Surgical Correction of Presbyopia in 2016

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Outline

• Non-Surgical Options
• Laser Vision Correction
• Multifocal / Accommodative IOLs
• Corneal Inlays
• Comanaging Presbyopia Surgery
Presbyopia Correction: Non-Surgical Options

- Bifocal Spectacles
- Monovision CTLs
- Multifocal CTLs
Presbyopia Correction: Surgical Options

- Monovision with LASIK or PRK
- Lensectomy with IOL
  - Monovision with Monofocal IOLs
  - Accommodative IOLs
  - Multifocal IOLs
- Corneal Inlays
  - Acufocus Kamra
  - Non FDA approved Inlays
Monovision Patient Selection

- Current happy monovision CTL patients
- LASIK best option
  - Myopic presbyopes with no significant cataract
- Lensectomy best option
  - Hyperopic Presbyopes
  - Presbyopes with any cataract
  - Avoid pushing refractive lensectomy to insurance covered cataract surgery
Monovision Lensctomy with IOL

- Astigmatic patients
  - Only option for presbyopia correction currently.
- Distance Eye
  - Requires near perfect refractive result.
- Near eye
  - More forgiving with sphere and cylinder.
- “Reversible”
  - Glasses for night driving or other tasks
Lensectomy with Accommodative and Multifocal IOLs

• First Generation Presbyopia IOLs
  • Array
  • Crystalens
  • ReStor
  • ReZoom
  • Tecnis MF

• Second Generation Presbyopia IOLs
  • Low add Tecnis MF 3.25, 2.75 and ReStor 2.5
  • Crystalens HD and AO
Crystalens AO

- Hinged optic to increase movement
- Lengthened haptics to maximize amplitude
- Smaller optic to maintain 10.5mm length
Ciliary Muscle

- Increased Pressure
- Relaxed
- Constricted

UBM

- Relaxed
- Constricted
Accommodative IOLs

Introducing new Synchrony lens implants
Balanced View Optics™ Technology

- **Low light/distance-dominant zone**: Provides additional distance-dominant support in low light conditions such as night-driving, when pupils are fully dilated.
- **Bright light/distance-dominant zone**: Large, distance-dominant central zone for bright light situations, including daytime driving, when pupils are constricted.
- **Large near-dominant zone**: Provides additional near vision in a broad range of moderate to low light conditions.
- **Aspheric transition**: Provides intermediate vision in all zones.
- **Distance zone**: Provides good distance vision in moderate to low light conditions.
- **Near-dominant zone**: Provides good near vision in a range of light conditions.
Multifocal IOLs
Multifocal IOLs

• Advantage: They work!
• First Generation Limitations
  • Poor intermediate vision
  • Halos or Waxy vision
• Second Generation
  • Excellent intermediate and near vision
  • Mild halos
• All
  • Require excellent refractive result (sphere and cylinder)
  • Require careful patient selection
Anatomy of the Apodized Diffractive IOL

Step heights decrease peripherally from 1.3 – 0.2 microns.

Central 3.6 mm diffractive structure.

A +4.0 add at lens plane equaling +3.2 at spectacle plane.
## Multifocal IOLs

<table>
<thead>
<tr>
<th>Restor</th>
<th>Spectacle Plane</th>
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<tbody>
<tr>
<td>4</td>
<td>3.25</td>
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<tr>
<td>3</td>
<td>2.50</td>
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<tr>
<td>2.5</td>
<td>2.00</td>
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<table>
<thead>
<tr>
<th>Tecnis Multifocal</th>
<th>Spectacle Plane</th>
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<tbody>
<tr>
<td>ZMB / 4.0</td>
<td>3.00</td>
</tr>
<tr>
<td>ZLB / 3.25</td>
<td>2.37</td>
</tr>
<tr>
<td>ZKB / 2.75</td>
<td>2.00</td>
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TECNIS® Multifocal IOLs

This presentation is for and on behalf of Abbott Medical Optics Inc. Doctors who participated are paid consultants for Abbott Medical Optics Inc.
TECNIS® Multifocal Family of IOLs
Clinical Outcomes

Ability to Function Comfortably Without Glasses at 6 Months (Bilateral Subjects)*

>80% of patients reported an ability to function comfortably without glasses at all distances.

