

Comparison Study of Funduscopy Exam of Pediatric Patients Using the D-EYE Method and Conventional Indirect Ophthalmoscopic Methods

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Abstract

Purpose: The D-EYE device, a new fundoscopic smartphone lens, has demonstrated its utility in a clinical setting to detect and document ocular pathology, but has not been tested in the pediatric population. A prospective study was performed to explore the application of D-EYE in pediatric fundus examinations. **Methods:** Patients ages 3 - 18 years old underwent dilated fundus examinations by masked examiners using the video function of the D-EYE, while indirect ophthalmoscopy was performed by a pediatric ophthalmologist. The examiners independently analyzed the D-EYE videos for the presence or absence of abnormalities, cup-to-disc (c/d) ratios and optic nerve size and color. The D-EYE video findings were compared to indirect ophthalmoscopy findings. **Results:** The study included 172 eyes from 87 patients. In comparing D-EYE to indirect ophthalmoscopy for detecting fundus abnormalities, the sensitivity was 0.72, specificity was 0.97, positive predictive value (PPV) was 0.77, negative predictive value (NPV) was 0.97, positive likelihood ratio (LR) was 27.8, and negative LR was 0.29. The agreement rate between the D-EYE video graders for the c/d ratio within a value of 0.1 was 97.0%. Multiple, distinct abnormalities were discovered using the D-EYE device, including nystagmus, optic nerve hypoplasia, optic disc edema, peripapillary atrophy, disc pallor, and optic disc drusen. **Conclusion:** Fundoscopic imaging using the D-EYE smartphone lens reliably detects the presence of fundus abnormalities and has good reliability in assessing c/d ratios. The video capability is useful in patients with nystagmus or those who are poorly compliant with the examination and allowed for effective teaching by the pediatric ophthalmologist.

Keywords

D-EYE, Fundoscopic Imaging, Pediatric Ophthalmologist

1. Introduction

In a world of rapidly-evolving technology and growing demand to lower health-care expenditures, the increasing availability and utility of smartphones are transforming the field of medicine. In the realm of ophthalmology, smartphones are now being used more routinely to document patients' ocular conditions. The use of smartphones to inexpensively capture fundus images to diagnose and document pathology shows great promise towards increasing accessibility of eye care both domestically and abroad [1]. Smartphones have been useful in the emergency department setting, for inpatient consultations, and during examinations under anesthesia since they provide a cheap, portable option for obtaining high-quality images of the fundus [2]. Additionally, smartphone fundus photography is well tolerated in awake patients since the light intensity is well below that in standard indirect ophthalmology [3]. However, methods that require using both a built-in smartphone camera and an external ophthalmic lens simultaneously prove difficult for many due to issues with controlling the focus and exposure during image capture, which may result in glare and poor image quality.

The D-EYE device (D-EYE Srl, Padova, Italy; <https://www.d-eyecare.com>), a magnetic fundus lens that attaches to an iPhone, utilizes a user-friendly smartphone application and the built-in iPhone camera to take fundus photographs and videos. D-EYE is FDA approved, and its corresponding smartphone application is HIPPA compliant. This makes it an effective and simple method to capture, document, and consult within a single interface. In a previous study, the Ross Eye Institute in Buffalo, NY, demonstrated the utility of the D-EYE technology in a clinical setting [1]. The device was successfully implemented in capturing photos of a diffuse range of pathology, including optic nerve hypoplasia/cupping/pallor, colobomas, and drusen. The captured photos were used in documentation, follow-up, and discussion of complex cases with colleagues and patients alike. Likewise, D-EYE has been shown to produce high-quality fundus images and successfully detected abnormal pathology in an emergency department setting and it has shown its usefulness as an alternative means to slit-lamp exams to determine VCDR [4] [5].

The D-EYE's simplistic, yet effective design, along with the image capturing and sharing capabilities of the iPhone, extends the system's potential utility to medical personnel with little ophthalmologic experience. It could also play a pivotal role in the future of telemedicine. Although studies have been conducted validating the utility of D-EYE, no prospective studies have compared D-EYE to traditional ophthalmoscopic methods in a pediatric population. Demonstrating that the D-EYE can detect fundus abnormalities in the pediatric population

would further substantiate a device which could aid numerous physicians and patients alike. This is a prospective study assessing the effectiveness and accuracy of imaging of the fundus using the D-EYE method (consisting of the D-EYE Portable Retinal Imaging System and an iPhone) in pediatric patients.

