American Society of Cataract and Refractive Surgery

06-10 May, 2016
New Orleans, Louisiana
Ernest N. Morial Convention Center

Course 10-105
Room 228-230

“Best of the Best : Advanced New Technologies Cataract Surgery”

Senior Instructor:
Richard L Lindstrom MD

Instructor:
Eric Donnenfeld MD
Jack Holladay MD MSEE
Stephen S Lane MD
Matteo Piovella MD
Steven C Schallhorn MD

Tuesday, May 10, 2016
8.30 AM – 9.30 AM
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“Femto Laser Assisted cataract Surgery: Virtuosity or Frontier?”

Matteo Piovella MD

Opportunity For Femtosecond Laser in Cataract & Presbyopia/Refractive Population

- > 30 million Cataract surgeries are being performed worldwide every year by 66,227 Eye Surgeons (2012) manually.
- Projected to grow to > 55 million procedures by 2018 (MarketScope estimates)
- Nearly all Cataract patients are presbyopic, and most have refractive errors (and 70% with S.O or greater astigmatism)

How to Measure Technology Diffusion?

- High volumes low cost cataract surgery is our standard
- Due to cost control in public health care systems, product selection is now being limited
- Doctors no longer have the freedom to choose the best technology for the patients
- How do we ensure that our patients will have access to advanced technology
- Who is responsible for that?
- Who should pay for that?
Use of Premium IOLs - US Cataract Surgeons

Laser Cataract Surgery
Projected to grow to 1.76M procedures by 2017

Where Is The Barrier to Entry?

Refractive Cataract Surgery

The laser is part of a tool set required to enhance procedural predictability

- Establish medical necessity to perform cataract surgery
- Discuss refractive goals of the patient:
  - Does the patient desire to depend less upon glasses after surgery?
  - If yes, then the cataract surgery becomes a refractive procedure

Figure 61: Greatest Concerns over IOLs

New istill needed
Efficiency
Increased chair time
Reduced Oil Efficiency
Runway

Source: 2012 ASCRS Ophthalmic Cataract Surgery in the New Millennium

Four Key Points Influencing Cataract Surgery

- More demanding patient for new technology adoption
  - Patient mean age:
    - From 72 y.o. (1970-1990) dropped down to 62.5 y.o.
  - More precision, safety and reproducibility
    - Corneal Incisions
    - Capsulotomy
    - Nucleation fragmentation

Femto Technology Up to Date

- No competition with Phaco
- It does what phaco machine does not
- Technology not effective in the beginning...
- No need of different patient organization
- No need significant patient selection
- Same surgical time
AMO Catalys Femtolasar Assisted Cataract Surgery
Surgeon: Burkhard Dick – Bochum - Germany

Case Presentation

Female 48 y.o.
Bilateral Myopia - 5 Diopters plus astigmatism (No data available)
Bilateral Radial Keratotomy (1990 (Columbia))
16 Incision plus 1 transversal to correct astigmatism

May 2014
RE BCFV: 20/20 +0.50 SF +0.75 CYL AX 35’ Plus 1.75 Near Vision
LE BCFV: 20/20 +1.00 SF +1.00 CYL AX 60’ Plus 1.75 Near Vision

Anterior Chamber Depth:
Right Eye: 1.65 mm
Left Eye: 1.54 mm

Results

- Left Eye IOL Implantation + 30.50 AT LISA tr
- Right Eye IOL Implantation +26.00 AT LISA tr

1 Month post Surgery
- RE BCFV 20/20 +2.00 SF +1.50 CYL AX 5°
- LE BCFV 20/20 +3.50 SF +2.00 CYL AX 0°

3 Months post Surgery
- RE BCFV 20/20 +2.50 SF +1.00 CYL AX 20°
- LE BCFV 20/20 +2.50 SF +2.00 CYL AX 40°

6 Months post Surgery
- RE BCFV 20/20 +2.50 SF +0.75 CYL AX 30°
- LE BCFV 20/20 +1.00 SF +1.75 CYL AX 40°

1 Year post Surgery
- RE BCFV 20/20 +2.50 SF +1.50 CYL AX 40°
- LE BCFV 20/20 +1.25 SF +1.50 CYL AX 40°

18 Months post Surgery
- RE BCFV 20/20 +2.00 SF +1.00 CYL AX 30°
- LE BCFV 20/20 +2.50 SF +2.00 CYL AX 40°

Left Eye: 3 Months PO

Left Eye: 3 Months PO
Female 55 y.o.

May 2014

RE Ferrito Laser Assisted Cataract Surgery using Catalys System (AMO Abbott)

RE AT TORBI IOL Implantation (Zeiss Meditec):
Toric Monofocal IOL +9 sf +12.00 cyl ax 145°

Results

Right Eye AT TORBI IOL Implantation +9 sf +12.00 cyl ax 145°

1 Month post Surgery
RE BCFV 40/20 -3.00 SF +6.00 CYL AX 160°

3 Months post Surgery
RE BCFV 40/20 -2.00 SF +6.00 CYL AX 100°

6 Months post Surgery
RE BCFV 63/20 +4.00 CYL AX 170°

12 Months post Surgery
RE ECF 63/20 +1.00 +5.00 CYL AX 175°

Left Eye 3 Months PO

AT LISA® tri:
IOL decentration
“Multifocal Accommodative and Toric IOL Implantation in Advanced cataract Surgery: 9 Years Up to date”
Matteo Piovella MD
Residual Refractive Error as Function of Pupil Size and Defocus

Diffractive Technology
Snellen Visual Acuity as Function of Pupil Size and Defocus

- Tonic vs. spherical is two times difference: the effect of 1 D cylinder error on VA is about 0.3 D spherical refractive error.
- In Multifocal lenses, VA sensitivity to refractive error depends on a multifocal design.
- Refractive Multifocal Technology was close to monofocal for the width of the Distance Peak in Defocus Curve measurements.
- Diffractive Multifocal Technology width of the Distance Peak was about half the monofocal width.
- The effect of refractive error was about twice more sensitive to than in case of a monofocal optic.

