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Hydrogel Corneal Inlay to Treat Pseudophakic Presbyopia

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Financial Disclosure: Drs DB Tran, Chayet and Barragan are consultants for RVO. Dr. Hai-Yen Tran is a clinical Investigator for RVO

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

Surgical Correction of Presbyopia in Pseudophakes

- Monovision
  - Difficult adaptation – imbalanced vision
  - Loss of depth perception
- Presbyopia Correcting IOLs
  - Halo, glare, loss of contrast
  - Some lack full range of vision
- Potential Alternative – treat with a technology that improves near and intermediate without compromising distance vision or inducing visual symptoms

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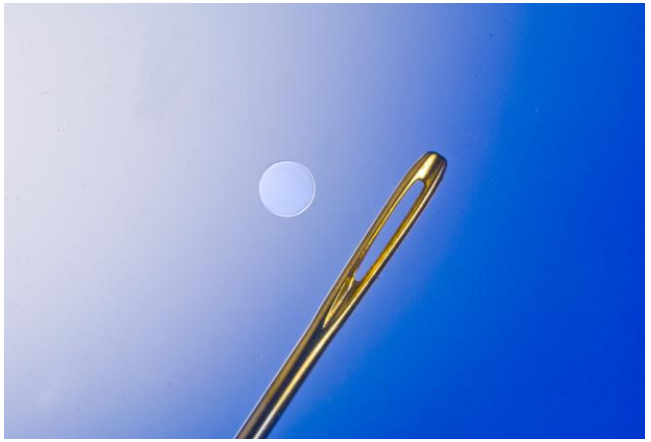
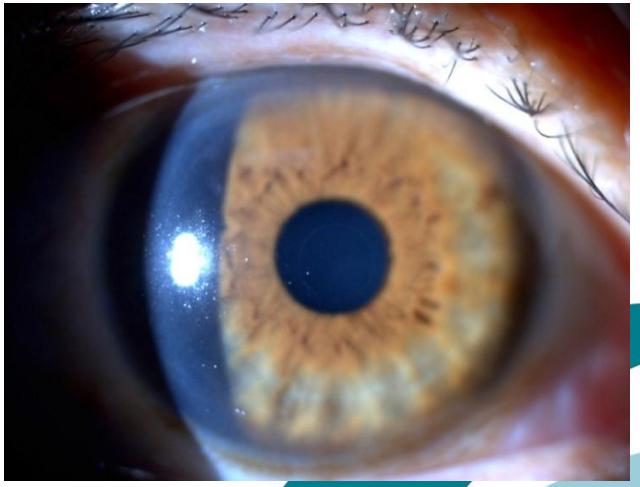
Raindrop® - What is it?

- Physiologically transparent corneal inlay
  - Hydrogel
  - 99.7% light transmittance
- Biocompatible
  - Similar water content and refractive index as the cornea
  - Excellent nutrient flow
- Small
  - 2.00 mm diameter, ≈30 microns thick
- Easily delivered under a femtosecond laser corneal flap
  - Thin edge allows cornea to lay flat and seal securely
- 100% Removable





