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Validation of the Non-Mydriatic and Mydriatic Remidio (FOP) Camera with Artificial Intelligence in Screening Diabetic Retinopathy at Northern-Tanzania (2023-2024)

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Aims: This study aimed to evaluate the validity of non-mydriatic fundoscopy using a Remidio FOP Camera with Artificial intelligence to screen for Diabetic Retinopathy in Northern Tanzania, 2023-2024.
Study Design: This study employed a community-based cross-sectional design.
Place and Duration of Study: The study was conducted at the Diabetic and eye clinics of the health facilities of the Kilimanjaro and Arusha regions for a duration of 10 months, for data collection from October 2023 to July 2024.

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Methodology: Type 2 Diabetic patients from 18 years and above were included in this study, and all patients with pupillary disorders that led to pupillary obstruction. The calculated sample size was 380 eyes in this study from 380 patients, This includes only one eye of interest from each participant, then the fundus images were taken from each consented participant, being non-mydriatic and mydriatic and then compared for quality and diagnosis through the AI (Medios). The reference group was the Mydriatic arm since it is the standard way of doing Fundoscopy.
Results: The sensitivity and specificity of non-mydriatic Remidio FOP Camera to grade fundus images was 43.9% (95 CI: 41.9 – 46.3) and 98.8 (95 CI: 94.2 – 99.7) respectively with PPV 99.3% (95 CI: 93.5 -99.7) and NPV 34.8 (95 CI: 31.6 -37.7) and Kappa Agreement score of 0.26 (95 CI: 0.000 – 0.008) with the p-value < 0.005. Also the sensitivity and specificity of mydriatic Remidio FOP has 87.5% sensitivity (95 CI: 83.2 – 89.7) in diagnosing Diabetic Retinopathy (DR) from gradable images with a specificity of 88.5% (95 CI: 82.9 – 88.7) in giving No Diabetic Retinopathy (No DR) gradable images with a Positive predictable value of 78.9% (95 CI: 73.3 – 79.1) and a Negative predictable value of 93.5% (95 CI: 93.1 – 99.7). This shows a Mydriatic FOP Camera when used has the most chance of giving a correct diagnosis of DR or No DR.
Conclusion: The Remidio FOP camera can be a useful equipment for screening Diabetic retinopathy cases on outreaches and hospitals, BUT it has to be used as a mydriatic tool to give a more precise images of the fundus, and the use of Artificial intelligence has revealed significance in grading the images as well.
Limitations: The artificial intelligence used can give only a diagnosis of Diabetic retinopathy or not which hinders further assessment and types of DR.
Recommendations: More Artificial intelligence algorithms should be developed to be able in diagnosing detailed Diabetic retinopathy.

Keywords: FOP-fundus on photo; DR- diabetic retinopathy; AI – artificial intelligence; DM – diabetic mellitus.

DEFINITIONS AND ABBREVIATIONS

Definition of Terms

- *Diabetic Retinopathy – This is a complication of Diabetes Mellitus in which there is are vascular changes to the retina of the eyes.*
- *Proliferative Diabetic Retinopathy -This is an advanced stage of Diabetic retinopathy in which there is a new formation of blood vessels*
- *Artificial Intelligence – A set of instructions/ rules that enable machines to learn, analyze data, and make decisions based on that knowledge.*
- *Fundoscopy – An ophthalmic procedure to examine the posterior segment of the eye*

List of Abbreviations

AI : Artificial Intelligence
DM : Diabetic Mellitus
DR : Diabetic Retinopathy
FOP : Fundus on Phone
KCMC : Kilimanjaro Christian Medical Center
NPDR : Non-Proliferative Diabetic Retinopathy
PDR : Proliferative Diabetic Retinopathy
STDR : Sight-Threatening Diabetic Retinopathy

1. INTRODUCTION

Currently at Kilimanjaro Christian Medical Centre – Eye Department, Diabetic Retinopathy screening is conducted in the ophthalmology department only as an opportunistic (patients willingly attend the clinic and not compulsory for every patient) screening. The screening practice for DR at KCMC –Eye department involves indirect ophthalmoscopy with a 90D lens and retinal image capture by a fixed fundus camera (Topcon), with the images being graded by a certified grader, an Ophthalmology trainee, and an ophthalmologist. With the evolution of technology, there is an increased use of portable non-mydriatic fundus Camera to screen DR with Artificial Intelligence (AI), Currently at KCMC among the cameras that we use, A smartphone-based 45 degrees mydriatic fundus camera (Remidio Fundus on Phone FOP; Remidio Innovative Solutions Pvt. Ltd., Bengaluru, India) co, is used for Outreach and clinic screening for DR to DM patient as well as for Research on the field of Diabetic Retinopathy, Hence it has necessitated us to evaluate the validation of non-mydriatic Fundoscopy by Remidio FOP camera in screening diabetic retinopathy at Northern-Tanzania. To extend the reach of DR screening into remote areas with poor access to ophthalmic

