New Horizons in Presbyopia

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Sondra Black Disclosure Statements:

Consultant to:
- Acufocus
- AMO
- Bausch & Lomb

Marc Bloomenstein Disclosure Statements:

I have no direct financial interest in any company or product that is mentioned in this lecture.

I am on the speaker panel for:
- Alcon
- Allergan
- Abbott Medical Optics
- Bausch + Lomb
- AMO
- TearLab

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- Akorn
- Allergan
- Abbott Medical Optics
- BioTissue
- Lunovus
- OcuSoft
- TearLab

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Advisory Board:
- Science Based Health
- BioTissue

Consultant:
- Tear Film Innovation

Speaker:
- Allergan
- AMO
- Alcon
Population Growing
- Incomes and Education Rising
- Life Expectancy Increasing
- Working longer
- Importance of Near Vision

### Global Presbyopic Population

<table>
<thead>
<tr>
<th>Country</th>
<th><em>2014</em> Total Population (Millions)</th>
<th><em>2019</em> Presbyopes (Millions)</th>
<th>% of Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>35.1</td>
<td>15.1</td>
<td>41.7</td>
</tr>
<tr>
<td>United States</td>
<td>321.9</td>
<td>131.6</td>
<td>41.7</td>
</tr>
<tr>
<td>South Korea</td>
<td>46.5</td>
<td>30.5</td>
<td>41.6</td>
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<tr>
<td>Japan</td>
<td>121.5</td>
<td>61.4</td>
<td>48.8</td>
</tr>
<tr>
<td>China</td>
<td>1,380.5</td>
<td>301.5</td>
<td>22.0</td>
</tr>
<tr>
<td>India</td>
<td>1,311.6</td>
<td>301.2</td>
<td>22.9</td>
</tr>
<tr>
<td>Western Europe</td>
<td>409.5</td>
<td>171.6</td>
<td>41.8</td>
</tr>
</tbody>
</table>

36.5% of Americans will be presbyopic by 2019

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**Presbyopes with Economic Means**

- 1.8 billion presbyopes worldwide in 2012
- 2.0 billion presbyopes worldwide by 2019
- 37% growth in population with economic means from 2014-2019
What do we know about Presbyopes?

**Willing to spend money**

<table>
<thead>
<tr>
<th>Group Name</th>
<th>% of Market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful Spenders</td>
<td>19%</td>
</tr>
<tr>
<td>Average Affluents</td>
<td>23%</td>
</tr>
<tr>
<td>Prudent Purchasers</td>
<td>30%</td>
</tr>
<tr>
<td>Poor Pennypinchers</td>
<td>21%</td>
</tr>
<tr>
<td>Struggling Subsisters</td>
<td>7%</td>
</tr>
</tbody>
</table>

**Self View**

- More than 50% of boomers exercise regularly
- 72% of boomers plan to keep working in some capacity after retirement
- 66% of boomers send text messages
- 90% of boomers are on the computer
- 83% of seniors 65+ have a cell phone
- 82% of seniors 65+ are on the road, driving
- 72% of seniors 65+ travel more than they used to
- 65% of seniors 65+ believe they maintain a very active lifestyle involving career, travel and outdoor activities

They are more active!
What do we know about Presbyopes?

- Onset mid-40's during height of career
- Presbyopic population is growing as baby boomers age
- They are concerned about their appearance
- This generation coined the phrase “anti-aging”
  - BOTOX (onabotulinumtoxinA)
  - Rogaine (minoxidil topical)
  - Viagra (sildenafil)

They don’t find reading glasses cool!

‡ 42% of presbyopes are also myopic or hyperopic but majority have never worn glasses before and FRUSTRATED.

Why do we concentrate on Myopes?

- Climbing the ladder
- Image conscious
- Surgery is a commodity
- Like finance
- 61% of those considering laser say cost is main concern
- Most friends are myopic

When we can concentrate on Presbyopes....

- Financially independent
- Age conscious
- Want richer information
- Not interested in finance
- Health is a priority
- Want to look & feel younger
- Most friends are presbyopic
**Word of mouth is KEY with this group**

- Make a Myope happy...
  - will tell 23% of friends

- Make a Presbyope happy...
  - will tell ALL their friends
  - as they ALL need glasses!

