SMALL APERTURE TECHNOLOGY:
Extending Depth of Focus for a Broad Spectrum of Presbyopic and Cataract Patients
Small-aperture technology relies on the small aperture, or pinhole effect to extend depth of focus by blocking unfocused peripheral light rays and allowing only central light rays to reach the retina. Initially introduced by AcuFocus, Inc. in the form of the KAMRA™ corneal inlay, it is now also available for intraocular use. The IC-8™ small aperture IOL is a single-piece hydrophobic acrylic IOL embedded with a central, opaque annular mask. The mask is 3.23 mm in overall diameter, with a 1.36-mm central opening, or aperture.

One year clinical data suggest that the IC-8 IOL functions like a premium lens with the ease of use of a monofocal IOL. It provides continuous vision over a wide range that includes intermediate distance, without the quality-of-vision problems that have been associated with multifocal IOLs. When both eyes are plano, the small-aperture IOL provides functional vision (20/40° or better) over 2.75 D of defocus. Aiming for a slightly myopic target (-0.75 D) in the IC-8 eye extends that range even further to provide continuous, functional vision over 3.00 D of defocus (Fig 1).

Monocular but not monovision

Both the KAMRA corneal inlay and the IC-8 small aperture IOL are monocular technologies, designed for implantation into a patient’s non-dominant eye. However, the result is quite different from monovision.

In the European post-market study for the IC-8 IOL, mean monocular UCDVA was 20/25. This is the distance vision in a real-world setting, regardless of what refractive target surgeons set or achieved. Distance-corrected (plano) and binocular far vision are even better, 20/20 and 20/16, respectively.

Another advantage over monovision is the maintenance of stereopsis with a small aperture. As we know, the visual system detects the true distance of an object by merging together similar images from the two eyes. When one of the images is grossly out of focus—as it will be coming from a myopic eye in monovision—stereopsis is compromised and the resulting distance vision cannot be as accurate. This may be especially bothersome to the patient with previously normal stereopsis before surgery.

With small aperture optics, the “near” eye still has excellent distant vision, as described above. The visual system receives two images that can be successfully converged. Pablo Artal PhD, and colleagues have demonstrated that small-aperture optics produce a benefit in stereoaucity compared to monovision and that, even when a small aperture is combined with a small amount of myopia, it preserves stereoaucity similar to that of normal binocular vision.1

Both patients and doctors can appreciate the benefits of implanting effective presbyopic IOL technology in one eye only because it supports the most natural far vision with the most accepted IOL technology—aspheric monofocal IOLs—in the dominant eye.

Overcoming the major source of dissatisfaction

Problems with driving, particularly at night, are a major source of dissatisfaction with bifocal multifocal technology, and a significant barrier for my European colleagues and our patients in adopting presbyopia-correcting technology. By eliminating or significantly reducing the chance of such problems, small aperture technology can help surgeons build a more successful refractive cataract practice.

A small aperture essentially provides continuous extended depth of focus. This is what allows the patient to achieve near and intermediate vision, but the same effect is working on far distance, too, allowing for good vision even with some defocus or astigmatism present.

With a bifocal or trifocal IOL a patient who is -0.75 D + 1.00 D would have poor quality vision with glare and halo. If the symptoms are severe enough, explantation may be needed. This same refractive result would provide excellent vision and high satisfaction with the small-aperture lens.


“The greatest advantage of the IC-8 IOL, in my opinion, is that it is unlikely to cause problems with distance vision or driving, regardless of the refractive outcome.”
The IC-8 small aperture IOL is an aspheric, extended depth of focus (EDOF) lens that is commercially available in Europe. It is made of a hydrophobic acrylic material with a high Abbe number, which means that different color wavelengths of light disperse less through the material, reducing its chromatic aberration. The lens has an embedded annular mask that focuses light through a central “pinhole” aperture, which not only extends the depth of focus, but also allows it to compensate for small amounts of defocus, astigmatism, and higher-order aberrations, further improving quality of vision.

The IC-8 IOL meets ANSI standards for EDOF lenses. At 6 months, 97% of eyes have binocular uncorrected acuity of 20/25 or better for far distance, 87% have 20/25 or better for intermediate, and 81% have 20/32 or better for near.

**Impressive MTF curves**

Through-focus image quality modeling, performed at a spatial frequency of 50 lp/mm using an ISO model eye and white light, shows that the IC-8 IOL provides higher overall quality of vision and a longer continuous range of high quality vision than any of the leading trifocal IOLs or the Symfony lens (Fig 1).

