



**STATE BOARD OF OPTOMETRY**  
2450 DEL PASO ROAD, SUITE 105, SACRAMENTO, CA 95834  
P (916) 575-7170 F (916) 575-7292 www.optometry .ca.gov



### Continuing Education Course Approval Checklist

Title:

Provider Name:

- Completed Application
  - Open to all Optometrists?  Yes  No
  - Maintain Record Agreement?  Yes  No
- Correct Application Fee
- Detailed Course Summary
- Detailed Course Outline
- PowerPoint and/or other Presentation Materials
- Advertising (optional)
- CV for EACH Course Instructor
- License Verification for Each Course Instructor
  - Disciplinary History?  Yes  No

Cashiering and Board Use Only			
Receipt #	Payor ID	Beneficiary ID	Amount
1-3206	5429872	427011	\$50.00



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## CONTINUING EDUCATION COURSE APPROVAL APPLICATION

**\$50 Mandatory Fee**

Pursuant to California Code of Regulations (CCR) § 1536, the Board will approve continuing education (CE) courses after receiving the applicable fee, the requested information below and it has been determined that the course meets criteria specified in CCR § 1536(g).

In addition to the information requested below, please attach a copy of the course schedule, a detailed course outline and presentation materials (e.g., PowerPoint presentation). Applications must be submitted 45 days prior to the course presentation date.

**Please type or print clearly.**

<b>Course Title</b> Annual Vitreo-Retinal Update Course - 2017 Diseases - Diagnoses - Treatment	<b>Course Presentation Date</b> 6:00 P.M. to 9:30 P.M. 05/04/2017
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### Course Provider Contact Information

<b>Provider Name</b> Marilyn Lambert J. (First) (Last) (Middle)	
<b>Provider Mailing Address</b> Street 3395 S. Bascom Ave city Campbell State CA Zip 95008 Suite 140	
<b>Provider Email Address</b> <u>marilyn_lambert@yahoo.com</u>	
<b>Will the proposed course be open to all California licensed optometrists?</b>	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
<b>Do you agree to maintain and furnish to the Board and/or attending licensee such records of course content and attendance as the Board requires, for a period of at least three years from the date of course presentation?</b>	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

### Course Instructor Information

Please provide the information below and attach the curriculum vitae for each instructor or lecturer involved in the course. If there are more instructors in the course, please provide the requested information on a separate sheet of paper.

<b>Instructor Name</b> #1, Amr Desrosier L. (First) (Last) (Middle)	
<b>License Number</b> <u>A 53889</u>	<b>License Type</b> <u>CA Medical License</u>
<b>Phone Number</b> (408) <u>559-0666</u>	<b>Email Address</b> <u>amr@desrosier.com</u>

I declare under penalty of perjury under the laws of the State of California that all the information submitted on this form and on any accompanying attachments submitted is true and correct.

*Marilyn Lambert*  
 Signature of Course Provider

05-08-17  
 Date

**COURSE INSTRUCTOR INFORMATION**

**Instructor #2:**

**Patrick Monahan, M.D.**

**License No: G 60723**

**Phone # 408 559-0666**

**License Type: CA Medical License**

**E-Mail Address: patserero@yahoo.com**

**Instructor #3:**

**Howard H. Chen, M.D.**

**License No. G83824**

**Phone # 408 559-0666**

**License Type: CA Medical License**

**E Mail Address: howardhchenmd@yahoo.com**

**Instructor #4:**

**Clement C. Chow, M.D.**

**License # A126226**

**Phone # 408 559-0666**

**License Type: CA Medical License**

**E Mail Address: clementchowmd@gmail.com**

**Instructor #5:**

**Lingmin He, M.D.**

**License # A118105**

**Phone # 408 559-0666**

**License Type: CA Medical License**

**E Mail Address: lisahe@gmail.com**

# **Retinal Diagnostic Center**

*Diseases & Surgery of the Retina, Macula & Vitreous*  
[www.Retinaldiagnostic.com](http://www.Retinaldiagnostic.com)

**BRIAN WARD, PH.D., M.D.**  
**AMR DESSOUKI, M.D.**

**PATRICK M. MONAHAN, M.D.**  
**CLEMENT CHOW, M.D.**

**HOWARD CHEN, M.D.**  
**LINGMIN LISA HE, M.D., M.S.**

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**March 2, 2017**

**Kristina Eklund**  
**CA State Board of Optometry**  
**2450 Del Paso Road. Suite 105**  
**Sacramento, CA 95834**

**Dear Kristina:**

**It was such a pleasure to speak with you on the telephone a few days ago regarding the upcoming seminar on May 4<sup>th</sup> 2017, that our physicians would like to present to the optometrists.**

**Enclosed please find the Course Approval application along with a check for \$50.00 for the Course Fee. I am also enclosed a brief outline with the Title of the Presentation and detailing the number of CE Hours we are requesting along with the name of the venue where the presentation will take place and the starting time and ending time of the event.**

**The doctor's are endeavoring to put their talk information into a format which I can then E-Mail to you. I will try and link together as many of the talks as possible into one E-Mail. If not possible I will have to either mail them or send a second E-Mail. I will also include copies of their CV's at that time.**

**The names of the presenting doctors from Retinal Diagnostic Center will be:**

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- 3395 S. Bascom Ave, Ste. 140 Campbell, CA 95008 Ph. # (408) 559-0666 Fax (408) 377-0811
- 200 Jose Figueres Ave, Ste. 240 San Jose, CA 95116 Ph. # (408) 937-0928 Fax (408) 254-8954
- 1663 Dominican Way, Ste. 110-A Santa Cruz, CA 95065 Ph. # (831) 476-5888 Fax (831) 476-5563
- 65 Nielson St., Ste. 115 Watsonville, CA 95076 Ph. # (831) 724-2626 Fax (831) 724-2676
- 123 DiSalvo Avenue, Ste E, San Jose, CA 95128 Ph. (408) 418-2200 Fax (408) 418-2205
- 7888 Wren Ave, Suite C-137 Gilroy, CA 95020 Ph. # (408) 767-2904 Fax (408) 767-2906
- 3301 El Camino Real, Suite 101 Atherton, CA 94027 Ph. #(650) 257-3861 Fax (650) 562-7843

Amr Dessouki, M.D.  
Howard Chen, M.D.  
Clement Chow, M.D.  
Patrick Monahan, M.D.  
Lingmin He, M.D.

My E-Mail is: [marilyn\\_lambert@yahoo.com](mailto:marilyn_lambert@yahoo.com). Could you send me a quick E-Mail just to let me know you have received this information along with the \$50.00 check. As soon as it clears the bank, I will include a copy of the cancelled check with the other material.

Thank you so much for your kind consideration of our presentation and thanks also for being so very kind and helpful on the telephone the other morning. Sending all the talk format by E-Mail is a little new to me from past times, and you helped clarify everything and answered all my questions, so again thank you very much.

Sincerely,



Marilyn Lambert

Office Manager and Program Co-ordinator  
Retinal Diagnostic Center, Inc.

# Retinal Diagnostic Center

*Diseases & Surgery of the Retina, Macula & Vitreous*  
[www.Retinaldiagnostic.com](http://www.Retinaldiagnostic.com)

BRIAN WARD, PH.D., M.D.  
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## ANNUAL VITREO-RETINAL UPDATE COURSE-2017

### Diseases – Diagnoses- Treatment

The physicians of Retinal Diagnostic Center will present a course on all aspects of retinal diseases and surgery. Each Speaker will give a presentation on a particular retinal disease and/or surgery of the back of the eye and show how it is diagnosed, give options for treatment and in some instances show how surgical intervention would be the best method of treatment.

All topics will be directly related to diseases and surgery of the retina and vitreous and therefore are directly tied together for this one presentation.

There will be a total of five physicians from Retinal Diagnostic Center giving presentations at this even: Amr Dessouki, M.D., Patrick Monahan, M.D., Howard Chen, M.D., Clement Chow, M.D., and Lingmin He, M.D.

Each physician will present a 30 minute talk on their particular aspect of retinal and/or vitreous disease and then there will be a 15 minute Question and Answer Period at the conclusion of these presentations for a total of 2.75 hours of Continuing Education.

A check for \$50.00 is being sent for the Course Fee. I have asked each physician from Retinal Diagnostic Center to prepare an Outline and a Summary of their talks and have also asked them to put their slides in a power point presentation form so that all this together can be considered for the Continuing Education Credits.

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- 3395 S. Bascom Ave, Ste. 140 Campbell, CA 95008 Ph. # (408) 559-0666 Fax (408) 377-0811
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  - 1663 Dominican Way, Ste. 110-A Santa Cruz, CA 95065 Ph. # (831) 476-5888 Fax (831) 476-5563
  - 65 Nielson St., Ste. 115 Watsonville, CA 95076 Ph. # (831) 724-2626 Fax (831) 724-2676
  - 123 DiSalvo Avenue, Ste E, San Jose, CA 95128 Ph. (408) 418-2200 Fax (408) 418-2205
  - 7888 Wren Ave, Suite C-137 Gilroy, CA 95020 Ph. # (408) 767-2904 Fax (408) 767-2906
  - 3301 El Camino Real, Suite 101 Atherton, CA 94027 Ph. # (650) 257-3861 Fax (650) 562-7843

**This presentation will be held on May 4, 2017 at the Saratoga Country Club ,  
21990 Prospect Road, Saratoga, CA 95070. This will be a dinner presentation for  
the OD's with cocktails at 6:00 P.M. and dinner and presentation beginning at  
6:45 P.M. The Event will conclude at 9:30 P.M.**

**We sincerely hope that this will be an interesting, educational and enjoyable  
event for all attending optometrists, and we very much look forward to seeing  
and meeting with all those who will be able to attend.**

**Thank you for your consideration of this presentation by our physicians and we  
sincerely hope that you will approve our course for the continuing education  
credits applied for.**

**We will look forward to hearing from you soon. Please let us know if there is  
anything further that you need.**

**Sincerely,**

A handwritten signature in cursive script, appearing to read "Marilyn Lambert", with a long horizontal flourish extending to the right.

**Marilyn Lambert**

**Office Manager**

**Retinal Diagnostic Center, Inc.**

*You are cordially invited . . .*

*Please join us for another informative and educational dinner seminar.*

*Annual Vitreo - Retinal Update Course -2017  
Diseases - Diagnoses - Treatment*

*Presented by the Physicians of Retinal Diagnostic Center*

*Thursday, May 4, 2017*

*Cocktails: 6:00 p.m. Dinner and Presentation to follow.*

*Saratoga Country Club*

*21990 Prospect Road, Saratoga, California 95070*

**2.75 hours of C.E. credit have been applied for.**

**Seating is limited, so we will accept reservations in the order they are received.**

*RSVP by April 21, 2017*

*408-559-0666*

*Menu selection, please choose one  
Filet Mignon, Baked Salmon or Vegetarian*



## **Title: What's New in Macular Degeneration**

Outline:

- Overview of Wet AMD.
- Current available therapies for Wet AMD.
- Future therapies for wet AMD, what's in the pipelines.
- Overview of dry AMD.
- Future therapies for dry AMD, what's in the pipelines.

## CURRICULUM VITAE

**Name:** Amr L. Dessouki, M.D.  
**Date of Birth:** 8 January 1965  
**Citizenship:** United States of America  
**Marital Status:** Married, Rasha E. Dessouki  
**Children:** Layla and Jimmy

**Address:**  
**Work:** 3395 S. Bascom Avenue, Suite 140  
Campbell, CA 95008  
Phone: (408) 559 - 0666  
Fax: (408) 377 - 0811

**Home:** 33 Mayer Court  
Los Altos, CA 94022  
Phone: (650) 949 - 2324  
Mobile: (650) 714 - 4079

**E-mail:** amr@dessouki.com

### Professional Experience:

**2002 – Present** Associate Partner and Director of Research, Retinal Diagnostic Center, Campbell, California  
**2000 – 2002** Private practice, Retina Associates, P.A., Jacksonville, Florida  
**1999 – 2000** Vitreo-Retinal Fellow, Bascom Palmer Eye Institute, University of Miami School of Medicine, Miami, Florida  
**1998 – 1999** Chief Resident, Department of Ophthalmology, Stanford University School of Medicine, Stanford, California  
**1996 – 1998** Resident, Department of Ophthalmology, Stanford University School of Medicine, Stanford, California  
**1995 – 1996** Research Fellow, Retina Division, Jules Stein Eye Institute, UCLA School of Medicine, Los Angeles, California  
**1992 – 1995** Resident, Department of Internal Medicine, Brown University School of Medicine, Providence, Rhode Island  
**1990 – 1992** Research Fellow and Transplant Coordinator, National Institute of Transplantation, SCOPC, University of Southern California, Los Angeles, California  
**1989 – 1990** Intern, Cairo University Hospitals, Egypt  
Ophthalmology rotation at The Vitreous and Retina Clinic (Dr. Aly El Mofty) Cairo, Egypt  
Thoracic Cardiovascular Surgery rotation at Queen of Angels-Hollywood Presbyterian Medical Center, Los Angeles, California

## **Executive Positions:**

- 2006 – 2007** President, Peninsula Eye Society, Los Altos, California  
**2004 – 2005** Chairman, Department of Ophthalmology, Community Hospital of Los Gatos, Los Gatos, California

## **Academic Positions:**

- 2005 – Present** Adjunct Clinical Instructor, Department of Ophthalmology, Stanford University School of Medicine, Stanford, California  
**1999 – 2000** Instructor, Bascom Palmer Eye Institute, University of Miami School of Medicine, Miami, Florida

## **Clinical Research Experience:**

- 2004 – 2006** Principal Investigator, PIER FVF3192g: *A Phase IIIb, Multicenter, Randomized, Double-Masked, Sham Injection-Controlled Study of the Efficacy and Safety of Ranibizumab in Subjects With Subfoveal Choroidal Neovascularization (CNV) With or Without Classic CNV Secondary to Age-Related Macular Degeneration*
- 2005 – 2007** Principal Investigator, SAILOR FVF3689g: *A Phase IIIb Single-Masked, Multicenter, Randomized Study to evaluate the Safety and Tolerability of Ranibizumab in Naïve and Previously Treated Subjects With Choroidal Neovascularization (CNV) Secondary to Age-Related Macular Degeneration (AMD)*
- 2007 – Present** Principal Investigator, BRAVO FVF4165g: *A Phase III, Multicenter, Randomized, Sham Injection-Controlled Study of the Efficacy and Safety of Ranibizumab Injection Compared with Sham in Subjects with Macular Edema Secondary to Branch Retinal Vein Occlusion.*
- 2007 – Present** Principal Investigator, CRUISE FVF4166g: *A Phase III, Multicenter, Randomized, Sham Injection-Controlled Study of the Efficacy and Safety of Ranibizumab Injection Compared with Sham in Subjects with Macular Edema Secondary to Central Retinal Vein Occlusion.*
- 2007 – Present** Principal Investigator, RISE FVF4170g: *A Phase III, Double-Masked, Multicenter, Randomized, Sham Controlled Study of the Efficacy and Safety of Ranibizumab Injection in Subjects with Clinically Significant Macular Edema with Center Involvement Secondary to Diabetes Mellitus.*
- 2007 – Present** Principal Investigator, CABERNET NVI-114: *A Randomized, Prospective, Active Controlled, Study of the Epi-Rad<sub>90</sub><sup>TM</sup> Ophthalmic System for the Treatment of Subfoveal Choroidal Neovascularization Associated with Wet Age-Related Macular Degeneration*

- 2007 – Present** Principal Investigator; VIEW 1 VGFT-OD-0605: *A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects with Neovascular to Age-Related Macular Degeneration*
- 2007 – Present** Principal Investigator; RADICAL BPD OCR 022: *A Multicenter, Randomized,, Single-Masked Comparing Reduced-fluence Visudyne®-Lucentis® Combination Therapies and Lucentis Monotherapy in Subjects with CN V Secondary to AMD*
- 2008 – Present** Principal Investigator; HORIZON FVF3426g: *Open-Label Study to Evaluate the Safety and Tolerability of Ranibizumab in Subjects with Choroidal Neovascularization (CNV) Secondary to Age-Related Macular Degeneration (AMD) or Macular Edema Secondary to Retinal Vein Occlusion (RVO) Who have completed a Genentech-Sponsored Ranibizumab Study. Present*
- 2008 – Present** Principal Investigator; RIDE FVF4168g: *A Phase III, Double-Masked, Multicenter, Randomized, Sham Injection-Controlled Study of the Efficacy and Safety of Ranibizumab Injection in Subjects with Clinically Significant Macular Edema with Center Involvement Secondary to Diabetes Mellitus.*
- 2008 – Present** Principal Investigator, HORIZON FVF3426G: *An Open-label, Multicenter Extension Study to Evaluate the Safety and Tolerability of Ranibizumab in Subjects with Choroidal Neovascularization (CNV) Secondary to Age-Related Macular Degeneration (AMD) or Macular Edema Secondary to Retinal Vein Occlusion (RVO) Who have Completed a Genentech-Sponsored Ranibizumab Study.*
- 2009 – Present** Principal Investigator, HARBOR FVF4579g: *A Phase III, Double Masked, Multicenter, Randomized, Active Treatment-Controlled Study OF The Efficacy and Safety of 0.5 mg and 2.0mg Ranibizumab Administered Monthly or on an As-Needed Basis (PRN) in Patients with Subfoveal Neovascular Age-related Macular Degeneration.*
- 2009 – Present** Principal Investigator, MICROPLASMIN TG-MV-007: *A Randomized, Placebo Controlled, Double-Masked, Multicenter Trial of Microplasmin Intravitreal Injection For Non-Surgical Treatment of Focal Vitreomacular Adhesion.*

**Education:**

1982 – 1988 M.B.B.Ch., Cairo University School of Medicine, Cairo, Egypt  
1970 – 1982 French Jesuits' Catholic School, Cairo, Egypt

**State Licensure:** California # A053889

**Board Certification:** Diplomate, American Board of Ophthalmology

**Awards and Honors:**

1996 Scholarship from the Dr. B. Kriesky Eye Foundation  
1986 Honors in Ophthalmology, Cairo University

**Membership in Scientific**

**Organizations:** American Academy of Ophthalmology (Fellow)  
California Society of Ophthalmology  
Santa Clara County Medical Society  
Santa Cruz County Medical Society

**Languages:** English, French, Arabic, and fair Spanish

## BIBLIOGRAPHY

**Publications:**

- Dessouki A, and Smiddy, W. Prophylactic endolaser photocoagulation with silicone oil removal. *MEJO (in press)*.
- Arevalo JF, Rodriguez FJ, Rosales-Meneses JL, Dessouki A, Chan CK, Mitra RA, Ruiz-Moreno JM. Vitreoretinal surgery for macular hole after laser assisted in situ keratomileusis for the correction of myopia. *Br J Ophthalmol* 2005;89(11):1423-6.

- Arevalo JF, Mendoza AJ, Valez-Vazquez W, Rodriguez FJ, Rodriguez A, Rosales-Meneses JL, Yopez JB, Ramirez E, Dessouki A, Chan CK, Mitra RA, Ramsay RC, Garcia RA, Ruiz-Moreno JM. Full-thickness macular hole after LASIK for the correction of myopia. *Ophthalmology* 2005;112(7):1207-12.
- Scott I, Lieb D, Flynn HW Jr, Dessouki A, Murray T, and Miller D. Endophthalmitis caused by mycobacterium chelonae: selection of antibiotics and outcomes of treatment. *Arch Ophthalmol* 2003;121:573-576.
- Yoshizumi M, Bhavsar A, Dessouki A, and Kashani A. Safety of multiple intravitreal injections of combined antibiotics and dexamethasone. *Retina* 1999;19:437-441.
- Yoshizumi M, Dessouki A, Lee DA, and Lee G. Determination of ocular toxicity in multiple applications of foscarnet iontophoresis. *J Ocular Pharm Therap* 1997;13:529-536.
- Travin M, Dessouki A, Cameron T, Yun C, and Heller G. Use of exercise technetium-99 sestamibi imaging to detect residual ischemia and for risk stratification after acute myocardial infarction. *Am J Cardiol* 1995;75:665-669.
- Dessouki A, and Travin M. Thallium-201 imaging following thrombolysis in a 48-year-old man. *Ch Cardiol* 1994;8:203-205.
- Mendez R, Aswad S, Dessouki A, Cicciarelli J, and Mendez RG. Costs and financing of kidney transplantation in the United States. *Transpl Proc* 1992;24,5:2027-28.
- Mendez R, Aswad S, Dessouki A, Mendez RG, Obispo E, Gavozof M, and Cicciarelli J. Difficulties of foreigners seeking transplantation in the United States. *Transpl Proc* 1992;24,5:2075-76.
- Aswad S, Cicciarelli J, Mendez R, and Dessouki A. Renal transplantation from donors over sixty years old. *Transplantation* 1992;53:213-214.

### **Abstracts and Presentations:**

- Arevalo JF, Mendoza AJ, Fernandez CF, Rodriguez FJ, Rodriguez A, Rosales-Meneses JL, Dessouki AL, Chan CK, Mitra RA, and Ramsay RC. Characteristics and surgical outcomes of full-thickness macular hole after LASIK. *Presented at the AAO/SOE Joint meeting, New Orleans, LA, October 2004.*
- Arevalo J, Ruiz-Moreno JM, Mendoza, AJ, Fernandez CF, Velez-Vazquez W, Rodriguez A, Rosales-Meneses JL, Dessouki A, Chan CK. Maculopathies after Laser-assisted in situ Keratomileusis (LASIK). *Presented at ARVO, Fort Lauderdale, Florida, May 2004.*
- Dessouki A, Davis JL, Song M, Freeman W, Fishman H, Mansour S, Postelmans L, Caspers-Velu L, Engstrom R, and Feuer W. Effects of Silicone Oil Removal on CMV-Related Retinal Detachments. *Presented at the Vitreous Society 18<sup>th</sup> Annual Meeting, Cancun, Mexico, January 2001.*

- Dessouki A. Eales Disease. *Presented at the Florida Society of Ophthalmology Meeting, Amelia Island, Florida, September 2000.*
- Dessouki A, and Smiddy, W. Prophylactic endolaser photocoagulation with silicone oil removal. *Presented at the Bascom Palmer Eye Institute 36<sup>th</sup> Annual Residents Day Meeting, Miami, Florida, June 2000.*
- Dessouki A, Flynn HW Jr, and Miller D. Mycobacterium chelonae endophthalmitis. *Presented at ARVO, Fort Lauderdale, Florida, May 2000.*
- Dessouki A, Blumenkranz M, and Sanislo S. Subretinal TPA for the treatment of CRVO. *Presented at the Stanford research and graduation day, June 1999*
- Dessouki A, Byrd S. The effect of the resident's dominant hand and the operated eye on the outcomes of cataract surgery. *Presented at ARVO, Fort Lauderdale, FL, May 1999.*
- Yoshizumi M, Bhavsar A, Dessouki A, and Kashani A. Safety of multiple intravitreal injections of combined antibiotics and dexamethasone. *Presented at the Retina Society meeting, Washington DC, September 1998.*
- Dessouki A, Blumenkranz M, and Wendel R. Gender Influence on the incidence of bilateral macular holes and on the outcome surgery. *Presented at the XXVIIIth International Congress of Ophthalmology, Amsterdam, June 1998.*
- Dessouki A, and Mansour S. Effect of newer anti-HIV therapy on the progression of CMV retinopathy. *Presented at the Stanford research and graduation day, June 1997.*
- Palmer J, Yoshizumi M, Mondino B, Adamu S, Lee G, Dessouki A, and Kashani A. Treatment of staphylococcus endophthalmitis with intravitreal ketorolac. *Presented at ARVO, Fort Lauderdale, Florida, April 1996.*
- Travin M, Dessouki A, Cameron T, Yun C, and Heller G. Prediction of cardiac events following acute myocardial infarction with exercise technetium-99m sestamibi SPECT imaging. *Presented at the American Heart Association 67th scientific sessions, Dallas, Texas, November 1994. Circulation 1994;90,2:1103.*
- Aswad S, Cicciarella J, Mendez R, and Dessouki A. The sex effect on cyclosporine A level in kidney transplant patients.
- Mendez R, Dessouki A, and Aswad S. Post-transplant urological complications.
- Aswad S, and Dessouki A. Effect of hemoglobin level on the outcome of kidney transplantation.
- Aswad S, Dessouki A, and Mendez R. Outcome of locally transplanted versus shared kidney.

**Amr Dessouki, MD**  
Curriculum Vitae Addendum - Clinical Research Experience

Diabetic Retinopathy	<b>ThromboGenics TG-MV-015 - A Phase 2, Randomised, Double Masked, Sham Controlled, Multi-Centre Study To Evaluate The Efficacy And Safety Of Ocriplasmin In Inducing Total Posterior Vitreous Detachment (Pvd) In Subjects With Non-Proliferative Diabetic Retinopathy (Npdr) (Circle)</b>	2015	Present	PI
Macular Degeneration	<b>Allergan 150998-006 - Safety and Efficacy of Abicipar Pegol (AGN-150998) in Patients with Neovascular Age-related Macular Degeneration.</b>	2015	Present	PI
Macular Degeneration	<b>Ionic IT-002 - A Phase 2 Randomized, Double-masked, Multicenter, Active-controlled Study Evaluating Administration of Repeated Intravitreal Doses of hi-con1™ in Patients with Choroidal Neovascularization Secondary to Age-related Macular Degeneration</b>	2015	Present	PI
Macular Degeneration	<b>Ophthotech OPH1002 - A Phase 3 Randomized, Double-Masked, Controlled Trial To Establish The Safety And Efficacy Of Intravitreal Administration Of Fovista® (Anti Pdgf-B Pegylated Aptamer) Administered In Combination With Lucentis® Compared To Lucentis® Monotherapy In Subjects With Subfoveal Neovascular Age-Related Macular Degeneration (Oph1002)</b>	2015	2015	PI
Macular Degeneration	<b>Ophthotech OP1004 - A Phase 3 Randomized, Double-Masked, Controlled Trial to Establish The Safety and Efficacy of Intravitreal Administration of Fovista™ (Anti PDGF-B Pegylated Aptamer) Administered in Combination With Either Avastin® OR Eylea® Compared to Avastin® or Eylea® Monotherapy in Subjects With Subfoveal Neovascular Age-Related Macular Degeneration (OPH1004)</b>	2015	Present	PI
Diabetic Macular Edema	<b>Pfizer B1261009- A Phase 2, Randomized, Double-Masked, Placebo-Controlled, Parallel Group, Multi-Center Study To Compare The Efficacy And Safety Of A Chemokine Ccr2/5 Receptor Antagonist (Pf-04634817) With That Of Ranibizumab In Adult Subjects With Diabetic Macular Edema</b>	2014	2015	PI
Macular Degeneration	<b>Roche GX29633 - A Multicenter, Prospective Epidemiologic Study Of the Progression Of Geographic Atrophy Secondary To Age-Related Macular Degeneration</b>	2015	Present	PI
Macular Degeneration	<b>Roche BP29647 - A Multiple-Center, Multiple-Dose And Regimen, Randomized, Active Comparator Controlled, Double-Masked, Parallel Group, 36 Week Study To Investigate The Safety, Tolerability, Pharmacokinetics, And Efficacy Of Ro6867461 Administered Intravitreally In Pa- Tients With Choroidal Neovascularization Secondary To Age Related Macular Degeneration</b>	2015	Present	PI
Macular Degeneration	<b>Lpath LT1009-OPH-003 - A Phase 2A, Multi-Center, Blinded, Randomized, Comparator Study Evaluating Isoneptm (Sonepcizumab [LT1009]) As Either Monotherapy or Adjunctive Therapy to Lucentis Alone in the Treatment of Subjects with Choroidal Neovascularization Secondary to age-Related Macular Degeneration</b>	2014	2015	PI
Observational Study	<b>ThromboGenics TG-MV-018 - Ocriplasmin Research to Better Inform Treatment (ORBIT)</b>	2014	Present	PI
Observational Study	<b>ThromboGenics TG-MV-022 - Phase 4, OZONE: Ocriplasmin Ellipsoid Zone Retrospective Data Collection Study</b>	2014	2015	PI

Investigator Signature

Date



Title: Plaquenil Toxicity Screening Update: What is new for 2017

Presenter: Clement C. Chow, MD

Retinal Diagnostic Center

May 4th, 2017

#### Brief Outline

- 1) Review current Plaquenil Toxicity screening guidelines from the American Academy of Ophthalmology
- 2) Discuss 2 new retrospective studies that prompted the update in 2016
- 3) Provide evidence for using real body weight rather than ideal body weight for calculating safe dosage of Plaquenil
- 4) Describe major risk factors for toxicity, including dose, duration, renal insufficiency, and Tamoxifen use
- 5) Describe racial differences in Plaquenil toxicity and show cases of a new pattern of Plaquenil toxicity – peri-macula changes -- which are found most commonly in Asian population
- 6) Review potential new imaging (adaptive optics) and functional (microperimetry) as screening tests for Plaquenil toxicity

# Plaquenil Toxicity Screening Update: What's new for 2017

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Clement Chow, MD  
Retinal Diagnostic Center

# Revised Recommendations on Screening for Chloroquine and Hydroxychloroquine Retinopathy

*Michael F. Marmor, MD,<sup>1</sup> Ulrich Kellner, MD,<sup>2</sup> Timothy Y. Y. Lai, MD,<sup>3</sup> Jonathan S. Lyons, MD,<sup>4</sup> William F. Mieler, MD,<sup>5</sup> for the American Academy of Ophthalmology*

- Ophthalmic Examination
- Automated Threshold Visual Field White 10-2

1 of 3 Objective tests

- Spectral Domain OCT
- Fundus Autofluorescence
- Multi-focal ERG

- Screening begins at baseline, and then annually after 5 years

Original Investigation

# The Risk of Toxic Retinopathy in Patients on Long-term Hydroxychloroquine Therapy

Ronald B. Melles, MD; Michael F. Marmor, MD



## Pericentral Retinopathy and Racial Differences in Hydroxychloroquine Toxicity

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Ronald B. Melles, MD,<sup>1</sup> Michael F. Marmor, MD<sup>2</sup>



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OF OPHTHALMOLOGY



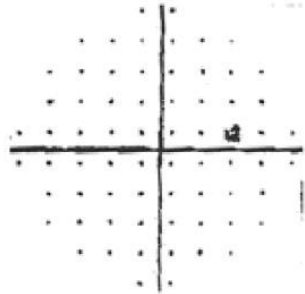
# American Academy of Ophthalmology Statement

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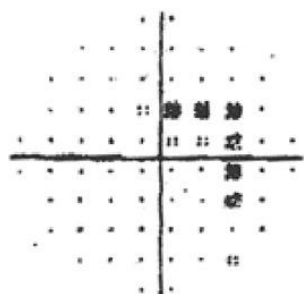
## Recommendations on Screening for Chloroquine and Hydroxychloroquine Retinopathy (2016 Revision)

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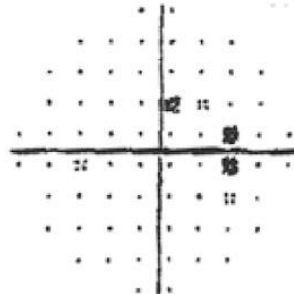
*Michael F. Marmor, MD,<sup>1</sup> Ulrich Kellner, MD,<sup>2</sup> Timothy Y.Y. Lai, MD, FRCOphth,<sup>3</sup> Ronald B. Melles, MD,<sup>4</sup>  
William F. Mieler, MD,<sup>5</sup> for the American Academy of Ophthalmology*



