Comparison of Contrast Sensitivity and Through Focus in Small-Aperture Inlay, Accommodating Intraocular Lens, or Multifocal Intraocular Lens Subjects

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• PURPOSE: To compare monocular and binocular mesopic contrast sensitivity and through focus following monocular implantation with KAMRA small-aperture inlay (AcuFocus, Irvine, California, USA) vs binocular implantation with an accommodating or multifocal intraocular lens (IOL) implant.

• DESIGN: Three-treatment randomized clinical trial of presbyopia-correcting IOLs with comparison to results from a previous nonrandomized multicenter clinical trial on the KAMRA corneal inlay.

• METHODS: Study population of 507 subjects with KAMRA inlays; predetermined subgroups included 327 subjects that underwent contrast sensitivity testing and another 114 subjects for defocus curve testing, along with 78 subjects randomized between bilateral Crystalens Advanced Optics (AO) (Bausch + Lomb Surgical, Aliso Viejo, California, USA), AcrySof IQ ReSTOR +3.0 D (Alcon Laboratories, Fort Worth, Texas, USA), or Tecnis +4D Multifocal (MF) (Abbott Medical Optics, Santa Ana, California, USA) IOL.

• RESULTS: KAMRA inlay subjects demonstrated improved intermediate and near vision with minimal to no change to distance vision, better contrast sensitivity in the inlay eye when compared to the multifocals, and better binocular contrast sensitivity when compared to all 3 intraocular lenses. Crystalens AO was superior in uncorrected intermediate vision compared to the KAMRA inlay, but not in distance-corrected intermediate, and was worse in near vision. The multifocals were superior in near vision at their respective optimum near focus points, but worse in intermediate vision compared to both KAMRA inlay and Crystalens AO.

• CONCLUSIONS: The demonstrated performance of these devices should be considered, along with subjects' visual demands and expectations, degree of crystalline lens dysfunction, and other ocular characteristics, in guiding the selection of small-aperture corneal inlay or specific intraocular lens in the correction of presbyopia. (Am J Ophthalmol 2015;160(1): 150–162. © 2015 by Elsevier Inc. All rights reserved.)

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PRESBYOPIA IS A DIRECT CONSEQUENCE OF THE AGE-related loss of accommodation resulting from the crystalline lens's inability to focus at near vergence.[1] The global prevalence of presbyopia is predicted to increase to 1.4 billion by 2020 and to 1.8 billion by 2050.[2] A corneal-based surgical approach to presbyopia can be achieved by monocularly implanting a small-aperture intracorneal inlay into a lamellar pocket in the nondominant eye (KAMRA inlay; AcuFocus, Irvine, California, USA). The KAMRA corneal inlay is designed to provide increased depth of focus by blocking unfocused peripheral light rays and reducing the size of the blur circle. The increased depth of focus provides an extended range of continuous vision expanding from near to intermediate to far.[3] Two-year follow-up on 24 subjects from 1 site in the US IDE clinical trial on the KAMRA inlay showed a mean uncorrected near and intermediate vision of 20/25 and uncorrected distance vision of 20/20 in the implanted nondominant eye.[4] Multifocal and accommodating intraocular lens (IOL) designs have been developed to address presbyopia following cataract or clear lens extraction. Multifocal IOLs distribute light among multiple energy foci for near and far distances, thereby improving near visual acuity over the standard monofocal IOL. Potential disadvantages of this design include reduction in contrast sensitivity, degraded image quality, and increased visual symptoms such as glare/haloes.[5–8] Accommodating IOLs have a single focal point and they have shown moderate, at times variable, near visual benefit, with improved intermediate vision.[9–12]

Contrast sensitivity (CS) or low-contrast visual acuity testing under different lighting conditions provides important information about quality of vision.[13,14] In a recent study, Pepose and associates compared 3 widely-used premium IOLs, Crystalens Advanced Optics (AO) accommodative IOL (Bausch + Lomb Surgical, Aliso Viejo, California, USA), AcrySof IQ ReSTOR +3.0 D multifocal IOL (Alcon Laboratories, Fort Worth, Texas, USA) and AMO Tecnis +4D Multifocal (MF) IOL (Abbott Medical

