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Outcomes of a multicenter U.S. clinical trial of a new monofocal single-piece hydrophobic acrylic IOL

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Purpose: To evaluate the safety and effectiveness of the CT LUCIA 611P intraocular lens (IOL) in patients with cataracts.

Setting: 23 surgeons at 15 different clinical sites.

Design: Prospective single-arm clinical trial.

Methods: The study was conducted under an Investigational Device Exemption for premarket approval of a new hydrophobic acrylic IOL in the United States. Patients were followed for 12 months, and the main measured variables included uncorrected (UDVA) and corrected (CDVA) distance visual acuities, manifest refraction, and adverse events.

Results: In total, 339 eyes of 339 patients were implanted with the study device, of which 310 (91.4%) reached the 12-month visit. The percentage of eyes within ±0.50 diopter (D) and ±1.00 D of emmetropia was 85.8% (266/310) and 96.8% (300/310), respectively. Manifest refraction spherical equivalent (MRSE) remained stable over the first year with the mean 12-month MRSE of −0.03 ± 0.45 D. The mean 12-month UDVA and CDVA were 0.09 ± 0.15 (≈20/25) and −0.02 ± 0.09 (≈20/19) logMAR, respectively. Of all patients, 99.4% (308/310) achieved postoperative CDVA ≥20/40. The incidence of Nd:YAG capsulotomy within the first year was 3.5% (11/310). Only 2 eyes had IOL tilt present at the 12-month postoperative visit with no associated visual symptoms. There were 2 cases of IOL decentration; one required removal of the IOL, whereas the other had no visual side effects related to decentration. There were no findings of glistening at any visit.

Conclusions: The CT LUCIA 611P IOL demonstrated excellent safety, efficacy, and stability of refractive outcomes. No significant issues related to the biocompatibility of the IOL material were observed.

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Despite the surge in multifocal intraocular lens (IOL) technology, monofocal IOLs continue to be the most common IOL type implanted after cataract removal.[1] For decades, monofocal IOLs have been an important tool to combat cataract-related blindness and remain the best choice in patients with uncertain visual prognoses or cases in which vision deterioration is expected over time.[2] Besides that, this type of IOL is also preferred in patients who require more consistent visual performance with fewer side effects, faster neuroadaptation, and the best possible clarity of vision.[1,3]

Although monofocal IOLs are well established in ophthalmology, the technology has continued to evolve. In recent years, emphasis has been placed on factors such as the ease of surgical manipulation (injectors and fully preloaded systems), clarity and long-term biocompatibility of IOL material, posterior capsule opacification performance, reduction of optical aberrations, and stability of the IOL in the capsular bag. All these areas could be improved; hence, new IOLs are continuously being developed and introduced into the market.

The CT LUCIA 611P (Carl Zeiss Meditec Production LLC) is a monofocal single-piece hydrophobic acrylic aspheric IOL that received approval from the U.S. Food and Drug Administration (FDA) in July 2021. The objective of this article is to present the outcomes of the Investigational Device Exemption study for premarket approval in the United States. The main features of the IOL, visual and refractive outcomes, adverse events (AEs), and the overall performance of the IOL will be discussed.

METHODS

This prospective, multicenter, single-arm clinical trial was designed to evaluate the safety and effectiveness of the CT LUCIA

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611P posterior chamber IOL for the correction of aphakia after cataract lens removal. The surgeries were performed by 23 surgeons at 15 surgical sites across the United States. All sites obtained approval to conduct the study from their respective institutional review board, and informed consent was obtained from all participating patients. The study adhered to the tenets of the Declaration of Helsinki and was registered at ClinicalTrials.gov (NCT03451786).

Only 1 eye of each patient was implanted with the study device. Fellow eyes underwent cataract extraction with the implantation of a commercially available IOL. Patients included in the study were required to be 22 years or older and have visually significant cataracts with projected (expected postoperative) corrected distance visual acuity (CDVA) 0.20 logMAR or better, as determined by the investigator's medical judgment. Patients with the fellow (nonstudy) eye with CDVA worse than 1.0 logMAR were excluded from the study.

Emmetropia was required to be the refractive target with a calculated IOL power between +4.0 diopters (D) and +34.0 D. The patient had to be willing to discontinue rigid contact lenses ≥30 days before preoperative biometry. In addition, patients with significant refractive error of axial or pathological origin in the study eye were excluded.

Other exclusion criteria were common to IOL-related investigational trials, such as any current or history of significant ocular disease or pathology other than cataract, systemic disease or systemic medications that could increase operative risk, any planned concomitant ocular procedure during cataract surgery, pregnancy or lactating, and a known allergy to heparin.

