

Capstone for Impact Submission | GY2019

Project Title: Usability testing for smartphone-based retinal camera

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Branch: Patients & Populations

Path of Excellence: Innovation and Entrepreneurship

Handover/Transition:

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Summary:

Smartphone-based retinal photography is a promising method for increasing accessibility of retinal screening in the primary care and community settings. Recent work has focused on improving quality of smartphone-based imaging and validating its use in detection of diseases such as diabetic retinopathy. However, retinal imaging can be technically challenging and additional work is needed to improve ease of retinal imaging in the primary care setting.

We therefore performed usability testing of a smartphone-based retinal camera, RetinaScope, among medical assistants in primary care who had never performed retinal imaging. A total of 24 medical assistants performed first-time imaging in a total of five rounds of testing, and iterative improvements to the device were made between test rounds based on the results. The time to acquire a single ~50 degree image of the posterior pole of a model eye decreased from 283 ± 60 seconds to 34 ± 17 seconds ($p < 0.01$) for first-time users. The time to acquire 5 overlapping images of the retina decreased from 325 ± 60 seconds to 118 ± 26 seconds ($p = 0.02$) for first-time users. Testing in the human eye demonstrated that a single wide-view retinal image could be captured in 65 ± 7 seconds and 5 overlapping images in 229 ± 114 seconds.

Users reported high Systems Usability Scores of 86 ± 13 throughout the rounds, reflecting a high level of comfort in first-time operation of the device. Our study demonstrates that smartphone-based retinal photography has the potential to be very easy to perform among medical assistants in the primary care setting.

Methodology:

Medical assistants and technicians were recruited for a total of five rounds of usability testing using the RetinaScope in conjunction with an iPhone 5S (Apple Inc., Cupertino, CA, USA). The RetinaScope consists of a handheld apparatus with a light-emitting diode (LED) illumination and an organic light-emitting diode (OLED) display that attaches to the RetinaScope apparatus using magnets (so that it can be moved from one

side of the apparatus to the other for imaging of both eyes). When positioned in front of the eye, the RetinaScope captures ~50 degree images of the retina, and the external display helps direct the patient's gaze for acquisition of multiple overlapping images to generate a ~100-degree montage of the retina with 52.3 pixels per retinal degree (Figure 1). The entire operation is controlled by a custom iPhone application, which is automated to simplify operations. RetinaScope was designed to meet minimum guidelines for photographic-based screening of diabetic retinopathy including at least 30 pixels per degree described by the National Health Service and greater than 90 degree view of the retina as established by the Early Treatment Diabetic Retinopathy study²⁴. None of the study participants had prior experience with ophthalmic imaging. Participants were given a brief ~5 minute standardized tutorial on how to use the smartphone camera and software application to take a picture of the retina. Instructions consisted of how to attach the iPhone onto the device, turn the device on, open the software application on the iPhone, enter patient identifying information, and capture an image through the custom software. Participants were shown a sample retinal image and asked to capture a similar photograph of the retina inside a model eye. Instructions were then given on how to attach the external fixation screen onto the device. The study facilitator rotated the gaze of the model eye in the direction indicated on the external fixation screen to mimic a patient's gaze, and participants captured five fields of the retina (central, superior, inferior, temporal, nasal).

Two rounds of imaging were recorded. For the first round, users were only asked to capture the central field of the retina of the model eye. For the second round, users captured all 5-fields. There were 6 main tasks to be completed during the testing. Failure to complete any of the steps were noted. Image capture duration was measured from the moment the user took the device out of the box to the time took to acquire an image of the retina. Users self-determined the quality of their photographs from an initial sample retinal photograph, and re-captured images when they deemed it was necessary. Immediately afterwards, users filled out a Systems Usability Survey (SUS), an industry standard 10 question questionnaire where users rate various aspects of their experience using the device on a 5-point scale. Users subsequently gave feedback about the device. Software, hardware, and/or instructional modifications were made in accordance with their feedback prior to the next round. This portion of the study was exempt from the University of Michigan Institutional Review Board approval because it did not involve patients or protected health information (PHI).