**Patients are more aware of decrease in quality of vision**

**First step:** Assess the lens
- Optical Scatter and DLI

**How do we look after these presbyopes?**

<table>
<thead>
<tr>
<th>MYOPES</th>
<th>PRESBYOPES WITH CLEAR LENS</th>
<th>PRESBYOPES WITH CATARACTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 20-44</td>
<td>Age 45-65</td>
<td>Age 66+</td>
</tr>
</tbody>
</table>
Presbyopic Decision Tree

Lens Changes??

- Glasses
- Contact Lenses
- Corneal Surgery
- Monofocal
- Multifocal
- Accommodating

Presbyopic Option in past...

Monovision

- Doks
- LASIK
- Monovision
- OK
- LTK
- CK
- PRK

Presbyope with Clear Lens...

Corneal Procedure

- Kamra
- Flexive
- Raindrop

KAMRA (3.8 mm)
- Flexive (Awaiting FDA approval)
  - By Presbia (Amsterdam, Netherlands)
  - 3.0 mm Diameter / 1.8 mm Central Zone
  - 0.15 mm Central Hole
  - 13 – 20 microns thick
  - Center 0 Power
  - Peripheral ring of + ADD (+1.50 to +3.00)
  - Hydrogel

Flexive (3 mm)
- Raindrop (2 mm)
Flexivue : Inlay Design

Method of action | Retinal
Reflective lens | Yes
Lens power | +1.50 to +3.50
Material used | Hydrophylic polymer
Biocompatible | Yes
Inlay diameter | 3.2 mm
Inlay thickness | 15-20 microns
Implantation depth | 300 microns
Nutrient flow process | Through central 0.15mm hole

Flexivue Microlens

- A transparent hydrogel implant, placed 280 to 300 microns deep, in the cornea of the patient’s non-dominant eye
- Flexivue Microlens received CE Mark in 2009
- Currently undergoing Phase 2 of clinical trial under the FDA
- Available in over 40 countries across Europe, Latin America, the Middle East, Africa and South Korea

Flexivue Candidates

- Presbyopic, aged between 40 and 65 years (ideal patient early 50’s so power swap not needed)
- UCVA in Dominant Eye, or BCVA if planning concurrent Laser correction >20/25
- UVA = 20/50
- Endothelial Cell count >2000 in the non-dominant eye
- Minimum 480um
- Monovision tolerance, patients must undergo a contact lens trial, the lens selection is the MSE based on refraction -0.25D
- Photopic Pupil >3mm
- Good LASIK candidate
- Stable refraction
- Clear lens

FLEXIVUE Inlay – Distance Vision

Distance vision: the rays pass through the central zone of the implant (blue line) and through the free peripheral corneal tissue (interrupted blue line).
For near vision the rays passing through the refractive peripheral zone (red lines) will be focused on the retina.

FLEXIVUE Inlay - Near Vision

Flexivue Microlens™ - OCT

KAMRA (3.8 mm)

- Raindrop (FDA approved June 29th, 2016)
- By Rezicon Optics (Lake Forest, CA)
- 2.0 mm Diameter
- SAME Refractive Index as Cornea
- Changes curvature of cornea (+ lens shape)
- Creates Multifocal Cornea (Dist, Int, Near)
- Proprietary material
Raindrop: Inlay Design

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
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</thead>
<tbody>
<tr>
<td>Method of action</td>
<td>Corneal Reshaping</td>
</tr>
<tr>
<td>Refraction index</td>
<td>No</td>
</tr>
<tr>
<td>Lens material</td>
<td>Medical grade hydrogel</td>
</tr>
<tr>
<td>Inlay diameter</td>
<td>2mm</td>
</tr>
<tr>
<td>Inlay thickness</td>
<td>30 microns</td>
</tr>
<tr>
<td>Implantation depth</td>
<td>150-180 microns</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Yes</td>
</tr>
<tr>
<td>CE Mark</td>
<td>Yes</td>
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</tbody>
</table>

Likely FDA approved early 2017

Raindrop® Near Vision Inlay

- Physiologically transparent, biocompatible hydrogel corneal inlay
- Size: 2mm diameter, 30 microns thick lens
- Similar water content and refractive index as the cornea
- Implanted under a femtosecond laser corneal flap (30% of the cornea thickness), centered over light-constricted pupil
- Placed in the non-dominant eye
- Removable, if needed

Profocal Shape Changing Technology

Inserted in Femtosecond flap

* Current Recommendation: 1/3 of the Central Corneal Thickness

Profocal Shape Changing Technology

- Inlay Naturally Reshapes the Cornea, Creating a Profocal Cornea with a Smooth Transition from Near to Intermediate to Distance
Raindrop Surgery

Who is the Ideal Raindrop Patient?