Baseline ophthalmic measurements included biometry, uncorrected (UDVA) and corrected (CDVA) distance visual acuities, manifest refraction, intraocular pressure (IOP; Goldmann tonometer), eye dominance assessment, slitlamp, and dilated fundus examination.

Follow-up visits were conducted at 1 day, 1 week, 1 month, 6 months, and 12 months. The postoperative examination consisted of UDVA, CDVA, manifest refraction (except for day 1), slitlamp examination, anterior and posterior capsular status (except for day 1), Goldmann tonometry, assessment of IOL tilt and decentration or any other device deficiencies, IOL glistening grade (6-month and 12-month visits only), dilated fundus examination (6-month and 12-month visits only), keratometry (6-month and 12-month visits only), and anterior chamber depth (ACD) measurement (6-month visit only).

All visual acuities were measured with an Early Treatment Diabetic Retinopathy Study chart with a testing distance of 4 meters. IOL tilt and decentration were assessed using a technique described by Guyton et al.[4] In short, IOL tilt was determined as the angle between the apparent optical axis of the implanted IOL (located by the alignment of the third and fourth Purkinje images from the front and back surface of the IOL) and the patient's line of sight. The IOL was considered tilted if the angle was greater than 5 degrees in either direction. Decentration was measured as the distance of the IOL optical axis from the center of the pupil, and a previously described methodology was used to assess IOL glistening.[5]

Surgical Technique

Qualified patients underwent phacoemulsification cataract extraction followed by implantation of the fully preloaded CT LUCIA 611P IOL, according to the standard surgical technique of each surgeon. Surgeries were performed with manual phacoemulsification without the assistance of a femtosecond laser. Investigators were required to record all relevant surgical information, such as the lens power, incision size, capsulotomy information, IOL unfolding time, any device deficiencies, and intraoperative AEs.

IOL Design

The CT LUCIA 611P is a single-piece foldable aspheric posterior chamber IOL made of optically clear hydrophobic acrylic material with a benzotriazole UV absorber (Figure 1). The IOL features a 6.0 mm optic diameter, 13.0 mm overall length, and heparin surface modification (fragment of heparin used in IOL surface coating with no pharmacological, immunological, or metabolic action). The available dioptric powers range from +4.0 D to +34.0 D in 0.5 D increments, and the IOL is nontoric. The haptic design is a modified C-loop, step-vaulted with 0 degree angulation. For PCO prevention, the IOL is equipped with a 360-degree square-edged design.

Figure 1. CT LUCIA 611P IOL.

The optic has a monofocal biconvex aspheric design, and the edges are designed to minimize mass to facilitate lens insertion through a smaller incision. The anterior surface of the IOL has an aspheric configuration, and the posterior segment of the optic is slightly thicker than the anterior segment. This design allows the IOL to unfold in the upward direction after release into the capsular bag. The IOL comes fully preloaded in the Blueject injector (Figure 2).

The IOL features the patented ZEISS Optic (ZO) Asphericity Concept (Carl Zeiss Meditec AG), also referred to as nonconstant aberration aspheric optic. Compared with other aberration-correcting optics where the correction of existing spherical aberration is derived from the mean spherical aberration of the normal human cornea, the ZO concept is based on the Liou and Brennan eye model.[6] This model takes into consideration other factors, such as the anatomic misalignment in the eye, the anterior and posterior curvatures of the cornea, and the position of the macula. In addition, the concept is optimized for pupil size 4.5 to 5.00 mm, the most common pupil size found

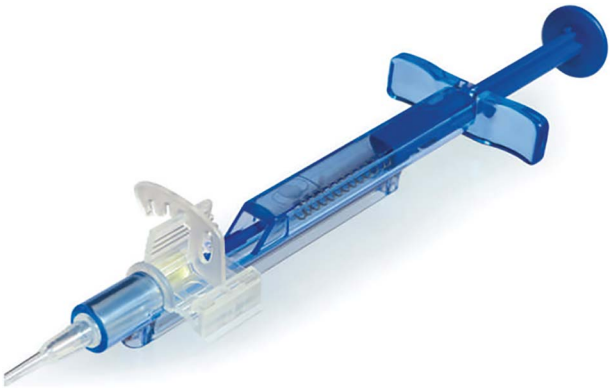

Figure 2. Blueject injector.

among patients with cataract. Therefore, the ZO concept is intended to better represent the normal human eye's anatomical and optical imaging properties, providing higher overall quality of vision, especially in mesopic conditions, and higher tolerance to decentration.

