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Training retinal imagers for retinopathy of prematurity (ROP) screening

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Abstract

Purpose—To report the training/certification process of nonphysician imagers, image quality, and factors that affected image quality in the National Eye Institute sponsored multicentered e-ROP study.

Methods—Nonphysician imagers underwent rigorous training and certification in obtaining retinal images, with attention to clarity, focus, and optic disk placement. Image readers measured pupil size in pupil image and graded posterior pole, temporal, nasal, superior, and inferior retinal images and classified them as good, adequate, poor, or missing. Good and adequate images were deemed acceptable.

Results—In 4,003 image sessions of 1,257 infants, 3,453 (86.8%) were complete. Of 39,550 retinal images, 91.7% had acceptable quality, 5.6% poor, and 2.7% were missing. Inadequate pupil dilation negatively affected acceptable image quality: 54% acceptable images for pupil <5 mm versus 93% for >6 mm ($P < 0.0001$). When ventilatory equipment obstructed access to imaged infant, the percent of acceptable image quality decreased: 94% for no support versus 66.6% for oscillatory ventilation ($P < 0.0001$). Acceptable image quality rates improved from 87% to 90% (P

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*A complete listing of the members of the e-ROP Cooperative Group is provided online as e-Supplement 1.

= 0.03) from first 6 months to last 6 months at low patient volume centers, while high patient volume centers remained stable at 95%.

Conclusions—Nonphysicians successfully obtained acceptable quality images for ROP evaluation. Skills improved with experience. Image quality was negatively affected by inadequate pupil dilation and the presence of obstructive ventilatory equipment.

Retinopathy of prematurity (ROP), which remains a significant comorbidity of very-low-birth-weight (VLBW) infants, can lead to blindness. Worldwide, an estimated 20,000 to 30,000 premature infants go blind or are severely visually handicapped from ROP each year.[1] Although blindness from ROP can largely be prevented by timely treatment, ROP of any stage is associated with a poorer prognosis for child development.[2] In the US, approximately 14,000–16,000 preterm infants undergo ROP screening annually, with 1,100–1,500 who develop severe acute-phase ROP considered for treatment.[3]

Screening for ROP, based on the American Academy of Pediatrics (AAP)/American Academy of Ophthalmology (AAO)/American Association of Pediatric Ophthalmology and Strabismus (AAPOS) guidelines,[4] has traditionally been the responsibility of an ROP-trained ophthalmologist. With the mismatch between the limited number of ophthalmologists and the large number of at-risk infants, other methods, such as using retinal images for remote evaluation, are gaining currency for efficiently, effectively, and safely evaluating infants at risk for ROP. Telemedicine-based remote evaluation of digital fundus imaging is now recognized by the AAP[5] as a potential means of ROP screening, helping to fill a void left by lack of ROP-trained ophthalmologists. The use of digital imaging enables nonophthalmologists to obtain retinal images that can be reviewed by ophthalmologists or trained readers to identify infants with potentially severe ROP. Such projects are already underway on a large scale in India[6] and California,[7] using different models.[8] The training of nonophthalmologists to obtain quality images is a cornerstone to the widespread use of retinal imaging in ROP screening.

The term referral-warranted ROP (RW-ROP)[9] describes morphology on retinal images that should activate an ophthalmic consultation. RW-ROP is defined as ROP in zone I, any stage 3 or worse ROP, or plus disease noted by the evaluation of retinal images. To evaluate the presence of RW-ROP reliably, image readers need to have diagnostic images of acceptable quality; therefore, a robust and reliable method for imager training and certification and maintenance of skills is required.

