Ocular Disease: Part I

Presented by MBKU | SCCO

Live Interactive CE Webinar | Day Two | AM Session

Sunday | July 11, 2021 | 8:00 a.m. - 11:50 a.m.

Marshall B.
KETCHUM UNIVERSITY
Southern California College of Optometry

Department of Continuing Education

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Ocular Disease: Part II

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Saturday, July 10

Pacific Time Zone | Live Webinar | COPE-Approved

8:00AM - 9:50AM
Comanaging Corneal Transplants: MD & OD Perspective
Presented by Lisa Wahl, OD & Asha Balakrishman, MD

10:00AM - 10:55AM
Thyroid Eye Disease: An Update on Clinical Management and Assessment
Presented by Jessica Yuen, OD

10:55AM - 11:50AM
Marine Omega-3s in Dry Eye Disease: Uncovering the Facts, Dispelling the Myths
Presented by Mark Roark, OD

11:50AM- 12:10PM
Lunch Break

12:10PM - 1:05PM
Evidence-Based Management of Retinal Artery Occlusions
Presented by Edward Chu, OD

1:05PM - 2:00PM
Neurotropic Keratitis: Rare, or Hiding in Plain Sight?
Presented by Douglas Devries, OD

2:10PM - 3:05PM
Anterior Segment Cases: OMD vs OD
Presented by David Sendrowski, OD & John Maher, MD

3:05PM - 4:00PM
Update on Cataract Work Up and Use of Multifocal IOLs
Presented by John Maher, MD & David Sendrowski, OD

Sunday, July 11

Pacific Time Zone | Live Webinar | COPE-Approved

8:00AM - 9:50AM
Oral Pharmaceuticals in Anterior Segment Disease
Presented by Blair Lonsberry, OD, MS, ME

10:00AM - 11:50AM
Legends of the Posterior Segment
Presented by Blair Lonsberry, OD, MS, ME

11:50AM- 12:10PM
Lunch Break

12:10PM - 1:05PM
Un-Nerved Conundrums of the Optic Disc
Presented by Mark Sawamura, OD

1:05PM - 2:00PM
PAMM, Plagues, and RAM: Uncommon Retinal Manifestations from Common Systemic Diseases
Presented by Xiao Xi Yu, OD

2:10PM - 3:05PM
Stargardt's Macular Dystrophy: A Family Affair
Presented by Ashley Deemer, OD

3:05PM - 4:00PM
Minimally Invasive Glaucoma Surgery (MIGS) Updates and Options
Presented by Igor Bussel, MD

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Instructor Biographies

Blair Lonsberry, OD, MS, MEd

Professor, Pacific University Oregon

Dr. Blair Lonsberry was named the Pacific Eye Clinic Portland Director in 2005. Prior to joining Pacific University he was an assistant professor at Southern College of Optometry, where he was the instructor for Anterior Segment Disease courses and named Teacher of the Year for 6 years in a row. During his time at SCO, he completed a Masters in Education degree with an emphasis in Post-Secondary Education. Dr. Lonsberry also practiced at a vitreoretinal surgery and low vision rehabilitation practice. Dr. Lonsberry's current responsibilities include supervising students during their clinical rotations and overseeing the Clinical Grand Rounds course. Dr. Lonsberry is a Fellow in the American Academy of Optometry, the Optometric Glaucoma Society and the Optometric Retina Society. He is also a Diplomate of the American Board of Optometry.

Mark Sawamura, OD

Associate Professor, MBKU | SCCO

Dr. Mark Sawamura is currently an Associate Professor with Tenure at the Southern California College of Optometry. He is a 1991 graduate of the Southern California College of Optometry and returned to teach at his alma mater following a post-graduate residency at the Pennsylvania College of Optometry / Hahnemann University. He joined the faculty of the Southern California College of Optometry in 1993. Dr. Sawamura serves as the Chief of the Jarnagin Center for Primary Eye Care and Chief of Ocular Disease at the University Eye Center at Ketchum Health as well as attending faculty in the Special Testing Service. He teaches the neuro-ophthalmic disease track at the College as well as advanced ophthalmic procedures, application of lasers in ophthalmic practice and ocular disease courses. He has presented multiple lectures up to the national level in the area of ocular disease management and has been involved in many therapeutics courses for California, Hawaii, and Washington. Dr. Sawamura currently is a Fellow of the American Academy of Optometry, Oral Examination Chair for the Diplomate in Neuro-ophthalmic Disease, Webmaster for the Disease Section of the AAO, Committee member of the National Board of Examiners in Optometry, Past Chairman of the ASCO SIG on Optometric Informatics, and has authored TPA guides for California Optometrists. He authors medical abstracts for the Optometry Journal and was recently President of the Faculty Council at SCCO.

Xiao Xi Yu, OD

Chief, Low Vision, Greater Los Angeles VA Healthcare System

Dr. Xiao (Shawn) X. Yu is a graduate of Pennsylvania College of Optometry at Salus University. He completed his residency training in 2011 at State University of New York College of Optometry and the Lighthouse International in the field of Low Vision Rehabilitation. He has served as an assistant professor at Nova Southeastern University College of optometry for nearly 3 years and since joined the optometric staff at the West LA and Sepulveda VA. He is currently serving as the Chief of Low Vision at the greater Los Angeles VA system and continuing to pursue his academic interest in low vision rehabilitation, ophthalmic disease, and traumatic brain injury.

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Instructor Biographies

Ashley Deemer, OD

Assistant Professor, MBKU | SCCO

Ashley Deemer, OD received her undergraduate degree at the University of California San Diego and her Doctor of Optometry degree from the New England College of Optometry. She completed her residency training at the Jamaica Plain Veterans Affairs Medical Center in Boston, MA with a focus in primary care optometry, low vision rehabilitation, and vision therapy. She then completed the Lions Vision Rehabilitation Fellowship at the Johns Hopkins Wilmer Eye Institute in 2016. During her training, Dr. Deemer was a recipient of the Charles Robert Soltes Scholarship, Beider Scholarship, and Bill Mattingly Memorial Scholarship. She also received grant awards for her work in functional outcome measures and depression prevention in patients with age-related macular degeneration. She now focuses her research on the development and implementation of low vision enhancement systems using head-mounted video displays and virtual reality. Dr. Deemer previously practiced at the Johns Hopkins Wilmer Eye Institute providing low vision rehabilitation care to optimize the remaining sight of patients with chronic visual impairment. She is a Fellow of the American Academy of Optometry.

Igor Bussel, MD

Ophthalmologist, UCI Health

Dr. Igor I. Bussel is a UCI Health ophthalmologist who specializes in cataract, glaucoma and advanced anterior segment surgery. Bussel earned his medical degree from Rosalind Franklin University of Medicine and Science in Chicago, where he also earned master's degrees in biomedical science and healthcare administration. He completed his residency in ophthalmology at the University of Pittsburgh School of Medicine and a fellowship in glaucoma and advanced anterior segment surgery at Washington University School of Medicine in St. Louis, as well as a hybrid fellowship in glaucoma at UCI School of Medicine. Bussel's clinical research interests include the development of micro-invasive glaucoma surgical devices, novel ophthalmic imaging modalities and glaucoma clinical trials. He has presented research and given talks at national and international meetings, and has written numerous peer-reviewed publications and book chapters. He speaks English and Russian.

Oral Pharmaceuticals in Anterior Segment Disease

Presented by Blair Lonsberry, OD, MS, MEd

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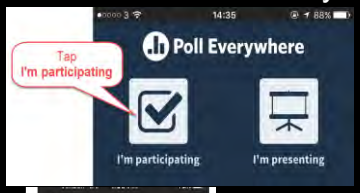

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Oral Pharmaceuticals in Anterior Segment Disease

Blair Lonsberry, MS, OD, MEd., FAAO
Professor of Optometry
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Disclosures:

- Maculogix,
- Sun Pharmaceuticals

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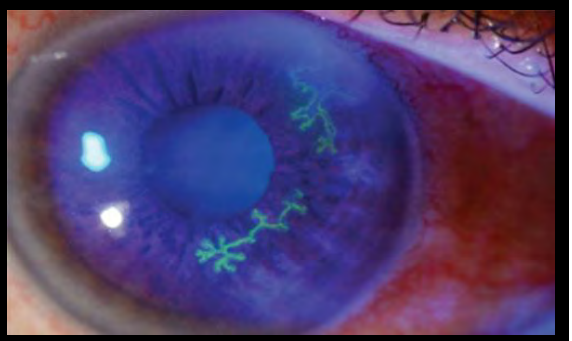
Case

- 20 year old male presents with a red painful eye
  - Started that morning when he woke up
  - reports a watery discharge, no itching, and is not a contact lens wearer
- SLE:
  - See attached image with NaFl stain



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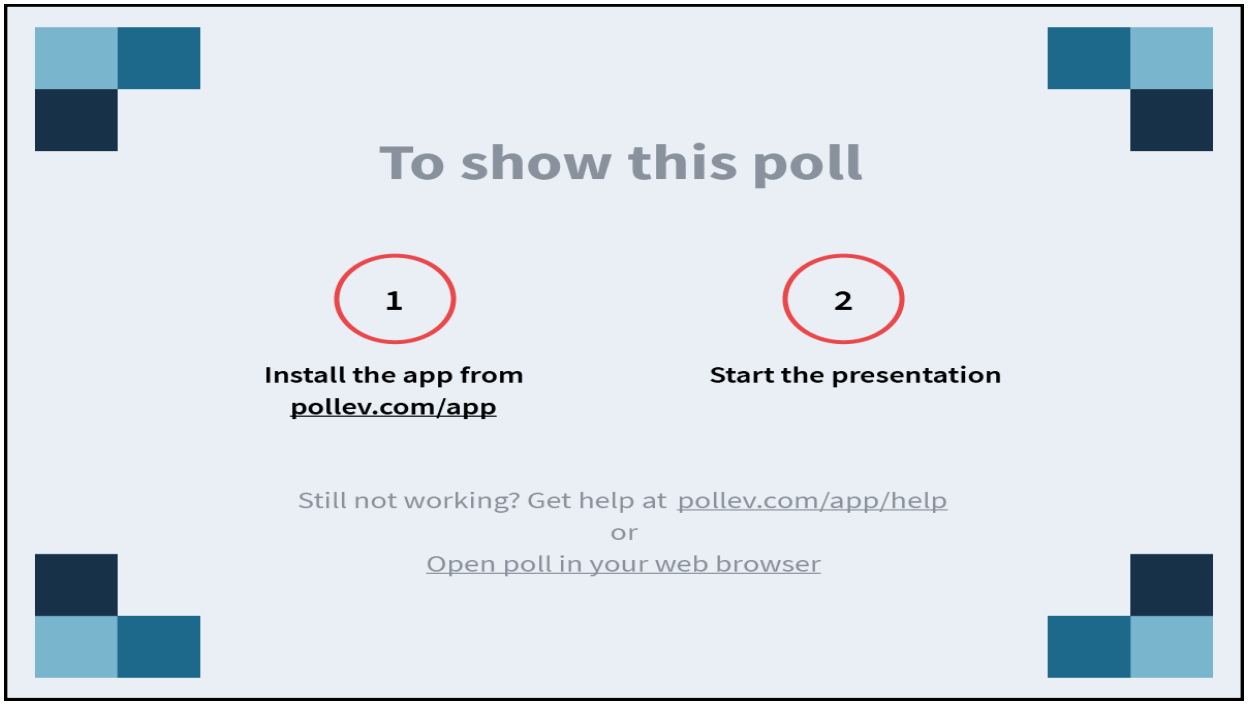

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Herpes Simplex Virus (HSV) Keratitis: Clinical Features

- Characterized by primary outbreak and subsequent reactivation
  - Primary outbreak is typically mild or subclinical (90% of people are asymptomatic)
  - Most clinical ocular infections are manifestations of virus reactivation; ocular involvement occurs in fewer than 5% of primary infections
- After primary infection, the virus becomes latent in the trigeminal ganglion or cornea
  - The majority of ophthalmic HSV cases are unilateral, with recurrences affecting the same eye. Bilateral disease (not necessarily concurrent) occurs in 1-12% of cases and is more common in patients with atopy or other immune abnormalities
- Stress, UV radiation, and hormonal changes can reactivate the virus
- Lesions are common in the immunocompromised (i.e. recent organ transplant or HIV patients)

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Herpes Simplex Virus Keratitis

- **<u>Epithelial Keratitis:</u>**
  - Symptoms:
    - Ocular irritation, redness, photophobia, watering, blurred vision
  - Signs:
    - Swollen opaque epithelial cells arranged in a course punctate or stellate pattern
    - Central desquamation results in a dendrite***
      1. Central ulceration
      2. Terminal end bulbs
    - ***Corneal sensation is reduced***

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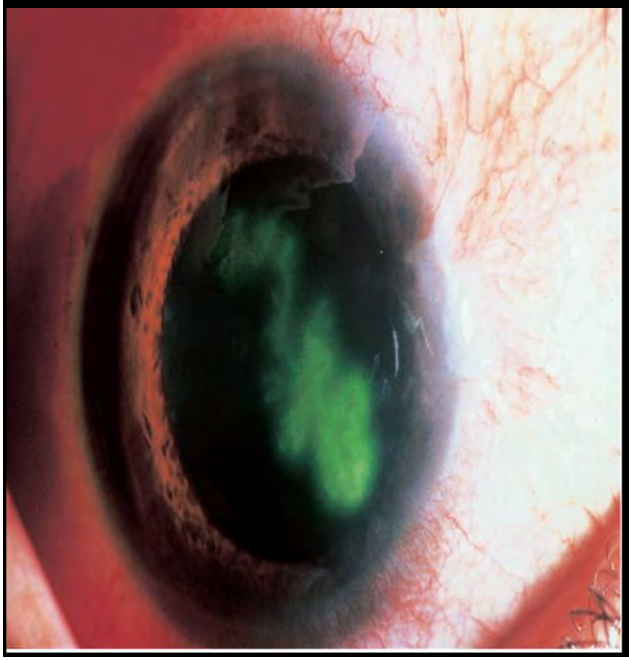
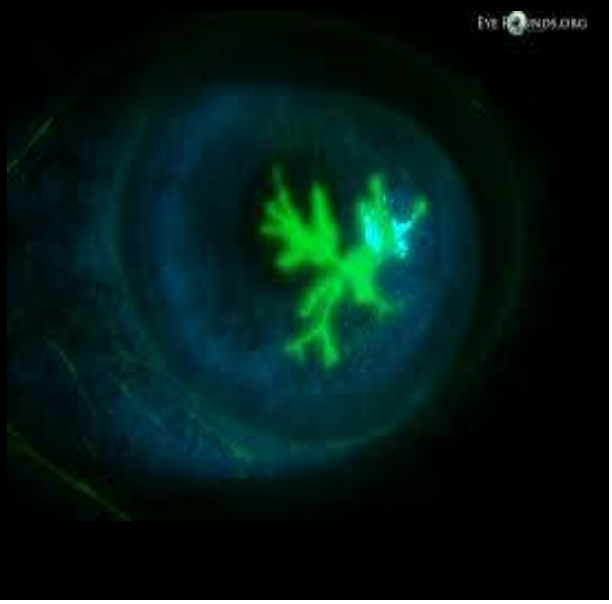
Dendritic Ulcers





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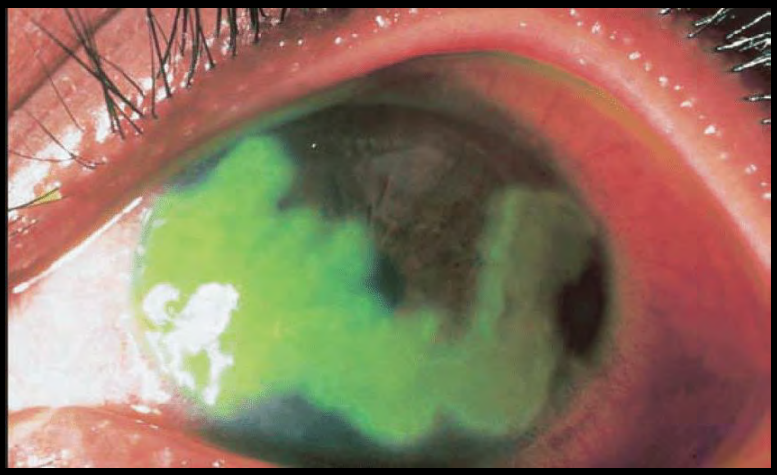
HSV Geographic Ulcer



https://www.researchgate.net/figure/Geographic-corneal-ulcer-caused-by-herpes-simplex-virus-keratitis_fig1_26730111

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Pediatric HSV Keratitis

- pediatric herpes simplex keratitis has an 80% risk of recurrence, a 75% risk of stromal disease, and a 30% rate of misdiagnosis
- 80% of children with herpes simplex keratitis develop scarring, mostly in the central cornea
  - results in the development of astigmatism
  - 25% of children have more than 2 D of astigmatism, most of which is irregular
- consider pediatric HSV when a patient has unilateral recurrent disease in the anterior segment

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Herpes Simplex Virus Keratitis Management

- Topical:
  - Viroptic (trifluridine) q 2h until epi healed then taper down for 10-14 days.
    - Viroptic is toxic to the cornea.
  - Zirgan (ganciclovir) available, use 5 times a day until epi healed then 3 times for a week (US only)

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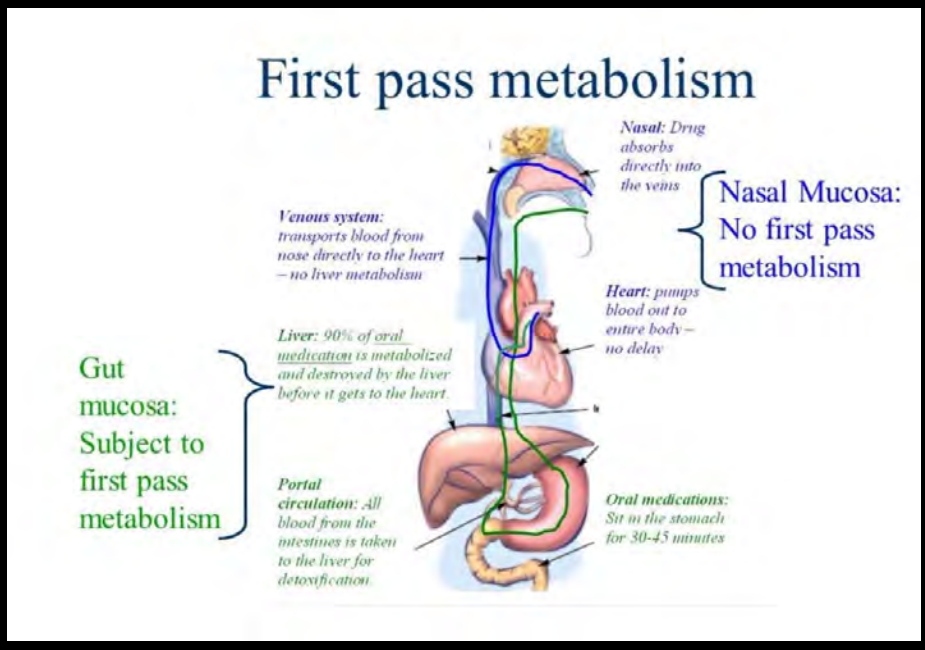

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Anti-Viral Medication

Drug	Mechanism of Action	Bioavailability	Dosing	Side Effects
Acyclovir	Acyclovir interferes with DNA synthesis inhibiting viral replication	10-30% gets absorbed Short ½ life *Metabolized in kidneys	Simplex: 400 mg 5x/day Zoster: 800 mg 5x/day	Overall very safe Nausea, vomiting, headaches, dizziness, confusion
Valacyclovir	Acyclovir pro-drug Equivalent to acyclovir but better for pain management	95% converted to acyclovir* Better bioavailability and longer 1/2 life	Simplex: 500 mg tid Zoster: 1 g tid	Same as acyclovir
Famciclovir	Inhibits DNA chain elongation It is metabolized to penciclovir where it is active 10-20x as long as acyclovir	Superior to acyclovir*	Simplex: 250 mgTID Zoster: 500 mg TID	Same as acyclovir

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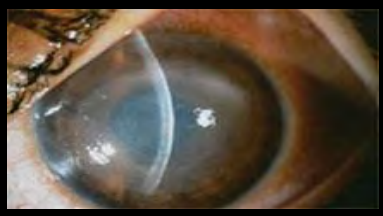
HSV Stromal Disease



- HSV Stromal disease is an immune-mediated disease
  - Stromal involvement is rarely an initial ocular finding, accounting for fewer than 2% of initial presentations but for 20 – 60% of recurrent corneal disease
- Increased risk of scarring and high risk of poor visual prognosis
- Requires corticosteroids (HEDS: corticosteroid reduced risk of progression by 68%)
  - Without epithelial defect: corticosteroids and prophylactic anti-viral dosage
  - With epithelial defect: active infection anti-viral dosage with judicious corticosteroids

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How much to dose steroid?

- HEDS used QID of *prednisolone phosphate*
- Current Recommendations:
  - Mod – severe (especially with neo): 1% Prednisolone or Lotemax QID to 6x/day
  - Want the lowest dose needed to control the inflammation
  - AAO EBM Treatment Guideline 2014
    - Topical steroid for 10 weeks (this is based on HEDS results) with oral antiviral

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HSV Epithelial Keratitis

- Treatment Regimen:
  - Zirgan (ganciclovir) available, use 5 times a day until epi healed then 3 times for a week OR
  - Oral Valtrex 500 mg 3x/day for 7-10 days
  - Artificial tears
  - L-Lysine 2 grams daily?
    - Proven to "slow down" and retard the growth of the herpes virus and inhibit viral replication
  - Debride the ulcer?
    - Prior to topical antiviral therapy debridement was treatment of choice
    - Generally try to avoid use of sharp instruments and use of cotton swab and anesthetic
- RTC 1 day, 4 days, 7 days

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Herpes Simplex Keratitis

- Prophylactic Treatment:
  - Reduces the rate of recurrence of epithelial and stromal keratitis by ≈ 50%
    - Acyclovir 400 mg BID
    - Valtrex 500 mg QD
    - Famvir 250 mg QD
    - L-lysine 1 gram/day:
      - Proven to "slow down" and retard the growth of the herpes virus and inhibit viral replication
    - Frequent debilitating recurrences, bilateral involvement, or HSV infection in a monocular patient

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Prophylaxis??

- **Pitfalls to Prophylaxis**:
  - Reduction of recurrence does not persist once drug stopped
  - Resistance????
    - van Velzen, et. al., (2013) demonstrated that long-term ACV prophylaxis predisposes to ACV-refractory disease due to the emergence of corneal ACVR HSV-1.

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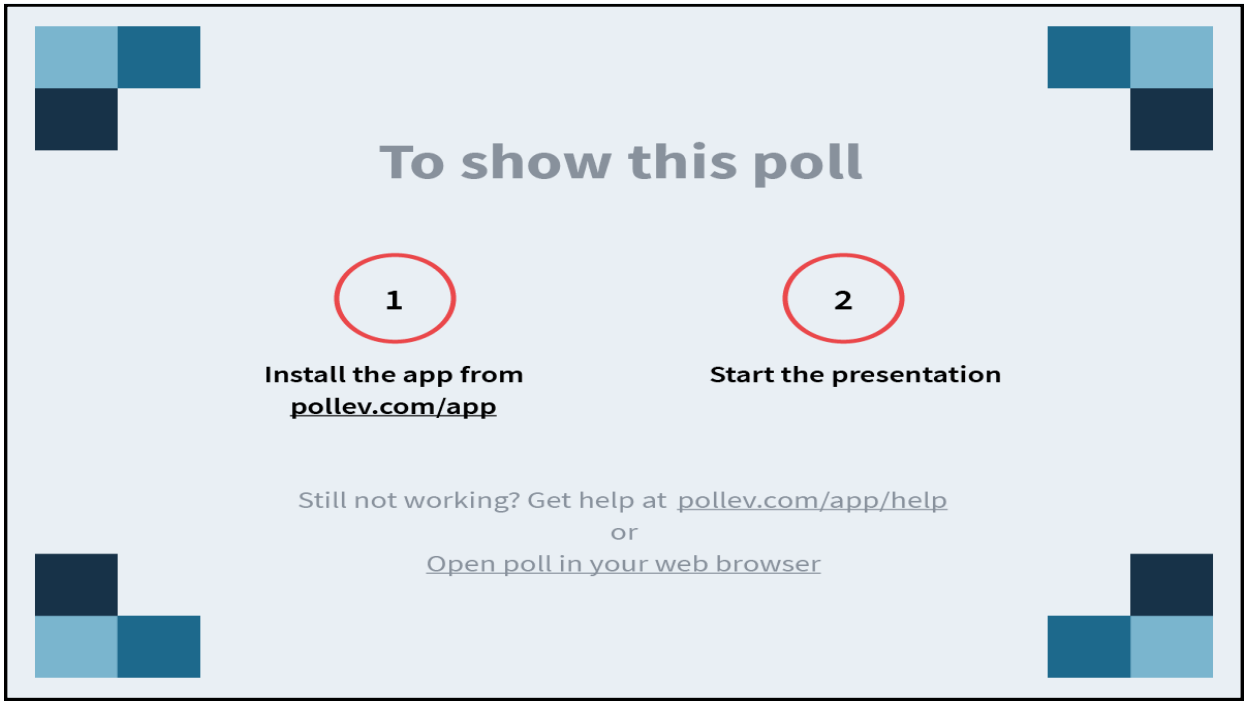

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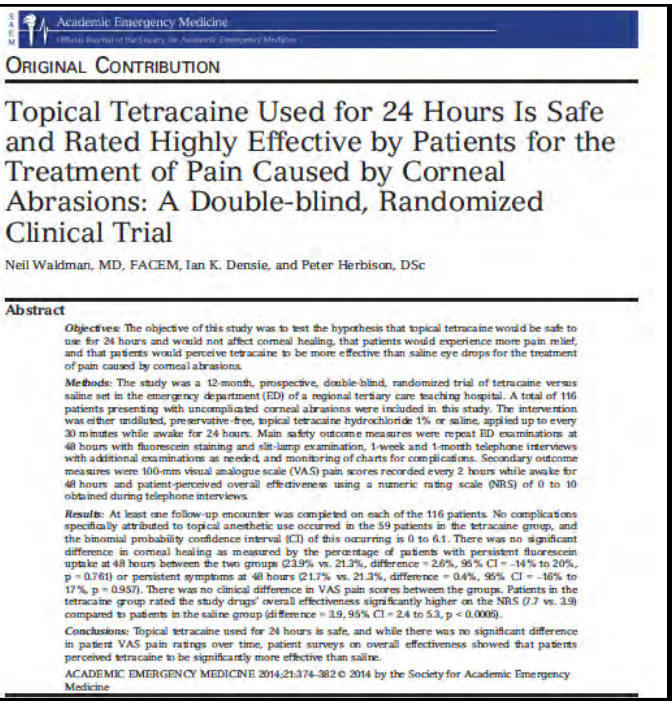

Academic Emergency Medicine
Official Journal of the Society for Academic Emergency Medicine

ORIGINAL CONTRIBUTION

Topical Tetracaine Used for 24 Hours Is Safe and Rated Highly Effective by Patients for the Treatment of Pain Caused by Corneal Abrasions: A Double-blind, Randomized Clinical Trial

Neil Waldman, MD, FACEM, Ian K. Densie, and Peter Herbison, DSc

Abstract

Objectives: The objective of this study was to test the hypothesis that topical tetracaine would be safe to use for 24 hours and would not affect corneal healing, that patients would experience more pain relief, and that patients would perceive tetracaine to be more effective than saline eye drops for the treatment of pain caused by corneal abrasions.

