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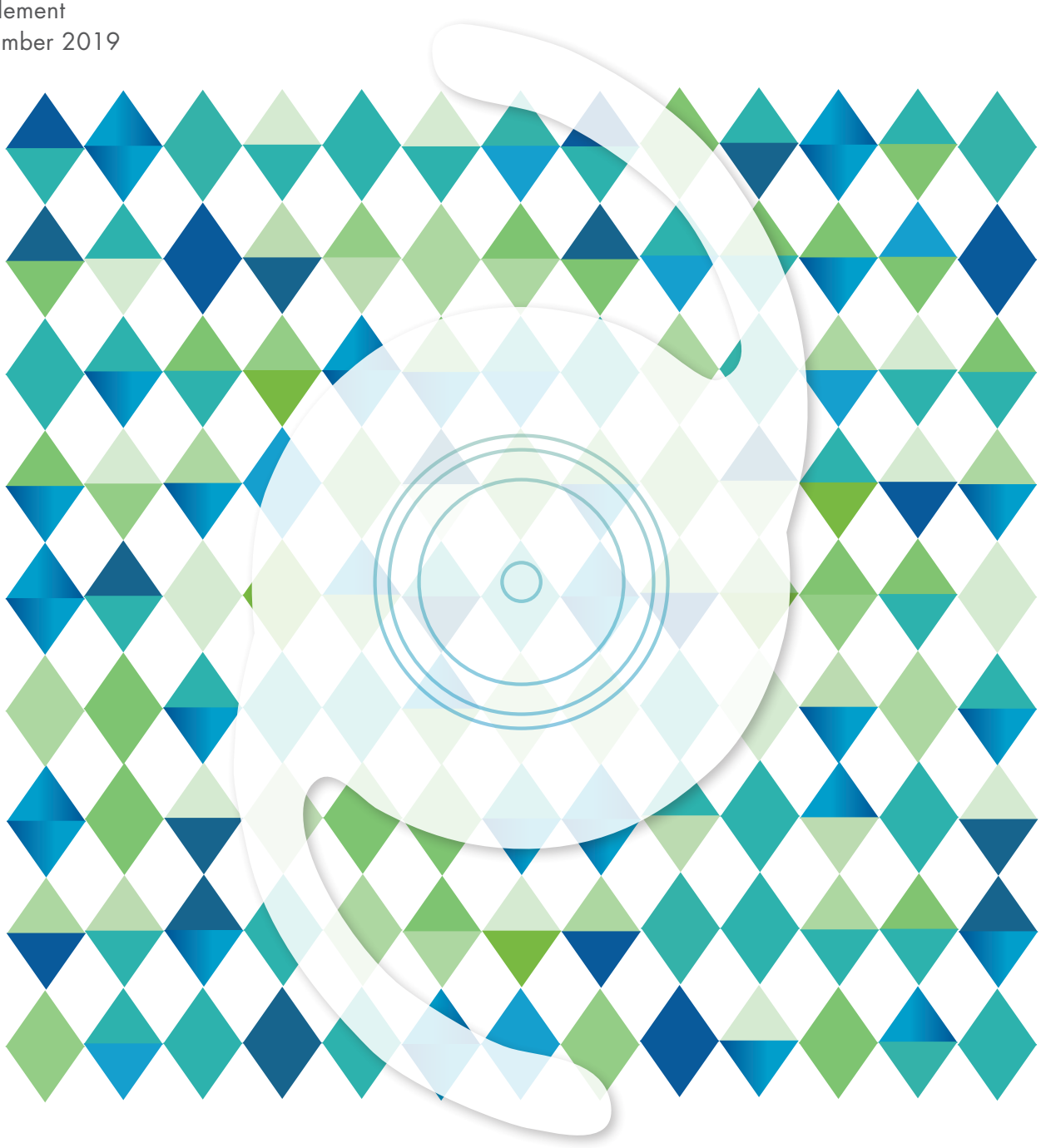


New Concept Monofocal IOL with Continuous Focus

PP-XACT-EMEA-0012 – Date of Preparation: Oct 2019

Please read the xact™ Mono-EDoF™ Instructions for Use carefully before using the device

Mono-EDoF™ Foldable Hydrophobic Acrylic Ultraviolet-Absorbing and Blue-Light Absorbing Posterior Chamber Intraocular Lens is indicated for visual correction of aphakia in adult patients in whom the cataractous lens has been removed by an extracapsular cataract extraction method.