- Presbyope
- MSE of +1.00 D to -0.50 D with <0.75 D of refractive cylinder (ideal patient +0.75)
- Does not require correction for clear distance vision
- Healthy ocular surface
- No prior refractive surgery
- Normal cornea/outer segment
- Easy-going personality

Patient Selection: Contraindications, Warnings, and Precautions

- Raindrop Patient Should Not Have...
  - Abnormal corneal topography of eye to be implanted
  - Corneal thickness that does not allow for a minimum of 300 microns of stromal bed thickness below the flap
  - Active eye infection or inflammation
  - Dry eye syndrome
  - Workup to severe AGD
  - Keratoconus or keratoconus suspect
  - Corneal dystrophy or degeneration
  - History of herpes eye infection
  - Uncontrolled diabetes
  - Glaucoma, including history of IOP rise due to steroids
  - Previous eye surgery, including LASIK, RK, ectactcs
  - Any sight threatening or sight compromising condition

Contact Lens Trial Evaluation

- Purpose
  - Tolerance to neuro-adaptation
  - Reaction to transient mild ocular discomfort
  - Personality assessment

- Method
  - Place multifocal soft CL in plano power with high add in non-dominant eye only
  - Allow patient to evaluate vision for up to 5 days

- Results
  - Good Results
    - Subjectively sees well distance and near
  - Poor Results
    - Complains of blurry binocular vision at all distances
    - Constantly compares dominant and non-dominant eyes
    - Extreme aversion to CL in eye may indicate poor compliance in using postop drops
Postop Drop Instructions

- 1W antibiotics (moxifloxacin) QID
- 1M of Strong Steroid taper (difluprednate)
  - 1st week: QID
  - 2nd week: TID
  - 3rd week: QID
  - 4th week: QD
- 2 additional months of Mild Steroid (loteprednol)
  - 2nd month: BID
  - 3rd month: QD
- Preservative-free artificial tears daily

Postop Follow Up Schedule

- Day One
- One Week
- One Month
- Six Months
- One Year
- Every Six Months after First Year

Expected Outcomes

- 1 Day
  - Blurry UDVA, UNVA focused close ~20 cm
- 1 Month to 3 Months
  - UDVA improvement, UNVA focused more comfortably
  - Stability of inlay centration
- 6 Month and Beyond
  - Stability of refraction
  - Stability of topography
  - Stability of K-readings
  - Neuro-adaptation for most patients

Simple Results: Lines Achieved

<table>
<thead>
<tr>
<th>VISITS</th>
<th>M=775</th>
<th>MEDIAN</th>
<th>U=0.050</th>
<th>U=0.045</th>
<th>U=0.040</th>
<th>U=0.035</th>
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<tr>
<td>1W</td>
<td>-0.5</td>
<td>-0.5</td>
<td>-1.0</td>
<td>-1.5</td>
<td>-2.0</td>
<td>-2.5</td>
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<tr>
<td>1M</td>
<td>1.0</td>
<td>1.0</td>
<td>2.0</td>
<td>3.0</td>
<td>4.0</td>
<td>5.0</td>
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<tr>
<td>3M</td>
<td>2.0</td>
<td>2.0</td>
<td>3.5</td>
<td>5.0</td>
<td>6.5</td>
<td>8.0</td>
</tr>
<tr>
<td>6M</td>
<td>3.0</td>
<td>3.0</td>
<td>4.5</td>
<td>6.0</td>
<td>7.5</td>
<td>9.0</td>
</tr>
<tr>
<td>9M</td>
<td>4.0</td>
<td>4.0</td>
<td>5.5</td>
<td>7.0</td>
<td>8.5</td>
<td>10.0</td>
</tr>
<tr>
<td>12M</td>
<td>5.0</td>
<td>5.0</td>
<td>6.5</td>
<td>8.0</td>
<td>9.5</td>
<td>11.0</td>
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<tr>
<td>18M</td>
<td>6.0</td>
<td>6.0</td>
<td>7.5</td>
<td>9.0</td>
<td>10.5</td>
<td>12.0</td>
</tr>
<tr>
<td>24M</td>
<td>7.0</td>
<td>7.0</td>
<td>8.5</td>
<td>10.0</td>
<td>11.5</td>
<td>13.0</td>
</tr>
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</table>
Simple Results: Raindrop Eye (Monocular)