The protocol used to train nonphysician imagers to acquire and submit retinal images in the Telemedicine Approaches to Evaluating Acute Phase ROP (e-ROP) Study was rigorous and systematic and can be implemented in a nonresearch setting. The e-ROP study was the first large-scale, National Eye Institute-sponsored, multicenter study in the US to train and assess the ability of nonphysicians to successfully obtain retinal images using a wide-angle 130° retinal camera (RetCam Shuttle, Clarity Inc, Pleasanton, CA) in obtaining digital images of preterm infants with birth weight of <1251 g. These images were evaluated by nonphysician trained readers to identify eyes with RW-ROP.[9] From May 2011 to October 2013, 1,257 infants were enrolled and underwent imaging in each eye. Trained nonphysician readers (vs trained nonphysician imagers) were able to detect the presence of RW-ROP in one or both

eyes of an infant with a sensitivity of 90% and specificity of 87%.[10] The purpose of this study was to describe the retinal *imagers'* training and certification process and examine the factors that affected image acquisition and image quality in the e-ROP study.

Methods

A standardized protocol for image submission and certification was developed for the e-ROP Study. The protocol and informed consent processes were approved by the Institutional Review Boards of the participating study centers, and informed consent was obtained. Monitoring, reporting of patient volume, image acquisition, and quality by clinical center was performed throughout the study in order to maintain proficiency of the certified retinal imagers (CRIs). Monthly conference calls were held among imagers to share technical tips for successful imaging.

Image acquisition requires a team of at least two persons: a CRI proficient in imaging and another person to monitor and support the infant. The imaging team selection was an essential component in e-ROP. The CRIs were registered nurses, nurse practitioners, ophthalmic technicians, or photographers. The support person was either another CRI or an experienced neonatal intensive care unit (NICU) nurse. The study visits were planned and timed around clinically indicated ROP examinations.

Imager Training and Certification

Imagers underwent an extensive training process. At the initial meeting of the entire e-ROP Cooperative Group, imagers learned about ROP, VLBW infants, and image acquisition, selection, and grading criteria. In addition to addressing the challenges of imaging VLBW infants, optimal positioning and comfort measures were emphasized. Additional training included further onsite instruction by representatives from Clarity Medical Systems. Also, hands-on technical training with the RetCam and use of a model eye allowed imagers familiarity with the camera and imaging techniques before imaging an infant in the NICU. Further education requirements included review of the e-ROP manual of procedures, the RetCam and the e-ROP imaging manuals, data entry, export, image selection, as well as import and transfer of images through a secure server to the Image Data Center. After completion of these tasks, imagers embarked on the certification process described below.

As per the e-ROP protocol, an imaging session included 2 sets of 6 images, one set from each eye for a total of 12 still images at each session selected from a video stream and uploaded to the server for grading at the e-ROP Reading Center. An image *set* included an external image to assess pupillary dilation, and 5 retinal views: disk center and 4 disk off-centered, giving views of the inferior, superior, temporal, and nasal retina. Off-center disk placement was emphasized at 12, 3, 6, and 9 o'clock positions, with the disk visible but as close to the edge of the image as possible (Figure 1).

After training on a model eye, the imager underwent general and role-specific e-ROP knowledge assessments along with a practical examination including submission of image sets with required fields from infants. To be certified, imagers were required to submit to the e-ROP Reading Center[11] image sets of good quality for 3 right and 3 left eyes; images were

judged according to placement, clarity, and focus. Feedback was provided to the imager and additional sets submitted if necessary until sufficient image quality was achieved. During the study, an image set was scored for both quality and the presence of RW-ROP (see Table 2 and Table 1 in Daniel and colleauges[11]).

Once imagers were certified, the clinical centers could initiate the acquisition and submission of images for the e-ROP study. During this early period, site visits were undertaken by the teams from Office of the Study Chair and the Data Coordinating Center to evaluate imaging onsite and establish readiness for enrolling patients. Image acquisition and quality for each retinal view was assessed and general feedback provided throughout the study and reported at monthly CRI calls and yearly technical group meetings.

