Inlay for Presbyopes

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A plethora of treatment approaches exists for presbyopia—from corneal laser surgery to conductive keratoplasty to intraocular lenses. Researchers are now testing a newer option: the corneal inlay. Presbia's Flexivue Micro-Lens is a minimally invasive and reversible technique for patients between the ages of 45 and 60.

With fixed powers available from 1.25 D to 3.25 D, this hydrophilic acrylic bifocal lens has a peripheral refractive zone that alters the refractive index of the cornea in the nondominant eye, said Ioannis G. Pallikaris, MD, PhD, lead author of the study and director of the Institute of Vision and Optics at the University of Crete, Greece.

Using wavefront analysis, Dr. Pallikaris and coinvestigators have found the inlay's maximum effect occurs in the 3- to 3.5-mm central zone, decreasing when the optical zone enlarges.

"That means we have maximum effect mainly during near vision when the pupil becomes smaller," said Dr. Pallikaris. "As a result, far vision is less influenced than with conventional monovision, an effect we call 'smart monovision.'"

Investigating the safety and visual outcomes of the Flexivue Micro-Lens, Dr. Pallikaris and fellow researchers implanted the lens inside corneal stromal tunnels they created in the eyes of 15 patients, then followed them over a period of 12 months. "Femtosecond laser created consistent, customized and accurate corneal depth for the pocket," said Dr. Pallikaris, who added that changing the direction of the pocket has the potential to eliminate astigmatism, too, particularly once software that's in the works becomes available.

POSTOP. One week after implantation of the Flexivue Micro-Lens.

In this study, overall patient satisfaction rates were 98 percent, with patients reporting very good near and binocular vision—results good enough for patients to dispense with glasses in most cases, said Dr. Pallikaris. Glasses were needed under certain lighting conditions, however, and some patients experienced glare and halos, as well as decreased contrast sensitivity in the operated eye.

"Patient selection is critical to success," said Dr. Pallikaris, explaining that clear eye dominance and tolerance for monovision are key. But the potential is great for upward of 400 million presbyopes worldwide, he said. He projects that patients in the United States can look for its launch in approximately four years.

Other corneal inlays implanted in the nondominant eye offer variations on this theme. The Kamra inlay (AcuFocus) uses an opaque circular micro-disc combined with a pinhole pattern to increase the depth of focus, and the PresbyLens (ReVision Optics) microscopically reshapes the cornea. By contrast, the Flexivue is a transparent lens with diopter power. Implanted in a corneal pocket instead of a flap, he said, it offers greater stability and less impact on the biomechanics of the cornea without influencing the transparency of the cornea.

—Annie Stuart

Dr. Pallikaris reports that he is chair of the medical advisory board of Presbia.

■ **Intracorneal Lenses for the Treatment of Presbyopia Using Femtosecond Laser: Visual Outcomes and Safety** *will be presented as part of the Refractive Surgery paper session, which takes place Tuesday, Oct. 19, from 10:30 a.m. to 12:30 p.m. in Room S406b. There is a MEACO Refractive Surgery paper session on Sunday, Oct. 17, from 2 to 3:30 p.m. in Room S102.*