Portable, Low-Priced Retinal Imager for Eye Disease Screening
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ABSTRACT

The objective of this project was to develop and demonstrate a portable, low-priced, easy to use non-mydriatic retinal camera for eye disease screening in underserved urban and rural locations. Existing portable retinal imagers do not meet the requirements of a low-cost camera with sufficient technical capabilities (field of view, image quality, portability, battery power, and ease-of-use) to be distributed widely to low volume clinics, such as the offices of single primary care physicians serving rural communities or other economically stressed healthcare facilities. Our approach for Smart i-Rx is based primarily on a significant departure from current generations of desktop and hand-held commercial retinal cameras as well as those under development. Our techniques include: 1) Exclusive use of off-the-shelf components; 2) Integration of retinal imaging device into low-cost, high utility camera mount and chin rest; 3) Unique optical and illumination designed for small form factor; and 4) Exploitation of autofocus technology built into present digital SLR recreational cameras; and 5) Integration of a polarization technique to avoid the corneal reflex. In a prospective study, 41 out of 44 diabetics were imaged successfully. No imaging was attempted on three of the subjects due to noticeably small pupils (less than 2mm). The images were of sufficient quality to detect abnormalities related to diabetic retinopathy, such as microaneurysms and exudates. These images were compared with ones taken non-mydriatically with a Canon CR-1 Mark II camera. No cases identified as having DR by expert retinal graders were missed in the Smart i-Rx images.

Keywords: fundus imager, retinal screening, low cost

1. INTRODUCTION

Visual impairment imposes a significant burden on patients, providers, and the healthcare system. Vision loss costs the US an estimated $51 billion each year [1]. Vision loss significantly impacts the individual’s quality of life [2,3]. In a survey by the National Eye Institute (NEI), when asked to rate a list of conditions on a scale of 1 to 10 according to their impact on daily living, 71% of those surveyed gave eyesight a 10 (highest impact) [4]. Most eye diseases are preventable and can be stopped or managed if they are detected before vision loss occurs. However, the current lack of medical resources and low-priced screening alternatives leads to unfavorable outcomes. Technologies such as the Smart i-Rx will enhance the capabilities of eye screening that can be performed by minimally trained personnel.

According to the National Institutes of Health, more than 80 million people in the US suffer from a potentially sight-threatening disease. Doctors see seven to eight million new cases of eye disease annually. More than two million Americans age 50 and older have advanced AMD, the stage that can lead to severe vision impairment and 10 million have early or intermediate AMD. Glaucoma affects more than 2.3 million Americans age 40 and older. Another two million individuals with glaucoma are undiagnosed [5].

Diabetes cases in the US and throughout the world have been on the rise. Poor eating habits and lack of exercise, factors that contribute to type 2 diabetes [6], have led to an increasingly overweight population. According to the International Diabetes Federation, there are 285 million cases of diabetes in the world as of 2010. This number is expected to increase to 438 million by 2030. There are 26.8 million diabetics in the US (12.3% of the population ages 20-79). For the type 2 diabetics, 50% will develop diabetic retinopathy within 15 years of disease diagnosis. Diabetic retinopathy alone, independent of related impairments such as cataracts and glaucoma, costs the nation more than $1 billion annually in direct medical expenditures. Regular eye disease screening is necessary to prevent the progression of eye diseases to advanced, sight-threatening stages.

Today there are vast underserved regions of the US where the ratio of population to eye care specialist is below the Health Professional Shortage Areas (HPSAs) criteria [7]. People in these areas have to travel long distances for eyecare, usually without having travel expenses paid and incurring loss of work time. Due to the high cost of imaging

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technology, such as retinal cameras, some urban and many rural clinics cannot afford these devices to diagnose or screen the population for early signs of disease when therapy and intervention is most effective. The Smart i-Rx is a low-priced alternative to these expensive cameras, and its development is aligned with the NIH objective to reduce disparities in medical care in rural and underserved populations.

2. CAMERA REQUIREMENTS

2.1 The Need

There is an urgent demand for services that will provide improved healthcare to people with diabetes and the technology that will enable a retinal screening service to be economically feasible. However, several barriers for adoption at the primary care level exist: Primary care providers do not routinely conduct retinal screening. Most providers do not perform retinal screening because of the challenge in using the direct ophthalmoscope, a device that is difficult to use and that provides only a limited view of the retina. Providers therefore refer their patients to optometry or ophthalmology for screening and evaluation. The alternative is to use a commercially available retinal camera from manufacturers like Canon, Zeiss, Nidek, and Topcon but these are priced at an average of $25,000 and require significant space for operation.

