



## Complications of Pharmaceuticals Every Optometrist Should Know!

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### Disclosures- Greg Caldwell, OD, FAAO

All relevant relationships have been mitigated


- \*\* Lectured for: Alcon, Allergan, Aerie, B&L, BioTissue, Kala, Maculogix, Optovue, RVL, Heru, Santen
- \*\* Disclosure: Receive speaker honorariums
- \*\* Advisory Board: Allergan, Alcon, Dompe, Eyenovia Tarsus, Visus
- \*\* I have no direct financial or proprietary interest in any companies, products or services mentioned in this presentation
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- \*\* Envision: PA Medical Director, Credential Committee
- \*\* Healthcare Registries - Chairman of Advisory Council for Diabetes and AMD
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### Which of these ocular complications have you seen?

1. Hydroxychloroquine / chloroquine retinopathy
2. Amiodarone - corneal whorls or optic neuropathy
3. Tetracycline: pseudotumor cerebri or other complications
4. Ethambutol optic neuropathy



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### Thoughts

- \*\* Always check the medication list
  - \* Review it with the patient (techs don't always update)
- \*\* Medications to H.A.T.E in neuro-op (Andy Lee, MD)
  - \* Hydroxychloroquine / chloroquine retinopathy
  - \* Amiodarone optic neuropathy - Anterior ischemic optic neuropathy
  - \* Tetracycline: pseudotumor cerebri
  - \* Ethambutol optic neuropathy
- \* The Erectile dysfunction agents (Viagra) -Anterior Ischemic optic neuropathy


Andy Lee, MD

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### Antibiotics (anti-inflammatory)

#### Adverse Drug Reactions

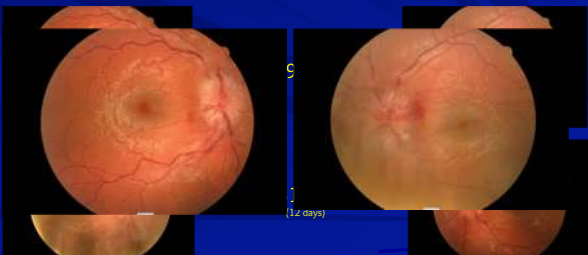
- \*\* Tetracycline analogs
  - \* Doxycycline
  - \* Minocycline
- \*\* Enhanced photosensitivity
- \*\* Avoid in children and pregnancy (Category D), and in breastfeeding women
  - \*\* Stained teeth
  - \*\* Small indoles
- \*\* Enhances the effects of
  - \* Coumadin
  - \* Digoxin
  - Comment on antibiotic drug interactions...
- \*\* Idiosyncratic intracranial hypertension
  - \* Pseudotumor cerebri
- \*\* Hyperpigmentation



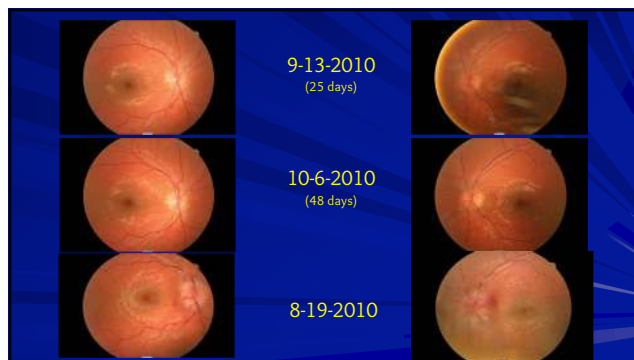
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### Benign intracranial hypertension

"It's not rare if it's in your chair"



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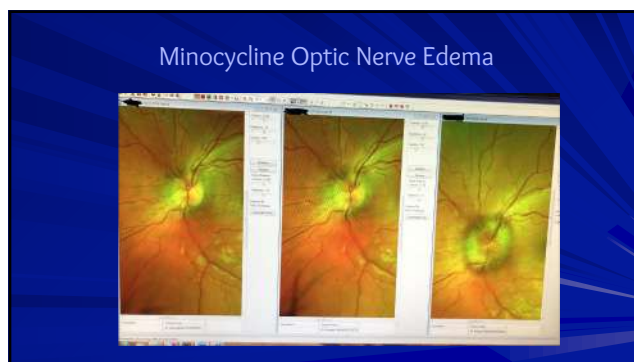


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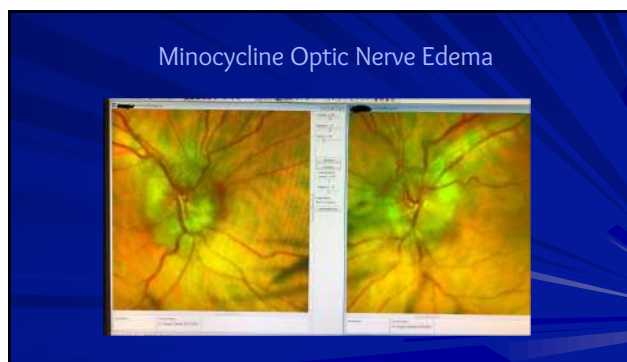
**PTC VS. IIH** (THANKS DR. JOE SOWKA)

- **Pseudotumor Cerebri (PTC)**
  - Increased intracranial pressure in the absence of an intracranial mass lesion
  - Many causative agents have been identified
    - IIH, venous sinus thrombosis, drugs
- **Primary PTC - IIH**
- **Secondary PTC** - venous sinus thrombosis, drugs
- **Idiopathic Intracranial Hypertension (IIH)**
  - Increased intracranial pressure without an identifiable cause
  - Young, obese females are at risk
  - Poor CFS drainage
- **Secondary Intracranial Hypertension (IIH)**
  - venous sinus thrombosis, drugs
    - ex. doxycycline

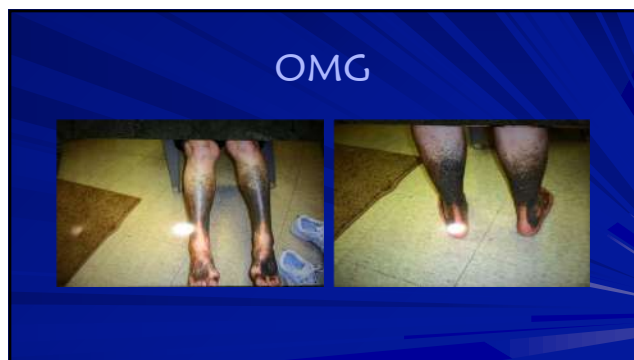
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1 Year Later



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## Antivirals

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Beside the dosing frequencies...

