

## REFRACTIVE SURGERY

# Corneal Inlays for Presbyopia Move Closer to Approval

BY MARIANNE DORAN, CONTRIBUTING WRITER

**W**ith more than 60 million emmetropic presbyopes in the United States, the potential market for a simple, reversible procedure to correct presbyopia is huge. Two companies—with three experimental corneal inlay devices between them—are vying for that market, hoping to capture the millions of middle-aged individuals who would like to be far less reliant on spectacles or contact lenses without undergoing a more permanent procedure.

That hope may be edging its way to reality. The corneal inlay devices currently under investigation are the ACI 7000 (AcuFocus), the InVue (also by AcuFocus but formerly under development by BioVision) and the PresbyLens (ReVision Optics).

The ACI 7000 is the furthest along, with a fully enrolled clinical trial of nearly 500 patients and an estimated completion date of 2012.

The three devices differ in the materials, size and approach used to restore near vision. They are implanted in the nondominant eye through surgical creation of a flap or corneal pocket, and the procedures are reversible.

Jack T. Holladay, MD, clinical professor of ophthalmology at Baylor College of Medicine in Houston, noted that the InVue and PresbyLens inlays achieve their near-vision improvement by adding power and creating a multifocal cornea, whereas the ACI 7000 increases depth of focus through an aperture device.

### ACI 7000

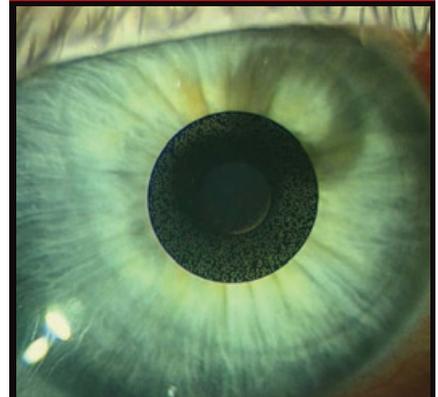
The ACI 7000 is the most mature technology, according to Richard L. Lindstrom, MD, founder and attending surgeon for Minnesota Eye Consultants in Bloomington, Minn., and adjunct professor emeritus of ophthalmology at the University of Minnesota. The device is 3.8 mm in diameter and 5  $\mu$ m thick, and it relies on a 1.6-mm central aperture optic surrounded by a nearly opaque material called Kynar. “The device works the same way a pinhole does to increase depth of focus, and it does not change the optics of the cornea,” Dr. Lindstrom said. “The company calls the device the Kamra because it functions like the f-stop on a camera.”

The ACI 7000 inlay can be placed on the bed of a deep (200 to 250  $\mu$ m) LASIK flap or inserted into a corneal pocket. Francisco Sánchez León, MD, medical and scientific director of the Instituto Novavision in Naucalpan, Mexico, believes pocket placement is preferable.

“Corneal flaps are very shallow and may compromise nutrition to the anterior cornea,” Dr. León said. “Dry eye issues and the possibility of lens decentration are other concerns. Lens decentration can occur because the flap adhesion is not tight enough in the early postoperative period to hold the lens in place.”

He added that using a femtosecond laser to dissect a corneal pocket allows the inlay to be placed more deeply. “The inlay should be injected into

### Another Aperture



The ACI 7000, shown here in a patient of Dr. Lindstrom's, is the inlay technology with the longest track record.

the middle stroma, where it will not compromise anterior nutrition or increase the risk of neurotrophic corneal disease. The inlay fits securely in a corneal pocket, preventing the movement that can lead to decentration.” Other potential advantages of pocket placement include avoidance of unexpected topographic changes and astigmatism, he said.

### InVue

The InVue corneal inlay, recently acquired by AcuFocus, is a small, round hydrogel optic that is implanted in the center of the cornea. The device is 2.0 to 3.0 mm in diameter and 10  $\mu$ m thick. It has a higher refractive index than the cornea and creates a bull's-eye or center-surround bifocal. Reading and other close work are accomplished

through the central zone, and distance vision is achieved through the peripheral zone.

According to Dr. Lindstrom, insertion of the InVue device involves making a small pocket about 400  $\mu\text{m}$  deep in the cornea with a lamellar dissector, a microkeratome capable of making a pocket or a femtosecond laser. The pocket is made under topical anesthetic and must be well centered on the visual axis.