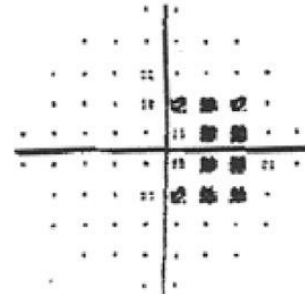
2005



2007

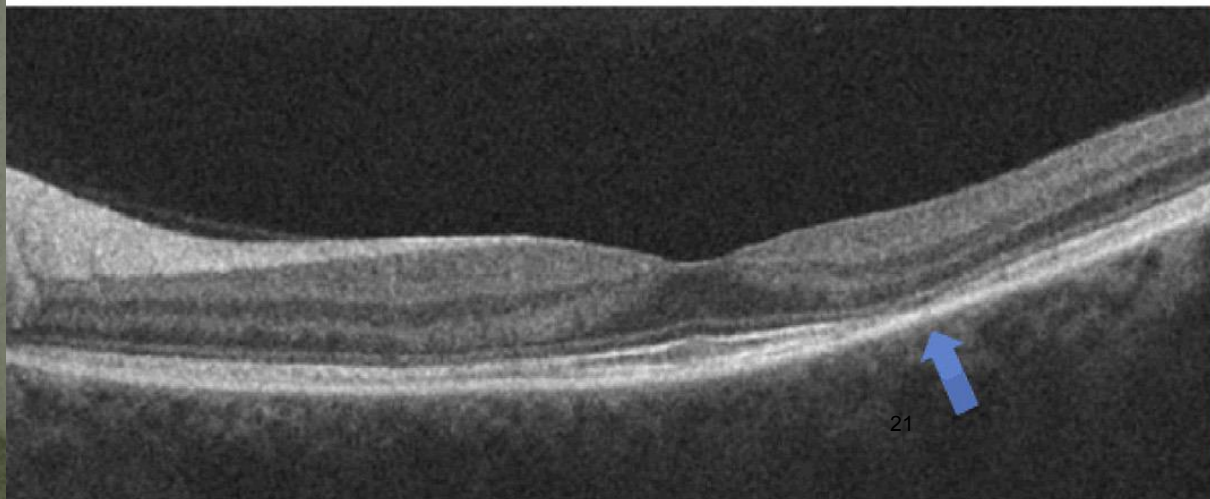
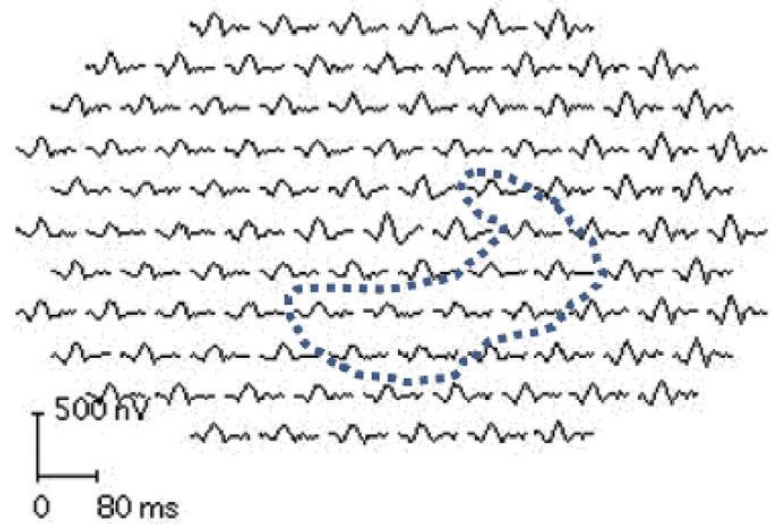


2008

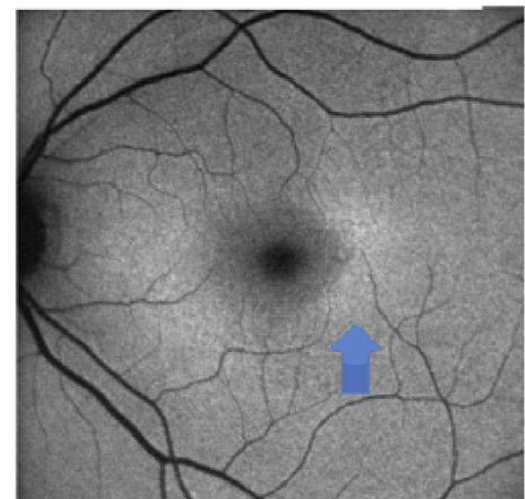


2009

**Retinal View**



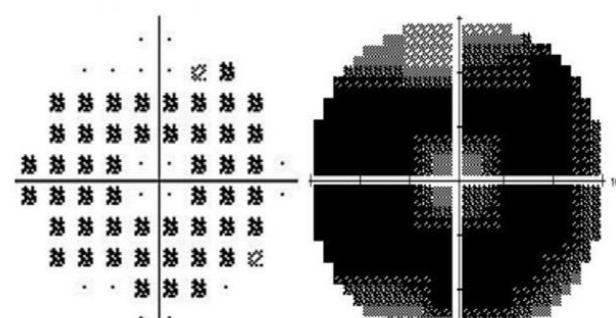
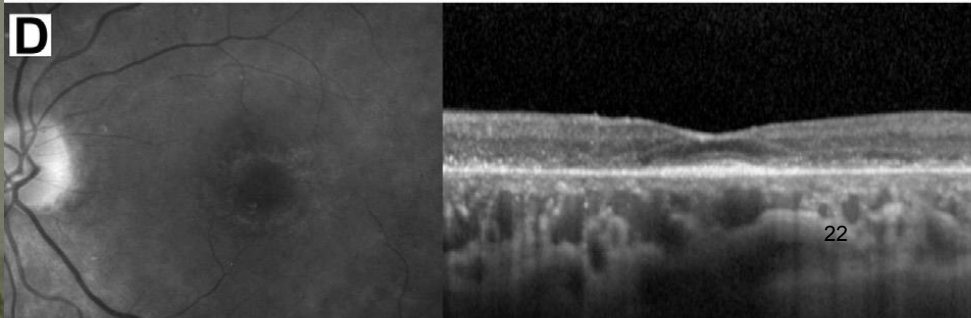
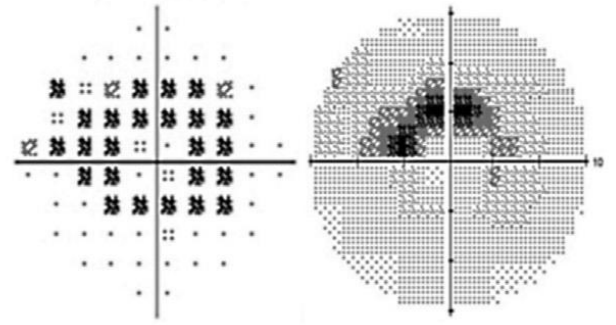
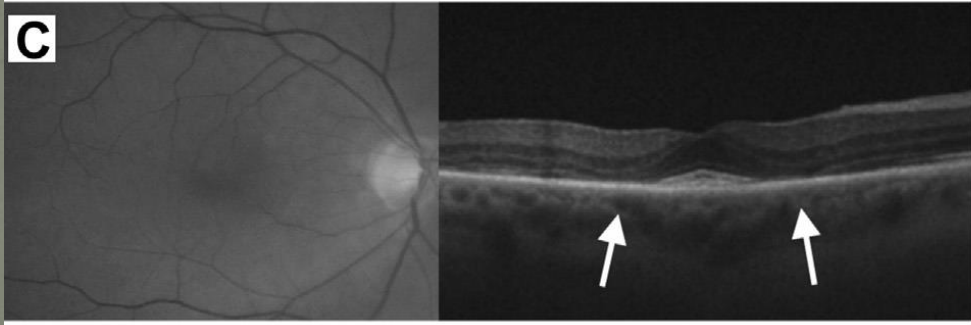
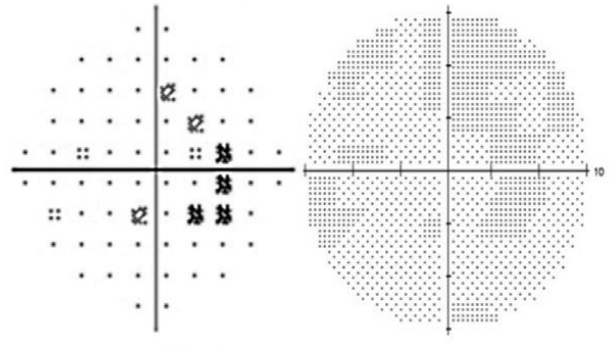
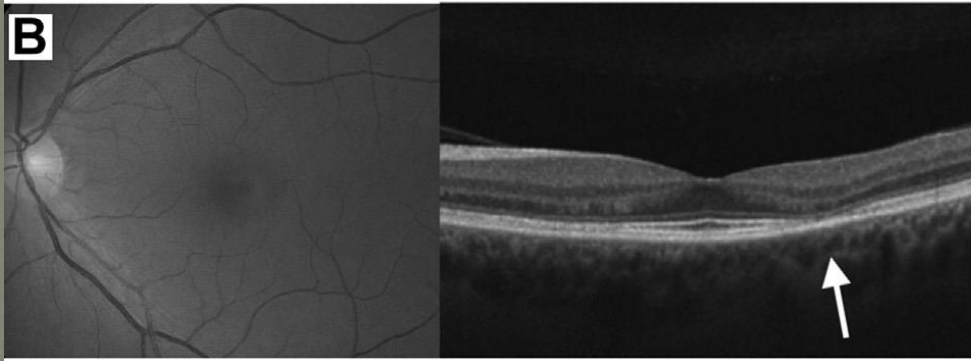
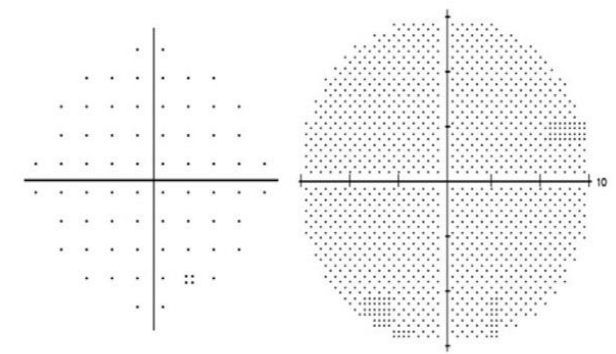
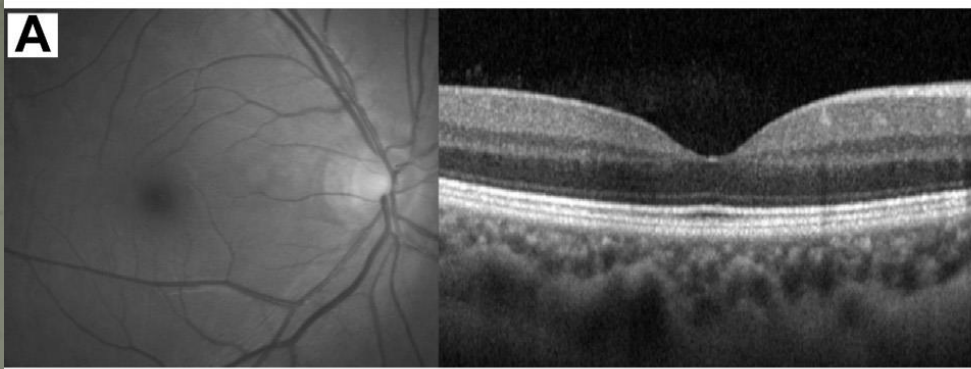
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Fundus photograph

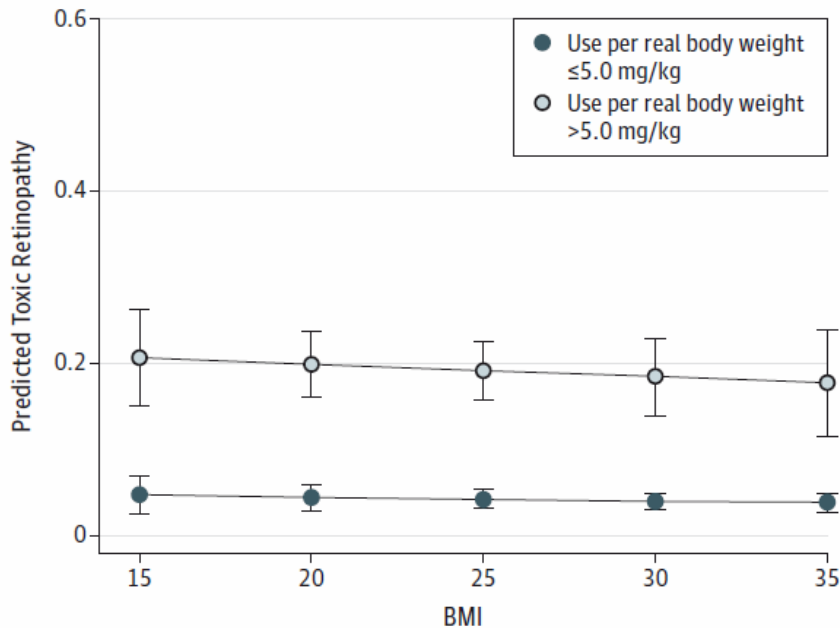
Spectral domain OCT

10-2 pattern deviation and threshold

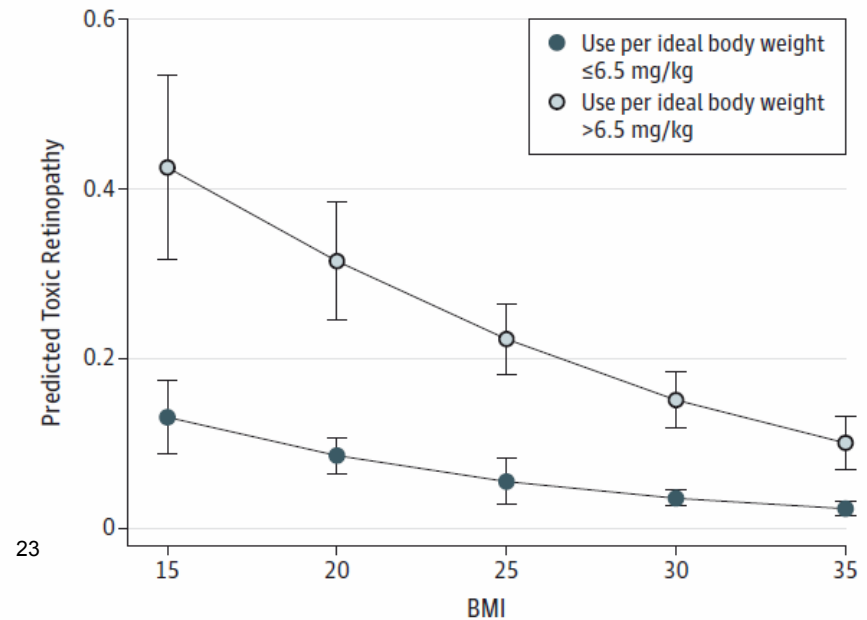


- Retrospective review of 2361 patients on Plaquenil >5 years, 201 with likely toxicity
- The prevalence of retinal toxicity relative to real bodyweight is essentially independent of body habitus, whereas the risk is much higher in thin individuals using ideal bodyweight

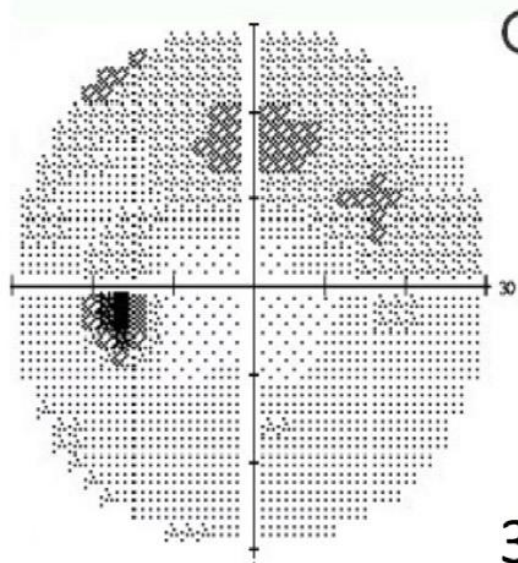
**B** Risk vs body habitus based on real body weight (5.0 mg/kg cutoff)



**C** Risk vs body habitus based on ideal body weight (6.5 mg/kg cutoff)

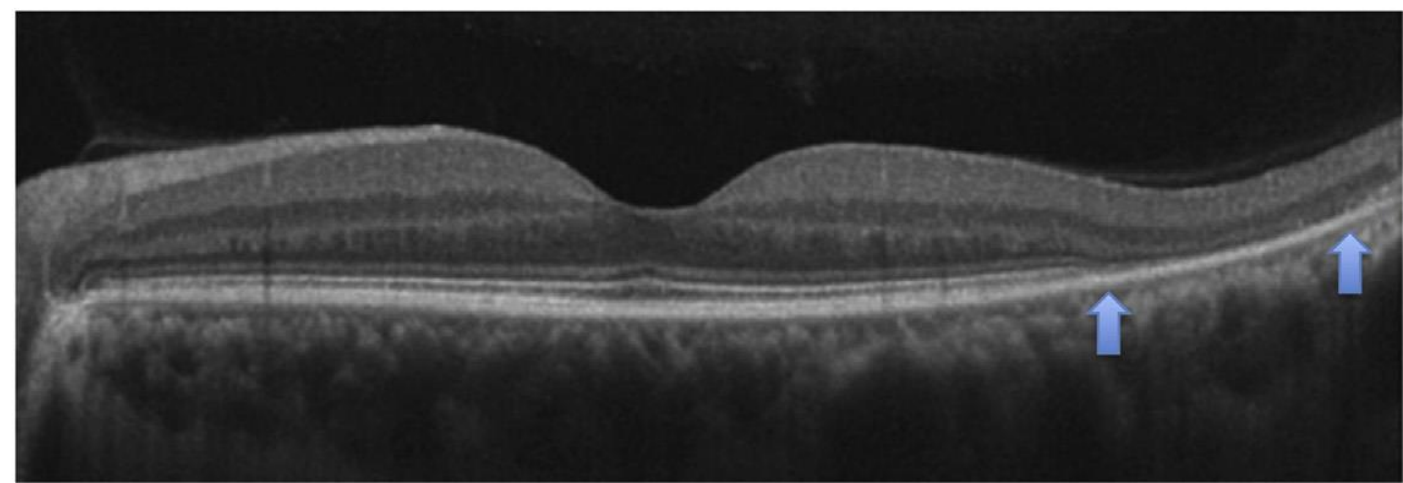
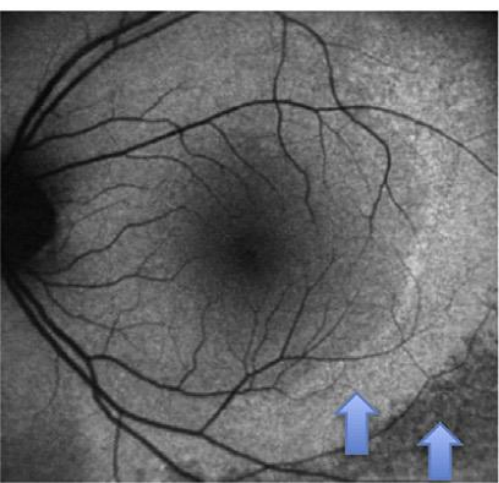
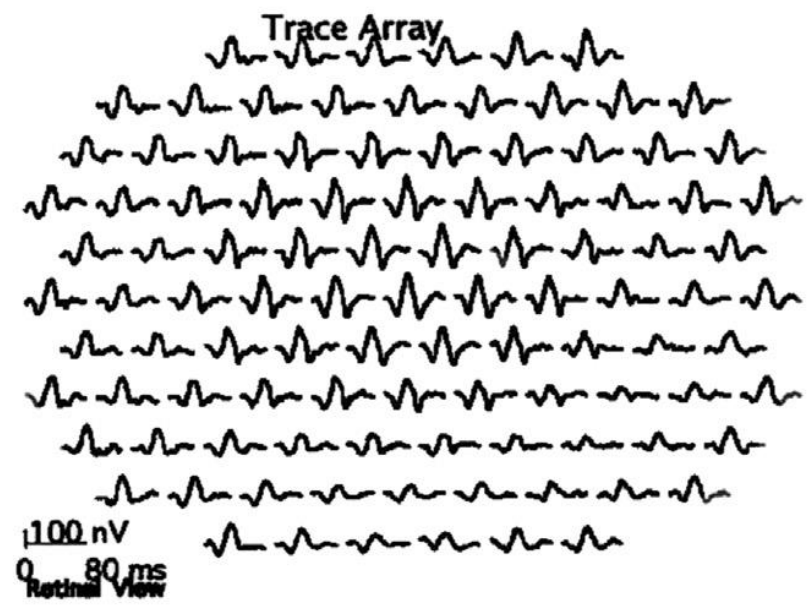
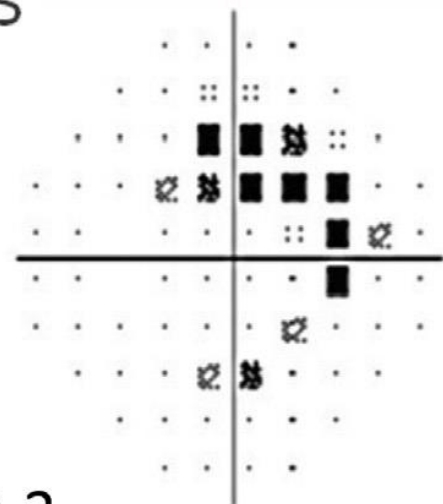


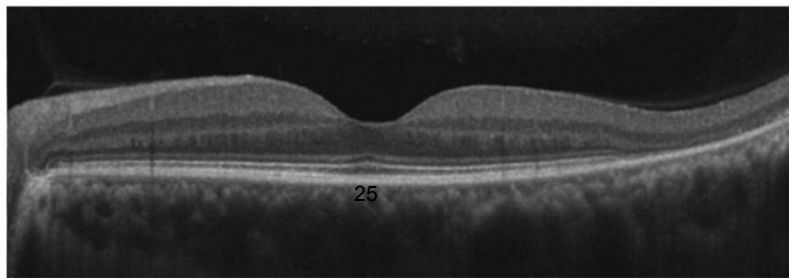
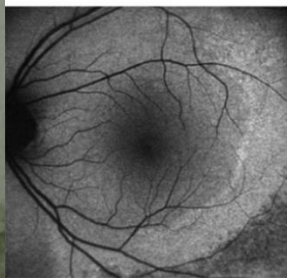
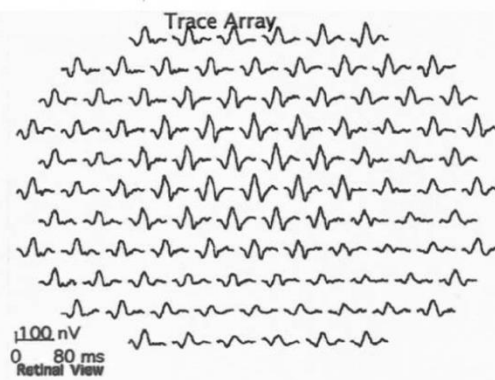
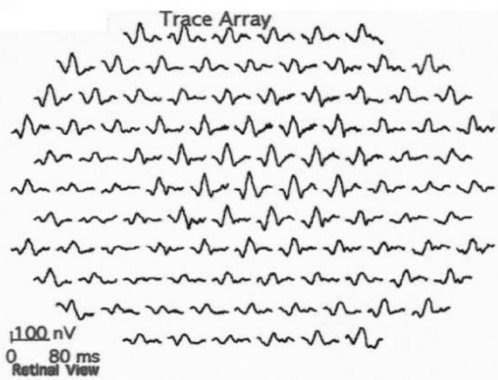
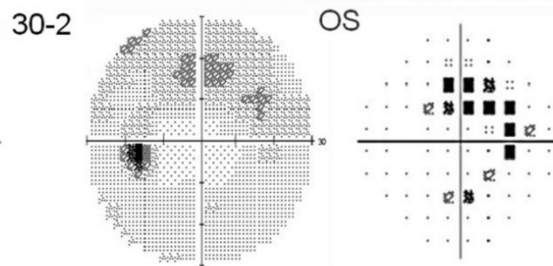
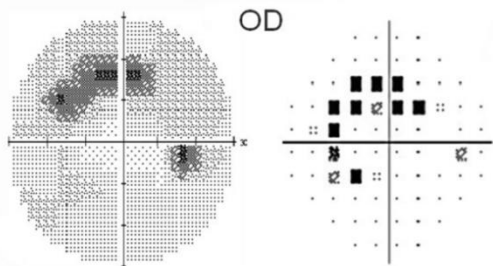


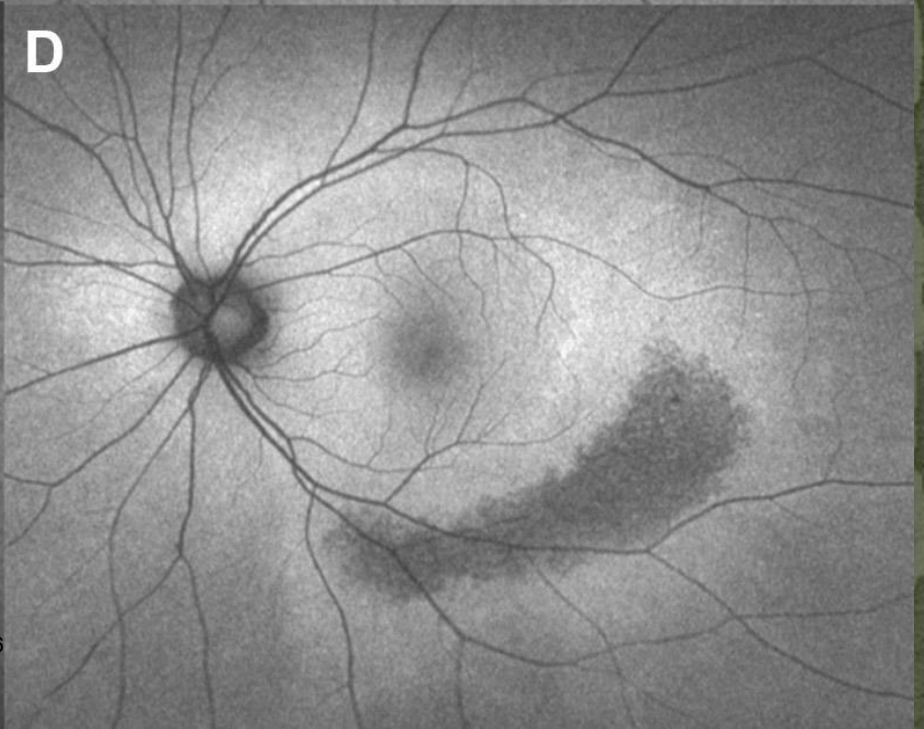
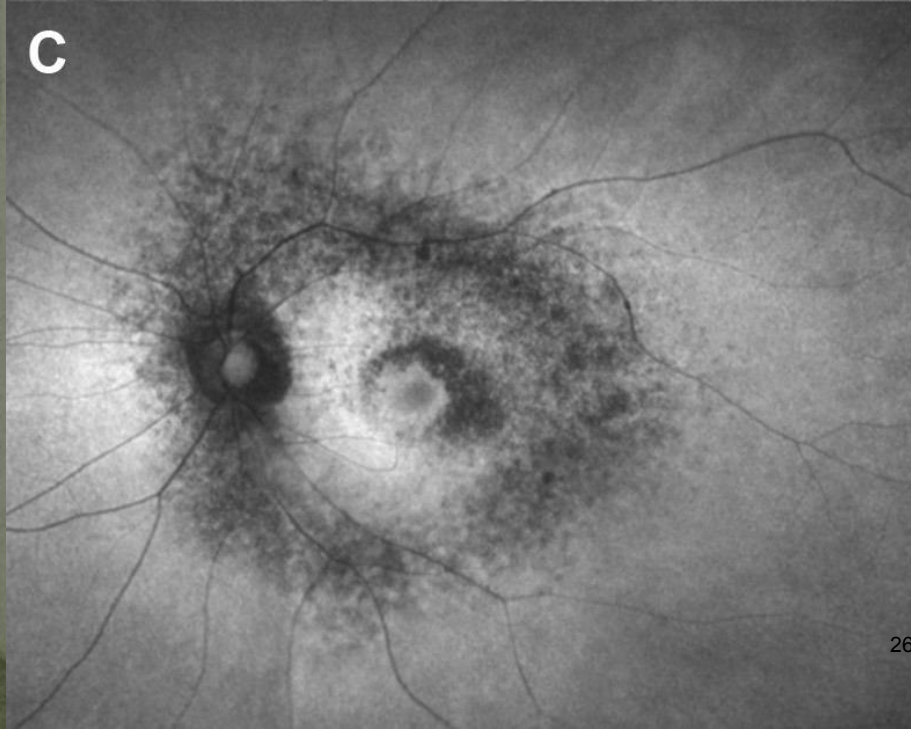
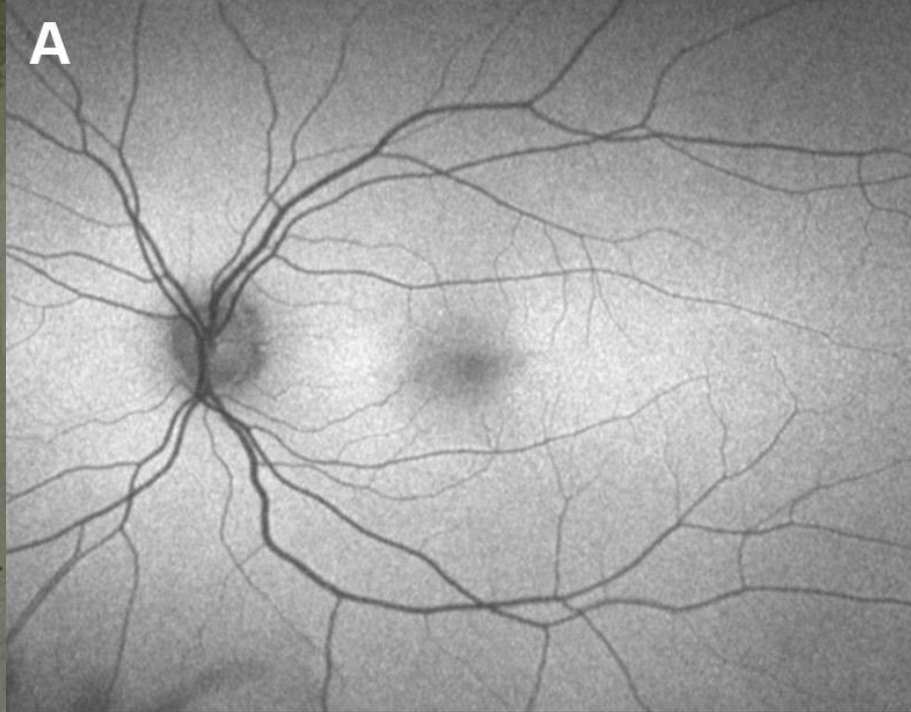


OS

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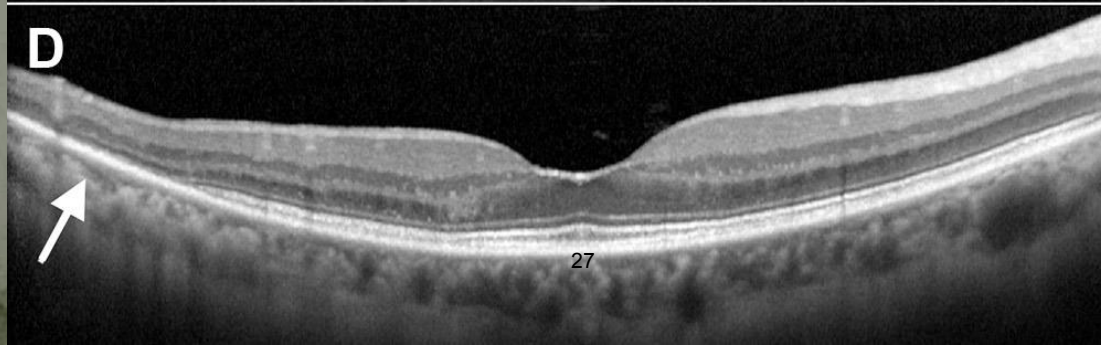
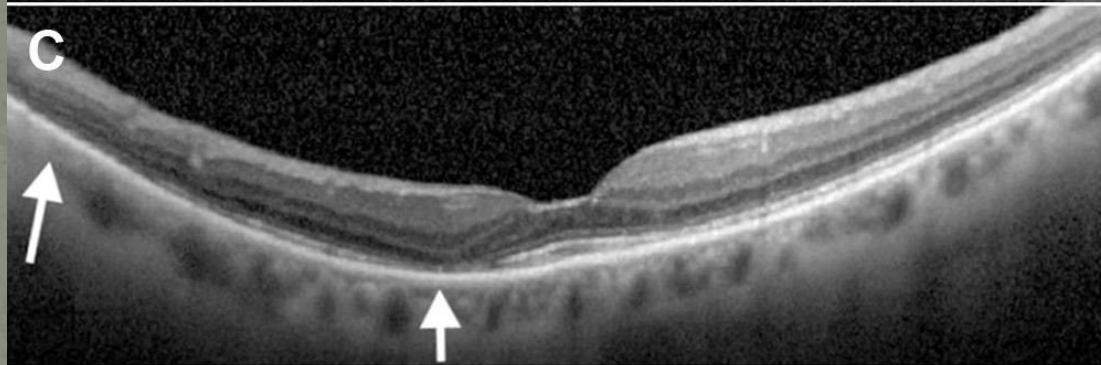
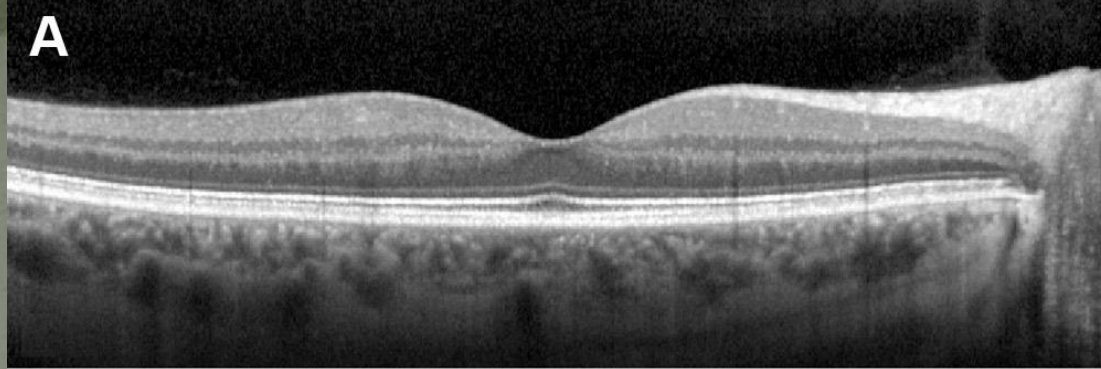


Table 1. Racial Distribution of Patients versus Patterns of Hydroxychloroquine Toxicity

	Asian*	Black	Hispanic	White	Other <sup>†</sup>	Total
Kaiser						
Parafoveal	5	11	17	101	1	135
Mixed	8		1	8		17
Pericentral	16	3	1	2		22
Total	29	14	19	111	1	174
Stanford						
Parafoveal	1		1	15	1	18
Mixed	4		2	1		7
Pericentral	2					2
Total	7	0	3	16	1	27

\*East Asian, Southeast Asian, and Filipino race.

