TECHNOLOGY REVIEW (MINI-HTA)

HANDHELD FUNDUS CAMERA - AN UPDATE

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
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EXECUTIVE SUMMARY

Background

Vision impairment affects at least 2.2 billion people globally, with 1 billion cases being preventable or unaddressed. The problem is exacerbated by an ageing population and lifestyle changes. In Malaysia, where 15.6% of adults have diabetes, conditions such as diabetic retinopathy, untreated cataracts, and glaucoma are leading causes of blindness, with 86.3% of these cases being avoidable. Poor access to eye care services remains a major barrier, hindering progress toward universal health coverage and Sustainable Development Goal 3. Fundus photography, which captures detailed images of the eye's internal structures, is critical for diagnosing and managing conditions like diabetic retinopathy, glaucoma, and age-related macular degeneration. The introduction of handheld fundus cameras provides an opportunity to improve access to eye care, especially in underserved areas, by making screening more accessible.

The development of fundus cameras began in 1926, with modern systems offering advanced features like wide-field imaging and portability. Traditional tabletop fundus cameras, though effective, are bulky, expensive, and limited in application to primary care settings. In contrast, handheld fundus cameras, such as a prototype that provides a 50º retinal field of view, offer comparable imaging quality and are more portable and cost-effective. However, a 2015 review conducted in Pahang State found inconclusive evidence regarding the effectiveness of handheld fundus cameras for diabetic retinopathy screening, with mixed results on sensitivity and specificity. The updated review aims to reassess the effectiveness, safety, and cost-effectiveness of handheld fundus cameras for detecting diabetic retinopathy and other retinal disorders, given recent technological advancements.

Objective/ aim

This technology review aimed to reassess the effectiveness, safety, and cost-effectiveness of handheld fundus cameras for detecting diabetic retinopathy, hypertensive retinopathy, or other retinal disorders such as age-related macular degeneration and glaucoma.

Results and conclusion:

Search results

A total of **79** records were identified through the Ovid interface and PubMed. No duplicate references were found; **79** potentially relevant titles were screened using the inclusion and exclusion criteria. Of these, **13** relevant abstracts were retrieved in full text. **Eleven** were included after reading, appraising and applying the inclusion and exclusion criteria to the 13 full-text articles. All full-text articles were selected for this review, comprising one systematic review, meta-analyses, and ten cross-sectional studies. The studies were conducted mainly in Europe (United Kingdom, Croatia, Finland) and Asia (Sri Lanka, China, Nepal, and India).

Efficacy/ effectiveness

Handheld fundus cameras have demonstrated high sensitivity and specificity in screening for various eye conditions, including diabetic retinopathy (DR), glaucoma, and other retinal abnormalities, making them comparable to traditional tabletop cameras. Sensitivity rates for DR detection range from 83% to 96.9%, with specificity rates up to 100%. In glaucoma

screening, handheld devices showed nearly equivalent results to gold-standard dilated fundus exams, with sensitivity and specificity above 94%. While non-mydriatic imaging is practical and effective, particularly in settings where dilation is impractical, mydriatic imaging offers slightly higher sensitivity and specificity and improves diagnostic reliability, especially for ungradable or complex cases. These cameras are particularly valuable in community and low-resource settings, proving their effectiveness for remote and routine screenings, especially in detecting vision-threatening conditions.

Safety

Multiple studies have confirmed that handheld fundus cameras are safe for clinical use, particularly in screening for diabetic retinopathy, glaucoma, and other retinal conditions. These studies reported no significant safety concerns, and patients generally tolerated the devices well. Handheld cameras were found to be non-invasive and comfortable for patients, even those with existing ocular conditions. In both diabetic retinopathy and glaucoma screening, the use of handheld fundus cameras resulted in no adverse events or complications. Additionally, their safety in broader applications, such as screening for various retinal conditions in clinical and community settings, has been well-established. Overall, the safety profile of handheld fundus cameras, combined with their diagnostic accuracy and portability, supports their widespread use in eye care, especially in resource-limited environments.

Organisational issues

The implementation of handheld fundus cameras in clinical settings presents several organisational challenges, particularly regarding training, standardisation, and integration into existing healthcare systems. Adequate training for non-specialist healthcare providers is necessary to ensure consistent image quality and accurate diagnoses, but this requires significant investment in training programs. Variability in operator skills may affect diagnostic outcomes, highlighting the need for standardised protocols. Additionally, integrating these devices into healthcare workflows could require adjustments to clinic operations, including patient flow, data management, and IT infrastructure upgrades to handle digital images and ensure compatibility with electronic health records. The use of AI-assisted grading systems for images, such as DeepDR, demonstrated high accuracy in diabetic retinopathy (DR) screening. However, its performance is influenced by image quality and operator expertise, with occasional misdiagnoses of mild DR and limited generalizability highlighting the need for further refinement and validation. Addressing these challenges is essential for the successful adoption and effective use of handheld fundus cameras in clinical practice.

Economic implication

The reviewed studies indicate that handheld fundus cameras offer significant economic benefits, particularly in resource-limited settings. These devices are much more affordable than traditional tabletop cameras, with some costing around [redacted] or conventional systems, making them a cost-effective option for clinics and screening programs. Handheld cameras have proven feasible in low- and middle-income countries, where general physicians, after training, can use them effectively, potentially reducing the need for specialist consultations. Additionally, these devices can enhance the efficiency of screening programs by enabling quicker examinations, reducing the time and cost of follow-up visits or more expensive diagnostic procedures. While initial training investment is required, handheld cameras could support more cost-effective and sustainable eye care programs, especially in underserved areas.

Conclusion

A substantial body of retrievable evidence has demonstrated that handheld fundus cameras have proven to be highly effective and safe tools for screening a variety of eye conditions, including diabetic retinopathy and glaucoma. Their affordability and portability offer significant advantages, particularly in resource-limited settings, making them a viable alternative to traditional tabletop cameras. Although non-mydriatic imaging is practical and effective, but mydriatic imaging offers higher accuracy and is better for complex or ungradable cases, highlighting the complementary benefits of both approaches. Despite their potential, the successful adoption of these devices requires addressing organisational challenges, such as standardised training for operators and integration into existing healthcare systems. Economically, handheld cameras reduce costs and improve the efficiency of screening programs, especially in underserved areas. However, limitations such as variability in operator skill and the need for further validation of newer devices should be considered when interpreting the results of current studies.

Methods

A systematic review was conducted. The primary author developed a review protocol and search strategy. In contrast, a literature search was conducted by an *Information Specialist* who searched for published articles related to the effectiveness, safety, and cost-effectiveness of handheld fundus cameras for detecting diabetic retinopathy, hypertensive retinopathy, or other retinal disorders. The following electronic databases were searched through the Ovid interface: MEDLINE (R) ALL 1946 to 25th July 2024, EBM Reviews - Health Technology Assessment 4th Quarter 2016, EBM Reviews - Cochrane Database of Systematic Reviews 2005 to 28th March 2023, EBM Reviews - Cochrane Central Registered of Controlled Trials February 2023, EBM Reviews - Database of Abstracts of Review of Effects 1st Quarter 2016, and EBM Reviews - NHS Economic Evaluation Database 1st Quarter 2016. Parallel searches were run in PubMed, US FDA and INAHTA databases, while additional articles were retrieved from reviewing the bibliographies of retrieved articles. The search was limited to articles on humans. The search was limited to articles on human and English text. The last search was conducted on 25th July 2024.

TABLE OF CONTENTS

ABBREVIATION

AI	Artificial Intelligence
BCVA	Best Corrected Visual Acuity
CSME	Clinically Significant Macular Edema
DM	Diabetes Mellitus
DR	Diabetic Retinopathy
EHR	Electronic Health Records
IOP	Intraocular Pressure
LMICs	Low- and Middle-Income Countries
NPDR	Non-Proliferative Diabetic Retinopathy
PDR	Proliferative Diabetic Retinopathy
ROP	Retinopathy of Prematurity
SDG	Sustainable Development Goal
VTDR	Vision-Threatening Diabetic Retinopathy

1.0 BACKGROUND

Globally, at least 2.2 billion people experience vision impairment or blindness, with at least 1 billion cases being preventable or unaddressed. This issue is growing due to an ageing population and changes in behaviour and lifestyle, leading to an increased burden of visual impairment. [1] In Malaysia, the National Health and Morbidity Survey 2023 reported that 15.6% of adults—about 1 in 6—have diabetes, which increases the risk of diabetic retinopathy. [2] Additionally, the National Eye Survey II Malaysia (2018) found that the most common causes of blindness were untreated cataracts (58.6%), diabetic retinopathy (10.4%), and glaucoma (6.6%). Notably, 86.3% of these cases were avoidable. [3] However, poor access to eye care services remains a significant barrier, making it harder to achieve universal health coverage and Sustainable Development Goal 3 (SDG 3), which aims to "Ensure healthy lives and promote well-being for all at all ages". [1, 3]

Fundus photography involves taking detailed images of the back of the eye with a specialised camera, which is essential for diagnosing and monitoring eye conditions. It helps visualise key structures such as the peripheral retina, optic disc, and macula. These images are vital in documenting abnormalities related to diseases like diabetes, age-related macular degeneration, and glaucoma. [4] The introduction of handheld fundus cameras is a significant step forward in addressing the accessibility challenges in eye care. These portable devices make screening easier in remote or underserved areas, helping close the eye care access gap. By bringing these diagnostic tools closer to those in need, handheld fundus cameras can play a crucial role in reducing preventable blindness and supporting global health goals.

The evolution of the fundus camera started with the invention of the ophthalmoscope in 1851 by Herman Von Helmholtz, which provides visualization of the posterior segment of the eye by an ophthalmologist. Carl Zeiss and J.W. Nordensen introduced the first reliable fundus camera in 1926, allowing documentation of ocular fundus structure. The camera provided a 20º field of view but then was improved to a 30º field of view as a standard of ocular fundus photography. Over the years, camera systems have evolved to boast sharper images, nonmydriatic wide field options, pupil tracking, and portability [5].

Traditional fundus cameras offer good-quality images but are bulkier, more office-based, technician-dependent, and more costly. The need for modern tabletop fundus camera devices has emerged from specific limitations accompanying traditional tabletop fundus cameras. However, most modern tabletop fundus cameras have add-on features that contribute to the additional size and weight of the camera. It is office-based and very costly, and the application in primary healthcare may be limited due to constraints. [5]

A prototype handheld fundus camera was designed by interfacing an optical module with the [redacted] consumer camera, providing a 50º retinal field of view. The images produced by the prototype camera are claimed to be comparable to those of the standard fundus camera. [6]

This technology review on handheld fundus cameras was initially conducted in 2015 at the request of the Pahang State Health Director to evaluate the feasibility of using handheld fundus cameras as an alternative tool for diabetic retinopathy screening in clinics across Pahang State. The review, however, found inconclusive evidence regarding the effectiveness of handheld fundus cameras for this purpose. While one study reported low sensitivity and specificity in detecting minimal non-proliferative diabetic retinopathy, another study found high sensitivity and specificity in detecting any retinopathy grade. Additionally, there was only limited and fair-quality evidence suggesting the potential of handheld fundus cameras for detecting retinopathy of prematurity (ROP) and glaucoma. As a result, the use of handheld fundus cameras for screening diabetic retinopathy, ROP, and glaucoma was not recommended. Furthermore, no evidence was found regarding the safety and cost-effectiveness of handheld fundus cameras in a clinical setting.

Given rapidly evolving technology and evidence, an updated review was conducted to reassess handheld fundus cameras' effectiveness, safety, and cost-effectiveness for detecting diabetic retinopathy, hypertensive retinopathy, or other retinal disorders such as age-related macular degeneration and glaucoma.

