New Therapeutics For The New Decade

Eric E. Schmidt, O.D., F.A.A.O.
Omni Eye Specialists
KeplrVision
Wilmington, NC

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Eric E Schmidt, O.D., F.A.A.O.

Disclosures

Aerie – Advisory Board
Allergan- Consultant, Advisory Board
Sensimed– Advisory Board
AMO – Consultant, Advisory Board
Carl Zeiss Meditec – Speakers Bureau
Novartis– Speakers Bureau
Sun Pharmaceuticals – Advisory Board

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Glaucoma Drug Update

- Lots of new stuff
- Lots of good stuff

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Glaucoma Drugs – Tapping that Pipeline!!!

- Nothing New For The Past 5 Years
- All Of A Sudden – BOOOM!

- Rhopressa
- Roclatan
- Vyzulta
- Xelpros
- Bimatoprost -SR

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But really, is there anything new????

- Latanoprostene bunod – B&L
  - Novel nitric-oxide donating prostaglandin
  - Improves perfusion pressure??
  - Lowers IOP 7.5 – 9.1 mmHg from baseline
  - QHS dosing
  - Vyzulta -Available Now

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A new PGA –Available…now!!

- Latanoprostene bunod 0.024%
  - Nitric oxide donating prostaglandin
  - F2-alpha analog
- 1 drop QHS
- B & L
- Vyzulta – available 2018!!!!

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Vyzulta – Latanoprost bunod 0.024%

- Nitric-oxide donating PGA
- B & L
- QD dosing
- Reduces IOP 7.5 – 9.1mm- superior to timolol
- How does it compare to the other PGAs??
- How is it different??
- How is it better ??

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Vyzulta

- Adding NO donor increases outflow through Schlemm's Canal and t.m.
- Increases relaxation of these tissues
- Non-inferior to timolol (LUNAR Study)
- However…nearly twice as many eyes had IOP lowered >25% as compared to timolol

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Vyzulta –Medeiros et al AJO, 2016

- Additional 1.2mm lowering of nocturnal IOP
- Hyperemia rate-9%
- Eye irritation – 7.2%

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LBN and OPP

- LBN exhibited better ocular perfusion pressure than timolol, *especially at night!!!*
- Better IOP reduction at night as well
- Liu et al, AJO 2016

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Latanoprostene bunod (LBN)

- Phase 2 study
- Head to head study vs Xalatan
- 413 patients
- LBN consistently lowered IOP in a dose-dependent manner
- Significantly lower IOP than Xalatan at day 28 (also at day 7 and 14)
- .98mm Hg lower at all time points
- Slightly higher hyperemia rate

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One more new PGA!!

- Xelpros (Sun Pharmaceuticals)
  - Latanoprost BAK-free drops
  - Preserved w/ potassium sorbate
  - New delivery option
  - Multi dose bottle
  - Similar in efficacy to latanoprost
  - Has not been compared to Xalatan
  - What about side effect profile?
  - What about cost?

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So What Do We Really Know About Xelpros??

- It is an emulsion formulation of latanoprost
- It IS NOT preservative free!!
- It IS BAK free!!
  - But is that a good thing really?
- Xelpros was equal in IOP reduction to Xalatan at all time points

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Xelpros – latanoprost 0.005%

- Lowers IOP 6-8 mm Hg
- From baseline 23-26mm Hg (25-33%)
- QHS dosing
- Multi dose bottle
- No generic equivalent
- Unique pricing and prescribing structure

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Xelpros – Adverse Events (>5% incidence)

- Eye pain/stinging
- Conjunctival hyperemia
- Eye Discharge
- Eyelash growth and thickening
- Sounds a lot like a PGA!!

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Xelpros

- <1% discontinued therapy due to redness or stinging
- Is their strategy a good one?
- What do we think?

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Aerie Pharmaceuticals

- 2 New Drugs
- Rhopressa – Novel molecule
  - Works on different receptor sites so..
  - Better IOP reduction with fewer side effects
  - No lash growth or skin darkening
  - Targets trabecular meshwork
- Roclatan – combo drug
  - Rhopressa and latanoprost
- Both are now commercially available

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Rhopressa (netarsudil) – Aerie Pharmaceuticals

New class of drugs – Rho-kinase inhibitor

MOA – "Triple Action"

- relaxes trabecular meshwork similar to pilocarpine (enhances outflow)
- lowers episcleral venous pressure
- blocks fibrotic response at t.m.(increases perfusion)

QD dosing

Looks especially effective at IOP 25 mmHg or less

Available Now!!

