ASCRS ♦ ASOA Symposium & Congress

Technicians & Nurses Program

May 6-10, 2016 – New Orleans

JCAHPO
JOINT COMMISSION ON ALLIED HEALTH PERSONNEL IN OPHTHALMOLOGY®

Review of current refractive inlays for the treatment of presbyopia: Raindrop, Kamra, Flexivue and Refocus VisAbility Implant

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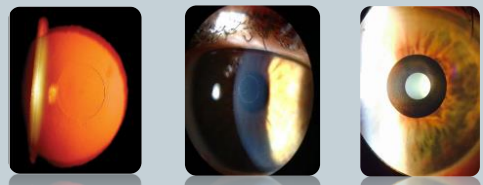
MAY 7, 2016

Clinical investigator for ReVision Optics, Inc and Refocus, Inc

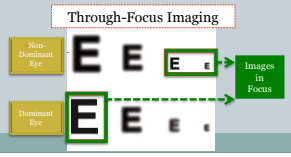
Corneal Inlay Approach to the Surgical Correction of Presbyopia

Flexivue Microlens-Presbia | Raindrop-Revision Optics | Kamra-Acufocus



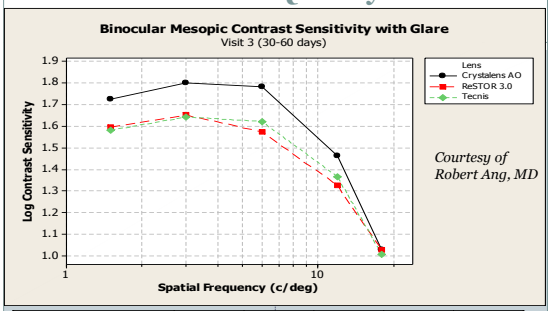
Monovision

- **Non-Dominant eye corrected for near**
  - **Target post-op sphere: -0.75 to -1.50D**
- **Dominant eye corrected for distance**
- ***No overlap of vision between eyes***
- **Significant reduction in stereopsis***
- **Decrease in visual discrimination capacity***



*Alarcon et al, J Cataract Refract Surg 2011; 37:1629–1635

Multifocal IOLs: Quality of Vision



Courtesy of Robert Ang, MD

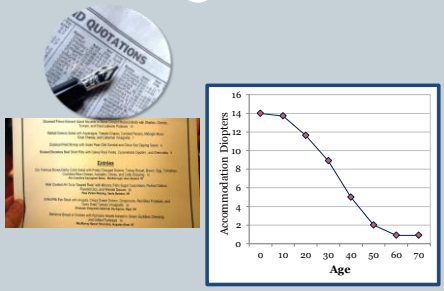
p-values	1.5 c/deg	3 c/deg	6 c/deg	12 c/deg	18 c/deg
Crystalens vs. ReSTOR	0.051	0.024	0.008	0.082	0.745
Crystalens vs. Tecnis	0.033	0.008	0.023	0.331	0.943
ReSTOR vs. Tecnis	0.577	0.580	0.939	0.526	0.786

Treatment of Presbyopia with Raindrop® Inlay

***CAUTION: The Raindrop Near Vision Inlay is an Investigational device. Limited by Federal (United States) law to investigational use.**

1 of 25

Presbyopia

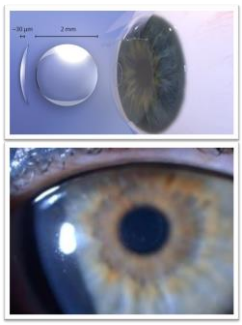


2 of 25

If You Have Difficulty…

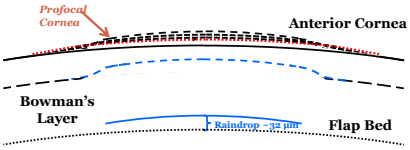
Raindrop Near Vision Inlay

- Transparent hydrogel inlay
- Small and thin
  - 2 mm diameter, ~30 µm thick
- Inserted under a femtosecond laser corneal flap
- Biocompatible material
  - Same refractive index as the cornea
  - Maintains natural nutrient flow within the cornea*
- Removable



*Pinsky PM. Three-dimensional modeling of metabolic species transport in the cornea with a hydrogel intrastromalinlay. *Invest Ophthalmol Vis Sci* 2014; 55:3093-3106.