Statistical Analysis

Standard graphs for reporting outcomes of IOL-based surgery were used to present all outcomes at the final (12 months) visit.[7] The stability of manifest refraction spherical equivalent (MRSE) over time was assessed in a cohort of patients who attended all postoperative visits, and the refractive change between visits was assessed with repeated measures analysis of variance (ANOVA). The incidence rate of all device-related and surgery-related AEs was calculated. AE rates and the percentage of patients achieving postoperative CDVA 0.3 logMAR or better were compared with the ISO Safety and Performance Endpoint (SPE) from ISO 11979-7:2006.[8] Percentages from the study were compared with SPEs with a 1-sided exact binomial test.

RESULTS

Of the 369 patients originally enrolled in the study, 339 (339 eyes of 339 patients) proceeded with the unilateral implantation of the CT LUCIA 611P IOL. The demographics of the study group and the preoperative and final postoperative visits are summarized in Table 1. The mean age of patients was 69.1 ± 8.10 years, and the majority of the patients (208/339 [61.4%]) were female. The percentages of patients attending each postoperative visit were as follows: 1 day 100% (339/339), 1 week 99.7% (338/339), 1 month 98.8% (335/339), 6 months 95.9% (325/339), and 12 months 91.4% (310/339).

Visual Acuity Outcomes

Figure 3, A depicts 12-month postoperative UDVA compared with postoperative CDVA. Of all eyes, 70.0% (217/310) achieved UDVA 20/25 or better at 12 months postoperatively. The mean UDVA improved from a preoperative value of 0.62 ± 0.41 (≈20/83) logMAR to 0.09 ± 0.15 (≈20/25) logMAR at 12 months. The postoperative CDVA of 20/25 or better was achieved in 95.8% (297/310) of eyes. The mean CDVA improved from 0.26 ± 0.22 (≈20/36) logMAR at baseline to −0.02 ± 0.09 (≈20/19) logMAR at 12 months. Supplemental Table 1 (http://links.lww.com/JRS/A559) presents CDVA and UDVA analysis for each postoperative visit.

Figure 3, B shows the difference in Snellen lines comparing postoperative UDVA and postoperative CDVA. At 12 months, 73.9% (229/310) of eyes had postoperative UDVA within 1 line of CDVA.

Corrected Vision Comparison With ISO SPE Standards

Of all patients, 99.4% (308/310) achieved postoperative CDVA 0.3 logMAR (20/40) or better at the 12-month visit. This outcome significantly exceeded the ISO SPE requirement of 92.5% ($P < .001$, 1-sided exact binomial test). There were only 2 patients who did not achieve a CDVA of 0.3 logMAR at the 12-month visit: 1 had corrected vision 0.36 logMAR (similar to the preoperative CDVA of 0.3 logMAR), likely because of the history of esotropia and amblyopia. The second case had ongoing cystoid macular edema (CME) with the CDVA reduced to 0.34 logMAR but still better than the baseline CDVA of 0.62 logMAR.

Loss of 2 or More Lines of CDVA

Of all patients who attended the 12-month visit, there was only 1 patient who had the CDVA reduced by 10 letters on the distance vision chart (2 full lines) from the baseline CDVA. The preoperative CDVA of the patient was −0.1

Table 1. Preoperative and postoperative characteristics of the study group

Variable	Preop (N = 339 eyes)	12 mo (n = 310 eyes)	*P* value[a]
Age (y)	69.1 ± 8.10 (40, 93)	—	—
Gender (M/F)	131 (38.6)/208 (61.4)	—	—
AL (mm)	23.75 ± 1.06 (21.14, 27.48)	—	—
ACD (mm)	3.20 ± 0.40 (2.17, 4.46)	—	—
Corneal astigmatism (abs K1-K2) (D)	0.79 ± 0.53 (0.00, 3.36)	—	—
IOL power (D)	21.58 ± 3.48 (9.5, 32.0)	—	—
Sphere (D)	−0.01 ± 2.72 (−10.00, +9.00)	+0.21 ± 0.52 (−1.50, +2.00)	<.01
Cylinder (D)	−0.84 ± 0.66 (−5.25, 0.00)	−0.48 ± 0.48 (−2.25, 0.00)	<.01
MRSE (D)	−0.43 ± 2.7 (−10.25, +8.50)	−0.03 ± 0.45 (−1.50, +1.75)	<.01
CDVA (logMAR)	0.26 ± 0.22 (−0.10, 1.00)	−0.02 ± 0.09 (−0.28, 0.36)	<.01
UDVA (logMAR)	0.62 ± 0.41 (0.00, 2.7)	0.09 ± 0.15 (−0.22, 0.60)	<.01

