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Usability testing of a smartphone-based retinal camera among first-time users in the primary care setting

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Abstract

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 validating its use in detection of 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

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CONTRIBUTORSHIP STATEMENT:

PL designed the study with significant contribution from TNK and YMP. PL and JRD collected data for the whole trial. PL analyzed the data and drafted the manuscript with assistance from YMP and TNK. All authors (PL, TNK, YMP, JRD, JG, TM, DAF) participated in manuscript revision and approve the final version of the manuscript.

DISCLOSURES:

TNK, DAF, and TM are inventors of RetinaScope on pending US patent applications.

photography has the potential to be quickly adopted among medical assistants in the primary care setting.

INTRODUCTION:

Routine retinal screening is recommended to prevent blindness from diseases like diabetic retinopathy (DR), glaucoma, age-related macular degeneration, and hypertension.[1–5] However, adherence to recommended screening intervals remains variable. For instance, despite well-established guidelines,[1,2] nearly half of adults with diabetes in the USA do not receive regularly recommended screening, and African-American and Hispanic populations have estimated yearly screening rates as low as 10-20%.[6,7] Barriers to obtaining eye care are multifactorial and range from limitations in health literacy, cultural differences, socioeconomic status, to access to transportation.[6,7] Telehealth is a promising approach for increasing the accessibility of retinal screening. Retinal photography combined with remote evaluation by an eye specialist has been validated as an effective approach in screening for DR in a cost-effective manner.[8–11] Even though routine retinal screening has been a focus as a measurement of quality of care as part of the Health Employers Data and Information Set (HEDIS), eye examination rates have been unacceptably low.[12,13] In order to increase screening rates, there are ongoing efforts to bring this approach to the primary care setting.[14–16] However, widespread implementation is hindered by the relatively high cost of benchtop retinal cameras and the need for skilled operators.

Smartphone-based photography has shown great promise in retinal imaging and screening of diseases such as DR.[10,16–22] Recent work demonstrated that smartphone-based retinal imaging can detect retinal pathologies and produce image quality similar to the reference standard, 7-field fundus photography.[20–22] However, retinal imaging is technically challenging, potentially hindering adoption in non-ophthalmic care or resource-limited settings where personnel have limited experience with ophthalmic imaging.[18,19,23–26] Ease of retinal imaging will be an important factor for implementation of DR screening in the primary care setting and community,[24–26] and ideally may be performed by medical assistants or technicians. The amount of training needed for retinal photography is a key consideration for the adoption of smartphone-based fundus screening.[24–26] Usability testing is an effective way to design a product to the user's preferred way of work and to reduce the time needed for user training and support.[27–30] Nielsen and Landaeur have shown that 4-5 users maximized the cost-to-benefit ratio of detecting usability problems.[29,31] Nielson has also stated that iterative design maximizes the utility of usability because it can detect a greater percentage of usability problems.[29,32]

We therefore conducted usability testing of a smartphone-based retinal camera, RetinaScope, among medical assistants in primary care who had never performed retinal imaging. RetinaScope is capable of capturing high-quality, wide-field images of the retina and utilizes software intelligence and automation to simplify imaging for the novice user.[22,33] The goal of this study was to evaluate the time-on-task, errors, and subjective preferences of primary care medical assistants and technicians using the RetinaScope for the first time, and to see if improvement could be realized based on iterative end-user feedback.

MATERIAL AND METHODS:

The RetinaScope is a handheld imaging adapter that attaches to an iPhone (Apple Inc., Cupertino, CA, USA). It consists of a light-emitting diode (LED) illumination and an organic light-emitting diode (OLED) external display that attaches to the RetinaScope apparatus (Figure 1a,b,c). When positioned in front of the eye, the RetinaScope captures ~50 degree images of the retina through the patient gazing at the green dot on the external fixation screen (Figure 1b). The green dot moves through a sequence of directions (central, inferior, superior, nasal, temporal), reorienting the patient's gaze each time, allowing for the acquisition of multiple overlapping images to generate a ~100-degree montage of the retina with 52.3 pixels per retinal degree (Figure 1b,d). The external display is attached using magnets (so that it can be moved from one side of the apparatus to the other for imaging of both eyes). 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 DR 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 study.[34]

Medical assistants and technicians were recruited for a total of five rounds of usability testing using the RetinaScope in conjunction with an iPhone 5S. Participants were recruited from The Kellogg Eye Center and The Dexter Health Center and Ypsilanti Health Center, all part of the University of Michigan Health System. Participants who owned smartphones, but did not have prior experience with ophthalmic imaging, were included. Participants who opted out due to time constraints were excluded. Participants were given a brief (< 5 minutes) standardized tutorial on how to use the smartphone camera and software application to take a picture of the retina. Participants were shown a sample retinal image and asked to capture a similar photograph of the retina inside a model eye. The model eye was a three centimeter sphere with a pre-dilated pupil of five millimeters and with internal vasculature that mimics the appearance of a human retina (Figure 1c). The study facilitator (PL, JRD) 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).

