

On behalf of Vision Expo, we sincerely thank you for being with us this year.

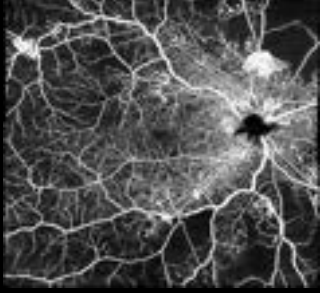
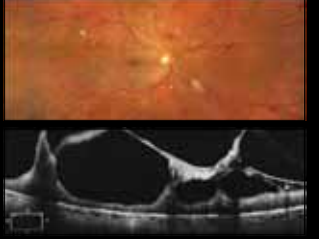
Reminder to Complete Your Session Evaluations!

Please be sure to complete your digital session evaluations for each course you attended! Your feedback is important to us as our Education Planning Committee considers content and speakers for future meetings to provide you with the best education possible.



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**DIAGNOSIS DIABETES:
THE OPTOMETRIC MANAGEMENT GUIDE**

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Disclosures:

- Paid consultant/speaker for:
 - Carl Zeiss Meditec
 - Regeneron Pharmaceuticals
 - Iveric Bio (Astellas)
 - Optomed
 - Apellis Pharmaceuticals
- Paid advisory board member for LENZ Therapeutics, Notal Vision, Topcon, Tarsus, Genentech

All relevant relationships have been mitigated



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Disclosures:

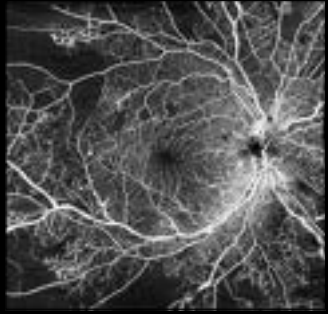

- Apellis: Advisory Board, Consultant, and Speaker
- Astellas/Iveric Bio: Advisory Board, Consultant, and Speaker
- Glaukos: Advisory Board
- Haag Streit: Advisory Board
- LKC: Advisory Board
- Notal Vision/FSH: Advisory Board and Consultant
- OcuTerra: Advisory Board
- Orasis/Qios: Advisory Board
- Reliance Medical Equipment: Advisory Board and Consultant
- Tarsus: Advisory Board
- Topcon: Advisory Board
- Visible Genomics: Advisory Board
- Zeiss: Advisory Board

All relevant relationships have been mitigated

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OVERVIEW

- DR Standard of care documents
- Introduction to DM and DR, multimodal imaging technologies
- DR staging/classification
- DR management and role of imaging
 1. Diabetic macular edema
 2. Mild –moderate NPDR
 3. Severe NPDR-low risk PDR
 4. High risk PDR
- Management updates

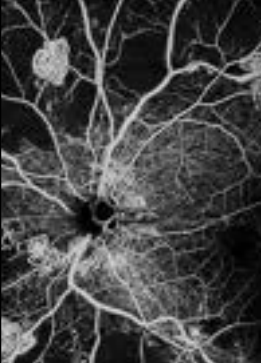



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DIABETIC RETINOPATHY

Standard of Care Documents

- American Optometric Association Clinical Practice Guideline (ACA CPG)- last revision Oct 2019
- American Academy of Ophthalmology Preferred Practice Pattern (AAO PPP)- last revision 2024
- DRICRest- Diabetic Retinopathy Clinical Research Network, a collaborative network of >109 participating sites, funded by the NEI of the NIH
 - <https://www.drircr.net/>



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TABLE 3. Retinal Management of Diabetic Macular Edema (DME) in Patients with Diabetes

Severity of Retinopathy	Presence of Macular Edema	Follow-up (months)	Perifocal Photocoagulation (Quadrant/Outer)	Focal and/or Grid Laser*	Intravitreal Anti-VEGF Therapy
Normal or minimal NPDR	No	12	No	No	No
Mild NPDR	No DME	3-6†	No	Sometimes	No
	CSME‡	3†	No	Often	Usually
Moderate NPDR	No DME	6-12†	No	No	No
	CSME‡	6-6	No	Sometimes	Sometimes
Severe NPDR	No DME	3-6	Sometimes	No	Sometimes
	CSME‡	3-6	Sometimes	Sometimes	Sometimes
Very-high-risk PDR	No	3-6	Recommended	No	Sometimes
	CSME‡	3-6	Recommended	Sometimes	Usually
High-risk PDR	No	3-6	Recommended	No	Sometimes
	CSME‡	3-6	Recommended	Sometimes	Usually

*Anti-VEGF = anti-vascular endothelial growth factor; CSME = center-involved diabetic macular edema; No DME = noncenter-involved diabetic macular edema; NPDR = nonproliferative diabetic retinopathy; PDR = proliferative diabetic retinopathy

American Academy of Ophthalmology – Preferred Practice Patterns 2024, p25

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	Referral	FU Frequency	PRP	Focal Laser	Anti-VEGF
Mild/Moderate NPDR					
No ME	communicate with PCP	Mild 12 mo , Moderate 6-9 mo	No	No	No
non-clinically significant DME	Retinal consult in 2-4 wks	4-6 mo	No	No	No
CSME or center-involved DME	Retinal consult in 2-4 wks	1-4 mo	No	Based on clinical judgement	Yes, if vision ↓
Severe or Very Severe NPDR					
No ME	Retinal consult in 2-4 wks	3-4 mo	Sometimes	No	Alternative, Sometimes
non-clinically significant DME	Retinal consult in 2-4 wks	2-3 mo	Sometimes	No	Alternative, Sometimes
CSME or center-involved DME	Retinal consult in 2-4 wks	1-4 mo	Sometimes	Based on clinical judgement	Yes, if vision ↓
Low risk PDR					
No ME	Retinal consult in 2-4 wks	3-4 mo	Sometimes	No	Alternative, Sometimes
non-clinically significant DME	Retinal consult in 2-4 wks	2-3 mo	Sometimes	No	Alternative, Sometimes
CSME or center-involved DME	Retinal consult in 2-4 wks	1-4 mo	Sometimes	Based on clinical judgement	Yes, if vision ↓
High risk PDR					
No ME	Retinal consult in 24-48 hrs	2-3 mo	Yes	No	Alternative
non-clinically significant DME	Retinal consult in 24-48 hrs	2-3 mo	Yes	No	Usually
CSME or center-involved DME	Retinal consult in 24-48 hrs	1-4 mo	Yes	Based on clinical judgement	Usually

American Optometric Association–Clinical Practice Guideline 2019, p61-63

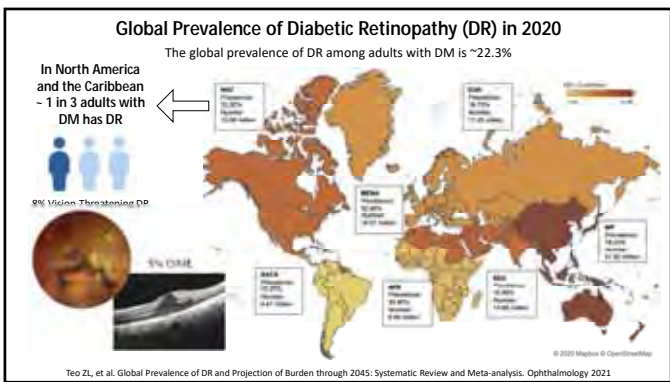
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DIABETES

Diabetes is a worldwide epidemic

- 10.5% in the U.S. (34.2 million, CDC 2018)
- Expected to increase to nearly 1 billion by 2050

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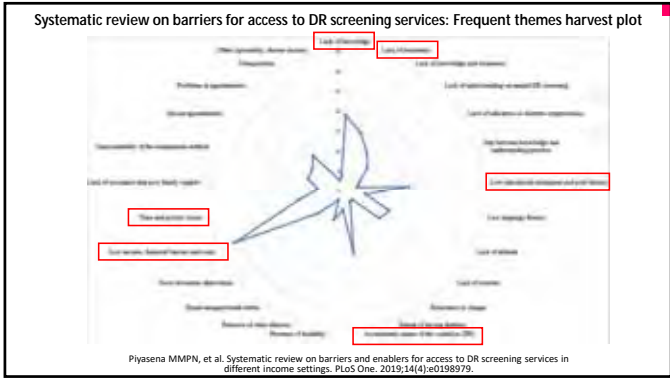
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DIABETIC RETINOPATHY

