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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*Financial Disclosure: I receive travel support from ReVision Optics, Inc.
*CAUTION: Investigational device. Limited by Federal (United States) law to investigational use.

Simulations Confirm Near Range

Simulations At Distance

Raindrop® Near Vision Inlay

Preop Non-dominant Eye
3 Months Postop

Emmetropic Non-Accommodating Model Eye With Minus Trial Lenses:
Clinical Comparison of Patients Implanted with Clear Hydrogel Corneal Inlay Under Various Femtosecond Laser Flap Thicknesses

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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 vision
  - 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?

Dry Eye Symptoms at 12M

No additional dry eye symptoms between groups
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 postoperative 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

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

**Corneal Clarity at 12M**

*(Any Incidence of Haze)*

Patients in Group C (32%-34% of CCT) had the least amount of corneal reaction.

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

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

**Uncorrected Binocular Visual Acuities at 12M**

**Incidence of Dryness at 12M**
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

Critical Strategies for Raindrop Success

- **Patient Selection**
  - Target low hyperopes for first cases
  - Easiest patients to please
  - Easy going personality
  - Realistic expectations
    - Understood 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)

- **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!
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)

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

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

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