

On the use of a new monocular-indirect ophthalmoscope for retinal photography in a primary care setting

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ABSTRACT

AIM: There is consensus among general practitioners regarding the difficulty of direct ophthalmoscopy. Hence, there is increasing interest in smartphone-based ophthalmoscopes; the New Zealand-made oDocs Nun ophthalmoscope is one such device, released in November 2018. This study aims to subjectively assess the quality of the images captured with it in order to determine the feasibility of its use in a primary care setting.

METHOD: Twenty-eight general practitioners (GPs) from different practices throughout New Zealand agreed to participate in this prospective observational study and were sent an oDocs Nun ophthalmoscope. Using the device, clinicians took retinal photographs of patients who presented with visual complaints and uploaded one image per eye onto a database. Three hundred and fifty-seven photographs were collated and rated by four professionals (two ophthalmologists and two optometrists) on the basis of image quality and the anatomical features visible.

RESULTS: On a Likert scale from 1 (poor quality) to 4 (very good quality), the median and mode values for each professional's rating of all photographs were both 2. On average, 94.5% of the photographs were deemed to have visible optic discs and 50.0% to have visible maculae adequate for detecting an abnormality. Pairwise comparison showed 93.7% agreement among the four professionals for optic disc visibility, and 74.2% agreement for macula visibility.

CONCLUSION: The oDocs Nun is a promising tool which GPs could use to circumvent the challenges associated with direct ophthalmoscopy. With appropriate training to ensure proficiency, it may have a valuable role in telemedicine and tele-referral.

In 1851, Professor von Helmholtz revolutionised the ophthalmoscope, an instrument which is an indispensable tool for examination of the human retina.^{1,2} It is a small-scale Galilean telescope, where the patient's refractive media, namely the cornea and the lens, act as the objective lens and the pin hole acts as the eye piece; the result is a magnified image of the retina but with a significantly reduced field of view.^{3,4} The modern direct ophthalmoscope, such as those manufactured by Welch Allyn (Hill-Rom Services Inc, Alabama, US) and Heine

(HEINE Optotechnik, Herrsching, Germany) are based on the above optical principle. It is widely agreed among primary care clinicians that the modern direct ophthalmoscope is difficult to use and requires a certain level of proficiency.^{5,6} Direct ophthalmoscopy is an old technique with multiple inadequacies, which are contributing to its demise, such as its limited field of view, extreme proximity to the patient, and the steep learning curve required to use it accurately. These factors have made the direct ophthalmoscope a poorly designed instrument for

mass-uses; for example, emergency ocular telemedicine or the diabetic retinopathy screening programme.^{5,7,8}

To address the aforementioned challenges of using the direct ophthalmoscope, Welch Allyn launched the PanOptic ophthalmoscope in the early 2000s. The product is generally well received by the clinical community; the device offers a wider field of view and allows a smartphone adapter to be attached to acquire retinal photographs.⁹ However, the maximum field of view in dilated eyes is only 25° and is deemed to be inadequate for detecting some retinal diseases, such as diabetic retinopathy, age-related macular degeneration, retinopathy of prematurity, and peripheral retinal tear or detachment.^{10–12} The company also launched an iPhone (Apple Inc, California, US) adapter called iExaminer that would allow clinicians to acquire images of the retina. Since then, there have been at least three known regulatory-approved smartphone ophthalmoscopes launched by different companies. Peek Retina (Peek Vision Inc, UK) and D-Eye (D-Eye Care, Italy) are smartphone ophthalmoscopes based on the same principles of direct ophthalmoscopes. These devices are also limited by their narrow field of view ranging from 10° to 20° field of view.¹³ Volk (Volk Inc, US) released a smartphone-based ophthalmoscope (Volk iNview) with a larger field of view (45°); however, there is limited clinical evidence of its quality and actual performance.^{14,15} Furthermore, the device is designed to fit only the older generations of iPhone devices.

A new ophthalmoscope, based on the principle of indirect monocular ophthalmoscopy, has been released by oDocs Eye Care (oDocs Eye Care Limited, New Zealand).¹⁶ The company claims that the device is capable of acquiring high-quality retinal photographs with a field of view of up to 40° in eyes with a 6mm pupil and above, or 15° in non-mydratic pupils as small as 2mm. Unlike the other smartphone ophthalmoscopes, the oDocs nun ophthalmoscope's phone adapter is compatible with a wider range of smartphones including those from Android (Alphabet Inc, US) and Apple. The device can be used in conjunction with a smartphone for retinal image and video acquisition for clinical photo-documentation and telemedicine.

