Profocal Cornea: Mechanism of Action of a Transparent Corneal Inlay and Clinical Implications

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*From data in Lombarde et al., Instituto Microcirugía Ocular de Barcelona.

**Raindrop® Near Vision Inlay**
- Transparent hydrogel corneal inlay
  - Similar water content and refractive index as the cornea
  - Biocompatible
  - Excellent nutrient flow
- Size
  - 2.00 mm diameter, ~30 microns thick
- Easily placed under a femtosecond laser corneal flap
- Thin edge allows cornea to lay flat and seal securely
- Removable

**Mechanism of Action: Profocal Cornea**
Epithelial remodeling over the inlay creates a Profocal cornea. Near vision is provided by the central region that has strongest curvatures. The curvature gradually reduces towards the periphery, naturally creating regions that provide intermediate and distance vision.

**Wavefront Measurements Reveal the Inlay's Postoperative Refractive Effect**
Inlay-induced anterior corneal surface change was derived from the difference between postop and preop wavefront measurements.

**Mean Refractive Inlay Effect: “Profocal Power Profile”**
N = 150
- Pupil Center
- Range of Power for near
- Axial power at a Radius
- Periphery: Returns to Unaffected Cornea
- Diameter Within Pupil (mm)
Photopic Pupil 3.5 mm Diameter

Percentage Area Within 3.5 mm Pupil

Zemax Ray-Trace Simulations:
A 3.5 mm Pupil
Preop Rx = +1.0 D

Distance
Postop (Inlay) Corrected
Uncorrected

Near (40 cm)
Preop Distance Corrected
Postop (Inlay) Corrected
Uncorrected

Using ray-trace (Zemax) in a finite eye model, we simulated letter charts to observe the dynamics of rays in order to understand the range of good near vision as a function of pupil size and spectacle defocus.

Clinical Outcomes with Raindrop Near VA (40 cm)
Monocular, Mean Uncorrected

Clinical Outcomes with Raindrop Intermediate VA (80 cm)
Monocular, Mean Uncorrected

Clinical Outcomes with Raindrop Distance VA (6 M)
Monocular, Mean Uncorrected

Mean Overall Satisfaction by Preop MRSE
Conclusion

- Raindrop creates a smooth steepening in the central cornea (Profocal cornea), which generates a gradient of power.
  - This smooth elevation provides clinically good near and intermediate visual acuities and high patient satisfaction.
Presbyopia Treatment Using a New Hydrogel Corneal Inlay with Concurrent LASIK Commercial Experience in High-Volume LASIK Clinics

Asian Experience
Professor Choun-Ji Joo, MD, PhD*

Co-Author:
Professor Yongwon Tchah, MD, PhD
Katsuei Yasuda, MD
Makoto Kitamura, MD, PhD

*Financial Disclosure: I am a consultant and receive travel support from Allure Vision Optx

Profocal Cornea
- Raindrop® Near Vision Inlay re-shapes the cornea by adding volume in the center
- Creates a Profocal cornea with more power in the center of the cornea (near zone), which gradually decreases towards the periphery (intermediate and distance zones)
- Induces mild myopia (approximately - 0.75 D)
  - Concurrent LASIK: target (± 0.75 D)

Clinical Setting
- High volume LASIK clinics in Asia
  - South Korea, Japan
  - Multicenter
    - 4 clinics in Korea
    - 5 clinics in Japan
  - Multisurgeon
    - 5 surgeons in Korea
    - 6 surgeons in Japan

Raindrop Patients
- Asian patients are more myopic preferring closer reading distance
- Unilaterally implanted Raindrop in the non-dominant eye with concurrent LASIK
  - Inlay refractive target + 0.25 D to + 0.75 D (decrease by 0.50 D if patient prefers closer reading distance)
  - Fellow eye: LASIK with target of plano
- Patients (N = 129)
  - Ages: 51.3 years (± 4.4)
  - GENDER: 64% Female, 36% Male

Preoperative Parameters: Inlay Eye

<table>
<thead>
<tr>
<th>Categories</th>
<th>Mean ± SD</th>
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<tbody>
<tr>
<td>Pupils (mm)</td>
<td>6.9 ± 1.3</td>
</tr>
<tr>
<td>Preop Pachys (μm)</td>
<td>536 ± 56</td>
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<tr>
<td>Flap Depth (μm)</td>
<td>151 ± 14</td>
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<td>Bed (μm)</td>
<td>348 ± 24</td>
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Stability of UVA