### What is different about the oral antivirals?



- Main reason for early discontinuation of oral acyclovir in HEDS
  - Gastrointestinal side effects
  - Rash
- Many patients on oral acyclovir have GI symptoms

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### Acyclovir vs. Valacyclovir vs. Famciclovir What is the difference?

ZOVIRAX is the brand name for acyclovir, a synthetic nucleoside analogue active against herpesviruses. ZOVIRAX Capsules, Tablets, and Suppositories are formulated for oral administration. Each capsule contains 200 mg of acyclovir and the inactive ingredients are lactose, croscarmellose sodium, and sodium lauryl sulfate. The capsule shell consists of gelatin, titanium dioxide, and iron oxides. The capsules are marked with the following information: ZOVIRAX, 200 mg, and the manufacturer's name. Tablets are marked with the following information: ZOVIRAX, 200 mg, and the manufacturer's name. Suppositories are marked with the following information: ZOVIRAX, 200 mg, and the manufacturer's name.

Valacyclovir is the brand name for valacyclovir, a synthetic nucleoside analogue active against herpesviruses. Valtrex Capsules, Tablets, and Suppositories are formulated for oral administration. Each capsule contains 500 mg of valacyclovir and the inactive ingredients are lactose, croscarmellose sodium, and sodium lauryl sulfate. The capsule shell consists of gelatin, titanium dioxide, and iron oxides. The capsules are marked with the following information: Valtrex, 500 mg, and the manufacturer's name. Tablets are marked with the following information: Valtrex, 500 mg, and the manufacturer's name. Suppositories are marked with the following information: Valtrex, 500 mg, and the manufacturer's name.

Famciclovir is the brand name for famciclovir, a synthetic nucleoside analogue active against herpesviruses. Famvir Capsules, Tablets, and Suppositories are formulated for oral administration. Each capsule contains 250 mg of famciclovir and the inactive ingredients are lactose, croscarmellose sodium, and sodium lauryl sulfate. The capsule shell consists of gelatin, titanium dioxide, and iron oxides. The capsules are marked with the following information: Famvir, 250 mg, and the manufacturer's name. Tablets are marked with the following information: Famvir, 250 mg, and the manufacturer's name. Suppositories are marked with the following information: Famvir, 250 mg, and the manufacturer's name.

Generics available in the US contain lactose  
\* In Europe you can get generic famciclovir without lactose (Teva Pharmaceuticals, Israel)

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### Acyclovir vs. Valacyclovir vs. Famciclovir What is the difference?

#### CNS Effects in Elderly Patients

- Acyclovir and valacyclovir carry a higher risk of CNS adverse effects in the elderly:
  - Agitation
  - Hallucinations
  - Confusion
- Clinical Take Home Point:
  - Consider famciclovir in older patients who CNS side effects with acyclovir or valacyclovir
  - Other major concern with elderly patients is age-related reduced kidney function

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## Alpha 1 Blockers

- Floppy iris syndrome!
- Treatment of enlarged prostate:
  - Uroxatrol™ (Alfuzosin)
  - Flomax™ (Tamsulosin)
    - These two agents LIKELY have the highest incidence of causing floppy iris syndrome, as they are selective for alpha 1a receptors, which also predominate in the eye
    - Complications can be intraoperative (eg. iris trauma) or postoperative (eg. intraocular pressure increases)
      - 57-100% incidence with tamsulosin
      - there may also be a correlation with higher doses?
- Treatment of CHF and/or hypertension
  - Coreg™ (Carvedilol)
    - Alpha1/beta2 blocker
  - Hytrin™ (Terazosin)
    - Alpha 1 blocker

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## Alpha 1 Blockers

- Floppy iris syndrome and miosis!
- After 4 rounds of phenylephrine, tropicamide, and cyclopentolate, if poor dilation
  - \* Iris hooks
- What happens at the time of making the incision?
  - \* Tricks with different viscoelastic agents
- Post op day 1, IOP 43
  - \* What's the caution?

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I have seen cornea verticillata cause vision loss?

1. Yes
2. No
3. It doesn't cause vision loss

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## Anti-arrhythmics

- Treatment of cardiac arrhythmia
  - \* Cordarone™ (amiodarone)
    - Corneal deposits - nearly universal in patients on amiodarone
      - usually bilateral with 10% complaining of blurred vision and halos around lights
    - Optic neuritis - 2% incidence
      - can occur anytime after starting amiodarone



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## Stages

Grade I	Punctate opacities in a horizontal linear pattern in the inferior cornea
Grade II	More aligned deposits in a linear pattern that extend into the inferior pupillary margin toward the limbus
Grade III	Increased numbers of branching patterns in the inferior pupillary area into the visual axis
Grade IV	Deposits form additional clumps compared with grade III