The rationale of this study is to subjectively determine the quality of retinal photographs acquired with the oDocs nun ophthalmoscope in a primary care setting by general practitioners (GPs), and see if anatomical regions of the human retina are identifiable in those photographs. It aims to assess if the oDocs Nun is a feasible tool to capture retinal images in a real-world clinical setting where patients present with ophthalmic problems, with implications for telemedicine and tele-referral.

Methods

This was a prospective and observational study designed to subjectively assess the quality of the retinal photographs acquired through the oDocs nun ophthalmoscope in a primary care setting. The study was approved by the University of Otago Human Ethics Committee. Māori consultation was carried out with Ngāi Tahu and Ngati Porou.

Participants and study members

A research participation invitation was sent to 52 general practices throughout New Zealand. A total of 28 general practitioners agreed to participate in the study. At the time of the study, the physicians were all practising and registered with the Royal New Zealand College of General Practitioners.

Study members were recruited from patients who presented to the primary care practices with visual complaints. Patients who fulfilled the study criteria were given the opportunity to participate in this study. The study criteria are listed in Table 1.

Clinical protocol

The participating clinicians received standard training protocol, which included reading the user manual of the device, watching a two-minute training video, and practices on fake eyes. The clinicians were allowed to practise the skill once they felt confident and competent in using the ophthalmoscope.

Patients who were accepted into the study had the symptomatic eye dilated with tropicamide 1%. The clinician instilled one drop of tropicamide 1% into the patient's eye. The patients were then asked to wait in the waiting room for at least 20 minutes. The clinician then used the video function of the phone to acquire a live video of the retina

Table 1: Inclusion and exclusion criteria for study participants.

Inclusion criteria	Exclusion criteria
1.1 Patient with visual symptoms as below: Visual disturbances (blurry vision, loss of vision or visual field) Other symptoms: Photopsia, floaters, aniseikonia, distortion Ocular pain	2.1 Patient with media opacities such as clinically significant cataract, corneal ulcers or scars.
1.2 Patients aged between 18 and 85 years old.	2.2 Patient incapable of giving informed consent.
1.3 Patients with clinical indications for pharmacological dilated retinal examination (as per criteria 1.1).	2.3 Patient with contraindications for pharmacological dilation. These include known history of narrow angle, angle closure glaucoma, and adverse drug reaction to tropicamide.
1.4 Patients capable of following orders for verbal commands such as direction of gaze.	2.4 Patient physically or mentally incapable of following commands. These include patients with photophobia and blepharospasm.

from which still photographs were extracted for analysis.

The clinician chose only one still image per eye to upload. The image selected was requested to be of the highest image quality, showing the widest field of view, and including the posterior pole of the human retina covering both the optic disc and the macula.

Smartphones and depository of the photographs

The smartphones used in the study were either iPhone 7 or iPhone 8. The photographs were stored on password-protected smartphones and transferred to a password-protected hard drive at the conclusion of the study.

Data protection and storage

Transfer of data between the GPs and researchers was done with encrypted technology. Clinicians uploaded the selected photographs onto Microsoft Azure (Microsoft Corp, US), an end-to-end encryption storage platform. Microsoft Azure supports HIPAA compliance, which can be regarded as equivalent to the New Zealand HIPC requirement.^{17,18}

Photographs used were anonymised. Information such as name, date of birth, gender and age were collected for epidemiological purposes but will not be linked or made publicly available. Protocols for data management and collection were compliant to the Health Information Privacy Code 1994.

Rating of the photographs

Four experienced ophthalmic professionals (two general ophthalmologists and two optometrists) were involved with rating each of the photographs collected, which were presented in the form of a questionnaire. Two factors were rated for each photograph in the questionnaire: photograph quality and the presence of anatomical features, namely the optic disc and macula. All professionals were blinded from each other's responses. The photographs were presented to the professionals on a digital computer screen with a minimum resolution of 1080 pixels by 720 pixels.

