

**Ocular Surface Point-of-Service
Diagnostic Center: Clinical
Asset, Surgical Necessity,
Patient Delight, Business
Essential, and Practice Builder**

John D. Sheppard, M.D., M.M.Sc.
Elizabeth Yeu, M.D.
Marguerite McDonald, M.D., F.A.C.S.

April 5th, 2015
ASCRS Meeting
San Diego, California

**Business Plan
Implementation
Diagnostic Test Specifics
Case Studies**

Business Plan

**Dry Eye Center of Excellence:
A Business Plan**

John D. Sheppard, M.D., M.M.Sc.
President, Virginia Eye Consultants, Norfolk, Virginia
Professor of Ophthalmology, Microbiology & Molecular Biology
Clinical Director, Thomas R. Lee Lab for Ocular Pharmacology
Medical Director, Lions Eye Bank of Eastern Virginia
Ophthalmology Residency Research Director

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Dry Eye Center of Excellence?

No choice if committed to continued
clinical leadership in our community.

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Professional Disclosures

- Alcon: Research Grants, Speaker, Advisor
- Aldeyra Pharmaceuticals: Advisory Board, Clinical Research
- Allergan: Research Grants, Speaker, Advisory Board, Media Spokesman
- Bausch & Lomb, Ista, Valeant: Research Grants, Speaker, Advisory Boards
- Abbvie, Shire: Research, Advisor, Spokesman
- BioTissue: Advisory Board, Clinical Research
- Doctors Allergy Formula: Advisor, Investor
- EyeGate Research: Advisory Board, Research, Shareholder, Speaker
- EyeRx Research: Clinical Research, Stock Ownership
- Imprimis Pharma: Advisory Board
- Isis Pharmaceuticals: Research, Advisory Board
- Inspire/Merck Pharmaceuticals: Research, Speaker, Advisory Board
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- Novartis/Ciba Vision: Speaker, Advisory Board
- NICom: Advisory Board
- Omeros: Advisory Board
- OcuCure: Advisory Board, Shareholder
- OcuHub: Advisor, Investor
- Pfizer: Research, Speaker
- RPS: Advisory, Research, Investor
- Rtech: Clinical Investigator, Advisory Board
- Santen: Research, Speaker, Advisory Board
- Shire, SarCode Biosciences: Advisory Board, Shareholder, Research Grant
- Synedgen: Advisory Board
- Science Based Health: Research, Advisory, Media Spokesman
- Senju: Research Grants
- Srathspey Crowne: Investor
- Talia Technology: Speaker, Advisory Board
- Tear Lab: Advisory Board, Speaker, Shareholder
- Tear Science: Advisory Board, Speaker
- Topcon: Clinical Research Grant
- Vistakon: Advisory Board, Clinical Research
- Xoma, Servier: Clinical Investigator
- 1-800-DOCTORS: Advisory Board, Shareholder

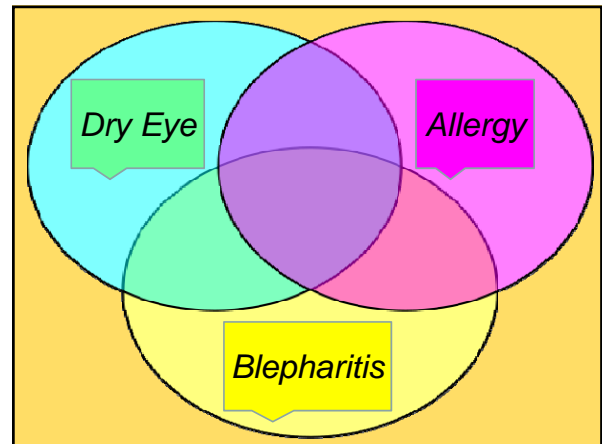
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Dry Eye: Accepted All Inclusive Term

- Keratoconjunctivitis sicca (KCS)
- Dry Eye Syndrome (DES)
- Dry Eye Disease (DED)
- Dysfunctional Tear Syndrome (DTS)
- Sjogren's Syndrome (SS)
- Meibomian Gland Disease (MGD)
- Ocular Surface Disease (OSD)
- Ocular Surface Inflammatory Disease (OSID)

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Dry Eye Center of Excellence?

- Objections
- Procedural Service Expansion
- Product Line Expansion
- Diagnostic Testing Expansion
- Practice Growth



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Objections

- Slows Me Down
- Low Margins
- Distraction From Surgical Focus

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Physician Extenders: Speed You Up

- ODs, PAs, RNPs
- Non-surgical Ophthalmologists
- Technicians: MA, COA, COT, COMT
- Scribes & Movers
- Counselors
- Check Out Staff

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Scribe



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Focus on Dry Eye Prevalence

• Cataract Surgery	77%
• Penetrating Keratoplasty	60%
• Lasik	27%
• Glaucoma Surgery	78%
• Blepharoplasty	26%

Trattler, ASCRS CME Supplement, 2013
 Sheppard, WCC, 2015
 Azuma, BMC Research Notes, 2014
 Leung, Journal of Glaucoma, 2008
 Prischmann, JAMA Facial Plastic Surgery, 2013

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Zero Tolerance:

- Cell
- Flare
- Keratic Precipitates
- Macular Edema
- Punctate Keratopathy

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Virginia Eye Consultants: Leaders in World Class Specialty Eye Care Since 1963

Slit lamp of cornea *after* treatment

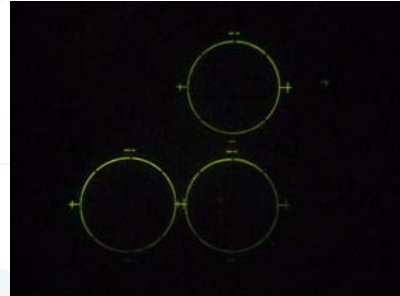


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Keratometry mires *after* treatment



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Hitting the Post-Operative Refractive Target

Keratometry

- Manual keratometry with skilled technician
- 1 diopter error in K = 1 diopter error in outcome

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Hitting the Post-Operative Refractive Target

Keratometry

- The most common error in keratometry is OSD
- OSD is present in 70% of cataract candidates

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ReStor Multifocal
Intraocular Lens (Alcon)

24

Most Neurodestructive Procedures

Procedure	Cord Length
• Penetrating Keratoplasty	• 25 mm
• Lasik, Corneal Inlay	• 21 mm
• Secondary AC IOL	• 6 mm
• Cataract with LRIs	• 6 mm
• LRIs	• 4 mm
• DSEK	• 4 mm
• Cataract, RLE or ICL	• 2 mm
• SMILE	• 2 mm



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Trattler, ASCRS CME Supplement, 2013
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 Leung, Journal of Glaucoma, 2008
 Prischmann, JAMA Facial Plastic Surgery, 2013



