Improving Visual Acuity in Accommodating IOL Patients with a Corneal Inlay

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The KAMRA Inlay is not approved for use in the United States and is considered an investigational device.

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Purpose

- To evaluate the effectiveness of corneal inlay (Kamra Inlay, Acufocus) implantation to improve near vision in patients previously implanted with an accommodating IOL (Crystalens, Bausch and Lomb).

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Methods

- Prospective, single center clinical trial
- The corneal inlay was implanted in the non-dominant eye after flap creation with a femtosecond laser
- Uncorrected and best-corrected visual acuities were measured pre-inlay and up to 9 months for:
  - Near
  - Intermediate
  - Distance
- Subject satisfaction and visual symptoms were measured using a subjective questionnaire

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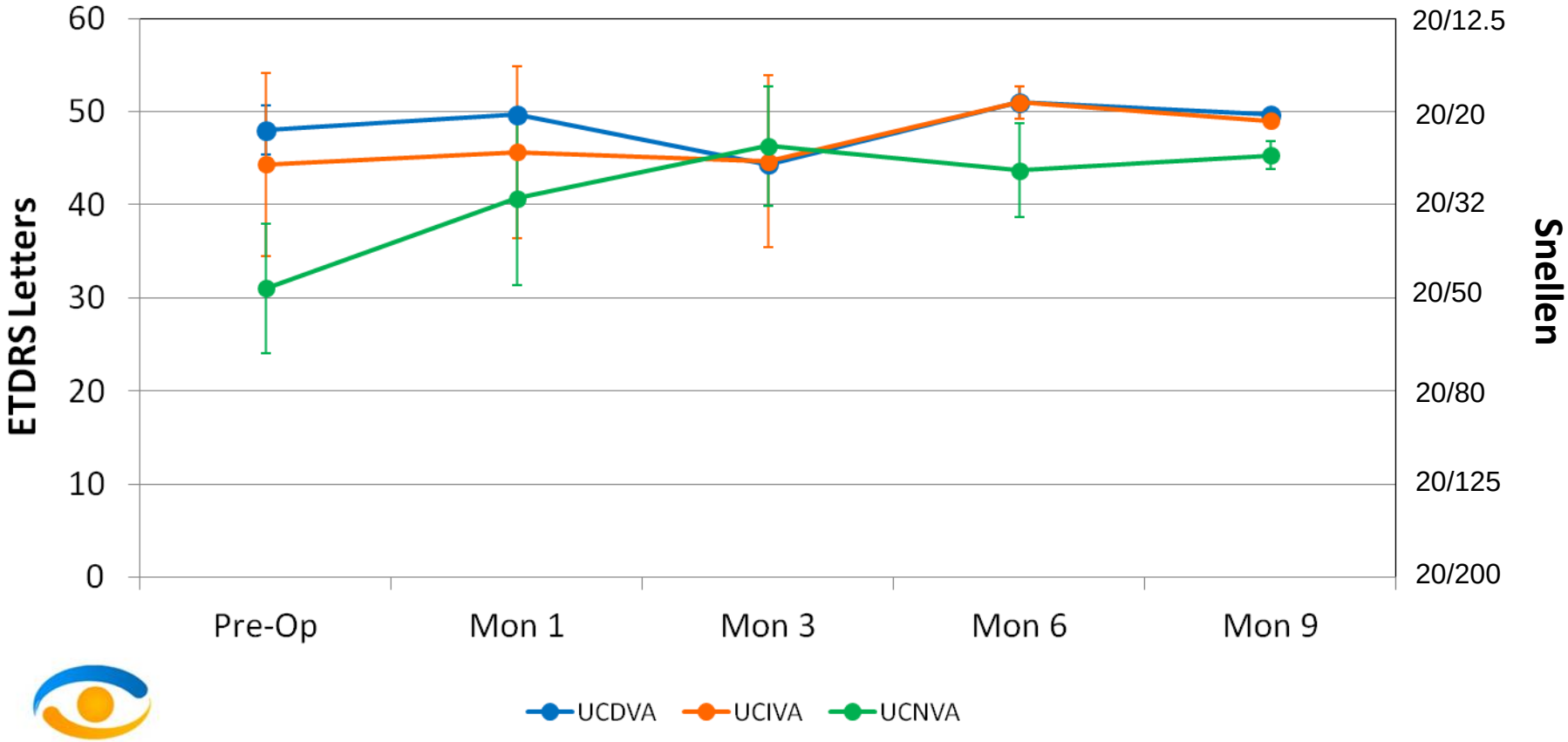
Implanted Eye Uncorrected Vision

- Mean UCNVA improved from 20/50 pre-inlay to 20/25 post-inlay at 9 months (Paired t-test p value=0.05)



