Femtosecond laser–assisted small-aperture corneal inlay implantation for corneal compensation of presbyopia: Two-year follow-up

Orang Seyeddain, MD, Alexander Bachernegg, MD, Wolfgang Riha, MD, Theresa Rückl, MD, Herbert Reitsamer, MD, Günther Grabner, MD, Alois K. Dexl, MD, MSc

PURPOSE: To report the 2-year postoperative safety and efficacy outcomes after monocular Kamra corneal inlay (ACI7000PDT) implantation in femtosecond laser–created corneal pockets of emmetropic presbyopic patients to improve near and intermediate vision.

SETTING: University Eye Clinic, Paracelsus Medical University, Salzburg, Austria.

DESIGN: Prospective interventional case series.

METHODS: Patients had corneal inlay implantation in the nondominant eye. Emmetropic presbyopic patients between 45 and 60 years old with an uncorrected distance visual acuity (UDVA) of 20/20 or better in both eyes and without additional ocular pathology were eligible. Contrast sensitivity, visual field examinations, endothelial cell count (ECC), and central corneal thickness (CCT) measurements were assessed preoperatively and 12 and 24 months postoperatively. The UDVA, uncorrected intermediate visual acuity (UIVA), and near visual acuity (UNVA) were assessed preoperatively and 1 day, 1 week, and 1, 3, 6, 9, 12, 18, and 24 months postoperatively. The minimum postoperative follow-up was 24 months.

RESULTS: After 24 months, the mean binocular UNVA improved from 20/50 to 20/25; 20 patients (83%) had a UNVA of 20/25 or better. The mean binocular UIVA was 20/20. The mean UDVA was 20/20 in the surgical eye and 20/16 binocularly after 24 months. Contrast sensitivity under photopic and mesopic conditions remained in the range of the normal population. No patient had detectable central visual field defect. No inlay was explanted. No inflammatory reactions were observed. The ECC and CCT remained stable.

CONCLUSION: The corneal inlay implanted in femtosecond laser–created pockets was effective and safe for the corneal compensation of presbyopia in emmetropic patients after 24 months.

Financial Disclosure: Acufocus Inc., Irvine, California, USA, financially supports the Research Foundation for Promoting Ophthalmology, Salzburg, Austria, as the clinical research center of the University Eye Clinic (Paracelsus Medical University). Dr. Grabner received travel expenses from Acufocus, Inc. Dr. Riha currently also works as a clinical application specialist for Acufocus, Inc. No other author has a financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2013; 39:234–241 © 2012 ASCRS and ESCRS

According to current estimates, presbyopia is the most common refractive error, affecting more than 2 billion people worldwide.[1] Therefore, many refractive surgical solutions have been developed in recent years to effectively treat this condition.[2–5] Advances in femtosecond laser technology as well as improvements in biomaterials have helped in the success of corneal inlays as a removable non-lens-based surgical approach for the corneal compensation of presbyopia. The benefit of better predictability may favor femtosecond laser technology over use of a mechanical microkeratome.[6]

Based on the mechanism of action, 3 corneal inlays for presbyopia correction are currently under investigation.[7] All 3 are implanted in the nondominant eye of the patient. The Vue+ system (Revision Optics, Inc.) is a permeable hydrogel lenticule that creates a hyperprolate corneal shape, resulting in a multifocal cornea. The Flexivue/Invue system (Presbia) is a refractive microlens with a lenticule addition (add)

0886-3350/$ - see front matter
http://dx.doi.org/10.1016/j.jcrs.2012.09.018

power in the annular peripheral zone. The Kamra corneal inlay (Acufocus, Inc.) has a small-aperture optic to increase depth of focus and restore sufficient uncorrected near (UNVA) and intermediate (UIVA) visual acuity while minimally affecting distance vision. This corneal inlay is currently being investigated in multicenter U.S. Food and Drug Administration (FDA) clinical trials inside and outside the United States for the treatment of plano presbyopia.[A]

Our study group recently published our 12-month data on the safety and efficacy of the current Kamra corneal inlay design (ACI7000PDT) implanted in femtosecond laser–created corneal pockets.[8] In this current article, we present a longer follow-up (24 months) and focus on the visual outcomes and contrast sensitivity results.

PATIENTS AND METHODS

This prospective interventional case series comprised presbyopic patients who had monocular implantation of the Kamra corneal inlay (ACI7000PDT) at the University Eye Clinic, Paracelsus Medical University, Salzburg, Austria. The study was performed in accordance with the Declaration of Helsinki and approved by the Ethics Committee, County of Salzburg. All patients gave written informed consent before study enrollment.

The study comprised healthy emmetropic patients. Key requirements for participation in the study were age between 45 years and 60 years; a preoperative manifest refraction spherical equivalent (SE) of plano, defined as +0.50 to −0.75 diopter (D), with no more than 0.75 D of refractive cylinder as determined by cycloplegic refraction; a preoperative UNVA between 20/40 (≈Jaeger [J] 5) and 20/100 (≈J10/J11) in the eye to have surgery; an uncorrected distance visual acuity (UDVA) of at least 20/20 in both eyes; a minimum central corneal thickness (CCT) of 500 μm; an endothelial cell density of 2000 cells/mm^2 or more; and a central corneal power of more than 41.00 D and less than 47.00 D in all meridians measured by manual keratometry in the eye to have surgery.