The lens is intended for placement in the capsular bag. For optimal performance of the Mono-EDoF™ it is suggested that this IOL is implanted in patients with preoperative corneal astigmatism of 1.0D and care should be excercised not to increase the postoperative astigmatism because of surgically induced astigamtisim.

Santen

New Concept Monofocal IOL with Continuous Focus

David Spalton, FRCS, FRCP, FRCOphth

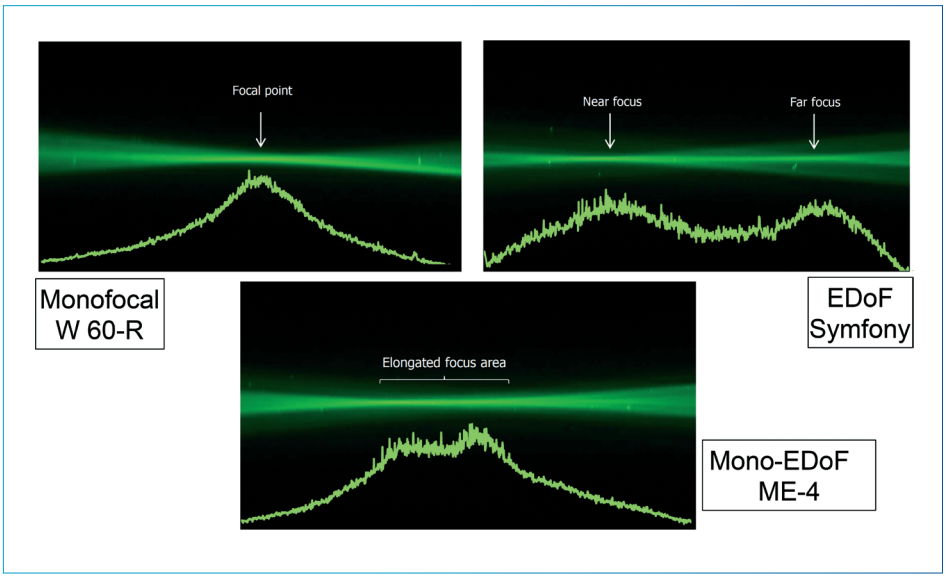
Recent years have seen the evolution of diffractive optics and extended-depth of focus (EDOF) intraocular lenses to new levels of sophistication. In this symposium we are focusing on a new diffractive-refractive IOL, the xact™ Mono-EDoF™ lens from Santen, which is designed to provide the same distance visual acuity as a monofocal IOL and also provide a range of intermediate vision similar to that of a conventional EDOF IOL. The session includes a panel of distinguished speakers who will describe the unique optical properties of the lens, first as assessed in a laboratory, and the confirmation of the IOL's extended range of focus in the first clinical trials with the lens.

Optical Comparison of a Novel Monofocal Extended Depth of Focus IOL and a Conventional Bifocal Extended Depth of Focus IOL

Mark Packer MD FACS CPI

There are a number of multifocal and extended depth of focus (EDOF) IOLs on the market that can provide varying degrees of multifocality. But in the end, there is some trade-off in the near vision the IOLs provide, often in the form of reduced contrast sensitivity under mesopic conditions and dysphotopsia. The concept behind the xact™ Mono-EDoF™ lens is that it provides a range of intermediate vision similar to that of a traditional EDOF lens with minimal optical side-effects similar to a monofocal.

This lens is called the ME4 because it has four diffractive rings. It is composed of the same hydrophobic glistening-free material as the enVista lens by Bausch + Lomb. The xact™ Mono-EDoF™ lens is CE marked and approved as a monofocal lens as it meets the international standards for a monofocal.



XACT™ MONO-EDOF™ ELONGATES FOCUS

The findings of a variety of tests in the optical lab provide a clear picture of the IOL's elongation of focus within the intermediate range. Optical bench testing shows the single peak and broad shoulder of the through-focus modulation transfer function (MTF) of the xact™ Mono-EDoF™ lens, as opposed to the narrow high single peak of a monofocal IOL or the two peaks of a conventional diffractive EDOF lens when assessed with a 3.0mm pupil.

