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# **Surgical Correction of Presbyopia in 2016**

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**Mount Ogden Eye Center**

# Outline

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

# Presbyopia Correction: Non-Surgical Options

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- **Bifocal Spectacles**
- **Monovision CTLs**
- **Multifocal CTLs**

# Presbyopia Correction: Surgical Options

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- **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

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- **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 Lensectomy with IOL

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- **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

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- **First Generation Presbyopia IOLs**

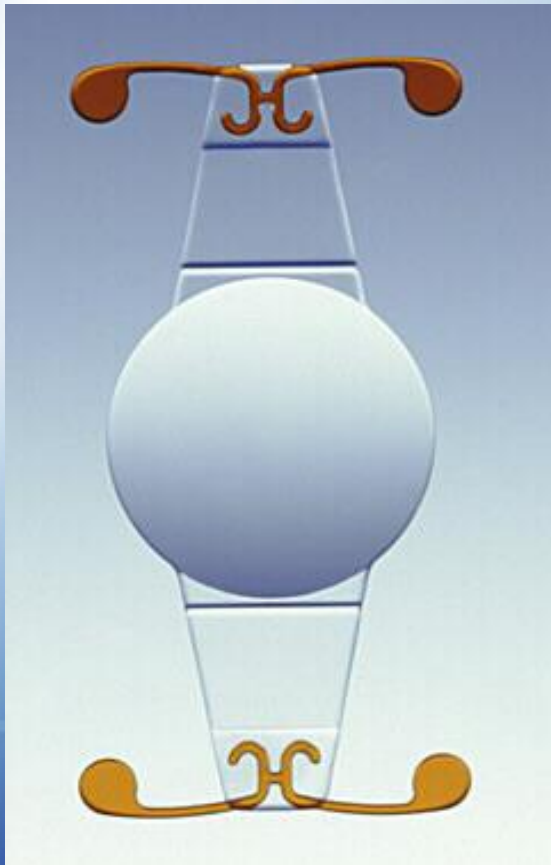
- Array
- Crystalens
- ReStor
- ReZoom
- Tecnis MF

- **Second Generation Presbyopia IOLs**

- Low add Tecnis MF 3.25, 2.75 and ReStor 2.5
- Crystalens HD and AO

# Crystalens AO

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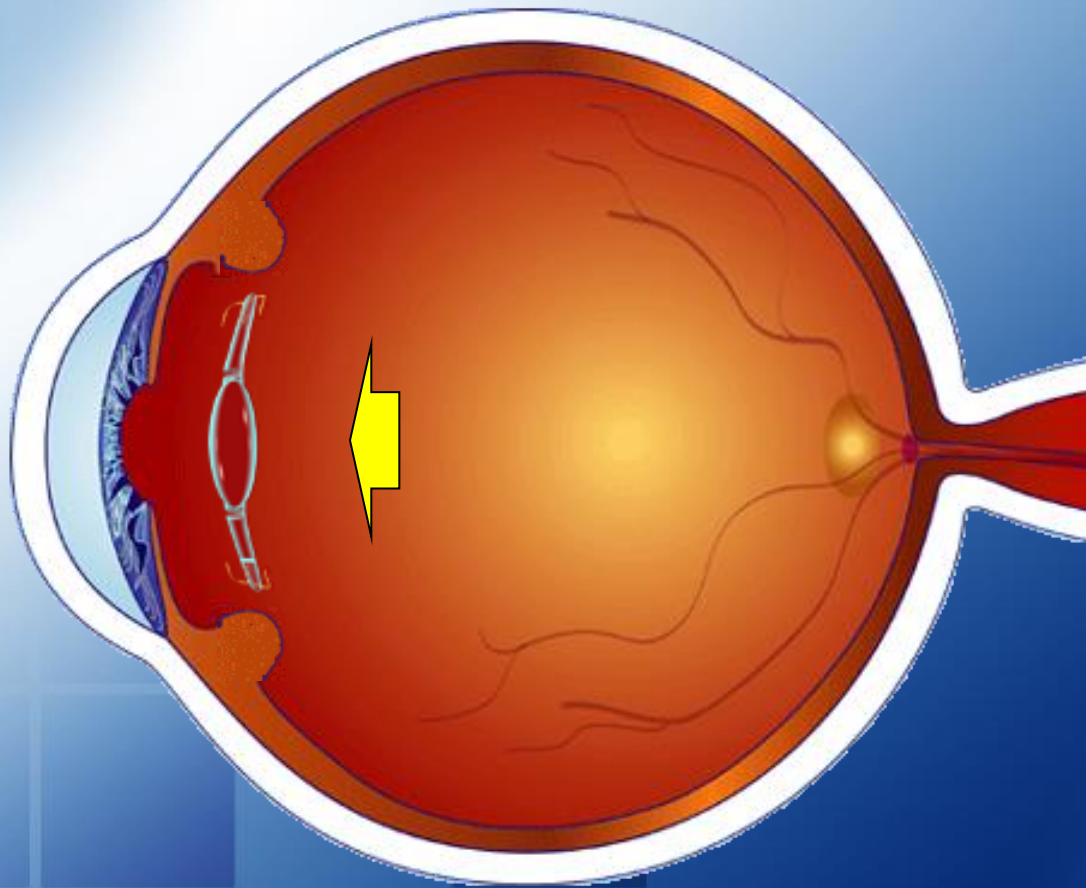
**Hinged optic  
to increase movement**

**Lengthened haptics  
to maximize amplitude**

**Smaller optic to  
maintain 10.5mm length**



# Ciliary Muscle



UBM

Relaxed

Constricted



# Accommodative IOLs

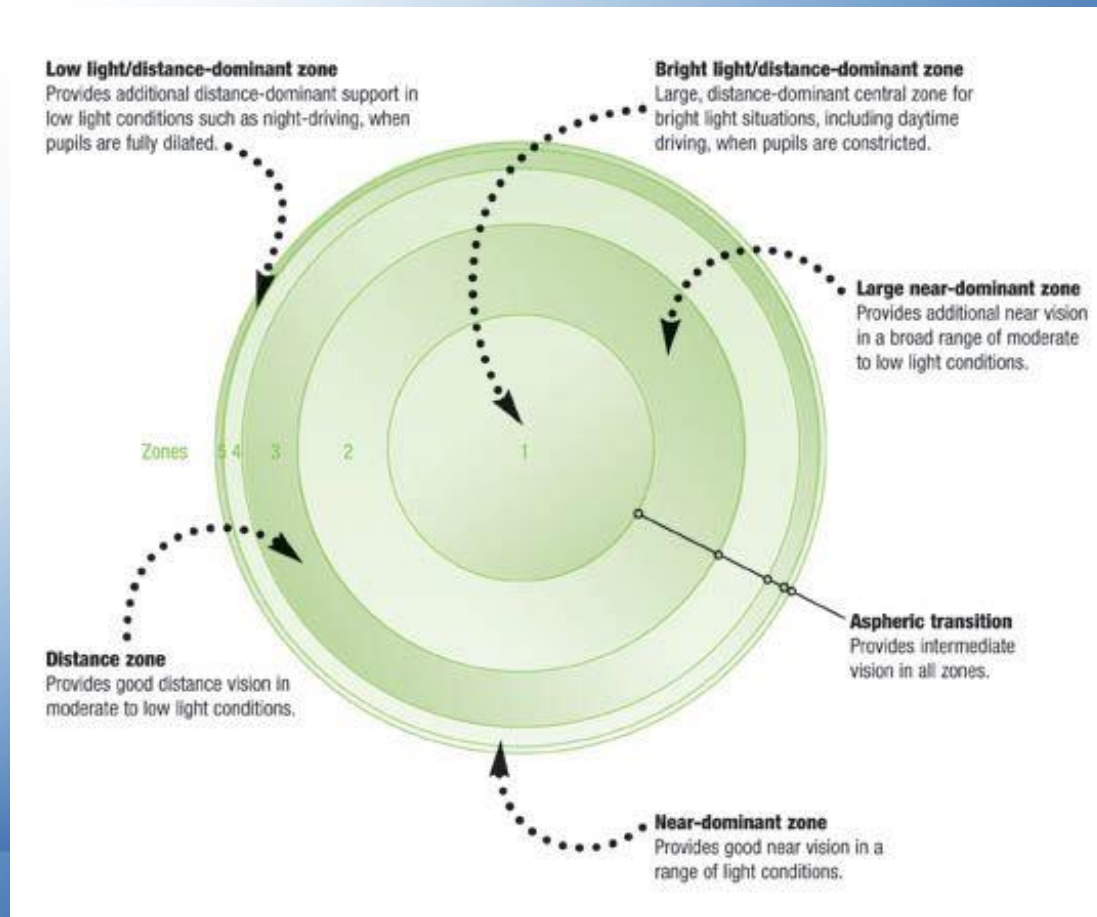


The logo features the word "ReZoom" in a white, sans-serif font. To the right of the text is a graphic consisting of three overlapping squares of decreasing size, each containing a small white dot. A trademark symbol (TM) is located at the bottom right of the graphic.