Key exclusion criteria were previous ocular surgery, anterior or posterior segment disease or degeneration, and any type of immunosuppressive disorder. Other exclusion criteria were the use of systemic medications with significant ocular side effects (eg, corticosteroids) and latent hyperopia, defined as a difference of more than 1.00 D between the manifest refraction and the cycloplegic refraction.

Submitted: May 12, 2012.
Final revision submitted: September 5, 2012.
Accepted: September 14, 2012.

From the University Eye Clinic (Seyeddain, Bachernegg, Riha, Rückl, Reitsamer, Grabner, Dexl), Paracelsus Medical University, Salzburg, Austria; Acufocus, Inc. (Riha), Irvine, California, USA.

Corresponding author: Orang Seyeddain, MD, University Eye Clinic, Paracelsus Medical University, Müllner Hauptstraße 48, 5020 Salzburg, Austria. E-mail: o.seyeddain@salk.at.

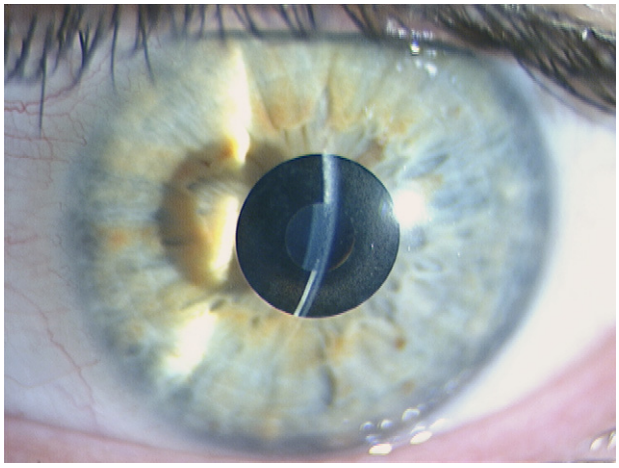

Figure 1. Corneal inlay in a patient's eye.

Corneal Inlay

The Kamra corneal inlay (ACI7000PDT) is a 5 μm thin microperforated artificial aperture (3.8 mm outer diameter, 1.6 mm inner diameter) made of polyvinylidene fluoride with nanoparticles of carbon incorporated to make it opaque (Figure 1). There are 8400 holes (5 to 11 μm in diameter) arranged in a pseudorandomized pattern (more holes in the inlay center versus the inlay periphery to minimize diffraction) to allow sufficient nutritional flow through the implant.[7,8] The mean light transmission through the annulus of the inlay is approximately 5%.[B] Based on the pinhole effect, the inlay increases depth of focus and consequently improves near and intermediate visual acuity.[9]

Surgical Technique

The surgical preparation and technique have been described in detail.[8] All surgeries were performed by the same experienced surgeon (G.G.) between February 2009 and October 2009. In brief, a stromal pocket (mean depth 230 μm; range 200 to 270 μm) was created with a femtosecond laser in the nondominant eye. Three femtosecond lasers were used in this study depending on when the surgery was performed. They were the FS60 60 kHz laser (Abbott Medical Optics, Inc.) using a mask, the iFS 150 kHz laser (Abbott Medical Optics, Inc.) using a mask, and the Femto LDV laser (Ziemer Group AG) using software for cutting corneal pockets. The inlay was implanted through a temporal corneal side cut and centered on the stromal bed in the pocket while the patient coaxially fixated on the microscope's single light source. Centration was regarded as successful when the Purkinje reflex on the cornea was in the center of the inner annulus of the inlay.

Preoperative and Postoperative Examinations

The preoperative examination included manifest refraction, uncorrected visual acuity (distance, intermediate, and near), distance-corrected visual acuity with and without near-power add (distance, intermediate, and near), slitlamp evaluation, central keratometry measured by an autorefractometer (KR 7000P, Topcon Corp.), computerized corneal topography (Keratron, Optikon

2000 SpA), cycloplegic refraction, and dilated fundus examination. The CCT was measured by ultrasound pachymetry (DGH 2000, DGH Technology, Inc.) a minimum of 3 times, with the corresponding mean value calculated afterward. Noncontact specular microscopy (Noncon Robo, Konan Medical) was performed preoperatively as well as 3, 12, and 24 months postoperatively.

For the endothelial cell count (ECC), 3 images of the central cornea were taken in each eye; up to 100 adjoining cells per image were marked, and the mean value was calculated by the same evaluator. All visual acuity measurements were performed with the Optec 6500P Vision tester (Stereo Optical Co., Inc.); the numbers of logarithmic Early Treatment Diabetic Retinopathy Study (ETDRS) targets identified correctly were identified, and the corresponding Snellen equivalent was derived. Visual acuity testing was performed at a standardized luminance level of 85 candelas [cd]/m^2 (ie, photopic lighting). Ocular dominance was determined preoperatively using a motor-dominance preferential-viewing test by asking the patient to make an aperture with his or her extended hands and to look through the hole while fixating on a test mark in the distance.