Procedural Service Expansion

Punctal Plugs: Collagen, Silicone, Cautery
 LipiFlow Thermal Pulsation
 Amniotic Membrane

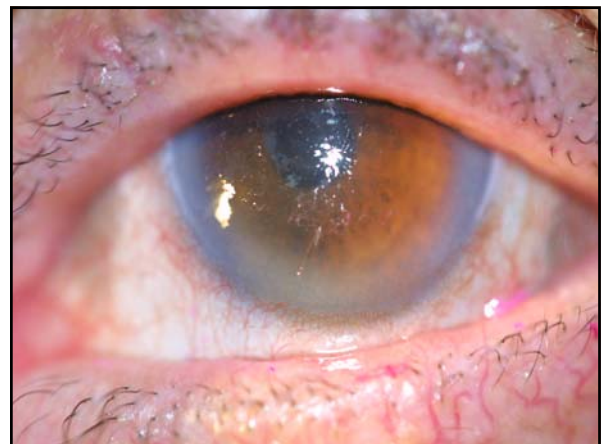


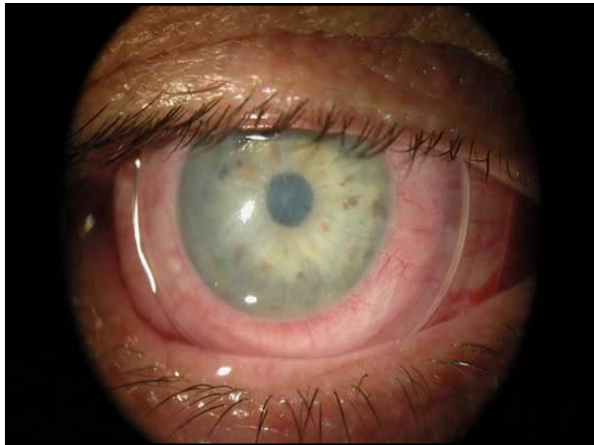
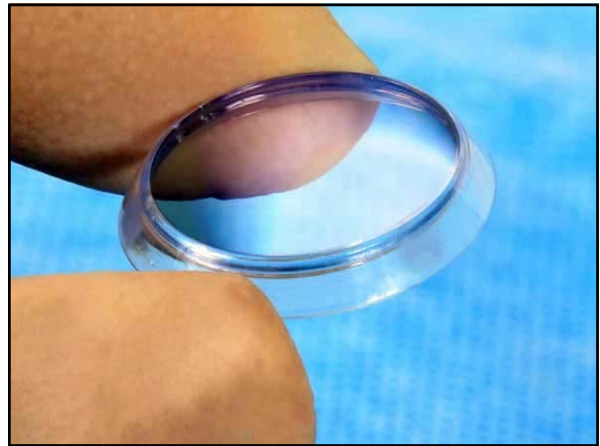
Collagen, ProLong, Silicone, Hyfercator



Punctal Occlusion Collections

• Collagen & Silicone Plugs	\$ 292,000
• <u>Punctal Cautery</u>	\$ 25,000
Total	\$ 317,000





ProKera Slim CPT 65778

- 1 per day entire practice
- 12 Doctors
- 2 Cornea Specialists
- \$ 1200.00/unit
- Debridement not performed for dry eye
- 260 work days/year
- \$ 312,000.00

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Product Line Expansion

Tranquileyes Compress
Fire & Ice Masks
Lid Scrubs: OcuSoft, Lavender, Cliradex
Nutritionals: Hydroeyes

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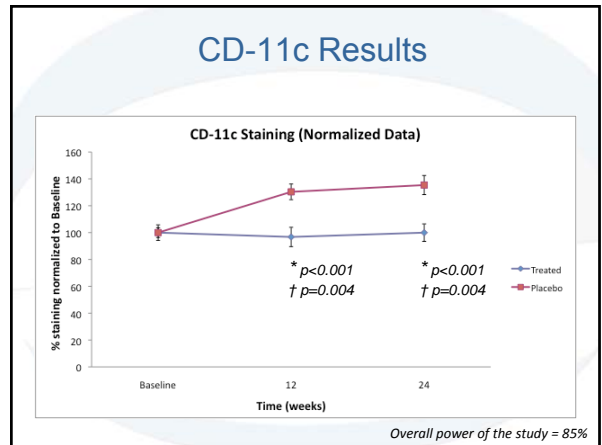
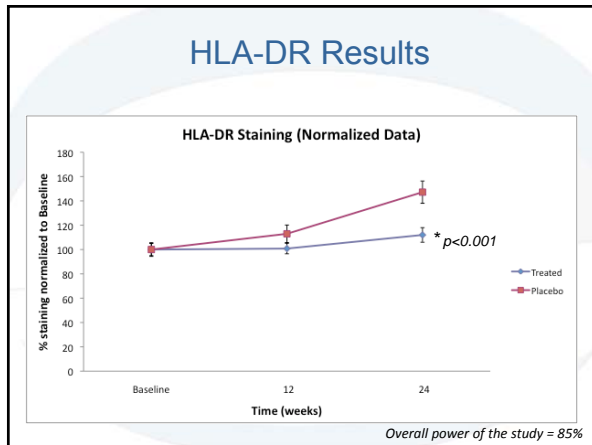
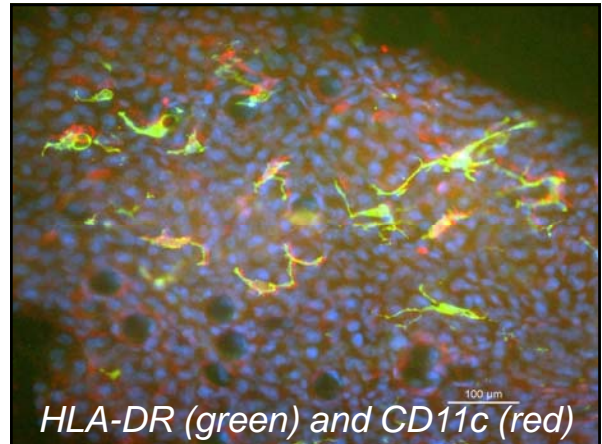
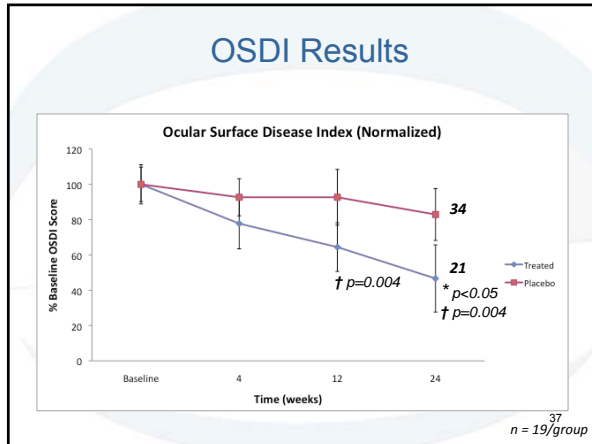
HydroEye 6 Month Clinical Trial

