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Retinal imaging in premature infants using the Pictor noncontact digital camera

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Abstract

Purpose—To evaluate, first, the feasibility of using Pictor, a new portable, noncontact digital fundus camera, to obtain high-quality retinal images of prematurely born infants and, second, the accuracy of grading these images for clinically significant posterior pole vascular changes, that is, pre-plus or plus disease, compared to indirect ophthalmoscopy.

Methods—Pictor retinal images were obtained on a convenience sample of prematurely born infants during routine examinations for retinopathy of prematurity (ROP). Images were reviewed and graded by two ROP experts, who were masked to demographic and clinical examination findings.

Results—A total of 96 eyes of 48 infants were included. The mean field of view was 5.0×6.1 disk diameters (DD). Grader 1 found quality to be fair or good in 96% of images; grader 2 in 97% of images. Grader 1 judged images as having at least 1 DD length of a major vessel in 3 or 4 quadrants in 80% of images; grader 2 in 86% of images. The sensitivity and specificity of grading pre-plus or plus disease on Pictor images was 100% and 79%, respectively, for grader 1, and 83% and 85%, respectively, for grader 2, compared to the reference standard of indirect ophthalmoscopy.

Conclusions—The Pictor fundus camera can capture digital retinal images of prematurely born infants that have quality sufficient for accurate expert grading in comparison to clinical examination. Pictor shows promise as an ROP screening tool.

Retinopathy of prematurity (ROP) is an important cause of blindness in high- and middle-income countries.^{1,2} Appropriate screening and treatment could reduce the burden of childhood blindness from ROP, but there are many barriers to effective ROP screening, including the shortage of ophthalmologists trained³ and willing⁴ to screen for ROP and the

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lack of patient access to these trained ophthalmologists. Alternative methods to screen for ROP are needed, not only to decrease the burden of screening on the limited number of trained ophthalmologists but also to enable more at-risk infants to have access to screening. To address the need for increased access to the limited number of trained ophthalmologists willing to screen for ROP, investigators have explored retinal imaging and telemedicine.⁵⁻⁸ This study investigated Pictor (Volk Optical Inc, Mentor, OH), a new, portable, noncontact digital fundus camera approved by the Food and Drug Administration (FDA), as a potential ROP screening tool (Figure 1A). Pictor is an FDA Class II medical device, registered by 510k premarket notification in 2011. The indication for use of the Pictor camera is “to capture digital images and video of the fundus of the human eye and surrounding area.”⁹ The camera has capability for both anterior and posterior imaging. For posterior imaging, it can record color and red-free images of the retina simultaneously, which can then be stored digitally for subsequent review. The purpose of this study was to evaluate, first, the feasibility of using the Pictor camera to obtain high-quality retinal images of prematurely born infants and, second, the accuracy of grading these images for pre-plus or plus disease.

Methods and Materials

This study was approved by the Duke Health System Institutional Review Board and conformed to the requirements of the US Health Insurance Portability and Accountability Act of 1996. A retrospective review was performed on all retinal images of infants taken with the Pictor camera during routine ROP rounds over a 6-month period from December 2011 to May 2012.

A convenience sample of images was originally obtained for quality assurance purposes; that is, prior to purchasing the camera, we tested the camera’s ability to image the infant retina. The imager was a pediatric ophthalmologist (SGP) who was using the Pictor camera for the first time on prematurely born infants after reading the user’s manual and practicing on undilated adults.

During image collection, the imager attempted to obtain a focused still image of the infant retina which included an image of the optic nerve. Most images were taken after the infant had been examined by indirect ophthalmoscopy by one of 2 pediatric ophthalmologists trained in ROP screening (DKW or SFF). All photographs were obtained by one imager (SGP) without the use of a lid speculum (Figure 1B) while a nurse monitored the infant from nearby. Most imaging was performed with the baby swaddled and without an additional person holding the infant. The imager attempted to obtain images on all infants undergoing routine ROP examinations unless the infant was clinically unstable, the infant’s nurse felt the child should not undergo imaging, the infant was a participant in a RetCam (Clarity Medical Systems, Pleasanton, CA) imaging research study, or the infant’s parents or legal guardian refused retinal imaging.

