Comparative Efficacy of Smartphone Imaging with 3D-Printed Adaptor versus Fundus Camera for Diabetic Retinopathy Screening

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ABSTRACT

Objective: To determine if dilated smartphone photography with a 3D-printed adaptor for a fundus lens can be an alternative screening tool for diabetic retinopathy.

Methods: Methods: This was a single-center, prospective, comparative study of 102 eyes of patients with diabetes mellitus. DR screening was performed using binocular indirect ophthalmoscopy (BIO) as the reference standard, alongside two imaging modalities: a traditional fundus camera and a smartphone equipped with a 3D-printed adaptor. Coded images were evaluated by three masked retina specialists. Sensitivity, specificity, predictive values, and likelihood ratios were calculated for both imaging modalities.

Results: DR gradings of both imaging modalities were compared to BIO and showed very good agreement (α 0.94-0.96 95% CI 0.93-0.99). Both have high levels of interobserver reliability (kappa value 0.88-0.92 95% CI 0.84-0.96) and intraobserver reliability (kappa value 0.85-1.00 95% CI 0.64-1.00). Smartphone and Visucam 500 images can detect presence of DR with a sensitivity of 93.9% (95% CI 83.1-98.7) and 91.8% (95% CI 80.4-97.7); and a specificity of 90.6% (95% CI 79.3-96.9) and 92.5% (95% CI 81.8-97.9), respectively, as well as the presence of vision threatening DR with a sensitivity of 100% (95% CI 91.2-100) and specificity of 85.5% (95% CI 74.2-93.1). Image quality was similar between the two imaging modalities (P=1.00)

Conclusion: Smartphone-based imaging with an attached 3D-printed adaptor offers high sensitivity and reliability comparable to a traditional fundus camera, and can be used an alternative for DR screening.

Keywords: diabetic retinopathy, diabetic retinopathy screening, smartphone imaging, condensing lens adaptor, mobile referral

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Diabetes mellitus (DM) is a major public health issue worldwide. According to a 2015 report by the International Diabetes Federation, the number of people suffering from DM worldwide is expected to exceed 640 million by the year 2040.1 With the increasing population and incidence of DM, the total number of diabetics suffering from any degree of vision loss due to diabetic retinopathy (DR) will also rise. A local study published in 2005 reported the prevalence of clinically detectable diabetic retinopathy to be 61.8%.2 DR screening requires the expertise of a trained ophthalmologist to determine the presence or absence of the disease and assess the severity of the condition, or alternatively, a skilled technician equipped with an expensive fundus camera. The gold standard imaging technique for DR screening is the stereoscopic color fundus photography, captured across seven standard fields (30°).3 Smartphone-based fundus imaging has been adapted in a few developing countries such as India, to enhance DR screening efforts.

At present, there are a limited number of published studies on the use of handheld imaging devices and smartphone cameras for DR screening. These studies have demonstrated good sensitivity and specificity in detecting the presence of DR. ⁴⁻⁹ This study utilized a locally fabricated three-dimensional (3D) printed smartphone adaptor compatible with a 20D condensing lens.

The primary objective of this study was to evaluate whether dilated smartphone fundus photography, using a 3D-printed adaptor for a 20D lens, could be used as an alternative tool for screening and grading DR. We compared the image quality, sensitivity, specificity, positive and negative predictive values, and likelihood ratios of both imaging modalities.

METHODS

This was a prospective, comparative study conducted at a tertiary government hospital from April 2021 to October 2022. It was approved by the institutional ethics review board. Adult patients with DM who were referred to the general ophthalmology clinic for DR screening were recruited for the study. Patients were excluded if they had significant corneal or lens opacity, active ocular infections, vitreoretinal incisional or laser surgery, poorly dilating pupils (\leq 5mm), contraindications for pupillary dilatation (e.g. intraocular pressure of \geq 21mmHg, angle closure glaucoma, narrow-occludable angles), unstable vital signs, low tolerance to flare or intense light, or cannot maintain an upright seating or supine position.^{4,5} Informed consent was obtained from all study participants.