2. Methods

2.1. Data Acquisition and Analysis

Patients ages 3 - 18 years old who had a clinically indicated dilated funduscopic exam were eligible for this study. Data collection occurred from July-December 2016 at the Children's Hospital and Medical Center pediatric ophthalmology clinic in Omaha, NE. Individuals with conditions preventing direct visualization of the retina were excluded from this study. Masked examiners, consisting of one undergraduate student, two medical students, and one post-doctoral pediatric ophthalmology research fellow, were trained by a board-certified pediatric ophthalmologist to conduct fundus examinations using the video function of D-EYE (D-EYE Srl, Padova, Italy; <https://www.d-eyecare.com>). After obtaining parental consent, videos were obtained in a dimly lit room using the autofocus capability of the D-EYE smartphone application. The D-EYE examiners analyzed the obtained videos for the presence of fundus abnormalities, optic disc characteristics, and quantified the cup-to-disc (*c/d*) ratios. Three D-EYE examiners analyzed each video. Subjects also received a dilated indirect ophthalmoscopy (IO) examination during the same clinic visit pediatric ophthalmologist or optometrist, who was blinded to the analysis of the D-EYE examiners. The findings of the IO examination were documented in the medical chart, specifically focusing on the same items the D-EYE examiners analyzed in the videos. This study was approved by the Institutional review board at the Children's Hospital & Medical Center.

2.2. Statistical Analysis

Using IO as the gold standard, the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (LR), and negative LR were calculated for the detection of fundus abnormalities, optic nerve size abnormalities, and optic nerve color abnormalities using D-EYE. These statistical measures were also determined for the detection of abnormalities at different age groups. Absolute agreement of the *c/d* ratios and agreement within a value of 0.1 were calculated between the different D-EYE examiners. Cup-to-disc ratio agreement was also calculated between D-EYE and the indirect fundus examinations. Statistical difference between the mean *c/d* ratio assessed during the D-EYE and IO examinations was assessed using an unpaired t-test.

3. Results

In the study, 172 eyes from 87 subjects were examined using D-EYE and IO. All the D-EYE videos were able to be analyzed. The mean age of the subjects was 7.6

years old (± 0.78) with 38 subjects between the ages of 3 - 6, 31 subjects between the ages of 7 - 10, and 18 subjects between the ages of 11 - 18. 48.2% of the subjects were male, while 51.8% female participants. Eighteen out of 172 (10.5%) eyes had clinically detectable abnormalities based upon the IO examination. The mean c/d ratio from the IO exam was 0.238 (± 0.095), while the mean c/d ratio assessed by the D-EYE examiners was 0.239 (± 0.091). This difference was not statistically significant ($P = 0.90$). Exact c/d ratio agreement between the IO and D-EYE occurred in 73.2% of eyes, while agreement within a value of 0.1 occurred in 94.0% of eyes. Similarly, exact c/d ratio agreement between the D-EYE examiners occurred in 69.2% of eyes, while agreement within a value of 0.1 occurred in 97.0% of eyes.

In comparing D-EYE to IO for detecting fundus abnormalities, the sensitivity was 0.72, specificity was 0.97, PPV was 0.77, NPV was 0.97, positive LR was 27.8, and negative LR was 0.29 (**Table 1**). For subjects ages 3 - 6, the sensitivity of detecting fundus abnormalities was 0.67, specificity was 1.00, PPV was 1.00, and NPV was 0.97. Sensitivity for those ages 7 - 10 was 0.60, specificity was 0.97, PPV was 0.6, NPV was 0.97, positive LR was 20, and negative LR was 0.41. For subjects ages 11 - 18 years of age, sensitivity of D-EYE in detecting fundus abnormalities was 0.60, specificity was 1.0, specificity was 0.91, PPV was 0.75, and NPV was 1.0. For detecting optic nerve size abnormalities with D-EYE, the overall sensitivity was 0.5, specificity was 0.98, PPV was 0.63, NPV was 0.97, positive LR was 26.3, and the negative LR was 0.51. Optic nerve color abnormality detection by D-EYE had a sensitivity of 0.55, specificity of 0.99, PPV of 0.86, NPV of 0.97, positive LR of 91.7, and negative LR of 0.45.