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Optics, Santa Ana, California, USA).[15] In that study, Crystalens AO subjects showed better uncorrected and distance-corrected intermediate vision and less optical scatter than subjects implanted with either multifocal IOL and showed fewer visual symptoms and photic phenomena than subjects with Tecnis +4D MF. In distinction, the multifocal IOL subjects showed better distance-corrected near vision.[15] Crystalens AO and ReSTOR +3.0 subjects demonstrated better monocular and binocular mesopic CS without glare at low to mid spatial frequencies when compared to Tecnis +4D MF IOL.[15] The purpose of the current study is to compare the mesopic monocular and binocular CS functions as well as quantitative visual metrics and defocus curve measurements of the KAMRA corneal inlay to the 3 presbyopia-correcting IOLs.

METHODS

THE MONOCULAR AND BINOCULAR MESOPIC CS FUNCTIONS, visual acuities, and defocus curves from a nonrandomized multicenter US IDE clinical trial (http://www.clinicaltrials.gov, NCT00819299 and NCT00850031) on the KAMRA corneal inlay were compared to data from a previous 3-treatment randomized clinical trial of presbyopia-correcting IOLs (http://www.clinicaltrials.gov, NCT01122576).[15] The study was performed in accordance with the Declaration of Helsinki and approved by the Ethics Committees of the respective investigational sites. Subjects were screened for eligibility, and informed consents were obtained from all eligible subjects.

In the multicenter clinical trial on the KAMRA inlay 507 subjects at 24 clinical sites were monocularly implanted with the intracorneal KAMRA inlay (ACI7000PDT) in their nondominant eye. The clinical trial sites were located in the following countries: United States, Philippines, Singapore, New Zealand, Australia, Germany, Austria, and United Kingdom. Subjects were screened for eligibility, and informed consents were obtained on all eligible subjects. Naturally emmetropic presbyopic subjects between 45 and 60 years of age, with preoperative spherical equivalent refraction of −0.75 diopter (D) to +0.50 D with no more than 0.75 D of refractive cylinder as determined by cycloplegic refraction, uncorrected near vision worse than 20/40 and better than 20/100, and best-corrected distance visual acuity 20/20 or better in both eyes were enrolled. Key exclusion criteria were previous ocular surgery, anterior or posterior segment disease or degeneration, immunosuppressive disorders, subjects using systemic medications with significant ocular side effects, subjects with latent hyperopia, subjects with intraocular pressure (IOP) >21 mm Hg, and dry eyes. Contrast sensitivity testing was done in a predetermined subgroup, which had 327 subjects tested at 6 months postoperatively. Defocus curve testing was done in another predetermined subgroup, which had 114 subjects tested at 12 months postoperatively. The subgroups were chosen before study initiation.

FIGURE 1. Image of KAMRA corneal inlay.

The multifocal IOL comparative group included 78 subjects randomly assigned to 1 of 3 groups and bilaterally implanted. The subjects and the clinic personnel performing the assessments were masked to the IOL type until study exit. Twenty-six subjects were implanted with the Crystalens AO IOL, 25 subjects were implanted with the ReSTOR +3.0 IOL, and 22 subjects were implanted with the Tecnis +4D MF IOL. These subjects were between 59.8 and 68 years of age. For Crystalens AO, the dominant eye was targeted between plano and −0.25 D and the nondominant eye was targeted between plano and −0.50 D. For ReSTOR +3.0, emmetropia was targeted in both eyes and for Tecnis +4D MF both eyes were targeted for plano to −0.25 D.

• **CORNEAL INLAY AND SURGICAL TECHNIQUE:** The appearance of the inlay from the anterior perspective is shown in Figure 1. The KAMRA corneal inlay is made from a highly biocompatible material, polyvinylidene difluoride (PVDF), and is proven to be stable in the eye.[16] The inlay has a 1.6 mm inside diameter and a 3.8 mm outside diameter; it is 6 μm thick. These holes are responsible for creating a visible light transmission of approximately 5% through the annulus of the inlay. The inlay was placed on the stromal bed and into the lamellar pocket of the nondominant eye. The surgical preparation and technique have been described in detail in prior publications.[17]

• **VISUAL ACUITY:** Visual acuities were measured using the Optec 6500 Vision Tester (Stereo Optical Company,

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