ReZoom™

Multifocal Intraocular Lens

# Balanced View Optics™ Technology



# Multifocal IOLs



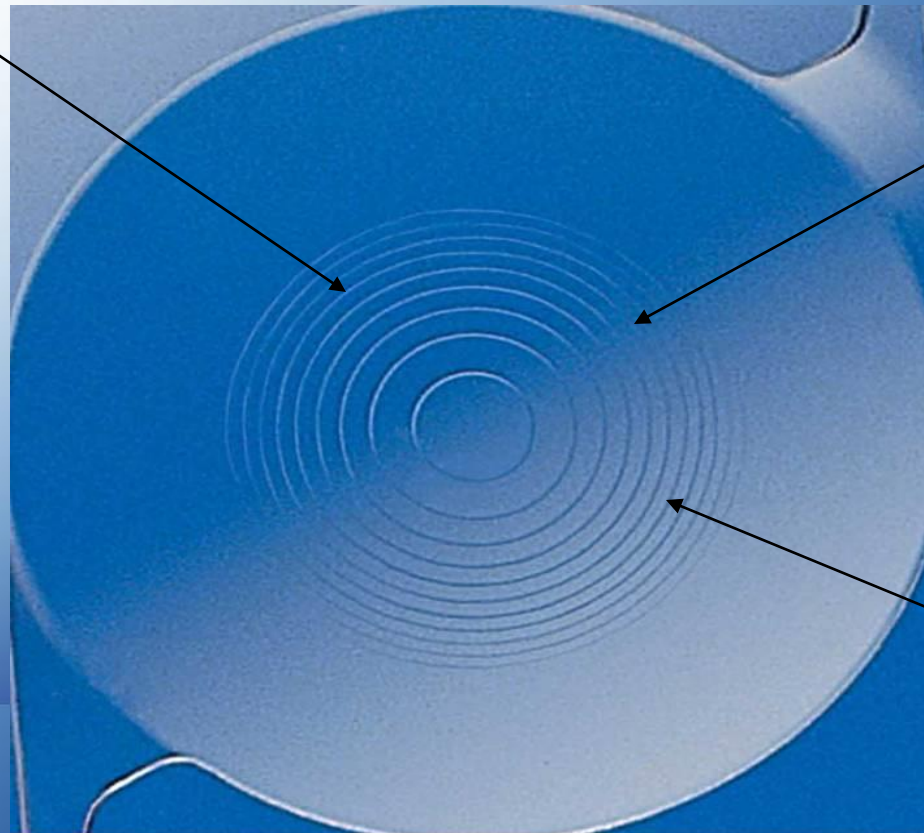
# Multifocal IOLs

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- **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

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## Restor

- |       |   |      |
|-------|---|------|
| ▪ 4   | → | 3.25 |
| ▪ 3   | → | 2.50 |
| ▪ 2.5 | → | 2.00 |

## Spectacle Plane

## Tecnis Multifocal

- |              |   |      |
|--------------|---|------|
| ▪ ZMB / 4.0  | → | 3.00 |
| ▪ ZLB / 3.25 | → | 2.37 |
| ▪ ZKB / 2.75 | → | 2.00 |

## Spectacle Plane





**TECNIS<sup>®</sup>**  
MULTIFOCAL IOL **+4.0**  
DIFFRACTIVE ASPHERIC



**NEW**

**TECNIS<sup>®</sup>**  
MULTIFOCAL IOL **+3.25**  
DIFFRACTIVE ASPHERIC



**NEW**

**TECNIS<sup>®</sup>**  
MULTIFOCAL IOL **+2.75**  
DIFFRACTIVE ASPHERIC

# TECNIS<sup>®</sup> 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.



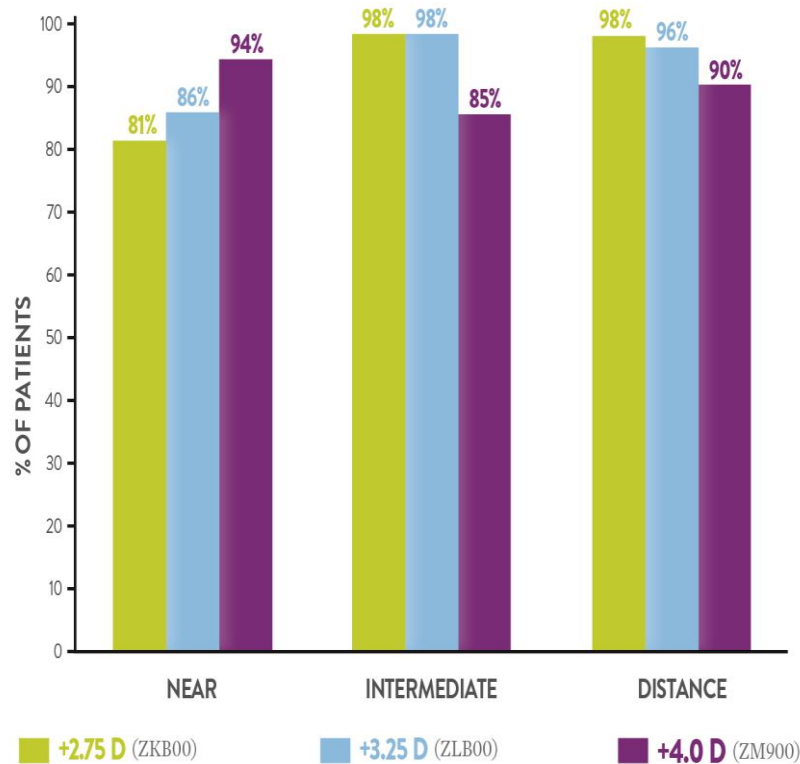
**Abbott**

PP2015CT0047

# TECNIS® Multifocal Family of IOLs

## Clinical Outcomes

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



**>80%**

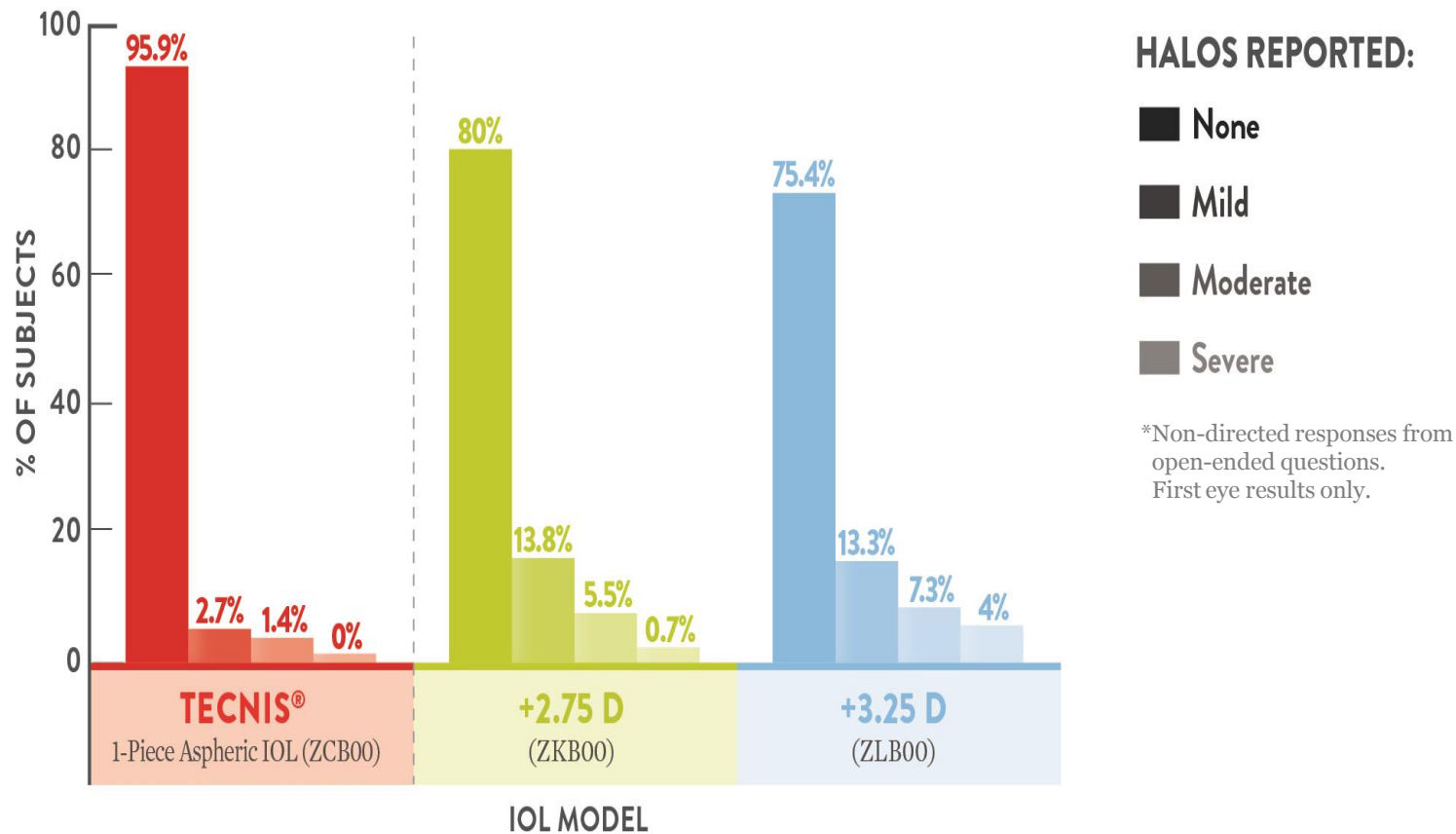
of patients reported an ability to function comfortably without glasses at all distances