Imaging Procedure

When approaching an infant for imaging, CRIs were instructed to concentrate on safety while obtaining highest image quality, with clarity and focus (especially of the periphery) and disk placement that optimized the view of the peripheral retina. Imagers acquired the techniques to overcome the physical barriers around the eye, such as the obstructive modes of ventilatory support, poor dilation, and low-contrast fundi, all of which may affect image acquisition and quality. CRIs were instructed to record findings if images were difficult to obtain, such as hazy vitreous or tunica vasculosa lentis, if present.

The numerous modes of ventilatory support that premature infants require often obstruct access to the infant's eye. In such difficult circumstances, imagers may devise new techniques to acquire quality images. The imaging team was trained in optimum positioning of the infant and the ventilator apparatus so that the equipment was away from the infant's eye and positioning the imager and support person in a stable, comfortable position to manipulate the camera head with minimal disturbance to the infant. Copious amounts of coupling gel were essential in aiding the movement of the camera head safely within that tight space. To complete the imaging sessions, CRIs used gentle manipulation and comfort measures, including sucrose, pacifier, swaddling, and sedation (if ordered by the NICU staff).

The CRI recorded the reasons for incomplete image sets, such as unstable infant, determined by preset ranges, and other parameters. Reporting adverse events and severe adverse events followed standardized procedures.

Statistical Analysis

Image quality was analyzed as the percentage of retinal images with acceptable quality, poor quality and missing image for each retinal view and for all retinal images combined. Acceptable images were a combined category of images graded as good and adequate by the trained readers. We analyzed factors associated with image acquisition and quality, including pupil size (as determined by the trained readers), clinical center patient volume, and infants' ventilatory support status (because it can affect success of imaging and/or change the stability of the infant). Image quality in each study center's first 6 months and last 6 months was compared to evaluate improvement over time in higher patient volume centers (HPVCs) and lower patient volume centers (LPVCs), based on a cut-off point of 17 visits per month

on average. The χ^2 test was used to compare the proportions between groups. To account for the correlation among images from multiple image sessions of an eye, and among images from both eyes of an infant, the generalized estimating equation (GEE)[12] was used for *P* value calculation.

Results

A total of 28 imagers from 13 participating clinical centers were trained and certified for the e-ROP study. The number of certification image sets submitted for certification ranged from 1 to 5, with an average of 1.8. The certification submission process took from 1 to 93 days because of availability of infants for imaging, frequency of ROP rounds, and the individual imager's learning curve.

During the e-ROP study, 1,257 infants were enrolled and imaged from May 2011 to October 2013, with an average of 3.4 image sessions per infant. There were 4,205 study visits that included the diagnostic examination, in which the ophthalmologist examination preceded imaging 65% of the time. Imaging sessions occurred at 4,003 visits (95.%), with 202 sessions (5%) not attempted because of parent refusal or the infant's medical status. In 26 sessions no images were submitted because of technical issues (eg, the images for an infant were recorded with the wrong ID). Of 3,977 image sessions with image submission, 3,453 (86.8%) were complete (6 required images in both eyes) and 550 (14%) had incomplete sets in one or both eyes.

The reasons for incomplete sets (not mutually exclusive) as recorded by CRIs on the case report form are reported in Table 1. Table 2 presents the image quality of 5 retinal images and the pupil dilation of each eye. Of the 39,550 images from 7,910 image sets that were evaluated by trained readers, 91.7% had acceptable image quality, 5.6% were poor, and 2.7% were missing.

The effect of pupil size on the image acquisition and quality is also reported in Table 2. Of the 280 attempted retinal images taken with pupils <5 mm in diameter, only 54% of images were graded as having acceptable quality, compared to 88% for pupils 5–6 mm and 93% for pupils >6 mm in diameter. The percentage of missing retinal images was also higher when pupil size was smaller; 28% missing for pupil size <5 mm compared to 3.3% for pupil size 5–6 mm and 2.1% in pupil size of >6 mm ($P < 0.0001$, Table 2).

