Visual outcomes after accommodating intraocular lens implantation

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PURPOSE: To evaluate and compare the visual outcomes and accommodative amplitude in cataract patients after implantation of the Crystalens intraocular lens (IOL) (Eyeonics) versus standard monofocal IOLs.

SETTING: Ten clinics in a nationwide multicenter study in the United States.

METHODS: A multicenter comparative interventional case series with masked randomized postoperative examination of 224 eyes of 112 patients was performed by a single observer. Patients were divided into 2 groups (56 patients; 112 eyes each) depending on which IOL was implanted (Crystalens or monofocal). Accommodation was measured using 1 objective (dynamic retinoscopy) and 2 subjective methods (defocus and near point of accommodation). Visual acuity measurements were performed under the same conditions with standard visual acuity charts.

RESULTS: Uncorrected monocular near vision was significantly better in the Crystalens group than in the standard monofocal group, with 101 of 112 eyes (90%) and 17 of 112 (15%), respectfully, reading J3 or better postoperatively. All 56 Crystalens patients had a binocular uncorrected near visual acuity of J3 or better compared with 16 of 56 (29%) standard monofocal patients. The mean postoperative monocular (0.85 $\pm$ 0.30 [SD] versus 0.70 $\pm$ 0.19, $P<.01$) and binocular (1.16 $\pm$ 0.17 versus 1.01 $\pm$ 0.14, $P<.01$) distance uncorrected visual acuities were also better in the Crystalens group than in the control group. All patients in the study achieved a corrected distance visual acuity of 20/20 or better. Measures of accommodation were significantly higher in Crystalens patients than in the monofocal IOL patients (dynamic retinoscopy 2.42 $\pm$ 0.39 diopters [D] versus 0.91 $\pm$ 0.24 D, $P<.01$; monocular defocus 1.74 $\pm$ 0.48 D versus 0.75 $\pm$ 0.25 D, $P<.01$; monocular near point of accommodation 9.5 $\pm$ 3.1 inches versus 34.7 $\pm$ 9.8 inches, $P<.01$). Perceived accommodation (5.79 D) was significantly greater than the measured accommodation (1.96 to 2.42 D) in Crystalens patients (paired *t* test, $P<.01$).

CONCLUSIONS: The Crystalens IOL provided better uncorrected near and distance visual outcomes than standard monofocal IOLs in all analyses performed. Patients perceived a greater accommodation than measured. Understanding why this occurred could lead to valuable advances in accommodating IOL technology.

J Cataract Refract Surg 2006; 32:628–633 © 2006 ASCRS and ESCRS

Modern cataract surgery comprises small-incision phacoemulsification and implantation of an intraocular lens (IOL). Standard IOLs are monofocal, and after implantation, patients usually have clear vision only at distance, requiring spectacles to provide usable near vision.[1–4] Postoperative presbyopia remains an unsolved challenge in ophthalmology.

Multifocal and bifocal IOLs were designed to overcome the lack of accommodation in pseudophakic patients, providing useful distance and near vision.[1,3–15] Several studies have shown that these IOLs allow good functional vision without the use of corrective lenses, but they are also known to cause decreased contrast sensitivity, glare disability, and halos.[8,14,16,17] This loss of image quality can affect visual performance, and a significant number of patients, such as professional drivers, are not good candidates for implantation.

The possibility of using a monofocal IOL with accommodative ability would result in cataract surgery with superior image quality and a decreased potential for photic phenomena compared with multifocal or bifocal IOLs.[18] Pseudophakic accommodation can be achieved by IOLs that are able to move along the optical axis, thereby increasing the effective power of the eye.[18]

Published by Elsevier Inc.

0886-3350/06/$-see front matter
doi:10.1016/j.jcrs.2006.01.027

The Crystalens IOL (Eyeonics) (Figure 1) was recently approved by the U.S. Food and Drug Administration (FDA) for intraocular implantation.[18] It is a silicone accommodating monofocal IOL designed to provide near, intermediate, and distance vision by allowing anteroposterior movement of the lens along the axis of the eye mediated by the ciliary muscle.[19] To decrease resistance of the optic to forward motion, the lens incorporates hinges adjacent to the optic across the plates. The IOL has a biconvex optic of 4.5 mm in diameter that rests posteriorly on the capsular bag in close proximity to the nodal point of the eye and therefore functions more like a 6.0 mm optic that rests more anteriorly.