Unlike the distinct peaks in modulation transfer function (MTF) at each of the focal points that one sees with other presbyopia-correction IOLs, the small-aperture lens provides high quality vision over a continuous range. That means that patients don’t have to find the “sweet spot” at which to hold reading material or a device, but can enjoy a more fluid, natural visual experience.

For extremely close work, the IC-8 IOL may prefer to wear reading glasses, but for most patients that will be a worthwhile compromise, given the relative gains in visual quality and intermediate acuity.

**Binocular CS unaffected**

Some surgeons have been concerned that the method of action of a small aperture lens, because it blocks some light from reaching the retina, may affect contrast sensitivity (CS).

Several studies of the KAMRA™ small aperture corneal inlay have now demonstrated that photopic and mesopic monocular contrast sensitivity (CS) remain within the range of the normal population one to three years after inlay implantation. Kamra inlay subjects have also been shown to have significantly better binocular mesopic CS than subjects implanted with three types of presbyopia-correcting IOLs.

In a substudy of the European post-market IC-8 IOL study, contrast sensitivity was slightly decreased in the IC-8 eye compared to the fellow eye implanted with an aspheric monofocal IOL. However, binocular CS at six months was not affected; it remained equivalent to that of the monofocal IOL eye. Contrast performance also continues to improve over time with neuroadaptation.

The binocular nature of the distance vision with the IC-8 lens also provides an important quality-of-vision advantage over monovision. Artal and colleagues have shown that binocular summation (which is reduced with monovision but not with the small-aperture IOL) mitigates poor visual performance under low-luminance conditions.

In summary, although light transmission to the retina is reduced in an IC-8 IOL eye, studies of subjects implanted with this lens or with its corneal counterpart, the KAMRA inlay, suggest that binocular summation and neuroadaptation allow patients to maintain very good contrast sensitivity.

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**References:**

The IC-8™ IOL received CE Mark in Europe since 2014. It offers a unique way to provide patients with greater depth of focus following cataract surgery. I have been participating in an ongoing post-market study in six European countries to validate the early results with this lens. We have enrolled a total of 115 subjects across all the sites; 90 subjects have reached the six-month mark thus far.

The IC-8 procedure
All subjects in the post-market evaluation have had contralateral implantation of the IC-8 IOL in the non-dominant eye and any clear, aspheric monofocal lens in the fellow eye.

The lens A-constant is 120.5. Keratometric data for calculating IOL power in the post-market study was obtained from the IOL Master. The target refractions were 0.00 D/plano in the monofocal lens eye and -0.75 D in the IC-8 eye.

The surgical implantation technique is no different than we would use for any other cataract surgery with a refractive lens. Surgeons can rely on their own customary cataract removal technique, with a choice of manual or femtosecond laser-created incisions, capsulotomy and lens fragmentation.

In-the-bag implantation of the lens is performed just as it would be with any other IOL. However, surgeons who are accustomed to making a sub-2.0-mm incision may have to make a slightly larger wound to accommodate the injector.

The small aperture is tolerant to decentration. Reports have suggested that it can be displaced by up to 1.0 mm without any degradation of visual quality or acuity because the optic is very close to the nodal point.1

Visual acuity results
Visual acuity results are shown in Figure 1, including uncorrected (UC) vision, distance corrected (DC, both eyes corrected to plano); and target corrected (TC, the IC-8 eye corrected to -0.75 D and the monofocal eye corrected to plano). The UC results are representative of what patients actually obtained in the study, but the TC results best illustrate the potential for the procedure, if surgeons attempt and achieve the recommended target refractive result in each eye.

The mean postoperative MRSE in the study population was -0.38 D in the IC-8 eyes and +0.02 D in the monofocal eyes, so it was slightly short of the targeted -0.75 D. When the eyes are target-corrected, we find that TC acuity is excellent at all distances and improves over time (Fig 2).

UC near visual acuity was very similar whether measured in the IC-8 eye or binocularly. These near acuities were achieved with UC distance of 20/25 or better in 97% of eyes. Only 6% of subjects had any spontaneous reports of dysphotopsia and 97% said they would have the procedure again.

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My early clinical experience with the IC-8™ small aperture IOL has been very encouraging. Thus far, I have implanted eight of these IOLs, two of them in post-refractive eyes. This small aperture IOL implanted in the non-dominant eye seems to provide excellent distance, intermediate, and near vision without significant night vision symptoms.

