



Telemedicine Diagnostic Challenges for Retinopathy of Prematurity (ROP)

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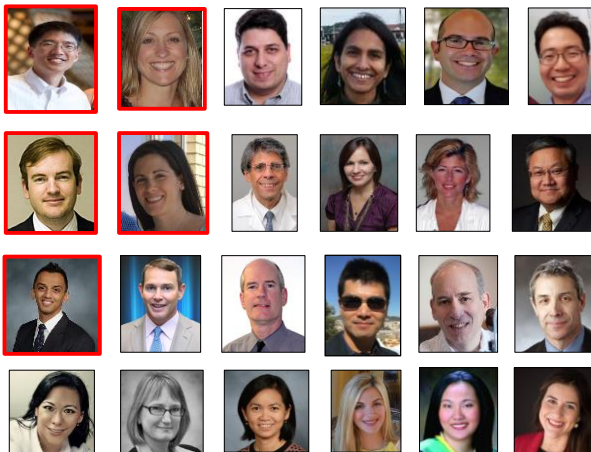
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i-ROP
Imaging and Informatics in Retinopathy of Prematurity

GEN-ROP
The Global Education Network for ROP



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Telemedicine Diagnostic Challenges for ROP

Image based diagnosis and telemedicine for ROP has been shown to be reliable, accurate, and cost-effective:

- Prospective and retrospective studies investigating the use of telemedicine and image-based diagnosis for detection of ROP
- Telemedicine screening can be more time efficient for the examiner
- Telemedicine for ROP is cost effective

Active Clinical ROP Telemedicine Programs:

- SUNDROP (USA)
- FOCUS ROP (USA)
- ROPE-SOS (India)
- KIDROP (India)
- ARTROP (New Zealand)

Ophthalmic Technology Assessment

Detection of Clinically Significant Retinopathy of Prematurity Using Wide-angle Digital Retinal Photography

A Report by the American Academy of Ophthalmology

Michael F. Chiang, MD,¹ Michele Melia, SM,² Angela N. Buffum, MD, MPH,³ Scott R. Lambert, MD,⁴ Frances M. Recchia, MD,⁵ Jennifer L. Simpson, MD,⁶ Michael S. Yang, MD⁷

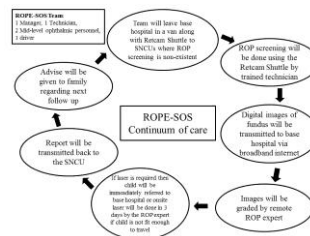


Image courtesy of Dr. Narendran Venkatapathy



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Telemedicine Diagnostic Challenges for ROP

Who is qualified to perform ROP telemedicine diagnosis?

- “Referral Warranted ROP”
 - ROP telemedicine programs have focused on prevention of retinal detachment by identifying disease that may soon progress to treatment-requiring ROP
- Potential diagnostic challenges
 - Inter-expert variability in Plus disease diagnosis
 - Studies have shown that experience matters
 - Stage 4, Stage 5, and AP-ROP
- Variability in Training for Image Grading in ROP Telemedicine Programs



Telemedicine for Evaluation of Retinopathy of Prematurity

Walter M. Fenton, MD, FACP, Antonio Goone Jr, MD, the AMERICAN ACADEMY OF PEDIATRICS SECTION ON OPHTHALMOLOGY, AMERICAN ACADEMY OF OPHTHALMOLOGY and AMERICAN ASSOCIATION OF CERTIFIED RETINOPELTISS evaluation techniques. These techniques have the potential to allow the diagnosis and monitoring of ROP to occur in lieu of the necessity for some repeated on-site examinations in NICUs. This report reviews the currently available literature on ROP-TEM evaluations for ROP and outlines pertinent practical and risk management considerations that should be used when including ROP-TEM in any new or existing ROP care structure.

