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AN INNOVATIVE EDOF ISOFOCAL IOL TECHNOLOGY

A detailed description of the IsoPure 1.2.3 and a report on early clinical results.

BY RAFAEL BILBAO-CALABUIG, MD, PHD, FEBOS-CR; AND PAVEL STODULKA, MD, PHD



Just recently, PhysIOL announced the availability of an IOL that represents a new segment of lenses—one between monofocal and premium multifocal

IOLs, meaning it can provide excellent distance vision and improve intermediate vision without inducing photic phenomena. This new IOL is the fully refractive, aspheric, isofoveal IsoPure 1.2.3 (PhysIOL).

ISOPURE 1.2.3: DESIGN DETAILS

By Rafael Bilbao-Calabuig, MD, PhD, FEBOS-CR



Extended depth of focus (EDOF) IOLs have been available for several years now. They intended to provide a better and broader intermediate range of vision compared to monofocal IOLs, theoretically without the unwanted photic phenomena and loss of contrast sensitivity related to multifocal IOLs.

However, some previous EDOF models have failed to achieve some of these goals and have induced similar dysphotopic phenomena and showed nonsuperior intermediate vision and worse near vision than trifocal lenses.

Now, with the introduction of the IsoPure 1.2.3, we have access to an IOL

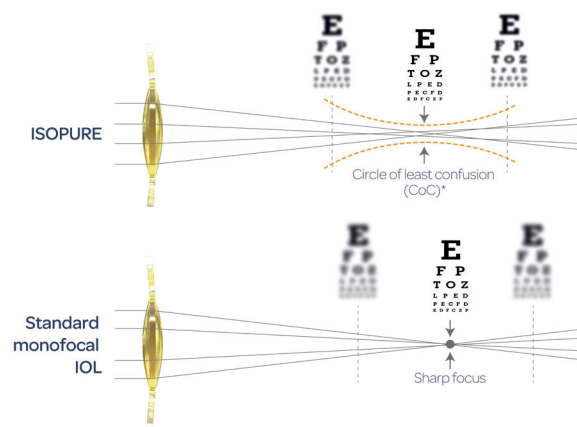


Figure 1. The IsoPure 1.2.3 accentuates the extended depth of focus.

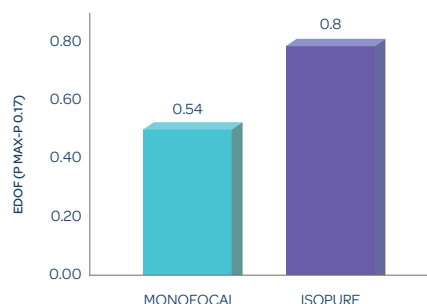


Figure 2. The IsoPure 1.2.3 IOL achieves about 1.00 D of EDOF in a 3-mm pupil.

with the best of both worlds, combining the advantages of a monofocal IOL with the elongated focus of a real EDOF lens. The IsoPure 1.2.3 is based on PhysIOL's Micropure monofocal lens platform, with which we have extensive experience in Clínica Baviera showing excellent visual, refractive, anatomic, and posterior capsular opacification rates. The lens is

manufactured with the company's hydrophobic glistening-free material (G-free) and has four closed haptics to enhance the predictive effective lens position, achieve a very comfortable insertion, and provide excellent centration and stability in the capsular bag.

HOW IT WORKS

In myopic patients, with a 6.5-mm pupil, the average level of spherical aberration is about $+0.24 \mu\text{m}$; it is likely

higher in hyperopic patients, at about $+0.34 \mu\text{m}$. A standard monofocal IOL with its nominal power focuses the light rays on a single focus, which provides a sharp image at only one distance. Alternatively, the IsoPure 1.2.3, with a 100% monofocal refractive optic, combines a unique anterior/posterior surface profile of increased negative spherical aberration (SA) that is fine-tuned for each diopter on the whole optic. This design ensures that central and peripheral rays entering the pupil do not converge identically, thus causing an extension of the foci on the retina. Succession of convergence points extends the focal points and provides depth of focus (Figure 1). In this system, the plane of the best image shifts between the different foci and over the retina. Then, as the pupil constricts, the focus of the peripheral rays is no longer visible—because the pupil interferes with the path. The eye becomes slightly myopic, and, as

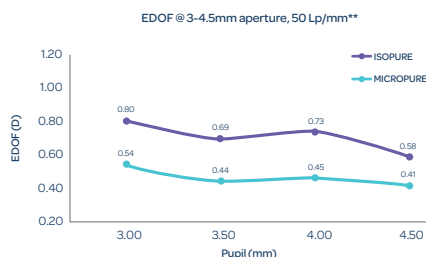


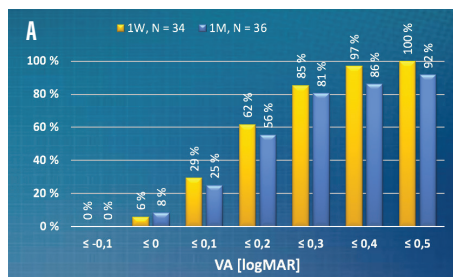
Figure 3. The IsoPure 1.2.3 maintains the extended depth of focus independent of pupil size.

a result, intermediate vision improves and an elongated depth of field is achieved.