Weak Points of Diffractive Multifocal Bifocal IOLs

- Reduction of Contrast Sensitivity (up to 30%)
- Diffraction Grooves (Blaze height) Creates Different Diffraction Efficiency and Light Loss
- Tonic Multifocal when 0.75 D of Corneal Astigmatism
- Halos, Glare and Ghost Images are Difficult to Manage in Suspicious Patients
- Poor Intermediate Distance Vision
- 0.50 Diffractive SE generates loss of one line of Visual Acuity
- Perfect Target: Piano Postop Refractive Results

% Distribution of Light Rays

- With Accommodative IOLS there is no loss of light, so quality of vision is not compromised.²

<table>
<thead>
<tr>
<th></th>
<th>Pupil</th>
<th>Synchony</th>
<th>RUSTOP®</th>
<th>TRUMOR® ME</th>
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<tr>
<td>Near</td>
<td>2 mm</td>
<td>100%</td>
<td>42%</td>
<td>41%</td>
</tr>
<tr>
<td></td>
<td>5 mm</td>
<td>100%</td>
<td>64%</td>
<td>41%</td>
</tr>
<tr>
<td>Distance</td>
<td>2 mm</td>
<td>100%</td>
<td>42%</td>
<td>41%</td>
</tr>
<tr>
<td></td>
<td>5 mm</td>
<td>100%</td>
<td>64%</td>
<td>41%</td>
</tr>
<tr>
<td>Intermediate</td>
<td>2 mm</td>
<td>100%</td>
<td>6%</td>
<td>5%</td>
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<tr>
<td></td>
<td>5 mm</td>
<td>100%</td>
<td>0%</td>
<td>0%</td>
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<td>LIGHT LOSS</td>
<td>2 mm</td>
<td>0%</td>
<td>20%</td>
<td>18%</td>
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<tr>
<td></td>
<td>5 mm</td>
<td>0%</td>
<td>0%</td>
<td>6%</td>
</tr>
</tbody>
</table>

²

Rays and Wavefront

Wavefront Error is commonly called Wavefront

Lens REFRACTS light ray = TRANSFORMS wavefront shape Rays and Wavefront.

The key advantage of Wavefront over Rays is that the wave nature of light can be introduced with the Wavefront and then the image is formed by constructive interference of the light waves.

Image is Constructive Interference of wave

Spherical wavefront

Plane wavefront (object at infinity)

Wavefront Error $W(x,y)$ is defined as the difference between the actual wavefront $W(x,y)$ and spherical wavefront, so called reference wavefront $WREF$. 

provita@provita.com
MTF (60 lp/mm) sensitivity to IOL rotation error up to 2.0 D cylinder correction - Pupil Size 5 mm

"E" (2014) sensitivity to IOL rotation errors of 0, 5, 10, 15, 20 degrees for 2.0D cylinder correction.

AT LISA® tri - Trifocal Optic

The optical zone of the AT LISA® tri 600MP provides:
- A near addition of ±1.00 D for a comfortable reading distance
- An intermediate addition of ±1.00 D

It improves intermediate vision without compromising near or far vision.

AT LISA® tri has three rings of the IOL optic surface for reduced astigmatism, visual distortion, and improved night vision.

AT LISA® tri - Specific Asymmetrical Light Distribution

AT LISA® tri: asymmetrical light distribution:
- 50% near
- 20% intermediate
- 30% far

This technology decreases light loss.

% LIGHT DISTRIBUTION

<table>
<thead>
<tr>
<th></th>
<th>Wear</th>
<th>Intermediate</th>
<th>Far</th>
<th>Outside Range of Vision</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 mm pupil</td>
<td>50%</td>
<td>20%</td>
<td>30%</td>
<td>Up to 15%</td>
</tr>
</tbody>
</table>

AT LISA® tri - Materials and Methods

- AT LISA tri implanted in 54 eyes of 54 patients
- Mean age 67.89 ± 11.18
- Mean Preoperative BCVA: 20/20 ± 40.27
- Mean Time Follow Up: 3 years, 1 month
- Mean Preoperative Sphere Equivalent: 0.01 ± 0.00

UCDVA - BCDVA and Sphere Equivalent (96 Eyes)
ATLISA® tri (96 Eyes)
YAG LASER TREATMENTS

- ATLISA® tri implanted in 96 eyes of 58 patients
- 29 Eyes: YAG Laser treatments (23.95%)
- Mean days PO: 528.13 ± 211.18 days