Ophthalmic Technology Assessment

Detection of Clinically Significant Retinopathy of Prematurity Using Wide-angle Digital Retinal Photography

A Report by the American Academy of Ophthalmology

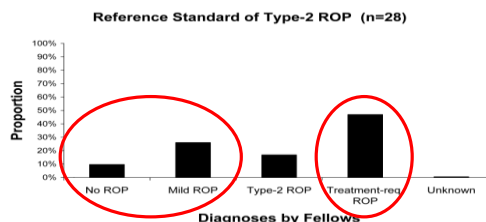
Michael F. Chiang, MD,¹ Michael Miller, SA,² Angela N. Duffner, MD, MPH,³ Scott R. Lambert, MD,⁴ Franco M. Eschke, MD,⁵ Jennifer L. Simpson, MD,⁶ Michael B. Yang, MD,⁷



Telemedicine Diagnostic Challenges for ROP

Diagnostic Accuracy – Board Eligible Ophthalmologists

- Board Eligible Ophthalmologists
 - Retina fellows
 - Variability in diagnostic accuracy
- Poor diagnostic accuracy for clinically significant ROP
 - Type 2-Prethreshold



Fellow	Type 2 or worse	Treatment requiring
1	0.884	1.000
2	0.907	1.000
3	0.512	0.933
4	0.814	1.000
5	0.651	0.867
6	0.535	0.677
7	0.953	0.933

Chan RVP, Williams SL, Yonekawa Y, Weissgold DJ, Lee TC, Chiang MF. Accuracy of Retinopathy of Prematurity Diagnosis by Retinal Fellows. *Retina*, 2010 Jun;30(6):958-65

Myung JS, Chan RV, Espiritu MJ, Williams SL, Lee TC, Granet DB, Weissgold DJ Chiang MF. Accuracy of Retinopathy of Prematurity Diagnosis Image-based Diagnosis by Pediatric Ophthalmology Fellows: Implications for Training. *JAAPOS*. 2011 Dec;15(6):573-8.



Telemedicine Diagnostic Challenges for ROP

Diagnostic Accuracy – Board Eligible Ophthalmologists

- Board Eligible Ophthalmologists
 - Pediatric ophthalmology fellowship
 - Variability in diagnostic accuracy
- Variability in diagnostic accuracy for both type 2 and treatment-requiring ROP
 - Higher accuracy for mild ROP

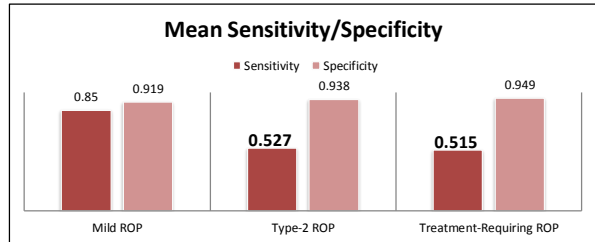


Table 3. Reasons for discrepancy by ROP diagnoses provided by five pediatric ophthalmology fellows, compared to diagnosis provided by expert reference standard

Reasons for discrepancy	Number of images ^a	Percentage
Identification of stage	43	91.5
Identification of plus disease	19	40.4
Identification of zone	16	34.0
Poor image quality	2	4.3
Total number of images	47 ^b	—

Myung JS, Chan RV, Espiritu MJ, Williams SL, Lee TC, Granet DB, Weissgold DJ Chiang MF, Accuracy of Retinopathy of Prematurity Diagnosis Image-based Diagnosis by Pediatric Ophthalmology Fellows: Implications for Training, JAAPOS. 2011 Dec;15(6):573-8.