* ZM900 (+4.0 D) data are historical from a separate clinical study using the same test methodology.

Data: DFU, TECNIS® Multifocal 1-Piece IOL, Models ZKB00 and ZLB00, and DFU, TECNIS Multifocal 1-Piece IOL, Model ZMB00.
TECNIS® Multifocal IOLs +3.25 D and +2.75 D
Clinical Outcomes

Spontaneous Reports of Halos in a Non-Directed Study

HALOS REPORTED:
- None
- Mild
- Moderate
- Severe

*Non-directed responses from open-ended questions. First eye results only.

Data: DFU, TECNIS® Multifocal 1-Piece IOL, Models ZKB00 and ZLB00, and DFU, TECNIS Multifocal 1-Piece IOL, Model ZMB00.
TECNIS® Multifocal IOLs +3.25 D and +2.75 D
Clinical Outcomes

Spontaneous Reports of Night Glare in a Non-Directed Study

NIGHT GLARE REPORTED:
- None
- Mild
- Moderate
- Severe

*Non-directed responses from open-ended questions. First eye results only.

Data: DFU, TECNIS® Multifocal 1-Piece IOL, Models ZKB00 and ZLB00, and DFU, TECNIS Multifocal 1-Piece IOL, Model ZMB00.
**Tecnis Multifocal IOL - Halo Performance**

<table>
<thead>
<tr>
<th>Model</th>
<th>ZKB00 (2.75D add)</th>
<th>ZLB00 (3.25D add)</th>
<th>ZMB00 (4D add)</th>
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<tbody>
<tr>
<td>Gamma 0.15 Relative Normalization</td>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
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Lower add power decreases the halo
Refractive MF and Diffractive IOLs

Zonal Refractive (5 Zones) – AMO ARRAY

Light energy dramatically varies with number of zones exposed by pupil, contributes to halos at night

Full Optic Diffractive – 3M

Light energy equally shared over broad range of pupils/lighting conditions, contributes to halos at night

Apodized Diffractive – Alcon ReSTOR

Light energy equally shared for bright to moderate lighting/pupils – apodization gradually increases distance energy with larger pupils - reduces halos at night
Multifocal IOL Patient Selection

Pre-operative Considerations

- Patients who no longer desire to wear glasses (Duh!)
- Minimal astigmatism
- No significant ocular disease
  - Cornea very healthy: Topography on every patient
    - Dry eye, ABMD, etc
    - Retina healthy: OCT on every patient
- Patients visual demands
- Patient expectations
Multifocal IOL Patient Selection

- What if the patient has had prior cataract removal with monofocal IOL in the other eye?
- What if the patient has irreversible poor vision in the other eye?
- What if the patient has had prior LASIK/PRK or RK?
- What is the patient’s preoperative reading distance?
Multifocal IOL: Postoperative Management

• Most patients very easy: rapid adaptation and excellent vision
  • Much less “hand holding” than prior generations

• Causes and treatment of delayed recovery
  • Surface disease: Aggressively treat dry eye
  • Residual refractive error
    • May require LRI, LASIK or PRK after stable for three months
  • CME
    • Not common using modern NSAIDS at least 3 weeks post operatively
Multifocal IOL: Postoperative Management

• Psychological
  • Managing expectations (different focal length, etc)
  • Concerns with halos—not common problem with lower add MF IOL

• Patience
  … yet don’t hesitate to refer unhappy patient back to surgeon
Corneal Inlays

- **Acufocus Kamra Inlay**
  - Only FDA approved inlay for presbyopia correction

- **Presbia Flexivue Microlens**

- **Revision Optics’ Raindrop**
Inlay Concept

- First conceived in 1949 by Dr. Jose Barraquer

- Primary advantages:
  - Tissue-sparing
  - Removable

- Primary design challenges:
  - Effective optics
  - Biocompatibility with the cornea
  - Stable and predictable results
KAMRA® Inlay
Acufocus Kamra Inlay