In the present study, we assessed the visual outcomes and the amplitude of accommodation in patients of some of the first U.S. surgeons certified to implant the Crystalens IOL approximately 6 months following cataract extraction and Crystalens implantation. Data were statistically compared to a closely age-matched group of patients who received standard monofocal IOLs.

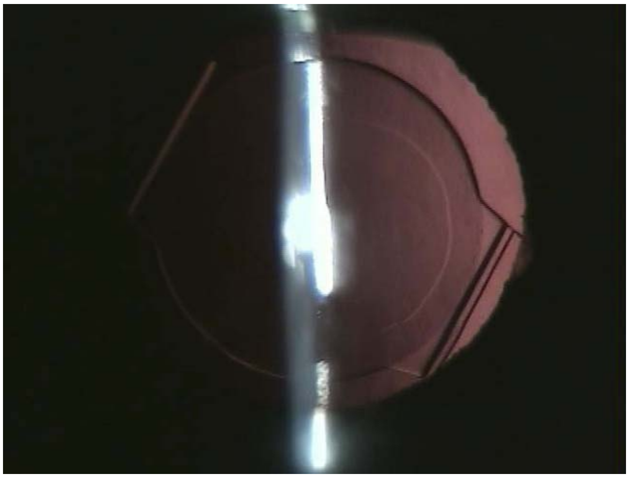

Figure 1. Crystalens IOL positioned in the capsular bag on the first postoperative day.

PATIENTS AND METHODS

A masked and randomized postoperative examination of 112 consecutive patients (224 eyes) from 10 different surgeons was performed by a single observer. Group 1 (56 patients, 112 eyes) had received the Crystalens IOL, and Group 2 (56 patients, 112 eyes) received standard monofocal IOLs in both eyes.

Patients receiving Crystalens IOL implantation had extensive and complete information about the IOL properties, including the accommodative capacity, before surgery and chose this specific IOL. The same refers to the control (standard monofocal IOLs) group.

The tenets of the Declaration of Helsinki were followed in this research, and informed consent was obtained from all patients after the nature, procedures, and possible consequences of the study were explained.

Exclusion criteria were more than 1.5 diopters (D) keratometric cylinder, incomplete or damaged zonules, any anterior segment pathologic characteristics (eg, chronic uveitis, iritis, iridociclytis, rubeosis iridis, corneal dystrophy), uncontrolled or undertreated glaucoma, retinal pathologic characteristics or history of retinal detachment, macular degeneration, proliferative diabetic retinopathy, congenital bilateral cataract, marked microphthalmos or aniridia, and blindness or previous ocular surgery in either eye.

Standard preoperative biometric measurements were taken using the A-Scan (immersion technique) or the Zeiss IOLMaster laser interferometer. The IOL power was calculated with the SRK/T or Holladay formula.

The standard monofocal IOLs are referred to as hydrophobic acrylic foldable posterior chamber IOLs, with anterior biconvex optics of 6.0 mm in diameter and overall length of 13.00 mm.

Outcome Measures

Visual acuity measurements were performed under standard conditions by the same examiner with standard Snellen visual acuity charts. Refraction was measured with retinoscopy and retested subjectively. Distance and near visual acuities were individually assessed with and without correction.

Accommodation was measured using 2 subjective (defocus and near point of accommodation) and 1 objective method (dynamic retinoscopy) (Table 1).

Surgical Technique

Cataract extraction was performed by 10 experienced surgeons (1 at each site) through a clear corneal or scleral tunnel incision no more than 4.0 mm in length, with a capsulorhexis of

Accepted for publication September 15, 2005.

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Presented in part at the annual meeting of the Association for Research in Vision and Ophthalmology, Fort Lauderdale, Florida, USA, May 2005.

Supported by an unrestricted grant from Research to Prevent Blindness to Northwestern University.

Dr. Macsai served as a consultant to Eyeonics. No author has a financial or proprietary interest in any material or method mentioned.

