

## OFF LABEL (Not off limits)

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## Disclosure

- ✓ Presenter is on speakers panel of Alcon, Allergan, Abbott, Bausch + Lomb, TearLab, BVI
- ✓ Past-President of the Optometric Council on Refractive Technology (OCRT)
- ✓ Presenter has NO financial interest in any products mentioned
- ✓ Except he does have stock in a certain coffee company...



“A lot of people go to college for seven years” “Yeah, they’re called doctors.”

## Introduction

- ✓ EDA Process
- ✓ Off-label
  - ✓ Familiarize yourself with the published literature and experience of colleagues
  - ✓ Be reasonably confident that patients will benefit
  - ✓ Heed the drug’s history of adverse events, and advise and monitor patient’s accordingly
  - ✓ Document the decision-making process and the informed-consent discussion that led to using a drug off-label
- ✓ What legally can we do

“Oh, and Senator, just one more thing. Love your suit!”

## Dilating Medications

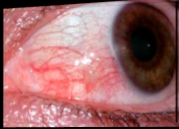
### ✓ Epinephrine

#### ✓ Indications:

- ✓ Dilate the pupil
- ✓ Mydriasis

#### ✓ Off-Label

- ✓ Diagnose Episcleritis
  - ✓ Drop of epinephrine
  - ✓ Wait 5 minutes
  - ✓ Evaluate the superficial blood vessels
- ✓ Getting the Red Out



## Getting the Red Out then in....



Yes, I've heard. Kills men by the hundreds! And if he were here, he'd consume the English with fire balls from his eyes and bolts of lightning from his arse!

## Antibiotic

### ✓ Fourth Generation Quinolones

#### ✓ Indications:

- ✓ For the treatment of bacterial conjunctivitis caused by susceptible strains of gram + and some gram -
  - ✓ Moxeza (moxifloxacin)
  - ✓ Zymarid (gatifloxacin)
  - ✓ Besivance (besifloxacin)

#### ✓ Off-Label

- ✓ Surgical Prophylaxis
- ✓ Corneal Infections
- ✓ Blepharitis

## Antibiotic

### ✓ Tetracycline Derivatives

#### ✓ Indications:

- ✓ Tetracycline's primary use is for the treatment of acne vulgaris and rosacea.

#### ✓ Off-Label

- ✓ Meibomitis
- ✓ Dry Eye

#### ✓ Warnings

- ✓ Stomach Aches
- ✓ Yeast Infections
- ✓ Diarrhea



## DOXYCYCLINE

- ✓ A tetracycline antibiotic that inhibits bacterial protein synthesis by binding to ribosomes

#### ✓ Bacteriostatic

#### ✓ Broad Gram +/-

#### ✓ Anti-inflammatory

- ✓ Anticollagenase activity
- ✓ IL-1 and MMP-9 inhibitor
- ✓ Inhibits conversion of staph lipase to fatty acids

#### ✓ MGD

#### ✓ Acne rosacea

#### ✓ RCE prevention

#### ✓ Prevent stromal melt

#### ✓ Staph marginal dx

#### ✓ Ocular Chlamydia

## DOXYCYCLINE THERAPY to Reduce Inflammation in MGD

- ✓ An abnormal production of esters &/or bacterial colonies cause the oils to become acidic leading to burning
- ✓ The AB inhibits staph lipase from converting lipids to fatty acids thereby reducing inflammation
- ✓ Dose: 100 mg BID x 1-2 mos
- ✓ Maintenance: 50-25mg qd-bid



## DOXYCYCLINE

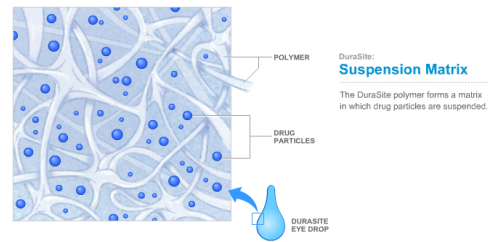
- ✓ Contra-indications: Category D < 8 years old, hypersensitivity to tetracyclines or sulfites, severe hepatic dysfunction, last 1/2 pregnancy\*\*
- ✓ Safe for Kidney dx since it is excreted in GI tract
- ✓ Drug interactions: Antacids (Al, Ca, Mg), Laxatives (Mg), Fe, and some barbiturates may reduce absorption of doxycycline