The mode of the infant's ventilatory support during the imaging session affected image quality (Table 3). The percentage of acceptable images decreased with the increasing difficulty of access to the infant's eye created by mode of ventilation; 94% for room air to 66.6% for JET/HFOV ventilation, both having very stiff, short tubing. NCPAP and NIMV had the next lowest percentage of acceptable quality images (89%), with extensive equipment centered on the nose and eyes; conventional mechanical ventilation had 92% acceptable quality images.

Among all clinical centers, incomplete image sets decreased from 10.4% in the first 6 months of imaging to 5.9% in the last 6 months of the study ($P < 0.001$, Table 4). Image quality also improved from the first 6 months to the last 6 months, particularly for the

images of the inferior retina (89% vs 94% acceptable quality, respectively; $P < 0.001$) and nasal retina (82% vs 85%, respectively; $P < 0.001$; Table 4).

Patient volume varied across clinical centers, with HPVCs having a higher percentage of acceptable image quality early on compared to LPVCs (Table 5). In the first 6 months the HPVCs had a mean (with standard deviation) of 25.4 ± 6.1 image sessions per month compared to the LPVCs, with 12.8 ± 5.6 image sessions per month; in the last 6 months, the HPVCs had 23.3 ± 5.0 versus LPVCs 11.9 ± 4.0 image sessions per month. Table 5 shows image quality and number of incomplete image sets in HPVCs and LPVCs. The image quality of the inferior retina showed improvement in both low- and high-volume centers. Image quality at HPVCs remained relatively stable throughout the study (95% acceptable quality), but the LPVC continued to show improvement over time, with 87% acceptable image quality in the first 6 months and 90% in the last 6 months ($P = 0.03$). In LPVCs, nasal and temporal missing images dropped from 8% to 4%, and 3% to 1%, respectively, from the first 6 months to the last 6 months, whereas in the HPVCs quality remained stable.

Discussion

The e-ROP study identified several key factors to improve imaging as a clinical tool. Maximizing pupil dilation is crucial to imaging success. Image quality often suffered as a result of the infant's medical condition, and the need for certain modes of ventilation that obstructed the eye. A thorough training program provides instruction on how to handle a fragile, premature infant and the surrounding equipment. Training also emphasized the need for the imager to image frequently with a varied patient population to maintain optimal imaging skills. A successful imaging program will also provide frequent feedback to the imager from the reading center with respect to clarity, field and focus, and optic disk placement. Training must also stress accurate data input; of course, proper safeguards be in place to ensure errors are corrected prior to evaluation of image sets. Overall success will rely on a consistent volume of patients so that proper systems can be developed and maintained.