2.0 OBJECTIVE / AIM

This technology review aimed to reassess handheld fundus cameras' effectiveness, safety, and cost-effectiveness for detecting diabetic retinopathy, hypertensive retinopathy, or other retinal disorders such as age-related macular degeneration and glaucoma.

3.0 TECHNICAL FEATURE

Handheld fundus cameras are recognised for their light weight, portability, and ease of use. They require minimal space and technical expertise, making them an accessible and cost-effective option for various clinical settings. The optical design of these cameras is based on the principle of monocular indirect ophthalmoscopy, which provides an upright, magnified view of the fundus. Several brands, such as , offer handheld fundus cameras with varying specifications to meet diverse clinical needs.

Key features of these devices include different design principles, such as reflective imaging with white light, conventional optics, or slit lamp-based designs. They are available in both mydriatic and non-mydriatic versions, allowing for flexibility depending on the clinical scenario. The field of view generally ranges from 25º to 40º, with a focusing range typically between -20D to +20D, ensuring precise imaging across various patient conditions (refer to Figure 1).

In addition to these core features, some handheld fundus cameras, such as those from Optomed, incorporate advanced technology like artificial intelligence (AI) for automated image analysis. This integration allows for the early detection of retinal diseases, particularly in settings where access to specialist care is limited. AI capabilities enhance the diagnostic potential of these devices, making them not only a tool for capturing images but also for interpreting them in real time.

Handheld fun[redacted]s often include advanced features like fixation targets, image sens[redacted]displays ranging from 2 to 5 megapixels, with LCD screens for real-time viewing. For example, the [redacted] provides image memory for 30 image files in flash memory, while the [redacted]r camera offers a 4GB SD memory card for storage. Additional functionalities may include colour imaging, general examinations, anterior eye module compatibility, and connecting to external devices via USB or Wi-Fi, enhancing their versatility in different environments.

Figure 1: Example of handheld fundus camera available in market [6]

4.0 METHODS

The main author and an Information Specialist developed the search strategy.

4.1 SEARCHING

The following electronic databases were searched through the Ovid interface:

- MEDLINE® All < 1970 to 25th July 2024>
- EBM Reviews - Health Technology Assessment 4th Quarter 2016
- EBM Reviews - Cochrane Database of Systematic Reviews 2005 to 28th March 2023
- EBM Reviews - Cochrane Central Registered of Controlled Trials February 2023
- EBM Reviews - Database of Abstracts of Review of Effects 1st Quarter 2016
- EBM Reviews - NHS Economic Evaluation Database 1st Quarter 2016

Other databases: PubMed, US FDA, INAHTA.

General databases such as Google were used to search for additional web-based materials and information. The bibliographies of retrieved articles were reviewed to retrieve additional articles. Only articles from Pubmed, Medline, and Ovid databases were taken due to its credibility. The search was limited to articles on human and English text. **Appendix 1** shows the detailed search strategies. The last search was conducted on 25 July 2024

4.2 SELECTION

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria. Relevant articles were then critically appraised depending on the type of study design. Studies were graded according to the US/ Canadian Preventive Services Task Force **(refer to Appendix 2)** and checklist of the National Collaborating Centre for Methods and Tools, A Risk of Bias Assessment Tool for Systematic Reviews (ROBIS) for systematic review and The Joanna Briggs Institute (JBI) Critical Appraisal tools for cross-sectional studies [7, 8]. All data were extracted and summarised in an evidence table as in **Appendix 3**.

The inclusion and exclusion criteria were:

Inclusion criteria:

a.	**Population**	Patient with diabetes, hypertension, retinal disease, glaucoma
b.	**Intervention**	Handheld fundus camera
c.	**Comparator**	Tabletop fundus camera, no comparator
d.	**Outcomes**	**Effectiveness:** Sensitivity, specificity and accuracy of handheld fundus camera for detecting diabetic retinopathy, hypertensive retinopathy or other retinal disorders such as age-related macular degeneration, and glaucoma **Safety:** Adverse events (AEs) related to usage of handheld fundus camera **Organisational issues:** procedural time, training or learning curve **Economic implications:** Cost, cost-effectiveness, cost-utility analysis
e.	**Study design**	HTA reports, systematic review with/out meta-analysis, randomised controlled trial (RCT), cohort, diagnostic, case-control, economic evaluation studies
f.	Full text articles published in English	

Exclusion criteria:

a.	**Study design**	Case report, case series, animal study, laboratory study, narrative review
b.	Non-English full text articles	

5.0 RESULTS

Search results

An overview of the search is illustrated in **Figure 2**. A total of **79** records were identified through the Ovid interface and PubMed. No duplicate references were found; potentially relevant titles were screened using the inclusion and exclusion criteria. Of these, **13** relevant abstracts were retrieved in full text. After reading, appraising and applying the inclusion and exclusion criteria to the **13** full-text articles, **11** were included. All full-text articles were selected for this review, comprising one systematic review, meta-analyses, and ten cross-sectional studies. The studies were conducted mainly in Europe (United Kingdom, Croatia, Finland) and Asia (Sri Lanka, China, Nepal, and India).

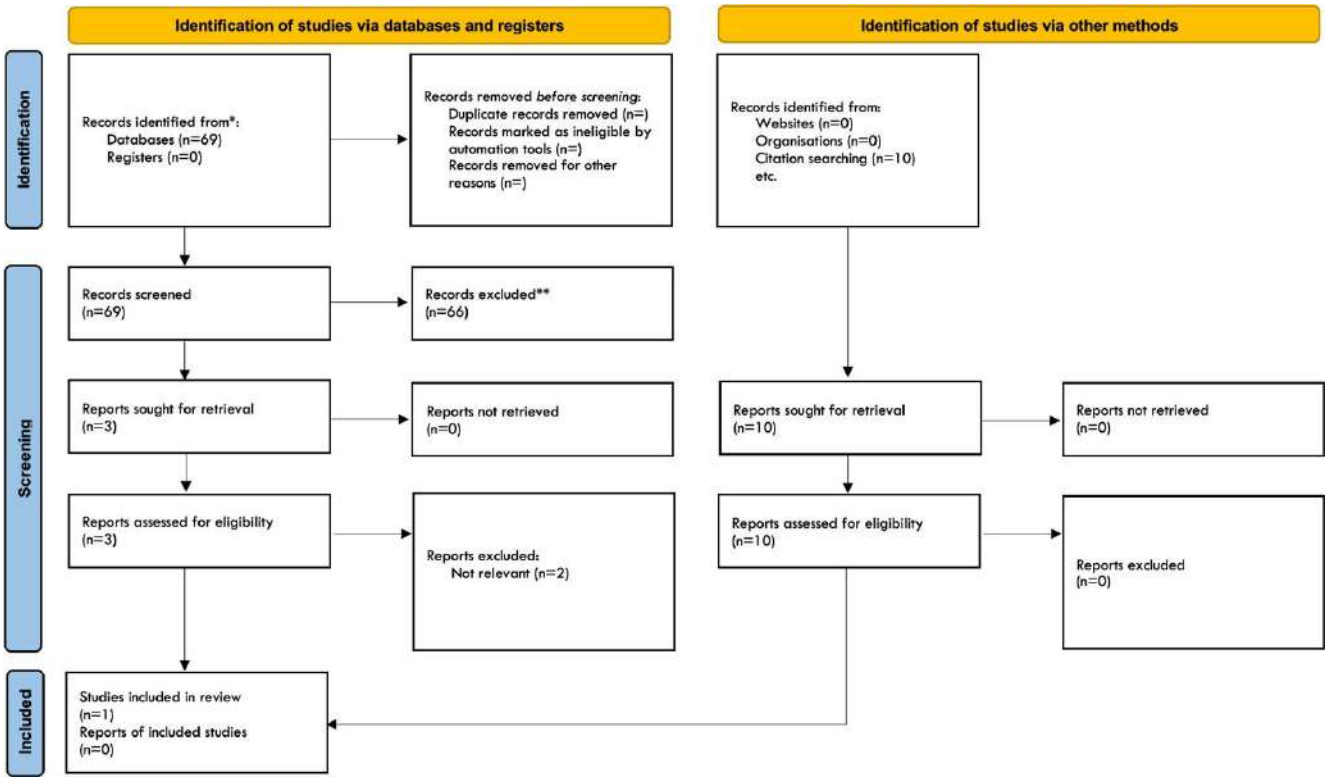

Figure 2: Flow chart of retrieval of articles used in the results

Quality assessment of the studies

The risk of bias or quality assessment (methodology quality) of all retrieved literature was assessed depending on the type of study design by two reviewers. These assessments involved answering a pre-specified question of those criteria assessed and assigning a judgement relating to the risk of bias using the relevant checklist of the National Collaborating Centre for Methods and Tools, A Risk of Bias Assessment Tool for Systematic Reviews (ROBIS) for systematic review and The Joanna Briggs Institute (JBI) Critical Appraisal tools for

cross-sectional studies. All full-text articles were graded based on guidelines from the *U.S. / Canadian Preventive Services Task Force* [9].

Risk of bias assessment for included systematic review

One study was included in this assessment and was judged to have an overall high risk of bias following uncertainty in the data collection or risk of bias assessment processes. The main concerns in the included studies were selection bias and a lack of formal risk-of-bias assessment. However, the clear eligibility criteria and appropriate synthesis methods provide some assurance of validity.

Palermo et al. (2022)

Table 1: Assessment of risk of bias of systematic review of cross-sectional studies.

Domain 1: Concerns regarding specification of study eligibility criteria	High
Domain 2: Concerns regarding methods used to identify and/or select studies	High
Domain 3: Concerns regarding methods used to collect data and appraise studies	Unclear
Domain 4: Concerns regarding the synthesis and findings	Low

Risk of bias assessment for included cross-sectional studies using JBI

Based on the JBI checklist, the studies had a low risk of bias (**Table 2**).

Table 2: Risk of bias assessment for cohort study using JBI

	CAJBI1	CAJBI2	CAJBI3	CAJBI4	CAJBI5	CAJBI6	CAJBI7	CAJBI8
Tomić et al. (2023)	+	+	+	?	+	+	+	+
Das et al. (2022)	+	+	+	+	+	+	+	+
Midena et al. (2022)	+	+	+	+	+	+	+	+
Upadhyaya et al. (2022)	+	+	+	+	+	+	+	+
Kubin et al. (2021)	+	+	+	+	+	+	+	+
Xiao et al. (2020)	+	+	+	+	+	+	+	+
Piyasena et al. (2019)	+	+	+	+	+	+	+	+
Sengupta et al. (2018)	+	+	+	+	+	+	+	+
Miller et al. (2017)	+	+	+	+	+	+	+	+
Zhang et al. (2017)	+	+	+	+	+	?	+	+

CAJBI1 Were the criteria for inclusion in the sample clearly defined?
CAJBI2 Were the study subjects and the setting described in detail?
CAJBI3 Was the exposure measured in a valid and reliable way?
CAJBI4 Were objective, standard criteria used for measurement of the condition?
CAJBI5 Were confounding factors identified?

CAJBI6	Were strategies to deal with confounding factors stated?
CAJBI7	Were the outcomes measured in a valid and reliable way?
CAJBI8	Was appropriate statistical analysis used?