One of the advantages of this lens is that the design and lens material as well as the loading and injection techniques are very similar to what one would find with any standard single-piece hydrophobic acrylic IOL. This eliminates a learning curve for cataract surgeons who want to incorporate this lens into their practices. Currently the lens requires a slightly larger incision—between 2.75 and 3.00 mm—however, the company is working on reducing the incision size. Care should be taken to ensure that the capsulorrhexis is centered on the visual axis for optimal performance.

I implant this IOL only in the non-dominant eye. I aim for a refraction of -0.75 D or -1.00 D in the IC-8 eye, pairing it with a plano target in the fellow dominant eye. This slightly myopic refraction will provide the patient with a good amount of intermediate and near vision due to the increased depth of focus. I find that it is not necessary to correct any astigmatism the patient may have because the pinhole effect of the IC-8 IOL corrects for it. However, I do try to make my incision on the steep meridian to prevent surgically induced astigmatism.

Post-refractive patients
In the past, I have been hesitant to recommend premium presbyopia-correcting IOLs for post-refractive patients. As we all know, implanting a multifocal IOL into an eye with induced aberrations in the cornea has the potential to reduce contrast and cause glare and halos. In addition, IOL power calculation and axis measurement can be quite challenging in these eyes. Although some surgeons would consider an extended-depth-of-focus IOL (like Symfony from Abbott Medical Optics) for post-refractive patients, I still hesitate to use IOLs with diffractive technology in eyes with previous laser vision correction.

The IC-8 lens gives us an excellent new option for post-refractive patients who, I would argue, are among those most interested in premium lenses. They have already demonstrated a willingness to pay out-of-pocket for elective surgery to achieve spectacle independence in the past and are likely to want to maintain that spectacle independence.

I use the ASCRS post-refractive calculator to help determine the correct IOL power. Because of the pinhole effect, leading to increased depth of focus, the IC-8 IOL is in some ways forgiving; patients can still achieve good range of vision even if the IOL power is a little off. The pinhole effect also gives post-refractive patients good visual performance without the contrast issues and glare and halos that have been associated with multifocals in these eyes.

Role in my practice
I recommend the IC-8 IOL to patients who are especially concerned with visual symptoms like glare and halos, in addition to post-refractive patients. Although there is a line or two of compromise in monocular distance vision, the monofocal lens in the dominant eye compensates for this, ensuring that patients do not experience any loss of acuity with both eyes open.

I am beginning to offer the IC-8 IOL to more and more patients to whom I would have offered a multifocal or extended-range-of-vision lens in the past. In addition, I think we will find an important role for it with post-refractive patients, and potentially those with significant corneal aberrations or damage to the pupil or iris. I believe the IC-8 lens has the potential to reach a wider group of patients in my practice, including many of those to whom I would have not previously recommended premium lens technology.

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Slit lamp photos of the IC-8 Small Aperture IOL in two eyes
**RETINAL EVALUATION AND PROCEDURES WITH SMALL APERTURE TECHNOLOGIES**

It is possible to effectively evaluate the retina and treat retinal pathology with a small-aperture inlay or IOL in place - Robert T. Ang, MD, and H. Burkhard Dick, MD, PhD

Increasingly, experience suggests that the full range of retinal diagnostics, imaging, and treatment of retinal pathology is possible with either the KAMRA™ corneal inlay or the IC-8™ small-aperture IOL in place, with only minor adjustments needed.

**Retinal examination**

Surgeons have reported that retinal exams and imaging were easily achieved with the KAMRA inlay in place. All retinal quadrants can be examined with a digital, wide-field lens or with Goldmann contact glass fundoscopy.

In selecting patients for IC-8 implantation, it is recommended that pupils are able to dilate to 6.0 mm for better retinal visualization. With this criterion, we have found that visualization of the retina through the IC-8 IOL mask's central aperture is possible, with only minimal differences in visual field, fundus photography (Fig 1) and retinal OCT noted between the IC-8 IOL and fellow eyes implanted with a monofocal IOL. Moreover, technicians have reported that OCT and other routine diagnostic testing can be performed successfully and that no special instructions are needed for carrying out this testing in IC-8 eyes.

The view and ease of performing retinal procedures was also recently studied in rabbit eyes implanted with the IC-8 lens compared to those implanted with a monofocal or multifocal IOL. The mean scores for image quality, stereopsis, depth perception and contrast sensitivity were the same for all three types of IOLs.

**Vitrectomy and surgery**

There have been anecdotal reports of successful pars plana vitrectomy (PPV) in KAMRA inlay eyes. PPV has also been successfully performed in IC-8 pseudophakic eyes for central and peripheral retinal detachment and for treatment of diabetic retinopathy.

