Small-aperture corneal inlay implantation to treat presbyopia after laser in situ keratomileusis

Minoru Tomita, MD, PhD, Tomomi Kanamori, George O. Waring IV, MD, Toru Nakamura, MD, Satoshi Yukawa, MD

PURPOSE: To evaluate the visual outcomes after implantation of a Kamra small-aperture corneal inlay into a femtosecond-created corneal pocket to treat presbyopia in patients who had previous laser in situ keratomileusis (LASIK).

SETTING: Private center, Tokyo, Japan.

DESIGN: Prospective interventional case series.

METHODS: Post-LASIK presbyopic patients had inlay implantation into a corneal pocket created by a femtosecond laser at a depth of 200 μm or 250 μm a minimum of 80 μm below the previous LASIK flap interface in the nondominant eye. Uncorrected and corrected distance visual acuities, near visual acuity, and a patient questionnaire on satisfaction, the use of reading glasses, and visual symptoms were evaluated.

RESULTS: The study enrolled 223 eyes (223 patients) with a mean age of 53.6 years (range 44 to 65 years) and a mean manifest spherical equivalent of −0.18 diopter (D) (range −1.00 to +0.50 D). The mean uncorrected distance visual acuity in the operated eye decreased 1 line from 20/16 preoperatively to 20/20 6 months postoperatively ($P<.001$). The mean uncorrected near visual acuity improved 4 lines from Jaeger (J) 8 to J2 ($P<.001$). At 6 months, significant improvements were observed in patient dependence on reading glasses and patient satisfaction with vision without reading glasses.

CONCLUSION: The 6-month results suggest that implantation of a small-aperture inlay in post-LASIK presbyopic patients improves near vision with a minimal effect on distance vision, resulting in high patient satisfaction and less dependence on reading glasses.

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More than a few decades have passed since the emergence of laser in situ keratomileusis (LASIK). As a result of its safety, efficacy, and quick visual recovery, the LASIK procedure has been widely accepted around the world. Millions of patients have had treatment and have experienced improved vision.[1,2] Today, an increasing number of patients who had previous LASIK are becoming presbyopic.

Presbyopia, a common aging condition, is the result of a natural loss of accommodation of the crystalline lens. This condition typically manifests in patients older than 40 years. Several treatments are available; these include bifocal or multifocal contact lenses,[3,4] conductive keratoplasty,[5] monovision LASIK,[6] multifocal LASIK (presbyLASIK),[7] multifocal intraocular lenses (IOLs), and accommodating IOLs.[8]

The Kamra (Acufocus, Inc.) is a small-aperture corneal inlay made of polyvinylidene fluoride (PVDF) and carbon. The concept of the corneal inlay goes back to Barraquer,[9] who is generally credited with the first corneal inlay implantation in 1949. Since that time, many corneal inlays have been developed using a variety of materials, designs, and surgical techniques.[9,10] Several studies[11–13] have shown that the Kamra corneal inlay, implanted under a corneal lamellar flap or pocket, is a safe and effective treatment for presbyopia. Our group previously described inlay implantation in combination with a LASIK procedure for simultaneous correction of

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ametropia and presbyopia; we found the procedure to be safe and effective.[14]

In this study, we examined a new treatment using the same intracorneal inlay for treatment of presbyopia in patients previously treated with LASIK. Visual acuity results, efficacy, safety, and patient satisfaction were evaluated.

PATIENTS AND METHODS

Patients

This prospective noncomparative single-center study comprised post-LASIK patients who had implantation of a Kamra inlay in the nondominant eye from February 2011 to October 2011 at Shinagawa LASIK Center, Tokyo, Japan. The study was performed in accordance with the ethics codes established by the Ethical Board Committee in Japan. All patients read and signed informed consent forms, which explained the surgical procedure, possible risks, and patient rights.

Inclusion criteria for this study included age from 40 to 65 years, a history of LASIK at least 1 month before inlay implantation, an uncorrected near visual acuity (UNVA) in the implanted eye of Jaeger (J) 3 or worse, binocular corrected distance visual acuity (CDVA) of at least 20/25, minimum endothelial cell density of 2000 cells/mm^2, and central corneal thickness (CCT) of more than 450 μm before inlay implantation. Patients were excluded from the study if they had ocular pathology including keratectasia, corneal degeneration, severe blepharitis, retinal disease, glaucoma, cataract, marked topographic irregularities, severe dry eyes, or previous ocular surgery other than LASIK.