Methods: The study was a 12-month, prospective, double-blind, randomized trial of tetracaine versus saline set in the emergency department (ED) of a regional tertiary care teaching hospital. A total of 116 patients presenting with uncomplicated corneal abrasions were included in this study. The intervention was either undiluted, preservative-free, topical tetracaine hydrochloride 1% or saline, applied up to every 30 minutes while awake for 24 hours. Main safety outcome measures were repeat ED examinations at 48 hours with fluorescein staining and slit-lamp examination, 1-week and 1-month telephone interviews with additional examinations as needed, and monitoring of charts for complications. Secondary outcome measures were 100-mm visual analogue scale (VAS) pain scores recorded every 2 hours while awake for 48 hours and patient-perceived overall effectiveness using a numeric rating scale (NRS) of 0 to 10 obtained during telephone interviews.

Results: At least one follow-up encounter was completed on each of the 116 patients. No complications specifically attributed to topical anesthetic use occurred in the 59 patients in the tetracaine group, and the binomial probability confidence interval (CI) of this occurring is 0 to 6.1. There was no significant difference in corneal healing as measured by the percentage of patients with persistent fluorescein uptake at 48 hours between the two groups (23.9% vs. 21.3%, difference = 2.6%, 95% CI = −14% to 20%, p = 0.761) or persistent symptoms at 48 hours (21.7% vs. 21.3%, difference = 0.4%, 95% CI = −16% to 17%, p = 0.957). There was no clinical difference in VAS pain scores between the groups. Patients in the tetracaine group rated the study drugs' overall effectiveness significantly higher on the NRS (7.7 vs. 3.9) compared to patients in the saline group (difference = 3.9, 95% CI = 2.4 to 5.3, p < 0.0005).

Conclusions: Topical tetracaine used for 24 hours is safe, and while there was no significant difference in patient VAS pain ratings over time, patient surveys on overall effectiveness showed that patients perceived tetracaine to be significantly more effective than saline.

ACADEMIC EMERGENCY MEDICINE 2014;21:374–382

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Pain Management: Oral Analgesics

- Conditions potentially requiring us of oral analgesics:
  - Corneal ulcers
  - Herpes simplex/zoster
  - Post-surgical
  - Trauma
  - Thermal burns

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Acetaminophen

- Mechanism of Action is not well understood.
  - Possibly some CNS component
  - Very weak inhibitor of prostaglandin synthesis
- One of the most commonly used analgesics for mild to moderate pain.
  - Equal analgesic properties to ASA unless associated with inflammation, where it is less effective.

Take home: Good for pain; Good for fever;
No effect on inflammation

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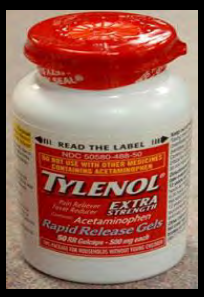
Consider Combining APAP with NSAID's for Mild to Moderate Pain Relief

1:00 pm: Two 325mg Tylenol

3:00 pm: Two 200mg Ibuprofen

5:00 pm: Two 325mg Tylenol

7:00 pm: Two 200mg Ibuprofen



Alternated every 2 hours while awake
- Each medication is q 4 hours.

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Ibuprofen

- Adult analgesic dose: 200-400mg q4hours
  - Maximum Dosage: 1200 mg/day OTC for pain (approved for 3200 mg/day in arthritis treatment)
- OTC: 200 mg tabs (US) 400 mg and 600 mg (Canada)
- Rx: 300, 400, 600, 800mg tabs
- Peak levels 1-2 hours
- Most renal toxic of all the NSAID's
- Brand Names: Motrin, Advil, and Nuprin

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Naproxen Sodium

- OTC: 220 mg (Aleve^{R})
- Rx: 550 mg tablets (Anaprox^{R} and Crysanal^{R})
- Adult Dose:
  - OTC: 1 tablet every 8-12 hours (can use two tablets on first dose)
  - Rx: 550 initial dose, followed by 275 (half tablet) every 6-8 hours.
    - Maximum Dose: 1375mg/day.

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Indoleacetic Acids: Indomethacin

- Adult Dosage: 25-50 mg TID
- Rx Only: 10mg - 75mg capsules
- Mainly used as a short term anti-inflammatory especially for conditions that do not respond to less toxic NSAIDS.
  - Indomethacin has a very high level of intolerance compared to other NSAID's.
- Oral NSAID most widely used in Tx of ocular inflammation.

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Cox-2 Inhibitors

- Selective agents for only COX-2 designed to protect the GI system from the side effects seen with NSAID's.
- Major agent available on the market is Celecoxib (Celebrex).
  - Other agents Valdecoxib (Bextra) and Rofecoxib (Vioxx) were removed from the market due to increased risk of heart attacks and strokes.
- It is approved for the treatment of osteoarthritis and rheumatoid arthritis.
  - Dosage: 100 mg BID or 200 mg daily

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Oral Analgesics: Guidelines

- Never exceed maximum recommended dosages:
  - ASA: 8 grams/day
  - Acetaminophen: 4 grams/day (newer data suggest should be closer to 3-3.2 grams/day)
  - Ibuprofen: 1200 mg/day OTC and up to 3200 mg/day prescription (for RA)
  - Naproxen: 1250/day
  - Naproxen sodium: 1375/day
  - Codeine: 360 mg/day

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Oral Analgesics: Guidelines

- Make the proper diagnosis first (ie. Don't prescribe without knowing what you are prescribing for!)
- Treat the underlying cause for the pain
- Treat the pain at presentation..don't wait!
- Treat pain continuously over a 24 hour schedule
- Non-prescription drugs should be first choice and tend to be low cost
- Treat patients with the simplest and safest means to alleve pain

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Opioids Information

- Drug of first choice for the treatment of **severe** acute pain.
- Block the body's natural protective mechanism for protecting areas in pain – thus never prescribe unless you know the direct cause of the pain.

- Often administered in combination with acetaminophen or aspirin to enhance the analgesic effect.
  - FDA recommended in 2011 that all prescription narcotics containing acetaminophen standardize and limit the dosage to 325 mg.
    - This is to be slowly phased in over three years (just required in January 2014).

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Opioids Side Effects

- Side Effects are very hard to predict because opioids can cause CNS depression or stimulation.
- CNS Side Effects
  - Dizziness, lightheadedness, sedation, and drowsiness are the most common.
  - Mood elevation (euphoria) and disorientation can occur in some patients.
  - Exacerbated if used in combination with alcohol, depression medications such as tricyclic antidepressants, anticholinergics, antihistamines, anti-seizure medications, or muscle relaxants, etc.
  - Visual symptoms such as blurry vision, miosis, and diplopia can occur.

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Opioid Side Effects

- GI Side Effects:
  - Nausea and Vomiting (more common in ambulatory pts.)
  - Constipation
    - Opioids inhibit intestinal trace motility.
    - Very commonly found side effect.
      - Can be relieved by OTC docusate sodium (Colace).

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Opioid Side Effects

Respiratory Side Effects:

- Respiratory Depression
  - Most serious side effect of the opioids
  - Opioids suppress the brainstem respiratory centers
    - Alter tidal volume, respiratory rate, rhythmicity, and responsiveness to CO_2
  - Does not commonly occur at therapeutic doses in healthy patients, but must use caution in patients with pulmonary disease.
- Cardiovascular Side Effects:
  - Peripheral vasodilation can result in orthostatic hypotension, decreased BP, and changes in pulse rate.
- Others Include: Urinary retention, cough suppression, headaches, rashes, itching.

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Scheduled Medications – Most Opioids

Schedule	Description	Optometric Medications
I	Not commercially available; no approved indication	
II	Very addictive medications that are accepted for medicinal use	Oxycodone = OxyContin, OxyFast Oxycodone + APAP = Percocet or Tylox Oxycodone + ASA = Percodan Oxycodone + NSAID = Combunox Hydromorphone (Dilaudid) Codeine Sulfate = Codeine Generic Meperidine (Demerol) **Hydrocodone + APAP = Lortab or Vicodin** **Hydrocodone + Ibuprofen = Vicoprofen**
III	Significant abuse risk, but less potent than I or II. May still contain narcotics.	Codeine + APAP = Tylenol 3 and Tylenol 4
IV	Relatively low abuse potential and limited risk	Propoxyphene (Darvon) Propoxyphene with APAP = Darvocet (Removed from Market in November 2010). Pentazocine + APAP (Talacen) Tramadol
V	Very limited abuse potential. May be OTC in some states.	Acetaminophen

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Opioids: Codeine

- Prodrug that relies on the cytochrome P-450 system to be metabolized to active drug morphine.
  - Schedule II medication if prescribed alone (Codeine Sulfate 15, 30, 60 mg generic.)
- Analgesic effect occurs within 20 minutes of ingestion and reaches a maximum at 1 – 2 hours.
  - Ceiling effect occurs.

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Opioids: Codeine

- Usually administered in combination with .
  - Tylenol 3 = Codeine 30 mg and Acetamenophin 300 mg
    - Dosage: 1-2 tablets every 4 hours.
  - Tylenol 4 = Codeine 60 mg and Acetamenophin 300 mg
    - Dosage: 1 tablet every 4 – 6 hours
  - Also available as generic with 15, 30, or 60 mg of Codeine with 300 mg of Acet. or elixer of 12 mg codeine + 120 mg Acet. per 5 mL.
    - Elixer can be used in children for pain management if >3 years.

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Opioids: Hydrocodone

- Approximately 6X more potent than codeine.
- Milder Side Effects than Codeine: Less constipation and sedation.
- Clinically believed to cause more euphoria than codeine, but this is not backed by clinical studies.

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Opioids: Hydrocodone

- Used in combination with APAP and Ibuprofen.
  - Lortab: Hydrocodone 5, 7.5, and 10 mg with APAP 325 mg
    - Dosage: 1-2 tablet every 4-6 hours
  - Lortab Elixer: Hydrocodone 10 mg with APAP 300 / 15 mL
    - Dosage: 3 tsp every 4-6 hours
  - Vicodin: Hydrocodone 5 mg with Acetaminophen 300 mg
  - Vicodin HP: Hydrocodone 10 mg with Acetaminophen 300 mg
    - Dosage: 1 tablet every 4-6 hours
  - Vicodin ES: Hydrocodone 7.5 mg with Acetaminophen 300 mg
    - Dosage: 1 tablet every 4 – 6 hours
  - Vicoprofen: Hydrocodone 7.5 mg with Ibuprofen 200 mg
    - Dosage: 1 tablet every 4-6 hours
  - Norco: Hydrocodone 5, 7.5, and 10 with 325 mg APAP

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Opioids: Oxycodone

- Approximately 10-12X more potent than codeine
  - As potent as parenteral morphine when given orally.
- Lower level of side effects in comparison to morphine, but high level of euphoria produced, thus higher level of abuse risk.

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Opioids: Oxycodone

- Available in combination with APAP, ASA, or Ibuprofen.
  - Percocet Tablets
    - 2.5, 5, 7.5 or 10 mg Oxycodone with 325 mg Acetaminophen
    - Dosage: 1 tablet every 6 hours
  - Tylox Capsules
    - 5 mg Oxycodone with 300 mg Acetaminophen
    - Dosage: 1 tablet every 6 hours
  - Percodan Tablets
    - 4.5 mg Oxycodone HCl
    - 0.38 mg Oxycodone terephthalate
    - 325 mg Aspirin
    - Dosage: 1 tablet every 6 hours
  - Combunox
    - 5 mg Oxycodone with 400 mg Ibuprofen
    - Dosage: 1 tablet daily to QID

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Tramadol (Ultram)

- Central acting narcotic
  - Synthetic analogue of codeine.
  - Binds to mu receptors and inhibits norepinephrine and serotonin reuptake.
  - Potential for abuse is very low, but has occurred.
- Available as 50 mg tablets.
- Dosage: 50 – 100 mg q4 – 6 hours.
  - Analgesia occurs after 1 hour.
  - Maximum dose: 400 mg/day

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Tramadol + APAP (Ultracet)

- Combination of:
  - 325 mg of APAP
  - 37.5 mg of Tramadol
- Dosage: 2 tablets every 4 – 6 hours
- Max: 8 tablets daily

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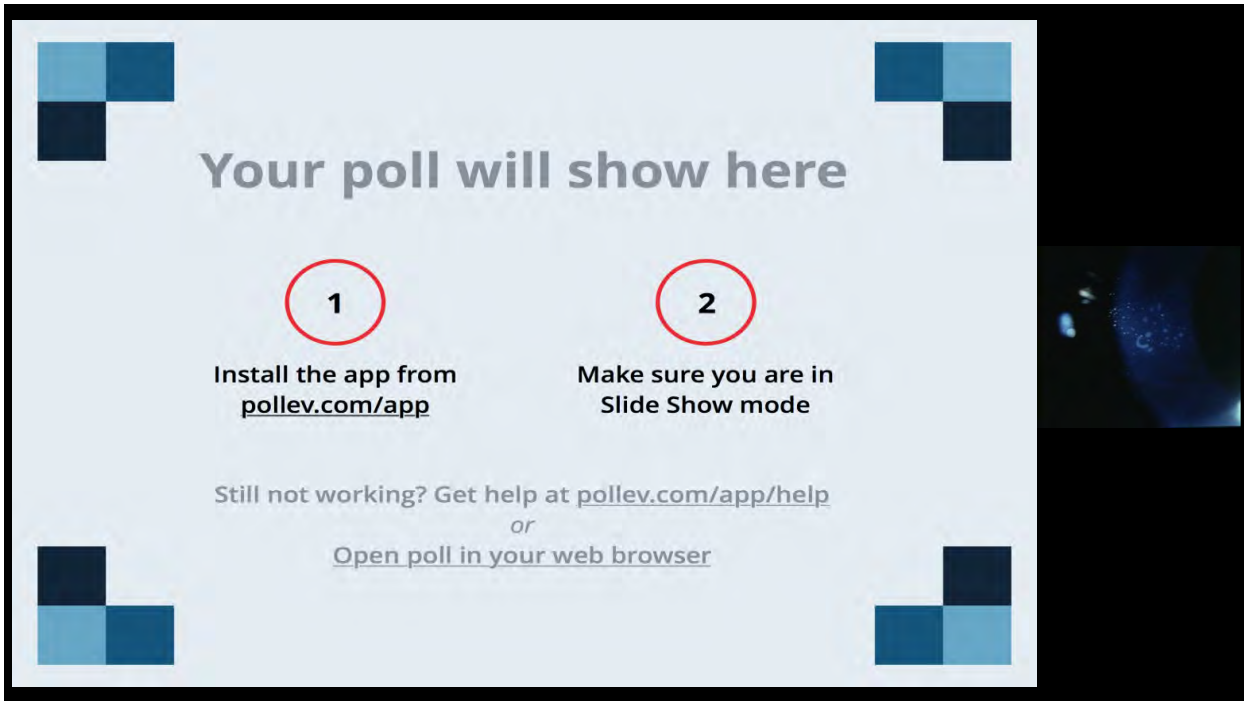

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Epithelial (Anterior) Basement Membrane Dystrophy (EBMD or ABMD)

- Primary features of this "dystrophy" are:
  - abnormal corneal epithelial regeneration and maturation,
  - abnormal basement membrane
- Often considered the most common dystrophy, but may actually be an age-related degeneration.
  - large number of patients with this condition,
  - increasing prevalence with increasing age, and
  - its late onset support a degeneration vs. dystrophy.

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Epithelial (Anterior) Basement Membrane Dystrophy (EBMD or ABMD)

- Not all patients are symptomatic
- Most common symptom is mild FB sensation which is worse in dry weather, wind and air conditioning
- Blurred vision from irregular astigmatism or rapid TBUT
- Pain is usually secondary to a RCE (recurrent corneal erosion) in apprx 10%

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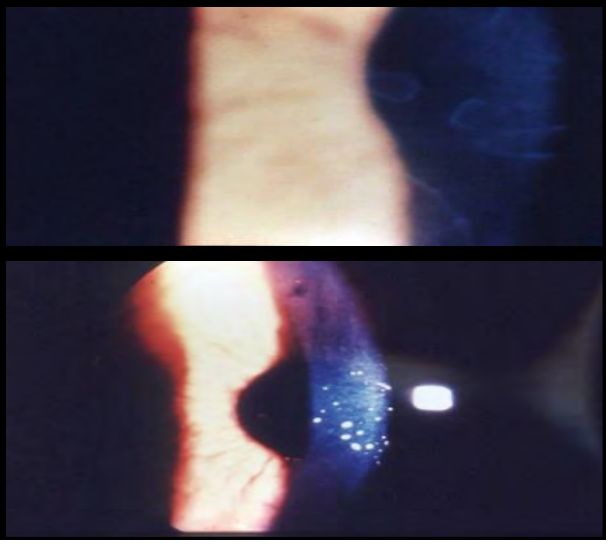
Epithelial (Anterior) Basement Membrane Dystrophy (EBMD or ABMD)

- Easy to overlook:
  - typically bilateral though often asymmetric,
  - females>males,
  - often first diagnosed b/w ages of 40-70

50

Epithelial (Anterior) Basement Membrane Dystrophy (EBMD or ABMD)

- Most common findings are:
  - chalky patches,
  - intraepithelial microcysts, and
  - fine lines (or any combination) in the central 2/3rd of cornea



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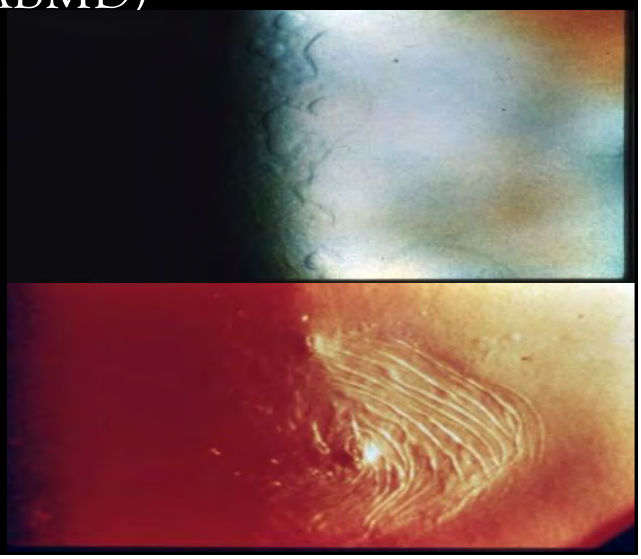
Epithelial (Anterior) Basement Membrane Dystrophy (EBMD or ABMD)

- Often referred to as:
  - maps,
  - dots or
  - fingerprints



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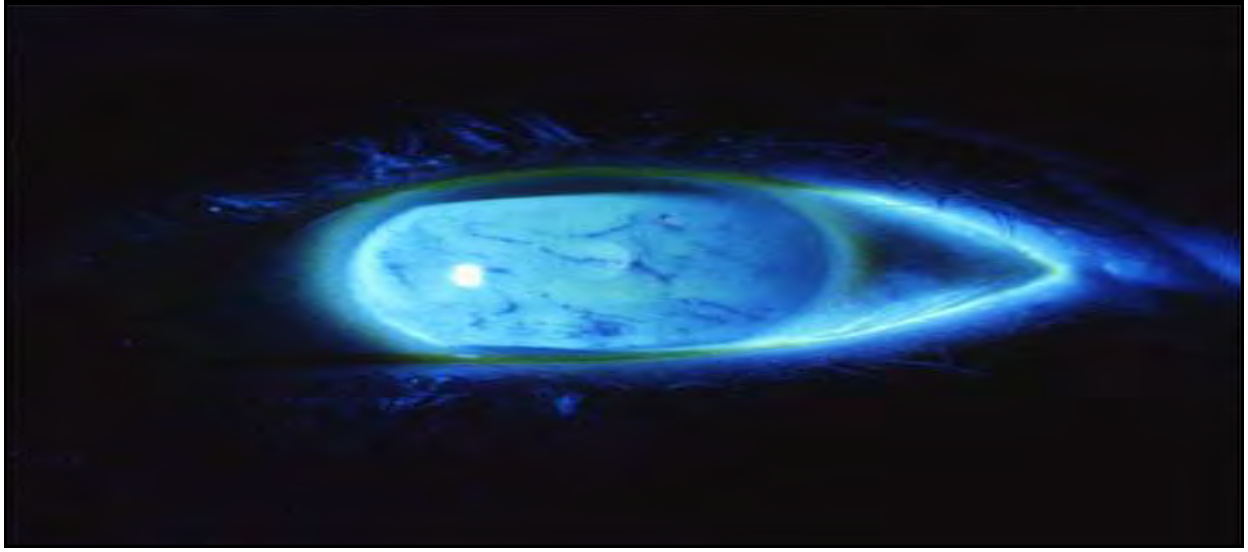
EBMD-Negative Staining



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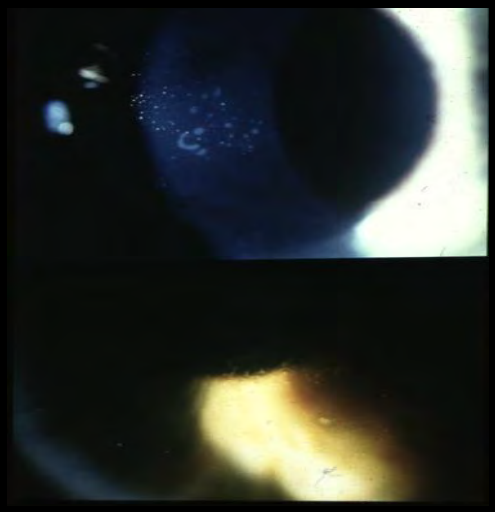
Epithelial (Anterior) Basement Membrane Dystrophy (EBMD or ABMD): Treatment



- Typically directed towards preventing RCE
- If RCE's develop:
  - awake with painful eye that improves as day wears on
  - chalky patches/dots in lower 2/3rd of cornea

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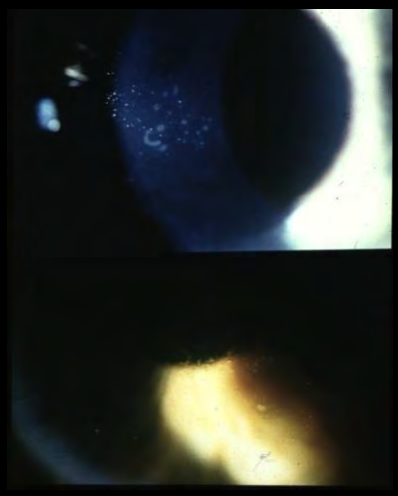
Acute Treatment of RCE



- use of hyperosmotic ointment at bedtime
- bandage contact lens
- Frequent lubrication
- Plugs
- Topical meds
- No ceiling fans
- Night time ointment
- PTK

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Recurrent Corneal Erosion: Treatment

- If severe enough to cause vision loss or repeated episodes:
  - oral doxycycline with/without topical corticosteroid
    - Doxy 50 mg bid and FML tid for 4-8 weeks
    - both meds inhibit key metalloproteinases important in disease pathogenesis
  - debridement,
  - Debridement + diamond burr polishing
  - stromal puncture (not commonly done anymore)
  - PTK
  - Latest development: amniotic membrane transplant e.g. Prokera typically after debridement

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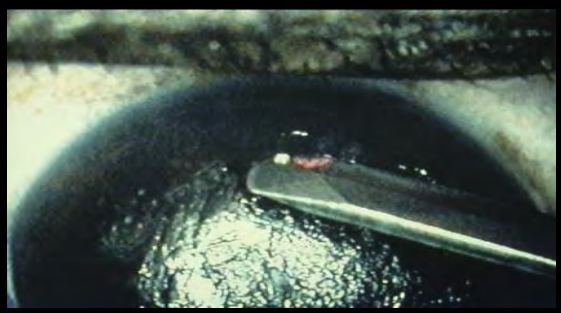
CORNEAL DEBRIDEMENT

- Soften epithelium
- 1-2 gtt topical anesthetic
- q 15-30 seconds for 2-3 minutes
- Use cotton swab, spatula, spud
- or jewelers forceps
- Remove flaps by pulling edges toward center
- Don't pull directly up or out
- Remove flaps down to tight,
- firm edges.
- Tx abrasion (>50-100%)
  - Recurrence Rate 18%