The optical bench testing also showed that the lens is relatively tolerant to tilt and decentration. For example, under conditions of 4.5 degrees of tilt or 0.3mm decentration and a 3.0mm aperture the xact™ Mono-EDoF™ lens and the Symfony (J&J Vision, Santa Ana, CA) function similarly, although the xact™ Mono-EDoF™ lens maintains higher MTF values. When the pupil is enlarged to 4.5mm, tilt has a greater impact on MTF values of the xact™ Mono-EDoF™ lens and the diffractive EDOF lens. However, the pattern of reduction in MTF values for the xact™ Mono-EDoF™ lens follows more closely that of the monofocal or the aspheric Eyhance (J&J Vision, Santa Ana, CA) than that of the Symfony.

Ray propagation studies performed at the David J Apple Laboratory, Heidelberg University, provide a further illustration of the IOL's unique refractive/diffractive optical design. The images it provides again show the elongated focus of the lens versus the single focal point of the monofocal lens, and the two focal points of the conventional diffractive EDOF lens.

Looking at the Air Force target brings some additional perspective into the differences between the different IOL types. The distance images are crispest with the monofocal and the Eyhance, followed by the xact™ Mono-EDoF™ lens and then the Symfony at the bottom. However, the sharpness of the image with the monofocal lens drops off steeply after about half a dioptre of defocus, whereas the xact™ Mono-EDoF™ image is still acceptable up to 1.5D and a little better than the Eyhance. With the Symfony, the image sharpness drops off after 2.0D.

Finally, we have real-world quad-camera polychromatic imaging. This involves recording images through a model cornea and an IOL placed in a wet cell. The model cornea is designed to match the asphericity of each lens in order to remove the impact of the different spherical aberration values of each lens from the images. The device has apertures of 3.0 or 4.5mm and allows tilting and decentring the lens.

In this study we compared four different lens types: the Acrysof IQ monofocal IOL (Alcon, Ft. Worth, TX), then the xact™ Mono-EDoF™, the Eyhance aspheric lens and the Symfony IOL, a traditional diffractive EDOF lens. When viewing the distance images with a 3.0mm aperture, you can see that the clarity, colour, resolution and contrast of the images with the xact™ Mono-EDoF™ lens are very similar

to those obtained with the monofocal. The big difference is in the dashboard images at a distance of 70cm. With 0.5mm decentration the resolution and contrast of the distance image of the xact™ Mono-EDoF™ lens remain well preserved and again the view of the dashboard is clearest with the xact™ Mono-EDoF™.

With 0.5mm of decentration and a 3.0mm pupil, the resolution and contrast of the xact™ Mono-EDoF™ image are very similar to the monofocal and the xact™ Mono-EDoF™ still provides the clearest dashboard image. Furthermore, with the combination of the same amount of decentration and a 4.5mm pupil, the quality of the xact™ Mono-EDoF™ distance image and the superiority of the 70cm distance image persists.

In night-time conditions with a 4.5mm pupil and no tilt or decentration, you start to see how the traditional EDOF lens, the Symfony, loses contrast, as does the Eyhance. But the xact™ Mono-EDoF™ is very similar to the monofocal with this larger pupil under the same conditions. And when you start to decentre you notice dysphotopsia with the negatively aspheric lens, you see some haloes around the headlights with the traditional EDOF lens, but the xact™ Mono-EDoF™ is still performing much like the monofocal.

In conclusion, these optical studies help us understand the nature of this lens. It has four diffractive rings, but the through-Focus MTF has a broad single peak, which is different from other lenses with EDOF designs. The lens has excellent image quality and distance and intermediate range in real-world polychromatic settings with relative tolerance to tilt and decentration. In addition, the ray propagation visualisation shows the elongated single-focus area, which is unique to this monofocal EDOF lens. Furthermore, the Air Force target shows that the xact™ Mono-EDoF™ lens increases depth of focus compared to a monofocal lens. The real-world polychromatic imaging showed an image quality at distance similar to that of a monofocal but with superior intermediate range vision as shown by the very crisp dashboard images. Moreover, the xact™ Mono-EDoF™ lens does not induce any glare or haloes. So, I think this is a very interesting and promising new diffractive/refractive IOL technology and my colleagues will show how it has shown significant benefits in clinical practice.