- 2 pills BID
- Postmenopausal Evaporative Dry Eye
- Improved OSDI
- Improved Topography
- Improved Inflammation: Impression Cytology



SBH ScienceBased Health®
(Sheppard, Cornea 2013)

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SBH ScienceBased Health®

Long-term Treatment with Nutritional Supplements Containing Gamma Linolenic Acid and Omega 3 Fatty acids improve Moderate to Severe Keratoconjunctivitis Sicca

John D. Sheppard, Jr.^{1,2}, Stephen C. Pflugfelder^{3,4}, Rishi Singh^{5,6}, Andrew J. McEllister⁷, Mitchell P. Weikert⁸, Stephen V. Scoper⁹, Thomas J. Joly¹⁰, Dayna M. Lago¹¹, Walter O. Whitby¹², Ekta Kakkar¹³, Mark Enochs¹⁴

¹Ophthalmology, Eastern Virginia Medical School, Norfolk, VA; ²Ophthalmic-Clinical Staff Clinician, Kullen Eye Institute, Ophthalmology, Baylor College of Medicine, Houston, TX; ³Virginia Eye Consultants, Norfolk, VA

Introduction:

- Patients with mild, moderate or severe dry eye continue to require medical treatment (artificial tears).
- Patients self-use TSP (Tear Substitutes Plus) and report that they are less likely to use artificial tears and report that they are less likely to use artificial tears and report that they are less likely to use artificial tears.
- Nutritional supplementation, particularly gamma linolenic acid (GLA) and omega 3 fatty acids may improve OSDI and ocular surface disease and improve dry eye symptoms.

Methods:

- This randomized, double-blind, placebo-controlled, prospective clinical trial was conducted in the dry eye clinic at Eastern Virginia Medical School.
- A total of 38 moderate to severe dry eye patients (moderate to severe keratoconjunctivitis sicca) were treated for 24 weeks. Patients were randomized at baseline, 12 and 24 weeks.
- Clinical parameters (OSDI score, conjunctival injection, tear film break-up time, and CD11c staining) were measured and were compared to baseline, 12 and 24 weeks.
- Primary endpoints were OSDI score, conjunctival injection, and CD11c staining.
- Secondary endpoints were frequency of artificial tear usage, tear film break-up time, and conjunctival injection.
- Clinical safety evaluation for adverse reactions was conducted. Adverse reactions were mild, and no serious adverse reactions were reported.
- Statistical analysis was performed using a two-tailed t-test.

Ocular Surface Disease Index (OSDI)

Hydrolyzed Supplement Composition

Ingredient	Amount
Gamma Linolenic Acid (GLA)	1000 mg
Omega 3 Fatty Acids (EPA/DHA)	1000 mg
Other nutrients	As listed

Secondary Evaluation Criteria:

- At baseline, OSDI scores were not significantly different between the treatment group (n=19) and the placebo group (n=19).
- Supplement therapy significantly decreased OSDI score from the treatment group compared to baseline (p<0.001, n=19).
- Supplement therapy significantly decreased OSDI score from the placebo group compared to baseline (p<0.001, n=19).

HLA-DR Staining

CD11c Staining

CONCLUSIONS:

- Significant improvement in self-reported patient assessments as well as reduced levels of inflammatory biomarkers indicate that targeted nutritional supplementation over time improves the signs and symptoms of keratoconjunctivitis sicca in post-menopausal women.

Primary Outcome Results:

- Significant improvement in self-reported patient assessments as well as reduced levels of inflammatory biomarkers indicate that targeted nutritional supplementation over time improves the signs and symptoms of keratoconjunctivitis sicca in post-menopausal women.

Secondary Outcome Results:

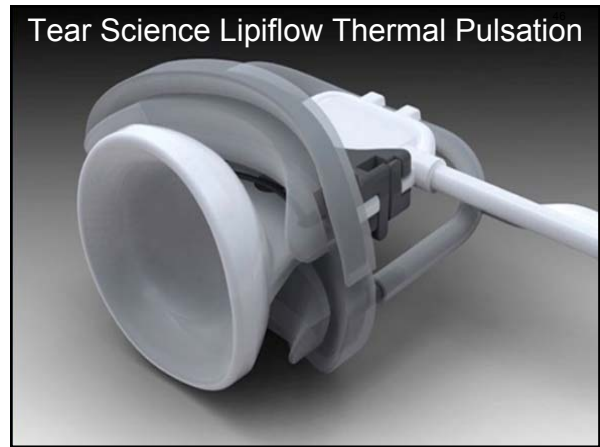
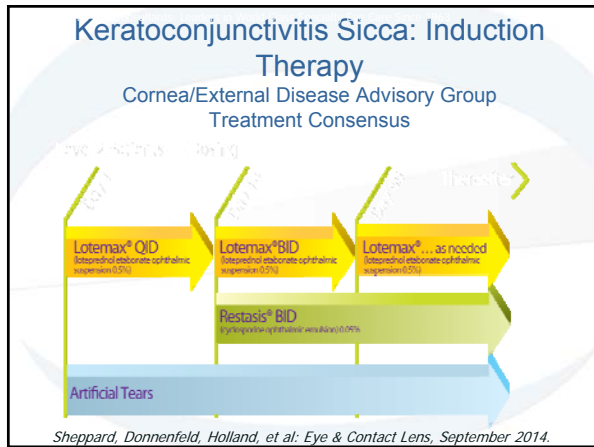
- In this study, a specifically formulated and nutritional preparation for the treatment of dry eye was shown to be beneficial in this patient population.

©2014 Trial Registration NCT02085365 www.clinicaltrials.gov

Retail Collections 2013

- Nutritional Sales \$ 112,000
- LipiFlow \$ 304,000
- Masks, Lid Scrubs \$ 15,000
- Total \$ 431,000

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Diagnostic Testing Expansion

POS Testing: Osmolarity, MMP-9, Sjo
Imaging: Oculus Keratograph, LipiView
Allergy Antigen Screening

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Dry Eye Diagnosis

Test	Sensitivity	Specificity
Osmolarity	90	95
Schirmer Strip	66	77
Lactoferrin	35	70
Rose Bengal	25	90
Tear Film Breakup Time	52	72

Compiled from Farris RL. Tear Osmolarity-a new gold standard? Adv Exp Med Biol. 350:495-503, 1994.