Patients achieve stability by 1 week
Near Visual Acuities at 3 months

Safety Profile
- 2 cases of mild strie
  - 1 central, 1 peripheral
  - Both resolving
  - At least visit UDVA: 1.0, 0.7
- 3 cases of moderate corneal haze and no severe haze (N = 125)
  - Appeared at 2-3 months postop
  - One due to patient noncompliance to steroids
  - No visual changes
  - Steroids were restarted – all events resolved

Summary
- Functional binocular visual acuities were achieved in Asian patient population
  - 20/25 binocular near
  - 20/16+ binocular distance
- Monocular distance vision is not greatly compromised
  - 65% are 20/40 or better UDVA
- Complications were low
  - Haze (2.4%), mild strie (3.6%)
- Raindrop is a safe and effective tool for treating presbyopia in the Asian patient population
CONCURRENT USE OF A HYDROGEL CORNEAL INLAY WITH LASIK TO PROVIDE FUNCTIONAL VISION IN PRESBYOPIES

Enrique Barragan MD
Arturo Chayet MD

Purpose

To investigate the safety and efficacy of implantation of the Raindrop® Near Vision Inlay (ReVision Optics, Inc., Lake Forest, CA) into the non-dominant eye of ametropic presbyopes concurrently with bilateral LASIK treatment.

Introduction

Method of Action

<table>
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<th>Hyperope</th>
<th>Myope</th>
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Trace™ wavefront aberrometry showing central near area (red) and smooth transition to intermediate and distance in both hyperopes and myopes.

Raindrop Implantation with Concurrent LASIK

Methods

- Two sites, prospective, non-randomized clinical study
- Inlay implanted in non-dominant eye concurrently with bilateral LASIK
- Hyperopes (n = 46), Myopes (n = 37)
- Prop. MRSE
  - Hyperopes: +1.77 D (0.75 to +2.75 D), Mean Age 51 (range 44-60)
  - Myopes: +2.05 D (0.55 to +0.22 D), Mean Age 50 (range 45-59)
- Measured outcomes at 6 Months
  - ETDRS Visual Acuity (Monocular and Binocular)
  - Near, Intermediate & Distance
  - Self-reported visual symptoms
  - Patient Satisfaction

Monocular Uncorrected Near Visual Acuity

<table>
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<th>Percentage of Patients</th>
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Mean uncorrected near vision at 12 months:

- Hyperopes: 0.87 (2023)
Conclusion

- Significant improvement in near, intermediate and distance vision with the Randpac Near Vision Inlay
- Consistent near vision outcomes
  - Average UNVA in the implanted eye is better than 20/25 (0.8) in both hyperopes and myopes.
  - Binocularly, 97% of hyperopes & 97% of myopes achieved 20/25 (0.8) or better at 12M.
- There is no loss of distance vision
  - Binocular UVA: 100% of hyperopes & 100% of myopes achieved 20/20 (1.0) or better at 12M.
- Very low visual symptom complaints at 12M (i.e. hazes, glare, and dryness)
- High post-op patient satisfaction with outcomes confirms that Randpac is a good solution for all presbyopic patients, independent of refractive error.
Clinical Outcomes in Patients Implanted with Transparent Hydrogel Corneal Inlay Under a Thick Femtosecond Laser Flap

Prof. Beatrice Cochener, MD, PHD

Financial Disclosure: Clinical Investigator
Revisen Optics, Inc.
Zeiss, Acton, Physioll, Thea, Allergan

Why Raindrop Inlay is Particularly Concerned with Ocular Surface?

- Related to the concept
  - Femto flap of 33% of central corneal thickness (CCT)
  - (minimal 150 microns)
  - +/− combined to LASIK (concurrent)
  - Changes in corneal curvatures (asphericity) = induced effect expected from the inlay

- Related to the patients population
  - > 40 years
  - Commonly concerned by MGD
  - Dry eyes?
    - Selection patients with minimal to no dry eyes

Patient Information and Care

- 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

- Excellent corneal health always
  - Reduced manage dry eye and Meibomian Gland Dysfunction (MGD) prior to surgery

Postoperative Management

- Goal: Optimize corneal healing by maintaining a healthy ocular surface

- Steroid (no BAK) regimen for 3 months
  - Strong steroid (Dexa-free) for 1 month taper, followed by
  - Weaker steroid (FXL) for 2 months
  - Taper BID/OD

- Antibiotic (no BAK) for 1 week

- Preservative-free Tears as needed during the whole time

- Post

Method

- Prospective, multicenter, series of cases
- Raindrop Inlays were implanted in the non-dominant eye of emmetropic
- Raindrop was implanted under a femtosecond flap with a targeted depth of 33% of the CCT

