Management of Ocular Surface Disease

John W. Lahr, O.D., FAAO
Current Studies and Surveys Reveal

Professionals Are Not Taking Dry Eye Conditions as Seriously as Our Patients Feel We Should!
Trials and Studies

• In a recent study by Robin Chalmers, O.D., FAAO at Indiana University - Presented at AAO-December 15, 2002
  – 210 patients from six practices with the following:
    • 48 control patients
    • 130 mild to moderate non-Sjogren’s dry eye conditions
    • 32 Sjogren’s syndrome
  – Subjects rated the severity of dry eye symptoms (0-5)
  – Professionals rated clinical severity on same scale (0-5)
Trials and Studies

- 19% of patients rated their condition severe while the doctors rated only 9% severe.
- 36% of patients rated their condition moderate while the doctors rated only 20% moderate.
- 23% of patients rated their condition mild while the doctors rated 47% as mild.

Patients rated the severity worse than professionals 23-60% of the time.
Trials and Studies

- K Nichols, O.D., Jason Nichols, O.D. - Presented study at ARVO 2002:
  - 75 patients - 70.4% female - ages 24 to 81
  - 30% CL wearers - 61% artificial tear use
  - Symptoms reported:
    - Dryness - 98.7%
    - Ocular fatigue - 85.1%
    - Grittiness - 78.4%
    - Redness - 71.6%
    - Soreness - 64.5%
  - Analysis - Symptoms do not correlate with clinical signs and doctors need to treat to relieve patient complaints
Trials and Studies

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- 23% of patients rated their condition mild while the doctors rated 47% as mild.

*Patients rated the severity worse than professionals 23-60% of the time*
Gallup Survey*

- 90 million Americans have two or more symptoms of dry eye
- 37% reported dry eye symptoms
- 65% of contact lens wearers report dry eye limiting wear
- 77% report their dry eye to be very or somewhat bothersome
- 49% experience problems daily
- 76% have had the problem for over 2 years

*The 2005 and 2008 Gallup Study of Dry Eye Sufferers*
Gallup Survey

• For those seeking professional care, 76% were prescribed artificial tears and 16% ointments
• Visited ECP an average of 6 times since symptoms began
• Purchased an average of 6.2 artificial tears in past year
• Desires of patients are for fast acting/long lasting solution to dry eye
• 74% wish there was a more effective treatment than the current artificial tears and ointments prescribed
1993-1995

• Definition of Dry Eye Syndrome
  – Dry eye is a disorder of the tear film due to tear deficiency or excessive evaporation, which causes damage to the interpalpebral ocular surface and is associated with symptoms of discomfort.
Dry Eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.
Predisposing Factors

- Age
- Gender
- Environment
- Anterior Segment Disease
- Medications
- CL Wear
- Refractive surgery
- Systemic Disease
Age

• 10,000 Americans turn 55 everyday from now until the end of 2020!
• Over age 50 population will increase by 10% per year over next 5 years
Environment

Top 5 intake causes of dry eye?

- Smoking
- Diet
  - Balance of Omega-3 : Omega-6
- P.O. medications
  - Antihistamines in particular but also HRT and Accutane as examples
- Alcohol consumption (more than moderate)
- Caffeine? (more than moderate)
Systemic Disease

• Two most common seen in primary eye care practice that are underlying to OSD are:
  – Rheumatoid Arthritis
  – Diabetes
Ocular Allergy

Rule Out or Manage Allergies
Diagnosing Dry Eye

Ideally, Treatment Should Be Selected After an Accurate Diagnosis
Diagnosis

• From the MGD International Workshop
  – Questionnaire
  – Measure blink rate and interval
  – Measure tear meniscus height
  – Measure tear osmolarity
  – Fluorescein for TBU and staining
  – Schirmer or phenol cotton red
  – Grade MGD (www.refractiveeyecare.com)
History

• Discovering the when, where and to what degree
  – Morning-meibomian gland disorder/cytokines
  – Evening-aqueous deficiency/evaporative
• Systemic and topical medications
• Contact lenses/refractive surgery
• Environment
• Allergy symptoms-treat first to differentiate
• History of past dry eye therapy-(self treatment and professional) what has and has not provided relief
# Ocular Surface Disease Index (OSDI)

**Note:** The OSDI® is assessed on a scale of 0 to 100, with higher scores representing greater disability. The index demonstrates sensitivity and specificity in distinguishing between normal subjects and patients with dry eye disease. The OSDI® is a valid and reliable instrument for measuring dry eye disease severity (normal, mild, moderate, or severe) and effect on vision-related function.