Judgment:

+	Yes
-	No
?	Unclear
x	Not applicable

5.1 EFFICACY/ EFFECTIVENESS

5.1.1 Diabetic retinopathy

Handheld fundus cameras have demonstrated high effectiveness in screening for diabetic retinopathy (DR) across multiple studies. The systematic review by Palermo et al. (2022) reported that handheld fundus cameras had a sensitivity of 87% and a specificity of 95% for detecting DR, making them comparable to traditional tabletop cameras in accuracy [10 level II-3]. Tomić et al. (2023) further validated these findings, showing that handheld cameras had a sensitivity of 83.2% and a specificity of 100% compared to standard fundus cameras, indicating their reliability in detecting various stages of DR [11 level II-3.] In another study by Midena et al. (2022), the Optomed Aurora handheld camera demonstrated a sensitivity of 96.9% and a specificity of 94.8%, with almost perfect agreement in detecting different levels of DR [12 level II-3].

Xiao et al. (2020) found that handheld fundus cameras were particularly effective in community screening settings, with high agreement between handheld and desktop cameras in diagnosing different levels of DR. However, desktop cameras performed slightly better in cases involving cataracts [13 level II-3]. Piyasena et al. (2019) emphasised the utility of handheld fundus cameras in low-resource settings, where they proved effective for DR screening by general physicians, especially when combined with mydriasis [14 level II-3]. The study by Sengupta et al. (2018) also supported using handheld fundus cameras for detecting vision-threatening DR, with high sensitivity and specificity comparable to dilated fundus examination [15 level II-3.]

5.1.2 Glaucoma

For glaucoma, handheld fundus cameras have shown promising effectiveness in detecting optic nerve abnormalities. Upadhyaya et al. (2022) reported high sensitivity (96.3% and 94.8%) and specificity (98.5% and 97.8%) for detecting glaucoma using the Smartscope handheld camera, which was comparable to gold-standard dilated fundus exams [16 level II-3]. Similarly, Miller et al. (2017) found no significant difference in cup-to-disc ratio (CDR) measurements between handheld and traditional mydriatic fundus cameras, indicating that handheld cameras are reliable for glaucoma screening, particularly in remote areas [17 level II-3].

5.1.3 Other eye conditions

No retinopathy of prematurity (ROP) was found among the studies, but other retinal conditions

were explored. Kubin et al. (2021) showed that handheld fundus cameras effectively detect a range of retinal abnormalities, including age-related macular degeneration and retinal vein occlusion, with high sensitivity and specificity [18 level II-3]. Das et al. (2023) highlighted the comparable performance of handheld devices like Remidio and Pictor Plus to traditional tabletop cameras in detecting optic disc and macular abnormalities, further validating their effectiveness across various retinal conditions [19 level II-3].

5.1.4 Mydriatics versus non-mydriatics features

The comparison of mydriatic and non-mydriatic imaging reveals nuanced findings. Palermo et al. (2022) noted slightly higher sensitivity and specificity with mydriatic imaging (87% and 90%, respectively) compared to non-mydriatic imaging (83% and 92%) [10 level II-3]. Studies such as Sengupta et al. (2018) and Piyasena et al. (2019) demonstrated that handheld cameras achieve better image quality and diagnostic accuracy with mydriasis, particularly in cases of ungradable images [14 level II-3, 15 level II-3]. Conversely, non-mydriatic imaging, as shown by Midena et al. (2022) and Xiao et al. (2020), is effective in scenarios where dilation is impractical, though it may result in slightly reduced image quality [12 level II-3,13 level II-3].

Studies comparing imaging methods reinforce these findings. Miller et al. (2017) and Zhang et al. (2017) reported comparable diagnostic accuracy between mydriatic and non-mydriatic approaches for glaucoma and DR, respectively, with improved gradability following dilation [17 level II-3,20 level II-3]. This suggests that while non-mydriatic imaging is practical and effective, mydriasis enhances diagnostic reliability, particularly for complex cases.

Handheld fundus cameras have proven practical tools for screening various eye diseases, including diabetic retinopathy and glaucoma. Their portability and accuracy make them especially valuable in settings with limited access to traditional diagnostic equipment, supporting their broader adoption in routine and remote screening programs.

5.2 SAFETY

Multiple studies have evaluated the safety of handheld fundus cameras, and the consensus indicates that these devices are safe for clinical use, particularly in screening for diabetic retinopathy (DR), glaucoma, and other retinal conditions.

The systematic review by Palermo et al. (2022) did not report any direct safety concerns associated with handheld fundus cameras, indicating that patients generally well-tolerated these devices. The studies included in this review focused primarily on the diagnostic accuracy of the devices, with no significant safety issues highlighted [10].

In diabetic retinopathy screening, several studies have confirmed the safety of handheld fundus cameras. Tomić et al. (2023) observed no adverse events related to using handheld cameras during their research on diabetic retinopathy screening. The study emphasised the cameras' non-invasive nature, making them safe and comfortable for patients, even those with existing ocular conditions [11]. Similarly, the study by Midena et al. (2022) reported that the handheld Optomed Aurora camera was safely used in a real-life screening setting without any reported

complications, further supporting the device’ s safety profile [12].

In glaucoma screening, the study by Upadhyaya et al. (2022) also confirmed the safety of the handheld Smartscope camera, with no adverse events reported during the study. The study involved both dilated and non-dilated imaging, and patients tolerated the procedures well, suggesting that the handheld camera is a safe alternative to traditional imaging methods in glaucoma detection [16].

The safety of handheld fundus cameras in broader applications, including other retinal conditions, was also supported by Kubin et al. (2021), who found that using these cameras in a clinical setting did not result in any safety concerns. The cameras were safely used to screen for various retinal conditions, and the study highlighted their potential to be used safely in routine clinical practice [18]. Das et al. (2023) confirmed that patients experienced no significant discomfort or safety issues when handheld devices were used, even in a non-clinical setting like a community screening program [19].

Across the studies reviewed, handheld fundus cameras are safe for use in various clinical settings. No significant safety concerns were reported, and the devices were well-tolerated by patients, including those with existing ocular conditions. With their portability and diagnostic accuracy, this safety profile makes handheld fundus cameras a viable option for widespread use in eye care, particularly in screening programs and settings with limited access to traditional imaging equipment.

5.3 ORGANISATIONAL ISSUES

Several potential organisational issues could arise with the implementation and use of handheld fundus cameras in clinical settings.

5.3.1 Training and Standardization

One significant organisational challenge is adequate training and standardisation across different healthcare settings. Many studies, such as those by Piyasena et al. (2019) and Xiao et al. (2020), involved training non-specialist healthcare providers to use handheld fundus cameras [13, 14]. Although most of the studies were conducted in specialized eye centres or tertiary healthcare settings, they demonstrated that ophthalmic photographers, even without prior experience in using handheld fundus cameras, were effectively trained to capture high-quality images. These images were subsequently validated by ophthalmologists, affirming the reliability of training protocols [12,13,15,16,17].

While this approach can broaden access to screening, it also requires a substantial investment in training programs to ensure consistent image quality and accurate diagnosis. Variability in operators' skill levels could lead to differences in diagnostic outcomes, making it essential to establish standardised training protocols and quality control measures across all settings where these devices are used. Additionally, the effectiveness of these cameras may vary depending on the experience and expertise of the operators, which could impact the reliability of screenings in less controlled environments.

5.3.2 Integration into Existing Healthcare Systems

Another potential organisational issue is the integration of handheld fundus cameras into existing healthcare workflows. Studies like those by Miller et al. (2017) and Tomić et al. (2023) suggest that these devices could increase efficiency and reduce costs. However, introducing new technology may require clinic workflow changes, including appointment scheduling adjustments, patient flow, and data management [11, 17.] For example, the storage and sharing of digital images captured by handheld cameras might necessitate upgrades to IT infrastructure, including secure data storage solutions and interoperability with existing electronic health records (EHR) systems. Furthermore, ensuring consistent follow-up care based on screening results could present logistical challenges, particularly in settings with limited referral networks or specialist care access. Effective integration will require careful planning and coordination among stakeholders, including healthcare providers, IT professionals, and administrative staff, to minimise disruptions and ensure smooth implementation.

5.3.3 Use of artificial intelligence (AI) in assisting diagnosis of diabetic retinopathy

The study by Tomic et al. (2023) demonstrated the effectiveness handheld fundus camera assisted with the DeepDR AI-based grading system for diabetic retinopathy (DR) screening, showing high diagnostic accuracy with a sensitivity of 89.1% and specificity of 100% compared to clinical examinations, and slightly lower sensitivity (83.2%) but equal specificity against standard fundus cameras. The system excelled in identifying severe DR stages, achieving excellent agreement with human graders and providing immediate recommendations for follow-up or referral. However, its performance depends heavily on image quality, with medium-quality images attributed to operator inexperience. While the AI system occasionally misdiagnosed mild non-proliferative DR (up to 10.6% compared to standard cameras), these cases typically required the same follow-up as non-DR cases. Limitations include the study's small sample size and single-center setting, limiting generalizability, and the absence of evaluations under noisy or adversarial conditions. Despite its utility in resource-limited settings, the AI system still requires human oversight, particularly for quality assurance and subtle diagnostic distinctions, highlighting the need for further refinement and real-world validation [11].

In summary, while handheld fundus cameras offer promising benefits, their widespread adoption may present organisational challenges related to training, standardisation, and integration into existing healthcare systems. Addressing these issues will be crucial to maximising the effectiveness and efficiency of these devices in clinical practice.

5.4 ECONOMIC IMPLICATION

The studies reviewed suggest that handheld fundus cameras offer significant economic advantages, particularly in resource-limited settings. Several studies, including those by Piyasena et al. (2019) and Miller et al. (2017), highlight that these devices are substantially less expensive than traditional tabletop cameras, making them a more affordable option for clinics and screening programs [14, 17.] For example, the Pictor camera costs around [redacted] in [redacted]

the US, compared to approximately for a traditional tabletop system, considerably reducing equipment costs. Additionally, the feasibility of using handheld cameras in low- and middle-income countries (LMICs) was demonstrated, with general physicians effectively using these devices after training, potentially reducing the need for specialist consultations and making screening programs more economically viable.

Furthermore, handheld fundus cameras could enhance the efficiency of screening programs by enabling quicker and more accessible eye examinations. Studies like Tomić et al. (2023) suggest that this efficiency could save costs by reducing the time required for screenings and decreasing the need for more expensive diagnostic procedures or follow-up visits [11]. While the initial investment in training healthcare providers to use these devices is a consideration, the overall reduction in resource utilisation and the ability to implement screening in underserved areas could contribute to more cost-effective and sustainable eye care programs.

5.5 LIMITATIONS

We acknowledge some important limitations in our review, and these should be considered when interpreting the results. During the search, only the full-text articles in English published in peer-reviewed journals were included in the report, which may have excluded some relevant articles and further limited our study numbers. Many studies were cross-sectional and limited by small sample sizes, often due to external factors like the COVID-19 pandemic or logistical issues. Some studies did not include a diverse population, excluding subjects with specific conditions like glaucoma suspects or those with milder forms of the disease, which limits the generalizability of the findings. Additionally, the variation in skill levels among photographers and graders of retinal images, mainly when using newer handheld fundus cameras, led to consistency in image quality and diagnostic accuracy. Several studies also acknowledged that more sophisticated or diverse imaging modalities needed to be incorporated, limiting their ability to fully validate the tools' performance. Moreover, some studies did not evaluate critical aspects like intraocular pressure (IOP) or clinically significant macular edema (CSME), which may have impacted the comprehensive diagnosis of eye diseases.

6.0 CONCLUSION

A substantial body of retrievable evidence has demonstrated that handheld fundus cameras have proven to be highly effective and safe tools for screening a variety of eye conditions, including diabetic retinopathy and glaucoma. Their affordability and portability offer significant advantages, particularly in resource-limited settings, making them a viable alternative to traditional tabletop cameras. While non-mydriatic imaging is practical and effective, particularly in settings where dilation is impractical, mydriatic imaging offers slightly higher sensitivity and specificity and improves diagnostic reliability, especially for ungradable or complex cases. This highlights the complementary roles of both approaches, with mydriasis enhancing image quality and accuracy where feasible.