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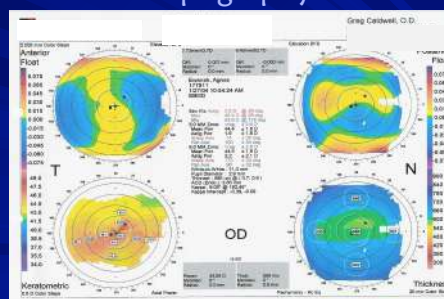
## 65-year-old woman

- Patient reports decreasing vision over past 6-9 months. Especially at near
- Vision 20/50 OU



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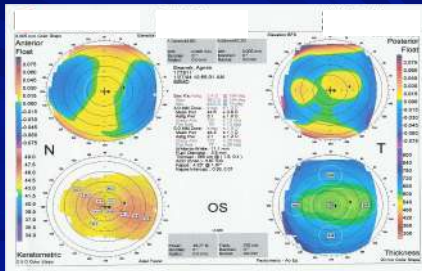
## Topography



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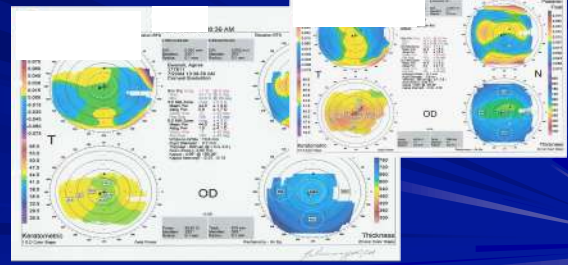


## Topography



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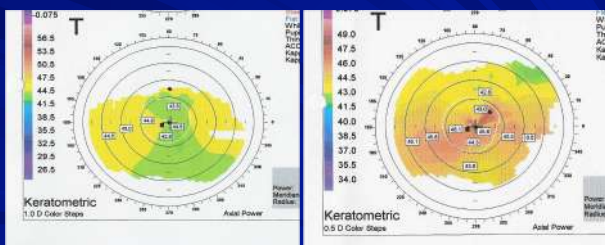
## 6 Months Later



20/25 BVA

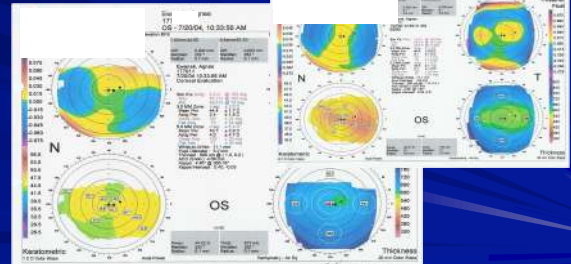
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## OD



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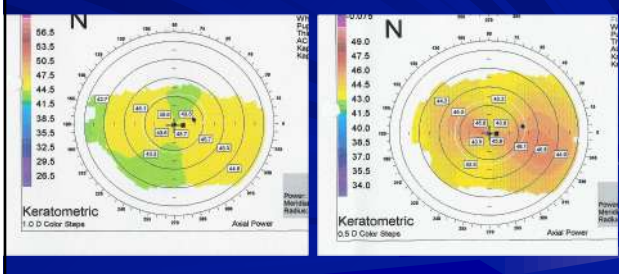
## 6 Months Later



20/25 BVA

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## OS

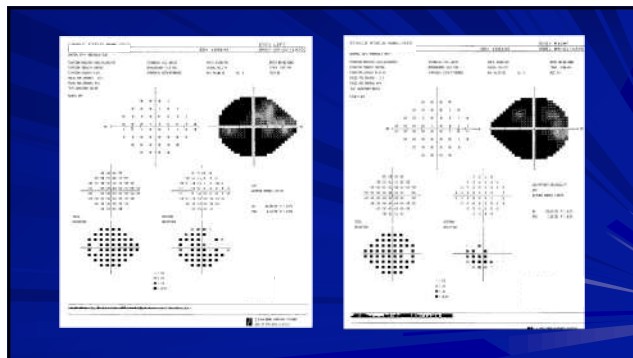


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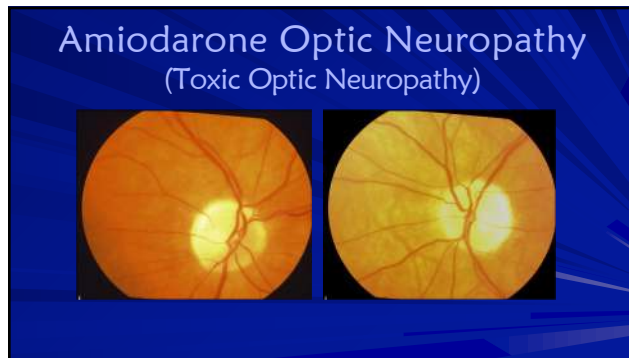
67-year-old man complains of vision slowly  
deteriorating over the past 8 months

- History of NA-ION 10 months ago OD
- Patient sees family physician for physical due to recent NA-ION
  - Patient has not been to PCP for 35 years
  - Patient started Cardarone™
  - VA 20/80 OD 20/25 OS (9 months ago)
- VA 20/400 OD 20/200 OS (today)
- CF: severe constriction OU
- SLE: vortex corneal whorls OU

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## Lanoxin™ (Digoxin)

- Anti-arrhythmic, used in CHF (+ inotrope, - chronotrope)
  - Digoxin toxicity = due to supratherapeutic levels
    - yellow or green vision
    - blurred vision
    - halos around objects

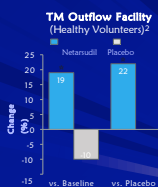
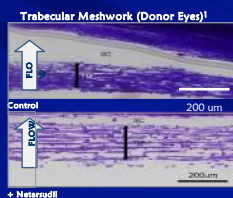
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## Rhopressa™ 0.02% (netarsudil ophthalmic solution)