In conclusion, the e-ROP Study demonstrated that nonphysicians can consistently acquire and submit quality images, with a 92% success rate in providing acceptable quality images to the e-ROP readers for evaluation. Such a system presents a way to offer preterm infants worldwide a safe[13] means for image acquisition and an effective system for ROP evaluation.[10,15] Imaging has also provided an important teaching aid for families and medical staff to illustrate the infant's ROP status, reinforcing the seriousness of the disorder and need for careful follow-up.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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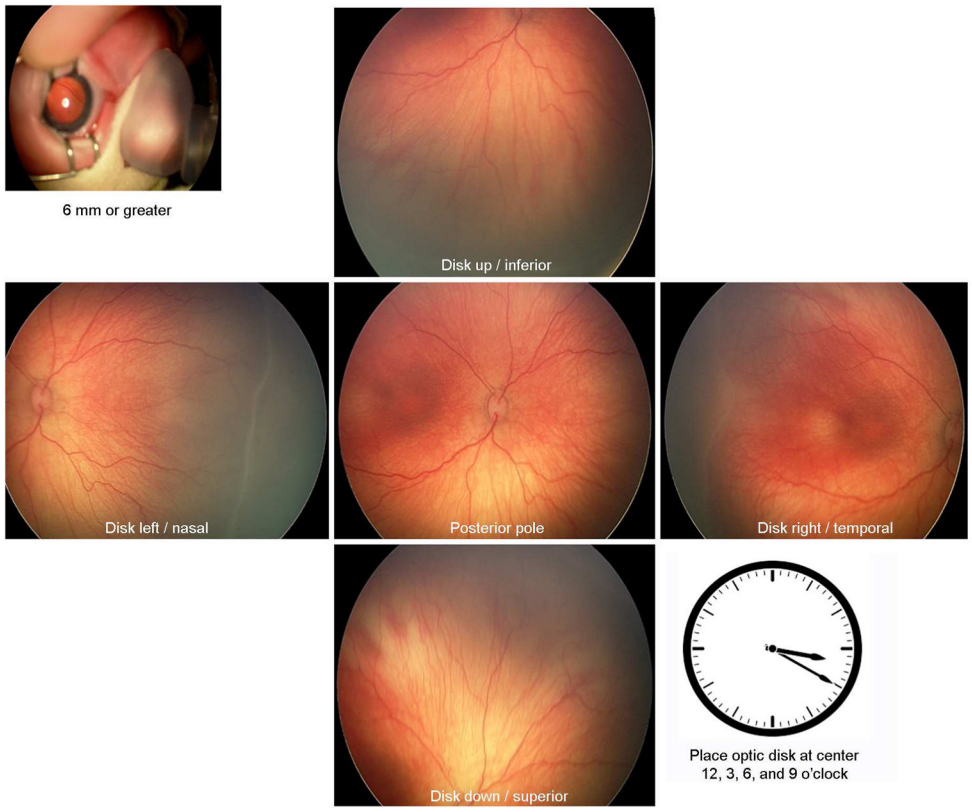

FIG 1.

Required retinal views. An image set included an external image to assess pupillary dilation, and 5 retinal views that provided views of the posterior, inferior, superior, temporal, and nasal retina.

Table 1

Completeness of imaging in image session and reasons for incomplete image sets

Label	Baby	Right eye	Left eye
No. infant approaches for imaging	4003/4205 (95.2%)	4003/4205 (95.2%)	4003/4205 (95.2%)
No. imaging sessions with any images sent	3977/4003 (99.4%)	3971/4003 (99.2%)	3939/4003 (98.4%)
No. complete images sets sent	3453/3977 (86.8%)	3679/3971 (92.6%)	3617/3939 (91.8%)
Reasons for incomplete image sets (n = 550)			
Agitated baby	12/550 (2.2%)	7/324 (2.2%)	9/386 (2.3%)
Baby became unstable	60/550 (10.9%)	38/324 (11.7%)	51/386 (13.2%)
Bell's phenomenon	78/550 (14.2%)	46/324 (14.2%)	46/386 (11.9%)
Poor access to eye	228/550 (41.5%)	152/324 (46.9%)	148/386 (38.3%)
Poor dilation	104/550 (18.9%)	63/324 (19.4%)	79/386 (20.5%)
Technical reasons	64/550 (11.6%)	36/324 (11.1%)	47/386 (12.2%)
Other	26/550 (4.7%)	16/324 (4.9%)	12/386 (3.1%)
Unknown	63/550 (11.5%)	25/324 (7.7%)	42/386 (10.9%)