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Rhopressa -MOA

Works at the cellular level within the trabecular meshwork

ROCK inhibitors improve outflow by relaxing contraction and stress fibers at the t.m.

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What Do We Know About Rhopessa (netarsudil 0.02%)

- Rhopressa QD is non-inferior to timolol 0.5% BID in lowering IOP
- Expected IOP reduction 3.7 -7.0mm Hg
- Rhopressa seems to better superior at lowering IOP (as compared to itself) in pressures < 25mm Hg
- IOP lowering effect is maintained over 12 months
- Was given a broad label by FDA

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Rhopressa – Adverse Effects

- Generally well tolerated
- Conjunctival hyperemia – 53%
  - Did not worsen with time
  - Mild-36.8%, moderate – 10.5%, severe -0.6%
  - D/C rate due to redness -~3%
- Corneal verticillata – 18%
- Conjunctival hemorrhage – 15%
  - All are transient and considered mild

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What's to like about Rhopressa?

- New MOA so… it is absolutely different
- It should be additive
- Definitely works better at lower IOP
- What about side effects?

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Rhopressa- some final thoughts

- How do you think you will position it in your practice??
- Is it a first line drug?
- What about insurance coverage?
- What color top does it have??

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Roclatan – Aerie

- Fixed Combination drug – Rhopressa + latanoprost
- QD dosing
- "Quadruple acting" MOA – (adds increased uveoscleral outflow)
- IOP lowering better than either of its components
- Potential to be very effective – lowered IOP an additional 2-3 mm compared to Rhopressa (and other PGAs)

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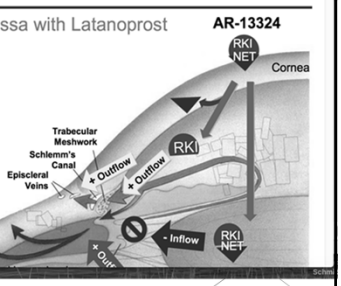
Roclatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%

Fixed Combination of Rhopressa with Latanoprost

4 Identified IOP-Lowering Mechanisms

- ROCK inhibition relaxes TM[1], increases outflow[1,2]
- NET inhibition reduces fluid production[2]
- ROCK inhibition lowers EVP[3]
- PGA receptor activation increases uveoscleral



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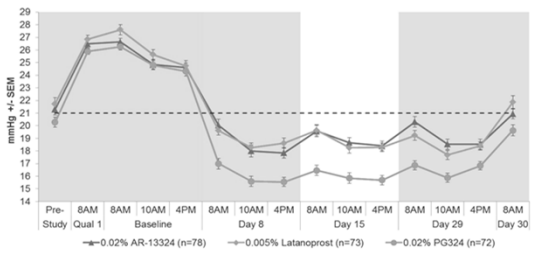
Mean IOP at Each Time Point (Primary Efficacy Measure)



PG324 Phase 2b, Intent to Treat

Source: Bacharach J, Levy B, Ramirez N, Kopczynski CC, Novack GD for the PG324-CS201 Study Group. Evaluation of PG-324, a fixed dose combination of AR-13324 and latanoprost, in patients with elevated intraocular pressure in a double-masked, randomized, controlled study. American Glaucoma Society 2015 (in press).

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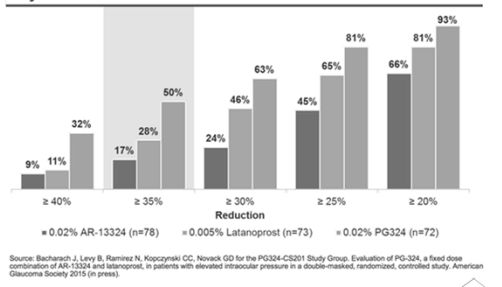
Roclatan (netarsudil/latanoprost) 0.02%/0.005% Phase 2b Responder Analysis