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TearLab Osmolarity Platform



- Nanofluidics
- Electrochemical Detection
- 1 Second Sampling Time
- 0.05 ul Tear Sample
- "Lab on a Chip"
- Disposable
- CLIA Waiver
- 2 Minute Results
- < 308 mOsm/L

12 Doctors: 192 Office Days/Year

Specialty	Tests/Day	Tests/Year
• Cornea/External	40 (20 patients)	7680
• Cornea/Refractive	30	5850
• Cataract/Refractive	20	3840
• Glaucoma/Cataract	20	3840
• Oculoplastic/Orbit	12	2304
• Comprehensive (3)	60	11520
• Optometry (4)	80	15360
Total	262	50304

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Osmolarity Testing

- New Dry Eye Patients
- All Surgical Patients
- Punctal Plug Decision Analysis
- Lipid or Aqueous Prioritization
- Treatment Follow Up Assessment
- Neurotrophic Assessment
- Post Lasik Hyperesthesia Syndrome
- Contact Lens Decision Analysis

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TearLab Osmolarity Collections

- 12 Doctors
- 50304 Tests/Year
- \$19.00/Test
- \$955,776.00/Year



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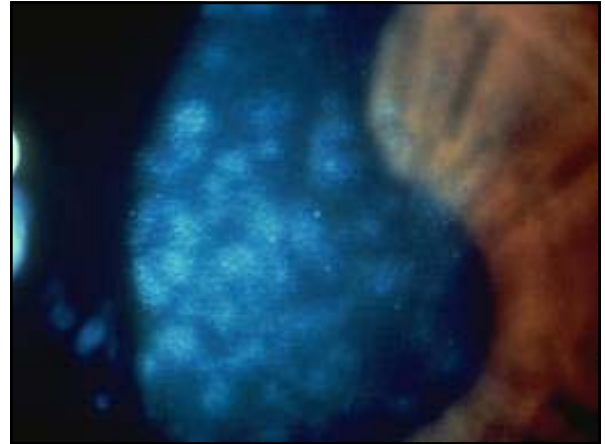
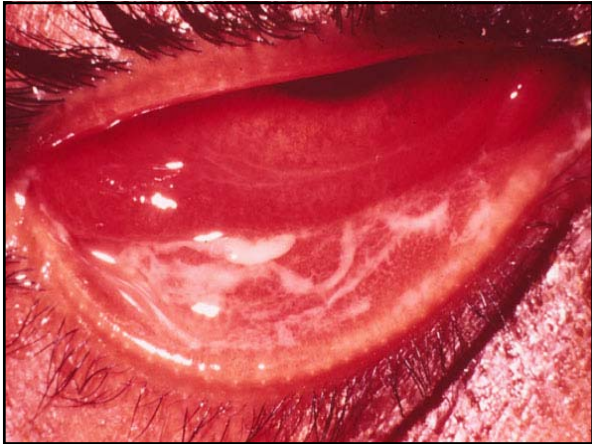
RPS InflammaDry Collections

- 12 Doctors
- 50304 Tests/Year
- \$12.00/Test
- \$603,648.00/Year



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Adenovirus Keratitis

- Induction: Ganciclovir Gel (Zirgan)
- Maintenance: Loteprednol (Lotemax)

RPS (NiCox) Adenovirus Assay

	Adeno Detector	Cell Culture
Sensitivity:	89%	92%
Specificity:	93%	100%
Overall agreement:	93%	98%
Positive predictive value:	82%	100%
Negative predictive value:	96%	98%

*Lower Detection Limits:
0.1 ng of Hexon (major immunogenic part of the Adenovirus)*

AdenoPlus Point of Service Diagnostic

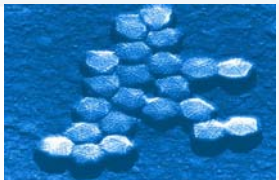

90% Sensitivity²

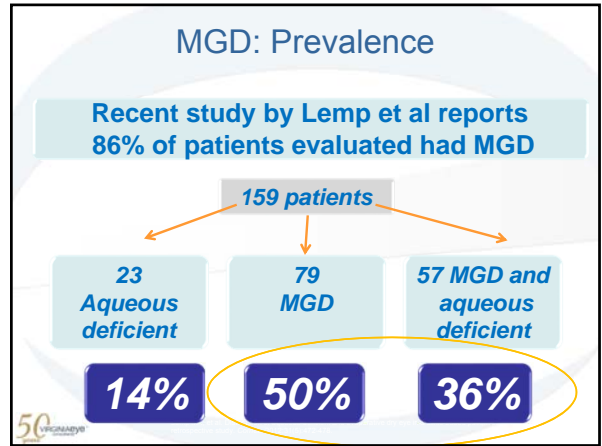
96% Specificity²

CLIA waived
Reimbursable: CPT 87809QW

RPS NiCox AdenoPlus

- Adenovirus
- Allergy IgE
- Herpes Simplex Virus
- Chlamydia
- Lateral Flow Immunoassay
- 10 minute turnover
- 3 second sample



LipiView® Ocular Surface Interferometer Measures Lipid Layer Thickness

Light source: The Illuminator

Chin rest

Camera, computer and drivers are housed by the device

Touch screen control panel

Measurement time: 20 seconds per eye

Device dimensions: 28" x 17" x 17"

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LipiView Collections

- 12 Doctors
- 1 Test/Day
- \$25.00 Cash/Test
- \$57,600.00/Year

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ANTIGEN SKIN TESTING

CPT 95004

DoctoRx

Allergy Skin Test Collections

- 12 Doctors
- 2 Tests/Week
- \$420.00/Analysis (60 Tests)
- \$483,840.00/Year

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Practice Growth

- Insurance Based Business
- Cash Based Business
- Value Added Services
- Patient Acquisition

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Insurance Based Business: Cigna

• Intermediate Visit	\$ 38.00
• Osmolarity	\$ 36.00
• <u>InflammaDry</u>	\$ 16.00
	\$ 90.00

237% Revenue Increase: POS Diagnostics
5 minutes extra Tech Time
10 seconds extra Doctor Time

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Ask Your Managing Partner:



“Doctor Time”

Is A Practice's Most Valuable Resource

Insurance Based Business Revenue

Procedure	Time	Fee	\$/minute
• Cataract	15 min	\$ 600	\$ 40
• Epilation	1 min	\$ 45	\$ 45
• Plugs OU	5 min	\$ 270	\$ 54
• Allergy Tests	5 min	\$ 420	\$ 84
• ProKera	10 min	\$ 1200	\$ 120
• Toric IOL	15 min	\$ 2100	\$ 140

