

# Corneal Inlays for the Surgical Treatment of Presbyopia

An update on the three devices under investigation in the United States.

BY GEORGE O. WARING IV, MD

Although much has been written on the topic, there is no universally accepted treatment for presbyopia. Therapies range from bifocal spectacles to scleral expansion to accommodating IOLs to corneal procedures such as presbyLASIK or conductive keratoplasty. An intrastromal approach is currently being investigated in FDA clinical studies for the treatment of near-plano presbyopia. The three inlays discussed in this article are in different stages of the FDA investigational device exemption (IDE) process and are not yet approved for use in the United States. Figure 1 provides a brief description of the technologies, their materials, and their mechanisms of action.

## CONCEPT

The concept behind intracorneal implants is not new; it has been reported on since the late 1940s,<sup>1,2</sup> and Professor José Barraquer is generally credited with the original idea.<sup>3</sup> These inlays were originally used to treat Fuchs dystrophy, high myopia, and aphakia, but the materials were neither optically ideal nor permeable. Common problems with earlier iterations of the technology included decentration, ketylolysis, and opacification.<sup>4-7</sup> Studies by McCarey, Klyce, and others enhanced eye care specialists' understanding of corneal hydration and nutritional gradients that necessitate permeability in the materials used in corneal inlays.<sup>7</sup> Because of that work, modern designs are highly permeable, and they have small diameters and thin profiles. Material problems associated with the early versions have been over-

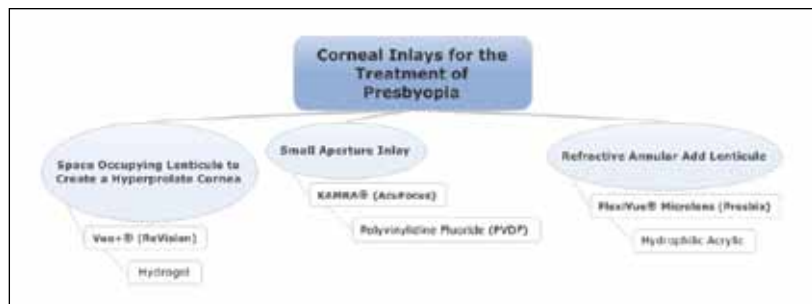


Figure 1. Corneal inlays currently in FDA clinical trials organized by mechanism of action and material. (Reproduced with permission from Wolters Kluwer Health.<sup>7</sup>)

come. Surgical technique has been modified, because decentration is now recognized as critical to the devices' proper performance.

The current group of corneal inlays can be implanted through a corneal pocket or under a lamellar corneal flap; all are typically implanted in the patient's non-dominant eye. Klyce and this author reviewed the steps involved in creating a pocket and the differences between traditional LASIK and inlay surgery.<sup>7</sup>

## KAMRA

### Design

The Kamra inlay (AcuFocus, Inc.) is 5  $\mu\text{m}$  thick and made of polyvinylidene fluoride. The device is inserted under either a lamellar flap or in a corneal pocket (Figure 2). The inlay has a 1.6-mm central annulus that acts as a pinhole, and its outer diameter is 3.8 mm. This small aperture allows unbent rays of light to filter through the lenticule, providing a broad depth of focus. A key benefit of a small aperture is that it provides stable near and intermediate visual acuity despite the progressive nature of presbyopia.



(Courtesy of Dave Allamby, MD.)

Figure 2. The Kamra inlay.

The Kamra has CE Mark approval and is commercially available in Europe and Asia for the treatment of presbyopia. In the United States, clinical trials are studying the inlay's use for the treatment of near-plano and plano presbyopia. Long-term results are available for earlier versions of the technology.