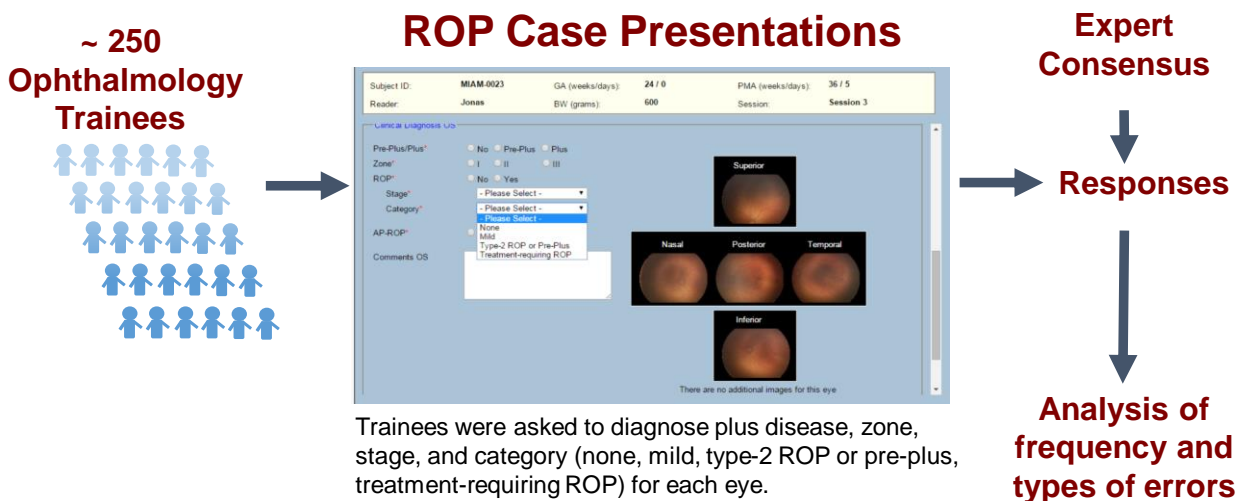
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Diagnostic Accuracy – Ophthalmology Trainees (US and International)



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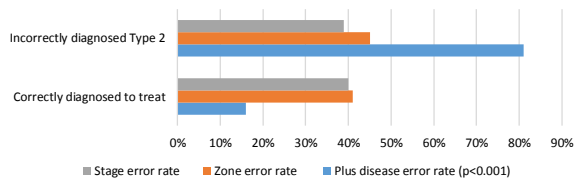
Swamy L, Patel S, Jonas KE, Ostmo S, Chiang MF, Chan RVP, Characterization of errors in retinopathy of prematurity (ROP) diagnosis by ophthalmology residents, J AAPOS, August 2016, Volume 20, Issue 4, Page e44

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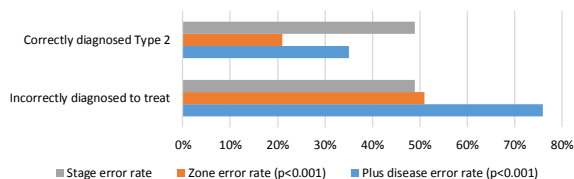
Diagnostic Accuracy – Ophthalmology Trainees (US and Canada)

What factors lead to an incorrect diagnosis of ROP?

Failure to diagnose treatment-requiring ROP was most commonly associated with **error in recognizing plus disease**.



Over-diagnosis of Type 2 as treatment-requiring was most commonly due to **error in recognizing plus disease and zone**.



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Swamy L, Patel S, Jonas KE, Ostmo S, Chiang MF, Chan RVP. Characterization of errors in retinopathy of prematurity (ROP) diagnosis by ophthalmology residents. *J AAPOS*, August 2016, Volume 20, Issue 4, Page e44

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Diagnostic Accuracy – Ophthalmology Trainees (International)

Diagnostic Error Rate (Percent of Incorrect Diagnosis)

	Country A	Country B	Country C	Mean
Error Rate (% incorrect) All categories of ROP	48%	58.9%	48.1%	50.5%
Error Rate Treatment-requiring ROP	45.2%	42.9%	31.6%	35.7%
Error Rate Type 2 ROP	73.6%	77.3%	78.9%	77.8%

Kang KB, Swamy L, Patel SN, Jonas K, Ostmo S, Venture CV, Martinez-Castellanos M, Anzures R, Chiang MF, Chan RVP. Characterization of Errors in Retinopathy of Prematurity (ROP) Diagnosis by International Ophthalmology Residents. *Invest. Ophthalmol. Vis. Sci.* 2016; 57(12)



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Telemedicine Diagnostic Challenges for ROP

Diagnostic Accuracy – Ophthalmology Trainees (US and International)

- **Inadequacies in Diagnostic Accuracy for ROP**
 - **US and International trainees misdiagnosed ROP more than 50% of the time**
 - Rates and reasons for misdiagnoses for each country were similar
 - Raises concerns for mismanagement by inexperienced examiners according to established guidelines
- **Implications for ROP telemedicine and image based diagnosis**
 - Wrong diagnosis of plus disease and zone are major factors leading to incorrect diagnoses
 - **Need to improve diagnostic accuracy of type 2 ROP**
 - Need for targeted education for ROP diagnosis