- First and only approved inlay for presbyopia correction
- Available in over 49 countries
- Over 25,000 implanted
- Performed over 13 years
- FDA study started 9 years ago
- FDA study included 507 patients
Inlay improves near vision by extending depth-of-focus
Central aperture is a hole in the inlay and has no power
Inlay provides an unobstructed pathway for focused light to reach the retina

Inlay Design

Made from Polyvinylidene Difluoride (PVDF)
Permeability

- 8,400 micro-perforations (5-11 μm)
- Pseudo-random pattern
- Maximize nutrient flow
- Minimize visual symptoms
Depth-of-Focus Pre-op and Post-op

Pre-op
0.25D of depth of focus

Several Months Post-op
2.50D of depth of focus

OQAS Accommodative Range (D): 0.25

OQAS Accommodative Range (D): >2.50

AcuTarget HD™ Instrument
Where the KAMRA® inlay falls within the Patient Spectrum

LASIK

Ages 20 – 40

Near vision loss begins

Ages 40 – 60

IOLs

Ages 60+

Too Old for LASIK
Too Young for IOLs
KAMRA® Inlay Indications for Use

- Patient who is between 45 and 60 years old
- Cycloplegic refraction between +0.50 D and -0.75 D with less than or equal to 0.75 D of refractive cylinder
- Patient does not require glasses or contact lenses for clear distance vision
- Patient requires near correction of +1.00 D to +2.50 D of reading add
Patient Selection

- Patient who is between 45 and 60 years old
- Cycloplegic refraction between Plano and -0.75 D with less than or equal to 0.75 D of refractive cylinder
- Patient does not require glasses or contact lenses for clear distance vision
- Pachymetry > 500 microns
- Mesopic pupil size > 6.0mm
Patient Selection

- Dislikes reading glasses
- Feels disabled by loss of near vision
- Lifestyle motivated
- Easy going
- Willing to participate in the recovery process
Patient Exclusions

- Any ocular or systemic disease that is a contraindication for other refractive surgery
  - Keratoconus
  - Severe dry eye
  - Cataracts
  - Macular degeneration
  - Corneal dystrophy or degeneration
  - Amblyopia

- Unrealistic Expectations / Psychological issues
Surgical Procedure

- **Description:** A femtosecond laser created pocket in the stroma at a depth of 200-250μm with femtosecond laser spot/line settings of ≤ 6x6 or equivalent is recommended.
Surgical Procedure
Surgical Procedure
US IDE - Study Design

- 24 Sites (US, Europe & Asia-Pacific)
- Prospective, non-randomized clinical trial
- Subjects:
  - 507 enrolled and implanted in non-dominant eye
  - Naturally occurring presbyopic emmetropes
  - 45 - 60 years old
  - Spherical equivalent between + 0.50 D to -0.75 D
  - Uncorrected Near VA
    - Worse than 20/40 (0.5), and
    - Better than 20/100 (0.2)
  - Best Corrected Distance VA ≥ 20/20 (1.0) in both eyes
Distance, Intermediate and Near Visual Acuities: Implanted Eyes

- An average 3 line gain at 12 months was achieved and sustained over the duration of the study.
- Achieved results remain stable over the 36 month follow-up.

Visual Acuity (ETDRS Letters)

- UCDVA IE
- UCIVA IE
- UCNVA IE

N= 507 499 478 445 436 398 417

Month

20/20
20/32
20/40
20/63

US IDE Patients
Influence of MRSE on Near Acuity at 12 Months

- Combination with a small amount of myopia improves near vision results

<table>
<thead>
<tr>
<th>Preop MRSE</th>
<th>Percent UCNVA 20/40 or Better</th>
</tr>
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<tbody>
<tr>
<td>-0.75 to &lt;0</td>
<td>91.9% (n = 148)</td>
</tr>
<tr>
<td>0 to +0.25</td>
<td>81.3% (n = 225)</td>
</tr>
<tr>
<td>&gt;+0.25 to +0.50</td>
<td>76.2% (n = 105)</td>
</tr>
</tbody>
</table>

