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

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Marguerite McDonald, M.D., F.A.C.S.
April 5th, 2015
ASCRS Meeting
San Diego, California

Business Plan Implementation
Diagnostic Test Specifics
Case Studies

Dry Eye Center of Excellence: A Business Plan

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Medical Director, Lions Eye Bank of Eastern Virginia
Ophthalmology Residency Research Director

Dry Eye Center of Excellence?

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

Professional Disclosures

- Alcon: Research Grants, Speaker, Advisor
- Allergan: Research Grants, Speaker, Advisory Board, Medical Spokesman
- Bausch & Lomb: Research Grants
- Alcon: Advisory Board, Clinical Research
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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)

Dry Eye Center of Excellence?

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

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

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

Scribe
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
Prischmann, JAMA Facial Plastic Surgery, 2013

Zero Tolerance:

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

Slit lamp of cornea before treatment

Keratometry mires before treatment
Hitting the Post-Operative Refractive Target

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

**Keratometry**
- The most common error in keratometry is OSD
- OSD is present in 70% of cataract candidates
Most Neurodestructive Procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cord Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penetrating Keratoplasty</td>
<td>25 mm</td>
</tr>
<tr>
<td>Lasik, Corneal Inlay</td>
<td>21 mm</td>
</tr>
<tr>
<td>Secondary AC IOL</td>
<td>6 mm</td>
</tr>
<tr>
<td>Cataract with LRIs</td>
<td>6 mm</td>
</tr>
<tr>
<td>LRIs</td>
<td>4 mm</td>
</tr>
<tr>
<td>DSEK</td>
<td>4 mm</td>
</tr>
<tr>
<td>Cataract, RLE or ICL</td>
<td>2 mm</td>
</tr>
<tr>
<td>SMILE</td>
<td>2 mm</td>
</tr>
</tbody>
</table>

Focus on Dry Eye Prevalence

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

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Procedural Service Expansion

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

Collagen, ProLong, Silicone, Hyfrecator

Punctal Occlusion Collections

- Collagen & Silicone Plugs: $292,000
- Punctal Cautery: $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

Product Line Expansion

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

HydroEye 6 Month Clinical Trial

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

(Shppard, Cornea 2013)
**OSDI Results**

- Ocular Surface Disease Index (Normalized)
  - Baseline: 120
  - Week 4: 40
  - Week 12: 20
  - Week 24: 10
  - p < 0.004

- n = 20/group

**HLA-DR Results**

- HLA-DR Staining (Normalized Data)
  - Baseline: 0
  - Week 12: 60
  - Week 24: 120
  - p < 0.001

**CD-11c Results**

- CD-11c Staining (Normalized Data)
  - Baseline: 0
  - Week 12: 60
  - Week 24: 120
  - p < 0.001

**Retail Collections 2013**

- Nutritional Sales: $112,000
- LipiFlow: $304,000
- Masks, Lid Scrubs: $15,000
- Total: $431,000
Premium Tears: Lipid Content

Premium Tears: Hyaluronate

Keratoconjunctivitis Sicca: Induction Therapy
Cornea/External Disease Advisory Group
Treatment Consensus


Diagnostic Testing Expansion

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

Tear Science Lipiflow Thermal Pulsation

Dry Eye Diagnosis

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osmolarity</td>
<td>90</td>
<td>95</td>
</tr>
<tr>
<td>Schirmer Strip</td>
<td>66</td>
<td>77</td>
</tr>
<tr>
<td>Lactoferrin</td>
<td>35</td>
<td>70</td>
</tr>
<tr>
<td>Rose Bengal</td>
<td>25</td>
<td>90</td>
</tr>
<tr>
<td>Tear Film</td>
<td>52</td>
<td>72</td>
</tr>
<tr>
<td>Breakup Time</td>
<td></td>
<td></td>
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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