Table 2

Image quality overall and by pupil size

Image	Pupil size[a]	Acceptable	Poor	Missing	*P* value
Posterior pole	<5 mm	34 (60.7%)	8 (14.3%)	14 (25.0%)	
	5–6 mm	1323 (94.1%)	58 (4.1%)	25 (1.8%)	<0.001
	>6 mm	6172 (97.6%)	103 (1.6%)	51 (0.8%)	
	All	7630 (96%)	176 (2%)	104 (1%)	
Nasal retina	<5 mm	27 (48.2%)	13 (23.2%)	16 (28.6%)	
	5–6 mm	1096 (78.0%)	248 (17.6%)	62 (4.4%)	<0.001
	>6 mm	5383 (85.1%)	755 (11.9%)	188 (3.0%)	
	All	6577 (83%)	1039 (13%)	294 (4%)	
Temporal retina	<5 mm	35 (62.5%)	8 (14.3%)	13 (23.2%)	
	5–6 mm	1297 (92.2%)	81 (5.8%)	28 (2.0%)	<0.001
	>6 mm	6134 (97.0%)	131 (2.1%)	61 (1.0%)	
	All	7555 (96%)	235 (3%)	120 (2%)	
Inferior retina	<5 mm	30 (53.6%)	9 (16.1%)	17 (30.4%)	
	5–6 mm	1227 (87.3%)	94 (6.7%)	85 (6.0%)	<0.001
	>6 mm	5837 (92.3%)	245 (3.9%)	244 (3.9%)	
	All	7171 (91%)	362 (5%)	377 (5%)	
Superior retina	<5 mm	26 (46.4%)	13 (23.2%)	17 (30.4%)	
	5–6 mm	1267 (90.1%)	106 (7.5%)	33 (2.3%)	<0.001
	>6 mm	5967 (94.3%)	251 (4.0%)	108 (1.7%)	
	All	7344 (93%)	390 (5%)	176 (2%)	
All retinal images	<5 mm	152 (54.3%)	51 (18.2%)	77 (27.5%)	
	5–6 mm	6210 (88.3%)	587 (8.3%)	233 (3.3%)	<0.001
	>6 mm	29493 (93.2%)	1485 (4.7%)	652 (2.1%)	
	All	36277 (92%)	2202 (6%)	1071 (3%)	

[*] Pupil size measured by e-ROP grading center.

Table 3

Image quality by respiratory status before imaging

Image	Quality	HFOV/JET	CPAP/NIPPV/HFNC	CMV	NC	Room air	*P* value
Posterior pole	Acceptable	49 (73.1%)	1710 (94.7%)	799 (96.0%)	2576 (96.8%)	2485 (98.1%)	<0.001
	Poor/missing	18 (26.9%)	95 (5.3%)	33 (4.0%)	86 (3.2%)	47 (1.9%)	
Nasal retina	Acceptable	45 (70.3%)	1429 (79.2%)	716 (86.1%)	2191 (82.3%)	2185 (86.3%)	<0.001
	Poor/missing	22 (34.4%)	376 (20.8%)	116 (13.9%)	471 (17.7%)	347 (13.7%)	
Temporal retina	Acceptable	45 (67.2%)	1694 (93.9%)	794 (95.4%)	2554 (95.9%)	2457 (97.0%)	<0.001
	Poor/missing	22 (32.8%)	111 (6.1%)	38 (4.6%)	108 (4.1%)	75 (3.0%)	
Inferior retina	Acceptable	37 (55.2%)	1569 (86.9%)	745 (89.5%)	2434 (91.4%)	2374 (93.8%)	<0.001
	Poor/missing	30 (44.8%)	236 (13.1%)	87 (10.5%)	228 (8.6%)	158 (6.2%)	
Superior retina	Acceptable	47 (70.1%)	1607 (89.0%)	768 (92.3%)	2491 (93.6%)	2421 (95.6%)	<0.001
	Poor/missing	20 (29.8%)	198 (11.0%)	64 (7.7%)	171 (6.4%)	111 (4.4%)	
All retinal images	Acceptable	223 (66.6%)	8009 (88.7%)	3822 (91.9%)	12246 (92.0%)	11922 (94.2%)	<0.001
	Poor/missing	112 (33.4%)	1016 (11.3%)	338 (8.1%)	1064 (8.0%)	738 (5.8%)	

CMV, conventional mechanical vventilation; *CPAP*, continuous positive airway pressure; *HFNC*, high-flow nasal cannula; *HFOV*, high-frequency oscillator ventilation; *JET*, JET ventilation; *NC*, nasal cannula; *NIPPV*, nasal intermittent positive pressure ventilation.

