Rayner

# RayOne EMV Clinical Updates

As submitted for review and presentation at ASCRS 2023

**1. Comparison of Clinical Outcomes of Two Extended Range of Vision Intraocular Lenses in a Real-World Setting**

Michael George, MD

Kirsten Ella Green

**2. Comparison of EDOF and Monofocal IOLs' UDVA, UNVA, and Patient Satisfaction**

Michael Endl, MD

**3. The Use of a Non-Diffractive EDOF IOL in Patients Targeted for Mini-Monovision Correction**

Phillips Kirk Labor, MD, FICS, FACS, ABES

**4. Positive Spherical Aberration IOL Outcomes in Laser Assisted Cataract Surgery and Lens Replacement with Low Astigmatism Targeting Distance**

Michael Shumski, MD, MSE

Nhat Nguyen, MD

Joel Hunter, MD

Kyle Callaway, OD

**5. Accuracy of IOL Formulae with RayOne EMV**

Michael Alterman, DO

RayOne EMV

# Comparison of Clinical Outcomes of Two Extended Range of Vision Intraocular Lenses in a Real-World Setting

**Michael George, MD and Kirsten Ella Green**


## PURPOSE

To investigate and compare clinical outcomes obtained in a real-world setting from subjects implanted with either RayOne EMV (Rayner) or Acrysof IQ Vivity (Alcon) extended range of vision intraocular lenses (IOL).

## METHODS

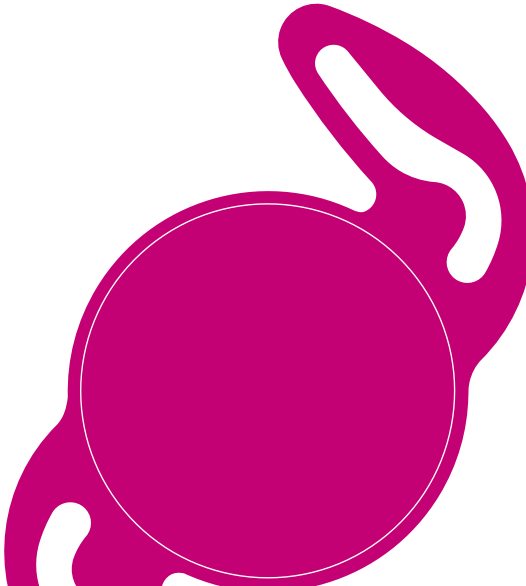
This retrospective data collection includes a total of 272 eyes which have been implanted with either RayOne EMV (135 eyes) or Vivity (137 eyes). Data was available preoperatively, 1 week and 1 month postoperatively and included manifest refraction, uncorrected (UDVA) and corrected distance visual acuity (CDVA) as well as uncorrected near visual acuity (UNVA).

## RESULTS

The 1-month post-operative mean refractive outcomes (MRSE) were -0.60 ± 0.60 logMAR for RayOne EMV and -0.49 ± 0.59 logMAR for Vivity with no statistically significant difference (p=0.18). Refractive predictability showed no statistically significantly difference (p=0.60) with mean outcomes of -0.21 ± 0.52 logMAR for RayOne EMV and -0.15 ± 0.53 logMAR for Vivity. Mean UDVA was 0.19 ± 0.20 logMAR and 0.18 ± 0.19 logMAR respectively (p=0.88). There was no statistically significant difference (p=0.09) in CDVA with 0.03 ± 0.09 logMAR for EMV and 0.04 ± 0.10 logMAR for Vivity. For UNVA a difference (p=0.04) was found with 0.24 ± 0.20 logMAR for EMV group and 0.21±0.25 logMAR for Vivity group.

## CONCLUSION

Both IOLs show a significant restoration of near and distance visual acuities. The clinical outcomes of refraction, UDVA and CDVA are equally good with differences between the two groups. On near visual acuity, eyes implanted with the Vivity IOL showed slightly superior results compared to eyes implanted with RayOne EMV.

# Comparison of EDOF and Monofocal IOLs' UDVA, UNVA, and Patient Satisfaction

**Michael Endl, MD**

## PURPOSE

To demonstrate comparative clinical outcomes of distance and near uncorrected visual acuity and patient satisfaction with an extended depth of focus acrylic IOL and a monofocal acrylic IOL in patients with low astigmatism.