<sup>†</sup>East Indian race.

Table 2. Pattern versus Severity of Toxicity (Kaiser and Stanford Patients)

Severity	Parafoveal	Mixed	Pericentral	Total
Mild	49	3	1	53
Moderate	62	4	8	74
Severe	42	17	15	75
Total	153	24	24	201

- Pericentral pattern was diagnosed at more severe stage, but possibly due to late recognition

Table 3. Comparison of Parafoveal Pattern with Pericentral Pattern Characteristics (Kaiser Patients Only)

Measurement	Pattern		P Value*
	<i>Parafoveal</i>	<i>Pericentral</i>	
Daily dose per weight (kg)	5.2 ( $\pm$ 1.5)	5.6 ( $\pm$ 1.3)	0.20
Daily dose per ideal body weight (kg)	6.4 ( $\pm$ 1.8)	6.3 ( $\pm$ 1.1)	0.80
Cumulative dose (g)	1826 ( $\pm$ 645)	2186 ( $\pm$ 622)	0.02
Duration (yrs)	15.0 ( $\pm$ 5.4)	19.5 ( $\pm$ 5.3)	<0.01
Female	125 (91%)	22 (100%)	0.22
Kidney disease <sup>†</sup>	48 (35%)	11 (50%)	0.15
Chronic hepatitis	1 (0.7%)	1 (4.5%)	0.25

\*Student *t* test for continuous variables or Fisher exact test for categorical variables.

<sup>†</sup>Average glomerular filtration rate <60 ml/min/1.73 m<sup>2</sup> or a problem list entry of chronic kidney disease stage 3, 4, or 5.

# A comparison between microperimetry and standard achromatic perimetry of the central visual field in eyes with glaucomatous paracentral visual-field defects

V C Lima,<sup>1</sup> T S Prata,<sup>1</sup> C G V De Moraes,<sup>1</sup> J Kim,<sup>1</sup> W Seiple,<sup>1,2</sup> R B Rosen,<sup>1,3</sup>  
J M Liebmann,<sup>1,4</sup> R Ritch<sup>1,3</sup>

- SLO-microperimetry detected retinal sensitivity reduction in areas of structural damage but with normal 10-2 HVF results

Lima VC, Prata TS, De Moraes CGV, et al. A comparison between microperimetry and standard achromatic perimetry of the central visual field in eyes with glaucomatous paracentral visual-field defects. *Br J Ophthalmol* 2010;94:64-67.



# Objective

- To report microperimetry findings in patients who are on hydroxychloroquine for more than 5 years with normal visual acuity, 10-2 HVF, SD-OCT, fundus FAF, and mfERG.

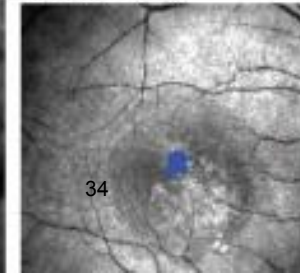
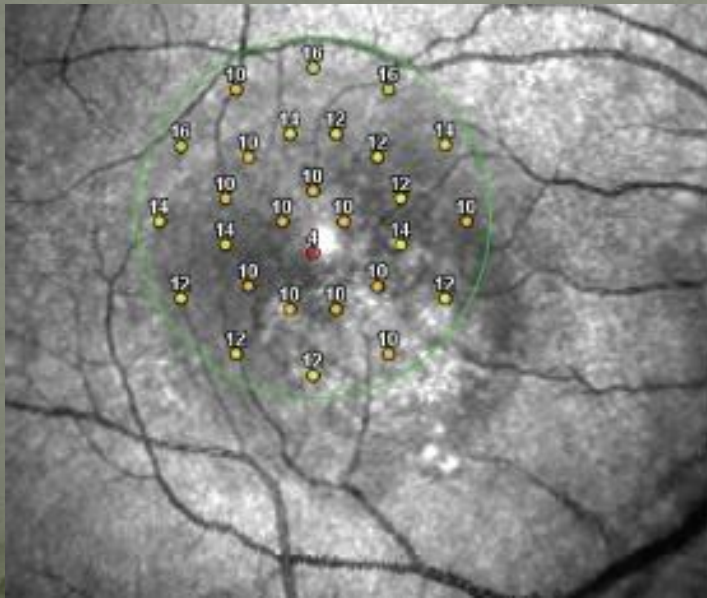
# Patients & Methods

## Inclusion criteria

- On plaquenil (200 or 400 mg)  $\geq$  5 years
- No body weight fluctuation  $>$  20%
- Age  $\geq$  18 years
- No other systemic diseases with the potential to affect the macula (diabetes, age-related macular degeneration)

# Methods

- Prospective, comparative study
- Microperimetry testing with the OPKO Spectral OCT/SLO microperimeter
- Standard Polar 3 program
- Real-time SLO fundus tracking



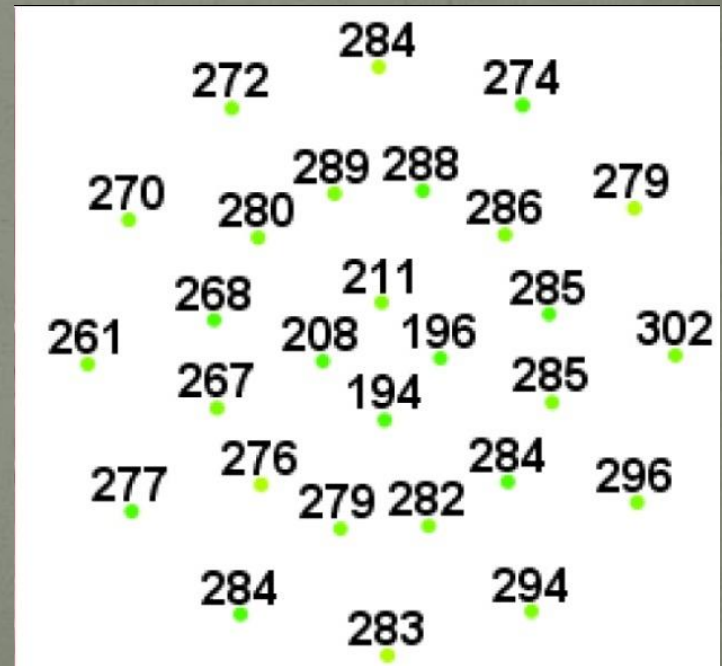
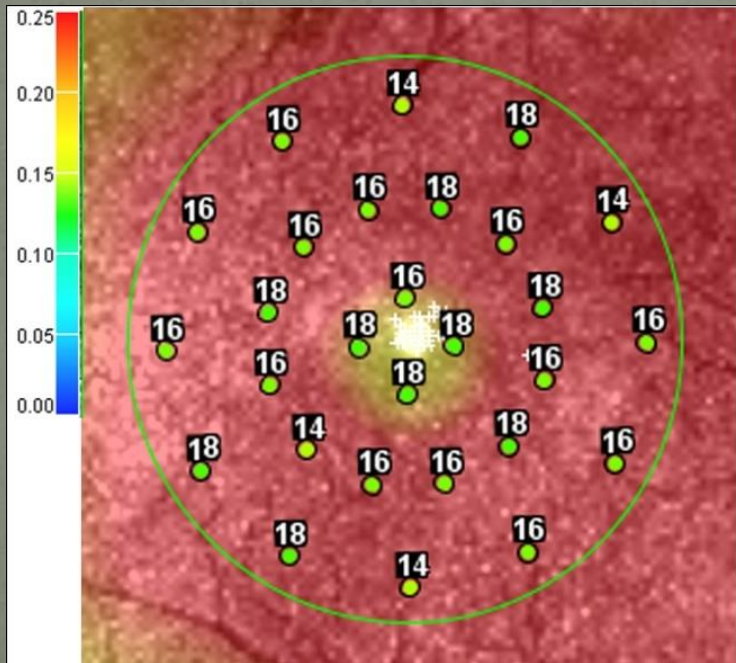
# Methods

- SD-OCT superimposes retinal thickness at each MP tested points

**Function:  
Microperimetry**




**Structure:  
SD-OCT thickness**



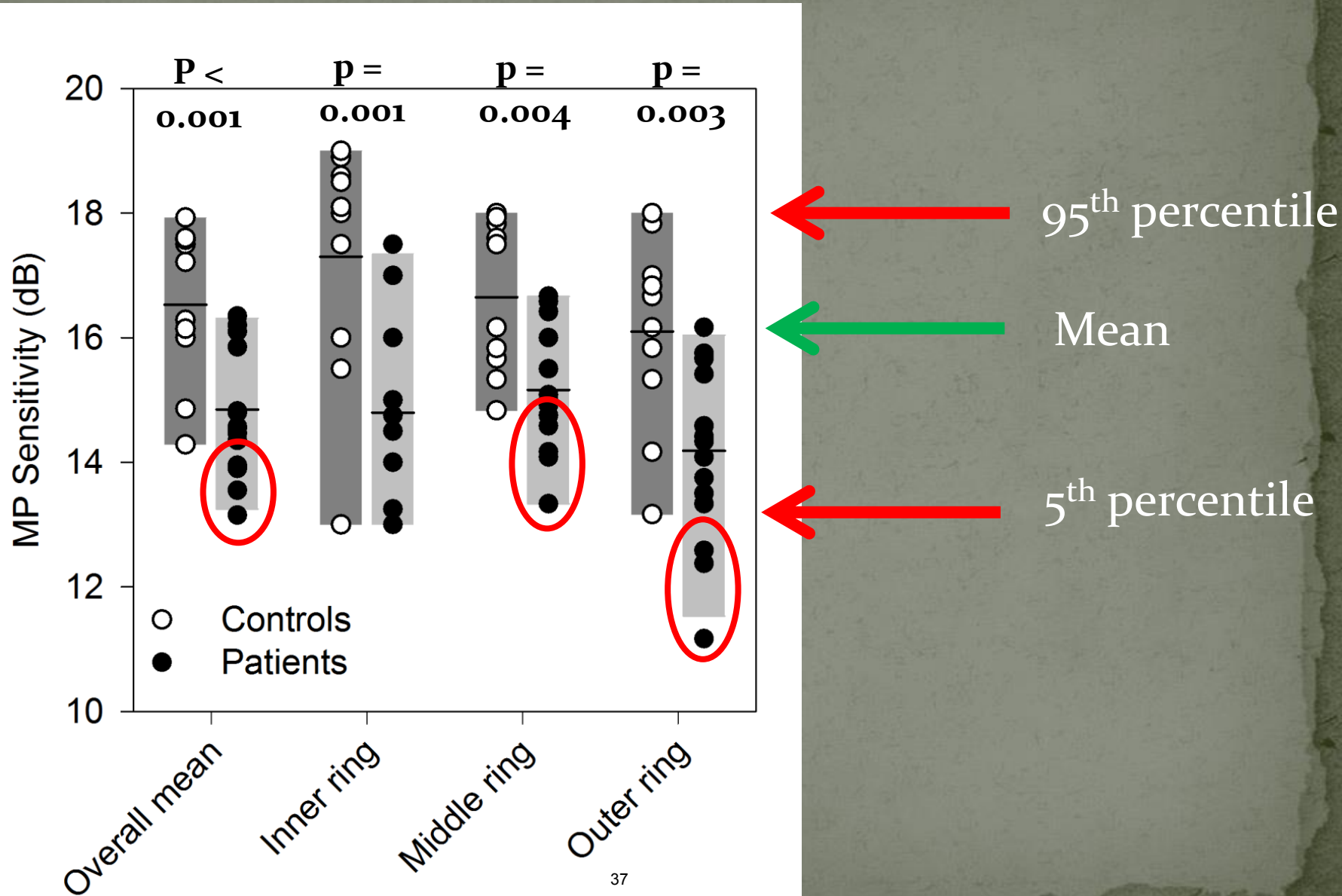
# Results

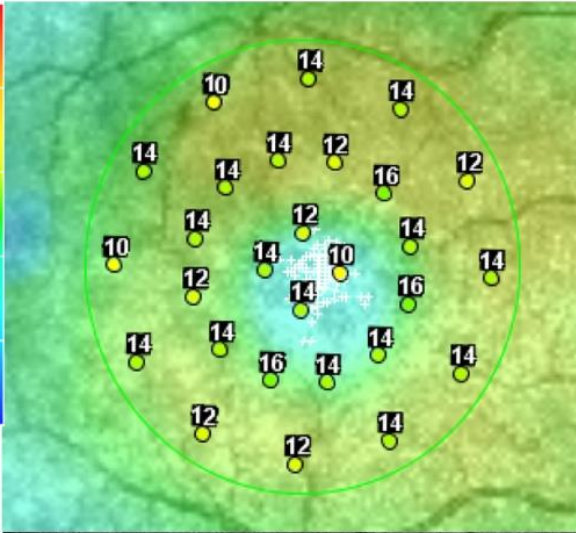
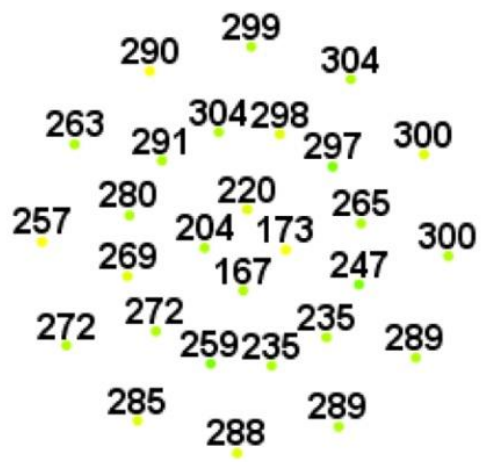
- 16 patients and 10 controls
  - Lupus (11 patients)
  - Rheumatoid arthritis (4 patients)
  - Dermatomyositis (1 patient)

	Patients	Controls	P value
<b>Age</b>	54.5 ± 10.3	53.4 ± 11.9	0.81
<b>Mean cumulative Plaquenil dose</b>	1485 g (256 – 3650)		
<b>Mean Daily dose</b>	4 mg/kg (1.77 – 6.67)		
<b>Central Macular thickness (µm)</b>	280.3 ± 18.3	287.2 ± 14.0	0.32
<b>Mean Microperimetry sensitivities (dB)</b>	14.7 ± 1.9	16.5 ± 2.1	<0.001

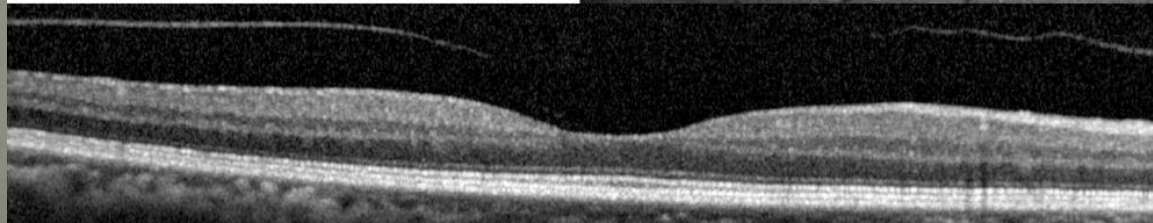
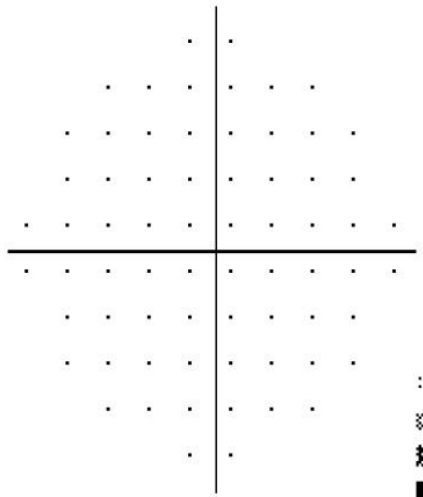


# Results





Pattern Deviation



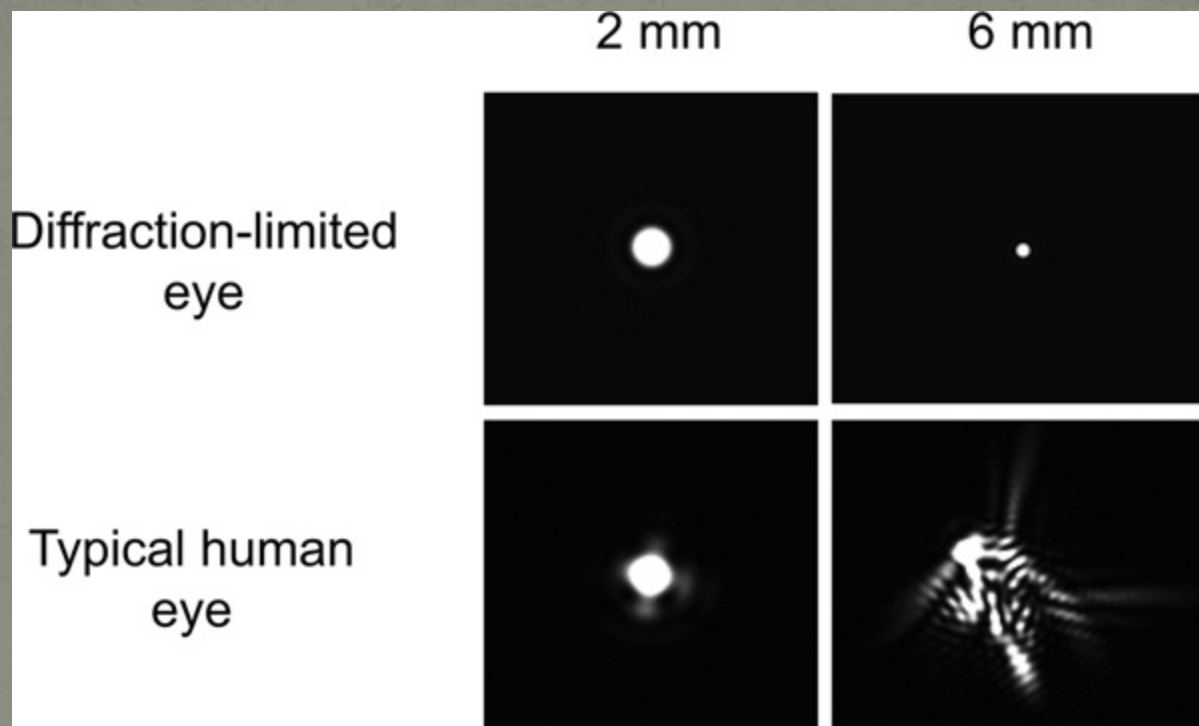
# Conclusions

- Patients on prolonged Plaquenil therapy (>5 years) with normal screening results can have decreased MP sensitivities throughout the central 12 degree of visual field
- Larger longitudinal studies are required to determine if findings represent early toxicity and whether MP can be used as a screening tool.



# Imaging single photoreceptors

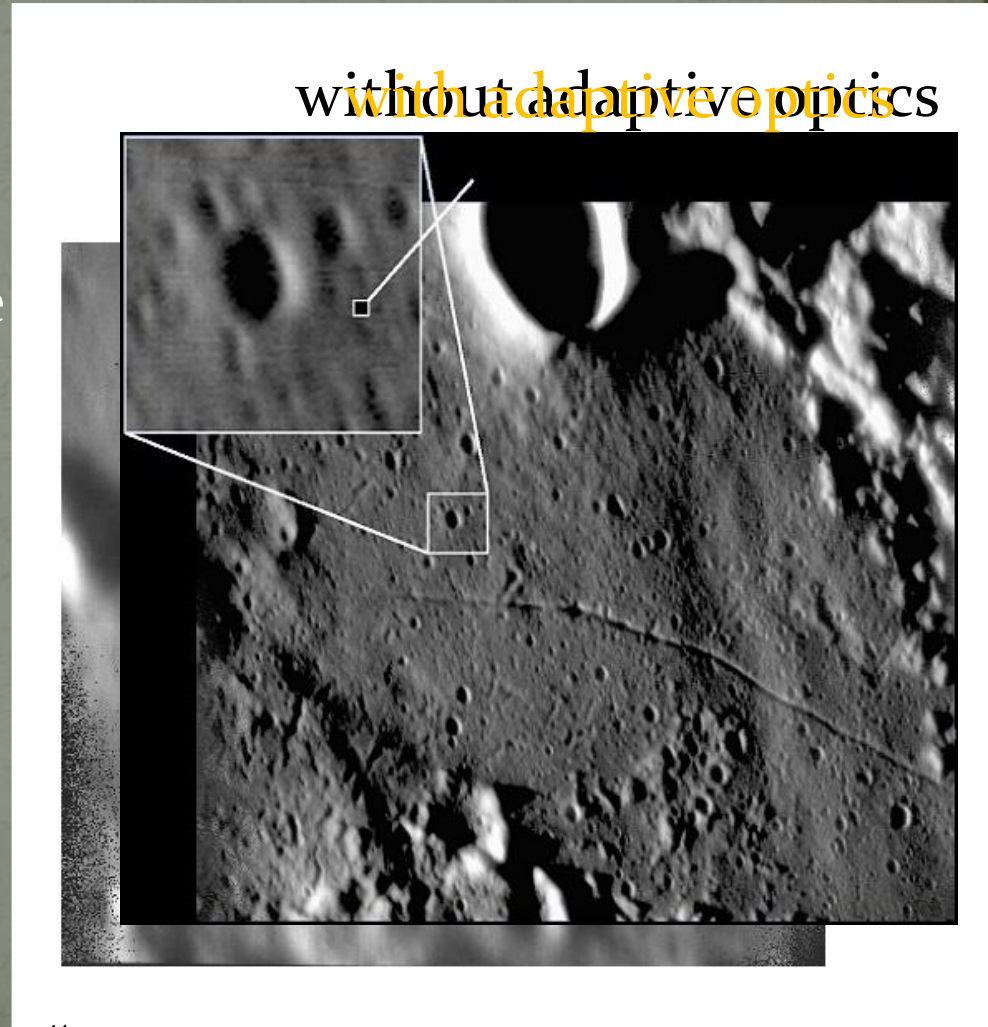
- Problem with lateral resolution



Yin, L., & Williams, D. R. (2011). Adaptive optics. In J. C. Behearse & D. Bok (Eds.), *The retina and its disorders*. Academic Press.

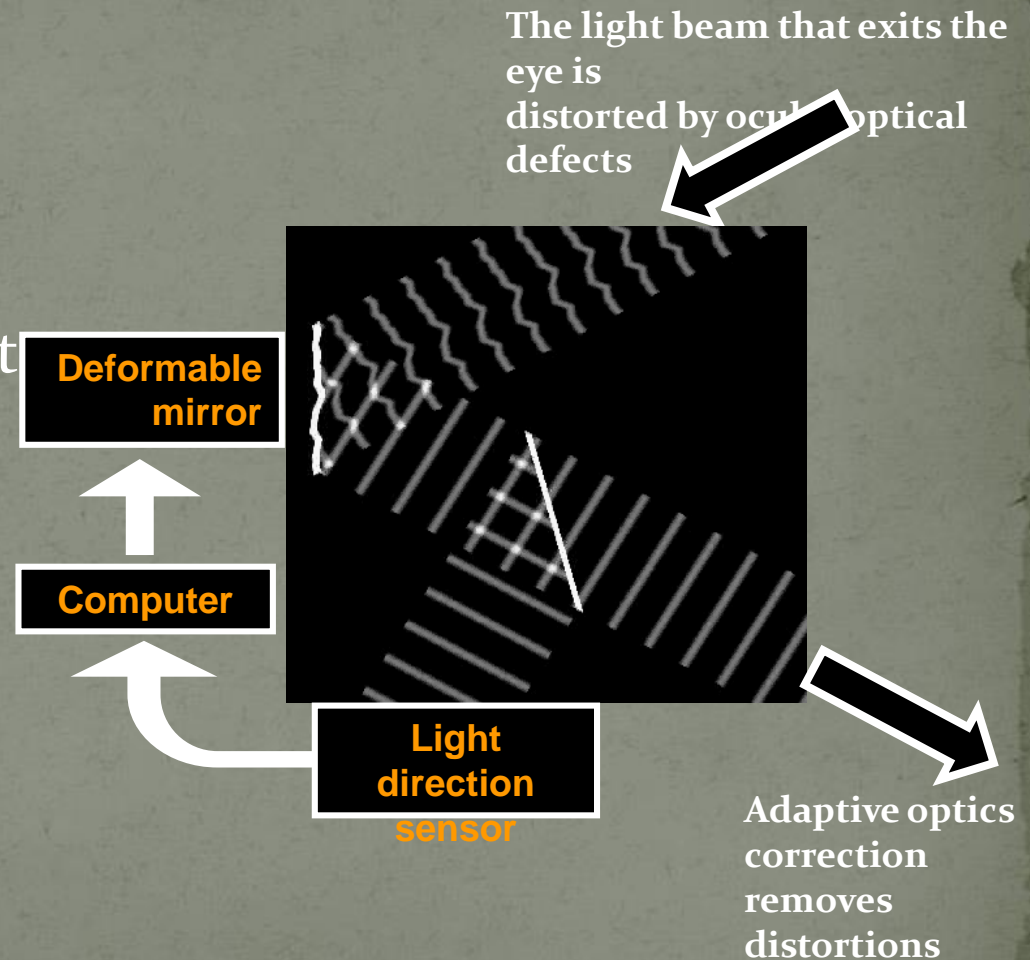
# A **breakthrough** technology originated from astrophysics

- **Adaptive optics** was invented by astrophysicists to enhance image quality in large ground-based telescopes



# How does the adaptive optics achieve superior optical resolution ?

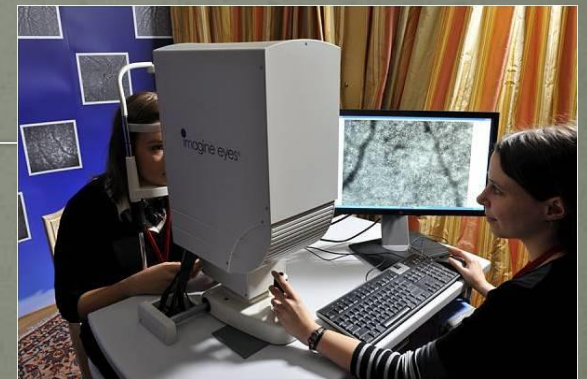
- In any other system, optical resolution is limited by the **irregular optical defects** that affect every living eye
- The **adaptive optics technology** corrects ocular optical defects in real time while imaging the retina





# rtx1™ Adaptive optics retinal camera

Cellular and micro-vascular imaging



# The **rtx1** adaptive optics retinal camera

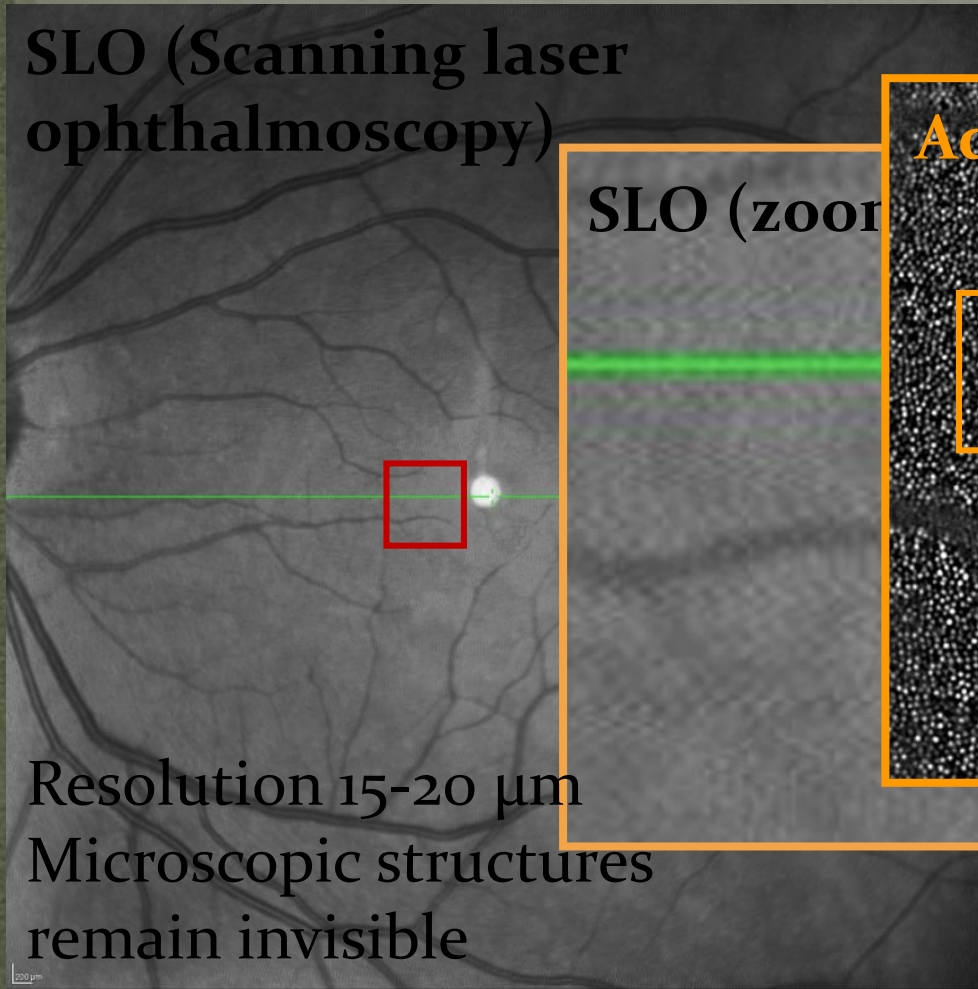
- The first and only instrument of its kind
- Enables **cellular** and **micro-vascular** retinal imaging