**Assessing Your Patient’s Dry Eye Disease**

Use your answers D and E from Side 1 to compare the sum of scores for all questions answered (D) and the number of questions answered (E) with the chart below. Find where your patient’s score would fall. Match the corresponding shade of red to the key below to determine whether your patient’s score indicates normal, mild, moderate, or severe dry eye disease.

### Example Calculation

<table>
<thead>
<tr>
<th>Number of Questions Answered (E from Side 1)</th>
<th>Sum of Scores for All Questions Answered (D from Side 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>10.0</td>
</tr>
<tr>
<td>11</td>
<td>10.0</td>
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<td>10</td>
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<td>9</td>
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<tr>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>2</td>
<td>10.0</td>
</tr>
</tbody>
</table>

### Key

- **Normal**
- **Mild**
- **Moderate**
- **Severe**

### Instructions

1. **Patient’s Name:**
2. **Date:**
3. **How long has the patient experienced dry eye?**
4. **Eye Care Professional’s Comments:**

---

**Restasi.**

(Clinical Trials Endpoint Co.)
Lid Evaluation
Diagnostic Surface Analysis

• Schirmer or Phenol Cotton Red test
• Observe the tear meniscus
• Tear break-up time
• Vital staining
  – Rose Bengal
  – Lissamine Green
  – Fluorescein
Tear Assay

Laboratory Values to Assist with Diagnosis and Treatment
Osmolarity Increase

- Multiple causes all leading to an inflammatory environment
- With increases, goblet cell density decreases
- Allows water to be pulled between conjunctival epithelial cells breaking the intracellular attachments (stain)
- Less glycoproteins to support cells
- Cornea stain follows shortly after and flouroscein staining and lower TBU occurs
Normal vs. Increased Osmolarity

Normal Tear Film

Electrolytes
- Na
- K
- Cl
- Ca

Proteins:
- Lysozyme
- Fe
- Lactoferrin
- Lipocalin
- Albumin
- EGF

Cytokines:
- IL-1β
- TNF-α
- IL- CRA
- TGF-β

- Mucin 1, Mucin 4
- Mucin 5AC
- Latent Proteases
- IgA
- IgG
- IgM
- Polar Phospholipid

Courtesy of Dry Eye and Ocular Surface Disorders
Studies With Highest Level of Accuracy

<table>
<thead>
<tr>
<th>Test</th>
<th>Refer.</th>
<th>Cut-Off Value</th>
<th>Sensitivity (%)</th>
<th>FPR(%)</th>
<th>Specificity (%)</th>
<th>PPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sch + Osmol</td>
<td>†Farris</td>
<td>&lt;1mm/min; &gt;312</td>
<td>25</td>
<td>0</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Lacto + Osmol</td>
<td>†Farris</td>
<td>&gt;90; &gt;312</td>
<td>35</td>
<td>0</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>TTR + Evap + Osmol</td>
<td>†Khana l</td>
<td>&lt;12%; &gt;33; &gt;317</td>
<td>38</td>
<td>0</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Specificity is proportion of normal population with negative result.

PPV is the probability of truly having Dry Eye Disease with a positive result

True Diagnostic Testing

• TearLab
• Europe C Mark approval March 2007
• Approved in the US in 2009
• 15 milli-microliters of tears (small enough for even the driest of Sjogrens’ patients)
• Instant measurements of osmolarity in your clinic!
### Osmolarity in the Diagnosis of Dry Eye Disease

- **Osmolarity** is the “gold standard” test for Dry Eye
  - 45 years peer reviewed research
  - Osmolarity has been added to definition of Dry Eye
  - Global marker of Dry Eye, indicating a concentrated tear film