However, as the rate of SA increases and the focal area extends, resolution power and contrast sensitivity of the eye decrease. The value of SA introduced is crucial in order to maximize its beneficial effect without introducing the deleterious effects of blur and loss of contrast sensitivity.

ACHIEVING EDOF

Optical bench testing showed that the IsoPure 1.2.3 IOL achieves about 1.00 D of EDOF in a 3-mm pupil, representing an increase of approximately 50% extended depth of focus compared to the standard aspheric monofocal MicroPure IOL (Figure 2). Further, the IsoPure 1.2.3 maintained the extended depth of focus independent of pupil size (Figure 3). Regarding the quality of vision, when we compared the IsoPure 1.2.3 to the MicroPure, the quality of the image was only minimally reduced with the IsoPure and was less reduced under myopic conditions. There was no significant difference between the lenses for distance vision, whereas the IsoPure maintained a much clearer intermediate vision image as compared with the MicroPure monofocal IOL.



We concluded that the IsoPure 1.2.3 makes the optical system less sensitive to defocusing and offers a continuous visual field between distance and intermediate vision.

FIRST CLINICAL OUTCOMES WITH THE ISOPURE 1.2.3

By Pavel Stodulka, MD, PhD



I am happy to present the first clinical outcomes with the IsoPure 1.2.3, a lens with a unique design for each

diopter. The multicenter, prospective study, performed by Dr. Bilbao-Calabuig in Clínica Baviera Spain and our clinics in the Czech Republic, included 38 eyes of 19 patients. The 12 female and seven male patients had a mean age of 69.9 years.

STUDY RESULTS

At the time of publication, 1-month follow-up was available for all eyes. We aimed for slight myopia in all cases. When we looked at postoperative refractive cylinder, we found no statistically significant difference in the results at 1 week and 1 month. In fact, the cylinder decreased slightly because the incision was created on the steep corneal meridian. As would be expected, uncorrected distance monocular vision improved significantly, with 45% of eyes achieving 20/20 or better at the 1-month visit. When we looked at corrected distance visual acuity, 89% of eyes achieved at least 20/20.

Monocularly, by 1-month postoperative, 56% of eyes had achieved 20/32 or

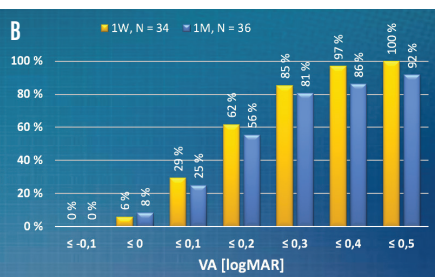


Figure 4. Distance-corrected intermediate visual acuity at 80 cm (A) and 66 cm (B) with the IsoPure 1.2.3.

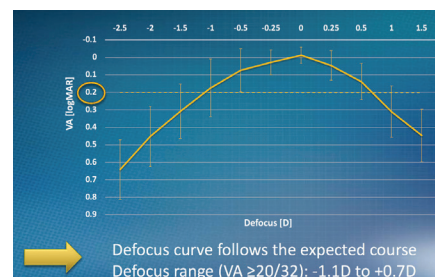


Figure 5. Defocus curve at 1-month postoperative.

better and 83% achieved 20/40 or better uncorrected intermediate visual acuity at 80 cm. For distance-corrected intermediate visual acuity at 80 cm, 56% of eyes had achieved 20/32 or better and 81% achieved 20/40 or better (Figure 4A). For distance-corrected intermediate visual acuity at 66 cm, 35% of eyes had achieved at least 20/32 and 68% at least 20/40 (Figure 4B). Our results confirm that this new implant provides both high-quality distance and intermediate uncorrected visual acuities.

Also at 1-month postoperative, the defocus curve (Figure 5) and contrast sensitivity were as expected. The defocus range for a visual acuity of at least 20/32 was -1.10 to 0.70 D, and contrast sensitivity for both photopic and mesopic was within the normal range for this age group.

CONCLUSION

The 1-week and 1-month outcomes shared here serve as a proof of concept for the IsoPure 1.2.3 IOL. Results indicate that patients can see well from 77 cm to infinity. As with any new technology, longer follow-up in a larger quantity of eyes is warranted. For now, I am looking forward to using the IsoPure 1.2.3 in many more of our patients. ■

Rafael Bilbao-Calabuig, MD

■ Clínica Baviera, Instituto Oftalmológico Europeo, Madrid, Spain
■ rbilbaocalabuig@hotmail.com
■ Financial disclosure: None acknowledged

Pavel Stodulka, MD, PhD

■ Chief Eye Surgeon, CEO, Gemini Eye Clinics, Czech Republic
■ stodulka@lasik.cz
■ Financial disclosure: None acknowledged

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- No induced photic phenomena.

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