# Cellular resolution

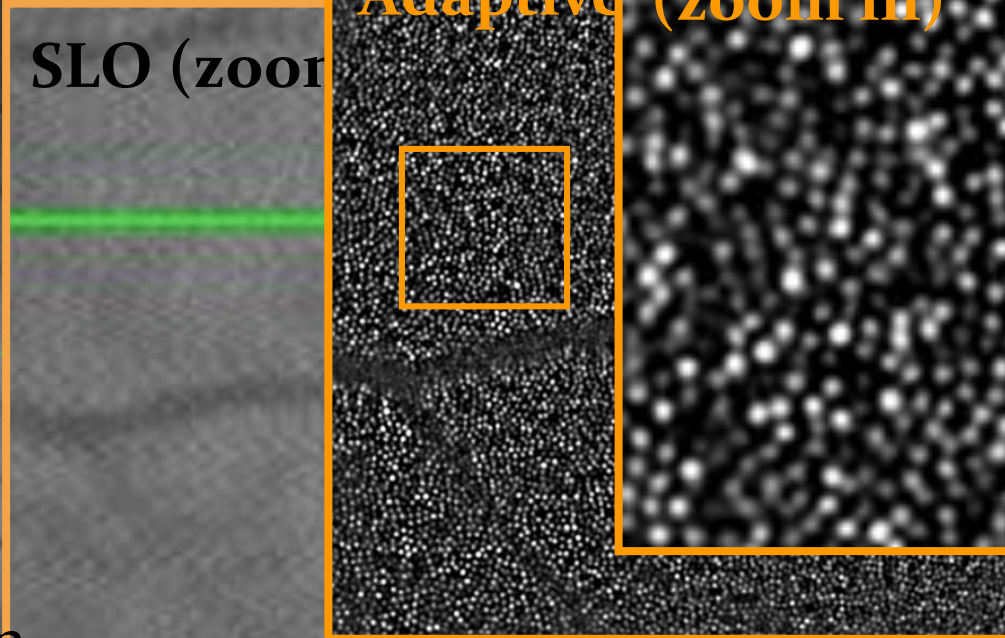
Comparison with conventional SLO

SLO (Scanning laser ophthalmoscopy)



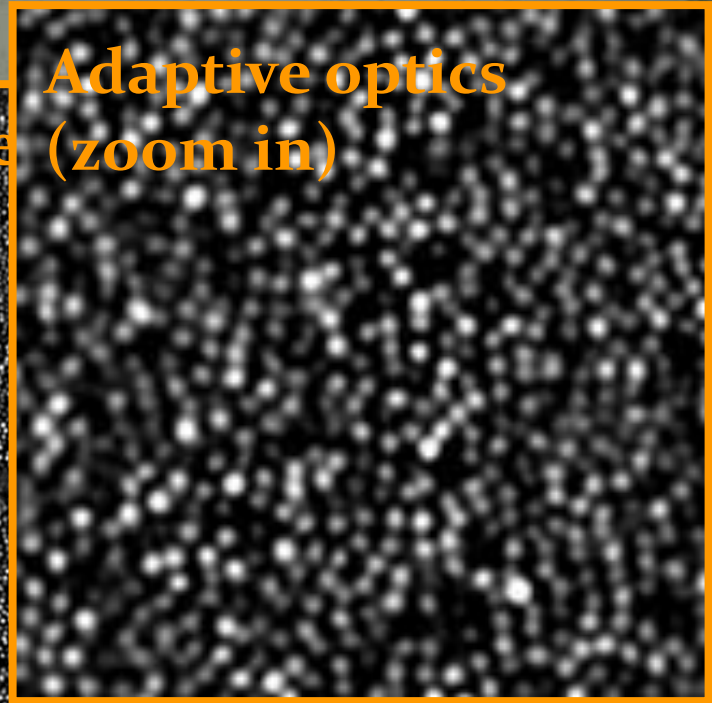
Resolution 15-20  $\mu\text{m}$   
Microscopic structures remain invisible

SLO (zoomed in)



Adaptive optics

Adaptive optics (zoom in)



Resolution 2-4  $\mu\text{m}$   
**Retinal cells are visible**

# Take Home Points

- Maximum daily Plaquenil use of 5.0 mg/kg real weight, which correlates better with risk than ideal weight.
- High dose and long duration of use are the most significant risks. Other major factors are concomitant renal disease, or use of tamoxifen
- SD-OCT, FAF, 10-2 HVF, mfERG are still standard for screening but these should look beyond the central macula in Asian patients
- New screening tests, such as microperimetry and adaptive optics are being investigated

# References

- Marmor MF, Kellner U, Lai TY, et al. **Recommendations on Screening for Chloroquine and Hydroxychloroquine Retinopathy (2016 Revision)**. *Ophthalmology* 2016;123:1386-1394
- 2. Melles RB, Marmor MF. The risk of toxic retinopathy in patients on long-term hydroxychloroquine therapy. *JAMA Ophthalmol* 2014;132:1453–60.
- 3. Melles RB, Marmor MF. Pericentral retinopathy and racial differences in hydroxychloroquine toxicity. *Ophthalmology* 2015;122:110–6.
- Marmor MF, Kellner U, Lai TY, et al. Revised recommendations on screening for chloroquine and hydroxychloroquine retinopathy. *Ophthalmology* 2011;118:415–22.



- Thank you for your attention!
- Questions, interesting cases/photos
- Email:
  - [Clementchowmd@gmail.com](mailto:Clementchowmd@gmail.com)

**Clement Chikai Chow, M.D.**  
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## EDUCATION

- 7/1/2011 – 7/6/2013  
 University of Illinois Medical Center, Vitreoretinal Fellowship, Chicago, IL
- 7/1/2008 – 6/30/2011  
 University of Illinois Medical Center, Ophthalmology Residency, Chicago, IL
- 7/1/2007 – 6/30/2008  
 Gundersen Lutheran Medical Center, Transitional Residency, La Crosse, WI.
- 7/1/2003 – 6/30/2007  
 University of Wisconsin School of Medicine and Public Health, Madison, WI.  
 M.D. Dean's GPA: 3.823/4.0
- 8/25/1999 – 6/30/2003  
 University of Wisconsin-Madison, Madison, WI.  
 B.S. Biochemistry and Chinese Language and Literature, Comprehensive Honors. GPA:  
 3.99/4.0

## HONORS AND AWARDS

- 2013 Fellow of the Year Award (Best teacher), University of Illinois-Chicago
- 2012 Fellow of the Year Award (Best teacher), University of Illinois-Chicago
- 2011 Best Paper Award (Pediatric session), American Academy of Ophthalmology Annual Meeting, Orlando, FL
- 2011 Best Publication Record Award during residency
- 2010 – 2011 Chief Resident, Ophthalmology residency, University of Illinois-Chicago
- 2011 Beem-Fisher Research Award - third place
- 2010 Illinois Society for the Prevention of Blindness Seed Grant Recipient
- 2006 Alpha Omega Alpha (AOA) Honor Society
- 2003 – 2007 Post Graduate Fellowship (4-year medical school scholarship) University of Wisconsin-Madison
- 2004 Herman Shapiro Summer Research Award
- 2003 Dean's Prize Winner (one of College of Letter and Science top 3 graduates)
- 2003 Letter and Science Dean's Distinguished Senior Honors Student Award
- 2003 Lawrence Louey Merit Scholarship
- 2002 Mark Mensink Honors Research Grant
- 2002 Ralph B. Abrams Scholarship
- 2002 Florence Waste Pulver Scholarship
- 2002 University Book Store Academic Excellence Award
- 2001 Hilldale Undergraduate Research Award

## CERTIFICATION

- American Board of Ophthalmology certification 6/9/2013 - 12/3/2023  
 State of California Medical License - Expiration 5/31/2019

## EMPLOYMENT

2013 - present Retinal Diagnostic Center, Campbell, California Title: Retina specialist and Partner  
2002 -- 2003 University of Wisconsin Hospital and Clinics Title: Patient Escort  
2002 EraGen Biosciences, Madison, WI. Title: Summer Intern  
2000 -- 2002 Wisconsin Department of Corrections, Bureau of Health Services, Madison, WI Title:  
Program Assistant  
1999 -- 2002 University of Wisconsin -- Madison. Title: Tutor

## CLINICAL TRIALS

**Role: Sub-investigator**

### **Study Name: SEQUOIA**

Phase 3 - Safety and Efficacy of Abicipar Pegol (AGN-150998) in Patients With Neovascular Age-related Macular Degeneration

Study Sponsor: Allergan

### **Study Name: Mako (Ohr-1601)**

A Phase III Study of the Efficacy and Safety of Squalamine Lactate Ophthalmic Solution, 0.2% Twice Daily in Subjects with Neovascular Age-Related Macular Degeneration

Study Sponsor: Ohr Pharmaceutical

### **Study Name: Avenue (BP29647)**

Phase 2, 36 weeks study comparing RO6867461 to Lucentis for Neovascular Age-related Macular Degeneration

Study Sponsor: Roche/Genentech

### **Study Name: Proxima A (GX29633)**

A multicenter, prospective epidemiologic study of the progression of geographic atrophy secondary to age-related macular degeneration.

Study Sponsor: Roche/Genentech

### **Study Name: CIRCLE**

Phase 2, Randomized, Double-masked, Sham Controlled, Multi-center study to Evaluate the Efficacy and Safety of Ocriplasmin (Jetrea) in Inducing Total Posterior Vitreous Detachment (PVD) in Subjects with Non-Proliferative Diabetic Retinopathy. (NPDR)

Study Sponsor: Thrombogenic

### **Study Name: OLE (GX29198)**

A multicenter, open-label extension study to evaluate the long-term safety and tolerability of Lampalizumab in patients with Geographic Atrophy who have completed Genentech sponsored Lampalizumab studies.

Study Sponsor: Roche/Genentech

### **Study Name: Acacia (150998-007)**

AbiCipar pegol safety and efficacy in Patients with Centrally-Involved Diabetic macular edema

Study Sponsor: Allergan

**Study Name: Exposure (GX29455)**

A Phase II, Multicenter, Randomized, Single-Masked, Sham Injection-controlled Exposure-Response Study of Lampalizumab Intravitreal Injections Administered Every Two Weeks or Every Four Weeks to Patients with Geographic Atrophy.

Study Sponsor: Roche/Genentech

**Study Name: Ophthotech Fovista**

A phase 3 study comparing intravitreal Fovista (Anti PDGF-B Pegylated Aptamer) in combination with Lucentis vs. Lucentis alone in patients with wet macular degeneration.

Study Sponsor: Ophthotech Corporation

**Study Name: DRCR-Protocol V**

A prospective study comparing 3 treatment options (Anti-VEGF injections vs. focal laser vs. observation) in patients with diabetic macular edema AND excellent vision (20/25 or better)

Study Sponsor: Diabetic Retinopathy Clinical Research Network

**Study Name: Ocriplasmin Research to Better Inform Treatment (ORBIT)**

Phase 4 study that will assess clinical outcomes and safety of JETREA® administered in a real-world setting for the treatment of symptomatic vitreomacular adhesion (VMA) by assessing anatomical and functional outcomes

Study Sponsor: ThromboGenics

**Study Name: B1261009**

A Phase 2, Multi-Center Study To Compare The Efficacy And Safety Of A Chemokine CCR2/5 Receptor Antagonist (Oral Pill) With Ranibizumab In Adults With Diabetic Macular Edema

Study Sponsor: Pfizer

**Study Name: L-Path**

A phase 2A study comparing a new medication called Sonepcizumab (iSONEPTM [LT1009]) to standard treatment (Eylea, Lucentis, or Avastin) in refractory exudative (wet) Age-Related Macular Degeneration

Study Sponsor: L-Path, Inc

**PEER REVIEWED PUBLICATIONS**

- |      |  |
|------|--|
| 2016 | Oltra EZ, <b>Chow CC</b> , Wrubben T, Lim JI, Chau FY, Moss H. Neurocognitive Function and Retinal Thinning by Spectral-Domain Optical Coherence Tomography in Sickle Cell Patients. <i>Middle East Afr J Ophthalmol</i> . 2016;23(1):79-83. |
| 2014 | Bui KM, <b>Chow CC</b> , Mieler WF. Treatment of Recalcitrant Radiation Maculopathy Using Intravitreal Dexamethasone (Ozurdex®) Implant. <i>Retin Cases Brief Rep</i> 2014;8(3)167-170.  |

- 2014 **Chow CC**, Mieler WF. Vitamin A Deficiency and Xerophthalmic Fundus in Autoimmune Hepatitis and Cirrhosis. *Retina Retin Cases Brief Rep* 2014;8(3):164-166.
- 2013 **Chow CC**, Shah RJ, Lim JI, Chau FY, Hallak JA, Vajaranant TS. Peripapillary Retinal Nerve Fiber Layer Thickness in Sickle Cell Hemoglobinopathies Using Spectral- Domain Optical Coherence Tomography. *Am J Ophthalmol* 2013;155(3):456-464.
- 2013 Patel KH, **Chow CC**, Rathod R, Mieler WF, Lim JI, Leiderman Y, Ulanski L, Arun V, Chau FY. Rapid Response of Retinal Pigment Epithelial Detachments to Intravitreal Aflibercept in Neovascular Age-Related Macular Degeneration Refractory to Bevacizumab and Ranibizumab. *Eye (Lond)* 2013;27(5):663-7.
- 2013 Dikopf MS, **Chow CC**, Mieler WF, Tu EY. Surgical Outcomes and Phacodonesis in Retinitis Pigmentosa Patients Who Underwent Phacoemulsification Cataract Extraction. *Am J Ophthalmol* 2013;156(1):82-88.
- 2013 Prickett AL, Salar S, **Chow CC**, Traish A, Leiderman YI, Chau FY, Kassem IS. Traumatic Eye Injuries from Collapsible Wire Laundry Hampers. *Pediatrics*. 2013;132(2):e522-5.
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- 2012 Krakauer M, **Chow CC**, Mieler WF, Lim JI. Scrolled Epiretinal Membrane: Case Series Of A Novel OCT Finding. *Am J Ophthalmology* (Under review)
- 2012 Shapiro MJ, **Chow CC**, Blair MP, Kiernan DF, Kaufman LM. Peripheral Non-perfusion and Tractional Retinal Detachment Associated With Congenital Optic Nerve Anomalies. *Ophthalmology* 2013;120(3):607-15.
- 2012 Oltra EZ, **Chow CC**, Lunde MW. Bilateral traumatic expulsive aniridia after phacoemulsification. *Middle East Afr J Ophthalmol*. 2012;19(3):334-336.
- 2012 Hu J, **Chow CC**, Kiernan DF, Garcia-Valenzuela E, Mafee MF, Blair MP, Shapiro MJ. Peripheral Retinal Nonperfusion Associated with Optic Nerve Hypoplasia and Lissencephaly *Arch Ophthalmol* 2012 Mar;130(3):398-400.
- 2012 **Chow CC**, Birnbaum A, Janowicz M, Goldstein DA. Lipemia retinalis as a presenting feature of hypertriglyceridemia associated with protease inhibitors in HIV patients. *Retin Cases Brief Rep* 2012;6(3):294-297.
- 2011 **Chow CC**, Blair MP, Shapiro MJ. Acquired vasoproliferative retinal tumor: A late sequela of retinopathy of prematurity. *Arch Ophthalmol*. 2011 Sep;129(9):1234-5.

- 2011 **Chow CC**, Chau FY, Kiernan DF, Lim JI. Response of myopic choroidal neovascularization to anti-VEGF therapy: spectral domain optical coherence tomography characteristics and visual outcomes. (In revision)
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- 2007 van Ginkel PR, Yang W, Marcet MM, **Chow CC**, Kulkarni, AD, Darjatmoko S, Lindstrom MJ, Lokken J, Bhaaftacharya S, Albert DM. 1 alpha-Hydroxyvitamin D2 Inhibits Growth of Human Neuroblastoma. *J Neurooncol*. 2007 Dec;85(3):255-62
- 2006 **Chow CC**, Kulkarni AD, Albert DM, Darlington JK, Hardten DR. Clinicopathological Correlation of Explant AlphaCor Artificial Cornea after Exposure of Implant. *Cornea*. 2007 Sep;26(8):1004-7.
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- 2012 **Chow CC**, Mieler WF, Mittra RA, Pollack JS. Retinal Arterial Macroaneurysms. In: Ophthalmology, Yanoff M and Duker J (Eds.) 4th ed.
- 2011 **Chow CC**, Mieler WF. 7 mini-chapters in the Retina Section of: Encyclopedia of Ophthalmology. Ursula M. Schmidt-Erfurth, George A. Williams and William F. Mieler (Eds.) Springer; in press.
- 2011 **Chow CC**, Genead MA, Lim JI. Retinitis Pigmentosa. EyeWiki, AAO, Aug 2011.

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- 2013 **Chow CC\***, Dikopf MS, Mieler WF, Tu EY. Cataract Extraction Outcomes and the Prevalence of Zonular Insufficiency in Retinitis Pigmentosa. Invest. Ophthalmol. Vis. Sci. 2011 E-Abstract 1262.
- 2012 Alleman N\*, Dikopf MS, **Chow CC**, Mieler WF. Serial Ultrasonographic Evaluation After Brachytherapy in Choroidal Melanomas. 24th Societas Internationalis Pro Diagnostica Ultrasonica in Ophthalmologia 2012 Congress. December 2012, Sao Paulo, Brazil.
- 2012 **Chow CC\***, Jivrajka RV, Genead MA, McAnany JJ, Fishman GA, Mieler WF. Early Detection of Functional Changes Using Microperimetry on Patients with Subclinical Hydroxychloroquine Toxicity. The 30th Annual American Society of Retina Specialists Meeting, August 2012, Las Vegas, NV.
- 2012 Jivrajka RV, Genead MA, McAnany JJ, **Chow CC**, Fishman GA, Mieler WF\*. Early Detection of Functional Changes Using Microperimetry on Patients with Subclinical Hydroxychloroquine Toxicity. The 35th Annual Macula Society Meeting, June, 2012, Jerusalem, Israel
- 2012 Chau FY\*, Leiderman Y, **Chow CC**, Rathod R, Vajaranant TS, Aref A, De La Cruz J, Cortina MS. Vitreoretinal Surgery and Retina Care in Boston Keratoprosthesis Type I Patients: The University of Illinois at Chicago, Illinois Eye and Ear Infirmary Experience. 8th KPro Study Group Meeting. Bascom Palmer Eye Institute, Miami, FL. May 12, 2012.
- 2011 **Chow CC\***, Blair MP, Kiernan DF, Shapiro MJ. Peripheral Non-perfusion and Tractional Retinal Detachment Associated with Congenital Optic Nerve Anomalies. AAO PA075 Oct, 2011, Orlando, Florida. **Best Paper Award**
- 2011 Kiernan DF\*, **Chow CC**, Singh R, Ulanski LJ, Lim JJ, Blair NP, Mieler, WF. Subsequent Intravitreal Triamcinolone is an Effective Treatment for I-125 Plaque-Associated Retinopathy Recalcitrant to Intravitreal Bevacizumab. Invest. Ophthalmol. Vis. Sci. 2011 E-Abstract 2105.
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- 2013 Jain S\*, **Chow CC**, Lim JJ, Ulanski LJ, De la Cruz J, Cortina MS, Chau FY. Retinal Detachments in Eyes After Boston Keratoprosthesis Type 1. Invest. Ophthalmol. Vis. Sci. 2012 E-Abstract 3473.
- 2013 Osmanovic S\*, **Chow CC**, Blair NP. 30 Year Clinical Follow-Up of Original Family With Autosomal Dominant Vitreoretinopathology (ADVIRC). Invest. Ophthalmol. Vis. Sci. 2012 E-Abstract 681.

- 2013 Miller RC\*, Wallace KM, Hou JH, **Chow CC**, De la Cruz J, Cortina MS, Chau FY. Treatment Outcomes of Cystoid Macular Edema in Patients with Boston Type I Keratoprosthesis. Invest. Ophthalmol. Vis. Sci. 2012 E-Abstract 263.
- 2013 Wallace KM\*, Hou JH, Miller RC, **Chow CC**, De la Cruz J, Chau FY, Cortina MS. Risk Factors Associated with Cystoid Macular Edema After Boston Keratoprosthesis Type 1 Implantation. Invest. Ophthalmol. Vis. Sci. 2012 E-Abstract 3462.
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- 2012 Bui KM, Dikopf MS, Hallak JA, Kiernan DF, Alleman N, **Chow CC**, Mieler WF. Treatment of Radiation Maculopathy with Intravitreal Bevacizumab versus Alternating Bevacizumab and Intravitreal Triamcinolone. The 30th Annual American Society of Retina Specialists Meeting, August 2012, Las Vegas, NV
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- 2011 Kiernan DF\*, **Chow CC**, Ulanski LJ, Lim JI, Blair NP, Mieler, WF. Intravitreal Triamcinolone Treatment for Brachytherapy-Associated Retinopathy Recalcitrant to Intravitreal Bevacizumab. Sept 2011 Poster 12, The Retina Society Meeting. Rome, Italy.
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- 2011 Shah RJ\*, **Chow CC**, Hallak JA, Lim JI, Vajaranant TS. Retinal Nerve Fiber Layer (RNFL) Thickness Analysis in Sickle Cell Disease: Implications for Glaucoma Evaluation Invest. Ophthalmol. Vis. Sci. 2011 E-Abstract 248.
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- 2004 **Chow CC\***, Marcet M, Yang W, Darjatmoko S, Lindstrom M, Lokken J, Albert DM. Annual Shapiro Poster & Presentation Symposium, Madison, WI
- 2004 Kurt N\*, Eun YJ, **Chow CC**, Chow CK, Cavagnero, S. Hereditary Disease Foundation Biennial Symposium, Cambridge, Massachusetts
- 2004 Cavagnero S\*, Kurt N, **Chow CC**, Chow CK. Gordon Research Conference on Protein Folding Dynamics, Ventura, California
- 2003 Cavagnero S\*, Rajagopalan S, **Chow CC**. 8th Keystone Symposium on the Frontiers of NMR in Molecular Biology, Taos, New Mexico
- 2002 Jungbauer, LM\*, **Chow CC**, Chow CK, Cavagnero S.\* FASEB Conference on Protein Folding in the Cell, Saxton River, Vermont
- 2002 Cavagnero S\*, **Chow CC**, Chow CK, Jungbauer L. Biopolymers Gordon Research Conference, Newport, Rhode Island
- 2001 **Chow CC**, Chow CK, Rhagunathan V, Huppert T, Kimball E, Jungbauer LM, Cavagnero S\* The 6th Johns Hopkins Folding Meeting, Berkeley Springs, West Virginia

#### **VOLUNTEER EXPERIENCE**

- 2005 – 2006 Wisconsin Council of the Blind-Low Vision Clinic, Madison, WI
- 2003 – 2005 MEDIC (Free clinic for the underserved) Madison, WI
- 2001 – 2004 Madison Community Health Center, Madison, WI
- 1999 – 2003 University of Wisconsin Hospital and Clinics, Madison, WI

**LANGUAGE**

Native in Cantonese, fluent in English, conversational in Spanish and Mandarin

## **Diabetic Retinopathy:**

1. Pathophysiology
2. Characteristics
3. Screening
4. Stages:
  - a. Mild NPDR
  - b. Moderate NPDR
  - c. Severe NPDR
  - d. Proliferative
    - i. Low-risk
    - ii. High risk
  - e. Diabetic Macular Edema
5. Management and Evidence:
  - a. Treatment of DME:
    - i. Focal Laser
      1. ETDRS
    - ii. Anti-VEGF
      1. Ranibizumab: Ride/Rise
      2. Aflibercept: Vivid/Vista
      3. Bevacizumab: Protocol H
    - iii. Steroids
      1. Efficacy
      2. Side effects: IOP, Cataract
      3. Triamcinolone
      4. Ozurdex
      5. Iluvien
    - iv. DRCR network:
      1. Protocol I: Laser vs. Anti-VEGF
      2. Protocol T: Eylea for patients
  - b. Treatment of PDR
    - i. ETDRS: When to perform PRP
    - ii. DRVS: When to consider surgery
    - iii. Protocol S: Comparing Anti-VEGF to PRP
6. Ongoing investigations
  - a. DRCR network:
    - i. Protocol V
    - ii. Protocol AB

- b. Jetrea
- c. Other studies

# Diabetic Retinopathy: Evidence-based Updates in Management

Lingmin Lisa He, MD, MS  
Retinal Diagnostic Center

# Epidemiology

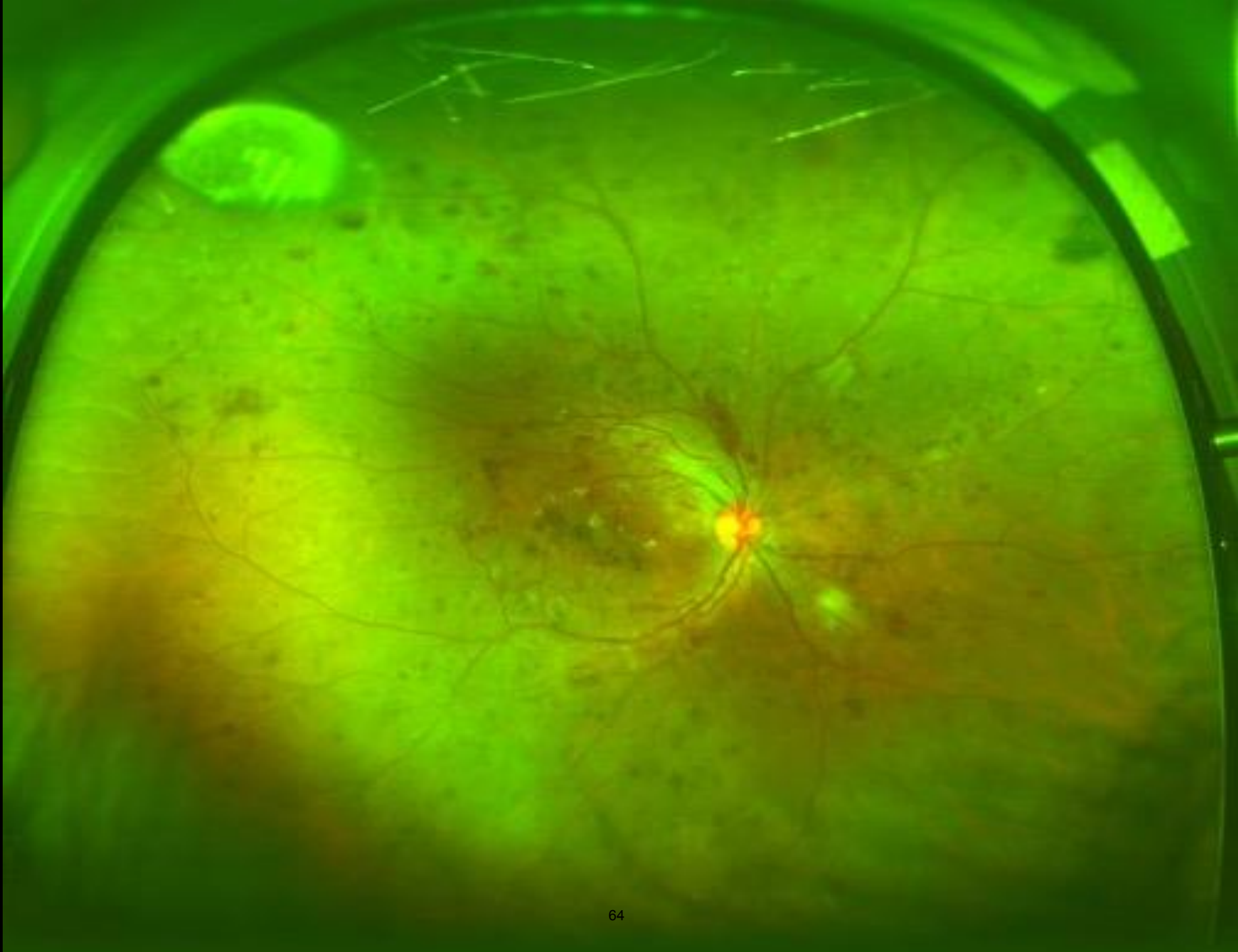
- 9.3% population has diabetes (29 million, approx 30% undiagnosed),
- Leading cause of vision loss in the young working population: 25-75
- Overall approx 40% of with diabetes have retinopathy, 8% vision threatening
- 75% affected if >15 yrs disease
- But only <50% ever develop proliferative disease
- Associations:
  - Glaucoma and myopia may be associated with less severe disease, lower prevalence

# Pathophysiology

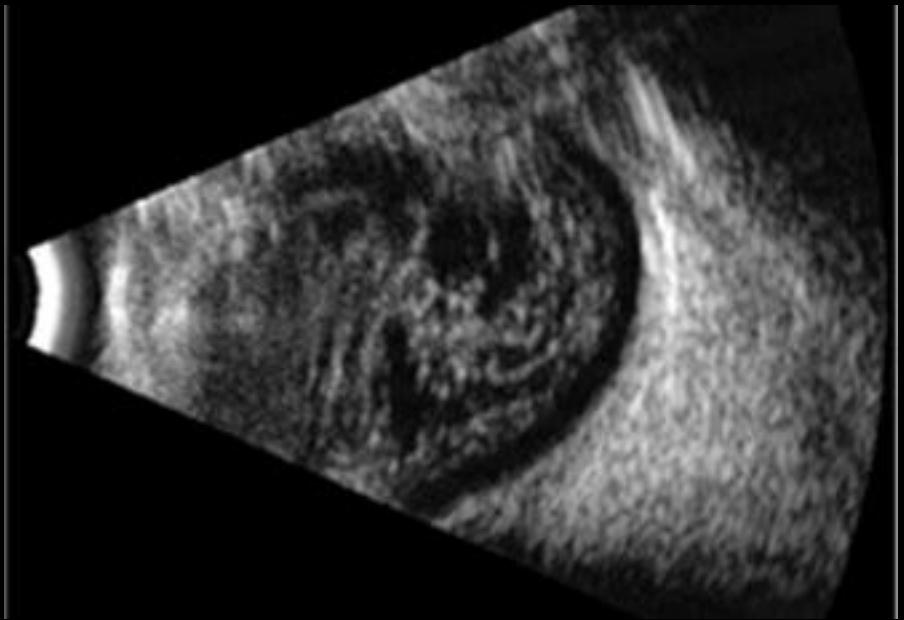
- Hyperglycemia => Loss of pericytes (microvascular autoregulation)
- Thickened capillary basement membrane
- Endothelial cell proliferation (pericyte inhibition) => microaneurysms
- Impaired blood-retina barrier=> Venous dilation/beading, macular edema
- Increased vascular permeability (VEGF)
- Chronic low grade inflammation (steroids)