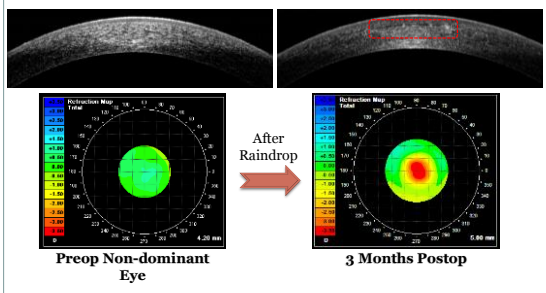
Mechanism of Action



Changes Anterior Curvature of Cornea

Improves Near and Intermediate Vision

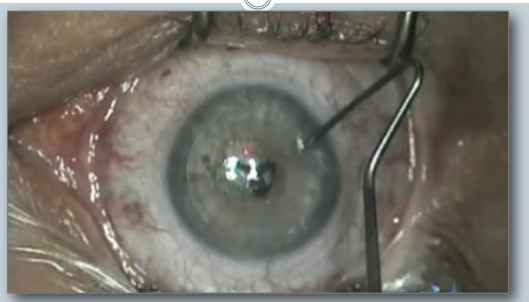
Mechanism of Action



Preop Non-dominant Eye

3 Months Postop

Raindrop Surgery



Ideal Raindrop Patients For The Study

- **MRSE: -0.50 D TO +1.00 D (<0.75 D OF CYL)**
  Raindrop Induces Mild Myopia (Approx. 1.00 D)
- **WHO REQUIRE +1.50 D TO +2.50 D ADD**

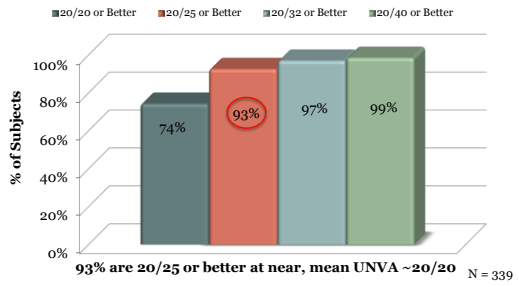
Good Ocular Health

- No Confounding Ocular Pathology
- Healthy Eyes: no corneal issues and no cataracts
- Healthy Ocular Surface
  - Similar to LASIK Flap Surgery, Select Only Candidates with Healthy Ocular Surfaces

Results: US FDA Study (1 year)

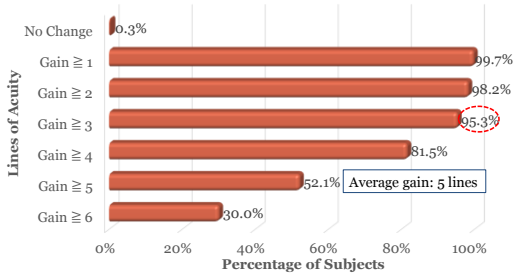
- Multicenter, prospective, non-randomized clinical study
- Presbyopic Emmetropes implanted in the non-dominant eye
  - Average age 57.3 years (range: 41- 65 years)
  - MRSE +0.24 D (range: -0.50 D to +1.00 D)
- **Outcomes reported:**
  - Visual Acuities
    - Near, Intermediate, Distance
    - Standardized ETDRS charts
  - Subject satisfaction survey
  - Safety

Uncorrected Near Visual Acuities (Monocular - Inlay Eye Only)



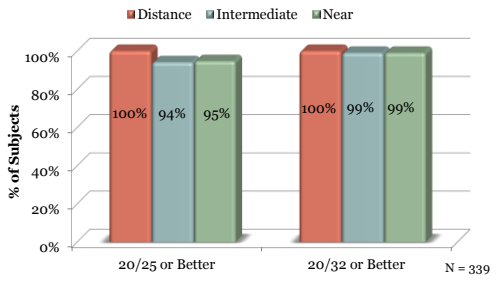
*Whitman J. (in press). Treatment of Presbyopia in Emmetropes Using a Shape-Changing Corneal Inlay: One-Year Clinical Outcomes. *Ophthalmol*