In total, five rounds of testing were completed. The first four rounds involved testing using the model eye. After the first four rounds of testing using the model eye, a proof-of-concept study was done with the dilated eye of a human volunteer. For each round, two trials of imaging were recorded. For the first trial, users were only asked to capture the central field of the retina. For the second round, users captured all 5-fields. There were 6 main tasks to be completed during each trial (Table 1). During the trials, participants performed all tasks autonomously without the guidance of the facilitator.

Failure to complete any of the steps were noted by the facilitator. Image capture duration was measured from the moment the user removed the device out of the box to the time to acquire an image of the retina that the participant decided was satisfactory. Users self-determined the quality of their photographs based on the sample retinal photograph shown during the initial tutorial, 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, with aggregate scores converted to a minimum of 0 and a maximum of 100. The survey is a robust and reliable tool used for the general assessment of usability. The average score is 68.[29,30] 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.

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 trained a few days before their testing. Instructions consisted of how to attach the iPhone onto the device, attach the external display, turn the device on, open the software application on the iPhone, enter patient identifying information, and capture an image through the custom software. For the second round and beyond, the testing was transitioned into a primary care setting (Dexter Health Center and Ypsilanti Health Center) with medical assistants who were naive to both ophthalmology and retinal photography (n = 17). Training was 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 a double-click image capture capability. 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, 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 eye of a human volunteer (TNK). 1% tropicamide solution was used for dilation. The final round retinal images (N=35) were de-identified and graded by a retinal specialist (YMP). Images were graded for retinal pathology, including DR and macular edema, using the following previously validated 5 point scale from the FOTO-ED study: 1) the quality is inadequate for diagnostic purposes; 2) grader unable to exclude all emergent findings; 3) grader only able to exclude emergent findings; 4) quality is not ideal, but grader able to exclude subtle findings; 5) ideal quality.[35] Emergent findings were defined as grade III/IV hypertensive retinopathy, optic disc edema, and optic disc pallor. Subtle findings included microaneurysms of background diabetic retinopathy.[35]

During this final round involving a human retina, the PI (TNK) volunteered to have his eye imaged. The study was exempt from the University of Michigan Institutional Review Board approval because it did not involve patients or protected health information (PHI).

Data was analyzed using statistical methods comparing image capturing time across trials. An independent T-test was done comparing the image capture time from the first trial with the image capture times in the 4th trial. 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:

A total of 31 medical assistants and technicians were recruited to participate. The average age of the participants was 34.1 years (standard deviation = 7, minimum = 21, maximum = 50). 42% of the participants were female, 58% were male. All users self-reported not having any experience with ophthalmic imaging. All reported having experience using their smartphones to take pictures.

There was an overall decrease in average image capture time after each round (figure 2). (Trial 1 (N = 7): 260 ± 60 seconds for 1 image, 325 ± 60 seconds for 5 images; Trial 2 (N = 5): 55 ± 20 seconds for 1 image, 121 ± 41 seconds for 5 images; Trial 3 (N = 6): 43 ± 16 seconds for 1 image, 108 ± 13 for 5 images; Trial 4 (N = 6): 34 ± 17 seconds for 1 image, 119 ± 26 seconds for 5 images). There was a statistically significant difference in 1 image and 5 image capturing times between the first trial and the last trial ($p = 0.01$ for 1 image; $p = 0.02$ for 5 images). For the proof-of-concept test on a human volunteer (N=7), the average time to capture 1 image was 66 ± 7 seconds, and 229 ± 114 seconds to capture 5 images (figure 2).

The user-reported SUS grades remained consistently high throughout all of the trials. In Trial 2, the average rating was 80 ± 14.5. In trial 3, the average rating was 78 ± 15.1. In trial 4, the average rating was 90 ± 10.4. Finally, in the human trial, the average rating was 93 ± 5.1.

All of the steps were closely observed with an established checklist of required steps and failure to complete them were tallied (Table 2). Attaching the device and opening the iPhone application to navigate to the capture screen did not cause any problems for any of the participants in all the trials. Turning the device on and syncing it with the iPhone's Bluetooth was a problem with 25.8% (8/31) of the participants involved in the first 2 trials. After a software modification to remind users to turn the device on for trial 3, none of the subsequent participants experienced difficulties with that step. 12.9% (4/31) of participants made errors in attaching the external fixation screen by either forgetting to attach the screen or putting it on the wrong side. After the software adjustment was made in round three to prompt users to adjust when the screen was attached to the wrong side, only one participant made an error. About 25.8% (8/31) of participants reported afterwards that the device felt heavy (Table 2).

