Advances in Refractive/Cataract Surgery: Optimizing the Ocular Surface
Eric Donnenfeld, MD, FAAO

Traditional Cataract Surgery
- Corneal incisions via hand-held blade
- Manually created capsulorhexis via blunt needle or forceps
- Intraocular ultrasonic phacoemulsification for lens aspiration
- IOL Implantation

Goals of Modern Cataract Surgery
For patients to achieve:
- Distance Vision
- Intermediate Vision
- Near Vision
Without correction!

AcrySof Toric Star Toric
Cylinder Powers SN60T3-T5

<table>
<thead>
<tr>
<th>AcrySof Toric IOL Model</th>
<th>Cylinder Power @ IOL Plane</th>
<th>Cylinder Power @ Corneal Plane*</th>
</tr>
</thead>
<tbody>
<tr>
<td>SN60T3</td>
<td>1.50</td>
<td>1.03</td>
</tr>
<tr>
<td>SN60T4</td>
<td>2.25</td>
<td>1.55</td>
</tr>
</tbody>
</table>

*Based on an average pseudophakic human eye
Initial Spherical Powers: 16.0 - 25.0 D

Accommodative IOLs
Accommodative IOLs

- Advantages:
  - Small change in surgical technique
  - Good Snellen visual acuity
  - Good monocular and binocular contrast sensitivity
  - Good depth perception, stereopsis

- Disadvantages:
  - Small increase glare and halo
  - Increased post-operative complications
    - Increased need for enhancements
    - Full visual spectrum – NO
      - 1 diopter of accommodation

Multifocal IOLs

- Advantages:
  - No change in surgical technique
  - Good Snellen visual acuity
  - Good monocular and binocular contrast sensitivity
  - Good depth perception, stereopsis
  - No increased postoperative complications
  - Full visual spectrum - YES

- Disadvantages:
  - Increase glare and halo

ReSTOR IOL

- Apodized Diffractive Optic
- UV and High-Energy Blue filtration
- Hydrophobic Acrylic
- Single piece
Binocular Defocus Curve

Tecnis Multifocal IOL
- Modified prolate anterior surface
- Square-edge optic
- Diffractive multifocal posterior surface with 32 concentric zones
- UV-absorbing
- 3-piece foldable
- 50/50 near/far split in effective light distribution for all pupil sizes
- +4 D near add

Last 12 Months

The Solution - Aspheric Optics
- Aspheric optics align the light rays to compensate for positive corneal spherical aberration, resulting in enhanced image quality.

Multifocal IOLs Pearls: Patient Selection
- Low myopes and emmetropes
  - Accustomed to great near or distance vision
- Hyperopes and moderate myopes
  better candidates

Multifocal IOLs: Pre-Operative Evaluation
- Optimize IOL calculations
- Confirm corneal topography
- Optimize ocular surface
Multifocal IOLs: OCT Analysis

- Superior in detecting epiretinal membranes and lamellar holes
- Avoid multifocal IOLs in patients with maculopathy
  - Macular thickness >230 µm pre-op correlated with worse VA post-op

Trouble Shooting the Refractive IOL Patient

Pre-Operative Considerations

- The more chair time you spend before the surgery, the less you will spend after surgery.
- Chair time prior to surgery eases the patient - Expectations.
- Chair time after surgery puts the patient and ophthalmologist on defensive - Complications.

Causes of Glare, Halo, and Loss of Contrast Sensitivity

- Cylinder and residual refractive error
- Cornea and ocular surface disease
- CME
- Capsular opacities
- Center Pupil on IOL
- Crazy

Slit Lamp Limbal Relaxing Incision

The Tear Film is the Most Important Refracting Surface of the Eye
Disruption of the Ocular Surface Induces Distortion that is Magnified by a Multifocal IOL

Cyclosporine Improved Contrast Sensitivity With Multifocal IOLs

Don’t Forget Meibomian Gland Disease

Pre-Operative Care to Optimize Outcomes: Treat Lid Disease
- Lid hyperthermia
  - Hot compresses and/or lid scrubs
- Nutritional supplements
- Topical azithromycin bid 2 days then qd 1 month
- Severe cases
  - Oral doxycycline

ASCRS 2015 Abstract Presented

“THE INFLUENCE OF OMEGA-3 NUTRITIONAL REGIMEN ON TEAR OSMOLARITY IN CASES OF DRY EYE DISEASE.”