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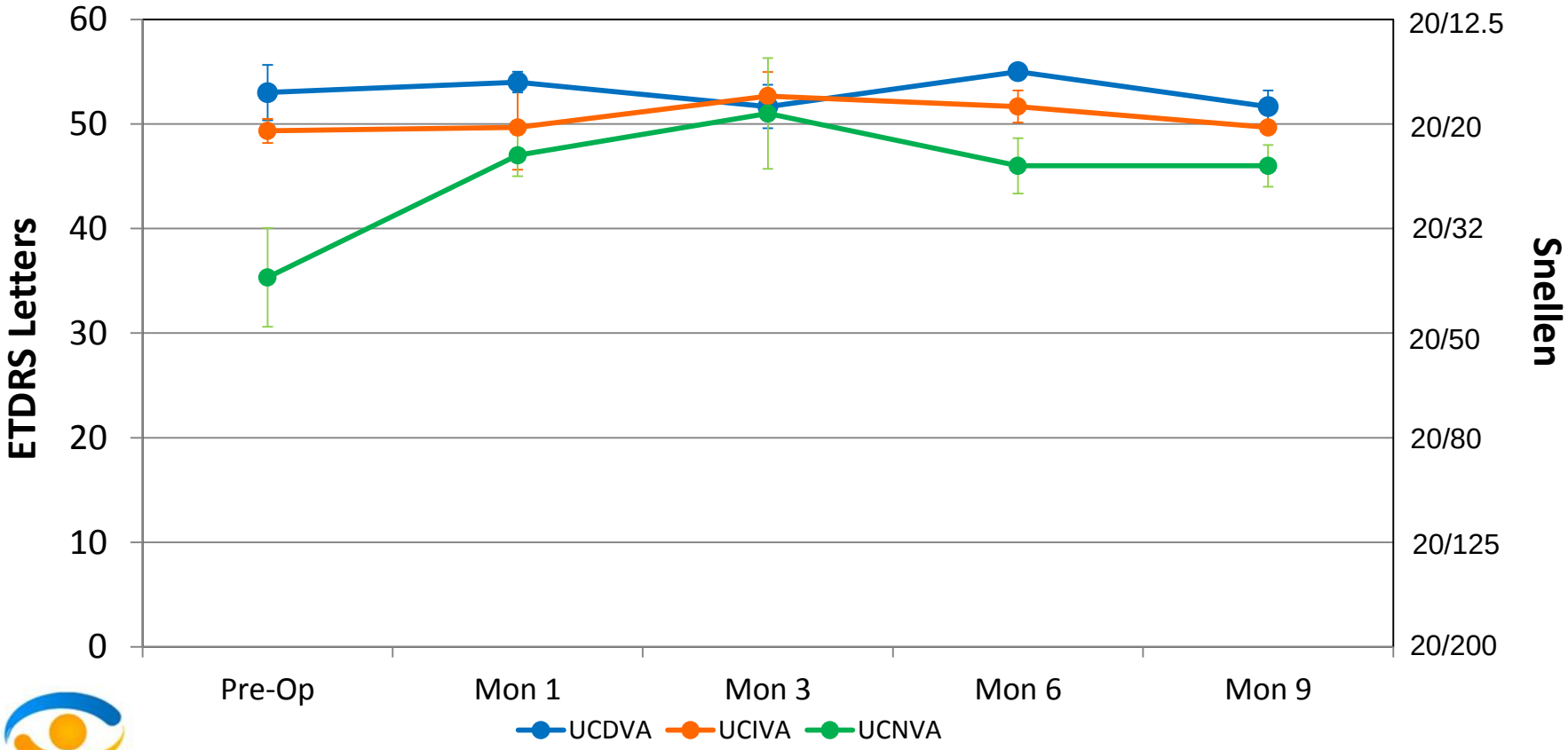
Binocular Uncorrected Vision

- Mean Binocular UCNVA significantly improved from 20/40 pre-inlay to 20/25 post-inlay at 9 months (Paired t-test, p value=0.034)



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Distance Corrected Visual Acuity

(9 Months)

- DCIVA improved 1 line and DCNVA improved 2 lines

Monocular Distance Corrected Vision	crystalens only	crystalens + KAMRA inlay
Distance	20/16	20/20
Intermediate	20/25	20/20
Near	20/40, J5	20/25, J2

- Binocular DCNVA improved 1 line
- Binocular DCIVA and BCDVA remained unchanged

Binocular Distance Corrected Vision	Preop	Postop
Distance	20/16	20/16
Intermediate	20/20	20/20
Near	20/32, J3	20/25, J2

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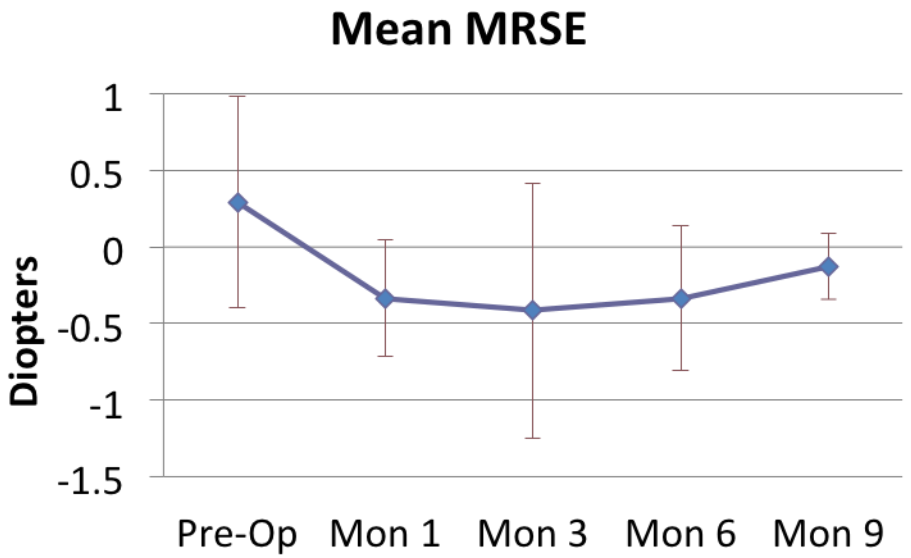
MRSE in the Inlay Eye