Several different microscope viewing systems can be used for visualization during vitrectomy, with direct contact lens or indirect wide-field viewing. Depending on the location of the work, central and/or peripheral lenses may be needed to visualize the posterior segment.

Epiretinal membrane peels have also been performed without any loss of stereopsis or ability to judge the depth of the membrane. A direct contact lens (Kilp) can improve detail visualization for peeling.

**Argon laser treatment**

Fortunately, intravitreal anti-VEGF injections have reduced the need for pan-retinal photocoagulation (PRP), but there will be occasions when argon laser treatment is necessary. In an eye with a KAMRA inlay, the inlay should be removed to prevent the laser from potentially damaging it or the surrounding corneal tissue. The inlay can be replaced after the procedure if desired.

If the small-aperture IOL has been implanted, the surgeon may perform argon laser treatment with the IOL in place, taking care to aim around the mask. In testing, when 150-mW argon laser energy was intentionally aimed at the outer region of the aperture mask, it created only a slight cosmetic mark on the anterior side of the mask (Fig 2). The lens remained intact with no laser energy disruption of the clear optic and no detectable effect on the posterior surface of the mask.

Surgeons should avoid implanting the small aperture inlay or IOL in eyes with active retinal disease. However, we are confident that experienced surgeons will be able to handle any unforeseen retinal issues that develop over time in eyes previously implanted with a small aperture device.

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COMMERCIAL EXPERIENCE WITH THE KAMRA INLAY: RESULTS AND LESSONS LEARNED

Gaining an understanding of what “small aperture vision” means helps surgeons explain it to prospective patients - Shamik Bafna, MD

Since the approval of the KAMRA™ corneal inlay in the United States, we have implanted more than 125 KAMRA inlays in our practice, learning some important lessons along the way about how to talk to patients, what to expect, and how to optimize the results.

Many surgeons have the misconception that the small-aperture inlay is similar to monovision because it is designed for monocular implantation. However, unlike monovision, the KAMRA inlay patients do not give up the distance vision in their non-dominant eye. A typical result is for patients to have J1 vision at near and still retain 20/20 to 20/25 vision at distance.

Based on an analysis of our first 77 patients, more than half the KAMRA inlay eyes (54%) have 20/25 or better uncorrected distance on Day 1 postop. By 1 month, more than 60% have both near and distance acuity of 20/25 or better uncorrected, and the results continue to improve, with impressive uncorrected acuity in the inlay eye at 3 months (Fig 1).

Secondly, the inlay continues to provide excellent near vision as presbyopia progresses with increasing age. Patients who are satisfied initially will continue to be satisfied until they develop cataracts, which is not the case when we give a 45-year-old a monovision correction.

State-of-the-art procedure

To get the most from the KAMRA inlay, patients should ideally have a healthy ocular surface with good tear film and a starting refraction of -0.75 D to -1.00 D in the nondominant eye and plano in the dominant eye. If they are not in this target range, it is well worth it to perform LASIK to get them to the correct target.

Some international surgeons may have had experience placing the inlay under a flap but we now know that when implanted in a deep stromal pocket—preferably around 250 µm deep—there is less inflammation, less chance of dry eye, and faster visual recovery. The pocket should be at least 100 µm below a LASIK interface, which can be identified with anterior segment OCT if necessary.

I also find that tighter spot-line separation settings on the femtosecond laser used to create the pocket yields better visual results. The company recommends 6x6 or below; I prefer 4x4.

The KAMRA inlay should be centered on the 1st Purkinje image unless the eye has a high angle kappa, in which case it can be centered halfway between the 1st Purkinje and the coaxially-sighted pupil center. Overall, I have found the KAMRA inlay to be quite forgiving in terms of centration.

Finally, it is important to set expectations correctly. Approximately one-third of our patients have had excellent vision in the first week, but most take longer to achieve the desired visual outcome. We counsel patients to expect continued improvement over the initial 4 to 8 weeks.

Now that we understand what “small aperture vision” entails and have honed the elements of the ideal procedure and best candidates, the KAMRA inlay has become a tremendous practice builder.

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US COMMERCIAL RESULTS

The KAMRA inlay was launched in the U.S. in June, 2015. To date, nearly 3,000 inlays have been implanted around the U.S.