Conclusion
This study demonstrated that oral consumption of re-esterified omega-3 fatty acids (1680 mg EPA and 580 mg DHA once daily for 12 weeks) resulted in a statistically significant improvement in tear osmolarity, corneal staining, OSDI, and omega index levels.

Study Design
- Double-Masked, randomized, placebo-controlled, multi-center study of a triglyceride omega-3
- 105 subjects completed the study (54 in treatment group and 51 in placebo group)
  - Average Age: 56.8 years
  - Gender: 71.4% women

https://ascrs.confex.com/ascrs/15am/webprogram/Paper18505.html
End Points

Primary:
- To determine the effect of 2240 mg triglyceride based Omega-3 (PRN Dry Eye Omega Benefits®) on tear osmolarity.

Secondary:
- OSDI (Symptoms)
- Tear Film Break-Up Time
- Corneal Staining
- Lipid Layer Thickness
- Schirmer Test
- MMP – 9 levels
- Omega-3 Index Score

Results

### Least Square Estimates for Tear Osmolarity Change from Baseline by Visit

<table>
<thead>
<tr>
<th>Tear Osmolarity</th>
<th>Screening (Week -1)</th>
<th>Baseline (Week 0)</th>
<th>Week 6</th>
<th>Week 12</th>
<th>Change from Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omega-3</td>
<td>328 (15)</td>
<td>326 (16)</td>
<td>309 (13)</td>
<td>307 (12)</td>
<td>-19</td>
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<tr>
<td>Placebo</td>
<td>326 (15)</td>
<td>326 (15)</td>
<td>317 (20)</td>
<td>318 (20)</td>
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<td>(p)-value*</td>
<td>0.042</td>
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### Chi Square Test for MMP-9 biomarker change from Baseline by Visit

<table>
<thead>
<tr>
<th>MMP-9 biomarker (N=105)</th>
<th>Baseline</th>
<th>Week 12</th>
<th>(p)-value*</th>
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<tbody>
<tr>
<td>Omega-3</td>
<td>43</td>
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<td>Placebo</td>
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<td>30</td>
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### Least Square Estimates for OSDI Change from Baseline by Visit

<table>
<thead>
<tr>
<th>OSDI (N=105)</th>
<th>Baseline</th>
<th>Week 6</th>
<th>Week 12</th>
<th>Change from Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omega-3</td>
<td>32 (19)</td>
<td>21 (14)</td>
<td>15 (11)</td>
<td>-17</td>
</tr>
<tr>
<td>Placebo</td>
<td>27 (23)</td>
<td>20 (17)</td>
<td>22 (19)</td>
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<tr>
<td>(p)-value*</td>
<td>0.285</td>
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### Least Square Estimates for Tear Break Up Time Change from Baseline by Visit

<table>
<thead>
<tr>
<th>TBUT (n=105)</th>
<th>Baseline</th>
<th>Week 6</th>
<th>Week 12</th>
<th>Change from Baseline</th>
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<tbody>
<tr>
<td>Omega-3</td>
<td>4.78 (2.96)</td>
<td>6.64 (3.17)</td>
<td>8.25 (4.78)</td>
<td>5.47</td>
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<tr>
<td>Placebo</td>
<td>4.61 (2.04)</td>
<td>5.55 (2.43)</td>
<td>5.81 (3.13)</td>
<td>1.20</td>
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<tr>
<td>(p)-value*</td>
<td>0.126</td>
<td>0.002</td>
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</table>
Least Square Estimates for Omega Index Change from Baseline by Visit