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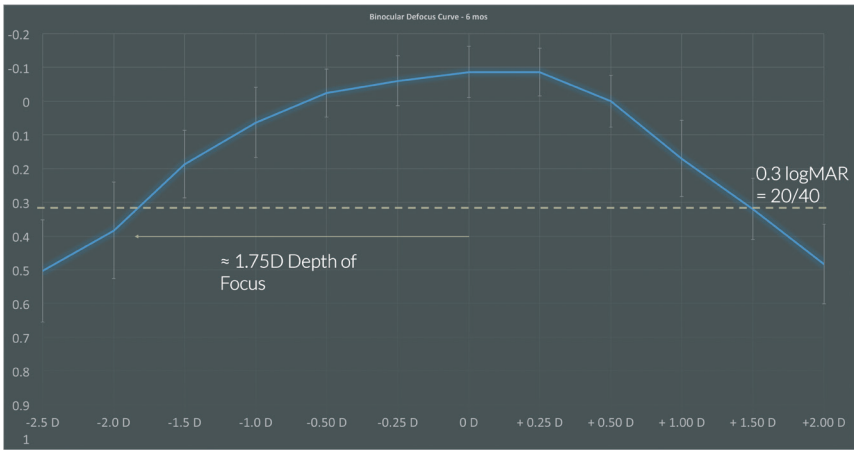
First-in-Human Clinical Outcome and Patient Satisfaction with a Novel Extended Depth of Focus IOL Satisfying ISO Standards for Monofocal IOL

Dr. med. Florian Kretz (FEBO)

The xact™ Mono-EDoF™ IOL is a new option for cataract patients who want excellent distance visual acuity and freedom from dysphotopsias provided by monofocal IOLs but who do not want to wear glasses for reading or watching television.

The lens provides the same distance visual acuity as a monofocal lens but also more intermediate vision, it provides less near visual acuity than other diffractive EDOF IOLs but also induces less dysphotopsias, it has a comparable performance to a refractive EDOF lens, is more predictable than an aberration-based or polyfocal lens and does not induce subjective visual field problems like the pinhole implants.

Furthermore, the new xact™ Mono-EDoF™ IOL is composed of Advanced Vision Science's Glistening-Free Hydrophobic Material, ensuring the long-term clarity of the optic.



Binocular Defocus Curve – 6 mos

FIRST CLINICAL TRIAL

We conducted a pilot study involving 12 eyes of six patients with visually significant cataract who underwent bilateral implantation of the new lens. The patients had a mean age of 69 years and their mean preoperative best-corrected visual acuity was 0.3 logMAR (range: 0.2 to 0.5 logMAR) and all had a keratometric cylinder less than 1.0D.

At six months' follow-up, the patients' mean monocular uncorrected distance visual acuity (UDVA) was 0.02 logMAR and their mean best-corrected visual acuity was -0.09 logMAR. At intermediate distances of 50cm, 60cm and 70cm, the mean monocular uncorrected visual acuities were 0.4, 0.3 and 0.2 logMAR and the mean best distance-corrected visual acuity values were almost identical at the same distances.

In our defocus curve analysis, we found a monocular depth of focus of 1.5D in which the patient had a visual acuity of 0.3 logMAR or better. That represents a high tolerance for refractive error. The lens allowed for postoperative refractive error of +/-0.5D while still leaving patients with around 20/20 monocular visual acuity.

Regarding the binocular defocus curves, the binocular summation provides a depth of focus of about 1.75D with visual acuity better than 0.3 logMAR.

Another interesting finding was that glare appeared to have no effect on contrast sensitivity in either mesopic or photopic conditions. That is in contrast to trifocal IOLs or other EDOF diffractive technologies, where there is usually a significant drop in contrast sensitivity under mesopic conditions at a higher cycle of degree.

To evaluate the effect on patients' quality of life, pre- and postoperatively, we obtained their responses to a 14-item questionnaire regarding their ease in performing daily activities. The responses were scored on a scale from 0-4, with 0 representing complete inability to perform the activity and 4 representing no difficulty.

Before surgery, the mean score was somewhere between 1 and 2

in most items but at six months' follow-up, all patients reported having a score of 4 for all activities except driving at night, which had a mean score of 3.5. Some of the greatest improvements were in activities such as reading and doing handiwork such as sewing.

In conclusion, we have an IOL that provides high-quality emmetropic vision. There is a continuous range of focus with no dips, binocularity of around 1.75 D and exceptional contrast sensitivity, even under mesopic light conditions and subjectively the patients are very happy.