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

# TECNIS® Multifocal IOLs +3.25 D and +2.75 D

## Clinical Outcomes

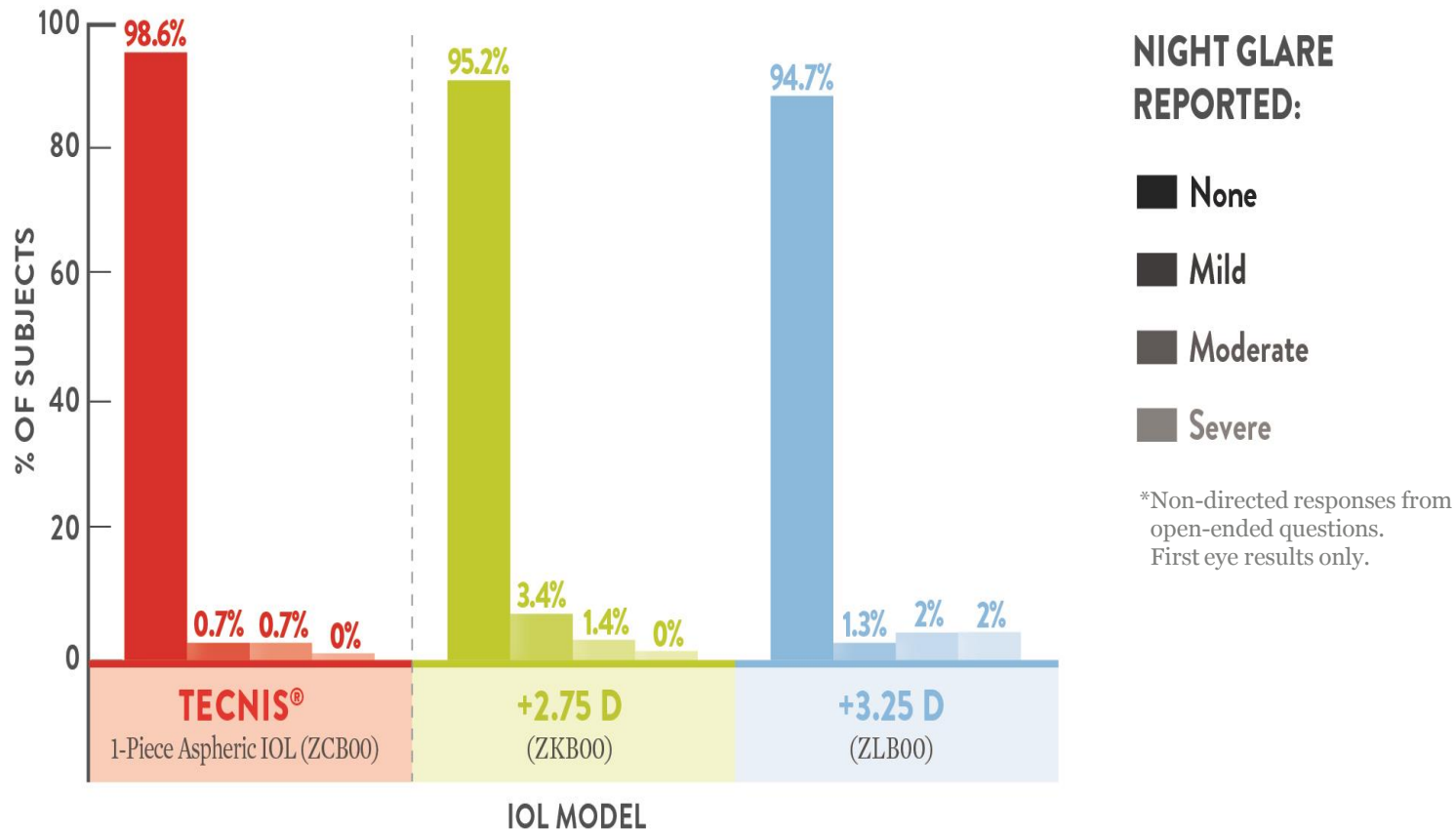
### *Spontaneous Reports of Halos in a Non-Directed Study*



# TECNIS® Multifocal IOLs +3.25 D and +2.75 D

## Clinical Outcomes

### *Spontaneous Reports of Night Glare in a Non-Directed Study*



# Tecnis Multifocal IOL - Halo Performance

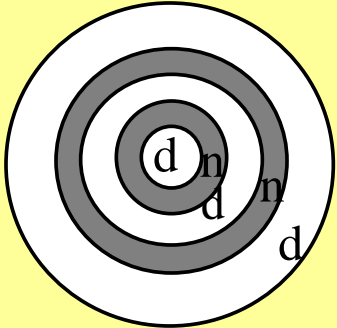
Model	ZKB00 (2.75D add)	ZLB00 (3.25D add)	ZMB00 (4D add)
Gamma 0.15 Relative Normalization			

Lower add power decreases the halo

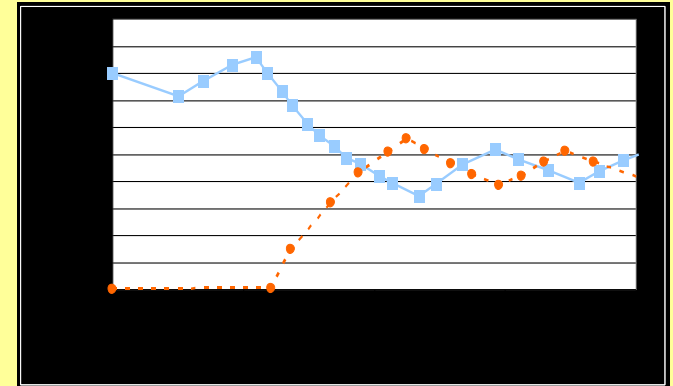
# Refractive MF and Diffractive

## IOLs

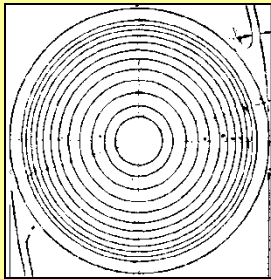
### Zonal Refractive (5 Zones) – AMO ARRAY



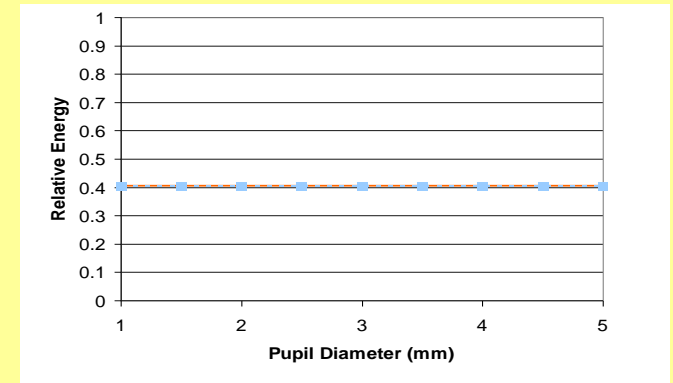
Light energy dramatically varies with number of zones exposed by pupil, contributes to halos at night



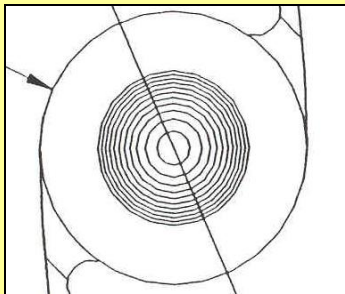
### Full Optic Diffractive – 3M



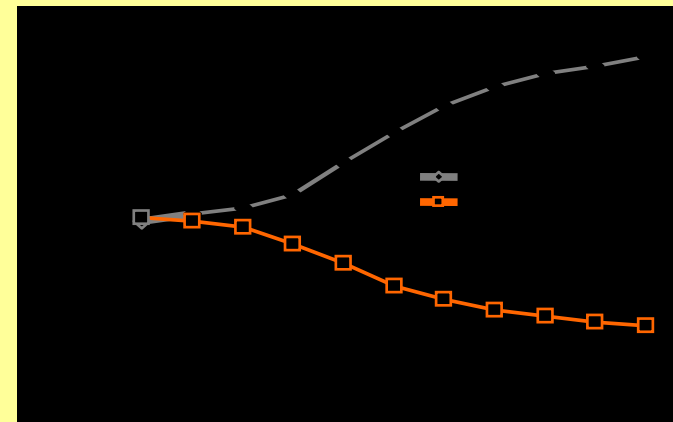
Light energy equally shared over broad range of pupils/lighting conditions, contributes to halos at night



### 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

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## 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

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- **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

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- **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

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## •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

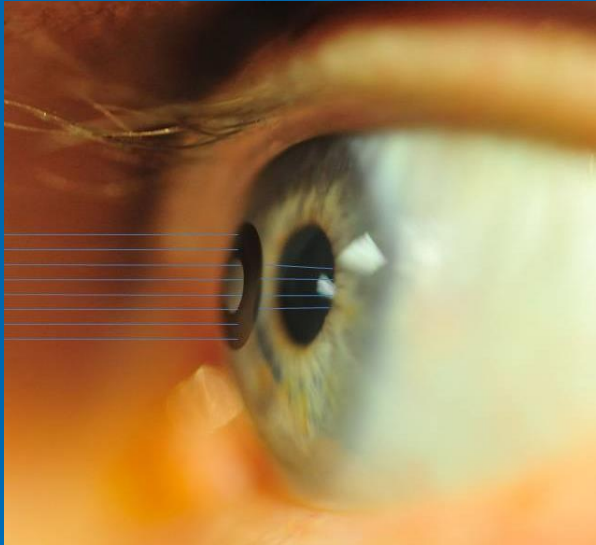
# Corneal Inlays

- Acufocus Kamra Inlay
    - Only FDA approved inlay for presbyopia correction
  - Presbia Flexivue Microlens
  - Revision Optics' Raindrop
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# 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<sup>®</sup> Inlay