“The KAMRA corneal inlay has been adopted at a faster rate in the U.S. than we have seen elsewhere,” said Steven Schallhorn, MD, Global Medical Director of Optical Express and a consultant to AcuFocus. “That may be because U.S. surgeons had the benefit of learning from the global experience and were able to begin performing inlay surgery with a very refined procedure.”

Six-month results from commercial use of the KAMRA inlay show that, as expected, distance vision in the inlay eye is reduced by about one line. Uncorrected distance visual acuity is 20/25 in the inlay eye and binocularly, and remains essentially unchanged across all postoperative visits. Uncorrected near vision improves by 3.5 lines, on average, by one month—a gain that is maintained out to six months. Mean uncorrected near acuity is J2 in the inlay eye and binocularly. The removal rate is very low—just 1.6%, with visual acuity, dysphotopsia, and refractive changes being the primary reasons for removal.
B}ased on my early experience with the IC-8™ IOL—both in the European post-market study and in my private practice—I am very enthusiastic about offering this option to my patients. I believe it is a much easier choice than traditional multifocal IOLs. Additionally, a small-aperture lens is well suited for challenging patients who might not otherwise have been candidates for a premium lens.

**Forgiving of refractive misses**

Due to the depth of focus provided by the small aperture, the IC-8 is quite forgiving of a missed target refraction. It has an approximately 3.0D range of 20/40 or better vision. Adding a small amount of myopia (up to -0.75 D) extends the functional range of vision without appreciably affecting distance vision.

Unlike with bifocals and trifocal IOLs, the outcome does not need to be within 0.25 D of the intended target for the patient to achieve an excellent outcome. In the European post-market study, for example, the mean postoperative refraction in the IC-8 eyes was -0.38 D—not quite the -0.75-D recommended target. Despite this, satisfaction very high, with 97% of 115 subjects saying they would elect to have the procedure again. Further analysis shows acuities and satisfaction remain essentially unchanged when the patient’s MRSE is within +/- 1.00 D of the -0.75 D target refraction.

The IC-8 lens is also very forgiving of residual astigmatism—again, in contrast to my experience with multifocal IOLs.

Optical modeling analysis had previously demonstrated that at every level of astigmatism up to 1.5 D, estimated visual acuity is better with a small aperture than without. Recently, Dr. Bobby Ang evaluated cylinder defocus curves for 10 patients implanted with the IC-8 lens in one eye and a monofocal IOL in the fellow eye. Cylinder was added to both eyes in the same axis as the existing axis of astigmatism, starting from the manifest refraction. The change in distance visual acuity was compared to the visual acuity corrected at manifest refraction at each cylinder defocus step (Fig 1). Even with 1.5 D of simulated cylinder error, patients lost less than one line of distance visual acuity in the IC-8 eye, which performed better than the monofocal eye.

Surgeons can be more confident that, even in the event of some unwanted residual refractive error, patients will be highly satisfied with the results.

This is very exciting because it gives us the opportunity to offer the benefits of an extended depth of focus lens to patients without having to perform an additional astigmatic procedure or worry about toric misalignment or post-op rotation.

In the European post-market study, in which I am participating in as an investigator, we enrolled patients with up to 1.75 D of corneal astigmatism and found that residual cylinder up to 1.50 D had little to no effect on visual acuity. About 12%-15% of the study subjects had >0.75 D of cylinder.

**Challenging eyes**

The IC-8 IOL is also a good choice for more challenging eyes or patients with high visual demands. For example, I have implanted it with very good results in a pilot who had a critical need for intermediate vision to see his instrument panel. I would have been reluctant to implant other presbyopia-correcting IOLs that have much more limited intermediate vision in this eye.

I am planning to implant one soon in an eye with high cylinder from a previous corneal transplant. The small-aperture lens may not completely eliminate this patient’s astigmatic error but it seems to me a very good option for a patient who may need another keratoplasty in the future and is therefore not a candidate for a toric lens.

Finally, I think the small-aperture lens will be a great choice for post-refractive eyes. These patients typically have more corneal aberrations and they present a challenge for accurate power calculation. Some (especially post-RK patients) have problems with severe glare and halo that could be eliminated with a small aperture.

I have already implanted the IC-8 lens in a post-LASIK patient whose corneal treatment was a little decentered but who still enjoyed very good distance vision prior to developing a cataract. I started with her dominant eye, just to be sure of the power calculation. After the IC-8 implantation in the non-dominant eye, she now has 20/20 binocular distance and can read J1.

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**Fig 1. The IC-8 small aperture IOL compensates for the effects of uncorrected astigmatism up to 1.5 D.**

Data courtesy of Dr. Robert T. Ang.