- At the time of implantation, no LASIK treatment was performed
- In testing refraction in an inlay eye, there is some inherent variability in the refraction repeatability as the small aperture allows the patient to tolerate a range of blur before noticing changes in acuity
- One patient did experience a myopic shift between 1 and 3 months, which recovered at 6 months

MRSE (D)	Pre-Op	1 M	3 M	6 M	9 M
Pt 1	+1.00	-0.25	-0.63	-0.88	-0.38
Pt 2	+0.25	-0.75	-1.13	-0.13	0.00
Pt 3	-0.38	0.00	+0.50	0.00	0.00
Mean	+0.29	-0.33	-0.42	-0.33	-0.13
St Dev	0.69	0.38	0.83	0.47	0.21



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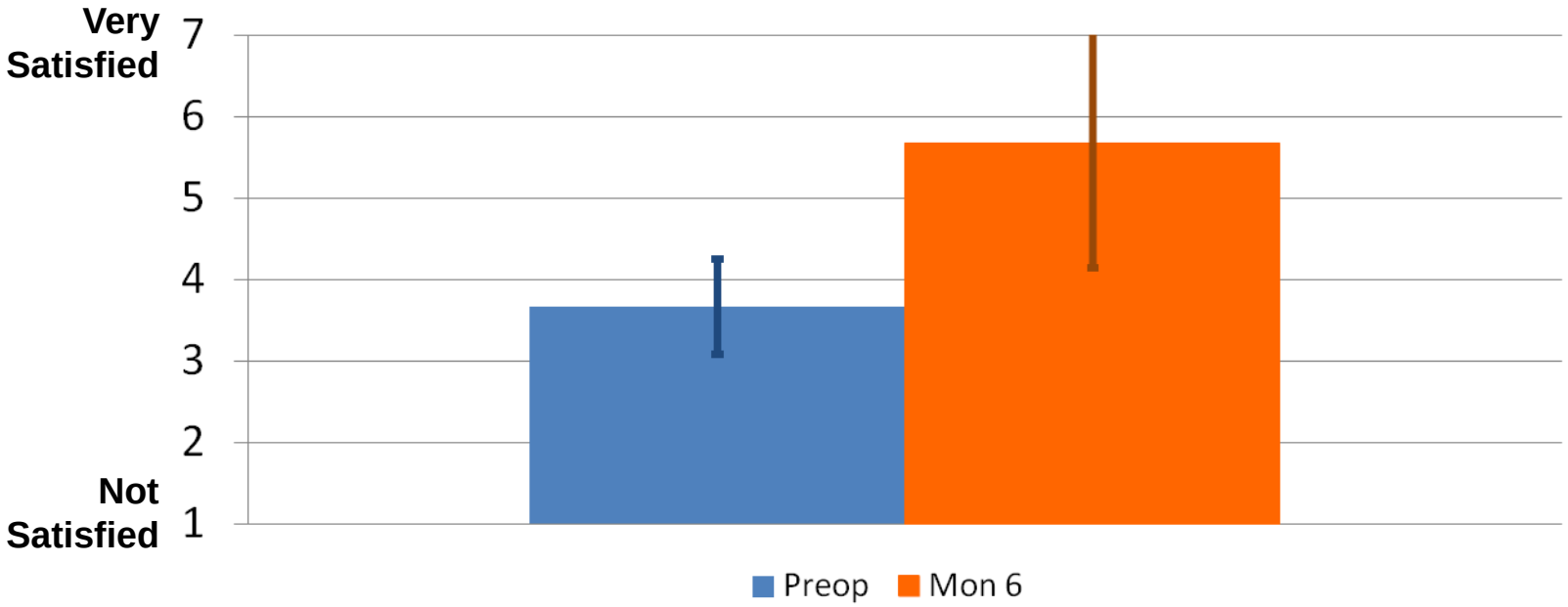
Patient Satisfaction & Visual Symptoms

- At 6 months, satisfaction with near vision without reading glasses improved from 3.7 +/- 0.58 to 5.7 +/- 1.5
- Pre-operatively, 2 out of 3 patients experienced glare, halos and double vision, but none were experienced at 6 months post-op



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Conclusion

- Small aperture corneal inlay implantation in eyes previously implanted with an accommodating IOL resulted in:
  - Statistically significant, 3 line improvement, in near vision
  - Minimal, if any, compromise to intermediate and distance vision
- Additional patient enrollment and follow-up are underway

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