ATLISA® tri toric No correction
Far Vision

ATLISA® tri toric No correction
Intermediate Vision

ATLISA® tri toric No correction
Near Vision

ATLISA® tri toric No correction
Near Vision

Quality of Vision
Contrast Sensitivity and Control Values

Control values for CS are derived from Hohberger paper

- 18-14 healthy phakic subjects for the following age groups:
  30-35, 35-40, 40-45, 45-50, 50-55
- Functional Image Analyzer OPTEC 6500
- Daytime (85 cd/m²), Nighttime (3 cd/m²) and Nighttime with Glare (7 cd/m²)
- Monocular testing
- Paper demonstrated strong age dependence of CS with age
Multifocal IOLs Contrast Sensitivity

Retina: normal
Vision Field: normal

Do not wear glasses at all: 56 patients – 36.32%
4 patients use discontinuously near glasses to feel confident with near vision
1 patient uses intermediate glasses
1 patient uses for glasses

Advanced Technologies IOLs

- Trifocal Technology has replaced Bilateral Technology
- Normally we are presenting long term data that do not match the old data technology
- Normally eye doctors that have enough direct experience on advanced technology IOLs make all their efforts and efforts to support the patients to not understand their positions
- The Eye after cataract surgery needs at least three months to get back to standard quality of vision
- By the point of view of the patients many complaints seem similar for monofocal and advanced technologies IOLs
- Adoption of new technologies takes time and is very expensive

The Advanced Technologies IOLs

- Costs / Benefits do not match the best possible results needed
- Costs / Benefits match High Volume Low Cost cataract system
- Normally the responsibility of the Eye Doctors is to provide best care and best results despite the costs
Small Aperture Moves Inside the Eye

KAMRA™ Corneal Inlay

IC-8™ Small-Aperture IOL

Pron Benfits of a Small Aperture

• Improves near and intermediate vision while maintaining good distance vision
• No competing focal points to degrade image quality
• Binocularity maintained despite monocular implantation
• Maintained binocular contrast sensitivity
• High patient satisfaction
• Much less sensitive to decentration

IC-8™ IOL Design

- IOL Material
  - Single-piece hydrophobic acrylic
- Mask
  - FVGF & nano-particles of carbon
  - 1.36mm aperture
  - 5.23mm total diameter
  - 3296 microperforations
  - 5 microns thick

Study Design

- Inclusion Criteria:
  - Subjects must be ≥45 years of age
  - Clear intraocular media other than cataract
  - BCVA 20/40 or worse as a result of cataract in the operative eye
  - Fellow eye could have either the natural crystalline lens or prior monofocal IOL implantation
- Procedure:
  - Patients were implanted monocularly with an IC-8 IOL

Procedure:

- First eye: DOMINANT EYE → monofocal IOL → target PLANO
- Second eye: NON DOMINANT EYE → IC-8 → target - 0.75 sf

Six Months PO UnmonocularVA Results

40 eyes of 20 patients

MORFOCIAL IOL UCVA/20

DISTANCE

INTERMEDIATE 20 cm

NEAR 40 cm

IC-8 IOL UCVA/20

DISTANCE

INTERMEDIATE 20 cm

NEAR 40 cm
**Fundus Photography**

- Imaging through the IOL mask central aperture is possible.
- Minimal differences noted when comparing IC-8™ IOL eyes to monofocal or multifocal IOL eyes.

**Retinal Evaluation and Surgery:**

**Single-center, prospective, animal Study**

- Conducted by Barry Kupersmann, PhD, MD.
  - 6 New Zealand Black rabbits implanted with IC-8 IOL.
  - Controls: Monofocal and Multifocal.
- Evaluations/Procedures Performed:
  - Anterior vitrectomy
  - Simulated endo-retinal laser photoagulation
  - Posterior vitrectomy
  - Air-fluid exchange
  - Epiretinal membrane peel
  - Binocular indirect ophthalmoscopic visualization and indirect laser treatment of the retina.
- Results: Virecroinal surgery in eyes implanted with the IC-8 IOL can be performed with ease and good visibility.

**Summary**

- Early results for the IC-8™ small aperture IOL show:
  - Extended range of vision after cataract extraction.
  - Mean score of 20/20 across near, intermediate and far distances.
  - No difference in symptoms or visual fields seen between IC-8 and fellow eyes.
  - Retinal evaluations and surgical procedures are possible and easy to perform.
- Additional data and results to be presented at future meetings.

**Ocular Assessments Post-Implantation**

- Four technicians were asked to assess the ease of performing the following routine diagnostic assessments in IC-8™ implanted eyes.
  - Visual Field
  - Fundus photography
  - Retinal OCT
- They reported that:
  - Successful diagnostic testing was completed in all patients.
  - No different instructions were required between IC-8 eyes and fellow eyes.
  - For most patients there was no additional time needed when performing evaluations.
**Visual Field**

- Visual field assessment in IC-8™ IOL implanted eyes shows a similar trend as the KAMRA™ IOL.
  - Visual field remains within normal limits after KAMRA implantation.
  - Data from the clinical trial showed a slight overall decrease in sensitivity (+1.5 dB change from baseline).
  - No statistically significant difference between implanted and non-implanted eyes.

**Retinal Optical Coherence Tomography**

- Retinal OCT through the IC-8™ IOL central aperture is possible.
- Minimal differences between implanted and fellow monofocal IOL implanted eyes were noted in this series.
- Minimal differences were found when comparing results with multifocal IOL implanted eye.