- Aerie Pharmaceuticals
  - \* Approved December 2017
  - \* Treatment of glaucoma or ocular hypertension
  - \* Rho kinase inhibitor
    - ROCK-NET inhibitor
  - \* Once daily in the evening
    - Twice a day dosing is not well tolerated and is not recommended
  - \* Side Effects
    - Conjunctival hyperemia
    - Corneal verticillata
    - Conjunctival hemorrhage

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## Rhopressa™ 0.02% (netarsudil) Causes Expansion of TM in Donor Eyes Increases TM Outflow Facility in Clinic



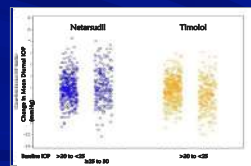
TM: Trabecular Meshwork; SC: Schlemm's Canal; Control: buffered saline solution; EDV: Episcleral Vein  
1. Ren R et al. Invest Ophthalmol Vis Sci. 2016;57(14):6197-6209. 2. Shi AJ et al. Presented at ACG 2017.

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## Netarsudil is Similarly Effective at Baseline IOPs <25 mmHg and ≥25 mmHg

Pooled Analysis Rocket 1, Rocket 2, Rocket 4

Day 90: Change from Baseline IOP by Baseline Subgroup (Pooled)



Baseline IOP >20 to <25 mmHg	
	Netarsudil QD
Median	-7.5
Mean	-8.1
Max	-12.7

Baseline IOP ≥25 to <30 mmHg	
	Netarsudil QD
Median	-4.0
Mean	-3.7
Max	-12.3

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## Rhopressa™ 0.02%

- No labeled contraindications for Rhopressa™
- No clinically relevant effects on vital signs
  - \* Blood Pressure
    - Changes were generally small and not clinically relevant in both groups
  - \* Heart Rate
    - Timolol caused statistically significant reduction in the phase 3 studies by an average of 2-3 beats per month

1. 10-027962-0001 (netarsudil-ophthalmic solution) 0.02% Prescribing Information, © Netarsudil et al., Association for Research in Vision and Ophthalmology and presentation 2017 (ID: 484944-24812)

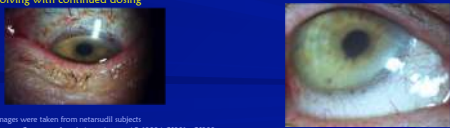
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## Conjunctival Hemorrhage was Sporadic and Severity did not Increase with Continued Dosing

Adverse Events	Netarsudil 0.02% QD (N=839) n (%)	Timolol 0.5% BID (N=839) n (%)
TEAE Conjunctival Hemorrhage	144 (17.2)	15 (1.8)
AE Resulting in Discontinuation	8 (1.0)	0

Majority 92.4% (133/144) of the conjunctival hemorrhage in netarsudil QD group was mild, 6.3% (9/144) was moderate and 1.4% (2/144) was severe

Self-resolving with continued dosing




Images were taken from netarsudil subjects  
Source: Courtesy of study investigators AR-13324-C3301, C3302

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## Cornea Verticillata Due to Phospholipidosis

Medications known to cause verticillata: amiodarone, chloroquine, naproxen, phenothiazine, ocular gentamicin and tobramycin\*



Due to phospholipidosis where the parent drug is complexed with phospholipids in the lysosomes

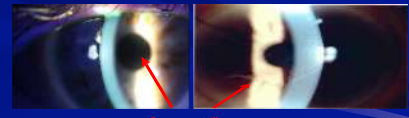
Literature review suggested it is an adaptive response by the body rather than an adverse pathology\*

Data on File Based on AR-13324-IPH07  
\* Rotstein H B et al. Surv Ophthalmol. 2017;62:286-301

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## Cornea Verticillata Observed in Phase 3 Studies

- Cornea verticillata refers to a whorl-like pattern of deposits typically localized to the basal corneal epithelium
- Subjects are asymptomatic
- The onset was ~6 to 13 weeks (netarsudil QD)




Images were taken from netarsudil subjects  
Source: Courtesy of study investigators AR-13324-C3302

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## My Experience

OD treated O5 gts



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## Summary of the Most Common Netarsudil Ocular TEAEs

Conjunctival Hyperemia	Cornea Verticillata	Conjunctival Hemorrhage
• 54.4% TEAE	• 20.9% TEAE	• 17.2% TEAE
• Severity did not increase with continued dosing	• Asymptomatic	• Mild in severity and transient
• Sporadic	• 7.4% experienced reduced visual acuity (not clear to a directly associated), all resolved after 13 weeks of D/C	• Self-resolving with continued dosing

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### Drugs Causing ACG – Angle Closure Glaucoma

- Acetazolamide
- Hydrochlorothiazide
- Trimethoprim-sulfamethoxazole
- Indapamide
- Promethazine
- Spironolactone
- Isosorbide dinitrate
- Viagra
- Bromocriptine
- Tetracycline
- Corticosteroids
- Penicillamine
- Quinine
- Metronidazole
- Isotretinoin
- Aspirin
- Topiramate\*



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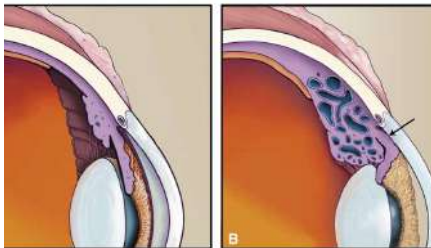
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### Ciliary Effusion

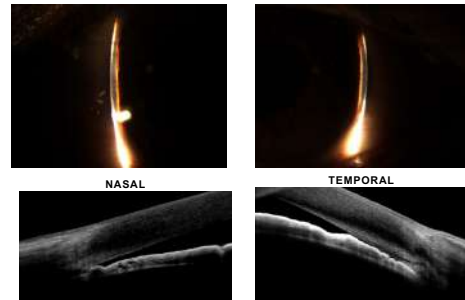
- Anterior Rotation of the Ciliary Body
  - Reduces tension on the zonules
    - Lens Thickening
      - Induces myopia
  - Iris-Lens diaphragm shifts anteriorly
    - Induces myopia by changing effectivity
  - Shallowing of Anterior Chamber
    - Potential for angle closure

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### Case

- 39 YOF
- Recently started on Topamax for migraine
- Sudden onset blurred vision and eye pain
- Formerly emmetropic, now (-) 6.00 DS
- IOP 44 mm Hg

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### What is the best management?

