D-EYE
Smartphone-Based Healthcare System

Alberto Scarpa – CEO
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Our Vision

We see a world where healthcare monitoring and prevention is available for everyone and everywhere.

Our Mission

Develop smartphone-based platforms to unleash mass screening like never before to improve people’s quality of life.
Vision Loss Affects Over 285 M People Globally

80% is Preventable or Curable
What’s the problem?

In Developed Countries, older adults living longer – Will lead to higher costs with more glaucoma, diabetic retinopathy and age-related macular degeneration.

In Developing Countries, health care system is not available in every city and medical devices are too expensive.

Shortage of Qualified Eye Care Professionals globally—prevents early detection of eye health problems

- Patients with eye health problems in rural areas do not get properly screened
- Need appropriate tool that can empower the next tier of healthcare professionals (General Practitioners, Nurse Practitioners, Emergency Medical Technicians, Medical Students) to perform retinal screenings
Current technology solutions are not well-suited to geographic regions where need is greatest:

- Traditional retinal imaging products (Fundus cameras) are too expensive and bulky and are used only by ophthalmologists
- Less expensive ophthalmoscopes cannot capture or transmit images

**Ophthalmoscope**

€ 200–800

**Fundus camera**

€ 5k–25k
Optics from ophthalmoscope

Connectivity from smartphone

Image Processing from Fundus Camera
D·EYE

Smartphone-Based Retinal Imaging System

€395
D-EYE Retinal Imaging System

D-EYE Retinal Imaging System mixes the ophthalmoscope optical qualities with fundus camera digital capabilities and with connectivity of a smartphone.

A portable, low-cost retinal imaging system using millions of smartphones

Screen patients quickly, capture, store and share high-resolution images to remote diagnosticians
The D-EYE Retinal Imagining System

D-EYE performs a direct ophthalmoscopy for leading causes of blindness including glaucoma, advanced non-proliferative retinopathy and age related macular degeneration. D-EYE can be used with un-dilated eyes.

D-EYE is currently being used by Ophthalmologists, Optometrists, Neurologists, Pediatricians, Endocrinologists, Primary Care and Emergency Medical Physicians, Nurse Practitioners and any clinician that uses a traditional ophthalmoscope.
Market Size

**D-EYE Retina**

3.3 M healthcare professionals:
- 500,000 Primary Care Physicians
- 210,000 Ophthalmologists
- 300,000 Optometrists
- 200,000 Neurologists
- 300,000 Nurse Practitioners
- 500,000 Emergency Medical Technicians
- 500,000 Medical Students
- 300,000 Pediatricians
- 500,000 Veterinarians

**D-EYE Glaucoma Screening**

Glaucoma Screening for 10% of people over 60

64.6M people world wide:
- 6.67 M in Europe
- 3.36 M in North America
- 39.00 M in Asia
- 8.29 M in Africa
- 6.59 M in South America
D-EYE App for FREE
D-EYE App
Certifications

European CE and US FDA registrations

D-EYE inspected by FDA with successful outcome

D-EYE company is certified ISO 9001, ISO 13485 and ISO 13485 Canada
The Competition

Ophthalmoscopes  (No imaging or image transfer capability)
  • Welch Allyn; Heine; Keeler Ophthalmic

Fundus Cameras  (Expensive, not portable)
  • Centervue; Optovue; Topcon; Kowa

Smartphone/Lens Attachments
  • Welch Allyn iExaminer (poor image, $900 price)
  • Peek Vision (no application . Only for use with dilated eyes)
  • Digisight (Indirect Ophthalmoscopy. Only for use with dilated eyes)
  • Volk iNview (Indirect Ophthalmoscopy. Only for use with dilated eyes)
Workflows

Specific workflows guide users to perform examination optimizing efficiency and effectiveness.