care, we need to develop and test portable technologies that are easy to use" (Cheung et al., 2010). Smartphones have positively changed our world and influenced health care in different, unique ways (Federation, 2019). However, there were drawbacks reported from the study done on the Remidio FOP Camera; the major drawback was that the quality of images can be acquired with a basal pupil size greater than or equal to 3 mm (non-mydriatic without basal stimulation). Hence recommend more studies to be done on validating the mydriatic version of the camera. Also, this study validated the Remidio FOP camera on screening DR in Northern Tanzania since there are no readily available published studies from Tanzania at large with regards to the effectiveness of non-mydriatic Remidio FOP Camera for screening Diabetic retinopathy.

2. MATERIALS AND METHODS

This is a community-based comparative cross-sectional study. It was conducted for 10 months, from October 2023 to July 2024, and data were collected at the Diabetic and eye clinics of the Kilimanjaro and Arusha regions' selected health facilities.

The Kilimanjaro Region is located in northeastern Tanzania and borders Kenya to the north. It has seven Districts: Same, Mwanga, Moshi Rural, Moshi Urban, Hai, Siha, and Rombo (Yau et al., 2012) (Hope K,2010). The screening was conducted in 18 health facilities providing Diabetic services across all Districts of the Kilimanjaro Region. These facilities are Jaffery, Mawenzi Hospital, St. Joseph Hospital, TPC Hospital, Hai District Hospital, Siha District Hospital, Same District Hospital, Mwanga District Hospital, Huruma Hospital, Karume Health Center, Tarakea Health Center, Kibosho Hospital, KCMC, Marangu Hospital, Kilema Hospital, and Keni Hospital. These facilities were randomly selected and involved both government and private hospitals.

Arusha region: The study was conducted only at Mount Meru Regional Referral Hospital in Arusha City. All patients were attended to at one facility (Arusha Regional Referral Hospital) from their respective districts. The selection was due to its capacity to accommodate many diabetic patients in the Region.

The Arusha region is located in the northern zone of Tanzania and has a population of 2,356,255 (CityPopulation, 2022). This population includes newly diagnosed or in-treatment Diabetic patients.

Inclusion criteria are all Type 2 Diabetic patients from 18 years old attending selected health facilities who have consented to participate in the study, all patients with obvious clear media on examination (cornea, anterior chamber, Lens, and vitreous humor) who were able to take their fundus images. While exclusion criteria are all patients with pupillary disorders that lead to pupillary obstruction, such as the pupillary membrane.

2.1 Sample Size and Sampling Technique

2.1.1 Sample size

$$n = p\,(1 - p)\,z^2/e^2$$

Where:

n = sample size p = the population proportion (p = 0.1) e = acceptable sampling error ((e = 0.05) z = z value at reliability level or significance level. - Reliability level 95% or significance level 0.05; z = 1.96 - Reliability level 99% or significance level 0.01; z = 2.58 (Burgess et al., 2013) (Uakarn C, 2021)

Hence, our population proportion (p) is 55.5% (0.555) (Cleland et al., 2016)

"z" is 1.96 from a reliability level of 95%

"e" is 5% (0.05)

Therefore, our sample size calculation is:

$$n = (1 - p)^2/e^2$$

$$n = 0.555\ (1 - 0.555)1.96^2/0.05^2 = 379.5$$ rounded off to 380

Hence, our calculated sample size is 380 eyes from participants

2.1.2 Sampling technique

Consecutive non-probability sampling technique. Participants were recruited from 18 centers, reaching all districts of the Kilimanjaro Region and 1 district of Arusha. The centers were those serving for Diabetic clinic with a high intensity of patients in the respective districts. Participants who had consented and reached the inclusion criteria for the study participation, Ocular examination was done by slit lamp bio-microscope to all qualified participants. The reference group was the Mydriatic images since it is the standard way of doing Fundoscopy.

The images were then graded as Gradable and Ungradable. The gradable group was further classified as DR and No DR for further analysis. Artificial Intelligence (Media Algorithm) manipulated and interpreted this grading. Variables are grouped into independent and non-independent ones. For the independent variables obtained from Demographic data, such as age, sex, level of education, residence, smoking status, history of DM or Hypertension (<12 months>), Anti-hypoglycemic agents used, and history of Stroke or Cardiac disease. While dependent variables were grading results by AI (Medios) from dilated and undilated, being DR and No DR, the time scale, which will be categorized as short(less than 7 minutes, medium, and long, and the quality of the images was categorized as ungradable and Gradable. The operational definition of the gradable fundus is when 4 fields are visible: the Optic disc, Macula, Vascular arcuate, and retinal background. There were continuous and categorical variables.