- Cycloplegic and topical steroids
- Oral Diamox
- Cosopt and Lumigan
- Immediate LPI
- I'm not sure. That's why I'm here.

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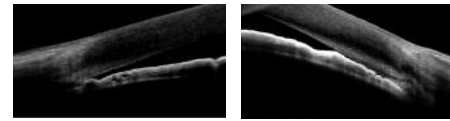


## Case

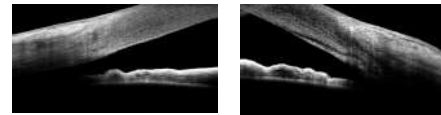
- 39 YOF
- Recently started on Topamax for migraine
- Sudden onset blurred vision and eye pain
- Formerly emmetropic, now (-) 6.00 DS
- IOP 44 mm Hg
- D/C Topamax; add PF Q1H, scopolamine BID, beta blocker BID

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Initial Presentation



Resolution

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## Choroidal Involvement in ACG

- Drug-induced choroidal expansion
- Choroidal expansion in ACG associated with shallowing of chamber
- Malignant glaucoma may not be aqueous misdirection, but poor fluid permeability and choroidal expansion
- Atropine may work by moving ciliary body and improving forward diffusional area for fluid
  - Atropine may be a better choice than pilocarpine

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## Toxic Optic Neuropathy

### \*\* Causes

- \* Ethambutol (TB)
- \* Isoniazid
- \* Antimicrobials
  - chloramphenicol, streptomycin, penicillamine
- \* Halogenated hydroxyquinolones
- \* Vigabatrin
- \* Disulfiram
- \* Tamoxifen
- \* Sildenafil

### \*\* Causes

- \* Methanol
- \* Heavy metals
- \* Fumes
- \* Solvents
- \* Alcohol abuse
- \* Tobacco abuse

Clinical Pearl: When you encounter a pt with these pharmaceuticals, consider and evaluate for toxic optic neuropathy (TON)

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## Ethambutol

- \*\* Still used in the 4-drug treatment plan for active *Mycobacterium tuberculosis* ("TB")
  - \* Patients will take isoniazid + rifampin + pyrazinamide + ethambutol for ABOUT 2 months
    - Organism sensitivities come back
    - Non-resistant TB = discontinuation of pyrazinamide and ethambutol
- \*\* Toxic optic neuropathy
- \*\* 2 cases in the past 12 months (2019)

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## 81-year-old woman

- \*\* Calls the office reporting decreased vision (3-13-19)
  - \* Was warned vision could decrease due her medications
  - \* Glaucoma patient
- \*\* *Mycobacterium avium* infection
- \*\* Ethambutol, rifampin, and azithromycin
  - \* Ethambutol started October 2017
- \*\* Glaucoma patient
  - \* Was on latanoprost and Rhopressa
  - \* Had KDB
    - No glaucoma drops currently

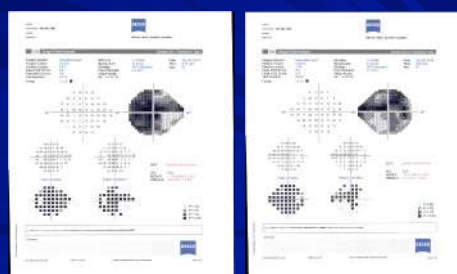
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3/13/19 20/30, 20/100, 20/25



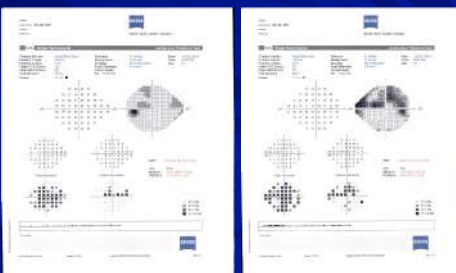
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4/29/19 20/25, 20/50, 20/20



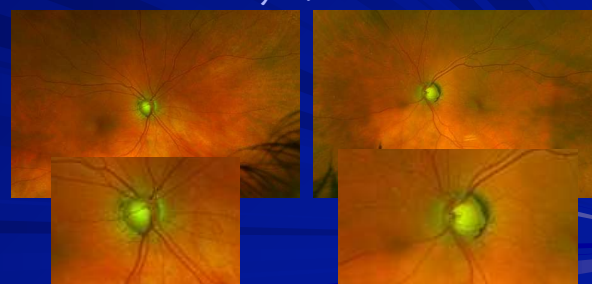
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7/29/19 20/20, 20/25, 20/20



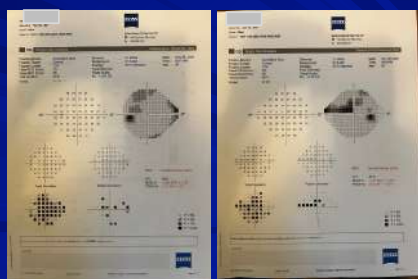
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May 9, 2022