## Antibiotic

- ✓ AzaSite (Merck)
  - ✓ Azythromycin 1%
    - ✓ Macrolide
    - ✓ Bacteriostatic
    - ✓ Approved for Bacterial Conjunctivitis
  - ✓ DuraSite
    - ✓ polymeric mucoadhesive matrix
    - ✓ bid X 2 days, qd x 5 days

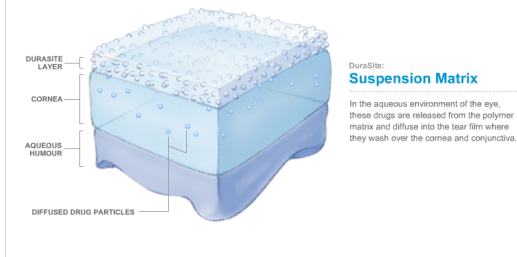


### DuraSite Mechanism of Action



## DuraSite® Vehicle

### DuraSite Mechanism of Action



## AzaSite® Ocular Tissue Concentration Conclusions

- ✓ AzaSite® achieves significant drug concentrations in a variety of ocular tissues including:
  - ✓ Conjunctiva
  - ✓ Cornea
  - ✓ Eyelids
- ✓ AzaSite® levels remain high and sustained in ocular tissues over time
- ✓ DuraSite® adheres AzaSite® to the ocular surface aiding the delivery of superior concentrations to ocular tissue

## Posterior Blepharitis

### ✓ Treatment Options

#### ✓ Lid disease

- ✓ 1 gtt qhs
- ✓ "Like ketchup"
  - ✓ FLIP-WHIP-DRIP
  - ✓ Remind patients that bottle is small
  - ✓ Rub in the remainder on the lid



## Showering

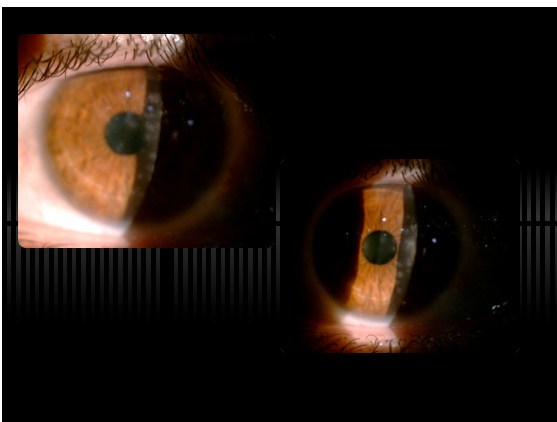
- ✓ Fun Activity
- ✓ Get clean
- ✓ Lid Treatment
- ✓ Ocusoft Lid Foam

"They call it a Royal with  
Cheese"



## Allergy Medications

- ✓ Indications
  - ✓ Treatment of signs and symptoms of allergic conjunctivitis
    - ✓ Mast Cell Stabilizers
    - ✓ Anti-histamine
    - ✓ NSAID's
- ✓ Off-Label
  - ✓ Dry Eye Treatment
  - ✓ Red Eye Control
  - ✓ Pterygium



"I don't know how to put this but I'm  
kind of a big deal"

## Betadine

- ✓ Purdue Pharma
- ✓ Povidone-iodine (PVPI) topical antiseptic
- ✓ Uses:
  - ✓ Used for cleaning minor wounds and prepare a patient skin prior to surgery
    - ✓ 10% povidone-iodine in water
  - ✓ Surgical Scrub, povidone-iodine with detergent

## Betadine

- ✓ Off-Label
  - ✓ Treatment of Adenoviral Conjunctivitis

## Zirgan™ (Ganciclovir Ophthalmic Gel) 0.15%

## Zirgan™ (ganciclovir ophthalmic gel) 0.15% Indication

### Indication and Usage

- ✓ Zirgan is a topical ophthalmic antiviral that is indicated for the treatment of acute herpetic keratitis (dendritic ulcers).

## Zirgan™ (ganciclovir ophthalmic gel) 0.15% Indication

### Dosage and Administration

- ✓ The recommended dosing regimen for Zirgan is 1 drop in the affected eye 5 times per day (approximately every 3 hours while awake) until the corneal ulcer heals, and then 1 drop 3 times per day for 7 days.