**Conclusions**

- Bifocal Diffractive IOLs technology is difficult to manage and avoid quality of vision penalization on a significant number of patients. Diffractive Diffractive IOLs technology has no significant % of light for intermediate distance and an important amount of light loss.
- The Bifocal Diffractive IOL technology overcomes this weak point providing specific % of light for intermediate distance and reduces the light loss % improving diffractive efficiency and quality of vision.
- Heats, Clara and Ghost images are difficult to manage in demanding Patients. Diffractive Diffractive IOL technology is an effective tool to reduce night driving problems due to non-symmetric % of light distribution.
- A 3 mm pupil size condition works the best to minimize patient complaints. Larger pupils fail to be detected preop. It is really important a proper patient selection related to pupil dynamics.
- Perfect Target after Diffractive IOLs technology implantation is Pair Postop results.

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**Catalys Femtolasr Assisted Cataract Surgery**

Surgeon: Burkhard Dix – Bochum - Germany

Surgery performed:
- on July 3rd 2014 (Right Eye) - 2011 RD
- on July 4th 2014 (Left Eye)

Preoperative data:
- Right Eye: BCVA 20/25 - 0.8 ph
- Left Eye: BCVA 20/25 - 0.8 ph - 1.50 cyl axis 105°
- Right Eye: ALT LISA 15° + 10.00
- Left Eye: ALT LISA 15° + 10.00 + 1.50 cyl axis 71

Two Months PO Results:
- Right Eye: UCVF 20/15 UCV 20/25 UCNV 20/12 (Bright Light)
- Left Eye: UCVF 20/15 UCV 20/25 UCNV 20/12 (Bright Light)
Accommodating IOLs Best

- No Contrast Sensitivity Penetration
- Halos or Glare similar to Monofocal IOLs
- Future AMD: No Future Visual Penetration due to IOLs Technology
- Best Choice for Suspicious Patient, with Possible High Sensitivity to Glare and Halos, but Highly Demanding for New Technology IOLs
- Provide Intermediate Vision

YAG LASER TREATMENTS 13 Eyes: yag laser treatments (39.4 %)

Bilateral Tecnis® MIOL
32 eyes of 16 patients
Mean Age 56.63 ± 3.50

AT LISA® Tri:
IOL decentration

52 Patients with ReZoom® + Tecnis® Implantation (10.4 eyes)
16 Patients with Bilateral Tecnis® Implantation (33 eyes)

AT LISA® Tri toric Materials and Methods

- AT LISA® Tri toric implanted in 53 eyes of 18 patients
- Mean Age 67.02 ± 10.06
- Mean PREOPERATIVE BCVA 77.83 ± 3.23
- Mean Time Follow Up 2 year
- Mean Preoperative Sphere Equivalent -1.36 ± 3.04
- Mean Preoperative Corneal Astigmatism 1.40 ± 0.57
- Mean Preoperative Refractive Astigmatism 5.90 ± 2.05
AT LISA® trif - toric
UCDVA - BCDVA and Sphere Equivalent (50 Eyes)

<table>
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<tr>
<th>Sphere Equivalent</th>
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<tr>
<td>UCDVA</td>
</tr>
<tr>
<td>BCDVA</td>
</tr>
</tbody>
</table>

AT LISA® trif toric 58 eyes
YAG LASER TREATMENTS

- AT LISA® trif toric implanted in 58 eyes of 58 patients
- 6 Eyes: YAG laser treatment (10.32%)
- Mean days PO: 33.14 ± 123.30 days

Thank you for your attention!
"What’s New in Multifocal IOLs"

Eric D. Donnenfeld MD

What’s New in Multifocal IOLs.

New Presbyopia IOL choices

Why So Many MF Powers?

Different Multifocal Near Points Have Very Different Defocus Curves

Disclosure: Eric Donnenfeld, M.D.

Multifocal IOLs

- My current best option for spectacle independence following cataract surgery
- Multifocal IOL patients are my happiest... and my most unhappy patients
- High spectacle independence but often complaints of halos
- In the past I told every multifocal IOL patient there is a 1/40 chance I will need to exchange their IOL

- Performance differences with different add powers
  - e.g. ReSTOR 4.03, 0.25, Tecnis MF 4.03, 0.25
  - Bifocal vs. trifocal designs
- Meet demand of patients with various near and/or intermediate task needs
- Differences in design influence visual disturbances such as glare and halos
- No single style MF IOL can fill in all the gaps throughout the entire range of vision
Patient Satisfaction With Multifocal IOLs is all About Their Quality of Vision at Distance

Simultaneous Vision in Multifocal IOLs May Lead to Halos and Glare

Spectacle Independence Increases With Closer Near Points

Closer Near Point Improves Near Vision but Reduces Quality of Vision at Distance

Closer Near Point Reduces Quality of Vision at Distance

Glare is Reduced With Extended Near Point
Halos are Reduced with Extended Near Point

Low Add Multifocal IOLs are Better Tolerated by Patients

AcrySof® IQ ReSTOR® IOL

ReSTOR +2.5 Glare and Halo

Low Add Multifocal IOLs are Better Tolerated by Patients

Blended Vision to Improve Depth of Field

Patients implanted with AcrySof® IQ ReSTOR® +2.5D IOLs experienced 3.3% severe glare and 10.5% severe halos.
AcrySof IQ ReStor +3.0 Multifocal Toric IOL