The following information were collected: general data, past medical and ophthalmic histories, as well as details regarding the patients' DM status and management. complete ophthalmologic А examination was done including visual acuity (both uncorrected and best corrected), slit-lamp biomicroscopy, and intraocular pressure (IOP) measurement using a Goldmann applanation tonometer. Pupils were dilated with 1 drop of Tropicamaide 0.5% + Phenyleprhine 0.5% (Sanmyd-P, Santen Pharmaceutical Co., Ltd. Japan) every 5 minutes to both eyes for 3 doses. DR screening using a binocular indirect ophthalmoscope (Vantage Plus, Keeler) with a 20D condensing lens (Volk, USA) was performed by a board-certified vitreoretinal specialist.

subject participant then underwent The smartphone-based fundus photography and 7-field fundus photos using a fundus camera. For the smartphone-based fundus photography, a Samsung Galaxy A51 (Samsung, Korea) smartphone equipped with a 3D-printed adaptor (Figure 1A) for a 20D lens was utilized. The Samsung Galaxy A5 smartphone has a 48 megapixel [MP] (wide) + 12 MP (ultrawide) + 5 MP (wide) dedicated macro camera and 5 MP depth sensor with a built-in light-emitting diode (LED) flash. This smartphone can capture up to four thousand kilopixels (4K) videos at 30 frames per second (fps). The smartphone was attached to a 3D- printed adaptor (Foxyyyprecision, Philippines) for a 20D condensing lens (Volk, USA) (Figure 1B). Study participants were positioned in supine, and the 20D lens was held approximately 3 inches above from the patient's eye, providing a 1.3x magnification of the camera (Figure 1C). A video of the fundus was captured using the smartphone (Figure 1D). The smartphone's auto focus feature was used to optimize image capture. Hypromellose (Sensomed, Philippines) eye drops were instilled to maintain corneal lubrication and ensure image clarity. Subjects were instructed to look at the light directly and then shift their gaze while the principal investigator

recorded the examination. This examination lasted for 2-3 minutes per eye. After the examination, the principal investigator reviewed the footage and selected the 7 images corresponding to the 7-field ETDRS images, which were then exported in a JPEG format (**Figure 2**). Images were assigned unique codes and were stored in a secure folder by the principal investigator.



Figure 1. (A) A 3D-printed smartphone adaptor for a 20D condensing made of plastic, resin, and carbon fiber measuring 9.2 inches x 2.75 inches and weighing approximately 10 grams. (B) 3D-printed adaptor attached to a smartphone Samsung Galaxy A51 smartphone and Volk 20D fundus lens. (C) Patient positioning during smartphone fundus photography. (D) Examiner's view of the fundus using the video mode.

For the fundus camera imaging, photos were taken by a single nurse trained to operate the Visucam 500 Zeiss Fundus Camera (Carl Zeiss Meditec, Germany). The 7-field program of the Visucam 500 was used, and the resulting montage image was saved and assigned a unique code by the principal investigator.

Grading of the images were performed by three board-certified vitreoretinal specialists. To standardize the grading process, 10 pre-determined DR fundus images obtained from the ETDRS image bank with their corresponding DR grading were provided to all three graders. These reference images served as benchmark for evaluating the study images.

Fundus photos taken using the smartphone and the Visucam were sent to the three graders' personal smartphones via the Telegram messaging app (Telegram FZ LLC Telegram Messenger Inc., United Arab Emirates). The Telegram app has encryption



Figure 2. Sample fundus photos from one eye with diabetic retinopathy taken with the smartphone.

capabilities for added privacy and images sent did not undergo digital compression which could decrease image quality. Two graders used an iPhone 11 (Apple, USA), which has a 6.1-inch liquid crystal display (LCD) screen with an 828x1792 pixel resolution. The third grader used an iPhone 6 (Apple, USA), which has a 4.7-inch LCD screen and a 750x1334 pixel resolution. The graders were allowed to zoom in on all the retinal images for up to 10x for proper grading. The classification of DR was based on the International Clinical Disease Severity Scale for DR, which categorized the severity of DR into the following stages: no retinopathy, mild nonproliferative diabetic retinopathy (NPDR), moderate NPDR, severe NPDR, proliferative diabetic retinopathy (PDR), and unable to grade. Referable DR was defined as at least moderate NPDR. Visionthreatening diabetic retinopathy (VTDR) was defined as at least severe NPDR.4 To eliminate recall bias, all the fundus camera images were sent and graded first followed by the smartphone images. Image quality was also graded using the criteria adapted from the study by Prathiba *et al.*⁷ (**Table 1**).