Pictured: Kimura Platinum Spatula

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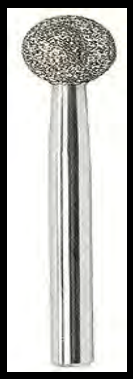
Diamond Burr Polishing

- Removes abnormal basement membrane
- Provides smooth surface for cells to grow



https://www.katena.com/pterygium-burr-3-5mm-w-chuck-k2-4913

Vo, et al (2014): epithelial debridement with diamond burr polishing was 95% effective after single treatment in preventing recurrence for an average of 32 months follow up time

59

Amniotic Membrane Transplant

- Amniotic membrane is a biologic tissue with:
  - antiangiogenic,
  - antiscarring,
  - antimicrobial, and
  - anti-inflammatory properties that promotes healing of the ocular surface
- Amniotic membrane grafts have been used for a variety of ocular conditions including:
  - Corneal burns
  - Neurotrophic ulcers
  - Stem cell damage
  - Persistent epithelial defects

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Amniotic Membrane Grafts (AMG)

Biotissue- Prokera, Prokera Slim, Prokera Clear, Amniograft, & Amnioguard

http://www.biotissue.com/products/prokera.aspx

IOP Ophthalmics- Ambiodisk

http://www.iopinc.com/store/ambiodisk/

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Case Example

- 67 YOF
- HA and vision loss x 2 days
- OHx: unremarkable
- LEE: 3 days ago!
- MHx: unremarkable

Case courtesy of Dr. Tammy Than

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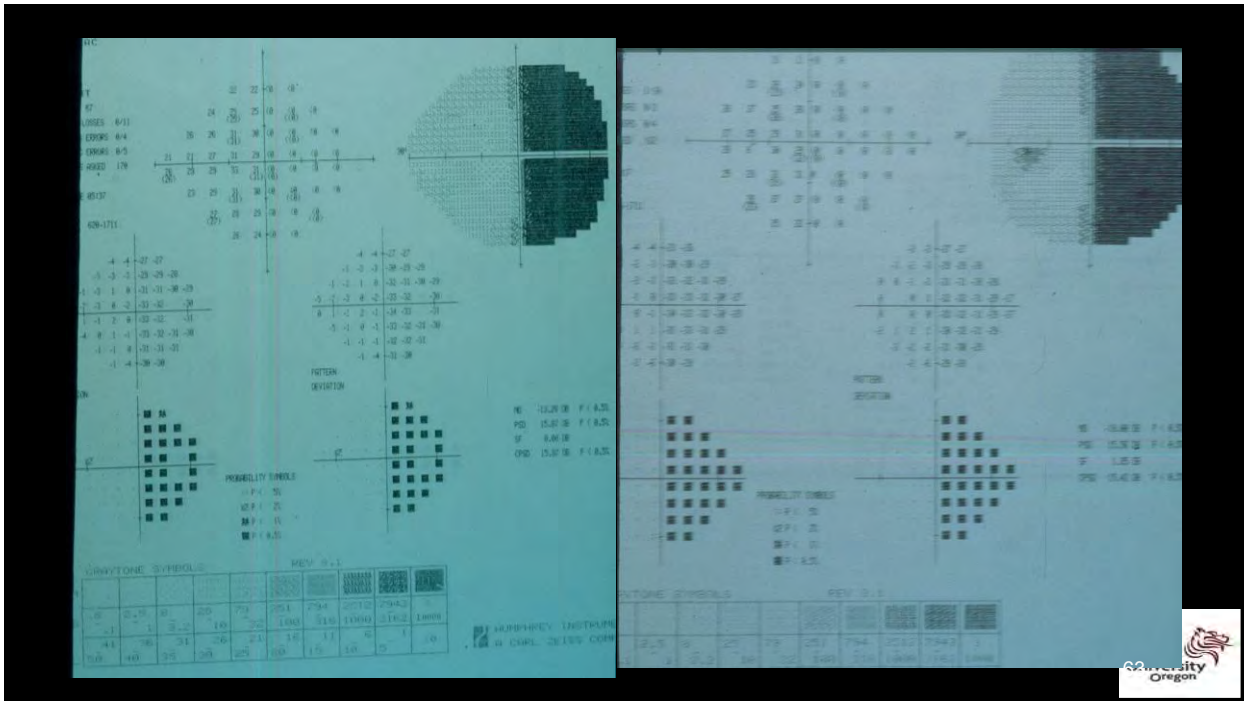

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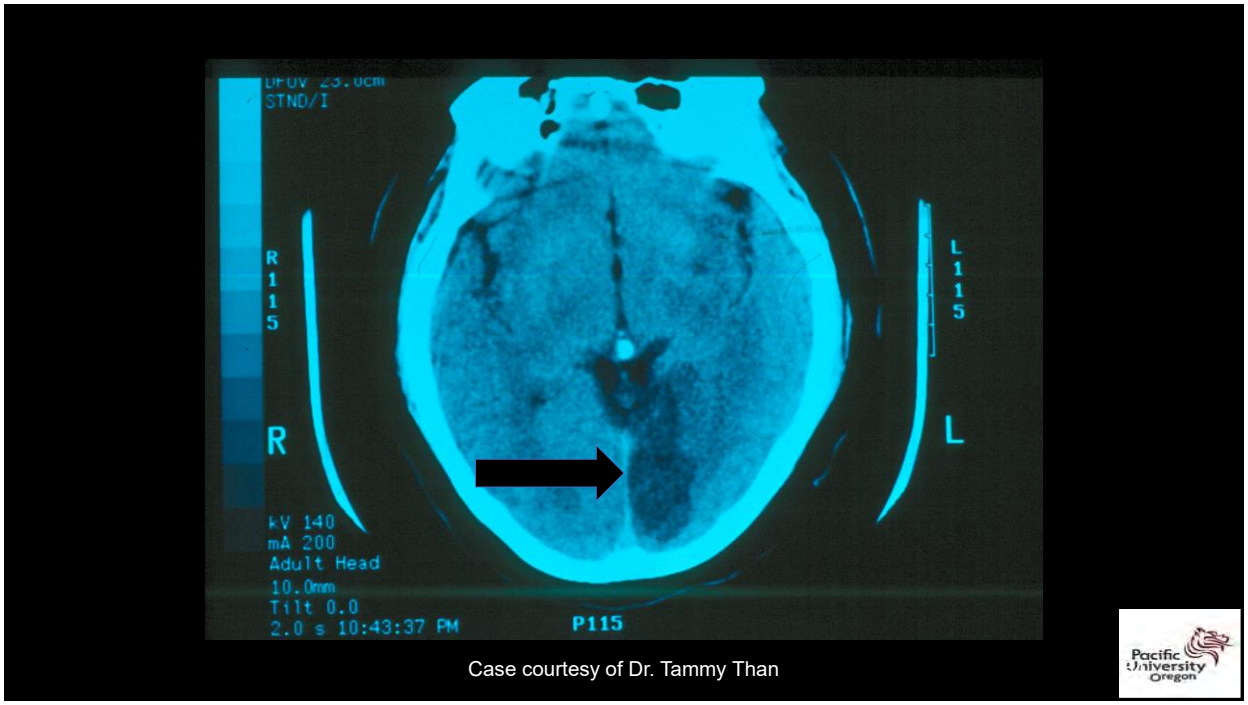

Case courtesy of Dr. Tammy Than

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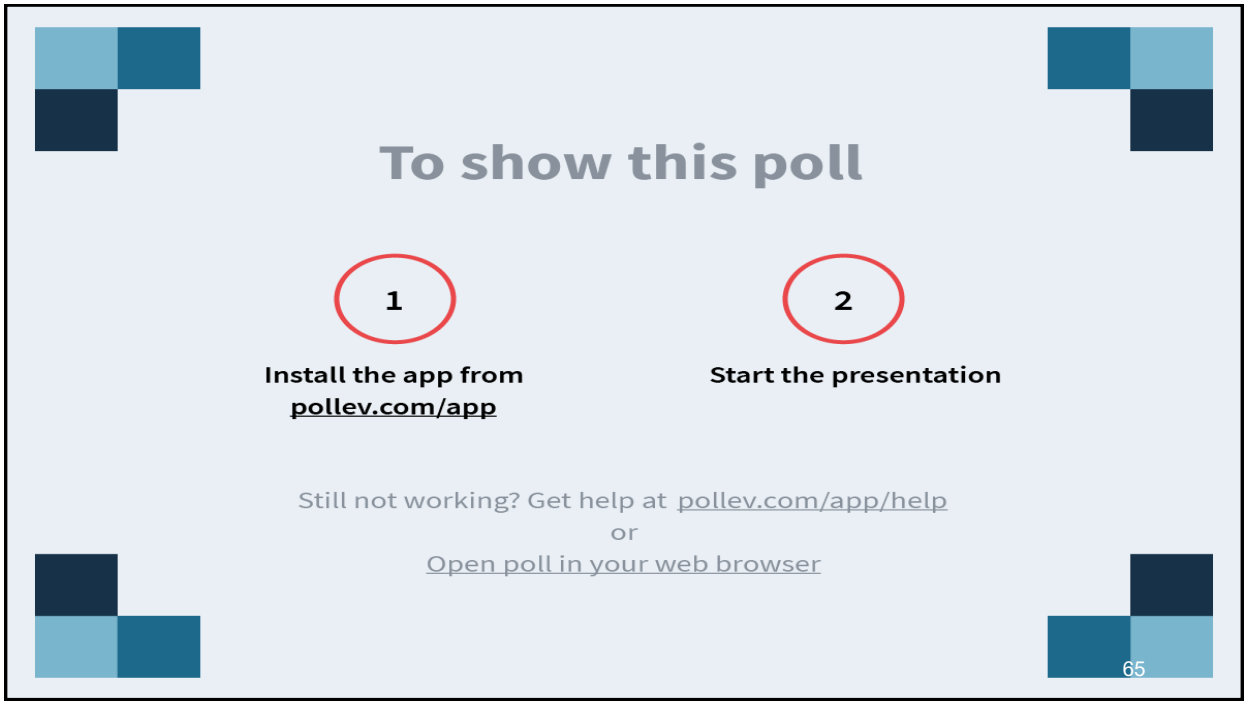

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Minocycline?

- Proposed mechanisms
  - Anti-inflammatory
  - Reduction in microglial activation
  - ↓ MMPs
  - Nitric oxide production
  - Inhibition of apoptotic cell death

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Acute Stroke Management

- N=152
- Open-label, evaluator masked study
- Minocycline 200 mg QD x 5 d or placebo
- Evaluated on NIH Stroke Scale
  - 0-1 complete/nearly complete improvement
  - 2-7 – mild
  - 8-14 – moderate
  - >15 – severe
  - Day 30: 1.8 versus 7.1

Lampl Y, Boaz M, Gilad R, Lorberboym M, Dabby R, Rapoport A, et al. Minocycline treatment in acute stroke. Neurology. 2007;69(14):1404–10

67

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TEST	Admission	Day 7	Day 30	Day 90
NIHSS - Min	7.5	6.5	1.8	1.6
NIHSS – Cont	7.6	8.1	7.3	6.5
mRS – Min	2.8	1.5	1.1	0.9
mRS – Cont	2.0	3.1	2.7	2.1
BI – Min	70.0	85.9	90.6	94.9
BI – Cont	63.9	61.9	68.5	77.6

Minocycline for acute stroke treatment: a systematic review and meta-analysis of randomized clinical trials. J Neurol. 2018 Aug;265(8):1871-1879

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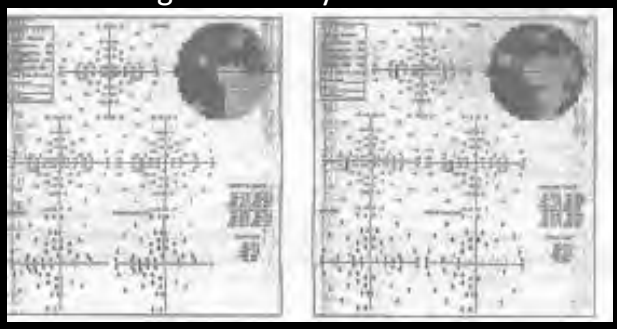
Case Report

- 77 YOM
- Right occipital infarct
- 3 weeks post stroke
  - Minocycline 100 mg BID x 5 days



Mark Tomsik, OD and Marlene Skulskie, OD

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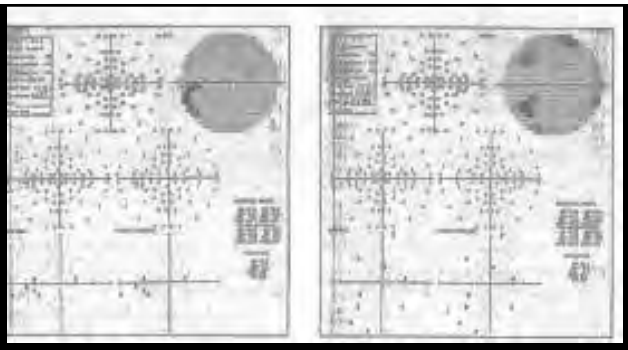
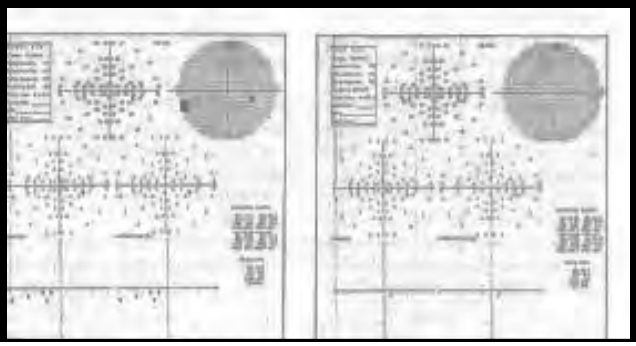
Shortly after TX



1 Year Later



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Tetracyclines

- This group includes:
  - Tetracycline (250mg - 500 mg cap BID-QID) needs to be taken 1 hour before or 2 hours after a meal.
  - Minocycline (100 mg cap BID)
  - **Doxycycline (20mg - 100 mg cap or tab BID)**
    - **In Canada: Apprilon (30 mg doxy + 10 mg slow release doxy)**
- **Rules of Thumb with Doxy:**
  - **Do not take before lying down (>2 hours before)**
  - **Do not take with calcium and avoid antacids**
  - **Do not take with dairy**
  - **Do take with food**
  - **Do educate on sun protection**

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Side Effects of Tetracyclines

- Side effects include gastric discomfort, phototoxicity, effects on calcified tissues, vestibular problems, pseudotumor.
- Pregnancy Category D.
  - Tetracyclines are attracted to embryonic and growing bone tissue.
    - Depress growth of long bones in pregnant women/children.
    - Cause changes in both deciduous and permanent teeth during the time of tooth development (Includes discoloration and increased cavities)
- Contraindicated in:
  - Women in the last half of pregnancy
  - Lactating women
  - Children under 8 years of age

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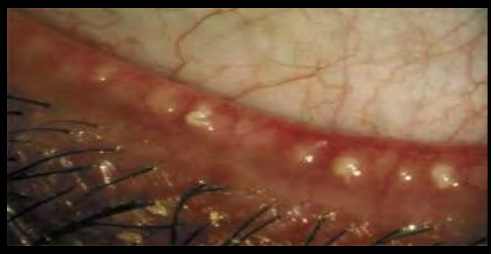
Meibomian Gland Dysfunction

- Meibomian gland dysfunction:
  - also referred to as meibomitis and patients experience dry eye problems secondary to increased evaporation of the tears.
  - signs include noticeable capping of the glands and frothing of tear film.
- Standard treatment includes:
  - good lid hygiene with warm compresses and lid scrubs in conjunction with
  - **doxycycline 50 mg po BID for 2-3 months**

Alternative treatment:

- **Azythromycin 500 mg/day for 3 days for three- four weeks**
  - **Recent study used single Z-pak treatment**



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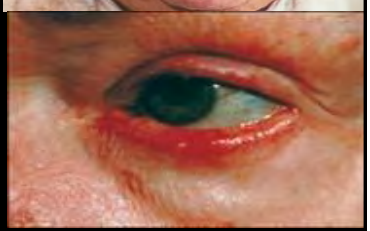
Acne Rosacea

- Acne rosacea:
  - affects females>males after 30 with peak incidence 4-7th decade of Celtic/Northern European descent. Males more disfigured.
- 4 subtypes with classic signs of flushing, papules or pustules usually in crops, telangiectasia.
  - secondary ocular complications (85% of patients) and often precede other skin manifestations include erythema, itching and burning.
  - Lipases secreted by bacteria on the skin metabolize sebum and produce metabolites that result in inflammation of the skin



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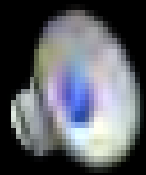
Acne Rosacea and Demodex

- Demodex is a natural part of human microbiome
- *Demodex folliculorum* live in hair follicles, primarily on the face, as well as in the meibomian glands of the eyelids;
- *Demodex brevis* live in the sebaceous glands of the skin.



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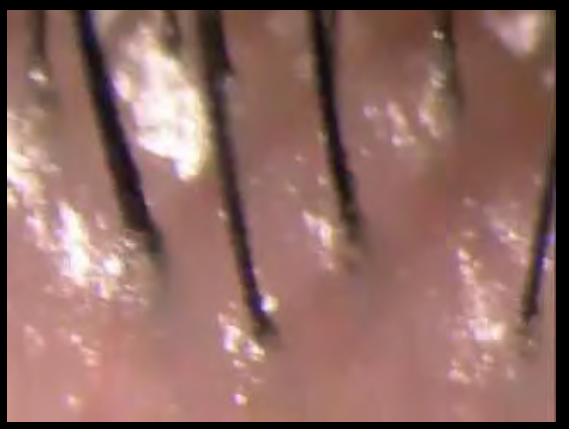
Acne Rosacea and Demodex

- *Demodex folliculorum* frequently occur in greater numbers in those with rosacea and this overabundance is thought to trigger an immune response or possibly certain bacteria associated with the Demodex



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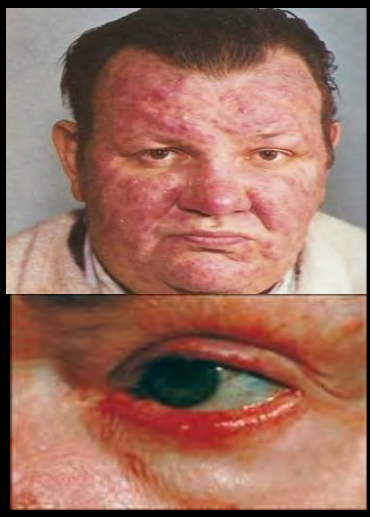
Acne Rosacea

- Mainstay oral Tx is **Oracea (40 mg** in morning) or
  - **doxycycline 50 mg po** or minocycline 100 mg po for 4-12 wks.
  - **NOTE: Oracea is subantimicrobial therapy**
  - **May want to consider Tea Tree oil wipes/foam for the face and lids to try and reduce the role Demodex plays**



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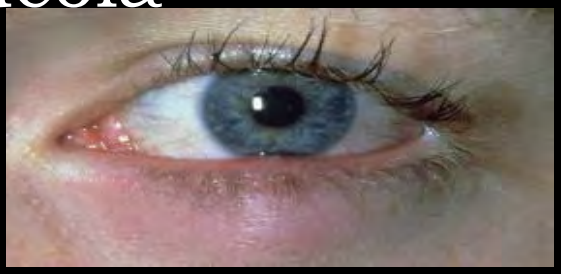
Hordeola

- Acute purulent inflammation
  - Internal occurs due to obstruction of MG
  - External (stye) from infection of the follicle of a cilium and the adjacent glands of Zeiss or Moll
- Painful edema and erythema,



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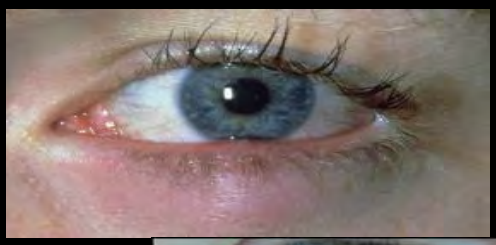
Hordeola

- Typically caused by Staph and often associated with blepharitis
- Treatment includes:
  - hot compresses (e.g. Bruder)
  - topical antibiotics (?)
  - possibly systemic antibiotics
    - Augmentin (Clavlulin) 500 mg bid-tid
    - Doxycycline 100 mg bid
    - Keflex 500 mg tid
- Treat concurrent blepharitis



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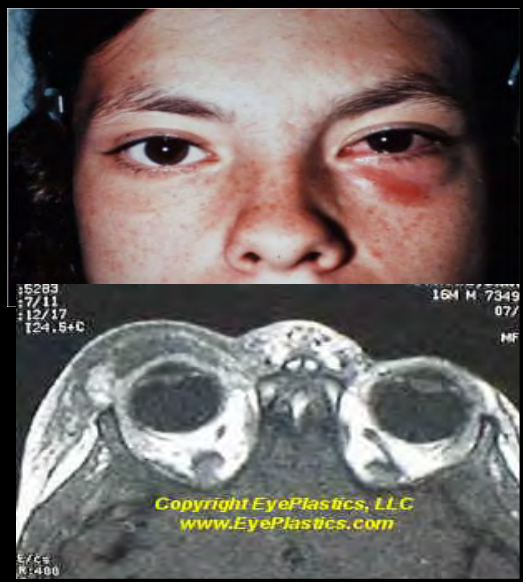
- Infection and inflammation located anterior to the orbital septum and limited to the superficial periorbital tissues and eyelids.
- Usually follows sinus infection or internal hordeolum (possibly trauma)
- Eyelid swelling, redness, ptosis, pain and low grade fever.



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Differentiating Orbital vs. Preseptal

FINDING	ORBITAL	PRESEPTAL
Visual Acuity	Decreased	Normal
Proptosis	Marked	Absent
Chemosis and Hyperemia	Marked	Rare/Mild
Pupils	RAPD	Normal
Pain and Motility	Restricted and Painful	Normal
IOP		Normal
Temperature	102 - 104	Normal/mild elevation
HA and Assoc. Symptoms	Common	Absent

Treatment: Orals for Preseptal, Often IV for Orbital

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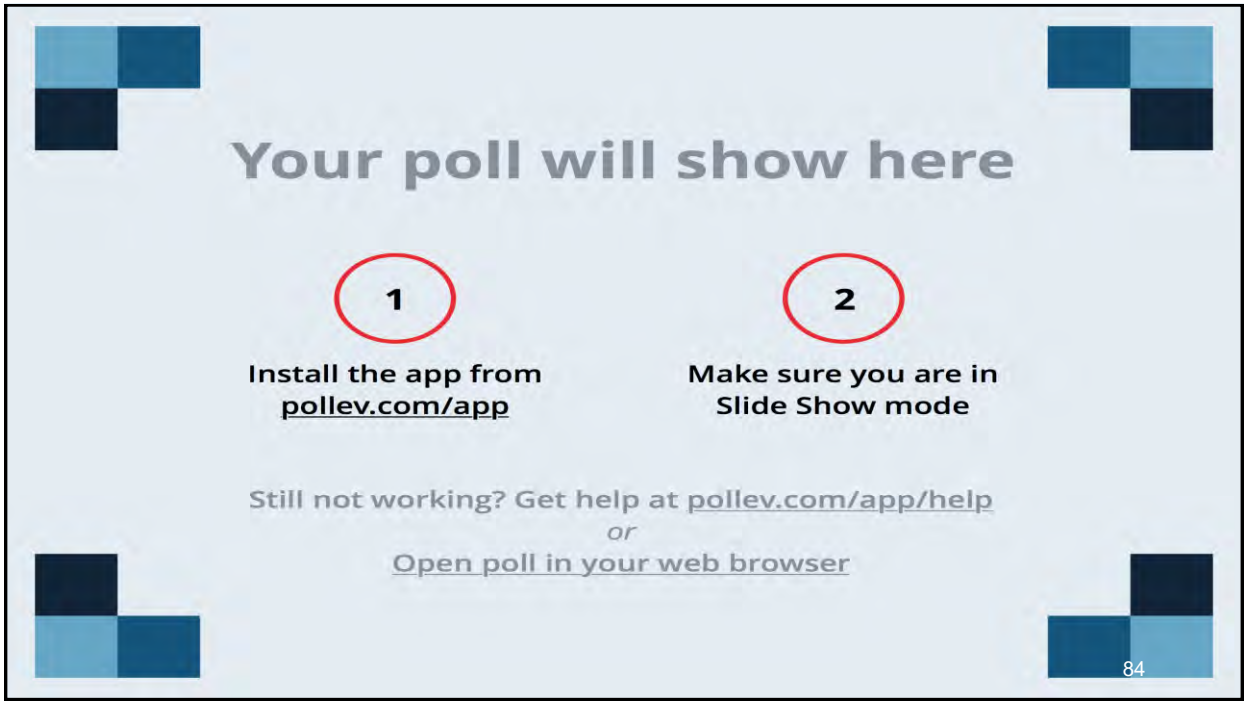

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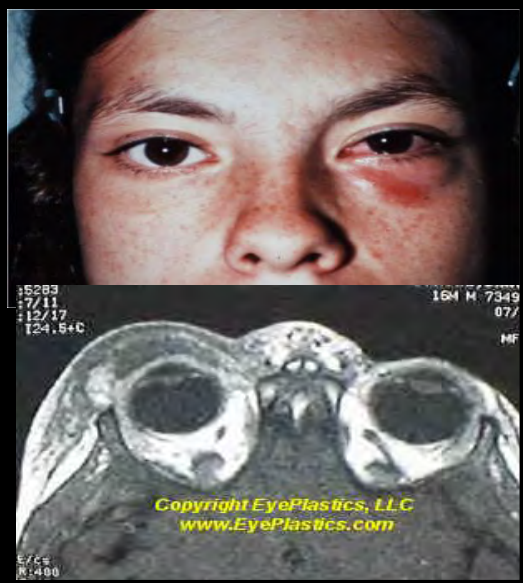
- Tx:
  - **Clavulin (*Augmentin) 500 mg TID or 875 mg BID for 5-7 days***
  - or if moderate to severe IV Fortaz (ceftazidime) 1-2 g q8h.
  - If MRSA possible, consider Bactrim/Septra



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Penicillins: Clavulin (Augmentin)

- **<u>Clavulin (Augmentin) is amoxicillin with potassium clavulanate (clavulanic acid 125 mg).</u>**
- Clavulanate is a B-Lactamase inhibitor which reduces a bacteria's ability to negate the effect of the amoxicillin by inactivating penicillinase (enzyme that inactivates the antibiotic affect).
  - Dicloxacillin can also be used in infections due to penicillinase-producing staph.