Cash Based Business Revenue

Procedure	Time	Fee	\$/minute
• Bleph OU	60 min	\$ 2400	\$ 40
• Botox	10 min	\$ 500	\$ 50
• Lasik OU	20 min	\$ 3000	\$ 150
• LipiFlow OU	10 min	\$ 1800	\$ 180

Combined Diagnostics Collections

• Osmolarity	\$ 955,776.00
• InflammaDry	\$ 603,648.00
• LipiView	\$ 57,600.00
• <u>Allergy Testing</u>	<u>\$ 483,840.00</u>
• Total	\$2,100,864.00

Combined Dry Eye Collections



\$ 3,160,864

Equivalent to 3 new providers, yet obtained entirely through internal marketing and existing but optimized providers

- ### National Dry Eye Awareness Month Ad
- 90 telephone calls: staff the call center
 - 60 screened, 30 dry eye
 - 15 enrolled in a dry eye clinical trial
 - 45 stay in the practice
 - 1 refractive surgery
 - 1 glaucoma
 - 3 cataracts
 - 2 family members
 - \$ 106 / patient acquisition cost

National Dry Eye Awareness Month Ad

- \$ 5,000 / 14 days half page ad
- \$ 106 / patient acquisition cost
- \$ 150 / clinical trial screening fee: 60
- \$ 4,000 / patient clinical trial income: 15
- \$ 1,510 / cataract patient (includes ASC): 3
- \$ 3,000 / refractive patient: 1
- \$ 1,800 / LipiFlow patient: 1
- \$ 400 / year routine patients acquired: 32
- \$ 91,130 total revenue: ROI 18:1

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Execution

- Provider Leadership
- Doctor Champion
- Engaged Administration
- Staff Education
- Staff Incentives
- Continuous Analysis
- Internal Marketing
- Targeted External Marketing



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Dry Eye Practice Optimization

- Patients Win: Diagnostic Accuracy
- Insurers Win: Targeted Therapy
- Doctors Win: Practice Growth
- Practices Win: Income Diversification



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Implementation

Dry Eye Center of Excellence: Implementation of Point-of-Care Diagnostic Biomarker Testing

Elizabeth Yeu, M.D.

Virginia Eye Consultants, Norfolk, Virginia
Assistant Professor of Ophthalmology
Eastern Virginia Medical School
Norfolk, Virginia

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Financial Disclosures

- Abbott Medical Optics: A, B
- Alcon Laboratories, Inc.: A, B
- Allergan, Inc.: A, B
- Bausch & Lomb, Inc./Valeant: A
- BioTissue: C, B
- GlassesOff: A
- iOptics: A
- RPS: B, I
- Shire: A
- Strathspey Crown: I
- TearLab Corporation: A, B
- Tear Science: A

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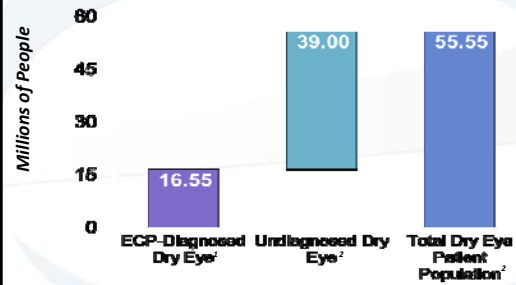
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PRACTICE FLOW IMPLEMENTATION & CONSIDERATIONS

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Dry Eye Is Underdiagnosed



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¹ Mattson J, et al. Epidemiology Analysis. 2005
² The 2004 Gallup Study of Dry Eye Sufferers. 2004.

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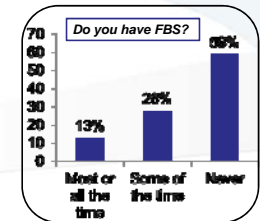
The Reality

- Dry eye disease patients = low back pain or headache patient
- Floodgates have opened for DED diagnostics and therapeutics
 - Superior to certain traditional tests, greater science to disease management
- Refractive cataract surgeons can't afford to ignore ocular surface disease
- It doesn't need to be that hard

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Testing only when Patients Complain of Dryness is Insufficient

- > 40% of people with objective evidence of dry eye are asymptomatic¹
- Cataract surgery patients often complain of fluctuating vision rather than dryness or FBS²



Despite a lack of discomfort, dryness or FBS, >60% of subjects had significant signs of OSD²

¹ Bron AJ, Tomlinson A, Foulks GN, et al. The Ocular Surface 2014. In press.
² Triller W, Reilly C, Goldberg D, et al. Prospective Health Assessment of Cataract Patients Ocular Surface Study. Poster, ASCRS 2011.

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What is a CLIA Waiver?

- Clinical Laboratory Improvement Amendments (CLIA): Lab testing standards established in 1998
 - “CLIA-waived” tests are simple with low risk of error
 - To perform waived tests a Certificate of Waiver is required
- CLIA-waived (Class I) tests in ophthalmology
 - TearLab Osmolarity Test
 - RPS InflammDry and AdenoPlus
- CLIA Class II: Moderate complexity
 - Lactoferrin and immunoglobulin (IgE) assays (Both ATD)
- >120,000 physician offices have CLIA certificates

...and How do I Get One?

- Steps to obtain a **CLIA Certificate of Waiver**
 - Complete Form CMS-116 from CMS website
 - Mail to the identified agency for your state
 - Wait several weeks
 - Receive CLIA certificate with 10-digit number
 - Pay fees (\$150 for 2 years)
 - Begin patient testing and 3rd party billing

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html

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**VIRGINIA DEPT OF HEALTH
Licensure & Certification**
9960 Maryland Drive,
Suite 401
Richmond, VA 23233
(804) 367-2107
FAX: (804) 527-4504
Contact: Sarah Pendergrass

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First: Ask the Patient

OSDI **SPEED** **Your Own**

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Practice Flow Considerations

- Tear analysis should be done before exposing the eye to vital dyes, dilation, bright lights or direct contact
- Empower staff to perform testing based on physician-ordered indications so physician can
 - Diagnose quickly
 - Begin OSD management right away

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Osmolarity or InflammDry in My Practice

- Both osmolarity and MMP-9 very useful
 - 1 can help to validate the other
 - Qualify severity of disease
- Dry eye complaint or history of dry eye
- Foreign body sensation, burning, redness
- Blurred vision intermittently
- Epiphora
- Preop cataract, LASIK
- Post infection
- Gauge treatment response

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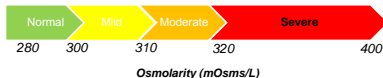
Osmolarity: How it Works

- Insert test card into pen device and remove cover
- Tilt chin up
- Blink 3 times
- Position pen on inner lid near corner of eye until beep – one 50-nL sample is collected
- Dock in TearLab unit and enter code
- Repeat for 2nd eye