<table>
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<tr>
<th>Specialty</th>
<th>Tests/Day</th>
<th>Tests/Year</th>
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<tbody>
<tr>
<td>Cornea/External</td>
<td>40 (20 patients)</td>
<td>7680</td>
</tr>
<tr>
<td>Cornea/Refractive</td>
<td>30</td>
<td>5850</td>
</tr>
<tr>
<td>Cataract/Refractive</td>
<td>20</td>
<td>3840</td>
</tr>
<tr>
<td>Glaucoma/Cataract</td>
<td>20</td>
<td>3840</td>
</tr>
<tr>
<td>Oculoplastic/Orbit</td>
<td>12</td>
<td>2304</td>
</tr>
<tr>
<td>Comprehensive (3)</td>
<td>60</td>
<td>11520</td>
</tr>
<tr>
<td>Optometry (4)</td>
<td>80</td>
<td>15360</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>262</strong></td>
<td><strong>50304</strong></td>
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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

TearLab Osmolarity Collections
- 12 Doctors
- 50304 Tests/Year
- $19.00/Test
- $955,776.00/Year

RPS InflammaDry Collections
- 12 Doctors
- 50304 Tests/Year
- $12.00/Test
- $603,648.00/Year
Adenovirus Keratitis

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

RPS (NiCox) Adenovirus Assay

<table>
<thead>
<tr>
<th></th>
<th>Adeno Detector</th>
<th>Cell Culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>89%</td>
<td>92%</td>
</tr>
<tr>
<td>Specificity</td>
<td>93%</td>
<td>100%</td>
</tr>
<tr>
<td>Overall agreement</td>
<td>93%</td>
<td>98%</td>
</tr>
<tr>
<td>Positive predictive value:</td>
<td>82%</td>
<td>100%</td>
</tr>
<tr>
<td>Negative predictive value:</td>
<td>96%</td>
<td>98%</td>
</tr>
</tbody>
</table>

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

AdenoPlus Point of Service Diagnostic

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

RPS NiCox AdenoPlus
Recent study by Lemp et al reports 86% of patients evaluated had MGD.

- 23 patients with aqueous-deficient dry eye (14%)
- 79 patients with MGD (50%)
- 57 patients with MGD and aqueous-deficient dry eye (36%)
LipiView® Ocular Surface Interferometer
Measures Lipid Layer Thickness

- Light source: The Illuminator
- Chin rest
- Touch screen control panel
- Camera, computer and drivers are housed by the device
- Device dimensions: 28” x 17” x 17”
- Measurement time: 20 seconds per eye

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

Practice Growth
Insurance Based Business
Cash Based Business
Value Added Services
Patient Acquisition

Allergy Skin Test Collections
- 12 Doctors
- 2 Tests/Week
- $420.00/Analysis (60 Tests)
- $483,840.00/Year

Insurance Based Business: Cigna
- Intermediate Visit $ 38.00
- Osmolarity $ 36.00
- InflammaDry $ 16.00
  $ 90.00

237% Revenue Increase: POS Diagnostics
5 minutes extra Tech Time
10 seconds extra Doctor Time
Ask Your Managing Partner:

“Doctor Time”

Is A Practice’s Most Valuable Resource

Insurance Based Business Revenue

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Time</th>
<th>Fee</th>
<th>$/minute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cataract</td>
<td>15 min</td>
<td>$600</td>
<td>$40</td>
</tr>
<tr>
<td>Epilation</td>
<td>1 min</td>
<td>$45</td>
<td>$45</td>
</tr>
<tr>
<td>Plugs OU</td>
<td>5 min</td>
<td>$270</td>
<td>$54</td>
</tr>
<tr>
<td>Allergy Tests</td>
<td>5 min</td>
<td>$420</td>
<td>$84</td>
</tr>
<tr>
<td>ProKera</td>
<td>10 min</td>
<td>$1200</td>
<td>$120</td>
</tr>
<tr>
<td>Toric IOL</td>
<td>15 min</td>
<td>$2100</td>
<td>$140</td>
</tr>
</tbody>
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Cash Based Business Revenue

