Innovations in Dry Eye and Primary Eye Care

Greg Caldwell OD, FAAO
Optometric Education Consultants
Music City Bell Classic
November 1, 2019

Disclosures- Greg Caldwell, OD, FAAO
- Will mention many products, instruments and companies during our discussion
- I don’t have any financial interest in any of these products, instruments or companies
- Pennsylvania Optometric Association – President 2010
  - PDA Board of Directors 2006-2011
- American Optometric Association, Trustee 2013-2016
- I never used or will use my volunteer positions to further my lecturing career
- Lectured for: Aerie, Alcon, Allergan, BioTissue, OptoVue
- Advisory Board: Allergan, Sight Sciences, Sun, Takeda
- Envent: PA Medical Director, Credential Committee
- OCT Connect – Facebook page co-administer with Dr. Julie Rodman
- Optometric Education Consultants - Scottsdale, St. Paul, Quebec City, and Nashville, Owner

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Financial Obligations

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Course Description and Learning Objectives

This course will reveal, feature, and spotlight innovations in dry eye and primary eye care that will impact every optometrist. Technologies, pharmaceuticals, products, services, and processes that advance eye care will be discussed in a rapid-fire presentation. This course will keep you “in the know” for delivering advanced patient care.

- Introduce the innovation to the clinician in each of the topic areas
- Discuss how the innovation will impact the diagnosis and treatment in eye care
- Reveal the benefit of embracing the innovation
- Demonstrate how it will impact patient care
- Demonstrate how to integrate the innovation into the clinician’s practice
- Enhance the clinician’s knowledge of selected innovations that impact eye care

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How Many People With

- Diabetes
- Thyroid
- Glaucoma
- Dry Eye
  - 30 million

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Experts Gather for Recommendations and Algorithms

- Corneal, External Disease, and Refractive Society
  - Dysfunctional Tear Syndrome (DTS)
- Tear Film & Ocular Surface Society
- Dry Eye Workshop 2 (TFOS DEWS II)
- Delphi Panel International Task Force
- Delphi Panel
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Vital Dyes

- **Fluorescein**
  - Detects disruption of intercellular junctions
  - Positive (stain) - pooling
  - Negative (stain) - high or elevated areas
- **Rose bengal and Lissamine green**
  - Stains devitalized cells and cells that have lost normal mucin surface
  - Detects abnormal epithelial cells
Why are Conjunctival Staining and SPK Often Missed or Under Scored?

Wratten Filter

What's the common denominator?
- Eye burn/discomfort/pain
- pH

What's the next question?
- When is it worse?
  - AM/PM

AM: bacteria/parasite related
PM: aqueous deficient

Aqueous Deficient vs Evaporative

Let’s Focus on Evaporative

48 year old man
OU red, gritty, sandy and dry feeling

Current Correction
- R: 2.00 sphere
- L: 3.00 sphere

EOMS: full, unrestricted
CT: ortho D/N
PERRL (APD)
CF: full by FC OU

Diagnosis
- Rosacea
- What findings support your diagnosis?
  - Telangiectasias
  - Erythema of the cheeks, forehead and nose
  - Rhinophyma
  - Telangiectasia

Let us get a closer look

A Closer Look
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Meibomian Gland Dysfunction
Exacerbated by Rosacea
Evaporative

- Treatment?
  - Warm compresses
  - Lid hygiene
  - Artificial tears
  - Omega 3 fatty acid
    - EPA and DHA total 1500 mg (1000 mg minimum)
  - Dermatological consult (Acne Rosacea)
  - Oral antibiotics...???
    - Which one and why?

How About Steroids?

