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# Evaluating a Portable, Noncontact Fundus Camera for Retinopathy of Prematurity Screening by Nonophthalmologist Health Care Workers

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***Purpose:*** To evaluate (1) the feasibility of nonophthalmologist healthcare workers (HCWs) obtaining images of sufficient quality for retinopathy of prematurity (ROP) screening using a Food and Drug Administration-approved portable, noncontact, narrow-field fundus camera (i.e., Pictor; Volk Optical, Inc, Mentor, OH) and (2) the accuracy of grading these images to identify infants in whom treatment-warranted (type 1) ROP developed.

***Design:*** Prospective cohort study.

***Participants:*** Infants undergoing routine ROP screening examinations (i.e., birth weight ≤1500 g, gestational age ≤30 weeks, or both, or selected infants with a birth weight of 1500−2000 g or gestational age >30 weeks and an unstable clinical course).

***Methods:*** We prospectively recruited infants undergoing ROP screening examinations at a community hospital. On the same day an ophthalmologist examined them, a trained HCW imaged their retinas using the noncontact camera. Two masked ROP experts graded these images remotely. We calculated both the percentage of gradable images (i.e., having at least 3 quadrants with sufficient image quality), as well as the accuracy of identifying infants in whom type 1 ROP developed.

***Main Outcome Measures:*** Percentage of gradable images and the sensitivity and specificity of each grader for identifying infants with type 1 ROP by grading for the presence of preplus or plus disease.

***Results:*** Ninety-nine infants were included. Overall, 92.4% and 94.2% of all infant imaging sessions were considered gradable by graders 1 and 2, respectively. Among gradable images, the sensitivity of both graders for identifying type 1 ROP by grading for the presence of preplus or plus disease was 100% (95% confidence interval [CI], 95%−100%), and the specificity was 91% (95% CI, 83%−95%) for grader 1 and 93% (95% CI, 86%−96%) for grader 2.

***Conclusions:*** It was highly feasible for trained HCWs to obtain digital retinal images of sufficient quality for ROP screening using a noncontact fundus camera. By grading for the presence of preplus or plus disease, graders identified infants in whom type 1 ROP developed with high sensitivity and specificity. The use of portable, noncontact retinal cameras by trained HCWs could increase our workforce in ROP screening and identify infants needing indirect ophthalmoscopy examinations by an ophthalmologist. *Ophthalmology Retina 2017;■:1−8 © 2017 by the American Academy of Ophthalmology*

Although the occurrence of childhood blindness resulting from retinopathy of prematurity (ROP) can be reduced by appropriate screening and treatment, there is a shortage of skilled ophthalmologists who are able and willing to screen for ROP.[1,2] To fill this gap, studies have explored the use of nonophthalmologist health care workers (HCWs) to increase the workforce screening for ROP. Previous studies have evaluated the use of nonophthalmologist HCWs to screen for ROP using a direct ophthalmoscope,[3] a teaching mirror of an indirect ophthalmoscope,[3] wide-field contact retinal imaging,[4,5] and narrow-field noncontact retinal imaging.[6]

A previous study found it was feasible for a trained nonophthalmologist HCW using a narrow-field noncontact retinal camera to obtain retinal images from infants that were of sufficient quality to identify infants with treatment-warranted (type 1) ROP.[6] Although these results showed promise as an alternative way to identify infants requiring examination by an ophthalmologist, the authors also noted the need to improve the ability of the HCW to obtain gradable images consistently. A limitation of this study was that it used a single imager who had a background in ophthalmic photography.

The purpose of the present study was to evaluate (1) the feasibility of having multiple nonophthalmologist HCWs in a community hospital setting obtain digital retinal images that were of sufficient quality to grade for ROP screening using a narrow-field noncontact camera and (2) the accuracy



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of grading these images to identify infants in whom treatment-warranted (type 1) ROP developed.

## Methods

Institutional review board approval was obtained from both Cape Fear Valley Health System and Duke Health System. Written informed consent was obtained from a parent or guardian of each study participant. This study was conducted in accordance with the Health Insurance Portability and Accountability Act and adhered to the tenets of the Declaration of Helsinki.

We prospectively recruited infants undergoing routine ROP screening examinations in a level III neonatal intensive care unit at a community hospital. If an infant was enrolled and later transferred to Duke University Hospital (standardly done if the infant was believed to be nearing type 1 ROP), imaging continued at Duke if the infant was re-enrolled at this site. Infants were eligible for inclusion if they fell within current ROP screening guidelines (i.e., birth weight $\leq$1500 g, gestational age $\leq$30 weeks, or both, or selected infants with a birth weight of 1500−2000 g or gestational age >30 weeks and an unstable clinical course).[7] Infants were excluded if they had been treated already for ROP (i.e., laser or anti−vascular endothelial growth factor injection).