• **Red Reflex** for new born
• **Screening of Glaucoma**
New Born Red Reflex exam

- Many national healthcare systems are enforcing this exam.
- Easy acquisition on pediatric patients.
- Examination without dilating; light is 50 times less intense than other devices.
- Reporting and sharing for easy examination storage.
Workflow screening Red Reflex

1. Identify the patient with barcode

2. Screening:
   a) Acquire anterior segment
   b) Acquire del fundus
   c) Acquire both eyes

3. Create the examination report

4. Print and Share
10% of people over 60 years old have Glaucoma

Screening of Glaucoma

Easy acquisition of images of optic disc

Examination without dilating the eye and without moving the patient

Reporting and sharing functions enables Telemedicine
Workflow of screening del Glaucoma

1. Patient identification with barcode

2. Screening of optic disc

3. Create Report

4. Print and share
Intellectual Property

Optical System
Title: Accessorio ottico per un dispositivo mobile
Italy: BS2013A000169 on 2013 November 15
PCT: PCT/IB2014/060842 on 2014 April 18

Stitching Algorithm
Title: Metodo per l’acquisizione e l’elaborazione di immagini di un fondo oculare mediante un dispositivo elettronico portatile
Italy: PD2014A000173 on 2014 July 02
PCT: PCT/IB2015/054990 on 2015 July 02
“Glaucoma Test”

New B2C service under evaluation

• It is a screening test for Glaucoma for final users.
• The screening is performed by pharmacist or general practitioner
• D-EYE provides examination station
• AI algorithms evaluate examination for triage
• Ophthalmologists provide diagnosis and use the service as a marketing tool
Image Processing: Stitching

Combine video frames into one image with a wider FOV

AI: Detection of the main features

Detection of retina and optic disc with ML algorithms
## Revenue Streams

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<td>Big Data subscription</td>
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Achievements

- 2 years in the market
- 32k Exams in 2017
- 3000 customers
- 35 countries
- 2 patents
- Distributor Network
32,000 Examinations
Mass Screenings and The Need for Mobile Tele-medicine Systems Case Studies

Diabetes is a global epidemic. Today, effectively screening 30 million people annually in the US alone has become a difficult effort with projections of 45 million patients with diabetes by 2030.

In the developed world, 30% of patients with diabetes do not have easy access to eye-care and in danger of being undiagnosed before it is too late.

Access to traditional eye care providers for face-face exams is limited by the number of providers. 5 million will face blindness each year.

Payers recognize the cost and are looking for cost effective screenings protocols for all diabetics.

The proliferation of the D-EYE system across the medical community will close the loop for those who do not access.
Usage of D-EYE in India and Southeast Asia
Scientific Papers and Clinical Studies

- **University of Bonn** – Nature - Undilated versus dilated monoscopic smartphone-based fundus photography for optic nerve head evaluation
- **University Eye Hospital Bonn** – Smartphone-Based optic nerve head evaluation
- **University of Pennsylvania** – D-EYE for detection of Optic Nerve Pathology in an Outpatient Clinical
- **University of Nebraska** – Comparison Study using the D-EYE and the direct ophthalmoscope
- **University of Nebraska** – Comparison Study Of Pediatric Patients Using D-Eye And Indirect Ophthalmoscopic
- **UC San Diego** – The Comparison Of Smartphone vs. direct Ophthalmoscopy as a teaching tool
- **University of Nebraska** – Smartphone device could revolutionize ophthalmology teaching
- **Rochester Institute of Technology** – Cell Phone Retinal Imaging
- **Ross Eye Institute** – D-EYE in the pediatric population with telemedicine potential
- **University of Brescia** – Comparison of D-EYE versus Dilated Ophthalmic Examination
- **Journal of Hypertension, University of Brescia** – Fundus Photography with D-EYE In Acute Hypertension
- **University of Brescia** – Comparison of D-EYE with Slit-Lamp for Grading Diabetic Retinopathy
- **Journal of Ophthalmology, University of Brescia** – A New Device for Fundus exam
- **Wake Forest School of Medicine** – D-EYE for funduscopic examination: a promising Teaching tool
- **University of Manchester** – Ease of use and vertical cup-to-disc ratio agreement
- **Newcastle University** – Assessing the validity of D-EYE alternative to the direct ophthalmoscope
Undilated versus dilated monoscopic smartphone-based fundus photography for optic nerve head evaluation

