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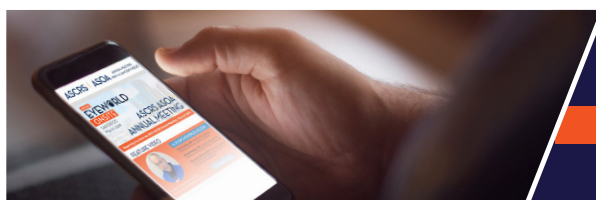
A BRAND NEW DAY

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IN FOCUS

INNOVATIONS IN LENSES

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Small aperture diaphragms make their way into IOLs, showing promise for presbyopia correction as well as treatment of some corneal irregularities.

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Despite progress in IOL designs and compatibility, there are still several key areas of unmet need.

Bringing small aperture optics to the IOL plane

by Liz Hillman
EyeWorld Senior Staff Writer

At a glance

- Bringing small-aperture diaphragms to the IOL plane is showing promise for presbyopia correction by providing increased depth of focus and treatment for corneal irregularities.
- The IC-8 is CE marked in Europe and under an FDA-approved clinical trial. XtraFocus also earned the CE mark and is hoping to enter a clinical trial in the U.S. within the next year.
- The IC-8 is primarily indicated for presbyopia correction.
- XtraFocus is indicated for the treatment of irregular corneal astigmatism.

Small aperture use to increase depth of focus in vision is nothing new, but bringing that pinhole effect to the IOL plane is an innovation in Europe that is beginning its journey in the U.S.

The concept is simple: Place a small-aperture diaphragm at the IOL plane during cataract surgery to get quality distance and near vision with natural transitions.

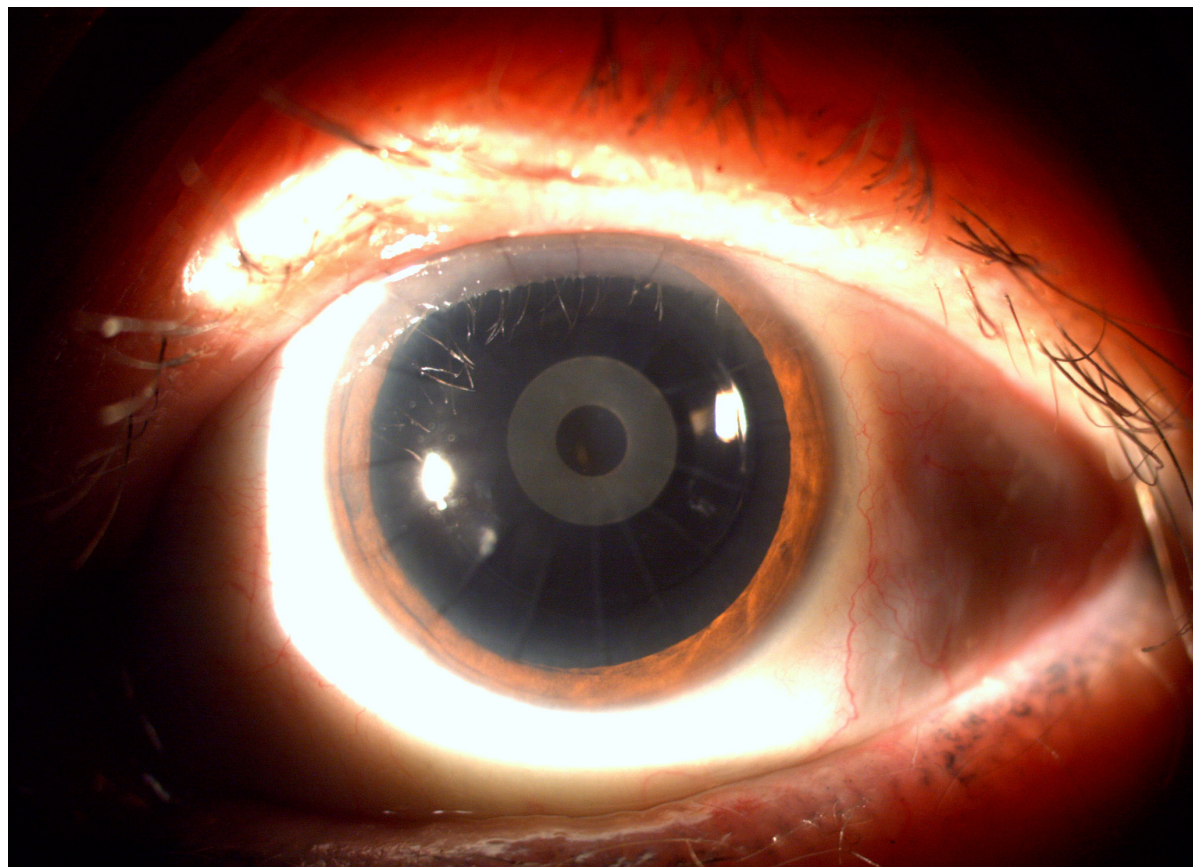
Research also shows this concept's utility in treating difficult corneal irregularities, such as post-RK, keratoconus, and scarring.

