



Comparison of Smartphone Ophthalmoscopy with Slit-lamp Biomicroscopy for Grading Diabetic Retinopathy

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BACKGROUND: In ophthalmology, images are used extensively for disease documentation, treatment monitoring, and educational purposes. Traditionally, fundus images have been obtained with expensive and bulky tabletop units operated by a trained technician in a hospital clinic setting. The pervasive adoption of smartphones by physicians and their ever-improving built-in camera technology has raised much interest in their use for medical and ophthalmic imaging. The portability and immediate connection capabilities of smartphones make them an attractive device for acquiring retinal pictures in remote non-hospital settings. Indeed, telemedicine has the potential to reach patients and communities that currently receive no or suboptimal eye care as a result of geographic and/or sociocultural barriers.

In the past decade, retinal screening programs for common eye diseases, such as diabetic retinopathy (DR), glaucoma, and age-related macular degeneration, have experienced rapid growth. The application of these screening programs in rural, nurse-operated, highly remote primary care facilities highlights the importance of having access to an inexpensive, portable, easy-to-operate, and high-image-quality fundus camera.

We developed a small optical device, which attaches magnetically to a smartphone, to conveniently examine and record videos or photographs of the retina. This attachment, which we call D-Eye, is a novel, inexpensive, and very portable optical device designed to be magnetically attached to a smartphone.

The purpose of this study was to validate the efficacy of D-Eye device to screen for diabetic retinopathy in the community. We compared the ability of smartphone ophthalmoscopy with that of dilated retinal biomicroscopy to grade DR in patients with diabetes mellitus (DM).

MATERIALS AND METHODS: Overall, 120 consecutive patients with diabetes, new to Diabetes Center's outpatient clinic, underwent dilated retinal digital imaging with a smartphone ophthalmoscope, as a part of their routine examination for diabetes.

Dilating eyedrops (0.5% tropicamide and 10% phenylephrine) were administered to outpatients with diabetes, who were scheduled for an examination at the Diabetes Center. After 20 minutes, smartphone ophthalmoscopy was performed in these patients by a retinal specialist (AR). Subsequently, retinal slit-lamp examination, according to normal clinical practice, was performed by another retinal specialist (FM) who was masked to the findings of smartphone ophthalmoscopy.

Smartphone Ophthalmoscopy: After pharmacological dilation, a retinal specialist (AR) performed a comprehensive dilated fundus examination with a final prototype (Figure 1) of the D-Eye adapter attached to an iPhone 5 (Apple Inc., Cupertino, CA). The images were captured on 3264 × 2448 pixels of the camera's sensor. Thus, direct fundus ophthalmoscopy was performed using live images displayed on the smartphone's screen (a video showing the acquisition procedure is attached). When the pupil is dilated, the device captures a field of view of approximately 25° in a single fundus image at a distance of 1 cm from the patient's eye. Color digital images and videos of the retina were obtained, encompassing the posterior pole, including the macula, optic disc, and peripheral retina.



Figure 1 - Picture of the prototype magnetically attached to an iPhone 5 (Apple, Cupertino, CA).

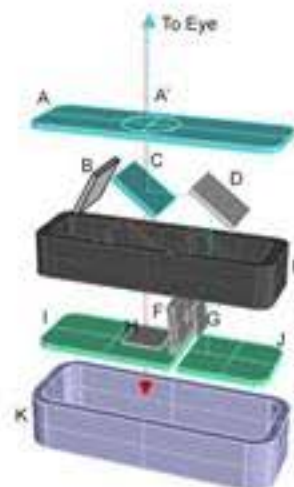


Figure 2 - Exploded view of the D-Eye module (angles and distances between components are approximated). Retinal images are acquired using coaxial illumination and imaging paths thanks to a beam splitter (C). The blue arrow depicts the path of the light; red arrow depicts the path of fundus imaging. Device components are: glass platelet (A) with imprinted negative lens (A'); photo-absorbing wall (B); beam splitter (C); mirror (D); plastic case (E); diaphragm (F); polarized filters (G, H); flash and camera glass (J, I); magnetic external ring (K).

RESULTS: Of the 120 patients with DM who underwent smartphone ophthalmoscopy and slit-lamp biomicroscopy, 55 (45.8%) were men and 28 (23.3%) had type I DM. The mean age at examination was 58.8 ± 16.4 years, and mean duration of DM was 11.6 ± 9.7 years.