2.2 Data Collection Tools, Methods, and Procedures

2.2.1 Data collection tools and methods

A guided questionnaire was introduced and used to collect demographic data with guided questions on diabetic information. A measurement collection form was also used to record the images and diagnoses given by the Artificial Intelligence. Also, images taken from the Remidio FOP Camera were stored with corresponding questionnaires and measurement collection forms for reference. Remidio FOP and Topcon fundus Camera were used as tools for enhancing data collection.

2.2.2 Study procedures

The Study participants were identified from the Diabetic clinics of the listed sites by the Field team. The study information sheet was explained to the participants by one of the field members, and consent was provided to them by the research team. Those who have consented, their anterior ocular segment were thoroughly examined, then photographed undilated by a Remidio FOP Camera, and then dilated by Tropicamide phenylephrine eye drop and waited for 20 – 30 minutes. Fundus images were taken by Remidio FOP Camera in mydriatic condition as well. Then all the images were collected and stored in the External hard disk for further reference. Assurance of the participants' anonymity was highly valued. After the examination and participation in the research, those diagnosed with DR were treated accordingly. Those who were not diagnosed with DR were counseled and advised to undergo routine screening and be appreciated for their participation in the research.

2.3 Data Management, Analysis Plan, and Ethical Clearance

2.3.1 Data management

Questionnaires were collected and counter-checked in the field by the researcher to find any missing data. this was done before the data collection and fundus image taking, immediately after fundus image taking, and at the end of the respective data collection day. Camera calibration, charging, and testing for functionality were done before conducting fundus photographing, as well as before dilating the participants. There was a meeting before and after data collection each day to assess the challenges and strengths of the process. Storage of the questionnaires and images was supervised by the Researcher and head of the data collection team, and then entered in SPSS version 27 on the laptop.

2.3.2 Analysis plan

Data entered, cleaned, and analyzed by Statistical Package for the Social Sciences (SPSS) version 27. Data presented in codes and study participants were given study numbers, which every participant had unique ones. Also, images were coded accordingly. Statistical measures such as proportions and means were presented, as well as the Kappa agreement score used for the association of validity of the Remidio FOP Camera between two graders, and as well as grading from the Topcon NW8 Camera. General logistic regression by Poisson model test is used in the association of independent variables with multiple dependent variables. Results were presented in tables and diagrams

2.3.3 Ethical clearance

The ethical clearance was requested from the Kilimanjaro Christian Medical University College Research and Ethics Review Committee (KCMU-CRERC). Permission to collect hospital data was obtained from the Director of Hospital Services

through the head of the Department of Ophthalmology at Kilimanjaro Christian Medical Centre. Also for other listed sites, permission was requested from the "In charge" of the respective clinics/centers. Ethical clearance certificate was granted with the number PG 91/2023. Participant data protection and confidentiality was guaranteed. Only the research team and supervisors allowed to access the data for this research purpose. Certificate for Good practice has already been acquired.

3. RESULTS AND DISCUSSION

3.1 Results

3.1.1 Demographic data

This study recruited 383 eyes from 200 individuals who were type 2 diabetic mellitus patients from the age of 18 years old and above. In the results for demographic characteristics, there was a slight difference in age group after being categorized in which age group of 61-90 years old had a higher prevalence of 50.7%. Females appeared to participate more in this study with a mean percentage of 73.1%. The majority of participants came from the Kilimanjaro region and its Districts. Most of the participants had a Primary level of education which is 67.4% and the lowest level of education for the participants was informal level of education with a prevalence of 5%.

3.1.2 Clinical characteristics of the participants.

The majority were not Smoking 85.4% and most of them were diagnosed with DM-type 2 85.4% more than 12 months, Most of the participants used oral hypoglycemic agents as the major way of treatment of DM. A history of hypertension was reported in 61.3% of the participants. Of those with hypertension, 59.8% used Anti-hypertensive agents. Many participants had No stroke and had no history of cardiac attacks by 95.8% and 96.3% relatively.

3.1.3 Clinical characteristics associated with the non-mydriatic images grading

It was observed that some clinical characteristics influenced the gradability of the images in both non-mydriatic and mydriatic images. Hence by using General linear regression with the Poison model, an association was calculated and it revealed that in non-mydriatic images taken by Remidio FOP: the age of the participant and hypertension were factors associated with the ungradable quality of the image in crude analysis compared to participants who were <60 years, participants who were ≥60 were 59% significantly more likely to have the ungradable quality of the image (CPR=1.59; 95%CI: 1.35-1.88; P-value<0.001) while participants who had hypertension were 43% significant more prevalent to have the ungradable quality of the image (CPR=1.43; 95%CI: 1.21-1.71; P-value<0.001).

