

Monofocal IOLs: Impact of Optical Design on Intermediate Vision



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INTRODUCTION

Despite the significant advancement of presbyopia-correcting IOL technology, monofocal IOLs—which are designed to restore distance vision at a lower cost and are covered by medical insurance—remain the most implanted type of IOL worldwide. Recently, certain monofocal IOLs with modified aspheric optical profiles, reportedly designed to slightly extend the range of vision into intermediate distance, have been introduced to the market.¹ It is important to understand the clinically meaningful benefit provided by these lenses versus other traditional monofocal IOLs, particularly given the associated additional cost.

TRADITIONAL ASPHERIC MONOFOCAL IOLS

The optical design of monofocal IOLs has long been focused on providing high-quality distance vision. They were originally developed with spherical surfaces. Unlike the young human crystalline lens, which provides negative spherical aberration (SA)² and can neutralize positive corneal SA,³ spherical IOLs introduce additional positive SA.⁴ Increased ocular SA reduces the clarity of an image as the aberrations cause light to deviate from the point of focus on the retina.⁴ The desire to provide sharply focused distance vision prompted the development of aspheric monofocal IOLs, which feature a gradual curvature reduction from center to the periphery, resulting in concomitant change in optical power from center to the peripheral portions of the optical zone.⁴ Today, we have a collection of aspheric lenses that are designed to neutralize all (e.g., TECNIS ZCB00* [Johnson & Johnson Vision], $-0.27 \mu\text{m}$ SA), partial (e.g., AcrySof IQ SN60WF, Clareon SY60WF [both Alcon], $-0.2 \mu\text{m}$ SA), or none (e.g., Akreos AO*, enVista MX60E* [both Bausch + Lomb], $0 \mu\text{m}$ SA) of the visual system's naturally occurring corneal SA ($+0.28 \pm 0.09 \mu\text{m}$ for a 6-mm pupil).³ Different aspheric monofocal IOLs may be selected based on a patient's corneal higher-order aberration profile to achieve higher-quality distance vision.

It should be noted that residual SA has the potential benefit of providing some depth of focus or tolerance to residual refractive error when it is not high enough to degrade retinal image quality. Patients with traditional monofocal IOLs, especially spherical or aspheric IOLs that do not fully neutralize corneal SA, have been reported to experience some intermediate vision.⁵⁻⁸

MODIFIED MONOFOCAL IOLS

Recently, a group of modified monofocal IOLs has emerged with optical designs aiming to extend the depth of focus slightly.

However, Fernandez et al⁹ showed that none of these lenses are clinically proven to meet the extended depth-of-focus (EDOF) IOL standard as defined by the American National Standard Z80.35-2018 (Table 1).¹⁰ These lenses are marketed as modified or enhanced monofocal IOLs designed to extend the depth of focus. TECNIS Eyhance (Johnson & Johnson Vision), for example, is an FDA-approved monofocal IOL with a modified aspheric anterior surface which facilitates a steady increase in lens power within the central 1-mm diameter of the IOL optic. It was introduced as a level A modification of the TECNIS ZCB00 monofocal IOL, and did not require additional clinical study to verify that the modified optical design provided any additional benefit. Different studies have compared Eyhance to its parent lens, the TECNIS ZCB00, and showed various degrees of improvement in intermediate vision with mean value ranging from 0.09 to 0.2 logMAR.¹¹⁻¹³ However, limited data is available comparing the range of vision between Eyhance and other traditional aspheric monofocal IOLs.

As mentioned above, having some intermediate vision with monofocal IOLs is not a novel concept nor a newly studied phenomenon. Rocha et al^{5,6} showed residual SA with spherical IOLs and aspherical neutral IOLs could improve depth of focus. Bilateral implantation of AcrySof IQ monofocal IOLs has also been shown to provide intermediate vision of 0.2 logMAR.^{7,8} The Clareon monofocal IOL is an innovation from Alcon with an advanced biomaterial to provide excellent optical clarity.¹⁴ It shares a similar optical design as the AcrySof IQ monofocal IOL with $-0.2 \mu\text{m}$ asphericity to partially compensate corneal SA, suggesting it may provide similar range of vision as the AcrySof IQ monofocal IOL. Blehm et al reported excellent distance vision and good intermediate vision (mean value of 0.16 and 0.23 logMAR at 80 cm and 66 cm, respectively) from a prospective study with the Clareon monofocal IOL.¹⁵