To determine intra-observer reliabilities, 10 random smartphone and 10 Visucam 500 images

were sent twice to the graders at different times to avoid recall bias. Interobserver reliability was determined by comparing the DR grades between the three graders to evaluate consistency across observers.

Table 1. Retinal Image Quality

Grading	Description
Grade 0	Ungradable (no retinal details visible due to media opacities such as dense cataract or total vitreous hemorrhage)
Grade 1	Poor (only gross retinal changes detectable such as hemorrhages and dense hard exudates)
Grade 2	Satisfactory (major retinopathy details visible; minor degrees of retinopathy and subtle new vessels not clearly detectable)
Grade 3	Good (most of retinopathy changes clear and detectable)
Grade 4	Excellent (lesions clearly visible)

Statistical Analysis

Descriptive statistics was used to summarize the demographic data. Intra- and inter-observer reliabilities were computed using Cohen weighted kappa. The strength of agreement was determined using the Landis and Koch interpretation of x statistics: 0.20 - slight agreement; 0.21-0.40 - fair agreement; 0.41-0.60 - moderate agreement; 0.61-0.80 - substantial agreement; and 0.81-1.00 - almost perfect agreement.⁴ Sensitivity, specificity, positive and negative predictive values as well as likelihood ratios for both smartphone-based photos and fundus camera photos were calculated, using results from the binocular indirect ophthalmoscopy as the reference standard. McNemar's test was utilized to compare the diagnostic accuracy indices between the two imaging modalities while T-test was used to compare the image quality between the two imaging devices. A p-value less 0.05 was considered significant. Medcalc (MedCalc Software Ltd. Belgium) was used to carry out statistical calculations.

RESULTS

A total of 51 study participants with DM (102 eyes) were included in the study. Majority of the participants were female (60.8%). Mean age was 49.1 \pm 12.9 years old. Majority (94.1%) had Type 2 DM with a mean of 9 \pm 8 years duration. The latest mean fasting blood sugar (FBS) and glycated hemoglobin (HbA1c) values were 8.93 \pm 4.61 and 11.66 \pm 18.8,

respectively. Majority (94.1%) were on antihyperglycemic medications (**Table 2**).

Table 2. Patient Demographics

Parameters	N=51
	participants
Mean age <u>+</u> SD	49.1 ± 12.9
Sex, n(%)	
Male	20 (39.2)
Female	31 (60.8)
Type of Diabetes mellitus, n(%)	
Type 1	3 (5.9)
Type 2	48 (94.1)
Mean duration of diabetes <u>+</u> SD, in years	9.1 ± 8.2
Latest mean fasting blood sugar \pm SD, in mmol/L	8.93 ± 4.61
Latest mean latest glycated hemoglobin (HbA1c), %	11.66 ± 18.8
Maintained on antihyperglycemic medications, n (%)	48 (94.1)
SD- standard deviation	•

Table 3 shows the maximum pupil size after dilation, lens status, DR grading of BIO. Out of the 102 eyes examined using the binocular indirect ophthalmoscopy, there were 46 (45.1%) eyes with no DR, 3 (2.9%) with mild NPDR, 13 (12.7%) with moderate NPDR, 16 (15.7%) with severe NPDR, and 24 (23.5%) with PDR. Meanwhile, images obtained via smartphone camera were graded as no DR in 44 (43.1%) eyes, mild NPDR in 7 (6.9%), moderate NPDR in 11 (10.8%), severe NPDR in 14 (13.7%), and PDR in 26 (25.5%) eyes. Images captured by the Visucam 500 camera were graded no DR in 43 (42.1%) eyes, mild NPDR in 10 (9.8%), moderate NPDR in 8 (7.8%), severe NPDR in 17 (16.7%), and PDR in 24 (23.5%) eyes.