<table>
<thead>
<tr>
<th>Omega Index</th>
<th>Baseline</th>
<th>Week 12</th>
<th>Change from Baseline</th>
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</thead>
<tbody>
<tr>
<td>Omega-3</td>
<td>4.19 (1.04)</td>
<td>7.19 (2.65)</td>
<td>3.00</td>
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<tr>
<td>Placebo</td>
<td>4.90 (1.36)</td>
<td>5.14 (1.74)</td>
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<tr>
<td><strong>p-value</strong></td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
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Conclusion:
Dry Eye and Omega-3 Supplementation
- The **natural triglyceride form** of omega-3 supplementation significantly
  - Improves tear osmolarity
  - Improves TBUT
  - Improves the OSDI
  - Increases the Omega-3 Index

Dry Eye in the Cataract Population
- Prospective evaluation of patients presenting for routine cataract surgery
  - 200 eyes of 100 patients
- 59% had a diagnosis of blepharitis
- 61% had a TBUT of ≤ 7 seconds

Tear Film Irregularities & Vision
- Irregularities in the tear film scatter light and can degrade retinal image quality by 20-40% between blinks in dry eyes vs. normal eyes
  - Visual acuity is more impaired
  - Higher Order Abberrations increase

Disruption of the Ocular Surface Induces Distortion That Is Magnified by a Multifocal IOL

Surgical Planning
- Potential consequences of dry eye during the surgical planning process may cause the surgeon to
  - Exclude a surgical candidate from consideration for MF IOL due to reduced acuity or suspicion of poor retinal image quality
  - Select the wrong IOL power
  - Select the wrong monofocal IOL design based on pre-op SA
  - Plan for a toric IOL or LRIs when not needed (or v.v.)
Possible Testing During Dry Eye Evaluation
Evaluate Tear Meniscus
NaFl Staining & Tear Break Up Time
Lissamine Green Staining or Rose Bengal
Meibomian Gland Expression
Schirmer's With Anesthetic or Quick Zone
TearLab Osmolarity System
Dilation & Irrigation
Naso-lacrimal probe

Tear Break Up Time

Conjunctival Staining

Moderate / Severe lissamine green staining

Schirmer Strips

Meibomian Gland Expression
Summary Statistics on Tear Osmolarity

- Normal subject average:
  - 296 ± 8 mOsm/L
- Dry Eye subject average:
  - 323 ± 16 mOsm/L
- Normal subject inter-eye difference:
  - 7 ± 6 mOsm/L
- Dry Eye subject inter-eye difference:
  - 17 ± 15 mOsm/L
- Inter-eye difference is the hallmark of DED (> 8 mOsm/L between eyes)¹


KEEP IT SIMPLE AND TAKE ADVANTAGE OF PPV

- MILD RANGE:
  - 300-320 mOsmol/L
- MODERATE RANGE:
  - 320-340
- SEVERE RANGE:
  - > 340

Osmolarity & Tear Film Instability in DED

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

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

- Reimbursement
  - NGS: $44.50
  - Medicaid: $43.50
  - Commercials: $29-40
- Code: 92071
- Card cost: $10

Myth:
CME is Not Common

Binocular Contrast Sensitivity
Mesopic Conditions - With Glare


Posterior Capsular Opacities

- Minimal posterior capsule opacities can markedly degrade quality of vision, however:
  If I Break it . . . . You Buy it
- Need to discuss with patients that once a posterior capsulotomy is performed it is much more dangerous to exchange the IOL.

