ORIGINAL RESEARCH Refractive and Visual Outcomes of a Monofocal Non-Constant Aberration Aspheric Intraocular Lens

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Purpose: To evaluate the refractive and visual outcomes following cataract surgery and implantation of a new monofocal nonconstant aberration aspheric intraocular lens (IOL).

Methods: Ninety eyes of 86 patients who underwent implantation the CT LUCIA 621P IOL (Carl Zeiss Meditec AG) were retrospectively analyzed in this study. Main outcome measures were refractive error and monocular corrected distance visual acuity (CDVA) and monocular uncorrected distance visual acuity (UDVA) values. Patients were evaluated at 1-month post-surgery and intraand post-operative complications were recorded.

Results: Eighty percent of the eyes showed a CDVA of 20/25 or better before surgery. The postoperative mean values of monocular distance Snellen decimal UDVA and CDVA were 0.64±0.22 and 0.89±0.13, respectively. All eves showed the same or better difference between UDVA and CDVA. In relation to the postoperative spherical equivalent, the highest percentage of eyes, 31.11%, was for the range between -0.50 and -0.14D followed by 22.22% for the $\pm 0.13D$ range. Ninety percent of the eyes were within ± 1.00 D and 73.33% of eyes within ± 0.50 D. The mean postoperative spherical equivalent was -0.18 ± 0.55 D. 37.78% and 76.67% of the eyes showed a value ≤ 0.50 D and ≤ 1.00 D, respectively, being the mean postoperative refractive cylinder -0.81 ± 0.50 D. No adverse events were reported in whole sample intra and postoperatively.

Conclusion: The present study shows that cataract surgery with an monofocal non-constant aberration aspheric IOL implantation resulted in good visual performance and refractive outcomes. This lens may be considered as a valid choice for patients in a standardroutine cataract surgery practice.

Keywords: intraocular lens, phacoemulsification, cataract, aspheric design, aberrations

Introduction

Today, one of the main purposes of cataract surgery is not only to restore visual acuity in our patients but also to provide the best possible visual acuity. One advance was the introduction of aspheric intraocular lenses (IOLs) in the market to correct the spherical aberration of the cornea and hence increase contrast sensitivity improving visual quality.^{1,2} Despite published studies showing discrepancies about whether these IOLs improve visual performance over that with spherical IOLs (mainly due to inter-eye corneal spherical aberration variability, centration, tilt and asphericity of the IOL),³ recent systematic reviews with meta-analysis concluded that aspheric monofocal IOL implantation resulted in less ocular spherical aberration and fewer ocular higher-order aberration than spherical IOLs. This might explain the better contrast sensitivity in patients with aspheric IOLs, especially under dim light.^{4,5}

It has been published that higher order aberrations can be induced with significant decentration or tilt of IOL with a negative aspheric optic due to the large difference in optical power between the intermediate and peripheral regions of the lens.^{6,7} IOL with aberration neutral design are less impacted by misalignment.^{8,9} A new design, called non-constant aberration aspheric, was proposed where the optical power is higher in the center and varies towards the periphery. It shows negative spherical aberration in the central region of the lens being reduced to zero near the periphery. Two models of this design have been evaluated reporting different outcomes for patients and surgeon satisfaction, optical and surface

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properties, visual performance, stability and Nd:YAG laser capsulotomy rates: the CT LUCIA 601P¹⁰⁻¹⁵ and the 611P¹⁶⁻²¹ IOLs (Carl Zeiss Meditec AG, Jena, Germany). The two main differences between these models are that the C-loop haptic design is angulated (5 degrees) for the 601P and step vaulted (no angulation) for the 611P model. Both show an aspheric Zeiss optic (ZO) design. The design of the 611P model, theoretically, offers more robustness to decentration and tilt, and taking into account that the profile of the optic-haptic junction is thicker and more expanded, there should be more stiffness to the IOL, which would result in better centering and alignment, improving refractive predictability and stability.¹⁶ The new model, the CT LUCIA 621P IOL (Carl Zeiss Meditec AG, Jena, Germany) shows the same C-loop haptic design than the 611P model but with an optimized ZO optical aspheric profile. To our knowledge, no study has analyzed the visual and refractive outcomes of the CT LUCIA 621P IOL in order to properly observe the clinical outcomes of this lens in a standard-routine cataract surgery practice. Only one in vitro study with computed tomography has been done to assess the geometry of the lens.²²

Then, the aim of the present clinical study is to assess the refractive and visual outcomes in a series of eyes that undergone the CT LUCIA 621P IOL implantation after cataract surgery.

Methods

This single-center retrospective study was approved by the Ethics Committee of the Hospital Clínico San Carlos (Madrid, Spain) and was conducted in accordance with the tenets of the Declaration of Helsinki. Exemption for patient consent was obtained from the Ethics Committee since the study was retrospective and we used a pre-existing database from our center for patients undergoing standard usual cataract surgery. In all cases, privacy and confidentially of patients' data were ensured throughout the study. The study was registered at the DRKS German Clinical Trials Register (clinical registration number DRKS00028270).

Patients

In this study, we have retrospectively examined data from 90 eyes of 86 patients at the Oftalvist Clinic in Huelva, Spain, between February 2022 and April 2022. Inclusion criteria were patients 50 years of age or older undergone age-related cataract removal (phacoemulsification), clear intraocular media except for cataracts and IOL power ranging from 0.00 to +34.00 D. Exclusion criteria were eyes with irregular cornea (ie, keratoconus), previous corneal refractive surgery, and ocular anomalies or pathologies that could reduce visual function or postoperative IOL stability (ie, severe amblyopia, macular degeneration).