Minocycline

Clinical Pearl
Treatment Failure

- If you continue to think of doxycycline and minocycline as antibiotics, treatment failure will be the result
- From this point on consider them a steroid

Minocycline / Doxycycline

- Drug of choice for MGD, marginal inflammatory blepharitis (posterior blepharitis)
- AB, anti-inflammatory and anti-collagenase
- Inhibits lipase enzyme
- No renal adjustment
- 50-100 mg qd-bid 2-12 weeks (pulse)
  - Lower maintenance dose
  - 20 mg Periostat (Doxycycline)
    - Helpful in those with stomach or GI sensitivity
    - Excellent for those requiring long maintenance dose

Hyclate vs Monohydrate

- I get calls from the pharmacist
  - Doxycycline
    - Enteric coated hyclate pellet
    - AdvaSta
    - Monohydrate

My Paradigm for Minocycline / Doxycycline

- Status of MG
  - Inspissated
    - Minocycline / Doxycycline Paradigm
      - Maximum dosage for 2-12 weeks (pulse)
      - 100 mg BID, QD
  - Turbid
    - 50-100mg qd while turbid
    - 20 mg longer treatments
      - Periostat (Doxycycline)
  - Clear
    - 20 mg if maintenance dose needed
What is an Inspissated MG?

I Can’t Believe It’s Not Butter!® Squeeze

2016 Treatment Current Precautions and Innovative Changes?
- Warm Compresses
- Salt Scrubs
- Artifical Tears, Systane Balance
- Omega 3 (1500 EPA and DHA)
- Mino 100 mg PO 6 weeks, 50 mg 3 months, 20 mg maintenance (Doxy)
- Steroids, Tobradex qid (5 weeks with taper)
  - Moderately red and thickened lid margins
  - Marginal edema

Precautions with Oral Tetracycline Analogs
- Tetracycline analogs
  - Doxycycline
  - Minocycline
- Enhanced photosensitivity
- Avoid in children and pregnancy (Category D)
- Enhances the effects of
  - Coumadin
  - Digoxin
- Idiopathic intracranial hypertension
  - Pseudotumor cerebri
- Hyperpigmentation

Benign intracranial hypertension “It’s not rare if it’s in your chair”
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Innovations

Dry Eye Disease

Procedures Currently Represent 4% of all US Dry Eye Revenue

Revenue for Dry Eye Products by Segment

Procedures 4%

OTC 25%

Rx 71%

Newer dry eye procedures offer the most significant potential for market growth.

– Market Scope

Heat to the MG

What has changed?
What is new?
Is it better you decide

Bruder Moist Heat Eye Compress

Dry Eye Relief and Daily Eyelid Hygiene

Bruder Moist Heat Eye Compress

Bruder Cold Therapy Eye Compress

Micro-fine sheets are designed to cleanse the eyelids

Moist heat treatment
Stabilize the tear film, improve gland function, slow tear evaporation
Ready in seconds, easy to use
Patent-pending MEDIbeads
Self-hydrating (no need to add water)
Anti-bacterial and non-allergenic
Washable and reusable
Safe for frequent use
Microwave for 20-25 seconds
Apply for 10 minutes
Unique pod design provides improved fit and performance
Mibo Heating Pad

- 5 settings
- Aromatherapy
  - Lavender
- USB powered

Mibo Thermoflo

- Ultrasound gel-based
- Comfortable treatment, no pressure
- No disposables (ROI for the practice)
- Technician driven eliminating the need to burn the doctors chair time
- Dry eye maintenance
- Pricing for patients is more affordable than other options making the treatment more easily accepted by patients

TearCare

Personalized Open Eye Experience

- Natural blink design
- Ultra-precise meibomian gland clearance
- Patented smart system

Pharma Update

Nuzyra™ (omadacycline)

- Tetracycline antibiotic
- Approved 2018
- Approved for PO/IV treatment of patients
  - Bacterial skin infections
  - Community-acquired bacterial pneumonia

- ADRs:
  - Nausea, vomiting, diarrhea, constipation, insomnia
  - Cholestatic jaundice: JUST like other tetracyclines
**Seysara™ (sarecycline)**
- Tetracycline drug
- Approved 2018
- Indicated for the treatment of inflammatory acne in non-nodular, moderate to severe acne vulgaris
- Potential for MGD treatment
- Can be taken WITH or WITHOUT food!
- ADRs: nausea

**Xerava™ (eravacycline)**
- Tetracycline antibiotic
- Approved 2018
- Indicated for the treatment of intra-abdominal infections in adults
- IV ONLY

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**Xiidra™ (lifitegrast) 5%**
- Company: Shire, Takeda, Novartis
- Approved July 2016
- Specific treatments/indication: dry eye disease
- Dosage: one drop twice daily in each eye, 12 hours apart
  - Dysgeusia, site irritation, blurred vision
  - Relief as soon as 2 weeks with symptoms
  - Eye Dryness Score
  - Signs improve as soon as 12 weeks
  - Inferior cornea staining