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Interpretation & Treatment

- Confirmation of DED
 - Either eye > 308 mOsm/L
 - Difference between 2 eyes > 8 mOsm/L
- Helps support decision process of which dry eye treatment
 - Does not qualify etiology: aqueous-deficiency, evaporative, mechanical or mixed mechanism
- Qualifies disease severity



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Matrix Metallo-Proteinase (MMP-9)

- InflammaDry (RPS)
- In-office analysis of tear film inflammation
 - Elevated MMP-9 levels: ≥ 40 ng/ml
- CLIA waived
- Reimbursable
- Results ~10 minutes

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MMP-9: How it Works

1. Dab sample collector in 6-8 places on conjunctiva, pausing to let patient blink
2. Snap into test cassette
3. Immerse in buffer vial for 20 seconds and lay flat
4. Wait at least 10 minutes to read results



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Interpretation & Treatment

- Tells you to treat with anti-inflammatories
- A strong line or a rapid response is indicative of more severe inflammation
- Great for following response to treatment – can see change in as little as 1 month

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Pearls for Success

- Educate staff how to read the test
 - Even a faint pink line is a positive result
- Borderline cases may take longer to develop



50 VIRGINIAeye

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Slit lamp Exam

- Examination of lids and diagnostic expression of meibomian glands to determine quality of secretions
 - Grading of MGD, meibum quality, presence of MG atrophy and/or telangiectasis
- Tear film height and quality, pre-corneal TBUT
- Conjunctiva: staining pattern using LG, conjunctivochalasis (location and any tear film break up from CCH)
- Cornea: staining pattern with NaFL, surface irregularities such as Salzmann's nodular changes and epithelial basement membrane dystrophy

Next: Refine Treatment Plan

- Based on results gathered from subjective data (questionnaire, patient history), point of care test, SLE findings, create thoughtful plan
- Additional testing
 - Sjogren's blood test, In-office allergy testing, Lipid layer interferometry and meibomography
- Customized treatment
 - Medical and/or procedural intervention
- Consider long-term needs, which may require more (or less) aggressive therapy based on findings



Conclusions

- Advanced point-of-care diagnostics provide quick, objective and highly specific results that are easy to use and to explain to patients
- Patients desire an efficient, streamlined, minimally invasive experience, which can be an easier, quicker process with advanced diagnostics



Conclusions

- Protocols are evolving but you don't have to wait for the "perfect" protocol to begin implementing advanced diagnostics
- In age of greater refractive surgical expectations, clinicians need to increase suspicion of dry eye and MGD in cataract population and lower threshold for treating prior to surgery



Virginia Eye Consultants
Leaders in World Class Specialty Eye Care Since 1963
Dry Eye Center of Excellence?

John D. Sheppard, M.D., M.M.Sc.
Stephen V. Scoper, M.D.
David M. Salib, M.D.
Elizabeth Yeu-Lin, M.D.
Walter O. Whitley, O.D., F.A.A.O., M.B.A.
Thomas J. Joly, M.D., Ph.D.
Rayna M. Lago, M.D.
Constance M. Okeke, M.D., M.S.C.E.
Esther I. Chang, M.D.
Mark S. Enochs, O.D.
Jay Starling, M.D.
Cecelia Koetting, O.D.
Christopher Kuc, O.D.
Samantha Dewandara, M.D.
Surajit Saha, M.D.

Diagnostic Test Specifics

Dry Eye Center of Excellence: The Available Diagnostic and Therapeutic Technologies in Ocular Surface Disease

Marguerite McDonald, M.D., F.A.C.S.

Clinical Professor of Ophthalmology
NYU Langone Medical Center
New York, New York

Adjunct Clinical Professor of Ophthalmology
Tulane University Health Sciences Center
New Orleans, Louisiana

Ophthalmic Consultants of Long Island
Lynbrook, New York



Surgery Impacts Dry Eye

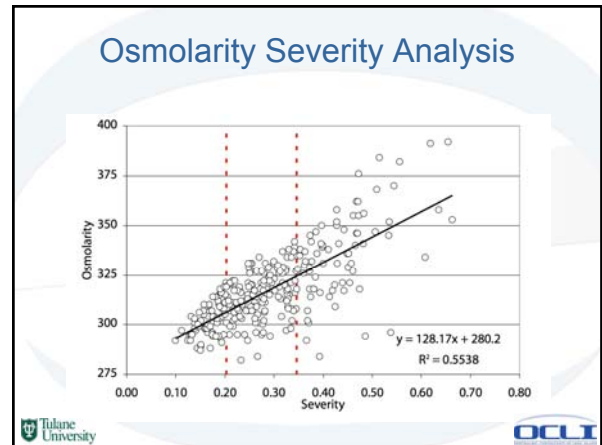
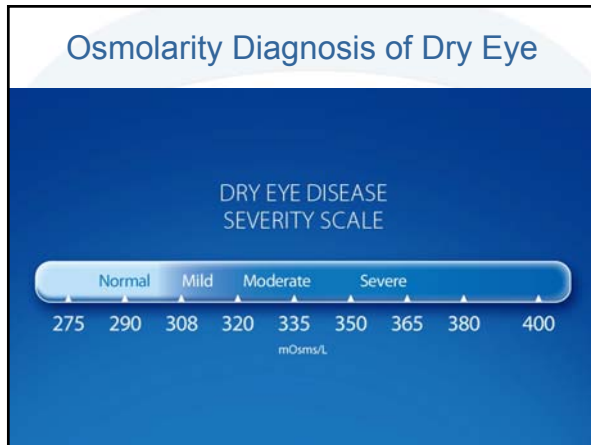
Severity Level	1	2	3	4
Symptoms	Mild to moderate	Moderate to severe	Severe	Extremely severe
Conjunctival Signs	Mild to moderate	Cataract Surgery adds 1 severity step	LASIK adds 2 severity steps	
Corneal Staining		Mild to moderate staining	staining; central striae; filamentary ker	Severe staining; corneal erosions
Other Signs		As assessed vision (blurring)		
Treatment Options				
	<ul style="list-style-type: none"> • Patient education • Environmental modification • Preserved tears • Control all 	<ul style="list-style-type: none"> • non-preserved tears • Gels, ointments • Cyclosporine A • Topical steroids 	<ul style="list-style-type: none"> • Oral tetracyclines • Punctal plugs (once inflammation is controlled) 	<ul style="list-style-type: none"> • Systemic anti-inflammatory therapy • Oral cyclosporine • Cysteine re goggles (punctal)
Plan pre-op and post-op care accordingly				
	If no improvement, add level 2 treatments	If no improvement, add level 3 treatments	If no improvement, add level 4 treatments	

