Point of Service Diagnostic Testing to Improve Patient Care
Evidence Based Medicine: Healthcare for the 21st Century

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Disclosure

- I am a consultant for:
  - Acufocus
  - Allergan
  - Alcon
  - AMO
  - AqueSys
  - Bausch + Lomb
  - CRST
  - Elenza
  - Glaukos
  - Kala
  - Lacripen
  - Lensx
  - Mati Pharmaceuticals
- Merck
  - Mimetogen
  - Novabay
  - Odyssey
  - Pfizer
  - QLT
  - RPS
  - Sarcode
  - Strathspey Crown
  - Tearlab
  - TearScience
  - TLC Laser Centers
  - TrueVision
  - Wavetec
Advantages of Point-of-Care Testing

- Clinical Advantages

  - Evidence-based treatment, using point-of-care diagnostic testing, is the future of medicine.
  
  - Objective measure and quality diagnosis = Physician confidence in diagnosis and patient care

  - Trend is to use evidence-based diagnosis that is creating a better correlation between diagnostic testing and signs and symptoms

  - Improved sensitivity and specificity
Advantages of Point-of-Care Testing

- Practice flow advantages
  - Empower staff to perform testing based on physician based indications
  - When the physician sees the patients, diagnosis has already been made and physician confirms
  - Permits physician to immediately institute proper management and allowing the patient to leave the office in a timely manner
  - Less time patients spend in the office / less diagnostic time and more quality treatment time
Developing New Protocols

- With the development of new point of care testing, we need to re-evaluate how we are approaching the patient
  - Dry Eye / MGD patient
  - Red eye patient
Goals of the new Dry Eye / MGD Protocol

- Improve diagnostic confidence with point-of-care testing to identify the type and extent of disease
  - Osmolarity levels
    - TearLab Osmolarity System
  - Lipid layer assessment
    - LipiView Interferometer
  - Tear film structure
    - Various Topography / OCT systems
  - Tear film markers
    - MMP-9
    - Lactoferrin
Goals of the new Dry Eye / MGD Protocol

- Improved diagnostic confidence and disease identification permits MD to:
  - Focus time with patient on patient management strategies
  - Make a more informed, evidence-supported diagnosis
  - Better communicate with patient regarding
    - Initial diagnosis
    - Severity of disease
    - Disease management (track test results over time)
Laboratory Testing in Perspective: A New Paradigm in Eye Care

- Every specialty other than Eye Care Practitioners (ECP) couldn’t practice without Lab Tests
  - Cholesterol
  - Strep throat

- FACT: Lab testing impacts 70% of all medical decisions / represents less than 3% of healthcare costs

- Only ECP do not have luxury of using reference laboratories
  - Must become a CLIA tear testing laboratory
Dry Eye / MGD Protocol Steps

1. Patient presents with dry eye complaints
2. Patient given a standardized symptoms questionnaire
3. Qualified technician confirms that symptoms are present
4. Non-invasive advanced tear film testing is performed based on standing physician orders
   - Osmolarity levels
   - Lipid layer thickness: Interferrometry
   - NITBUT: Topography
   - Tear meniscus height: OCT
   - Inflammatory mediator assessment
Eye Health Questionnaire

Name: ____________________________ (Please Print Last) ____________________________ (Please Print First)

Year of Birth: ____________ Sex: M F (Circle)

Kindly complete this form to assist us in more fully understanding the present condition of your eyes today.

Check off if you have any of the below symptoms (chief complaint):

- [ ] Occasional blurring of vision especially with reading or computer work
- [ ] Excess tearing / Watering eyes
- [ ] Redness
- [ ] Contact lens discomfort
- [ ] Burning/Pain
- [ ] Feeling of sand or grit in the eye
- [ ] Itching
- [ ] Light sensitivity

Did you use eye drops today to treat your eye dryness? [ ] Y [ ] N

Report the FREQUENCY of symptoms you are experiencing by checking Never, Sometimes, Often or Constant using the numbering system below:

0 = Never, 1 = Sometimes, 2 = Often, 3 = Constant

<table>
<thead>
<tr>
<th>SYMPTOMS</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dryness, Grittiness or Scratchiness</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soreness or Irritation</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Burning or Watering</td>
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<td></td>
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<tr>
<td>Eye Fatigue</td>
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</tbody>
</table>

Do you use:

- [ ] Over the Counter Drops to treat your Dry Eyes
- [ ] Prescription eye drops for Dry Eyes
- [ ] Eye drops for Glaucoma
- [ ] Eye drops for Allergy
- [ ] Nutritional supplements for Eyes

Have you had surgery for:

- [ ] Cataract: [ ] Y [ ] N
- [ ] Glaucoma: [ ] Y [ ] N
- [ ] Refractive surgery (LASIK): [ ] Y [ ] N

If the information provided in this form, in conjunction with other clinical data, raises the suspicion of dry-eye disease, then obtaining a tear osmolarity test may be indicated.

Are you bothered by Eyelid Heavyness? [ ] Y [ ] N

Are you interested in any of the cosmetic services that OCLI offers? [ ] Y [ ] N

Prescriptions for eyeglasses (Refractions)

A written prescription for eyeglasses is a separate service from your eye examination. This service is not covered by most insurance companies including Medicare. A $50 payment is required for this service.