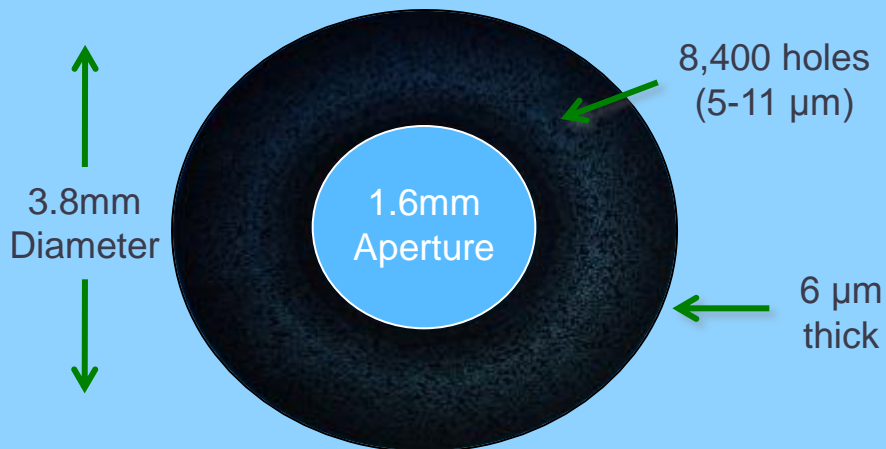
# Acufocus Kamra Inlay

- 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

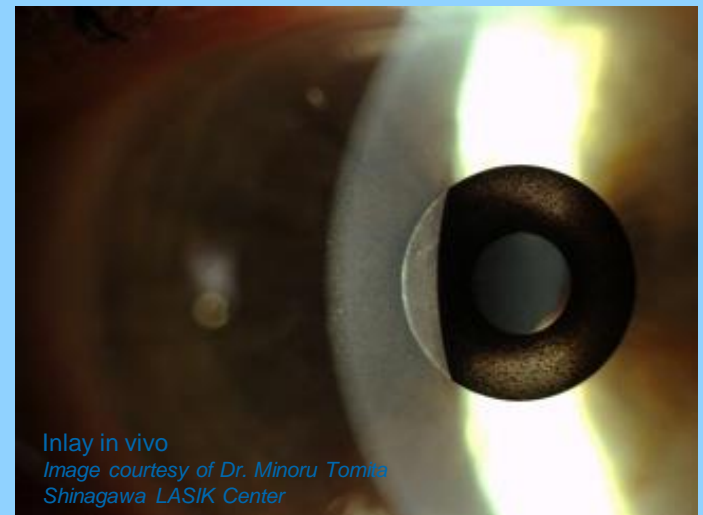
# KAMRA<sup>®</sup> Inlay Design

- 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

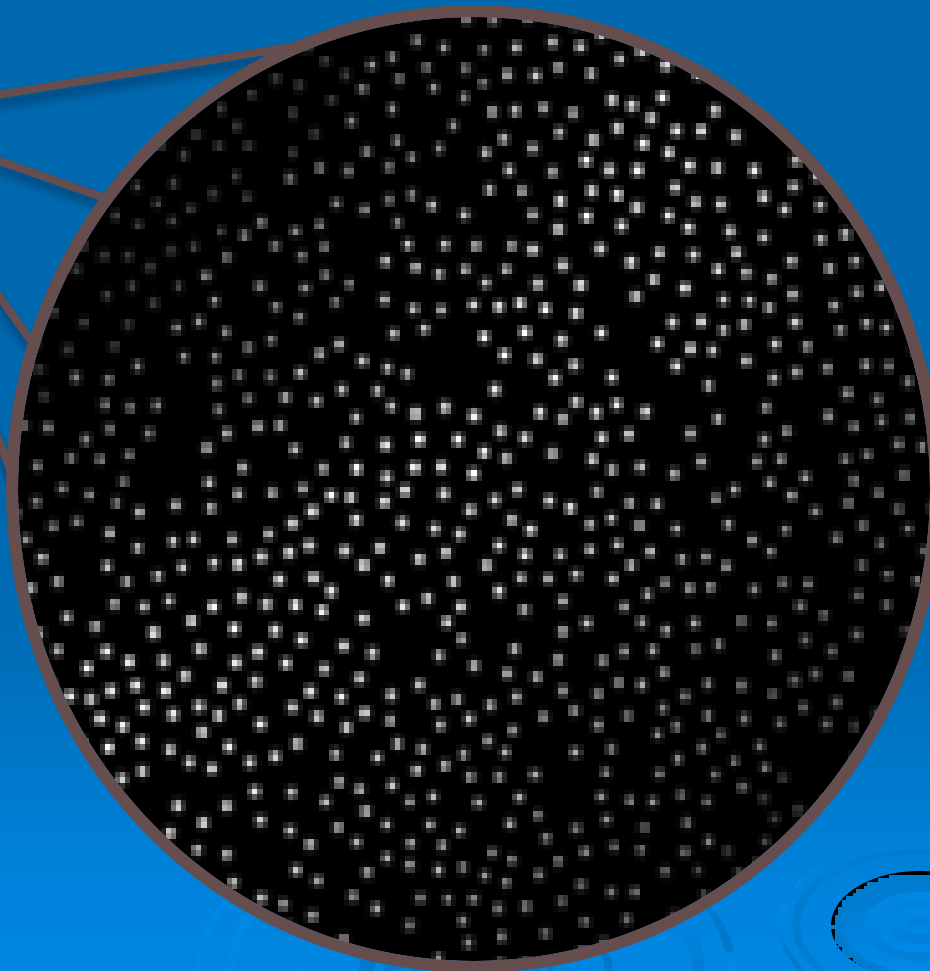
## Inlay Design



Made from Polyvinylidene Difluoride (PVDF)



# Permeability



8,400  
micro-perforations  
(5-11  $\mu\text{m}$ )

Pseudo-random  
pattern

Maximize nutrient  
flow

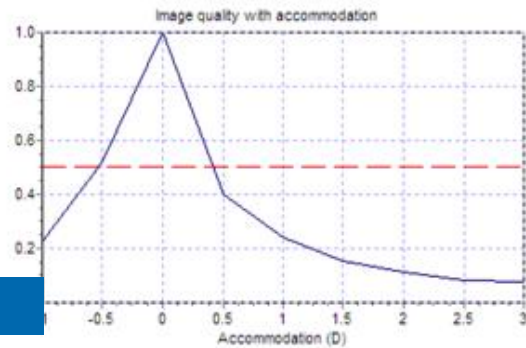
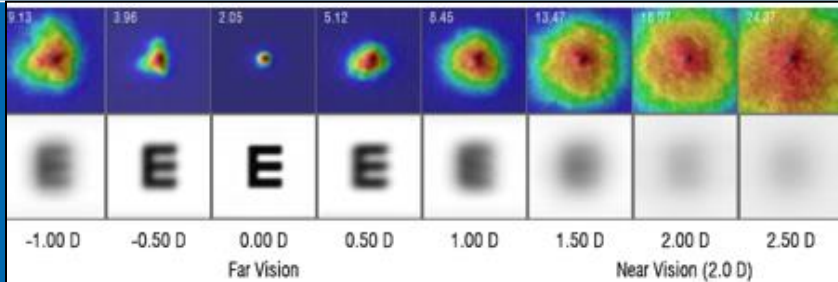
Minimize visual  
symptoms



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

Pre-op

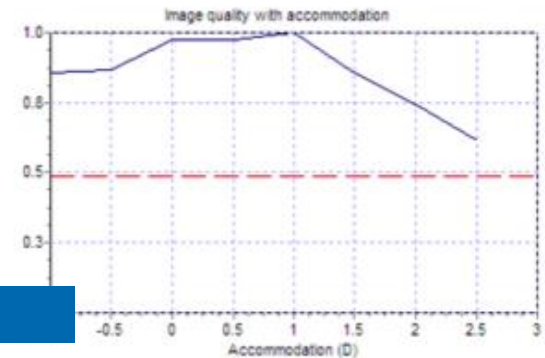
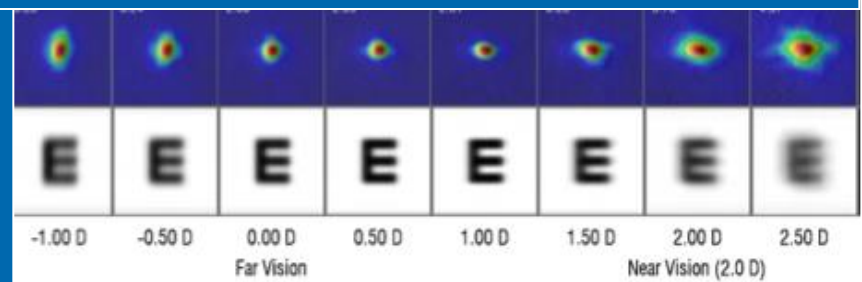
0.25D of depth of focus