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Penicillins: Clavulin (Augmentin)

- **Clavulin (Augmentin) is very effective for skin and skin structure infections** such as:
  - dacryocystitis,
  - internal hordeola,
  - pre-septal cellulitis.
- Treatment of:
  - otitis media,
  - sinusitis,
  - lower respiratory and urinary infections.
- Given prophylactically to dental surgery patients.

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Penicillins: Clavulin (Augmentin)

- It has ***low***:
  - GI upset,
  - allergic reaction and anaphylaxis.
- Serious complications include:
  - anemia,
  - pseudomembranous colitis and
  - Stevens-Johnson syndrome.

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Penicillins: Augmentin.

Adults:

- **250 TID, 500 mg tab BID-TID depending on what you are treating** (also available in chewable tablets and suspension)
- or **875 mg q 12hr (bid)**
- 1000 mg XR: q12 hr and not for use in children <16

Peds: <3 mos 30mg/kg/day divided q12hrs using suspension

- >3 mos 45-90mg/kg/day divided q12hrs (otitis media 90mg for 10 days)

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Cephalosporins

- Closely related structurally and functionally to the penicillins,
  - **have the same mode of action,**
  - affected by the same resistance mechanisms.
  - tend to be more resistant to B-lactamases.
- classified as 1st, 2nd, 3rd, 4th and now 5th generation based largely on their bacterial susceptibility patterns and resistance to B-lactamases.
- Typically administered IV or IM, **poor oral absorption**

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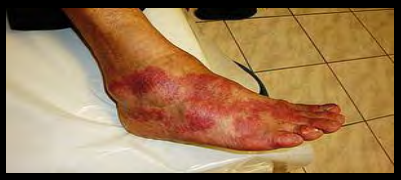
Side Effects and Contraindications

- Hypersensitivity Reactions are common.
  - Risk of cross sensitivity with PCN's is higher for 1st generation, but often overestimated for later medications.
  - Used to state the cross sensitivity was ~10%, but now believed to be closer to 3%.



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Cephalosporins

- 1st generation: **cefadroxil (Duricef)**, **cefazolin (Ancef)**, **cephalexin (Keflex)**, and cephalothin
- 2nd generations: **cefaclor (Ceclor)**, cefprozil, **cefuroxime (Zinacef)**, cefotetan, cefoxitin
- 3rd generation: cefdinir (Omnicef), cefixime, **cefotaxime (Claforan)**, **ceftazidime (Fortaz)**, ceftibuten, ceftizoxime, **ceftriaxone (Rocephin IM/IV)**.
- 4th generation: cefepime
- *Keflex, Ceclor, Omnicef,* (all orally administered) are effective against most gram positive pathogens and especially good for skin and soft tissue infections.

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Cephalosporins

- **Keflex (cephalexin):**
  - treatment of respiratory, GI, skin and skin structure, and bone infections as well as otitis media
  - Adults: 250-1000 mg every 6 hours
    - **- typical dosing 500 every 6 hours**
  - Children: 25-100 mg/kg/day divided 6-8 hours

93

Co-Trimoxazole (Bactrim/Septra)

- Combination of trimethoprim and sulfamethoxazole
  - shows greater antimicrobial activity than equivalent quantities of either drug alone.
- Has broader spectrum of action than the sulfa's and is effective in treating:
  - UTIs and respiratory tract infections
  - often considered for treatment of MRSA skin infections

94

94

Co-Trimoxazole (Bactrim/Septra)

- Available:
  - **Bactrim/Septra tablets**:
    - contains 80 mg trimethoprim and 400 mg sulfamethoxazole
    - dosing **2 tablets every 12 hours**
  - **Bactrim DS/Septra DS (Double Strength)**
    - contains 160 mg trimethoprim and 800 mg sulfamethoxazole
    - Dosing **1 tablet every 12 hours**

95

Cephalosporins

- Cefaclor (Ceclor) (2nd generation):
  - Immediate-release: 250 to 500 mg every 8 hours
  - Extended-release: 500 mg every 12 hours

Note: An extended-release tablet dose of 500 mg twice daily is clinically equivalent to an immediate-release capsule dose of 250 mg 3 times daily; an extended-release tablet dose of 500 mg twice daily is **NOT** clinically equivalent to 500 mg 3 times daily of other cefaclor formulations.

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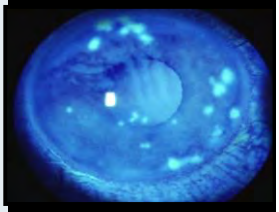
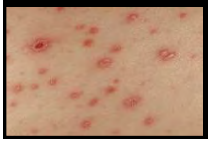


97

97

Herpes Zoster

1. Primary infection – Chicken pox (Varicella)
   - Usually in children
   - Highly contagious***
   - Very itchy maculopapular rash with vesicles that crust over after ≈ 5 days
   - 96% of people develop by 20 years of age
   - Vaccine now available



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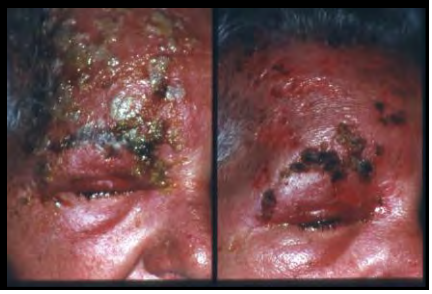
Herpes Zoster

2. Reactivation – Shingles (Herpes Zoster)
    - More often in the elderly and immunosuppressed (AIDS)
        - Systemic work-up if Zoster in someone < 40
    - Can get shingles anywhere on the body
    - Herpes Zoster Ophthalmicus (HZO)
        - Shingles involving the dermatome supplied by the ophthalmic division of the CNV (trigeminal)
            - 15% of zoster cases

99

Herpes Zoster

- Symptoms:
    - Generalized malaise, tiredness, fever
    - Headache, tenderness, paresthesias (tingling), and pain on one side of the scalp
        - Will often precede rash
    - Rash on one side of the forehead
    - Red eye
    - Eye pain & light sensitivity



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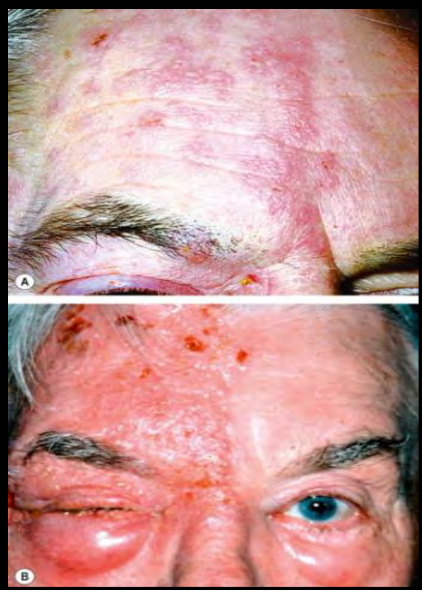
Herpes Zoster

- Signs:
  - Maculopapular rash -> vesicles -> pustules -> crusting on the forehead
  - Respects the midline***
  - Hutchinson sign
    - rash on the tip or side of the nose***
  - Classically does not involve the lower lid
  - Numerous other ocular signs



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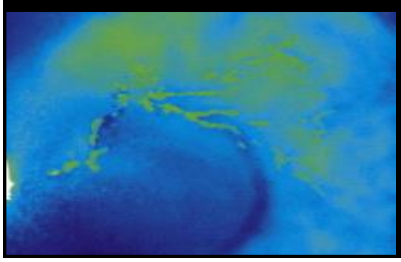
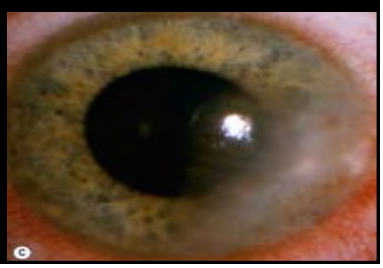
Herpes Zoster

- Other Eye Complications (Acute):
  - Anterior uveitis (most common ocular manifestation)
  - Acute epithelial keratitis (pseudodendrites)
  - Conjunctivitis
  - Stromal (interstitial) interstitial keratitis
  - Endotheliitis (disciform keratitis)
  - Neurotrophic keratitis





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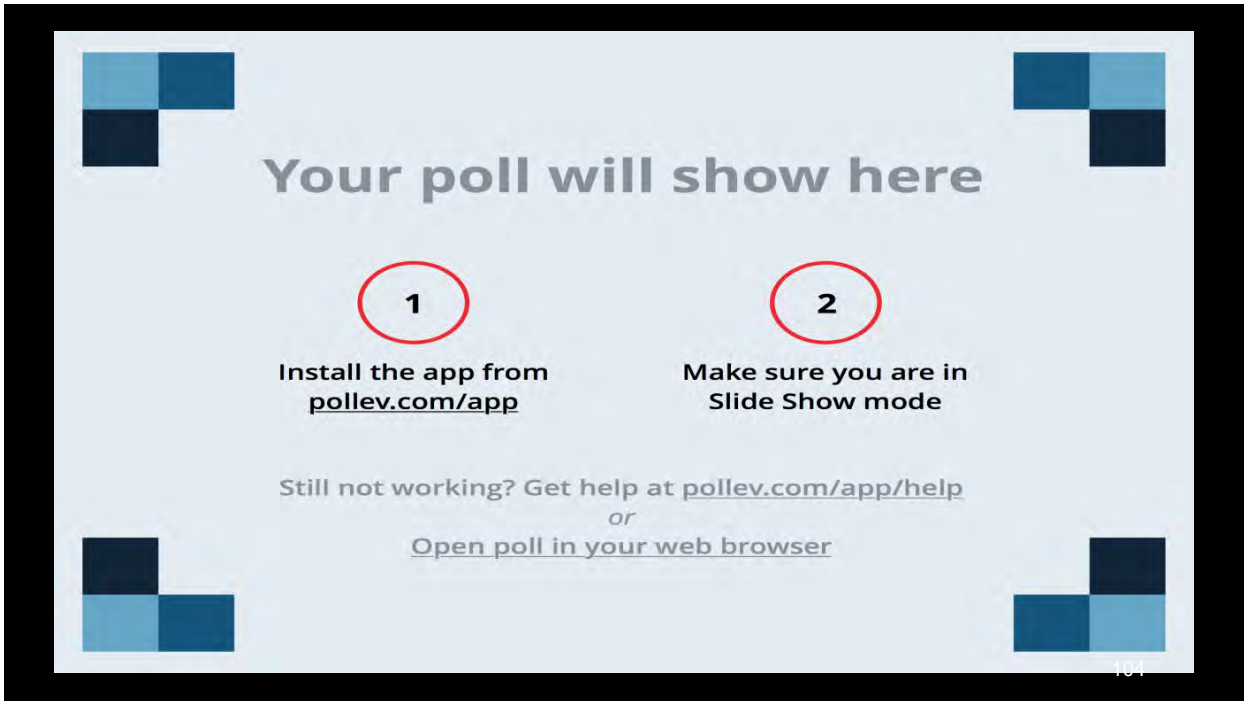

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Herpes Zoster

- Associated factors include increasing age, immune deficiency and stress.
- Only people who had natural infection with wild-type VZV or had varicella vaccination can develop herpes zoster.
- Children who get the varicella vaccine appear to have a lower risk of herpes zoster compared with people who were infected with wild-type VZV.

105

Herpes Zoster

- A person's risk for herpes zoster increases sharply after 50 years of age.
- Almost 1 out of 3 people in the United States will develop herpes zoster during their lifetime.
- A person's risk of developing post-herpetic neuralgia also increases sharply with age.

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Herpes Zoster

- Management includes:
  - oral antivirals:
    - 800mg acyclovir 5x/day
    - valacyclovir (Valtrex) 1g TID,
    - famciclovir (Famvir) 500 mg TID
  - effectiveness of therapy is best started within 72 hours
  - oral steroids (clinical trials show variable results but often prescribed with antiviral to reduce pain)
  - management of pain (capsaicin, tricyclic antidepressants, gabapentin).
  - If ocular complications, consider topical steroids (Pred Forte QID).

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Oxervate^{R}

- August 22nd, 2018 the FDA approved Oxervate for the treatment of neurotrophic keratitis (first ever approved treatment)
- Oxervate^{R} (cenegermin): recombinant human nerve growth factor
- The safety and efficacy of the topical eye drop was studied in 151 patients with neurotrophic keratitis in two 8-week, randomized, controlled, multi-center, double masked studies. In both studies, patients were given the drops six times daily in the affected eyes for 8 weeks. Across both studies, 70% of patients treated with Oxervate experienced complete corneal healing in 8 weeks compared with 28% of patients who were not treated with the active ingredient, cenegermin

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NEW!! Shingrix HZ Vaccine

- Approved in US/Canada as of October 2017
- non-live antigen, to trigger a targeted immune response, with a specifically designed adjuvant to enhance this response and help address the natural age-related decline of the immune system
- Shingrix is 97% effective against shingles for people between the ages of 50 and 69 and 91% effective for people 70 or older.
- It is 91% effective against postherpetic neuralgia for people 50 and older.
- These rates are based on evidence presented to the committee from clinical trials with over 38,000 total participants.

110

NEW!! Shingrix HZ Vaccine

- recommended for healthy adults aged 50 years and older to prevent shingles and related complications
- recommended for adults who previously received the current shingles vaccine (Zostavax®) to prevent shingles and related complications
- the preferred vaccine for preventing shingles and related complications

111

Legends of the Posterior Segment

Presented by Blair Lonsberry, OD, MS, MEd

Marshall B.
KETCHUM UNIVERSITY
Southern California College of Optometry
Department of Continuing Education
ketchum.edu/ce | ce@ketchum.edu

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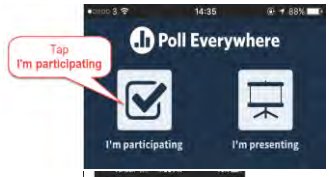

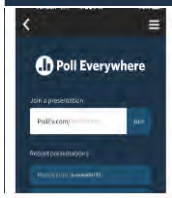

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Disclosures

Paid consultant for:

Maculogix: Honoraria-Advisory Board

Sun Pharmaceuticals: Advisory Board/Speakers Bureau

3

Case History

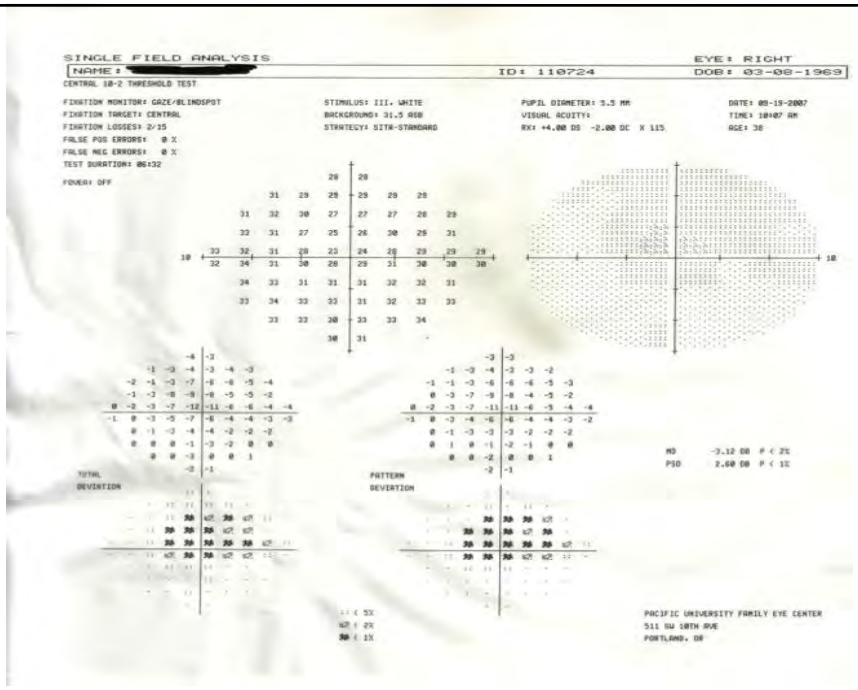
- 38 black male, complaining that the vision in his right eye is blurry.
  - Got the current Rx 3 weeks previously, and started out good but in last couple of days OD vision has become blurry
- Medical Hx: no current health concerns and no medications

4

Entrance Skills

- Va's: OD: 20/25, OS: 20/20
- Pupils: PERRL
- CVF: full to finger count
- EOM's: FROM
- Amsler: central metamorphopsia OD
- HVF: 10-2 (see VF)

5



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Which of the following OCT's goes with this patient?

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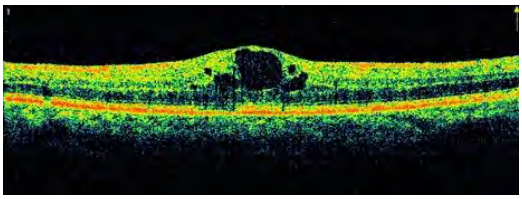

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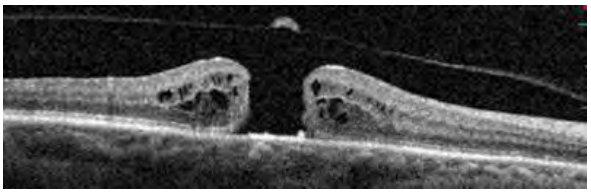

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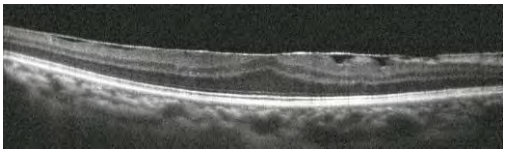

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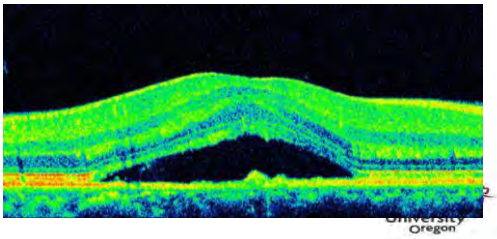

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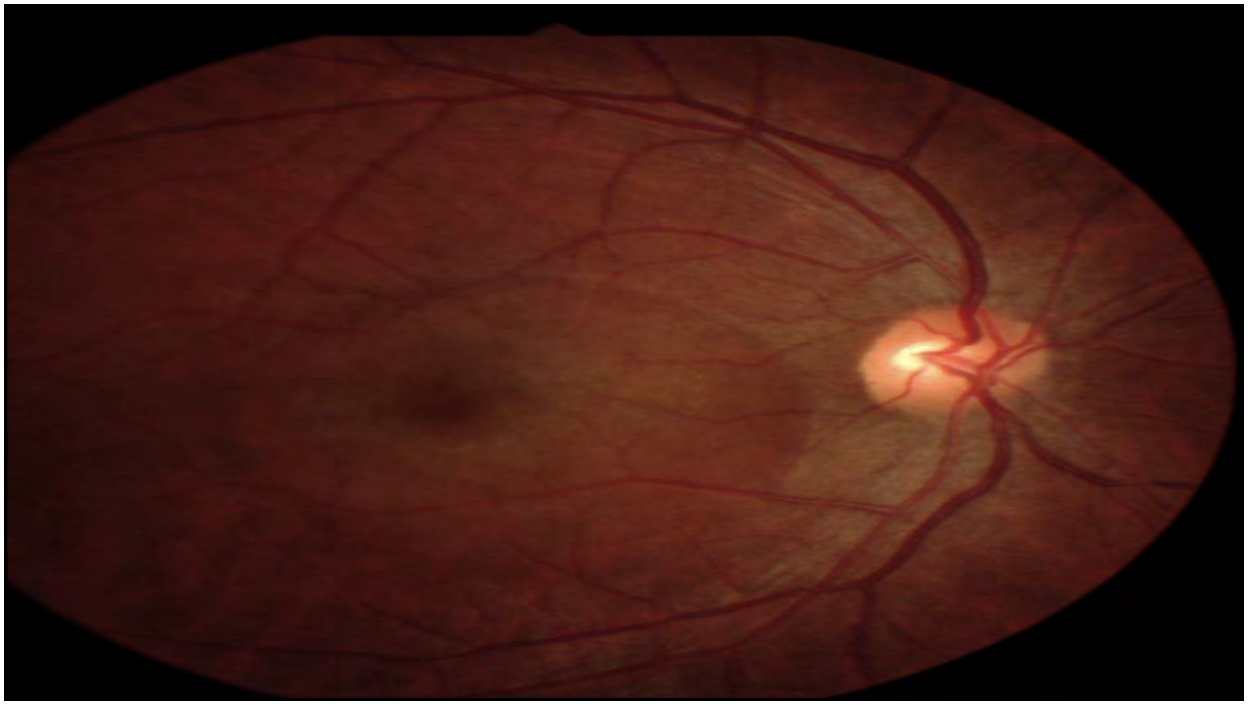

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Central Serous Retinopathy

- an exudative chorioretinopathy characterized by an exudative neurosensory retinal detachment with or without an associated detachment of the retinal pigment epithelium (RPE)
- Patients experience blurry vision, metamorphopsia and micropsia
- individuals between 20 and 50 years of age

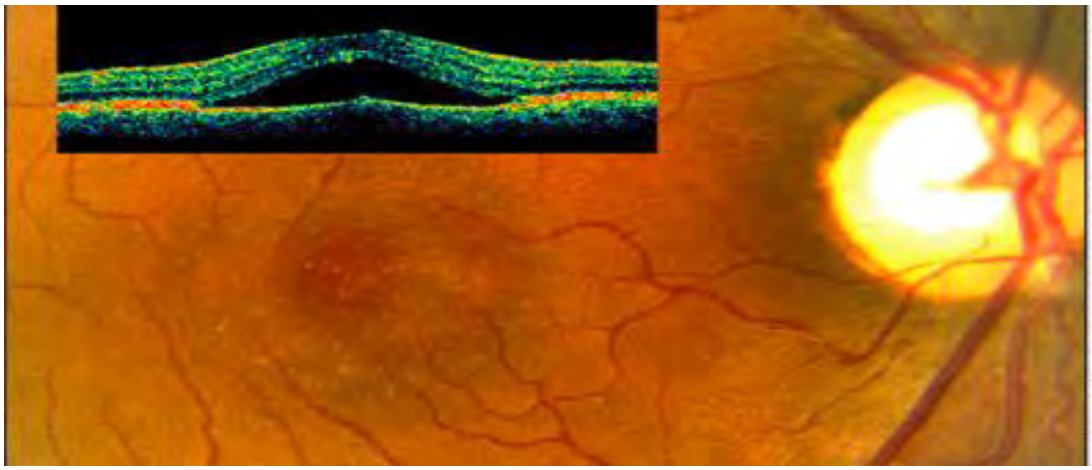
11

Central Serous Retinopathy

- incidence in men vs women is approximately 6:1
- associated with stress and stress hormones (ie, corticosteroids and epinephrine);
- individuals with a "type A personality" who are under stress
- recurrence in the ipsilateral eye is approximately 30% and CSR in the fellow eye was 32%

12

Central Serous Retinopathy



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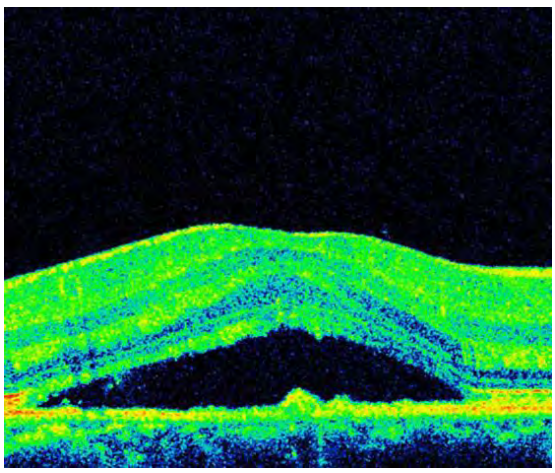
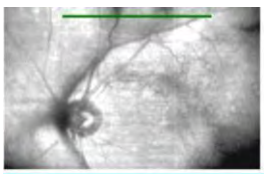
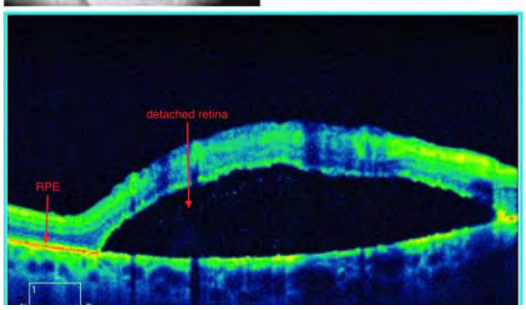
CSR versus RD







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Central Serous Retinopathy

- 80% to 90% of cases resolve spontaneously within 3 months
- Treatment options:
  - include laser photocoagulation,
  - "safety-enhanced" PDT,
  - Acetazolamide reduced the time for subjective and objective CSR resolution, but it had no effect on final VA or recurrence rate. Most patients in the experimental group in that study had side effects from the acetazolamide, including paresthesias, nervousness, and gastric upset

15

Central Serous Retinopathy

- Treatment options:
  - Topical NSAIDs:
    - Conflicting reports
    - Michael Singer, MD, from Medical Center Ophthalmology in San Antonio reported an increase in resolution time by 50%
    - PRADEEP VENKATESH, MD reports that NSAIDS treatment could possibly slow down or cause a rebound CSR

16

Latest Treatment Under Investigation

- Eplerenone is a mineralocorticoid antagonist receptor currently used in the treatment of hypertension and congestive heart failure.
- Literature has demonstrated improved resolution of CSR with no serious adverse effects.
- Several randomized clinical trials are currently underway.