Infants were included if there was at least one color and one red-free photograph taken of each eye at the same imaging session that included an image of the optic nerve. If eligible images were obtained at more than one imaging session, the session with the better-quality images was selected. After the eligible infants and their respective images were selected, one

of the authors (SGP) created an electronic slide show where each slide included either the color or red-free image(s) of either the right or left eye of an infant. On each slide, up to 3 images were included for each eye (Figure 2). Thus 4 slides were included for each infant—one of 1–3 color image(s) of the right eye, one of 1–3 color image(s) of the left eye, one of 1–3 red-free image(s) of the right eye, and one of 1–3 red-free image(s) of the left eye. The slides created, along with a sample of repeat images, were randomly placed in the slideshow, with no accompanying demographic or clinical information for the graders. The small subset of repeat slides included an enhanced sample of about 10% of the original slides ($n = 20$), with an equal number of color and red-free images selected from right and left eyes. The repeats were randomly chosen and were selected to enhance the proportion of repeats with pre-plus and plus disease. Images from the “International Classification of ROP (ICROP) Revisited” publication¹⁰ were cropped to an oval to display a field of view similar to that of the Pictor images in order to create an introductory slide showing the range of disease for pre-plus and plus disease (Figure 3). This introductory slide was given to the graders to be used as a basis for comparison with Pictor images. For each eye, the image with the greatest field of view was quantified in disk diameters (DDs), using the average DD measured from the same image.

Two ROP experts (DKW and SFF) reviewed the slide show of color and red-free images independently and evaluated them for quality, number of gradable quadrants, and posterior pole disease. Image quality was graded as good, fair, or poor based on the ability of the grader to determine the dilation and/or tortuosity of the vessels in the image(s). “Good” was defined as an image in which there was a clear view of the optic nerve and vessels and the grader could easily discern the dilation and tortuosity of the vessels in the image; “fair” as an image in which it was difficult to clearly discern either the dilation or tortuosity of the vessels; and “poor” as an image in which the grader was unable to clearly determine both characteristics (dilation and tortuosity) of the vessels. The number of gradable quadrants (0–4) was based on the adequate visibility of at least 1 DD length of a major vessel in a given quadrant. Posterior pole disease was graded as normal, pre-plus, or plus disease. For this study, pre-plus disease was defined according to the ICROP revisited definition of “vascular abnormalities of the posterior pole that are insufficient for the diagnosis of plus disease but that demonstrate more arterial tortuosity and more venous dilatation than normal.”¹⁰ Plus disease was defined as the presence of sufficient vascular dilation and tortuosity present in at least 2 quadrants of the eye as compared to a standard photograph.^{10,11} Because each of the graders had performed ROP screening during the time period of image acquisition by the Pictor camera, they agreed to recuse themselves from grading any images that they recognized.

SAS 9.3 (SAS Institute Inc, Cary, NC) was used for all statistical analysis. Before examining the data, the reference standard was defined as the diagnosis of plus disease by indirect ophthalmoscopy during the clinical examination. Clinically significant posterior pole vascular changes was defined as the presence of pre-plus or plus disease. For the primary analysis of accuracy, we evaluated the ability of each grader to accurately identify pre-plus or plus disease on Pictor images compared to the reference standard. We reasoned that in a screening program, it would be important to flag all cases that are pre-plus or worse, with the goal of detecting all cases of true plus disease. A secondary analysis for

accuracy compared the grading of Pictor images for pre-plus or worse disease to the diagnosis of pre-plus or worse disease by indirect ophthalmoscopy during the clinical examination on the same infant at the same screening session. Analysis was carried out for all images and then separately for color and red-free photographs.

Results

Of the 54 infants for whom retinal images were taken with the Pictor camera during the study period, 6 (11%) did not fulfill inclusion criteria. Five infants had images of only one eye obtained at a given imaging session and one infant did not have an image that included a view of the optic nerve. A total of 96 eyes of 48 infants were included. Mean gestational age was 27 weeks (range 23–34), mean birth weight was 872 g (420–1480), and mean postmenstrual age at examination was 38 weeks (31–47). On clinical examination by indirect ophthalmoscopy during the screening sessions, 6 (6%) of eyes had plus disease, 7 (7%) had pre-plus disease, and 83 (86%) had a normal posterior pole. Neither of the graders recognized any of the Pictor images presented to them and did not need to recuse themselves from grading any of the images. The mean field of view for all eyes was 5.0 DD $\times$ 6.1 DD. Overall, grader 1 found image quality to be good or fair in 96% of images; grader 2 in 97% of images (Table 1). Grader 1 judged images as having at least 3 gradable quadrants in 80% and grader 2 in 86% of images (Table 2).