Day 29 – % of Patients with IOP Reductions of ≥ 20%



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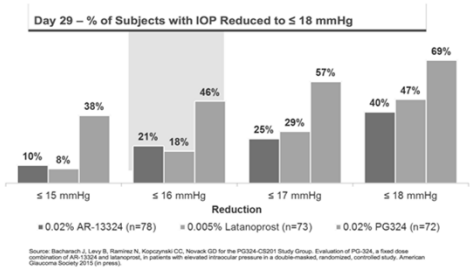
Roclatan
Phase 2b Responder Analysis

Day 29 – % of Subjects with IOP Reduced to ≤ 18 mmHg



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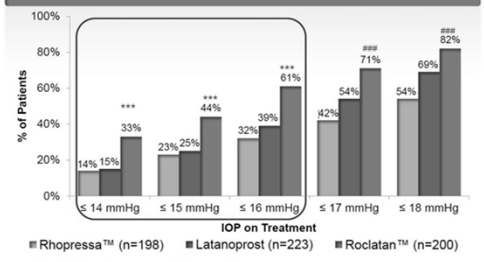
Roclatan™ Phase 3 Responder Analysis

Day 90: % of Patients with IOP Reduced to 18 mmHg or Lower



***p<0.0001 vs Latanoprost and Rhopressa™

###p<0.0001 vs Rhopressa™, p<0.05 vs Latanoprost

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Roclatan (netarsudil/latanoprost) 0.02%/0.005% Phase 3 Clinical Trial (Mercury 1)

- Roclatan reduced mean diurnal IOPs to 16 mmHg or lower in 61 percent of patients, a significantly higher percentage than observed in the comparator arms.
- The most common Roclatan adverse event was hyperemia, which was reported in approximately 50 percent of patients, or 30 percent above baseline, and was scored as mild for the large majority of these patients. Conjunctival hemorrhage was also noted. There were no drug-related serious adverse events for any of the comparators in the trial.
- NDA expected near end 2017.

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Newest Rocklatan Data

- 1400 pxs
- Rocklatan vs Rhopressa vs Latanoprost
  - 60% achieved >30% reduction in IOP
  - 1/3 achieved > 40% reduction in IOP
  - CIGTS showed 38% drop to STOP VFG progression
  - 75% achjieved <18mm Hg
  - 1/3 achieved 14mm or less
  - On average 3.2 mm lower IOP than either latanoprost or Rhopressa

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Newest side effect data

- No tachyphylaxis at 12 months
- No unexpected A.E.
- Very few serious A.E.- majority are mild

- 58% hyperemia but 5% d/c rate
- 20% Instillation pain – 0% d/c
- 10% subconj heme – 0% d/c

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Rocklatan

- What do we think?

- Side effects- same as Rhopressa
- Place in therapy?
- Clinical impressions
  - What do pxs think?
  - What is the discontinuation rate?

- Cost concerns

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Presbyopia correcting drops

- Presbysol?? – Allergan

  - 1% Pilocarpine/ Oxymetazoline
  - Reduces pupil size by 40-60%

  - Phase 3 trials now
  - Primary outcome – improve UNVA 3 lines or better without reducing DVA

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Presbysol – what we know

- 40-50% reduction of pupil size is optimal for improving NVA
- Smaller pupil size may actually enhance glare and aberrations
- Oxymetazoline was added in hopes of reducing HA and brow ache
- Vehicle (as of now undisclosed) seems to make drop more comfortable and decrease HA

35

Presbysol results…

- Safety study
  - HA rate of 20%
    - 2/27 were moderate, rest were mild
  - 50% only occurred at Day 1
  - ~50% occurred for <10 days
    - HA usually occurred in 1st hr and resolved by Hr 3

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Presbysol – Up To The Minute…

- QD dosing vs BID
- 3 lines of NVA improvement seems very achievable
- Better improvement seen with better lighting
- DVA seems unaffected
- Not yet tried in post-LASIK or pseudophakic pxs

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What about generics??

- Latanoprost
  - Pros?
  - Cons?
- Brimonidine
  - Pros?
  - Cons?
- Timolol
  - Pros?
  - Cons?

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Xalatan vs Latanoprost

They both are 0.0005% latanoprost but that's where the similarity ends
BAK concentration is different (even between the generics)
Bottles are different
Head-to-head study
Anecdotal data

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Is there a generic Lumigan?

There will be soon
… it will be OLD Lumigan (0.03%)

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What about generic Travatan?

