

HOT POCKETS

New software enables precise creation of stromal channels for the placement of corneal inlays.

BY JOHN A. VUKICH, MD



The next wave in refractive surgery in the United States will be the correction of presbyopia with corneal inlays. Inlays are an additive, removable technology. Implanted monocularly, they offer better binocularity and distance acuity than monovision^{1,2} and may carry less risk than intraocular surgery.³ For these reasons, corneal inlays

are an exciting option for presbyopes who do not yet have lens changes.

Important material and design innovations over the past decade have made the implantation of an optical device in the intrastromal space a viable option. There are now at least three different inlays that have either completed or are undergoing US clinical trials, two of which are designed for implantation in a deep stromal pocket. (A third type is designed to reshape the cornea and is placed under a flap.) Globally, more than 20,000 inlays have been implanted commercially. Just as important to the success of these tiny devices has been the evolution of surgical technique made possible by advances in femtosecond laser technology.

LASER ADVANCES

The most important change to femtosecond lasers has been their speed. The first femtosecond laser on the market operated at just 15 kHz. Since then, the speed of corneal femtosecond lasers has increased tenfold, enabling smoother beds and a nearly infinite variety of cuts. For example, in addition to LASIK flaps, the iFS laser (Abbott Medical Optics) has been used to create advanced arcuate incisions, to customize corneal trephination patterns that have dramatically improved visual acuity after penetrating keratoplasty and made big-bubble deep anterior lamellar keratoplasty easier to perform, and form a variety of corneal channels and pockets.

Early innovators used a mask or shield to block some of the laser pulses to create pockets for corneal inlays. Users of the iFS platform can now take advantage of specialized pocket software that was recently cleared by the FDA for marketing in the United States; this software was already in use internationally. The pocket software provides a level of control and precision that further enhances the surgeon's ability to create the pocket exactly how and where desired. For example, surgeons will be able to customize many

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parameters, including the channel's width and depth, side-cut radius and angles, offset from the center of the surgical field, and raster parameters (Table). The pocket can be designed, viewed, and easily adjusted on a touchscreen, the same as for a LASIK flap (Figure).

TABLE. iFS POCKET SOFTWARE PARAMETERS

Parameter	Available Range	Sample Settings ^a
Channel width	3.6 to 4.7 mm	4.40 mm
Channel depth	100 to 400 μ m	215 μ m
Channel offset	0 to 2.8 mm	0 mm
Side-cut radius	3.7 to 7.6 mm	4.7 mm
Side-cut angle	30° to 90°	30°
Spot separation	3 to 6 μ m	4 μ m
Line separation	3 to 6 μ m	4 μ m
Channel energy	0.3 to 2.5 μ J	0.7 μ J

^aSample settings are for implantation of the Kamra small-aperture inlay (AcuFocus). Courtesy of Guillermo Rocha, MD, FRCSC, attending surgeon, ImagePlus Laser Eye Centre, Winnipeg, Manitoba, Canada.

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).

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 polyvinylidene 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

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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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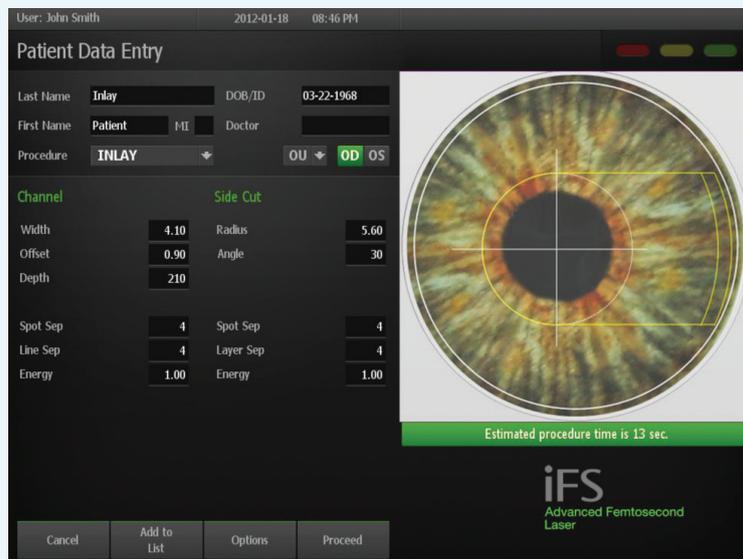


Figure. Femtosecond laser software is available to create customizable pockets for corneal inlays.

Customizability of the pockets is key. The Kamra inlay (AcuFocus) is 3.8 mm in diameter and 5 μm thick. The Flexivue Microlens (Presbia) is slightly smaller but thicker, at 3.2 mm in diameter and 15 to 20 μm in thickness. Surgeons will need to create pockets specifically for each inlay. As we ophthalmologists continue to learn more about the optimal placement for each of these devices, the ability to place the pocket precisely will be very important to the adoption of and success with corneal inlays when one or more of these devices become available in the United States.

POCKET BENEFITS AND LESSONS

One of the first lessons learned from early inlay experience is that, for several of the designs, deeper implantation is better.^{3,4} Current recommendations suggest a depth of at least 200 μm for the Kamra inlay and 280 to 300 μm for the Presbia lens.^{1,3} I initially implanted the Kamra inlay under a flap, but I found that the thick flap required to position the inlay at an appropriate depth was not desirable. The shift to corneal pockets—now recommended even when LASIK will be performed simultaneously—brought immediate benefits. For example, pocket implantation reduced the incidence of dry eye, improved refractive outcomes and visual recovery, made it easier to center the inlays, and reduced the removal rate (Kamra Global Registry, data on file with AcuFocus).

Another important lesson from clinical trials and international experience is that a tighter spot/line separation (at least 6 x 6 or the equivalent) results in a smoother pocket, with better results.⁵ Adjusting the side-cut angle is also an

important technical modification, because it inhibits epithelial incursion into the pocket.

In short, many of the key pearls from corneal inlay experience to date reinforce the idea that accurate, customizable channels are critical to optimizing results. New software that makes pocket creation easy and repeatable with the proven iFS femtosecond laser platform is a welcome step toward incorporating presbyopia-correcting inlay technology into practice. ■

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