Improvement at Near (Inlay Eye)



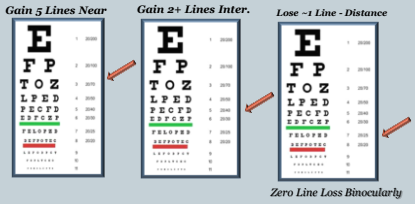
*Whitman J. (in press). Treatment of Presbyopia in Emmetropes Using a Shape-Changing Corneal Inlay: One-Year Clinical Outcomes. *Ophthalmol*

Uncorrected Binocular Visual Acuities

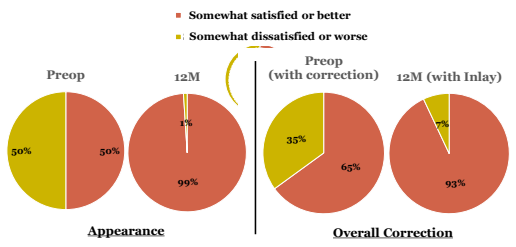


*Whitman J. (in press). Treatment of Presbyopia in Emmetropes Using a Shape-Changing Corneal Inlay: One-Year Clinical Outcomes. *Ophthalmol*

Eye Chart Performance (Inlay eye)



Subject Satisfaction

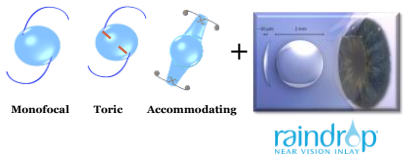


99% satisfaction with appearance, 93% satisfaction with correction

N = 325

*Whitman J. (in press). Treatment of Presbyopia in Emmetropes Using a Shape-Changing Corneal Inlay: One-Year Clinical Outcomes. Ophthalmol

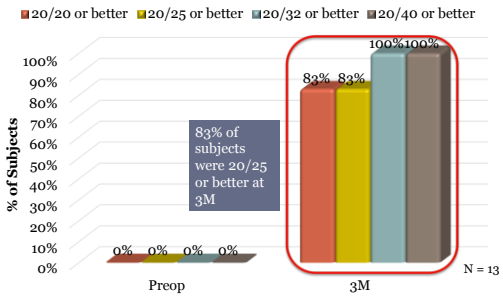
Raindrop in Pseudophakes



Early Results: US FDA Pseudophake Study (3 Months)-Still Enrolling

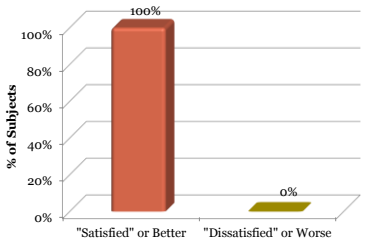
- Multicenter, prospective, non-randomized clinical experience
- Pseudophakes with monofocal IOL
  - Raindrop Inlay implanted in the non-dominant eye
    - 13 subjects
    - Average age: 65 years (range: 47-78 years)
    - MRSE: -0.02 D (range -0.50 D to 0.38 D)
    - Preoperative Add: 2.06 D (range: 1.75 D to 2.50 D)
    - **Initial Outcomes:**
      - Visual Acuities
      - Subject Satisfaction

Uncorrected Near Visual Acuities (Monocular)



*Presented by Ralph Chu, MD at ASCRS 2015 in San Diego, CA

Subject Satisfaction



High satisfaction for pseudophakic subjects (100%)

N = 13

*Presented by Ralph Chu, MD at ASCRS 2015 in San Diego, CA

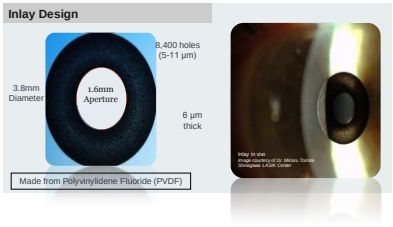
Summary

- Raindrop Inlay improves near vision equally in phakic and pseudophakic presbyopes
  - 93% of phakic subjects were 20/25 or better
  - 83% of pseudophakic subjects were 20/25 or better
- Subject satisfaction was high in both groups
  - 93% satisfied for phakic subjects
  - 100% satisfied for pseudophakic subjects