OQAS Accommodative Range (D): 0.25

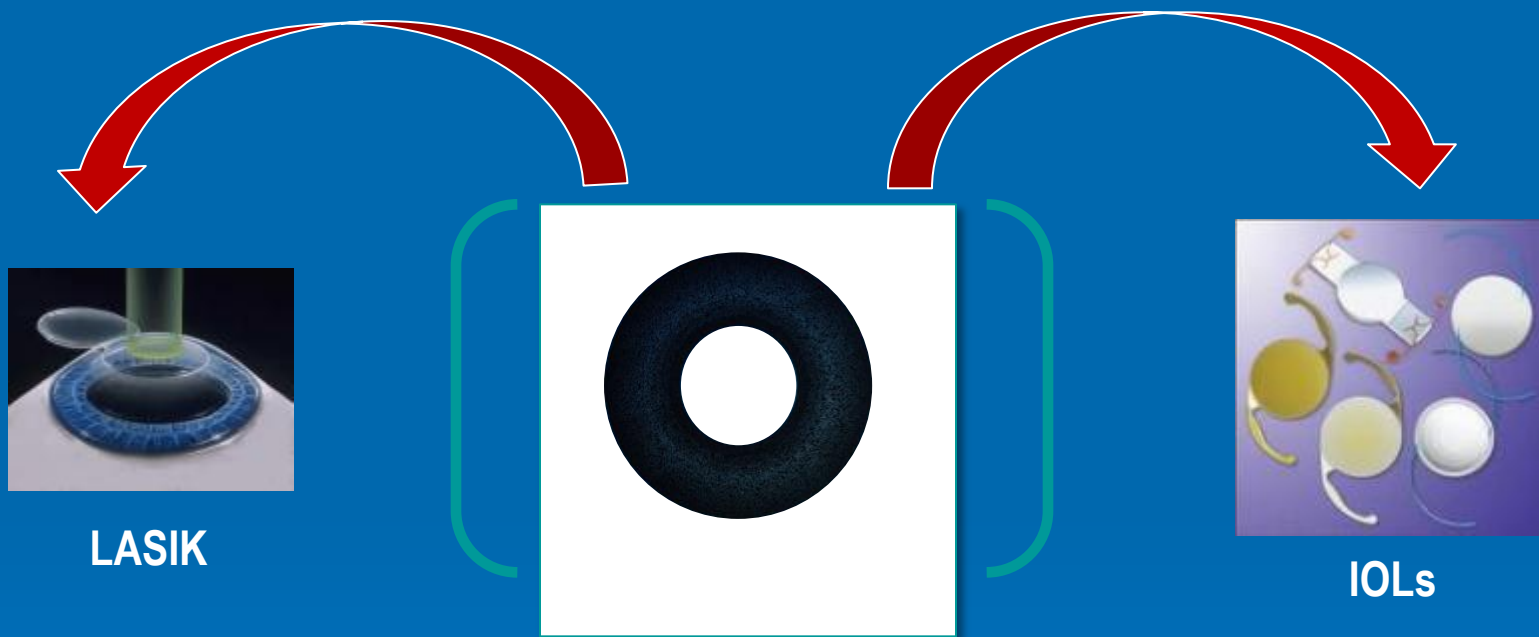
Several Months Post-op

2.50D of depth of focus



OQAS Accommodative Range (D): >2.50

# Where the KAMRA® inlay falls within the Patient Spectrum



Ages 20 – 40

Ages 40 – 60

Ages 60+

Near vision loss begins

# KAMRA<sup>®</sup> 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

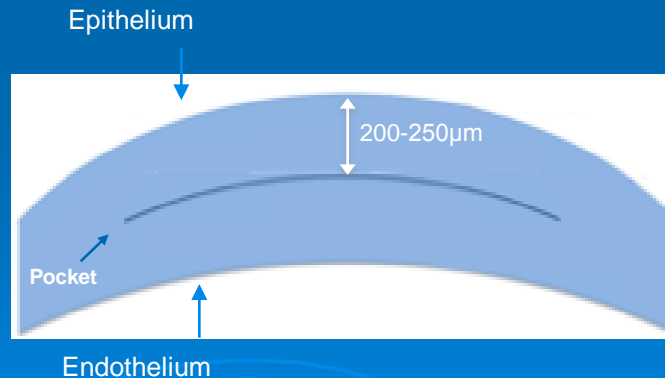
# Patient Exclusions

- 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

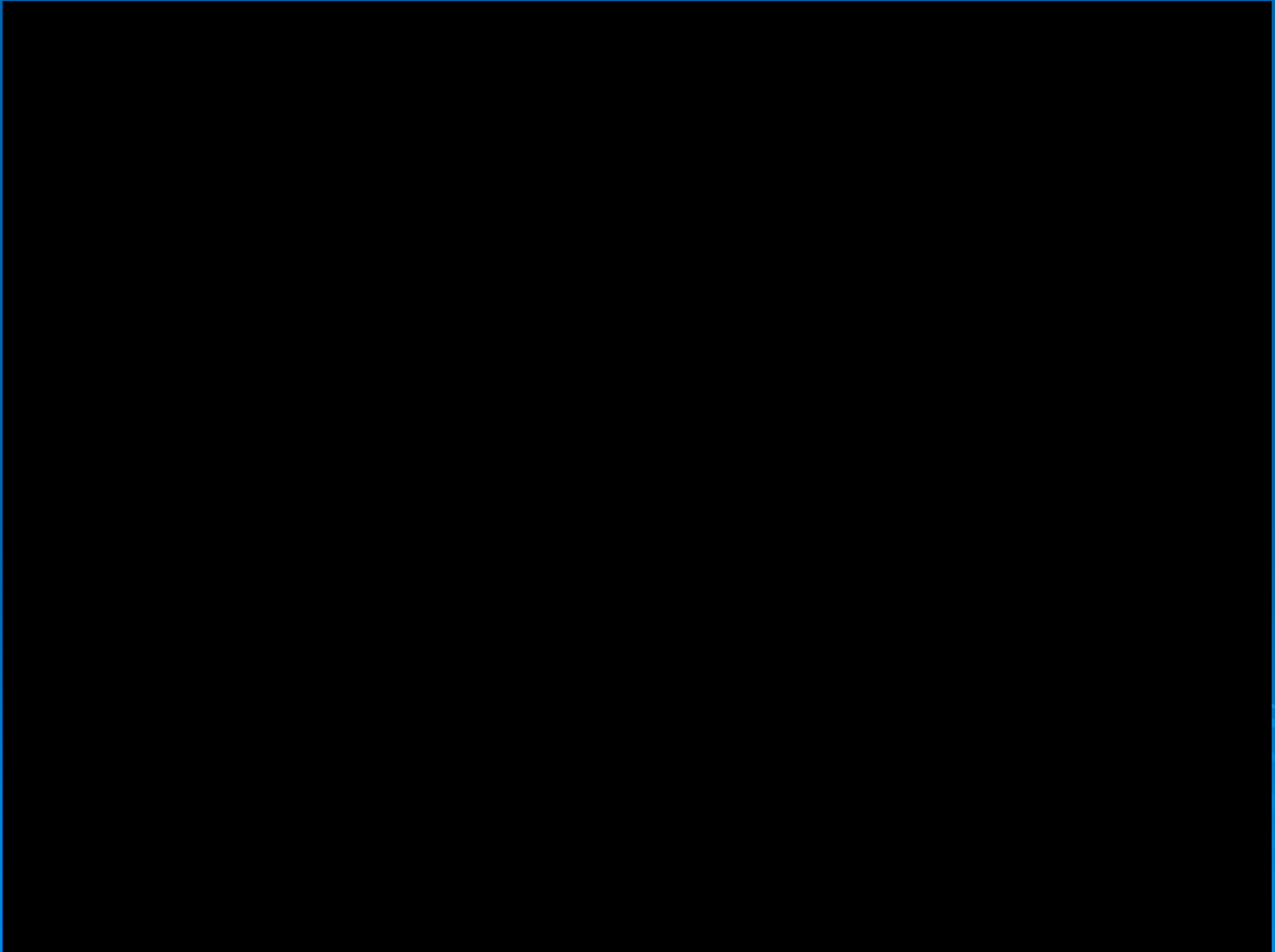
# Surgical Procedure

- **Description:** A femtosecond laser created pocket in the stroma at a depth of 200-250 $\mu$ m with femtosecond laser spot/line settings of  $\leq 6 \times 6$  or equivalent is recommended.