Tulane University Behrens A, et al. Cornea. 2006;25:900-907. OCLI

Tear Osmolarity Testing

- Available now as a rapid point of care test from TearLab
- Normal eyes have low and stable osmolarity: 295 – 307 mOsm/L
- Dry eye patients exhibit hyperosmolarity (308 and higher) and inter-eye differences that are usually greater than 8 mOsm/L

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Matrix Metalloproteinase 9 Detection

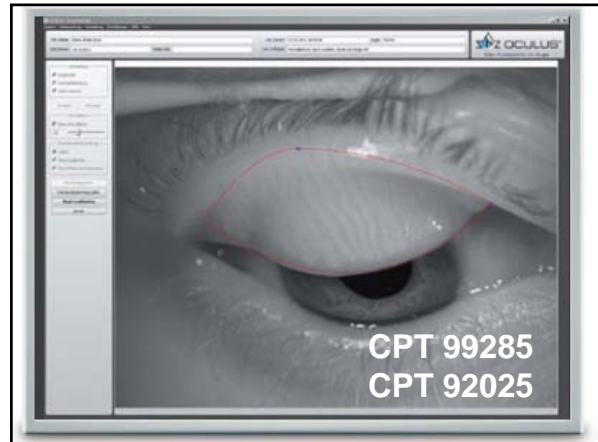
- MMP 9 is a non-specific marker for inflammation
- MMP 9 levels are elevated in dry eye
- Helpful in diagnosing dry eye and documenting response to treatment, especially immune modulators such as cyclosporine, steroids, and NSAIDs
- available as InflammDry from RPS

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Meibography

- As 86 – 92 percent of dry eye patients have meibomian gland disease, it is useful to evert all four lids and image the glands
- Meibomian gland distention, inspissation, tortuosity, and---eventually---dropout can be documented with meibography
- Meibograph can be performed with the OCULUS Keratograph 5 M and the Lipiview unit from TearScience



Non-invasive and Automated Tear Break Up Time

- Tear film break up time correlates with the severity of evaporative dry eye
- As with many of these tests, the automated tear break up time is useful in making the diagnosis of dry eye and tracking response to treatment



Non-invasive and Automated Tear Break Up Time

- Automated detection and classification of the level of severity is available through the OCULUS Keratograph 5 M, which displays the information in a color coded map, which shows how many seconds have passed before the tear film breaks up, and the pattern in which it breaks up, i.e., which areas break up first. Cool colors represent long break up times, and hot colors represent short break up times.



Automated Tear Film Particle Movement: a Measurement of Viscosity

- The small bits of material that can be seen in the tear film (mucous, pieces of broken cilia, makeup, dust, etc) can be identified individually and tracked as they move between blinks
- Their speed and trajectory are a direct reflection of tear viscosity
- This test is available with the OCULUS Keratograph 5 M



Automated Classification of Ocular Redness

- Conjunctival erythema is evaluated as the conjunctiva to sclera ratio; this is done by identifying the conjunctival vessels and sclera with digital image processing
- An average adult eye has a vessel-to-conj ratio of about 16%
- Available with the OCULUS Keratograph 5M as the R Scan



Tear Meniscus Height Measurement

- The height of the tear meniscus is lower in dry eye patients
- Difficult to assess, as the curvature of the meniscus is not always constant, due to mucous, debris, etc.

Tear Meniscus Height Measurement

- The OCULUS Keratograph 5M performs image analysis to evaluate the tear meniscus height and area
- AS-OCT (anterior segment OCT) is also widely available in most offices but not yet widely used in DED diagnosis

Anterior Segment OCT

- Not yet widely used in DED diagnosis
- is non-invasive, objective, quick & easy
- Measures tear meniscus height (TMH)
- Oculus Keratograph 5M also measures TMH
- Lower TMH has a diagnostic sensitivity of 92% & specificity of 90% for dry eye
- Also performs measurement of lid-parallel conjunctival folds (LIPCOF)

Lid Parallel Conjunctival Folds (LIPCOF)

- LIPCOF has a strong positive predictive value for dry eye: 93%
- LIPCOF has a strong correlation with symptoms

Lipid Layer Assessment

- Can be performed by observing the colors on the surface of the tear film: the more colors, the thicker the tear film
- Historically, it has been performed by observing the small reflection, approximately 0.5 – 0.5 mm, on either side of the beam at the slit lamp at 3 or 9 o'clock, but it is difficult to do

Lipid Layer Assessment

- The Keeler TearScope gives a 4 mm view
- The OCULUS Keratograph 5M
- TearScience Lipiview both provide much wider views of the ocular surface, for automated detection of the colors and classification of the level of evaporative dry eye

LipiView® Ocular Surface Interferometer Measures Lipid Layer Thickness

Light source: The Illuminator

Chin rest

Camera, computer and drivers are housed by the device

Touch screen control panel

Measurement time: 20 seconds per eye

Device dimensions: 28" x 17" x 17"

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LipiView® Report

Results are displayed for printout & patient viewing

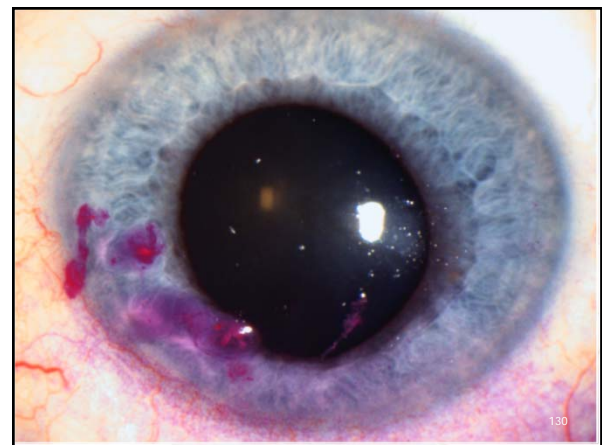
- ✓ Educate patients
- ✓ Establish baseline for improvement
- ✓ Identify if patient is a partial blinker (PB)
- ✓ Monitor treatment response

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Lactoferrin and IgE Microassays

- Available from Advanced Tear Diagnostics
- 2 separate tests – same unit
- Evaluates lacrimal gland secretory function by testing for presence of lactoferrin
- Lactoferrin modulates inflammation and is antimicrobial
- Evaluates presence of the antibody IgE
- CLIA Class II: Moderate complexity
- Reimbursable
- 1-4 minutes

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Serum Testing for Biomarkers of Sjogren's Syndrome

- New proprietary serum tests
- Nicox, recently acquired by Bausch & Lomb
- Standard biomarkers (the older tests) have specificity of 40-60% and don't detect at early stages of disease¹
- Early biomarkers appear 4 years before standard biomarkers