MEAN VISUAL ACUITY (SNELLEN)

<table>
<thead>
<tr>
<th>VISIT</th>
<th>UCIVA</th>
<th>UCIVAOU</th>
<th>UCIVAOUOU</th>
</tr>
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<tr>
<td>1W</td>
<td>20/12.5</td>
<td>20/12.0</td>
<td>20/12.0</td>
</tr>
<tr>
<td>1M</td>
<td>20/12.0</td>
<td>20/12.0</td>
<td>20/12.0</td>
</tr>
<tr>
<td>3M</td>
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<td>20/12.0</td>
<td>20/12.0</td>
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<tr>
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<td>20/12.0</td>
<td>20/12.0</td>
<td>20/12.0</td>
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<tr>
<td>9M</td>
<td>20/12.0</td>
<td>20/12.0</td>
<td>20/12.0</td>
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<tr>
<td>12M</td>
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<td>20/12.0</td>
<td>20/12.0</td>
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<tr>
<td>18M</td>
<td>20/12.0</td>
<td>20/12.0</td>
<td>20/12.0</td>
</tr>
<tr>
<td>24M</td>
<td>20/12.0</td>
<td>20/12.0</td>
<td>20/12.0</td>
</tr>
</tbody>
</table>

Preop (N=373)

Evaluating Raindrop on Slit-lamp

The best way to see the Raindrop Inlay is by asking the patient to look straight at the light while covering the opposite eye.

Normal Inlay Response

- Normal finding: A thin, white circle of cells fills the tiny gap around the inlay
- No treatment required
- Inlay centrally clear
- No symptoms
- Good VAs
12/12/2016

Haze Development
- Faint peripheral circle occurs in almost every case and does not require treatment
- If you see any activation and progression, topical steroid treatment is necessary

**Postop Management: Slit Lamp Examination**

- Normal ring, no treatment recommended
- Periphery progression
- Central haze, treatment recommended

**Central Corneal Haze**

- **Subjective Measurements**
  - Reduced near point of focus
  - Increased visual symptoms: glare, halos, ghosting
  - Slit lamp evaluation
  - Decrease in uncorrected distance visual acuity
  - Mild refractive shift (0.50 D to 1.00 D)

- **Objective Measurements**
  - Corneal topography: Corneal steepening
  - Wavefront Aberrometry: Look for Changes Over Time

**When to Refer Back**

- Decentered Inlay
  - Not centered over pupil resulting in poor near vision
  - Refer for possible flap lift and repositioning

- Haze
  - If haze persists or recurs after treatment, refer for possible inlay removal

- Patient dissatisfaction with visual outcome after 3M postop

**Features and Benefits**

<table>
<thead>
<tr>
<th>Features</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear</td>
<td>- No Cosmetic Issues</td>
</tr>
<tr>
<td></td>
<td>- Near 100% Light Transmission</td>
</tr>
<tr>
<td>Hydrogel Material</td>
<td>- Safe for the Cornea</td>
</tr>
<tr>
<td></td>
<td>- Same Refraction Index as the Cornea</td>
</tr>
<tr>
<td></td>
<td>- Allows Nutrient &amp; Oxygen Flow Through the Cornea</td>
</tr>
<tr>
<td>2mm in Diameter</td>
<td>- Helps in the Periphery - does not obstruct near and intermediate vision</td>
</tr>
<tr>
<td></td>
<td>- Gently Reshapes the Cornea Changing Refractive Power Giving Patients Back Their Near and Intermediate Vision</td>
</tr>
</tbody>
</table>
KAMRA (3.8 mm) Flexivue (3 mm) Raindrop (2 mm)

- KAMRA Inlay – FDA approved April 2015
  - By AcuFocus (Irvine, CA)
  - 3.8 mm Diameter / 1.6 mm Aperture
  - Made of Polyvinylidene Fluoride (PVDF)
  - Small Aperture – Increased Depth of Focus