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First Clinical Experience with a New Monofocal Intraocular Lens with Enhanced Depth of Focus

Gerd Auffarth, MD, PhD, FEBO

The xact™ Mono-EDoF™ ME4 (Santen) is a recently introduced intraocular lens (IOL) with an extended depth of focus (EDOF), which aims to provide excellent distance vision but with an elongated focus range. In our optical laboratory, we compared the new lens with an established EDOF lens, namely, the Symfony ZXR00 (J&J Vision). The two IOLs are both hydrophobic acrylic IOLs with a refractive diffractive design; however, the new lens has only four diffractive rings, as opposed to the nine diffractive rings of the Symfony.

The data we obtained shows that the through-focus (TF) modulation transfer function (MTF) curve of the xact™ Mono-EDoF™ lens is similar to that of a monofocal lens, but has a broad peak compared to the two peaks in the TF-MTF curve of the Symfony lens. The absence of a second peak in the xact™ Mono-EDoF™ lens also minimises the occurrence of haloes in night-time conditions. The comparison also showed the superior performance of the xact™ Mono-EDoF™ lens in the intermediate range.

We also carried out a ray-propagation study. Our study demonstrated very nicely the single focal point of the monofocal lens, the two focal points of the symphony and the real elongated focus area of the xact™ Mono-EDoF™ lens.

The conclusions we can draw from these optical bench studies are that the xact™ Mono-EDoF™ provides a good image quality and an increased range of vision from far to intermediate through a defocus of around 1.5D. In addition, the ray propagation study confirmed an enhanced range of vision of the xact™ Mono-EDoF™ that cannot be achieved by a standard monofocal.

Results – Refraction at 3 months

Refraction	Median (Range)
target spherical equivalent	-0.14D (-0.36D to -0.14D)
achieved spherical equivalent	-0.25D (-1.00D to +0.13D)
difference target SE – achieved SE	0.05D (-0.40D to +0.93D)
A-Constant used	119,50

PHASE IV STUDY

We have conducted a phase IV clinical study involving a total of 39 eyes that underwent implantation of the xact™ Mono-EDoF™ lens and included seven patients undergoing monocular and 16 patients undergoing binocular implantation of the monofocal lens. The patients had a mean age of 70 years, a preoperative uncorrected distance visual acuity (UDVA) of 0.59 logMAR and a mean best-corrected distance visual acuity (BCDVA) of 0.33 logMAR.

The target spherical equivalent was -0.14D, using the IOLMaster we achieved a mean -0.25D, leading to a difference between the target and achieved spherical equivalent of 0.05D. The A constant used was 119.50.

In terms of visual acuity, at six months the mean monocular UDVA was 0.12 logMAR, and the monocular BCDVA was -0.05 logMAR. In addition, in those implanted bilaterally, binocular UDVA was -0.01 logMAR and the binocular BCDVA was -0.06 logMAR.

Regarding intermediate vision, at six months the monocular values without correction at reading distances of 50cm, 60cm and 70cm were 0.36 logMAR, 0.28 logMAR and 0.23 logMAR, respectively. The respective binocular values without correction at those reading distances were 0.27, 0.17 and 0.13 logMAR. The distance-corrected intermediate visual acuities were similar to the uncorrected values.

In addition, our defocus curve analysis showed that patients maintained a visual acuity of 0.2 logMAR, about 20/30, or better with defocus ranging from -1.4D to 1.1D. They also maintained a visual acuity of zero logMAR or better with a defocus of around plus or minus half a dioptre. Furthermore, as with the MTF curve of the lens, the defocus curve in eyes with the lens had a wide peak with an extended depth of focus.

To examine the contrast sensitivity in the absence of a control group, we used historical data. For photopic contrast sensitivity we compared outcomes with a population of healthy 55-to-70-year-olds without cataracts and we found little difference between the groups. For mesopic contrast sensitivity, we used a different population of healthy 20-to-50-year-olds and in this comparison both groups performed similarly at lower frequencies but slightly worse at higher frequencies.

Therefore, we can conclude that the xact™ Mono-EDoF™ ME4 IOL provides good functional results for far and intermediate visual acuity and the defocus curve is typical for an IOL with extended depth of focus. Furthermore, contrast sensitivity is comparable to a control group without cataracts and there was a low level of photic phenomena and a high level of patient satisfaction.

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