The four professionals first rated the quality of each photograph using a Likert scale ranging from 1 to 4. The score translations were:

1. Poor quality and unacceptable
2. Average quality and acceptable
3. Good quality
4. Very good quality

The terms 'acceptable' and 'unacceptable' referred to the adequacy of the quality of the images to detect an abnormality.

The four professionals then rated if the anatomical features of the retina, namely the optic disc and macula, were visible in each image and adequate for detecting an abnormality, with binary responses of 'yes' or 'no'.

Statistical analysis

The end results were collated on a spreadsheet and Microsoft Excel (Microsoft Corp., Albuquerque, NM, US) was used for statistical analysis. Statistical measures such as median and mode were calculated for image quality, and percentages were calculated for identifiable anatomical features. For both factors, inter-professional agreement was calculated as a percentage. This was done using pairwise comparisons, which involved taking the number of times a professional was in agreement with another professional over the total number of pairwise comparisons.

Results

Patient demographics

A total of 339 participants were recruited during the study period. Eighteen patients had bilateral retinal photographs and the rest of the participants had only one eye examined with the oDocs Nun ophthalmoscope. A total of 357 retinal photographs were acquired with the device. The mean age of the participants was 68.2 years old and the median age was 71 years old. One hundred and ninety-four (57.2%) of the participants were female and 145 (42.8%) were male.

Photograph quality: the quality of most photographs was rated as at least average and acceptable by the ophthalmic professionals.

On a Likert scale from 1 (poor quality and unacceptable) to 4 (very good quality), the median and mode values for each professional's rating of all photographs were either 2 or 3. The detailed medians and modes are given in Table 2. Across the four professionals, on average, 7.1% of the images were rated as 1, 46.3% were rated as 2, 37.9% were rated as 3 and 8.7% were rated as 4. Pairwise comparison showed that there was 44.6% agreement between all four professionals regarding these ratings.

Table 2: Median and mode values for each professional's rating of all photographs for photograph quality.

	Median	Mode
Professional 1	3	3
Professional 2	2	2
Professional 3	2	2
Professional 4	2	2
Overall	2	2

Figure 1: Graph depicting the individual percentages of each professional for the proportion of photographs having a visible optic disc adequate for detecting an abnormality.