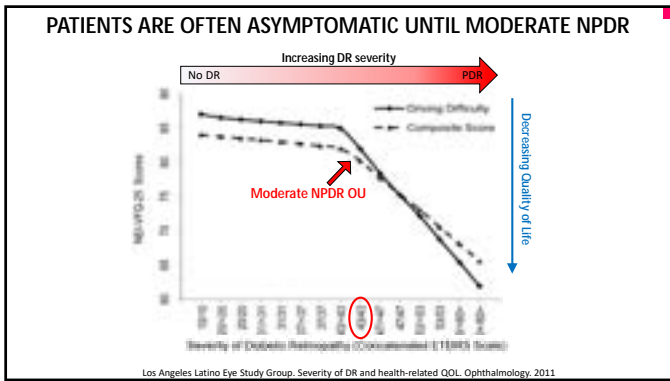
Increasing demand for diabetic retinopathy care

- Leading cause of new cases of blindness among working aged Americans
- Affects 28.5% of diabetics over age 40 in the US (4.2 million, CDC 2005-2008)
- # with DR is expected to nearly triple by 2050

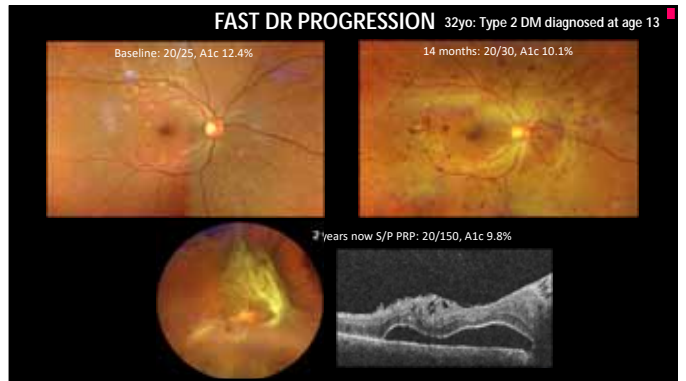
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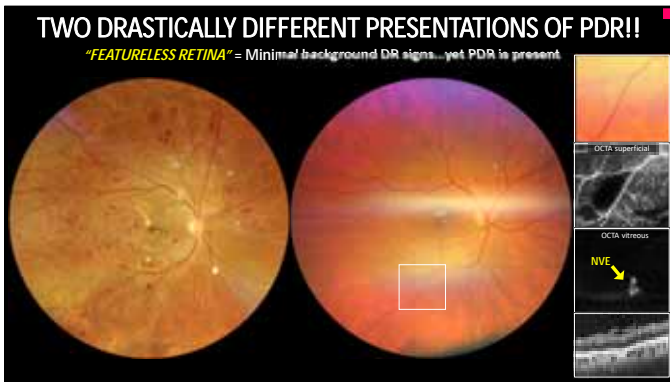
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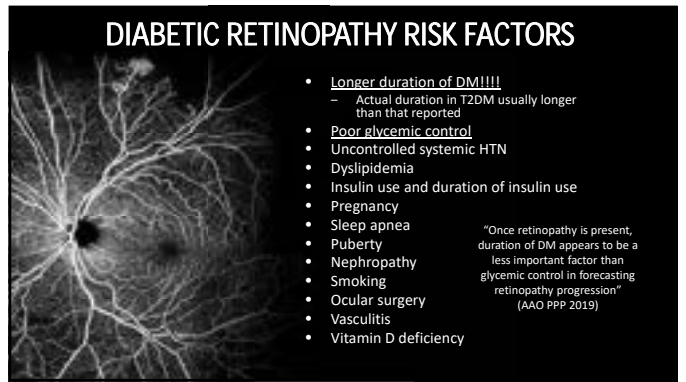
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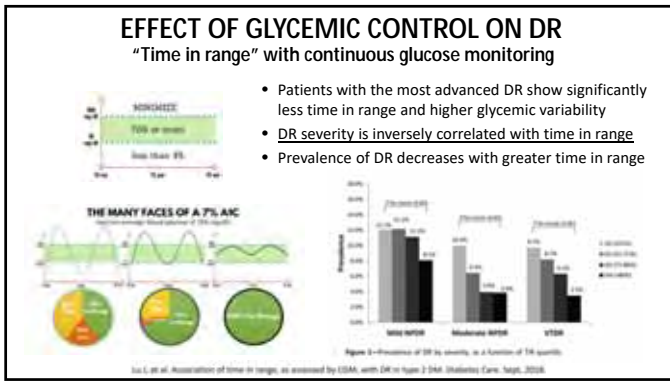
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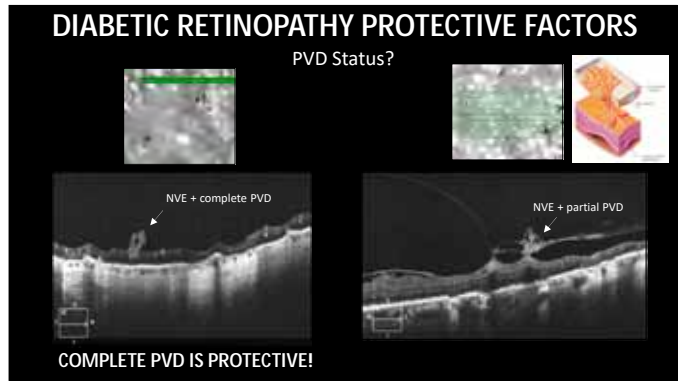
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THE POWER OF IMAGING IN DR

Multimodal Imaging = more accurate and efficient staging of DR

- Wide field (WF)/ultra wide field (UWF) fundus imaging
- Structural OCT
- OCT angiography (macula, ONH, montage)
- B-scan

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WIDEFIELD & ULTRA-WIDEFIELD CFP

WF= Up to the vortex vein ampullae, >50%

UWF= Includes at least 4 vortex vein ampullae, ~200° and 80% retinal surface

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OCT ANGIOGRAPHY (OCTA)

- Non-invasive "flow" imaging (NO DYE INJECTION REQUIRED)

Bright → blood flow

Dark → no flow or too slow to detect

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OCT ANGIOGRAPHY: THE BASICS

- Absence of late stage hyperfluorescence patterns (aka leakage) = Precise delineation/measurement of neo

HIGH RESOLUTION IMAGING OF NEOVASCULAR MEMBRANES = MEASURE SIZE & CLASSIFY MORPHOLOGY PATTERNS

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OCT ANGIOGRAPHY: THE BASICS

Enface Displays (3mm macula)

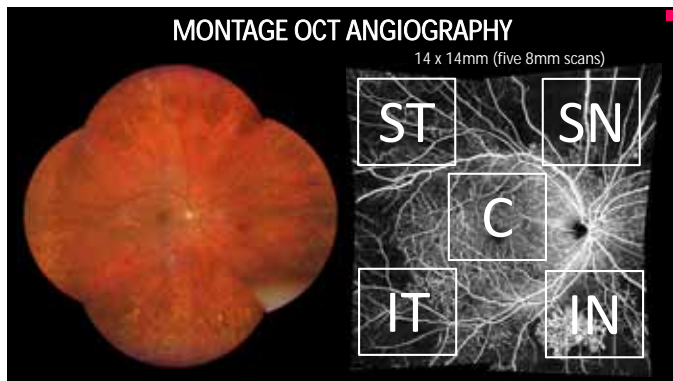
<p>Look here for inner retina disease (DR, VO, etc.)</p>	Vitreoretinal interface	Superficial Retina	Deep Retina
	PRERETINAL NEO		
<p>Look here for outer retina disease (AMD, CSCR, myopic degen, etc.)</p>	Avascular/Outer Retina	Choriocapillaris	Choroid
	CHOROIDAL NEO		