IOL Centration on Pupil

- Argon Laser Iridoplasty 4 spots in iris mid periphery
  - 500 milliwatt energy
  - 500 micron diameter
  - 500 millisecond duration

Center the Pupil on the IOL

BCVA Pre-Argon Laser Iridoplasty vs. BCVA Post-Argon Laser Iridoplasty

The Bottom Line: Presbyopic IOLs

- **Surgeon and patient perspective**
  - Multifocal IOLs
    - Homeruns - true spectacle independence
    - Outs - more demanding surgically and psychologically. Rare IOL removal
  - Accommodating IOLs
    - Singles - many happy patients who still wear glasses
    - Walks - some patients do not read any better than a monofocal IOL
    - Errors - many more refractive enhancements

Limitations of Manual Cataract Surgery

- **Visual Outcomes**
  - Distance Correction Predictability
    - Half that of LASIK
  - Astigmatism Correction
  - Effective Power of IOL
  - Limits Presbyopia Correction
- **Safety**
  - Complications 10x LASIK
  - Ultrasound use in phaco associated with post-op complications such as corneal burn, corneal edema and endothelial cell loss

Goals of Laser Refractive Cataract Surgery

- Improve every procedure, technology and surgeon
  - Presbyopia, astigmatism and monofocal
  - Refractive precision and integration
- The LenSx Laser

Incidence of Capsular Tear

Unal M, Yücel I, Sarici A, Artunay O, Devranoğlu K, Akar Y, Altn M.

Phacoemulsification with topical anesthesia: Resident experience.
- Anterior tear of capsulorhexis in 5.3%
- Irregular anterior capsulorhexis in 9.3%
- Posterior capsule tears with vitreous loss in 6.6%
Laser Refractive Cataract Surgery

A New Category in Ophthalmic Surgery

One precise, image-guided femtosecond laser procedure to:

- Effectively liquefy or fragment the nucleus
- Create a perfectly centered and sized capsulotomy
- Perform complex multi-planar corneal incisions, and
- Arcuate incisions to address pre-existing astigmatism

Image-Guided LenSx Femtosecond Laser

- Integrated OCT scans entire anterior segment; projects images of cornea, lens, irid capsule onto video microscope
- Surgeon selects incisions and lens treatment; patterns are projected onto OCT images and confirmed
- Procedure time < 1 minute. Intraoperative OCT projects real-time images as lens is fragmented, capsulotomy is created and then all corneal incisions.

Refractive Capsulotomy

Optimized Effective Lens Position for Optimized IOL Performance

- 100% of LenSx procedures achieved an accuracy of ±0.25 mm
- Only 10% of manual procedures achieved an accuracy of ±0.25 mm
- No radial tears

Laser Corneal Incisions

Computer-controlled depth, shape and location

- Precise, DPT corneal thickness measurement
- Flexible femtosecond laser incision architecture
- Automated reproducibility allows surgeon to address astigmatism
- Efficacy of femtosecond lasers established in more than 3 million corneal incision procedures for LASIK flaps and LRIs, which were previously an art form, have now become a science

Effective Lens Position Variability

- LenSx (n=25) vs Manual (n=12)
- Procedure performed by Zoltan Nagy, MD at Semmelweis University, Budapest, Hungary
- "Clinical Evaluation of FS Laser-Assisted Cataract Surgery"
Accuracy to Target
Cataract Outcomes vs. LASIK

Improved Refractive Cataract Surgery

- IOL Position Predictability
- Corneal Astigmatism
- Early ‘WOW’ Factor

- Uniform shape and size of capsulotomy
- Reproducible corneal entry and arcuate incisions
- Reduced phaco power and corneal edema

Image-Guided Refractive Cataract Surgery

- Integrated OCT scans entire anterior segment; projects images of cornea, lens, etc., capture with video microscope
- Surgeon selects incisions; patterns are projected onto OCT image and confirmed
- Procedure time < 1 minute; intra-operative OCT projects real-time images as lens is fragmented; capsulotomy is created and all corneal incisions

LenSx Laser Corneal Incisions

- Customized wound architecture and placement
- Self-sealing incisions
- Predictable incision width, tunnel length
- Adjustable during surgery
- Adjustable post-op at slit lamp

Laser Corneal Incisions

- Computer-controlled depth, shape and location
- Precise, OCT corneal thickness measurement
- Flexible femtosecond laser incision architecture
- Automated reproducibility allows surgeon to address astigmatism
- Efficacy of femtosecond lasers established in over 3 million corneal incision procedures for LASIK flaps and keratoplasty
Effective Lens Position Variability