ACD = anterior chamber depth; AL = axial length; MRSE = manifest refraction spherical equivalent
Data are presented as n (%) or mean ± SD (range)
[a]Paired *t* test comparing patients who attended preoperative and 12-month visit

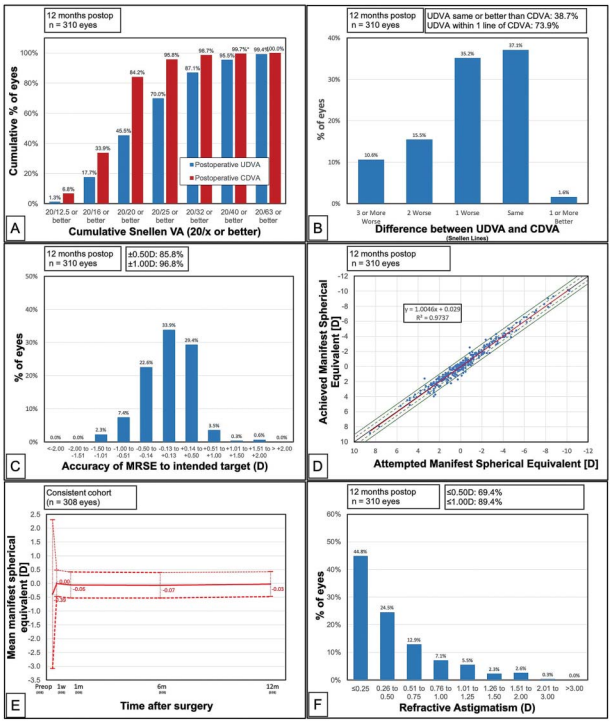

Figure 3. *A*: Postoperative UDVA vs postoperative CDVA. *Note that the percentage of patients achieving 20/40 or better CDVA (99.7% or 309/310) is different from the value presented in the ISO comparison in the text of the article (99.4% or 308/310). The ISO comparison is based on the number of patients achieving 0.30 logMAR or better, whereas the 20/40 calculation of visual acuity in this histogram was based on the range between 0.25 logMAR and 0.35 logMAR. *B*: Difference between postoperative UDVA and postoperative CDVA. *C*: Distribution of postoperative MRSE. *D*: Scattergram of attempted vs achieved MRSE. *E*: Stability of MRSE over time calculated for a consistent cohort of patients who attended all postoperative visits. *F*: Distribution of postoperative refractive astigmatism (absolute value). MRSE = manifest refraction spherical equivalent

logMAR and reduced to 0.1 logMAR. Although the preoperative CDVA was good, the patient had visual symptoms associated with developing nuclear cataracts (glare and halos). The patient's slitlamp examination, dilated fundus examination, and IOP were all within normal limits at the 12-month visit. The IOL had no tilt, discoloring, or decentration. No AEs were recorded for this patient, and the reduction in CDVA was unexplained.

Of the patients who did not attend the 12-month postoperative visit, there was 1 patient with the CDVA reduced by more than 2 lines at the last available visit. The patient presented with rhegmatogenous retinal detachment (RD), and the case will be further described in the "Adverse Events" section of this article.

Refractive Outcomes

Figure 3, C depicts the distribution of postoperative MRSE at 12 months. Of all eyes, 85.8% (266/310) were within ±0.50 D, and 96.8% (300/310) were within ±1.00 D of emmetropia.

Figure 3, D shows the scattergram of attempted and achieved MRSE. The graph shows a very tight relationship between the 2 variables, with the coefficient of determination close to 1 (R^2 = 0.97).

Stability of MRSE Over Time

Figure 3, E demonstrates refractive stability for a cohort of patients who attended the 1-week, 1-month, 6-month, and 12-month postoperative visits (n = 308). With repeated measures ANOVA, there was a significant change in the mean MRSE from preoperative to the 1-week visit (P = .001), but there was no statistically significant change in the mean MRSE from 1 week onward (P > .05).

The percentage of eyes that had a change in MRSE less than or equal to 0.50 D was 86.4% (266/308) between the 1-week and 1-month visits, 89.6% (276/308) between the 1-month and 6-month visits, and 92.5% (285/308) between the 6-month and 12-month visits.