The KAMRA® Inlay

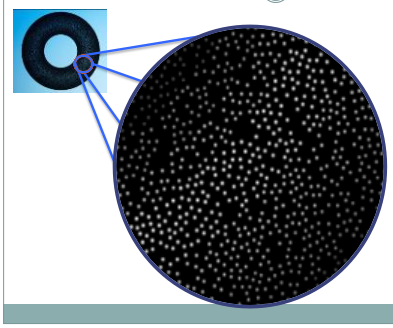
- Designed to improve near vision in patients with presbyopia
  - Easily implanted
  - Minimal impact on distance vision
  - It has no power and doesn't change corneal power
  - It only needs to be implanted in one eye
  - Removable
  - FDA approved

KAMRA Inlay Design



- Inlay improves 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



8,400 micro-perforations(5-11µ)

Pseudo-random pattern

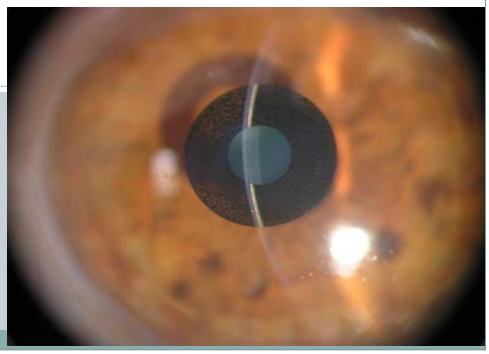
Maximize nutrient flow

Minimize visual symptoms

Corneal Nutrition

- The corneal epithelium will starve if an impermeable barrier is placed intrastromally that restricts the diffusion of glucose and other metabolites
- Diffusion holes cover approximately 5% the inlay
- The strategically designed hole pattern of the KAMRA® inlay allows proper diffusion of metabolites to support the health of all areas of the corneal epithelium

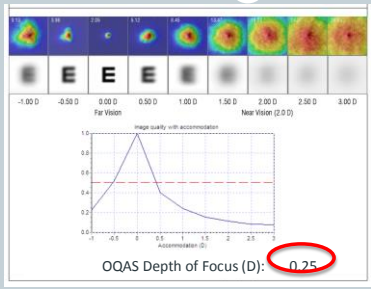
Slit Lamp



How Does IT Work?
Foundations in Photography

- A photographic lens aperture is used to adjust the amount of light reaching the film or image sensor.
- Depth of field is a function of both the aperture and focal length of the camera lens
- Smaller apertures (larger F-Stop numbers) produce a longer depth of field

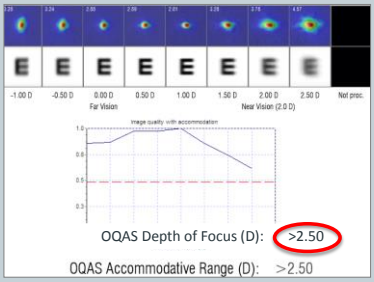
Depth of Focus *without* Correction



49 Year Old Presbyope, Non-Implanted Eye

(minimal residual accommodation)

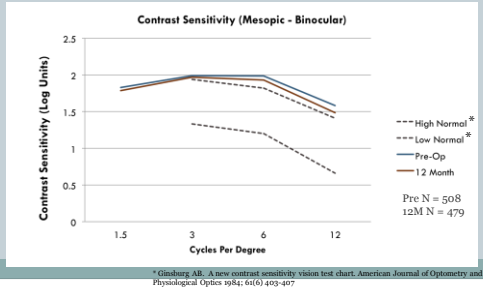
Depth of Focus *with* KAMRA Correction



49 Year Old Presbyope, Implanted Eye

Binocular Mesopic Contrast Sensitivity

Binocular mesopic contrast sensitivity remains within normal limits at 12 months post-op