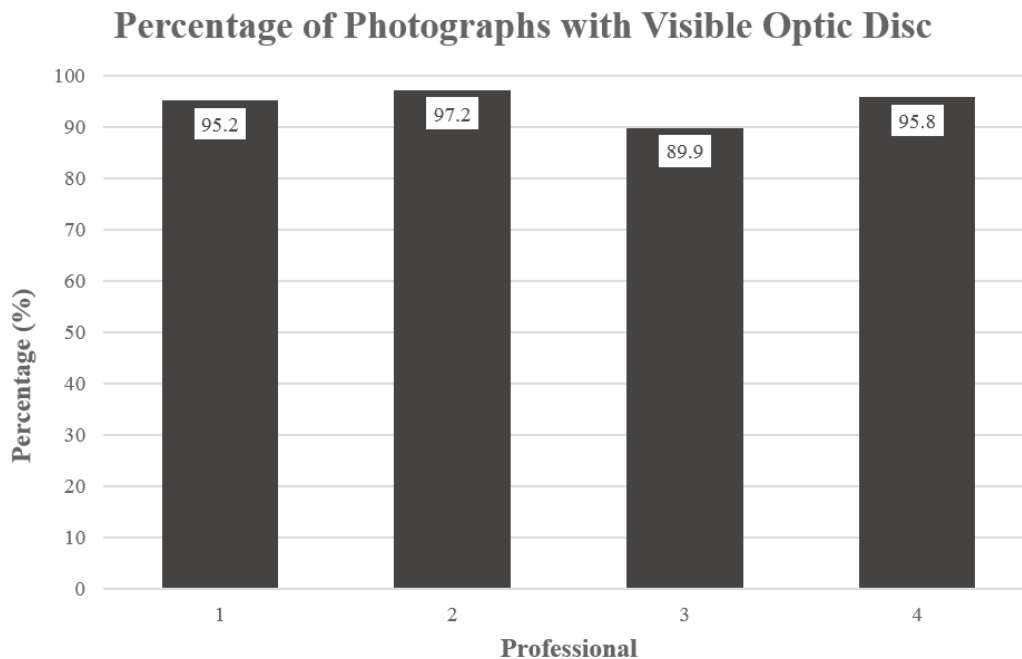
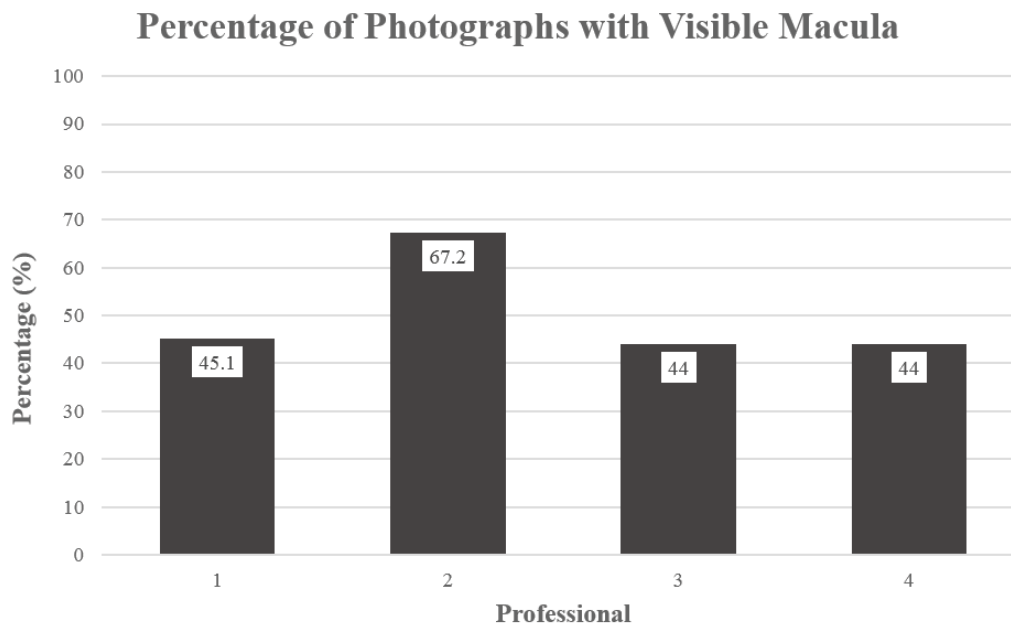


Figure 2: Graph depicting the individual percentages of each professional for the proportion of photographs having a visible macula adequate for detecting an abnormality.



Optic disc: all professionals agreed that the majority of the photographs had a visible optic disc adequate for detecting an abnormality.

Professionals' ratings of the percentage of photographs in which there was a visible optic disc adequate for detecting an abnormality ranged from 89.9% to 97.2%, with the average being 94.5% (see Figure 1). Pairwise comparison showed an inter-professional agreement of 74.2%. Out of the 357 images, there were only three images that all four professionals agreed did not adequately show the optic disc.

Macula: on average, at least half of the photographs were deemed to have a visible macula adequate for detecting an abnormality.

Professionals' ratings of the percentage of photographs in which there was a visible macula adequate for detecting an abnormality ranged from 44.0% to 67.2%, with the average being 50.0% (see Figure 2). Pairwise comparison showed an inter-professional agreement of 74.2%.

Discussion

This study has successfully demonstrated that the oDocs Nun is a promising tool which could be used to circumvent the challenges associated with direct ophthalmoscopy. Despite only 8.7% of photographs

being rated as 4 (very good quality), there was sufficient agreement among all four ophthalmic professionals that the quality of most of the retinal photographs taken by GPs using the oDocs Nun was acceptable. This was supported by the high inter-professional agreement that the majority of the photographs had an image of the optic disc that was sufficient to detect any abnormalities. However, there was also agreement among the four professionals that only half of the photographs had an adequate image of the macula to detect an abnormality. Although there is rising popularity of indirect ophthalmoscopes, GPs are still more accustomed to using the direct ophthalmoscope despite its various drawbacks.^{19,20} As a result, there is need for a longer training time before the user becomes proficient at utilising unfamiliar equipment such as the oDocs Nun. Nevertheless, the success of the oDocs Nun in capturing many images that professionals rated as being of acceptable quality for identifying an abnormality indicates the potential of this instrument to be used as an ophthalmoscope in the primary care setting.