It exists but it is Travatan without Sofzia
When is the last time you chose Travatan w/BAK over Travatan Z?

41

Are generics really as good as branded products?

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DROP Study – Myers, 2014

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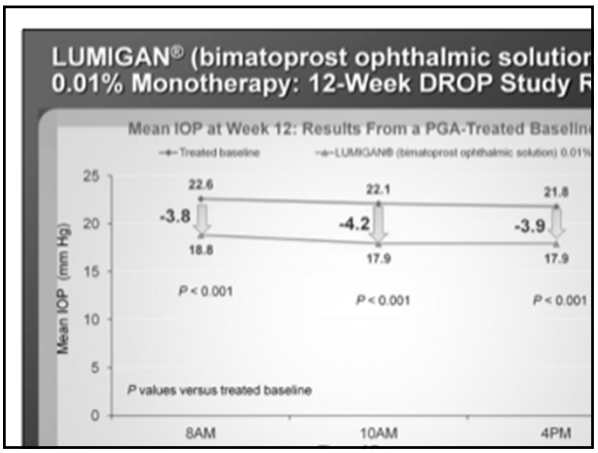

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Hot Off The Presses

Effect of Switching From Latanoprost to Bimatoprost…

Renato et al. J Glaucoma 2016;25(4)

Conclusion:

Pxs who exhibited IOP rise while on latanoprost achieve further IOP-lowering when switched to bimatoprost

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Switch Study #2

- Switch Resulted in reduction of >15% in peak IOP in 73%
- 43.9% had reduction of IOP between 15-30%
- 29.6% had IOP reduced >30%

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Brimonidine

- Alphagan P 0.1%
- Generics are 0.15% or 0.2%
- Generics are drastically different from branded

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Brimonidine Formulation Comparison

	ALPHAGAN® P		ALPHAGAN®
Concentration of Brimonidine	**0.1%**	**0.15%**	**0.2%**
pH	**7.7**	**7.2**	**6.3-6.5**
Preservative	**PURITE®**		**BAK**
Viscosity agent	**Carboxymethylcellulose**		**Polyvinyl alcohol**
Electrolytes	**Potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate**		–

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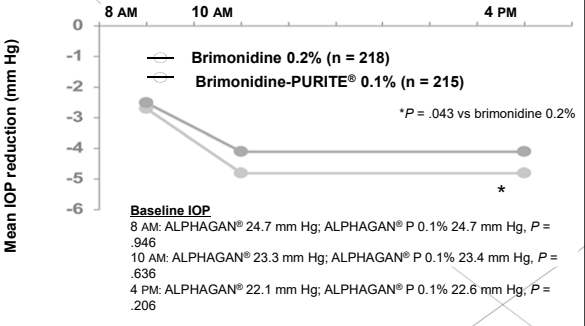
Mean Change From Baseline at Month 12



Baseline IOP
8 AM: ALPHAGAN® 24.7 mm Hg; ALPHAGAN® P 0.1% 24.7 mm Hg, *P* = .946
10 AM: ALPHAGAN® 23.3 mm Hg; ALPHAGAN® P 0.1% 23.4 mm Hg, *P* = .636
4 PM: ALPHAGAN® 22.1 mm Hg; ALPHAGAN® P 0.1% 22.6 mm Hg, *P* = .206

ALPHAGAN® P 0.1% demonstrates IOP-lowering efficacy equivalent to ALPHAGAN® 0.2% over 12 months

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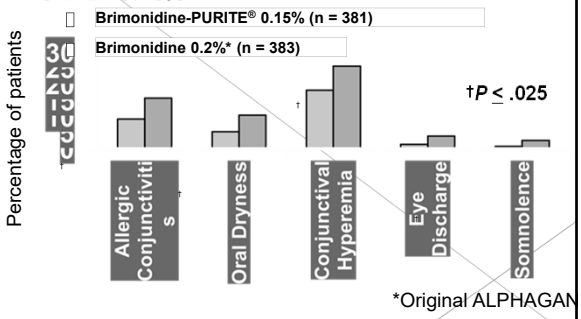
Adverse Events Typically Associated With Brimonidine 0.2%* Are Lower With Brimonidine-PURITE® 0.15%



*Original ALPHAGAN

Katz. *J Glau*

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Effect of Brimonidine-PURITE® 0.1% Formulation on Safety

- Ocular surface exposed to 50% less drug with new formulation
  - Less allergy, redness, irritation
- Lower concentration also means fewer systemic effects as less drug enters nasolacrimal duct
- Remember branded Alphagan is preserved with Purite, Generic (either .15 or .2) is preserved with BAK

Katz. *J Glau*

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In regards to Brimonidine:

- There is a huge difference between generic and branded
- Both in side effects and desired effects
- THERE IS NO GENERIC ALPHAGAN P 0.1% !!!