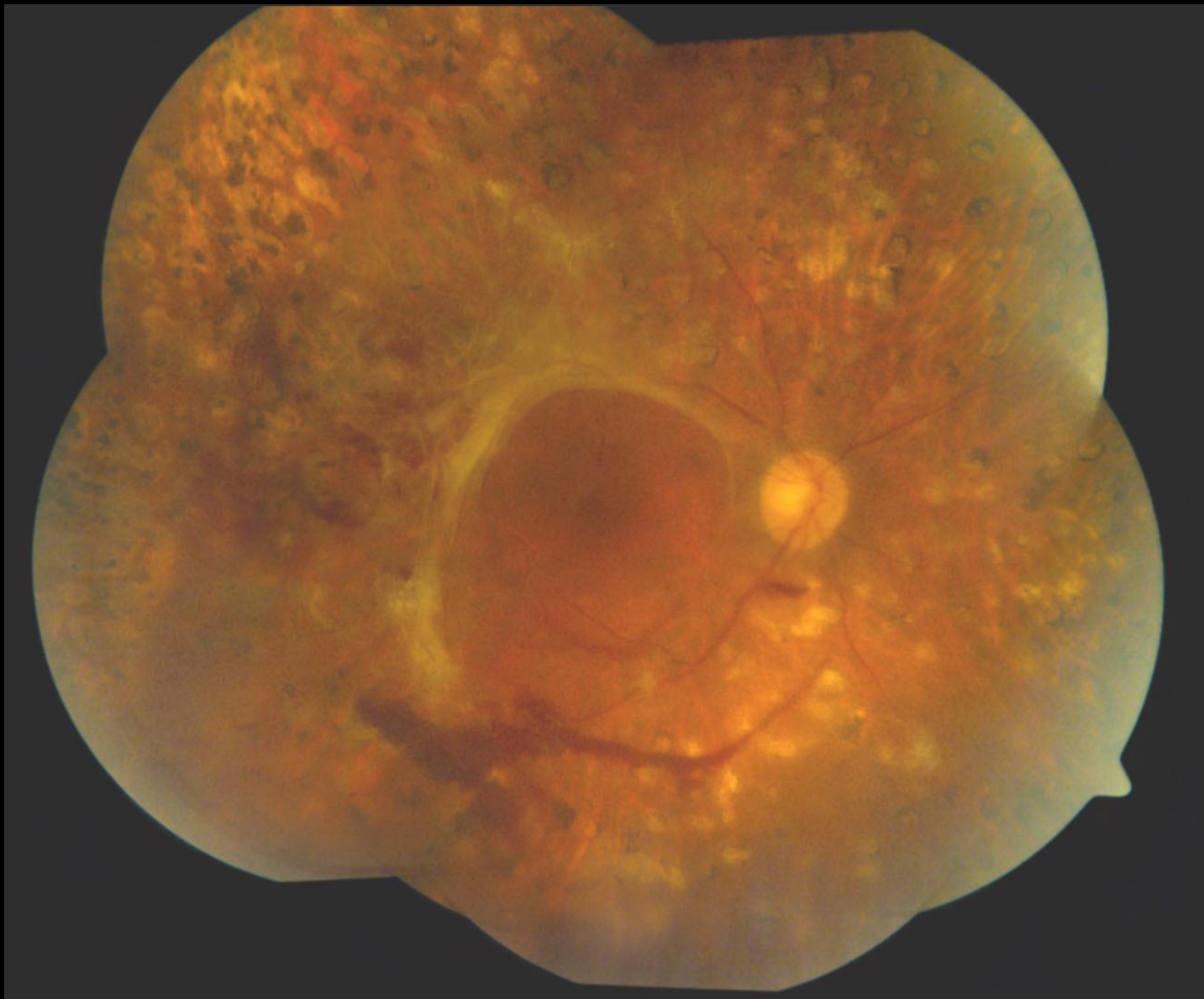
# Clinical Characteristics



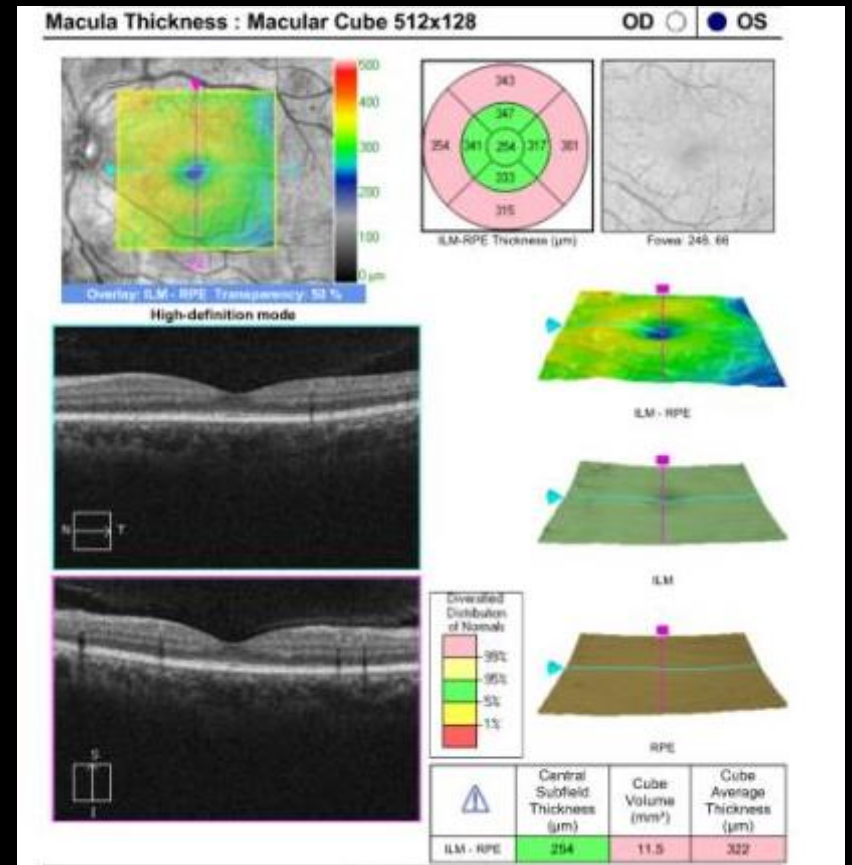
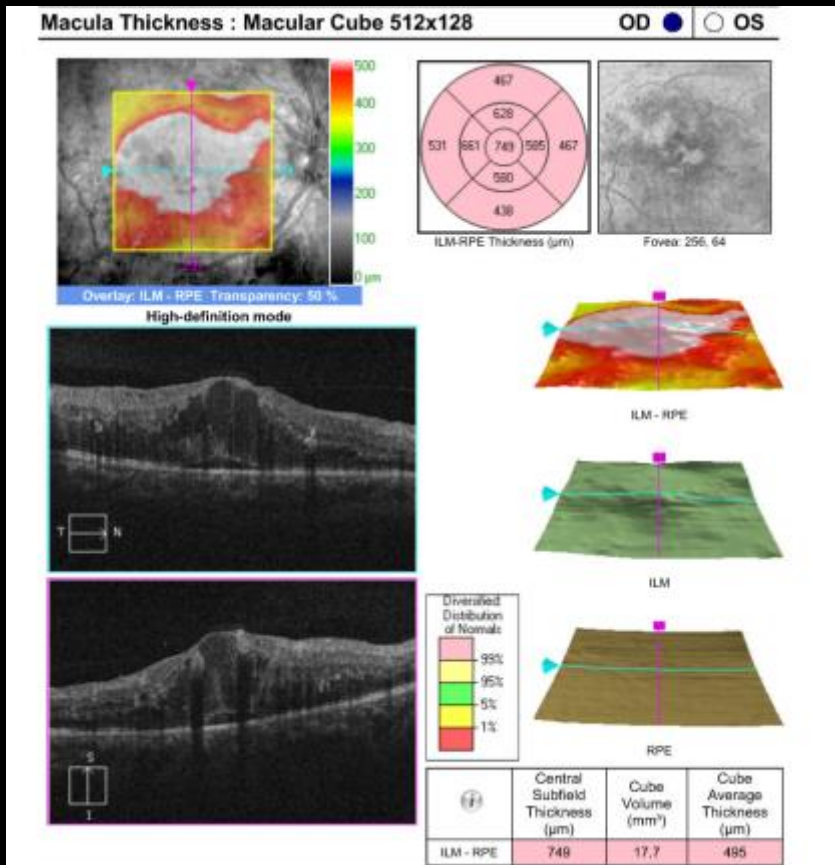








# OCT



# Screening: 2016 AAO Preferred Practice Pattern

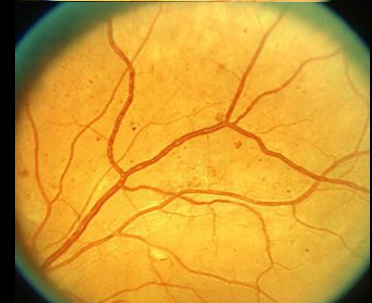
## RECOMMENDED EYE EXAMINATION SCHEDULE FOR PATIENTS WITH DIABETES MELLITUS

Diabetes Type	Recommended Time of First Examination	Recommended Follow-up*
Type 1	3-5 years after diagnosis <sup>15 [A:II]</sup>	Yearly <sup>15 [A:II]</sup>
Type 2	At time of diagnosis <sup>19,69 [A:II]</sup>	Yearly <sup>19,69 [A:II]</sup>
Prior to pregnancy (type 1 or type 2)	Prior to conception and early in the first trimester <sup>70-72 [A:I]</sup>	No retinopathy to mild or moderate NPDR: every 3–12 months <sup>70-72 [A:I]</sup> Severe NPDR or worse: every 1–3 months <sup>70-72 [A:I]</sup>

NPDR = nonproliferative diabetic retinopathy

# Classification: ETDRS

ETDRS level	ETDRS severity	ETDRS definition
10	No retinopathy	Diabetic retinopathy absent
20	Very mild NPDR	Microaneurysms only
35	Mild NPDR	Hard exudates, cotton-wool spots, and/or mild retinal hemorrhages
43	Moderate NPDR	43A:retinal hemorrhages moderate (>photograph 1A) in 4 quadrant or severe (≥ photograph 2A) in 1 quadrant 43B:mild IRMA (<photograph 8A) in 1 to 3 quadrants
47	Moderate NPDR	47A:both level 43 characteristics 47B:mild IRMA in 4 quadrants 47C:severe retinal hemorrhage in two to three quadrants 47D:venous beading in one quadrant"
53A-D	Severe NPDR	53A:≥2 level 47 characteristics 53B:severe retinal hemorrhages in 4 53C:moderate to severe IRMA (≥ photograph 8A) in at least 1 quadrant 53D:venous beading in at least 2 quadrants"
53E	Very severe NPDR	≥2 level 53A-D characteristics
61	Mild PDR	NVE <0.5 disk area in 1 or more quadrants
65	Moderate PDR	65A:NVE≥0.5 disk area in 1 or more quadrants 65B:NVD<photograph 10A (0.25-0.33 disk area)
71 and 75	High-risk PDR	NVD ≥ photograph 10A, or NVD < photograph 10A or NVE ≥ 0.5 disk area plus VH or PRH, or VH or PRH obscuring ≥ 1 disk area
81 and 85	Advanced PDR	Fundus partially obscured by VH and either new vessels ungradable or retina detached at the center of the macula



# Classification - simplified

## DIABETIC RETINOPATHY DISEASE SEVERITY SCALE

Disease Severity Level	Findings Observable upon Dilated Ophthalmoscopy
No apparent retinopathy	No abnormalities
Mild NPDR	Microaneurysms only
Moderate NPDR	More than just microaneurysms but less than severe NPDR
Severe NPDR	Any of the following (4-2-1 rule) and no signs of proliferative retinopathy: <ul style="list-style-type: none"><li>◆ Severe intraretinal hemorrhages and microaneurysms in each of four quadrants</li><li>◆ Definite venous beading in two or more quadrants</li><li>◆ Moderate IRMA in one or more quadrants</li></ul>
PDR	One or both of the following: <ul style="list-style-type: none"><li>◆ Neovascularization</li><li>◆ Vitreous/preretinal hemorrhage</li></ul>

IRMA = intraretinal microvascular abnormalities; NPDR = nonproliferative diabetic retinopathy; PDR = proliferative diabetic retinopathy

NOTE: Any patient with two or more of the characteristics of severe nonproliferative diabetic retinopathy is considered to have very severe nonproliferative diabetic retinopathy

High risk PDR

NVD  $\geq \frac{1}{4}$   $\frac{1}{3}$  disc area (standard photo 10A, left) or NVD and hemorrhage, or NVE  $\geq \frac{1}{4}$  disc area and hemorrhage



# Macular Edema

## INTERNATIONAL CLINICAL DIABETIC MACULAR EDEMA DISEASE SEVERITY SCALE

Proposed Disease Severity Level	Findings Observable upon Dilated Ophthalmoscopy
Diabetic macular edema apparently absent	No apparent retinal thickening or hard exudates in posterior pole
Diabetic macular edema apparently present	Some apparent retinal thickening or hard exudates in posterior pole

**If diabetic macular edema is present, it can be categorized as follows:**

Proposed Disease Severity Level	Findings Observable upon Dilated Ophthalmoscopy*
Diabetic macular edema present	<ul style="list-style-type: none"><li>♦ Mild diabetic macular edema: some retinal thickening or hard exudates in posterior pole but distant from the center of the macula</li><li>♦ Moderate diabetic macular edema: retinal thickening or hard exudates approaching the center of the macula but not involving the center</li><li>♦ Severe diabetic macular edema: retinal thickening or hard exudates involving the center of the macula</li></ul>

\* Hard exudates are a sign of current or previous macular edema. Diabetic macular edema is defined as retinal thickening; this requires a three-dimensional assessment that is best performed by dilated examination using slit-lamp biomicroscopy and/or stereoscopic fundus photography.

# Randomized Clinical Trials

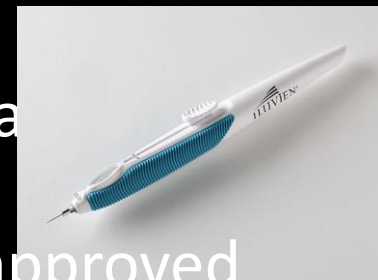
- Diabetic Retinopathy Study (DRS, 1972-1979)
  - PRP for patients with high risk proliferative disease reduces chance of severe vision loss by 50-60%
- Early Treatment of Diabetic Retinopathy (ETDRS, 1985-1990)
  - Focal laser for clinical significant macular edema reduces vision loss by 50%
  - Only high risk PDR should get PRP because comparable rates of progression to severe vision loss in severe NPDR, not high risk PDR
  - Aspirin does not change diabetic retinopathy
- Diabetic Retinopathy Vitrectomy Study (1983 – 1987)
  - Early vitrectomy (vs delaying 1 year) helpful for type 1 diabetics with VH or monocular patients
  - Also for patients with active advanced PDR and vision 20/400 or better
  - TRD's not involving fovea can wait until fovea detached
  - Subsequently, advances made in vitrectomy

# Management: Macular Edema

- Early Treatment of Diabetic Retinopathy (ETDRS, 1985-1990)
  - Focal /grid laser for clinical significant macular edema reduces vision loss by 50%
  - Laser treats visible microaneurysms to blanch or grid in area of thickening without identifiable MA
  - Clinically significant macular edema (by biomicroscopy)
    - Thickened the retina at or within 500  $\mu\text{m}$  of the center of the macula
    - Hard exudates at or within 500  $\mu\text{m}$  of the center of the macula, if associated with thickening of the adjacent retina (not residual hard exudates remaining after the disappearance of retinal thickening)
    - Zone or zones of retinal thickening one disc area or larger, any part of which is within one disc diameter of the center of the macula

# Macular Edema: Steroids

- Efficacy: Small studies, DRCR.net Protocol B: triamcinolone vs laser showed improved vision with steroid at 4 months, but laser was better at 2 years
- Side Effects:
  - IOP elevation
  - Cataract acceleration
  - Corneal decompensation (lens status)
- Formulations:
  - Triamcinolone (Kenalog or Triescence)
  - Ozurdex: lasts for 3 months or longer, FDA approved in 2014, MEAD study
  - Iluvien: FAME study, lasts for 3 years, FDA approved



# Macular Edema: Anti-VEGF

- Ranibizumab: FDA approved 0.3mg dose in 2012 with studies Ride/Rise
  - 759 patients received Lucentis 0.3, 0.5. or sham
  - 3 months after start of study, rescue laser available to all
  - Patients who received Lucentis had average vision gains exceeding two lines (10 letters) on the eye chart at 24 months vs. < 1 line (approx 2 letters) in control
- Aflibercept: FDA approved 2 mg injection q 8 weeks after 5 initial loading doses based in studies Vivid/Vista 2014
  - 862 patients comparing monthly Eylea, monthly x 5 then q8 weeks to macular laser
  - Both treatment groups read approx 2 lines better vs. no improvement in control
- Bevacizumab: Protocol H, BOLT

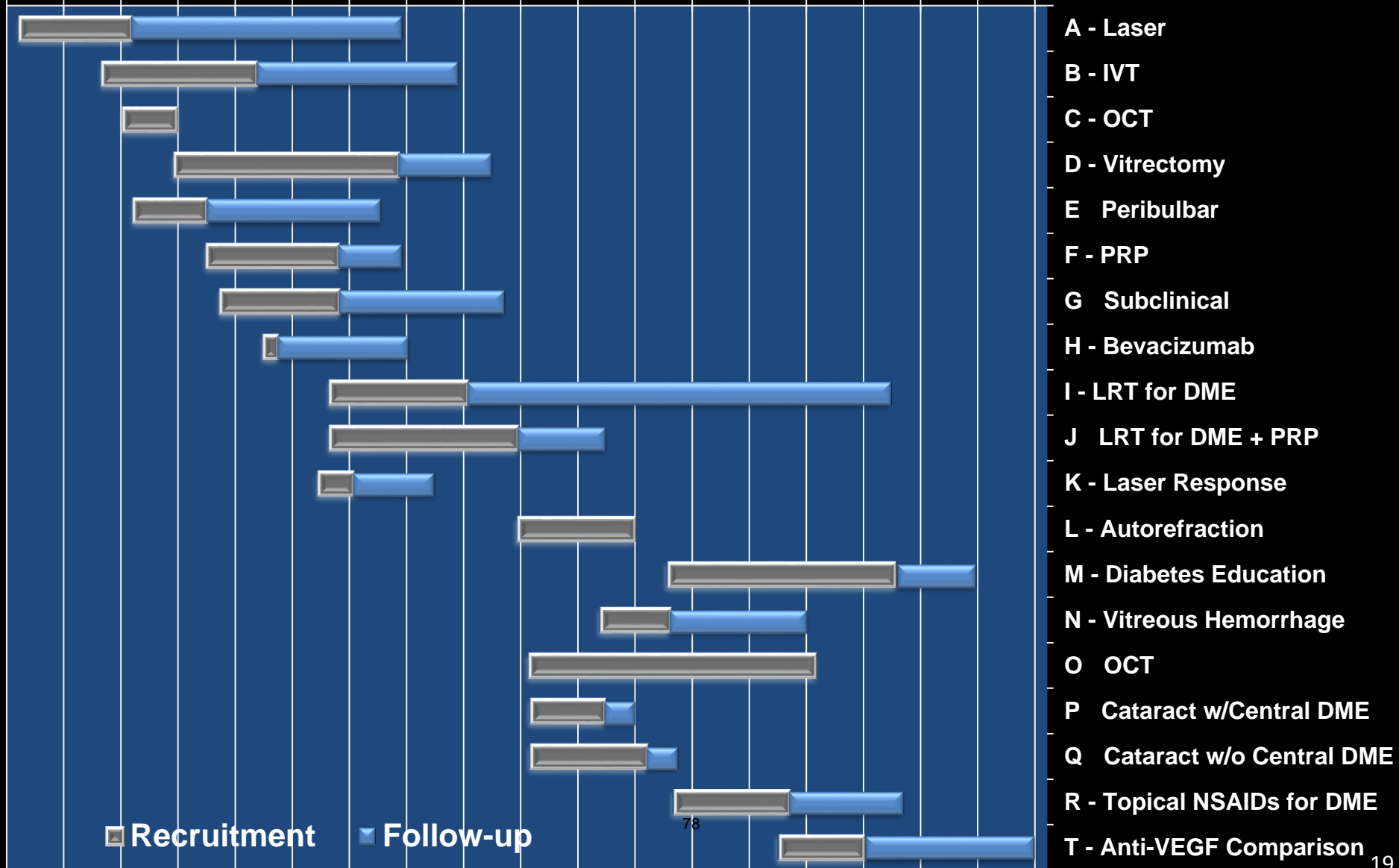
# DRCR network

- **Began in 2002, collaborative network to facilitate multicenter clinical research on diabetic retinopathy, DME and other retinal diseases.**

	Active	Total
<b>Sites</b> (Community & Academic Centers)	<b>132</b>	<b>318</b>
Community Sites	88 (67%)	204 (64%)
<b>Investigators</b>	<b>423</b>	<b>1183</b>
<b>Other Personnel</b>	<b>1072</b>	<b>4128</b>
<b>States</b>	<b>34</b>	<b>49</b>
<b>Provinces in Canada</b>	<b>5</b>	<b>5</b>

# Completed DRCR.net Protocols

5/03 1/04 9/04 5/05 2/06 10/06 6/07 2/08 10/08 7/09 3/10 11/10 7/11 4/12 12/12 8/13 4/14 12/14 9/15



# Macular Edema: What's Better?

- DRCR.net
  - Protocol I: Laser vs. Steroids vs. Anti-VEGF
    - **Anti-VEGF with ranibizumab was better than laser**
  - Protocol T: Which Anti-VEGF is best
    - Aflibercept for vision 20/50 or worse
    - **The 2-year clinical trial compared 3 drugs for diabetic macular edema (DME) and found that gains in vision were greater for participants receiving the drug aflibercept than for those receiving bevacizumab, but only among participants starting treatment with 20/50 or worse vision. At one year aflibercept had superior gains to ranibizumab in this vision subgroup, however a difference could not be identified at 2 years. The 3 drugs yielded similar gains in vision for patients with 20/32 or 20/40 vision at the start of treatment.**



# Protocol I Study Design

Randomized, multi-center clinical trial

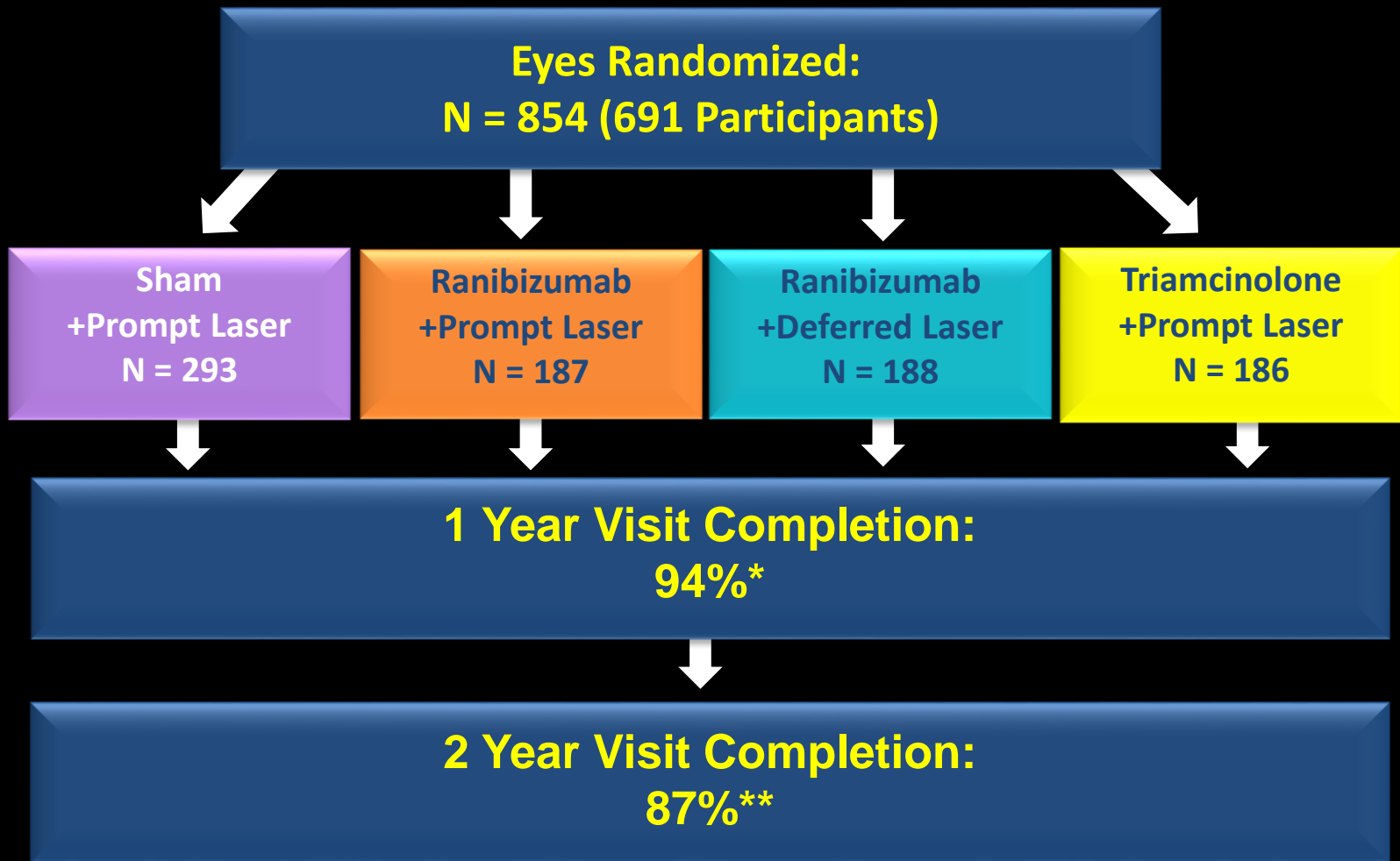
**At least one eye meeting all of the following criteria:**

- Electronic-ETDRS<sup>®</sup> best corrected visual acuity letter score of 78 to 24 (~20/32 to 20/320)
- Definite retinal thickening due to diabetic macular edema involving the center of the macula on clinical examination
- Central subfield (Stratus OCT<sup>™</sup>)  $\geq 250$   $\mu\text{m}$



**Primary outcome: Change in visual acuity from baseline to 1 year (intent to treat analysis)**

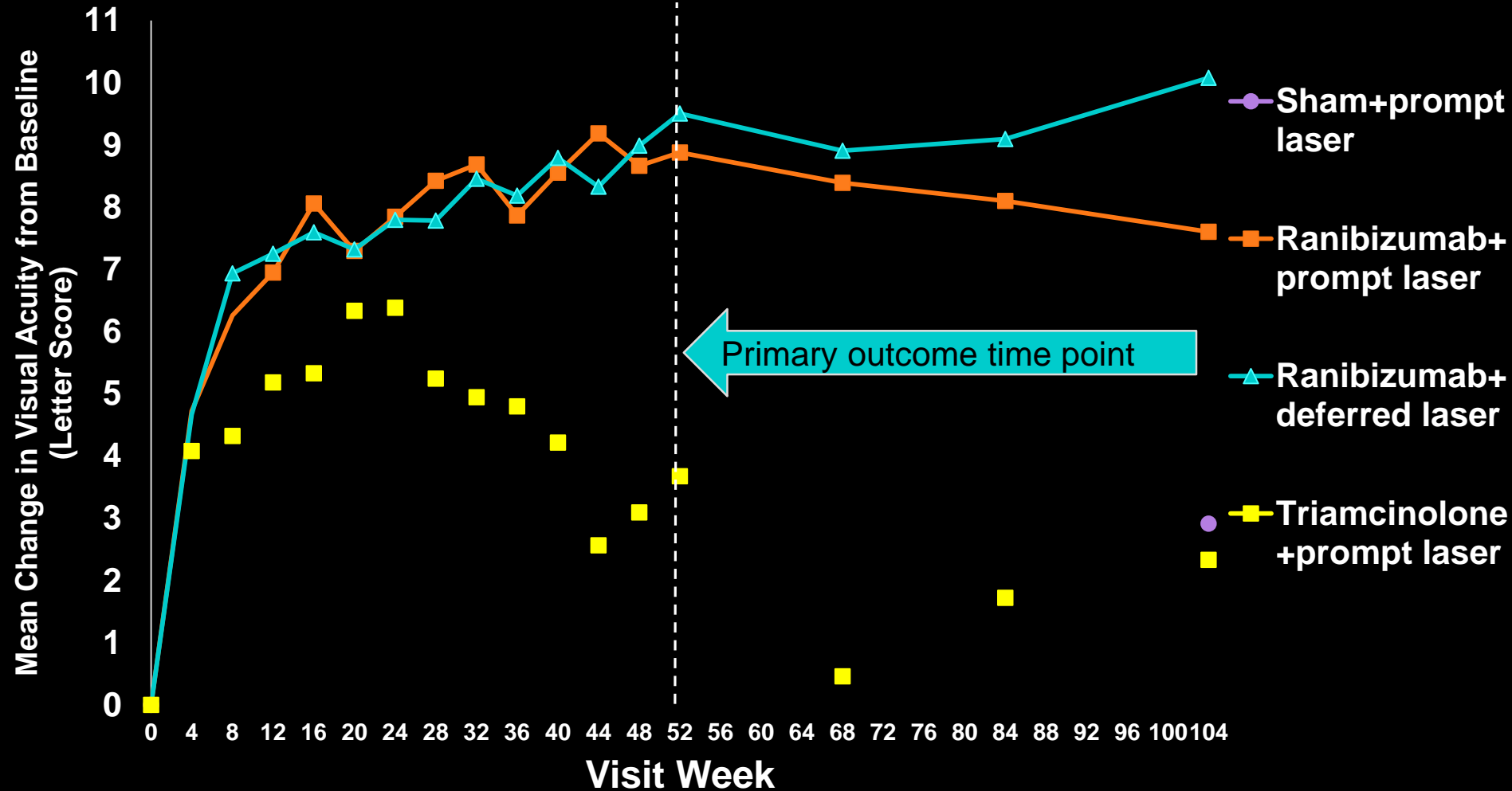
# Study Enrollment and Completion



\* Includes deaths

\*\* Includes deaths and excludes pending and dropped who are not yet in window

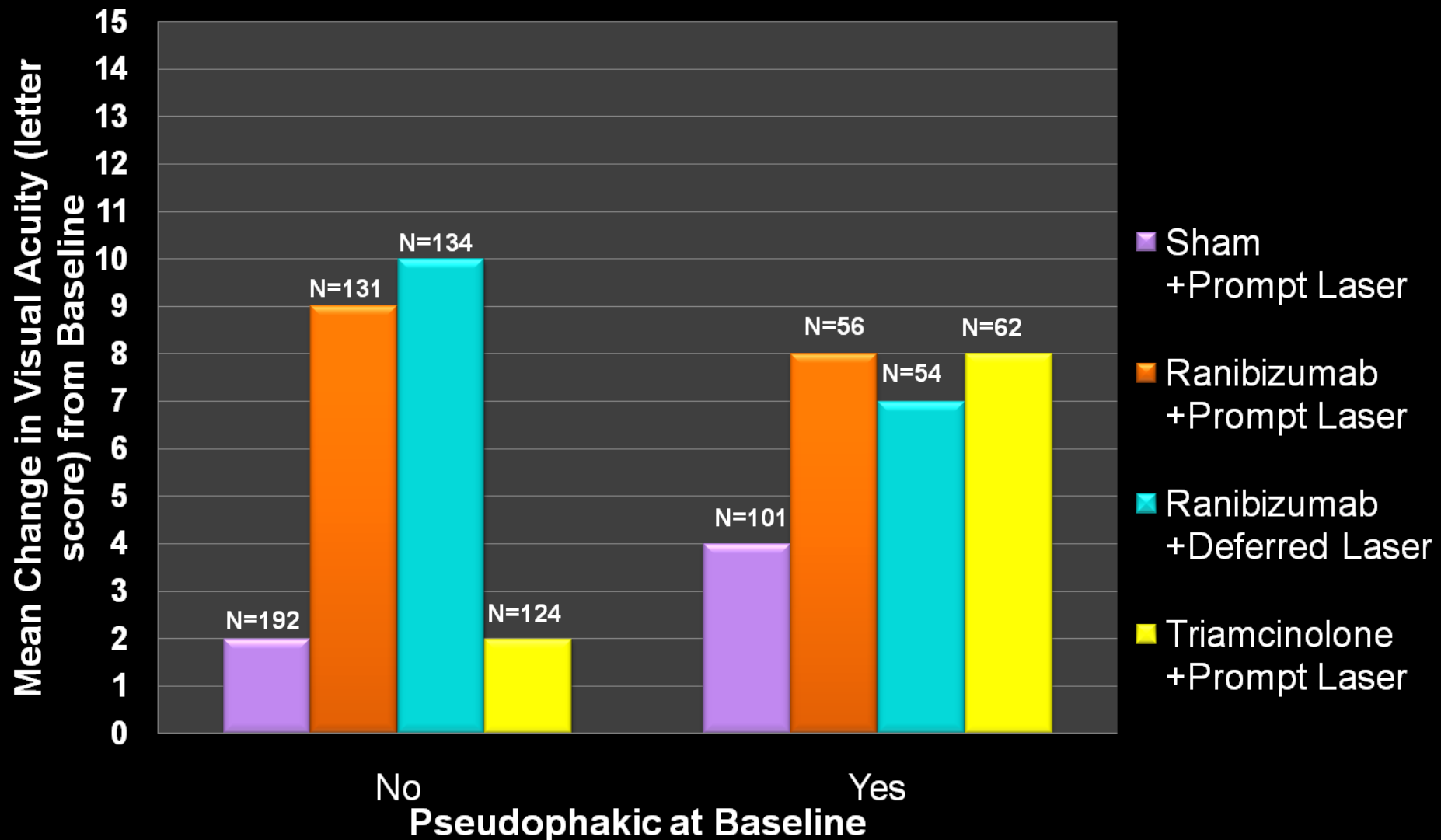
# Mean Change in Visual Acuity\* (Letter Score) at Follow-up Visits



