UPDATE ON CORNEAL INLAYS AND US AVAILABILITY

BY MICHAEL LACHMAN

Corneal inlays represent a promising new option for the surgical correction of presbyopia. These implants are designed to improve near and intermediate vision, typically in a patient's nondominant eye, with minimal compromise of distance acuity. Because the devices are placed within the cornea, they are less invasive surgically than lens-based procedures, and unlike presby-LASIK approaches that involve excimer laser ablation, no corneal tissue is removed. Another key benefit of corneal inlays is that they can be removed if a patient's needs or preferences change in the future. Three corneal inlays that have received CE Mark approval in Europe and are progressing toward FDA approval in the United States are the Kamra inlay (AcuFocus), the Raindrop Near Vision Inlay (ReVision Optics), and the Flexivue Microlens (Presbia).

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SMALL-APERTURE OPTICS

The Kamra inlay works on the principle of small-aperture optics to extend depth of focus. The device, which is made from polyvinyldene fluoride, or PVDF, has an outside diameter of 3.8 mm, with a central aperture of 1.6 mm. The inlay is 5 µm thick and contains 8,400 randomly placed perforations to facilitate nutrient flow within the cornea. The inlay is placed in a corneal pocket created by a femtosecond laser at a depth of 180 to 200 µm. Use of the company's AcuTarget HD diagnostic and surgical planning instrument helps ensure proper device centration. AcuFocus submitted the final module of its premarket approval application to the FDA in March 2013. In June of last year, the FDA Ophthalmic Devices Advisory Panel voted that the benefits of the Kamra inlay outweigh the risks for presbyopic patients, and AcuFocus is currently awaiting an approval decision.

CORNEAL EPITHELIAL REMODELING

The Raindrop Near Vision Inlay works through corneal epithelial remodeling over the inlay to create a Profocal cornea with near refractive power centered over the pupil and gradually transitioning to intermediate and distance vision out to the periphery. The device, which measures 2 mm in diameter with a central thickness of about 32 µm, is made from a proprietary transparent hydrogel material composed of nearly 80% water, reportedly ensuring effective nutrient diffusion through the cornea. The inlay is centered over the light-constricted pupil under a femtosecond laser flap measuring one-third of the central corneal thickness at a depth of at least 150 µm. ReVision Optics completed enrollment of its US phase 3 clinical trial in 2013, and the product could reach the US market by 2017.

MULTIFOCAL OPTICS

The Flexivue Microlens works on the principle of multifocal optics to enhance near vision. The hydrophobic acrylic implant measures 3.2 mm in diameter, with a 0.5-mm central hole and 15-µm edge thickness. The lens provides a refractive add power of between +1.50 and +3.50 D, depending on an individual patients' needs. It is placed in a corneal pocket created by a femtosecond laser at a depth of about 280 to 300 µm. Earlier this year, Presbia received approval from the FDA to commence the second stage of its US pivotal trial, and the product could reach the US market by 2018 or 2019.

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