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One final word about glaucoma drugs

- A lot of money is being spent on delivery systems
- These may be cheaper alternatives
- Optometry cannot sleep on this

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Bimatoprost SR

- Biodegradable sustained –release implant
- Injected intracamerally using single use applicator
- Implant is visible in irido corneal angle
- Could make a big impact on non-compliance issues
- Lowers IOP over a 4-6 month period

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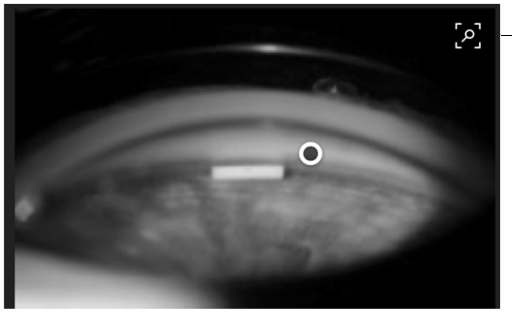

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Bimatoprost SR

- Phase 1 data
  - Proved safety and good tolerance
- Phase 2 data
  - 2 weeks
  - IOP 23.8 in Bimatoprost group
  - 24.1 in timolol group
  - At 6 months
    - 20.1 in implant group
    - 19.0 in timolol group

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Bimatoprost SR

- Second study showed IOP decrease of 7.2 -9.5 mm Hg
- At month 6, 70% of subjects did not require topical IOP gtt
- Biggest side effect is transient hyperemia and FB sensation
- Implications for ODs

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Novel Drug Delivery Systems- the next frontier

- Drug Eluting Punctal Plugs
  - QLT – latanoprost
  - 75% -80% retention rate
  - Results- 3-4mm drop in IOP
- Ocular Therapeutix – Intracanalicular latanoprost
  - Good sustained release of drug but doesn't lower IOP as good as topical Xalatan
- SOOOO????

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Brimonidine Drug-Eluting Plugs

- Similar technique to inserting collagen lacrimal plugs
- Early studies show better and more sustained IOP release than latanoprost plugs
- Good safety profile
- SOOOO>>>???

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Bimatoprost Ring

Implantable ring onto globe

Phase 1 study shows 5mm reduction in IOP for 6 months – from baseline of 24mm Hg

Very few adverse effects

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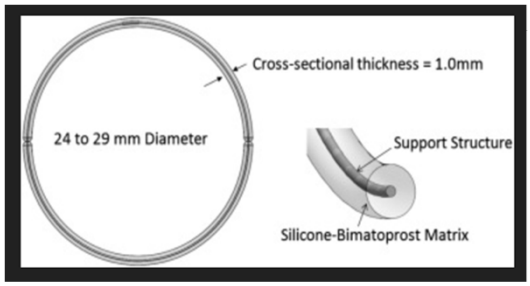

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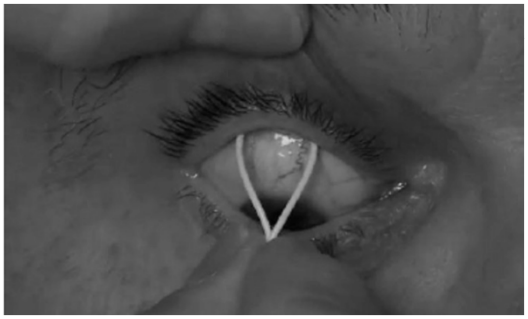

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True Tears- Allergan

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True Tears - Allergan

- Hand held neurostimulator that stimulates production of tears
- Increases reflex tearing
- Dosage – PRN??