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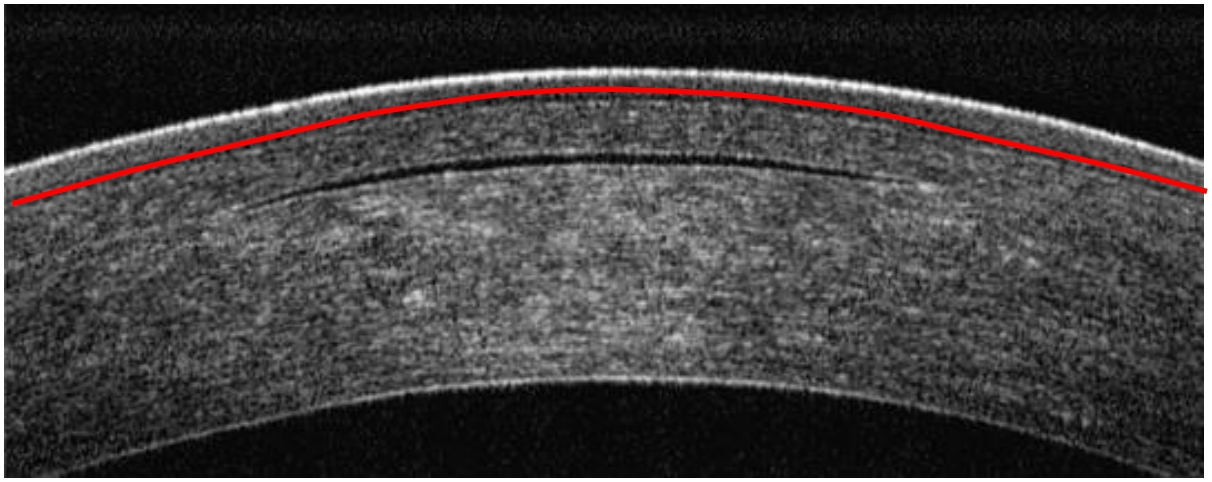
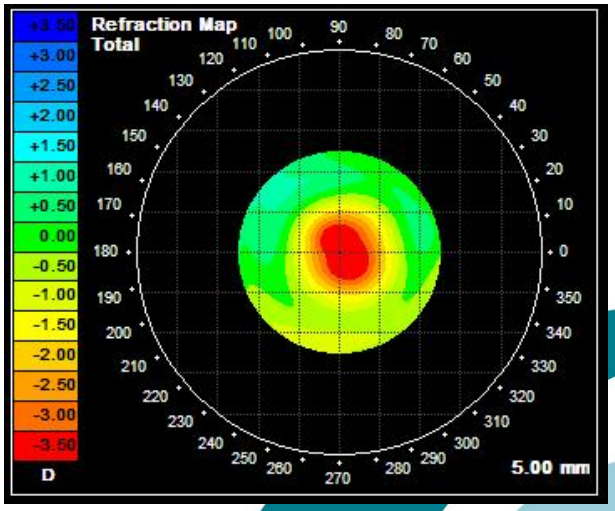
Mechanism of Action
Profocal Cornea

Epithelial re-modeling over the inlay creates a Profocal cornea with near refractive power centered over the pupil and gradually transitioning to intermediate and distance vision out to the periphery





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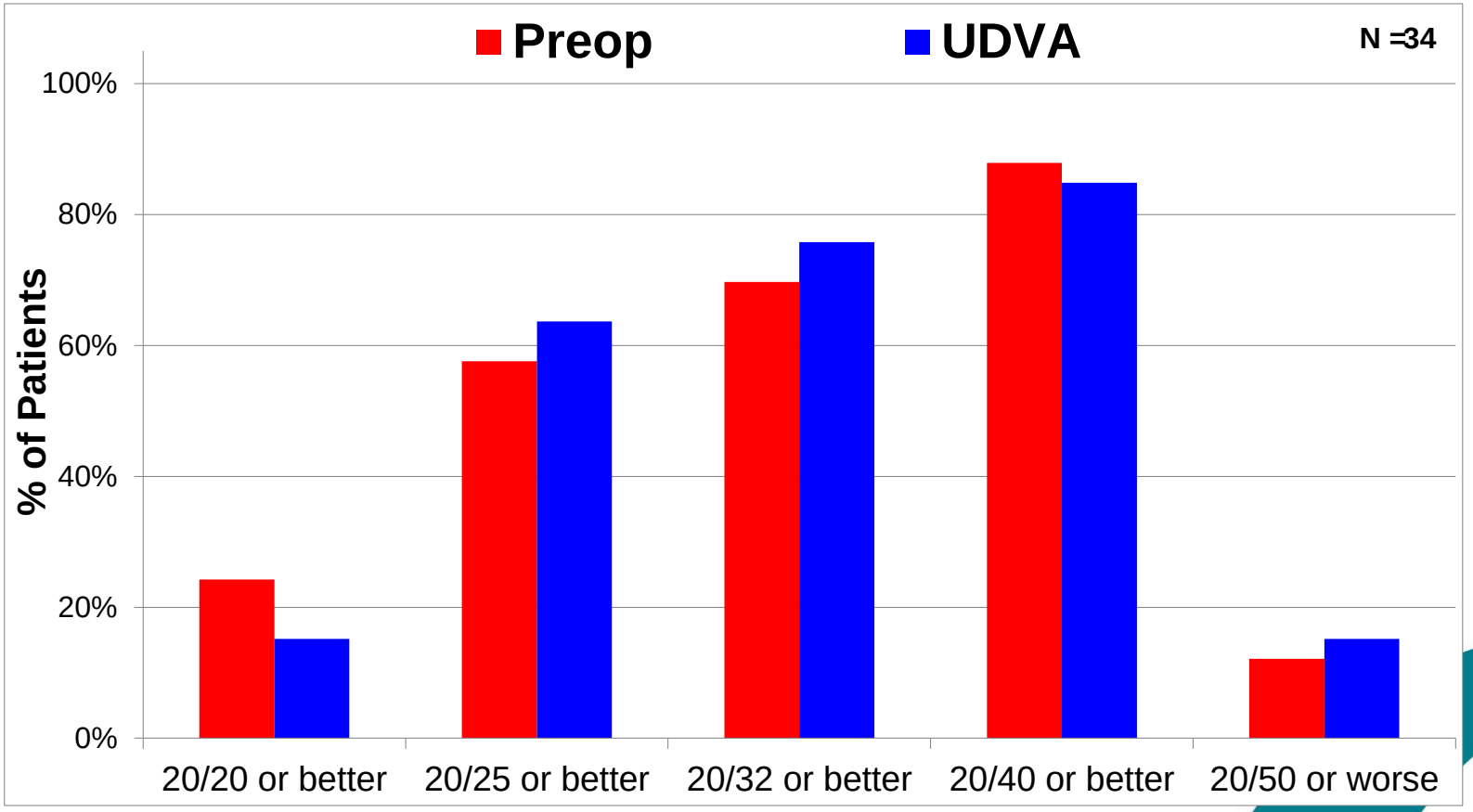
Purpose & Methods