So far, two companies are developing such technology, albeit with different primary aims. The IC-8 IOL (AcuFocus), CE marked in Europe as of 2014 and currently in an FDA-monitored Phase 3 clinical trial in the U.S., is a single-piece,

hydrophobic, acrylic lens with refractive power. XtraFocus (Morcher, developed with Claudio Trindade, MD) is a foldable, hydrophobic, acrylic, piggyback, sulcus-based implant with no refractive power; it earned the CE mark in 2016.

IC-8 IOL

The IC-8's primary goal is to provide extended depth of focus to patients seeking spectacle independence at the time of cataract surgery. Enrollment for the prospective, multicenter trial with the goal of comparing the extended depth of focus achieved with the IC-8 to a monofocal IOL is going well, according to Kevin Waltz, OD, MD, medical monitor for AcuFocus. Dr. Waltz, who used earlier iterations of the IC-8 overseas since 2009, said experience has shown the concept has



The IC-8 IOL is primarily indicated to extend patients' depth of focus.

Source: Gabriel Quesada, MD, and Rodrigo Quesada, MD

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good visual acuity and natural range of vision with less variation as you move an object closer or farther.

“The pinhole works beautifully through distance, intermediate, and some level of close, and starts to fall off in a typical way that normal vision falls off,” he said.

John Vukich, MD, an investigator in the U.S. trial, said that so far, this lens has provided high quality vision with smooth transitions.

“There is a smooth depth of focus without any transitions like we would see with a traditional multifocal or trifocal lens,” he explained. “It is a lens that has shown it does not diminish distance visual acuity and has minimal symptoms of glare, halo, and some of the more troubling optical aberrations that are inherently part of what we see with traditional multifocal lenses.”

Vance Thompson, MD, who is also an investigator on the current trial, said patients seeking spectacle independence is the fastest growing area of his practice. Experience from international colleagues, Dr. Thompson continued, shows an impressive range of vision and quality of vision with this IOL.

The original lens was essentially taking a KAMRA inlay (CorneaGen, originally produced by AcuFocus) and putting it into a three-piece silicone IOL, Dr. Waltz said. The current iteration IC-8 incorporates more sophisticated sizing of the aperture (1.36 mm) and overall diameter (3.23 mm), and a single-piece acrylic design, which Dr. Thompson said is a very comfortable platform for cataract surgeons.

The physicians noted this lens is very forgiving and centers well. Though the IC-8 centers well, in general, Dr. Waltz said that decentration at the IOL plane seems much less of an issue than it is at the corneal plane (centration of the KAMRA inlay is very important). This lens also tolerates up to 1.5 D of astigmatism, Dr. Vukich said, putting less burden on the physician.

“This lens is forgiving and produces equal quality of measurements up to a diopter and a half of astigmatism,” Dr. Vukich said.

Dr. Thompson said the IC-8 is a benefit for patients with astigmatism at or below this level, compared to a toric IOL, because it makes rota-

▶ What is the pinhole effect?

A pinhole, or small aperture, blocks peripheral rays of light, letting only focused light through the center of the optic to enter the eye. This improves the quality of the light that is getting through, and, thus, image quality is improved.

tion a non-issue. He also said that while they are trying to hit -0.75 D in the IC-8 eye and plano in the monofocal eye, international colleagues find this combination tolerates small deviations from the intended target, reducing the need for postop enhancements.

Dr. Waltz said those who need to do more close work or who are shorter in stature may be better suited for other presbyopia-correcting options. Retinal issues, however, are not contraindications, Dr. Waltz said, explaining that the retina and optic disc can be viewed and imaged well through the pinhole.