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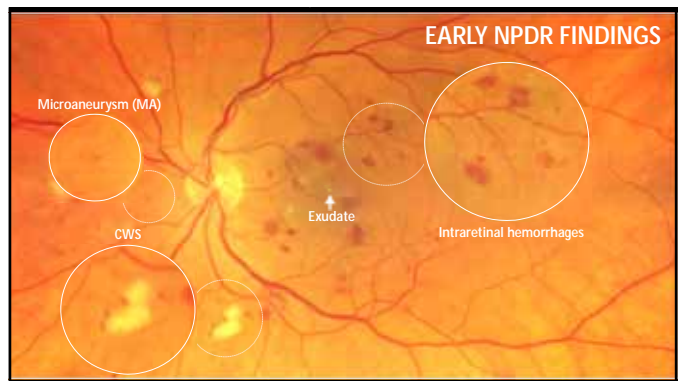
OCT ANGIOGRAPHY: THE BASICS

	Superficial	Vitreoretinal Interface (VRI)
		PRERETINAL NEO

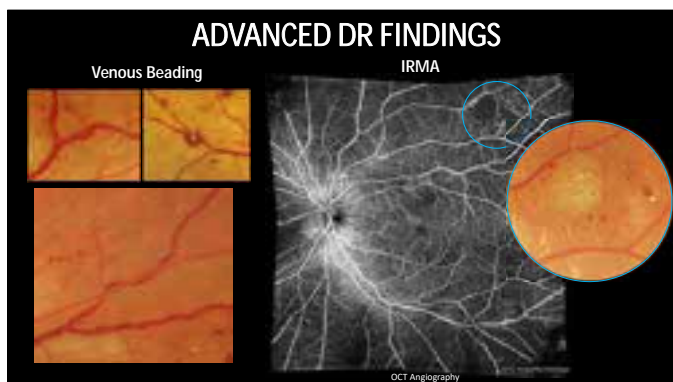
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DIABETIC RETINOPATHY STAGING

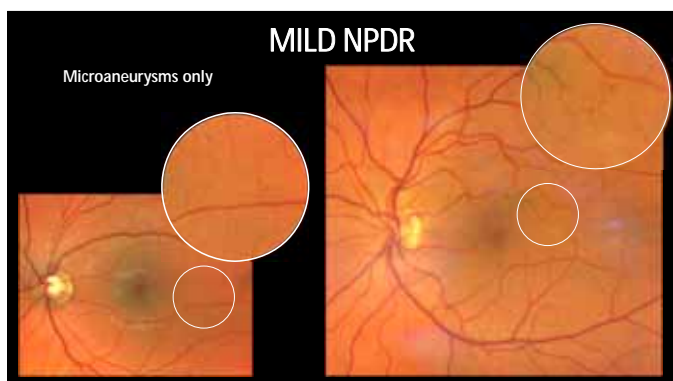
AAO PPP 2019 (p8)

TABLE 1. Classification of Diabetic Retinopathy. Clinical Classification of Diabetic Retinopathy

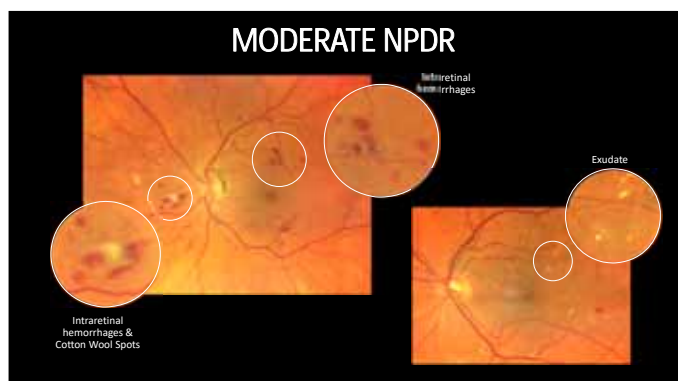
Diabetic Retinopathy Level	Findings (Characteristic signs listed in parentheses)
Non-proliferative diabetic retinopathy	No neovascularization
Mild NPDR (see text)	Microaneurysms only
Moderate NPDR (see text)	More than just microaneurysms but not just severe NPDR
Severe NPDR	Any of the following and no signs of proliferative retinopathy: <ul style="list-style-type: none"> • More than 13 intraretinal hemorrhages in 1 eye or 1000 or more • Distorted normal venous or arterial loops • Presence of MA in 1 eye or more quadrants
PDR	One or both of the following: <ul style="list-style-type: none"> • Neovascularization • Vitreous or subretinal hemorrhage

* AAO CPG Mild NPDR - marked by at least one retinal MA. Only hemorrhages & MAs are present and the severity is less than that depicted in ETDRS standard photograph 2A

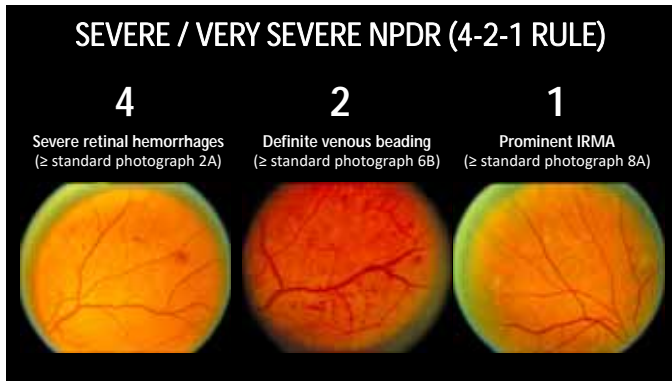
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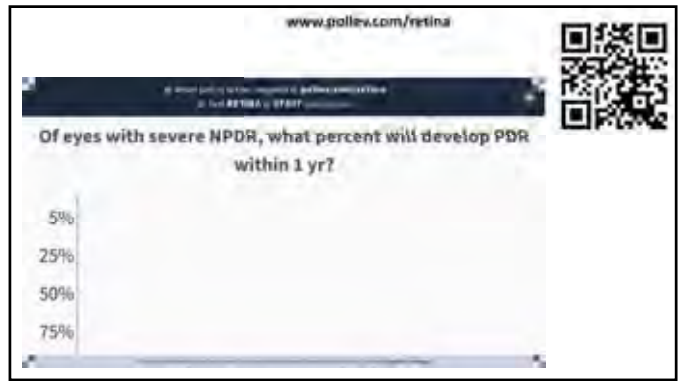
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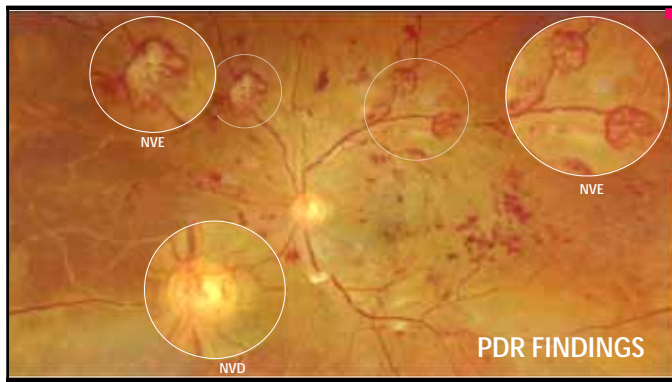
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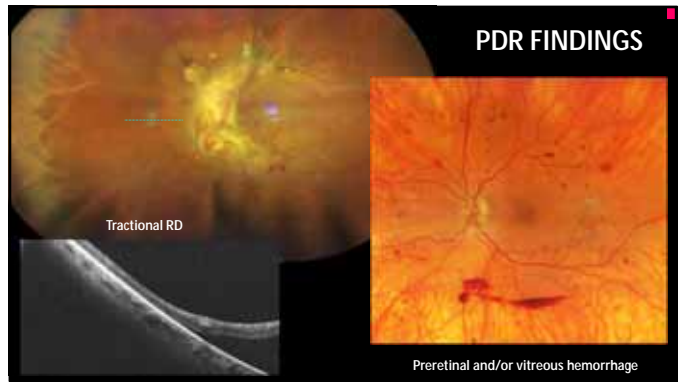
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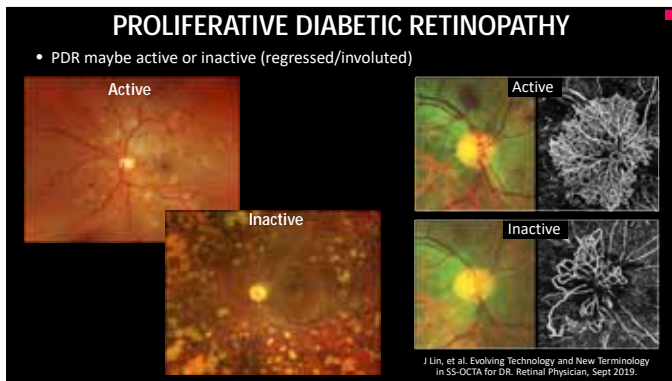
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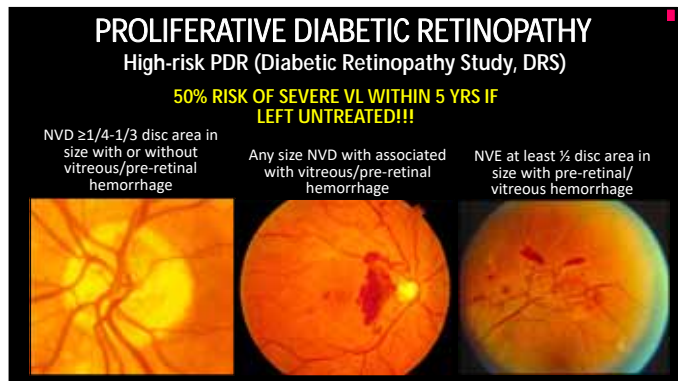
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DME STAGING