David Tanouye, OD, Paul J. Dougherty, MD, Harvey L. Carter, MD, Jeffery Whitman, MD, David A. Kleiman, MD, Sheri L. Rowen, MD, Neil F. Martin, MD, Stephen J. Merfeld, MD, Herman D. Sloane, MD, and Mitchell A. Jackson, MD, contributed to data collection and assistance in writing the article.

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Table 1. Accommodation measurement techniques.

Method	Description
Defocus	Prince Rule card positioned at a fixed length and brought into focus Lenses tested in 0.25 D steps Lens strength at first blurring of Prince Rule card
Dynamic retinoscopy	Patient streaked while looking at a distant target Patient streaked while looking at an accommodative target at 14 inches Difference between distant and 14 inch streaking in diopters
Near point of accommodation	Comfortable reading distance determined in inches Converted to diopters of accommodation (D = 40/in)

4.0 to 6.0 mm and capsular bag implantation of the IOL. All cases were done using conventional phacoemulsification chop techniques without major differences (eg, capsule polishing) between centers using commercially available viscoelastic substances and materials standardly selected by each individual surgeon. All surgeons received training regarding Crystalens IOL implantation, including monitoring of their first 20 cases by a certified observer.

Intraoperative and postoperative medications of the surgeon's choice were used, with each site adhering to standardized perioperative regimens. All patients with the Crystalens IOL received treatment with topical atropine 1% immediately following surgery and on the first postoperative day.

Statistical Analysis

All visual acuity data were converted to the decimal form of the Snellen visual acuity for analysis using Microsoft Excel. The corresponding Snellen visual acuity and Jaeger scales are displayed throughout for reference and convenience. All measurements for the Crystalens IOL and the standard monofocal IOL were compared using unpaired *t* tests. Statistical significance was defined as a *P* value less than 0.05. All data are presented as mean ± standard deviation.

RESULTS

Patient characteristics in both groups are summarized in Table 2. Sample size was the same in both groups (56 patients; 112 eyes each), with comparable ages and postoperative time. Cataract surgery and IOL implantation was uneventful in all 224 eyes, and at the time of examination, all lenses were well centered, with no reports of corneal edema, inflammation, or posterior capsule opacification.

Table 2. Patient characteristics in both groups.

Parameter	Standard Monofocal	Crystalens
Patients (n)	56	56
Eyes (n)	112	112
Patient age (y)	65.5 ± 4.2	60.1 ± 7.2
Postoperative time (mo)	7.1 ± 3.0	5.9 ± 2.6

Visual Outcomes

Postoperative monocular uncorrected near visual acuity was significantly better in the Crystalens patients than in standard monofocal patients (Table 3). The mean monocular uncorrected near acuity was 0.69± 0.23 (J2) in Crystalens patients and 0.35 ± 0.12 (J6) in the monofocal group (P<.01). Additionally, 101 of 112 Crystalens eyes (90%) and 17 of 112 standard monofocal eyes (15%) had a resultant uncorrected near acuity of J3 or better. Analyzing binocular uncorrected near acuity, 56 of 56 (100%) of Crystalens patients achieved J3 or better compared with 16 of 56 (29%) standard monofocal patients. Mean binocular uncorrected near acuity was 1.00 ± 0.00 (J1) in Crystalens patients and 0.40 ± 0.13 (J6) in the monofocal group (P<.01).

Best corrected visual acuities, both distance and near, were comparable between the 2 groups (Table 4). There were no statistically significant changes in postoperative amount or axis of astigmatism from preoperative measurements.

In the Crystalens group, there were minor differences in both mean monocular uncorrected distance visual acuity (range 20/20 to 20/30) and uncorrected near acuity (range J2 to J3) outcomes between the different centers, although no surgeon had consistently better results than the others.

Measures of Accommodation

Focal point change through accommodation was significantly higher in Crystalens patients in all measurement methods used. Mean dynamic retinoscopy was 2.42 ± 0.39 D in the Crystalens group and 0.91 ± 0.24 D in the monofocal IOL group (P<.01). Mean monocular defocus measured 1.74 ± 0.48 D in the Crystalens eyes and 0.75 ± 0.25 D in the monofocal eyes (P<.01). The mean

Table 3. Postoperative uncorrected visual acuities.