- **Purpose**
  - To assess visual function in pseudophakic patients treated with a shape-changing hydrogel corneal inlay (Raindrop)

- **Methods**
  - Raindrop Inlays were implanted in the non-dominant eye of 35 patients previously implanted with monofocal IOLs
    - 13 subjects were also treated with concurrent LASIK
    - Mean: Age 51.0 (range: 27 to 77 years)
    - PreOp Mean MRSE: 0.09 D (range: -1.12 to 1.00 D)
    - PreOp Mean Add: +2.44 D (range: 2.00 to 2.50 D)
  - Outcomes at last available visit (Minimum 3 Months)
    - ETDRS visual acuities
    - Visual symptoms
    - Patient satisfaction

Monocular Uncorrected Distance VA

Inlay Eye Only



Uncorrected distance visual acuity remains stable after inlay implantation.

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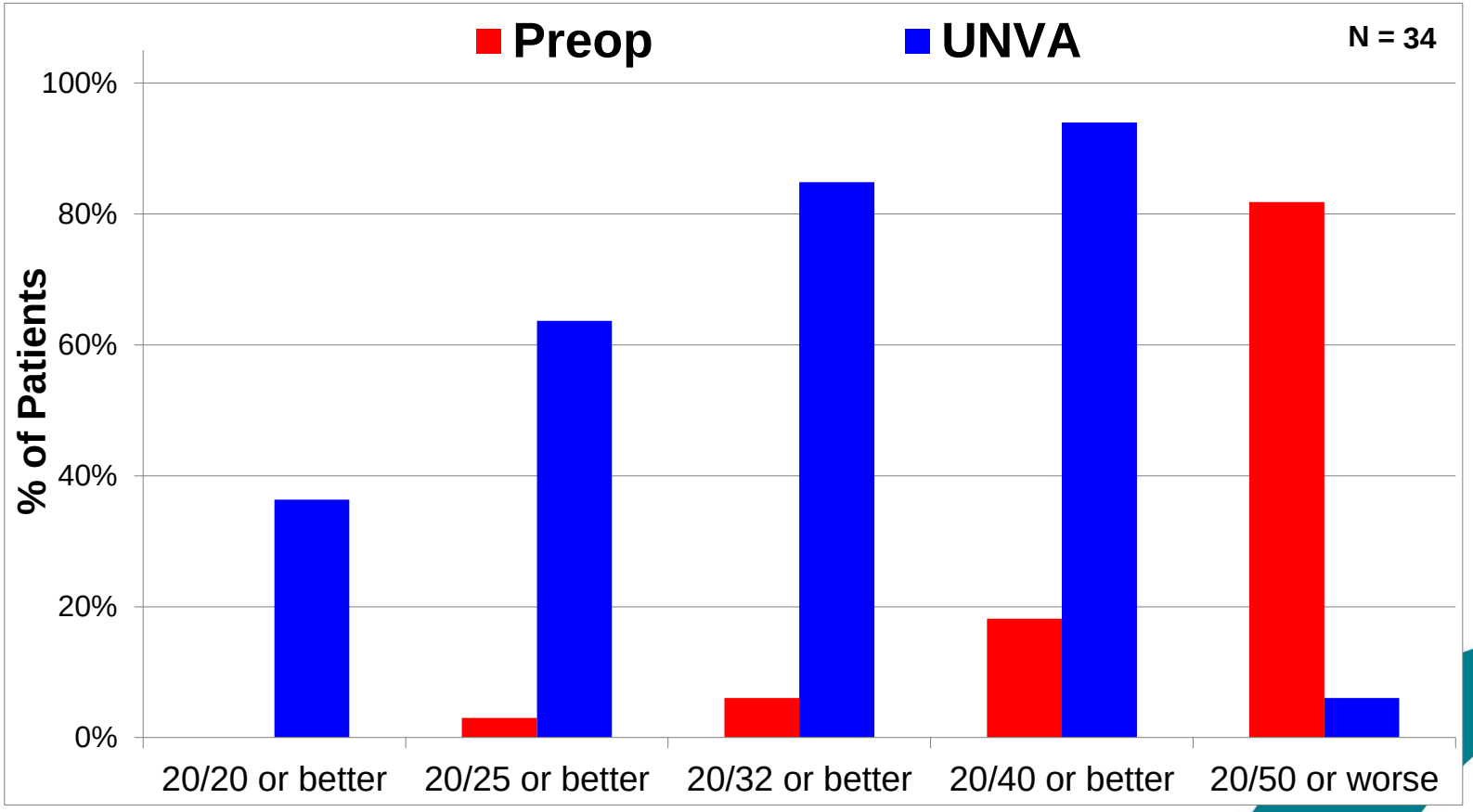
Monocular Uncorrected Near VA

Inlay Eye Only



85% of patients are 20/32 or better for near

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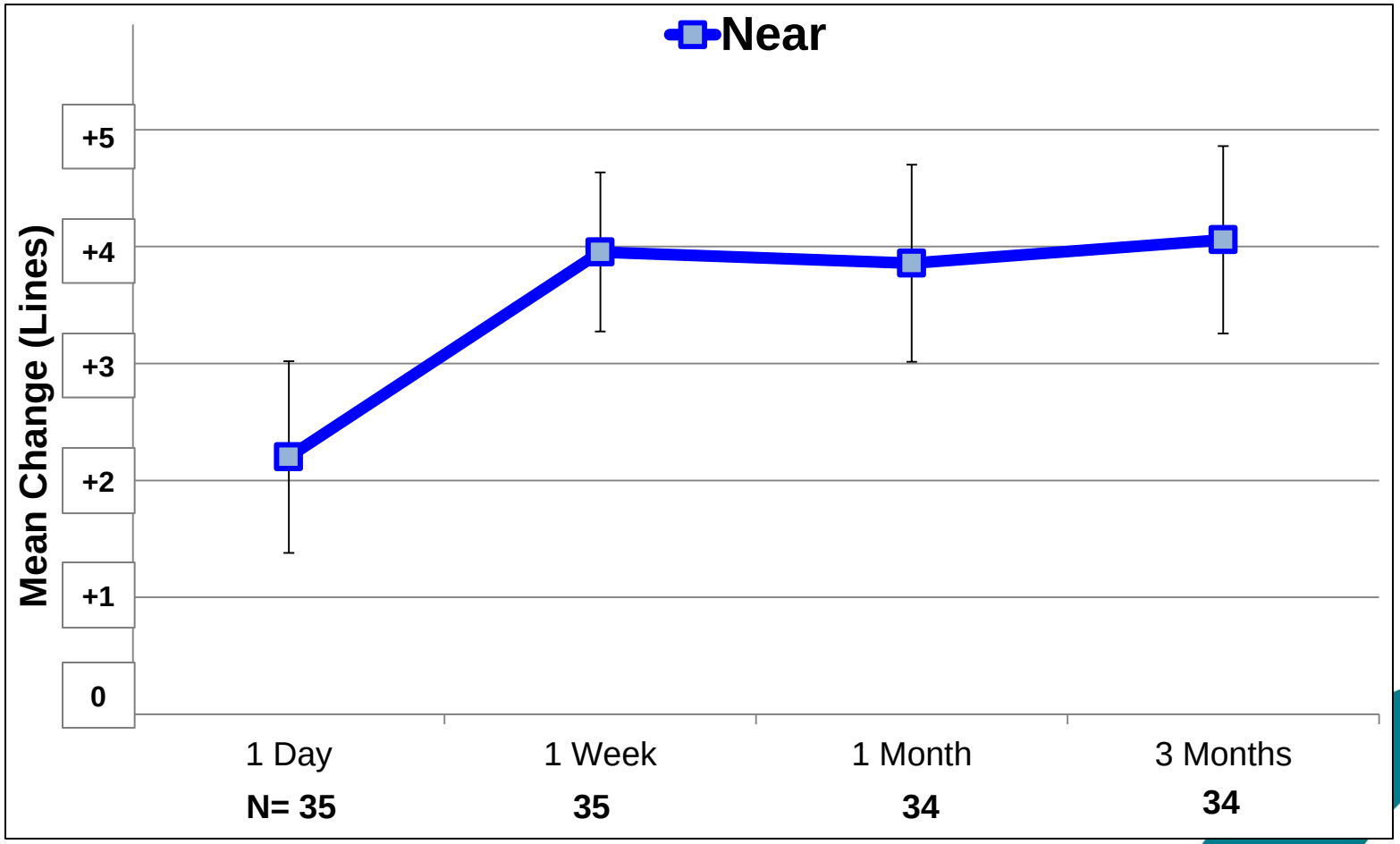
Lines of Near Vision Gained (Average, 95% CI)