* Ginsburg AB. A new contrast sensitivity vision test chart. American Journal of Optometry and Physiological Optics 1984; 61(6) 403-407

KAMRA Inlay Surgical Procedures

- **Pocket Emmetropic KAMRA (PEK)**: Implantation of an inlay into a femtosecond created lamellar pocket.
- **Combined LASIK KAMRA (CLK)**: combination of a LASIK procedure with inlay implantation post-ablation.
- **Post-LASIK KAMRA (PLK)**: creation of a lamellar pocket 100 microns below a previous LASIK flap for inlay implantation.
- **Planned LASIK KAMRA – 2 Step (PLK2)**: planned traditional thin flap LASIK procedure followed by insertion of an inlay into a lamellar pocket 1 month after primary LASIK procedure. Leave -.75

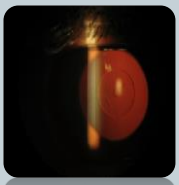
US IDE - Study Design

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

Summary

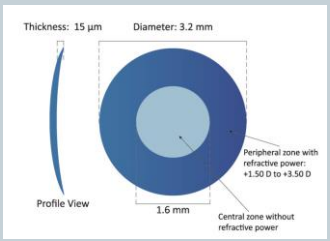
- **Mean uncorrected visual acuities at 24 months in the inlay eye are:**
  - **J2 for near (3.5 line gain)**
  - **20/25 for intermediate**
  - **20/20 for distance**
- **Binocular uncorrected distance visual acuity is unchanged from pre-op to 24 months post-op**
- **Binocular photopic and mesopic contrast sensitivity is within normal limits**
- **FDA approval in 2015**

Flexivue Microlens



Transparent hydrophilic polymer material

Flexivue Microlens



- Plano central zone with peripheral refractive powers ranging from +1.5 to +3.5 D
- 0.5 mm hole in the center of the disc that permits the transfer of oxygen and nutrients

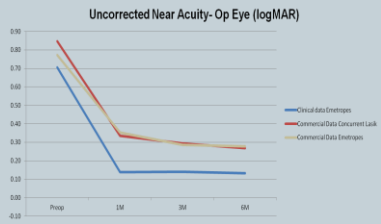
Procedure

- Performed on nondominant eye
- Utilizes femtosecond laser to create a pocket in the cornea
- Customizable to specific patient vision needs
- Ten minute procedure

Presbia Flexivue Microlens™

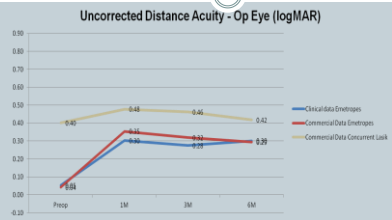
Slit lamp image of Presbia Flexivue Microlens™

Uncorrected Near Acuity- Op Eye

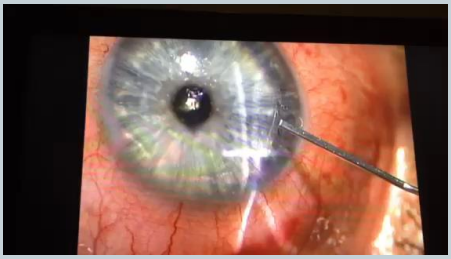


All three groups managed on average a 4-5 line gain within 1 month
Near vision remained stable through 3 and 6 months

Uncorrected Distance Acuity- Op Eye



- Both groups of emmetropes lose 2-3 lines initially, improving through 3 and 6 months
- The concurrent LASIK group lose less than a line and settle back around 6 months however
- The concurrent group show approximately 3 lines loss compared to UCDVA of LASIK treated Fellow Eye



U.S. FDA Phase III trial

- Enrollment completed last June: 337 eyes (over 10 sites)
- Cleveland Eye Clinic implanted: 38 eyes
- Overall experience: Good
- Patient satisfaction: Extremely high

Conclusion:

- The Presbia Flexivue Microlens™ provides for a safe and effective means of correcting presbyopia
  - 6 line improvement in Near vision
  - >75% fully independent of reading glasses
  - Small compromise in distance vision of treated eye not perceived binocularly
  - <2% Explant rate
- The outcomes achieved in a clinical study setting are mirrored in commercial application
- The product can be combined with other refractive surgical corrections i.e. LASIK/PRK