In the adjusted analysis, still, age of the participant and hypertension were factors associated with the ungradable quality of the image. After adjusting for DM duration, hypertension, and smoking status, compared to participants who were <60 years, participants who were ≥60 were 47% significantly more likely to have the ungradable quality of the image (APR=1.47; 95%CI: 1.24-1.75; P-value<0.001) while participants who had hypertension were 23% significant more prevalent to have the ungradable quality of the image (CPR=1.23;95%CI:1.03-1.47; P-value=0.022) after adjusting for age of the participants, DM duration and smoking status

Table 1. Participants' particulars and demographic information

Variable	Frequency	Percentage
Age in years old:		
18 – 60 years	189	49.3
61 -90 years	194	50.7
Sex		
Female	280	73.1
Male	103	26.9
Residence		
Kilimanjaro	198	51.3
Arusha	185	48.7

Variable	Frequency	Percentage
Level of Education		
Informal Education	19	5.0
Primary level	258	67.4
Secondary level	77	20.1
University level	29	7.6
Median	1.00	

Table 2. Clinical characteristics of the participants

Variable	Frequency (n)	Percentage (%)
History of smoking		
Smoking	56	14.6
No smoking	327	85.4
History of Diabetes Mellitus Type 2		
Below 12 months	56	14.6
Above 12 months	324	85.4
Hypoglycemic agents		
Oral hypoglycemic agents	322	84.1
Insulin	37	9.7
Other	24	6.2
History of hypertension		
Yes	235	61.3
No	139	38.7
Hypertensive drugs		
Yes	229	59.8
No	154	40.2
History of stroke attack		
Yes	16	4.2
No	367	95.8
History of Cardiac Disease		
Yes	11	3.7
No	372	96.3

Table 3. Clinical characteristics associated with non- mydriatic grading

Variable	CPR	P-value	APR	P-value
Participant Age				
<60	Ref		Ref	
≥60	1.59(1.35-1.88)	.001	1.47(1.24-1.75)	.001
Participant sex				
Male	Ref			
Female	0.96(0.82-1.13)	.628		
Hypoglycemic drugs				
Oral hypoglycemic agents	1.25(0.86-1.83)	.235		
Insulin	1.05(0.66-1.67)	.844		
Others	Ref			
History of DM				
Below 12 months	Ref		Ref	
Above 12 months	1.10(0.88-1.38)	.391	1.03(0.83-1.28)	.808
History of Hypertension				
Yes	1.43(1.21-1.71)	.001	1.23(1.03-1.47)	.022
No & Unknown	Ref		Ref	
History of smoking				
Yes	1.00(0.81-1.22)	.998	0.99(0.81-1.21)	.937
No	Ref		Ref	

3.1.4 Clinical characteristics associated with the mydriatic images grading

Association for factors associated with the quality of mydriatic images among the study participants while the age of the participant and smoking status were factors associated with the ungradable quality of the image in crude analysis compared to participants who were <60 years, participants who were ≥60 were 2.1 times significantly more likely to have the ungradable quality of the image (CPR=2.06; 95%CI: 1.37-3.11; P-value= 0.01) while participants who were smokers were 69% significant more prevalent to have the ungradable quality of the image (CPR=1.69; 95%CI: 1.12-2.55; P-value= 0.012). In the adjusted analysis, still age of the participant and smoking status were factors associated with the ungradable quality of an image. After adjusting for DM duration, hypertension, and smoking status, compared to participants who were <60 years, participants who were ≥60 were 80% significantly more likely to have the ungradable quality of the image (APR=1.80; 95%CI:1.19-2.96; P-value= 0.007) while participants who were smokers were 68% significant more prevalent to have the ungradable quality of the image (APR=1.68;95%CI:1.12-2.54; P-value= 0.012) after adjusting for age of the participants, DM duration and Hypertension.

3.1.5 Duration on image taking between non-mydriatic and mydriatic fundoscopy by Remidio FOP Camera

In our study, there is a slight difference between the times used to take a picture in non-mydriatic, whereby the majority had taken a shorter time to have an image by 94.5% and the moderate were only 5.5%. No image was taken over a longer time. For the mydriatic image taking, all participants had a shorter time.

3.1.6 Gradability comparison between non-mydriatic and mydriatic images by remidio FOP camera

The capacity of the Remidio FOP Camera to grade images between non-mydriatic and mydriatic was measured and the results were 130 images out of 383 (33.9%) gradable for non-mydriatic while mydriatic gradable images were 294 out of 383 (76.8%). This is illustrated in the Fig.1.