## Pocket Emmetropic KAMRA (PEK)

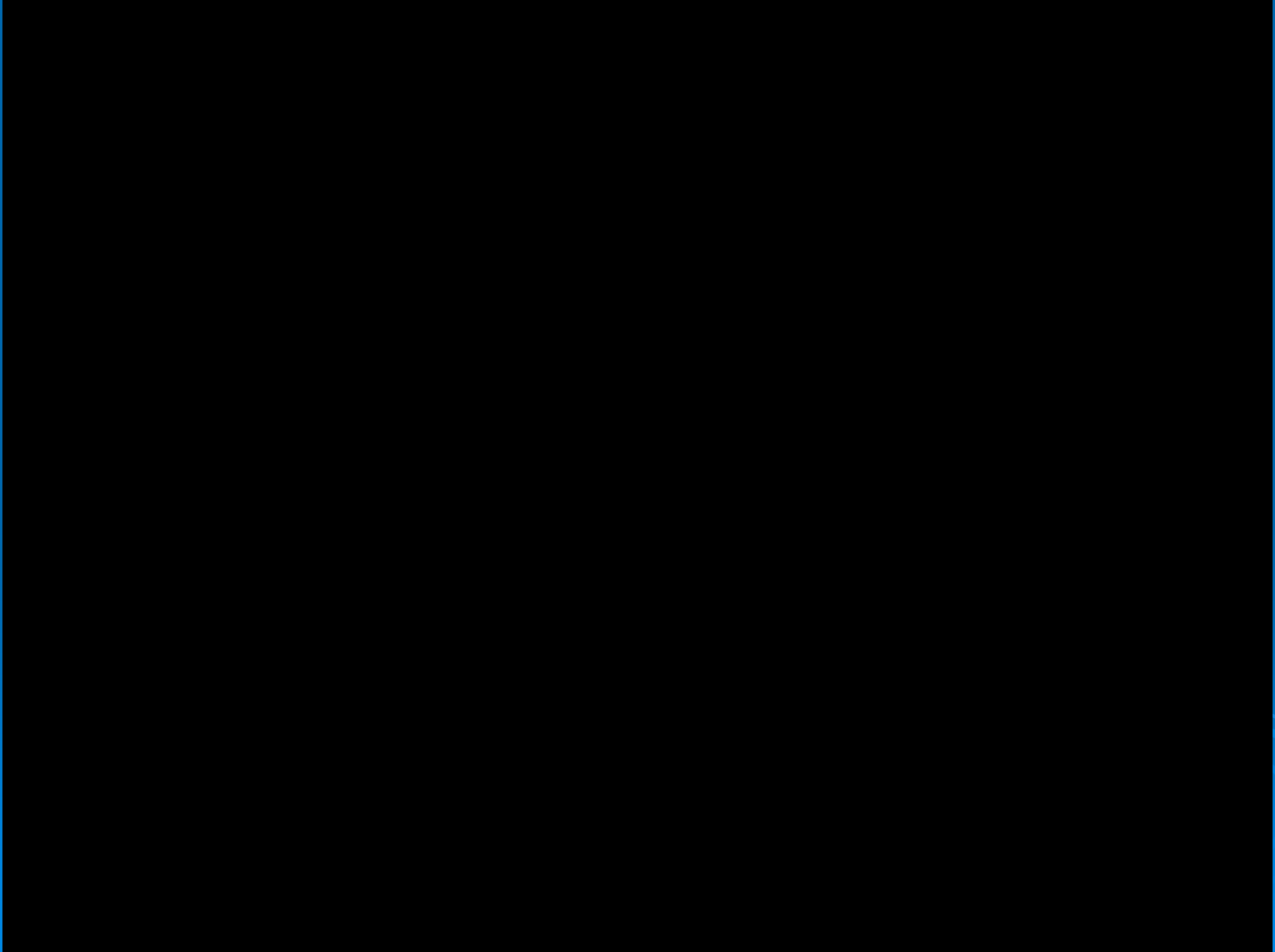


# Surgical Procedure





# Surgical Procedure

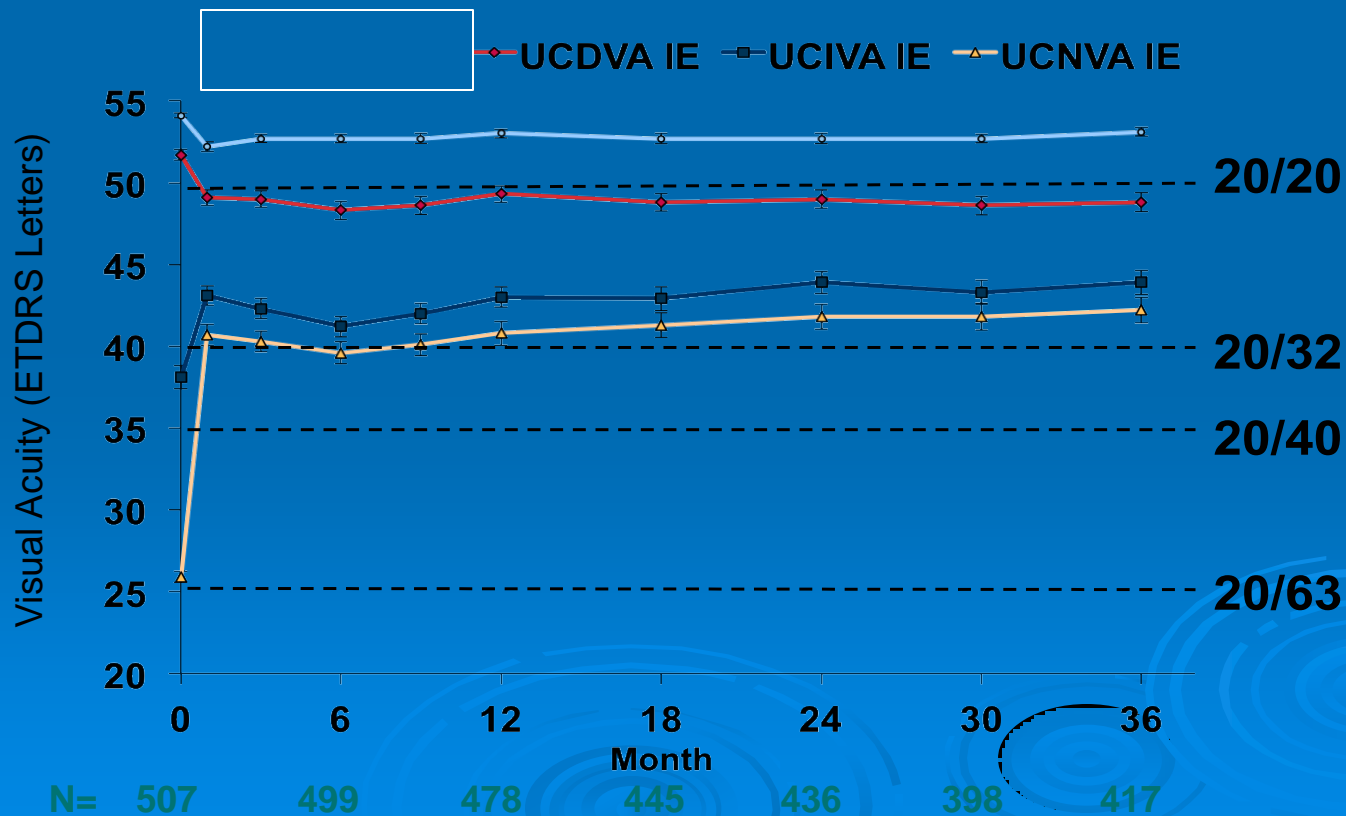


# US IDE - Study Design

- 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  $\geq$  20/20 (1.0) in both eyes

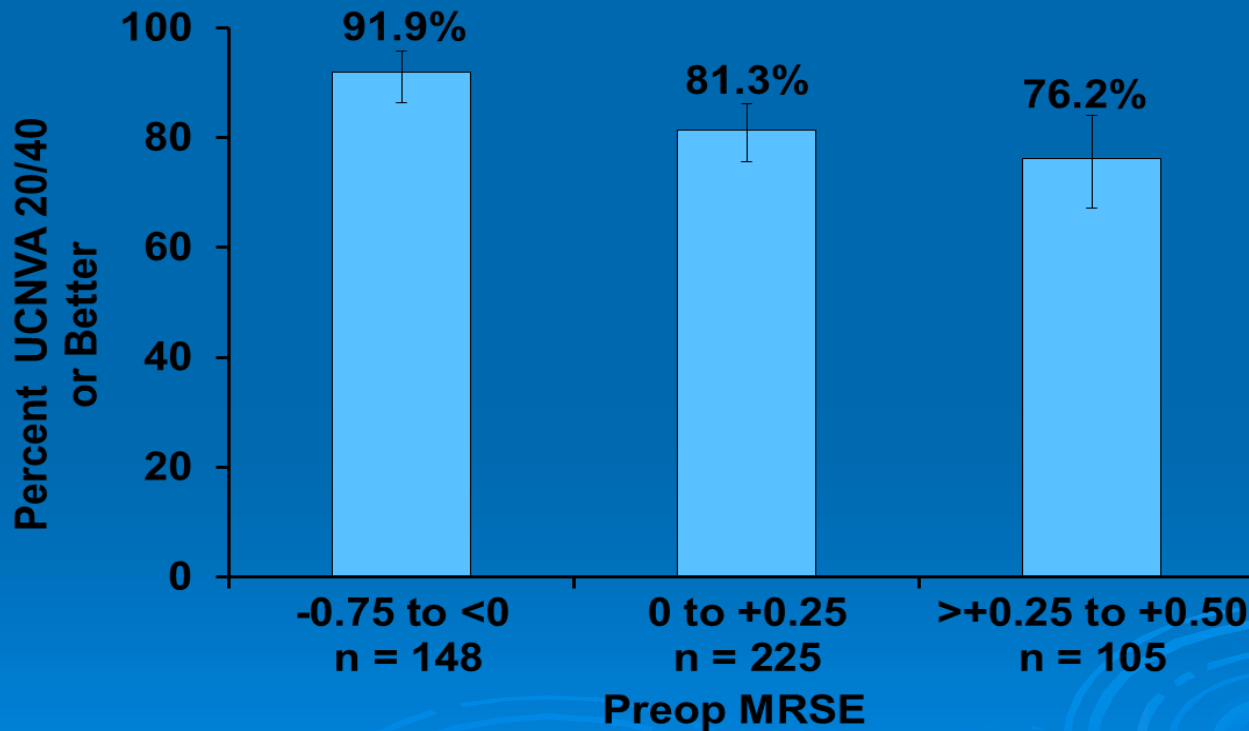
# Distance, Intermediate and Near Visual Acuities: Implanted Eyes

- 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



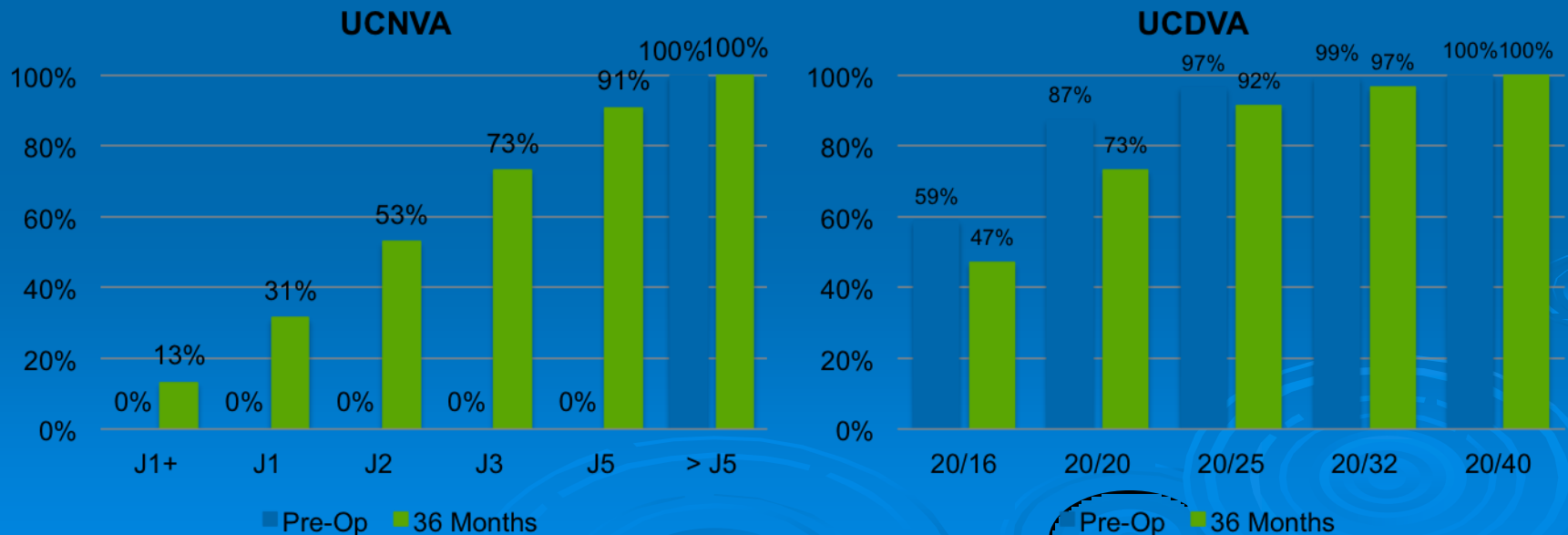
# Influence of MRSE on Near Acuity at 12 Months