Low-cost, hand-held devices are on the market, such as the Volk Pictor non-mydriatic camera and others. These cameras have not had wide adoption by the primary care clinics, though priced at about $10,000. A hand-held retinal imaging device has been found to be difficult to use. It requires practice and ultimately full cooperation of the patient for proper alignment and successful image capture.

Any screening device must be easy to use and must not disrupt patient and clinic flow. Medical assistants and nurses are best suited to take on screening procedures but an imaging device must be easy to use so that minimally trained personnel can operate the device. Moreover, screening has to take less than five minutes and results must be available by the time the patient sees the doctor.

It would be desirable to give the imager (photographer) feedback as to the acceptability of the quality of the images. Because of the likely large variations in skill and experience of the imagers, real-time, i.e. within seconds, they must be given an indication as to the quality and usefulness for screening of the acquired images.

Any screening device or service must produce a sustainable revenue stream. This is not a technical requirement but it makes sense that no practice will adopt a procedure or device that will not produce a sustainable revenue stream. Factors affecting the decision to adopt a procedure are thus related to initial capital expenditure and return on investment.

2.2 VisionQuest’s Smart i-Rx addresses these barriers to adoption

Smart i-Rx (Figure 1) is a $2,500, or less, alternative to retinal cameras costing ten times more on average but that can be placed at any primary care practice. Smart i-Rx is a low-cost, portable, retinal camera that provides 30-degree field of view digital images of the retina without the need for dilation. When taking two images of the retinal, one centered on
the macula and one centered on the optic disc, the information provided is enough to determine stage of DR and the risk for other diseases such as macular degeneration and glaucoma.

The Smart i-Rx provides real time feedback on image quality and risk of disease. Feedback on image quality helps the photographer take better images in less time. Feedback on presence of disease provides a quick, precise, and accurate account of the status of the retina. Smart i-Rx provides one output with three possible results: “non-Refer” when images show no disease or levels of disease that do not call for referral to Optometry or Ophthalmology; “Refer” when image show the need for referral to Optometry or Ophthalmology for confirmation and further evaluation; and “Indeterminate” when it is not possible to assess the status of the retina due to inadequate image quality for example, in cases of small pupils or cataracts when it is not possible to obtain adequate images.

The imaging protocol of the Smart i-Rx is designed to provide the most clinical information with the fewest number of images. For each eye, three images are taken, one centered on the macula (F2), one centered on the optic disc (F1), and one of the pupil (external). The Smart i-Rx provides real time feedback of image quality, including alignment to the retina, so that the photographer successfully obtains properly aligned and well focused images. This speeds up imaging, and allows minimally trained photographers to take adequate images. The Smart i-Rx can be rolled around in a medical cart or attached to a wall-mounted articulated arm. This allows flexibility and minimum footprint. Images can be taken at check-in or while the patient awaits the doctor, so doctors do not see their patient flow disrupted. It takes five seconds for the image quality assessment.

The Smart i-Rx costs less than $2,500. In one business model, the primary care practice may opt not to buy it. Rather, it may be more attractive to the practice to enter into a revenue sharing plan based on a per click reimbursement. This model allows the practice to see a revenue stream from day one, and have this increase over time, as more patients are images. Other plans and incentives are feasible depending on practice size and patient base.

2.3 Smart i-Rx Attributes

Our proposed Smart i-Rx imager provides the following features:

- A FOV of 40 degrees, achieved by using a 40D objective lens.
- The re-engineered commercial prototype will incorporate an external fixation light. Alignment will be accomplished with verbal instructions to the subject to fixate on the light which will be adjusted to align on the desired field or area of the retina.
- The 10ms flash will remove any eye motion artifacts, much as the current commercial cameras.
- Adjustable light intensity better illumination of light and dark fundi.
- A portable chin rest to avoid head motion.
- A simple camera tripod to further aid in removal of motion artifacts.
- Utilize a commercial digital camera to capture the image of the fundus, conduct the focusing, trigger the illumination light, provide image stabilization as well as enable user control.
  - The retinal imagining device will be completely battery powered, i.e., no need for a cord or connection to a conventional external power supply. The camera will be able to operate for 8 hours without the need to be recharged, allowing for a full day of data collection.
  - The system has to be designed to avoid any potential reflection artifact often seen in images and produced by the illumination source reflecting off the front objective lens.
  - Optimized manufacturing designs that will introduce changes to reduce the current weight and size.
  - The design will use a nonconventional pupil arrangement with only small central obscuration and partial overlapping of imaging and illumination pupils. The residual corneal and lens reflex will be controlled by a nano-wire polarizer.
- The target price of sale of the fundus imager with mounting hardware is $2,500.
3. METHODS