Table 4. Clinical characteristics associated with mydriatic grading

Variable	CPR	P-value	APR	P-value
Participant Age				
<60	Ref		Ref	
≥60	2.06 (1.37-3.11)	0.001	1.80(1.19-2.96)	0.007
Participant sex				
Male	Ref			
Female	0.76(0.52-1.11)	0.161		
Hypoglycemic drugs				
Oral hypoglycemic agents	0.92(0.44-1.89)	0.819		
Insulin	0.97(0.39-2.39)	0.952		
Others	Ref			
History of DM				
Below 12 months	Ref		Ref	
Above 12 months	1.52(0.81-2.86)	0.190	1.53(0.83-2.83)	0.175
History of Hypertension				
Yes	1.37(0.92-2.04)	0.119	1.11(0.72-1.69)	0.641
No & Unknown	Ref		Ref	
History of smoking				
Yes	1.69(1.12-2.55)	0.012	1.68(1.12-2.54)	0.013
No	Ref		Ref	

Table 5. Frequency table of time scale for non-mydriatic fundoscopy by Remidio FOP

Variable	Frequency (n)	Percentage (%)
Short (Less than 7 min)	362	94.5
Medium (below 7 min)	21	5.5

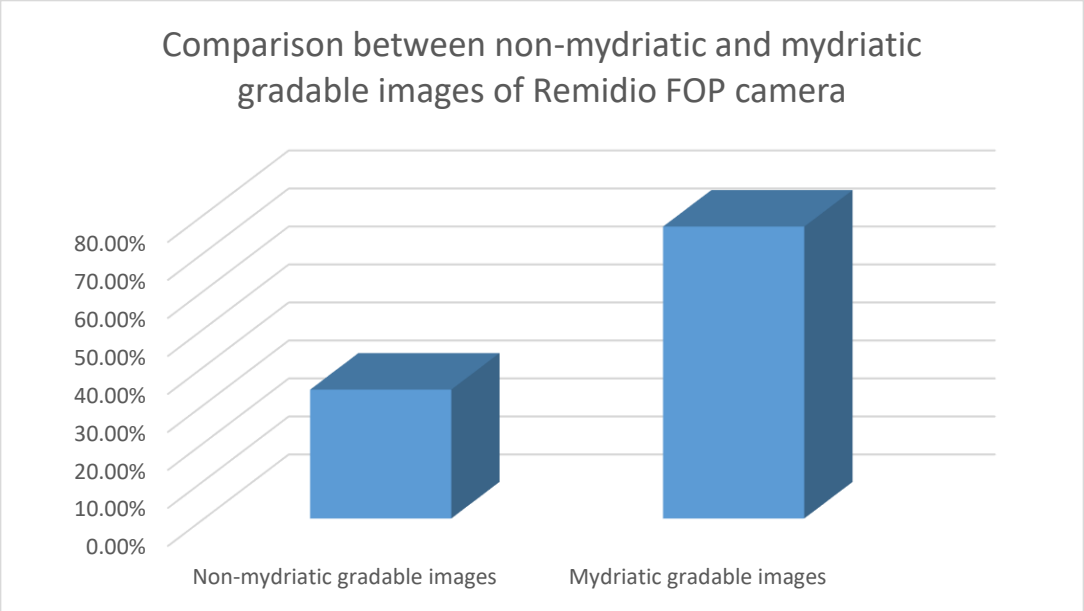

Fig. 1. Histograms showing the comparison of gradable images between non-mydriatic and mydriatic by Remidio FOP Camer

3.1.7 The capacity to diagnose any DR by non-mydriatic and mydriatic gradable image

The overall capacity of the Remidio FOP Camera to diagnose any type of DR either by non-mydriatic or mydriatic tool was measured through Artificial intelligence (Medios). The cumulative prevalence of any Diabetic Retinopathy (DR) from both Non-mydriatic and mydriatic images was 34.9% and for Non-mydriatic alone, DR was observed in 26.2% and Mydriatic was 38.8% respectively.

3.1.8 Sensitivity and specificity of Remidio FOP Camera non-mydriatic to grade fundus images

Non-mydriatic Remidio FOP Camera was measured for its sensitivity and specificity with positive predictable values and negative predictable values on diagnosing any type of DR. This was done with reference to the mydriatic tool. Remidio FOP Camera has 43.9% (95 CI: 41.9 – 46.3) sensitivity in giving gradable images with a specificity of 98.8% (95% CI: 94.2-99.7) in giving ungradable images with a Positive predictable value of 99.3% (95 CI: 93.5 – 99.7) and a Negative predictable value of 34.8% (95% CI: 31.6 – 37.7). This shows a Non-mydriatic FOP Camera has a small chance of grading the images hence providing less-quality images. The kappa coefficient score for the Gradability by the quality of images between Non-mydriatic and mydriatic FOP Remidio camera was 0.260 (0.000-0.008) at a 95% confidence interval, which is poor /less reliable (low agreement) and this is statistically significant (p-value 0.005).

3.1.9 Sensitivity and specificity of the non-mydriatic remidio FOP Camera to diagnose any type of diabetic retinopathy

Remidio FOP Camera has 75.0% (95% CI:73.8 - 79.4) sensitivity in diagnosing Diabetic Retinopathy (DR) from gradable images with a specificity of 98.8% (95% CI: 94.2 -99.6) in giving No Diabetic Retinopathy (No DR) gradable images with a Positive predictable value of 79.4% and a Negative predictable value of 90.6% (95%CI: 89.3-95.9) in non-mydriatic (FOP) Camera. This shows a Non-mydriatic FOP Camera when it has managed to grade the images has a greater chance of giving a correct diagnosis of DR or No DR. The sensitivity and specificity values are in approximately moderate agreement.