Postoperative follow-up examinations were scheduled for 1 day, 1 week, and 1, 3, 6, 9, 12, 18, and 24 months. Manifest refraction and visual acuity testing were performed at every follow-up visit except on the first day. Contrast sensitivity, visual field tests, CCT measurement, cycloplegic refraction, and dilated fundus examinations were performed preoperatively and postoperatively at 12 months and 24 months. Contrast sensitivity was tested with best distance correction with the Optec 6500P Vision tester using the Functional Acuity Contrast Test chart. The surgical eye was tested first under photopic conditions (85 cd/m^2) and then dark adapted for 10 minutes before mesopic (3 cd/m^2) contrast sensitivity was tested; this was followed by binocular testing. Mesopic contrast sensitivity was tested with a glare source of 28 lux binocularly.

Visual fields were tested with best near correction using the Humphrey Instruments Field Analyzer (Model 750, Carl Zeiss Meditec AG.). A test was repeated if more than 2 of 14 fixation losses were recorded. The maximum of false-positive or false-negative errors allowed for each test was set at 3%. The mean deviation and pattern standard deviation (SD) of the Humphrey visual field indices were determined and compared between preoperative and subsequent postoperative visual field test values.

Statistical Analysis

Descriptive analysis with 95% confidence intervals (CIs) for means was performed. The mean comparison with a control using the Dunnett method was applied to analyze the data. A *P* value less than 0.05 was considered statistically significant. All analyses were performed with JMP software (version 9.0.2, SAS Institute, Inc.).

RESULTS

All 24 patients completed every scheduled follow-up visit. The mean follow-up was 23.9 months ± 1.0 (SD) (range 23 to 26 months). Table 1 shows the patients' demographics. Ten of the 24 patients (42%) had a UNVA of 20/50 and 14 patients (58%) had a UNVA worse than 20/50 before surgery. The preoperative monocular UIVA was 20/25 or better in 8 patients (33%) in the surgical eye and in 14 patients (58%) binocularly. The preoperative UDVA in the surgical eye was 20/20 in 8 patients (33%) and 20/16 or better in 16 patients (67%) (95% CI, 20/20-20/16).

The first 11 cases were performed with the FS60 laser. The next 10 cases were performed with the iFS laser. The last 3 cases were performed with the Femto LDV laser.

Table 1. Patient demographics (N = 24).

Demographic	Value
Age (y)	
Mean ± SD	52.2 ± 3.2
Range	48, 58
F/M sex (%)	50/50
R/L eye with inlay (n)	8/16
Preop SE (D)	
Mean ± SD	0.06 ± 0.26
Range	−0.38, +0.50
Preop UDVA (lines)	
Monocular	
Mean ± SD	20/16 ± 0.5
Range	20/20, 20/16
Binocular	
Mean ± SD	20/16 ± 0.0
Range	20/16, 20/16
Preop UIVA (lines)	
Monocular	
Mean ± SD	20/32 ± 1.6
Range	20/80, 20/20
95% CI	20/4, 20/32
Binocular	
Mean ± SD	20/25 ± 1.6
Range	20/63, 20/16
95% CI	20/32, 20/25
Preop UNVA (lines)	
Monocular	
Mean ± SD	20/63 ± 1.2
Range	20/80, 20/50
95% CI	20/63, 20/50
Binocular	
Mean ± SD	20/50 ± 1.0
Range	20/80, 20/32
95% CI	20/50, 20/40
Preop CNVA (lines)	
Monocular	
Mean ± SD	20/16 ± 0.2
Range	20/20, 20/16
Binocular	
Mean ± SD	20/16 ± 0.0
Range	20/20, 20/16

CI = confidence interval; CNVA = corrected near visual acuity; SE = spherical equivalent refraction; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity

