

## The Surgical Correction of Presbyopia Using Non-refractive Hydrogel Corneal Inlay

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## Raindrop Course Agenda

- Introduction: Professor Steinert
- Method of Action: Professor Tchah
- Patient Selection, Surgical Pearls: Professor Cochener
- FDA Study Update (1 year): Professor Steinert
- Complications Management: Enrique Barragan, MD
- Questions
- Closing Remarks: Professor Steinert

## Refractive Range and Mechanism of Action: Raindrop® Near Vision Inlay

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 \*CAUTION: Investigational device. Limited by Federal (United States) law to investigational use.

## Raindrop® Near Vision Inlay

## Simulations Confirm Near Range

Emmetropic Non-Accommodating Model Eye With Minus Trial Lenses:

Near Images: 3.5 mm Pupil

Near Rx: 1.0 D (100 cm)    2.0 D (50 cm)    2.5 D (40 cm)    3.0 D (33 cm)    4.0 D (25 cm)

## Simulations At Distance

Emmetropic Non-Accommodating Model Eye With Minus Trial Lenses:

Distance Images: 3.5 mm Pupil

Preop MSE: -0.5 D    0.0 D    +0.5 D    +1.0 D    +1.5 D

### Clinical Comparison of Patients Implanted with Clear Hydrogel Corneal Inlay Under Various Femtosecond Laser Flap Thicknesses

Prof. Beatrice Cochener, MD, PHD

**Financial Disclosure: Clinical Investigator**  
 ReVision Optics, Inc.  
 Zeiss, Alcon, Physiol, Thea, Allergan

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### Raindrop® Near Vision Inlay

- ◆ Physiologically transparent corneal inlay
  - Hydrogel
- ◆ Biocompatible
  - Similar water content
  - Same refractive index as the cornea
  - Excellent nutrient flow
- ◆ Small
  - 2.00 mm diameter, ~30 µm thick
- ◆ Easily inserted under a femtosecond laser corneal flap
  - Centered on the light constricted pupil
- ◆ Removable

### Why Particularly Concerned with Ocular Surface?

- ▶ Related to the concept
  - ▶ Femto flap of 33% of central corneal thickness (CCT)
  - ▶ +/- combined to LASIK (concurrent)
  - ▶ Changes in corneal curvatures (asphericity) = induced effect expected from the inlay
- ▶ Related to the patients population
  - ▶ Older (> 40 years)
  - ▶ Commonly with MGD
  - ▶ Dry eyes?
    - ▶ Select patients with minimal to no dry eyes

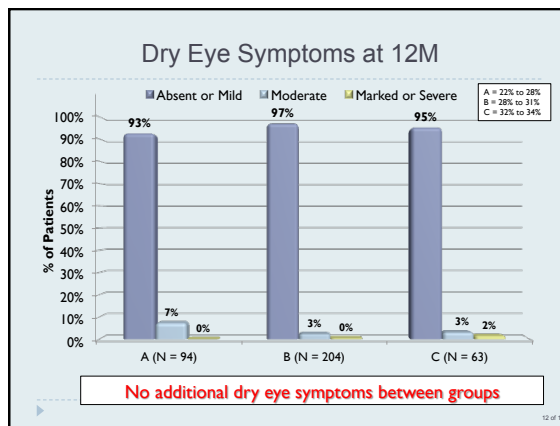
### Patient Information and Care

- ▶ Excellent corneal health always
  - ▶ Reduce/manage dry eye and Meibomian Gland Dysfunction (MGD) prior to surgery
- ▶ Visual improvements within the first few months postop
  - ▶ Initial acute myopia provides excellent uncorrected near
  - ▶ Distance vision will improve over time, but will fluctuate during the first month
- ▶ Compliance with Postoperative Regimen is critical
  - ▶ Supports a healthy ocular surface
  - ▶ Helps corneal healing process
  - ▶ Prevents interface inflammation

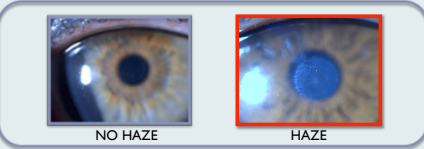
### Raindrop Inlay Surgery

- ▶ Non-refractive inlay (powerless) that changes the sphericity and asphericity at the center of the cornea
  - ▶ Additive technology
- ▶ Implanted under a femtosecond corneal flap
  - ▶ Minimum 150 µm flap
  - ▶ Minimum residual stromal bed 300 µm
- ▶ **Broad range of flap thicknesses**