Table 3. Maximum Dilation, Lens Status, Diabetic Retinopathy Grade by Binocular Indirect of Ophthalmoscopy of 102 eyes

Ocular Findings	N=102 eyes
Maximum Dilation, n(%)	
7mm	13 (12.7%)
8mm	61 (59.8%)
9mm	28 (27.5%)
Lens Status, n(%)	
Phakic	91(89.2%)
Pseudophakic	11(10.8%)
Diabetic Retinopathy Grade, n(%)	
No DR	46 (45.1)
Mild NPDR	3 (2.9%)
Moderate NPDR	13 (12.7%)
Severe NPDR	16 (15.7%)
PLDR	24 (23 5%)

NPDR - non-proliferative diabetic retinopathy, PDR - proliferative diabetic retinopathy

Table 4 also shows the inter- and intraobserver reliabilities. The kappa values for interobserver reliabilies for the smartphone and the Visucam 500 images ranged from 0.88 to 0.90 (95% CI 0.84-0.94) and 0.91 to 0.92 (0.87-0.96), respectively, indicating almost perfect agreement among the 3 graders. For

the intraobserver reliability, the smartphone imaging yielded perfect agreement for each of the three graders (1.00, 95% CI 1.00 to 1.00). The intraobserver reliabilities for the Visucam 500 images ranged from 0.85-0.95 (95% CI 0.64-1.00).

Table 4. Interobserver and Intraobserver Reliabilities

Parameter	Visucam 500 Image	Smartphone Image
Interobserver Reliability, κ (95% CI)	0.88-0.90 (0.84-0.94)	0.91-0.92 (0.87-0.96)
Intraobserver Reliability, ¤(95% CI)	0.85-0.95 (0.64-1.00)	1.00 (1.00-1.00)

CI - confidence interval

The images taken using the Visucam 500 demonstrated a very high sensitivity of 91.8% (95% CI 80.4 to 97.7) and specificity of 92.5% (95% CI 81.8 to 97.9) in distinguishing referable and non-referable DR. The positive predictive value was 91.8%, and the negative predictive value was 92.5% (**Table 5**). In terms of detecting VTDR, the Visucam 500 imaging has a sensitivity of 100% (95% CI 91.2-100) and a specificity of 85.5 (95% CI 74.2-93.1). The positive predictive value was 81.63%, and the negative predictive value was 100%.

 Table 5. Diagnostic Accuracy using the Visucam 500 Images in

 Detecting Referable and Vision Threatening DR

DR Severity	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	LR+	LR-
Referable DR	91.8 (80.4 to 97.7)	92.5 (81.8 to 97.9)	91.8	92.5	12.2	0.09
Vision Threatening DR	100 (91.2 to 100)	85.5 (74.2 to 93.1)	81.63	100.0	6.89	0.00
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DR – diabetic retinopathy; CI – confidence interval; PPV – positive predictive value; NPV – negative predictive value; LR+ – positive likelihood ratio; LR – negative likelihood ratio

Meanwhile, smartphone imaging demonstrated the ability to distinguish between referable and nonreferable DR, with sensitivity of 93.9 (95% CI 83.1 to 98.7) and specificity of 90.6% (95% CI 79.3 to 96.9). The positive and negative predictive values were 90.2 and 94.1%, respectively. Positive predictive value was 90.2 and the negative predictive value was 94.1 (**Table 6**). Sensitivity and specificity for detecting VTDR were 100 (95% CI 91.2 to 100) and 85.5 (95% CI 74.2 to 93.1), respectively.

Table 7 compares the diagnostic accuracy indices of the smartphone-based fundus imaging and Visucam 500 fundus camera. There were no statistical differences in the sensitivity, specificity, positive and negative predictive values between the two modalities in detecting referable and VTDR.

 Table 6. Diagnostic Accuracy using the Smartphone-Based Fundus

 Images in Detecting Referable and Vision-Threatening DR

Parameter	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	LR+	LR-
Referable DR	93.9 (83.1 to 98.7)	90.6 (79.3 to 96.6)	90.2	94.1	10.0	0.07
Vision Threatening DR	100 (91.2 to 100)	85.5 (74.2 to 93.1)	81.63	100	6.89	0.00

DR – diabetic retinopathy; CI – confidence interval; PPV – positive predictive value; NPV – negative predictive value; LR+ – positive likelihood ratio; LR – negative likelihood ratio

Table 7. Comparison of the Diagnostic Accuracy Indices of theSmartphone-Based Fundus Images and Visucam 500 Images