Macular edema: Retinal thickening within 2 DD of the center of the fovea

- Center involved (CI-DME) vs non-center involved (NCI-DME)
- CI-DME= thickening within the central subfield zone that is **1mm in diameter**

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Center-involved DME (CI-DME)

Mild vs Severe

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Non-center involved DME (NCI-DME)

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COMMON CAUSES OF VISION LOSS IN DR

Center-Involved DME (CI-DME)
Most common cause of VL & can occur at any stage of DR

Preretinal/Vitreous Hemorrhage (Sudden onset)

Macular Ischemia

OCTA Shows Macula

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UTILITY OF OCT/OCTA IN DME

- Aids in the classification of DME as center involved (CI-DME) vs non-center involved (NCI-DME)
- Identification of subclinical DME
- OCTA may aid in identifying sources of DME such as MAs or IRMA
- OCTA allows for detection of macular ischemia
 - Significant macular ischemia = guarded prognosis following treatment of DME
- Monitor response to treatment /determine when retreatment is necessary (change analysis)

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UTILITY OF OCT/OCTA IN DME

Identification of Subclinical DME

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THE CASE OF THE FORLORN FOVEA

OCTA- Identify Macular Ischemia

61yo Hispanic Male

- DM type 2 x 27 years
- OS VA 20/100

The image shows a fundus photograph of the left eye with a pale macula. To the right is a composite of OCTA images including a color-coded perfusion map, a structural OCT scan, and a 3D volume rendering of the macula.

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THE CASE OF THE FORLORN FOVEA

OCTA- Identify Macular Ischemia

Macular Ischemia

Normal

OCT Angiography (3mm Macula)

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THE CASE OF THE FORLORN FOVEA

OCTA Identification of Macular Ischemia

Change after 10 months, observation only
20/100 to 20/60

Baseline

10 month FU

Resolved DME

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MANAGEMENT OF DME

- Who should be treated (anti-VEGF 1st line therapy)?
 - CI-DME with VA 20/32 or worse- referral within 2-4 weeks (AOA-CPG 2019)
- Who can usually be observed?
 - NCI-DME
 - CI-DME with VA 20/25 or better - defer tx until VA is 20/30 or worse (DRCR net Protocol V)
 - Re-examine every 2-4 months
- Consider early treatment if:
 - DR stage is severe NPDR or worse
 - Planning PRP or cataract extraction
 - Systemic risk factors for progression exist (HTN, renal failure, pregnancy)
 - Pt is unobservant/uncompliant

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Utility of OCT/OCTA in Mild-Moderate NPDR

OCTA highlights subtle vascular abnormalities = more accurate DR staging

The OCTA image shows areas of nonperfusion (red arrows) and intraretinal microvascular abnormalities (IRMA, yellow arrows).

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OCTA DETECTION OF SUBCLINICAL DR

NO CLINICALLY DETECTABLE DR!!!

Normal

Diabetic without DR

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PREDOMINANTLY PERIPHERAL DIABETIC RETINOPATHY

Silva PS, et al. UWF Peripheral Lesions Predict DR Progression. Ophthalmology 2015.

- Followed 200 DR eyes for ~ 4 yrs
- Eyes with predominantly peripheral DR = majority of lesions outside the 75° ETDRS standard 7 fields
- Compared to eyes without, eyes with predominantly peripheral DR had ↑ risk of DR progression and a 4.7-fold ↑ risk for progression to PDR (6% vs. 25%).

DRCR.net Protocol AA

- ↑ risk of DR progression with UWF FA predominantly peripheral lesions but not with CFP
- Greater risk with worsening FA NP index

EYES WITH PREDOMINANTLY PERIPHERAL DR HAVE A GREATER RISK FOR DR PROGRESSION AND DEVELOPMENT OF PDR!!

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MANAGEMENT OF SEVERE NPDR-LOW RISK PDR

- Refer all regardless of DME status
- Start considering anti-VEGF therapy/PRP at the severe NPDR stage **even without CI-DME** (optional)
 - Anti-VEGF: reverse DR stage/prevent development of vision threatening complications
 - Both ranibizumab and aflibercept FDA approved even if no DME

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DRCR.net Protocol W- Effect of Intravitreal anti-VEGF vs Sham for Prevention of Vision-Threatening Complications of DR, 4 Year Results

- Randomized eyes with moderate to severe NPDR without CI-DME to sham (tx deferred until CI-DME or high risk PDR developed) vs periodic intravitreal aflibercept
- Lower rates of developing CI-DME with vision loss (11% vs 19%) or PDR (28% vs 49%) in treated eyes vs sham at 2 years
- Change in VA at 4 years: -2.7 letters vs -2.4 letters (not significant)

% Developing PDR

% Developing CI-DME

Maturi RK, et al. 4-Year Visual Outcomes in the Protocol W Randomized Trial of Intravitreal Aflibercept for Prevention of Vision-Threatening Complications of DR. JAMA Ophthalmology 2023.

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UTILITY OF IMAGING IN SEVERE NPDR-LOW RISK PDR

Wide-field Fundus Imaging

- Efficient identification/documentation of DR lesions
- Document predominantly peripheral DR

OCT/OCTA

- Live scan OCT to look for neo and determine PVD status
 - Complete PVD = lower risk for neo growth and resultant vitreoretinal traction
- OCTA definitely differentiates severe NPDR from early PDR
 - Distinguish small NVE from IRMA
 - Early detection of NVN
- Detection and quantification of nonperfusion to determine likelihood of neo/risk for progression

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MANAGEMENT OF SEVERE NPDR-LOW RISK PDR

Normal

Very Severe NPDR

- Increased risk for progression to PDR
- Consider early PRP/anti-VEGF treatment

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Utility of OCTA Montage Imaging in DR

OCTA – Visualization of peripheral NP (nearly invisible without)