17

Case

- 50 YR WM
- POHx: had cataract surgery in his left eye at age 25 secondary to trauma to the eye,
  - Has a mid-dilated pupil post trauma
- PMHx: no known health problems and no medications
- VA: 6/6 (20/20) OD, OS

18

Health Assessment

- SLE:
  - OD unremarkable
  - OS: mid-dilated pupil with sluggish response to light
    - PCIOL well centered and no haze
- IOP: OD 12 and OS 26 mm Hg (TAG)
    - NCT OS (31 and 23)
    - Second visit: OD: 13 and OS: 27

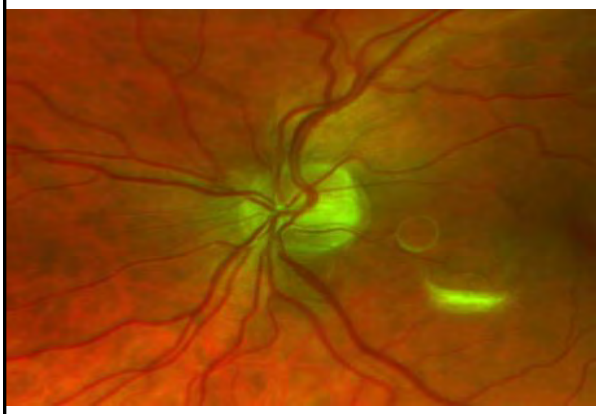
19

Health Assessment

- Gonioscopy:
  - OD: unremarkable
  - OS: see photo

20

Optic Nerves



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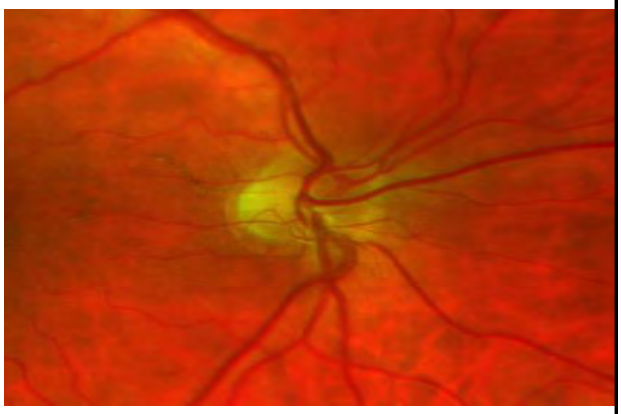

OD

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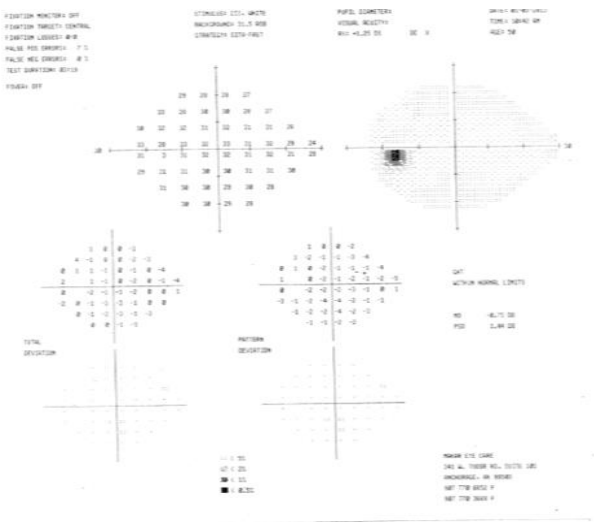
Visual Fields



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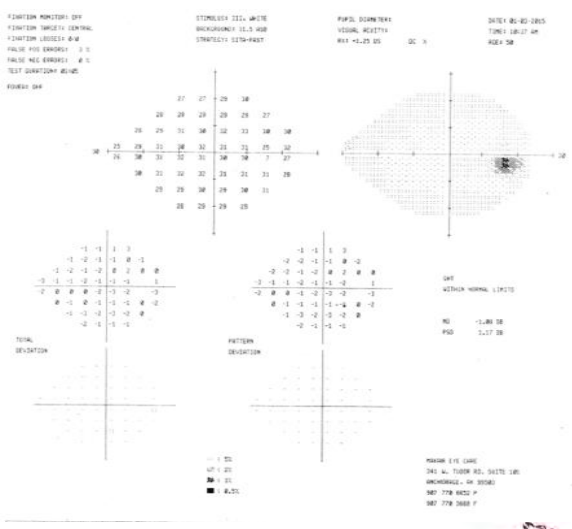

OD

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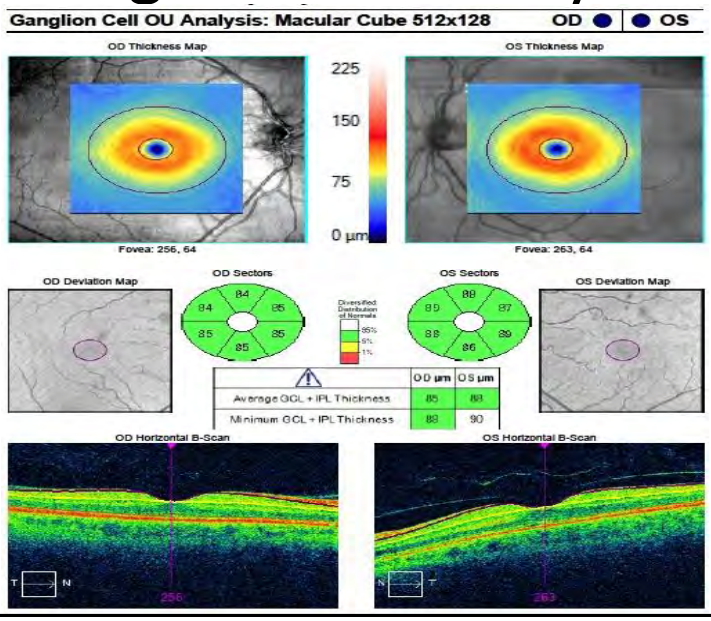
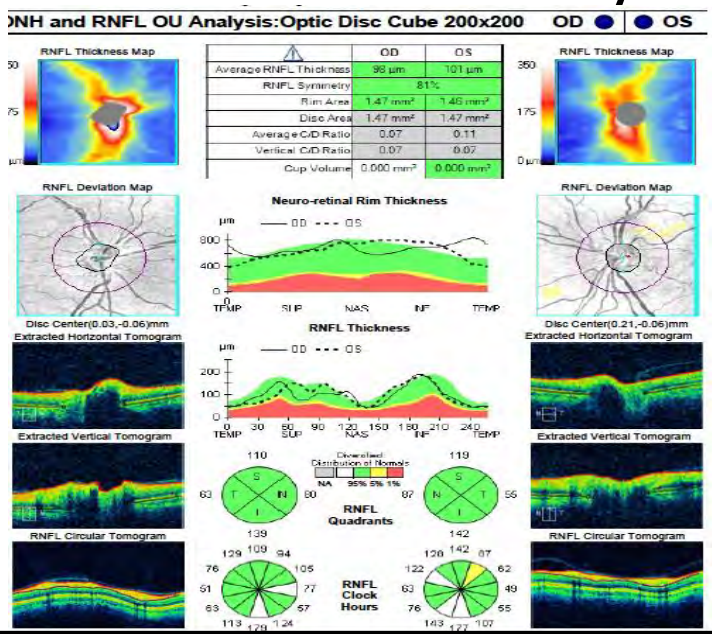
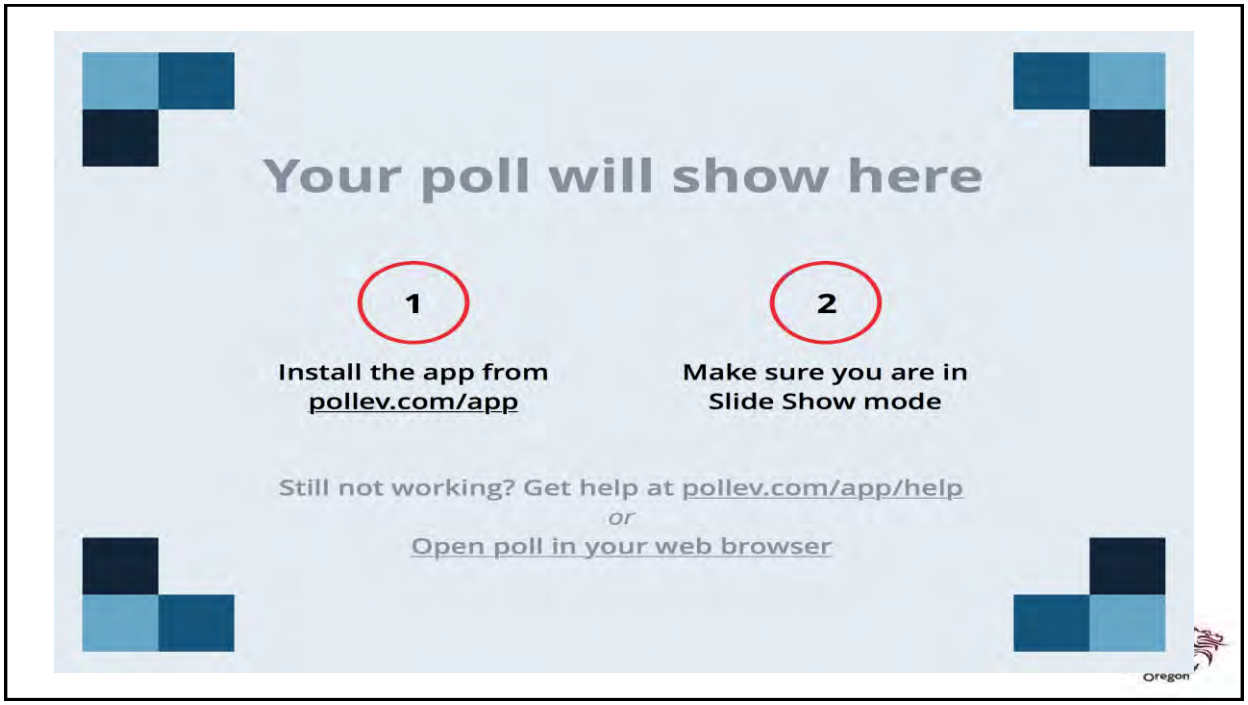
Ganglion Cell Analysis



RNFL and ONH Analysis

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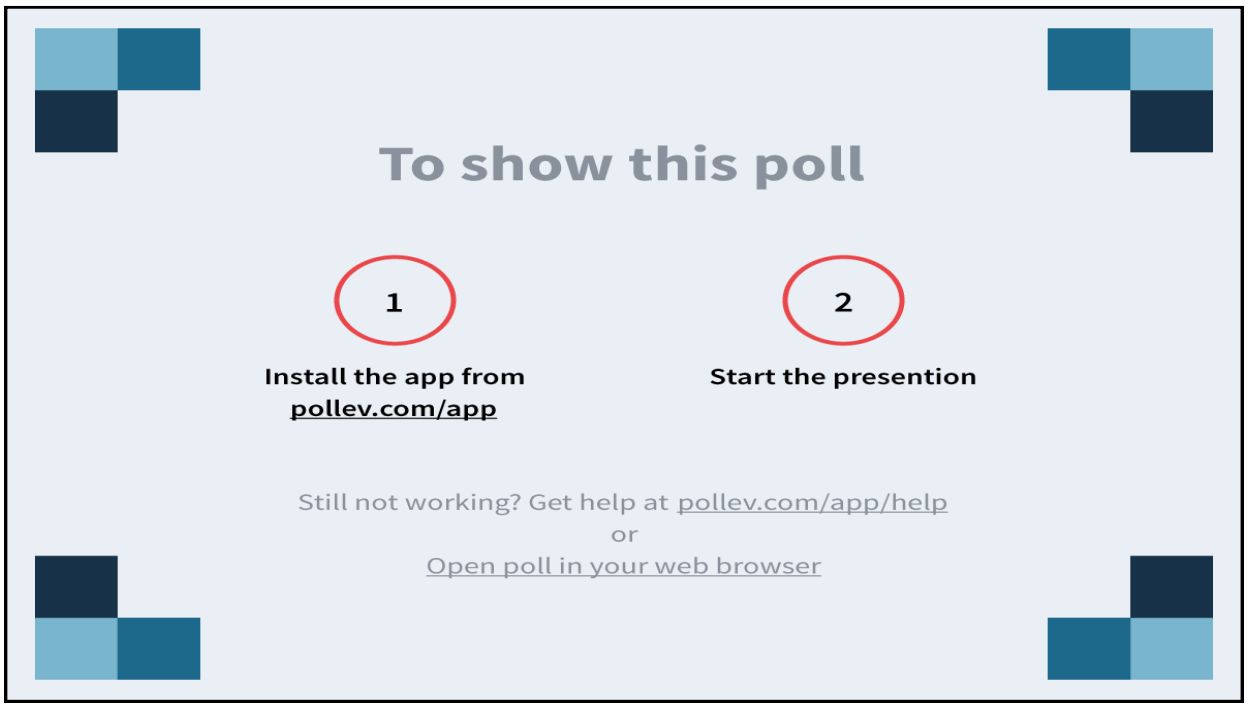
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Patient Update

- Patient was seen a year later
- Latanoprost qhs (remembers 5 days out of week)
- IOP's: OD: 14 and OS: 13 mm Hg
- No change in OCT

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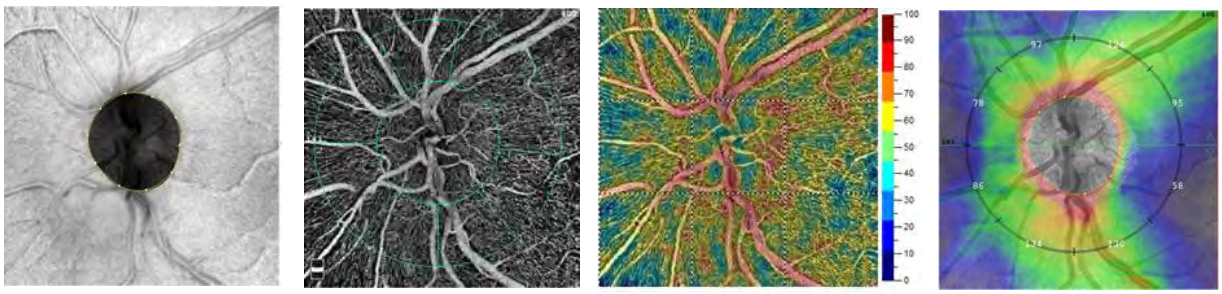
The Future of Glaucoma Diagnosis and Management???

29

Normal Eye

OCT En Face | *RPC* | *RPC Vessel density* | *RNFL Thickness*

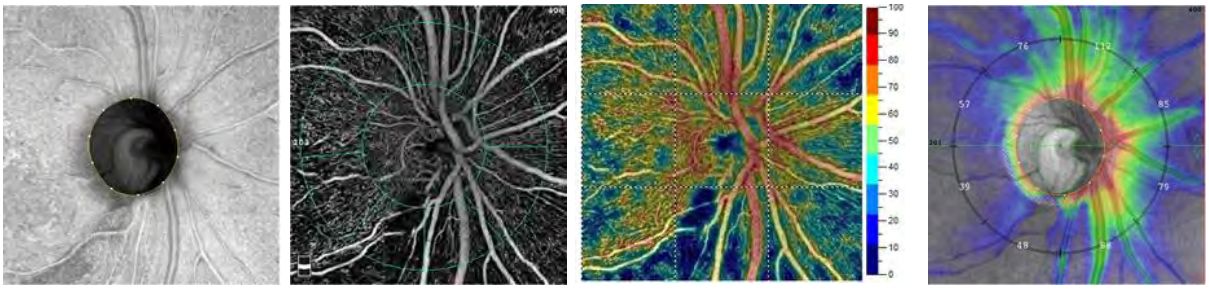


Images and data courtesy of Robert Weinreb, MD and Linda Zangwill, PhD, UC San Diego

30

Moderate Glaucoma

OCT En Face | *RPC* | *RPC Vessel density* | *RNFL Thickness*



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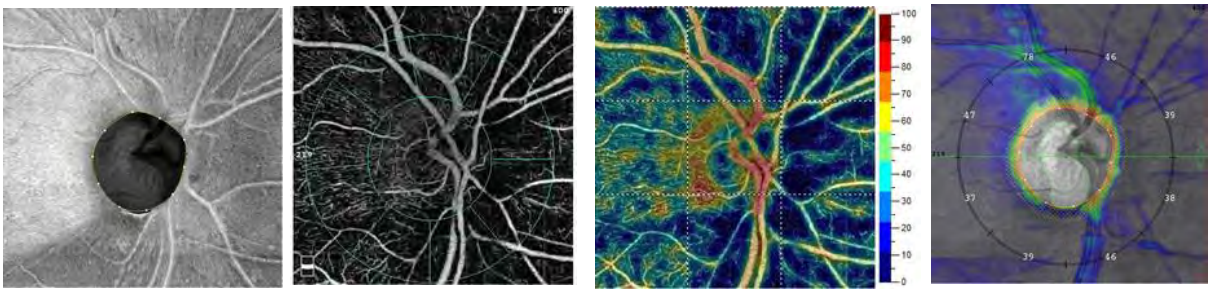
Advanced Glaucoma

OCT En Face | *RPC* | *RPC Vessel density* | *RNFL Thickness*



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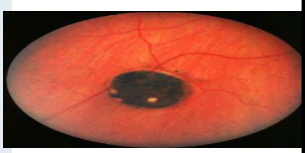

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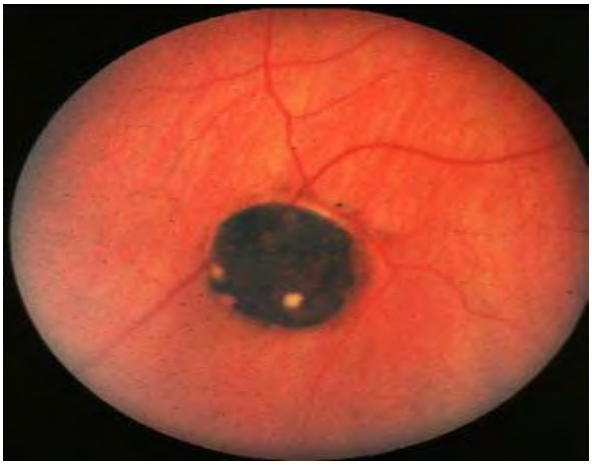
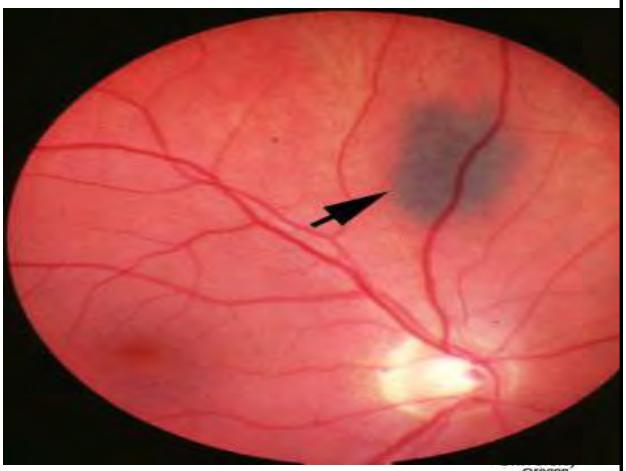
CHRPE vs Nevus





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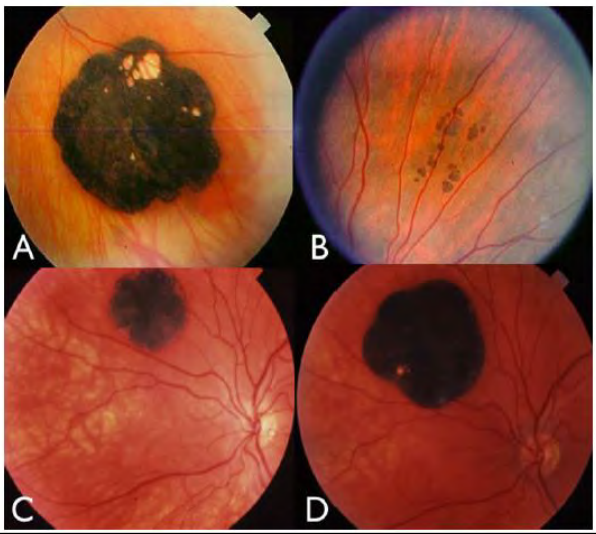
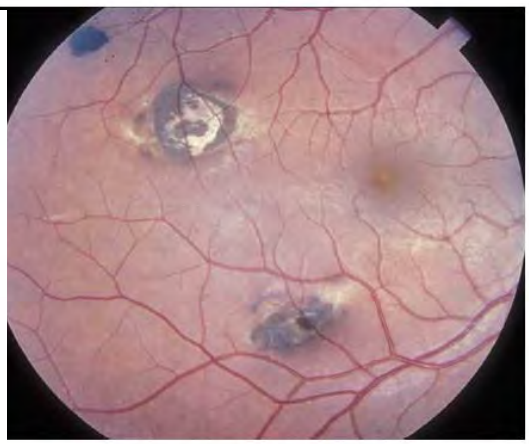
CHRPE vs Hamartomas





URE 4. Retinal pigment epithelial hamartomas (pigmented ocular ndus lesions) associated with familial adenomatous polyposis ardner syndrome).

36

37

Nevi Trivia

- 31% of choroidal nevi show slight enlargement over time without the transformation to a melanoma (Ophthalmology 2011)
- The prevalence of choroidal nevi in the white U.S. population ranges from 4.6% to 7.9%
  - If it is assumed that all choroidal melanomas arise from preexisting nevi, then the published data suggest a low rate (1/8845) of malignant transformation of a choroidal nevus in the U.S. white population. (Ophthalmology 2005)
- Choroidal melanoma risk for metastasis, ranging from 16% to 53% (at 5 years of follow-up) depending on the size of the tumor at the time of diagnosis. (Arch Ophthalmol 1992)

38

TFSOM—"To Find Small Ocular Melanoma"

Thickness: lesions >2mm
Fluid: any subretinal fluid (suggestive of serous retinal detachment)
Symptoms: photopsia, vision loss
Orange pigment overlying the lesion
Margin touching optic nerve head (<3mm)

- *None* of these factors = 3% risk of a nevus converting to melanoma in five years.
  One of these factors = 8% risk of conversion in five years. *Two* or more factors = 50% risk of conversion in five years. For any changes noted during the course of follow-up, refer the patient to a retinal practice or an ocular oncology service.