DR severity	Diagnostic Accuracy Index	Smartphone-Based Fundus Images	Visucam 500 Images	P-Value
Referable	Sensitivity	93.9	91.8	0.69
DR	Specificity	90.6	92.5	0.83
	PPV	90.2	91.8	0.78
	NPV	94.1	92.5	0.75
Vision-	Sensitivity	100.0	100.0	1.00
Threatening DR	Specificity	85.5	85.5	1.00
	PPV	81.6	81.6	1.00
	NPV	100.0	100.0	1.00

DR – diabetic retinopathy; PPV – positive predictive value; NPV – negative predictive value

Table 8 presents a comparison of diabetic retinopathy grading between the reference standard, binocular indirect ophthalmoscopy, and the imaging modalities evaluated in the study: Visucam 500 fundus camera and the smartphone-based fundus imaging. Kappa values for the Visucam 500 images and smartphone-based photography images were 0.94 (95% CI 0.93 to 0.97) and 0.96 (95% CI 0.93 to 0.99), respectively, indicating an almost perfect agreement for both imaging modalities with the reference standard. Discrepancies were observed, with 12 eyes exhibiting DR grades that did not align with the reference standard for the Visucam 500 images and 8 eyes showing similar discrepancies for smartphone-based photography.

Table 9 summarizes the image quality scores of the two imaging modalities. Visucam 500 images were mostly marked as excellent (38.2%) and good (39.9%). The quality of the smartphone images was rated as good in 49.3% and satisfactory in 38.2%. The differences in the distribution of imaging quality scores between the two modalities were not statistically significant (p=1.00).

Terroine		Binocular Indirect Ophthalmoscopy					
Modality	DR Grade	No DR	Mild NPDR	Moderate NPDR	Severe NPDR	PDR	Kappa (95% CI)
Visucam 500	No DR	43	0	0	0	0	
	Mild NPDR	3	3	4	0	0	0.94
	Moderate NPDR	0	0	7	1	0	(0.90-0.97)
	Severe NPDR	0	0	2	14	1	
	PDR	0	0	0	1	23	
Smartphone-	No DR	44	0	0	0	0	
Based Photography	Mild NPDR	2	2	3	0	0	0.96
	Moderate NPDR	0	1	10	0	0	(0.93-0.99)
	Severe NPDR	0	0	0	14	0	
	PDR	0	0	0	2	24	

 Table 8. Comparison of Diabetic Retinopathy Grading of the 3

 Screening Modalities

DR – diabetic retinopathy; NPDR – nonproliferative diabetic retinopathy; PDR – proliferative diabetic retinopathy; CI – confidence interval;

 Table 9. Image Quality Scores of Visucam 500 Images and Smartphone-Based Fundus Images

Image quality,	Visucam	Smartphone-Based	P-Value
n(%)	500 Images	Images	(95% CI)
Ungradable	0 (0)	0 (0)	
Poor	15 (4.9)	10 (3.3)	1.00
Satisfactory	52 (17)	117 (38.2)	(-91.4 to
Good	122 (39.9)	151 (49.3)	91.4)
Excellent	117 (38.2)	28 (9.2)	

CI – confidence interval

DISCUSSION

Smartphones and other handheld mobile devices, along with internet connectivity, have simplified and increased the efficiency of various tasks and processes. In an ophthalmology clinic, clinical features can be photographed easily and shared instantaneously which can aid in prompt referral, diagnosis and treatment. A few studies have established that smartphones can be utilized in DR screening with reported sensitivity and specificity of 50-94% and 94.5-100%, respectively. 4-9 Previous studies on smart-phone based fundus imaging, such as those by Duyongco et al. and Ryan et al., employed the traditional method of holding the smartphone in one hand and a 20D lens in the other.4,5 Russo used the D-Eye adaptor with an iPhone 5.6 Other researchers used the Remidio Fundus on Phone device which integrates a smartphone dock and built-in light source.7-9 All these studies used two masked retina specialist graders and employed the international criteria for DR grading, with standardized viewing monitors.4-9 This study, however, intentionally avoided standardizing the viewing system to better replicate real-world mobile referral scenarios.