Despite their potential, the successful adoption of these devices requires addressing organisational challenges, such as standardised training for operators and integration into existing healthcare systems. Economically, handheld cameras reduce costs and improve the

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9.0 APPENDICES

APPENDIX 1: LITERATURE SEARCH STRATEGY

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions <1946 to July 24, 2024>
Search Strategy:

1 DIABETES MELLITUS/ (145532)
2 DIABETES MELLITUS.tw. (249535)
3 DIABETES MELLITUS, TYPE 1/ (88590)
4 iddm.tw. (6913)
5 ((insulin dependent or insulin-dependent or type I or type 1) adj1 diabetes mellitus 1).tw. (22)
6 DIABETES MELLITUS, TYPE 2/ (181717)
7 niddm.tw. (6976)
8 ((noninsulin-dependent or noninsulin dependent or type 2 or type ii) adj1 diabetes mellitus).tw. (71850)
9 HYPERTENSION/ (264529)
10 (blood pressure* adj1 high).tw. (18998)
11 hypertension.tw. (467399)
12 OCULAR HYPERTENSION/ (7335)
13 (ocular adj1 hypertension*).tw. (6217)
14 (glaucoma* adj1 suspect).tw. (674)
15 (hypertension adj1 malignant).tw. (2140)
16 INTRACRANIAL HYPERTENSION/ (6079)
17 (intracranial adj1 hypertension).tw. (9652)
18 ((hypertension or (pressure increase or elevated)) adj1 intracranial).tw. (11145)
19 RETINAL DISEASES/ (24453)
20 (retinal adj1 disease*).tw. (7944)
21 GLAUCOMA/ (42680)
22 glaucoma*.tw. (72783)
23 GLAUCOMA, NEOVASCULAR/ (919)
24 (glaucoma* adj1 neovascular).tw. (1963)
25 or/1-24 (1120799)

26 DIAGNOSTIC TECHNIQUES, OPHTHALMOLOGICAL/ (7530)
27 (ophthalmologic* diagnostic adj1 (technique* or technic*)).tw. (1)
28 Handheld fundus camera.tw. (29)
29 Hand-held fundus camera.tw. (15)
30 Table top fundus camera.tw. (4)
31 Table-top fundus camera.tw. (4)
32 Fundus camera.tw. (1073)
33 retinal camera.tw. (275)
34 or/26-33 (8738)
35 25 and 34 (2339)
36 limit 35 to (english language and humans) (2027)
37 limit 36 to yr="2015 -Current" (714)
38 limit 37 to (observational study or randomized controlled trial or "systematic review") (69)

Other Databases

PubMed
INAHTA
US FDA

} Same MeSH and keywords as per MEDLINE search

APPENDIX 2: HIERARCHY OF EVIDENCE FOR EFFECTIVENESS

DESIGNATION OF LEVELS OF EVIDENCE

I	Evidence obtained from at least one properly designed randomized controlled trial.
II-I	Evidence obtained from well-designed controlled trials without randomization.
II-2	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.
II-3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
III	Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001

APPENDIX 3: EVIDENCE TABLE

Evidence Table : Effectiveness/ safety/ organisational/ economic implication

Question : What is the effectiveness, safety and cost- effectiveness of handheld fundus camera for detecting diabetic retinopathy, hypertensive retinopathy or other retinal disorders such as age-related macular degeneration, and glaucoma.

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
1) Palermo BJ, D'Amico SL, Kim BY, Brady CJ. Sensitivity and specificity of handheld fundus cameras for eye disease: A systematic review and pooled analysis. Surv Ophthalmol. 2022;67(5):1531-9.	**Systematic review** **Objective:** To evaluate the accuracy of commercially available handheld fundus camera for variety of ophthalmic diagnoses **Method:** Literature search was done through PubMed and PubMed Central on 28th December 2020, including search terms: "handheld fundus camera" and "portable fundus camera". After reviewing the initial search papers, specific camera names were included in the search strategy: "horus scope," "visuscout," "pictor plus," "retinavue," "versacam," "kowa genesis," "epicam,"	II-3	Total of 219 eligible articles were identified, 175 articles obtained after removal of duplicates. After exclusion, 23 articles screened, and 11 articles were finally included. Patient with any ocular diseases were included	Handheld fundus cameras including: • Pictor Plus (Volk Optical) • Visus cout 100 (Carl Zeiss AG) • Pictor (Volk Optical inc.) • Horus DEC 200 (Miis)	1. Table top fundus camera • AFC-330 • Fujix DF-10M (Fuji) • CR-2 (Canon) 2. Clinically trained ophthalmic specialist	-	i. For both mydriatic and nonmydriatic images, the handheld fundus camera had a sensitivity of 85% (95% Confidence Interval (CI): 80-89%; and a specificity of 91% (95% CI: 83-95%). ii. For nonmydriatic images alone, the sensitivity was 83% (95% CI: 77-88%) and specificity was 92% (95% CI: 79-97%). iii. For mydriatic images alone, the sensitivity was 87% (95% CI: 79-92%) and specificity was 90% (95% CI: 78-96%). iv. Since diabetic retinopathy was the most common diagnosis in the analysis, the handheld fundus camera's sensitivity and specificity were also assessed for diabetic	High risk of bias due to unclear study population, study characteristics and assessment of risk of bias between studies.

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
	"smartscope,"and "microclear luna." Inclusion criteria: Studies on human subjects, validated handheld fundus camera against an acceptable gold standard method (i.e: clinical exam by trained specialists or standard desktop fundus camera images graded by trained evaluators. Exclusion criteria: Non-English text, duplicate papers, studies on non-commercially available handheld fundus cameras and nonvalidating studies were excluded. Each studies underwent full-text review among authors to ensure inclusion criteria were met.			• Smart scope (Optomed) • Nidek NM-100 (Nidek)			retinopathy alone to compare with other diagnoses. a. For diabetic retinopathy screening (considering both mydriatic and nonmydriatic images), sensitivity was 87% (95% CI: 80-92%) and specificity was 95% (95% CI: 85-98%). b. For all other diagnoses, sensitivity was 81% (95% CI: 74-87%) and specificity was 83% (95% CI: 76-89%).	

Evidence Table : Effectiveness/ safety/ organisational/ economic implication

Question : What is the effectiveness, safety and cost- effectiveness of handheld fundus camera for detecting diabetic retinopathy, hypertensive retinopathy or other retinal disorders such as age-related macular degeneration, and glaucoma.

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
1) Tomić et al. (2023)	**Cross sectional instrument validation study** **Objective:** 1. To assess the role of a hand-held fundus camera and AI-based grading system in diabetic retinopathy (DR) screening 2. To determine its diagnostic accuracy in detecting DR compared with clinical examination and photography using the standard fundus camera. **Method:** Inclusion criteria:	II-3	n=160 Type 2DM patients (320 eyes) Median age 65 (45-83 years) Median diabetes duration 14 (2-33 years) Mean best corrected visual acuity (BCVA): 0.98 ± 0.10 Mean intraocular pressure (IOP): 15.21± 1.01mmHg. 16 (5%) eyes had primary open angle glaucoma, 36 (11.25%) eyes had clear crystalline lens, 230 (71.87%) had initial	Handheld fundus camera (TANG)	Indirect slit lamp fundoscopy Standard fundus camera: 45° fundus camera VISUCAM Zeiss (Carl Zeiss Meditec AG)		<u>Based on photography with handheld fundus camera:</u> 202 (63.1%) eyes had no DR, 58 (18.1%) had mild or moderate NDPR, 60 (18.8%) eyes had severe NDPR or PDR. Eyes with no retinopathy had significantly better BCVA compared to those with severe NDPR or PDR (Scheffe test, p=0.029) <u>Handheld vs standard examination:</u> Sensitivity: 89.1% (81.3-94.4%) Specificity: 100% (93.9-100%) PPV: 100% (95.9-100%) NPV: 91.4% (85.9-94.9%) Kappa ± SE: 0.86 ± 0.04 (0.77-0.94) Diagnostic OR: 936.48 (54.2-16194.6) Diagnostic effectiveness: 94.9% (90.3-97.8%)	The study found that the handheld fundus camera effectively detects diabetic retinopathy (DR) with high sensitivity and specificity, showing similar diagnostic accuracy to standard clinical examinations and fundus cameras. Most images were of good quality. However, the handheld camera sometimes missed mild NPDR that standard methods detected. Overall, the handheld camera is a reliable tool for DR screening, especially in settings with limited access to standard

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
	Patients who were referred to the ophthalmology department were randomly selected by the author, over 3 months (Sept – Dec 2019). Medical history regarding diabetes mellitus (DM) and other eye conditions and diseases were obtained Exclusion criteria: Patients with other posterior eye segment diseases or anterior and posterior eye segment diseases that does not allow fundus visualization and photography, poor cooperation patient. **Digital imaging:** Patient's pupils dilated with 0.5% tropicamide eye drops and standard clinical examination using indirect slit-lamp fundoscopy were performed. Fundus photography taken with a standard 45° fundus camera (VISUCAM		cataract, 54 (16.88%) eyes were pseudophakic due to previous cataract surgery				Handheld vs standard fundus camera: Sensitivity: 83.2% (74.4-89.9%) Specificity: 100% (93.9-100%) PPV: 100% (95.7-100%) NPV: 87.3% (81.7-91.4%) Kappa ± SE: 0.78 ± 0.05 (0.69-0.88) Diagnostic OR: 574.6 (33.8-9743.5) Diagnostic effectiveness: 92.2% (86.9-95.8%) AUC: for DR by handheld fundus camera vs standard clinical examination and standard fundus camera. Standard clinical examination: AUC 0.921 (SE 0.026), (95%CI 0.870-0.973), p 0.000. Standard fundus camera: AUC 0.883 (SE 0.030), (95%CI 0.824-0.942), p 0.000. 248 (77.5%) of images taken by handheld camera were good	diagnostic equipment. Single centre study, small sample size.

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
	Zeiss) and a handheld fundus camera (TANG). The photographs were independently graded by two medical retina specialists, M.T. and R.V., using international clinical guidelines for diabetic retinopathy and diabetic macular edema severity. Color fundus photography of two fields (macula-centered and optic disc-centered) for both eyes was conducted using a standard VISUCAM Zeiss camera and a handheld TANG camera according to the IDF Diabetic Retinopathy Screening Project guidelines, taken by ophthalmology nurse, which were graded using AI-based software (DeepDR) and reviewed by an independent IDF ophthalmologist. The AI and ophthalmologist provided image quality assessments,						quality, only 72 (22.5%) were medium quality, none of low or unreadable quality. Most significant discrepancy: assessment between eyes with no DR and those with mild NPDR (single microaneurysms). Among 202 eyes identified as having no DR by the handheld camera, mild NPDR was found in 22 eyes (6.9%) during standard clinical exams and in 34 eyes (10.6%) using the standard camera.	