Using the reference standard of indirect ophthalmoscopy–reported plus disease, the sensitivity of grading pre-plus or plus disease in Pictor images was 100% for grader 1 and 83% for grader 2 for both the color and red-free images (data for grading of color images are shown in Table 3). Figure 4 shows the Pictor images of the right eye of the infant who was diagnosed with plus disease in both eyes by indirect ophthalmoscopy on clinical examination and whose Pictor images of the right eye were judged as having pre-plus disease by grader 1 and no disease by grader 2. Using the reference standard of indirect ophthalmoscopy–reported plus disease, the specificity of grading pre-plus or plus disease in Pictor images was 79% (80% for the color and 79% for the red-free images) for grader 1 and was 85% (87% for the color and 83% for the red-free images) for grader 2 (data for grading of color images are shown in Table 3).

Using the reference standard of indirect ophthalmoscopy–reported pre-plus or plus disease, the sensitivity of grading pre-plus or plus disease in Pictor images for grader 1 was 92% for both the color and red-free images and for grader 2 was 81% (77% for the color and 85% for the red-free images). The specificity of grading pre-plus or plus disease in Pictor images for grader 1 was 86% (88% for the color and 84% for the red-free images) and for grader 2 was 90% (92% for the color and 89% for the red-free images).

Intragrader reliability for grading pre-plus or plus disease was 95% for both graders ($\kappa = 0.9$). Excluding the 2 color images grader 1 considered to have insufficient quality to be graded, the intergrader reliability for pre-plus or plus disease was 93% ($\kappa = 0.8$) for color and 91% ($\kappa = 0.7$) for red-free images (data for grading of color images are shown in Table 4).

Discussion

The Pictor camera was able to obtain images of the retina that had a wide enough field of view and sufficient quality to grade for the presence of pre-plus or plus disease in prematurely born infants at risk for ROP. While the images of the fundus captured by the Pictor camera had a wider field of view (45°) than the NIDEK NM200-D camera (Nidek Inc, Gamagori, Japan) (approximately 30°), it did not have as wide a field of view as shown in other studies using other imaging systems, such as the RetCam⁵ (120° or 130° field of view) or the Optos Panoramic 200Tx imaging system (Optos PLC, Scotland, UK)¹² (approximately 200° field of view). However, the view afforded by the Pictor images was adequate to evaluate the posterior pole for the presence of pre-plus or plus disease (Figure 5).

The presence of plus disease drives the decision to treat ROP¹³; however, we included the presence of pre-plus disease in our definition of clinically significant posterior pole vascular changes because the presence of pre-plus disease has been shown to be highly associated with the development of treatment-requiring ROP and to contribute prognostic value regarding the future need for laser therapy beyond that already offered by birth weight, gestational age, ROP zone, and ROP stage.¹⁴ A study comparing posterior pole disease to peripheral retinal pathology in ROP found that normal posterior pole vessels are a reliable marker for the absence of stage 3 ROP.¹⁵ Thus, whereas the presence of stage 3 ROP in zone I without the presence of plus disease is an indicator for treatment in ROP, it may be reasonable to base a screening program on the analysis of images of posterior retinal vessels alone. Also, in a previous study using images of the posterior pole acquired using the Vantage Plus LED Digital Binocular Indirect Ophthalmoscope imaging system (Keeler Instruments Inc, Broomall, PA), we found that the sensitivity of identifying plus disease diagnosed by clinical examination was increased if the presence of not only plus disease but also pre-plus disease was identified when grading images of the posterior pole.¹⁶ Of course, this approach reduces specificity, but high sensitivity is more important when screening for ROP that might require treatment.