39

TFSOM-UHHD: "To Find Small Ocular Melanoma Using Helpful Hints Daily"

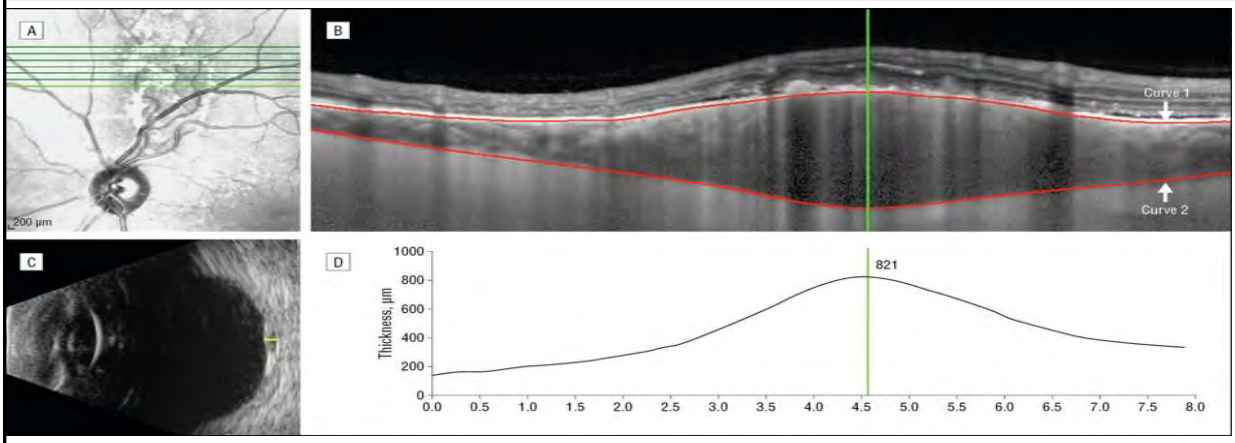
Thickness: lesions >2mm
Fluid: subretinal fluid
Symptoms: photopsia, vision loss
Orange pigment overlying the lesion
Margin touching optic nerve head (<3mm)
Ultrasound **H**ollowness
Halo absence
Drusen absence

- Choroidal nevi showing no features should be initially monitored twice yearly and followed up annually
- 1 or 2 features should be monitored every 4 to 6 months.
- Nevi with 3 or more features should be evaluated at an experienced center for management alternatives and possible treatment owing to the high risk of ultimate growth

40

The JAMA Network

From: **Enhanced Depth Imaging Optical Coherence Tomography of Small Choroidal Melanoma: Comparison With Choroidal Nevus**
Arch Ophthalmol. 2012;130(7):850-856. doi:10.1001/archophthalmol.2012.1135



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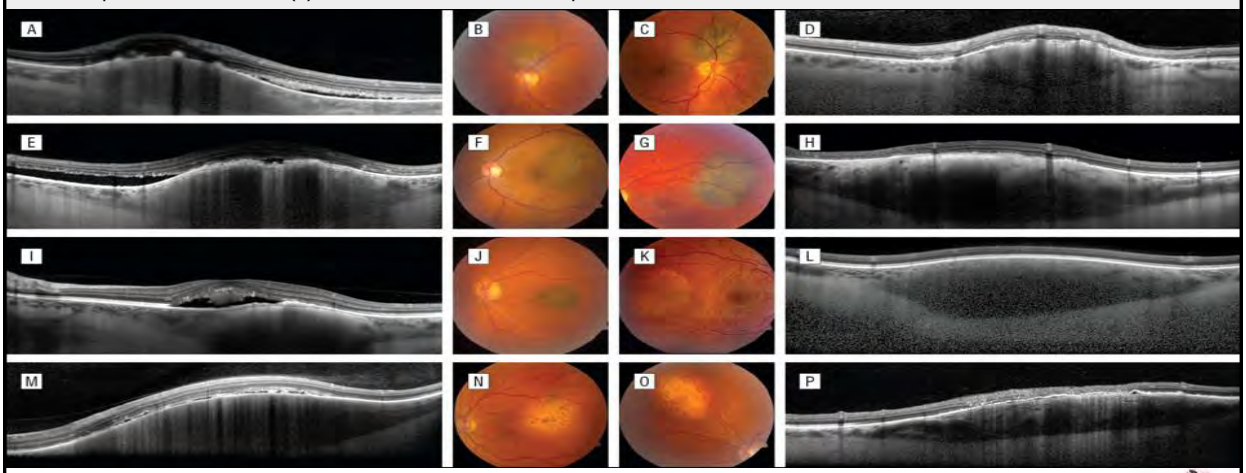
The JAMA Network

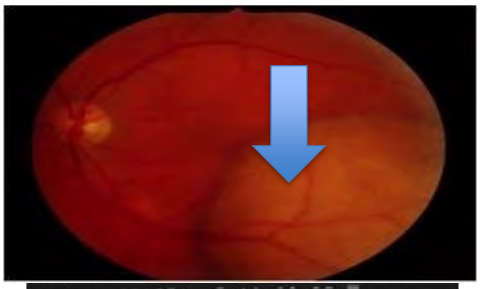
From: **Enhanced Depth Imaging Optical Coherence Tomography of Small Choroidal Melanoma: Comparison With Choroidal Nevus**
Arch Ophthalmol. 2012;130(7):850-856. doi:10.1001/archophthalmol.2012.1135

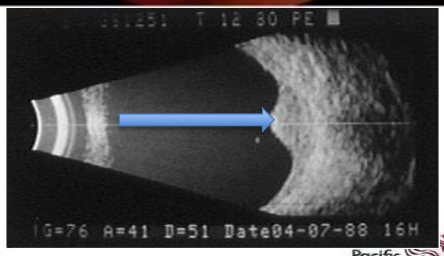


42

Case

- 65 yr old white male
  - Notices spot in vision in his left eye
  - Diabetes for 15 years
- Vision:20/20 (6/6) and 20/40 (6/12)
- Dilated exam:
  - Large lesion noted in left eye (not noted in exam 6 months previously
  - See photo and B-scan





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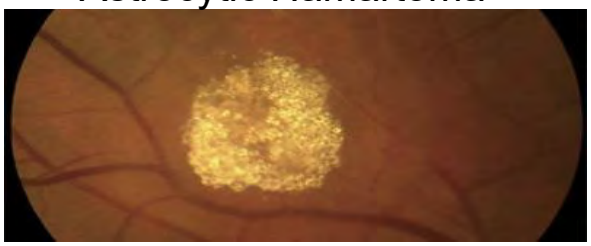
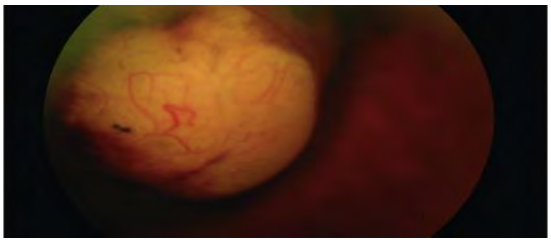
Ocular Tumors

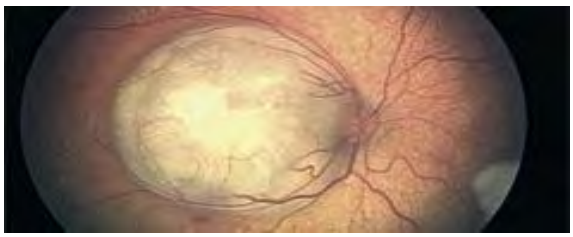
Astrocytic Hamartoma



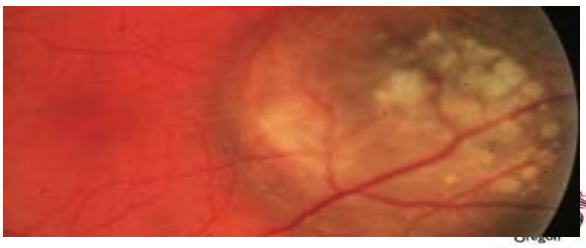
Amelanotic Melanoma



Retinoblastoma



Metastatic Choroidal Tumor



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Choroidal Melanoma Metastases

- 80 to 90% of metastases from uveal melanoma occurred in the liver, less common sites being the skin and lung.
  - Gragoudas ES, Seddon JM, Egan KM, et al. Long-term results of proton beam irradiated uveal melanomas. Ophthalmology. 1987;94:349–53.

47

Melanoma and Mortality

- Tumor Size:
  - 5-year mortality after enucleation:
    - 16% for small melanoma,
    - 32% for medium melanoma, and
    - 53% for large melanoma.
  - the prognostic importance of tumor size:
    - each 1-mm increase in melanoma thickness adds approximately 5% increased risk for metastatic disease at 10 years
- Tumor genetics:
  - Chromosome monosomy 3 (apprx 50% of patients)
    - 50% of them develop metastasis within 5 years of diagnosis
    - 70% mortality within 4 years of ocular treatment
    - one of the most important independent risk factors of poor survival

48

New Treatment for Choroidal Melanoma

- light-activated AU-011 agent represents the first potential new therapy for choroidal melanoma
- AU-011 is a viral nanoparticle conjugate delivered by intravitreal injection, which targets tumor cells in the choroid and then is activated by ophthalmic laser to disrupt the tumor cell membrane, leading to necrosis.
- Two year prospective study complete

49

New Treatment for Choroidal Melanoma

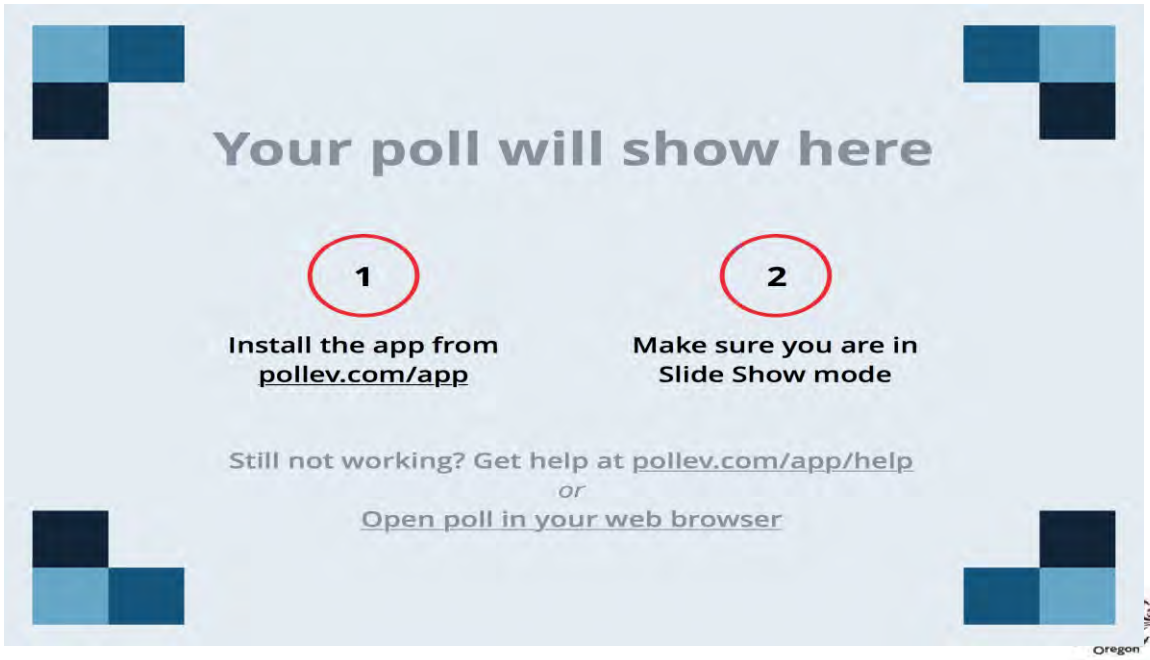
- Total cohort of 36
  - 12 patients in the single-dose cohort demonstrated a modest tumor control rate of 67% with a follow-up period of 9 to 24 months, and
  - 22 patients in the multiple-dose cohort (2 patients lost to follow-up) demonstrated a modest tumor control rate of 77% with a follow-up period of 0.5 to 18 months.
  - Subjects treated with the maximum safe and tolerated dose (80 µg with 2 lasers) with 0.5 months to 6 months follow-up have a tumor control rate of 92% (13 of 14 subjects).
  - Vision was preserved in all patients at 3 months or longer up to 24 months.

50

Case

- 65 year old Caucasian patient presents with sudden onset loss/blurring of vision in the right eye
- PMHx: HTN for 15 years, takes "water pill"
- VA's: 20/60 OD, 20/25 OS
- Pupils: PERRL –APD
- CVF: Inferior defect right eye, no defects noted in the left eye

51



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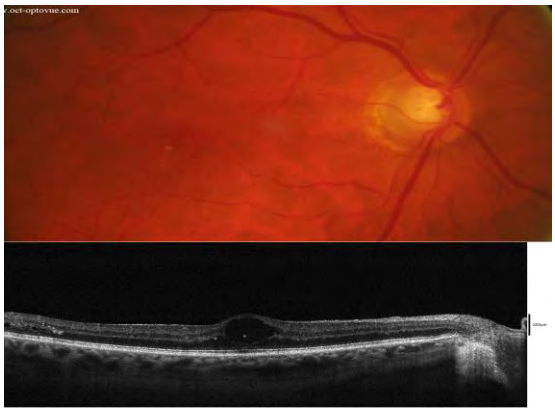
Vision Loss Without Pain: Diabetes/Diabetic Retinopathy

- Microvascular complications resulting in capillary closure & abnormal permeability
- S&S include;
  - blurring of vision (maculopathy and refractive error shifts),
  - sudden drop in vision (vitreous heme),
  - dot and blot hemes,
  - exudate,
  - cotton wool spots,
  - neovascularization (iris, retina and disc)

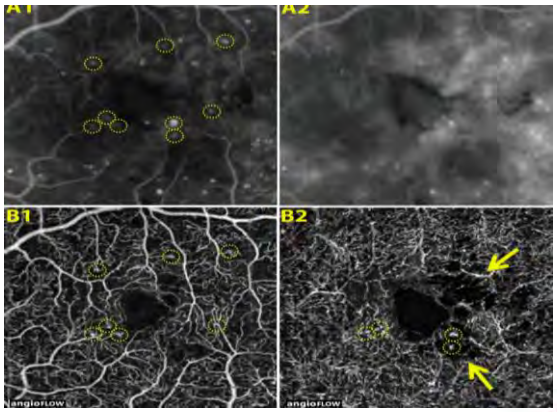
53

Diabetic Retinopathy

CSME (DME)



CSME (DME) OCTA



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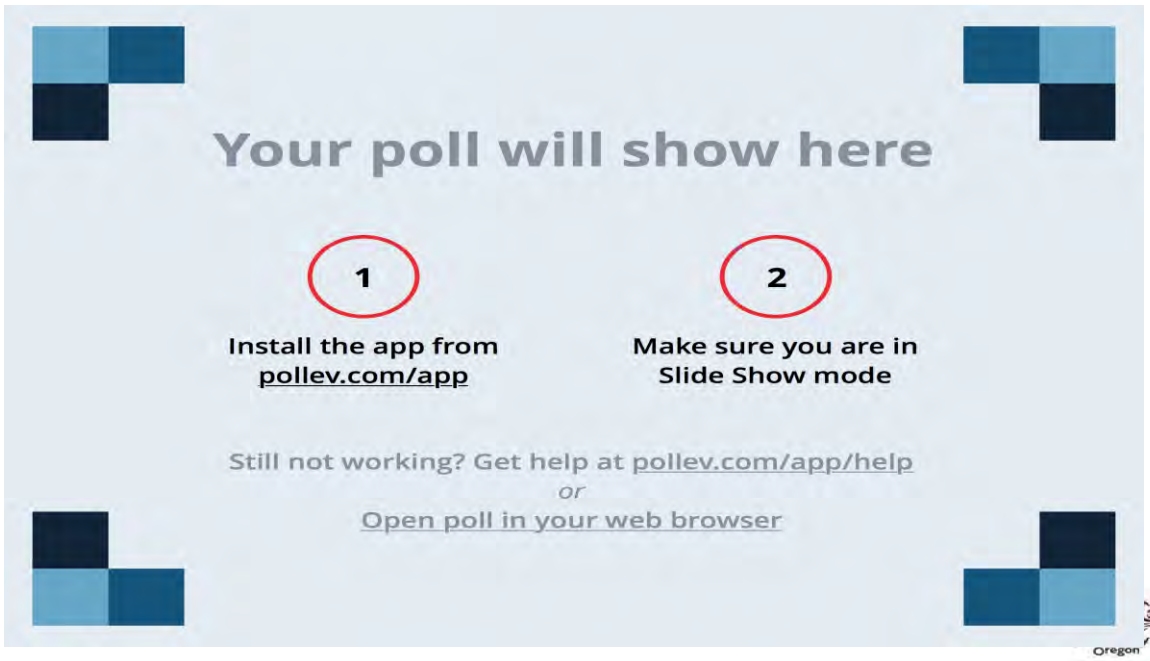

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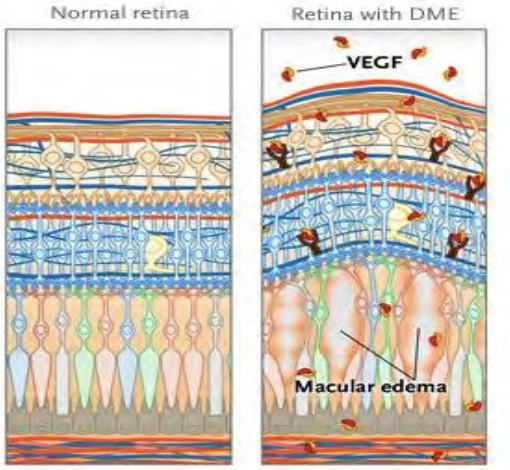
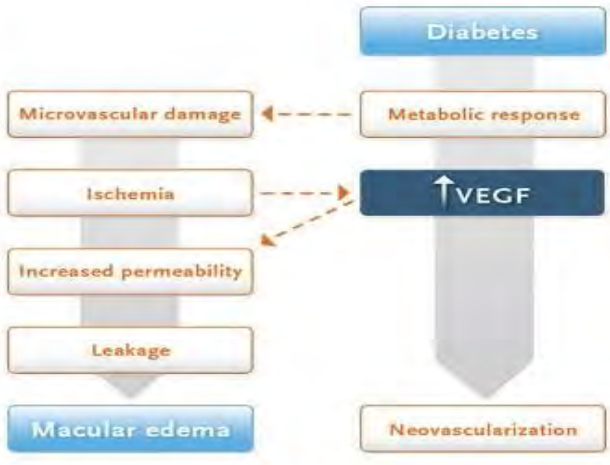
VEGF and DME



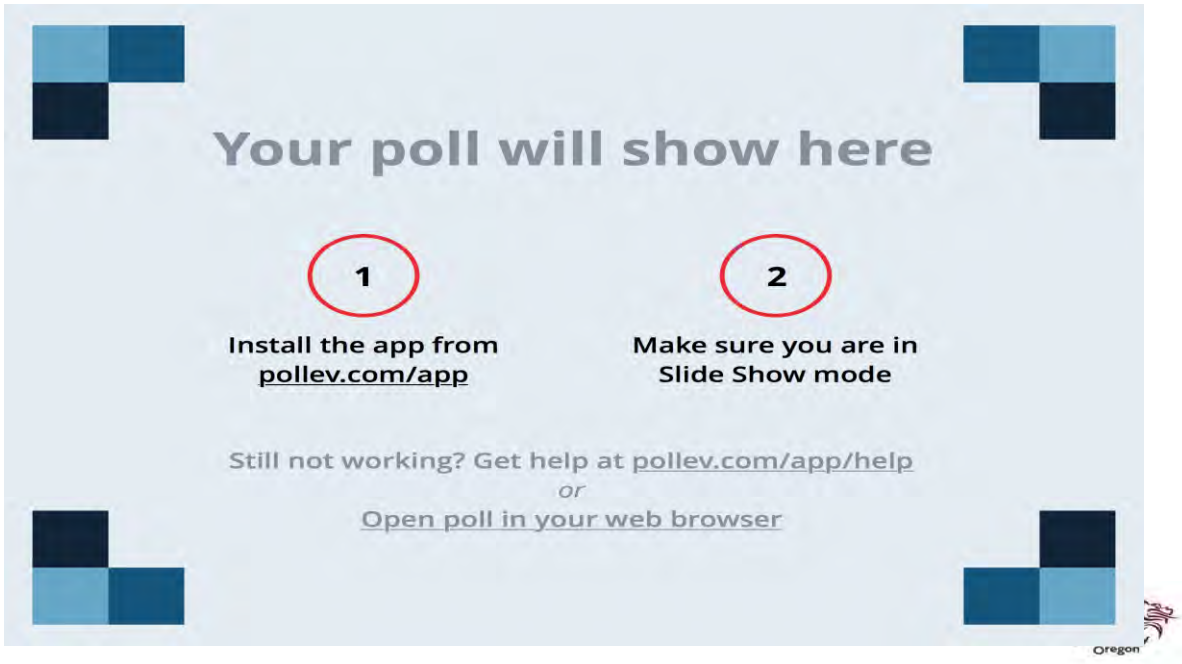


56

Vision Loss Without Pain: Vein Occlusion

- Associated with:
  - hypertension,
  - coronary artery disease,
  - DM and
  - peripheral vascular disease.
- Usually seen in elderly patients (60-70), slight male and hyperopic predilection.
- Second most common vascular disease after diabetic retinopathy.

57



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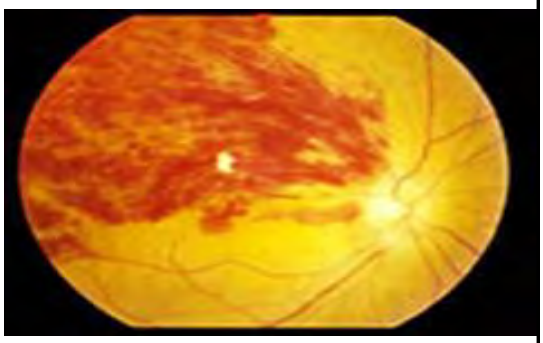
Branch Retinal Vein Occlusion: Signs/Symptoms

- BRVO: sudden, painless, visual field defect.
  - patients may have normal vision.
  - quadrantic VF defect,
  - dilated tortuous retinal veins with superficial hemes and CWS
  - typically occurs at A/V crossing (sup/temp)



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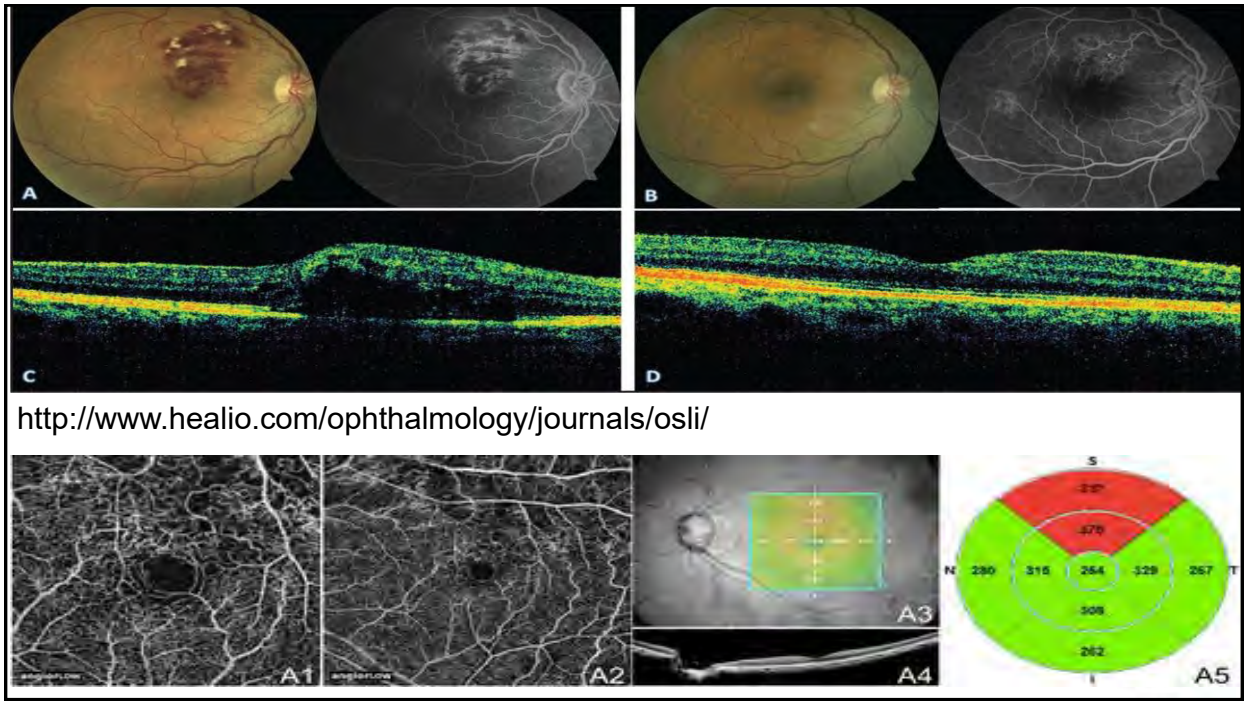
BRVO

- BRVO more common than CRVO and has more favorable prognosis
  - Overall 50-60% of BRVO patients will maintain VA of 20/40 or better
- Visual loss results from:
  - Macular edema
  - Foveal hemorrhage
  - Vitreous heme
  - Epiretinal membrane
  - RD
  - Macular ischemia
  - Neovascularization complications

60



http://www.healio.com/ophthalmology/journals/osli/

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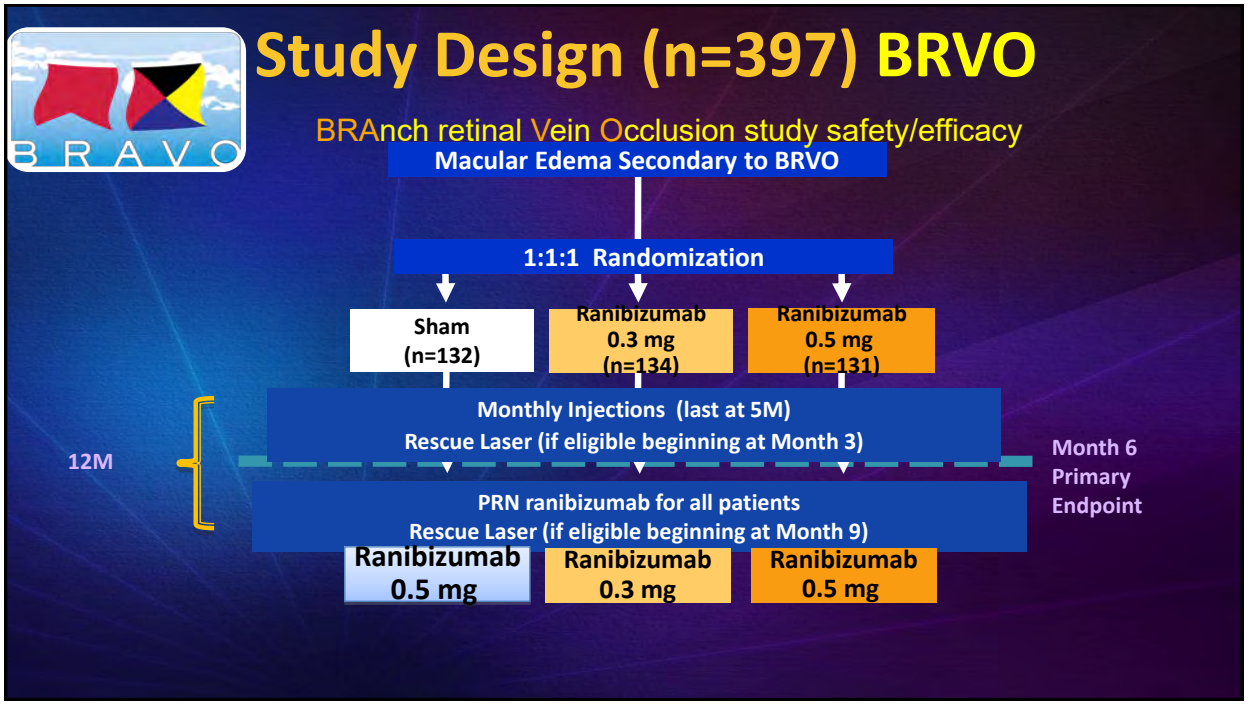
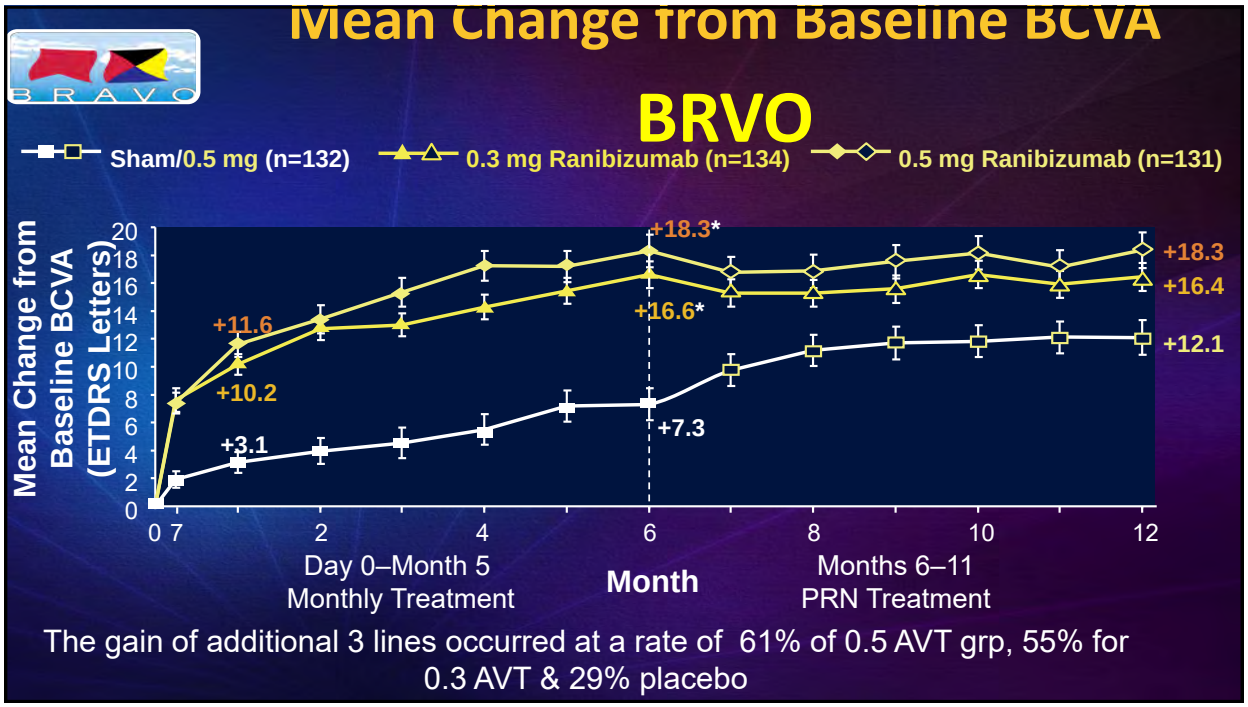