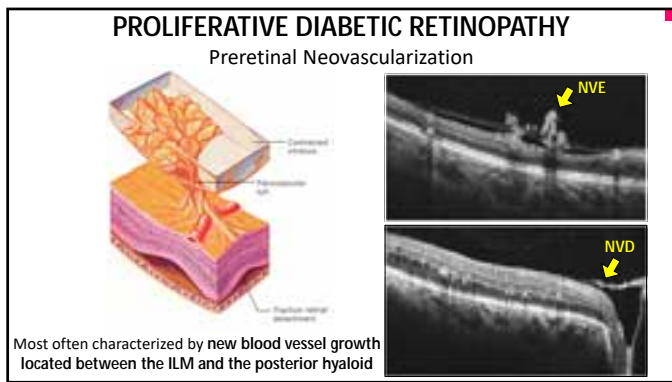
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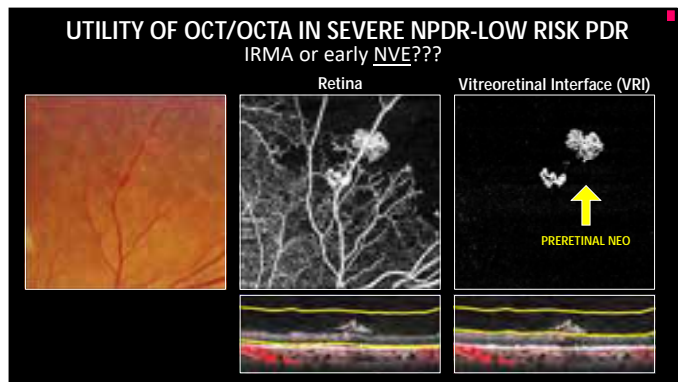
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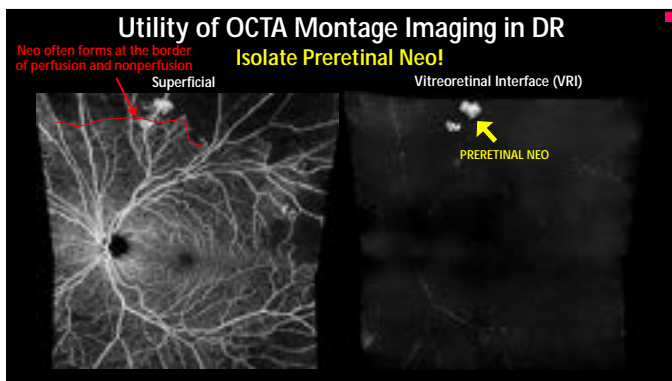
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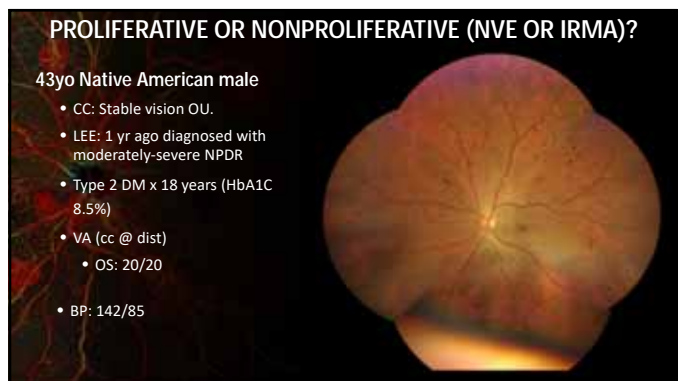
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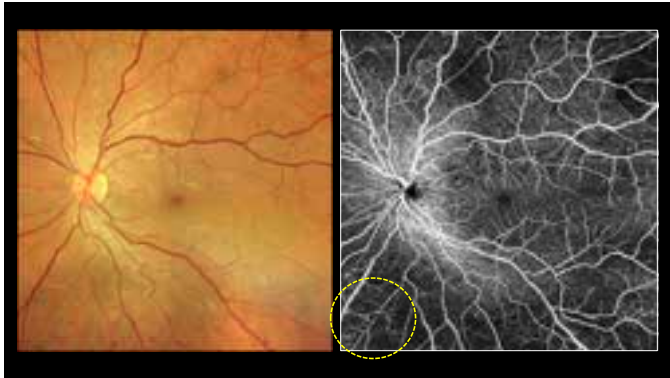
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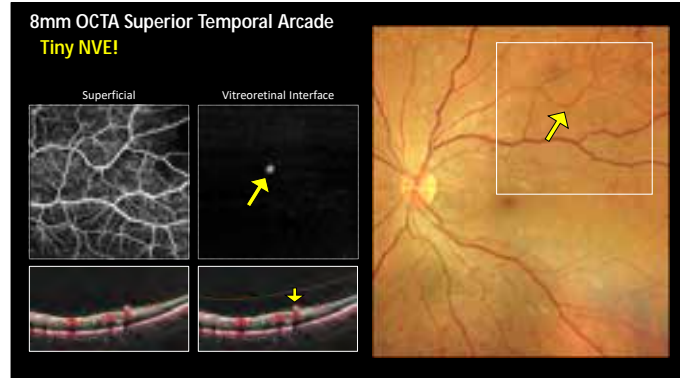
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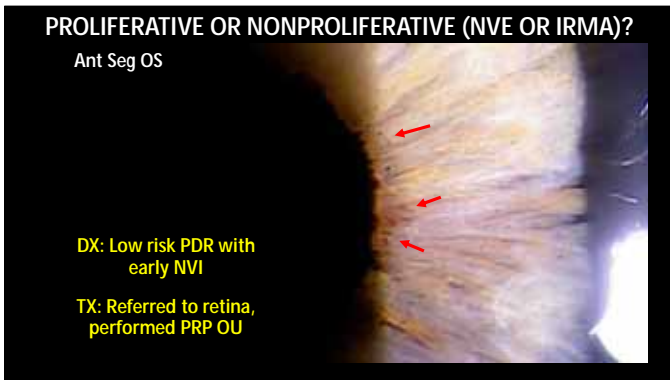
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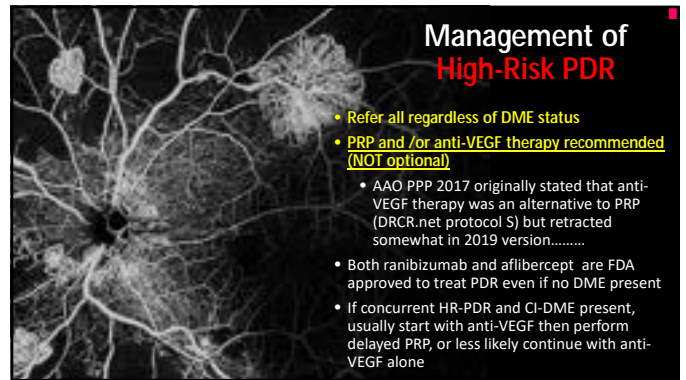
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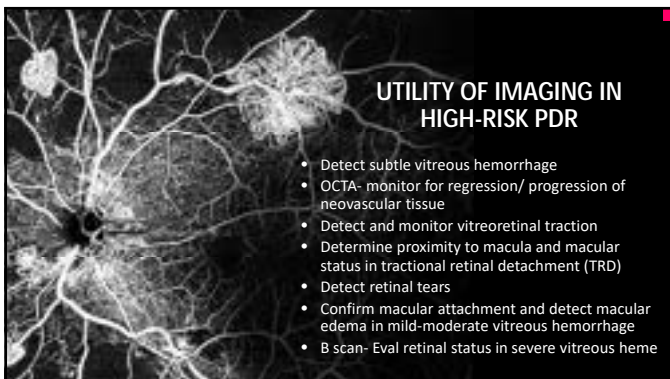
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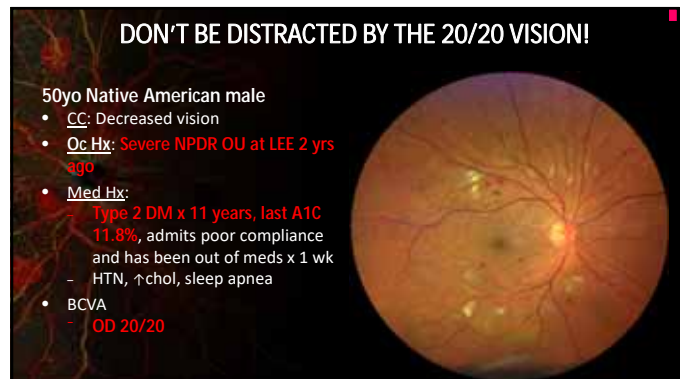
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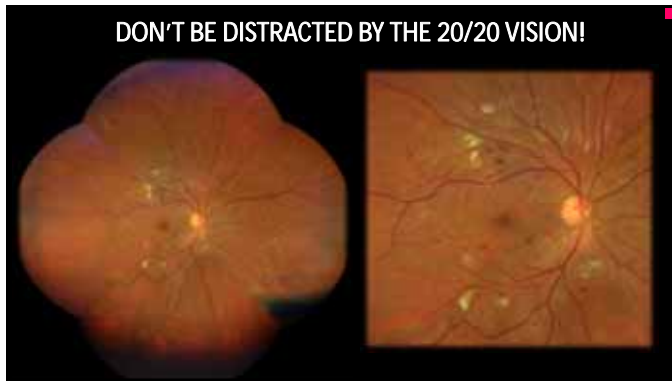
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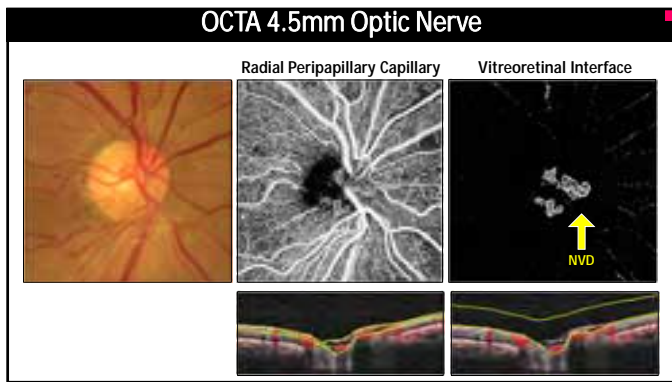
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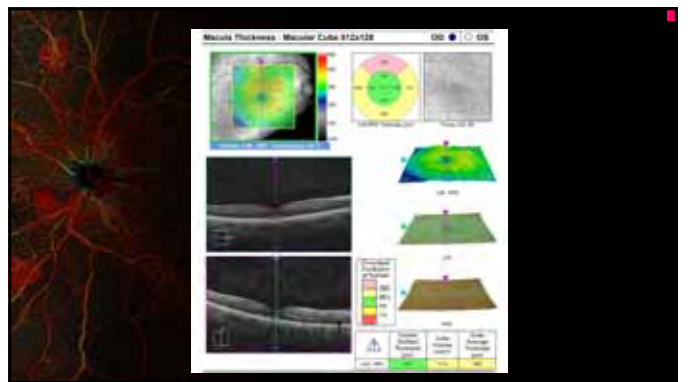
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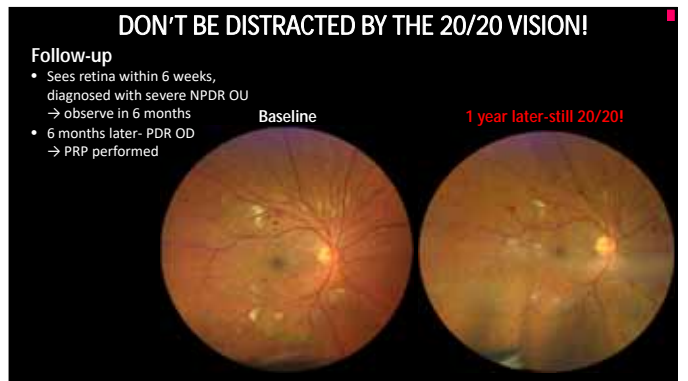
TABLE 3. Severe, Moderate, or Recommended retinopathy in Patients with Diabetes