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
	diagnoses, and advice. If images were of sufficient quality, they could result in: (1) no DR or mild non proliferative (NP) DR with advice for regular follow-up, or (2) moderate/severe NPDR or PDR with advice for referral to an ophthalmologist.							
2) Das et al. (2023)	**Cross sectional study** **Objective:** To compare the feasibility and clinical utility of four handheld fundus cameras/retinal imaging devices (Remidio NMFOP, Volk Pictor Plus, Volk iNview, oDocs visoScope) to a table-top camera (Zeiss Visucam$^{NM/FA}$). **Method:** Patient were recruited from Eye casualty, Emergency department and outpatient clnics at University of Leicesters Hospital, UK, in 2 stages: January-March 2020 and August-September 2021.	II-3	Stage 1: n=10 + without any eye diseases Stage 2: Optic disc abnormalities: n=8 Macular abnormalities: n=10	Four handheld fundus cameras/retinal imaging devices: Remidio NMFOP, Volk Pictor Plus, Volk iNview, oDocs visoScope	Table-top camera (Zeiss Visucam$^{NM/FA}$).	-	<u>Image acquisition:</u> ● Zeiss, Remidio and Pictor: 100% success rate for image acquisition in both mydriatic and non-mydriatic settings. ● oDocs and iNview, 10% success rate in non-mydriatic setting, 60% and 80% success rate after mydriasis. <u>Image quality and gradeability:</u> ● Zeiss and Remidio : median score=7.0 ● Pictor median=6.0 ● iNview median=3.5 ● oDocs median=2.0 Compared to Zeiss, there was no difference in image quality for both	Small sample size, single centre study, may limits generalisability. Remidio and Pictor (handheld fundus camera) had equivalent image acquisition success and image quality in comparison with Zeiss (tabletop fundus camera) Patient preference: Remidion and Pictor had similar or higher level of acceptability in comparison to Zeiss. Good agreement between clinician estimates of CD

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
	Stage 1: Imaging of healthy participants without any ophthalmic pathology Stage 2: imaging of participants with optic disc or macular abnormalities All image acquisition was done by one examiner. Imaging modalities: 3 handheld smartphone-enabled (oDocs visoScope, Remidio NMFOP, Volk iNview), 1 handheld adaptor-detector based (Volk Pictor Plus), traditional table-top (Zeiss Visucam PRO$^{NM/FA}$) Participant imaging: Stage 1: all five fundus cameras/retinal imaging were used to acquire image in mydriatic and non-mydriatic setting. Tropicamide 1% eye drops used in only right eye for comparison of mydriatic and non-mydriatic setting. Participants score overall						Remidion and Pictor. However, iNview and oDocs had significantly lower quality scores compared to Zeiss ($p<0.0001$) Most gradable optic disc images: ● Remidio device, 91.1% ● oDocs 30.0% ● iNview 31.0% Most gradable images for vessel morphology (VM) ● Remidio 94.4% ● oDocs 5.1% ● iNview 35.0% Zeiss and Pictor devices produced gradable images for the optic disc and VM in at least 70% of cases. <u>Participant experience:</u> In comparison to Zeiss, no significant difference in overall comfort scores for all four handheld devices ($p>0.05$) <u>Examiner experience:</u> Shortest examination time: (in ascending order)	ratio for Remidion, Pictor, Zeiss and reference standards.

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
	comfort of examination using 10-point Likert scale and examiner ranked ease of use of each instrument. Stage 2: Top three scoring devices were used based on the rating from stage 1 partcipants and image captured in non-mydriatic setting only. All images were acquired by single examiner. Image validation done by expert panel of clinicians, with mean experience of 15 years in ophthalmology						● Zeiss ● Remidio ● Pictor ● iNview ● oDocs. Highest image acquisition stability: (in descending order) ● Zeiss ● Remidio ● Pictor ● iNview ● oDocs. Best portability: (in descending order) ● oDocs ● iNview ● Pictor ● Remidio ● Zeiss <u>Diagnostic sensitivity and specificity:</u> <u>Sensitivity: (mean)</u> ● Zeiss: 84.9%, 95% CI: 78.2–91.5%. ● Pictor: 78.1%, 95% CI: 66.6–89.5%. ● Remidio: 77.5%, 95% CI, 65.9–89.0%. <u>Specificity:</u> (mean)	

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
							• Zeiss: 82.0%, 95% CI: 77.5–86.5% • Remidio: 79.0%, 95% CI: 73.7–84.3% • Pictor: 83.0%, 95% CI: 79.5–86.5%. <u>Agreement with reference standard cup:disc (CD) ratios:</u> • Smallest bias: Pictor, -0.05 (± 0.16) • Remidio, bias of -0.07 (± 0.14) • Zeiss, bias of -0.09 (± 0.15)	
3) Midena et al. (2022)	**Observational cross-sectional study** **Objective:** To validate the performance of new handheld color fundus camera, the Aurora®, compared to a standard table-top fundus camera for the screening of DR in real-life screening setting **Method:** <u>Population and setting:</u> Patient with type 1 and 2 DM, referred to local screening service at University Hospital of	II-3	N=213, 423 eyes, 2538 retinal photos analyzed. Mean age: 62.6 ±12.6 (SD 26-85) years	Handheld fundus camera, Optomed Aurora	Tabletop fundus camera, Nidek AFC-230	-	**Handheld fundus camera, Aurora:** <u>Recognizing DR:</u> • DR detected, 110 eyes (26%), ungradable, 2 (0.47%) • Sensitivity: 96.9% • Specificity: 94.8% Almost perfect agreement (k 0.81–1.00) was obtained for: • Absent DR • Present DR • Moderate DR • Severe DR • Proliferative DR • Ex-proliferative DR	Single centre study The study was done in a screening centre, by untrained photographer. However, achieved good sensitivity and specificity in detecting patients requiring complete ophthalmological examination and excellent image gradability.

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
	Padova's (center for management of DR and ocular vascular diseases, enrolled from January-December 2021. <u>Inclusion criteria:</u> Patients aged ⩾18 years, had a diagnosis of diabetes, based on the diagnostic criteria established in 2011 by the WHO (World Health Organization); glycated hemoglobin >6.5% on two occasions, or glycemia ⩾126 mg/dL after at least 8h of fasting on two occasions, or blood glucose ⩾200 mg/dL after 2h of an oral glucose load to be confirmed with a fasting test, or random blood glucose ⩾200 mg/dL in the presence of typical symptoms (polyuria, polydipsia, weight loss). <u>Exclusion criteria:</u> Patients with poor collaboration or, the presence of disabilities that made the procedures difficult to perform or prevented						• Referable cases (including DM) Substantial agreement (k 0.61–0.80) was observed for: • Mild DR • DR gradability Overall concordance coefficient, k (95% CI) was: • 0.889 (0.828–0.949) with linear weighting CA • 0.870 (0.743–0.998) with quadratic weighting FC Both cases showed an almost perfect agreement. <u>Recognizing DM:</u> • DM detected, 15 eyes (3.55%), ungradable, 2 (0.47%), 15 (3.55%) eyes that needed to be referred to specialist consultation. • Sensitivity: 96.9% • Specificity: 94.8% Near perfect agreement was obtained for:	

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
	adequate patient's collaboration for the execution of the photos; allergy to mydriatics. <u>Image acquisition:</u> Both table-top, Nidek AFC-230 and handheld camera, Optomed Aurora already in used at the screening service centre. Both eyes were evaluated for each patient. 3 images were acquired using both cameras. A trained, blinded operator, had no prior experience in fundus imaging, trained for 4 weeks did image acquisition. <u>Optomed Aurora:</u> ● High resolution (2368 × 1776 pixels, 300 dpi) color images ● 50◦ angle of view, manual focus, with correction from −20 to +20 diopters and auto-focus, with correction from −15 to +10 diopters auto-exposure						● Absent DM ● Present DM ● Mild DM ● Severe DM Substantial agreement was observed for: ● Moderate DM ● DM gradability Overall k (95% CI) was: ● 0.831 (0.658–1.004) with linear weighting CA (almost perfect agreement) ● 0.794 (0.544–1.044) with quadratic weighting FC (substantial agreement) <u>Recognizing referable cases:</u> ● Sensitivity: 100% ● Specificity: 99.8% <u>Recognizing HR:</u> ● HR detected, 54 eyes (12.77%), not evaluable, 1 (0.24%) ● Sensitivity: 100% ● Specificity: 100% Overall k (95% CI) was:	

Bibliographic Citation	Study Type/ Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow-up (if applicable)	Outcome Measures/ Effect Size	General Comments
	• Nine internal fixation objectives for peripheral imaging • Minimum pupil diameter for photo acquisition is 3.1 mm. • Equipped with Wi-Fi has integrated Cloud, which allows images to be sent to an optional artificial intelligence (AI) service for image analysis. Nidek AFC-230: 45° angle of view Tropicamide 1% were used for eyedrops (1 instillation). <u>Image analysis:</u> All images were analysed by single blinded operator, using 17-inch high-definition screen. <u>Parameters assessed:</u> • gradable/ungradable • grade of DR • grade of DM • presence of hypertensive retinopathy (HR) and;						• 0.960 (0.906–1.015) with linear weighting CA (almost perfect agreement) • 0.926 (0.827–1.025) with quadratic weighting FC (almost perfect agreement) <u>Recognizing other diseases:</u> 53 (12.53%) **Tabletop fundus camera:** • DR detected in 96 eyes (22.70%), ungradable, 4 (0.95%) • DM detected, 14 eyes (3.31%), ungradable, 4 (0.95%), 14 (3.31%) eyes that needed to be referred to specialist consultation • HR detected, 54 eyes (12.77%), not evaluable in 3 (0.71%)	

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	● the presence of other diseases DR and DM grading was performed according to the International Clinical Diabetic Retinopathy and Diabetic Macular Edema Severity Scale: absent, mild, moderate, severe non-proliferative (NP) and Diabetic Edema Severity Scale: absent, mild, moderate, severe non-proliferative (NP) and proliferative DR (PDR), and absent, mild, moderate and severe DM.							
4) Upadhyaya et al. (2022)	Cross sectional, observational, instrument validation study **Objective:** To evaluate the sensitivity and specificity of a portable non-mydriatic fundus camera to assess the optic disc for glaucoma. **Methods:** Site: Aravind Eye Hospital Inclusion criteria:	II-3	N=138, 276 eyes Groups: 68 glaucoma patients, 70 control participants. Mean age: ● Glaucoma patients: ~60 years ● Control group: ~48 years).	Smartscope non-mydriatic fundus camera (Optomed M5, Oulu, Finland)	Standard table-top (50°) fundus camera TRC-50DX (Topcon, Tokyo, Japan)	NA	Intraobserver Reliability: ● High consistency in VCDR grading between the gold standard dilated fundus exam and undilated Smartscope images, with ICCs of 0.98 and 0.94 for the two graders. Interobserver Agreement: ● Strong agreement between the two graders using undilated	Non-mydriatic Smartscope fundus camera demonstrated high sensitivity and specificity (both over 90%) for detecting glaucoma The portable nature and effectiveness of the Smartscope camera suggest it could be a valuable tool in community outreach programs

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	Two groups aged 30 to ⩽ 70 years were recruited: (1) glaucoma patients with typical optic nerve head (ONH) and visual field changes, and (2) control patients with no clinical evidence of glaucoma. Glaucoma cases included: ● Patients with primary open-angle glaucoma (POAG) ● Primary angle-closure glaucoma (PACG) ● Normal-tension glaucoma (NTG) with reliable visual field tests Control group criteria: Patient who had IOP <20 mmHg, no glaucoma or family history of it, a CDR of ⩽0.5, inter-eye asymmetry of ⩽0.2, and myopia or hyperopia ⩽ 3D. Exclusion Criteria: Patient who had secondary glaucoma, significant cataracts		37% of the participants were female, no significant gender difference between the glaucoma and control groups. Glaucoma Types: ● 45 POAG ● 15 PACG ● 8 NTG Average VCDR: 0.7 in the glaucoma group and 0.3 in the control group.				Smartscope images, with a mean difference of 0.01 and limits of agreement from -0.14 to +0.16. Diagnosis Agreement: The two graders showed strong agreement in diagnosing glaucoma using non-dilated fundus images, with a kappa value of 0.95. Sensitivity: Compared to Gold Standard: ● Grader 1: 96.3% ● Grader 2: 94.8% Compared to Dilated Images: ● Grader 1: 97.7% ● Grader 2: 95.5% Specificity: Compared to Gold Standard: ● Grader 1: 98.5% ● Grader 2: 97.8% Compared to Dilated Images: ● Grader 1: 96.5%	The Smartscope camera's performance in diagnosing glaucoma was comparable to the gold standard dilated fundus exam