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



# Uncorrected Visual Acuity in the KAMRA® Inlay Eye

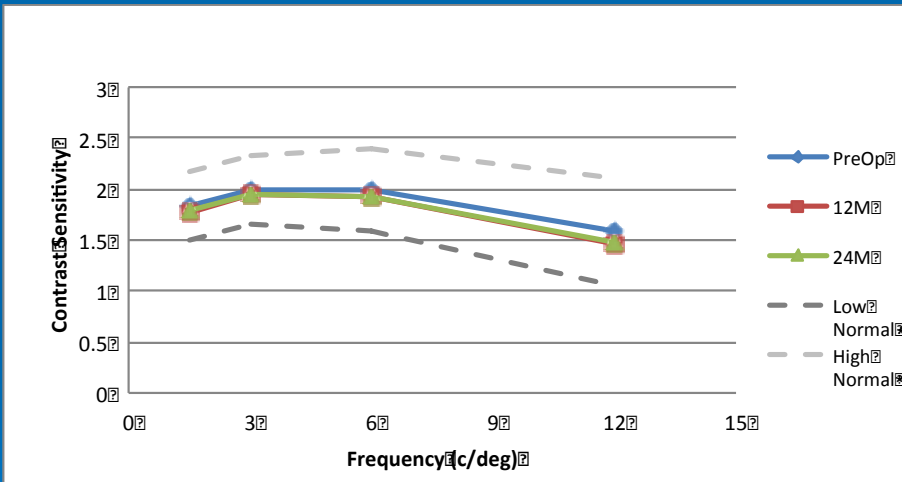
- Change between Pre-Op and 36 Months:
  - Mean UCNVA improved 5 lines from J8 to J2
  - Mean UCDVA reduction from 20/18.5 to 20/20
  - Mean MRSE changed from 0.02 + 0.28 D to 0.14 + 0.72 D



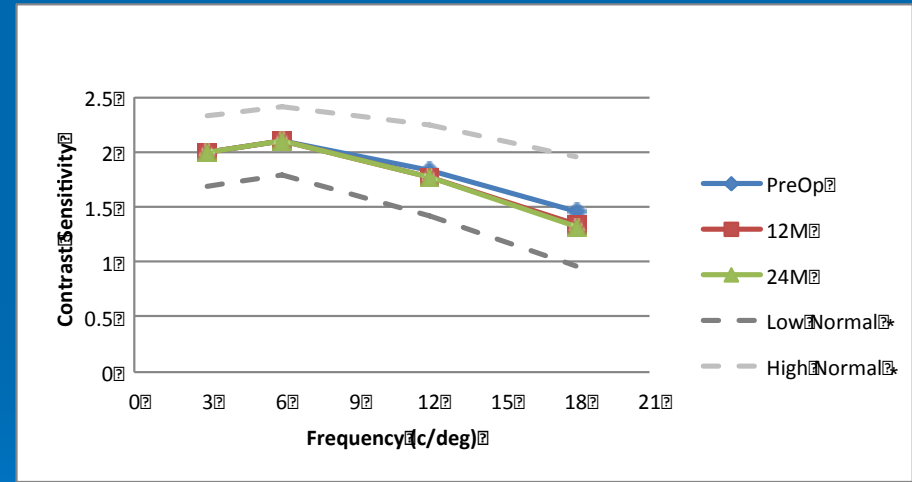
\*N=153 at 36 months, ≤ 6x6 group, data on file at AcuFocus™

# 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

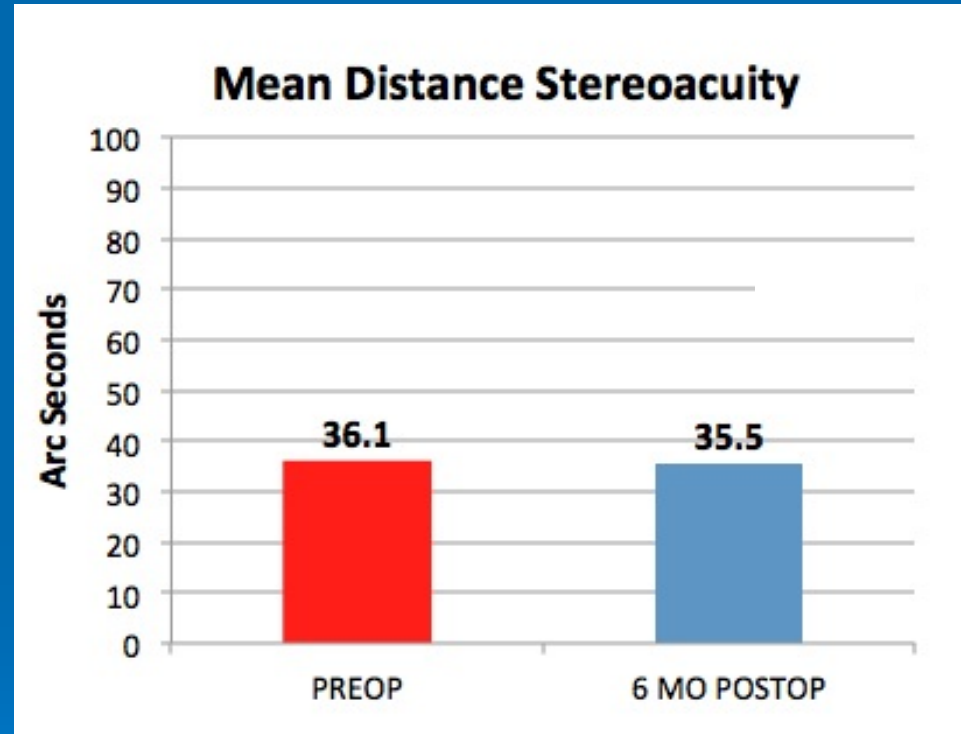


\*Data on file at AcuFocus

\*\*Seyeddain et al. Small-aperture corneal inlay for the correction of presbyopia: 3-year follow-up. J Cataract Refract Surg 2012; 38:35-45

# Stereoacuity with the KAMRA® Inlay

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

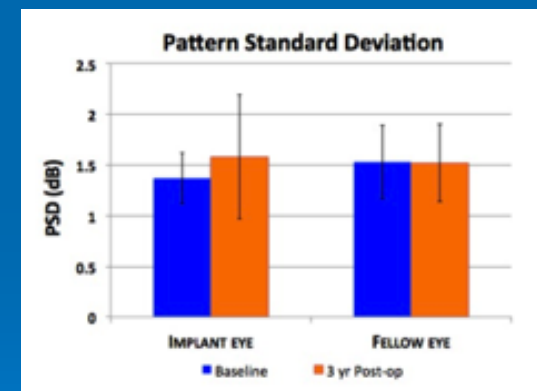
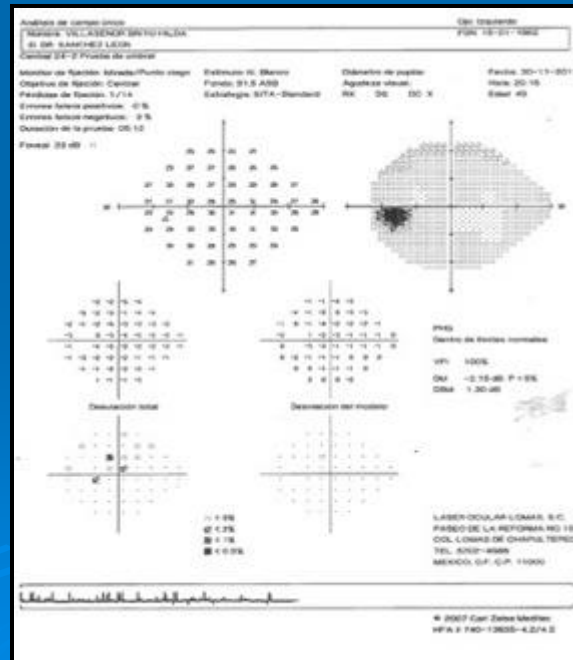
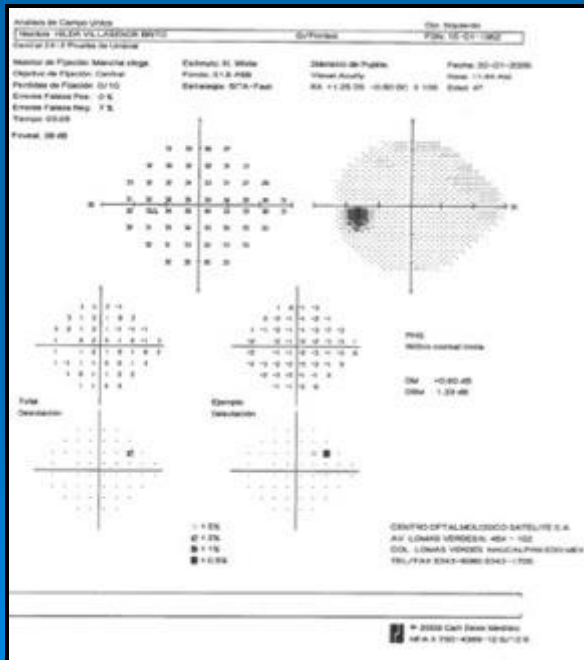


# Visual Field

- 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).<sup>1</sup>
- No scotomas induced by the presence of the inlay<sup>1,2</sup>
- No statistically significant difference in extent and total area of the visual field was found between implanted and non-implanted eyes<sup>3</sup>