Most eyes had the change in MRSE between postoperative visits within ±1.00 D. Of all eyes, 97.4% (300/308), 98.4% (303/308), and 98.7% (304/308) had the change in MRSE within ±1.00 D between the 1-week and 1-month, 1-month and 6-month, and 6-month and 12-month visits, respectively.

The mean change in MRSE between the 1-month and 12-month visits was 0.033 ± 0.362 D, which equals a projected monthly change of 0.003 D and a projected yearly change of 0.036 D.

Refractive Astigmatism

Figure 3, F shows the distribution of postoperative refractive astigmatism. Of all eyes, 69.4% (215/310) had postoperative refractive astigmatism (absolute value) ≤0.50 diopter (D). The percentage of eyes with refractive astigmatism ≤1.00 D at 12 months was 89.4% (277/310).

The mean value of refractive astigmatism reduced from −0.84 ± 0.66 D preoperatively to −0.48 ± 0.48 at 12 months (P < .01, Table 1).

Study-Related AEs

Ocular AEs that were likely associated with the study device or the study procedure are summarized in Table 2. A total of 58 study procedure–related ocular AEs were reported for 49 patients (14.5% or 49/339; some patients experienced more than 1 AE), whereas device-related AEs were noted in 3 patients (0.9% or 3/339).

Device-Related AEs

Three patients experienced positive dysphotopsia (2 possibly related and 1 probably related to the device), and all cases were classified as mild. At the 12-month follow-up examination, no IOL tilt or decentration was observed, and all patients had refractive error close to emmetropia with very good CDVA (case 1: 0.06 logMAR, case 2: −0.04 logMAR, and case 3: −0.06 logMAR). In 2 patients, the event was ongoing at the final examination, and in the remaining case, the event resolved without sequelae.

Procedure-Related AEs

Of all procedure-related AEs, the change in IOP from the baseline was the most common AE observed in 7.4% of

Table 2. Adverse events

Adverse event	Patients (N = 339) Eyes, n (%)
Study device related	3 (0.9)
Photopsia	3 (0.9)
Study procedure related	49 (14.5) (58 events in 49 patients)
IOP increased	25 (7.4)
Cystoid macular edema	7 (2.1)
Vitreous detachment	4 (1.2)
Iritis	3 (0.9)
Device dislocation	2 (0.6)
Eyelid ptosis	2 (0.6)
Cataract operation complication	2 (0.6)
Anterior capsule contraction	1 (0.3)
Anterior chamber flare	1 (0.3)
Anterior chamber inflammation	1 (0.3)
Corneal edema	1 (0.3)
Eye pain	1 (0.3)
Macular edema	1 (0.3)
Macular fibrosis	1 (0.3)
Photophobia	1 (0.3)
Photopsia	1 (0.3)
Surgical failure	1 (0.3)
Vital dye staining cornea present	1 (0.3)
Vitreous disorder	1 (0.3)
Vitreous floaters	1 (0.3)

patients (25/339). The increase in IOP was documented as an AE if it required medical or surgical treatment or was ≥25 mm Hg and ≥10 mm Hg higher than the baseline. All IOP events resolved without sequelae.

The second-most common AE was CME, noted in 2.1% of cases (7/339). Of these, only 2 patients experienced persistent CME, which was still ongoing at 12 months. The CDVA at the time of the 12-month visit was 0.34 logMAR in the first case and 0.28 logMAR in the second case, and both patients were under the management of a retinal specialist.

Posterior vitreous detachment was recorded in 4 patients (incidence 1.2%, 4/339). All posterior vitreous detachment cases were mild and had the last recorded CDVA of 20/25 or better with no visual side effects.

Postoperative procedure-related iritis occurred in 3 eyes (0.9%, 3/339), and all resolved without sequelae. There were 2 eyes with cataract operation complications (0.9%, 3/339) involving the presence of cortical remnants. Of these 2 events, one required anterior chamber washout, and the other resolved without surgical intervention.

There were 2 cases of IOL dislocation (0.6%, 2/339). The first case underwent uneventful cataract surgery. At the 1-month visit, the IOL was noted to be decentered downward without tilt (2.0 mm in magnitude). The posterior capsule was intact, but the zonular fibers were weakened between 3 and 6 o'clock. Haptics were placed in the bag during surgery, and no capsule phimosis, zonular issues, or ocular trauma was noted at the time. The patient underwent an IOL exchange with the removal of the study device and the implantation of a commercially available 3-piece IOL in the sulcus. The second case had IOL optic decentration (0.5 mm in magnitude) observed at the 6-month visit. However, no decentration was noted for this patient at the 12-month visit, and the patient exited the study with the refraction of +0.50 −0.25 × 105 and the CDVA of −0.14 logMAR.