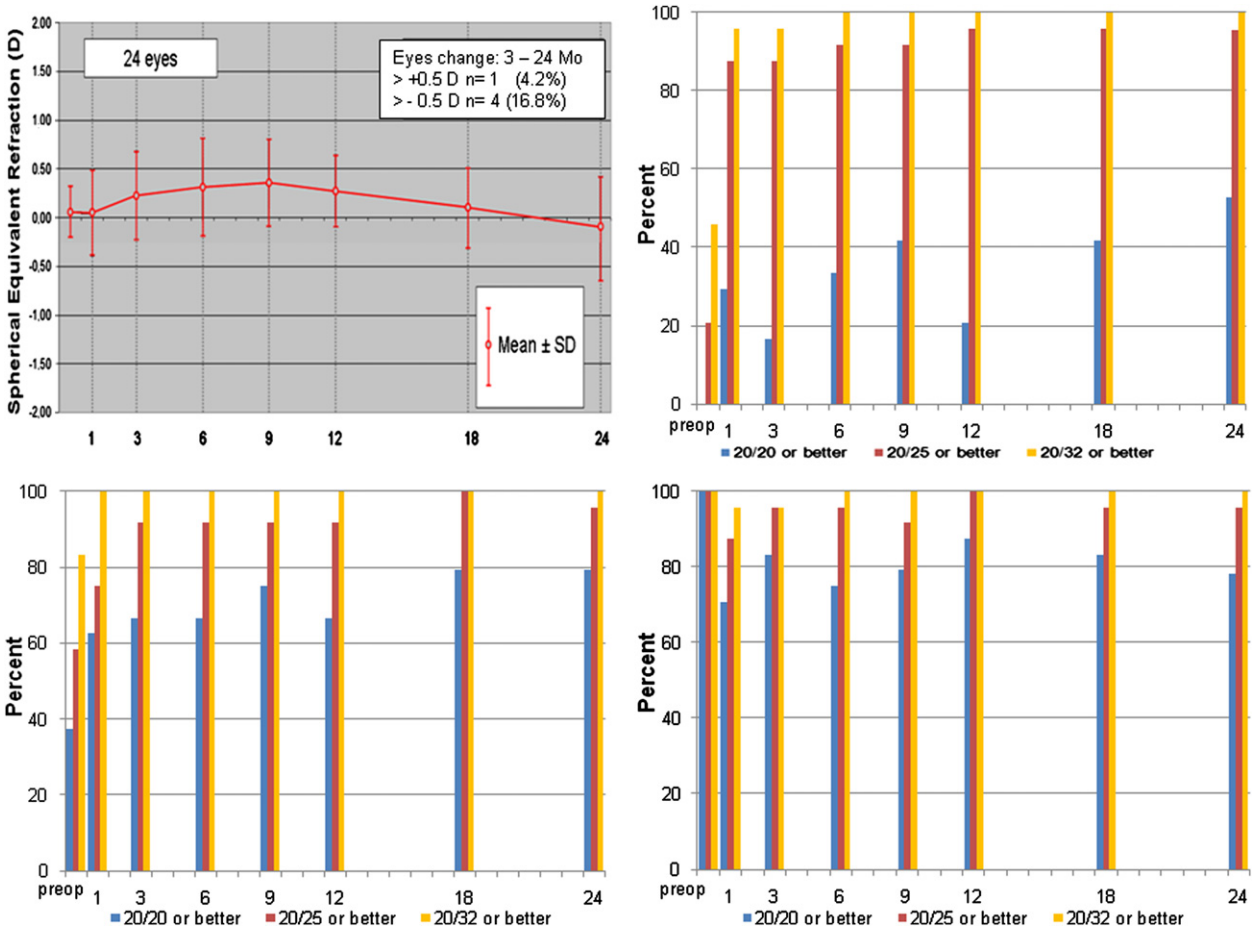

Figure 2. Spherical refractive error after inlay implantation (*top left*), binocular UNVA (*top right*), binocular UIVA (*bottom left*), and UDVA (*bottom right*) in the surgical eye. The *x*-axis represents the time (months) after inlay implantation.

Efficacy

The mean SE refractive error shifted slightly, with a mean value of −0.11 ± 0.53 D (range −1.25 to +0.75 D) 24 months postoperatively (Figure 2, *top left*).

The mean UNVA in the surgical eyes increased significantly to 20/32 at 1 month ($P<.001$) and improved further to 20/25 after 12 months. The UNVA remained stable throughout the 24-month follow-up (95% CI, 20/32-20/25). The mean binocular UNVA increased to 20/25 after 1 month ($P<.001$) and remained stable through the last follow-up. After 12 months, 3 patients (12.5%) had a monocular UNVA of 20/20 without glasses; however, the percentage of patients with a binocular UNVA of 20/20 increased to 50% (12/24) at 24 months (95% CI, 20/25-20/20). Ninety-six percent had a UNVA of 20/32 or better binocularly ($P<.001$) (Figure 2, *top right*).

The mean UIVA in the surgical eyes increased to 20/25 at 1 month and remained stable throughout the study. After 24 months, 19 patients (79%) had a binocular UIVA of 20/20 and 23 patients (96%) of 20/25 or better. The mean binocular UIVA improved from 20/25 preoperatively to 20/20 after 1 month ($P<.01$) and remained stable over the 24-month follow-up (95% CI, 20/20) (Figure 2, *bottom left*).

The mean UDVA in the surgical eyes was 20/20 after 1 month and remained stable thereafter ($P=.21$). After 24 months, 19 patients (79%) had a UDVA of 20/20 and 23 patients (96%) read 20/25 in the surgical eye (95% CI, 20/20) (Figure 2, *bottom right*). The mean binocular UDVA was 20/16 postoperatively and remained stable through the last follow-up ($P=.83$). One patient lost 2 lines of UDVA (decrease from 20/16 to 20/25) caused by a myopic shift (difference −0.625 SE). Another patient lost 3 lines of UDVA (decrease from 20/16 to 20/32) caused by a hyperopic shift (difference +1.75 SE).

Safety and Complications

After 24 months, the mean corrected distance visual acuity (CDVA) in the surgical eyes decreased slightly

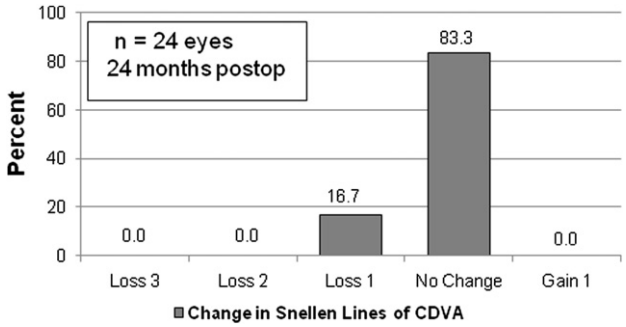

Figure 3. Change in Snellen lines of CDVA from preoperatively to 24 months postoperatively (CDVA = corrected distance visual acuity).