**Mechanism of Action**
- Lymphocyte function-associated antigen-1 antagonist
- LFA-1 is found on the T-cell
- Blocks ICAM-1/LFA-1 interaction
- Intercellular adhesion molecule-1
- ICAM is overexpressed in dry eye:
  - Cornea, conjunctiva, lacrimal gland
- Anti-inflammatory by inhibiting
  - T cell activation
  - T cell migration
  - Cytokine Release

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**Xiidra™ - What I Have Learned**
- Only pharmaceutical indicated for signs and symptoms of dry eye disease
- Works within:
  - 2 weeks for moderate DED
  - 4 weeks for mild
  - Cornea staining takes 12 weeks
- Use as a diagnostic
- 30 million USA adults with DED
- BID means 12 hour apart
- Can in front of the dysgeusia
- Works great for GPC and SAC. Look for post IOL patient
Cequa™ (cyclosporine ophthalmic solution) 0.09%

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Hypochlorous Acid

- Natural antibacterial agent
- Found in white blood cells
- Bifunctional mechanism of action of antibiotics
  - Oxidant
  - Bactericidal
- Skin microbiome contributes to infection, blepharitis, and MGD
  - Staphylococcus aureus, Staphylococcus epidermidis, Corynebacterium, and Propionibacterium acnes

HyClear
(hypochlorous acid 0.1%)

HyClear™ is Pure
HyClear is a non-cytotoxic, non-irritating solution recommended for daily use

HyClear™ is Stable
HyClear provides up to an 18 month shelf life after opening

HyClear™ is Effective
HyClear kills the majority of ocular pathogens in seconds

Nutraceutical Therapies

What has changed?
What is new?
Is it better you decide

Nutraceutical Therapies in Dry Eye

- Looking for anti-inflammatory fatty acids
- Dry eye efficacy
- “Fish oil” will provide nice hair, nails, and skin
- Gamma-Linoleic Acid GLA
  - Specific action that “life oil” omega lacks
  - 7 randomized controlled trials for dry eye

- Prostaglandins - Myth buster: they are not all bad
  - Prostaglandin E1 (PGE 1) - good
    - Shown to stimulate lacrimal production (Phalpramool, 1980, 1983)
    - Supports mucin production
    - Conjunctiva, other membranes (Viau, 2009, Willemsen, 2003, Nygren, 1984)
  - Prostaglandin E2 (PGE 2) - bad
    - Precursor AA
  - Prostaglandin E3 (PGE 3) - good
    - Precursor EPA in Erba

Nutraceutical Therapies

- Prostaglandin E1 (PGE 1) - good
  - Shown to stimulate lacrimal production (Phalpramool, 1980, 1983)
  - Supports mucin production
  - Contributes to other conditions (Knecht, 2006, Stenberg, 2005, Lipman, 1996)
  - Experimental deprivation of vitamin C a required cofactor for PGE 1
  - Stops lacrimal production, produces Sjögren’s-like signs & symptoms (Wood, 1970)
  - Precursor GLA

- Prostaglandin E2 (PGE 2) - bad
  - Precursor AA
- Prostaglandin E3 (PGE 3) - good
  - Precursor Omega-3 - “fish oil”
Gamma-Linolenic Acid GLA

- Consistently shown improvement in markers of inflammation / inflammatory mediators in dry eye
- Shown promise in other inflammatory diseases, like rheumatoid arthritis, IBD, dermatitis, and diabetic retinopathy
- In Sjögren’s increases tear production, raises PGE1 in tears (Aragona, 2005)
- Supports meibomian glands (Pinna, 2007)
  - Probably through anti-inflammatory action
- 2,000-3,000 mg omega-3s usually required to have significant effect
  - In contrast 235 mg of GLA significantly reduced 2 different inflammatory markers (HLA-DR, CD11c) in the HydroEye trial (Sheppard, Pflugfelder, Whitley et al. Cornea, 2013)

Is GLA offered in the triglyceride (TG) form? aka “re-esterified”

