CORNEAL INLAYS ON THE HORIZON

The FDA approval of the first of these implants could mean more devices in this category will soon become available in the United States.

BY JOHN A. HOVANESIAN, MD

Emmetropic presbyopes are typically accustomed to perfect vision for most of their lives, making them challenging refractive surgery patients. Corneal inlays offer this patient population—once presbyopic—a more tolerable alternative to monovision by improving their near and intermediate visual acuity, typically in their nondominant eye.

In April 2015, the Kamra inlay (AcuFocus) received FDA approval, the first US approval for a technology of this kind. Two other inlays, the Raindrop Near Vision Inlay (ReVision Optics) and the Flexivue Microlens (Presbia), have received CE Mark approval in Europe and are progressing toward FDA approval in the United States.

INLAY TECHNOLOGIES

The Raindrop Near Vision Inlay

The Raindrop inlay is 2 mm wide and 30 µm thick. Placed under a LASIK flap or in a 150-µm corneal pocket, this hydrogel implant creates a dedicated near vision zone in the central cornea. Hydrogel, which is used in soft contacts, is biocompatible with the cornea and performs well from a refractive standpoint. Unlike the Kamra, which is dark in color and visible from the side in eyes with light-colored irides, the Raindrop inlay is transparent. As such, the device does not obstruct the surgeons' view of internal structures of the eye in the event later surgery is needed.

Patients' satisfaction (> 90%), visual acuity, and other measures of success are remarkably similar with the Kamra, Raindrop, and Flexivue Microlens.[1] Based on 1-year results, patients implanted with the Raindrop achieve a visual acuity of 20/40 as early as 1 week postoperatively and report a high level of satisfaction.[2]

ReVision Optics completed enrollment of its US phase 3 clinical trial in 2013. Six-month follow-up data from 75 of 100 subjects enrolled in the first portion of the trial are promising.[1,3] All subjects had a near UCVA of 20/25 (J1) or better in the treated eye and achieved 20/25 (J1) or better when tested bilaterally. Almost all of the subjects (97%) achieved an intermediate UCVA of 20/32 or better in the treated eye, and 99% achieved 20/32 or better when tested bilaterally. In terms of distance UCVA, 96% of subjects achieved 20/40 or better in the treated eye, and all subjects achieved 20/20 or better when tested bilaterally. Ninety-one percent of subjects gained 4 or more lines of near UCVA in the treated eye, as measured on a standard eye chart. None of the subjects experienced a loss of 2 or more lines of distance BCVA compared to their preoperative measurements. Almost all subjects (94%) were satisfied with the correction they received after implantation of the Raindrop inlay.[1,3] More recent data on a subset of patients who were tested with defocus found a functional range of vision of 3.50 D and no loss of contrast sensitivity in either photopic or mesopic conditions, with and without glare, with the Raindrop inlay.[4]

THE FLEXIVUE MICROLENS

The Flexivue Microlens is a hydrophobic acrylic implant that measures 3.2 mm in diameter, with a 0.5-mm central hole and 15-µm edge thickness. The lens, which is clear, provides a refractive add power of between +1.50 and +3.50 D, depending on an individual patient's needs. It is placed in a corneal pocket. Whereas the Kamra uses a pinhole effect to increase depth of focus, both the Raindrop and the Flexivue Microlens do not, making more light available in dim light settings with the latter two implants.

Earlier this year, Presbia received approval from the FDA to commence the second stage of its US pivotal trial.

AT A GLANCE

- Corneal inlays offer presbyopes an alternative to monovision and improve near and intermediate visual acuity, typically in the nondominant eye.
- The Kamra inlay is available in the United States. The Raindrop Near Vision Inlay and Flexivue Microlens are available in Europe and are progressing toward FDA approval.
- Reported rates of satisfaction among patients have been similar for all three inlays.

> **"It will not be long before other inlays are also approved, giving surgeons more technologies to choose from."**

Published case studies suggest improvements in near visual acuity from J6 to J1 or 20/50 to 20/20.[5,6] Limnopoulou et al evaluated 47 emmetropic presbyopes. At 12 months, near UCVA was 20/32 or better in 75% of operated eyes, whereas mean distance UCVA was statistically significantly decreased from 0.06 ±0.09 logMAR (20/20; range, -0.08 to 0.26) preoperatively to 0.38 ±0.15 logMAR (20/50; range, 0.12 to 0.8; $P < .001$), and mean binocular distance UCVA did not change significantly ($P = .516$).[7]

LOOKING FORWARD

The Kamra's availability in the United States suggests that it will not be long before the other inlays are also approved, giving surgeons more technologies to choose from to best suit their patients' needs. Although the three inlays are available outside the United States, their use has been limited. Based on my experience, the FDA's approval will represent a level of safety and trustworthiness for inlay technology that will likely increase the use of all three implants around the world. ■

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