Kappa coefficient score for the capability to diagnose gradable images between Non-mydriatic and mydriatic FOP Remidio Camera. The score is 0.687 (95% CI: 0.000- 0.008) which is, moderately reliable (moderate agreement) and this is statistically significant (<0.001).

Table 6. Sensitivity and specificity of non-mydriatic Remidio (FOP) on quality of fundus images

Quality of images (Gradable Vs Ungradable)	Sensitivity (%)	Specificity (%)	Positive predictable value (PPV)	Negative Predictable value (NPV)
Non-Mydriatic FOP Remidio	43.9	98.8	99.3	34.8

Table 7. Degree of agreement of non-mydriatic with reference to mydriatic Remidio fop camera

		Value	Standard. Error	P- Value
Measure of Agreement	Kappa	0.260	.030	0.000 (95%CI: 0.00-00.008)
N of Valid Cases		383		

Table 8. Sensitivity and specificity of non-mydriatic remidio (FOP) camera in diagnosing any type of diabetic retinopathy (DR VS no DR)

Diabetic Retinopathy (DR and No DR)	Sensitivity (%)	Specificity (%)	Positive predictable value (PPV)	Negative Predictable value(NPV)
Non-Mydriatic FOP Remidio	75.0%	92.6%	79.4%	90.6%

Table 9. Sensitivity and specificity of non-mydriatic Remidio (FOP) camera in diagnosing any type of diabetic retinopathy (DR VS no DR)

		Value	Standard. Error	P- Value
Measure of Agreement	Kappa	0.687	0.072	0.000 (95%CI: 0.00-00.008)
N of Valid Cases		130		

3.2 Discussion

In this study, a non-mydriatic Remidio FOP camera has shown a 33.9% gradability prevalence indicating that approximately one-third of the images captured without pupil dilation were of sufficient quality for grading. This lower proportion could be attributed to several factors: Insufficient Pupil Size: without dilation, the pupil may not be large enough to allow for a clear retina view. Light Reflection and Artifacts: Non-mydriatic imaging often faces challenges like light reflection from the cornea and lens, leading to artifacts that can obscure retinal details.

Mydriatic Gradability: The significantly higher gradability rate of 76.8% in mydriatic images suggests that pupil dilation improves the quality of the retinal images. Dilation enlarges the pupil, providing a clearer and wider view of the retina, the increased field of view and better focus on the retina improve the detail and quality of the photos.

In our study, the Remidio FOP Camera to grade images between non-mydriatic and mydriatic was measured and the results were 130 images out of 383 (33.9%) gradable for non-mydriatic while mydriatic gradable images were 294 out of 383 (76.8%). Other studies have similarly reported that mydriatic conditions generally yield higher-quality retinal images compared to non-mydriatic conditions. For instance, a study by Davila et al. (2016) A total of 2,475 photographs were taken of the 275 eyes, including the 3 fields from each modality; 628 (76.1%) of the total of 825 non-mydriatic images were gradable, compared with 90.1% of the mydriatic images (n = 743/825) and 92% of the Topcon images (n = 759/825). Dilation improved image gradability with the handheld Smartscope by 14% (RISP Ltd., n.d.).

This shows a Non-mydriatic Remidio FOP Camera has a small chance of grading the images hence providing less-quality images compared to mydriatic Remidio FOP Camera.

Relative to the capacity of the non-mydriatic Remidio FOP camera to diagnose DR and no DR with the gradable images, our study found that 75.0% (95% CI: 73.8 -79.4) sensitivity in diagnosing Diabetic Retinopathy (DR) from gradable images with a specificity of 98.8% (95% CI: 94.2 -99.6) in giving No Diabetic Retinopathy (No DR) gradable images with a Positive predictable value of 79.4% (95% CI: 77.2 – 81.7)

and a Negative predictable value of 90.6% (95%CI: 89.3-95.9) in non-mydriatic (FOP) Camera. This shows a Non-mydriatic FOP Camera when it has managed to grade the images has a greater chance of giving a correct diagnosis of DR or No DR. The sensitivity and specificity values are in approximately moderate agreement.

There was a systemic review and pool analysis which showed for mydriatic images, pooled sensitivity was 87% (95% CI: 79-92%) and specificity was 90% (95% CI: 78-96%). Overall pooled sensitivity was 85% (95% CI: 80-89%) and specificity was 91% (95% CI: 83-95%). Of the 11 studies included, 5 assessed the diagnosis of diabetic retinopathy, for which sensitivity was 87% (95% CI: 80-92%) and specificity was 95% (95% CI: 85-98%). For all other diagnoses combined, sensitivity was 81% (95% CI: 74-87%) and specificity was 83% (95% CI: 76-89%). These findings suggested that handheld fundus cameras are capable of achieving acceptable sensitivity and specificity values for eye disease, with mydriatic images being more sensitive for disease. Diabetic retinopathy was the single diagnosis with the strongest data to support the use of handheld fundus cameras for disease screening (Rajalakshmi et al., 2015)(Parlemo et al, 2021).