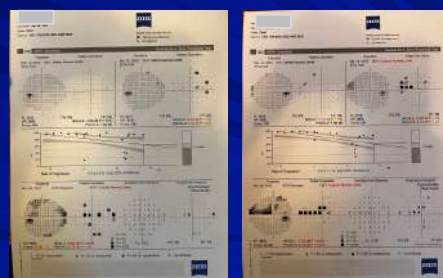
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November 21, 2021



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Progression thru 11-08-2021



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### Dupixant (dulipumab) injection

- **Atopic Dermatitis:** indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
  - \* DUPIXENT can be used with or without topical corticosteroids
- **Asthma:** indicated as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. Limitation of Use: DUPIXENT is not indicated for the relief of acute bronchospasm or status asthmaticus.
- **Chronic rhinosinusitis with nasal polyps (CRSwNP):** DUPIXENT is indicated as an add-on maintenance treatment in adult patients with inadequately controlled CRSwNP.
- **Eosinophilic Esophagitis:** DUPIXENT is indicated for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).

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### Dupixant (dulipumab) injection

#### Warnings and Precautions

- **Conjunctivitis and Keratitis: (ocular warning and precautions of many)**
  - \* Conjunctivitis and keratitis occurred more frequently in atopic dermatitis subjects who received DUPIXENT versus placebo, with conjunctivitis being the most frequently reported eye disorder.
  - \* Conjunctivitis also occurred more frequently in chronic rhinosinusitis with nasal polypsis subjects who received DUPIXENT compared to those who received placebo.
  - \* Conjunctivitis and keratitis have been reported with DUPIXENT in postmarketing settings, predominantly in atopic dermatitis patients.
  - \* Some patients reported visual disturbances (e.g., blurred vision) associated with conjunctivitis or keratitis.
  - \* Advise patients to report new onset or worsening eye symptoms to their healthcare provider.
  - \* Consider ophthalmological examination for patients who develop conjunctivitis that does not resolve following standard treatment or signs and symptoms suggestive of keratitis, as appropriate.

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### Before and After

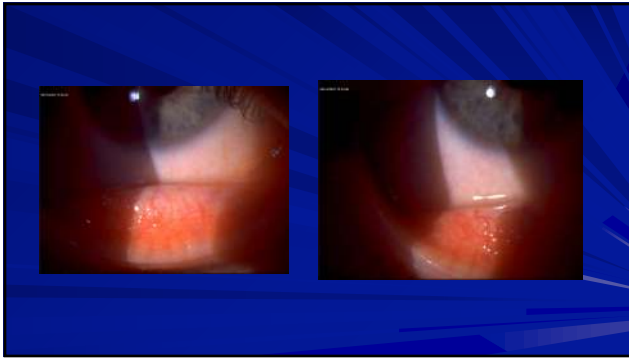
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### Before and After

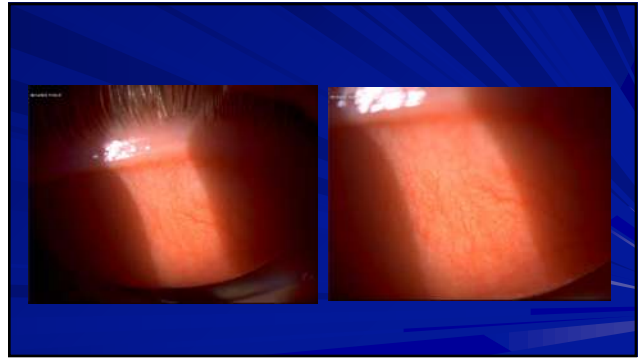
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### Dupixant

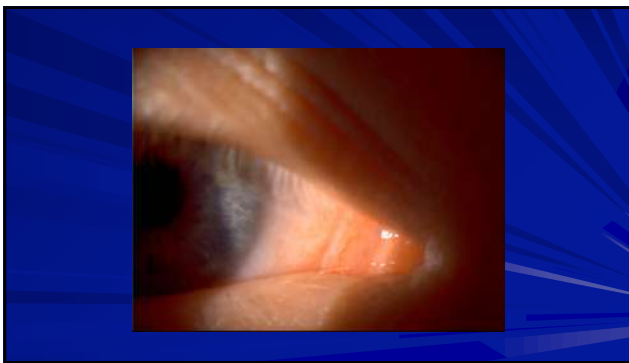
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I have seen hydroxychloroquine/Plaquenil retinal toxicity  
in my practice:

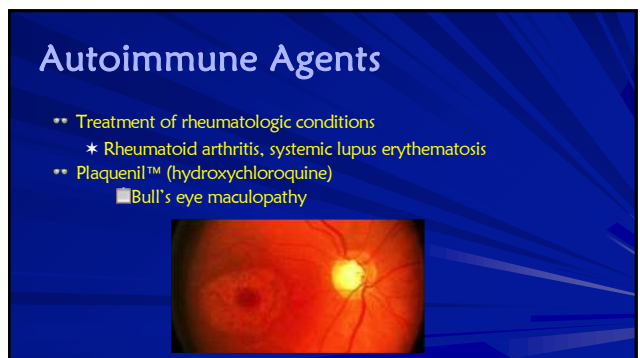
1. Yes
2. No
3. I don't think it really happens



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## Immunosuppressive Medications

Disease-Modifying Anti-Rheumatic Drugs (DMARDs)  
Traditional Meds and Biologics

Methotrexate +/-  
Hydroxychloroquine (Plaquenil™)

☐  
Tumor Necrosis Factor  $\alpha$  Inhibitors  
Adalimumab (Humira™)  
Infliximab (Remicade™)  
Etanercept (Enbrel™)  
Certolizumab (Cimzia™)

☐  
Additional Agents  
Abatacept (Orencia™)  
Tocilizumab (Actemra™)  
Tofacitinib (Xeljanz™)  
Rituximab (Rituxan™)