Study Design (n=397) BRVO
BRAnch retinal Vein Occlusion study safety/efficacy
Macular Edema Secondary to BRVO
1:1:1 Randomization
Sham (n=132)
Ranibizumab 0.3 mg (n=134)
Ranibizumab 0.5 mg (n=131)
Monthly Injections (last at 5M)
Rescue Laser (if eligible beginning at Month 3)
12M
Month 6 Primary Endpoint
PRN ranibizumab for all patients
Rescue Laser (if eligible beginning at Month 9)
Ranibizumab 0.5 mg
Ranibizumab 0.3 mg
Ranibizumab 0.5 mg

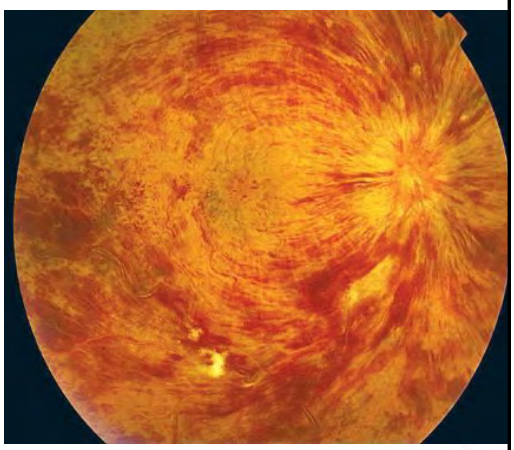
63


Mean Change from Baseline BCVA
BRVO
Sham/0.5 mg (n=132)
0.3 mg Ranibizumab (n=134)
0.5 mg Ranibizumab (n=131)
Mean Change from Baseline BCVA (ETDRS Letters)
+18.3*
+16.6*
+11.6
+10.2
+3.1
+7.3
+18.3
+16.4
+12.1
Day 0–Month 5 Monthly Treatment
Month
Months 6–11 PRN Treatment
The gain of additional 3 lines occurred at a rate of 61% of 0.5 AVT grp, 55% for 0.3 AVT & 29% placebo

64

Central Retinal Vein Occlusion: Signs/Symptoms

- CRVO: thrombus occurring at lamina is classical theory but new evidence indicates that the occlusion is typically in the optic nerve posterior to the lamina cribrosa
  - decreased VA ranging from near normal to hand motion with majority 20/200 range
  - dilated tortuous vessels, with numerous retinal hemes and CWS



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Central Retinal Vein Occlusion

- Visual morbidity and blindness are primarily from:
  - persistent macular edema,
  - macular ischemia and
  - neovascular glaucoma

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Central Retinal Vein Occlusion

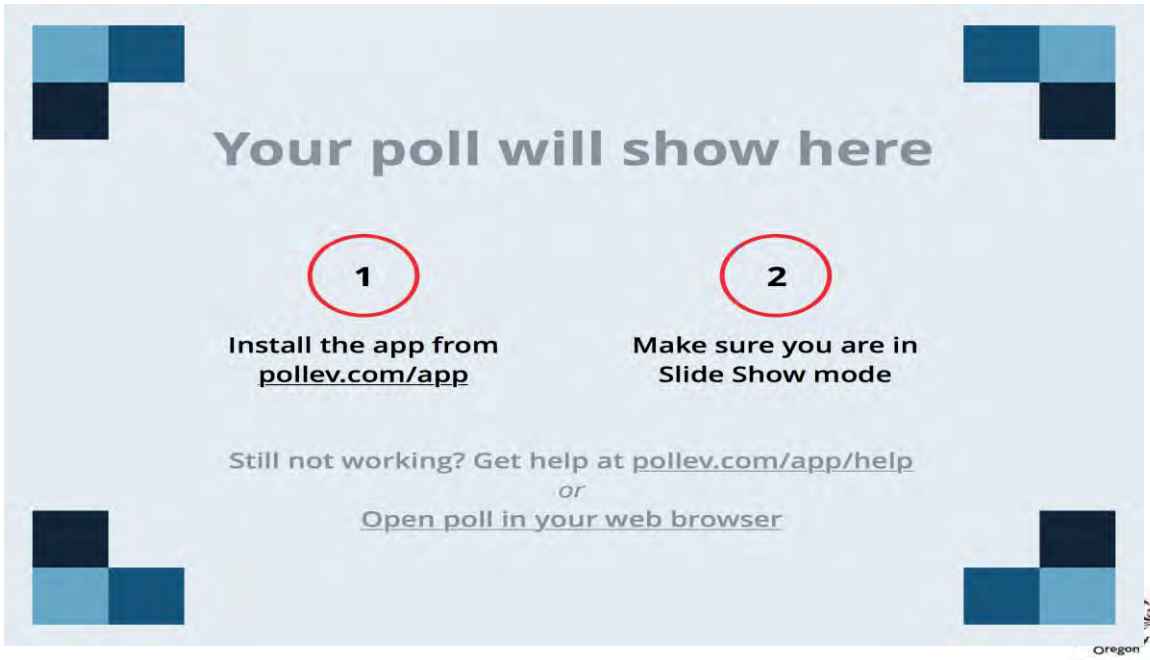
- CRVO's can be ischemic or non.
  - Classical definition of ischemic is 10-disc area of non-perfusion found on angiography
  - RAPD and ERG maybe better predictor
  - VA's typically worse in ischemic
  - Increased number of cotton wool spots with decreased VA maybe predictive

68

Central Retinal Vein Occlusion

- Ischemic CRVO may lead to iris neovascularization and neovascular glaucoma
  - Estimated apprx 20% of CRVO's are ischemic with 45% of those developing neo
- Regular examinations (1-2 wks) to monitor for ischemia or neo development
  - should include gonio as angle neo can precede iris rubeosis

69



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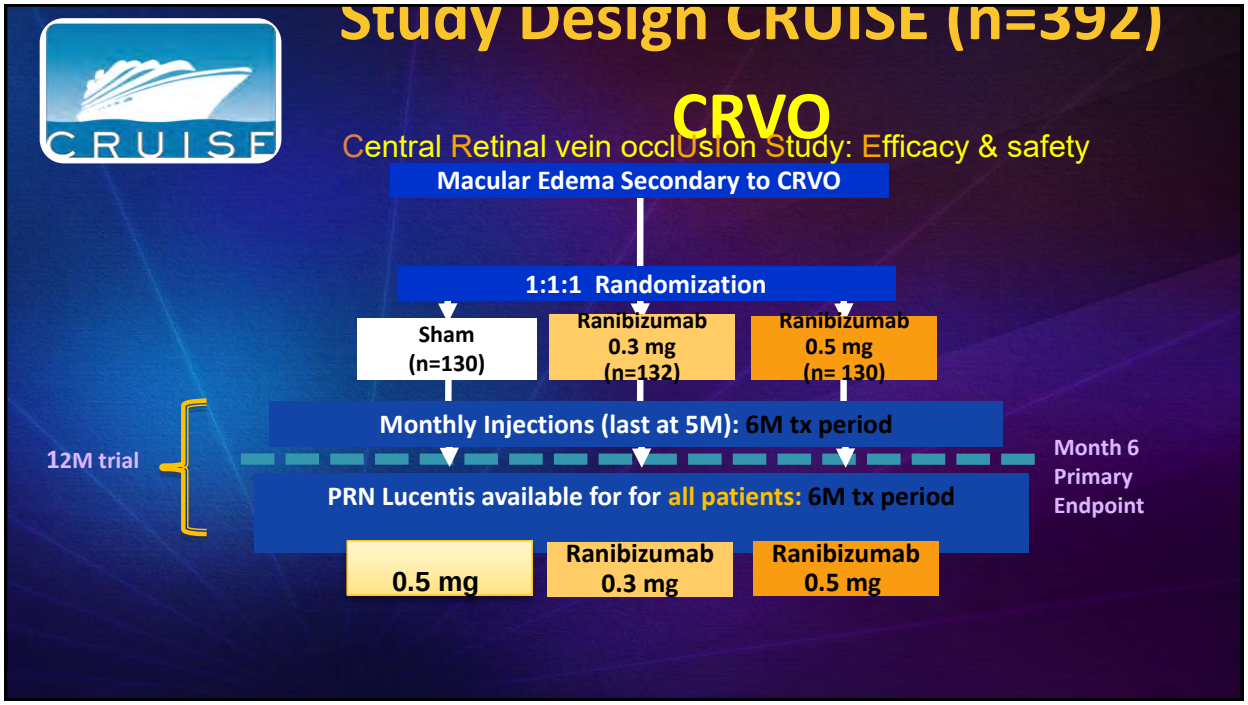
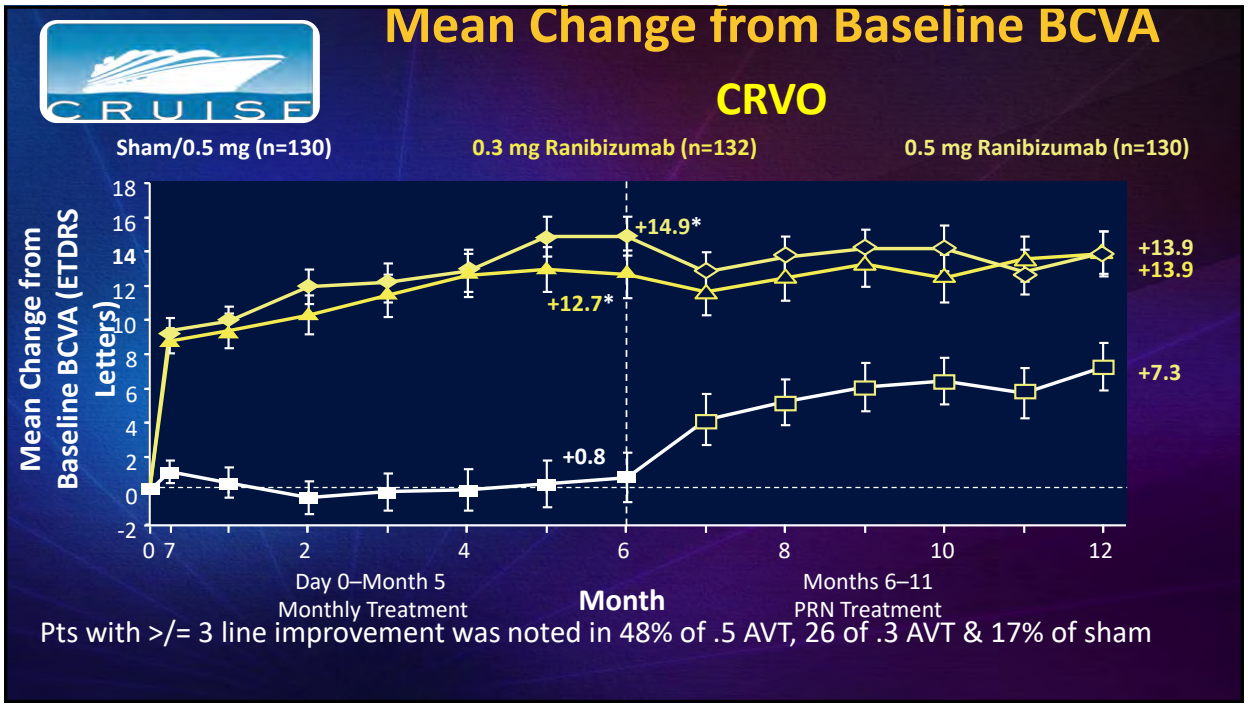

Study Design CRUISE (n=392)
CRVO
Central Retinal vein occlUsion Study: Efficacy & safety
Macular Edema Secondary to CRVO
1:1:1 Randomization
Sham (n=130)
Ranibizumab 0.3 mg (n=132)
Ranibizumab 0.5 mg (n= 130)
Monthly Injections (last at 5M): 6M tx period
12M trial
Month 6 Primary Endpoint
PRN Lucentis available for for all patients: 6M tx period
0.5 mg
Ranibizumab 0.3 mg
Ranibizumab 0.5 mg

71


Mean Change from Baseline BCVA
CRVO
Sham/0.5 mg (n=130)
0.3 mg Ranibizumab (n=132)
0.5 mg Ranibizumab (n=130)
Mean Change from Baseline BCVA (ETDRS Letters)
+14.9*
+12.7*
+0.8
+13.9
+13.9
+7.3
Day 0–Month 5 Monthly Treatment
Month
Months 6–11 PRN Treatment
Pts with >/= 3 line improvement was noted in 48% of .5 AVT, 26 of .3 AVT & 17% of sham

72

Vision Loss Without Pain: Artery Occlusion

- Primarily embolic in nature from cholesterol, calcifications, plaques.
- Usually occurs in elderly associated with:
  - hypertension (67%),
  - carotid occlusive disease (25%),
  - DM (33%) and
  - cardiac valvular disease.
- Sudden loss of unilateral, painless vision
  - defect dependent upon location of occlusion

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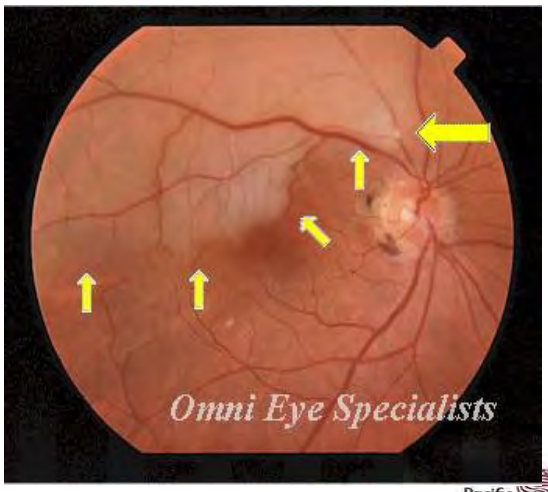
Vision Loss Without Pain: Artery Occlusion

- BRAO typically located in temporal retinal bifurcations.



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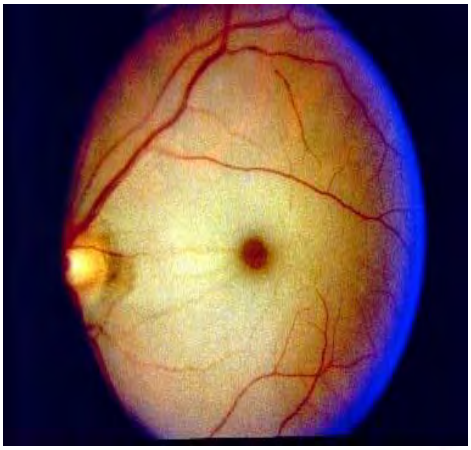
CRAO

- CRAO has profound vision loss with history of amaurosis fugax.
  - Vision is usually CF (count fingers) to LP (light perception) with positive APD.
  - Diffuse retinal whitening with arteriole constriction, cherry red macula.



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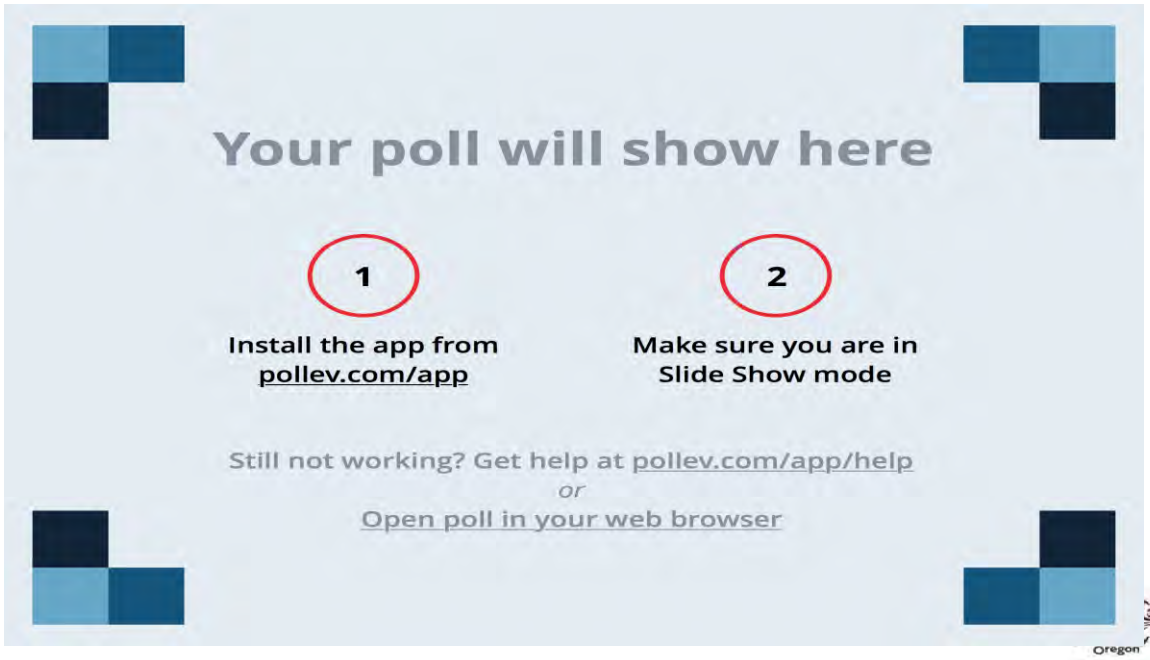

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Ophthalmic Emergency

- Treatment is controversial due to poor prognosis and questionable benefit.
- Treat immediately before workup, if patient presents within 24 hours of visual loss:
  - Digital ocular massage,
  - systemic acetozolamide (500 mg IV or po),
  - topical ocular hypertensive drops (Iopidine, B-blocker),
  - anterior chamber paracentesis,
  - consider admission to hospital for carbogen Tx (high carbon dioxide)

77

QUICKIE

78

13 YR Female

CC: noticed that her left eye became blurry and objects were "wavy" a couple of days ago. Sudden onset and she had experienced a headache over the left eye just prior to the vision going blurry.
Ocular Hx: she currently wear glasses for distance
Medical Hx: she is currently not diagnosed with any health problems and is not taking any medications

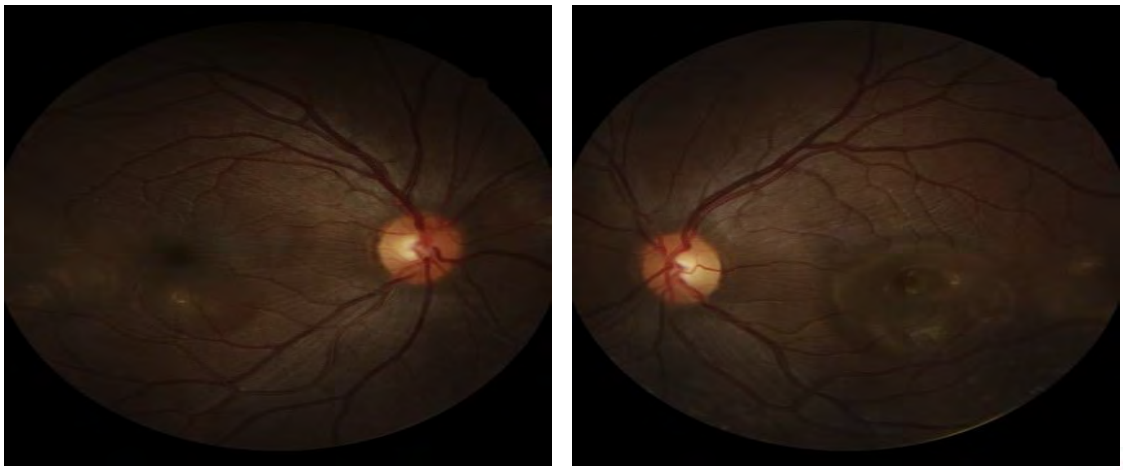
79

Entrance Skills

VA with current Rx: 20/30 OD and 20/30 OS
Entrance skills unremarkable
Amsler: metamorphopsia OS
BCVA: 20/20 OD with increased minus, no improvement possible in the left eye
IOP's: 13 mm Hg OD and OS

80

Fundus Photos



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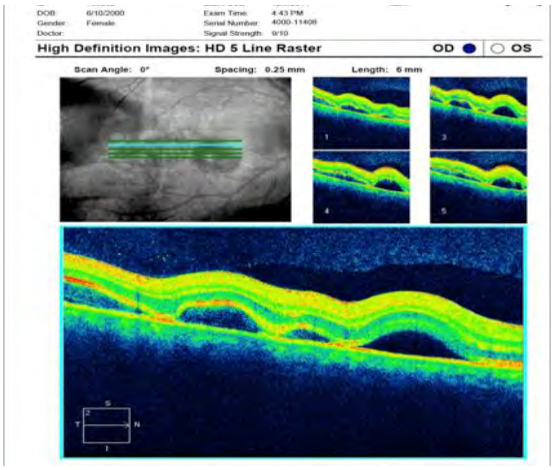

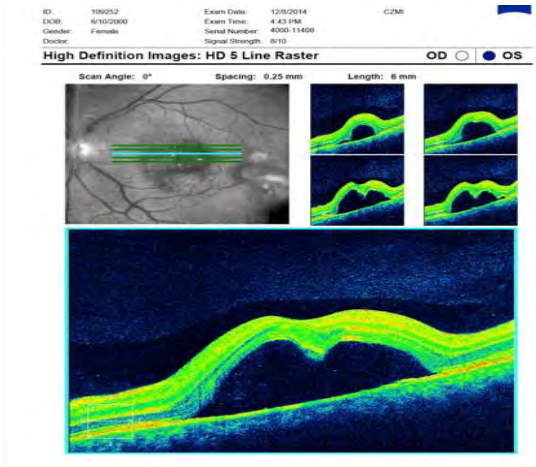

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Retina Consult

- Referred patient to retina and they confirmed the diagnosis of VKH.
- She was begun on oral prednisone 60 mg per day and she was re-evaluated in 1 week.
- At the follow up, there was reduction in her serous retinopathy and vision was improved.

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From the Experts

- Vogt-Koyanagi-Harada (VKH) disease is a multisystemic disorder characterized by granulomatous panuveitis with exudative retinal detachments that is often associated with neurologic and cutaneous manifestations.
- VKH disease occurs more commonly in patients with a genetic predisposition to the disease, including those from Asian, Middle Eastern, Hispanic, and Native American populations.

85

From the Experts

- VKH:
  - Patients have no prior history of ocular trauma or surgery
  - Patients have no evidence of another ocular disease based on clinical or laboratory evidence
  - Patients have bilateral ocular involvement.

86

From the Experts

- VKH:
  - The neurologic and auditory signs include the following:
    - Malaise, fever, headache, nausea, abdominal pain, stiffness of the neck and back, or a combination of these factors; headache alone is not sufficient to meet the definition of meningitis
    - Tinnitus
    - Cerebrospinal fluid pleocytosis
  - Integumentary signs include the following:
    - Alopecia: loss of body hair
    - Poliosis: loss of pigment in hair
    - Vitiligo: loss of skin pigmentation in blotchy pattern

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VKH Treatment

- For most patients with bilateral serous detachments and severe visual loss, begin therapy with systemic prednisone (1-2 mg/kg/day).
- The length of treatment and subsequent taper must be individualized for each patient.
  - Most patients require therapy for 6 months and occasionally up to 1 year before successful tapering of systemic corticosteroids.
  - Systemic therapy should not be discontinued during the 3 months following the onset of the disease because of the risk for recurrence.