Refocus VisAbility Implant System

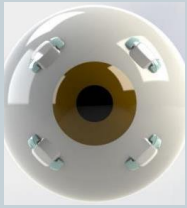
SINGLE CENTER EXPERIENCE USING SCLERAL IMPLANTS FOR TREATMENT OF PRESBYOPIA: PRELIMINARY FINDINGS

Disclosures

- Investigational Disclosure
  - This device is CE marked and available in Europe and elsewhere through Refocus Ocular B.V., Netherlands
  - The material presented here is not to be construed as indicative of the final outcome of the clinical trial data. Full results will be provided when allowed by US Regulation.
  - "CAUTION Investigational device. Limited by Federal (or US) law to investigational use." This device is under FDA IDE in the USA through Refocus Group Inc., Dallas, TX

Refocus VisAbility™ Procedure

- Create a lamellar scleral tunnel
- Insert the Refocus Scleral Implant
- Repeat in all four oblique quadrants
- Repair conjunctival opening
- No surgery in the visual axis



Refocus Scleral Implant

- Two-Piece Locking Implant
  - Locked in place with filler piece (insert)
    - Implant ends are wider than tunnel
    - Prevents the implant from slipping out
  - Pulled into place by shuttle assembly

Demographics at Study Site

- Sample
  - 10 Subjects (20 eyes) of 70 total operative subjects.
- Age (at time of surgery)
  - Average = 53.3 (range = 46 to 57)
- Gender
  - Male : Female = 7 : 3 (70% : 30%)
- Manifest Refraction Spherical Equivalent (MRSE)
  - Average = +0.138D (range = –0.25D to +0.50D)
- Acuity (DCNVA)
  - Monocular Average = 20/64.2 (range = 20/50 to 20/80)
  - Binocular Average = 20/51.6 (range = 20/25 to 20/80)

The material presented here is not to be construed as indicative of the final outcome of the clinical trial data. Full results will be provided when allowed by US Regulation. *The VisAbility™ Implant System is an investigational device and is limited by United States law to investigational use.*

Data through January 6th, 2016

Percentage of Eyes Achieving 20/40 (J3) or Better
Uncorrected Near Visual Acuity @ 40cm – Sloan EDTRS Chart (Binocular (OU), n=10)

The VisAbility™ Implant System is an investigational device and is limited by United States law to investigational use.

Data through January 6th, 2016

Change in UCDVA: Number of Lines improved/lost
Uncorrected Distance Visual Acuity (Primary Eyes, n=10)

Change in Monocular UCDVA (SLOAN)

	Month 1 N=10	Month 2 N=10	Month 3 N=10	Month 6 N=10
Sloan UCDVA Primary Eye				
Improved ≥ 2 lines	0/10 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)
Improved ≥ 1 line	2/10 (20%)	4/10 (40%)	7/10 (70%)	8/10 (80%)
No Change	8/10 (80%)	5/10 (50%)	3/10 (30%)	2/10 (20%)
Lost ≥ 1 line	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)
Lost ≥ 2 lines	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)

The VisAbility™ Implant System is an investigational device and is limited by United States law to investigational use.

Data through January 6th, 2016

Clinical Site Trial Summary

- Monocular Results (Primary Eyes):
  - 100% achieved DCNVA 20/40 (J3) or better at 6 months
  - Average of 3.4 lines of improvement
- Binocular Results:
  - 100% achieved UCNVA 20/40 (J3) or better at 6 months
  - Average of 3.8 lines of improvement
- **Preliminary Findings:**
  - Significant improvement in near vision
  - Effect increases over time
  - The greater the presbyopia… the greater the effect

The VisAbility™ Implant System is an investigational device and is limited by United States law to investigational use.

Inlay Options for Presbyopia Conclusion

- The future is bright
- There will be a number of options that do no involve invasive lens replacement surgery
- By looking *Closely* at the clinical results, we will be able to *See* which are the best options

- Thank you for your attention
- whitman@keywhitman.com