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WELCH ALLYN® RETINAVUE® 700 IMAGER

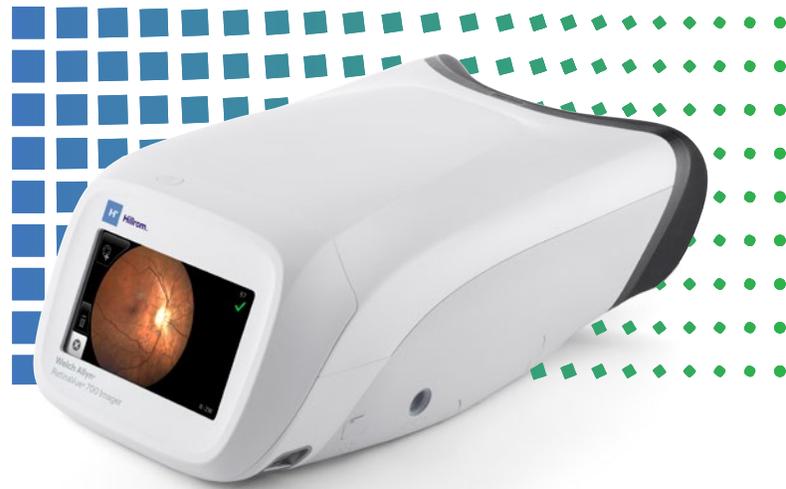
Image Readability Compared to a Tabletop Retinal Camera

BACKGROUND

Tele-retinal programs in primary care practices have demonstrated their ability to dramatically increase patient compliance rates for the diabetic retinal exam.^{1,2} Most successful programs have used tabletop retinal cameras like the Nidek® NM-1000 or TopCon® NW400,² which are easy to operate and require minimal user training and workflow interruption. However, tabletop retinal cameras are not always a feasible choice for primary care practices, as they require a dedicated exam room and can be costly.³

The Welch Allyn RetinaVue 700 Imager (RV700) was designed for use in primary care. It is a handheld retinal camera that automatically captures right and left retinal images with minimal training and no technique required by the user. Studies have shown that handheld retinal cameras currently on the market may not produce images of high quality to allow for adequate diabetic retinal imaging.³⁻⁵ However, the new technology in the RV700 has the potential to deliver tabletop image quality in a portable and affordable device.

This study aimed to evaluate the image quality of the RV700 compared to tabletop camera by examining the readability of retinal images when graded by retina specialist readers. It was hypothesized that the RV700 would have readability rates as good as those of a tabletop retinal camera.



“...standard tabletop digital retinal cameras are still the predominant imaging devices used in telemedicine-based diabetic retinopathy screenings (TMDRS) throughout the world, although smaller, low-cost, lightweight, handheld retinal cameras are beginning to emerge as a convenient alternative to the traditional bulky cameras. These smaller devices fit better with the constraints of space and mobility that are often encountered in diabetes care outside of the eye care practice.”³

METHODS

This study recruited patients from an ophthalmology clinic located in Syracuse, NY. Patients were eligible to participate if they had no known eye sensitivity to light exposure and did not have an implantable or external medical device. Patients were excluded from participation if they had a media opacity like cataracts or another eye condition that would impact the ability to capture retinal images. Demographics collected included age, ethnicity, diabetes status and pupil size.

Eligible patients had retinal images captured with the RV700 and the TopCon NW400 tabletop camera. Prior to image capture, patients were placed in a dark room for five minutes to allow their pupils to naturally dilate. A trained camera operator captured right and left eye images using the tabletop camera with a one-minute wait between images. After a one-minute wait, the camera operator then captured right and left eye images using the RV700 with a one-minute wait between images. If an image was determined to be low quality, one additional image of that eye was captured before moving on to the next eye.

Captured retinal images from both the RV700 and the tabletop camera were submitted for over-read by three retina specialist graders through the RetinaVue Network, Hillrom's data management software. Graders evaluated each image for readability based on their ability to visualize the retina from the image color, brightness, clarity, contrast and resolution. A readability score was calculated for each patient by averaging the number of readers able to grade the image. A readability score of 0 indicated that no reader could grade the image and a readability score of 1 indicated that all three readers could grade the image.

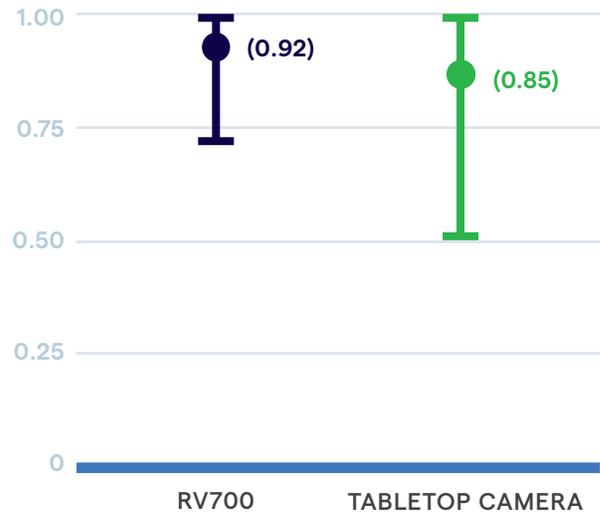


RESULTS

A total of 70 patients were screened for enrollment. 14 patients were excluded from participation. Of these, nine (64.3%) patients were excluded for confirmed or probable cataracts, two (14.3%) patients were excluded for pupil sizes below device specifications, and three (21.4%) patients were excluded because of previous eye surgeries or glaucoma surgery. Of the remaining 56 patients, the average age was 52 (range 23 to 82). There were 36 (66.7%) Caucasian, eight (14.3%) black, seven (12.5%) Hispanic, two (3.6%) Native American, one (1.8%) Indian and two (0.4%) people with unreported ethnicity enrolled in the study. There were eight (14.3%) patients with Type 2 diabetes. The average size pupil was 5.4 mm (range 2 mm to 8 mm).

The mean readability score for RV700 was 0.946 ± 0.227 and for the tabletop camera was 0.857 ± 0.353 ($P = 0.029$).

EXAM READABILITY:



LIMITATIONS

This study was limited by its small sample size. Patients attending an appointment for eye care with an ophthalmologist were enrolled in the study as a convenience sample. These patients may not be similar to patients receiving teleretinal exams in primary care. Future studies can investigate larger samples sizes of patients in primary care settings to better understand the retinal camera's readability.



CONCLUSION

This study examined the readability of images captured with the handheld RV700 compared to a tabletop retinal camera, which are commonly found in eye care specialist settings and also in some primary care-based teleretinal imaging programs. The RV700 demonstrated statistically significantly better readability than the tabletop camera in this small study. This study demonstrates that the image quality from the RV700 is at least as good as that of a tabletop camera when used on the same patient. Future studies can continue to investigate camera performance in larger and unbiased patient groups.



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