Maximilian W. M. Wintergerst, Christian K. Brinkmann, Frank G. Holz & Robert P. Finger

Scientific Reports 8, Article number: 10218 (2018) | Download Citation

Abstract

Smartphone-based fundus photography (SBFP) allows for a cheap and mobile fundus examination with the potential to revolutionize eye care especially in low income settings. The purpose of this study was to assess the impact of pupil dilation on image quality in optic nerve head (ONH) imaging and vertical cup-to-disc ratio (vCDR) evaluation with SBFP. Eyes with glaucoma or suspected to have glaucoma were imaged with conventional digital fundus photography (CFP) and SBFP undilated and following dilation, all monoscopically. SBFP was possible in 74% of eyes without dilation and in 98% following dilation. Better image quality on SBFP was achieved with dilation and complete visualization of the
Comparison of Smartphone Ophthalmoscopy With Slit-Lamp Biomicroscopy for Grading Vertical Cup-to-Disc Ratio

Andrea Russo, MD,* William Mapham, MD,† Raffaele Turano, MD,*
Ciro Costagliola, MD,‡ Francesco Morescalchi, MD,* Nicola Scaroni, MD,*
and Francesco Semeraro, MD*

Purpose of the Study: The purpose of the study was to determine the agreement between smartphone ophthalmoscopy and slit-lamp indirect biomicroscopy when assessing vertical cup-to-disc ratios (VCDRs).

Materials and Methods: This was a clinical-based, prospective, comparative instrument study performed in 110 patients with ocular hypertension (OH) or primary open angle glaucoma (POAG). Patients underwent estimation of VCDR by undilated smartphone ophthalmoscopy and slit-lamp biomicroscopy by 2 masked glaucoma specialists.

Results: The differences between the mean VCDR estimations obtained by each technique were not statistically significant. Overall, exact agreement between the 2 modalities was found in 21 of 29 eyes (72.4%); simple κ = 0.63, confidence interval, 0.52–0.73, P < 0.001 in POAG patients and in 52 of 78 eyes (66.7%) in OH patients. The optic nerve head was gradable with smartphone ophthalmoscopy in 1 eye with POAG and in 2 eyes with OH because of media opacities and/or small pupil diameter.

Conclusions: Smartphone ophthalmoscopy showed substantial agreement with slit-lamp examination for the estimation of the VCDR. The ubiquitous diffusion of the smartphones, together with their connectivity and portability features, enables an extensive benefit for this technology to be used in glaucoma screening, especially in low-resource settings.

rural or remote areas have limited access to optometrists or ophthalmologists, hence to glaucoma tests. Widespread screening is therefore critical for early diagnosis, treatment, and limiting the incidence of glaucoma-associated blindness.

The pervasive diffusion of smartphones might represent a resource for glaucoma screening, thanks to the recent development of dedicated ophthalmic software and hardware. Indeed, smartphones are capable of accurate and repeatable visual acuity measurements² and can be reliably used as ophthalmoscopes with the help of very portable optical devices.³,⁴ Certainly, ophthalmoscopic examination of the optic nerve head (ONH) is crucial in the diagnosis and management of glaucomatous patients. Particularly, ophthalmoscopic estimation of the vertical cup-to-disc ratio (VCDR) of the ONH is important in the screening and follow-up of patients with glaucoma,⁵ and has been found to correlate with visual field indexes.⁶

The purpose of this study was to validate the efficacy of smartphone ophthalmoscopy with that of undilated retinal biomicroscopy to screen for glaucoma in the population. We compared the ability of smartphone ophthalmoscopy with that of undilated retinal biomicroscopy to grade the VCDR of the optic disc.
OCULAR FUNDUS PHOTOGRAPHY WITH A SMARTPHONE DEVICE IN ACUTE HYPERTENSION


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Objective: The ocular fundus (FO) examination is infrequently and poorly performed in the emergency department (ED) clinical settings, placing patients at risk for missed diagnosis of hypertensive emergencies.