- These forms of omegas triglyceride (TG) vs ethyl ester (EE) mainly apply only to fish oils
- Fish oil when it’s purified is transformed from the natural TG form in fish to the EE form
  - Which allows the omegas to be concentrated & purified
- Fish oil companies have heavily marketed re-esterified or TG fish oils as vastly more absorbable and bioavailable
- GLA only comes as TG form
  - No other form
  - TG vs EE discussion is purely about different fish oils

Nutraceutical Therapies

- Pick the right nutraceutical not “fish oil” ad get:
  - Improvement in irritation symptoms
  - Better cornea smoothness
  - Significantly lower levels of inflammatory markers

Regenerative Healing

Amniotic Membrane

Prokera

Amniotic Membrane

- To help reset the eye from a stage 3-4 back to something manageable
- Failure on multiple therapies
- Sjögren’s and the rheumatological patient

Dry Eye and Amniotic Membrane
Neurostimulation

What has changed?
What is new?
Is it better you decide

Ocular Surface Disease/Dry Eye

- Aqueous production
- True Tear/Allergan
  - FDA approved (April 25, 2017)
  - New development for treatment of ocular surface disease
  - Intranasal Tear Neurostimulator
    - Low millivolt pulses to stimulate branch of trigeminal V
    - Research showing stimulation of 3 layers of tear film
    - Disposable end caps need to be replaced daily
    - Sold by docs and/or Allergan and tips prescribed by optometrist

In-Office Lab Testing

- Helps with:
  - Switching patient to dailies
  - Starting nutraceuticals
  - Starting pharmaceuticals
  - Following patients over time

TearLab Osmolarity Test

- 300 and above
  - Helps confirm dry eye
- Asymmetry
  - Helps confirm unstable tear film
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TearLab Discovery™ Assay Platform

- Panel Testing of Tear Fluid Biomarkers
  - Tear Osmolarity plus inflammatory marker
  - Capable of quantitative measurement
- Single 100 nanoliter tear collection.
- Fluorescent Immunooassay
- Rapid < 2 minutes from collection to result
- Study Panel: BED + Inflammation
  - Osmolarity
  - MMP-9

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TearLab Discovery™ Assay Platform

Traditional Lateral Flow Tests Highly Volume Dependent

Traditional lateral flow tests require at least several microliters of tear fluid to perform reliable measurements. This is not generally feasible to sample in clinical practice, especially in DED patients where much less than 1 µL is readily available without reflex tearing.

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TearLab Discovery™ Compares Well to InflammaDry®

Despite using 1/100th the volume of tear fluid, TearLab Discovery shows good agreement with the InflammaDry® method.

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TearLab Discovery™ Platform Timing

- 510(k) submission in January 2017
- Expected approval → 2019

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InflammaDry®
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InflammaDry®
For inflammatory dry eye detection
Normal levels of MMP-9 in human tears ranges from 3-41 ng/ml

**NEGATIVE TEST RESULT**
MMP-9 < 40 ng/ml

**POSITIVE TEST RESULT**
MMP-9 ≥ 40 ng/ml

InflammaDry®
For inflammatory dry eye detection
Normal levels of MMP-9 in human tears ranges from 3-41 ng/ml

**POSITIVE TEST RESULT**
MMP-9 ≥ 40 ng/ml

**NEGATIVE TEST RESULT**
MMP-9 < 40 ng/ml

Sjö Diagnostic Test
- Uses proprietary biomarkers to create an advanced diagnostic panel
- Early detection of Sjögren’s syndrome in your patients

Innovations
Outside of Dry Eye
Pharma Update
Glaucoma

Xelpros™ (latanoprost ophthalmic solution 0.005%)
- Sun Pharmaceuticals
- Approved September 2018
- Dosage: QD
- Reduce IOP in open-angle glaucoma and ocular hypertension
- Xelpros is the first latanoprost product not formulated with the preservative benzalkonium chloride
  - Potassium sorbate 0.47% - preservative
- Mechanism of delivery with castor oil
- Reduces IOP in patients with open-angle glaucoma and ocular hypertension
  - Up to a mean of 6 mm Hg to 8 mm Hg in randomized clinical trials