Swamy L, Patel S, Jonas KE, Ostmo S, Chiang MF, Chan RVP. Characterization of errors in retinopathy of prematurity (ROP) diagnosis by ophthalmology residents. *J AAPOS*, August 2016, Volume 20, Issue 4, Page e44

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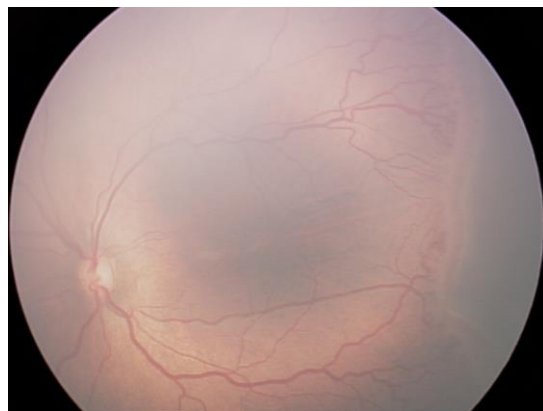


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Telemedicine Diagnostic Challenges for ROP

Diagnostic Accuracy – Ophthalmology Trainees (US and International)

- Ophthalmology trainees misdiagnosed ROP **more than half of the time**
- Identification of **plus disease** and **zone** being the salient factors leading to incorrect diagnosis.



General ophthalmologists may provide ROP care.
Therefore, it is important to improve competency in ROP diagnosis.



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Telemedicine Diagnostic Challenges for ROP

Diagnosis of Stage 4 and Stage 5



Telemedical Diagnosis of Stage 4 and Stage 5 Retinopathy of Prematurity

Samir N. Patel, MD,¹ Ranjodh Singh, BPhil, BSc,¹ Kazryn E. Jonas, RN,^{1,2} Susan Ostmo, MS,⁴ Mrinali P. Gupta, MD,¹ J. Peter Campbell, MD, MPH,⁴ Michael F. Chiang, MD,^{3,4} R.V. Paul Chan, MD, FACS,^{1,2,5} for the Imaging and Informatics for Retinopathy of Prematurity Research Consortium*

Purpose: To determine the accuracy of image-based diagnosis for stage 4 or worse retinopathy of prematurity (ROP) disease.

Design: Prospective cohort study.

Participants: We prospectively obtained data, from 8 major ROP centers, for 1220 eye examinations from 230 infants.

Methods: An ophthalmologist at each center provided a clinical diagnosis using indirect ophthalmoscopy. Wide-angle retinal images (RetCam; Clarity Medical Systems, Pleasanton, CA) were then obtained, and these were independently read by 2 ROP experts using a web-based system for an image-based diagnosis.

Main Outcome Measures: Sensitivity and specificity of image-based diagnosis from the ROP experts were calculated using the clinical diagnosis as the reference standard.

Results: Of 1220 examinations, 28 (2%) had a clinical diagnosis of stage 4 or worse. Sensitivity and specificity for stage 4 or worse disease were 75% and 99% for expert 1, and 86% and 99% for expert 2. Sensitivity and specificity for the detection of stage 5 disease were 69% and 99% for both experts.

Conclusions: There are inconsistencies in the accuracy of image-based diagnosis of stage 4 and stage 5 ROP when compared with the clinical diagnosis. *Ophthalmology Retina* 2017;■:1–6 © 2017 by the American Academy of Ophthalmology



Patel SN, Singh R, Jonas KE, Ostmo S, Gupta MP, Campbell JP, Chiang MF, Chan RVP on behalf of the Imaging & Informatics in ROP Research Consortium, Telemedical Diagnosis of Stage 4 and Stage 5 Retinopathy of Prematurity, *Ophthalmology Retina*, 2017 June.

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Diagnosis of Stage 4 and Stage 5 - Results

Table 2. Sensitivity and Specificity of Image-based Retinopathy of Prematurity Diagnosis by Retinopathy of Prematurity Experts

Diagnosis	Expert 1*		Expert 2*	
	Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Stage 4 or worse (N = 28)	75 (55–89)	99 (99–100)	86 (67–96)	99 (99–100)
Stage 5 (N = 13)	69 (39–91)	99 (99–100)	69 (39–91)	99 (99–100)

CI = confidence interval.