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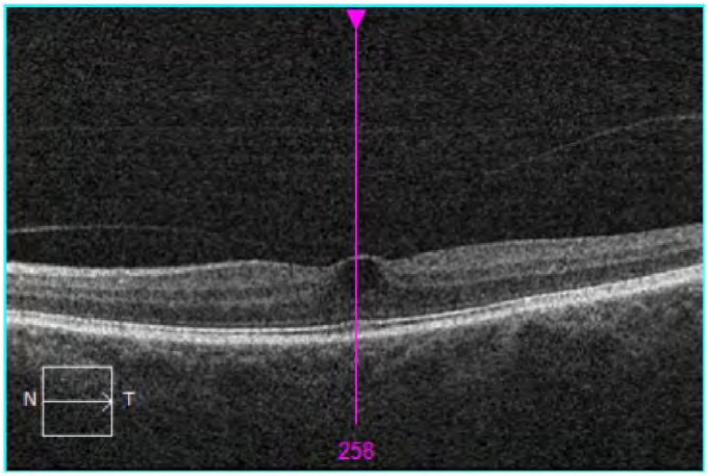
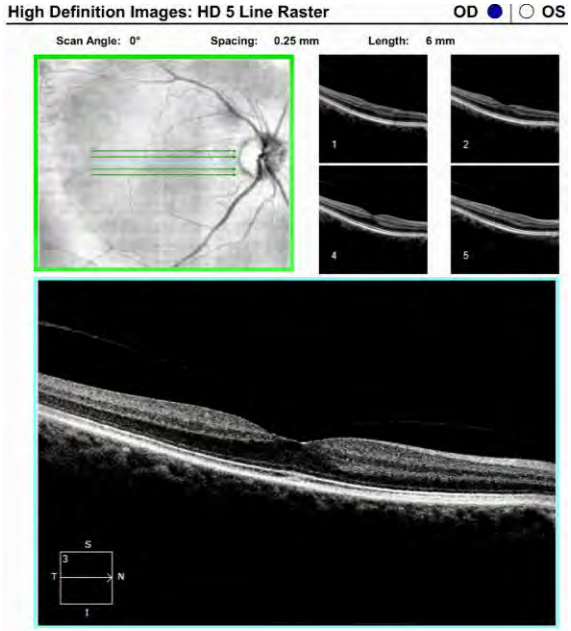
What does this look like???



89

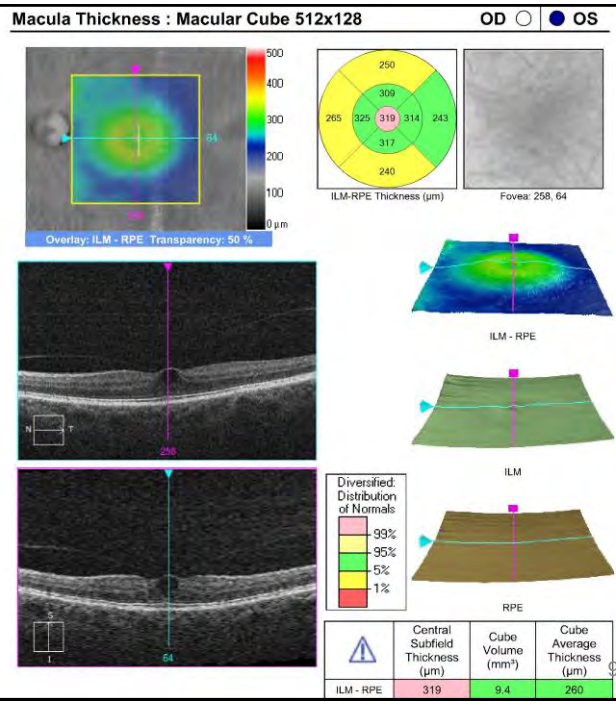
VMT



Patient 1 year later: resolved with PVD

90

OS 1 year after the OD resolution



91

Macular hole

- Unilateral, decreased vision
  - Often in 60-80 year old women
  - Anyone w/ a history of trauma
- Symptoms:
  - Decreased vision, metamorphopsia
    - 20/200 for full thickness holes
- Signs:
  - Red hole in the macula
  - (+) Watzke-Allen sign

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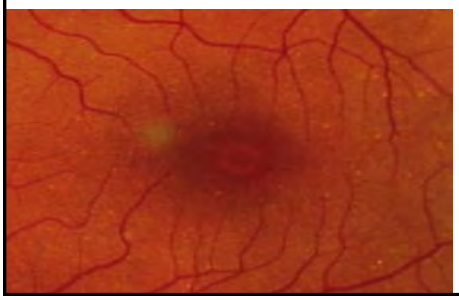
Macular hole

- Stages
  - Stage 1a -> impending hole. Normal foveal depression with yellow spot/dot in fovea.
  - Stage 1b -> Abnormal foveal depression with yellow ring.

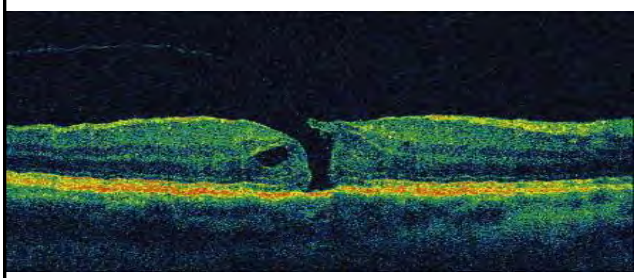


Stage 1b macular hole

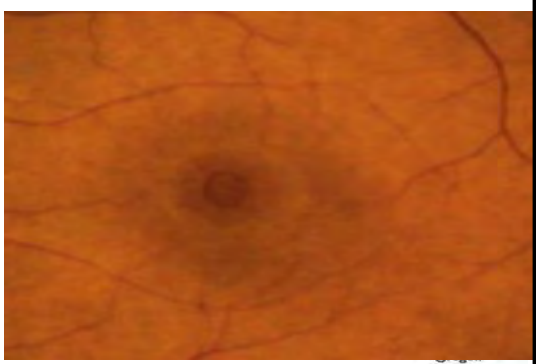
93

Macular hole

- Stages
  - Stage 2 -> Small full-thickness hole. 20/80 - 20/400.
  - Stage 3 -> Full-thickness hole w/ cuff of SRF. No PVD
  - Stage 4 -> Full-thickness hole with cuff of SRF, with complete PVD.



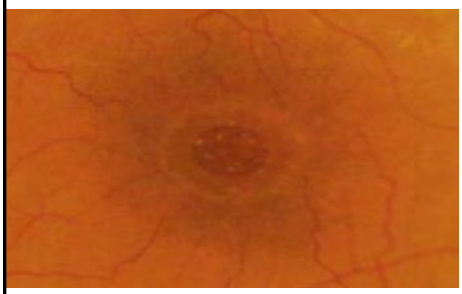
Stage 2 macular hole



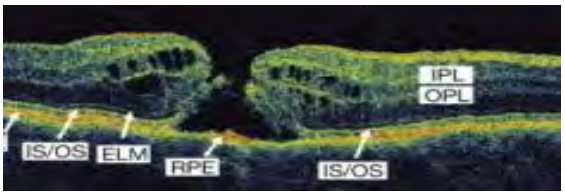
94

Macular hole

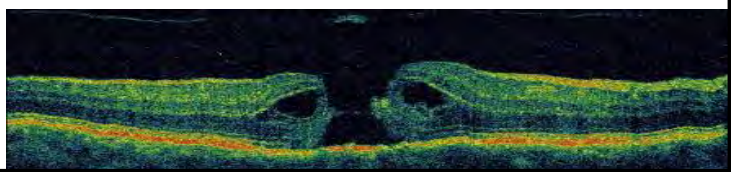
- Stages
  - Stage 2 -> Small full-thickness hole. 20/80 - 20/400.
  - Stage 3 -> Full-thickness hole w/ cuff of SRF. No PVD
  - Stage 4 -> Full-thickness hole with cuff of SRF, with complete PVD.



Stage 3 Macular hole



Stage 4 macular hole →



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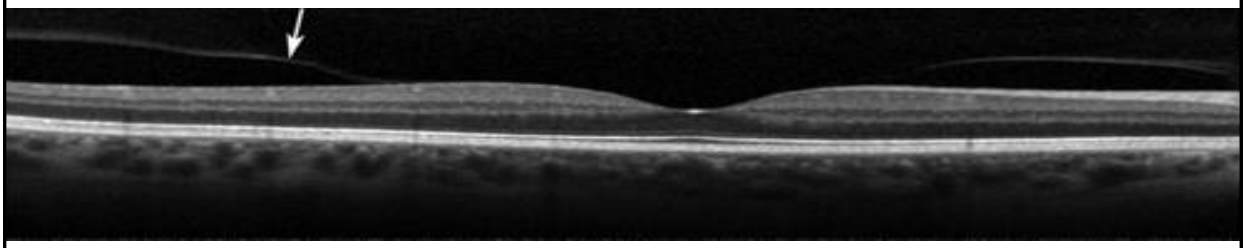
New Macular Hole Staging

Table 2. Correlation between Commonly Used Clinical Macular Hole Stages and the International Vitreomacular Traction Study Classification System for Vitreomacular Adhesion, Traction, and Macular Hole

Full-Thickness Macular Hole Stages in Common Use	International Vitreomacular Traction Study Classification System
Stage 0	VMA
Stage 1: impending macular hole	VMT
Stage 2: small hole	Small or medium FTMH with VMT
Stage 3: large hole	Medium or large FTMH with VMT
Stage 4: FTMH with PVD	Small, medium, or large FTMH without VMT



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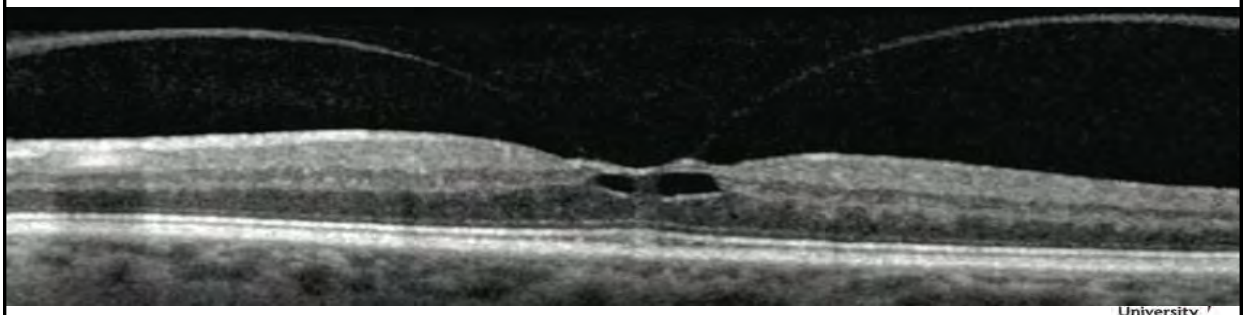

97

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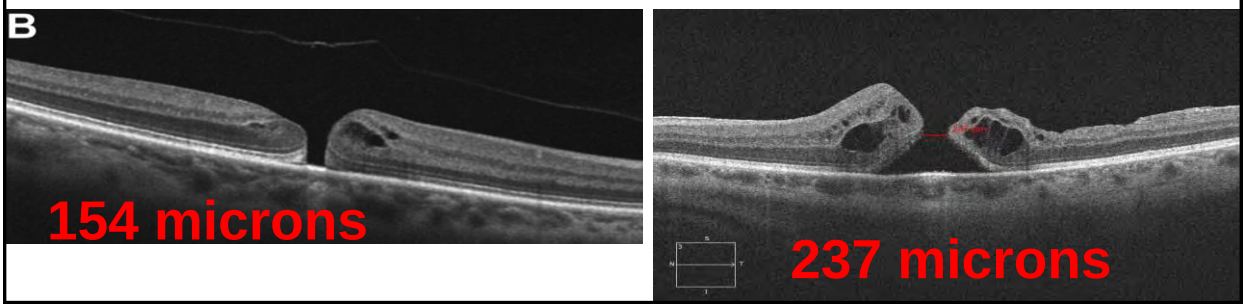
Small FTMH w/o traction



98

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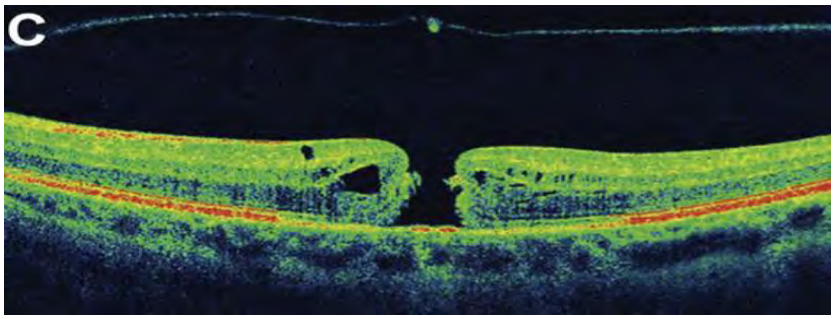
Stage 3: large hole	Medium or large FTMH with VMT
Stage 4: FTMH with PVD	Small, medium, or large FTMH without VMT

Medium FTMH w/o traction



250-400 microns

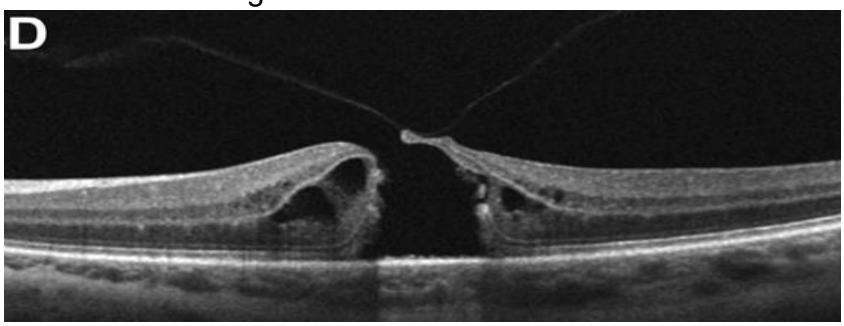
99

New Macular Hole Staging

Table 2. Correlation between Commonly Used Clinical Macular Hole Stages and the International Vitreomacular Traction Study Classification System for Vitreomacular Adhesion, Traction, and Macular Hole

Full-Thickness Macular Hole Stages in Common Use	International Vitreomacular Traction Study Classification System
Stage 0	VMA
Stage 1: impending macular hole	VMT
Stage 2: small hole	Small or medium FTMH with VMT
Stage 3: large hole	Medium or large FTMH with VMT
Stage 4: FTMH with PVD	Small, medium, or large FTMH without VMT

Large FTMH with traction



> 400 microns

100

SOUTHERN CALIFORNIA COLLEGE OF OPTOMETRY

CONTINUING EDUCATION COURSE SCHEDULE

2021 COURSE SCHEDULE

DATE	LOCATION	COURSE TOPIC	CE UNITS
July 10 & 11	**SCCO	MBKU** *Live Webinar*	**Ocular Disease Part II** *COPE Approval Pending*	16
September 19	**SCCO	MBKU** *Live Webinar*	**Joint SCCO I USC I VA Symposium** *COPE Approval Pending*	8
December 12	**SCCO	MBKU** *Live Webinar*	**Contemporary Topics in Optometry** *COPE Approval Pending*	8

GENERAL INFORMATION

MBKU CAMPUS LOCATIONS

SCCO I FULLERTON CAMPUS
2575 Yorba Linda Blvd. Fullerton, CA 92831

LEARN MORE & REGISTER *ketchum.edu/ce*

CONTACT US

email: ce@ketchum.edu

Marshall B. KETCHUM UNIVERSITY
Southern California College of Optometry

Neurotrophic keratitis is a degenerative disease that warrants immediate attention[1]

oxervate®
(cenegermin-bkbj ophthalmic solution) 0.002% (20 mcg/mL)

OXERVATE is the first FDA-approved pharmacologic treatment that targets the root pathogenesis of neurotrophic keratitis (NK)[2]

Cenegermin-bkbj, the active ingredient in FDA-approved OXERVATE, is structurally identical to the human nerve growth factor (NGF) protein made in ocular tissues.[3]

Endogenous NGF is a protein involved in the differentiation and maintenance of neurons and is believed to support corneal integrity through three mechanisms (in preclinical models): corneal innervation, tear secretion, and epithelial cell growth.[3-5]

In clinical studies, with a single 8-week course of therapy:

- Up to **72%** of patients with NK achieved complete corneal healing*†[2]
- **80%** of patients who achieved complete corneal healing remained completely healed at 1 year (REPARO trial)[6]

OXERVATE is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis.

Important Safety Information

WARNINGS AND PRECAUTIONS

Patients should remove contact lenses before applying OXERVATE and wait 15 minutes after instillation of the dose before reinsertion.

ADVERSE REACTIONS

The most common adverse reaction in clinical trials that occurred more frequently with OXERVATE was eye pain (16% of patients). Other adverse reactions included corneal deposits, foreign body sensation, ocular hyperemia, ocular inflammation, and increase in tears (1%-10% of patients).

Please see additional Important Safety Information on accompanying page and full Prescribing Information, including patient information, at OXERVATE.com/prescribing-information.

You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Dompé at 1-833-366-7387 or Usmedinfo@dompe.com.

TREAT NK TODAY
OXERVATE.com/HCP

*Study NGF0212 (REPARO): 52 patients per group; European patients with NK in one eye; 72% of patients completely healed; key findings were after 8 weeks of treatment; 6 times daily; vehicle response rate 33.3%.[2] Study NGF0214: 24 patients per group; US patients with NK in one or both eyes; 65.2% completely healed; vehicle response rate 16.7%[2,7]

†Complete corneal healing was defined as the absence of staining of the corneal lesion and no persistent staining in the rest of the cornea after 8 weeks of OXERVATE treatment.[2]

References: 1. Sacchetti M, Lambiase A. Diagnosis and management of neurotrophic keratitis. *Clin Ophthalmol.* 2014;8:571-579. **2.** OXERVATE (cenegermin-bkbj) ophthalmic solution 0.002% (20 mcg/mL) [US package insert]. Boston, MA: Dompé U.S. Inc.; 2019. **3.** Voelker R. New drug treats rare, debilitating neurotrophic keratitis. *JAMA*. 2018;320:1309. **4.** Mastropasqua L, Massaro-Giordano G, Nubile M, Sacchetti M. Understanding the pathogenesis of neurotrophic keratitis: the role of corneal nerves. *J Cell Physiol*. 2017;232:717-724. **5.** Muzi S, Colafrancesco V, Sornelli F, et al. Nerve growth factor in the developing and adult lacrimal glands of rat with and without inherited retinitis pigmentosa. *Cornea*. 2010;29:1163-1168. **6.** Data on file. Dompé U.S. Inc.; 2021. NGF0212. **7.** Pflugfelder SC, Massaro-Giordano M, Perez VL, Hamrah P, Deng SX, Espandar L, et al. Topical recombinant human nerve growth factor (cenegermin) for neurotrophic keratopathy. *Ophthalmology*. 2020;127:14-26.

Dompé

US-OXE-1900180.02 02/21

oxervate™
(cenegermin-bkbj ophthalmic solution) 0.002% (20 mcg/mL)

Brief Summary of Safety

Consult the full Prescribing Information for complete product information.

INDICATIONS AND USAGE

OXERVATE™ (cenegermin-bkbj) ophthalmic solution 0.002% is indicated for the treatment of neurotrophic keratitis.

DOSAGE AND ADMINISTRATION

Contact lenses should be removed before applying OXERVATE and may be reinserted 15 minutes after administration.

If a dose is missed, treatment should be continued as normal, at the next scheduled administration.

If more than one topical ophthalmic product is being used, administer the eye drops at least 15 minutes apart to avoid diluting products. Administer OXERVATE 15 minutes prior to using any eye ointment, gel or other viscous eye drops.

Recommended Dosage and Dose Administration

Instill one drop of OXERVATE in the affected eye(s), 6 times a day at 2-hour intervals for eight weeks.

ADVERSE REACTIONS

Clinical Studies Experience Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

In two clinical trials of patients with neurotrophic keratitis, a total of 101 patients received cenegermin-bkbj eye drops at 20 mcg/mL at a frequency of 6 times daily in the affected eye(s) for a duration of 8 weeks. The mean age of the population was 61 to 65 years of age (18 to 95). The majority of the treated patients were female (61%). The most common adverse reaction was eye pain following instillation which was reported in approximately 16% of patients. Other adverse reactions occurring in 1-10% of OXERVATE patients and more frequently than in the vehicle-treated patients included corneal deposits, foreign body sensation, ocular hyperemia, ocular inflammation and tearing.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary There are no data from the use of OXERVATE in pregnant women to inform any drug associated risks.

Administration of cenegermin-bkbj to pregnant rats or rabbits during the period of organogenesis did not produce adverse fetal effects at clinically relevant doses. In a pre- and postnatal development study, administration of cenegermin-bkbj to pregnant rats throughout gestation and lactation did not produce adverse effects in offspring at clinically relevant doses.

Animal Data

In embryofetal development studies, daily subcutaneous administration of cenegermin-bkbj to pregnant rats and rabbits throughout the period of organogenesis produced a slight increase in post-implantation loss at doses greater than or equal to 42 mcg/kg/day (267 times the MRHOD). A no observed adverse effect level (NOAEL) was not established for post-implantation loss in either species. In rats, hydrocephaly and ureter anomalies were each observed in one fetus at 267 mcg/kg/day (1709 times the MRHOD). In rabbits, cardiovascular malformations, including ventricular and atrial septal defects, enlarged heart and aortic arch dilation were each observed in one fetus at 83 mcg/kg/day (534 times the MRHOD). No fetal malformations were observed in rats and rabbits at doses of 133 mcg/kg/day and 42 mcg/kg/day, respectively. In a pre- and postnatal development study, daily subcutaneous administration of cenegermin-bkbj to pregnant rats during the period of organogenesis and lactation did not affect parturition and was not associated with adverse toxicity in offspring at doses up to 267 mcg/kg/day. In parental rats and rabbits, an immunogenic response to cenegermin-bkbj was observed. Given that cenegermin-bkbj is a heterologous protein in animals, this response may not be relevant to humans.

Lactation

There are no data on the presence of OXERVATE in human milk, the effects on breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for OXERVATE, and any potential adverse effects on the breastfed infant from OXERVATE.

Pediatric Use

The safety and effectiveness of OXERVATE have been established in the pediatric population. Use of OXERVATE in this population is supported by evidence from adequate and well-controlled trials of OXERVATE in adults with additional safety data in pediatric patients from 2 years of age and older [*see Clinical Studies (14)*].

Geriatric Use

Of the total number of subjects in clinical studies of OXERVATE, 43.5 % were 65 years old and over. No overall differences in safety or effectiveness were observed between elderly and younger adult patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis and Mutagenesis Animal studies have not been conducted to determine the carcinogenic and mutagenic potential of cenegermin-bkbj.

Impairment of fertility Daily subcutaneous administration of cenegermin-bkbj to male and female rats for at least 14 days prior to mating, and at least 18 days post-coitum had no effect on fertility parameters in male or female rats at doses up to 267 mcg/kg/day (1709 times the MRHOD). In general toxicology studies, subcutaneous and ocular administration of cenegermin-bkbj in females was associated with ovarian findings including persistent estrus, ovarian follicular cysts, atrophy/reduction of corpora lutea, and changes in ovarian weight at doses greater than or equal to 19 mcg/kg/day (119 times the MRHOD).

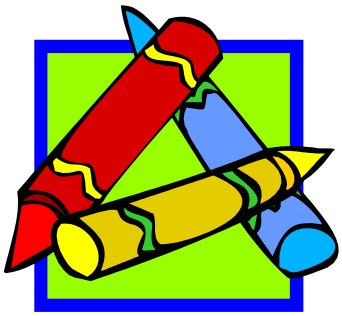
Dompé

Amblyopia Treatment Study

RECRUITMENT UNDERWAY FOR NIH-SPONSORED STUDY

Amblyopia is the most common cause of monocular visual impairment in children. The choice of a sequential approach versus a simultaneous approach to "optical treatment (glasses) plus patching treatment" remains unresolved, with some existing data supporting one approach and some data supporting the other. There is a reasonable rationale for either approach. This unresolved controversy results in a dichotomy of current clinical practice, with some care providers favoring one approach and others favoring the opposite approach. In addition, the influence of adherence to patching on treatment response is not well understood.

The Pediatric Eye Disease Investigator Group (PEDIG) is conducting a clinical trial to evaluate if treating amblyopia with glasses and patching at the same time improves vision as well as treating amblyopia first with glasses and then with patching, if needed. This study will also use occlusion dose monitors (ODMs) to record adherence with prescribed patching treatment, to study dose-response. The study is supported through funding from the National Eye Institute of the U.S. National Institutes of Health and is being coordinated by the Jaeb Center for Health Research in Tampa, Florida.



Study Specifics

- 544 children are expected to be enrolled
- Children must be between 3 to < 13 years old
- Visual acuity in the amblyopic eye must be between 20/40 and 20/200
- Random assignment to either:
  - **Sequential treatment**: full-time glasses first, with subsequent patching for 2 hours per day/7 days per week if there is no further improvement in amblyopic eye visual acuity with glasses alone and there is residual amblyopia, OR
  - **Simultaneous treatment:** full-time glasses and part-time patching for 2 hours per day/7 days per week
- Occlusion dose monitors (ODMs) will be used to record actual patch wear time during prescribed patching
- Follow-up visits every 8 weeks for 56 weeks
- No previous treatment for amblyopia is allowed, including glasses or contact lenses.

How Can You Help?

- Your assistance is needed in referring children who may qualify.
- Referrals can be sent to the investigator listed below, or for more information, visit the PEDIG website at http://pedig.net/ or call the PEDIG Coordinating Center toll free at 1-888-797-3344

National Eye Institute
NATIONAL INSTITUTES OF HEALTH

Susan Parker – Study Coordinator
Ketchum Health
5460 E. La Palma Avenue
Anaheim, CA 92807
(714) 463-7580 sparker@ketchum.edu

Pediatric Eye Disease Investigator Group