## METHODS

30 patients were implanted with the extended depth of focus RayOne EMV (Rayner) IOL and 30 patients were implanted with the monofocal PreVue (Bausch + Lomb) IOL. All patients were calculated for a plano to -0.25 spherical target and had less than or equal to one diopter of preoperative astigmatism on both refraction and pre-operative placidity topography. Inclusion criteria includes patients with visually significant cataracts over the age of 45 with no history of ocular comorbidities, active inflammation, or amblyopia. Refractions, distance, and near measurements were taken at 4-to-6-week post-op appointments following IOL surgery. Subjective patient satisfaction questionnaires were filled out at 4 to 6 weeks post-op appointments.

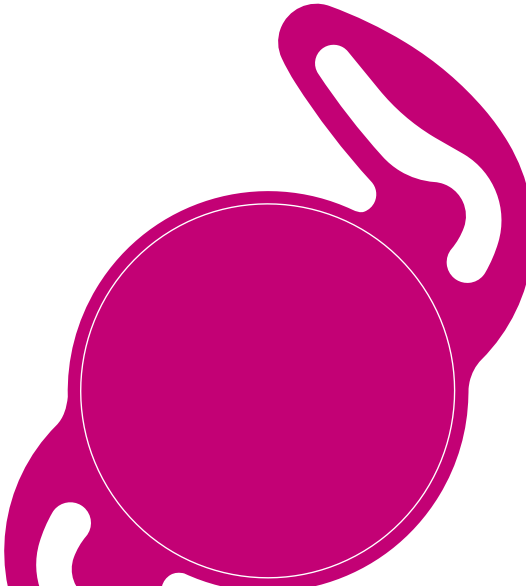
## RESULTS

98% of patients implanted with RayOne EMV achieved monocular UDVA of 20/40 or better and 100% had 20/40 or better binocular UDVA. UNVA in the RayOne EMV cohort showed 83% of patients with 20/40 (J3) or better monocularly and 94% of patients achieved 20/30 (J2) or better binocular UNVA. In the PreVue cohort, 94% of patients achieved monocular UDVA of 20/40 or better and 98% had 20/40 or better binocular UDVA. UNVA in the PreVue cohort showed 55% of patients with 20/40 (J3) or better monocularly and 65% of patients achieved 20/30 (J2) or better binocular UNVA.

Preliminary patient surveys showed no statistical difference in distance vision satisfaction, complaints of positive or negative dysphotopsias, or nighttime driving quality between the two cohorts. Subjective patient satisfaction with ability to perform intermediate or near tasks were statistically higher in the RayOne EMV cohort compared to the PreVue cohort. The RayOne EMV cohort had an 80% patient satisfaction rate compared to 50% in the PreVue cohort.

## CONCLUSION

This study suggests that RayOne EMV provides greater depth of focus and higher patient satisfaction with no increase in dysphotopic side effects or loss of distance visual acuity compared to the standard PreVue monofocal IOL.



# The Use of a Non-Diffractive EDOF IOL in Patients Targeted for Mini-Monovision Correction

**Phillips Kirk Labor, MD, FICS, FACS, ABES**

## PURPOSE

Evaluating outcomes of cataract patients utilizing three IOL calculating formulas for correction of presbyopia. The EDOF IOL used in this study, RayOne EMV, has an optical design that features +SA at the center of the optic to help extend vision. Peripherally, the SA is reduced to minimize the loss of VA and ensures low levels of dysphotopsia.

## METHODS

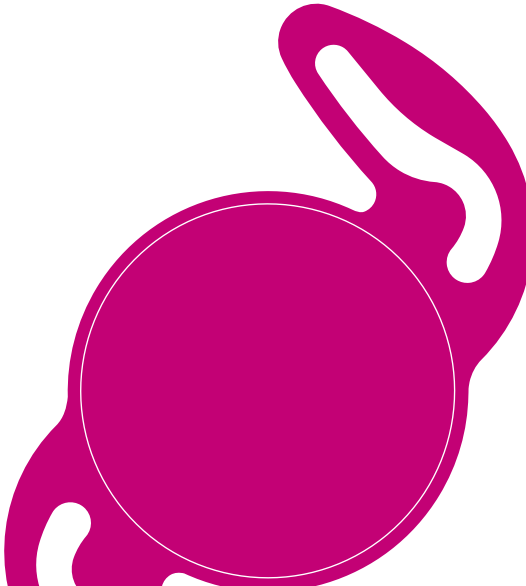
A prospective, consecutive case series of presbyopic patients who underwent cataract surgery requesting a mini-monovision correction pre-operatively. Patients with less than -0.75 D of pre-existing cylinder underwent implantation with a target refraction of -1.00 D in the non-dominant eye and a plano target refraction in the dominant eye. Calculating formulas used: Holladay II, SRK-T, Hill-RBF.