## Ganciclovir Mechanism of Action

- ✓ Penetrates cell infected with the virus
- ✓ Activation continues due to several cell kinases leading to formulation of ganciclovir triphosphate, which:
  - ✓ Inhibits viral DNA polymerase
  - ✓ Incorporates into viral DNA preventing replication
- ✓ Used for Viral Infections

## Glaucoma Medications

### ✓ Alphagan-P

#### ✓ Indications

- ✓ The lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension

- ✓ Alpha adrenergic agonist

#### ✓ Off-label Use

- ✓ Refractive Surgery
  - ✓ Treatment of glare and halos
  - ✓ Stabilizes pupil at 4mm
  - ✓ Use 1 drop q4-6h when needed (dusk)
- ✓ Getting the Red out!



“The greatest trick the Devil ever pulled was convincing the world he didn't exist”

## Restasis

### ✓ Indications

- ✓ Approved by the FDA for the **treatment of dry eye**
- ✓ Only prescription available for dry eye treatment
- ✓ Safe and well tolerated
- ✓ Level 2 DTS
- ✓ Widely accepted on formularies
  - ✓ Very inexpensive for patients
  - ✓ Effective within 1-3 weeks
  - ✓ Long lasting effects
  - ✓ Practice builder

## Restasis

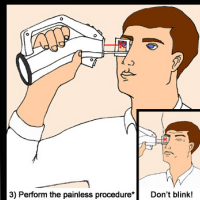
### ✓ Off-label Indications

#### ✓ Post-LASIK Dryness

- ✓ Anti-inflammatory
- ✓ Increases Goblet cells
- ✓ Promotes regular surface for the cornea
- ✓ Encourages healing
- ✓ \*Pre-treat ALL LASIK patients

#### ✓ Cataract Surgery

- ✓ Refractive in nature
- ✓ Patient expectations
- ✓ Increase in inflammation with surgery



## Restasis

### ✓ Off-label Indications

- ✓ Allergic conjunctivitis
  - ✓ Eczema or atopic dermatitis
  - ✓ Severe conjunctival inflammation
- ✓ Atopic keratoconjunctivitis
- ✓ Vernal keratoconjunctivitis
  - ✓ More common in males
  - ✓ Typically steroids are used
    - ✓ Complications associated with steroids



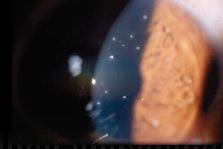
## Restasis



### ✓ Off-label Indications

- ✓ Corneal transplant (rejection prevention)
  - ✓ T-lymphocytes mediator in rejection
  - ✓ Cyclosporine potent T-cell inhibitor
- ✓ Post-corneal transplant glaucoma
  - ✓ Steroids can induce IOP spikes
- ✓ Meibomian Gland Dysfunction
  - ✓ N=33 study with Restasis and Placebo
    - ✓ Restasis group improved gland inclusions

## Restasis



### ✓ Off-label Indications

- ✓ Thygeson's Keratitis
  - ✓ Young
  - ✓ Avoid complications of steroids
- ✓ Superior limbic keratoconjunctivitis
- ✓ Herpetic stromal keratitis

“My name is Maximus Decimus Meridius, commander of the Armies of the North, General of the Felix Legions, loyal servant to the true emperor, Marcus Aurelius. Father to a murdered son, husband to a murdered wife. And I will have my vengeance, in this life or the next.”

## The Intraocular Lens

“I think I have the black lung..”

## CrystaLens HD/AO

Bausch & Lomb  
(eyeonics)

### CURRENT DESIGN 5.0 AO



- ✓ Hinged optic to increase movement
- ✓ Larger 5 mm optic
- ✓ Haptics more square
- ✓ Arc length of haptics increased
- ✓ Lengthened haptics to maximize amplitude
- ✓ Advanced Optics
- ✓ Suitable for in bag placement only

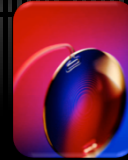
# AcrySof® ReSTOR® Aspheric IOL

Alcon

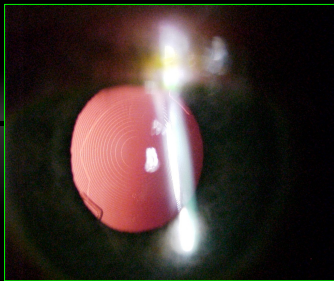
## TECNIS® Multifocal IOL Specifications\*

