IC-8™ Apthera™ IOL

Harness the Power of **Focused Light**

Maximizing Range of Vision with the IC-8™ Apthera™ IOL

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Maximizing Range of Vision with the IC-8 Apthera IOL

To help your patients achieve their best personal vision with the **Apthera™ IOL**, it is important to understand the influence refraction will have on their visual acuity and range of vision. By shifting the distance-corrected defocus curve and evaluating the intersection at far (plano), intermediate (-1.5 D) and near (-2.5 D) it ispossible to predict visual acuity and range of vision delivered by an IOL with a given refraction.

Refraction Influence on Monofocal IOL Results

- In an eye with an aspheric monofocal IOL, refraction will greatly influence visual function, localizing it around a discrete focal zone
  - Plano: Best focus for distance
  - -1.5 D: Best focus for intermediate
  - -2.5 D: Best focus for near

Monofocal IOL Eyes (dominant eye)
(Mean photopic pupil size 3.72 mm +/- 0.83)

REFRACTION	+2.0	+1.5	+1.0	+0.5	Plano	-0.5	-0.75*	-1.0	-1.5	-2.0
DISTANCE	20/57	20/41	**20/30**	**20/22**	**20/18**	**20/23**	**20/29**	20/34	20/53	20/78
INTERMEDIATE	20/120	20/97	20/77	20/57	20/41	**20/30**	20/34	**20/22**	**20/18**	**20/23**
NEAR	20/159	20/142	20/120	20/97	20/77	20/57	20/49	20/41	20/30	20/22

Best Focus

Refraction Influence on **Apthera IOL Results**

- Addition of the small aperture boosts range of vision versus a monofocal IOL
  - -0.75 D: Best balance between near and far vision (target refraction)
  - More myopia results in more near dominant vision
  - More hyperopia results is more distance dominant vision

Apthera™ IOL Eyes (non-dominant eye)
(Mean photopic pupil size 3.70 mm +/- 0.83)

REFRACTION	+2.0	+1.5	+1.0	+0.5	Plano	-0.5	-0.75*	-1.0	-1.5	-2.0
DISTANCE	**20/32**	**20/26**	**20/22**	**20/21**	**20/20**	**20/25**	**20/27**	**20/32**	20/41	20/52
INTERMEDIATE	20/56	20/41	20/38	**20/32**	**20/26**	**20/22**	**20/23**	**20/21**	**20/20**	**20/25**
NEAR	20/83	20/71	20/56	20/41	20/38	**20/32**	**20/30**	**20/26**	**20/22**	**20/21**

DISTANCE DOMINANT — BALANCED — NEAR DOMINANT

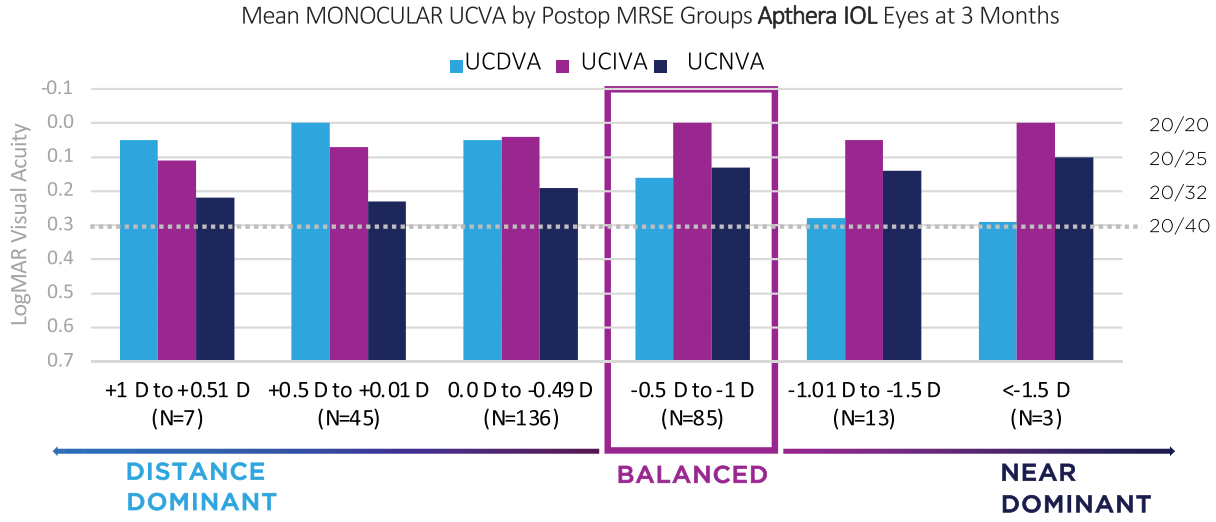
* +0.75 Distance-Corrected VA at 6 months, Apthera IOL eyes N=335, Monofocal eyes N=100
Directions for Use, Bausch & Lomb Inc., Actual and predicted visual acuity based on the monocular distance-corrected defocus curve and +0.75 D distance-corrected visual acuity for the monofocal IOL fellow eye from the IC-8 Apthera IOL US IDE study. VA = Visual Acuity

Maximizing Range of Vision with the IC-8 Apthera IOL

Analysis of the 3-month **Apthera IOL** patient monocular visual acuity results align with the predicted acuity scores based on the defocus curve. The **Apthera IOL** delivers, on average, 20/40 or better for near, intermediate and far vision even if the MRSE ranges from +1.0 D to -1.5 D.