On the same day enrolled infants underwent standard-of-care ROP screening by an ophthalmologist, a trained HCW imaged their retinas with a Food and Drug Administration-approved narrow-field noncontact retinal camera (Pictor; Volk Optical, Inc, Mentor, OH) within 4 hours of the screening examination. All clinical eye examinations at the community hospital were performed by a general ophthalmologist (J.W.R.) with more than 15 years of experience in ROP screening and at the academic referral center by 1 of 2 fellowship-trained pediatric ophthalmologists (S.F.F. or D.K.W.), each with more than 20 years of experience in ROP screening and treatment. No additional eye drops were administered for the purposes of this study. Imaging was performed without using an eyelid speculum; rather, the eyelids were held open gently with the fingers of the imager, another HCW, or both (Fig 1). During imaging, a member of the infant's care team monitored the infant for clinical stability. If the infant became unstable during imaging, the imager was allowed to reattempt imaging with the permission of the care team when the infant was more stable.

Before recruiting study participants, nonphysician HCWs were trained to use the noncontact camera. Training consisted of: (1) reviewing the user's manual; (2) imaging undilated adult volunteers under supervision; (3) independently practicing imaging of undilated adult volunteers; (4) submitting images obtained from undilated adult volunteers showing the optic nerve centered, to the left, and to the right of the images; and (5) imaging study participants with the noncontact camera under supervision of the study principal investigator (S.G.P.). None of the imagers at the community hospital had any prior experience performing retinal imaging.

At each imaging session, the goal was to obtain focused images showing the major retinal vessels in all 4 quadrants of both eyes. Because of the noncontact camera's narrow field of view (45°), only images showing the optic nerve were eligible for inclusion to provide orientation. The noncontact camera was set to capture and store simultaneously an image pair (i.e., the color and corresponding red-free image) when images were obtained. After each imaging session, an imager chose up to 3 image pairs per eye to display the maximum length of retinal vessels captured in all 4 quadrants. To simulate real ROP screening, the imager uploaded these images along with documentation of the birth weight, gestational age, and postmenstrual age at the time of imaging into web-based software (FocusROP; Trumbauersville, PA; Fig 2).

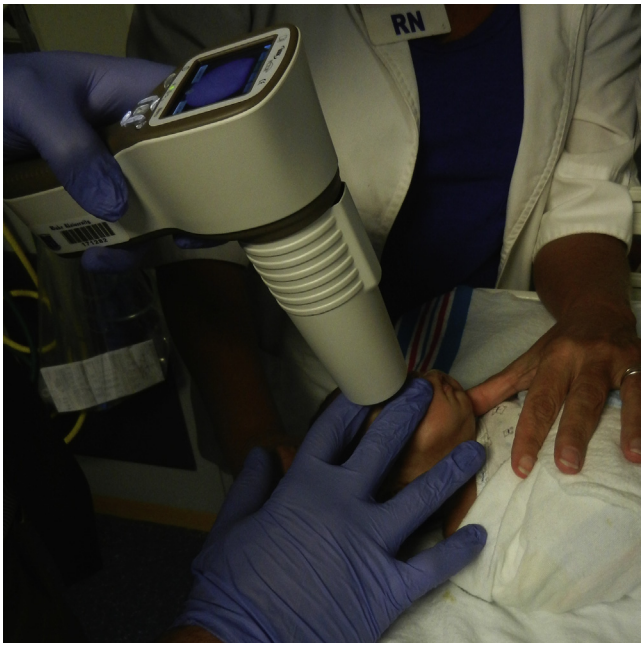


**Figure 1.** Photograph showing a trained nonophthalmologist health care worker using a Food and Drug Administration-approved narrow-field noncontact retinal camera, Pictor (Volk Optical, Inc, Mentor, OH) to image the fundus of a prematurely born infant. The eyelids are being held open gently by the fingers of the imager. Imaging was performed without the use of an eyelid speculum.

Using the web-based interface, these digital retinal images were graded independently by 2 masked ROP experts (S.F.F. and A.K.H.) from a remote location. Although 1 of the graders (S.F.F.) did examine some of the study participants, she did not recognize their identity in the uploaded images. To simulate a real telemedicine screening scenario, graders viewed images in chronological order (by increasing postmenstrual age) for each infant and could review images from previous weeks, but were not allowed to preview future imaging sessions. Graders evaluated uploaded images for: (1) image quality (good/fair/poor), (2) number of gradable quadrants (0−4), and (3) the presence of preplus or plus disease. Image quality was considered good if there was a clear view of the optic nerve and retinal vessels and the grader could determine vessel dilation and tortuosity, fair when it was difficult to determine either vessel dilation or tortuosity, and poor when the grader could determine neither vessel dilation nor tortuosity (Fig 3). As defined in previous studies, the number of gradable quadrants was the number of quadrants where the grader could visualize adequately 1 or more disc diameter lengths of a major retinal vessel.[6,8] We believe that this is the minimum length of a major retinal vessel that must be visualized to allow the grader to be able to make some assessment of the dilation and tortuosity of a vessel in that quadrant. The presence of preplus or plus disease was based on International Classification of ROP definitions.[9,10] SAS software version 9.4 (SAS Institute, Inc, Cary, NC) was used for all statistical analysis.

For the feasibility portion of this study, we evaluated the percentage of gradable imaging sessions by eye, infant, and postmenstrual age. For each eye, an imaging session was considered