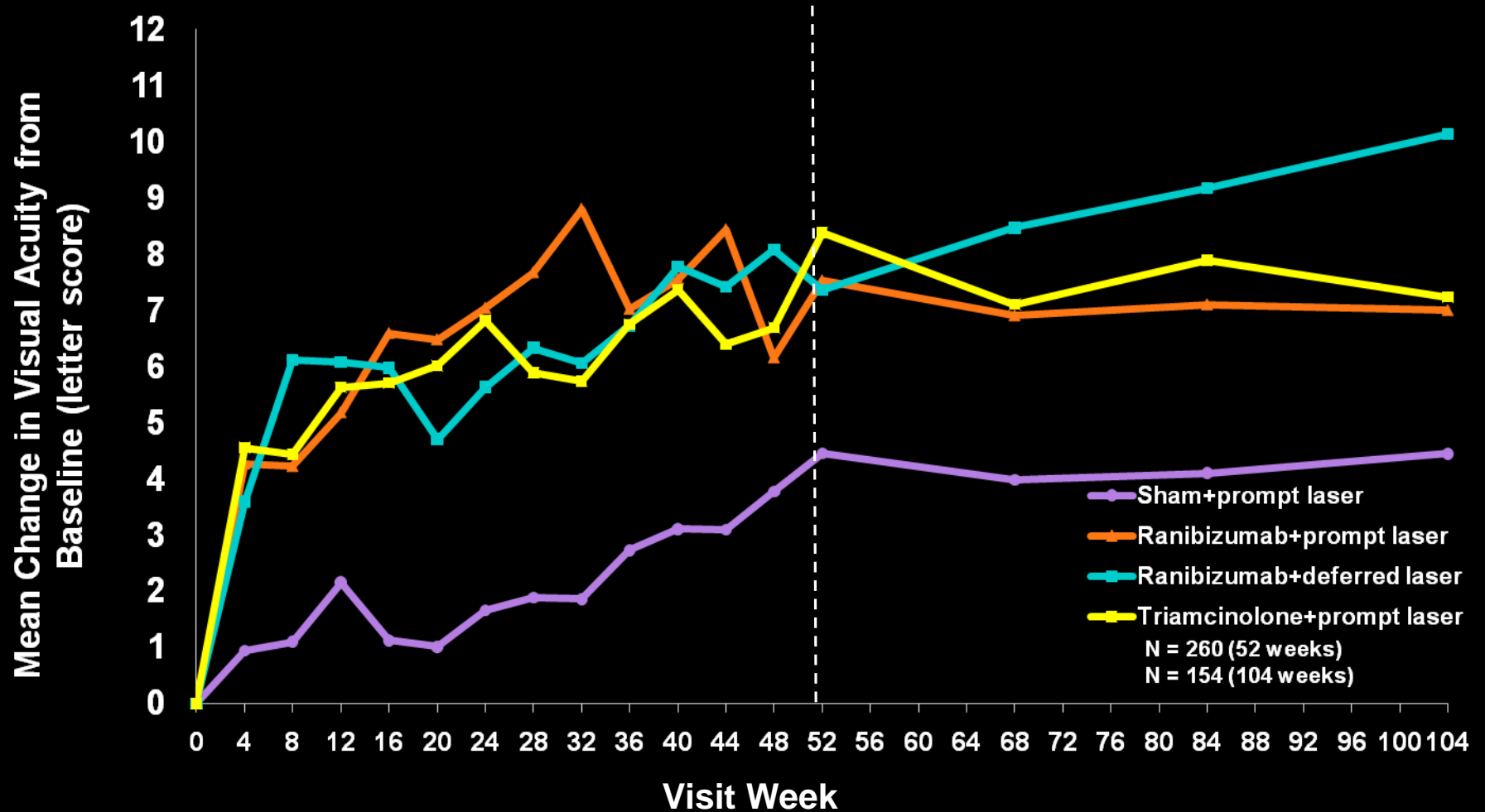
\* Values that were  $\pm 30$  letters were assigned a value of 30

P values for difference in mean change in visual acuity from sham+prompt laser at the 52 week visit: ranibizumab+prompt laser  $<0.001$ ; ranibizumab+deferred laser  $<0.001$ ; and triamcinolone+prompt laser  $=0.31$ . 23

# Change in Visual Acuity at 1 Year Stratified by Pseudophakic at Baseline

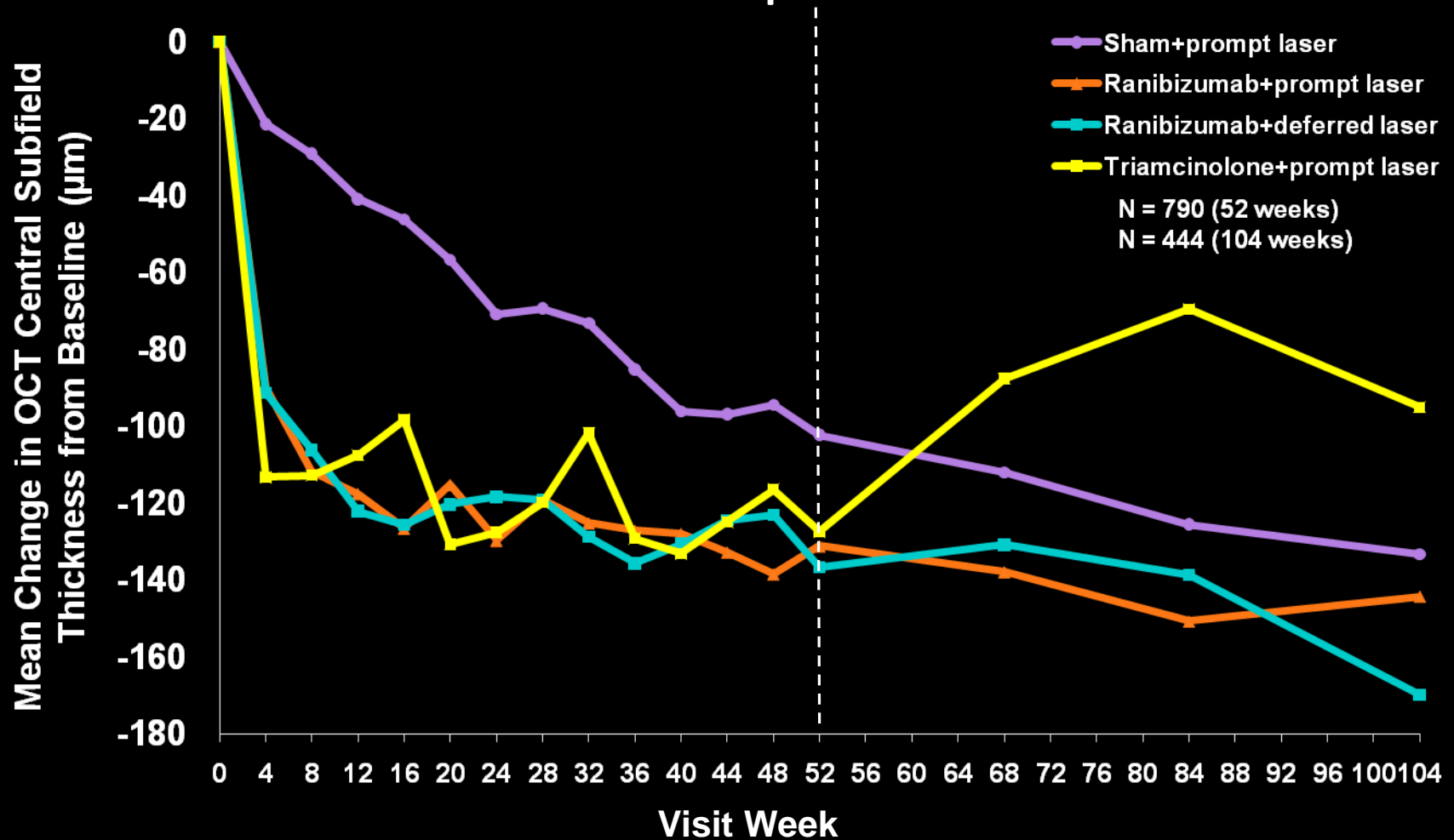


# Mean Change in Visual Acuity at Follow-up Visits among Eyes that were Pseudophakic at Baseline\*



\* Values that were  $\pm 30$  letters were assigned a value of 30

# Mean Change in Central Subfield Thickening at Follow-up Visits

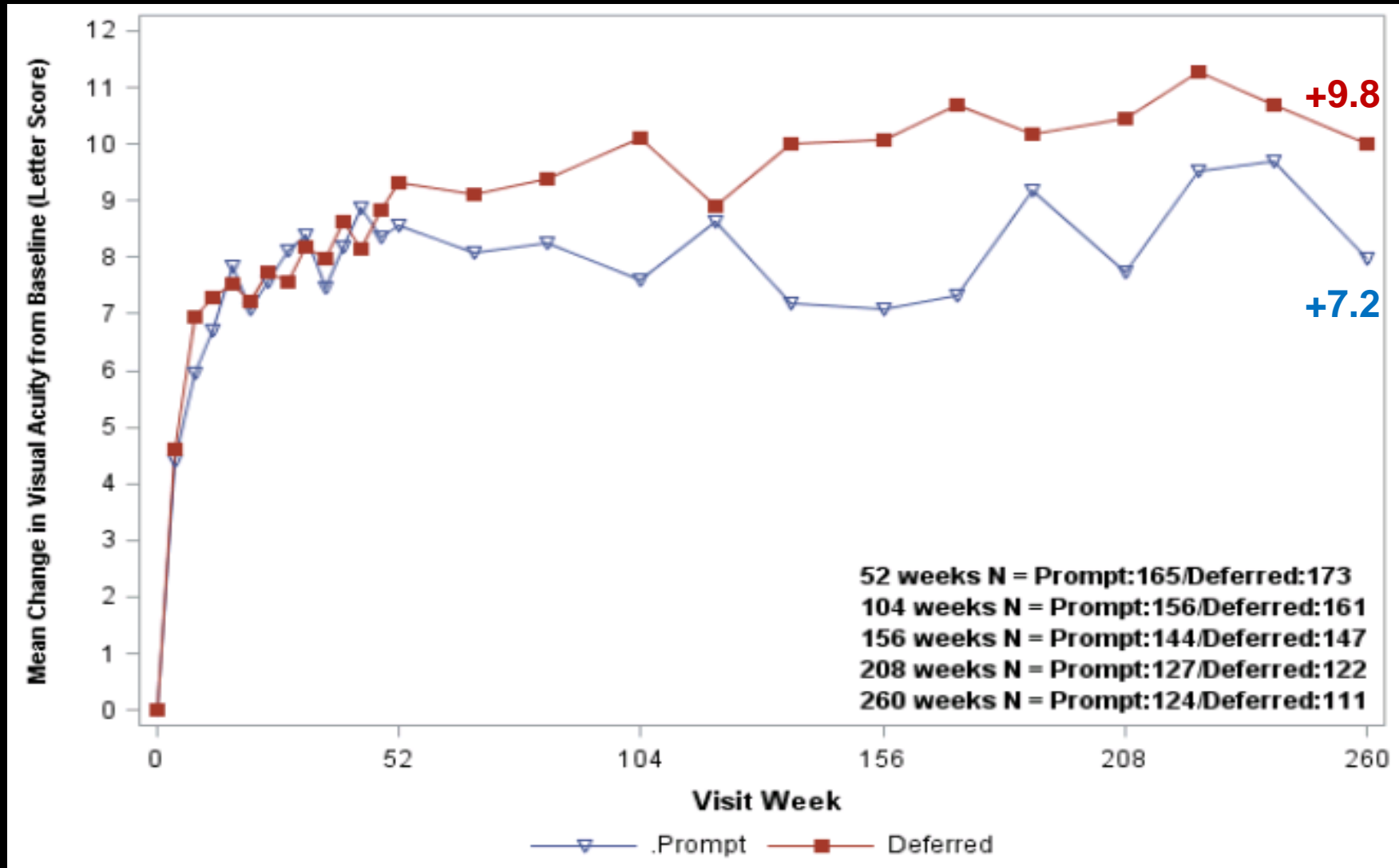


*P* values are for the difference in mean change in OCT CSF retinal thickness from sham+prompt laser at the 52 week visit: ranibizumab+prompt laser <0.001, ranibizumab+deferred laser <0.001, and triamcinolone+prompt laser <0.001.

# Completion of 5 Year Visit

	<b>Ranibizumab + Prompt Laser</b>	<b>Ranibizumab + Deferred Laser</b>
<b>Eyes originally randomized</b>	<b>N = 180</b>	<b>N = 181</b>
<b>Completed 5 Year (excl deaths)</b>	<b>69% (76%)</b>	<b>61% (74%)</b>
<b>Death prior to 5 Year</b>	<b>9%</b>	<b>17%</b>
<b>Discontinued/Dropped prior to 5 Year</b> <i>Includes pts who did not consent to extension</i>	<b>21%</b>	<b>22%</b>
<b>Eyes in the extension study</b>	<b>N = 132</b>	<b>N = 136</b>
<b>Completed 5 Year (excl deaths)</b>	<b>94% (97%)</b>	<b>82% (92%)</b>
<b>Death prior to 5 Year</b>	<b>3%</b>	<b>11%</b>
<b>Dropped prior to 5 Year</b>	<b>3%</b>	<b>7%</b>

# Mean Change in Visual Acuity\* at Follow-up Visits





# Injections Prior to 5 Year\*

	<b>Ranibizumab + Prompt Laser N=124</b>	<b>Ranibizumab + Deferred Laser N=111</b>
<b>Median # of injections in year 1</b>	<b>8</b>	<b>9</b>
<b>Median # of injections in year 2</b>	<b>2</b>	<b>3</b>
<b>Median # of injections in year 3</b>	<b>1</b>	<b>2</b>
<b>Median # of injections in year 4</b>	<b>0</b>	<b>1</b>
<b>Median # of injections in year 5</b>	<b>0</b>	<b>0</b>
<b>Median # of injections prior to 5 year visit</b>	<b>13</b>	<b>17</b>
<b>% of eyes that received &gt;1 injection in year 4</b>	<b>46%</b>	<b>55%</b>
<b>% of eyes that received &gt;1 injection in year 5</b>	<b>38%</b>	<b>48%</b>

\*Only eyes that completed 5 year visit

# Protocol T

Aflibercept, Bevacizumab, or Ranibizumab  
for DME:  
Two-year Results

# Study Design

**Randomized, multi-center clinical trial (89 Sites)**

**Participants meeting all of the following criteria:**

- At least 18 years old
- Type 1 or type 2 diabetes

**Study eye meeting all of the following criteria:**

- ~Snellen equivalent visual acuity 20/32 or worse and 20/320 or better
- Central-involved DME on clinical exam
- Central subfield thickness (CST)  $\geq$  protocol-defined gender and optical coherence tomography (OCT) machine-specific thresholds
- No history of an anti-VEGF treatment for DME in the past 12 months or any other DME treatment in the past 4 months

# Main Outcome

Change in visual acuity at 1 and 2 years adjusted for baseline visual acuity using the intent-to-treat principle

**Aflibercept  
vs.  
Bevacizumab**

**Aflibercept  
vs.  
Ranibizumab**

**Bevacizumab  
vs.  
Ranibizumab**

- **Visits were every 4 weeks during year-1 and 4 to 16 weeks during year-2, depending on treatment course**
- **Starting at the 6-month visit, focal/grid laser treatment was administered if DME persisted and was not improving**
- **Participants unmasked to treatment group following the publication of the primary results: though discouraged, decision could be made at that time to switch to a non-study anti-VEGF agent.**
- **Doses: aflibercept 2.0-mg; bevacizumab 1.25-mg; ranibizumab 0.3-mg**

# Conclusions

- **Vision gains at 2 years were seen in all 3 groups with ~half the number of injections, slightly decreased frequency of visits, and decreased amounts of laser in the 2<sup>nd</sup> year**
- **Among eyes with better VA no differences in 2-year vision outcomes identified**
- **Among eyes with worse baseline VA:**
  - **Aflibercept, on average, had superior 2-year VA outcomes compared with bevacizumab, although the difference was diminished**
  - **The VA difference between aflibercept and ranibizumab that was noted at 1 year had decreased at 2 years.**
- **The implication of the increased rate of APTC events with ranibizumab found in the current study is uncertain due to inconsistency with prior trials, warranting continued evaluation**

# Management: Proliferative Diabetic Retinopathy

- Diabetic Retinopathy Study (DRS, 1972-1979)
  - PRP for patients with high risk proliferative disease reduces chance of severe vision loss by 50-60%
- Early Treatment of Diabetic Retinopathy (ETDRS, 1985-1990)
  - Only high risk PDR should get PRP because comparable rates of progression to severe vision loss in severe NPDR, not high risk PDR
  - Aspirin does not change diabetic retinopathy

# Management: Proliferative Diabetic Retinopathy

- DRCR.net Protocol S
  - **Ranibizumab injections are effective in treating proliferative diabetic retinopathy. At two years, vision of the ranibizumab group on average improved by half a line on an eye chart. Vision of the laser group remained unchanged.**

# Protocol S

DRCR.net Prompt PRP vs  
Ranibizumab+Deferred PRP for PDR Study



# Primary Question

- Is visual acuity using ranibizumab for PDR not worse than treatment with PRP at 2 years?
  - Non-inferiority margin of 5 letters

## Secondary Question

- Are there potential benefits of ranibizumab on:
  - Vision throughout follow-up (area under the curve)
  - Peripheral vision
  - Macular edema
  - Incidence of vitrectomy

# Study Design

**Randomized, multi-center clinical trial**

**(N = 305 patients, 394 eyes, 55 Sites)**

**Study eye meeting all of the following criteria – (note: a participant can have 2 study eyes):**

- **PDR**
- **No history of PRP**
- **Best corrected visual acuity letter score  $\geq 24$  (~Snellen equivalent 20/320 or better)**
- **Eyes with or without central-involved DME were eligible**

# Conclusions

## Ranibizumab injections for Proliferative Diabetic Retinopathy ...

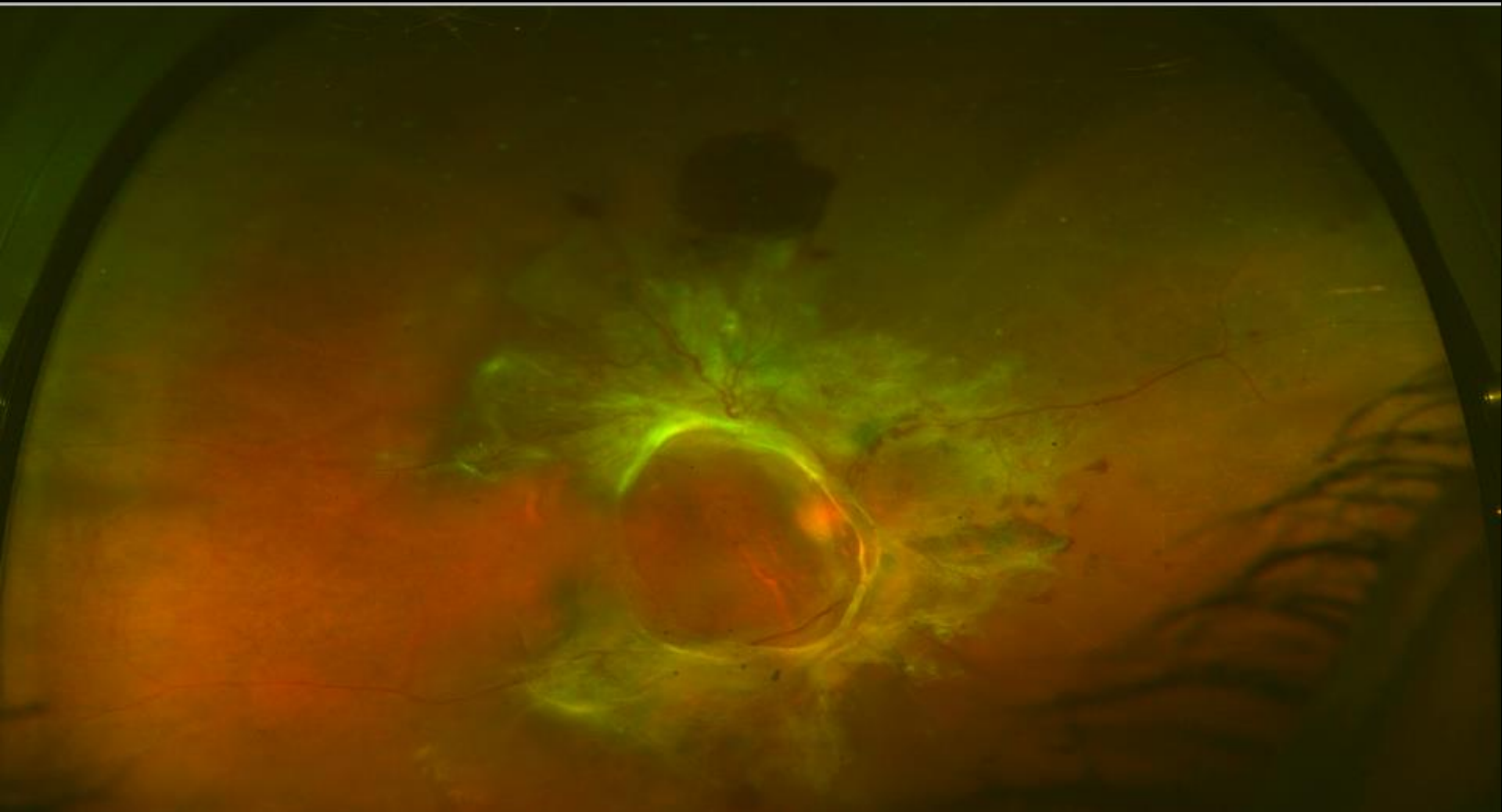
- No worse than (not inferior to) PRP for visual acuity at 2 years
- Superior vision over the course of 2 years (area under the curve)
- Reduces the incidence of DME
- Less peripheral VF loss
- Fewer vitrectomies
- No major safety differences from PRP identified except one case of endophthalmitis

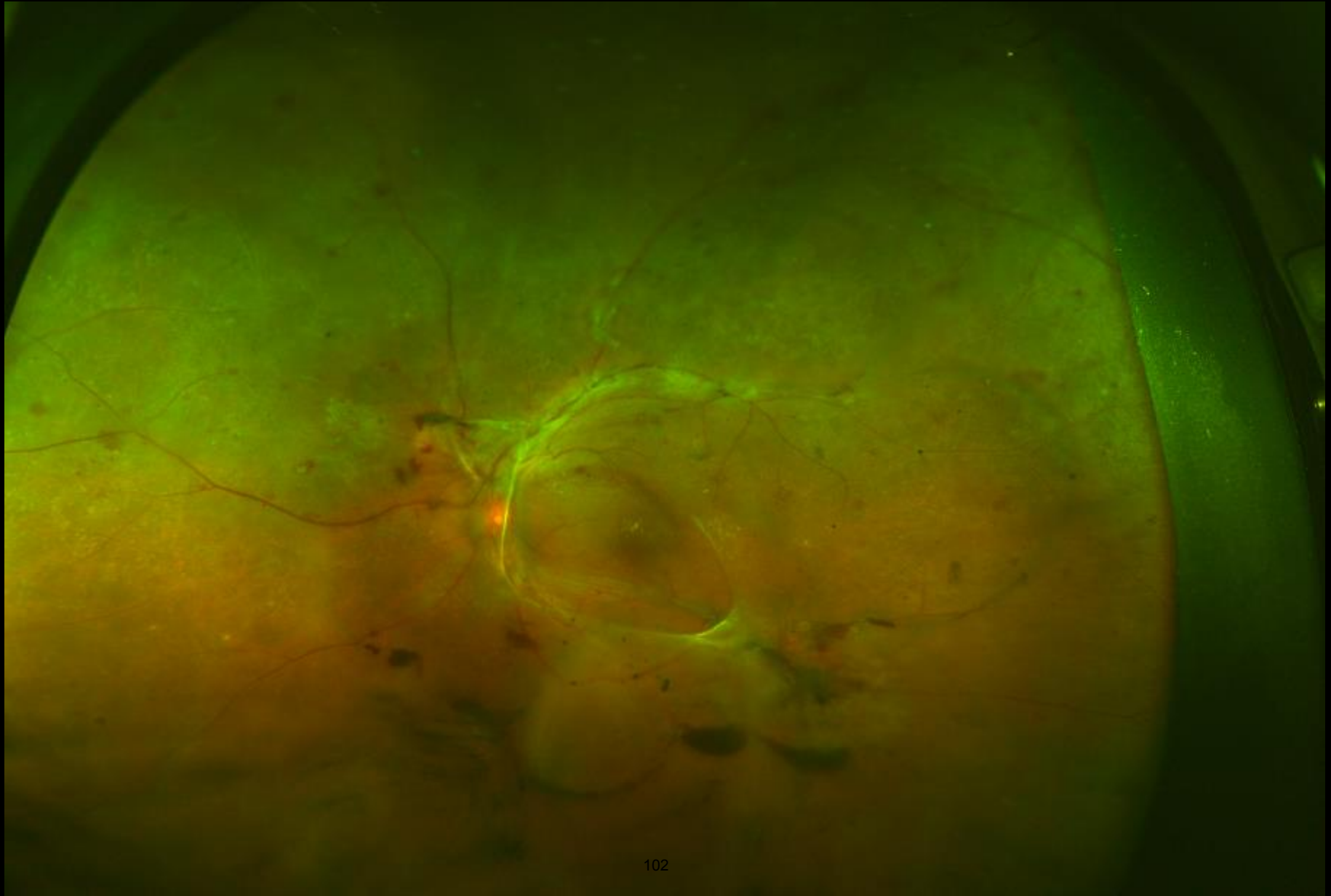
# Conclusions

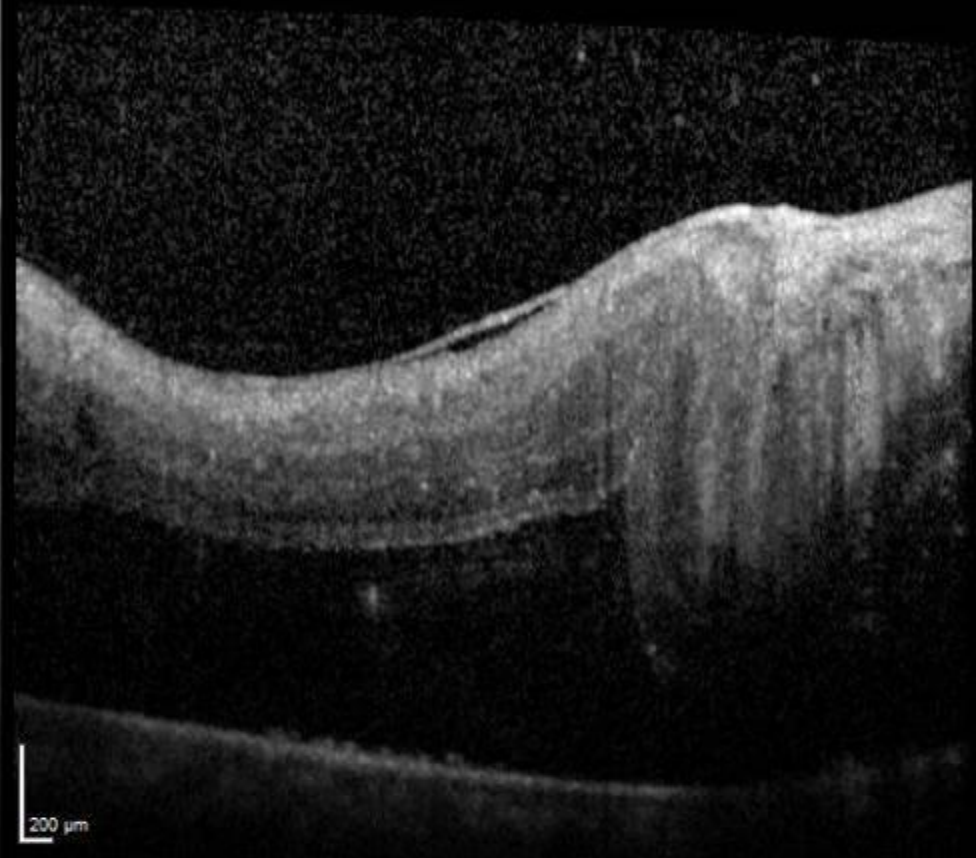
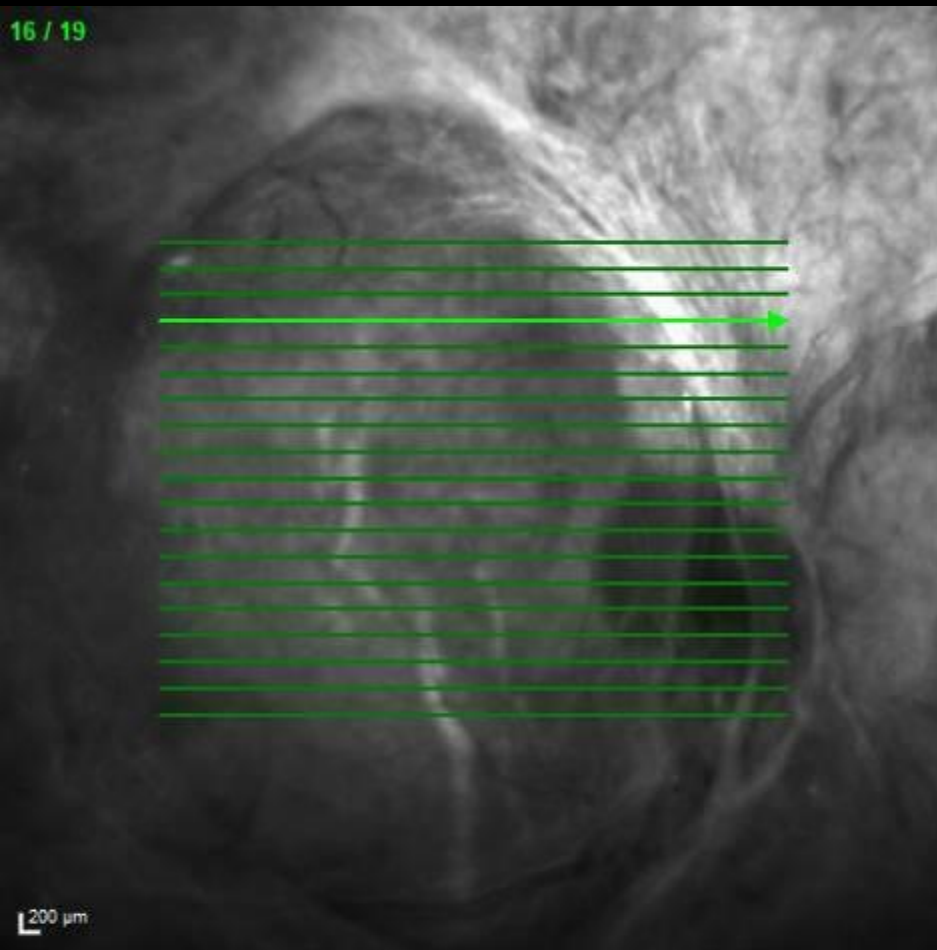
- PRP effective for PDR over last 4 decades; remains effective in 21<sup>st</sup> century
- Ranibizumab for PDR is at least as good as (non-inferior to) PRP for visual acuity at 2 years
  - Ranibizumab is an effective treatment alternative to PRP
  - No substantial safety concerns for at least 2 years
  - May be the preferred initial treatment approach for some patients, for example, those who have both PDR and DME
- Longer follow-up should determine whether effects sustained through 5 years