Eyelid ptosis was present in 0.6% (2/339), of which 1 was still ongoing at 12 months but was considered to be mild.

All other procedure-related ocular AEs listed in Table 2 occurred in 1 patient each. These events resolved without sequelae, except for 1 case of floaters and 1 case of ocular pain, which were still ongoing at the last available visit, but considered to be mild. Both patients were lost to follow-up after the 1-month visit, and no other details of these 2 events are available.

Table 3. Cumulative and persistent events compared with IOS SPE

Parameter	Observed AE rates (N = 339), n (%)	SPE rate (%)[a]	*P* value[b]
Cumulative			
Cystoid macular edema	8 (2.4)	3.0	.7988
Hypopyon	0	0.3	NE
Endophthalmitis	0	0.1	NE
Lens dislocated from the posterior chamber	0	0.1	NE
Pupillary block	0	0.1	NE
Retinal detachment	1 (0.3)	0.3	.6389
Secondary surgical intervention	13 (3.8)	0.8	<.0001
Persistent			
Corneal stromal edema	0	0.3	NE
Cystoid macular edema	3 (0.9)	0.5	.2413
Iritis	0	0.3	NE
Raised IOP requiring treatment	0	0.4	NE

AE = adverse event; NE = not evaluable; SPE = Safety and Performance Endpoint
[a]The ISO standard SPE rate in ISO 11979-7:2006(E)
[b]p value based on a 1-sided exact binomial test comparing the proportion of eyes with the event to the ISO standard SPE rate. The null hypothesis: observed AE rate ≤SPE rate for the specific AE.

Of all procedure-related AEs, only 1 was classified as a serious AE, and it was the case of anterior capsule contraction (Table 2). The patient had uneventful cataract surgery and was diagnosed with anterior capsular phimosis approximately 6 months postoperatively. Anterior capsulotomy was performed without complications, and the AE resolved without sequelae. The patient had a CDVA of 0.02 logMAR at the 12-month visit, with no other findings reported.

Comparison of AEs With ISO SPE Rates

Table 3 presents the comparison of AEs with the Safety and Performance Endpoint from ISO 11979-7:2006(E).[8] It includes surgery-related events already described in the previous section, secondary surgical interventions, and some other events that were not associated with the surgery but are required to be reported in the SPE comparison.

All cumulative AEs were comparable with or below the SPE rate, except for the secondary surgical interventions where the incidence was higher (3.8%, 13/339 vs SPE rate of 0.8%, <0.0001, Table 3). The most common secondary surgical intervention was paracentesis (n = 7). The reason for the procedure was a retained ophthalmic viscosurgical device with associated elevated IOP. Of the 7 patients who underwent paracentesis, all completed the procedure on postoperative day 1, and all had IOP within normal limits by 1 week.

Other secondary surgical procedures included pars plana vitrectomy with membrane stripping/peel (n = 2, 1 for an epiretinal membrane unrelated to surgery and 1 for procedure-related macular edema), anterior chamber washout for cortical remnants (n = 1), YAG vitreolysis for a vitreous strand (n = 1), IOL removal of a previously described dislocated IOL (n = 1), and intravitreal injection of triamcinolone for persistent CME (n = 1).

CME was the only persistent event recorded in the study. Except for the cases already described in the previous section (Procedure-Related AEs), there was 1 additional case of persistent CME. The patient first had a procedure-related CME at the 6-month visit, which resolved within 1 month. The second occurrence of CME was recorded at 12 months, outside the window considered to be related to cataract surgery (more than 35 weeks). The CME eventually resolved with the use of topical corticosteroids, topical nonsteroidal anti-inflammatory agents, and an injection of triamcinolone acetate.

Of all events listed in Table 3, only 1 was considered a serious AE, and it was the case of rhegmatogenous RD. The case was considered unrelated to the study device and occurred around the 6-month visit. After uneventful cataract surgery, the RD was first noted 7.5 months postoperatively, but the patient was aware of flashes and floaters 1 month before SAE reporting. The patient underwent successful pars plana vitrectomy RD repair. However, 5 months after the repair, the site became aware of a recurrent episode of RD. Multiple attempts to contact the patient were made with no success. The patient was exited from the study, and the last known visual acuity was hand motion from the 6-month visit.

Nd:YAG Capsulotomy Rates

A total of 11 patients (3.5%) underwent Nd:YAG capsulotomy for clinically significant PCO within the first postoperative year. In addition, 4 patients were diagnosed with clinically significant PCO, likely to require Nd:YAG capsulotomy, which increased the total number of patients who developed clinically significant PCO in the first postoperative year to 15 (4.8%, 15/310).