Xelpros™ (latanoprost ophthalmic solution 0.005%)
- Not available in pharmacies
- A direct pay between patient and partnering pharmacies
- No prior authorizations
- No coupon activation
- No callbacks
- Prompt fulfillment and refills
- $55 for 30 days, $110 for 90 days
Rhopressa™ 0.02% (netarsudil ophthalmic solution)

- 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
  - Conjunctival hemorrhage
  - Conjunctival hyperemia

No clinically relevant effects on vital signs
No labeled contraindications for Rhopressa™

ROCK inhibition relaxes TM;
NET inhibition reduces fluid production;
ROCK inhibition lowers episcleral venous pressure (EVP)

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

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

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


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

Phospholipid accumulation

Control
Amiodarone
Netarsudil

Oxervate™ (cenegermin-bkbj)
- Approved 2018
- Dompé farmaceutici SpA
- Ophthalmic solution indicated for the treatment of neurotrophic keratitis
- Dosing: Instill 1 drop in affected eye 6 times per day (at 2 hour intervals) for 8 weeks
- Storage issues: in the freezer at the pharmacy; patient keeps the individual vials in the fridge—once “actively ready” for use, then it is only stable for 12 hours
- ADRs: eye pain, inflammation, corneal deposits

Innovation
Neurotrophic Keratitis

Rocklatan™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%
- Approved March 14, 2019
- Aerie pharmaceuticals
- Once-daily eye drop
- First PGA combination in USA
- Passed superiority testing

Bimatoprost SR Sustained Release
- Allergan
- Phase 3 Clinical Trial Update
  - 20-month efficacy and safety study
  - 528 people with POAG or Ocular HTN
    - 33% reduced IOP over 12-week primary efficacy period
      - Met predefined criteria for noninferiority to the comparator
    - Results similar to topical PGA
- Designed to lower IOP for 4 months
- Well tolerated to this point
- New drug application most likely second half of 2019

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Endogenous NGF maintains corneal integrity by three mechanisms

1. NGF binds receptors on the corneal nerves and stimulates the regeneration and survival of the sensory neurons.
2. NGF stimulates proliferation, differentiation, and survival of corneal epithelial cells.
3. NGF plays a role in nerve function and the control of corneal sensation.

OXERVATE™ (cenegermin-bkbj) ophthalmic solution 0.002% Weekly Device Kit

- OXERVATE™ is supplied in a weekly carton containing 1 multiple dose vial*.
- A separate weekly Delivery System Kit contains the supplies needed to administer treatment.

The Delivery System Kit Contains:
- 7 vial adapters
- 42 pipettes
- 42 sterile disinfectant wipes
- 1 dose recording card
- 1 extra adapter, 3 extra pipettes, 3 extra wipes are included as spares.

*Extra drug is available in each carton to take into consideration for loss or spillage during treatment administration.

Active ingredient structurally identical to human nerve growth factor produced in ocular tissues

- Naturally occurring neurotrophins are responsible for differentiation, growth, and maintenance of neurons.
- The regenerative potential of nerve growth factor (NGF) was discovered by Nobel prize winning scientist in the early 1950s.
- Cenegermin-bkbj, a novel recombinant human nerve growth factor (hNGF), is STRUCTURALLY IDENTICAL to the NGF protein.

OXERVATE™ [cenegermin-bkbj] ophthalmic solution 0.002% Dosing and Administration

Panel 1: 2 drops of OXERVATE™ (cenegermin-bkbj) ophthalmic solution 0.002% in the affected eye(s).
Every 2 hours
Apply 6 times daily
Continue for 8 weeks

Panel 2: Prednisolone acetate molecule modified to undergo predictable degradation to inactive metabolites by local esterases.
- Corticosteroids, C-20 ketone replaced with a C-20 ester
- C-20 ester steroids are associated with a lower incidence of IOP elevations vs. C-20 ketone steroids
- IOP and cataracts
- Retrometabolic drug design of loteprednol aims to improve safety while maintaining efficacy.