<table>
<thead>
<tr>
<th>Clinical Test</th>
<th>PPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osmolarity</td>
<td>87%</td>
</tr>
<tr>
<td>Schirmers</td>
<td>31%</td>
</tr>
<tr>
<td>TBUT</td>
<td>25%</td>
</tr>
<tr>
<td>Staining</td>
<td>31%</td>
</tr>
<tr>
<td>Meniscus Height</td>
<td>33%</td>
</tr>
</tbody>
</table>
CPT Code for Tear Lab

• CPT 83861
  – CLIA waiver approved!
• Fee-$24.01/eye
• Disposable tip~$15
Signs vs. Symptoms

• Unfortunately, there is poor correlation between dry eye patient’s reports and clinical signs: (Supported by earlier studies)
  – Reports of discomfort with minimal clinical signs or indications
  – Few reported symptoms with significant clinical indications of KCS
  – Aggressive treatment should be initiated with symptoms but more importantly, education and treatment for clinical indications to prevent further extensive damage
Treating and Managing Dry Eye

Sorting the Options to Obtain Optimal Outcomes and Patient Satisfaction
Listen to Patients!

• If they feel the condition is serious, you must treat it in that manner
• Even if clinical signs would indicate the condition seems less serious than reported, judge the treatment needed by the patient’s responses and complaints
• Don’t retrace a road already traveled and failed (Ocular lubricant samples)
• Go beyond what other professionals are doing and specialize in the dry eye patient
Basic Treatment

- Drink more water!
- Avoid evaporative environments
- Average person should have intake of 4-6 glasses or 75 oz. of water per day
- Ask patients about normal intake of fluids and advise those that are deficient
- Educate concerning caffeine and alcohol

- *Sun Rx*-reduces *ocular surface inflammation from UV*
Lid Therapy
Lid Disease

- Blepharitis/Meibomitis
- Patients are 2 x more likely to have dry eye symptoms
- Could be related to systemic conditions such as acne rosacea
Acute presentation of MGD?

Frothy tear film – surfactant produced
Acute presentation of MGD?
Next Stage:

Expression shows turbid or thicker meibum
Advanced Stage:

Telangiectasia, capped glands and missing glands
Mild/Acute

- Hot compresses
- Lid hygiene
Recent Study Results

- From Eye Contact Lens-2003
  - Measure of Tear-film Lipid Layer Thickness (TFLLT)
  - Measured at 5, 15 and 30 minutes of warm compresses vs. room temperature compresses
  - Results: Baseline TFLLT-57.8nm
    - Room temperature compresses-no change
    - After 5 minutes-105.8nm
    - After 15 minutes-117.8nm
    - After 30 minutes-121.5nm
Moderate/Chronic

• Blepharitis: add antibiotic ointment to base of lashes after hot compresses or AzaSite
• Meibomitis: antibiotic/steroid drops – Zylet, Tobradex ST or AzaSite
Ophthalmic Azithromycin: AzaSite®

- AzaSite® pairs DuraSite® drug delivery technology with azithromycin (1.0%)
- Azithromycin has not been previously used in eye care
  - A stable aqueous formulation is difficult to produce
- AzaSite®: A stable, easily delivered formulation of azithromycin
  - All the advantages of topical ophthalmic delivery
  - All the advantages of the anti-microbial properties of azithromycin
Azithromycin: Well-Suited for Ophthalmic Use

• Broad-spectrum: active against Gram-positive, Gram-negative, and atypical bacteria
  – Proven efficacy against the most common causative pathogens of bacterial conjunctivitis (*Streptococcus pneumoniae*, *Haemophilus influenzae*, *Staphylococcus aureus*)

• Oral and IV forms known for high tissue penetration
  – Topical ophthalmic dosing results in sustained high levels in rabbit tear film and conjunctiva

AzaSite® Maintained Therapeutic Concentrations in Human Conjunctiva

- Six days after the last dose, AzaSite maintained therapeutic concentrations in human conjunctiva.