Severity of Retinopathy	Presence of Macular Edema	Follow-up Interval	Fluorescein Angiography (FA) or Laser	Focal and/or Grid Laser*	Intensity of Anti-VEGF Therapy
Minimal or no retinopathy	No	12	No	No	No
Mild NPDR	No	12	No	No	No
	NO-DMR†	3-6	No	Sometimes	No
Moderate NPDR	CI-DMR‡	1*	No	Rarely	Usually
	No	3-12†	No	No	No
Severe NPDR	NO-DMR	3-6	No	Sometimes	Rarely
	CI-DMR‡	1*	No	Rarely	Usually
High-risk PDR	No	3-6	Sometimes	Sometimes	Sometimes
	NO-DMR	2-4	Sometimes	Sometimes	Sometimes
Very-high-risk PDR	CI-DMR‡	1*	Recommended	No	Sometimes
	No	3-6	Recommended	No	Sometimes
High-risk PDR	No	3-6	Recommended	No	Sometimes
	NO-DMR	2-4	Recommended	Sometimes	Sometimes
High-risk PDR	CI-DMR‡	1*	Recommended	Sometimes	Usually
	No	3-6	Recommended	No	Sometimes

Anti-VEGF = anti-vascular endothelial growth factor; CI-DMR = center-involved diabetic macular edema; NO-DMR = non-center-involved diabetic macular edema; NPDR = nonproliferative diabetic retinopathy; PDR = proliferative diabetic retinopathy.

American Academy of Ophthalmology – Preferred Practice Patterns 2019, p20

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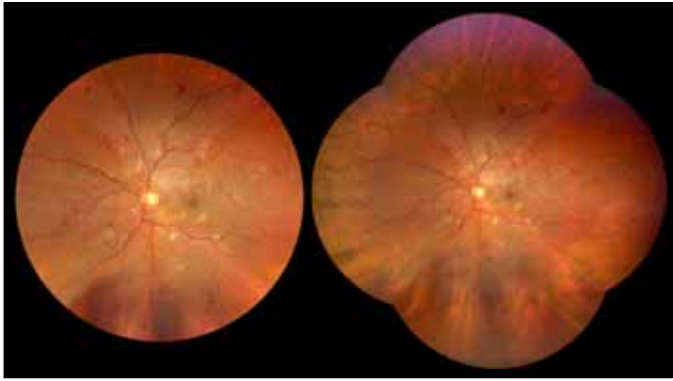
TAKING IT TO THE EXTREME

29yo Native American male – Presents for routine DM exam, needs gls

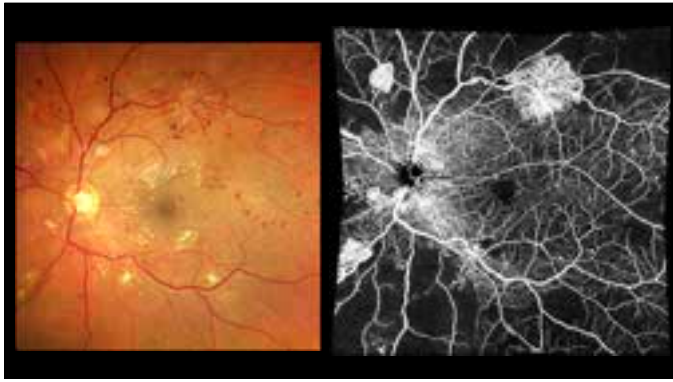
- POH: Severe NPDR OU at LEE 5 yrs ago
- MH:
 - DM Type 2 x 20 yrs, last HbA1C 8.2%
 - 2 toes amputated recently due to DM ulcer
- Vision: BCVAs @dist
 - OS 20/30⁺²
- Entrance testing: Normal
- External exam: Normal OU



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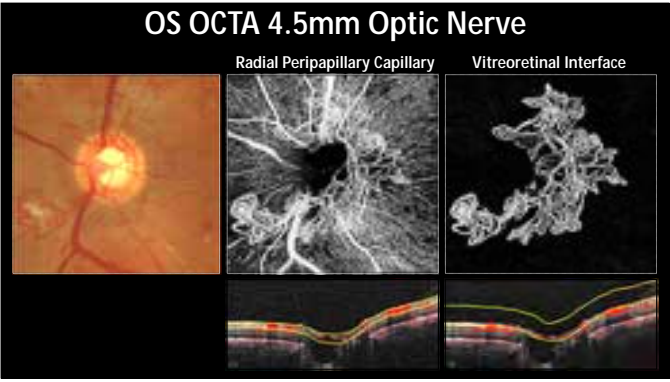
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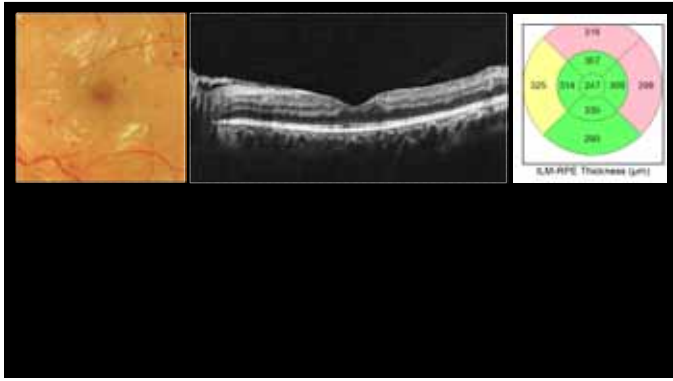
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OS OCTA 4.5mm Optic Nerve