Table 4

Image quality in the first 6 months and last 6 months of the imaging period

	First 6 months[a]				Last 6 months[a]				
Image view	**N**	**Acceptable**	**Poor**	**Missing**	**N**	**Acceptable**	**Poor**	**Missing**	***P* value**
Pupil size	1860	1763 (95%)	66 (4%)	31 (2%)	2007	1874 (93%)	109 (5%)	24 (1%)	0.01
Posterior pole		1789 (96%)	37 (2%)	34 (2%)		1932 (96%)	59 (3%)	16 (1%)	0.003
Nasal retina		1519 (82%)	256 (14%)	85 (5%)		1713 (85%)	248 (12%)	46 (2%)	<0.001
Temporal retina		1774 (95%)	49 (3%)	37 (2%)		1935 (96%)	55 (3%)	17 (1%)	0.01
Inferior retina		1650 (89%)	100 (5%)	110 (6%)		1881 (94%)	76 (4%)	50 (2%)	<0.001
Superior retina		1736 (93%)	87 (5%)	37 (2%)		1858 (93%)	103 (5%)	46 (2%)	0.64
All retinal images		8468 (91%)	529 (6%)	303 (3%)		9319 (93%)	541 (5%)	175 (2%)	0.02

[a]The first 6 months and the last 6 months is center specific, depending on when they start imaging and stop imaging.

Table 5

Image quality in high versus low patient volume centers in first and last 6 months of the imaging period

		First 6 months				Last 6 months				
Clinic	**Image**	**N**	**Acceptable**	**Poor**	**Missing**	**N**	**Acceptable**	**Poor**	**Missing**	***P* value**
LPVCs	Pupil size	891	834 (94%)	28 (3%)	29 (3%)	929	844 (91%)	63 (7%)	22 (2%)	0.001
	Posterior pole		837 (94%)	29 (3%)	25 (3%)		876 (94%)	45 (5%)	8 (1%)	0.002
	Nasal retina		661 (74%)	162 (18%)	68 (8%)		773 (83%)	123	33 (4%)	0.001
	Temporal retina		831 (93%)	32 (4%)	28 (3%)		880 (95%)	40 (4%)	9 (1%)	0.004
	Inferior retina		747 (84%)	60 (7%)	84 (9%)		848 (91%)	47 (5%)	34 (4%)	0.001
	Superior retina		802 (90%)	58 (7%)	31 (3%)		819 (88%)	69 (7%)	41 (4%)	0.42
	All retinal images	4455	3878 (87%)	341 (8%)	236 (5%)	4645	4196 (90%)	324 (7%)	125	0.03
HPVCs	Pupil size	969	929 (96%)	38 (4%)	2 (0%)	1078	1030 (96%)	46 (4%)	2 (0%)	0.92
	Posterior pole		952 (98%)	8 (1%)	9 (1%)		1056 (98%)	14 (1%)	8 (1%)	0.53
	Nasal retina		858 (89%)	94 (10%)	17 (2%)		940 (87%)	125	13 (1%)	0.24
	Temporal retina		943 (97%)	17 (2%)	9 (1%)		1055 (98%)	15 (1%)	8 (1%)	0.72
	Inferior retina		903 (93%)	40 (4%)	26 (3%)		1033 (96%)	29 (3%)	16 (1%)	0.03
	Superior retina		934 (96%)	29 (3%)	6 (1%)		1039 (96%)	34 (3%)	5 (0%)	0.87
	All retinal images	4845	4590 (95%)	188 (4%)	67 (1%)	5390	5123 (95%)	217 (4%)	50 (1%)	0.57

HPVC, higher patient volume centers; *LPVC*, lower patient volume center.