**International Clinical Trial Results**

Published data from a 24-month study of 32 implanted eyes (32 patients) in Europe showed an improvement in all tested parameters of reading performance.<sup>8,9</sup> Using the Salzburg Reading Desk, Dexl et al<sup>9</sup> found a change in patients' mean reading distance from the preoperative value of 48.1 ±5.5 cm to 38.9 ±6.3 cm ( $P < .0001$ ). Mean reading acuity with best distance correction improved from 0.3 ±0.14 logRAD to 0.24 ±0.11 logRAD ( $P < .0001$ ). In addition, mean reading speed increased from 142 ±13 to 149 ±17 words per minute ( $P = .029$ ). One patient lost 1 line of vision, and one patient experienced no change after implantation. There was a mean bilateral improvement in reading distance of 2.7 ±1.6 lines in the other 30 patients. In this group of patients, a superiorly hinged flap with an intended depth of 170 μm was created in the nondominant eye. Seyeddain et al noted that 97% of patients read J3 or better in their implanted eye.<sup>8</sup>

Grabner et al recently reported on 15 patients with 4-year results; these patients had the inlay placed under a 170-μm flap in their nondominant eye.<sup>10</sup> At 4 years, there was a mean gain of 3.8 lines of uncorrected near visual acuity from preoperative values in the implanted eye, with patients reaching J2. There was a mean gain of 1.6 lines in intermediate visual acuity (20/25) and a mean loss of 1 line of distance visual acuity, although mean uncorrected distance visual acuity was still 20/20. Bilateral uncorrected distance visual acuity remained unchanged at 20/16.

Researchers are evaluating the simultaneous treat-

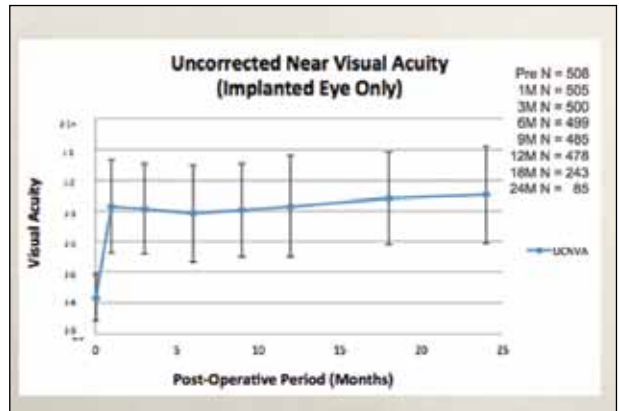


Figure 3. Uncorrected near visual acuity up to 2 years with the Kamra. (Data courtesy of AcuFocus, Inc.)

“Corneal inlays ... are quickly becoming a mainstay of [presbyopic] treatment where they are available.”

ment of ametropia and presbyopia with combined LASIK and Kamra implantation. In these studies, the inlay is placed under a 200-μm LASIK flap after excimer laser ablation. Emerging procedures include the Kamra's implantation into pockets for presbyopic patients after previous LASIK as well as its implantation in monofocal pseudophakic patients. To date, the results of these combined procedures have been promising and could greatly expand potential candidacy for the Kamra.

**US IDE Clinical Trial Results**

In the US IDE study, 24 sites have enrolled 508 patients between 45 and 60 years of age. The inlay was implanted at a depth of 200 μm into a pocket created with a femtosecond laser. Inclusion criteria were a preoperative spherical equivalent of between +0.50 and -0.75 D and an uncorrected near visual acuity of between 20/40 and 20/100, with a best-corrected distance acuity that was no worse than 20/20 OU.

The results for the implanted eye were an uncorrected near visual acuity of between J2 and J3 at 18 months (n = 243), which remained stable through 24 months (n = 85). Intermediate visual acuity remained stable as well, with a mean intermediate measurement of 20/25 from 18 to 24 months. Distance visual acuity remained stable throughout the study, with a mean uncorrected value of 20/20. Best-corrected distance visual acuity was better than 20/20 in the treated eye in all patients. Uncorrected

(Courtesy of Presbia Cooperatief UA and Ioannis Pallikaris, MD.)