Parameter	Standard Monofocal	Crystalens	*P* Value
UDVA–monocular	0.70 ± 0.19 (20/29)	0.85 ± 0.30 (20/24)	<.01
UNVA–monocular	0.35 ± 0.12 (J6)	0.69 ± 0.23 (J2)	<.01
UDVA–binocular	1.01 ± 0.14 (20/20)	1.16 ± 0.17 (20/17)	<.01
UNVA–binocular	0.40 ± 0.13 (J6)	1.00 ± 0.00 B (J1)	<.01

UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuity

Table 4. Postoperative best corrected visual acuities.

Parameter	Standard Monofocal	Crystalens
Ref. spherical equivalent (D)	−0.45 ± 0.47	−0.19 ± 0.51
BCDVA–monocular	0.98 ± 0.15 (20/20)	1.06 ± 0.17 (20/19)
BCNVA–monocular	0.96 ± 0.10 (J1)	1.04 ± 0.19 (J1)
BCDVA–binocular	1.01 ± 0.14 (20/20)	1.16 ± 0.17 (20/17)
BCNVA–binocular	Not measured	1.00 ± 0.00 B (J1)

BCDVA = best corrected distance visual acuity; BCNVA = best corrected near visual acuity

monocular near point of accommodation was 4.78 D in the Crystalens group and 1.23 D in the monofocal group ($P<.01$). Perceived accommodation (5.79 D) was much greater than the measured accommodation (1.96 to 2.42 D) in Crystalens patients (paired *t* test, $P<.01$). Table 5 summarizes the accommodation results for the 3 measurement methods used.

DISCUSSION

New medical technologies should not only be clinically efficacious but should also result in outcome benefits from the patient's perspective. Dolders et al.[20] showed that the use of multifocal IOLs in cataract surgery resulted in a significant reduction in costs for patient's postoperative spectacles. Alternatively, Nijkamp et al.[3] noticed that the patient's overall satisfaction with cataract surgery did not differ between monofocal or multifocal IOLs. Multifocal IOLs can result in undesirable photic phenomena caused by a simultaneous projection of multiple focal points on the retina.[1,4,7,8,10,12,16,17,21] Additionally, intermediate visual acuity with multifocal IOLs is significantly worse than that obtained with monofocal IOLs.[22] An accommodating IOL not only restores functional near vision, it also gives high-quality intermediate and distance vision without distortion in images because only 1 image at a time is formed on the retina.[23]

With Crystalens IOL implantation, Alió et al.[23] and Hoffman et al.[24] found a near uncorrected visual acuity of J3 or better in 100% of patients, while Cumming et al.[19] found 96% of patients achieved the same results. In our study, all patients (100%) and 90% of eyes (101 of 112) in the Crystalens group were able to read J3 or better without correction. In the monofocal IOL group, only 29% of patients using binocular vision were able to read J3 ($P<.01$) (Figure 2). The different results between studies could be explained by different follow-ups. Accommodating IOLs are expected to work better over the course of time because the ciliary muscle would gain more strength after a long period of not being used.

It is thought that under ciliary muscle contraction, increased vitreous pressure forces the Crystalens IOL optic forward.[19] An axial optic movement of approximately 720 μm for a 20 D IOL is expected to correspond to a 1 D change in refraction.[18] In an experimental model, Stachs et al.[25] documented the axial shift of the Crystalens IOL. Marchini et al.[26] showed forward movement of the Crystalens IOL and a corresponding anterior rotation of the ciliary body during near vision effort, which were proportional to the accommodating capacity of the IOL. Using wavefront technology, it has been shown that this IOL movement induces myopia associated with spherical aberrations and coma (personal communication, Renato Ambrosio Jr.). These aberrations are expected to add additional benefits to near vision and help patients' reading performance.[27] Pseudophakic accommodation is an active, dynamic dioptric change in the eye's refracting power due to ciliary muscle action and IOL movement.[28,29] Pseudoaccommodation is defined as the achievement of functional near vision in distance-corrected eyes through nonaccommodative means, such as corneal multifocality, monovision, and increased depth of field caused by pupillary constriction and ocular aberrations.[18] There appears to be no consensus on the best objective means for determining true pseudophakic accommodative function. Distance defocus curves have become a widely used tool for measuring the accommodative and pseudoaccommodative effects of IOLs and were used in the FDA trials of the Array multifocal IOL (Advanced Medical Optics).[18]

Langenbucher et al.[29] validated the usefulness of defocusing techniques and also found the evaluation of

Table 5. Postoperative measured accommodation.