There was also an overall decrease in the errors made across trials. In total, eight errors were made in trial one, five errors in trial two, zero errors in trial three, and one error in trial four (Table 2).

In terms of image quality of the photograph from the human eye trial, the grader could exclude all emergent findings in 94% (33/35) of the photos. The grader could exclude subtle findings in 51% (18/35) images.

DISCUSSION:

The inherent qualities of smartphones make them well suited for primary care based DR 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 DR screening have been effective in decreasing the rates of blindness in countries such as the United Kingdom and Ireland.[36] 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.[20–22,26] 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.[27–29] Based on literature review performed on July 2019, this is the first study to test the usability of a smartphone ophthalmoscope by non eye-care specialists.

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.[30]

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. 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 five minutes. The results from this study show that the RetinaScope was able to meet this demand for both single photograph and five-image photograph. The number of errors made was also reduced across the trials. 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 a diagnostic image of a human retina within minutes of first-time operation. To our knowledge, 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 ultrawide field retinal imaging (UWFI) have reported similar image times of 12.8 minutes and 9.2 minutes per patient respectively.[37] Based on the results from this pilot study, RetinaScope can capture retinal images more rapidly than reported with existing imaging modalities. The image quality had the ability to detect nearly

all emergent findings.[35] This is promising for a screening device like this, as it allows for the appropriate referral of suspected retinal pathology.

It is also worth noting that the ability to capture 5-field images is important in the screening accuracy of DR, as single-field images may not be adequate to determine the severity of DR.[38–40] However, capturing multiple fields is technically challenging. The RetinaScope was specifically designed and tested to simplify the process of capturing wide-field images.

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 (ie. opening smartphone application and navigating to capture screen, capture image) were easier to perform than those additional steps not part of standard smartphone photography (ie. turning on Bluetooth display, attaching external fixation screen). 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 (ie. 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, the majority 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. Participant feedback at the end of the session confirmed this suspicion. 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 fundoscopy, optimizing usability of the device to reduce the steps that are extraneous to typical smartphone picture taking may further improve its usability.

There were several limitations in our study. Our data focused primarily on image capture using a model eye for 4 rounds of testing with limited capture on a human eye only in one final round of testing, which may not be representative of clinical usage on patients with varying anatomy and retinal pathology. In addition, participants using the device immediately after receiving directions may not be representative of a true clinical encounter. We recognize that this difference in timing of instructions is an additional variable contributing to the difference in image capture time between rounds. Our data was limited by a relatively small sample size per iteration, and were not directly compared with other devices. Additionally, image quality was not evaluated on the model eye, so it is unclear how well they would be graded. All participants in our study reported familiarity with using a smartphone to take photos, and thus it is unclear if people without this familiarity will be able to use the RetinaScope equally well and rapidly. However, with the growing ubiquity of smartphones in the general population worldwide, this likely is not a major issue. In

addition, our subject was pharmacologically dilated, and photographing through an undilated pupil could pose greater challenges to medical assistants. However, this study serves as a proof of concept study for larger usability studies of the RetinaScope.

Despite these limitations, our study demonstrated the usability of the RetinaScope by ancillary health workers without prior retinal experience to capture quality retinal photos in a timely manner. Future studies will involve usability testing on human eyes directly comparing the different types of existing retinal cameras with a larger group of users and with multiple masked graders evaluating the quality of the images taken. Prior to future studies, modifications will include a brief video or tutorial refresher so that instructions are standardized immediately prior to device use.

CONCLUSION:

Smartphone-based retinal photography is a promising method for increasing accessibility of retinal screening in the community. This study demonstrates that usability testing and feedback-driven engineering is capable of rapidly improving smartphone-based retinal imaging among novice users. RetinaScope enables high-quality retinal photography among medical assistants in primary care within minutes of first-time operation. Further investigation is required to validate screening of retinal disease in the primary care setting using RetinaScope operated by medical assistants and non-ophthalmic personnel.

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Figure 1. Handheld operation of RetinaScope:

A) Side view of RetinaScope being used to image a model eye B) Front view of RetinaScope with illumination camera and the magnetically attached side display that provides an external fixation target for the contralateral eye C) RetinaScope mobile phone application allows for one-click image capture D) Image of human retina captured by RetinaScope