# Management: Surgery

- Vitreous Hemorrhage
  - Diabetic Retinopathy Vitrectomy Study (1983 – 1987)
    - Early vitrectomy (vs delaying 1 year) helpful for type 1 diabetics with VH or monocular patients
    - Also for patients with active advanced PDR and vision 20/400 or better
- Tractional Retinal Detachment
  - TRD's not involving fovea can wait until fovea detached (DRS) - advances made in vitrectomy



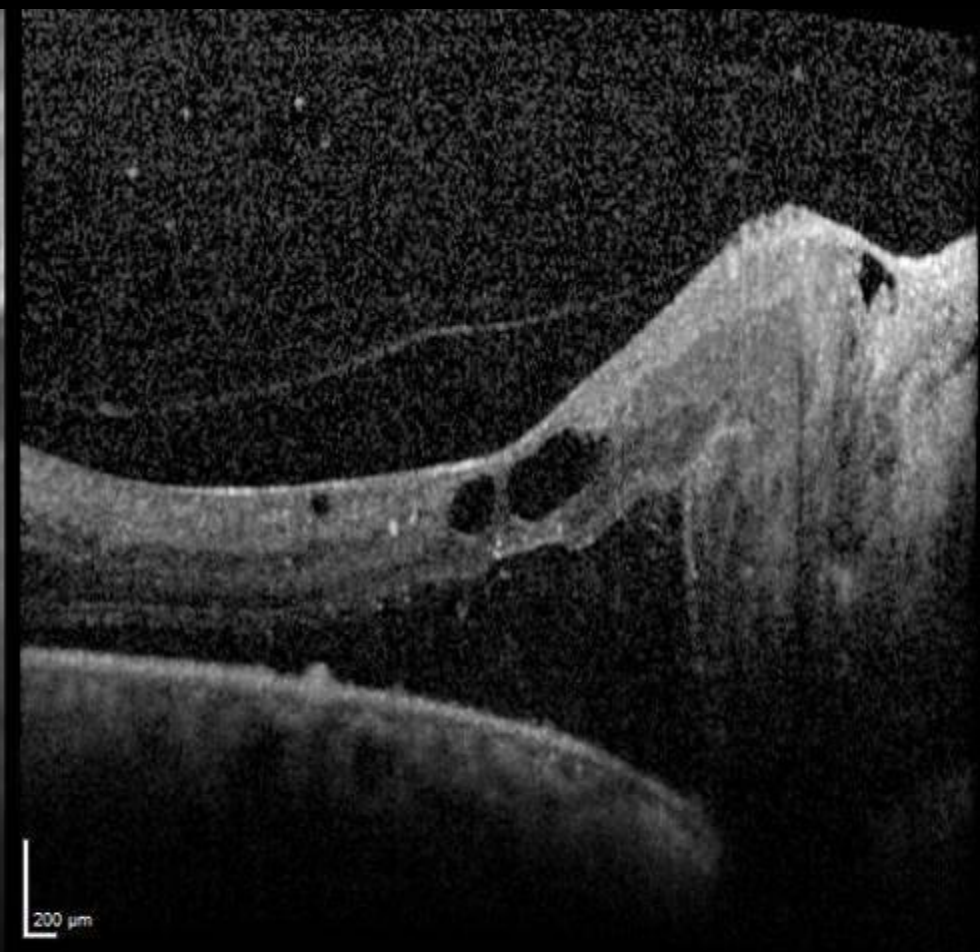
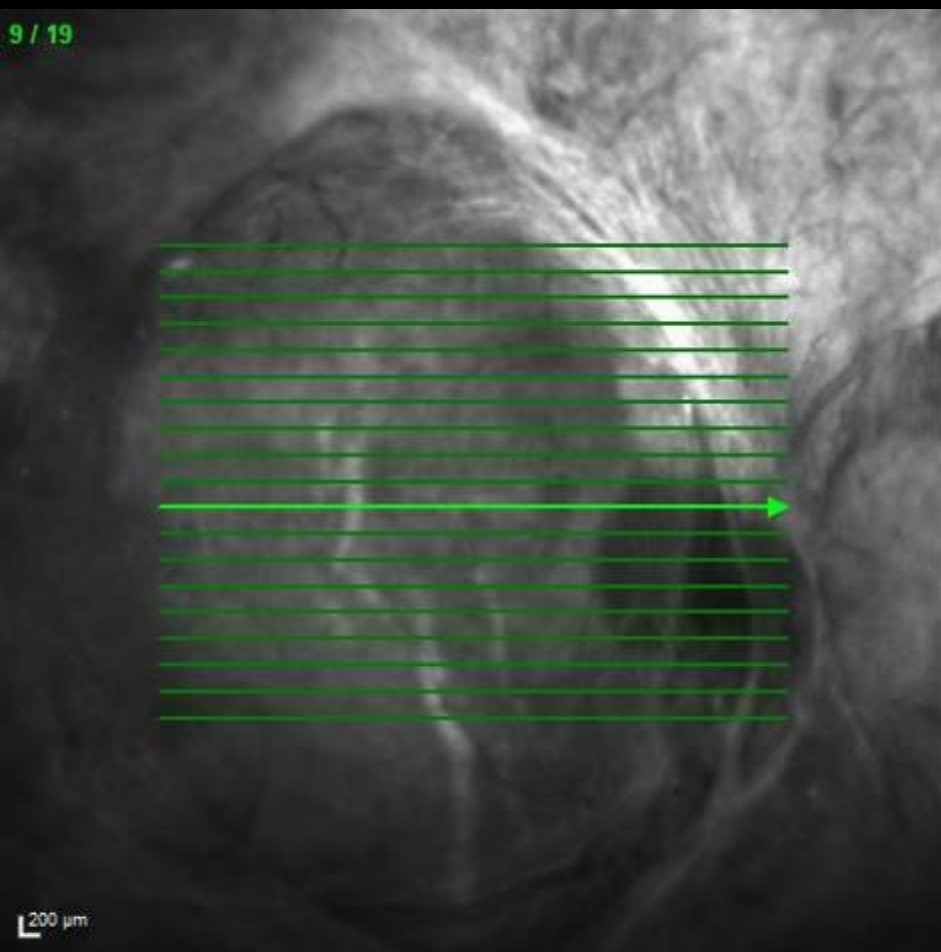




8/19/2013, OD

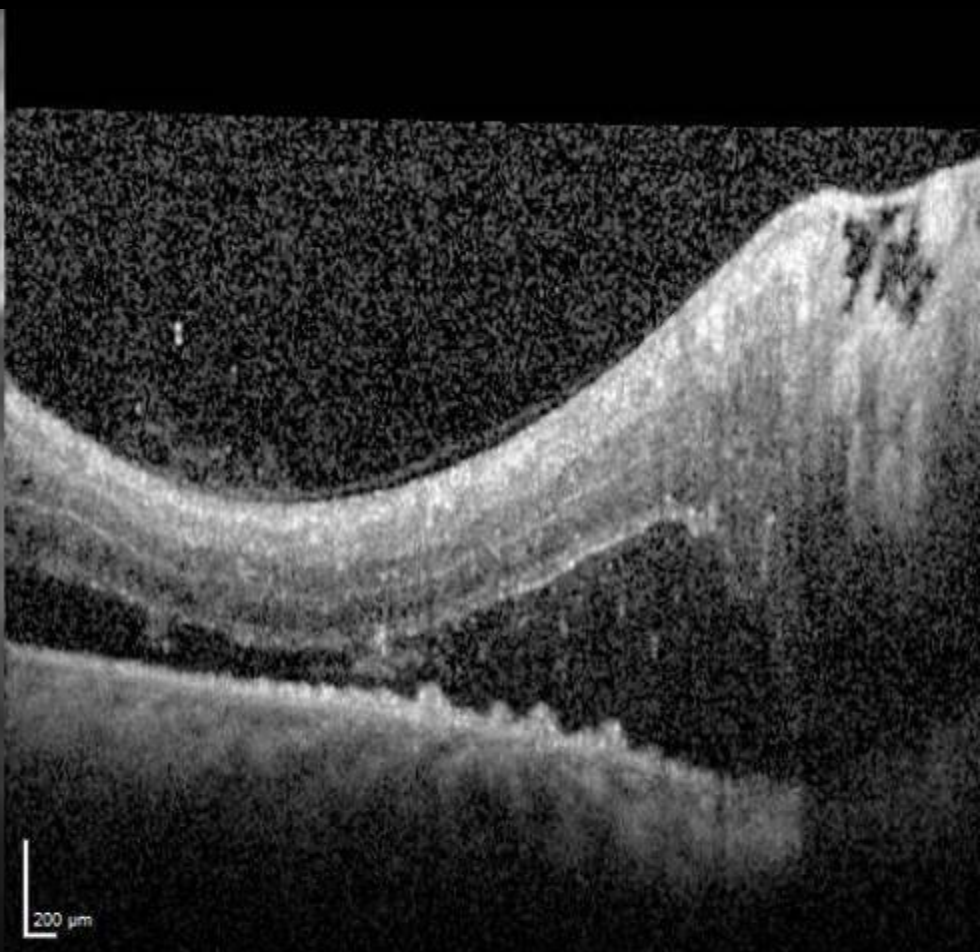
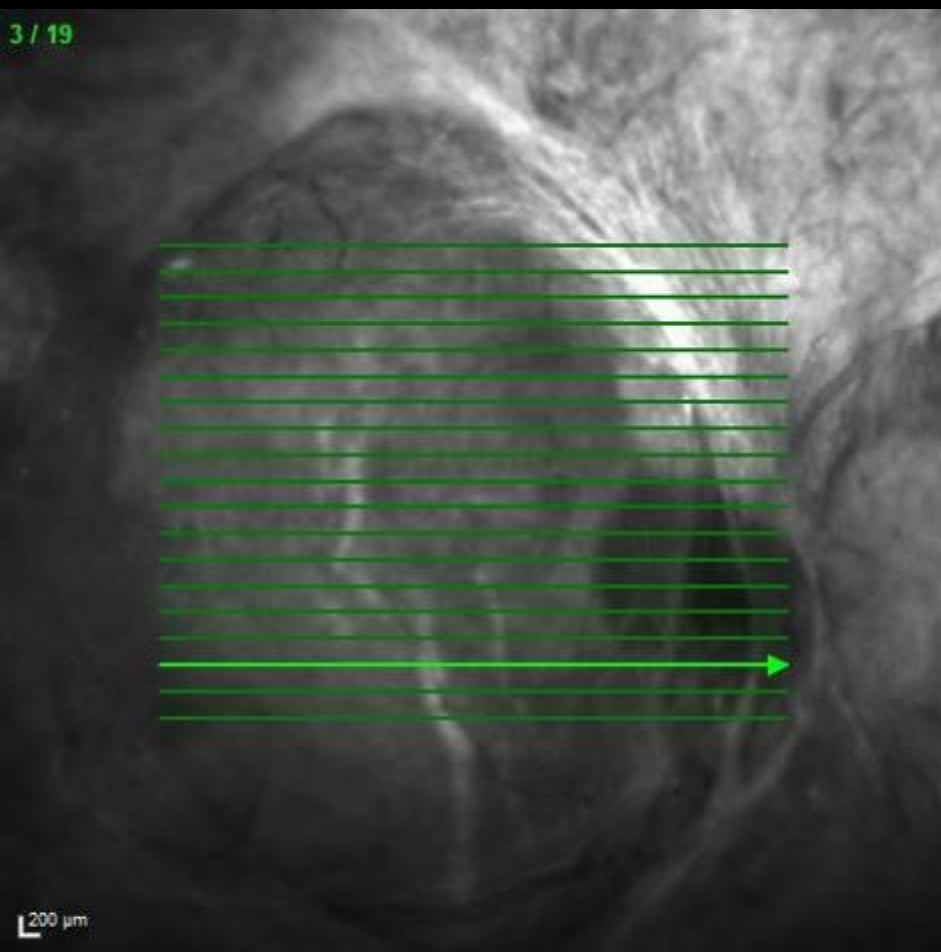
IR&OCT 30° ART [HS] ART(10) Q: 22





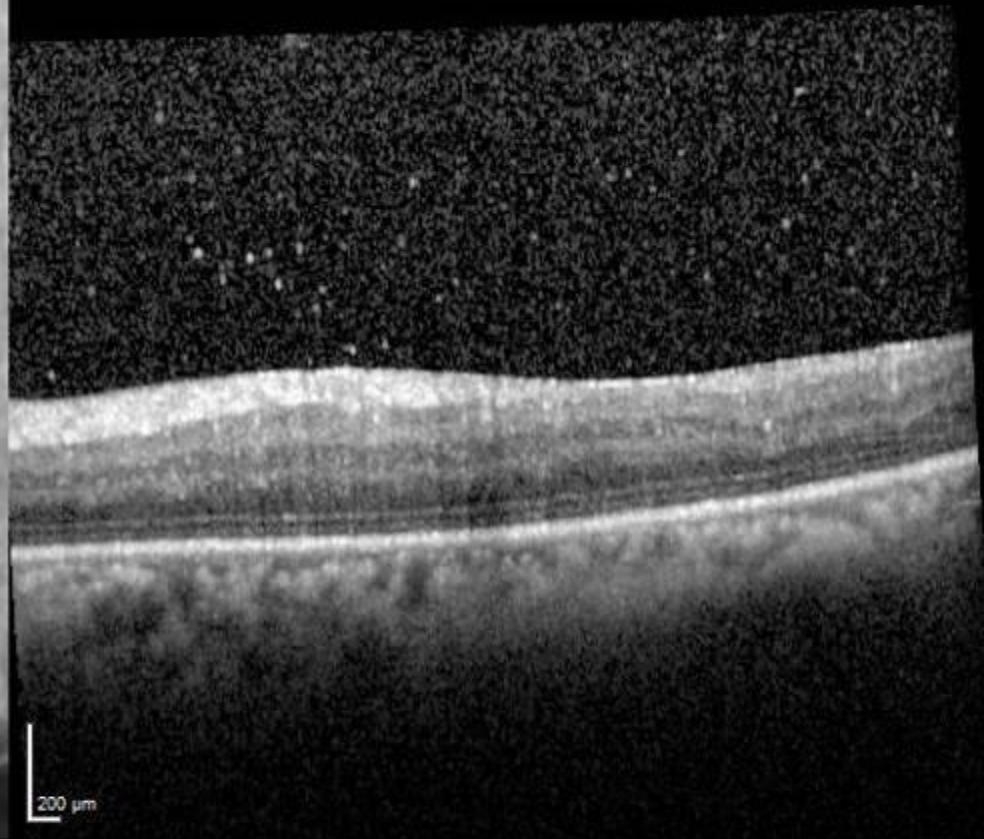
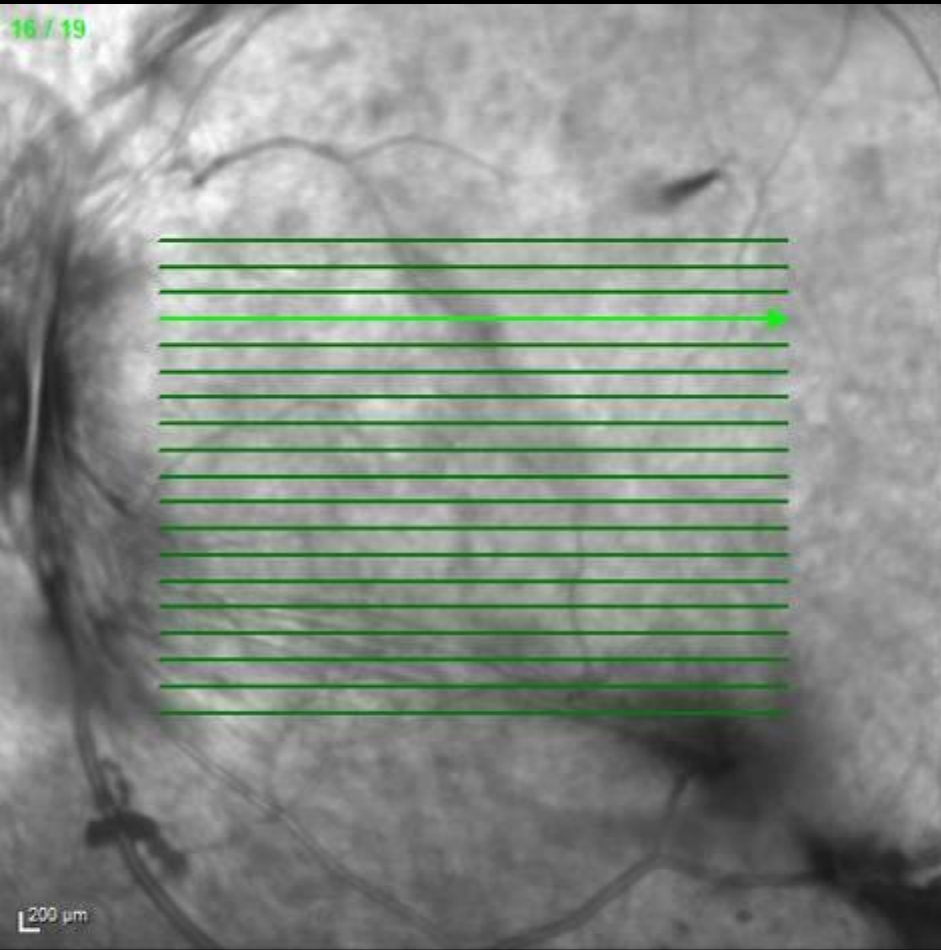
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IR&OCT 30° ART [HS] ART(11) Q: 20



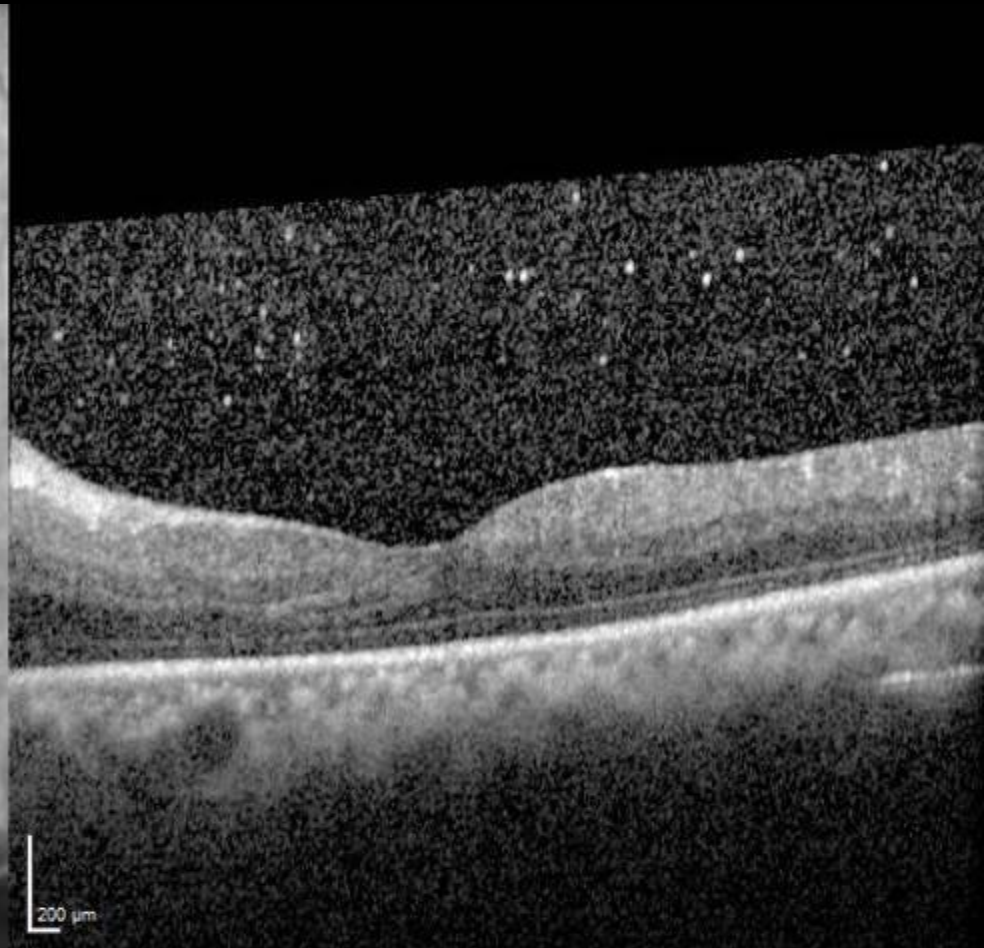
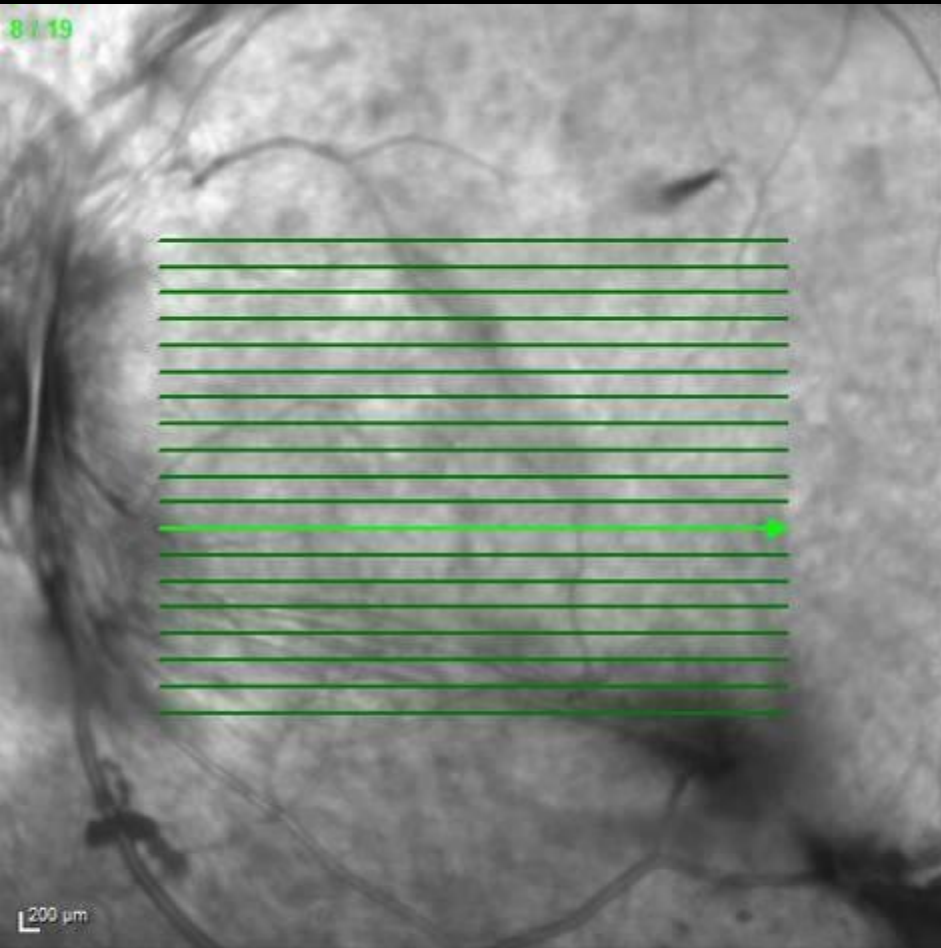
8/19/2013, OD

IR&OCT 30° ART [HS] ART(9) Q: 18



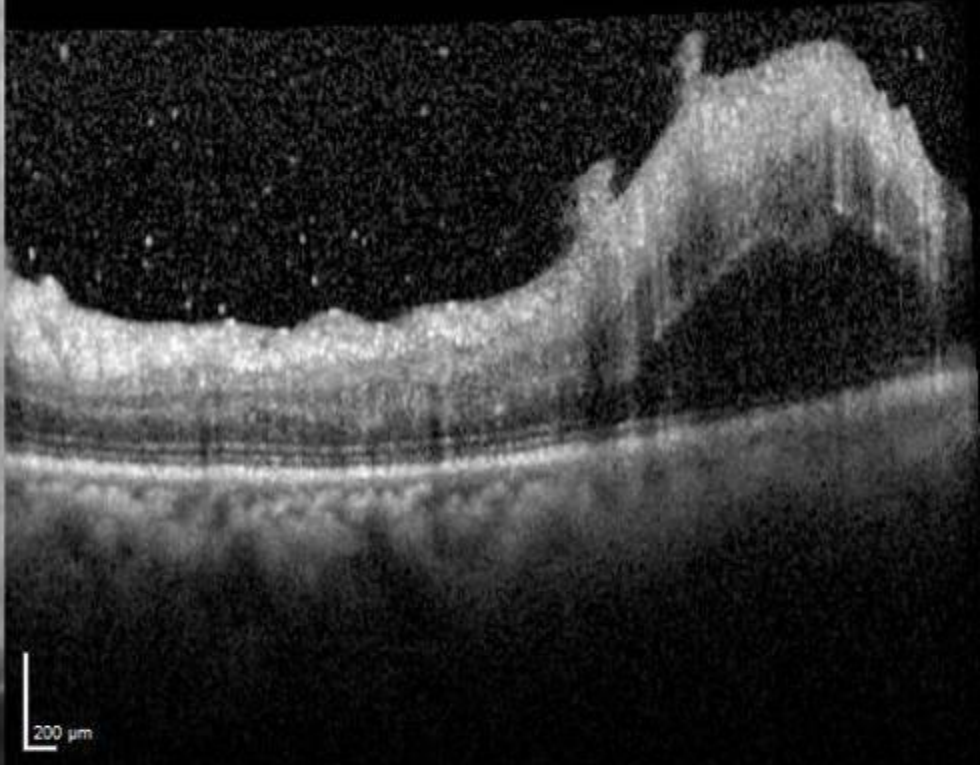
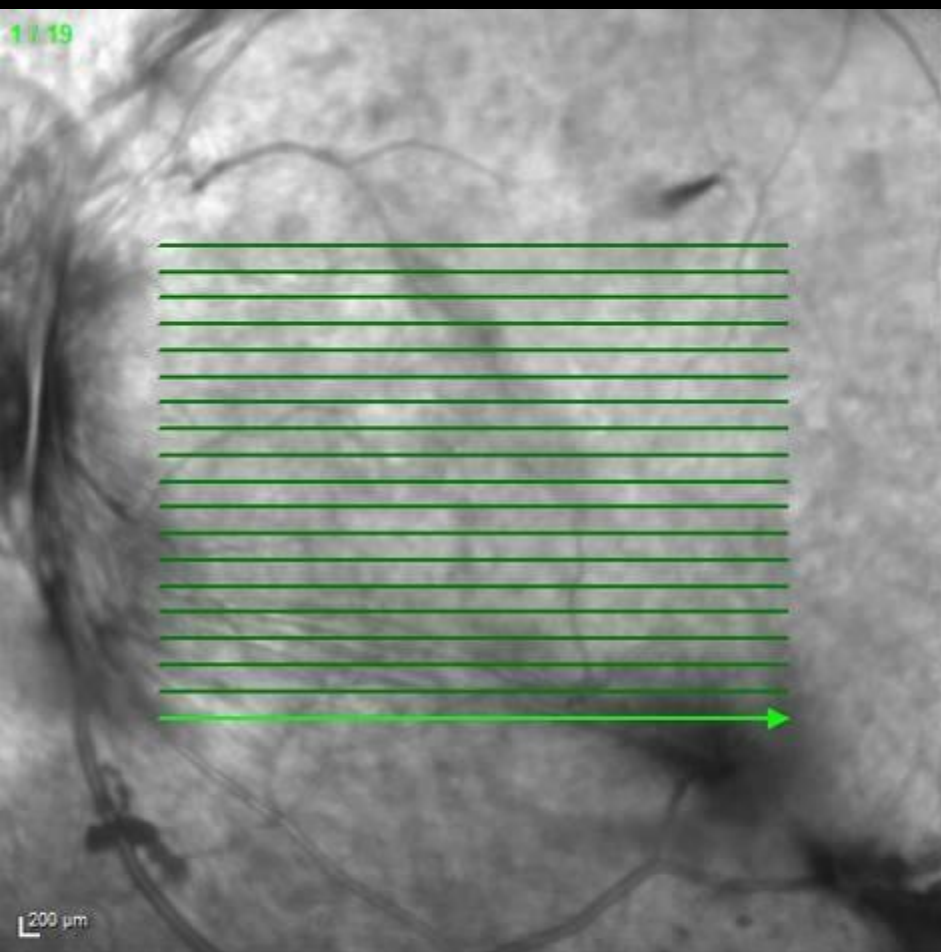
8/19/2013, OS

IR&OCT 30° ART [HS] ART(11) Q: 21



8/19/2013, OS

IR&OCT 30° ART [HS] ART(8) Q: 17



8/19/2013, OS  
IR&OCT 30° ART [HS] ART(10) Q: 21

# Clinical Trials

# Diabetic Retinopathy Trials

- 1. Acacia, PHASE 3** – ABICIPAR PEGOL SAFETY AND EFFICACY IN PATIENTS WITH CENTRALLY INVOLVED DIABETIC MACULAR EDEMA
- 2. DRCR Network Studies:**
  - **Protocol AB** – INTRAVITREOUS ANTI-VEGF VS. PROMPT VITRECTOMY FOR VITREOUS HEMORRHAGE FROM PROLIFERTIVE DIABETIC RETINOPATHY

# Diabetic Retinopathy Trials - Completed

## **DRCR network**

- **Protocol S** – Prompt PRP vs Ranibizumab+Deferred PRP for PDR Study
- **Protocol V** – Treatment for CI-DME with Very Good VA Study



Thank You!

# Lingmin (Lisa) He

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408-307-6501

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## EDUCATION:

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- Fellowship: Medical and Surgical Retina** 07/14 – 06/16  
○ Wilmer Eye Institute, Johns Hopkins School of Medicine
- Residency: Ophthalmology** 06/11 – 06/14  
○ Byers Eye Institute, Stanford University School of Medicine, Chief Resident 2013-2014
- Internship: Medicine, Preliminary** 06/10 – 06/11  
○ Department of Internal Medicine, Santa Clara Valley Medical Center
- M.D. Stanford University School of Medicine** 08/06 – 06/10  
○ Scholarly Concentration: Bioengineering; Application: Neuroscience, Behavior, and Cognition
- M.S. Management Science and Engineering, Stanford University** 09/05 – 06/06  
○ Concentration: Biochemical Engineering
- B.S. Biological Sciences, Stanford University** 09/02 – 01/06  
○ Graduated with Distinction, Phi Beta Kappa

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## EMPLOYMENT:

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- Retinal Diagnostic Center, Campbell CA** 09/16 - Present  
○ Associate Vitreoretinal Surgeon

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## LICENSURE AND CERTIFICATION:

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- American Board of Ophthalmology Certified** 10/18/2015  
**California License** 09/11 – Present  
**Maryland License** 04/14 – 09/16

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## HOSPITAL CREDENTIALS:

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- Good Samaritan Hospital 09/16 - Present  
El Camino Hospital Ambulatory Surgery Center 08/16 - Present  
VA Palo Alto Health Care System 08/16 - Present  
Johns Hopkins Hospitals 07/14 – 06/16
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## **PROFESSIONAL SOCIETIES/MEMBERSHIPS:**

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American Academy of Ophthalmology  
American Society of Retina Specialists  
American Society of Cataract and Refractive Surgery  
Association for Research in Vision and Ophthalmology  
Chinese American Ophthalmology Society  
American Medical Association

## **AWARDS AND HONORS:**

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Women in Retina Mentorship Program Travel Grant	2015
Heed Ophthalmic Foundation Resident's Retreat	2013
US Department of Education Foreign Language Areas Studies Fellowship - Mandarin	2007-2008
Stanford Medical Scholars Research Fellowship	2007-2008
Bases Social Entrepreneurship Challenge Finalist	2005
Chappell-Lougee Scholarship Recipient	2004
President's Award for Academic Excellence in the Freshman Year	2003

## **TEACHING EXPERIENCE:**

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Ophthalmology small-group section leader, Practice of Medicine	02/13-06/14
Primary Care Associate Lecture "Case Studies - external eye disorders"	09/5/13
Teaching Assistant, Developmental Biology, DBIO 201	05/07-01/08
Teaching Assistant, International Finance, F323/MS&E247	04/06-06/06
Course Assistant Molecular Biology and Ecology, Biology 44X and Biology 44Y	10/05-06/06

## **PUBLICATIONS:**

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### **Patents:**

1. Myung D, Chang R, He L, Nugent A, Van H, Wong I, Blumenkranz M, "Modular lens adapters for mobile anterior and posterior segment ophthalmoscopy." PCT/US2014/040203 Filed 5/14.