Parameter	Standard Monofocal	Crystalens	*P* Value
Dynamic retinoscopy, D	0.91 ± 0.24	2.42 ± 0.39	<.01
Defocus–monocular, D	0.75 ± 0.25	1.74 ± 0.48	<.01
NPA–monocular, inches (D)	34.7 ± 9.8 (1.23)	9.5 ± 3.1 (4.78)	<.01
Defocus–binocular, D	0.91 ± 0.22	1.96 ± 0.50	<.01
NPA–binocular, inches (D)	27.6 ± 6.2 (1.51)	7.7 ± 2.6 (5.79)	<.01

NPA = near point of accommodation

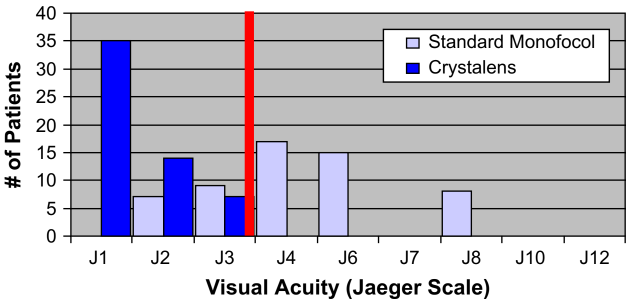

Figure 2. Uncorrected binocular near visual acuity in all patients. The red line represents the boundary at which most patients will feel they need reading glasses.

subjective near point to be the most repeatable and reliable clinical parameter. In a normal prepresbyopic and presbyopic phakic population, Ostrin and Glasser[30] found that the measurements of accommodative amplitude were best achieved with objective methods and true accommodative amplitude was overestimated by subjective testing.

Pseudophakic pseudoaccommodation is most likely responsible for our findings in 29% of patients (16 of 56) with standard monofocal IOLs who were able to read J3 or better with binocular uncorrected vision. The Crystalens IOL group had a significantly better uncorrected near visual acuity (both monocular and binocular) than the monofocal IOL group, and we believe this is due to the accommodating capacity of the Crystalens. Nevertheless, the effects of accommodation and pseudoaccomodation can be superimposed. Because our main objective was to measure the visual outcomes with the Crystalens IOL, additional complementary examinations (eg, UBM, partial coherence interferometry, high-resolution magnetic resonance imaging, Scheimpflug slitlamp imaging, corneal topography, wavefront measurements) were not done. These measurements might be useful to objectively differentiate possible pseudoaccommodative effects, such as the greater perceived accommodation (5.79 D) than measured (1.96 to 2.42 D) in Crystalens patients (paired t test, $P<.01$).

Although our results demonstrated a high success with the Crystalens IOL, reading glasses may still be required for certain tasks, such as reading small print. Patients' expectations should be assessed and clinical results discussed to prevent postoperative frustration. Because our study was not conducted as a prospective, randomized clinical trial, it may be subject to many issues of bias and confounding factors, and patients enrolled may differ from the general population in several ways. Our follow-up was short, and capsule fibrosis can be a long-term limiting factor for the Crystalens IOL's axial movement and therefore accommodative capacity.

In contrast to our successful results and those in previously cited studies, Koeppl et al.[31] found a drug-induced counterproductive backward shift of the Cystalens IOL and that a significantly better reading performance could not be found compared to that achieved with standard monofocal IOLs. Therefore, in this study, the variability in postoperative refraction was found to be large and was correlated to the axial position of the IOL. The measurements were based only on a drug-induced basis, and these results should not be extrapolated to standard conditions. Nevertheless, additional studies are warranted to evaluate the visual outcomes of the Crystalens IOL in a larger number of patients.

Given our study limitations, we found successful distance and near vision results with the implantation of Crystalens IOL. Further studies to evaluate long-term results of the accommodative capacity of the Crystalens IOL and to help sort out the effects of pseudoaccommodation are warranted.

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