To better understand the visual performance of the Eyhance IOL versus an aspheric monofocal IOL other than TECNIS ZCB00, we

TABLE 1. SUMMARY OF ENDPOINTS AND EFFECTIVENESS CRITERIA FOR EDOF IOLS

Clinical Endpoints	EDOF Effectiveness Criteria
Monocular depth of focus at 0.2 logMAR	At least 0.5 D greater than the monofocal control
Mean monocular photopic DCIVA* at 66 cm	Superior to the monofocal control (1 sided test using significance of 0.025)
Monocular photopic DCIVA at 66 cm	Achieving 0.2 logMAR or better in 50% of eye
Mean monocular photopic BCDVA*	Non-inferior to the monofocal control with a non-inferiority margin of 0.1 logMAR (1 sided test using significance level of 0.05)

*BCDVA: best corrected distance visual acuity
DCIVA: distance corrected intermediate visual acuity

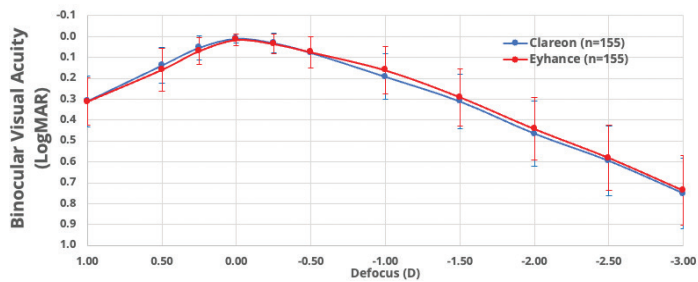


Figure 1. Binocular distance-corrected defocus curve of Clareon vs Eyhance IOL.

conducted a large, non-interventional, single-center, multisurgeon, head-to-head study comparing visual outcomes in patients bilaterally implanted with either Clareon or Eyhance IOLs.¹⁶ Non-inferiority of the Clareon monofocal IOL relative to the Eyhance IOL was demonstrated in both BCDVA and DCIVA measured at 66 cm (Table 2) in an apples-to-apples comparison with both groups corrected to plano. A 2.5-ETDRS letter difference in DCIVA was observed between the two IOLs, which is well within the range of non-inferiority (<0.1 logMAR) and not considered to be a clinically meaningful difference. The binocular distance corrected defocus curve measurements were extremely similar from -3.00 D to +1.00 D defocus level ($P > 0.05$), suggesting comparable range of vision achieved by the two IOLs (Figure 1).

Additionally, it's crucial to underscore the importance of evaluating distance-corrected visual acuities at the relevant point of focus—distance, intermediate, or near—when comparing the visual performance of two IOLs. This approach allows us to rule out the influence of residual refractive error, ensuring a fair comparison of the visual benefits each IOL provides.

SUMMARY

Monofocal IOLs remain an important option for cataract patients, typically providing excellent distance VA, but they also provide some intermediate vision depending on the optical design. The Eyhance IOL has been demonstrated to have slightly better intermediate VA compared to its parent IOL. However, this observation cannot be generalized to all monofocal IOLs. Our data conclude that the Clareon monofocal IOL can provide a comparable range of vision to the Eyhance IOL and has a similar potential to decrease spectacle wear at the intermediate range. The Clareon monofocal IOL may be an equally suitable choice with a relatively lower cost for surgeons who want to provide patients with the potential of some intermediate vision after cataract surgery. For patients who desire excellent vision from distance to intermediate and functional near vision with a low incidence of visual disturbance, non-diffractive EDOF IOLs should be considered. They are known to consistently deliver extended range of vision without the dependency on targeting strategies like mini-mono or monovision.^{7,8} ■

TABLE 2. VISUAL AND NON-INFERIORITY OUTCOMES OF CLAREON VS EYHANCE IOL

Binocular Visual Acuity (logMAR)		Clareon (n = 155 patients)	Eyhance (n = 155 patients)	Non-inferiority (<0.1 logMAR)
BCDVA	Mean ± SD	0.01 ± 0.02	0.02 ± 0.03	Met
	Median	0.00	0.00	
	Range	(0.00, 0.10)	(0.00, 0.10)	
DCIVA (66 cm)	Mean ± SD	0.24 ± 0.11	0.19 ± 0.11	Met
	Median	0.20	0.18	
	Range	(0.00, 0.60)	(0.00, 0.48)	

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Important Product Information - Clareon® Family of IOLs

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