Post-RK, post-refractive surgery, keratoconic, and scarred corneas all give cataract surgeons pause because they complicate accuracy in hitting refractive targets. Dr. Vukich called the IC-8 a “rescue option” for these patients. Though neither the lens’ primary use nor one being studied in the FDA trial, this technology has found “great utility” in difficult cases, Dr. Vukich said.

As Dr. Thompson said, “the landing strip is wider because you are extending depth of focus and there is a much higher chance of patient satisfaction by doing so. We’re seeing internationally high patient satisfaction at those small levels of residual refractive error because we are extending depth of focus.”

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XtraFocus is a piggyback pinhole implant indicated for treatment of irregular corneal astigmatism.

Source: Claudio Trindade, MD

XtraFocus

While corneal irregularities are a secondary focus of the IC-8, XtraFocus, a piggyback implant for the ciliary sulcus, is specifically designed to address them. The main indication for this implant, according to Dr. Trindade, is for irregular astigmatism with secondary indications being enhanced depth of focus and dysphotopsias related to previous multifocal IOL implantation.

“It is a matter of going after the most relevant unmet need, which in my opinion, is irregular corneal astigmatism,” Dr. Trindade said. “As with any new technology, it is best suited for cases where currently available treatments have shown to be ineffective.”

The fourth-generation XtraFocus with a total diameter of 14 mm, an optic diameter of 6 mm, and pinhole diameter of 1.3 mm was CE marked in September 2016, and according to Dr. Trindade, Morcher is planning an FDA trial for 2020. The implant’s larger overall diameter and thin (250 μm) haptics angled at 14 degrees with rounded, polished edges help prevent uveitis-glaucoma-hyphema syndrome, according to Morcher.

Dr. Trindade said XtraFocus could be implanted at the time of cataract surgery or after cataract surgery.

“In some cases of irregular astigmatism, conventional cataract surgery may give surprisingly good results. Therefore, a secondary pinhole implantation is usually advisable,” he said. “However, in cases of larger pupils (>4 mm mesopic), a primary approach is reasonable to spare a probable second surgical intervention. Therefore, pupil diameter assessment is key to assist this decision.”

Dr. Trindade sees a benefit of XtraFocus being piggyback: Surgeons have the freedom to choose their preferred IOL with no power restriction, which he noted is important in post-RK and keratoconus cases.

“In keratoconus, a low-powered IOL is often needed because of the high corneal curvature, while in post-RK cases a high-powered IOL is usually necessary because of the very flat cornea,” he explained, noting what he thinks are limitations of the IC-8, namely its power range (+15.5 to 27.5 D) and lack of a toric version.

Although the pinhole effect is able to “neutralize” some regular astigmatism, in some post-PK and keratoconus patients, a high-cylinder toric IOL plus XtraFocus may be a good combination, Dr. Trindade said. Confirmation of topographic stability is mandatory before surgery.

The ideal refractive target when XtraFocus is implanted at the time of cataract surgery for treatment of irregular astigmatism is -2 D, while patients with normal corneas seeking extended depth of focus should be targeted for -0.75 D.

Fitting in with other innovations

With continued innovation in other areas of IOL technology, such as adjustable IOLs, where does the pinhole effect fit in? Dr. Vukich envisions that the two might be synergistic. An adjustable IOL can achieve a specific refractive endpoint, Dr. Vukich said, but it doesn’t provide depth of focus.

“The IC-8 is intended to be used in one eye, in a monocular state. It might be that the fellow eye could be treated with a Light Adjustable Lens [RxSight], and given that combination, you could pinpoint the vision where you want it to be and provide a consistent outcome,” he said.

Overall, Dr. Waltz said because the IC-8 is only implanted in one eye, it could be a less expensive presbyopia-treatment compared to others on the market and thus could provide access to more patients.

Pinhole optics is something that ophthalmologists and optometrists use every day, Dr. Thompson said.

“The beauty is its simplicity and how used to it we all are. The patient explanation is so easy. I’ve enjoyed the ease of patient education and the simplicity and power of this timeless optical principle now applied to the IC-8 implant,” he said. ●

Financial interests

Thompson: AcuFocus

Trindade: Morcher

Vukich: AcuFocus

Waltz: AcuFocus