Stable improvement in near vision (average gain is 4 lines over preop)

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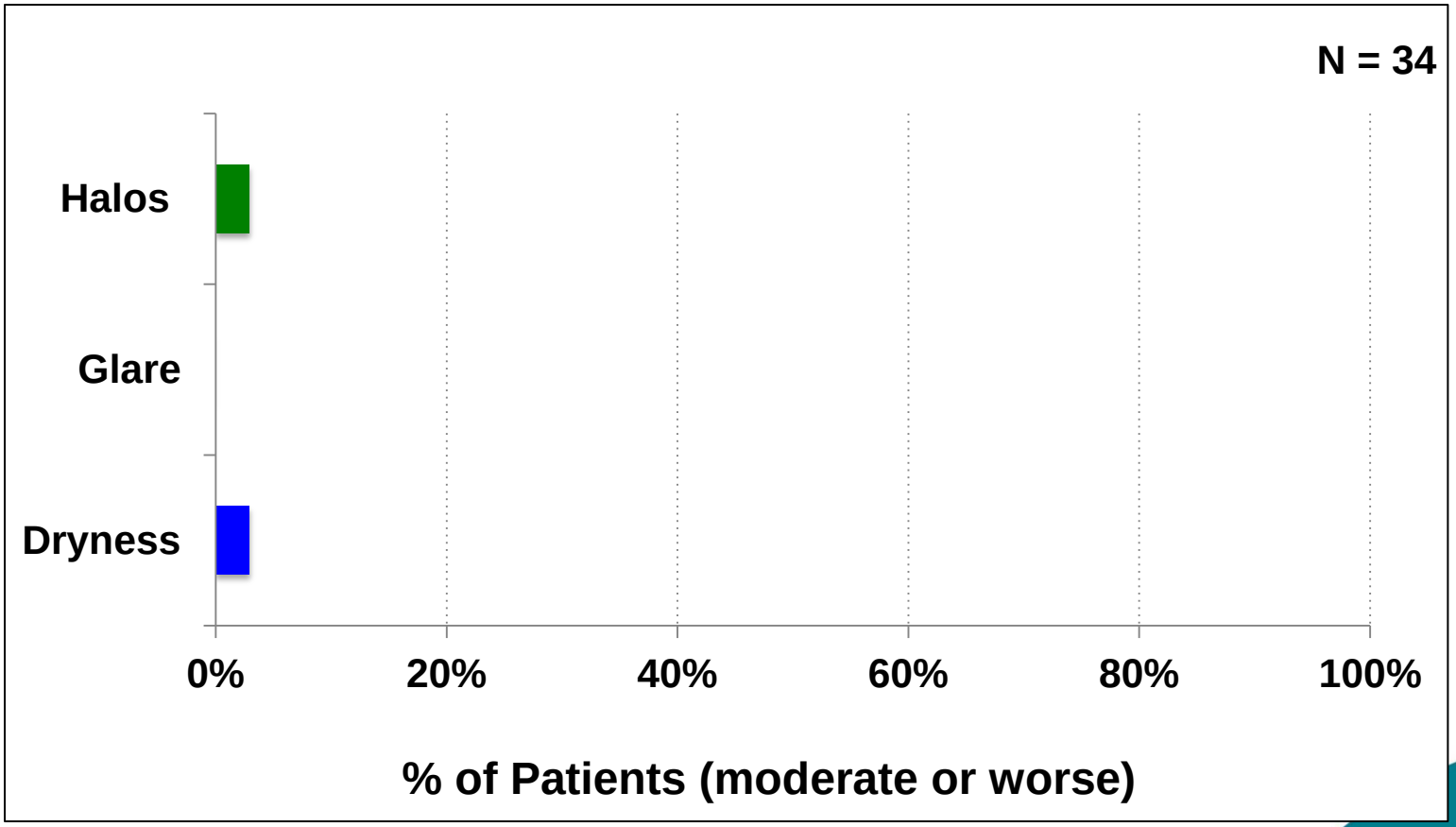
Visual Symptoms