Unmet Need: Astigmatic Correction

Importance of Astigmatic Treatment

Astigmatism and Cataract Surgery

Astigmatism Treatment Options

Astigmatism is Common In Patients Undergoing Cataract Surgery
Astigmatism Treatment Options

- Easy to perform
- Inexpensive
- Lack of side effects
- Repeatable
- Performed at time of cataract surgery
- Fast recovery
- Increase the percentage of patients who fulfill inclusion criteria for premium IOLs
- Does not preclude future excimer treatment
- Reimbursement (additional revenue stream)

Challenges of Astigmatic Incisions

PREOPERATIVE MEASURES
- Determining the exact quantity and location of cylinder
TREATMENT
- Variable response to limbal relaxing incisions due to imprecise depth, length and position of incision.
- Risk of perforation
- “LRIs are an art form not a science”
- Reason: Imprecise, Non-Repeatable Incision Architecture

Laser Refractive Cataract Surgery – Arc Incisions

- Fully Customizable and adjustable
- Refractive incisions are no long an art form. They are a science.
- Place Desired Incisions:
  - Of the EXACT Size,
  - In the EXACT Place,
  - With the EXACT Depth,
  - Every Time.

Increased Accuracy of all Femtosecond Corneal Incisions

- Keratome limbal and corneal cataract incisions are less accurate than femtosecond incisions
- Femtosecond cataract incisions are more reproducible, stable, do not leak and are more refractively predictable

Programming FS Laser Arc Incisions

Fully Customizable and Precise Arc Incisions

Laser
- Precise:
  - Size
  - Length
  - Depth
  - Location
Laser Procedure

Phaco

Conclusion

- A new Category is emerging in private pay ophthalmic surgery
- LenSx technology will drive innovation for true Laser Refractive Cataract Surgery
  - Patients already thought they were having “laser” surgery anyway!
  - Unique precision for capsulotomy and corneal incisions
  - Smaller incisions and laser optimized wound architecture
  - Improved IOL performance via Effective Lens Positioning
  - Correction of pre-existing astigmatism at time of surgery
  - A more predictable, safe and reproducible procedure
  - Technology that will enable surgeons to deliver better vision

Topography Guided Laser Systems

- Allegretto Laser System
- Approval for Irregular Corneas
- Keratoconus
- Ectasia

KCN Diagnosis

Early
- Relative pachymetry

Late
- Corneal Hydrops
- Munson’s sign
- Apical Scarring
- Vogt’s Striae
- Irregular Mires
- Abn(anterior)Topo
- High Coma
- Epithelial thickness abnormalities
- Posterior Corneal Curvature

Corneal Collagen Cross-Linking

Less Cross-linking (weaker)  More Cross-linking (stronger)

Creates chemical bonds between fibers
CXL and Ectasia
- Kannalopoulos, J
- Review of CXL post LASIK with ectasia
- Analysis at one year
  - Corneas stable
  - Mild refractive error shift
- No PK required at two years

CXL and PRK
- Requires wavefront scan at level 4 reliability
- Predictability is less than standard PRK
- Contraindicated with apical scar
- Post-op similar to standard PRK
- CL’s same algorithm

Radial Keratotomy

CXL Technique
- Riboflavin drops every 2 min x 30 min
- Pachymetry checked > 400 μm
- Check UV light source calibration
- UV light source applied focused onto the cornea
- Riboflavin drops instilled every 2 min while UV light application for 5/30 min
- 1 drop of fluoroquinolone and steroid
- Homatropine 5% x2
- NSAID pre op x2
- Bandage contact lens

Haze?
CXL

- Post Epi-On CXL Contact Lens Tx
  - Soft lens several days
  - HCL 1 week
  - Hybrid 2 weeks
- Topo’s at 3M/6M
- Crosslinking can continue up to 6M