- Anterior Apodized Diffractive Aspheric Surface
- Same design as current AcrySof IQ ReStor +3.0D
  - 9 apodized diffractive steps for +3.0D add power
  - Negative 0.5 micron spherical aberration factor corrects for the positive spherical aberration of the cornea
- Posterior Toric Lens Surface
- Same design as current AcrySof Toric IOL
  - Posterior toric axis marks
  - Posterior toric marks
  - Allows the lens to correct pre-existing corneal astigmatism

Trifocal IOLs

Trifocal options

- FineVision: +3.50 (36cm) +1.75 (73cm)
- PanOptix: +3.25 (39.4cm) +2.37 (59.1cm)
- Zeiss: +3.33 (38cm) -1.66 (78cm)

Alcon Panoptix Presbyopia IOL

Fine Vision (Bausch & Lomb)
AT LISA tri839MP (Zeiss)

Comparison of 3 available Trifocals

<table>
<thead>
<tr>
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<th>Finemis</th>
<th>AT LISA tri839MP</th>
<th>Panoptix</th>
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<tr>
<td>Ingression</td>
<td>3.0 mm</td>
<td>3.0 mm</td>
<td>3.6 mm</td>
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<tr>
<td>Optic design</td>
<td>3 superimposed diffractive optics</td>
<td>Diffractive, trifocal centered 3.34 and peripheral trifocal (posterior incision)</td>
<td>Diffractive, quadrifocal with 3 step heights in 4 planes</td>
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<tr>
<td>Haptic design</td>
<td>Single plane IOL, Micro f - Micro boxed haptic, PostT - Haptics (open haptic)</td>
<td>Single plane haptic IOL</td>
<td>Single plane haptic IOL, Single plane modified L design - 2 haptics (open haptic)</td>
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<td>Face</td>
<td>3 Distance, 75 mm (2.5 add) and 50 mm (5.75 add)</td>
<td>3 Distance, 60 mm 3.05 add (add) and 40 mm (3.33 add)</td>
<td>4 Distance, 110 mm, 60 mm and 40 mm</td>
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<td>Asphericity</td>
<td>-3.00 spherical aberration on posterior surface</td>
<td>-0.50 spherical aberration on posterior surface</td>
<td>-0.30 spherical posterior surface</td>
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<tr>
<td>Square edge</td>
<td>35°</td>
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Trifocals - comparison

<table>
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<td>Filtration</td>
<td>UV &amp; blue light blocker</td>
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<td>UV and blue light blocker</td>
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<td>Material</td>
<td>25% polyhydrophilic acrylic</td>
<td>25% polyhydrophilic acrylic (hydrophilic surface)</td>
<td>Hydrophilic acrylic</td>
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<td>Optic Diameter (mm)</td>
<td>Micro 6.35 PostT 6.0</td>
<td>6.0</td>
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<td>Overall Diameter (mm)</td>
<td>Micro 7-6.35 PostT 7.0</td>
<td>7.0</td>
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<tr>
<td>Haptic angulation</td>
<td>0°</td>
<td>0°</td>
<td>15°</td>
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<tr>
<td>Sphere Power</td>
<td>+0.00 to +15D (4 steps)</td>
<td>+0.00 to +15D (4 steps)</td>
<td>+0.00 to +15D (4 steps)</td>
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<tr>
<td>Toxic vision Power</td>
<td>+0.50 to +3.00D (3 steps)</td>
<td>+0.50 to +3.00D (3 steps)</td>
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Extended Range of Vision

A New Segment of IOLs – Extended Range of Vision IOLs

The Symfony Extended Depth of Focus IOL
Extended Depth of Field IOL

Diffractive echelette design feature introduces a novel pattern of light diffusion that elongates the focus of the eye resulting in an extended range of vision.

Conclusion

- The use of MF IOLs remains a tradeoff between decreased spectacle independence and visual disturbances
- New options give patients more choice in near and intermediate vision
- New options give the surgeon the ability to correct corneal astigmatism
- MF echelettes
- Extended depth of focus is an exciting and entirely new category
- Tribool IOLs are coming
- Surgeons now have options of blended vision with different add powers to meet the individual patient needs
“Delivering Improved Outcomes for Today's Cataract Patient”

Stephen S Lane MD

Delivering Improved Outcomes for Today's Cataract Patient
Stephen Lane, MD

Cataract Surgery Outcomes***

- Patient expectations are at an all-time high for refractive surgery
- Positive experiences with LASIK have produced high expectations
  - 92.6% of LASIK patients achieve vision of 20/40 or better*
  - 95.4% of patients were satisfied with their outcome after LASIK surgery*
- Cataract surgery outcomes may not be meeting the target of ±0.5D that is considered the standard

What are the issues that affect hitting the refractive target?