Aim: to investigate the feasibility of the FO photography with a smartphone small optical device (D-Eye; J Ophthalmol. 2015) in an ED setting and to compare it to a traditional FO examination.

Design and method: The study included 41 consecutive patients (mean age 69 ± 16 years, 50% women) presenting to an hospital ED with an acute increase in blood pressure (SBP > 180 and/or DBP > 100 mmHg). When admitted to the ED all patients had mydriatic FO examination obtained by an Emergency physician (EP) using both a traditional ophtalmoscope and a commercially available FO smartphone device (D-Eye, SI44 S.p.A., Padova). All FO images and videos recorded with the D-Eye system were analysed by 2 independent expert (ophthalmologist) and inexpert (EP) observers. A quantitative score of hemorrhages, exudates and/or papillary edema was used (0 absent, 1 early, 2 moderate, 3 severe, 4 very severe). The Cohen K coefficient (K1) was used to assess the inter-observer concordance index.

Results: Six patients had headache, 6 had focal neurologic symptoms, and 4 had acute visual changes. The mean duration of FO examination was 130 ± 39 and 74 ± 31 seconds for traditional ophtalmoscopy and for smartphone D-Eye, respectively. No relevant abnormalities of their FO were detected by traditional ophtalmoscopy, performed by the EP, while a significant number of abnormal FO findings were detected by the use of the D-eye device in 17 and 19 patients by the EP and ophthalmologist, respectively. The K1 value ranged from 0,66 to 0,77 (good concordance) for the assessment of hemorrhages and exudates, and from 0,89 to 0,90 (optimal concordance) for the evaluation of presence and severity of papilledema.

Conclusions: Our results show that a new small smartphone device (D-Eye) may be feasible in an ED setting for the fundoscopic examination, detecting a significant number of abnormal FO. The reliability of relevant FO abnormalities seems to be superior in respect to traditional fundoscopy.
Comparison of Smartphone Ophthalmoscopy With Slit-Lamp Biomicroscopy for Grading Diabetic Retinopathy

ANDREA RUSSO, FRANCESCO MORESCALCHI, CIRO COSTAGLIOLA, LUISA DELCASSI, AND FRANCESCO SEMERARO

- **Purpose:** To assess the accuracy and reliability of smartphone ophthalmoscopy, we compared the ability of a smartphone ophthalmoscope with that of a slit-lamp biomicroscope to grade diabetic retinopathy (DR) in patients with diabetes mellitus (DM).
- **Design:** Clinical-based, prospective, comparative instrument study.
- **Methods:** This comparative clinical study was performed in 120 outpatients (240 eyes) with type 1 or type 2 DM. After pupil dilatation, the patients underwent smartphone ophthalmoscopy with the Di-Eye device, followed by dilated retinal slit-lamp examination, to grade DR according to a 5-step scale.
- **Results:** Overall exact agreement between the 2 methods was observed in 204 of 240 eyes (85%) (simple \( \kappa = 0.78 \); CI 0.71-0.84) and agreement within 1 step was observed in 232 eyes (96.7%). Compared to biomicroscopy, the sensitivity and specificity of smartphone ophthalmoscopy for the detection of clinically significant macular edema were 81% and 98%, respectively. Smartphone ophthalmoscopy and biomicroscopy could not be used to examine the fundus and grade DR in 9 eyes (3.75%) and 4 eyes (1.7%), respectively, because of cataract and/or small pupil diameter.
- **Conclusions:** Smartphone ophthalmoscopy showed considerable agreement with dilated retinal biomicroscopy for the grading of DR. The portability, affordability, and connectivity of a smartphone ophthalmoscope make smartphone ophthalmoscopy a promising technique for community screening programs.