A nonvalidated subjective questionnaire was developed to assess patient satisfaction at the preoperative and 6-month postoperative examinations. Patients were asked to rate their satisfaction on a scale of 1 to 7, with 1 being least satisfied (need reading glasses for near vision) and 7 being most satisfied (no need for reading glasses for near vision).

Also, patients were asked to rate their visual symptoms on a scale of 0 to 7, with 0 being no symptoms and 7 being very heavy symptoms.

Preoperative Examinations

All patients had comprehensive preoperative examinations including measurement of monocular and binocular uncorrected (UDVA), CDVA, UNVA (30 cm), and corrected near visual acuity (CNVA) (30 cm) (Handaya Near Visual Acuity Chart, Handaya Co., Ltd.); manifest refraction; pupil size (OPD-Scan II, Nidek Co., Ltd.); cycloplegic refraction; intraocular pressure (noncontact tonometer, Topcon Corp.); keratometry (ARK-530A, Nidek. Co., Ltd.); ultrasound pachymetry; CCT (SP-3000 contact pachymeter, Tomey Corp.); corneal aberrometry (Wavefront Analyzer, Topcon Corp.); slitlamp biomicroscopy (Carl Zeiss Meditec AG); contrast sensitivity analysis (CGT-1000, Takagi Seiko Co., Ltd.); specular microscopy (FA-3509, Konan Medical, Inc.); corneal topography (TMS-4, Tomey Corp.); rotating Scheimpflug imaging (Pentacam, Oculus Optikgeräte GmbH); and fundus evaluation. For dry-eye evaluation, tear breakup time and a phenol red-thread tear test (Zone-Quick, Showa Yakuhin Kako) were also performed.

In Japan, visual acuity is customarily reported in decimal form. Using the *Journal of Cataract & Refractive Surgery* Visual Acuity Conversion Chart, each patient's decimal values were converted into logMAR notation. After conversion to logMAR values, the means and ranges were determined and are reported here in Snellen- and Jaeger-equivalent terms. With respect to near visual acuity measurement in Japan, it is customarily measured at 30 cm in decimal form. In this article, the 30 cm near visual acuity was converted into standard 40 cm Jaeger results to reflect the international standard of near vision measurement. The method used for conversion was based on a previous study,[14] which found a correlation between near visual acuity tested at 30 cm versus 40 cm. In this near vision study of 830 eyes of 415 patients, patients gained 1 line of near acuity when the reading distance was increased from 30 cm to 40 cm. Based on this finding, the near visual acuity was converted accordingly. Also, 1 day postoperatively, a punctal plug (Eagle Vision) was inserted in the operated eye in all cases.

Eye Dominance

Motor and sensory dominance tests were performed twice preoperatively, first on the day of the preoperative examination and again on the day of surgery, to determine which eye was to have inlay implantation. Motor dominance was determined by asking the patient to view a distant object through an aperture created with their hands. The sensory-dominant eye was measured with a blur test by adding a +1.50 diopters (D) spectacle trial lens to each eye until vision blurred. The eye more tolerant to plus-power blur was defined as the sensory-nondominant eye. When the motor- and sensory-dominance tests provided conflicting results, the inlay was implanted in the sensory-nondominant eye, based on the previous studies by Durrie,[15] in which high satisfaction and improvement in near vision were observed when the sensory-nondominant eye was targeted as the near eye for contact lens monovision.

Corneal Inlay Specifications

The Kamra inlay used in this study was the latest model (ACI 7000PDT) and is made of PVDF and nanoparticles of carbon. The inlay has a 3.8 mm outer diameter and a 1.6 mm central aperture. It is 5 μm thick and has 8400 microperforations varying in size from 5 to 11 μm in diameter to allow nutrient flow through the cornea and minimize photic phenomenon.[A] The microperforations allow a 5% light-transmission rate through the inlay into the eye.[14] The inlay is designed to allow only focused light to enter the eye through the central aperture, which decreases retinal blur and increases depth of focus. The same principle is used in

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From Shinagawa LASIK Center (Tomita, Kanamori, Nakamura, Yukawa), Tokyo, Japan; the Department of Ophthalmology (Tomita), Wenzhou Medical College, Wenzhou, China; the Storm Eye Institute, Medical University of South Carolina, and Magill Vision Center (Waring), Charleston, South Carolina, USA.

Corresponding author: Minoru Tomita, MD, PhD, Shinagawa LASIK Center, Yurakucho ITOCiA, 14th Floor, 2-7-1, Yurakucho, Chiyoda-Ku, Tokyo, 100-0006 Japan. E-mail: tomita@shinagawa-lasik.com.