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Time</th>
<th>Fee</th>
<th>$/minute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleph OU</td>
<td>60 min</td>
<td>$2400</td>
<td>$40</td>
</tr>
<tr>
<td>Botox</td>
<td>10 min</td>
<td>$500</td>
<td>$50</td>
</tr>
<tr>
<td>Lasik OU</td>
<td>20 min</td>
<td>$3000</td>
<td>$150</td>
</tr>
<tr>
<td>LipiFlow OU</td>
<td>10 min</td>
<td>$1800</td>
<td>$180</td>
</tr>
</tbody>
</table>

Combined Diagnostics Collections

- Osmolarity $955,776.00
- InflammaDry $603,648.00
- LipiView $57,600.00
- Allergy Testing $483,840.00
- 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

Execution

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

Dry Eye Practice Optimization

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

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

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

Implementation

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
PRACTICE FLOW IMPLEMENTATION & CONSIDERATIONS

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

Testing only when Patients Complain of Dryness is Insufficient

• > 40% of people with objective evidence of dry eye are asymptomatic
• Cataract surgery patients often complain of fluctuating vision rather than dryness or FBS

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 InflammaDry 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

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

Osmolarity or InflammaDry 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

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
Interpretation & Treatment

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

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

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

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

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

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, conjunctivchalasis (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
**Severity Level**

<table>
<thead>
<tr>
<th>Level</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td>Mild to moderate</td>
<td>Moderate to severe</td>
<td>Severe</td>
<td>Extremely severe</td>
</tr>
<tr>
<td>Conjunctival Signs</td>
<td>Mild to moderate</td>
<td>Staining</td>
<td>Scarring</td>
<td></td>
</tr>
<tr>
<td>Corneal Staining</td>
<td>Mild punctate staining</td>
<td>Marked punctate staining; central staining; filamentary keratitis</td>
<td>Severe staining; corneal erosions</td>
<td></td>
</tr>
<tr>
<td>Other Signs</td>
<td>Tear film; decreased vision (blurring)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Treatment Options**

- Patient education
- Environmental modification
- Preserved tears
- Control allergy
- Non-preserved tears
- Gels, ointments
- Cyclosporine A
- Topical steroids
- Secretagogues
- Nutritional support
- Oral tetracyclines
- Punctal plugs (once inflammation is controlled)
- Systemic anti-inflammatory therapy
- Oral cyclosporine
- Acetylcysteine
- Moisture goggles
- Surgery (punctal cautery)

If no improvement, add level 2 treatments
If no improvement, add level 3 treatments
If no improvement, add level 4 treatments

**Surgery Impacts Dry Eye**

- Cataract surgery adds 1 severity step
- LASIK adds 2 severity steps

**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

**Osmolarity Diagnosis of Dry Eye**

**Dry Eye Disease Severity Scale**

- Normal
- Mild
- Moderate
- Severe

**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 InflammaDry from RPS
Meibography

- As 86 – 92 percent of dry eye patients have meibomian gland disease, it is useful to ever 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

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

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 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-conjunctival 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
- Touch screen control panel
- Camera, computer and drivers are housed by the device
- Device dimensions: 28" x 17" x 17"
- Measurement time: 20 seconds per eye

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

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

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 disease
- Early biomarkers appear 4 years before standard biomarkers

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)
- Expresses earlier in the disease and have higher specificity/sensitivity
- Detect & Prevent Extra-ocular Sequelae: Xerostomia, Pulmonary Fibrosis, Lymphoma
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 1º and 2º Sjögren’s Syndrome

<table>
<thead>
<tr>
<th>Number of Samples Positive</th>
<th>Primary SS</th>
<th>Secondary SS</th>
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<tbody>
<tr>
<td>24</td>
<td>60</td>
<td>15</td>
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<tr>
<td>176</td>
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<td>200</td>
<td></td>
<td></td>
</tr>
<tr>
<td>250</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- ONLY PROPRIETARY EARLY MARKERS
- ONLY CLASSIC MARKERS-RO AND OR LA
- BOTH

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

- The Lacrisert also acts to lubricate and protect the eye.
- The Lacrisert has been proven to relieve the following symptoms: 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

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)

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.

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.

LipiFlow® Thermal Pulsation System
- Meibomian gland obstruction
- Upper and lower eyelids
- In-office procedure
- 12 minutes per eye

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