3.1 Overview

Previously in Figure 1 we showed the prototype Smart i-Rx. This camera was built using the design given in Figure 2. Two LED sources, an IR (#12 on Figure 2) and a visible light (#10 on Figure 2) are combined by a dichroic beam splitter (hot-mirror #8 in Figure 2). The IR source has a central wavelength of 850nm (CW). The IR LED is mounted on a passive heat sink. The visible light LED is mounted on an aluminum plate and operated in pulsed mode (20ms-1s). The high spherical aberration of the +28D Volk lens for the illumination imaging path removes non-uniformity of the LED source. This also leads to an annulus (ring) of illumination on the pupil of 4.5mm. A fixed focal length objective (50mm focal length) is used. The IR blocking filter on the camera’s sensor is removed and replaced by normal glass (t=1.05mm) with AR coating on both sides.

The camera is attached to a tripod fixed onto a sliding frame with four degrees of freedom (Figure 1). The complete camera mount ($50) has six degrees of freedom (right-left, forward-backward, and up-down) to give the operator complete control of the device for alignment and focus. The chin rest is a simple collapsible frame that can be attached to any tabletop.

3.2 Development Strategy

In a departure from today’s retinal camera design philosophy, a number of changes and improvements have been combined into an innovative implementation of a retinal imager:

Off-the-shelf Technology. A significant reduction in cost of goods was achieved through the use of off-the-shelf optics and recreational digital SLR cameras. To reduce risk and cost of our Smart i-Rx camera, we are leveraging the advances of professional and recreational digital cameras. Optical components and the main objective lens are easily available in bulk in the US. Total cost of parts, including the digital camera and power supply, is less than $1,500.

Leveraging Digital SLR Autofocus. Focus is achieved by taking advantage of the digital SLR’s image stabilization and autofocus capability to remove the need for the photographer to focus while aligning the camera. To avoid pupil constriction during the alignment process, we use near infrared (IR) illumination. This required the removal of the sensor’s IR filter, a standard component in digital SLRs. We found that the IR illumination and reflection characteristics of the retina did not provide sufficient contrast for the autofocus to operate successfully. This required the projection of a high contrast target onto the retina in the IR. The focusing is accomplished by displacement of primary lens. This approach brings the target and retina into focus simultaneously.
**Integration into Table-Top Camera Structure.** Other new camera developers as well as commercial devices have adopted similar approaches for their low-cost hand-held devices, but have failed to appreciate the challenges faced by the targeted user, such as a minimally trained medical assistant in a primary care clinic or a community healthcare worker, when mastering a hand-held camera. Tests with one such hand-held retinal imaging device, the Pictor by Volk, reveals the shortfalls of hand-held imagers. For example, the Pictor is difficult to align to image a specific protocol, such as the macula- and optic-disc-centered fields. Even at 450 grams (1 pound), the Pictor is difficult to align along the optical axis of the eye and centered on the pupil. The need for a chin rest and camera mount is clearly evident in our testing on 39 subjects. To eliminate the problems with camera-patient alignment inherent in all hand-held devices, we have developed a low-cost, low-weight chin rest and camera mount. This structure is described in the Technical Section. The Smart i-Rx can be transported in a small carrying case weighing 3.2 kilograms (6 lbs. 12oz), Figure 3.

![i-RxCam™ in carrying case.](image)

**Illumination Approach.** We use a polarization technique that allows the shape of the light emitting area to have only a small central obscuration (~2mm in diameter) while the outer diameter remains 4.5mm, allowing for appropriate illumination of the retina through undilated pupils.

**Built-in Image Transmission.** The Smart i-Rx camera employs off-the-shelf wireless technology to transmit retinal photos to a reading center. After an image is automatically assessed for image quality using VisionQuest’s proprietary algorithms [8,9,10], they will be transmitted instantly to a reading center or an eye care specialist for complete medical evaluation.