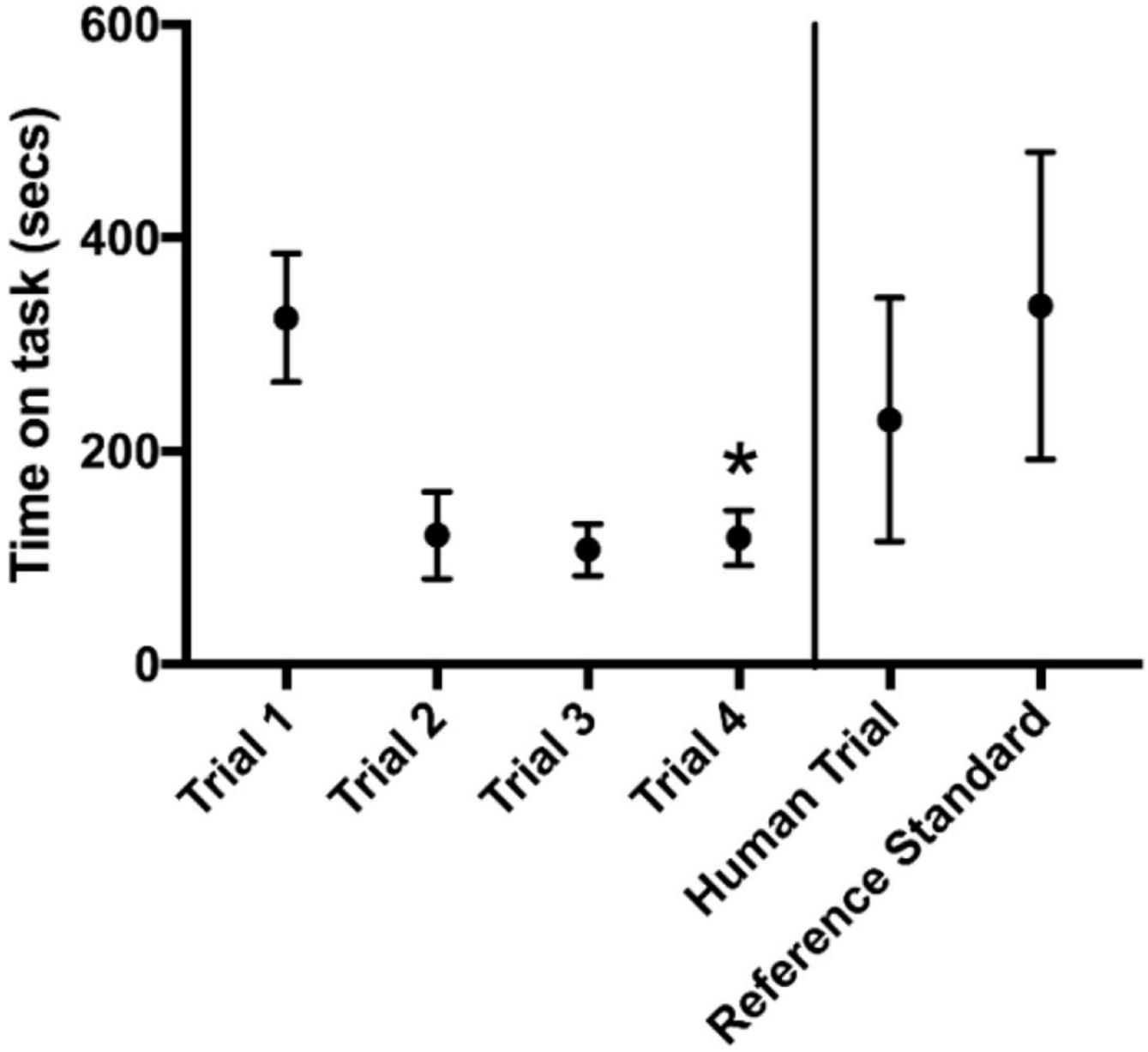

Figure 2. Average time spent capturing 5 retinal photos per trial:

There was a significant decrease in image capturing time throughout the trials, with average time decreasing from 324.9 ± 60.3 seconds to 118.5 ± 25.6 seconds by trial 4 ($p = 0.02$). The average time on task for the human trial (229.4 ± 114 seconds) was comparable to the standard reference (336 ± 114 seconds) set by existing devices.

Table 1:

Tasks to be completed during RetinaScope usability testing

1. Attaching device to smartphone
2. Turning the device on/iPhone Bluetooth
3. Open App and navigate to capture screen
4. Attach eye target on the correct side
5. Select imaging field
6. Capture image

Table 2:

Failure to complete task

	Trial 1 ***(N = 7)***	**Trial 2** ***(N = 5)***	**Trial 3** ***(N = 6)***	**Trial 4** ***(N = 6)***	**Human Trial** ***(N = 7)***
1. Attach device	0	0	0	0	0
2. Turn device on/iPhone Bluetooth	3	5	0	0	0
3. Open App and Navigate to capture screen	0	0	0	0	0
4. Attach eye target on the correct side	3	0	0	1	0
5. Select imaging field	2	0	0	0	0
6. Capture image	0	0	0	0	0
Total	8	5	0	1	0

Note: Post-trial additions included Bluetooth reminder after trial 1; double-clock capability after trial 2; handle-grip after trial 3