Intrastromal Corneal Inlays for the Treatment of Presbyopia

Ophthalmologists share their experiences with various designs.

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Refractive Surgical Correction Of Presbyopia With The Kamra Corneal Inlay

By Alois K. Dexl, MD, MSc

Within the past few decades, various surgical procedures for the treatment of presbyopia have been implemented in cataract and refractive surgery. Recently introduced into the market was the Kamra corneal inlay (AcuFocus, Inc., Irvine, California). This inlay has the Conformité Europééne (CE) Mark and is currently commercially available in the European Union and other markets around the world. The inlay is under investigation in US Food and Drug Administration (FDA) clinical trials for the treatment of near-plano and plano presbyopia; the study is fully enrolled, and 2-year follow-up data are now being collected.

The annulus design (3.8 mm outer diameter and 1.6 mm inner diameter; Figure 1A) is intended to increase the depth of focus based on the principle of small-aperture optics to restore near and intermediate visual acuity with minimal impact on distance vision. The inlay is made of polyvinylidene fluoride, with nanoparticles of carbon incorporated that make the annulus opaque. Studies have supported the efficacy and safety of the prior-generation Kamra corneal inlay (ACI 7000) for the treatment of presbyopia with follow-ups extending to 4 years.1 Within the past 3 years, AcuFocus has changed specifications of the inlay; the latest design is 5 µm thick and has more (and smaller) laser-drilled porosity holes than the previous inlay design. These 8,400 holes (diameter, 5 to 11 µm), arranged in a pseudorandomized pattern, allow sufficient nutritional flow through the inlay to sustain the viability of the anterior stromal lamella.

The Kamra inlay can be implanted under a LASIK flap or in a femtosecond laser-created intrastromal pocket. In the clinical trial, the inlay was inserted primarily into a pocket via a temporal opening (Figure 1B). The inlay was then centered on the stromal bed using the microscope fixation light. A new intraoperative device, the AcuTarget System (AcuFocus, Inc.), will provide real-time centration guidance for the surgeon to ensure that the inlay is centered appropriately. Since 2006, we have implanted approximately 90 Kamra corneal inlays within clinical trials. More than 6,000 inlays have now been commercially implanted worldwide.

In a recent clinical trial of 24 emmetropic, presbyopic patients implanted with the current Kamra inlay design, we found significant changes in reading performance parameters when evaluated with the Salzburg Reading Desk.2 After 12 months, the mean reading distance changed from 46.7 cm before implantation to 42.8 cm after, and the mean reading acuity at best distance improved from 0.33 logRAD to 0.24 logRAD, which is equivalent to the values achieved after bilateral implantation of diffractive multifocal IOLs and...
better than bilateral refractive IOL implantation.3

Additionally, mean reading speed values (156 words per minute) were better after monocular inlay implantation than after bilateral implantation of refractive or diffractive multifocal IOLs.3 At 12 months, mean distance UCVA was 20/20 in the implanted eye and 20/16 binocularly, and mean binocular intermediate UCVA was 20/20. Patients reported no change in distance vision, and their need for reading glasses statistically significantly decreased. No inlay was explanted or required recentration.

In a recent publication, Yilmaz and colleagues were able to show the long-term stability and safety of the procedure over a 4-year follow-up.1

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The Vue+ Inlay for Presbyopia

By A. John Kanellopoulos, MD

We have studied, in several cases, the Vue+ corneal inlay (formerly the PresbyLens; ReVision Optics, Inc., Lake Forest, California), which is an inlay made of a soft malleable polymer material. The Vue+ comes in a vial and is placed on the cornea through an open LASIK-like flap, with extreme care for its orientation and placement to avoid wrinkling. This enables implantation to be combined with hyperopic or myopic LASIK. The optimal depth for the LASIK flap under which the Vue+ inlay is implanted is about 150 µm, and the results are diaphanous and clear (Figures 1 and 2).

The inlay is difficult to recognize on slit-lamp biomicroscopy, but is clearly evident on corneal optical coherence tomography (OCT; Figure 3), as it has a 30-µm thickness that creates a clear space within the hyperreflective corneal lamellae. The ideal position for this inlay is the geometric center of the cornea, which hopefully corresponds with the patient’s visual axis (Figure 4).