Corneal Inlay

- Weight = 100 mcg
- Thickness = 5 µm
- Material = Polyvinylidene Fluoride PVDF (IOL haptics)
- Inlay matches corneal curvature

Inlay Design

- 8,400 micro-perforations (5-11 µm)
- Pseudo-random pattern
- Maximize nutrient flow
- Minimize visual symptoms

Well Tolerated in the Cornea

- Images of implanted cornea obtained via confocal microscopy

OCT
How It Works

- The inlay works like an aperture in a camera (opening)
- This small opening allows only focused images in the eye
- Only focused light rays allowed to reach the retina
- Same principle used in camera lenses to increase depth-of-focus

Pinhole Principle: "Increased Depth of Focus"

Presbyopic Defocus Curve

- Before surgery, patients had a narrow range of vision

KAMRA® Inlay Defocus Curve

- Patients gained significant functional depth-of-focus with essentially no change in distance vision
KAMRA® Inlay Defocus Curve

- When paired with a small amount of myopia (-0.75 D), patients can achieve up to 2.75 diopters of functional depth-of-focus.

Some patients can adapt due to NO OVERLAP @ ANY DISTANCE.

Advantage to the inlays: OVERLAP @ DISTANCE

Comparison of Stereopsis Results

<table>
<thead>
<tr>
<th>MonoVision</th>
<th>Contact Lens Monovision</th>
<th>Small Aperture Corneal Inlay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Dominant Eye</td>
<td>Non-Dominant Eye</td>
<td>Dominant Eye</td>
</tr>
<tr>
<td>Non-Dominant Eye</td>
<td>Non-Dominant Eye</td>
<td>Dominant Eye</td>
</tr>
<tr>
<td>Non-Dominant Eye</td>
<td>Non-Dominant Eye</td>
<td>Dominant Eye</td>
</tr>
<tr>
<td>Non-Dominant Eye</td>
<td>Non-Dominant Eye</td>
<td>Dominant Eye</td>
</tr>
</tbody>
</table>

* Indicates difference from pre-op is statistically significant.

Depth-of-Focus Pre-op and Post-op

Depth of focus before and after KAMRA® inlay surgery.
100% Pockets

- Faster Visual Recovery
- Less Dry Eye
- More Stable Cornea
- Ability to place Inlay deeper
- Flaps for LASIK remain at 100 microns

**Pre-Op AcuTarget HD™ Measurements**

**Centering on 1st Purkinje Light Reflex**

**Create Pocket - 250 microns**
Pocket Dissection

Grasping the Inlay

Insert Corneal Inlay

KAMRA procedure
Post-Op AcuTarget HD
Will not look centered at slit lamp

Does The Inlay Affect Ophthalmic Assessments?
Cataract Surgery

- If a cataract develops, there are several options:
  - Phacoemulsification and monofocal IOL implantation can be performed with the inlay in situ.
  - Inlay can be removed and replaced after monofocal IOL implantation.
  - Inlay can be removed and an MF or accommodating IOL implanted.

- Phacoemulsification and monofocal IOL implantation can be performed with the inlay in situ.
- Inlay can be removed and replaced after monofocal IOL implantation.
- Inlay can be removed and an MF or accommodating IOL implanted.

Monofocal IOL is functionally the same as a non-accommodating crystalline lens.

Ophthalmic Assessments and the KAMRA® Inlay

- The following ocular assessments are possible with the KAMRA inlay in situ:
  - Fundus photography
  - OCT
  - Visual field assessment
  - Intraocular pressure measurement
  - Gonioscopy
  - Contrast sensitivity testing
  - Gonioscopy

Visual Fields

- Results of a contralateral comparative study of 9 patients implanted monocular with the KAMRA inlay showed:
  - Reliable standard automatic perimeter results
  - No difference between PSD scores for implanted and non-implanted fellow eyes
  - No localized constrictions, or scotomas
  - GHT calculations were not impacted

* Dr. Brooker and Sanchez, ARVO 2012.
Removable

- Additive procedure
- Doesn’t restrict future options
- Post-removal vision returns to baseline/LASIK target within 6 months
- Inlays have been successfully removed out to 4 years post-op
- 2% removal rate

Who is our KAMRA patient?

EMMETROPES (No refractive error)

AMETROPES (Far aarthed or nearsighted)

MONOFOCAL PSEUDOPHAKES

Who are our patients?