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	(grade ⩾3), severe vitreoretinopathy, or optic neuropathy other than glaucoma. Ophthalmologic Evaluation: All participants underwent a comprehensive eye exam, including visual acuity, slit lamp examination, IOP measurement, and gonioscopy. Visual Field Testing: Diagnosed glaucoma patients had their visual fields tested using the Humphrey perimeter with a specific strategy for accuracy. Fundus Photography: Each eye had an undilated color image of the optic disc taken using a handheld, non-mydriatic Smartscope camera in a dim room. Dilated Exam: After pupil dilation, a senior glaucoma specialist assessed the						• Grader 2: 97.1%	

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	optic nerve head (ONH) using slit lamp biomicroscopy to determine glaucoma status. Image Capture and Grading: Images were captured by a trained photographer, and glaucoma was diagnosed based on specific optic disc characteristics using both the undilated Smartscope and dilated fundus images. Final Diagnosis: The glaucoma diagnosis from the Smartscope images was compared with the gold standard dilated fundus examination for validation. Remote interpretation: Two masked glaucoma specialists reviewed de-identified fundus images for glaucoma diagnosis, with strong agreement between their assessments and comparison to the gold							

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	standard dilated fundus exam.							
5) Kubin et al. (2021)	**Cross sectional, observational study** **Objective:** To compare the performance and image quality of the handheld fundus camera to standard table-top fundus cameras in diabetic retinopathy (DR) screening. **Methods:** 1st phase: 107 patients, with either type I or II DM attending screening of DR were evaluated Patients had two images taken consequently with both traditional table-top fundus (Canon CF-1) and handheld camera (Optomed Aurora) after given mydriatics 1% tropicamide 2nd phase: 50 patients with more severe DR and other retinal changes (age-related macular	II-3	1884 fundus images analyzed from all cameras. 107 patients attended DR screening. 50 patients attended follow-up visits for more advanced DR. DR Screening Results: ● 68% had no DR. ● 13% had mild NDPR ● 13% had moderate NPDR. ● 1% had severe NPDR. ● 4% had PDR. Overall Study Results: ● 53% of all eyes had	Optomed Aurora cameras	Canon CF-1 and Zeiss Visucam 524	NA	**Overall Agreement:** ● DR grading outcomes from Optomed Aurora images were highly comparable to those from Canon or Zeiss cameras. ● Almost perfect agreement in identifying DR from Aurora images: ○ Ophthalmologist: kappa= 0.93, 95% CI 0.91-0.96 ○ Photographer: kappa= 0.89, 95% CI 0.85-0.93 ● Almost perfect agreement between ophthalmologist and photographer in identifying DR from table-top camera images: kappa = 0.95, 95% CI 0.93-0.98 <u>Sensitivity and Specificity (Optomed Aurora):</u> Detecting Any DR:	The Optomed Aurora handheld camera worked well for diabetic retinopathy (DR) screening. Had high accuracy, with sensitivity at 91.8% and specificity at 100%. The images from the Optomed Aurora were good enough for diagnosis in 84-88% of cases. The image quality was similar to that of traditional table-top cameras. Involving photographers in grading DR immediately after taking images could speed up the screening process and reduce costs. This could maintain accuracy while making the process

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	degeneration, retinal vein occlusion, etc.) attending follow up visits in hospital's outpatient eye clinic were examined. Patients had two images taken consequently with both tabletop fundus (Zeiss Visucam 524) and handheld camera (Optomed Aurora) Images quality: ● Black-and-white images were graded for quality; grades 1-3 were considered good for interpretation. DR Severity: ● DR severity classified using a five-stage system, with stages 2-4 marked as needing a referral. Assessment Process: ● The more severe eye determined the overall DR level and referral need. ● An ophthalmologist's grading from a		no signs of DR. ● 10% had mild NPDR. ● 16% had moderate NPDR. ● 6% had severe NPDR. ● 16% had PDR. Other Detected Retinal Abnormalities: ● Choroidal nevus: 17 patients. ● Age-related macular degeneration: 10 patients. ● Central retinal vein occlusion: 4 patients. ● Branch retinal vein occlusion: 2 patients.				● Sensitivity: ○ Ophthalmologist: 91.8% (95% CI 85.4 to 95.2) ○ Photographer: 91.2% (95% CI 85.4 to 95.2) ● Specificity: Both Ophthalmologist and Photographer: 100% (95% CI 97.8 to 100) Detecting Referable DR (Moderate NPDR and Above): ● Sensitivity: ○ Ophthalmologist: 94.2% (95% CI 88.1 to 97.6) ○ Photographer: 92.3% (95% CI 86.9 to 96.4) ● Specificity: Both Ophthalmologist and Photographer: 100% (95% CI 98.1 to 100) <u>Sensitivity and Specificity (Tabletop cameras) by photographer:</u> Detecting Any DR:	faster and more efficient. Challenges: The study had a small number of graders, so more research is needed to confirm these findings in different settings. Larger studies are needed to fully validate the handheld camera's use in regular DR screening. Handheld fundus cameras like the Optomed Aurora could be a cost-effective option for DR screening, especially in areas with limited resources. Training photographers to grade DR could make screening programs more efficient and effective.

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	traditional fundus camera served as the gold standard for comparing results. Independent Review: ● DR severity and image quality were reviewed separately by both an ophthalmologist and a photographer. ● Any other eye issues were also noted.		● Macular pucker: 2 patients.				● Sensitivity: 99.3% (95% CI 96.3 to 100) ● Specificity: 100% (95% CI 97.8 to 100) Detecting Referable DR: ● Sensitivity: 100% (95% CI 96.9 to 100) ● Specificity: 98.5% (95% CI 95.6 to 99.7) <u>Image Quality Grading:</u> Tabletop cameras: ● Quality of black-and-white fundus images graded by ophthalmologist: 1.4 (on the grading scale). Optomed Aurora: ● Quality of black-and-white fundus images graded by: ○ Ophthalmologist: 2.5 ○ Photographer: 2.3 <u>Sufficiency of Image Quality:</u> <u>Optomed Aurora:</u> ● Ophthalmologist's Analysis: 84% of images met sufficient quality criteria.	

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							• Photographer's Analysis: 88% of images met sufficient quality criteria. <u>Image Types:</u> Quality of macula- and papilla-centered images was similar. <u>Challenges in Image Capture:</u> 3% of patients could not be reliably photographed by either camera type due to factors like cataract, corneal, or vitreous haze.	
6) Xiao et al. (2020)	**Cross sectional prospective comparison study** **Objective:** To validate retinal images from a handheld portable retinal camera for diabetic retinopathy screening (DRS), using a desktop digital camera as the comparison **Method:** <u>Population and setting:</u> Patients were recruited from hospitals in Zhenjiang District	II-3	N=305 diabetic patients, 252 (82.6%) had no diabetic complications. Total eye images = 610 41.6% was 61-70 years old, 165 (54.1%) were female. Mean age: 61.3 years (SD ±10.1) Mean age at diagnosis of	Handheld fundus camera (Horus Scope DEC 200)	Desktop digital camera (standard test), Canon (model CR-2)	-	Image quality: Desktop digital camera: • 482 (79.3%) good quality and gradable • 116 (19.1%) poor quality but gradable • 12 (1.9%) not gradable Handheld fundus camera: • 479 (78.7%) good quality, gradable • 111 (18.2%) poor quality but gradable • 20 (3.2%) not gradable	• No significant difference in the proportion of gradable images, good images, and referable retinopathy between the desktop and handheld cameras when mydriasis was used. • The handheld camera is simple, easy to install, pack up, and carry due to

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	(Shaoguan prefecture), hospital in Chenghai District (Shantou city) and community health centres in Yuexiu District (Guangzhou city) in consecutive series in Guangdong Province, China with a range of DR severity, including patients without DR to obtain representative spectrum of patients <u>Inclusion criteria:</u> Patient age ⩾18 years old, with diabetes, able to provide informed consent, agreed to attend dilated eye examination with both index and standard tests <u>Training:</u> ● Pilot study was conducted in community screening clinic in Guangzhou city. ○ Technicians with at least 1-year experience of operation for handheld and desktop		diabetes: 52.4 years (SD ±10.5) Median duration of diabetes: 5 years (4-12 years) 108 (35.4%) participants had fasting glucose below 7mmol/L, 112 (36.7%) used insulin, 262 (85.9%) took oral medication and 12 (4%) reported no treatment, not even diet. 48.2% participants had hypertension, 7.5% had nephropathy, 11.2% had cardiovascular disease. Visual acuity:				No significant difference between good and poor quality but gradable images by 2 cameras (McNemar's test). When both group's images added together, images taken by desktop gained slightly better quality than handheld, although the difference is not significant (p>0.05). Both cameras agreed on five non-gradable eyes, with issues such as vitreous opacity and dense cataracts. There were discrepancies in grading between the cameras, with 14 eyes graded as R1 by the desktop camera but ungradable by the handheld camera. Desktop Camera ● Graded 8 cataract eyes as R1, ungradable by the handheld camera. ● Graded 14 eyes as R1, ungradable by	its light and foldable stand. Training was relatively quick and easy. ● High agreement between the two cameras in grading diabetic retinopathy (DR) with kappa coefficients ranging from 0.79 to 1.00. ● In cases of disagreement, desktop cameras captured clearer images for eyes with severe cataracts or vitreous opacity compared to handheld cameras. ● The use of mydriatics improves images quality ● The study was not population-based, which may affect the representativeness of DR

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	camera, examined 30 cases with both undilated and dilated pupils, performed by ophthalmologist, according to the assessment on quality of images and operation on camera ● Other study sites: ○ Experienced technicians were trained to capture images using both handheld and standard camera to ensure standardised process. ○ They practiced taking ~20 pilot cases		● ≥0.3: 276 (90.5%) ● <0.05: 3 (0.98%)				the handheld camera. ● 132 eyes (21.7%) with evidence of retinopathy (R1+R2+R3). ● 83 eyes (13.7%) with referable retinopathy (R2 and above). ● R3 detected in 28 eyes (4.6%). ● 79 eyes (59.8% of 132) with macular involvement. Handheld Camera: ● Unable to grade 8 cataract eyes graded as R1 by the desktop camera. ● Unable to grade 14 eyes graded as R1 by the desktop camera. ● 119 eyes (19.5%) with evidence of retinopathy (R1+R2+R3). ● 81 eyes (13.3%) with referable retinopathy (R2 and above). ● R3 detected in 28 eyes (4.6%). High agreement between the two cameras in diagnosing:	severity and complications ● The study used experienced eye care staff with standardized training, which may not match real-world settings where staff have different levels of expertise.