The mean CDVA before Nd:YAG capsulotomy was 0.08 logMAR (≈20/24; range 0.3 to −0.08 logMAR), whereas 8 of 11 patients had CDVA 0.1 logMAR (=20/25) or better before the procedure. After Nd:YAG capsulotomy, the mean CDVA increased to −0.01 logMAR (≈20/20; range 0.1 to −0.1 logMAR).

There were considerable differences in Nd:YAG capsulotomy rates among clinical sites. Most Nd:YAG capsulotomy procedures (6 of 11) were performed at 1 clinical site, whereas 11 of 15 clinical sites had no cases of Nd:YAG capsulotomy.

Postoperative Assessment of the IOL

Of all patients, only 2 had an IOL tilt present at the 12-month visit. One patient had CDVA −0.06 logMAR with the manifest refraction of 0.00 −0.25 × 090. The second had CDVA −0.04 logMAR and the manifest refraction +1.00 −1.00 × 075. Both patients had normal slitlamp examination (except for the tilt), an IOP within normal limits, and no visual symptoms associated with the tilt.

Slitlamp assessment of decentration was observed in 2 patients, and both are already described in detail in the "Procedure-Related AEs" under IOL dislocation events.

IOL glistening was formally assessed at the 6-month and 12-month visits. There were no findings of glistening of any grade for any patient. In addition, no IOL discoloration, haze, or surface damage has been observed on slitlamp examination at any visit.

DISCUSSION

This study presents the safety and efficacy of a new FDA-approved monofocal IOL. The lens material originated from the 3-piece hydrophobic EC-3 Precision Aspheric Lens, originally manufactured by Aaren Scientific Inc., a company acquired by Carl Zeiss Meditec AG in 2014. Their hydrophobic IOLs (EC-3 and EC-3 Precision Aspheric Lens) were FDA-approved in October 2010. However, the EC-3 IOLs have been implanted in the European market since February 2005 with no reported issues related to the biocompatibility of the hydrophobic lens material.

The CT LUCIA 611P IOL is manufactured from the same material and has the aspheric concept as described in the Methods section (ZO concept, developed and patented by Carl Zeiss Meditec AG). In addition, it has a heparin coating and a single-piece design. The C-loop haptics were designed to provide stability of the IOL in the capsular bag while maintaining the 360-degree sharp edge at the optic–haptic junction for posterior capsular opacification protection.

The physical design of an IOL is among the most critical factors affecting the stability of an IOL in the capsular bag.[9,10] In the current study, the CT LUCIA 611P IOL

exhibited excellent refractive stability in the first postoperative year with minimal and insignificant changes in the MRSE. Consistent with our conclusions, a study designed to measure axial stability of the CT LUCIA 611P IOL showed a minimal shift (change in postoperative ACD) over the period of 6 months.[10] In fact, some eyes in the study had no change in postoperative ACD after the first postoperative week.[10] Similar findings were documented in an experimental in vitro study, in which the CT LUCIA 611PY IOL (blue light–filtering equivalent of the 611P model) appeared stable in its position despite the expected distortion and modification of the capsular bag.[11] In addition, a small study found the platform of this IOL suitable for challenging cataract cases with pseudoexfoliation syndrome and phacodonesis, conditions that can make IOLs prone to postoperative decentration and tilt.[12]

The refractive predictability of the study cohort, with 85.8% of eyes within ±0.50 D and 96.8% within ±1.00 D of targeted refraction, was above international cataract surgery benchmarks.[13–15] For example, the most recent large-population European study, performed to benchmark outcomes of standard cataract surgery, found refractive prediction error within ±0.50 and ±1.00 D in 72.7% and 93.0% of eyes, respectively.[15] The CDVA in our cohort significantly exceeded the requirements set in ISO 11979-7:2006 standards.[8] The reported AEs were those expected after routine cataract surgery, but very few of them were related to the study device. The number of secondary procedures was higher, but approximately half of them consisted of day 1 postoperative paracentesis because of retained ophthalmic viscosurgical device, which was reported in 2 of 15 surgical sites.