- Clinical outcomes:
  - Visual acuities (near, intermediate, distance)
  - Visual and ocular symptoms (glare, halos, dryness, etc.)
  - Aberrations, mild, moderate, masked, and severe

Clinical Cohort

- N = 30
- Mean Age: 50.5 y/o (range: 44 to 61 y/o)
- Mean MRSE: +0.49 D (range: -0.25 D to +1.37 D)
- Mean CCT: 525.1 µm (range: 501 to 552 µm)
- Femto flaps achieved: 33.6% (176 µm)
  - Range: 32% (168 µm) to 38% (204 µm)
89% of patients are 20/20 by 1 month postop

96% of patients are 20/20 by 1 month postop

By 3 months after implantation, all means are better than 20/25

Low ocular discomfort at 1 year, similar to LASIK

Low visual symptoms at 1 year
Conclusion

- Near and intermediate vision improved from preop
  - 89% of eyes were 20/25 UNVA by 1 month
  - 96% of eyes were 20/32 UNVA by 1 month
- At 3M, all eyes were 20/25 or better for near, intermediate, and distance
- Visual and ocular symptoms at 1 year were low, consistent with LASIK
- Careful selection of patients preop and aggressive management postop resulted in excellent clinical outcomes in patients implanted with Raindrop under thick femtosecond flap

THANK YOU!
Shaping a Profocal Cornea Using a Hydrogel Inlay: Clinical Trial Update

Roger F. Steinert, MD
Intraocular Lens Professor and Chair
Professor of Biomedical Engineering
Director, Gavin Herbert Eye Institute
University of California, Irvine

Why Raindrop?
1. Surgical technique similar to LASIK
2. Provides great near results early in the postop with minimal compromise in distance vision
3. Consistent Visual Outcomes Independent of Age
   - One Inlay Fits All
4. Patients can function during the day and at night
5. Does not induce unwanted phobic phenomena
6. Happy Patients – Excellent Patient Satisfaction
7. Removable

US FDA IDE Study
- Multicenter, prospective, non-randomized clinical study
  - Surgery ONLY in non-dominant eye
- Emmetropes Only (-0.50 to +1.00 D MRSE)
- Outcomes reported:
  - Visual Acuities - Near (40 cm), Intermediate (60 cm), Distance (4 m)
  - Standardized ETDRS charts, consistent luminance
  - Patient satisfaction survey (NEI-RIQL Questionnaire)
- 1 year results:
  - 180 patients
  - Mean age 50.6 years (range: 41-64 years)
  - MRSE -0.24 D (range: -0.50 to +1.00 D)

1. Surgical Technique Similar to LASIK

Video Courtesy of Jeff Whitman, MD

2. Uncorrected Monocular Visual Acuities (Inlay Only)

Monocular Data at 1 Year - Implanted Eye Only
93% are 20/20 or better at near, 85% are 0.6 or better at distance

2. Uncorrected Binocular Visual Acuities - 12 Months

93% are 20/20 (0.6) or better at all distances
3. Effect of Age and Refraction on Near Vision

Consistent performance independent of age or residual refractive error

4. Night Driving Performance

93% of patients have little to no difficulty driving at night, scores are similar to preop values

5. Low Incidence of Unwanted Symptoms

At 1 year, there are low reports of glare and halos (Moderate or worse)

5. Low Incidence of Dryness

Consistently low reports of ocular dryness from 1M to 1 year (Moderate or Worse)

6. 94% Patient Satisfaction

94% of patients are satisfied with Raindrop at 1 Year

7. Removable

- N = 195

- Four patients were explanted:
  - One due to mild haze and complaints of mild glare and halos
  - 6M post explant: BCVA returned to preop values
  - One due to recurrent haze
  - 6M post explant: cornea was clear, BCVA near baseline
  - One due to binocular imbalance, fellow eye was hyporeopic
  - 1 week post explant: UDVA was 20/20
  - One due to patient request
  - Patient moved out of state and did not want to continue with the study
  - 1M post explant: BCVA returned to preop values
Summary – Why Raindrop?
1. Surgical technique similar to LASIK
2. Provides a full range of uninterrupted vision
   - 93% of patients can see 20/25 or better at all distances
3. Consistent near outcomes across all ages
4. Patients can function at night
   - Night driving is not an issue
5. Minimal symptoms at 1 year
   - Minimal complaints of dryness (6%) halos (6%) and glare (3%)
6. 94% patient satisfaction
7. Removable
   - Vias return to baseline values