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	using the handheld camera until no further questions asked and images quality were accepted by senior ophthalmologist. ○ The training took 2 hours, and the trainer were observed for the whole 1-day before the technician operated independently. <u>Pilot study:</u> Initially, participants were not given mydriatics and were required to rest in a darkened room for better image quality. However, due to poor images and patient dissatisfaction, mydriatics were given to every participant.						● R1: Kappa coefficient (KC) = 0.79 ● R2: KC = 0.96 ● R3: KC = 1.0 ● M1: KC = 0.94 ● Other lesions: KC = 0.82 Desktop Camera ● Detected 49 eyes at R1 ○ Sensitivity: 71.4% (95% CI: 56.7 to 83.4) ○ Specificity: 99.4% (95% CI: 98.4 to 99.9) ○ Positive Predictive Value (PPV): 92.1% (95% CI: 78.6 to 98.3) ● Detected 55 eyes at R2 ○ Sensitivity: 94.6% (95% CI: 84.0 to 98.9) ○ Specificity: 99.8% (95% CI: 99 to 100)	

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	<u>Formal study:</u> Imaging: All participants underwent several tests in one clinic visit, including basic information collection, VA test, slit lamp examination, intraocular pressure test, eye dilation, and fundus photographs using both handheld and desktop cameras, followed by a survey on camera preference. Tests were completed within 2 hours to ensure maximal dilation. Patients were randomly assigned different camera sequences with sufficient time between tests to minimize discomfort. 2 images were taken for each eye by both fundus cameras operated by one technician (total 3 technicians for 3 study sites). Fundus photographs were uploaded on the DR online grading system						○ PPV: 98.1% (95% CI: 89.9 to 100) ● Reached 100% agreement with handheld camera for R3 ● Captured six more eyes with maculopathy not detected by handheld camera ○ Sensitivity: 91.1% (95% CI: 82.6 to 96.4) ○ Specificity: 99.6% (95% CI: 98.9 to 100) ○ PPV: 98.6% (95% CI: 92.6 to 100) ● Captured two more eyes with other lesions not detected by handheld camera Handheld Camera ● Detected 38 eyes at R1 ● Detected 53 eyes at R2 ● Reached 100% agreement with	

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	and graded independently at the grading centre where experienced graders were masked to the mode of photograph where possible. Two graders graded all the study images separately. If disagreed, an ophthalmologist became an arbitration grader to discuss disagreement until they reached consensus. The graders were trained, had at least 5 years' experience and constantly monitored by ophthalmologist supervisors on quality of their work. Image quality: ● Good quality: focused, well illuminated retinal field, clear fundus vessels and any retinopathy ● Poor but still gradable: partially focused, illuminated or retinal field showed						desktop camera for R3 ● Did not detect maculopathy in six eyes captured by the desktop camera Camera preference: Participants' Preferences ● 51.2% had no preference for either camera ● 37.4% preferred the desktop camera ○ Reasons: less bright flash, more complicated and bigger (perceived as better), more convenient height adjustment on an elevator platform ● 11.1% preferred the handheld camera ○ Reasons: simplicity, looks smart, easy to mobilize with	

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	● Not gradable: blurred images without recognition of retinal vessels or retinopathy features Grading system: Using grading definitions for referable disease by the English NHS Diabetic Eye Screening Programme ● R0: Absence of any DR feature, including microaneurysms. ● R1: Presence of microaneurysms with or without exudation, without other DR features. ● R2: Presence of any of the following features: ○ Venous beading ○ Cotton wool spots ○ Venous reduplication ○ Multiple blot hemorrhages ○ Intraretinal microvascular abnormality						or without foldable stand for patient's chin rest Technicians' Comments ● Handheld camera is sufficient for community DR screening ● Easy to install and pack up ● Focusing process easier and quicker with the simple stand for patient's chin rest	

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	● R3a: Presence of proliferative retinopathy, such as: ○ New blood vessels ○ Hemorrhage within retina or in vitreous ○ Vitreous traction ● R3s: Evidence of retinal laser treatment with stable DR features. ● M1: Presence of microaneurysms, haemorrhage, or exudates within two-disc diameters of the centre of the fovea.							
7) Piyasena et al. (2019)	**Prospective screening validation study** **Objective:** ● To demonstrate the functional and technical feasibility of using a hand-held non-mydriatic digital camera in a LMIC non-ophthalmic setting. ● To assess the diagnostic test accuracy (DTA) of DR deection by	II-3	N=700 PwDM Mean age: 60.8 years, Mean duration of diabetes: 9.9 years. ● Response rate: 84.7% (700/826) ● Mean age: 60.8 years (SD±10.08)	Hand-held non-mydriatic digital retinal camera (Visuscout 100®-Germany).	Two-field retinal imaging	-	Outcome measures: detection of signs of DR (any DR or referable level) Ungradable Images: ● Non-mydriatic imaging: ○ 31.0% ungradable for at least one eye (217/700) ○ 12.0% both eyes	Use of handheld camera is effective for 2-field retinal imaging at medical clinics. Mydriasis required for ungradable images to improve detection accuracy. Physician graders can accurately identify diabetic retinopathy needing referral.

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	general physicians using this method compared to the local clinical reference standard of mydriatic indirect ophthalmoscopy and bio-microscopic examination by a retinologist. **Method:** Conducted between May 2017-May 2018, at tertiary level, public sector outpatient medical clinic in the Western province Sri Lanka. Participants: 700 people with diabetes (PwDM) over 18 years old, without previous DR screening, recruited at a tertiary medical clinic in Sri Lanka. Camera and Imaging ● Hand-held non-mydriatic digital retinal camera (Visuscout 100®-Germany). ● Two-field retinal imaging was conducted before		● 66% women (462/700) ● 98.4% had type 2 DM (689/700) ● 1.6% diagnosed with DM at age <30 years and on insulin (11/689) ● Mean age at DM diagnosis: 50.9 years (SD±11.03) ● Mean duration of diabetes: 9.9 years (SD ±8.09) ● Mean fasting plasma glucose (last 3 months): 140.4 mg/dl (SD±55.43) ● Maximum time between index and				ungradable (84/700) ● After pupil dilatation: ○ 11.4% one eye ungradable (80/700) ○ 1.1% both eyes ungradable (8/700) ● Reference Test Ungradable: ○ 40 eyes (2.8%, 21 participants) due to advanced lens opacity or other conditions 1342 image sets (by eyes) included in DTA analysis ● 1041 DR positive eyes ● 301 DR negative eyes identified at reference test High gradability agreement (k = 0.72–0.96) between physician graders and retinologist's findings	Suitable for people with diabetes at risk of sight-threatening retinopathy in healthcare facilities.

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	and after pupil dilatation using 2% phenylephrine. Training: ● Nine general physicians underwent competency-based training delivered by two retinologists. ● Training included capturing retinal images and identifying signs of DR using the camera. ● Physicians were tested and selected based on agreement levels with the retinologist. Image Grading: ● Images graded by two trained, masked independent physician graders. ● Ungradable images decreased significantly after pupil dilatation.		reference test: 4 weeks				DTA after including gradable images: ● Non-Mydriatic Imaging with Ungradable Images as Screen Positives: ○ Sensitivity: ▪ Grader 1: 82.7% (95% CI 78.4–86.5%) ▪ Grader 2: 78.3% (95% CI 73.7–82.5%) ○ Specificity: ▪ Grader 1: 70.4% (95% CI 67.6–73.1%) ▪ Grader 2: 76.2% (95% CI 73.6–78.7%) ● Mydriatic Imaging with Ungradable Images Included: ○ Sensitivity: ▪ Grader 1: 79.3% (95% CI 74.7–84.8%) ▪ Grader 2: 78.0% (95%	

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							CI 73.4–82.2%) ○ Specificity: ▪ Grader 1: 89.2% (95% CI 87.2–90.9%) ▪ Grader 2: 91.5% (95% CI 89.7–93.1%) DTA after excluding ungradable images: ● No significant difference in DTA by pupil status for each grader. ● Similar results were observed in the detection of macular signs. ● Higher PPV for detecting referable level DR (79.7–92.8%) (moderate non-proliferative DR and above). ● Lower PPV for identification of macular signs (63.2–73.5%) (presence of haemorrhage/s or exudate/s within 2-disc diameters of the fovea).	

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							• No significant differences observed in NPV.	
8) Sengupta et al. (2018)	**Prospective, single-site, comparative instrument validation study** **Objective:** To evaluate the sensitivity and specificity of a portable non-mydriatic fundus camera to diagnose vision-threatening diabetic retinopathy (VTDR). **Method:** Study population were patients presented to retina clinic at Aravind Eye Care System (AECS), Pondicherry, India from 1/1/2014-31/1/2015). Inclusion criteria: Both diabetic and non-diabetic patients. Patients aged >21 were invited to return for study visit. Exclusion criteria: Patient whose fundus cannot be visualised or	II-3	N=155 subjects, 275 eyes (89% of total), excluded eyes: 35 eyes (due to incomplete imaging) Mean Age: 55.7 years (± 9.1), 63% male, 106 (68%) subjects had DM Average DM duration: 9.6 years (± 7.7) Median DM duration: 8 years (range: 3 months - 30 years) DR status: • No DR: 142 eyes (51.6%) • R1 Disease: 21 eyes (7.7%)	Portable camera (Smartscope)	Table-top fundus camera (Topcon) and direct fundus examination (DFE)		Outcome measures: 1. Sensitivity and specificity to detect VTDR using both fundus cameras compared to a reference standard clinical examination. 2. Sensitivity and specificity of detecting VTDR using the non-mydriatic Smartscope images compared with the mydriatic Topcon images. 3. Graders' inter- and intra-observer reliability Non-Mydriatic Smartscope: Grader 1: • Sensitivity: 93% (95% CI: 87–97%) • Specificity: 84% (95% CI: 77–89%)	Single center study Handheld non-mydriatic Smartscope is feasible and effective for screening vision-threatening diabetic retinopathy (VTDR), especially in resource-limited settings. High sensitivity (88-93%) and specificity (84-99%) for VTDR detection comparable to dilated fundus examination (DFE). Moderate inter-observer agreement for image quality, with higher agreement for VTDR detection (κ = 0.82–0.91). Portable fundus cameras like the Smartscope can

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	had undergone prior vitreoretinal or incisional surgery Photography protocol: Desktop Camera ● Taken with a Canon CR2 desktop digital camera. ● Two photos were taken for each eye: one centered on the macula and the other on the papilla optica. ● Images captured under mydriasis to reduce poor image rates. ● A trained technician operated the camera and ensured image quality. Handheld Camera: ● Taken with a Forus handheld fundus camera. ● Similar protocol as the desktop camera: two photos per eye, one on the macula and one on the papilla optica. ● Images captured under mydriasis to improve quality.		● R2 Disease: 25 eyes (9.1%) ● R3 Disease: 87 eyes (31.8%) Clinically Significant Macular Edema (CSME): 50 eyes (18.2%) Vision-Threatening Diabetic Retinopathy (VTDR): 120 eyes (43.6%) No adverse events from DFE or photography protocol				Grader 2: ● Sensitivity: 88% (95% CI: 81–93%) ● Specificity: 90% (95% CI: 84–94%) Mydriatic Smartscope: Grader 1: ● Sensitivity: 94% (95% CI: 88–97%) ● Specificity: 85% (95% CI: 78–89%) Grader 2: ● Sensitivity: 89% (95% CI: 82–94%) ● Specificity: 92% (95% CI: 86–95%) Mydriatic Topcon: Grader 1: ● Sensitivity: 97% (95% CI: 92–99%) ● Specificity: 89% (95% CI: 83–93%) Grader 2: ● Sensitivity: 95% (95% CI: 90–98%) ● Specificity: 90% (95% CI: 84–94%) Inter and intra-observer reliability: Inter-Observer Reliability:	expand DR screening access, reduce the burden on ophthalmologists, and prevent blindness in underserved areas.