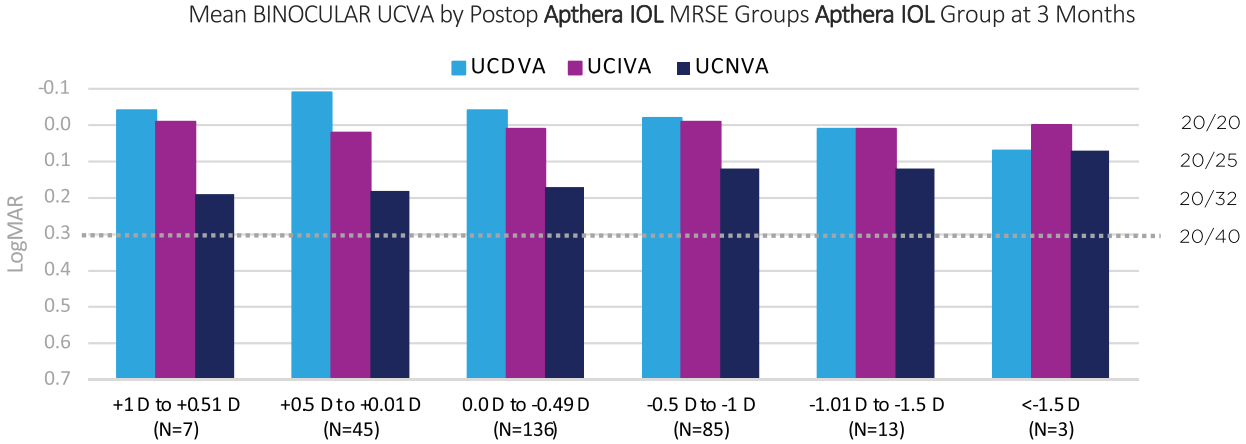
Apthera IOL Monocular UCVA by Post-Op MRSE Group

- The best balance between near, intermediate and far vision is achieved with an MRSE between -0.5 and -1.0 D.



Binocular UCVA by Apthera IOL Eye Post-Op MRSE Group

- Regardless of the MRSE in the **Apthera IOL** eye, contralateral implantation of a Monofocal IOL and **Apthera IOL** provides patients with:
  - Improvement across the full range of vision
  - 0.1 logMAR (20/25) or better OU for UCDVA and UCIVA
  - 0.2 logMAR (20/32) or better for UCNVA



IC-8 Apthera Directions for Use, Bausch & Lomb Inc.

IC-8™ Apthera™ IOL

Indications and Important Safety Information for IC-8 Apthera IOL

INDICATIONS: The IC-8 Apthera IOL is indicated for unilateral implantation for the visual correction of aphakia and to create monovision in patients of age 22 or older who have been diagnosed with bilateral operable cataract, who have up to 1.5 D of astigmatism in the implanted eye, and who do not have a history of retinal disease and who are not predisposed to experiencing retinal disease in the future. The device is intended for primary implantation in the capsular bag, in the nondominant eye, after the fellow eye has already undergone successful implantation (uncorrected distance visual acuity 20/32 or better and best-corrected distance visual acuity 20/25 or better) of a monofocal or monofocal toric IOL that is targeted for emmetropia. The refractive target for the IC-8 Apthera IOL should be -0.75 D. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal or monofocaltoric IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity.

CONTRAINDICATIONS: (1) Patients with dilated pupil size less than 7.0 mm. (2) Patients with a history of retinal disease including but not limited to, high myopia, diabetes, macular disease, sickle cell disease, retinal tear, retinal detachment, retinal vein occlusion, ocular tumor, uveitis, and patients who are predisposed to experiencing retinal disease in the future.

WARNINGS: The lens should not be implanted if appropriate intraocular support of the lens is not possible. Severe subjective visual disturbances (e.g., glare, halo, starburst, hazy vision) may occur after device implantation. There is a possibility that these visual disturbances may be significant enough that a patient may request removal of the lens. Contrast sensitivity in eyes implanted with this lens is significantly reduced when compared to the fellow eye implanted with a monofocal or monofocal toric IOL. Although there was no significant reduction in binocular contrast sensitivity in the IDE clinical study, it is essential that prospective patients be fully informed of this visual effect in the implanted eye before giving their consent for unilateral implantation of the lens. Patients should be informed that they may need to exercise caution when engaging in activities that require good vision in dimly lit environments (such as driving at night or in poor visibility conditions). There is a possibility that visual symptoms due to reduced contrast sensitivity may be significant enough that a patient may request removal of the lens. This lens should not be implanted bilaterally because bilateral implantation is expected to cause significant reduction in contrast sensitivity under all lighting conditions. The use of this lens in patients with corneal astigmatism greater than 1.5 D is not recommended. Diagnostic tests in patients implanted with the lens may take longer and require some additional effort from the patient and the physician to perform. Use of some medical lasers to treat certain eye conditions may present potential risks of damaging the FilterRing component of the lens. Removal of the lens may be necessary prior to retinal or vitreal procedures. Surgeons should perform a careful benefit-risk assessment based on individual patient characteristics, weighing all the risks disclosed in the Directions for Use labeling against the benefit of extended depth of focus. Nd:YAG laser capsulotomy treatments may be more difficult to perform and may be less effective in an IC-8 Apthera IOL implanted eye. Specific training from Bausch + Lomb or an authorized representative of Bausch + Lomb related to YAG capsulotomy is required before a surgeon is authorized to implant the IC-8 Apthera IOL.

PRECAUTIONS: Prior to surgery, prospective patients should be informed of the possible risks and benefits associated with this lens and a Patient Information Brochure should be provided to the patient. Patients with a predicted postoperative astigmatism between 1.0 D and 1.5 D may not obtain as great an amount of improvement in intermediate vision compared to patients with lower amounts of astigmatism.

CAUTION: Federal law restricts this device to sale by or on the order of a licensed physician.

ATTENTION: Reference the Directions for Use labeling for a complete listing of important safety information.

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