients screened required treatment. This detection yield is substantially higher than that reported in a recent meta-analysis, which found an average number needed to screen of 175 among people without DR at their previous screening and 19 among people with mild non-proliferative DR at their previous screening.²⁰ This high detection yield likely reflects the high-risk profile of our cohort (patients attending an endocrine clinic in a public hospital), but it also highlights the substantial burden of DR in South Africa and the importance of implementing effective screening in this setting.

High referral burden

A primary concern arising from this study is the very high referral rate to ophthalmology, with 88.7% of participants being referred either for 'referable DR' on AI screening (58.1%) or because of ungradable images (30.6%). This could

overwhelm already overburdened ophthalmology services, a caution widely echoed in literature on AI deployment in LMIC settings.²¹ Despite the high AI-driven referral rate in our study, only 12.9% of the total cohort ultimately required DR treatment based on the ophthalmologist's assessment. This discrepancy is likely multifactorial and includes the high rate on ungradable images, possible low specificity of AI in our population, and the current threshold for referral by AI.

Ungradable images

In our study, a substantial proportion of participants (62.9%) had initial non-mydratic images deemed ungradable by the AI system, and for 30.6% of all participants, images remained ungradable even after pupillary dilatation. This is markedly higher than the 3.9% ungradable rate observed in the pivotal trial for LuminetixCore® (IDx-DR®), the same system employed in our research, which was conducted in a high-income country setting.¹⁵ Cataracts were identified as the leading cause of ungradable AI images in our cohort. This finding is consistent with the high prevalence of cataracts as a significant barrier to clear fundus imaging and a major cause of visual impairment in LMICs, such as our South African setting. Of note, despite these AI-related image quality challenges, the ophthalmologist in our study was able to clinically assess and grade all referred eyes, including those for which the AI system could not provide a grade. Strategies to minimise and manage ungradable images, such as optimising photographer training, potentially augmenting AI with human oversight (e.g. via telemedicine), and critically, integrating DR screening with accessible pathways for managing common causes of poor image quality like cataracts, are paramount for the practical implementation of AI in our setting.

TABLE 3: Causes of ungradable artificial intelligence images as assessed by ophthalmologist (*N* = 15).

Cause	<i>n</i>	%
Poor fundal view		
Cataracts	10*	66.7
Previous uveitis with posterior synechiae	1	6.7
Asteroid hyalosis	1*	6.7
Associated posterior segment pathology		
Primary open-angle glaucoma	1*	6.7
Myelinated nerve fibres	1	6.7
Myopic tilted discs	1	6.7
No cause found	2	13.3

*. Two patients had two causes of ungradable images (one patient had cataracts and asteroid hyalosis, and one patient had cataracts and primary open-angle glaucoma).

TABLE 2: Comparison between artificial intelligence grading and ophthalmologist grading.

Ophthalmologist grading	AI grading			Total (<i>n</i> = 46)	
	Referable (<i>n</i> = 31)		Ungradable (<i>n</i> = 15)	<i>n</i>	%
	Moderate NPDR (<i>n</i> = 17)	Vision-threatening DR (<i>n</i> = 14)			
Not referable	11	6	11	28	60.9
No DR	0	3	8	-	-
Mild NPDR	11	3	3	-	-
Referable	6	8	4	18	39.1
Mod NPDR	6	1	3	-	-
Vision-threatening DR	0	7	1	-	-

Note: Non-referrable: No or mild NPDR; Referrable: Moderate NPDR or worse; Vision-threatening DR: Severe NPDR, PDR and/or DMO.

DR, diabetic retinopathy; NPDR, non-proliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy; Mod, moderate; DMO, diabetic macular oedema.

Artificial intelligence specificity in the African population

While our study was not designed to formally evaluate the diagnostic accuracy of the AI system, our findings suggested that the AI may have a lower specificity for treatment-requiring conditions in our population, generating a considerable number of false positives. Approximately half of the patients identified by AI with referable DR (moderate NPDR or worse) were subsequently graded as non-referable (no DR or mild NPDR) by the ophthalmologist. This raises concerns about the cross-ethnic performance and generalisability of AI algorithms. Although AI specificity for referable DR in other LMIC studies is often reported as high (ranging from 68.8% to 98%), these studies are predominantly from Asian populations, with limited data from Africa.¹⁸ The study by Bellemeo et al. in Zambia, however, did show good AI performance using an algorithm trained on non-African data, suggesting cross-ethnic generalisability is possible but requires thorough validation in each specific population.²²

Artificial intelligence referral threshold

The international standard AI grading threshold for referable DR (moderate NPDR or worse) inherently includes DR grades that do not require treatment by an ophthalmologist. For resource-limited settings, it may be more appropriate to adjust the AI referral threshold to vision-threatening DR (severe NPDR, PDR and/or DMO). This adaptation, also suggested in other AI studies from LMICs, would better align referral volumes with local healthcare capacity.²² In our study, changing the referral threshold from any referable DR to only vision-threatening DR would have halved the number of AI-generated referrals from gradable images.