Radial Peripapillary Capillary Vitreoretinal Interface



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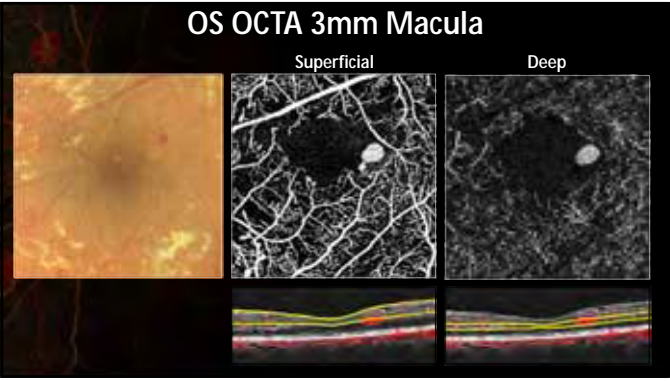
Macular Thickness (µm)

878	812	808
325	314	343
326	308	308
308	308	308

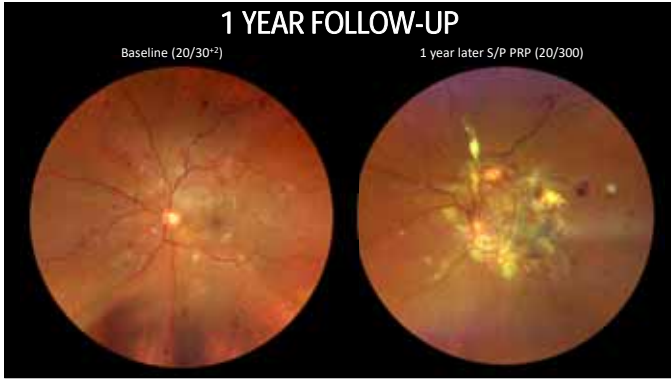
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OS OCTA 3mm Macula

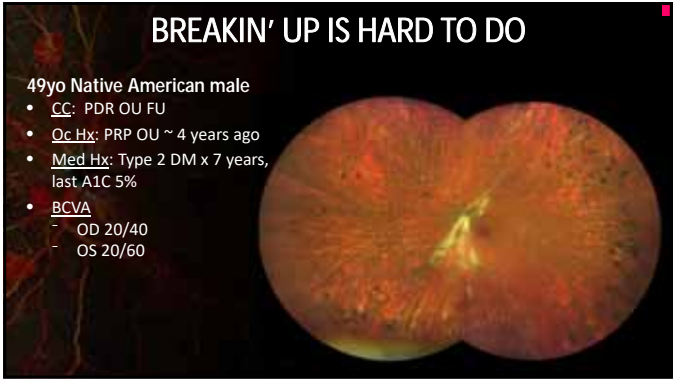
Superficial Deep



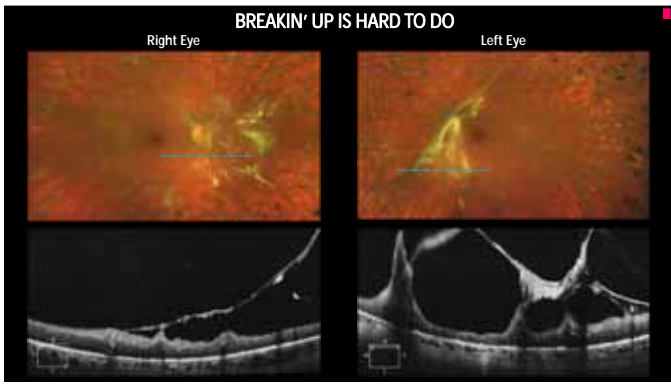
78



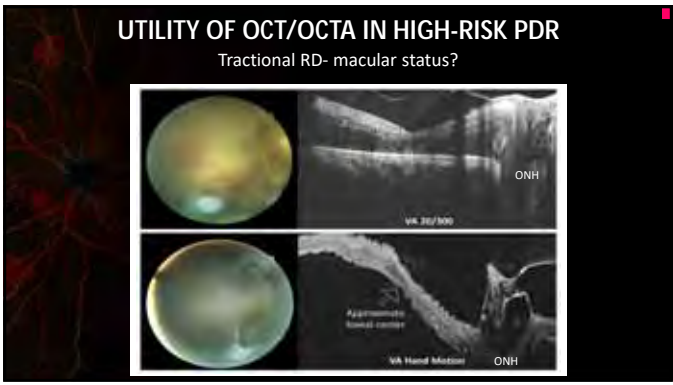
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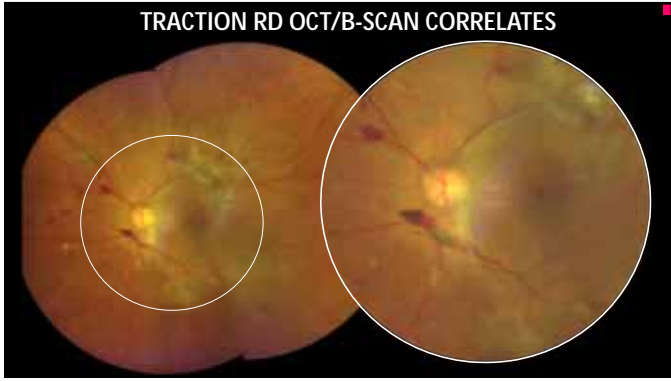
80



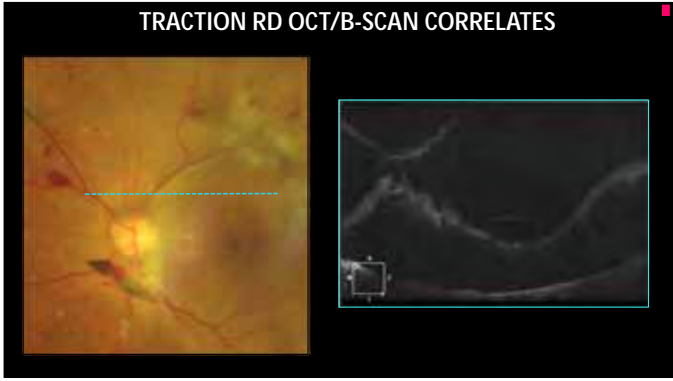
81



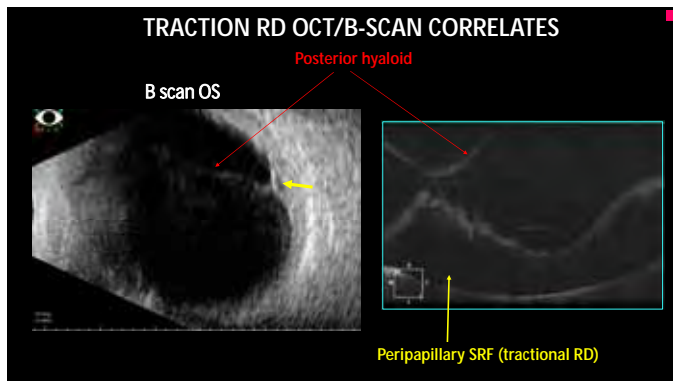
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AOA-CPG REFERRAL RECOMMENDATIONS

When to refer to a retinal specialist:

High Risk PDR	• Within 24-48 hrs
PDR	• Within 2-4 weeks
Severe NPDR (with or without macular edema)	• Within 2-4 weeks
DME	• Within 2-4 weeks

American Optometric Association- Clinical Practice Guideline 2019, p61-63

Also consider referral when:

- You are unsure of retinopathy stage
- NVI/NVA (urgent)
- TRD

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Anti-VEGF Biosimilars

Per the FDA:

- "A biosimilar is a biological product that is approved based on data showing that it is highly similar to a biological product already approved by the FDA (reference product) and has no clinically meaningful differences in terms of safety, purity and potency (i.e., safety and effectiveness) from the reference product, in addition to meeting other criteria specified by law."