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True Tears –Clinical Studies

- Study 1 – True Tears instrument used intranaasally (as intended) vs True Tears extranasally and vs Sham Device intranasally
- Endpoint – Increased tear production as measured by Schirmer's Test
- Result – True Tear device, used correctly, improved tear production consistently

67

True Tears – Study #2

- Longer term study
- Compared True Tears treatment to sham
- Significantly improved Schirmer's score at day 7, 30, 60 and 180
- No reported side effects

68

Brand New Study!!

- Gumus, Schuetzle and Pflugfelder – AJO 5/17
- Showed that properly used the Tru Tears device also triggers and increases conjunctival goblet cell mucin secretion when compared to sham therapy
- Could be another benefit of this therapy

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So What Do We Think of TrueTears??

- Will it be dispensed through pharmacy or doctor's office
- Who explains correct usage technique?
- Who decides the proper dosage?
- How expensive are the disposables?
- What will patients think?

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Autologous Serum – The How

- More aptly called Eye-Platelet Rich Plasma (EPRP)
- Eyedrops created from patient's own blood
- Blood is drawn and spun down
- WBC and RBC are all removed by centrifugation; platelets and growth factors remain
- Plasma is placed in sterile eyedrop bottle

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Autologous Serum

- 100% Platelets
- No Preservatives, No additives

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Autologous Serum – The Why

- Autologous plasma is rich in platelets and growth factors
- Growth factors enhance proliferation and wound healing
- Effective on hard and soft tissues
- Growth factors restore damaged ocular surface by inducing mesenchymal and epithelial cells to migrate and proliferate

73

Autologous Serum – The What For?

- Severe Dry Eye
- Corneal Ulcers (especially if dormant)
- Non-healing epithelial defects
- LASIK complications
- Chronic Dystrophies (EBMD)

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Kojima study – Am J Ophthalmol, 2005

- E-PRP for Dry Eye
- Conclusion- Autologous plasma is superior to conventional treatment for improving ocular surface health and subjective comfort
- E-PRP improved tear stability and vital staining scores (RB)

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Autologous Serum Studies

- Alio – Ophthalmology 2007
- E-PRP improved symptoms – photophobia, pain, inflammation
- E-PRP facilitated re-epithelialization
- E-PRP promoted wound healing
- Improved VA
- ".. In the majority of the patients in the study."

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Autologous Serum

- Autologous Serum brings growth factors directly to compromised eye.
- Diseased eye is not getting nutrients to help healing
- Diseased eye is undergoing chronic tissue breakdown
- E-PRP breaks that cycle

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Autologous Serum – Clinical Questions

- What is the dosage?
- Where should it be kept?
- When should it be Rx'd?

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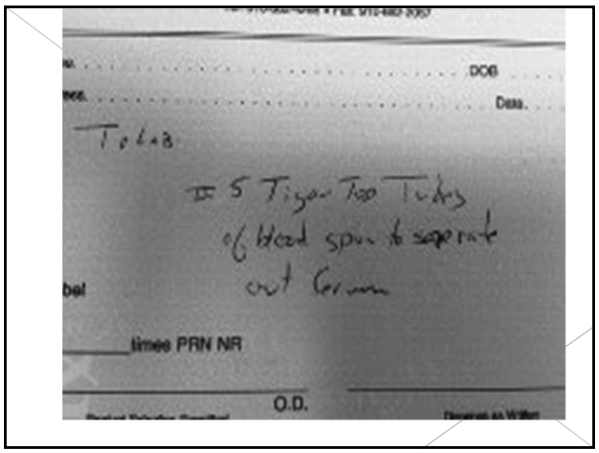

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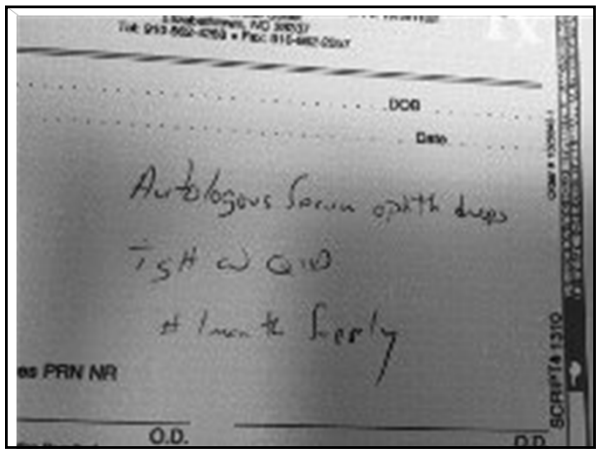

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What's New In NSAIDs?