Would you like this service performed during today’s examination? [ ] Y [ ] N

Patient Signature: ____________________________ Date: ____________

OCLI DOCTOR SECTION ONLY

I reviewed this form and based on the information contained therein and other available clinical data, I suspect that this patient has dry eye disease and obtaining a tear osmolarity measurement is medically necessary for the diagnosis and management of this patient’s ocular problem(s).

OCLI Doctor Signature: ____________________________ Date: ____________
5. Interpret results from tear film testing
   - Abnormal levels of osmolarity and markers or abnormal NIBUT or tear meniscus height
     - Aqueous or evaporative tear deficient dry eye suspect
   - Abnormal levels of lipid layer thickness
     - MGD suspect

6. Slit lamp exam and invasive follow-up testing in the lane with the MD to confirm diagnosis

7. Treat accordingly
Strong Dry Eye / MGD testing protocols also directly impact outcomes!

Presurgical Hyperosmolarity Predicts Refractive Outcomes

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Joel Sturm²
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1 Ophthalmic Consultants of Long Island
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ESCRS 2011 E Donnenfeld
Osmolarity in Refractive Surgery

- How tear osmolarity levels relate to visual outcomes following LASIK; & if differences exist in patients who are pre-treated with ocular lubricants vs. those treated only post-operatively

- 128 subject (256 eyes) interim analysis
  - @ 1 month n = 81 normal, n = 47 hyperosmolar
  - Classified as hyperosmolar if the *preoperative* osm was ≥ 308 mOsms/L

- LASIK vision correction with the VISX STAR S4 with IR
Preoperative hyperosmolarity was predictive of UCVA & BCVA
Two Numbers Crucial to Understand Osmolarity

The MAXIMUM of the two eyes: 314
Tears higher than 300 mOsm/L demonstrate loss of homeostasis and likely become pathogenic > 308

The DIFFERENCE b/w two eyes: 24
This tells you how stable the tear film is. Normal tears are stable and near 300 mOsm/L bilaterally. A difference of > 8 mOsm/L is a hallmark of tear instability.
Summary: Donnenfeld et al

- Patients with pre-operative hyperosmolarity (≥ 308 mOsms/L) demonstrated worse UCVA
  - For patients with preoperative osmolarity > 308 mOsms/L, it may be important to continue therapy for at least 3 months

- Surgeons should measure tear osmolarity preoperatively
  - Staining was too insensitive to identify at-risk patients

ESCRS 2011 E Donnenfeld
Acute Conjunctivitis

- Highly infectious
- Often confusing presentation with 3 major subtypes with similar clinical presentation
  - Viral
  - Allergic
  - Bacterial
- Accurate diagnosis only 27-50% of the time

Goals of Red Eye Protocol

- Improve diagnostic confidence with point-of-care system to rule out or confirm presence of adenovirus
  - AdenoPlus test
    - Detects adenovirus with 90% sensitivity and 96% specificity
- Minimize risk of patients spreading disease
- Permits MD to:
  - Focus time with patient on patient management strategies
  - Make a more informed, evidence-supported diagnosis
  - Appropriate treatment (not everyone gets an antibiotic script)
Red Eye Protocol Steps

1. Patient presents with red eye
2. Immediately triaged by front desk to isolated exam room
3. Technician confirms presence of acute conjunctivitis
4. AdenoPlus diagnostic test performed
   - 2 minute test, results available in 10 minutes
<table>
<thead>
<tr>
<th></th>
<th>Negative</th>
<th>Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RPS Adeno Detector Plus</strong>&lt;br&gt;LOD = 6 ng/ml</td>
<td><img src="image1" alt="Negative result" /> <img src="image2" alt="Positive result" /></td>
<td><img src="image3" alt="Negative result" /> <img src="image4" alt="Positive result" /></td>
</tr>
<tr>
<td><strong>RPS Adeno Detector</strong>&lt;br&gt;LOD = 50 ng/ml</td>
<td><img src="image5" alt="Negative result" /> <img src="image6" alt="Positive result" /></td>
<td><img src="image7" alt="Negative result" /> <img src="image8" alt="Positive result" /></td>
</tr>
</tbody>
</table>
Red Eye Protocol Steps

5. Interpret Adenovirus test

- Positive Adenovirus test
  - Patients given written protocol for treatment
    - Instructions to apply lubricating drops and cold compresses to the infected eye
  - No antibiotics are necessary and many increase infectivity and duration of viral shedding
  - Consider use of the antiviral ganciclovir
  - Patients are advised to refrain from work until adenovirus is resolved
Red Eye Protocol Steps

5. Interpret Adenovirus test

- Negative Adenovirus test
  - Continue the diagnosis to identify if conjunctivitis is either bacterial or allergic
  - Consider antibiotic or antihistamine therapy (or a combination)
  - Follow-up or refer if decreased vision or pain, or lack of improvement over 7 days
  - Patients may return to work the same day
Red Eye Protocol Steps

6. Exam rooms containing patients with confirmed conjunctivitis are vigorously cleaned with a dilute bleach to prevent epidemic spread
Summary

- Gaining information from more reliable and advanced tear film testing can increase diagnostic accuracy, effective treatment and patient satisfaction.
- Exciting new tests are being developed to better assess both the chemistry and structure of the tear film.
- By offering these tests at the point of care with updated protocols, patient care can be improved, and practice flow can be optimized.