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## Plaquenil

Hydroxychloroquine (Plaquenil) - Anti-malarial

•• Ophthalmic side effects (infrequent with current dosing ranges):

- \* Irreversible retinal damage has been observed ("chloroquine retinopathy").
- \* If there are any indications of abnormality in the color vision, visual acuity, visual field, or retinal macular areas, or any visual symptoms (eg, light flashes or streaks), d/c drug stat

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## Revised Recommendations on Screening for Chloroquine and Hydroxychloroquine Retinopathy

•• Recommendations were 2002 by the American Academy of Ophthalmology

•• Improved screening tools and new knowledge about prevalence of toxicity have prompt the change

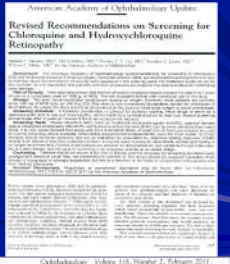
- \* 1% after 5-7 years of use or a cumulative dose of 1000 grams (100mg/ml)

•• There is no treatment for this condition

- \* Therefore must be caught early

•• Screening for the earliest hints of functional or anatomic change

•• Plaquenil toxicity is not well understood



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## Revised Again



Revised Again

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**Background:** The American Academy of Ophthalmology recommendations on screening for chloroquine (CQ) and hydroxychloroquine (HCQ) retinopathy are revised in light of new information about the prevalence of toxicity, risk factors, toxicity distribution, and effectiveness of screening tools.

**Pattern of Retinopathy:** Although the focus of toxic damage is paracentral in many eyes, Asian patients often show an macular pattern of damage.

**Dose:** We recommend a maximum daily HCQ dose of 5.0 mg/kg ideal weight, which correlates better with risk than total weight. There are no similar demographic data for CQ, but dose comparisons in older literature suggest using 2.5 mg/kg ideal weight.

**Risk of Toxicity:** The risk of toxicity is dependent on daily dose and duration of use. At recommended doses, the risk of toxicity up to 5 years is under 1% and up to 10 years is under 2%, but it rises to almost 20% after 20 years. However, even after 10 years, a patient without toxicity has only a 4% risk of converting in the subsequent year.

**Major Risk Factors:** High dose and long duration of use are the most significant risks. Other major factors are concomitant renal disease, or use of tamoxifen.

**Screening Schedule:** A baseline fundus examination should be performed to rule out preexisting macular pathology. Begin annual screening after 5 years for patients on acceptable doses and without major risk factors.

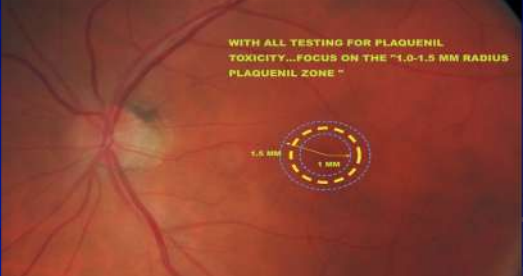
**Screening Tests:** The primary screening tests are automated visual fields plus spectral-domain optical coherence tomography (SD OCT). These should look beyond the central macula in Asian patients. The multifocal electroretinogram (mfERG) can provide objective confirmation for visual fields, and fundus autofluorescence (FAF) can show damage topographically. More often screening should detect abnormalities before it is visible in the fundus.

**Toxicity:** Retinopathy is not reversible, and there is no present therapy. Recognition at an early stage (before any 1% loss) is important to prevent central visual loss. However, questionable test results should be repeated or validated with additional procedures to avoid unnecessary cessation of valuable medication.

**Counseling:** Patients (and prescribing physicians) should be informed about risk of toxicity, proper dosing levels, and the importance of regular annual screening. Ophthalmology 2016;151:1681-1696. © 2016 by the American Academy of Ophthalmology.

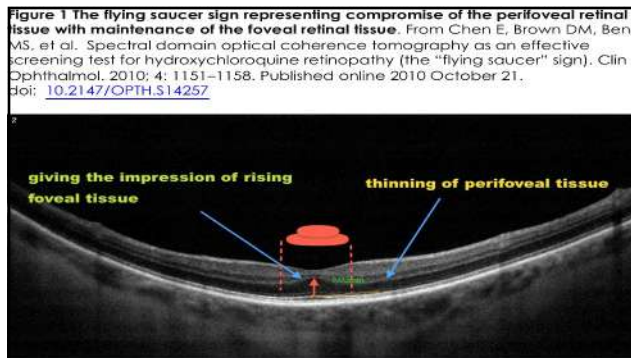
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## PLAQUENIL ZONE

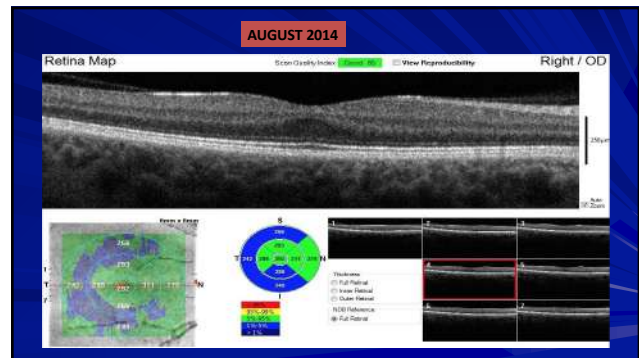


WITH ALL TESTING FOR PLAQUENIL TOXICITY...FOCUS ON THE "1.0-1.5 MM RADIUS PLAQUENIL ZONE"

