ASCRS ♦ ASOA Symposium & Congress

Technicians & Nurses Program

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

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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*

Through-Focus Imaging

Multifocal IOLs: Quality of Vision

Binocular Mesoic Contrast Sensitivity with Glare
Visit 3 (30-60 days)


Images in Focus

Dominant Eye

Non-Dominant Eye

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.

Presbyopia
If You Have Difficulty...

- 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

Raindrop Near Vision Inlay

Mechanism of Action

Preop Non-dominant Eye

After Raindrop

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)
- 97% are 20/25 or better at near, mean UNVA ~20/20

Improvement at Near (Inlay Eye)
- Average gain: 5 lines

Uncorrected Binocular Visual Acuities
- % of Subjects

Eye Chart Performance (Inlay eye)
- Gain 5 Lines Near
- Gain 2+ Lines Inter.
- Lose ~1 Line - Distance
- Zero Line Loss Binocularly

Subject Satisfaction

- Somewhat satisfied or better
- Somewhat dissatisfied or worse

Preop | 12M (with correction) | 12M (with Inlay)

Appearance: 99% satisfaction with appearance, 93% satisfaction with correction

Overall Correction

N = 325

Raindrop in Pseudophakes

Monofocal | Toric | Accommodating

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: 0.19 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)

Subject Satisfaction

High satisfaction for pseudophakic subjects (100%)

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 (5-11 µ)
- 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% of 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

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 - a 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

Binocular Mesopic Contrast Sensitivity

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

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

**Procedure**

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

**Uncorrected Near Acuity - Op Eye**

- 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

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 UCVA 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 = 20/35 to 20/80)

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

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
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
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