Innovation

Loteprednol etabonate
Lotemax

Ketones versus Esters

- Ketones versus Esters
- Prednisolone as an ester
- Corticosteroids, C-20 ketone replaced with a C-20 ester
- C-20 ester steroids are associated with a lower incidence of IOP elevations vs. C-20 ketone steroids
- IOP and cataracts
- Retrometabolic drug design of loteprednol aims to improve safety while maintaining efficacy.
Loteprednol Etabonate Products
Ester Steroids

- Lotemax suspension 0.5%
- Alrex suspension 0.2%
- Lotemax gel 0.5%
- Lotemax 0.4% gel 0.38%
- Inveltys suspension 1.0%
- KPI-121 loteprednol etabonate suspension 0.25%

Lotemax SM (loteprednol etabonate) 0.38%

- Indicated for the treatment of post-operative inflammation and pain following ocular surgery
- SubMicron - Particle size reduced to facilitate ocular penetration
  - Allowing for a decrease in drug concentration and dosing frequency (TID)
  - Increase intracocular penetration
  - Median particle diameter size reduced 5 to 12.5-fold
    - Lotemax gel 0.38% = 0.4 - 0.6 µm
    - Lotemax gel 0.5% = 3 - 5 µm
  - Potential for a ~10-fold increase in rate of drug dissolution
  - Based on a 10-fold increase in relative surface area with smaller particles

Lotemax SM (loteprednol etabonate) 0.38%

- Increased concentrations demonstrated in ocular tissues
  - Cornea and aqueous humor
  - Following single topical ocular instillation of Lotemax SM 0.38% vs Lotemax gel 0.5% in rabbits
- Compared to Lotemax Gel 0.5%
  - Single topical instillation of Lotemax SM 0.38% were greater in the aqueous humor and cornea
  - Concentrations in the conjunctiva remain the highest out of the ocular tissues, with ample drug to mediate anti-inflammatory effects at the ocular surface
- Formulation advancement while maintaining a low BAK
  - Formulation builds on the heritage and advantages of Lotemax gel 0.5%:
    - Retrometabolically designed corticosteroid
      - Retains potent anti-inflammatory activity
      - Minimal potential for class Aes
    - Mucoadhesive, non-settling, shear-thinning gel
      - A gel in the bottle; transitions to a liquid upon instillation
      - Becomes mucoadhesive liquid on dilution with tears
      - No need to shake - uniform dosing
      - Non-blurring

Inveltys™ - loteprednol etabonate suspension 1.0%

- Kala (Kala Pharmaceuticals)
- August 2018
- Novel in distribution center and pharmacies
- Nanoparticle-based Mucus Penetrating Particles (MPP)
  - Amplified Technology
  - MPP
  - Allows drug to penetrate through tear mucins
  - Increased penetration 10 to 100-fold through impeded
- 1.0% post-operative inflammation and pain after ocular surgery
- Dosing BID
  - First ocular corticosteroid to be BID

Stay Tuned
- Kala (Kala Pharmaceuticals)
- First product indicated for the temporary relief of signs and symptoms of dry eye disease
- Phase 2 and Phase 3 efficacy and safety trials
  - STRIDE - Short Term Relief in Dry Eye
  - 500 or 1000 patient clinical trials

KPI-121 loteprednol etabonate suspension 0.25%

- Kala (Kala Pharmaceuticals)
- First product indicated for the temporary relief of signs and symptoms of dry eye disease
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Innovations

Glaucoma
Minimally Invasive Glaucoma Surgery
MIGS

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The iStent inject Trabecular Micro-bypass

For patients with cataracts and glaucoma, iStent inject is:
- FDA approved therapy for the treatment of elevated IOP in adult patients with mild-to-moderate primary open-angle glaucoma in conjunction with cataract surgery
- The first available 20 intrasinus, micro-bypass system designed to restore natural physiological outflow through two openings through the trabecular meshwork

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iStent

iStent inject creates two patent bypass pathways through the trabecular meshwork Resulting in multi-directional flow through Schlemm’s canal

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MIGS Technologies

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Innovations

Instruments

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OCT Angiography
A New Approach to Protecting Vision

Non-invasive visualization of individual layers of retinal vasculature
Pathology not obscured by fluorescein staining or pooling
Image acquisition requires less time than a dye-based procedure
Reduced patient burden allows more frequent imaging to better follow disease progression and treatment response

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Enface OCT-A Slabs Based on Retinal Anatomy

OCT-A (Angiography) Normal Retinal Vasculature

What Does Glaucoma Look Like?