As previously mentioned, the oDocs Nun is a new device based on the principle of indirect monocular ophthalmoscopy; compared to the direct ophthalmoscope, it has a wider angle of view (40°),²¹ as well as potential greater ease and comfort of use due to having reduced patient proximity.⁸

Moreover, compared to other smartphone retinal imaging devices mentioned earlier which are simple direct ophthalmoscopes, the oDocs Nun has a wider field of view, and has coaxial illumination.²⁴ Beyond this, the oDocs Nun could potentially have a significant role in the field of telemedicine. Telemedicine refers to the practice of remote medicine through technological means, which includes remote consultation, treatment, surgery and monitoring.^{22,23} Teleophthalmology is a branch of telemedicine which involves delivering eye care through either a store-and-forward method or real-time communication.²⁴ There is robust evidence to support that teleophthalmology is suitable for things such as screening for diabetic retinopathy.^{25,26} In this, teleophthalmology essentially involves a trained individual, such as a GP, using a device which can produce adequate photographs of the retina that can be sent to ophthalmologists for further evaluation; the oDocs Nun could therefore potentially become an integral part of teleophthalmology and emergency teleophthalmology.²⁷ Ethical issues revolving around patient security and privacy are no longer hindrances as there are multiple platforms now built with legal compliance; there is also global progress towards creating paperless automated digital workflows in hospitals.^{28,29} Fundamentally, the advancement of the field of teleophthalmology with novel devices such as the oDocs Nun enables many advantages: short examination time, electronic medical photographs, the ability of non-ophthalmologists to screen for diseases, and a decreased need for further resources, especially in rural or deprived areas, for example.^{26,27}

There are various limitations of this study as well as areas which may be improved for future research. Firstly, the questionnaire for the four professionals used subjective terms in the questions, which were dependent on the interpretation of the professionals. This may have introduced systematic errors if the definitions of the terms were different for each professional. Regarding image quality, although all professionals rated the majority of the photographs as above average and acceptable, there was low inter-professional agreement of only 44.6%. This may have been due to there being four points on the Likert scale; as mentioned above,

only 15.8% of the responses were either 1 or 4. This indicates that only two options for image quality (acceptable vs unacceptable for detection of an abnormality) may have been needed in the questionnaire, which could have significantly increased the inter-professional agreement. Secondly, there were no measures taken to determine intra-professional reliability; for future research, it would be advantageous to randomly select some images to be reassessed by the same professional. Moreover, the GPs may have needed more extensive training or longer time to become accustomed to using the oDocs Nun before uploading an image; greater practice with the device for all GPs may have increased the number of photographs with an adequate image of the macula.

This study has indicated that the oDocs Nun is a suitable device that GPs can use in the primary care setting, which sidesteps the challenges associated with the direct ophthalmoscope. Previous studies have also indicated the preference for indirect ophthalmoscopes by health practitioners;^{21,30-32} utilisation of devices such as the oDocs Nun could improve the implementation of complete eye examinations by GPs. Although mydriasis was used in this study, the oDocs Nun is suitable for non-mydriatic pupils, hence saves time during consultations. The oDocs Nun also may have a role in screening programmes because of its ease of use and potential application of telemedicine. Moreover, it is a device which could also be used to teach ophthalmological techniques to medical students because of its ease of use.

In conclusion, it was found that the oDocs Nun is a new and promising indirect ophthalmoscope. Overall, most photographs were rated by professionals to be of acceptable quality; 94.5% of photographs were deemed to a visible optic disc and 50.0% had visible maculae which were adequate for detecting an abnormality. As compared with other similar devices, the oDocs Nun offers a wider field of view, co-axial illumination and image acquisition capabilities when used in conjunction with a smartphone. The device has potential roles in telemedicine, screening programmes, and student learning, and it may successfully reduce the obstacles GPs face in ophthalmic consultations related to the direct ophthalmoscope.

Competing interests:

Dr Sime and Dr Hong report non-financial support from oDocs Eye Care Ltd outside the submitted work. In addition, Dr Hong has a patent Co-axial illumination issued.

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