US IDE Patients
Uncorrected Visual Acuity in the KAMRA® Inlay Eye

Change between Pre-Op and 36 Months:

- Mean UCNVA improved 5 lines from J8 to J2
- Mean UCDVA reduction from 20/18.5 to 20/20
- Mean MRSE changed from 0.02 + 0.28 D to 0.14 + 0.72 D

*N=153 at 36 months, ≤ 6x6 group, data on file at AcuFocus™
Binocular Contrast Sensitivity

- There is a small reduction in photopic and mesopic contrast sensitivity however scores remain within normal limits at 24 months post-op.
- Ultimately the reduction is minor when compared to the benefits of the inlay**

*Data on file at AcuFocus

Stereoacuity with the KAMRA® Inlay

- There is **no change** in mean distance stereoacuity scores between pre-op and 6 months post-inlay implantation.
Visual Field

- Visual field remains within normal limits after inlay implantation
- Data from the clinical trial showed a slight overall decrease in sensitivity (~1.0 dB change from baseline).\(^1\)
- No scotomas induced by the presence of the inlay\(^{1,2}\)
- No statistically significant difference in extent and total area of the visual field was found between implanted and non-implanted eyes\(^3\)

Pre-Op: Inlay Eye  36 Mo Post-Op: Inlay Eye

1 - US IDE Clinical Trial
2 – Sanchez et al, ARVO 2012
3 – Brooker et al, ARVO 2013
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
- Contrast sensitivity testing
- Gonioscopy

Images courtesy of Günther Grabner, MD
Post-Op Care

- F/U 1 day, 1 week, 1-2-3 months, 1 year
- Topical Antibiotic for 1 week
- Topical 1% Pred QID for 1 week
- FML QID 2\textsuperscript{nd}-4\textsuperscript{th} week, TID 2\textsuperscript{nd} month, BID 3\textsuperscript{rd} month
- AcuTarget HD analysis 1 day and 1 month
- VA near, intermediate, far
- midpoint refraction (red-green balance)
- Topography at 1 month and beyond
- SLE looking for tear film stability
Summary

- The KAMRA® inlay is an effective solution for presbyopia to bridge the gap between LASIK and cataract surgery.
- The small aperture inlay reliably extends depth of focus providing uninterrupted vision from near to far.
- Maintains stereopsis and binocular vision, regardless of monocular implantation.
- The effect is proven to be stable over time.
- Design does not interfere with ocular assessments or secondary surgical procedures.
Future Corneal Inlays

- **Presbia Flexivue Microlens**
  - Clear hydrophilic acrylic refractive inlay
  - 3.2mm wide with a 1.6mm hole in the center
  - The power of the inlay ring ranges from +1 to +3.5
  - Center hole for long distance
  - Causes slight myopic shift
  - Combination of monovision and multifocality
Future Corneal Inlays

- ReVision Optics’ Raindrop
  - A hydrogel inlay 2mm in diameter and 32 microns thick in the center
  - Works by causing corneal steepening in the center, creating a multifocal cornea
Future Corneal Inlays

- ReVision Optics’ Raindrop
Future Corneal Inlays

- ReVision Optics’ Raindrop

Corneal map of Raindrop patient illustrating prolate shape
Summary

- The KAMRA® inlay is the first of the new corneal inlays FDA approved as an effective solution for presbyopia to bridge the gap between LASIK and cataract surgery.
- The Kamra inlay is by far the most studied inlay with more than 20,000 implanted worldwide.
- Kamra inlay increases depth of focus like a high f-stop camera lens.
- Other inlays are taking a different approach to correcting presbyopia by using multifocality.
- Look for many new technologies to emerge in this new surgical frontier.
Comanagement: Final Considerations

- You know your patients, their needs and interests.
- Your patients trust your opinion.
- You help them begin learning their options.
- Hearing more than once builds confidence.
Thank You