A multicenter, open-label, randomized, pharmacokinetic clinical study evaluated the tissue concentrations of azithromycin 1% in healthy, normal human adult conjunctiva at 10 time points throughout a 7-day dosing period and 7-day follow-up using the recommended course of dosing. The per protocol pharmacokinetic population contained 3 to 6 subjects per time point. The most common pathogens for ocular infections are *Streptococcus pneumoniae*, *Staphylococcus aureus*, and *Haemophilus influenzae*.1,2,3

Antibiotic/Steroid Combinations

• ZYLET
  – Loteprednol etabonate 0.5%
  – Tobramycin 0.3%

• Tobradex ST
  – Dexamethasone 0.05%
  – Tobramycin 0.3%
Moderate/severe or not improving

- Add PO tetracycline
- Recommendation:
  - Doxycycline 50mg bid x 4 weeks then taper to qd
  - Periostat (20 mg doxy) bid
  - Alodox Kit (20 mg doxy) bid
Long Term Lid Therapy

- Lid hygiene
- Omega-3s
  - EPA
  - DHA
Topical Therapy
Many tear choices...

Equals patient confusion
Q.17 Please check the brands of artificial tears you currently use most often.

*Trademarks of another company

Multi-sponsor Surveys, Inc.
2008 Gallup Study of Dry Eye Sufferers
Dry Eye or Allergy?
Topical Lubricant Therapy

• Lipid Relacements
  – Soothe XP (current voluntary recall by B + L)
  – Systane Balance

• Wetting agents
  – Systane Ultra
  – Blink
  – Oasis Tears

• Cornea Edema/Moderate to Severe OSD
  – Freshkote
Viscoadaptive eye drops

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
</table>
|   | • Active Ingredient is glycerin  
   | • **First** viscoadaptive HA-based  
   |   |   | “comfort drop” in U.S.  
   |   | • No harmful preservatives  
   |   |   | (i.e. BAK)  
   |   | • No blurred vision  
   |   | • Superior symptomatic relief  
   |   |   | (burning, itching, dryness, etc)  
   |   | • Prolonged residence time  
   |   | • Fewer applications required  

---

Viscoadaptive eye drops are a type of lubricant eye drops that provide comfort and relief for dry eyes. They contain glycerin as the active ingredient and are the first viscoadaptive HA-based “comfort drop” in the U.S. These drops do not contain harmful preservatives like BAK and are designed to provide superior symptomatic relief from burning, itching, and dryness. They also offer prolonged residence time and require fewer applications compared to other drops.
Viscoadaptive Lubricant Eye Drops

visco = Low Molecular Weight Biopolymer(s)

adaptive = more than one physical characteristic with multiple physical properties and medical benefits

hyaluronan
or

- **Oasis TEARS™** = mild to moderate dry eye symptoms during day or at nighttime sleeping hours
- **Oasis TEARS™ PLUS** moderate to severe symptoms during day or nighttime sleeping hours
• Superior moistening and lubrication of the cornea and other surfaces of the eye
• **Prolonged Residence Time**, blink-activated coating and recoating of the corneal surface
• Superior Comfort due to viscoelastic and elastoviscous properties
• Fewer applications during the day & night
• No blurred vision or foreign body sensation
• Natural, no toxic biopolymers
• Documented safety and efficacy of each biopolymeric component and low phosphate buffer concentration
• **No** harmful Preservatives
from Oasis TEARS®

Multidose

For use by patients who

- have difficulty using the twist-off vials
- only need drops twice a day

REF # OT6310

Oasis TEARS Multidose
10ml/0.3 fl oz. bottle

Multidose will be available in one formulation, between Tears and Tears Plus in concentration. Contains a mild preservative.
FreshKote® Lubricant Eye Drop

- Treats Moderate to Severe Dry Eye
- Recurrent Corneal Erosion

Now available OTC!
FreshKote

*FreshKote has a high oncotic pressure of 65 mmHg which helps to...*

- Re-establish the integrity of epithelium
- Reduce microcystic edema
- Prevent recurrent damage
Inflammatory Eye Disease

Managing Short and Long Term
Managing Inflammation

• Steroid-short-term treatment only, up to 4-6 weeks w/ taper
  – Alrex-.2%
  – Lotemax-.5%
• Lotemax Ointment or Gel
• Restasis and/or
• Oral supplements containing high-quality Omega 3 (EPA/DHA)
Essential Fatty Acids (EFA)