Currently, 2 FDA approved Ranibizumab Biosimilars

- Byovoiv (Samsung) approved Sept 2021
- Cimerli (Coherus) approved Oct 2022

www.reviewofophthalmology.com/article/an-update-on-the-anti-vegf-biosimilar-pipeline

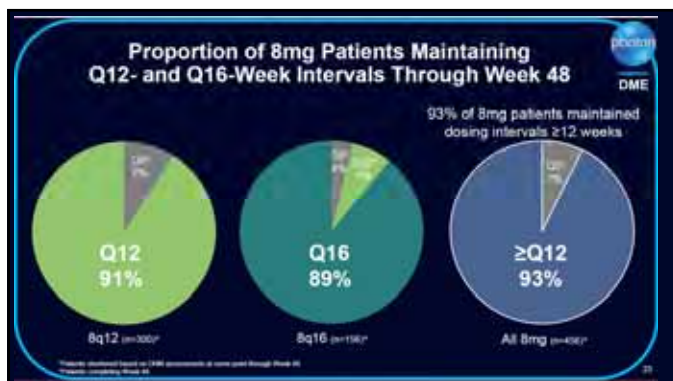
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Extended Duration Anti-VEGF Therapies

High Dose Aflibercept (8mg Eylea)

- FDA approved in Aug 2023 for nAMD, DME, & DR
- 8mg high dose vs 2mg standard dose
- Phase III PULSAR (nAMD) & PHOTON (DME) clinical trials
 - Demonstrated non-inferior and clinically equivalent vision gains at 48 wks with 8 mg at 12 and 16 week dosing after 3 initial doses compared to 2mg Eylea every 8 weeks after initial dosing
- Recommended dose 1 injection every 4 weeks for first 3 mos for all indications, then every 8-16 weeks (2-4 mos) for AMD and DME and every 8-12 weeks (2-3 mos) for DR
- No new safety signals

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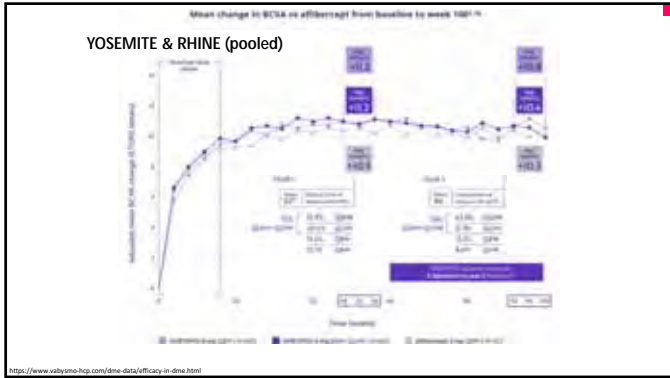
Extended Duration Anti-VEGF Therapies

Faricimab (Vabysmo)

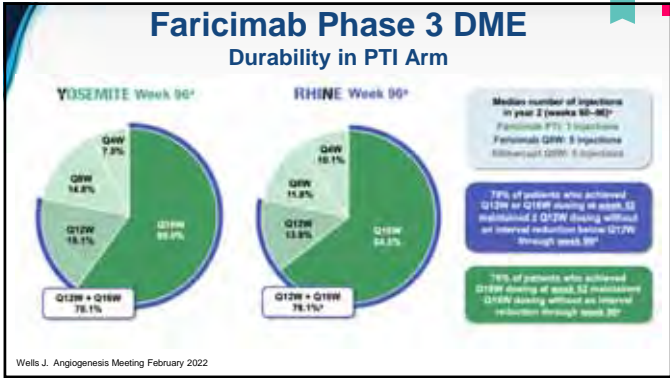
- FDA approved in Jan 2022 for nAMD & DME, Oct 2023 for RVO
- Dual MOA (bi-phasic antibody) inhibits VEGF-A & Angiopoietin-2 (Ang-2)

- Phase III DME clinical trials YOSEMITE & RHINE
 - Dosing monthly x4 months than flexible dosing based on pt need
 - 60% eligible for extended dosing could be treated every 4 months at 2 yrs

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FENOFIBRATE FOR DIABETIC RETINOPATHY

- Safe and inexpensive PO fibric acid derivative conventionally used to treat dyslipidemia, off-label for DR
 - Licensed in Australia and Singapore for the treatment of DR, generic in the US
- Experimentally has been shown to decrease vascular leakage, downregulate VEGF, & reduce endothelial cell and pericyte loss
- Dose: 160mg per day (54mg qd if mild-moderate renal disease)
- Contraindications: Severe renal disease, liver disease, possibly potentiates warfarin anticoagulation

Stewart S, et al. Fenofibrate for DR. Asia Pac J Ophthalmol (Phila). 2018 Nov-Dec;7(6):422-426.

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PERSPECTIVE

Fenofibrate – A Potential Systemic Treatment for Diabetic Retinopathy?

TEN YIN WONG, RAJESH SRIVASTAVA, AND PAUL MITCHELL
Am J Ophthalmol. 2013

"There are now robust and consistent clinical data to recommend fenofibrate as an adjunctive treatment for early DR in patients with type 2 DM, taking into account the risks vs benefits of therapy."

- Two large RCTs have demonstrated that fenofibrate in pts with Type 2 DM decreased the rate of progression in eyes with preexisting DR:
 - FIELD (Fenofibrate Intervention and Event Lowering in DM) 2005**
 - In eyes with preexisting DR, 14.6% on placebo had 2 step worsening vs 3.1% on 200mg/day fenofibrate after 22 years FU.
 - Fenofibrate also decreased need for laser treatment for PDR or DME.
 - ACCORD (Action to Control Cardiovascular Risk in DM) 2007**
- Does not reduce the risk of new DR development in eyes with no DR at baseline

SUBSTANTIAL EVIDENCE EXISTS SHOWING THAT FENOFIBRATE DECREASES DR PROGRESSION IN TYPE 2 DM!!!

Stewart S, et al. Fenofibrate for DR. Asia Pac J Ophthalmol (Phila). 2018 Nov-Dec;7(6):422-426.

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NUTRITIONAL SUPPLEMENTATION FOR DIABETIC RETINOPATHY

Pts with DR have high incidences of vitamin and mineral deficiencies

Supplementation with vitamins, minerals, and nutraceuticals may complement current tx approaches

Goals of supplementation:

- Reduce oxidative stress
- ↓ ischemic injury
- Combat elevated homocysteine
- Support retinal metabolism/function
- Promote microvascular health

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NUTRITIONAL SUPPLEMENTATION FOR DIABETIC RETINOPATHY

THE KEY PLAYERS!!

- L-methylfolate
- Natural vitamin E complex
- Vitamin D
- Vitamin C
- N-acetylcysteine
- Vitamins B1, B2, B6 & B12 (methylcobalamin)
- Lutein & zeaxanthin
- Alpha-lipoic acid

Shi C, Wang P, Airen S, et al. Nutritional and medical food therapies for diabetic retinopathy. Eye Vis (Lond). 2020;7:33.

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DIABETIC RETINOPATHY
Study shows the DR Score was the strongest predictor of progression to VTC

REVal DR Score was the strongest predictor of progression to vision-threatening complications!

RELATIVE RISK

Factor	Relative Risk
OCT-based DR Scores = 26.4	26.4
ETWT FA Index (baseline Index)	5.3
ETWT DR Scores = 3.3	3.3
OCT-A FAZ area	5.6
FP DRSS	2.1

© Quentin Davis, PhD, Nadia K. Waheed, MD, Mitchell Bragdon, PhD. Predicting Progression to Vision-Threatening Complications in Diabetic Retinopathy. Ophthalmology Science. online June 17, 2025. 00089

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DIABETIC RETINOPATHY
Sample report

- Must NOT be dilated
- DR score factors in implicit time, amplitude, pupil response, and age

DR Score	6-month Progression Risk	1-year Progression Risk
≤ 19.9	0%	0%
20.0 – 23.4	9%	48%
23.5 – 26.8	35%	60%
≥ 26.9	49%	79%

*Every 1-point increase in the DR Score increases the patient's likelihood of intervention by 20%.

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THE "TAKE HOME" MESSAGE

OCT Clinical Applications in DR

- Detect, classify, and monitor DME
- Determine PVD status
- Detect preretinal tissue suggestive of neo
- Detect and monitor vitreoretinal traction/ TRD

OCTA Clinical Applications in DR

- Detection of sub-clinical DR
- Highlight vascular abnormalities = more accurate staging
- Detection and quantification of non-perfusion
 - Peripheral and macular
- Early detection of PDR
- Monitor PDR regression with treatment

Wide-field Clinical Applications in DR

- Detection/documentation of predominately peripheral DR
 - ↑ risk for DR progression and proliferation
- More accurate and efficient staging of DR

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THANK YOU!
majcher@nsuok.edu

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