Artificial intelligence screening time

Our study found a mean AI screening time of 11.7 min per patient, predominantly for image acquisition. Additionally, 62.9% of patients required dilatation, which was not included in the calculation of the screening time. Although our technician was proficient, further training could potentially reduce image capture times. Nevertheless, this duration was considered acceptable as screening was incorporated into patients' waiting times for their endocrine clinic appointment. This aligns with findings from other LMIC setting studies, where patients appreciated screening during their routine diabetes appointments.¹⁷ Such a model, employing a mobile camera and technician, demonstrates potential for integration into various existing diabetic care services during patient waiting periods, thereby minimising additional time burdens on patients' healthcare visits.

Loss to follow-up

A potential advantage of automated AI DR screening is the provision of point-of-care results, enabling immediate feedback and prompt scheduling of ophthalmology appointments. A recent randomised controlled trial in Rwanda demonstrated that immediate feedback of AI-generated DR screening results significantly improved patient uptake of referral services compared to delayed

communication following human grading (51.5% vs. 39.6%).¹⁷ Notably, even with immediate feedback after AI screening, 48.5% of patients were still lost to follow-up between the screening visit and the ophthalmology appointment, a finding consistent across most African studies, including ours. Ideally, ophthalmology assessment should occur on the same day as AI screening, but this is often logistically impossible in most resource-limited settings.

Other barriers to artificial intelligence screening

Intermittent electricity supply and consequent internet connectivity issues, common in South Africa, frequently disrupted the reliable use of our AI screening tools and necessitated regular IT support. These infrastructural deficits are recognised as significant barriers to sustainable AI implementation in many LMICs and are important factors to consider for programme success.

Strengths and limitations of the study

This study's main strength lies in its real-world evaluation of an FDA and SAHPRA-approved autonomous AI system within a public sector LMIC clinic. It provides practical data on screening time and highlights specific operational challenges, such as ungradable images and high referral burdens. This research contributes to the call for more real-world evidence from such settings, particularly primary healthcare environments in Africa.

The primary limitation is the small sample size, which means the findings are preliminary and require validation in larger cohorts. Furthermore, this study was designed to assess feasibility, not the diagnostic accuracy (sensitivity and specificity) of the AI system, and it utilised a single ophthalmologist for comparative human grading. Factors, such as high prevalence of cataracts in the study population, as well as photographer training, may also have influenced the ungradable image rate observed. Finally, this study used an AI algorithm, which was commercially available during data collection in 2022. Artificial intelligence screening tools are evolving rapidly, and newer versions are likely to have higher specificity and lower rates of ungradable images than those observed here.

Conclusion

This real-world study demonstrates that autonomous AI-based screening for DR is operationally feasible in terms of screening time within a South African public sector clinic and identified vision-threatening DR at a clinically meaningful rate, with approximately one in every eight patients screened requiring treatment. This supports the value of AI in this setting. However, the study also revealed two critical implementation challenges, namely a high referral burden and a significant rate of ungradable images, largely attributable to cataracts. Without adaptation, these risks overwhelm existing ophthalmology services in resource-limited settings.

For AI to become a transformative and sustainable tool in combating DR-related blindness in LMICs, its implementation must be part of a carefully adapted and integrated eye care strategy. Such a strategy may include increasing the AI referral threshold from any referable DR to specifically vision-threatening DR and incorporating cataract screening and management pathways alongside DR screening. Further large-scale, context-specific research is crucial to validate these findings, optimise implementation models and confirm the long-term clinical and economic benefits of AI in diverse resource-constrained environments.

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Competing interests

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

CRedit authorship contribution

Margaretha M. Roux: Conceptualisation, Data curation, Formal analysis, Resources, Writing – original draft. James C. Rice: Formal analysis, Validation. Jonel Steffen: Data curation, Formal analysis, Resources, Writing – original draft. All authors reviewed the article, contributed to the discussion of results, approved the final version for submission and publication, and take responsibility for the integrity of its findings.

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Data availability

The data supporting the findings of this study are not publicly accessible in order to protect patient confidentiality and comply with ethical standards. However, de-identified data may be made available from the corresponding author, Jonel Steffen, upon reasonable request and subject to approval by the relevant institutional review board or ethics committee, if applicable.

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