The first round of testing was conducted with ophthalmic technicians at the University of Michigan Kellogg Eye Center (n = 7). This was considered an appropriate initial test group because they have some familiarity with eye care, but no previous experience with ophthalmic imaging. Users were given the instructions a few days before their testing, and then asked to capture images without guidance the day of the trial. For the second round and beyond, the testing was transitioned into a primary care setting (Dexter Health Center and Ypsilanti Health Center, both affiliated with the University of Michigan Medical School) with medical assistants who were naïve to both ophthalmology and retinal photography (n = 17). Instructions were given immediately prior to testing for these rounds. Based on user feedback, software graphic user interface (GUI) adjustments were made, including a reminder to turn the device Bluetooth on, an alert if the external fixation screen was attached on the wrong side, and double-click image capture capabilities. The modifications made for the fourth round included improved handlebar grip to enhance the device ergonomics and improved device illumination for image capture. After the fourth round, when user timing stabilized and there was no new user feedback, a final, a proof-of-concept test was performed with a different group of participants (N = 7), with the same skill level as those in previous rounds, on the dilated eye of a human volunteer (TK). The final round retinal images (N=35) were de-identified and graded by a retinal specialist (YP) using a 5-point scale previously validated for retinal imaging.^[25]

Data was analyzed using statistical methods comparing image capturing time across trials and against reference standards. An independent T-test was done comparing the image capture time from the first trial with the image capture times in the 4th trial. One sample T-test was used to compare the time on task in the human trial against generally accepted ophthalmoscopy image duration standards. All data analysis was conducted using Statistical Package for the Social Sciences (SPSS) version 24 (Armonk, NY, USA). In addition, the SUS scores were tabulated according to the preset formula, and a score out of one hundred was calculated. SUS scores were calculated with only the group of medical assistants, and not in the group of ophthalmic technicians, in order to maintain consistency in the score across trials. All data was collected using Microsoft Excel version 15.16 (Redmond, Washington, USA).

Results/Conclusion:

The inherent qualities of smartphones make them well suited for primary care based diabetic retinopathy screening. They are portable, affordable, and have high resolution cameras and powerful computer processing capabilities to capture and transfer photographs electronically. Such telemedicine-based approaches for diabetic retinopathy screening have been effective in decreasing the rates of blindness in countries such as the United Kingdom and Ireland.[26] While smartphone retinal imaging is a promising tool for retinal screening, published studies have shown significant variability in image quality and our own early testing demonstrated that smartphone retinal imaging can be quite variable.[14,23] We therefore incorporated user feedback when designing the RetinaScope to make it intuitive to use. Taking this approach, usability testing is a valuable means for assessing the effectiveness, efficiency, and satisfaction of a product.[22] It has proven to be an effective way to tailor the design of a product to the user's preferred way of work and to reduce the time needed for user training and support.[22,27,28] Nielsen and Landauer have shown that 4-5 users maximized the cost-to-benefit ratio of detecting usability problems.[29] Nielsen has also stated that iterative design maximizes the utility of usability because it can detect a greater percentage of usability problems.[30] The goal of this study was to utilize usability testing to evaluate the time on task, errors,[22] and subjective preferences of primary care medical assistants and technicians using the RetinaScope and to see if improvement can be made through iterative end-user feedback. This is the first study to test the usability of a smartphone ophthalmoscope by non eye-care specialists.[13]

It is worth noting that the ability to capture 5-field images is important in the screening accuracy of diabetic retinopathy, as single-field images may not be adequate to determine the severity of DR.[31-33] However, capturing multiple fields is technically challenging. The RetinaScope was specifically designed and tested to simplify the process of capturing wide-field images.