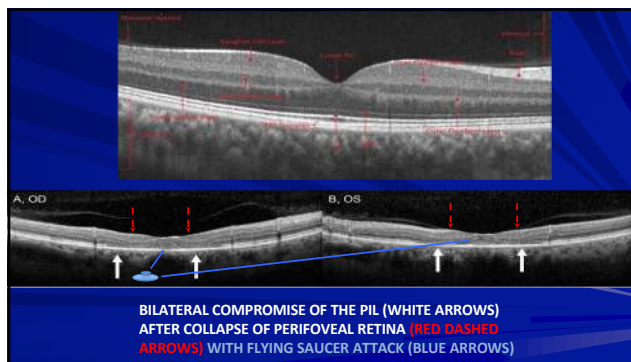
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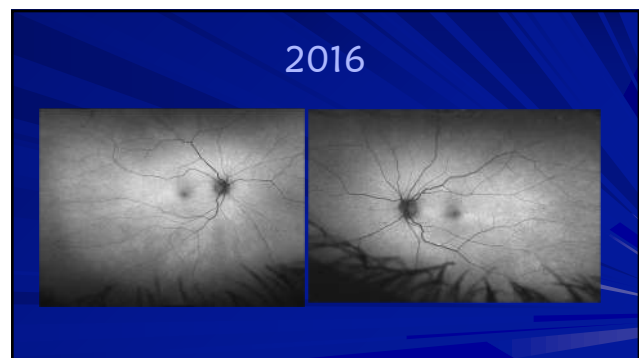
**71 yo woman**

- \*\* With Lupus and hypertension
- \*\* Medications:
  - \* Clonazepam™
  - \* Plaquenil™ 200 mg BID, 15 years
  - \* 81 mg ASA
  - \* Prednisone
  - \* Losartan™
- \*\* VA 20/25 OD/OS (mild cataracts)
- \*\* Patient was told to see an ophthalmologist in 2013

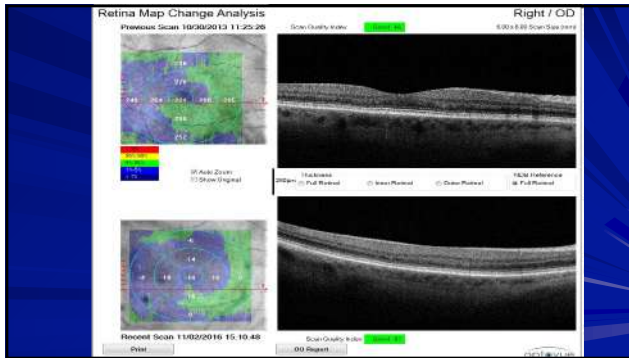
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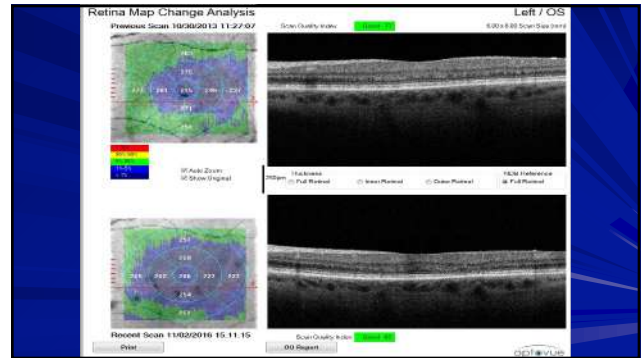
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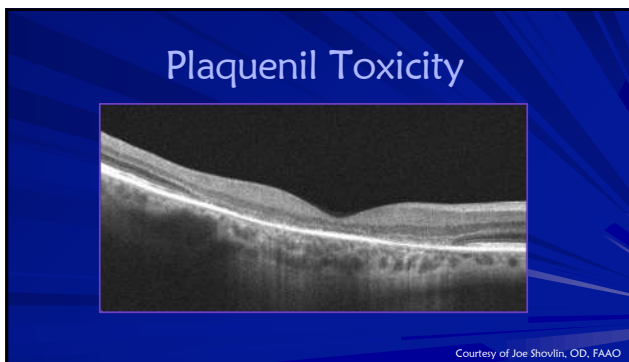
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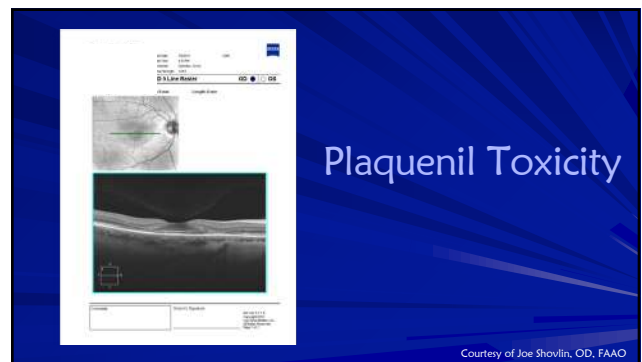
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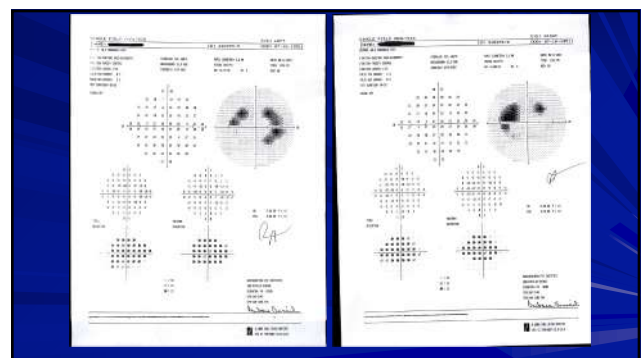
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 <p>Optometric Education Consultants</p>	<p>Thank you! Questions?</p> <p>Complications of Pharmaceutical Every Optometrist Should Know!</p> <p>Greg Caldwell, OD, FAAO</p> 
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