*Sensitivity and specificity for the image-based diagnosis of both experts were computed using the clinical diagnosis by indirect ophthalmoscopy as the reference standard.



Patel SN, Singh R, Jonas KE, Ostmo S, Gupta MP, Campbell JP, Chiang MF, Chan RVP on behalf of the Imaging & Informatics in ROP Research Consortium, Telemedical Diagnosis of Stage 4 and Stage 5 Retinopathy of Prematurity, *Ophthalmology Retina*, 2017 June.

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Clinical Diagnosis of \geq Stage 4 and an Image-based Diagnosis of $<$ Stage 4



Clinical Diagnosis: Stage 4a
 Examiner 1: Stage 4a
Examiner 2: Stage 3 (no treatment)
 Outcome: Vitrectomy



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Telemedicine Diagnostic Challenges for ROP

Diagnosis of Aggressive Posterior-ROP (AP-ROP)

Original Manuscript

ASRS American Society of Retina Specialists

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Inconsistencies in the Diagnosis of Aggressive Posterior Retinopathy of Prematurity

Samir N. Patel, MD¹, Ranjodh Singh, BPhil, BSc¹, Karyn E. Jonas, RN^{1,2}, Susan Ostro, MPH^{3,4}, Paul Petrakos, MD¹, Mrinali P. Gupta, MD¹, J. Peter Campbell, MD⁴, Michael F. Chiang, MD^{1,4}, and R. V. Paul Chan, MD, FACS^{1,2,5}, on behalf of the I-ROP Research Consortium

Abstract
Purpose: To determine the accuracy and reliability of diagnosing aggressive posterior retinopathy of prematurity (AP-ROP).
Methods: A total of 1220 eye examinations from 230 infants were prospectively obtained at 8 major ROP centers. An ophthalmologist at each center provided a clinical diagnosis using indirect ophthalmoscopy. Wide-angle retinal images were then obtained, which were independently read by 2 ROP experts using a web-based system for an image-based diagnosis. Sensitivity and specificity of image-based AP-ROP diagnosis by the ROP experts were calculated using the clinical diagnosis as the reference standard. Agreement of AP-ROP diagnosis through image-based diagnosis and clinical diagnosis was calculated using the unweighted κ statistic. **Results:** One hundred four (9%) of the 1220 examinations had a clinical diagnosis of AP-ROP. Sensitivity and specificity for the presence of AP-ROP were 35% and 96% for expert 1 and 17% and 99% for expert 2. Using the κ statistic, expert image-based versus clinical diagnostic agreement for the diagnosis of AP-ROP was 0.34 (fair) for expert 1 and 0.24 (fair) for expert 2. Agreement for the diagnosis of AP-ROP between the image-based diagnoses of expert 1 and expert 2 was 0.49 (moderate). **Conclusion:** There are inconsistencies between the clinical diagnosis of AP-ROP (as determined by indirect ophthalmoscopy) and the image-based diagnosis of AP-ROP. This may have important implications for ROP management and the current international ROP classification system.

Keywords
 aggressive posterior retinopathy of prematurity, retinopathy of prematurity, telemedicine



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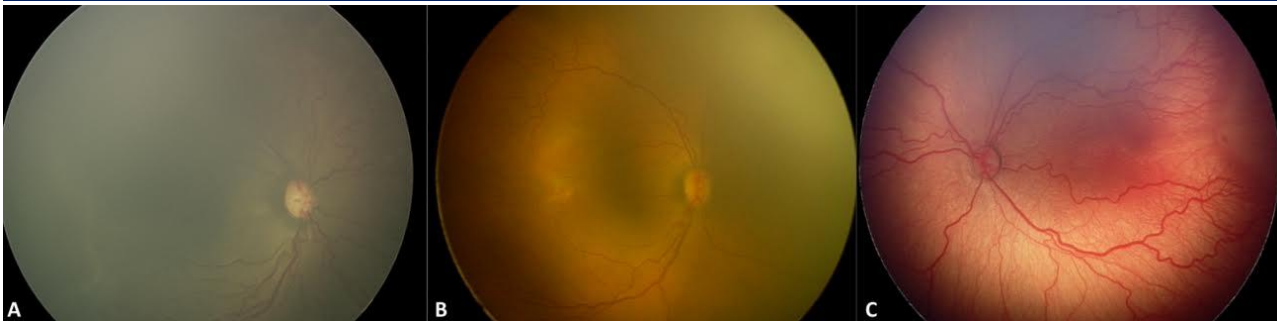


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Diagnosis of Aggressive Posterior-ROP (AP-ROP)



A: Clinical diagnosis of no AP-ROP. Both experts provided an image-based diagnosis of AP-ROP.