## RESULTS

70 eyes of 35 patients are included (35 dominant eyes and 35 non-dominant eyes). At 3 months post-operatively, the dominant and non-dominant eyes had an average spherical equivalent (SEQ) of -0.29 D and -0.83 D respectively. The mean uncorrected binocular distance visual acuity was 20/20, the mean binocular intermediate VA was 20/20 and the mean binocular near VA was 20/30 (n=35).

## CONCLUSION

This non-diffractive EDOF provides very good visual results with similar spherical equivalent outcomes and uncorrected visual acuities for all three formulas (Holladay II, SRK-T, Hill-RBF) when utilized in presbyopic patients targeting mini-monovision following cataract surgery.



# Positive Spherical Aberration IOL Outcomes in Laser Assisted Cataract Surgery and Lens Replacement with Low Astigmatism Targeting Distance

**Michael Shumski, MD, MSE, Nhat Nguyen, MD, Joel Hunter, MD and Kyle Callaway, OD**

## PURPOSE

To demonstrate clinical outcomes of distance and near uncorrected visual acuity in patients with low astigmatism who underwent laser-assisted cataract surgery or laser-assisted lens replacement with a non-diffractive aspheric intraocular lens that induces positive spherical aberration when targeting distance vision with astigmatism management.

## METHODS

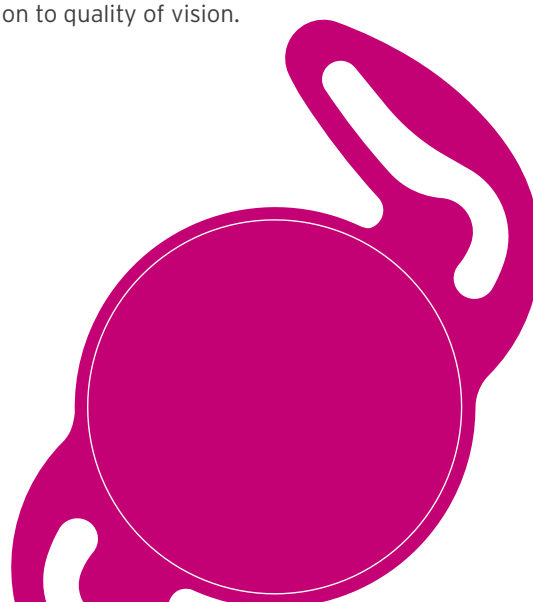
Retrospective case series of 26 eyes from 25 consecutive patients undergoing laser-assisted cataract surgery or lens replacement in a private practice with an office-based surgery suite. All patients met the following criteria: RayOne EMV IOL implanted, axial length calculations between 22.00mm and 25.00mm, biometry predicted spherical equivalent less than –0.50D myopia, corneal astigmatism less than 1.00D, and no visually reducing ocular co-morbidities. All patients had biometric measurements collected with an IOL master 500 or 700 model and Pentacam tomography. Uncorrected distance and near (40cm) visual acuity were the outcomes recorded. History was reviewed for complaints of glare or halos.

## RESULTS

The outcomes on monocular uncorrected distance visual acuity show a mean value of 0.05 (+/0.08) logMAR (range: -0.04 to 0.32 logMAR), corresponding to a mean outcome of 20/22 in Snellen equivalent. 58% of the treated eyes achieved 20/20 and 92% achieved 20/25 or better on postoperative monocular uncorrected distance visual acuity. 12% of the treated eyes achieved J1 or better, 20% are J2 or better, 44% are J5 or better, and 72% are J7 or better on monocular uncorrected near visual acuity at 40cm. No patients reported glare or haloes after 1 month.

## CONCLUSION

Our study suggests that patients requesting an increased range of vision without quality of vision disturbances can benefit from implanting a Rayner RayOne EMV lens model. The study shows that functional near vision can be reliably achieved when choosing a distance target without a degradation to quality of vision.



# Accuracy of IOL Formulae with RayOne EMV

**Michael Alterman, DO**

## PURPOSE

To investigate and compare clinical data from subjects implanted with RayOne EMV regarding accuracy of IOL power calculation.