- Bromsite (bromfenac 0.075%)– Sun Pharmceuticals
  - Only NSAID approved for treating pain AND inflammation post cataract surgery
  - Same concentration as Prolensa
  - Durasite added
  - Sustained release
  - True QD Dosing
- But what does this mean clinically?

81

Bromsite- Clinically

- Improved contact time – opens up another option for Dry Eye Therapy
- Higher concentration in vitreous (as compared to Bromday)
- Better tolerated
- Fewer ocular surface side effects

82

Steroid Update

- Lotemax SM (loteprednol 0.38%)– B & L
  - SM = submicron particles
  - Enhances dissolution of drug into tear film
  - This effectively doubles penetration through cornea when compared to LE Gel

83

Lotemax SM

- Emulsion so no shaking required
  - Btw why is that a big deal?
- Very low concentration of BAK (.003%)
- Does not blur vision as much as LE Gel
- Quickly turns into a viscous liquid
- Steroid response rate?
  - 2 out of 409 had 10mm or higher rise in IOP after 18 days

84

Inveltys (Kala Pharmaceuticals)

- Loteprednol etabonate 1%
- Indication – Tx of post-op inflammation and ocular pain
- BID dosing
- Nanoparticle technology allow sfor increased penetration and increased drug concentration into target tissue
- Doesn't bind (as much) to mucin

85

Inveltys

- Time to Zero inflammation
  - 24% at Day 8
  - 50% at Day 15
- Time to Zero pain
  - 43% at Day 4
  - 69% at Day 15
- 0.5% IOP rise

86

So what do we make of Inveltys?

- Would you change your post-op regimen?
- What about for Ocular Surface inflammation?

87

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- Would you change your post-op regimen?
- What about for Ocular Surface inflammation?

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Cequa –(SunPharmaceuticals)

- Cequa (cyclosporine 0.09%)
  - Improves both Schirmer score and decreases NaFl Corneal Staining

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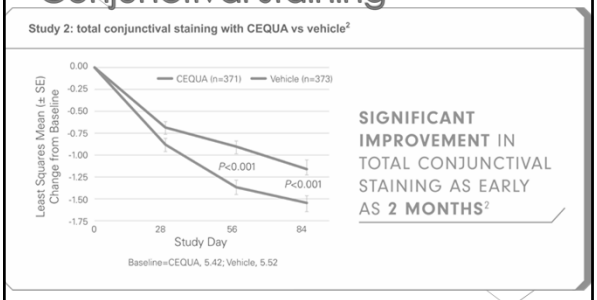
Conjunctival staining



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Cequa -Conjunctival staining

- Significant improvement in LG stain noted at 2 mths
- Significance improved even more at 3 mths

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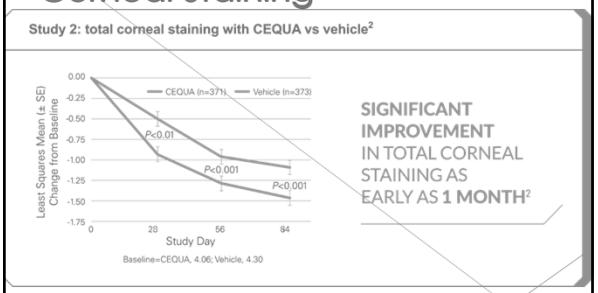
Corneal Staining



98

Cequa and Corneal staining

- Significant central corneal staining improvement seen at 1 mth
- 65% of all corneas were clear at 3 mths

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Designer Drugs!!

- Sounds awesome doesn't it!
- You can make whatever you want to make
- Glaucoma
- Dry Eye
- Antibiosis
- Post-operative meds

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So Let's Talk About This

- Imprimis
  - Triple antibiotic
  - NSAID, Steroid, Antibiotic combo
  - Cyclosporine A (unpreserved)
  - Glaucoma meds
    - Single agent
    - Double agent
    - Triple agent
    - 4 agent!!!!

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Xiidra - lifitegrast ophthalmic solution

- Indicated for the treatment of SIGNS and SYMPTOMS of Dry Eye
- Preservative Free
- BID dosing
- Unit Dose Vials
- SO it's just another version of Restasis …Right?