B: Clinical diagnosis of AP-ROP. Both experts provided an image-based diagnosis of no AP-ROP.

C: Clinical diagnosis of AP-ROP. Expert 1 provided an image-based diagnosis of AP-ROP. Expert 2 provided an image-based diagnosis of no AP-ROP.



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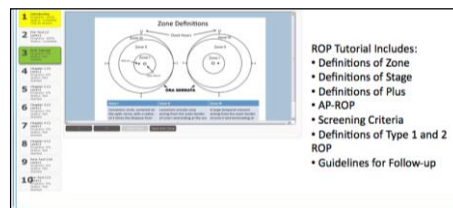
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Tele-Education, Imaging, and Image Analysis

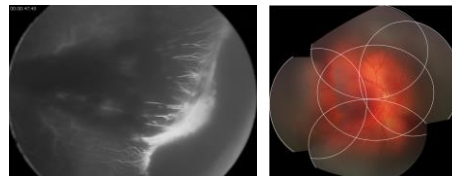
Tele-Education

- GEN-ROP
 - Improved diagnostic accuracy through a web-based learning platform.
 - Implications for ROP training and telemedicine.



Imaging

- Fluorescein Angiography for ROP
 - May improve diagnostic accuracy for certain categories of ROP (e.g. stage 2 or worse, stage 3 or worse, pre-plus or worse, and type-2 ROP or worse)
- Digital Mosaic Images for ROP
 - May improve diagnostic accuracy and intergrader agreement of clinically-significant ROP (e.g. Plus disease)



Chan RV, Patel SN, Ryan MC, et al. The Global Education Network for Retinopathy of Prematurity (GEN-ROP): Development, Implementation, and Evaluation of a Novel Tele-Education System, *Trans Am Ophthalmol Soc*. 2015;113:T2 21-226.

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Improvement in Diagnostic Accuracy with Tele-Education

United States and Canada Trainees

TABLE 7. ACCURACY OF ROP DIAGNOSIS IN THE PRETEST AND POSTTEST BY ALL 31 TRAINEES WHO PARTICIPATED IN THE ROP TELE-EDUCATION PROGRAM

DIAGNOSIS	SENSITIVITY, % (SE)			SPECIFICITY, % (SE)		
	PRETEST	POSTTEST	P VALUE	PRETEST	POSTTEST	P VALUE
Stage						
Stage 1 or worse	90 (2)	96 (1)	<i>P</i> =.004*	75 (6)	87 (3)	<i>P</i> =.111
Stage 2 or worse	82 (3)	96 (1)	<i>P</i> <.001*	79 (5)	92 (1)	<i>P</i> =.027*
Stage 3 or worse	60 (4)	78 (3)	<i>P</i> <.001*	87 (3)	92 (1)	<i>P</i> =.127
Zone						
Zone I or II	65 (3)	89 (2)	<i>P</i> <.001*	...†	...†	...†
Zone I	44 (7)	74 (5)	<i>P</i> <.001*	84 (3)	90 (2)	<i>P</i> =.112
Plus						
Pre-plus or worse	69 (4)	81 (3)	<i>P</i> =.003*	81 (5)	95 (2)	<i>P</i> =.028*
Plus	49 (8)	67 (5)	<i>P</i> =.016*	89 (2)	92 (1)	<i>P</i> =.235
Category						
Mild or worse	91 (1)	95 (1)	<i>P</i> =.007*	74 (6)	87 (3)	<i>P</i> =.105
Type 2 or worse	70 (4)	84 (3)	<i>P</i> <.001*	81 (4)	89 (1)	<i>P</i> =.054
Treatment-requiring	48 (7)	78 (4)	<i>P</i> <.001*	85 (3)	90 (1)	<i>P</i> =.103
Presence APROP	35 (9)	77 (6)	<i>P</i> =.003*	86 (4)	94 (1)	<i>P</i> =.051
Presence ROP	90 (2)	96 (1)	<i>P</i> =.004*	75 (6)	87 (3)	<i>P</i> =.111

APROP, aggressive posterior retinopathy of prematurity; ROP, retinopathy of prematurity.
 *Statistically significant (*P*<.05) using paired *t* test.
 †Specificity is undefined as all eyes contained disease in zone I and/or zone II.