Subjective Criteria

- Dislikes reading glasses
- Views loss of near vision as a disability
- Cosmetic and lifestyle motivated
- Easy going
- Optimistic
- Willing to participate in recovery process
- Financial means

Pre-op considerations

Refractive Target and Visual Acuity

Key Learning:

Dominant eye plano -0.50 to 0.00 would be happy
Non-Dominant eye -0.75 to 0.50

66% of patients enrolled in the clinical trial had a pre-op MRSE in the optimal range of -0.01D to -0.75D

31.5% of patients enrolled in the clinical trial had a pre-op MRSE between 0.00D to 0.50D

Optimal visual refractive error between 0.50D to -1.25D

25% of patients enrolled in the clinical trial had a plano MRSO in the optimal range
How important are the following activities in your daily life?

- Reading Text
- Reading Numbers
- Working on a Computer
- Seeing your Mobile Phone
- Performing Detailed Tasks
- Driving at Night

**Assessing Patient Lifestyle**

**Exclusion Criteria**

- Prior corneal procedures (Except LASIK and PRK)
- Any ocular or systemic disease that is a contraindication for corneal refractive procedures including:
  - Keratoconus
  - Uncontrolled and/or severe dry eye
  - Cataracts
  - Macular degeneration
  - Corneal dystrophy or degeneration
  - Aniridia or Symblepharon
  - Patients with unrealistic expectations
  - Patients with psychological conditions

---

**Long-Term Results**

- Emmetropic Patients

  - Over a 5 year time period a presbyopic patient on average can expect to lose a line of vision
  - Patients with a KAMRA inlay, over the same time period, do not experience a loss of near vision

**What Patients Can Expect**

- Resume most activities the next day
- Clarity of vision may occur within the first 24 hours, but generally takes 1-3 months (80% of patients)
- Vision may fluctuate for the first few months
- Magnification or LIGHT may still be needed for:
  - Seeing tiny print, reading in dim light conditions, or performing a task for an extended period of time
  - EASIER TO FIND LIGHT THAN GLASSES

---

**Uncorrected Near Visual Acuity**

- Data courtesy of Günther Grabner, MD

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Visual Recovery

- Takes time and careful management
- Reassure patients regarding the recovery process and their progress
- Adherence to the therapeutic and dry eye regimen post-operatively can accelerate the healing process

Post-Op Exams

- Follow-up:
  - 1 day
  - 1 week
  - 1, 3, 6 months
  - 1 year

- Remember to check IOP’s as patients are on steroids
- Patients should be seen more frequently for complications or abnormal post-op findings

Post-Op Regimen

- Pred Forte qh x 48 hours then qid remainder of week.
- Then FML or LOTEMAX
  - QID x 3 W
  - BID x 1 MO
  - QD x 1 MO
- At 3 months assess whether to d/c steroid or continue
- ALWAYS CONFIRM STEROID REGIME WITH REFRACTIVE CENTER
- If your patient is a steroid responder utilize beta blocker or similar to reduce IOP immediately

Post-Op Regimen

- Ocular Surface Management
  - Preservative free artificial tears
  - Hourly for the first week, then
  - Q s/day for a month,
  - then RN
  - Temporary or permanent punctal plugs in EVERYONE
  - Omega-3 fatty acids
  - Topical cyclosporine (if needed)
  - Restasis has been a godsend!
- Minimize use of preservatives
Meeting Postop Expectations

- We tell patients NOT LIKE LASIK:
  - Long slow heal (20%-day 1, 80%-weeks)
  - I talk about my experience
  - "Moments of clarity"
  - Blog
  - Flashlight app
  - Show them my slit lamp photo
  - Patients want honesty
  - WIL not make them 20 again
  
  UNDERPROMISE and OVERDELIVER

Pre-operative considerations: Discussion is Crucial with Myopes

- Make them understand it is like “gluing their glasses onto their face”
- Don’t over promise to this group
- Used to sharp near without glasses and binocularity
- Reduce dependence on glasses

Day 1 - NORMAL

What to expect:

- UCDA (monocular) - 20/50
- UCNVA (binocular) - 20/50
- Check VA and reassure
  - Patient expects haze so “this is normal”