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Serum Testing for Biomarkers of Sjogren's Syndrome

- Novel early biomarkers have been identified
 - Salivary protein-1 (SP-1)
 - Carbonic anhydrase (CA-6)
 - Parotid secretory protein (P-SP)
- Expressed earlier in the disease and have higher specificity/sensitivity
- Detect & Prevent Extra-ocular Sequelae: Xerostomia, Pulmonary Fibrosis, Lymphoma

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Early Identification of Sjögren's Syndrome: The Sjo Test Panel

- PSP1
- CTA
- ST-A
- Ro
- La
- ANA
- RF
- Early Parotid Antigen
- Early Parotid Antigen
- Early Parotid Antigen
- SS-1
- SS-2
- Lupus
- Rheumatoid Arthritis

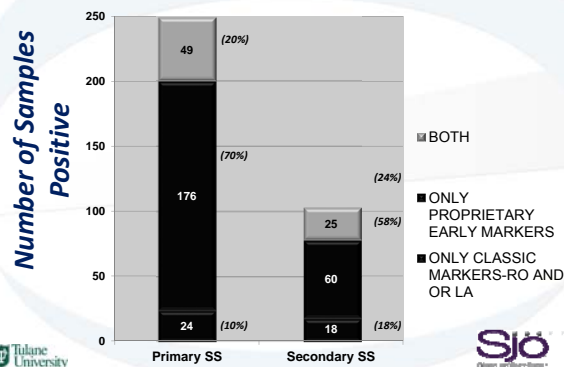


B&L NiCox Sjo Testing

- Point of Service
- Finger Stick
- Blood Draw
- LabCorps Visit
- Office Testing
- Staff sticks & ships
- Staff draws & ships
- Lab handles everything



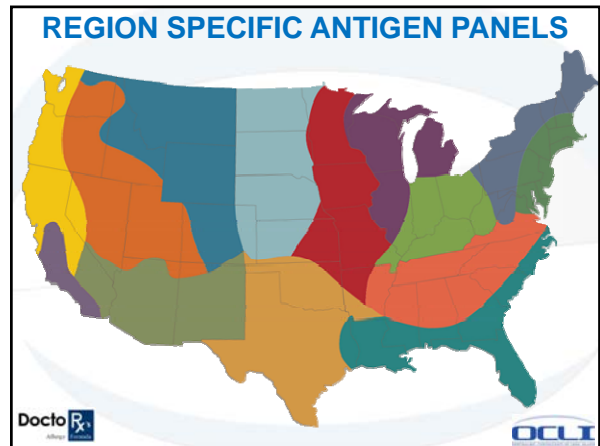
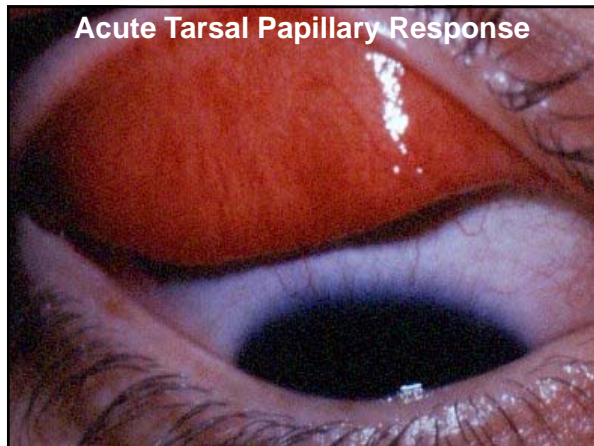
Identification of 1^o and 2^o Sjögren's Syndrome



Skin Testing for Ocular Allergies

- Clinical benefits to the patients: 10 minute test for ocular allergens found in the local region
- 39 separate regions identified in the continental U.S., each with its own set of 60 allergens
- Further establishes a comprehensive OSD Clinic
 - In-Office Patient Testing
 - Tech Driven
- CPT-95004 Multidisciplinary code
 - Code used since 1993
 - Covered by most Major Medical Insurance





Hydroxypropyl Cellulose Ophthalmic Inserts

- Lacriserts from Bausch & Lomb
- They are sterile, translucent, rid-shaped, water soluble, preservative-free, slow release lubricants which are placed into the inferior cul-de-sac of the eye
- The Lacrisert acts to stabilize and thicken the precorneal tear film and prolongs the tear film breakup time which is usually accelerated in patients with dry eye states.

Lacrisert: Valeant, Bausch & Lomb

Lacrisert

- The Lacrisert also acts to lubricate and protect the eye.
- The Lacrisert has been proven to relieve the following symptoms¹: dryness, burning, tearing, foreign body sensation, itching, photophobia, and blurred vision. It also can be used to treat the following eye conditions: dry eye, exposure keratitis, decreased corneal sensitivity and recurrent corneal erosions.

Punctal Plugs

- Punctal plugs are placed in the upper & lower lid puncti to prevent the escape of tears into the canaliculi
- Ocular surface retains more moisture
- Available from numerous companies;
- Some are designed to dissolve over time
- Others are designed to be permanent (though all can be removed if necessary)

Collagen, ProLong, Silicone, Hyfercator



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Punctal Plugs

- There are two basic designs: intracanalicular and “collar button”
- Punctal plugs have all but eliminated the need for punctal cautery in mild to moderate Dry Eye
- Promising drug delivery platform (Ocular Therapeutix)

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Thermal Pulsation Therapy and Intense Pulsed Light Treatments

- Both are methods designed to assist in evacuating the inspissated material---the altered meibum---that clogs the meibomian glands of most dry eye patients
- Both methods are designed to stabilize and thicken the precorneal tear film and prolong the tear film breakup time which is usually accelerated in patients with dry eye states.

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Thermal Pulsation Therapy: LipiFlow from Tear Science

- Lipiflow heats the lids with disposable activators
- After approximately 2 minutes into the 12 minute treatment, the altered meibum has become liquefied and easier to evacuate
- At this point, gentle pulsations then push the altered meibum out of the glands and into the disposable, one-use-only activators.

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LipiFlow® Thermal Pulsation System



Meibomian gland obstruction
Upper and lower eyelids
In-office procedure
12 minutes per eye

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LipiFlow® Thermal Pulsation System



Diagnostic Interferometry Included
Investigational: Not Covered
Professional Fee = \$1700 per patient
Disposable Eye Piece = \$350/eye

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IPL from Dermamed

- IPL warms the lids without pulsation
- Brief, powerful bursts of light at specific wavelengths (between 500 and 800 nm) are applied to the lower lids
- These wavelengths are said to cause changes in blood vessels near the surface of the skin, raise skin temperature and eliminate problematic flora on the skin and eyes, all of which may have a beneficial effect on MGD.