Chan RVP, Patel SN, Ryan MC, Jonas KE, Ostmo S, Port AD, Sun GI, Lauer AK, Chiang MF, The Global Education Network for Retinopathy of Prematurity (GEN-ROP): Development, Implementation, and Evaluation of a Novel Tele-Education System, *Trans Am Ophthalmol Soc*. 2015;113:T2[1-26]

International Trainees

Table 2. Accuracy of retinopathy of prematurity (ROP) diagnosis in the participants in the ROP tele-education program.

ROP Disease Category	Sensitivity, % (SE)			Specificity, % (SE)		
	Pretest	Posttest	P value	Pretest	Posttest	P value
All programs (N=81)						
Mild or worse	81 (2)	93 (1)	<.001	69 (4)	88 (2)	<.001
Moderate or worse	71 (3)	79 (2)	<.002	79 (3)	90 (1)	<.001
Severe (treatment requiring)	55 (4)	66 (4)	<.022	79 (2)	89 (1)	<.001
Program 1 (N=27)						
Mild or worse	83 (3)	95 (1)	<.001	81 (5)	94 (2)	<.001
Moderate or worse	67 (5)	81 (3)	.003	88 (3)	92 (1)	.018
Severe (treatment requiring)	54 (6)	71 (6)	.012	85 (3)	89 (2)	.027
Program 2 (N=43)						
Mild or worse	80 (3)	92 (1)	<.001	59 (6)	83 (3)	<.001
Moderate or worse	73 (4)	81 (2)	.011	71 (4)	88 (2)	<.001
Severe (treatment requiring)	57 (6)	62 (5)	.052	74 (3)	89 (2)	<.001
Program 3 (N=11)						
Mild or worse	78 (7)	90 (3)	.076	81 (9)	95 (3)	.076
Moderate or worse	73 (7)	82 (4)	.377	84 (6)	89 (3)	.082
Severe (treatment requiring)	48 (10)	66 (11)	.343	81 (3)	89 (4)	.012

ROP, retinopathy of prematurity; SE, standard error.

Campbell JP, Swan R, Jonas K, Ostmo S, Ventura CV, Martinez-Castellanos MA, Anzures RG, Chiang MF, Chan RV, Implementation and evaluation of a tele-education system for the diagnosis of ophthalmic disease by international trainees, *AMIA Annu Symp Proc*. 2015 Nov 5;2015:366-75.



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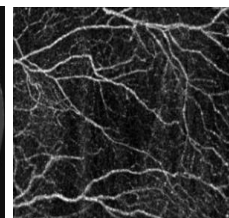
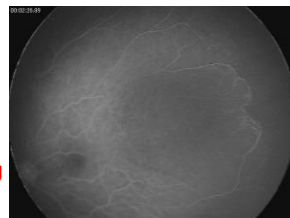
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Telemedicine Diagnostic Challenges for ROP

Summary

“There is more to ROP Telemedicine than just reading an image”

- **Challenges in image based diagnosis of ROP**
 - Variability in diagnostic accuracy for **type 2 ROP and Plus disease**
 - Discrepancies between image based diagnosis and clinical diagnosis for **Stage 4, Stage 5, AP-ROP**
- **Potential strategies to improve ROP telemedicine**
 - **Tele-Education and a standardized certification process**
 - Improved imaging and multimodal imaging with FA, OCT, OCTA
 - Computer-based image analysis and Deep learning
- **Who should be responsible for ROP telemedicine programs?**
 - The nature of ROP care is time sensitive
 - **Skilled Ophthalmologists should be responsible for determining diagnostic and management decisions for ROP**



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