However, some studies gave higher sensitivity and specificity to non-mydriatic Remidio FOP cameras, The sensitivity and specificity of retinal images using FOP to diagnose any DR was very high (92.7% and 98.4% respectively) with Kappa score 0.90 (95% confidence interval: 0.85 - 0.95). (Sengupta et al., 2019; Cleland et al., 2016).

The Remidio FOP Camera demonstrates a commendable performance in non-mydriatic conditions with high specificity and moderate sensitivity. The Kappa score indicates moderate agreement with reference standards, which is a positive indication of its reliability in diagnosing any DR. When compared to other non-mydriatic systems, it shows competitive sensitivity and excellent specificity, making it a viable option for DR screening in settings where mydriasis is not feasible.

Time efficiency: Non-mydriatic imaging, 94.5% of images were captured in a shorter time (less than 7 minutes). 5.5% of images took a moderate time (7 minutes). No images took longer than 7 minutes. Mydriatic imaging: 100% of images were captured in a shorter time (less than 7 minutes). The slight difference in the distribution of time categories suggests that non-mydriatic imaging is slightly more variable in terms of time taken, but still highly efficient. Mydriatic imaging consistently achieves the shortest capture times, which could be attributed to the enhanced visibility and ease of capturing clear images with dilated pupils.

There was a study conducted by Ramachandran et al, Chennai –India 2015 stated that time taken for retinal imaging with FOP is less than 1 minute for each eye and the autofocus (for mydriatic) in FOP helps to obtain sharp focus and good (Cleland et al., 2016). This is much lower than the time that we have observed in our study in the mydriatic tool but synonymous in the meaning that it takes a shorter time when the images are taken mydriatically.

Another survey done by Akil and Elloumi (2019) revealed a wide field of employment view is limited by the processing execution time. The method related indicated that five montages of images in iPhone 5 having a resolution equal to 52.3 pixels/retinal degree require approximately 5 minutes (Gajiwala et al., 2022).

This study reinforces the efficiency of non-mydriatic imaging for quick screenings, with most images being captured in under 7 minutes. However, mydriatic imaging proves to be consistently faster for all participants, supporting its use in scenarios where time and image quality are critical. These findings can guide clinical practices in choosing the appropriate imaging method based on the specific needs of the patient and the setting (Sheikh et al., 2021).

For the clinical factors affecting the gradability of the captured images, "In the mydriatic tool of Remidio FOP Camera, age and smoking were factors associated with ungradable quality of an image. Participants who were >60 years of age were 80% significantly more likely to have ungradable images (APR = 1.80: 95% CI: 1.19-2.96, P value = 0.007). In the non-mydriatic tool, age is still a factor and hypertension is 23% more likely to have ungradable images (APR = 1.23: 95% CI: 1.03-1.47, P value = 0.022)."

The stipulated reason for the older age contributing to the poor grading of images could be explained as the presence of cataracts (missed during examination) since older age is more prone to have cataracts but evidently the retina atrophy also could bring effects on

gradability of the images. This has appeared to affect both non-mydriatic and mydriatic tools.

Relevant to the effect of age, A study by P.H Scanlon et al, 2005 from the Department of Ophthalmology in Cheltenham Hospital revealed “the ungradable image rate for non-mydriatic photography was 19.7% (95% CI18.4 –21.0) and for mydriatic photography was 3.7% (3.1– 4.3). The odds of having one eye ungradable increased by 2.6% (1.6 –3.7) for each extra year since diagnosis for non-mydriatic, by4.1% (2.7–5.7) for mydriatic photography irrespective of age, by 5.8% (5.0 – 6.7) for non-mydriatic, and by 8.4% (6.5–10.4) for mydriatic photography for every extra year of age, irrespective of years since diagnosis (Sheikh et al., 2021) (Peter Henry Scanlon et al, 2005).

Smoking has been linked to poorer retinal health and image quality. According to a Meta-analysis report by Yang et al in (2019) reported that” no significant effect of tobacco smoking on retinal or choroidal thickness change was detected. However, smoking would influence the thickness of RNFL and GCL. Furthermore, subgroup analyses demonstrated that the results based on studies in some regions (America and Africa), and cross-sectional studies showed a reduced choroidal thickness in smokers (Sivaraman et al., 2021).

4. CONCLUSION

Due to the advancement of technology, it is necessary to use more portable, reliable and easily manipulated equipment such as Remidio FOP and similar cameras, but more of validation studies should be done to have a real and reliable Non-mydriatic FOP which can be adopted by the National health system of screening and diagnosing Diabetic Retinopathy.