Pre-operative
- Biometry
- Managing astigmatism
- Transcription errors
- Cyclorotation
- Manual marking

Intra and Post Operative
- Rhexis shape and size?
- Posterior corneal astigmatism
- Alignment, centration
- A-constant optimization

Cataract Refractive Diagnostics
Image Guidance

DISCLOSURE
- Alcon
- ClarVista
- Bausch and Lomb
- Ivantis
- i-Veena
- Kala
- Lifecore
- Mati
- Ocular Therapeutics
- Omeros
- PowerVision
- PRN
- RPS
- Shire
- TearLab
- TearScience
- VisionCare
- WaveTec

Cataract Refractive Diagnostics
Image Guidance

Manual Toric Marking

**Solomon, K et al. (2009) "LASIK world literature review: quality of life and patient satisfaction." Ophthalmology. 16(4): 691-701
The Verion™ Image Guided System

**Designed to help you consistently achieve your refractive target.**

The VERION™ Image Guided System is designed to add greater accuracy and efficiency during surgical planning and execution. Consisting of the VERION™ Reference Unit and the VERION™ Digital Marker, it is designed to help you perform cataract surgery.

Introducing the VERION™ Image Guidance

**IMAGE. PLAN. GUIDE.**

VERION™ Reference Unit

VERION™ Microscope Integrated Display

Capturing the Reference Image

Comprehensive Astigmatism Planner

Closing the Loop: Optimization
Digital Marker Guidance

Registration Process at the LenSx® Laser - Digital Marker L

Image Guided System and Centration

MICROSCOPE INTEGRATED DISPLAY

Verion Digital Marker M

Intraoperative Surgical Aberrometry
“Yardstick” to measure Cataract Surgery Success

• Driven by LASIK outcomes
  – Refractive component and Visual Acuity component
  – >95% of outcomes within 0.50 D of nomogram predicted refractive target
  – 90% of eyes achieving UDVA of 20/20 or better
  – <3% enhancement rates expected

Outcomes in Modern Cataract Surgery Literature

• Narvaez / Stulting JCRS Dec. 2006
  – 46% within 0.50 D of formula predicted target
  – Mean prediction error: 0.52 D +/- 0.44 D

• Gale et al, Eye Aug. 2007
  – 55% of eyes within 0.50 D of formula predicted target
  – 85% of eyes within 1.00 D of formula predicted target
  – Findings considered the benchmark for the NHS in the UK
  – Enhancement Rates on Premium IOL cases (Presbyopic and Toric IOLs)
  – Range from 10% to 35%

Conventional IOL Power Determination Approach

• Various characteristics of the eye are measured preoperatively
  • Axial Length
  • Corneal Power
  • Other measurements that may be used (formulae dependent)
    – Anterior Chamber Depth
    – Lens Thickness
    – White to White
    – Formula applied

The ORA System® with VerifEye®
Overview

- The ORA System® uses wavefront aberrometry data in the measurement and analysis of the refractive power of the eye (i.e. sphere, cylinder, and axis measurements) to support cataract surgical procedures.
- Accounts for contribution of anterior and posterior corneal astigmatism in its measurements.
- Real-time, intraoperative refractometer plus a working algorithm supported by a large clinical database (100k+ cases), and a platform for additional enhancements.

Improve astigmatic outcomes for your patients with real-time intraoperative Validation

- Provides streaming refractive information to determine power, cylindrical magnitude and axis, even for post-refractive-procedure eyes.
- Accounts for contribution of anterior and posterior corneal astigmatism in its measurements.
- Reduces risk of residual postoperative astigmatism.

Primary Efficacy Result
Residual Refractive Cylinder at 3 Months

Secondary Efficacy Result
Postoperative MRSE Accuracy at 3 Months

Improved astigmatic outcomes with VerifEye®

This carefully controlled clinical study confirms that the ORA System® with VerifEye® provides better astigmatic outcomes in cataract surgery.

Percent of Patients Within ≤ 0.50 D of Intended Target at One Month; n = 111 patients, p = .006

1. Results of this study demonstrated better achievement of the intended target and non-antitarget determination in IOL cylinder power.

2. Standard of Care: Conventional biometry measurement of the pre-op corneal astigmatism and toric calculator determination of IOL cylinder power.
Improved astigmatic outcomes with VerifEye®

53.8% fewer patients were outside the intended target.

Synergism of Guidance with Aberrometry and Femtosecond Cataract Surgery

- Paired with the VERION™ Image Guided System aberrometry provides the opportunity to address potential sources of error at each procedural step imaging, planning, guidance and verification.
- Aberrometry gives you the confidence to effectively treat astigmatism for toric IOL patients.

How I use the systems together

- Toric case
  - Establish initial plan with Verion guidance
  - K’s will help establish initial cylinder power and axis – registration will help identify this axis during surgery
  - Pre-op will supply preliminary spherical power for the toric lens
  - Obtain consistent VerifEye aberrometry aphakic measurements intraoperatively
  - Will provide the actual spherical power of the lens, cylinder power and the target axis of placement
  - Use Verion guidance to locate axis obtained during pre-op
  - Place lens and use VerifEye’s toric pseudophakic aberrometry application to refine axis of placement by rotating as directed

Conclusions

- Aberrometry and Guidance are complimentary
- Using both together results in refined IOL power selection and astigmatic treatment
“Preliminary Results of Intrastromal Femtosecond Astigmatism keratotomy”
Steve C. Schallhorn MD

Preliminary Results of Intrastromal Femtosecond Astigmatic Keratotomony

Femtosecond Intrastromal AK

- Advantages
  - The accuracy and precision of the femtosecond laser
  - No epithelial injury
  - Quick procedure
  - Fast visual recovery

- Disadvantages
  - Requires femtosecond laser/cost
  - Nomogram under development
  - Limit on maximum cylinder correction

