CONCURRENT USE OF A HYDROGEL CORNEAL INLAY WITH LASIK TO PROVIDE FUNCTIONAL VISION IN PRESBYOPIES

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*CAUTION: Investigational device. Limited by Federal (United States) law to investigational use.
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.
iTrace™ 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 = 45), Myopes (n = 37)
- Preop MRSE
  - Hyperopes: +1.77 D (+0.75 to +2.75 D); Mean Age 51 (range 44-60)
  - Myopes: -2.36 D (-5.25 to -0.25 D); Mean Age 50 (range 46-59)
- 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

Mean uncorrected near vision at 12 months

Hyperopes 0.87 (20/23)
Excellent binocular uncorrected visual acuities at all distances.
Monocular Uncorrected Near Visual Acuity

Mean uncorrected near vision at 12 months
Myopes: 0.95 (20/21)
Excellent binocular uncorrected visual acuities at all distances
Visual Symptoms at 12 months

Low visual symptoms complaints at 12 months

- Hyperopes
  - N=41

- DRYNESS: 7%
- GLARE: 0%
- HALOS: 2%

Percentage of Patients

Moderate or Worse

N=41

Low visual symptoms complaints at 12 months
Low visual symptoms complaints at 12 months
Results

Overall Patient Satisfaction with Outcome at 12M

High overall satisfaction rates

*One myopic patient was dissatisfied with distance vision
Conclusion

- Significant improvement in near, intermediate and distance vision with the Raindrop 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, 90% of hyperopes & 97% of myopes achieved 20/25 (0.8) or better at 12 M

- There is no loss of distance vision
  - Binocular UDVA, 98% of hyperopes & 100% of myopes achieved 20/25 (0.8) or better at 12 M

- Very low visual symptom complains at 12M (i.e. halos, glare, and dryness)

- High post-op patient satisfaction with outcomes confirms that Raindrop is a good solution for all presbyopic patients, independent of refractive error