Grading of Diabetic Retinopathy: the eye fundus was not gradable for DR in 9 eyes (13.3%) by smartphone ophthalmoscopy and in 4 eyes (3.3%) by biomicroscopy because of cataract and/or small pupil diameter. The clinical level of DR found with both techniques is reported in Table 1. An exact agreement was found in 204 (85%) of 240 eyes and an agreement within one step was observed in 232 eyes (96.7%). Simple κ was 0.78 (95% confidence interval 0.71–0.84; P < 0.001), showing a substantial agreement for the grading of DR between smartphone ophthalmoscopy and slit-lamp biomicroscopy. In 82% of one-step disagreements and 93% of disagreements by two or more steps, the severity level was higher by biomicroscopy grading. Figure 3 shows representative images of healthy and pathological retinas.

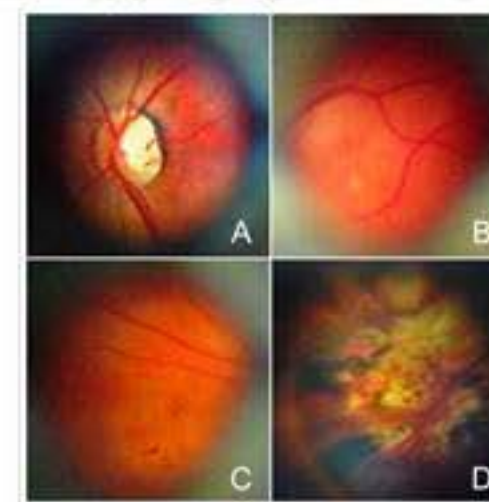


Figure 3 - Representative retinal images taken with D-Eye. (A) Optic disc in a healthy retina. (B) Mild nonproliferative diabetic retinopathy. (C) Moderate nonproliferative diabetic retinopathy. (D) Pannetinal photocoagulation scars in a proliferative diabetic retinopathy.

	Smartphone Ophthalmoscopy Number of eyes (%)	Dilated Slit-lamp Biomicroscopy Number of eyes (%)
No apparent retinopathy	122 (50.0%)	115 (47.9%)
Mild nonproliferative diabetic retinopathy	57 (23.0%)	59 (24.6%)
Moderate nonproliferative diabetic retinopathy	32 (13.3%)	33 (13.0%)
Severe nonproliferative diabetic retinopathy	12 (5%)	20 (8.3%)
Proliferative diabetic retinopathy	8 (3.3%)	9 (3.8%)
Not gradable	9 (3.8%)	4 (1.7%)
• Cataract	4 (1.7%)	3 (1.2%)
• Small pupil	6 (2.5%)	1 (0.4%)

Table 1 - Assessment of Diabetic Retinopathy Severity by Smartphone Ophthalmoscopy and Biomicroscopy.

Diabetic Macular Edema: The examiners were asked to note only the presence or absence of clinically significant macular edema. Seventeen eyes (7.1%) were classified as true positive and 4 eyes (1.7%) as false negative (sensitivity 81%); 215 eyes (89.6%) were classified as true negative and 4 eyes (1.7%) as false positive (specificity 98%). Simple κ was 0.79 (95% confidence interval 0.65–0.93; P < 0.001), indicating a substantial agreement between the examined techniques.

DISCUSSION: We believe that smartphone ophthalmoscopy using the mobile D-Eye system offers specific practical advantages over the currently available tabletop fundus cameras and other portable ophthalmic imaging devices. First, the ergonomic usability makes this direct ophthalmoscopy technique easier than traditional direct ophthalmoscopy, since the examiner does not need to bring his face too close to the patient, but can position himself at a convenient distance and focus the smartphone's camera on the patient's eye by looking at the smartphone's screen. Second, the portability of the system together with the wireless connectivity of smartphones presents a unique opportunity for applications such as telemedicine even in non-hospital or rural settings. Developments in telemedicine networks, along with advances in cloud storage, electronic medical records accessible by smartphones, and encryption technology, now present the prospect for a wholly smartphone-based teleophthalmology system.

Third, owing to the relatively low hardware and production costs, the final retail price could be less than \$300, making the device suitable for community vision screening by a variety of non-ophthalmic medical personnel.

In conclusion, this study shows that smartphone ophthalmoscopy with the D-Eye system can accurately detect retinal lesions for grading DR. The combination of affordability, portability, connectivity, and easy-to-use features of this ophthalmoscopy system provides a foundational platform, based on which a number of revolutionary screening programs can potentially be designed.