This study compared two retinal imaging modalities for detecting referable and visionthreatening DR: the Visucam 500 fundus camera, a widely accepted and commonly used diagnostic imaging device, and a novel, smartphone-based photography using a 3D-printed adaptor for a condensing lens. The smartphone-based system demonstrated a sensitivity and specificity of 93.9% and 90.6%, respectively, for detecting referable DR and 100% sensitivity and 85.5% specificity for detecting VTDR. These outcomes align with the recent studies by Duyongco et al. and Segupta et al.4,7 The diagnostic accuracy of both imaging devices showed strong agreement with the reference standard of binocular indirect ophthalmoscopy performed by a board-certified retina specialist. Notably, the smartphone-based system in this study exhibited higher sensitivity at 93.9-100% compared to previous studies, where sensitivities ranged from 50-75%.7-9

While stereoscopic color fundus photography captured across seven standard fields remains the gold standard technique for DR screening, BIO was utilized as the reference standard in this study, as DR screening in our institution is typically conducted using this method.³ Published studies have compared DR grading of smartphone images with either fundus camera images or to dilated funduscopic exam via slitlamp.4-9 Standard DR screening methods including BIO, stereoscopic fundus photography, and slit-lamp-based dilated fundus exams, require highly skilled medical professionals, and costly equipment which must be stored in a climatecontrolled area. These methods also demand a steep learning curve, making them less practical for community-based screening programs. In lowresource settings, these challenges may limit the feasibility of traditional DR screening approaches.

The image quality of the two imaging modalities utilized in this study was comparable, though more Visucam 500 images were graded as excellent, albeit without statistical significance. This finding aligns with the study by Rajalakshmi *et al.*, which also indicated that fundus camera images tend to have superior image quality.⁷ This difference may be attributed to the limited zooming capability of the smartphone's built-in high-definition camera, which required further magnification compared to the Visucam 500 fundus camera's built-in highmagnification camera lens. However, with the rapid advancements in smartphone technology – where cameras are becoming more powerful every passing year – enhancements in zoom and resolution may enable smartphone-based fundus imaging to achieve image quality at par with conventional tabletop fundus cameras.

Handheld fundus imaging devices are now becoming a popular alternative to table-top fundus cameras, offering greater versatility and mobility. However, these devices remain costly, with limited availability in low-GDP countries including the Philippines. In this study, a 3D-printed adaptor was used, which is relatively inexpensive, durable, and facilitates easier image capture by maintaining a fixed distance between the smartphone camera and the condensing lens. The locally-made 3D-printed adaptor used in this study costs only PhP2,000 and can be customized for various smartphone models and fundus lenses. This method offers a costeffective solution for DR screening and can be performed without the need for a medical professional. Fundus images can be transmitted directly to a retina specialist's smartphone for immediate interpretation and referral. Notably, this study demonstrated a high level of agreement among graders, despite the use of different mobile devices for image viewing. This did not affect the reliability of DR severity grading, as reflected in the results.

Patient selection plays a crucial role in obtaining high-quality fundus images. The clarity of the natural crystalline lens of the eye is one of the major determinants of image quality, particularly for fundus photography. smartphone-based In pseudophakic patients, the edge of the artificial intraocular lens may cause image distortion or glare when capturing fundus images or videos with a smartphone. Other ocular factors that may affect image quality are the degree of pupil dilation and clarity of the cornea. Ensuring optimal conditions in these areas is essential for achieving clear and diagnostically useful images.

The limitations of this study include the requirement for pupil dilation when using the two fundus imaging devices and the use of the international criteria for grading DR, which did not account for the presence or absence of diabetic macular edema or subclassification of proliferative DR into early or high-risk categories. Furthermore, this study did not assess the ease of smartphone retinal photography or the associated learning curve. The authors recommend exploring other smartphones equipped with high-end cameras to determine potential improvements in image quality and resolution. Future research should investigate the usability of smartphone photography among ophthalmologists, ophthalmology resident trainees and allied ophthalmic staff. Lastly, a multicenter validation study involving a larger patient population and more image graders is necessary to confirm the findings of this study.

In conclusion, smartphone-based fundus imaging with a 3D-printed adaptor for a 20D lens can obtain acceptable fundus photos for DR grading. It is also important to note that good patient selection and pupil mydriasis are key elements to obtain clear images using a smartphone. This study also demonstrated a very high level of agreement among the graders despite the use of different viewing devices to grade the images. Smartphone-based fundus imaging can be considered as an alternative method for DR screening particularly in mobile clinics or in settings where a traditional fundus camera is unavailable for mobile referrals.

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