The procedure has a short learning curve and appears to deliver what it promises. It adds curvature to a central part of the cornea at a diameter of approximately 2.5 to 3.0 mm, creating a multifocal cornea and adding significantly to the depth of field. Most patients can read J1 or J2 postoperatively, and special care is taken for any possible inflammation or dryness with use of steroids and topical cyclosporine.

For a video demonstration of implantation, visit eyetube.net/?v=molam. As a commentary, implantation of inlays can block nutrient transmission within the cornea. Further studies with longer-term follow-up are therefore needed to establish the safety of this inlay. As with other inlays, there is a danger of corneal thinning and melting.

It would be ideal if this inlay could be implanted through a tunnel as other designs can be implanted today; however, the form and material of the lens prohibit this type of implantation because it would wrinkle the inlay and would not guarantee proper placement. Also, because this inlay is placed under a LASIK flap, it can potentially move with normal blinking or residual fluid within the flap. Further studies and longer-term follow-up will establish the safety and efficacy of the Vue+ corneal inlay.

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The Flexivue Microlens

By Ioannis G. Pallikaris MD, PhD; and Dimitrios I. Bouzoukis, MD

In recent years, intrastromal corneal inlays have been introduced in refractive surgery for the corneal compensation of presbyopia. The Flexivue Microlens (Presbia Coöperatief UA, Amsterdam, Netherlands) is a new-generation intrastromal corneal inlay that has a higher refractive index than the cornea; it is made of a highly biocompatible hydrogel-based material. The Flexivue is 3.2 mm in diameter, between 15 and 20 µm in edge thickness, and available in fixed refractive powers from 1.50 to 3.50 D in 0.25 D steps.

This inlay is implanted into an intrastromal pocket in a patient’s nondominant eye. The pocket is created using a 150-kHz femtosecond laser at 280 to 300 µm deep. The inlay is implanted precisely on the line of sight using a special inserter. The entire procedure lasts less than 10 minutes. For a video demonstration of implantation, visit eyetube.net/?v=repiz.

At the most recent European Society of Cataract and Refractive Surgeons (ESCRS) meeting in Vienna, we presented the 9-month results of our study conducted at the

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Institute of Vision and Optics at the University of Crete. The Flexivue Microlens was implanted inside a corneal pocket created in the nondominant eye of 40 patients using a femtosecond laser (iFS 150; Abbott Medical Optics Inc., Santa Ana, California). The results were encouraging, as mean UCVA for near increased from 20/100 to 20/25. Mean distance UCVA decreased in the operated eye from 20/20 to 20/32; however, binocular distance vision remained stable.

The inlay did not decrease the visual acuity of the operated eye as much as with a classic monovision approach. To prove this, we recorded the expected distance vision preoperatively in the eye undergoing surgery using an external lens with the same refractive power used in the implanted inlay. We compared these with the distance vision in the operated eye after surgery. We found that average distance vision in the operated eye was expected to be 20/80 using the external lens; however, using the Flexivue Microlens inlay, the average distance vision was recorded at 20/32 after surgery.

In zonal reconstruction, there was significant refractive effect only when the central 3.5-mm optical zone was analyzed (Figure 1); this was almost neutralized in the 5.0-mm optical zone, meaning that the effect of the inlay is also pupil-dependent. With near vision, when the pupil decreases in diameter, there is maximum effect. With distance vision, however, when the pupil increases in diameter, the effect is minimal, thus yielding a smaller influence on overall vision.

The majority (92%) of patients reported that they no longer used reading glasses after undergoing Flexivue Microlens surgery. Using confocal microscopy, we found no signs of stromal reaction in any of the patients, confirming the high biocompatibility of the inlay (Figure 2).

The significant advantage of the Flexivue Microlens is that it uses a minimally invasive technique. The lens does not interfere with fundus or slit-lamp examinations (Figure 3), and the surgeon can remove and replace the implant anytime. Additionally, the procedure can be performed in any modern refractive surgery center equipped with a femtosecond laser.

We believe that intrastromal corneal inlays, specifically the Flexivue Microlens, may be the best choice for the target group of emmetropic presbyopes aged 45 to 60 years.

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