Functional Range of Vision with a Profocal Shape Changing Corneal Inlay

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*CAUTION: Investigational device. Limited by Federal (United States) law to investigational use.
Presbyopia Correction
What Do Patients Expect?

- Unaided Functional Range of Vision
  - Distance
  - Intermediate
  - Near

- Good Quality of Vision
  - Contrast Sensitivity
  - Absence of Unwanted Visual Phenomena

- Reversibility
Options for Presbyopia Correction

- Monovision
  - Difficult adaptation
  - Loss of depth perception

- Multifocality
  - Known side effects (halo, glare, loss of contrast)
  - Lack full range of vision

- Alternative – treat with a technology that delivers near and intermediate without compromising distance vision
Raindrop Near Vision Inlay

- Raindrop is a hydrogel corneal inlay that is placed under a 1/3 central corneal thickness femtosecond flap (minimum 150 microns)
- Centered on the light constricted pupil
- Profocal cornea
  - Creates a power gradient with more power in the center of the cornea (near), which gradually decreases (intermediate) towards the periphery (distance)
Purpose

- To determine the range of optimal preoperative refractive error that results in excellent visual outcomes in patients implanted with the Raindrop Near Vision Inlay without concurrent LASIK correction.
Methods

- 188 subjects implanted with Raindrop in the non-dominant eye as a sole solution for presbyopia
  - Preoperative MRSE: **-0.50 to +1.50 D**
  - Preoperative Cylinder: 0.75 D or less
  - No concurrent LASIK

- Subjects were divided into 4 groups depending on their preoperative MRSE:
  - -0.50 to 0.00 D (n=57)
  - +0.25 to +0.50 (n=58)
  - +0.75 to +1.00 D (n=50)
  - +1.25 to +1.50 D (n=23)
Methods

Parameters analyzed:

- Mean monocular VAs (Uncorrected):
  - Near (40 cm)
  - Intermediate (80 cm)
  - Far (6M)
- Patient satisfaction
- Visual task performance and symptoms (not shown here)

Criterion for Excellent VA
Unaided visual acuity of 0.14 logMAR or better
(~ 20/25 or better on ETDRS chart)
Mean Monocular UNVA by Preop MRSE

Optimal Zone: at least -0.50 D to +1.50 D
Mean Monocular UNVA by Age

No influence of age therefore inlay effect *not* related to residual accommodation
### Mean Monocular UIVA by MRSE

<table>
<thead>
<tr>
<th>MRSE Range</th>
<th>Preoperative</th>
<th>3 Months</th>
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<tbody>
<tr>
<td>-0.50 to 0.00 D</td>
<td>57</td>
<td></td>
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</tbody>
</table>

**Optimal Zone:** at least -0.50 D to +1.50 D
Mean Monocular UDVA by Preop MRSE

Optimal Zone: +0.25 D to +1.25 D
Mean Overall Satisfaction by Preop MRSE

Overall satisfaction more strongly influenced by near and intermediate
Summary Emmetrope Experience

- Raindrop Near Vision Inlay provides functional vision and patient satisfaction across a wide range of pre-op refractive errors without LASIK

- Patients with pre-op MRSEs between +0.75 D and +1.50 D show an improvement in uncorrected vision at all distances

- In subjects that require a concurrent LASIK procedure, a target refraction of +0.75 D is suggested in order to optimize visual outcomes