## 4. RESULTS

Forty four diabetic subjects were enrolled in a prospective study to test the feasibility of the Smart i-Rx. For all subjects matching images using the CR-1 Mark II non-mydriatic camera were used. All the images for both cameras were collected without mydriasis. Of the 44 subjects, we were able to capture images adequate for grading on 41 (93% adequacy rate). Figure 4 shows an example case for a subject with severe non-proliferative DR. Image A is a right eye collected with CR1 Mark II. Image B is the same eye as Image A, but taken more superior to better image the pathology in that region of the retina. Image C is peripheral to Image B. Images B and C were collected with the Smart i-Rx. The subject presents lesions consistent with a level of severe non-proliferative diabetic retinopathy. Hard exudates and dot blot hemorrhages can be seen in this field 2 image, running along the superior arcuate vein and artery, with a large hemorrhage and cotton wool spot visible at the superior, lateral side of the image. The images B and C are from the the Smart i-Rx and exhibit the same pathological features. Images in the bottom row are zoomed in regions marked in Figures 4 A, B, and C.
Figure 4. Image A is the Canon CR1 Mark II image. B is a Smart i-Rx and C is another view taken with Smart i-Rx. “a, b, c-1, and c-2” are regions in the full images.

4.1 Clinical Test Data: Controls

Figure 5 displays a close-up of the optic disc region of subject C2, the older Hispanic subject. Note that the Smart i-Rx image (Fig. 5a), although slightly darker in intensity, has the same level of detail as the Canon CR1 image. All capillaries, even those of small diameter (15 pixels wide), emanating from the optic disc are visible. This is also the case for the disc and features such as the choroid, which in this case is a highly variegated tigroid pattern. The Smart i-Rx can easily capture minute anatomical features to a resolution that makes it the perfect imager for large-scale screening.

Figure 5. Optic Disc close-up taken with a) Smart i-Rx and (b) Canon CR1 Mark II.

Figure 6 shows one example of a normal control case of a 69-year old Hispanic male with no known eye disease and with clear media. This figure shows a Canon image that has been sized to 32 degrees FOV to better compare the region of the retina imaged with the Smart i-Rx. The level of detail in both images is comparable, from the details of the choroidal vessels to the detail on the optic disc and surrounding areas.
4.2 Clinical Test Data: Pathological Results

Figure 7 shows an example of an advanced case of DR in a 59 year old Hispanic female. In this Figure, the Canon images have been cropped to similar FOVs (32°) for comparison to the Smart i-Rx camera. Images (a) and (b) show that the Smart i-Rx captures the same level of detail on the lesions present, which include several microaneurysms superior to the macular region. Images (c) and (d) are close ups of one of these lesions.
Figure 8 shows the images of the right eye from a 47 year old male, Hispanic, who has had diabetes for 15 years. This subject has no history of glaucoma or cataracts. The subject is hypertensive. The image A was collected with our CR 1 Mark II camera and image B with the Smart i-Rx. The subject presents lesions consistent with a level of moderate non-proliferative diabetic retinopathy (NPDR). A series of hard exudates can be clearly seen in both images in the superior temporal region. The same lesion pattern in clearly distinguished in both cameras as shown in the detailed view in the bottom part of Figure 8 (a for the CR1 camera, and b for the Smart i-Rx). More subtle but equally visible with both cameras are the microaneurysms (MAs) less than one disc diameter to the fovea. Dot blots are also recognizable with both cameras surrounding the superior part of the hard exudates area. Given the pattern of lesions, the same level of DR was assigned to the images from both cameras with equal confidence.

Figure 9 shows three images of the right eye of a 61 year old male, Hispanic who has had diabetes for 16 years. Image A is a right eye collected with CR1 Mark II. Image B is the same eye as Image A, but taken more superior to better image the pathology in that region of the retina. Image C is peripheral to Image B. Images B and C were collected with the Smart i-Rx. The subject presents lesions consistent with a level of severe non-proliferative diabetic retinopathy. Hard exudates and dot blot hemorrhages can be seen in this field 2 image, running along the superior arcuate vein and artery, with a large hemorrhage and cotton wool spot visible at the superior, lateral side of the image. The images B and C are from the Smart i-Rx and exhibit the same pathological features. The right image demonstrates the Smart i-Rx’s ability to align to image field 3, thus capturing the large bleed and cotton wool spot. Images in Figure 9a, 9b, 9c-1 and 9c-2 are zoomed in regions marked in Figures 9A, 9B, and 9C. Figure 10 presents images from a subject with advanced DR.
Figure 9. Image A is the Canon CR1 Mark II image. B is a Smart i-Rx. C is another view taken with the Smart i-Rx. “a, b, c-1, and c-2” are regions in the full images.