**QUESTION:**  
 What is the impact of implanting the Raindrop® Near Vision Inlay shallower or deeper in the cornea?

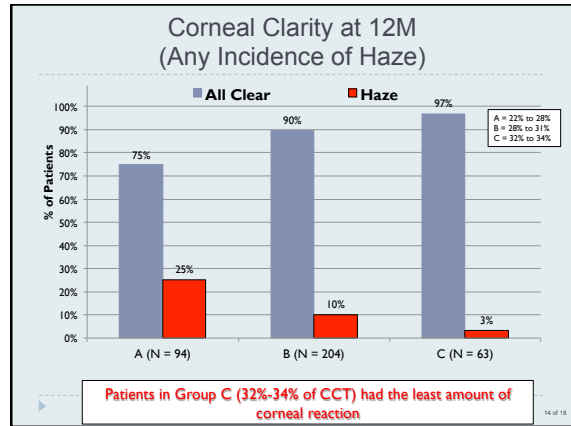


### Haze Diagnosis



- ▶ Slit lamp – use retro-illumination
- ▶ Diffuse haze covering mid-periphery and center of inlay
- ▶ Signs and Symptoms
  - ▶ Increase in central K power from previous post operative visits
  - ▶ Mild myopic shift (0.50 – 1.0 D)
  - ▶ Reduced near point of focus
  - ▶ Decrease in uncorrected distance visual acuity
  - ▶ Increased visual symptoms: glare, halos, ghosting

13 of 18



### Summary

**QUESTION**

- ▶ What is the impact of implanting the Raindrop Inlay shallower or deeper in the cornea?
  - ▶ Excellent visual acuities for all groups
  - ▶ Better than 91% satisfaction for all groups
  - ▶ Similar dry eye symptoms for all groups
  - ▶ Significantly lower corneal reaction when implanted deeper into the cornea

15 of 18

### Using a Transparent Hydrogel Inlay to Create a Profocal Shape Cornea: Clinical Trial Update

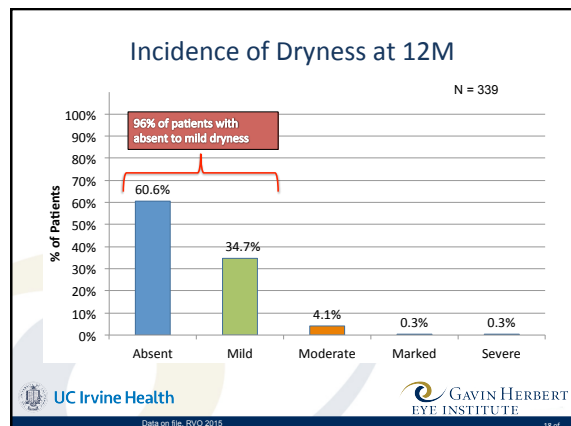
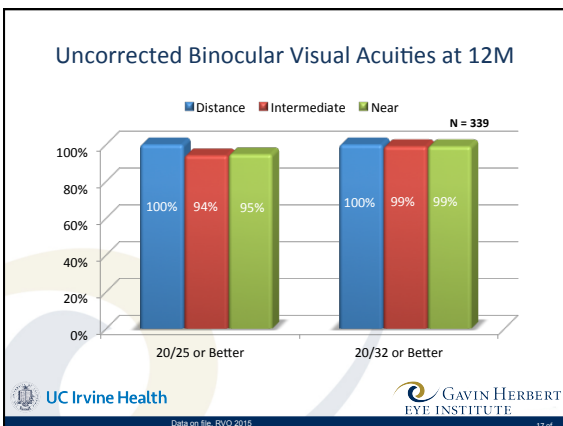
Financial Disclosure: Consultant to ReVision Optics, Medical Monitor of US FDA Trial