Demographics

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient (eyes)</td>
<td>105 pts (122 eyes)</td>
</tr>
<tr>
<td>Age</td>
<td>58 yrs range 21 to 78 yrs</td>
</tr>
<tr>
<td>Gender</td>
<td>53% male; 47% female</td>
</tr>
<tr>
<td>Eye treated</td>
<td>46% left; 54% right</td>
</tr>
</tbody>
</table>

Months from Primary Procedure

![Graph showing months from primary procedure to ISAK](image)

ISAK Nomogram

- Paired symmetric (same length) arcuate incisions centered on the steep axis
- Optical Zone: 7mm
- 80% corneal thickness
- 60 micron from epithelium

<table>
<thead>
<tr>
<th>Intended Cylinder Correction (D)</th>
<th>Arc length (degrees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>-0.50 to -1.25</td>
<td>40</td>
</tr>
<tr>
<td>-1.50 to -1.75</td>
<td>50</td>
</tr>
<tr>
<td>-2.00 to -3.50</td>
<td>80 to 75</td>
</tr>
</tbody>
</table>

Preop and Postop Refraction

<table>
<thead>
<tr>
<th></th>
<th>Preoperative</th>
<th>1 month (p&lt;0.05)</th>
<th>5 month (p&lt;0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sphere (D)</td>
<td>-0.51 ± 0.10</td>
<td>-0.21 ± 0.10</td>
<td>-0.26 ± 0.10</td>
</tr>
<tr>
<td>Min. Max.</td>
<td>0.75 to 1.25</td>
<td>-1.00 to -1.50</td>
<td>-1.00 to -1.50</td>
</tr>
<tr>
<td>Cylinder (D)</td>
<td>-1.27 ± 0.60</td>
<td>-0.71 ± 0.66</td>
<td>-0.65 ± 0.60</td>
</tr>
<tr>
<td>Min. Max.</td>
<td>-3.50 to -0.50</td>
<td>-3.00 to 0.00</td>
<td>-2.75 to 0.00</td>
</tr>
<tr>
<td>Spheric</td>
<td>-0.65 ± 0.43</td>
<td>-0.47 ± 0.18</td>
<td>-0.01 ± 0.06</td>
</tr>
<tr>
<td>Min. Max.</td>
<td>-1.50 to -1.25</td>
<td>-1.00 to -0.50</td>
<td>-1.50 to -1.25</td>
</tr>
</tbody>
</table>

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Conclusions

- Initial results of intra-stromal femtosecond AK show that it can safely reduce moderate levels of astigmatism
  - Can be titrated but significant variability
- No change in MSE
- CR 0.78 indicates under-correction
- Appears stable
  - 1 week to 3 month followup
- Nomogram refinement underway
"The Promise of No Glasses or Contact Lenses!"

Jack T. Holladay MD, MSEE, FACS

Financial Disclosure

- I have the following financial interests or relationships to disclose:
  - Abbott Medical Optics (C)
  - Alcon Laboratories, Inc. (C)
  - Allergan, Inc. (C)
  - Carl Zeiss Meditec (C)
  - Santen (C)
  - Orbsen, Inc. (C)
  - Valeant Pharmaceuticals (C)
  - WaveLight (C)

Requirements

- Centration
- Accurate Biometry – Optical (IOL Master or LenStar)
- Accurate K’s - Repeatable
- 4th Generation Formula (WTW)
- Personalized Lens Constant
- Eliminate Corneal Astigmatism

Multifocal IOL

Optimal Location

- Cannot place on Pupil Center & Visual Axis (near P1) where axial ray is perpendicular to foveola.
- Optimal location is different for each patient and somewhere between Pupil Center & P1.
Optimizing intraocular lens power calculations in eyes with axial lengths above 25.0 mm

**Requirements**

- Accurate Biometry – IOL Master
- Accurate K’s – Repeatable
- 4th Generation Formula (WTW)
- Personalized Lens Constant
- Eliminate Corneal Astigmatism

**Zaldivar-Holladay JCRS May 2000**

**Zeiss - IOL Master – 2000**

---

**Measured 36 vs 34 mm**

Linear Regression to compensate for AVERAGE Index of Refraction in Long Eyes

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**Fig. 5-L Myopic cornea.**
IOL Power Calculations
- Pentacam can measure FRONT & BACK SURFACE POWER
- Can Calculate:
  - Equivalent K-Reading (EKR)
  - 65% Mean, Peak & Average
  - NET POWER

EKR
- Reports Keratometry value but adjusts for Back Surface Power from Normal (Current IOL Formulas)
- If corneal front surface is 7.5 mm (45 D), but if back surface -0.3 D > normal:
  \[ EKR = 45.0 - 0.3 = 44.7 \text{ D} \]
  Note: Net Power = 43.3 D

New algorithm for intraocular lens power calculations after myopic laser in situ keratomileusis based on rotating Scheimpflug camera data

IOL Calcs – Abnormal Cornea
(Use 65% **MEAN EKR**)
- Post Refractive Surgery
- Post PKP
- Keratoconus
- Corneal Scar
- Any Irregular Astigmatism
Use 65% Mean EKR
(@ 4.5, 4 & 3 mm zones)

Normal
LASIK
RK

POST LASIK

Post LASIK CALC
- $K_{\text{mean}} = 39.8$ D
- Used 39.8 D $\Rightarrow$ SEQ = +1.12 D
  $(+1.00 + 0.25 \times 155 = 20/20)$
- 65% mean = 38.8 D $\Rightarrow$ +0.12 D
- Use 65% mean K