Figure 10. Example of a subject with advanced DR. (c) and (d), detail of pre-retinal hemorrhages. The Smart i-Rx images show more detail especially of the lesions.
5. IMAGE QUALITY

In a retinal image screening system, a reader deems an image as inadequate when it is difficult or impossible to make a reliable clinical judgment regarding the presence or absence of disease [8]. Various studies have documented image quality statistics for single field non-mydriatic (no pupil dilation) images. One such study reported that the percentage of inadequate quality images can be as high 20.8% [9]. Major causes of inadequate image quality in retinal screening images can be either technical or operator error. The sources of poor image quality include illumination crescents due to small pupil size, loss of contrast due to poor focus or movement of the eye or media opacity, and imaging of part of the eyelid and eyelash due to blinking, as well as insufficient illumination.

Several approaches to automatically determine the quality of retinal images have been suggested. Usher et al. [10] used vessel detection in the whole image for image quality assessment. To assess quality of macula-centered images, Fleming et al. measured vessel density in a region around the macula [11]. Another approach to automatic retinal image quality assessment is based on the classification of global and local features that correlate with the human perception of retinal image quality as assessed by eye care specialists. The overall image content, such as lightness homogeneity (detect crescents, etc.), brightness, and contrast are measured by global histogram, textural features, vessel density, and local sharpness. The sharpness of local structure, such as optic disc and vasculature network, is measured by a local perceptual sharpness metric and vessel density. It is this approach that we have adopted for integration into our low-cost camera. The result is a sensitivity for detecting inadequate quality images is 95.3% with a specificity of 80%.

Additionally, two other computer algorithms have been developed to provide feedback to the photographer on image quality:

1) Detection of crescents and shadows
2) Detection of incorrect alignment

The detection of crescents and shadows algorithm addresses the issue shown in Figure 11, where images present bright artifacts along the periphery of the image, i.e. crescents, and/or shadows on any part of the image. Both crescents and shadows obscure parts of the retina that can be important for clinical inspection or further processing. These artifacts, however, are mainly caused by two different processes. Crescents are mainly caused by light reflected off of the pupil or corneas due to misalignment of the camera with the eye. In some instances, small pupils can also produce crescents since the light from the camera bounces off the pupil even if the camera is perfectly aligned with the eye.

Small pupils are the main cause of shadows, since there is not enough light reaching the retina. The position of the shadow is determined by the alignment of the camera with the eye and in some instances, it is possible to manipulate this alignment in order to position the shadow as far as possible from the area of interest on the retina. The crescent/shadow detection algorithm developed by VisionQuest has a demonstrated performance greater than 95% on detecting significant artifacts in a retinal image. These algorithms are based on gradient and morphological image analysis and on region-based segmentation.

![Figure 11. Subject image demonstrating upper-left edge crescent and lower hemisphere wash-out, two examples of artifacts which reduce feature visibility and overall image quality.](image-url)
6. CONCLUSIONS

We found that using either the Pictor as an example of a hand-held, low-cost camera or our own Smart i-Rx camera in a hand-held mode that the difficulty in alignment and focus was significantly greater than using our Smart i-Rx with a chin rest and a camera mount. 65% of images, taken either by a highly experienced and certified Clinical Ophthalmic Medical Tech (COMT) or an inexperienced member of the technical staff, were inadequate when imaged without the aid of the chin rest and camera mount. The inadequacy rate decreased by 20% when the Smart i-Rx camera was used in the configuration shown in Figure 1. Further improvements to the prototype camera have led to a 47% improvement of the initial 65% inadequate rate. At this later stage of development, the Smart i-Rx in its present configuration had a 19% higher image adequacy rate than the Pictor camera when used by the same COMT imager.

The strategy for the development of new low-cost cameras must consider not only the cost of the components and design for low-cost manufacturing. It must also consider the ergonomics, especially the usability of these cameras in non-eye care environments when specialists, physicians or technicians, are not available.

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