Understanding the Omegas
The Omega Rx Zone

- Adults should consume at least 2 grams of EPA/DHA per day
- Adults with specific chronic conditions should consume at least 3.5-4.0 grams of EPA/DHA per day
- Children/Infants should consume at least 1/2 gram of EPA/DHA per day

Plant based (Flax) Omegas do not convert to EPA/DHA
Triglycerides OR Ethyl Esters

- **Fish oil as Triglycerides**
  - Found in nature, 98% of the fats we consume are in TG form
  - Faster breakdown by *pancreatic lipase*
  - More labor intensive to manufacture
  - More stable, less prone to oxidative stress

- **Fish oil as Ethyl Esters**
  - NOT found in nature
  - Slower breakdown by *pancreatic lipase*
  - Easier and cheaper to manufacture
  - Potentially more liable to oxidative stress
Fish Oil Absorption

TG (Natural Triglyceride Form)

is 70% more absorbable than Ethyl Ester form with no toxicity

References:
What makes a superior Omega-3 EFA dietary supplement?

- Quality & Purity: Pharmaceutically Licensed
- No “fish” taste
- Bioavailability: Natural TG form
- Age, Lifestyle and Condition Specificity
- Price

[cGMP Pharmaceutical Grade Manufacturing]
How Omega 3s Treat Dry Eye

- Essential fatty acids provide the raw material for the production of meibum.

- Omega 3s effect the lipid profiles of meibomian gland secretions in Sjögren’s patients. (HPLC/mass spectrometry studies) (Sullivan BD et al 2002)

- Clinical reports have observed clearer and thinner oils with Omega-3 treatment. (Boerner CF 2000)

- EPA in Omegas decrease ocular surface inflammation via PGE 3
Market Eye Formulations

- Theratears Nutrition-Advanced Vision Research
- Fortifeye
- Hydrate
- HydroEye-Science Based Health
- Biotears-Biosyntrx
- Lifeguard-Dry Eye
- Nordic Naturals-Pro Omega
## Supplement Fact Comparison - Per Capsule

| *Fortifeye-Super Omega | 430 mg | 290 mg |  |
|------------------------|--------|--------|
| Hydroeye               | 25 mg  | 18 mg  | 393 mg |
| Hydrate                |        | 250 mg | 125 mg |
| Biotears               | 15 mg  | 11 mg  | 60 mg  |
| Dry Eye Omega          | 420 mg | 140 mg |  |
| Theratears Nutritional | 150 mg | 100 mg | 333 mg |
| Pro Omega              | 325 mg | 225 mg |  |

* 1200 mg capsule
## Supplement Fact Comparison - Per Capsule

<table>
<thead>
<tr>
<th>Product</th>
<th>DHA (mg)</th>
<th>EPA (mg)</th>
<th>GLA (mg)</th>
<th>ALA (mg)</th>
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<tbody>
<tr>
<td>Fortifeye- Super Omega</td>
<td>358</td>
<td>241</td>
<td></td>
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</tr>
<tr>
<td>Hydroeye</td>
<td>25</td>
<td>18</td>
<td>393</td>
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<tr>
<td>Hydrate</td>
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<td>250</td>
<td>125</td>
</tr>
<tr>
<td>Biotears</td>
<td>15</td>
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<td></td>
<td>60</td>
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<tr>
<td>Dry Eye Omega</td>
<td>420</td>
<td>140</td>
<td></td>
<td></td>
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<tr>
<td>Theratears Nutritional</td>
<td>150</td>
<td>100</td>
<td>333</td>
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<tr>
<td>Pro Omega</td>
<td>325</td>
<td>225</td>
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</table>

Note: all values adjusted to 1000 mg capsule
Punctal Occlusion
Occlusion Options

- Temporary collagen plugs
- Extended duration plugs
- Permanent formed silicone plugs
  - Surface plugs
  - Intracanalicular-colors available
- Synthetic collagen for longer applications (Allergy and LASIK)
- Heated silicone injection formed
- Thermosensitive hydrophobic acrylic
- Hydrogel (hydrophylic) plug
- Surgical closure
Barriers to Occlusion

• Professionals comfort with procedure
  – Sizing, dilation of the punctum and insertion
• Lack of understanding when to add this treatment modality
• Past experience and patient complaints with current plugs:
  – Patient comfort with surface plugs
  – Dislodged or lost plugs
  – Inability to remove plugs if needed
Oasis FormFit Plug

Easiest Plug to Insert and Manage
ONE SIZE SOUTION

- FormFit™ is truly a one size fits all plug.