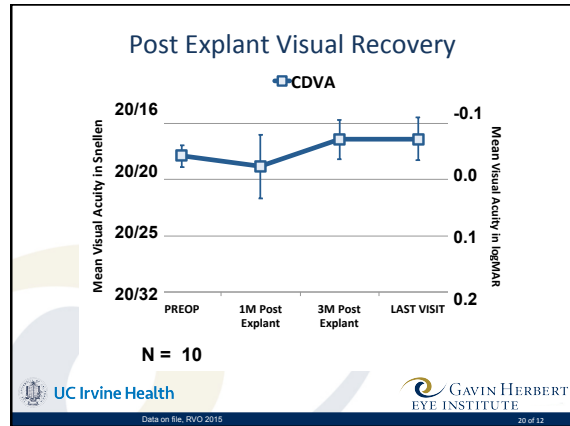
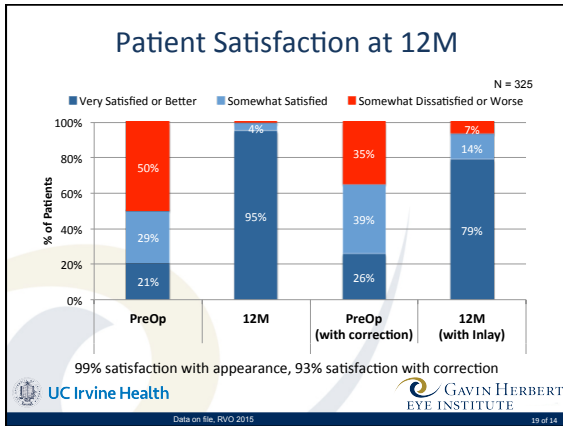
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16 of 18





- ### Summary
- Provides a full range of uninterrupted vision
    - ~94% of patients can see 20/25 or better at all distances
    - 81% of patients gained 4 or more lines for near
  - Stable refraction after surgery
    - ≥ 98% of patients with less than 1.0 D (MRSE) change at all time points
  - Minimal ocular dryness at 1 year
    - 96% with absent to mild symptoms
  - Great patient satisfaction
    - 99% satisfaction with appearance and 93% overall patient satisfaction
  - Inlay is removable
    - Refraction and visual acuity in eyes explanted returned to baseline
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- 21 of 12

### COMPLICATIONS MANAGEMENT

Enrique Barragan Garza, MD\*

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\* Dr. Barragan is a consultant for ReVision Optics, Inc.

22 of 18

- ### Critical Strategies for Raindrop Success
- Patient Selection**
    - Target low hyperopes for first cases
      - Easiest patients to please
    - Easy going personality
    - Realistic expectations
      - Understand what is achievable and what is not
      - Compromised distance vision in treated eye
      - May need readers for small print or longer reading
    - Normal cornea
      - No previous LASIK
      - Corneal thickness 480 μm to 600 μm
    - Healthy Eye
      - No dry-eye or MGD
      - Good visual system (no cataracts, no macular diseases)
- 23 of 18

- ### Raindrop: Critical Strategies
- Surgery**
    - Minimal manipulation leads to faster visual recovery
  - Postop Management**
    - Patient compliance is crucial for SUCCESS!
      - Postop medication and follow up visits:
        - Need to use steroids for 3 months, tears up to 1 year
        - Patient should return every 2-3 months during the first year
    - Maintain healthy ocular surface ALWAYS!
- 24 of 18

## Flap-related Complications

### Flap Complications

- Flap edema
  - Observation – assess inlay centration next day
- Striae
  - Same management as LASIK
- Flap Misalignment
  - Re-lift flap and align
- Epithelial Ingrowth
  - Same management as LASIK

### Raindrop Specific Complications

- Decentration (Early)
- Haze (Late)

25 of 18

## Inlay Centration

- Due to its mechanism of action, Raindrop is very forgiving to decentration
  - Decentration of 0.75 mm or less do not need repositioning
- Decentration is typically seen shortly after surgery, associated with
  - Excessive manipulation during surgery
  - Corneal (flap) edema at the end of procedure
  - Use of Brimonidine immediately after surgery
  - Eye rubbing

26 of 18

## Haze Management

- Medical Treatment
  - Strong steroid (Dexa-free 1%) for 1 month (Taper)
  - Mild steroid (Lotemax or FML) for 2 months (Taper BID/QD)
  - Treat aggressively concurrent associated factors (Dry eye, MGD, environmental factors, etc)
- Expected Outcomes
  - Central corneal steepening and/or myopic shift regress to pre-haze values
  - Haze covering the center of the inlay should regress to peripheral haze or complete clarity within a month

27 of 18

## Inlay Removal for Haze

- Chronic Haze
  - Corneal steepening and/or myopic shift remain after 3 month steroid treatment associated with haze
- Recurrent Haze
  - If clinically significant haze reappears anytime after the first treated occurrence

28 of 18