Day 1 - NOT

- DRY EYE
  - Drops
  - Plugs
  - Omega 3
**Week 1 - NORMAL**
- VA usually improved to 20/30 at distance and near
- “Moments of clarity”

**Week 1 - NOT**
- VA has NOT improved
- Expect:
  - Decentration
  - Dry eye

**Month 1 - NORMAL**
- UCVA/UCNVA: 20/25 to 20/20
- Slit lamp clear
- Acutarget-good tear film
- Refraction as targeted

- Patient still healing
- Remind to continue all drops
  - **COMPLIANCE!**

**Month 1 - NOT**
- No improvement in VA
  - Decentration
  - Be more critical
  - Tear Film
    - If not on Restasis-consider starting/ Omega 3’s
  - Rx (regression)
Post-Op Refractions

- Increased myopia:
  - Dryness:
    - lubrication, punctal plugs +/- Restasis, Omega 3's
  - If post-LASIK, possible regression

Month 3-6 - NORMAL

- Patient happy
- Cornea Clear and Quiet

- Will still improve
- Reminder
- lubrication

Month 3-6 - NOT

Check refraction

- Increased hyperopia:
  - Corneal Wound healing effect/Regression
  - Examine for haze around inlay
  - Examine topography for changes - Red Ring
  - Manage with Steroids

Year 1 - NORMAL

- Stable Vision
- Clear Cornea
- HAPPY PATIENT

Patient may have noticed further improvements over past 6 months especially in dim lighting
Year 1 - NOT

- Reduced VA
- Lens Changes
- Haze
  - Hyperopic Shift

Cosmesis

<table>
<thead>
<tr>
<th>Inlay Specific: Strengths &amp; Weaknesses Comparison</th>
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<tbody>
<tr>
<td><strong>STRENGTH</strong></td>
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<tr>
<td>- Patient-specified outcomes (customizable)</td>
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<tr>
<td>- Enhanced, natural range of vision</td>
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<tr>
<td>- Lesions noted at 6 months</td>
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<tr>
<td>- Significant improvements in near and mid vision while maintaining distance vision</td>
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<tr>
<td>- Significant improvement in near vision</td>
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<tr>
<td>- Clear, does not restrict light</td>
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<tr>
<td>- Centration</td>
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**Comparison**

<table>
<thead>
<tr>
<th>Method of action</th>
<th>KAMRA Inlay</th>
<th>Raindrop</th>
<th>Flexivue</th>
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<tbody>
<tr>
<td>Refractive lens</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Lens power</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Material used</td>
<td>Polyvinylidene Fluoride (PVDF)</td>
<td>Hydrophylic polymer</td>
<td>Hydrophylic polymer</td>
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<tr>
<td>Biocompatible</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Inlay diameter</td>
<td>3.8mm</td>
<td>2mm</td>
<td>3.2mm</td>
</tr>
<tr>
<td>Inlay thickness</td>
<td>5 microns</td>
<td>30 microns</td>
<td>15-20 microns</td>
</tr>
<tr>
<td>Implantation depth</td>
<td>200 microns</td>
<td>150-180 microns</td>
<td>300 microns</td>
</tr>
<tr>
<td>Nutrient flow process</td>
<td>8,400 microperforations, 1.6 mm central opening</td>
<td>Proprietary micro-porous material</td>
<td>Through central 0.15mm hole</td>
</tr>
<tr>
<td>Surgical Procedure</td>
<td>PEK, PLK, PLK2, CLK</td>
<td>Flap only</td>
<td>Studying combination with LASIK, working on pockets</td>
</tr>
</tbody>
</table>

Actual patient images courtesy of David Allamby, MD, Focus Clinics London

‡ Product commercially available (50 countries)
‡ FDA approved
‡ Continuous, natural range of vision
‡ Protect against presbyopic progression
‡ Uninterrupted optical pathway
‡ Significant improvements in near and mid vision while maintaining good distance vision
‡ Wound healing
‡ Restricts light
‡ Chair time
‡ Multiple powers to allow for customization

‡ Product commercially available Europe
‡ Good outcomes across full range
‡ Clear, does not restrict light
‡ Will lose effect (presbyopia progression & epithelial remodeling)
‡ Haze formation over visual axis
‡ Shallow implantation risks thinning/melt
‡ Limited ability to address post-LASIK presby as only flap procedure
‡ May be difficult to find in future if removal required
THANKS!!!