- Once inserted into the punctum, FormFit™ hydrates over a 10 minute period until it fills the punctal cavity.
Phase III: Fully Hydrated
(time elapsed 10 minutes)
INSERTION

FormFit™ still inside polyimide tip

FormFit™ partially expressed from polyimide tip
To remove the FormFit™ plug, simply flush saline solution through the punctal opening and the plug, which behaves like a viscous solution, will be easily flushed through the lacrimal system.
### Progression of OSD Severity Levels

| LEVEL 1 | Mild to moderate symptoms, no signs  
Mild to moderate conjunctival signs |
|---------|----------------------------------------------------------------------------------|
| LEVEL 2 | Moderate to severe symptoms  
Tear film signs, Visual signs  
Mild corneal punctate staining  
Conjunctival staining  |
| LEVEL 3 | Severe symptoms  
Marked corneal punctate staining  
Central corneal staining  
Filamentary keratitis |
| LEVEL 4 | Extremely severe symptoms/altered lifestyle  
Severe corneal staining, erosions  
Conjunctival scarring |

Behrens et al, *submitted*
Treatment Algorithm

LEVEL 1
- Patient education/Dietary Modifications
- Environmental modifications
- Control offending systemic medications
  
  - If no improvement, add level 2 treatments
  - Preserved lubricants
  - Lid Therapy/Allergy control

LEVEL 2
- Unpreserved lubricants
- Nutritional support
- Punctum plugs
- Tetracyclines
  
  - If no improvement, add level 3 treatments
  - Cyclosporin A
  - Topical steroids
  - Secretagogues
  - Moisture Chamber Spectacles

LEVEL 3
- Serum
- Permanent punctal occlusion
- Contact lenses
  
  - If no improvement, add level 4 treatments

LEVEL 4
- Systemic anti-inflammatory therapy
- Surgery-amnion membrane transplant, tarsorrhaphy, lid surgery
Cost and Value of the OSD Patient

What You May Gain or Lose Without an Aggressive Approach in the Treatment of OSD
Value of the OSD Patient

- Annual comprehensive examination
  - 92014-$126.23
  - 92015-$ ?
- Office calls-99213-$72.47
- Tear assay-$10-15 profit per test
- Nutritional supplement (Lifeguard or Nordic)-
  ~$10 profit per month
- OTC products (Oasis Tears)-$5-10 per month profit
Value of the OSD Patient

• Dilation w/ or w/o irrigation-68801-$119.12 per opening
  – Best to not perform on same day as insertion and not as a routine component of 68761

• Punctal occlusion:
  – Collagen plugs-diagnostic mode
    • 68761-E2 100% $154.80
    • 68761-E4 50% $  77.40
  – Permanent plugs-treatment (after 10 day post-op period)
    • 68761-E2 100% $154.80
    • 68761-E4 50% $  77.40
    • Total $464.41

Profit after plug costs should range from $355-380

*This cycle may need to be repeated if the upper punctal openings would provide positive outcomes without excess tearing
Value of the OSD Patient

• The value of the OSD patient to the primary care practice can easily range from $250 to as high as $1350 in the first year of treatment excluding any charges for refraction or refractive appliances.

• Ongoing care can provide an additional $250 or more per year before factoring in refractive testing/devices.
Value of the OSD Patient

- Jobson data indicates patient loss by professionals not taking OSD treatment and management seriously
- Practice management experts have placed the value of a single patient at over $100,000, with some estimates much higher when considering family and referrals
Value of the OSD Patient

- Remember, every person has a circle of influence of 30-50 people:
  - Satisfied patients will tell 2-3 in their circle about a positive experience
  - Those unhappy or indifferent about their care are likely to tell 8-10 others about the failure to resolve the problem

*Can you afford to treat OSD patients any differently than you treat other eye disease?*