## METHODS

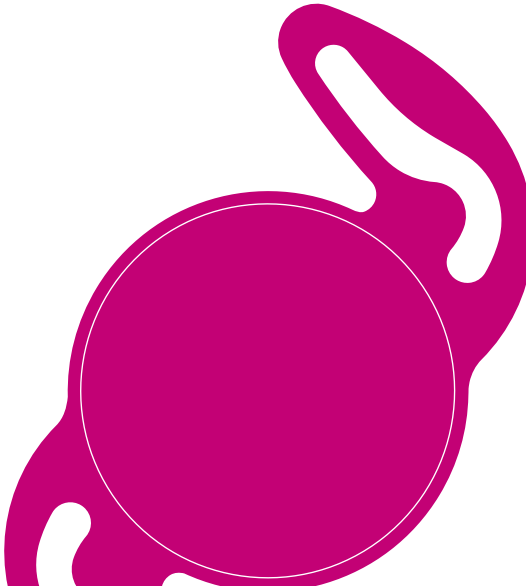
This retrospective data collection includes a total of 74 eyes who have been implanted with RayOne EMV from September 2021 to August 2022. IOL selection was made using Barrett Universal II Formula with 118.6 A-Constant. Data available preoperatively and postoperatively included pre-op refraction, biometry measurements using the Pentacam AXL, and manifest refraction performed at 1-month post-op. Targeted refraction calculated post hoc with the Hill-RBF, Kane, and HofferQST were compared to actual patient results using the Barrett Universal II formula.

## RESULTS

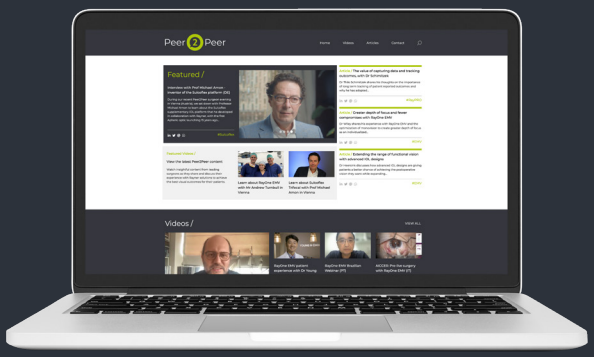
Preoperatively mean refractive outcomes (MRSE) were -0.38 ± 2.29 D. The mean target refraction was -0.44 D (Barrett), -0.39 D (Hill-RBF), -0.51 (Kane) and -0.36 D (HofferQST), respectively. The achieved postoperative refraction was -0.69 ± 0.46 D. The prediction error was -0.25 ± 0.42 D using Barrett calculator, -0.30 ± 0.44 D (Hill-RBF), -0.17 ± 0.42 D (Kane) and -0.33 ± 0.44 (HofferQST), respectively. Differences between these prediction errors were statistically not significant except between Kane and HofferQST (p=0.031).

## CONCLUSION

Refractive outcomes showed higher myopia than predicted which did not negatively affect visual outcomes. Kane IOL power calculator provided the smallest prediction error, the largest error was observed with HofferQST. The prediction error is similar between the formulae. A statistically significant difference was seen between Kane and HofferQST.



Learn more about RayOne EMV and other Rayner solutions on Rayner's clinical content hub at **rayner.com/Peer2Peer**




Peer 2 Peer

Search for **#Peer2Peer**

Rayner

PRECAUTION: The safety and effectiveness of the RayOne EMV (RAO200E) has not been substantiated in clinical trials. The effects of the RayOne EMV IOL optical design on quality of vision, contrast sensitivity, and subjective visual disturbances (glare, halo, etc.) have not been evaluated clinically. Certain lab-based testing of the RayOne EMV IOL may aid surgeons in understanding the theoretical image quality expected with the RayOne EMV IOL compared to other Rayner FDA approved lenses, but such testing does not fully assess all aspects of clinical difficulties under all conditions. You must discuss with your surgeon the potential benefits of the modified optical design of the RayOne EMV IOL against the potential for risks associated with a degradation in vision quality and the lack of clinical data to characterize the impact of the RayOne EMV IOL optical design on contrast sensitivity and subjective visual disturbance. These considerations may be especially relevant to patients with certain preexisting ocular conditions (prior eye surgery, irregular corneal astigmatism, severe corneal dystrophy, macular disease, optic nerve atrophy, etc).

CAUTION: United States Federal Law restricts this device to sale and distribution by or on the order of a physician and its use is restricted to a properly licensed physician.