Minimal induction of symptoms by the Profocal Cornea created by Raindrop

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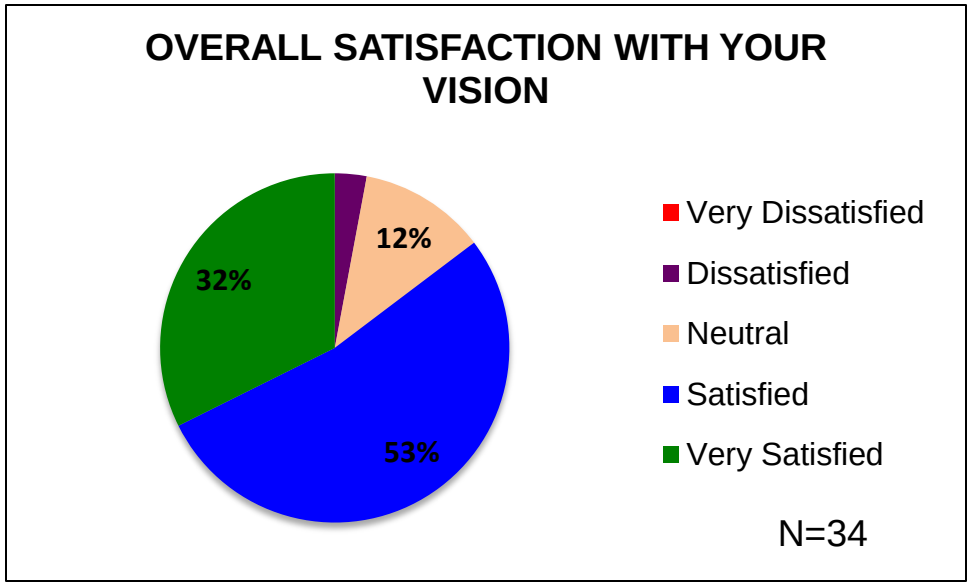
Overall Patient Satisfaction



Excellent satisfaction scores

Only one patient was dissatisfied at the 3 month follow-up visit

- Patient still needs reading glasses for near

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Complications

- 3 cases of haze
  - All treated with steroids
    - 1 resolved completely
    - 2 were diagnosed at 3M, have not yet returned for follow up visit

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Conclusion

- Raindrop changes the shape of the cornea producing a consistent power gradient (Profocal Cornea)
- This shape change improves near vision significantly
  - Average 4 lines of vision gained
- Minimal compromise in distance vision
  - In this cohort on average there was no compromise to uncorrected distance VA
  - Advantage vs monovision
- Minimal incidence of glare and halos
  - Advantage vs multifocal IOLs
- Excellent patient satisfaction confirms that Raindrop is a valid alternative for the correction of presbyopia after cataract surgery

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THANK YOU
FOR
YOUR ATTENTION

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