Pre-Op: Inlay Eye

36 Mo Post-Op: Inlay Eye



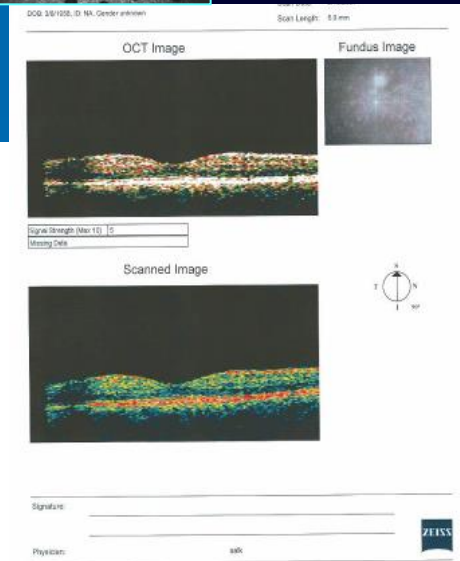
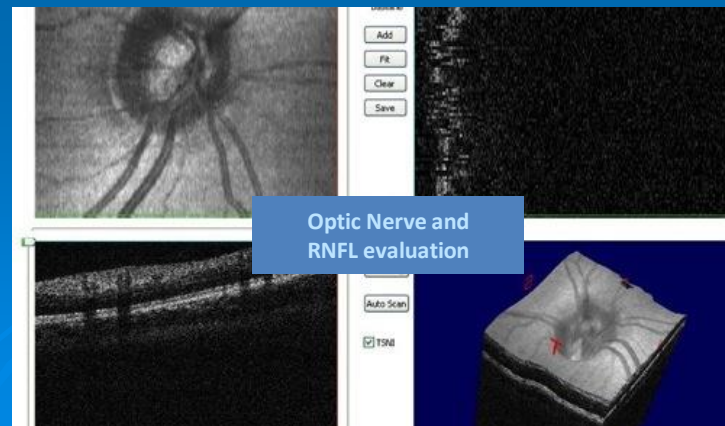
- 1 - US IDE Clinical Trial
- 2 - Sanchez et al, ARVO 2012
- 3 - Brooker et al, ARVO 2013



# Ophthalmic Assessments and the KAMRA<sup>®</sup> 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



# 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<sup>nd</sup>-4<sup>th</sup> week, TID 2<sup>nd</sup> month, BID 3<sup>rd</sup> 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

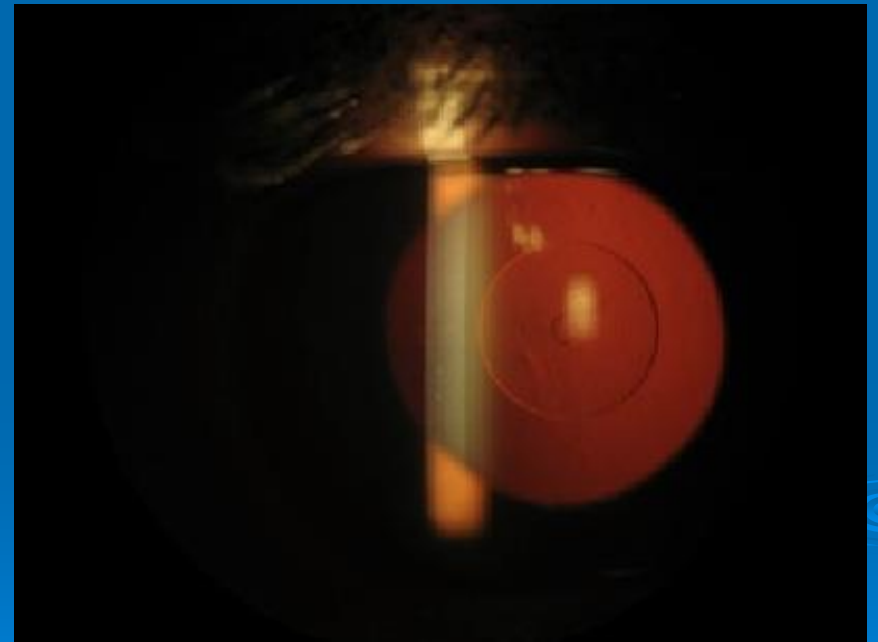
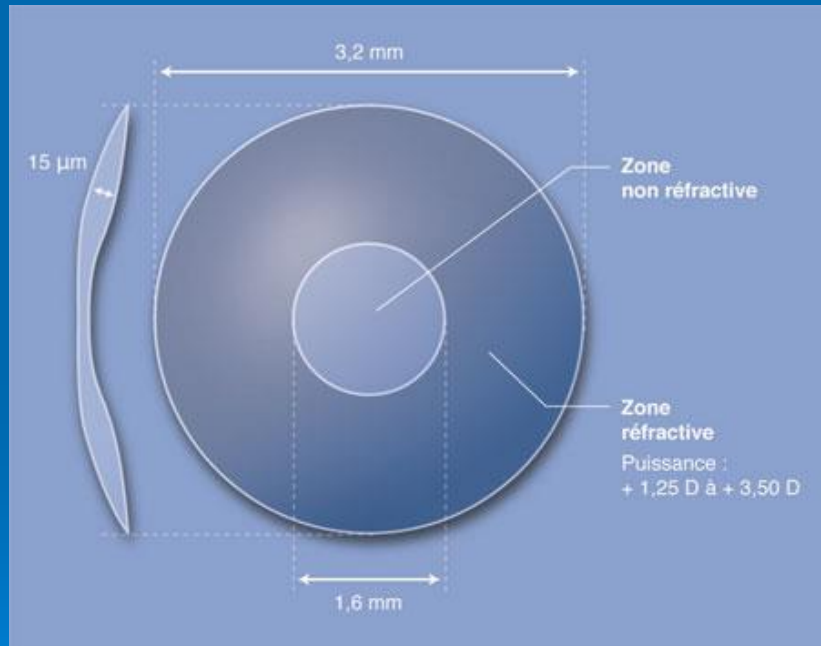
- The KAMRA® inlay is an effective solution for presbyopia to bridge the gap between LASIK and cataract surgery
- The small aperture inlay reliably extends depth of focus providing uninterrupted vision from near to far
- Maintains stereopsis and binocular vision, regardless of monocular implantation
- 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

# Presbia Flexivue Microlens Inlay



# Future Corneal Inlays

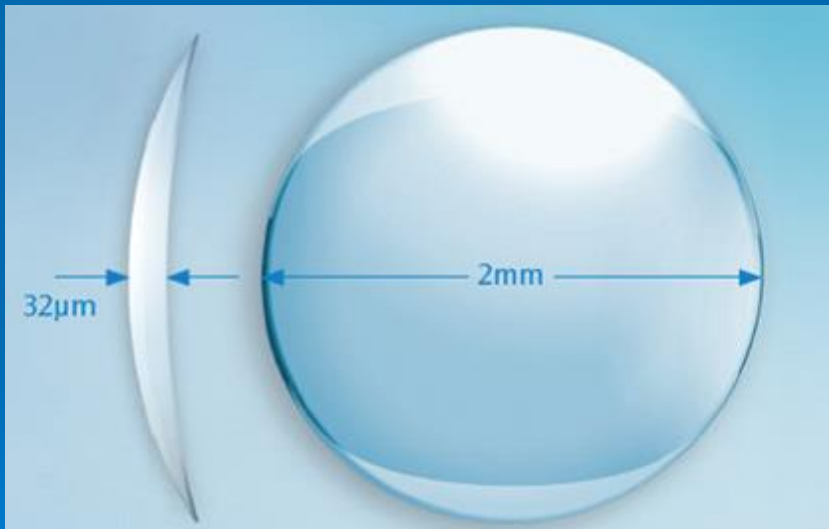
## ➤ ReVision Optics' Raindrop

- 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



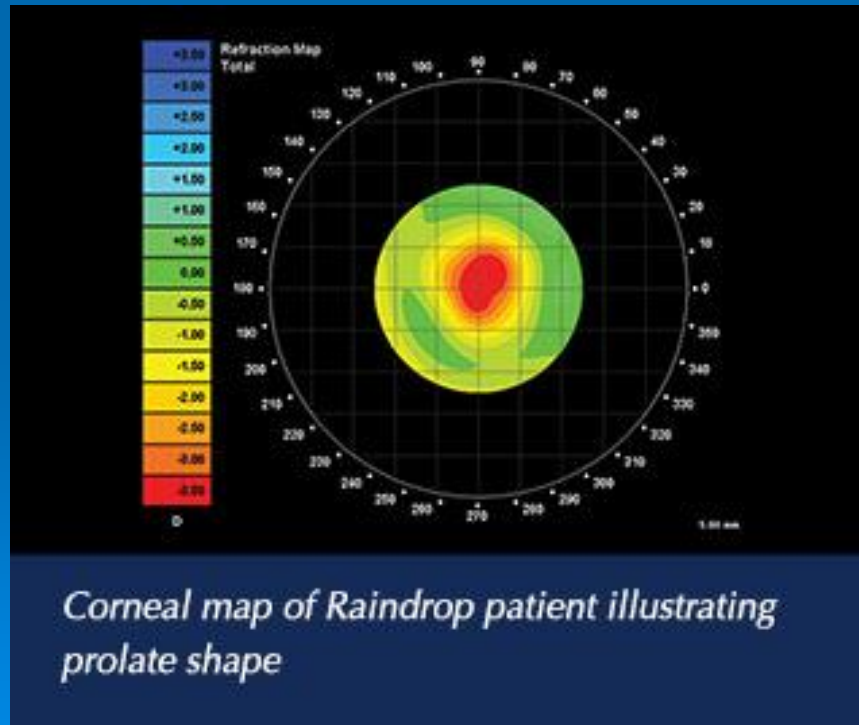
# Future Corneal Inlays

## ➤ ReVision Optics' Raindrop



# Future Corneal Inlays

## ➤ ReVision Optics' Raindrop





# 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 world wide
- 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