In the current study, the proportion of patients requiring Nd:YAG capsulotomy within the first 12 months was 3.5%. The difference in rates between surgical sites, the reasonably good CDVA before the procedure, and possible differences in the judgment of the severity of the PCO suggests that Nd:YAG capsulotomy rates could be associated with practice patterns of different surgeons rather than the device itself. PCO rates are often difficult to interpret and compare between studies because of the inconsistency in reporting the severity of PCO and different criteria used for proceeding with Nd:YAG capsulotomy. A recent meta-analysis of PCO incidence found a large variation in Nd:YAG capsulotomy rates, ranging from 0% to 77%, depending on the length of follow-up and lens type.[16] It is also possible that rates reported in carefully designed investigational trials with excellent patient accountability are higher than reports in other studies in which patients are more likely to be lost to follow-up before the 12-month visit. For example, premarket approval trials of other recently FDA-approved hydrophobic acrylic IOLs report the 12-month Nd:YAG capsulotomy rates higher than 4%.[17,18]

Although PCO development is multifactorial, design features of IOLs play a major role in the prevention of this common postoperative event.[19] A sharp optic edge is thought to be one of the main inhibitory factors providing a mechanical barrier for lens epithelial cell migration.[20,21] However, the sharpness of the edge greatly varies between different IOL models that claim to have a square-edged design. Using scanning electron microscopy, a study by Nanavaty et al. compared the sharpness of the posterior optic edge between 14 commercially available IOLs.[22] A radius of curvature (RoC) was calculated to quantify the sharpness of the edge profile, with lower RoC values indicating sharper edges. The reported RoC values varied between 4.6 μm and 20.6 μm, with the CT LUCIA IOL having the sharpest edge among all examined IOLs. For better PCO protection, the IOL also features step-vaulted haptics to increase contact between a 360-degree optic edge and the posterior capsule.

Nevertheless, the CT LUCIA 611P IOL is a relatively new IOL, and more evidence is required to assess its PCO performance in clinical practice. So far, the IOL has shown great potential for PCO prevention in in vitro settings.[11] From the currently available clinical evidence, Ling et al. reported the incidence of clinically significant PCO requiring Nd:YAG capsulotomy 3.5% at 1 year and 8.5% at 2 years.[23] Their cohort consisted of 200 real-world unselected consecutive cataract surgery cases with a variety of systemic diseases and ocular comorbidities, some of them known to exacerbate PCO. Other 2 studies reported Nd:YAG capsulotomy incidence of 1.04% at 1 year (1 case of 96 eyes) and 2.2% at 6 months (1 case of 46 eyes).[10,24] Further long-term studies are required to address the PCO performance of this IOL.

Glistening is a well-described phenomenon associated mainly with IOLs made of hydrophobic acrylic material, but the susceptibility to glistening considerably varies between hydrophobic IOLs of different manufacturers.[25] Although the effect of glistening on visual acuity remains controversial, there are ongoing efforts to develop IOL biomaterials free from this phenomenon.[26,27] In the current study, no glistening of any grade was found in any patient during the 12-month follow-up.

The multicenter clinical trial presented in this article was designed to meet the requirements of an Investigational Device Exemption study and prospectively capture refractive and visual outcomes as well as AEs over the period of 12 months. A limitation of this study is the absence of more specific measurements, such as higher-order aberrations or contrast sensitivity. These would be beneficial to address the nonconstant aberration optic design of this IOL and assess the advantage of the concept in patients with different corneal shapes or those with misaligned IOLs. A recent study of CT LUCIA 601P, an IOL with the same optic as the 611P model but different haptics configuration, showed that cataract surgery with a nonconstant aberration IOL resulted in lower coma and better intraocular stray light compared with the IOLs with negative spherical aberration.[28] Thus, the promising outcomes of this concept deserve further investigation.

Overall, the CT LUCIA 611P IOL demonstrated excellent safety, efficacy, and stability of refractive outcomes over a 12-month period. In the current study, the IOL was glistening free, and the incidence of clinically significant PCO was low. This study provides valuable data for a new hydrophobic acrylic IOL that will enhance the portfolio of monofocal IOLs available in the United States.

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WHAT WAS KNOWN

- Monofocal IOLs remain the most common type of IOLs implanted for a variety of reasons, such as clarity of postoperative vision, ocular comorbidities, concern about visual side effects, visual recovery, and cost.
- Recent innovations in this space include preloaded injector systems, unique aspheric profiles, and minimization of posterior capsule opacification.

WHAT THIS PAPER ADDS

- The CT LUCIA 611P IOL is a newly FDA-approved single-piece hydrophobic acrylic aspheric IOL with excellent refractive predictability, stability, and visual performance.
- The CT LUCIA 611P IOL is glistening free and has a favorable incidence of posterior capsule opacification over 1 year postoperatively.

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