- ◆ Full diffractive posterior surface
  - Pupil-independent
- ◆ Wavefront-designed aspheric anterior surface
- ◆ Light distribution 50/50
- ◆ +5D to +34D in 0.5D increments
- ◆ Optical power add +4.0D
  - To optimize acuity at preferred reading distance of 33 cm
- ◆ Edge Design:
  - Acrylic: OptiEdge™ design
  - Silicone: Square edge

TECNIS® Acrylic MIOL ZMA00



## Tecnis® Multifocal IOL

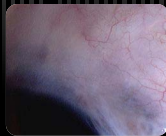
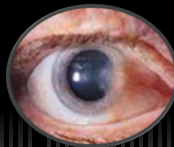


Ophthalmic Consultants of Long Island

“It’s K-Billy’s super sounds of the 70’s weekend”

## Mitomycin C (MMC)

- ✓ Indicated
  - ✓ Replaces a key component of the DNA replication process
  - ✓ Antimetabolite
  - ✓ Bladder Cancer; Pancreatic cancer; Breast cancer
- ✓ Off-Label
  - ✓ Pterygium Surgery
  - ✓ Filtering Glaucoma Surgery
  - ✓ PRK Refractive Surgery



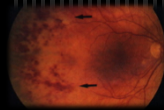
“Doodie!”





## Retinal Surgery

- ✓ No Vitreal Medication has been approved for the last 30 years
  - ✓ Until Macugen and Lucentis
    - ✓ Indicated for the treatment of AMD
- ✓ Off-Label
  - ✓ CMV Treatment
    - ✓ Gangcyclovir injections
    - ✓ Foscarnet

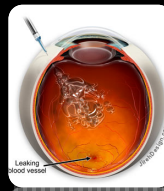


## Retinal Surgery

- ✓ Triamcinolone (Kenalog)
  - ✓ Indicated for intramuscular use
  - ✓ Used by retinal surgeons injected into the retina
    - ✓ AMD
    - ✓ Diabetic macular edema
    - ✓ Retinal vein occlusion

## Retinal Surgery

- ✓ Off-label
  - ✓ Avastin
    - ✓ Manufactured by Genentech
    - ✓ Indicated for the treatment
      - ✓ Colon Cancer
      - ✓ Rectal Cancer
    - ✓ Larger molecule of Lucentis
    - ✓ Monetary issues
    - ✓ Used by OMD's for the treatment of AMD



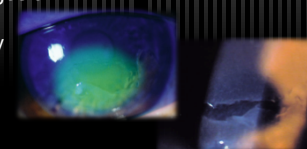
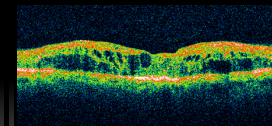
“Don't Move until you See it”

## NSAID's

- ✓ Indications
  - ✓ ACULAR® ophthalmic solution is indicated for the temporary relief of ocular itching due to seasonal allergic conjunctivitis. ACULAR® ophthalmic solution is also indicated for the treatment of postoperative inflammation in patients who have undergone cataract extraction.
  - ✓ Bromday is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract extraction.
  - ✓ ACULAR LS® ophthalmic solution is indicated for the reduction of ocular pain and burning/stinging, following corneal refractive surgery
  - ✓ Acuvail® solution is indicate for the treatment of pain and inflammation following cataract surgery

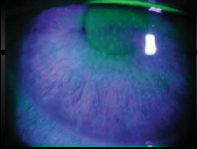
## NSAID's

- ✓ Off-label
  - ✓ Treatment of CME
    - ✓ W/Steroid
  - ✓ Corneal Analgesic
    - ✓ Abrasion
    - ✓ Foreign body
    - ✓ Scratch



## Contact Lenses

- ✓ Indicated for the correction of myopia and hyperopia
- ✓ Off-label
  - ✓ Bandage lens
    - ✓ PRK
    - ✓ Abrasion
    - ✓ Dry Eye
      - ✓ Useful for severe exposure
      - ✓ Patients with lid disease



“No, baby, you’re money”

## Myokymia

- ✓ Spontaneous, fine fascicular contractions of muscle without muscular atrophy or weakness
- ✓ Most likely nerve fiber irritation
  - ✓ Stress
  - ✓ Fatigue
  - ✓ Caffeine
  - ✓ Alcohol

## Myokymia

- ✓ Treatment
  - ✓ Self-limiting
  - ✓ Quinine
    - ✓ Tonic Water