Many distinct abnormalities were detectable using the D-EYE, including nystagmus, optic nerve hypoplasia, optic disc edema, peripapillary atrophy, disc pallor, optic disc drusen, optic disc coloboma, and Wyburn-Mason Syndrome. Some of these findings may be seen in **Figure 1**.

4. Discussion

The findings of this study indicate that D-EYE is indeed a useful method for detecting fundus abnormalities. D-EYE proved to be highly specific for detecting abnormalities and had excellent likelihood ratios, making it helpful in determining

Table 1. Positive Predictive Value (PPV), Negative Predictive Value (NPV), Likelihood Ratio (LR).

	Fundus Abnormalities	Optic Nerve Size	Optic Nerve Color
Sensitivity	0.72	0.5	0.55
Specificity	0.97	0.98	0.99
PPV	0.77	0.63	0.86
NPV	0.97	0.97	0.97
Positive LR	27.8	26.3	91.7
Negative LR	0.29	0.51	0.45

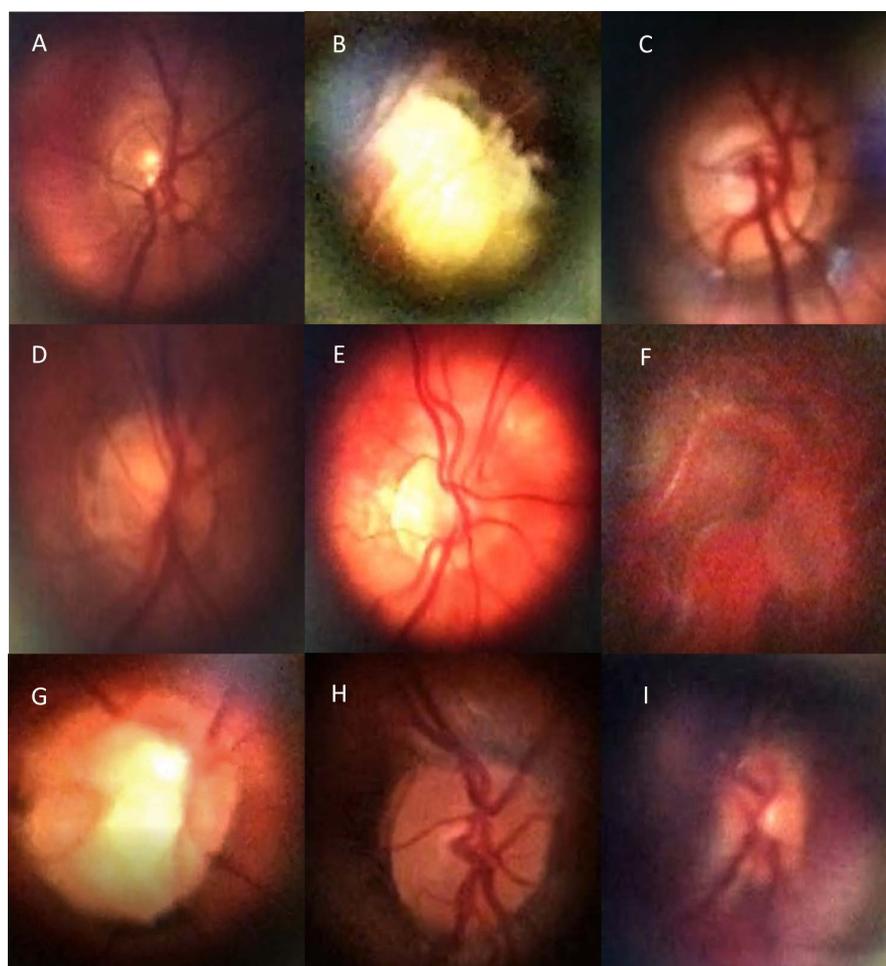


Figure 1. (A) D-EYE image of a normal optic disc. (B) D-EYE image of an optic nerve coloboma. (C) D-EYE image of a 0.5 c/d ratio. (D) D-EYE image of an optic disc in a patient with a congenital cataract and nystagmus. (E) D-EYE image of optic nerve hypoplasia and peripapillary atrophy. (F) D-EYE image of a patient with Wyburn-Mason Syndrome. (G) D-EYE image of a patient with an optic nerve pit. (H) D-EYE image of optic disc pallor. (I) D-EYE image in a patient with a congenital cataract.