Diabetes 12-19-2018 OD

Diabetes 12-19-18 OS

Diabetes 12-19-2018
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Glaucomatous damage of the macula is common and can occur early in the disease. Can be missed or underestimated or both, with standard 24-2 VF tests that use a 6° grid.

Opportunities for Improvement in Central 10 Degrees

24-2 and 10-2 VF Example
Blue zone region on the 24-2 VF = central 10-2 VF
(a) Both are abnormal
(b) 24-2 VF normal, 10-2 VF abnormal
(c) 24-2 VF abnormal, 10-2 VF normal

The expert group selected specific 10-2 test point locations. Prevalence and depth of glaucomatous macular defects were systematically evaluated to select optimum test points. Pattern covers areas known to be susceptible to glaucomatous defects both from structural and functional studies.

Selected test locations are shown in red boxes.

The expert group: Donald C. Hood, Stuart K. Gardiner, Allison M. McKendrick and William H. Swanson.

Resulting SITA Faster 24-2C Pattern on HFA3

The 24-2C test pattern combines all 24-2 points + ten selected 10-2 points (shown in OD orientation).

Large Gray 24-2 points
Large Orange Ten additional 24-2C points
Small Gray 10-2 pattern

SITA Faster 24-2C showed enhanced sensitivity to detect visual field loss in Central 10 degrees.
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Minimize Time and Maximize Information with HFA3

- **SITA Faster 24-2**
  - 25 to 30% faster than SITA Fast
  - More information in the central field

- **SITA Faster 24-2C**
  - ~20% faster than SITA Fast 24-2

**Mixed SITA GPA**
- Clinical equivalence of tests allows screening SITA Faster, Fast, Standard, 24-2, 2-2, 24-2C in progression analysis
- Add new tests to patient progression
- Helps immediately adopt SITA Faster

24-2C SITA Faster
Flagged points detected centrally in OD

24-2 SITA Standard 24-2C SITA Faster

What is it?
- The Icare® HOME tonometer
  • Handheld
  • Battery operated device
  • Without the need for topical anesthetic
- Intended as an adjunct for monitoring IOP of adult patients (self-use)
- Caregivers in cases where the patient is not able to obtain their own measurements

Icare® HOME tonometer
- IOP, date, time, eye recognition (right/left) and measurement quality are all stored in the internal memory.
- Data is transferred to a PC for further analysis by the prescribing physician.
- New features: positioning light, automatic eye recognition system, series or single measurements, new user interface panel.

Technology
- Light weight (26.5 mg) probe touches the cornea with low speed (0.25-0.30 m/s)
- Minimal energy

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Icare EyeSmart: Automatic Eye Recognition

The tonometer includes an automatic eye recognition system that identifies which eye is being measured.

- Two infrared LED transmitters below probe (1)
- One infrared LED sensor above probe (2)
- The infrared light is reflected from nose back to the sensor
- The sensor knows from which transmitter the reflected infrared light came from and thus which eye, right or left, was measured
- The resulting eye indication is stored into the memory of the tonometer

Rebound Tonometry is Safe

- No significant safety issues reported for the Icare® i100 & TA01 tonometers with a large number sold worldwide (60,000) and in the United States (9,000)
  - In use by health care personnel with varying degrees of tonometer experience and some of which have little or no ophthalmic training
- No significant safety issues reported for the Icare® HOME tonometer or its predecessor, Icare ONE; over 2,000 tonometers in use worldwide
  - Majority in Europe after Icare ONE received CE mark in late 2009 and was introduced in 2010

Why 24 Hr Monitoring?

24 hour IOP monitoring can reveal higher peaks and wider fluctuations of IOP than those found during routine office visits. Research reports a steady daily increase in IOP in some patients being treated for glaucoma.


Studies have shown IOP rises when a patient is supine; IOP peaks were measured upon awakening and declined within 30 minutes.


Innovations

Instruments

Wide Field

Monaco... provides more information faster

Monaco can capture color and optomap® of images along with posterior pole OCT scans of both eyes in as little as 30 seconds. This quick, comprehensive look inside the eye has been shown to enhance pathology detection and significantly improve clinic flow.
Innovations in Dry Eye and Primary Eye Care

Monaco:
Imaging modalities

Color
Sensor
Choroid
Simulated White Light

Thank You and Hope You Enjoyed

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