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	Fundus photographs uploaded to the DR online grading system for grading by experienced graders. Examination: ● All participants underwent slit-lamp biomicroscopy and indirect ophthalmoscopy using both a +90D and +20D lens by a single retina specialist (SS). ● Retina specialist noted anterior segment findings including corneal opacities, iris neovascularization, and lens status. DR status: ● Mild ● Moderate ● Severe non-proliferative DR (NPDR) ● Proliferative DR (PDR) ● Clinically significant macular edema (CSME)						● High for identifying VTDR: ○ κ = 0.82–0.91 Intra-Observer Reliability: ● High for identifying VTDR: ○ κ = 0.82–1.00 Moderate inter-observer agreement for image quality (excellent, acceptable, or ungradable). Non-Mydriatic Smartscope: ● κ = 0.59–0.65 for three fields of view. ● Macular image ungradable by grader 1 in 17% of eyes and by grader 2 in 18% of eyes (26% and 25% of subjects, respectively). Mydriatic Smartscope: ● κ = 0.52–0.60 for three fields of view. ● Macular image ungradable by grader 1 in 12% of eyes and by grader 2 in 8% of	

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	VTDR status: As per the National Health Service (NHS) as severe NPDR or worse (4R2 level disease) and/or the presence of CSME Cataracts: According to Lens Opacities Classification System (LOCS) III grading Remote interpretation of the fundus photographs: Graders: ● Two masked retina specialists (CB, MS) graded the photographs. ● Received batches of 400 de-identified images from three photographic modalities: 1. Non-mydriatic Smartscope 2. Mydriatic Smartscope 3. Mydriatic Topcon Image Sets:						eyes (17% and 13% of subjects, respectively). Mydriatic Topcon: ● κ = 0.64–0.74 for three fields of view. ● Macular image ungradable by grader 1 in 5% of eyes and by grader 2 in 7% of eyes (6% and 10% of subjects, respectively).	

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	● Consecutive images were from three fields of the same eye and imaging modality. ● Images from the same patient taken with different cameras were not included in the same reading batch to minimize bias. Grading Criteria: ● Graded the quality of the photograph. ● Reported presence of vision-threatening diabetic retinopathy (VTDR) (proliferative DR or clinically significant macular edema). ● Graded the level of DR based on NHS guidelines. Ungradable Images: ● If the macular image was rated 'ungradable,' the entire image set was considered ungradable. ● If one eye of a subject was							

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	ungradable, the entire subject was considered ungradable. Intra-observer Reliability: ● Readers re-graded 25% of the images after one month. ● Stratified randomization ensured equal representation from all imaging modalities and images with and without VTDR. Reading Stations: ● Followed NHS guidelines for reading station quality. ● Grading done on a single designated computer in a darkened room at each institution (MS, AECS, Pondicherry, India and CB, Kellogg Eye Center, Ann Arbor, Michigan, USA). ● Computers had screens ≥ 17 inches							

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	diagonal and resolution ≥ 1600 × 2000 pixels. ● Standard brightness and contrast settings were used; image manipulation was not allowed.							
9) Miller et al. (2017)	**Prospective, cross sectional, comparative instrument validation study** **Objective:** To compare cup to disc ratio (CDR) measurements from images taken with a portable, 45° non-mydriatic fundus camera to images from a traditional table-top mydriatic fundus camera. **Method:** Clinic based setting, Tilganga Institute of Ophthalmology Inclusion Criteria: Individuals aged 13 years or older, living near Kathmandu, Nepal, and attended the Tilganga Institute of	II-3	N=211 Total Eyes Examined: 422 Mean Age: 45.2 years (± 15.4) 38.2% female Glaucoma Diagnosis: ● With glaucoma: 196 eyes (46.5%) ● Without glaucoma 226 eyes (53.5%)	Portable, 45° non-mydriatic fundus camera (Pictor, Volk, Mentor, OH)	Traditional table-top mydriatic fundus camera	-	Outcome measures: 1. Effect of camera modality on CDR measurement 2. Inter- and intra-observer agreement for each camera for the diagnosis of glaucoma. Glaucoma detection: Overall Detection: ● 41.2%-59.0% of eyes diagnosed with glaucoma across all levels of grader, repeat measurement, and camera modality. ● CDR measurement ,≥0.7 in 39.6%-55.8% of eyes with the Topcon camera and	Single site No significant difference in CDR measurements between images taken with the portable non-mydriatic fundus camera and the traditional mydriatic fundus camera, after adjusting for grader and measurement order Moderate inter-observer and intra-observer reliability was observed for diagnosing glaucoma with both camera types. However, not clinical significant, suggesting that the portable camera is

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	Ophthalmology. Two groups of subjects: (1) control subjects with healthy eyes and visual pathways except for corrected refractive errors or diabetes with or without retinopathy, (2) patients with clinically confirmed glaucoma. Exclusion Criteria: Best-corrected visual acuity of 20/60 or worse, uncorrected refractive error greater than 4 diopters sphere and/or 3 diopters cylinder, participants with high myopia to exclude myopic discs, high hyperopia or astigmatism that may impact their ability to complete the visual field test, other known ocular, neurologic, or systemic conditions that may affect visual field sensitivity, medications known to affect visual field sensitivity, healthy control participants with intraocular pressure (IOP) of 21 mm Hg or more and no disease of						41.0%-58.6% of eyes with the Pictor camera. Notch Presence: ● Noted in 20.4%-25.4% of eyes with Topcon camera. ● Noted in 16.6%-23.3% of eyes with Pictor camera. Disc Haemorrhage Presence: Less frequently observed: 0.2%-1.9% with Topcon, 0.2%-1.4% with Pictor. Discrepancies: ● Grader 1: 18.7% discrepancy in glaucoma diagnosis between first measurements from Topcon and Pictor (20.4% on repeat grade). ● Grader 2: 27.6% discrepancy in first grades and 22.0% in second grades between Topcon and Pictor images.	reliable for glaucoma screening Suitable for use in remote and underserved areas – lightweight, inexpensive, not requiring mydriasis.

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	the posterior pole, glaucoma patients had eyes with evidence of optic nerve abnormalities and characteristic visual field changes, diabetic patients had a diagnosis based on haemoglobin A1C levels. Comprehensive ophthalmic examination for glaucoma and diabetic retinopathy was performed on all subjects. Pre-Dilation Testing: ● Non-mydriatic optic disc photographs taken. ● Visual field testing conducted using the Humphrey Visual Field Analyzer (SITA Standard testing). ● Additional visual field testing done using an iPad-based app (Visual Fields Easy). Post-Dilation Testing: ● Mydriatic optic disc photographs taken after pupil dilation.						Variation in measuring CDR: ● No statistically significant difference in CDR measurements between the Topcon and Pictor cameras after adjusting for grader and measurement order (p=0.24). Moderate to substantial reliability in detecting glaucoma, with kappa values indicating consistent inter- and intra-observer agreement across different graders and imaging modalities.	

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	Diagnosis: A fellowship-trained glaucoma specialist determined the presence of glaucoma in each eye based on examination and ancillary testing. Photography protocol: Non-Mydriatic Imaging: ● Camera: Pictor handheld, non-mydriatic 45° digital fundus camera (Volk Optical, Mentor, Ohio). ● Features: 5 mega-pixel image sensor, autofocus, built-in LED light source, Wi-Fi enabled. ● Image Resolution: 2560x1920 pixels, compressed to 1280x960 pixels post-transmission. ● Cost: Approximately US $8,000 in the US, $4,000 in India. ● Procedure: Images taken in a darkened room. Mydriatic Imaging:							

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	● Camera: Topcon TRC 50 DX tabletop system (Oakland, New Jersey) with an attached Canon SLR camera. ● Image Resolution: 1078x960 pixels post-transmission. ● Cost: Approximately US $25,000. ● Procedure: Mydriatic imaging performed on the same day as non-mydriatic imaging. Image Handling: ● All photographs stored as JPEG files after removing patient identifiers and assigning unique random numbers linked to the eye and participant. Training: ● A single ophthalmic assistant, previously unfamiliar with the portable camera, was trained to take all Pictor photographs.							

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	● Training involved photographing the posterior pole on a sample of patients until the images were deemed adequate by a glaucoma specialist (ST). Image Selection: The assistant took 2-3 photos of the posterior pole with each camera and selected the best for study inclusion Remote interpretation and grading protocol: Grading Process: ● Two glaucoma specialists (IP, PN) graded the Pictor and Topcon photographs. ● Specialists were masked to the patients and their diagnoses. Measurements and Observations: ● Cup-to-disc ratio (CDR) measured to the nearest 0.05 interval.							

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	● Recorded presence of notches or disc hemorrhages. ● Presumptive epidemiologic diagnosis of glaucoma if one of the following was present: ○ Vertical CDR ≥0.7 ○ Notch ○ Disc hemorrhage Image Handling: ● De-identified images of the posterior pole were provided in batches of approximately 400 randomly chosen images. ● Images taken from both photographic modalities: non-mydriatic Pictor and mydriatic Topcon. ● Eyes from the same patient were not presented concurrently. ● Specialists were masked to the							

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	photographic modality. Reliability Assessment: ● Readers re-graded all images after one month to evaluate intra-observer reliability. Viewing Conditions: ● Images viewed on computer screens at each institution (Wilmer Eye Institute, Johns Hopkins University, and Kellogg Eye Center, University of Michigan). ● Screens were at least 17 inches diagonal as per NHS guidelines. ● Standard luminance and contrast settings set by Windows were used.							
10) Zhang et al. (2017)	**Prospective study** **Objective:** To evaluate the feasibility of using Pictor as a screening tool to obtain retinal images in both dilated and undilated	II-3	N=56 diabetic patients, 111 eyes with 1 patient only had one eye due to enucleation				Out of 111 eyes examined: ● 20% had no diabetic retinopathy (DR) ● 80% had varying levels, with 46 eyes having vision-threatening DR.	The Pictor camera effectively captured retinal images in both dilated and undilated eyes, demonstrating high sensitivity in screening for

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	eyes and the accuracy of ophthalmologists at different levels of training/experience in grading these images for referable disease to identify the presence of vision-threatening DR. **Method:** Study was conducted at Duke Eye Center, from January-May 2014. Inclusion criteria: Diabetic patients ≥18 years old, undergoing a dilated eye examination by a board-certified ophthalmologist. Procedures: ● A first-year ophthalmology resident was trained to use the Pictor device by reading the manual and practicing on volunteers, capturing retinal images before and after dilation. ● The imager aimed to obtain focused		● On average, 7 images were taken per eye before and after dilation, with similar numbers of images taken (P = .6). ● Image acquisition took 5 minutes for undilated eyes, 3 minutes for dilated eyes, with dilated eyes being faster (P < .01). ● 86-94% of predilation and 94-97% of postdilation images gradabl ● Most ungradable images				Predilation images: ● Sensitivity for detecting vision-threatening DR: 64-88% ● Specificity for detecting vision-threatening DR: 72-84% ● Sensitivity when considering both eyes together: 91-100% ● Specificity when considering both eyes together: 38-81% Postdilation Images: ● Sensitivity for detecting vision-threatening DR: 65-87% ● Specificity for detecting vision-threatening DR: 71-90% ● Sensitivity when considering both eyes together: 85-100% ● Specificity when considering both eyes together: 53-84%	diabetic retinopathy (DR). Pictor is lightweight and portable Both dilated and undilated images were graded with high sensitivity and specificity, hence screening could be primarily done with undilated eyes, reserving dilation for difficult cases. Most ungradable images belonged to eyes with vision-threatening DR The study highlighted the need for formal training protocols for graders to improve the accuracy of DR screening, especially for non-ophthalmologists.

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	retinal images centered on the macula, recording the number of photos and average acquisition time, with the camera saving both color and red-free images. Image grading: ● The imager selected the best pre- and postdilation image pairs for each eye, creating an electronic slideshow with these pairs displayed consecutively for grading by ophthalmologists. ● Five ophthalmologists independently graded the images, determining if they were gradable and assessing the level of diabetic retinopathy, while also commenting on the usefulness of the red-free photos.		from eyes with severe diabetic retinopathy.					

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