(a mean of 2.5 letters ETDRS; one-half line) to 20/20. At the last follow-up visit, 20 eyes (83.3%) with a corneal inlay had no line change in CDVA and achieved 20/20 or better acuity, while 4 eyes (16.7%) lost 1 line and achieved 20/20 acuity (Figure 3). The mean binocular CDVA remained stable throughout the study at 20/16.

No inlay had to be explanted or recentered during the 24-month follow-up. No inflammation occurred within this time.

One eye developed an epithelial ingrowth at the temporal pocket entrance (pocket created with a mask) 1 month after implantation but remained stable without further conservative or surgical intervention. Another eye developed brown iron deposits in the epithelium that was first seen at the 18-month follow-up. The iron deposits were in a half-moon shape in the inferior cornea parallel to the outer margin of the inlay and remained unchanged until the last follow-up. Some eyes developed a thin hazy appearance adjacent to the anterior surface and at the outer and/or inner rim of the inlay as evaluated by slitlamp examination.

The mean ECC in the surgical eyes was 2417 ± 255 cells/mm^2. It remained stable at 2392 ± 58 cells/mm^2 12 months postoperatively (P=.74) and 2347 ± 14 cells/mm^2 at 24 months (P=.67). At no time was it difficult to measure the central cornea in any case. The endothelial cell appearance was normal in the

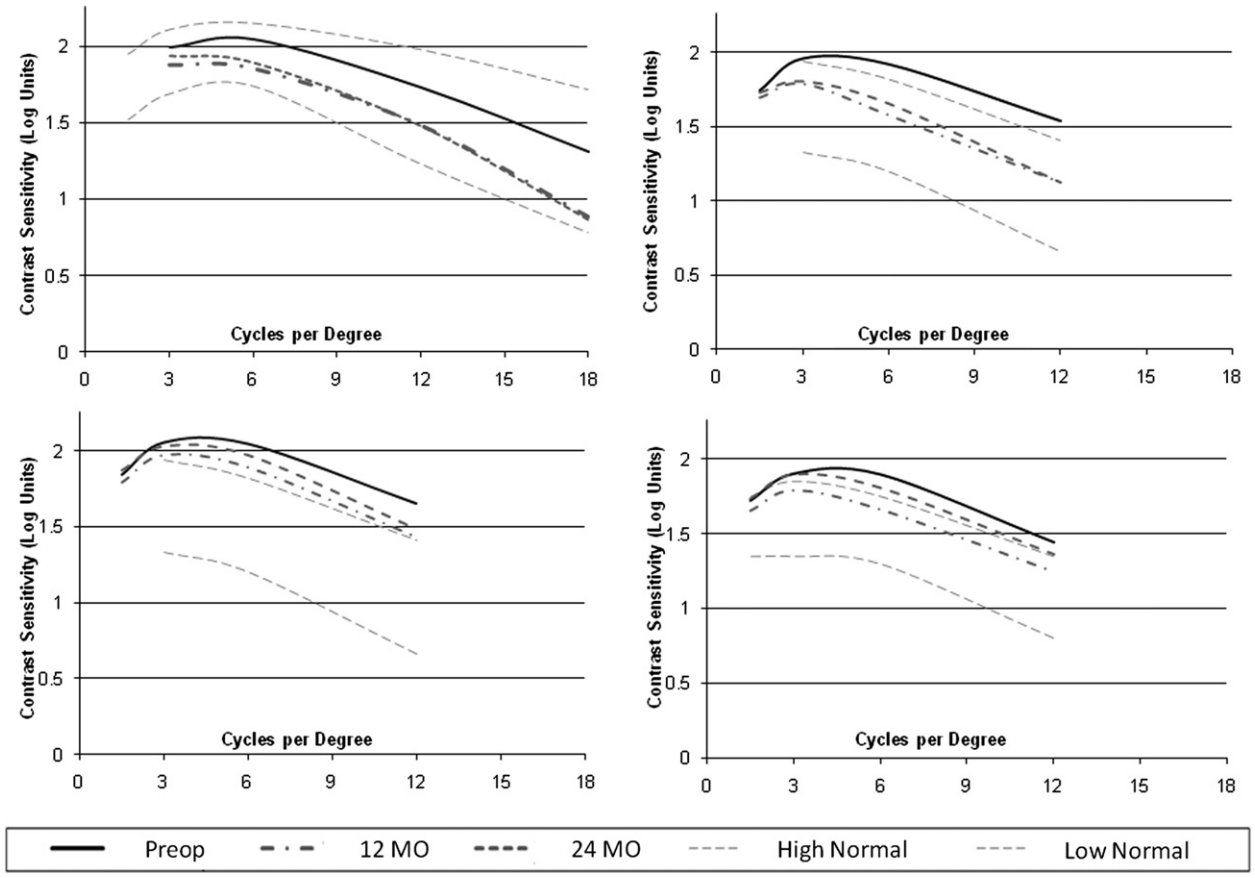

Figure 4. Contrast sensitivity before and after inlay implantation. Monocular photopic (*top left*), monocular mesopic (*top right*), binocular mesopic (*bottom left*), binocular mesopic with glare (*bottom right*).

surgical eyes after 2 years of follow-up. The mean CCT was 558 ± 31 µm preoperatively, 565 ± 34 µm 12 months postoperatively, and 558 ± 38 µm at 24 months. The change was not statistically significant ($P = .82$).