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Xiidra _Mechanism of Action

- Integrin Antagonist
- Blocks binding of ICAM-1 molecule (intercellular adhesion molecule) to LFA-1 (Lymphocyte –function associated antigen)
- Prevents and reduces T-cell lymphocye driven inflammation on the ocular surface and within the cornea
- Does NOT produce more tears!!!

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Xiidra characteristics

- Strong inhibition of T-cell aadhesion to ICAM-1 expressiing surfaces
- Highly soluble in aqueous
- Absorbs rapidly into ocular tissues
- Blocking ICAM stops inflammation and "downstream" effect on cytokines

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Xiidra – Phase 2 Data

- Primary outcome measures :
  - Reduction of corneal staining
  - Improvement of OSDI score
  - VS placebo
- Result: Significant improvement in K staining and OSDI score seen AS EARLY AS 14 days!

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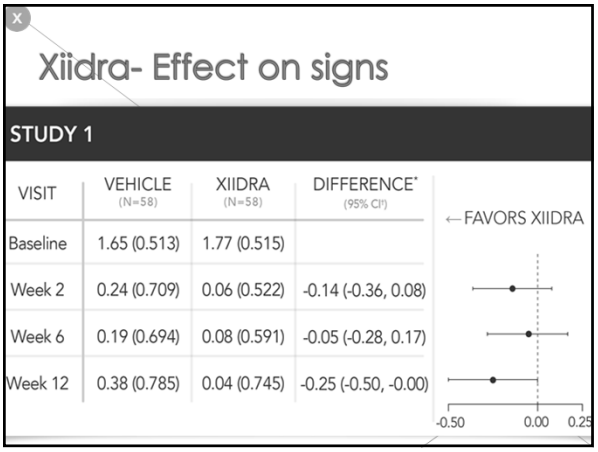
Xiidra- Effect on signs



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Xiidra Study 2

- Similar Study showed that clinical significance was still exhibited at day 84

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Xiidra – OPUS III Study (Phase 3)

- Only difference in study design was that all subjects had to have been treated with AT for at least 30 days and within 30 days of beginning the study
- Significant treatment differences were seen at Day 14 but biggest difference was noted at day 42

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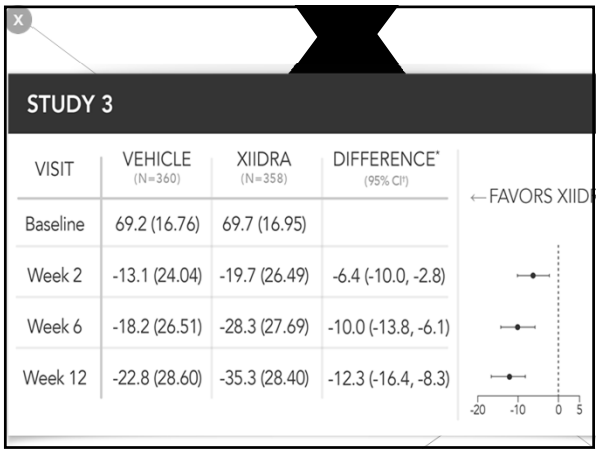

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SONATA Study

- 1 year safety data study
- Xiidra BID for 360 days vs Placebo BID for 360 days
- Results:

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Safety Study results

- 1. 53.6% in tx group vs 34.2% in control group reported at least 1 TEAE
- 2. All were rated as mild-moderate
- 3. Discontinuation rate 12.3% in Xiidra group , 9.0% in Placebo group

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Most Common Adverse Effects of Xiidra (>5%)

- 1. Instillation site burning (most often noted at first instillation
- 2. Instillation site redness
- 3. reduced VA
- 4. Dry Eye
- 5. Dysgeusia

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SO what do we think of Xiidra?

- Does it work?
- Do patients like it?
- IS it additive to Restasis?
- Can we use it with steroids concommitantly?
- Is it the gift that keeps on giving?
- Will it replace Restasis?

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Newest info on Xiidra

- Xiidra actually increases goblet cell number, area and function!
  - 39% increase in # of goblet cells
  - 22% increase in area of goblet cells
  - Measured improved secretory function
  - Less corneal staining in treatment cohort
  - Sousa, Yu, Stern etal – Journal of Ocular Pharmacology and Therapeutics, Vol 34, No 7, 2018.

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