the probability of fundus abnormalities and ruling in the presence of fundus abnormalities as well. The sensitivity in detecting abnormalities is similar to that of direct ophthalmoscopy (DO) in detecting different pathologies, such as hypertensive and diabetic retinopathy [6] [7] [8] [9]. Similarly, DO has been reported to only properly assess c/d ratios 10% of the time with a tendency to underestimate the true c/d ratio when compared to retinal tomography, while D-EYE had exact c/d agreement to IO 73.2% of the time in this study [10].

During the data collection, it was evident that the D-EYE was especially useful in the pediatric population, as many of the study subjects were not highly compliant with the examination. The video capabilities of D-EYE allow the examiner to pause the video at any point of the examination for a closer, prolonged look at the area of the fundus in question. This unique feature makes it ideal for pediatric fundus examinations and fundus examinations for other poorly-compliant patients. Likewise, children may be afraid of a large ophthalmic instrument, but

many are accustomed to touching and playing with a smartphone. Besides its utility in children, it was also noted that D-EYE was particularly useful in fundus examinations for patients with nystagmus, since you may pause the video at any time (see **Figure 1(D)**). D-EYE effectively captured fundus images of patients with cataracts (**Figure 1(I)**) and a variety of other pathologies seen in **Figure 1**. D-EYE was useful in patients with high levels of refractive error as well, including a patient with +9.5 D of refractive error.

Due to its low degree of operational difficulty, D-EYE shows great promise as a new examination tool for ophthalmologists and non-ophthalmologists alike. As many physicians who are not ophthalmology-trained are not comfortable with pediatric funduscopic exams using conventional methods, the use of smartphones to capture funduscopic images and the ability to have these evaluated remotely by a trained ophthalmologist may help in timely diagnosis of eye diseases in the pediatric population. D-EYE would be extremely useful for pediatricians who would like to do fundus examinations and subsequently send the images to ophthalmologists through the HIPPA-compliant application for the ophthalmologists' recommendations. The use of D-EYE for routine screening in primary care offices can reduce financial burden and inconvenience for parents and patients [11].

The D-EYE system is a promising alternative to conventional fundus-viewing methods. Traditionally, digital retinal photography is cumbersome in that it requires the use of tabletop or wall-mounted units that are expensive and not user-friendly. By utilizing the advanced technology of smartphone cameras with D-EYE, the funduscopic exam can feasibly be attained efficiently and effectively throughout clinics worldwide. D-EYE is a simple, effective, and affordable method for visualizing the fundus, and it can potentially eliminate problems of poor exam skills and inexperienced observer bias. D-EYE improves the ease of retinal screening for both doctors and patients, and it possesses the potential to create greater collaboration between non-ophthalmologists and ophthalmologists. In addition, the D-EYE system would allow patients and parents to see physical images of their own eye and this will aid in better understanding their disease. These images could be saved in patients' electronic medical records for comparison with future exam images.

Retinal exams have already been successfully performed with the iPhone in developing countries, and this cost-effective method has diagnosed a number of cases of retinopathy of prematurity in Sub-Saharan Africa [12]. Conventional ophthalmologic exams are uncommon in these areas and most patients do not have access to facilities with expensive conventional ophthalmoscopes. In the case that a whole team of clinical staff could not logistically travel to developing countries or no eye specialists are available in a given area, training local staff and remotely analyzing images could be a solution in helping to overcome eye care disparities abroad.

Limitations to this study include examinations being conducted at a single hospital. The prevalence of abnormalities may be higher in this study than that

seen in the general population due to the location of this study being at a tertiary referral center. Future studies are warranted directly comparing D-EYE to direct ophthalmoscopy and to evaluate the effectiveness of D-EYE in a telemedicine setting.

5. Conclusion

Based on results from this study, D-EYE is an effective tool for fundus evaluation and diagnosing retinal pathology. This device is especially useful for pediatric retinal examination, and retinal examination for poorly compliant patients.

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