Contrast Sensitivity

Figure 4 shows the mean postoperative log10 contrast sensitivity values plotted as a series of contrast sensitivity functions under photopic and mesopic conditions in the surgical eye and binocularly under mesopic light conditions with or without glare. The graphs compared the results with those in the normal age group. Monocular contrast sensitivity in the surgical eye decreased more than the binocular contrast sensitivity postoperatively.

After 24 months, the decrease in contrast sensitivity in the surgical eye was statistically significant under photopic conditions at higher spatial frequencies and binocularly under mesopic conditions at the highest measured spatial frequency. However, photopic and mesopic contrast sensitivity in the surgical eye and binocularly were within the range of the normal population at all frequencies preoperatively and 12 months and 24 months postoperatively.

Visual Field

No patient had detectable central visual field defects (>1 spot preoperatively and postoperatively). In the surgical eyes, the mean deviation was 0.21 ± 1.25 dB preoperatively, −0.35 ± 0.87 dB 12 months postoperatively ($P = .12$), and −0.68 ± 0.94 dB at 24 months ($P < .001$). Although the mean deviation at 24 months was statistically significant, none of the changes was clinically significant. In the fellow eyes, the mean deviation was 0.42 ± 1.03 dB preoperatively, 0.88 ± 0.81 dB 12 months postoperatively, and 0.85 ± 0.71 dB at 24 months.

The mean pattern SD in the surgical eye was 1.51 ± 0.49 dB preoperatively, 1.50 ± 0.23 dB 12 months postoperatively ($P = .90$), and 1.63 ± 0.51 dB at 24 months ($P = .50$). The mean pattern SD in the fellow eye was 1.49 ± 0.24 dB preoperatively, 1.52 ± 0.22 dB 12 months postoperatively, and 1.43 ± 0.21 dB at 24 months. None of the changes was statistically significant.

DISCUSSION

In this prospective interventional case series, we evaluated the safety and efficacy of the Kamra corneal inlay implantation in a femtosecond laser–created corneal pocket as a surgical approach for the corneal compensation of presbyopia in emmetropic presbyopic patients within the first 24 months. Based on the pinhole effect, the depth of focus increases by artificially reducing the pupil's aperture size; therefore, near and intermediate visual acuities increase.[B]

With the pocket technique, significantly less corneal peripheral nerves are damaged than when a conventional flap is cut; this should theoretically decrease the prevalence of dry-eye symptoms. Another advantage of the pocket technique may be the preservation of the biomechanical properties of the cornea, especially the anterior corneal lamellae.

Precise centration of the inlay in the pocket over the visual axis by using the first Purkinje reflex as a target on the corneal surface remains a key factor for a positive outcome. In a previously published paper,[9] we found that recentration of the inlay can lead to a significant increase in UDVA and UNVA. No recentration was necessary in the present study. Hence, we believe the pocket technique is better than the flap technique in terms of centration because the first Purkinje reflex is always visible during surgery as a reference point and no flap lifting, which can induce a blurry image of the reflex, is necessary.

Four patients had a myopic shift of more than −0.50 D (1 patient −0.875 D, 2 patients −1.00 D, 1 patient −1.625 D) from the 3-month visit to the 24-month visit. These 4 patients had a binocular UNVA of 20/20 (20/16 in 3 patients) and lost only 1 line of UDVA in the surgical eye while gaining at least 3 lines in binocular UNVA. At the last follow-up, 3 of these patients were older than 55 years, an age at which cataract progression is more prevalent. However, we did not detect obvious clinical cataract progression via slitlamp examination as a possible reason for the refractive shift.

In a study using a theoretical eye model, Tabernero and Artal[10] suggest that one can obtain the best depth of focus in Kamra cases with small residual myopia (range −0.75 to −1.00 D). Their eye model simulation calculated a UDVA and UNVA of 20/20, similar to our clinical results. The manufacturer's current strategy for the simultaneous correction of refractive error and presbyopia through combined laser in situ keratomileusis (LASIK) and inlay implantation also targets a residual target refraction of −0.75 D in the surgical eye to maximize the depth of focus.

During the 24-month follow-up, only 1 patient developed epithelial ingrowth. The ingrowth was peripheral at the pocket entrance 1 month after implantation and remained stable until the last follow-up visit without conservative or surgical intervention. We believe this complication was not inlay related. Some eyes developed a thin hazy appearance adjacent to the anterior surface and at the outer and/or inner rim of the inlay on slitlamp examination. These changes were not the same as those reported by

other authors after implantation of a hydrogel intracorneal inlay.[11] No other pocket- or inlay-related complications were detected after 24 months. In addition, no inlay was explanted or had to be recentered through the last follow-up. The inlay did not appear to affect the ECC density or CCT after 2 years of follow-up.