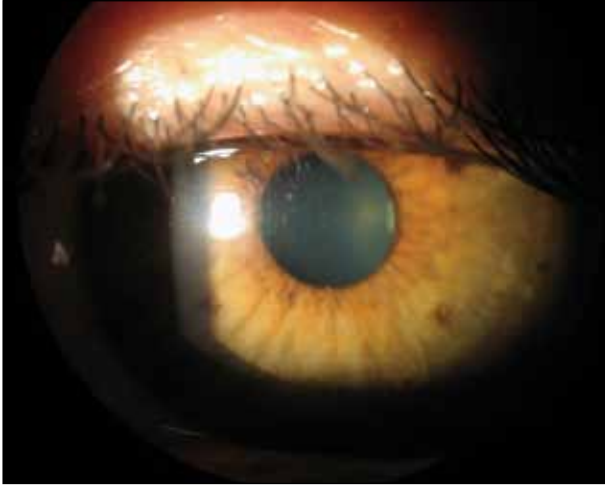


Figure 4. The Flexivue Microlens.

binocular distance visual acuity improved at 24 months to 20/16. In mesopic conditions, a slight decrease in contrast sensitivity was noted compared with preoperative values, although this parameter remained within normal limits (Figure 3).

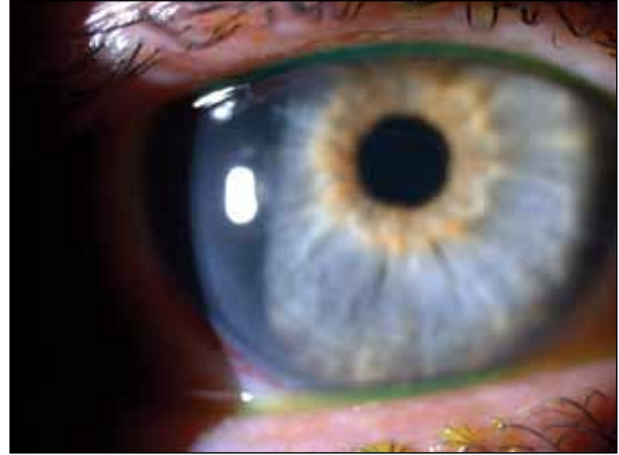
### FLEXIVUE MICROLENS

The Flexivue Microlens (Presbia Coöperatief UA) has CE Mark approval in Europe. Of the inlays currently being investigated, the Flexivue Microlens is the only one to use refractive add power. The hydrophilic acrylic lens is 3 mm in diameter, and its edge is about 15  $\mu\text{m}$  thick (Figure 4). The device is placed in a corneal tunnel at a depth of 200  $\mu\text{m}$  in the patient's nondominant eye. Dubbed *smart monovision* by Ioannis Pallikaris, MD, this bifocal optical inlay has separate distance and near focal points. Its central zone is free of refractive power, whereas its peripheral zone has refractive power with an index of refraction higher than that of the cornea, varying from +1.50 to +3.25 D.<sup>7</sup>

### VUE+

Formerly known as the Presbylens, the Vue+ (ReVision Optics, Inc.) is 2 mm in diameter. This permeable hydrogel lenticule is implanted under a lamellar flap (about 120-130  $\mu\text{m}$  thick) in the patient's nondominant eye for the treatment of plano presbyopia. Recent changes to the inlay's design increased its diameter from 1.5 to 2 mm.

Distance acuity is minimally affected, because light rays paracentral to the 2-mm lenticule remain focused primarily on the retina, particularly with a dilated pupil (Figure 5). Pupillary constriction creates a pseudo-accommodative state, using the steepened central cornea.<sup>7</sup> This inlay has CE Mark approval in Europe and is also under investigation in Mexico.



(Courtesy of ReVision Optics, Inc.)

Figure 5. The Vue+. (Reproduced with permission from Wolters Kluwer Health.<sup>7</sup>)

### CONCLUSION

With close to 5 million baby boomers turning 50 years old in 2011, the demand for presbyopic treatment options is increasing. Corneal inlays represent a promising technology for the surgical management of this condition and are quickly becoming a mainstay of treatment where they are available. ■

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