Images have been obtained with expensive and bulky tabletop units operated by a trained technician in a hospital or 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 hospital settings. Indeed, telemedicine has the potential to reach patients and communities that currently receive no or subspecialty 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.

Particularly, diabetes mellitus (DM) is a complicated chronic disease that requires continual medical care and patient education to minimize acute and long-term complications. Most clinical practice recommendations suggest that a comprehensive eye examination must be performed at least annually to assess the DR grade in all patients with DM. However, a large percentage of patients with DM (35%-70%) do not receive the recommended level of ophthalmic care. To capitalize on the potential versatility of smartphones in the screening of DR and other ocular diseases, various...
Current and Next Generation Portable Screening Devices for Diabetic Retinopathy

J. Morgan Micheletti, MD¹, Andrew M. Hendrick, MD¹, Farah N. Khan, MD², David C. Ziemer, MD, MPH², and Francisco J. Pasquel, MD²

Abstract
Diabetic retinopathy (DR) is the leading cause of legal blindness in the United States, and with the growing epidemic of diabetes, a global increase in the incidence of DR is inevitable, so it is of utmost importance to identify the most cost-effective tools for DR screening. Emerging technology may provide advancements to offset the burden of care, simplify the process, and provide financially responsible methods to safely and effectively optimize care for patients with diabetes mellitus (DM). We review here currently available technology, both in production and under development, for DR screening. Preliminary results of smartphone-based devices, “all-in-one” devices, and alternative technologies are encouraging, but are largely pending verification of utility when used by nonophthalmic personnel. Further research comparing these devices to current nonportable telemedicine strategies and clinical fundus examination is necessary to validate these techniques and to potentially overcome the poor compliance around the globe of current strategies for DR screening.
Comparison Study of Funduscopic 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 funduscopic 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)
Add more Medical Devices
Strategy

Mass Screening
- Provide low-cost medical devices (D-EYE Devices) for mass screening.

Telemedicine
- D-EYE Telemedicine platform supports not specialist people to get a diagnosis.

Data Collection

Disease Recognition
- Provide algorithms for diseases recognition and categorization.

Data Mining
- D-EYE Big Data service provide big data access, analysis and reports.
A privately held, high technology firm specializing in designing, manufacturing and marketing mobile telemedicine sensing and examination devices, along with companion applications, that enable mass health screenings and data collection to improve access to vital health examination services.

Founded in 2015 D-EYE received many awards and prestigious Italian VC joined the project: Innogest, Invitalia Venture, Fondazione Cottino
2014 Winter
- Start the Project
- Best Paper of AAO
- Won Premio Applico - 100k€

2015 Summer
Start selling

2016 June
- ISO 9001 and ISO 13485 certification

2017 December
- Won Premio Marzotto: 300k€
- Revenue: 150k€

2015 Mar
D-EYE is created

2016 Feb
- Innogest, Invitalia and Fondazione Cottino joined D-EYE
- 1.5M€

2017 Nov
- 2500 customers

2018 Feb
- Won POR 1.4.1: 70k€ in 2019
- H2020 under evaluation
Data Services Roadmap & Timeline

**Data Repository** – image and video data storage

**Telemedicine Service** – communication through ImageVault™ between remote field team and central medical operations for diagnosis from a remote location for NGO's, int'l. agencies, rural medical clinics, hospitals, etc..

**Pathologies Recognition and Categorization** – the ability to auto diagnose incoming images not yet classified by comparing them to images in the database categorized by diagnosis; requires a large database of previously diagnosed and classified images and advanced retinal recognition and analysis software; referral fee opportunities.

**New Medical Devices** – Develop new medical devices. In roadmap we have a lens for the anterior segment of the eye and a device for the skin.

**Big Data Mining** – with sufficiently sized database of images, conditions and diseases represented, and populations screened, begin offering fee-based data mining services, analytics and reports for medical researchers, pharma companies, gov't health agencies and healthcare insurance companies.
Our Social Presence

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