We previously reported central and peripheral iron deposits in more than 56% of eyes (18/32) with the ACI7000 corneal inlay (first-generation design) implanted under a femtosecond laser–assisted flap (170 μm depth) after 3 years of follow-up.[12] In our current study, only 1 patient developed paracentral deposits in the form of a half moon in the inferior cornea parallel to the outer margin of the inlay after 24 months.[13] This change was not associated with the visual or refractive outcomes. We assume that the thinner (5 μm) design of the ACI7000PDT inlay and the deeper implantation (230 μm) induce minor topographic changes to the cornea. In addition, in the first 24 months, there were no cases of any type of deposits in the interface; these have been reported with other intracorneal implants, including hydrogel intracorneal inlays[11,14] and intracorneal ring segments.[15]

Although the amount of light transmission through the inlay is reduced, there was no evidence of visual field constriction or any indication of a ring scotoma specific to the position of the inlay in the field of view. This is likely explained by the ability of the retina and visual system to adapt to the available luminance. In addition, the lack of ring scotoma is also likely explained by the fact that the inlay is behind the first refracting surface of the eye. Therefore the inlay is not "imaged" on the retina.

In the surgical eye, contrast sensitivity was statistically significantly reduced after 24 months under photopic conditions at higher spatial frequencies. It was reduced binocularly under mesopic conditions at the highest measured spatial frequency. However, the postoperative contrast sensitivity scores remained within the range of the normal population.[16] The loss of contrast sensitivity was lower when tested binocularly under mesopic conditions (without glare lower than with glare). However, at 24 months, contrast sensitivity values were better under all tested light conditions (monocular photopic/mesopic, binocular mesopic/mesopic with glare) than at 12 months. A certain adaptation effect over time might have played a role in the better contrast sensitivity results 24 months postoperatively.

Another limitation of the inlay is the small reduction in the mean UDVA in the surgical eye 24 months postoperatively compared with preoperatively (minus 2.5 letters mean); however, the mean binocular UDVA was stable (20/16) throughout the follow-up.

A significant advantage of this corneal inlay is its potential removability and there is no ablation over the optical axis. This is in contrast to other corneal laser refractive surgeries (presbyopic LASIK, Intracor, or monovision treatment). Yılmaz et al.[17] report the simplicity of inlay explantation in cases of patient dissatisfaction or unexpected complications. In that study, all 4 patients with a removed inlay returned to within ±1.00 D of their preoperative refraction with no loss of CDVA. In addition, the inlay implantation technique does not have a steep learning curve and is rather easy to handle for the experienced refractive surgeon. Because it is a non-lens-based refractive surgery technique, sight-threatening intraocular complications do not occur.[18–20]

Clinical trials for FDA approval are currently underway for both other corneal inlay techniques for presbyopia correction (ie, Vue+ system and the Flexivue/Invue Microlens system). However, after performing a PubMed literature search before submitting this paper, we found no peer-reviewed study of the Vue+ system and found 2 studies of the Invue system. One Invue case report described inlay implantation in a femtosecond laser pocket with a postoperative follow-up of 1 week (UNVA gain from 20/50 to 20/20),[21] and a recent study by Bouzoukis et al.[22] of 45 eyes showed a UNVA of 20/32 in 98% of operated eyes. In the study by Bouzoukis et al., only 20% of patients had a binocular UDVA of 20/20 after 1 year; this is compared with 79% of patients in our study after 2 years of follow-up. Nevertheless, further clinical trials with a longer follow-up might confirm the safety and efficacy of these types of corneal inlays.

A limitation of our study is the small sample size (24 patients). A study comprising more patients might confirm our findings. Another limitation of our study might be the use of 3 different femtosecond lasers for pocket creation, although we could find no difference in the final surgical outcomes between the 3 laser groups.

The presented data on this clinical trial indicate that implantation of the Kamra corneal inlay (ACI7000PDT) seems to be a safe, stable, and effective surgical approach for the corneal compensation of presbyopia up to 24 months. Based on the small-aperture concept to increase depth of focus, the mean UNVA (20/25) and UIVA (20/20) increased significantly and remained stable without significantly affecting the binocular UDVA.

WHAT WAS KNOWN

- The small-aperture corneal inlay (Kamra) implanted monocularly in femtosecond laser–created pockets for the corneal compensation of presbyopic emmetropia was reported to be stable and effective over a 1-year follow-up.
- A longer follow-up to prove this surgical approach, including data on visual field and contrast sensitivity, was lacking.

WHAT THIS PAPER ADDS

- After 2 years, implantation of the small-aperture corneal inlay in femtosecond laser–created pockets seemed to be safe and effective for corneal compensation of presbyopic emmetropia.
- The mean contrast sensitivity values decreased slightly postoperatively but remained within the range of the normal population.
- There was no evidence of visual field defects in the surgical eye after 2 years. No inlay-related complication, recentration, or explantation occurred.