InVue—and PresbyLens—produce results similar to those obtained with a multifocal contact lens or a multifocal intraocular lens. “You gain a second image, so there is some loss of contrast sensitivity,” Dr. Lindstrom said. “Depending on the power applied, there also can be some loss of intermediate vision, or with a lower-powered implant you can have good intermediate vision but less-than-perfect distance vision.” Mild color distortion or halos at night are also possible, he said.

### PresbyLens

ReVision Optics’ PresbyLens is another hydrogel implant, but its refractive index matches that of the cornea. The device is only 1.5 mm in diameter and is placed just beneath the surface in the center of the cornea. The result is similar to what is achieved with the InVue inlay, but the PresbyLens actually changes the shape of the cornea.

“It’s somewhat akin to the optics that are utilized in an excimer laser presbyLASIK procedure or in an IntraLase IntraCore procedure,” Dr. Lindstrom said. “A central steepening in the range of 2 to 3 mm is created, leaving the peripheral cornea for distance vision.”

PresbyLens is inserted through a large flap that resembles a LASIK flap but is not open as far around. Dr. León noted that the flap is typically 120 to 130  $\mu\text{m}$  thick and can be made with a microkeratome or a femtosecond laser. PresbyLens is supplied preloaded onto a delivery device, he added, and is slid into place in the center of the pupil. After the lens is allowed to dry for a few seconds, the flap is folded back across the lens.

### Multifocality vs. Apertures

Each of the inlays compromises night vision to some degree, but Dr. Holladay pointed out that the multifocal inlays have some additional downsides.

“The difficulty we have seen with these devices is that they do provide some near add, but it depends on the person’s pupil size,” he said. “If someone with a large pupil receives a 2.2-millimeter 2-diopter add, the area occupied by the inlay add is so small that the patient doesn’t see much benefit. If the area of the pupil is small, the person will have some problems with distance vision because the near power occupies too much of the pupil at a distance. Also, if you use multifocality as the basis for presbyopic correction, greater multifocality will be directly proportional to loss of contrast sensitivity.

“With apertures, you don’t have that problem,” Dr. Holladay continued. “When you cone the aperture down, the cone of light is so narrow that the quality of the image is the same whether you are at 33 centimeters or infinity.”

Dr. Lindstrom also gave the aperture device good marks. “The contrast sensitivity and quality of vision have been quite good in the daytime. You retain good distance vision, and you gain good near vision, but the near vision has been more of a J2. With the other two devices, you can get J1 or J1+ near vision, but you lose a line or two of distance vision.”

Dr. Holladay noted that the FDA trial of the aperture-based ACI 7000 is in its final stage. “The product has been slightly revised over the last four or five years in terms of thickness and in the size and location of the fenestrations in the annulus that allow glucose and other metabolites to diffuse through the cornea,” he said. “With these changes, the product now performs as well as it did before, but without any complications in the cornea.”

He noted, however, that in dim light, such as candlelight, a person whose pupil is just up to 3.8 mm does not receive any light coming around the 3.8-mm annulus. The only light received is through the 1.6-mm aper-

ture. In a very low-light situation, he added, the effect is similar to being on pilocarpine or another miotic, and a person may feel that it is too dim to read. However, this does not interfere with an individual’s ability to walk around in the dim light because the other eye is functioning normally and the balance of the two provides more than enough light.

Dr. Holladay added that the ACI 7000 is now available in Europe and in China. He said that he expects the international experience to be similar to the success seen in the U.S. studies.

### Who Is the Best Candidate?

The ideal candidate for a corneal inlay is an emmetropic early- to mid-presbyope, said Dr. Lindstrom. He noted that corneal inlays may be performed in combination with other procedures to correct refractive error. “They can be done along with LASIK or PRK to correct myopia, hyperopia or astigmatism or on a patient who has had LASIK or PRK,” he said. “A corneal inlay procedure also can be performed on a patient who has a phakic intraocular lens or a standard monofocal intraocular lens after cataract surgery. Once a patient is emmetropic or is surgically made emmetropic, the device simply adds near vision.”

Dr. Holladay sets the upper age limit for implanting a corneal inlay at around age 60 because the natural lens is already too hard to provide additional accommodation. “After age 60, a patient may move into the intraocular lens with clear lensectomy possibility or into early cataract surgery as opposed to going into corneal surgery.”

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*Dr. Holladay is a consultant for AcuFocus. Dr. León reports a travel grant from Mediphacos. Dr. Lindstrom is a consultant and shareholder in AcuFocus and an equity owner in ReVision Optics.*

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