The grading of retinal images acquired by the Pictor camera for pre-plus or plus disease showed a high sensitivity and specificity, suggesting that the Pictor camera shows promise as an ROP screening tool. We had the graders evaluate the retinal images taken by the Pictor camera for the presence of pre-plus or plus disease to determine if infants would pass or fail the screening test and require a standard diagnostic examination by an experienced ophthalmologist using indirect ophthalmoscopy. Infants would fail the screening test if the images obtained by the Pictor camera showed the presence of pre-plus or plus disease. This would in turn trigger the need for an examination by a trained ophthalmologist.

In the study eyes with clinically diagnosed plus disease by indirect ophthalmoscopy, one grader judged all cases as either pre-plus or plus, whereas the other grader underdiagnosed one case of clinically diagnosed plus disease as normal in both the color and red-free images. On further inspection of these images, it appeared that in the superotemporal quadrant, the vessels appeared slightly more tortuous than what one might see in a normal posterior pole (Figure 4). Thus the decision to call these images pre-plus or worse would

depend on subjective evaluation of the individual grader, who in this case graded the infant as normal. If infants were screened in only one eye or on one occasion, this may be a greater concern; however, we advocate that in this “screening” test, both eyes need to be adequately screened, so that if either eye fails the screening examination, the infant would require a standard diagnostic examination by an experienced ophthalmologist using indirect ophthalmoscopy. In this case, at the same session, both graders graded the color and red-free images of the other (left) eye as pre-plus or worse disease. Thus this infant would have failed the screening test and would have been referred for examination by an ophthalmologist.

The Pictor camera offers many qualities that are suitable to a screening tool. It weighs about 1 pound (450 g), is portable, and can easily be fit into a bag or briefcase. The camera is noncontact, and even though it comes with a silicone eyepiece to help position and support the camera over the eye to be imaged, we did not find this attachment necessary and did not use it during our imaging sessions. During this study, all images were acquired by having the imager hold the eyelids open without using a lid speculum, thus eliminating the need for topical anesthesia, as well as eliminating an additional source of discomfort for the infant. In our experience, imaging was relatively quick and could sometimes be completed in less than one minute. The camera was easy to operate and the aid of an additional person was not required either to hold the child or to open the eyelids for imaging.

Our study has several limitations. Because study images were acquired from a convenience sample, we were unable to evaluate the feasibility of obtaining digital fundus images on all infants who qualified for an ROP screening examination at a given time. Also, our sample may not be representative of all infants undergoing ROP screening, and our results may not be generalizable to all infants undergoing ROP screening; we excluded infants who were not clinically stable, and these infants are likely at higher risk for ROP, particularly severe ROP. Of those infants for whom retinal images were taken with the Pictor camera but who did not fulfill inclusion criteria, it is unclear whether images were not obtained because of poor dilation, the true inability to obtain images of the fundus despite adequate dilation, imager effort, or nurse discretion. Also, images were acquired early in our experience with this camera and not expressly for the purpose of a study; thus we did not have a standardized protocol for maximizing image quality and centration. Our resultant analysis may therefore have underestimated the Pictor camera’s ability to obtain high-quality and well-centered images, affecting the reported sensitivity and specificity of graded images. It is possible that, with higher quality images, the sensitivity and specificity of grading the images for pre-plus or worse disease would improve. Since images captured with the Pictor camera were performed for quality assurance reasons (ie, to test the camera’s ability to image the infant retina), we did not systematically monitor the infants during imaging for signs of distress other than alarming of their monitors during the imaging sessions. Thus we could not quantify the stress to the infants during Pictor imaging.

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FIG 1.
A, The Pictor camera. B, Positioning of the Pictor camera in front of the infant eye while gently holding open the eyelids.

FIG 2.

Electronic slides with 1 (A, B), 2 (C, D), and 3 (E, F) color (A, C, D), and red-free (B, D, F) retinal images taken by the Pictor camera. The number symbol indicates the electronic slide number.

FIG 3.

Introductory slide showing the range of disease for pre-plus and plus disease. Images were cropped ovally to display a field of view similar to that of the Pictor images for comparison. Copyright © 2005 and 2006 by the American Medical Association. All rights reserved. Reprinted, with permission, from The International Classification of Retinopathy of Prematurity revisited, Arch Ophthalmol 2005;123:991-9; and Capone A Jr, Ells AL, Fielder AR, et al. Standard image of plus disease in retinopathy of prematurity, Arch Ophthalmol 2006;124:1669-70, respectively. Personal use of this material is permitted. However, permission to reuse this material for any other purpose must be obtained from the American Medical Association.