REFERENCES

1. Werner LP, Werner L, Pandey SK, Apple D. Physiology of accommodation and presbyopia. In: Agarwal A, ed, Presbyopia: A Surgical Review. Thorofare, NJ, Slack, 2002; 29–60
2. Holzer MP, Mannsfeld A, Ehmer A, Auffarth GU. Early outcomes of INTRACOR femtosecond laser treatment for presbyopia. J Refract Surg 2009; 25:855–861
3. Alió JL, Amparo F, Ortiz D, Moreno L. Corneal multifocality with excimer laser for presbyopia correction. Curr Opin Ophthalmol 2009; 20:264–271
4. Patel S, Alió JL, Feinbaum C. Comparison of Acri. Smart multifocal IOL, Crystalens AT-45 accommodative IOL, and Technovision presbyLASIK for correcting presbyopia. J Refract Surg 2008; 24:294–299
5. Ehrlich JS, Manche EE. Regression of effect over long-term follow-up of conductive keratoplasty to correct mild to moderate hyperopia. J Cataract Refract Surg 2009; 35:1591–1596
6. Chen S, Feng Y, Stojanovic A, Jankov MR II, Wang Q. IntraLase femtosecond laser vs mechanical microkeratomes in LASIK for myopia: a systematic review and meta-analysis. J Refract Surg 2012; 28:15–24
7. Waring GO IV, Klyce SD. Corneal inlays for the treatment of presbyopia. Int Ophthalmol Clin 2011; 51(2):51–62
8. Dexl AK, Seyeddain O, Riha W, Hohensinn M, Rückl T, Reischl V, Grabner G. One- year visual outcomes and patient satisfaction after surgical correction of presbyopia with an intracorneal inlay of a new design. J Cataract Refract Surg 2012; 38:262–269
9. Seyeddain O, Riha W, Hohensinn M, Nix G, Dexl AK, Grabner G. Refractive surgical correction of presbyopia with the AcuFocus small aperture corneal inlay: two-year follow-up. J Refract Surg 2010; 26:705–715. Available at: http://kamrainlay.com/sites/kamrainlay.com/files/JRS-Orang-Seyeddain-April-2010.pdf. Accessed October 4, 2012
10. Tabernero J, Artal P. Optical modeling of a corneal inlay in real eyes to increase depth of focus: optimum centration and residual defocus. J Cataract Refract Surg 2012; 38:270–277
11. Mulet ME, Alio JL, Knorz MC. Hydrogel intracorneal inlays for the correction of hyperopia; outcomes and complications after 5 years of follow-up. Ophthalmology 2009; 116:1455–1460
12. Dexl AK, Ruckhofer J, Riha W, Hohensinn M, Rueckl T, Messmer EM, Grabner G, Seyeddain O. Central and peripheral corneal iron deposits after implantation of a small-aperture corneal inlay for correction of presbyopia. J Refract Surg 2011; 27:876–880
13. Dexl AK, Seyeddain O, Grabner G. Follow-up to "central and peripheral corneal iron deposits after implantation of a small-aperture corneal inlay for correction of presbyopia" [letter]. J Refract Surg 2011; 27:856–857
14. Alió JL, Mulet ME, Zapata LF, Vidal MT, De Rojas V, Javaloy J. Intracorneal inlay complicated by intrastromal epithelial opacification. Arch Ophthalmol 2004; 122:1441–1446. Available at: http://archopht.jamanetwork.com/data/Journals/OPHTH/9930/ECS30149.pdf. Accessed October 4, 2012
15. Ruckhofer J, Twa M, Schanzlin DJ. Clinical characteristics of lamellar channel deposits after implantation of Intacs. J Cataract Refract Surg 2000; 26:1473–1479
16. Hohberger B, Laemmer R, Adler W, Juenemann AGM, Horn FK. Measuring contrast sensitivity in normal subjects with OPTEC® 6500: influence of age and glare. Graefes Arch Clin Exp Ophthalmol 2007; 245:1805–1814
17. Yılmaz ÖF, Alagöz N, Pekel G, Azman E, Aksoy EF, Çakır H, Bozkurt E, Demirok A. Intracorneal inlay to correct presbyopia: long-term results. J Cataract Refract Surg 2011; 37:1275–1281
18. Yip C-C, Au Eong K-G, Young VSH. Intraoperative capsular block syndrome masquerading as expulsive hemorrhage. Eur J Ophthalmol 2002; 12:333–335
19. Lundström M, Wejde G, Stenevi U, Thorburn W, Montan P. Endophthalmitis after cataract surgery; a nationwide prospective study evaluating incidence in relation to incision type and location. Ophthalmology 2007; 114:866–870
20. Shirodkar AR, Pathengay A, Flynn HW Jr, Albini TA, Berrocal AM, Davis JL, Lalwani GA, Murray TG, Smiddy WE, Miller D. Delayed- versus acute-onset endophthalmitis after cataract surgery. Am J Ophthalmol 2012; 153:391–398
21. Bouzoukis DI, Kymionis GD, Limnopoulou AN, Kounis GA, Pallikaris IG. Femtosecond laser-assisted corneal pocket creation using a mask for inlay implantation. J Refract Surg 2011; 27:818–820
22. Bouzoukis DI, Kymionis GD, Panagopoulou SI, Diakonis VF, Pallikaris AI, Limnopoulou AN, Portaliou DM, Pallikaris IG. Visual outcomes and safety of a small diameter intrastromal refractive inlay for the corneal compensation of presbyopia. J Refract Surg 2012; 28:168–173

OTHER CITED MATERIAL

A. National Institutes of Health Clinical Trials. Safety and Effectiveness of the AcuFocus Corneal Inlay ACI7000PDT in Presbyopes. NCT01352442. Available at: http://clinicaltrials.gov/ct2/show/NCT01352442?term=kamra+acufocus&rank=1. Accessed October 4, 2012

B. Acufocus, Inc. Irvine, California, USA. Data on file.

First author:
Orang Seyeddain, MD

University Eye Clinic, Paracelsus Medical University, Salzburg, Austria