Conclusions
- EKR – Use 65% Mean for all IOL Calcs
- Look @ smaller zones than 4.5 mm if pupil very small
  (< 3.0 mm in dim light)

Requirements
- Accurate Biometry – IOL Master
- Accurate K’s – Repeatable
- 4th Generation Formula (WTW)
- Personalized Lens Constant
- Eliminate Corneal Astigmatism
Vergence Formula

\[
IOL = \frac{1336}{AL-ELP} - \frac{1336}{1000} + K(\text{Post R}) - \frac{ELP}{1000} \cdot \frac{Y}{D\text{PostRx}}
\]

CONCLUSION: 9 EYES

<table>
<thead>
<tr>
<th>Anterior Segment Size</th>
<th>Megatomecan (86%)</th>
<th>Megatomecan (86%)</th>
<th>Megatomecan (86%)</th>
<th>Megatomecan (86%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Axial Length</td>
<td>Short</td>
<td>Normal</td>
<td>Long</td>
<td>Normal</td>
</tr>
</tbody>
</table>

Measurements taken for Predictors of ELP

- Axial Length
- Average K (Pre Ref)
- Horizontal WTW
- ACD
- LT
- Pre-opRefraction
- Age

FORMULA PERFORMANCE

![Graph showing FORMULA PERFORMANCE with Mean Absolute Error (M) vs. Axial Length (mm) for N = 997.](image)

Requirements

- Accurate Biometry – IOL Master
- Accurate K’s- Repeatable
- 4th Generation Formula (WTW)
- Personalized Lens Constant
- Eliminate Corneal Astigmatism
**Personalized Lens Constant**
- Never use Manufacturer’s Constant except to start
- 20 to 40 cases and continue
- Factors
  - IOL Style
  - Lens placement
  - Post op medications
  - Biometer, keratometer, ...

**Requirements**
- Accurate Biometry – IOL Master
- Accurate K’s – Repeatable
- 4th Generation Formula (WTW)
- Personalized Lens Constant
- Eliminate Corneal Astigmatism

**TORIC IOL Calculations**
- Commercial Calculators use a constant ratio (1.46) for the corneal cylinder to the IOL cylinder
- Exact Calculation depends on IOL SEQ Power and ELP … to correct 2D of corneal astigmatism
  - 10 D IOL ⇒ 3.5 D Cylinder
  - 22 D IOL ⇒ 2.9 D Cylinder
  - 34 D IOL ⇒ 2.4 D Cylinder
- A 1.1 D difference from 10 D to 34 D!

**Toric Optimization**
- Calculated for PIK’s & PIK’s
  - IOL Toricity & Axis: 1.47 0.00°
  - Flat K: 42.87 0.445
  - Steep K: 45.04 0.145
  - Ideal Replant Axis: 135°
  - Predicted Residual RPE: 0.08 + 1.33 X 133°
- Calculated for observed PIK’s, Miradon & PIK’s
  - Ideal Replant Axis: 135°
  - Predicted Residual RPE: 0.06 + 1.33 X 133°
PREOP 6 D Toric IOL

PREOP 6 D Toric IOL – OD

PREOP 6 D Toric IOL – OS

Thank You!
<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Phone</th>
<th>Fax</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>RICHARD L LINDSTROM MD</td>
<td>Minnesota Eye Consultants, PA Ste 200 9801 Dupont Ave S</td>
<td>952-567-6051</td>
<td>952-567-6182</td>
<td><a href="mailto:rllindstrom@mneye.com">rllindstrom@mneye.com</a></td>
</tr>
<tr>
<td>ERIC DONNENFELD MD</td>
<td>Ophthalmic Consultants of Long Island Garden City, New York</td>
<td>516-766-2519</td>
<td></td>
<td><a href="mailto:ericdonnenfeld@gmail.com">ericdonnenfeld@gmail.com</a></td>
</tr>
<tr>
<td>JACK T HOLLADAY MD MSEE</td>
<td>5108 Braeburn DR, BALLAIRE TX 77401-4902</td>
<td>(713) 668 7337</td>
<td>(713) 669 9153</td>
<td><a href="mailto:holladay@docholladay.com">holladay@docholladay.com</a></td>
</tr>
<tr>
<td>STEPHEN S LANE MD</td>
<td>Adjunct Clinical Professor, University of Minnesota</td>
<td></td>
<td></td>
<td><a href="mailto:sslane@associatedeyecare.com">sslane@associatedeyecare.com</a></td>
</tr>
<tr>
<td>MATTEO PIOVELLA MD</td>
<td>C. M. A. Centro Microchirurgia Ambulatoriale Via Donizetti, 24 - 20900 Monza- Italy</td>
<td>+39 039389498</td>
<td>+39 0392300964</td>
<td><a href="mailto:piovella@piovella.com">piovella@piovella.com</a></td>
</tr>
<tr>
<td>STEVEN C. SCHALLHORN MD</td>
<td>5 Deerdykes Road Westfield Industrial Estate Cumbernauld</td>
<td>01236 795 010</td>
<td></td>
<td><a href="mailto:scschallhorn@yahoo.com">scschallhorn@yahoo.com</a></td>
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