FIG 4.
A, Color and (B) red-free retinal images of the right eye of an infant with clinically diagnosed plus disease. Image set was graded as pre-plus by grader 1 and normal by grader 2.

FIG 5.

Comparison of a RetCam retinal image (A) as published and (B) as cropped ovally to display a field of view similar to that of an image obtained by the Pictor camera. Copyright © 2005 by the American Medical Association. All rights reserved. Reprinted, with permission, from The International Classification of Retinopathy of Prematurity revisited, Arch Ophthalmol 2005;123:991-9. Personal use of this material is permitted. However, permission to reuse this material for any other purpose must be obtained from the American Medical Association.

Table 1

Image quality of Pictor fundus photographs

	Grader	Image quality, no. (%) ^a		
		Good ^b	Fair ^c	Poor ^d
Color images	1	57 (59)	34 (35)	5 (5)
	2	61 (64)	33 (34)	2 (2)
Red-free images	1	61 (64)	32 (33)	3 (3)
	2	64 (67)	29 (30)	3 (3)

^a Percentages do not add to 100% due to rounding.^b Clear view of the optic nerve and vessels; grader could easily discern dilation and tortuosity of vessels.^c Difficult to clearly discern either dilation or tortuosity of vessels.^d Grader unable to clearly discern both dilation and tortuosity of vessels.

Table 2

Number of gradable quadrants of Pictor fundus photographs

	Grader	Number of gradable quadrants ^a				
		4	3	2	1	0
		No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
Color images	1	59 (61)	15 (16)	19 (20)	2 (2)	1 (1)
	2	69 (72) ^b	13 (14) ^b	13 (14) ^b	1 (1) ^b	-
Red-free images	1	63 (66) ^b	17 (18) ^b	15 (16) ^b	1 (1) ^b	-
	2	71 (74)	12 (13)	10 (10)	3 (3)	-

^aNumber of gradable quadrants (0–4) based on the adequate visibility of at least 1 disk diameter length of a major vessel in a given quadrant.

^bPercentages do not add to 100% due to rounding.

Table 3

Accuracy of grading posterior pole disease in color Pictor fundus photographs compared to reference standard^a

Grader		Reference standard ^a		
		Plus ^b	Pre-plus ^c	Normal
1	Plus ^b	3	1	0
	Pre-plus ^c	3	5	10
	Normal	0	1	71
	Don't know	0	0	2
2	Plus ^b	3	1	0
	Pre-plus ^c	2	4	7
	Normal	1	2	76
Total, no. (%)		6 (6) ^d	7 (7) ^d	83 (86) ^d

^aGrading of posterior pole disease by indirect ophthalmoscopy on the clinical examination.

^bImage(s) in which there was sufficient vascular dilation and tortuosity present in at least 2 quadrants of the eye as compared to a standard photograph.^{10, 11}

^cImage(s) in which there was "vascular abnormalities of the posterior pole that are insufficient for the diagnosis of plus disease but that demonstrate more arterial tortuosity and more venous dilatation than normal."¹⁰

^dPercentages do not add to 100% due to rounding.

Table 4
Intergrader reliability of grading posterior pole disease in color Pictor fundus photographs

	Grader 2			Total, no. (%)
	Plus ^a	Pre-plus ^b	Normal	
Plus ^a	4	0	0	4 (4)
Pre-plus ^b	0	12	6	18 (19)
Normal	0	1	71	72 (75)
Don't know	0	0	2	2 (2)
Total, no. (%)	4 (4)	13 (14)	79 (82)	96 (100)

^a Image(s) in which there was sufficient vascular dilation and tortuosity present in at least 2 quadrants of the eye as compared to a standard photograph.^{10,11}

^b Image(s) in which there was "vascular abnormalities of the posterior pole that are insufficient for the diagnosis of plus disease but that demonstrate more arterial tortuosity and more venous dilatation than normal."¹⁰