This study has shown that Remidio FOP camera can be a useful equipment on screening and referring Diabetic retinopathy cases on high quantity screening camps as well as screening at the periphery during the outreach. The challenge is having low sensitivity on grading images if used as non-mydriatic but having a satisfactory capacity to grade fundus images as mydriatic tool.

More studies that will use a larger sample size should be done on other No-mydriatic FOP cameras as well as more portable equipment to facilitate a complete precise diagnosis of DR without a presence of an ophthalmologist should be done.

We recommend using a Remidio FOP Camera with mydriasis for screening DR.

Also, the development of Artificial intelligence algorithms should be emphasized to have Artificial intelligence that can diagnose every type of Diabetic Retinopathy precisely.

A portable OCT (Ocular Computed Tomography) machine should be considered to be used in further studies that will concentrate on DR screening.

CONSENT

"All authors declare that ‘written informed consent was obtained from the participants (or other approved parties) for publication of this report and accompanying images. A copy of the written consent is available for review by the Editorial office/Chief Editor/Editorial Board members of this journal."

ETHICAL APPROVAL

“All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.”

DISCLAIMER (ARTIFICIAL INTELLIGENCE)

The author (s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc.) and text-to-image generators have been used during the writing or editing of this manuscript.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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APPENDIX

Appendix I: Data Collection Form

TITLE: Validation between non-mydriatic and mydriatic Remidio FOP Camera with Artificial intelligence in screening Diabetic Retinopathy at Northern-Tanzania, 2O23-2024.

ID NUMBER ……..

S/N	Question	Options
Sociodemographic Data		
1.	Age of respondent in complete years (at time of screening)	…….
2.	Sex of the respondent	1. Male 2. Female
3.	Level of residence	1. Primary level 2. Secondary level 3. University or college level
4	Residence	
5	History of smoking	1. Yes 2. NO
Diabetic History		
5	History of DM	1. Below 12 months 2. Above 12 months 3. Newly diagnosed
6.	Hypoglycemic agents	1. Oral hypoglycemic agents 2. Insulin 3. Others
7.	History of Hypertension	1. Yes 2. NO 3. Unknown
8.	History of anti-hypertensive agents	1. Yes 2. No
9.	History of stroke	1. Yes 2. NO
10.	History of Cardiac disease	1. Yes 2. NO
Fundus Image Results		
11(a)	Quality of Image	1. Gradable 2. Ungradable
11(b)	For Gradable image	1. DR 2. No DR 3. PDR 4. VTDR
13.	Time scale	1. Short 2. Medium 3. Long

STUDENT SUPERVISION RECORD
(KCMUCo/IPH/UG/F2)

Name of student (s) & exam #	ALLY SONGORO MAGERO TUMA/KCMUCo/MMEDOPH.2021/2022/TZ.0087
Date of supervisory meeting:	17th JUNE, 2024
Degree Program	MMED. OPHTHALMOLOGY
Title of project:	VALIDATION BETWEEN NON-MYDRIATIC AND MYDRIATIC REMIDIO FOP CAMERA WITH ARTIFICIAL INTELLIGENCE IN SCREENING DIABETIC RETINOPATHY AT NORTHERN TANZANIA 2023-25
Supervisor	Dr. William Makupa
Co-supervisors	Dr. Maria Kissanga
Personnel present	Dr. Andrew, Makupa.

Supervisor(s) comments: (*include an agreed plan for the next research period*)

Key aims set at last meeting	ESTABLISH THE PROPORTIONS OF UNGRADABLE IMAGES BETWEEN MYDRIATIC AND NON MYDRIATIC.
Progress made on each item:	THIS WAS DONE.
Conclusions that can be drawn	THE THESIS IS READY FOR SUBMISSION.
Proposed plan and action points for next meeting	NONE.

Signed: _____ (Supervisor) Date: 2024-07-10.

Student's comments	The supervisor's comments and corrections were taken and worked upon.

Signed: _____ (Student/s) Date: 10/07/2024

CRERC 07

KILIMANJARO CHRISTIAN MEDICAL UNIVERSITY COLLEGE

(A Constituent College of Tumaini University Makumira)

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RESEARCH ETHICAL CLEARANCE CERTIFICATE

No. PG 91 / 2023

Research Proposal No. 91

Study Title: Validation between non-mydriatic and mydriatic remidio FOP camera with Artificial Intelligence in screening Diabetic retinopathy at Northern Tanzania

Study Area: Kilimanjaro

PI's Name: Ally Songoro Magero

Institution (s): Kilimanjaro Christian Medical University College

The Proposal was approved by CRERC on: 18th September, 2023

Duration of Study: One year

From: 18th September, 2023 to 17th September, 2024

Ephata E. Kaaya MD, PhD
PROFESSOR

PROF. MRAMBA NYINDO
Chair – CRERC

PROF. EPHATA KAAYA
Provost - KCMU College

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