### **Peer Reviewed Publications:**

1. Campochiaro PA, Hafiz G, Mir TA, Scott AW, Zimmer-Galler I, Shah SM, Wenick SM, Brady CJ, Han IC, He L, Channa R, Poon D, Meyerle C, Aronow MB, Sodhi AS, Handa JT, Kherani S, Han Y, Sophie R, Wang G, Qian J. "Pro-permeability Factors in Diabetic Macular Edema; the Diabetic Macular Edema Treated with Ozurdex Trial." *AJO. In Press*
2. He L, Sodhi A, "Intraoperative Optical Coherence Tomography Demonstrates Immediate Closure of a Traumatic Macular Hole Following Posterior Hyaloid Elevation." *Canadian Journal of Ophthalmology. In Press*
3. Mir TA, Kherani S, Hafiz G, Scott AW, Zimmer-Galler I, Wenick A, Solomon S, Han I, Poon D, He L, Shah SM, Brady C, Meyerle C, Sodhi A, Linz MO, Campochiaro PA. "Changes in Retinal Nonperfusion Associated with Suppression of Vascular Endothelial Growth Factor in Retinal Vein Occlusion." *Ophthalmology*. 2016 Mar; 123(3):625-634

4. Toy BC, Myung D, **He L**, Pan C, Chang R, Polkinhorne A, Merrell D, Foster D, Blumenkranz M, "Smartphone-Based Tele-Ophthalmology Screening For Diabetic Eye Disease" *Retina*. 2016 e-pub Jan 2016
5. Zheng LL, **He L**, Yu CQ, "Mobile Virtual Reality for Ophthalmic Image Display and Diagnosis" *J Mobile Technol Med*. 4:3:35-38, 2015
6. **He L**, Silva R, Moshfeghi D, Blumenkranz MS, Leng T. "Aflibercept for the treatment of retinal pigment epithelium detachments." *Retina*. 2016: Mar;36(3):492-8.
7. **He L**, Silva R, Ayoub N, Moshfeghi D, Leng T, "Experience with aflibercept for the treatment of neovascular age-related macular degeneration." *Ophthalmic Surg Lasers and Imaging*. 2015 May 1;46(5):542-9
8. Silva R, Leng J, **He L**, Brock-Utne J, Drover D, Leng T. "Risk factors for respiratory depression in patients undergoing retrobulbar block for vitreoretinal surgery." *Ophthalmic Surg Lasers and Imaging*. 2015 Feb 1;46(2):243-7
9. Perry A, Huie P, **He L**, Milman T, Ta C, "India ink infiltration in scleral wounds after intravitreal injections." *Int J Ophthalmic Pathol* 2014, Oct: 3:5.
10. **He L**, Liu A, Manche EE. "Reply" *Am J Ophthalmol*. 2014 Dec;158(6):1357-8.
11. **He L**, Manche E. "A prospective, randomized, contralateral eye-to-eye comparison of wavefront-guided and wavefront-optimized photorefractive keratectomy." *JAMA Ophthalmol*. 2014 Oct 16.
12. **He L**, Moshfeghi D, Wong I. "Perivascular Exudates in Frosted Branch Angiitis." *Ophthalmic Surg Lasers and Imaging*. 2014 Sep 18:1-4.
13. **He L**, Liu A, Manche E, "Wavefront-guided versus wavefront-optimized LASIK for patients with myopia: a prospective randomized contralateral eye study." *Am J Ophthalmol*. 2014 Feb 19.
14. Myung D, Jais A, **He L**, Chang R, "Development of Anterior Segment Smartphone Lens Adapter for Rapid, High Quality Ocular Surface Imaging: A Photo Diary." *J Mobile Technol Med*. 2014; 3(1):2-8.
15. Myung D, Jais A, **He L**, Blumenkranz M, Chang R, "3-D Printed Smartphone Indirect Lens Adapter for Rapid, High Quality Retinal Photography." *J Mobile Technol Med*. 2014; 3(1):9-15.
16. **He L**, Manche E. "Prospective randomized contralateral-eye controlled evaluation of quality of vision after wavefront-guided or wavefront-optimized photorefractive keratectomy." *J Refract Surg*. 2014;30(1):6-12.
17. **He L**, Manche E. "Fibrin Glue for the Prevention of Recurrent Epithelial Ingrowth Under a LASIK Flap with a Central Buttonhole Defect." *J Cataract Refract Surg*. 2012. Oct;38(10):1857-60
18. Nentwich MM, Rajab M, Ta CN, **He L**, Grueterich M, Haritoglou C, Gandorfer A, Kampik A, Mino de Kaspar H. "Application of 10% Povidone Iodine Reduces Conjunctival Bacterial

Contamination Rate in Patients Undergoing Cataract Surgery." *Eur J Ophthalmol*. 2012. Jul-Aug;22(4):541-6

19. El-Sawy T, He L, Chiang MF, Anyane-Yeboa K, Morel KD, Folberg R, Marr BP, Abramson D. "Retinoblastoma Presenting in a Child with Hypomelanosis of Ito." *Open Ophthalmol J*. 2011;5:55-8
20. He L, Chan A, Leng T, Blumenkranz MS. "Kinetics of Reduction in Central Macular Thickness in Patients with Macular Edema After Intravitreal Drug Therapy." *Clinical Ophthalmology*. 2011;5:1751-8
21. He L, Sheehy K, Culbertson W. "Femtosecond Laser-Assisted Cataract Surgery." *Curr Opin Ophthalmol*. 2011. Jan; 22(1):43-52
22. He L, Ta CN, De Kaspar HM. "One-day Application of Topical 0.5% Moxifloxacin Selects for Fluoroquinolone Resistant Coagulase Negative Staphylococcus." *J Cataract Refract Surg*. 2009 Oct;35(10):1715-8.
23. He L, Ta CN, Hu N, Sinnar S, De Kaspar HM. "Prospective Randomized Comparison of a One-Day and Three-Day Application of Topical 0.5% Moxifloxacin in Eliminating Preoperative Conjunctival Bacterial Flora." *J Ocular Pharmacology*. 2009 Aug;25(4):373-8.
24. Yactayo-Miranda Y, Ta CN, He L, Kreutzer T, Nentwich M, Kampik A, De Kaspar HM, "A Prospective Study Determining the Efficacy of Topical 0.5% Levofloxacin on Bacterial Flora of Patients with Chronic Blepharoconjunctivitis" *Graefes Arch Clin Exp Ophthalmol*. 2009 Jul;247(7):993-8
25. Wu C, Cui B, He L, Chen L, Mobley WC. "The Coming of Age of Axonal Neurotrophin Signaling Endosomes." *J Proteomics*. 2009 Feb 15;72(1):46-55.
26. Ta CN, He L, HM de Kaspar. "In vitro Antibiotic Susceptibility of Preoperative Normal Conjunctival Bacteria." *Eye*. 2009 Mar;23(3):559-60.
27. Ta CN, Sinnar S, He L, Myung D, De Kaspar HM. "Prospective Randomized Comparison of One-Day versus Three-Day Application of 0.5% Topical Levofloxacin in Eliminating Conjunctival Bacterial Flora." *Eur J Ophthalmol*. 2007 Sep-Oct;17(5):689-95.
28. Ta CN, He L, Nguyen E, De Kaspar HM. "Prospective Randomized Study Determining Whether a 3-day Application of Ofloxacin Results in the Selection of Fluoroquinolone-Resistant Coagulase-Negative *Staphylococcus*." *Eur J Ophthalmol*. 2006 May-Jun;16(3):359-64.
29. De Kaspar HM, Koss MJ, He L, Blumenkranz MS, Ta CN. "Antibiotic Susceptibility of Preoperative Normal Conjunctival Bacteria." *Am J Ophthalmol*. 2005 Apr;139(4):730-3.

#### **Chapters:**

1. He L, Blumenkranz M. "Retinal Vein Occlusions." AAO ONE Network Laser Surgery Education Center. <http://one.aao.org/munnerlyn-laser-surgery-center/retinal-vein-occlusion>. Oct 2013.

2. **He L**, Manche E, “How do I manage a buttonhole or free cap during LASIK?” Curbside Consultation in Refractive and Lens-Based Surgery: 49 Clinical Questions. SLACK Incorporated. 2015.

### Articles

1. Sales C, Yu C, **He L**, Fredrick D, “Review of ‘Residual lens cortex material: Potential risk factor for endophthalmitis after phacoemulsification cataract surgery’.” *Eyeworld*. February, 2013.

### Abstracts/Scientific Presentations:

1. **He L**, “Retinal Crystals.” Atlantic Coast Retina Society Meeting. New York, NY. January 2016.
2. Blumenkranz M, Toy B, **He L**, Myung D, Pan C, Polkinhorne A, Merrell D, Foster D, Chang R. “Camera Phone Telemedicine-based Screening for Diabetic Eye Disease.” Macula Society Annual Meeting, Scottsdale, February 2015.
3. **He L**, “Retinal Telangectasia.” Atlantic Coast Retina Society Meeting. Boston, MA. January 2015
4. Myung D, Jais A, **He L**, Chang R, “Design and Rapid Prototyping of a Novel, 3D Printed Smartphone Lens Adapter System.” American Academy of Ophthalmology Annual Meeting, Chicago, November 2014.
5. **He L**, Toy B, Polkinhorne A, Merrell D, Foster D, Myung D, Blumenkranz M. “Integrated smartphone system for comprehensive retinal care.” ASRS Annual Meeting, San Diego, August 2014.
6. Toy B, **He L**, Myung D, Foster D, Polkinhorne A, Merrell D, Chang R, Blumenkranz M. “Camera phone telemedicine-based screening for diabetic eye disease.” ASRS Annual Meeting, San Diego, August 2014.
7. Myung D, Roy B, Jais A, Chang R, **He L**, Blumenkranz M. “3D printed smartphone adapter for mobile retinal imaging: new technical developments.” ASRS Annual Meeting, San Diego, August 2014.
8. **He L**, Myung D, Pershing S, Chang R, “iPhone Photography of Eye Pathology for Remote Triage.” ARVO, Orlando, May 2014
9. **He L**, Silva R, Leng T, “Is aflibercept more effective in the treatment of retinal pigment epithelial detachments?” American Academy of Ophthalmology Annual Meeting, New Orleans, November 2013.
10. **He L**, Manche E. “Fibrin glue for the treatment of LASIK buttonholes and recalcitrant epithelial ingrowth” ISRS Subspecialty Day, New Orleans, November 2013

11. **He L**, Manche E, "Comparison of Intraoperative Subtraction Pachymetry and Postoperative Anterior Segment Optical Coherence Tomography with 150kHz and 60 kHz Femtosecond Laser" ESCRS, Amsterdam, Netherlands, October 2013
12. Leng T, **He L**, "What Happens When You Switch Wet-AMD Patients to Aflibercept?" American Society of Retinal Specialists Annual Meeting, Toronto, August 2013
13. **He L**, Leng J, Silva R, Leng T, "Correlation of anesthetic medications with required airway interventions during retrobulbar anesthesia," ARVO, Seattle, May 2013
14. **He L**, Manche E, "Comparison of Intraoperative Subtraction Pachymetry and Postoperative Anterior Segment Optical Coherence Tomography with 150kHz and 60 kHz Femtosecond Laser" ASCRS, San Francisco, April 2013
15. **He L**, Manche E, "Quality of Vision after Wavefront-Guided or Wavefront-Optimized LASIK" ARVO, Fort Lauderdale, May 2012
16. Herminia Mino de Kaspar, Larissa E. Hoffmann, **He L**, Bing Li, Martin M. Nentwich, Christos Haritoglou, Daniel Kook, Martin Grueterich, Anselm Kampik. "Conjunctival Bacterial Flora And Antibiotic Resistance Patterns After Pre-operative Application Of Topical Levofloxacin 0.3%." ARVO, Fort Lauderdale, May 2012
17. **He L**, Manche E, "Quality of Vision after Wavefront-Guided or Wavefront-Optimized LASIK" American Society of Cataract and Refractive Surgeons Annual Meeting, Chicago, April 2012
18. **He L**, Manche E, "Quality of Vision after Wavefront-Guided or Wavefront-Optimized PRK" American Society of Cataract and Refractive Surgeons Annual Meeting, Chicago, April 2012
19. **He L**, Zhao G. "Periorbital Swelling Refractory to Antibiotics, What's Next?" American College of Physicians, Northern California Region Scientific Meeting, San Francisco, November, 2010.
20. **He L**, Chan A, Leung L, Blumenkranz M. "Acute Changes in Central Macular Thickness and Volume after Intravitreal Triamcinolone and Bevacizumab for Macular Edema Associated with Diabetic Retinopathy and Retinal Vein Occlusion." The Association for Research in Vision and Ophthalmology, Fort Lauderdale, May 2010.
21. Mino de Kaspar H, Rajab M, **He L**, Yactayo-Miranda Y, Gandorfer A, Haritoglou C, Grueterich M, Kampik A. "Efficacy of 10% Povidone Iodine Application in Reducing the Conjunctival Bacterial Load of Patients Undergoing Cataract Surgery." The Association for Research in Vision and Ophthalmology, Fort Lauderdale, May 2009.
22. Yactayo YM, **He L**, Weimann S, Kreutzer T, Kampik A, Miño de Kaspar H. "Efficacy of 0.5% Levofloxacin Therapy against Aerobic-Anaerobic Bacterial Flora in Chronic-Blepharoconjunctivitis Patients: A Prospective Semi-Randomized Study." The Association for Research in Vision and Ophthalmology, Fort Lauderdale, May 2008.

23. **He L**, Wu CB, Chen L, Mobley WC, “Amyloid Precursor Protein C-Terminal Fragments Form Larger Aggregates and are Trafficked More Slowly than Full-Length Counterparts.” Bay Area Alzheimer’s Research Symposium hosted by Stanford University, June 2007.
24. Wu CB, Cui BC, Ramirez A, **He L**, Chen L, Allen E, Yang Y, Chu S, Mobley W. “A High-Resolution Analysis of Axonal Trafficking of NGF Using Quantum Dots” Gordon Research Conference on Neurotrophic Factors, June 2007.
25. **He L**, Carron A, Cibils D, Ramirez L, Carron JE, Samudio M, Laspina F, Fariña N, Sanabria R, Miño de Kaspar H. “Efficacy of Topical Ciprofloxacin 0.3% Application in Reducing the Conjunctival Bacterial Load of Patients Undergoing Cataract Extraction” The Association for Research in Vision and Ophthalmology, Fort Lauderdale, May 2007.
26. **He L**, Ta CN, Sinnar S, Myung D, Miño de Kaspar H. “One-Day Application of 0.5% Topical Levofloxacin Has Similar Efficacy as a Three-Day Regimen in Eliminating Bacteria From the Ocular Surface.” The Association for Research in Vision and Ophthalmology, Fort Lauderdale, May 2005.
27. **He L**, Ta CN, Nguyen EV, Blumenkranz MS, Miño de Kaspar H. “Three Day Application of Topical Ofloxacin Does Not Induce Fluoroquinolone-Resistant Coagulase-Negative Staphylococci.” The Association for Research in Vision and Ophthalmology, Fort Lauderdale, FL, April 2004.
28. Ta CN, Kossakiewicz M, **He L**, Blumenkranz MS, Miño de Kaspar H. “Impact of Topical Ofloxacin on the Resistance Rate of Coagulase-Negative Staphylococci to Fluoroquinolones in Patients Undergoing Intraocular Surgery.” The Association for Research in Vision and Ophthalmology, Fort Lauderdale, FL, April 2004.
29. Kossakiewicz M, Ta CN, **He L**, Klauß V, Blumenkranz MS, Miño de Kaspar H. “Antibiotic Resistant Pattern of Conjunctival Streptococci.” The Association for Research in Vision and Ophthalmology, Fort Lauderdale, FL, April 2004.
30. Miño de Kaspar H, Kossakiewicz, M, Egbert PR, Singh K, Egbert, **He L**, Blumenkranz MS, Ta CN. “Gatifloxacin and Moxifloxacin Outperform Older Fluoroquinolones in Multiresistant Conjunctival Strains.” American Academy of Ophthalmology, Anaheim, CA, November 2003.

#### **EDITORIAL ACTIVITIES:**

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Reviewer for JAMA Ophthalmology, Graefe’s Archive for Clinical and Experimental Ophthalmology, Ophthalmic Surgery Lasers and Imaging Retina

#### **COMMUNITY AND INTERNATIONAL WORK:**

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##### **Arbor Free Clinic**

**2007-2014**

- Patient advocate, financial chair in medical school, ad-hoc clinical volunteer in residency



**Vision Plus Clinique, Cap Haitien, Haiti**

**05/2014**

- Participated with University of Utah Moran Eye Center outreach and education program to provide glaucoma and cataract surgery training
- Delivered diabetic retinopathy lecture

**INDUSTRY EXPERIENCE:**

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**Consultant, Oculeve**

**10/11 -11/13**

- Coordinate clinical investigations on safety and efficacy of electrical stimulation of the lacrimal gland
- Conduct animal studies to determine efficacy and long-term effects of stimulation

**Consultant, Auris Surgical Robotics**

**03/11 – 03/14**

- Assess market opportunity in ophthalmic subspecialty surgeries
- Advise product development team on system requirements and clinical applicability

**Consultant, Optimedica Corporation**

**10/09 – 03/11**

- Optimedica is an ophthalmic device company that initially made patterned scanning laser treatments for retinal disease. It has recently launched a femtosecond laser cataract surgery system.
- Worked with marketing team on product requirements, sales team training for the Catalys<sup>TM</sup> Precision Laser System

**Marketing Intern, Optimedica Corporation**

**06/08 – 08/08**

- Assessed opportunity for cataract surgery laser system with financial and sales models
- Initiated customer requirements documentation from key stakeholder interviews and site visits
- Worked closely with R&D team on animal studies and feasibility testing

**Consultant, Aviir Inc.**

**11/07 – 01/08**

- Aviir is a venture-funded biotechnology company focused on diagnostics for cardiovascular disease
- Worked with senior executives to identify and evaluate biomarkers for further development

**Intern, Calderome Inc.**

**05/07 – 10/07**

- Calderome is an incubator started by Kleiner Perkins Caufield & Byers, TPG Growth, and Versant Ventures to create a molecular diagnostics company
- Identified opportunity for cancer diagnostics through physician interviews and literature review
- Secured \$23 million to start a new company, Veracyte, to pursue cancer diagnostics

**ADDITIONAL LANGUAGES:**

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Fluent in Mandarin, basic proficiency in Spanish and French (high school coursework)

**PERSONAL INTERESTS:**

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Travel, photography, food, racket sports, piano

## **"Vitreoretinal Surgery and Surgical Outcomes. All Aspects**

**(1) Vitreoretinal Surgery - Types- All aspects of Vitreoretinal surgery will be covered from repair of retinal detachments, dropped lenses, Epiretinal membranes, Vitrectomy for floaters, etc.**

**(2) Procedures: Each Procedure will be discussed in depth. Need for surgical intervention will be outlined.**

**(3) Preparing the Patient - What the patient needs to know both before and after surgery.**

**(4) Handling Patient Expectations.- Important for the Patient to be informed of his or her unique condition and what they reasonably can expect following surgery in each patient's unique time frame.**

**(5) Realistic Outcomes. National Averages and Local Averages.**

**Dr. Monahan will discuss all forms of Vitreoretinal Surgery and give a full and complete documentation of each procedure he performs and what the patients can expect from these surgeries and/or procedures. There will be a 30 minute talk by each of our 5 physicians during the course of the evening, and then there will be a 15 Minute Question and Answer Session at the Conclusion of all the talks for a total of 2.75 CE Hours.**

# CURRICULUM VITAE

NAME: PATRICK MICHAEL MONAHAN, M.D.

DATE OF BIRTH: June 14, 1958

BOARD CERTIFICATION:

American Board of Ophthalmology

STATE LICENSURE:

State of California: G060723

State of Louisiana: 08714R

EDUCATION:

Bachelor of Science Degree in Botany/Biology,  
June, 1981 – University of California at Riverside

Masters of Science Degree in Biochemistry, July, 1982  
University of California at Riverside

Doctor of Medicine, May 1986  
University of Virginia

INTERNSHIP:

Transitional: Santa Clara Valley Medical Center,  
Stanford Affiliate, June 1987

RESIDENCY:

Ophthalmology: University of Tennessee, Chattanooga.  
June 30, 1991

CLINICAL FELLOWSHIPS:

Fellow in Retina and Vitreous Surgery, Touro  
Infirmary, New Orleans, LA., Kurt Gitter, M.D. &  
Gerald Cohen, M.D. 1992

PROFESSIONAL FELLOWSHIPS:

Fellow of the American Academy of Ophthalmology

PM Page 1 of 4

**PROFESSIONAL MEMBERSHIPS:**

American Academy of Ophthalmology  
Santa Clara County Medical Association  
California Medical Association  
The Assoc. for Research in Vision & Ophthalmology (ARVO)  
American Society of Retina Specialists (ASRS)

**APPOINTMENTS ACADEMIC:**

Stanford University Medical Center, Stanford, CA  
Associate Volunteer Clinical Professor, Ophthalmology

**HOSPITAL STAFF MEMBERSHIPS:**

Good Samaritan Hospital, San Jose, CA:  
Community Hospital of Los Gatos, Los Gatos, CA  
O'Connor Hospital, San Jose, CA  
Regional Medical Center, San Jose, CA

**RESEARCH & PUBLICATIONS:**

Telemedicine Screening for Diabetic Retinopathy  
Surgical Treatment of Macular Holes, using Cryoprecipitated  
Fibrinogen  
Monahan, Funderburk, Feinberg, Current  
Presented at the Vitreous Society Meeting, 1993

Evaluation of Persistence of Subretinal Neovascular  
Membrane using Digitized Angiographic Analysis  
Monahan, Gitter, Eichler & Cohen. Presented at the  
25<sup>th</sup> annual Retina Society Meeting, Sept. 1992  
Retina 1993, Vol. 13, No. 3 196-201

Intraocular Pentastomiasis - Human Subretinal  
Invasion of Linguatula Serrata  
Monahan, Senecal, Kozakas  
Vitreous Society Abstract

Use of Digitized Fluorescein Angiogram System to Evaluate  
Laser Treatment of SRNVM: Technique.  
Monahan, Gitter, Eichler, Cohen, Schomaker.

## RESEARCH & PUBLICATIONS CONTINUED:

Presented at the 15<sup>th</sup> Annual Macual Society Mtg. Feb. 1992  
Retina 1993, Vol. 13, No 3, 187-195  
Internal Sclerotomy using a Manual Trephine in Rabbits  
Monahan, Faerber, Funderburk.

Invest Ophthal. Vis. Sci. 33 (suppl.): 2885; 1992  
Effects of Endothelial Cell Longevity in Corneal Grafts with  
Addition of Free Radical Scavengers to Corneal Storage Media  
Monahan & Debarge.

Presented Residents Research Day, April 1989  
Awarded Best Research Paper.

## CLINICAL RESEARCH EXPERIENCE:

Sub-Investigator, PIER FVF3192g: *A Phase IIIb, Multicenter, Randomized, Double-Masked, Sham Injection-Controlled Study of the Efficacy and Safety of Ranibizumab in Subjects With Subfoveal Choroidal Neovascularization (CNV) With or Without Classic CNV Secondary to Age-Related Macular Degeneration 2005 – 2007*

Sub-Investigator, SAILOR FVF3689g: *A Phase IIIb Single-Masked, Multicenter, Randomized Study to evaluate the Safety and Tolerability of Ranibizumab in Naïve and Previously Treated Subjects With Choroidal Neovascularization (CNV) Secondary to Age-Related Macular Degeneration (AMD) 2005 – 2007*

Sub-Investigator, BRAVO FVF4165g: *A Phase III, Multicenter, Randomized, Sham Injection-Controlled Study of the Efficacy and Safety of Ranibizumab Injection Compared with Sham in Subjects with Macular Edema Secondary to Branch Retinal Vein Occlusion. 2007 – Present*

Sub-Investigator, CRUISE FVF4166g: *A Phase III, Multicenter, Randomized, Sham Injection-Controlled Study of the Efficacy and Safety of Ranibizumab Injection Compared with Sham in Subjects with Macular Edema Secondary to Central Retinal Vein Occlusion. 2007 – Present*

**CLINICAL RESEARCH EXPERIENCE CONTINUED:**

Sub-Investigator, RISE FVF4170g: *A Phase III, Double-Masked, Multicenter, Randomized, Sham Controlled Study of the Efficacy and Safety of Ranibizumab Injection in Subjects with Clinically Significant Macular Edema with Center Involvement Secondary to Diabetes Mellitus. 2007 – Present*

Sub-Investigator, CABERNET NVI-114: *A Randomized, Prospective, Active Controlled, Study of the Epi-Rad<sub>90</sub><sup>TM</sup> Ophthalmic System for the Treatment of Subfoveal Choroidal Neovascularization Associated with Wet Age-Related Macular Degeneration 2007 – Present*

Sub-Investigator, VIEW 1 VGFT-OD-0605: *A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects with Neovascular to Age-Related Macular Degeneration 2007 – Present*

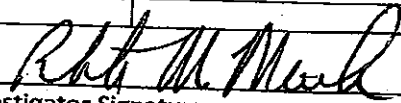
Sub-Investigator, RADICAL BPD OCR 022: *A Multicenter, Randomized,, Single-Masked Comparing Reduced-fluence Visudyne ®-Lucentis® Combination Therapies and Lucentis Monotherapy in Subjects with CNV Secondary to AMD 2007 – Present*

Sub-Investigator, HORIZON FVF3426G: *An Open-label, Multicenter Extension Study to Evaluate the Safety and Tolerability of Ranibizumab in Subjects with Choroidal Neovascularization (CNV) Secondary to Age-Related Macular Degeneration (AMD) or Macular Edema Secondary to Retinal Vein Occlusion (RVO) Who have Completed a Genentech-Sponsored Ranibizumab Study. 2008 – Present*

Sub-Investigator, HARBOR FVF4579g: *A Phase III, Double Masked, Multicenter, Randomized, Active Treatment-Controlled Study OF The Efficacy and Safety of 0.5 mg and 2.0mg Ranibizumab Administered Monthly or on an As-Needed Basis (PRN) in Patients with Subfoveal Neovascular Age-related Macular Degeneration. 2009 – Present*

**Patrick Monahan, MD**  
Curriculum Vitae Addendum - Clinical Research Experience

Indications	Study Name	Year	Status	Type
Diabetic Retinopathy	<b>ThromboGenics TG-MV-015</b> - A Phase 2, Randomised, Double Masked, Sham Controlled, Multi-Centre Study To Evaluate The Efficacy And Safety Of Ocriplasmin In Inducing Total Posterior Vitreous Detachment (Pvd) In Subjects With Non-Proliferative Diabetic Retinopathy (Npdr) (Circle)	2015	Present	Sub I
Macular Degeneration	<b>Allergan 150998-006</b> - Safety and Efficacy of Abicipar Pegol (AGN-150998) in Patients with Neovascular Age-related Macular Degeneration.	2015	Present	Sub I
Macular Degeneration	<b>Iconic IT-002</b> - A Phase 2 Randomized, Double-masked, Multicenter, Active-controlled Study Evaluating Administration of Repeated Intravitreal Doses of hI-con1™ in Patients with Choroidal Neovascularization Secondary to Age-related Macular Degeneration	2015	Present	Sub I
Macular Degeneration	<b>Ophthotech OPH1002</b> - A Phase 3 Randomized, Double-Masked, Controlled Trial To Establish The Safety And Efficacy Of Intravitreal Administration Of Fovista® (Anti Pdgf-B Pegylated Aptamer) Administered In Combination With Lucentis® Compared To Lucentis® Monotherapy In Subjects With Subfoveal Neovascular Age-Related Macular Degeneration (Oph1002)	2015	2015	Sub I
Macular Degeneration	<b>Ophthotech OP1004</b> - A Phase 3 Randomized, Double-Masked, Controlled Trial to Establish The Safety and Efficacy of Intravitreal Administration of Fovista™ (Anti PDGF-B Pegylated Aptamer) Administered in Combination With Either Avastin® OR Eylea® Compared to Avastin® or Eylea® Monotherapy in Subjects With Subfoveal Neovascular Age-Related Macular Degeneration (OPH1004)	2015	Present	Sub I
Macular Degeneration	<b>Pfizer B1261009</b> - A Phase 2, Randomized, Double-Masked, Placebo-Controlled, Parallel Group, Multi-Center Study To Compare The Efficacy And Safety Of A Chemokine Ccr2/5 Receptor Antagonist (Pf-04634817) With That Of Ranibizumab In Adult Subjects With Diabetic Macular Edema	2014	2015	Sub I
Macular Degeneration	<b>Roche GX29633</b> - A Multicenter, Prospective Epidemiologic Study Of the Progression Of Geographic Atrophy Secondary To Age-Related Macular Degeneration	2015	Present	Sub I
Macular Degeneration	<b>Roche BP29647</b> - A Multiple-Center, Multiple-Dose And Regimen, Randomized, Active Comparator Controlled, Double-Masked, Parallel Group, 36 Week Study To Investigate The Safety, Tolerability, Pharmacokinetics, And Efficacy Of Ro6867461 Administered Intravitreally in Patients With Choroidal Neovascularization Secondary To Age Related Macular Degeneration	2015	Present	Sub I
Macular Degeneration	<b>Lpath LT1009-OPH-003</b> - A Phase 2A, Multi-Center, Blinded, Randomized, Comparator Study Evaluating Isonepzmab (Sonepcizumab [LT1009]) As Either Monotherapy or Adjunctive Therapy to Lucentis Alone in the Treatment of Subjects with Choroidal Neovascularization Secondary to age-Related Macular Degeneration	2014	2015	Sub I
Observational Study	<b>ThromboGenics TG-MV-018</b> - Ocriplasmin Research to Better Inform Treatment (ORBIT)	2014	Present	Sub I
Observational Study	<b>ThromboGenics TG-MV-022</b> - Phase 4, OZONE: Ocriplasmin Ellipsoid Zone Retrospective Data Collection Study	2014	2015	Sub I

  
Investigator Signature

4/25/16  
Date



**PATRICK MONAHAN, M.D.**

**Curriculum Vitae – Addendum:**

**YouTube 27 Gauge - Floater only Vitrectomy.**

## **CURRICULUM VITAE**

**PATRICK MICHAEL MONAHAN, M.D.**

### **EMPLOYMENT HISTORY:**

**Associate Partnership: Retinal Diagnostic Center, Inc. 1992 to Present**

**3395 S. Bascom Avenue, Suite 140**

**Campbell, CA 95008**

**(408) 559-0666**

**[www.retinaldiagnostic.com](http://www.retinaldiagnostic.com)**

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