The consistently high SUS metrics, ranging from 80.5 to 89.6 throughout the trials, suggest a general ease-of-use and high level of user satisfaction with the RetinaScope.[34]

Furthermore, iterative testing improved the ophthalmic device's usability, as measured by average time of image capture and errors made. After 4 trials, there was a statistically significant decrease in average one-image capturing time decreased from 283 seconds to 34 seconds, and the five-image capturing time decreased from 325 seconds to 119 seconds ($p = 0.01$ for 1 image; $p = 0.02$ for 5 images). Customer discovery interviews with 36 primary care physicians consistently demonstrated that the time required to perform a photograph of the eye was critical for the adoption of this technology and that the time needed to be less than 5 minutes. RetinaScope was able to meet this demand with a single photograph captured in 66 seconds and five images in under 4 minutes. The number of errors made was also reduced across the trials from 8 in trial one to 1 in trial four. These changes, including the Bluetooth notification, handle-grip improvement and

double-click image capture capability, over the course of the trials suggest that the adjustments made throughout the trials resulted in improved usability of the device.

The proof-of-concept round demonstrated that ophthalmic technicians and medical assistants without an ophthalmic background can use the RetinaScope to capture an image of a human retina in significantly less time ($p < 0.02$) than existing devices after a brief training session. The average image capture time of one human eye with the RetinaScope in the last trial was 66 ± 7 seconds for 1 image and 229 ± 114 seconds for 5 images. The image quality was good, with the ability to detect over 94% of emergent findings. This was defined as optic disc edema, optic disc pallor, retinal vascular occlusion, intraocular hemorrhages, and grade III/IV retinopathy.[25] There have been no other reports of retinal image capture time using smartphone ophthalmoscopy, so our comparisons are with other non-smartphone fundus cameras. The DigiScope, a well-accepted fundus camera for teleretinal imaging, reported one-eye imaging times of 5.6 ± 2.4 minutes.[18] Other DR telehealth imaging technologies, such as nonmydriatic fundus photography (NMFP) and ultra-wide field retinal imaging (UWFI) have reported similar image times of 12.8 minutes and 9.2 minutes per patient respectively.[35] RetinaScope requires minimal training and can capture retinal images more rapidly than existing imaging modalities (Figure 2).

We postulate that users' familiarity with the smartphone interface contributes to the ease-of-use of the RetinaScope device. Our results indicate that the steps associated with conventional smartphone imaging were easier to perform than those additional steps not part of standard smartphone photography. In trial 1, where there was a 3-4 day delay between the giving of the instructions and the testing of the device, the tasks that the most users struggled with were those not shared with smartphone picture-taking, for example turning on the RetinaScope Bluetooth button, attaching the external fixation, and selecting the imaging fields (Table 2). Of all the documented errors across the usability studies, 93.3% (14/15) were steps that were outside of normal smartphone imaging, which includes turning the device Bluetooth on, attaching the external fixation screen, and selecting the imaging field (Table 2). The functions that resembled everyday smartphone picture-taking, such as opening the smartphone application and navigating to the capture screen were successfully completed by all users. When the time between instructions and device use was removed in trial 2, the number of users who completed tasks not related to smartphone photography increased. This suggests that the tasks themselves are understandable and executable, but that the novelty of the actions affected the abilities of the users to remember them. This highlights the need to have a rapid video or fact sheet as a refresher for people when using the device. Also, since the ubiquitous act of taking photos on smartphones equipped users with an intuitive understanding of many aspects of the operation of smartphone funduscopy, optimizing usability of the device to reduce the steps that are extraneous to typical smartphone picture taking may further improve its usability.

Reflection/Lessons Learned:

From the project itself, I learned how to take a research idea from inception through to completion. I learned how to bring a master's student to work with me, teach and delegate tasks. I had the opportunity to synthesize my findings and present them in a concise and accessible way to people without any background in the field. I had the chance to practice scientific writing and distilling the main ideas and presenting them in a logical and compelling way on paper.