Intraocular Lens

All eyes were implanted with the monofocal CT LUCIA 621P IOL. This hydrophobic acrylic lens has a design with a C-loop platform with an optimized ZO non-constant aberration aspheric design. The IOL is fully preloaded and has a heparin-coated surface for smoother injection and unfolding process. The IOL has step-vaulted haptics to translate the optic posteriorly for better contact with the posterior capsule and shows a 360° square edge design. The overall diameter of the lens is 13.0 mm with an optical zone of 6.0 mm. The diopter range varied from 0.00 to +34.00 D in 0.50-D steps. The Abbe number was 51 and the refractive index 1.49. The IOL comes preloaded in the Zeiss Bluesert injector with different tip sizes that need the following incision sizes: 2.2 for lenses between 0.00 and +24.0D, 2.4 for lenses between +24.50 and +30.00 D and 2.6 for lenses between +30.50 and +34.00D.

Surgical Procedure

All cataract surgical procedures were performed under topical anaesthesia using the Centurion Silver (Alcon, Fort Worth, TX, USA) through a 2.2-mm temporally located clear corneal incision. After cataract removal and posterior capsule polishing, the capsular bag was filled with sodium hyaluronate 1.0% (Ocu+, CIMA, Pittsburgh, PA, USA). The IOL was implanted using a preloaded injector through the 2.2-mm corneal incision expanding it for IOL higher than 24D. After centering the IOL and complete removal of the viscoelastic, the surgery ended sealing the incisions by means of hydration (without sutures in all cases) and administration of 1 mg of cefuroxime (Prokam, Laboratories Théa, Clermont-Ferrand, France) in the anterior chamber.

Preoperative and Postoperative Assessment

Preoperative examination was performed in all patients measuring Snellen decimal monocular best-corrected distance visual acuity (CDVA), slit-lamp biomicroscopy, intraocular pressure tonometry and funduscopy through dilated pupils. Cataracts were graded according to Lens Opacities Classification System (LOCS) III classification. Ocular biometry was performed with the Allegro Biograph (Wavelight AG, Germany) optical biometer, and IOL power calculation was based on this measurement considering the SRK/T (n=83) and Hoffer-Q (n=7) formula, and a historical level of surgically induced astigmatism by the incision of 0.25 D. In those cases when the measurement of optical biometry failed an ultrasound biometer (Tomey AL-4000, Tomey Corporation, Nagoya, Japan) was used (n=20). The targeted refraction in all cases was emmetropia. Post-operative assessments were performed at 1 month after implantation and considered: uncorrected distance visual acuity (UDVA), CDVA, refraction, and slit-lamp biomicroscopy. Adverse events were also recorded.

Statistical Analysis and Sample Size

Statistical analysis was carried out using SPSS software (22.0 version, IBM Corp., Armonk, New York, USA). All the measurements are shown as the mean \pm standard deviation (SD). Assuming a sample size of 90 patients, a 95% confidence interval, a standard deviation of 0.12 logMAR (based on a previous similar published paper¹⁴) the precision for the primary estimate will be 0.0335 logMAR. This was considered appropriate for the purpose of this study.

Results

In this retrospective study, we have examined 90 eyes of 86 patients. In four patients, cataract surgery was performed bilaterally and in 82 patients, surgery with implantation of the CT LUCIA 621P IOL was performed unilaterally. Table 1 shows the preoperative patients' demographics. Mean patient age was 72.53 ± 7.40 years (ranging from 57 to 88 years) and 44 were female (51.16%) and 42 were male (48.83%). Cataracts were graded using the LOCS III classification in 57 nuclear (2 × NC2, 3 × NC3, 10 × NC4, 21 × NC5 and 21 × NC6), 10 cortical (1 × C2 and 9 × C3), and 23 subcapsular posterior (3 × P2, 14 × P3, and 6 × P4) lens opacities. Phacoemulsification was uneventful in all cases, and no problems or complications were found in any of the cases at the 1 month of follow-up.

Standard graphs for reporting refractive and visual acuity outcomes were constructed. For the efficacy of the procedure, Figures 1 and 2 were plotted. Figure 1 provides the cumulative postoperative Snellen UDVA and CDVA, and Figure 2 shows the change in lines of visual acuity between the postoperative UDVA and CDVA. Eighty percent of the eyes showed a CDVA of 20/25 or better and all eyes showed the same or better difference between UDVA and

Parameter	Values
Eyes (n)	90
Age (years)	72.53±7.40 (57 to 88)
Sex (male/female)	42/44
CDVA (Snellen decimal)	0.18±0.17 (0.01 to 0.70)
KI (D)	42.80±1.47 (40.02 to 47.62)
K2 (D)	43.62±1.47 (40.68 to 47.87)
Axial length (mm)	23.38±1.17 (21.41 to 28.46)
Anterior chamber depth (mm)	3.14±0.38 (2.35 to 3.88)
Central corneal thickness (µm)	539.1±37.26 (453 to 647)
Lens thickness (mm)	4.61±0.40 (3.76 to 5.66)
White to white (mm)	12.05±0.42 (10.99 to 13.15)
IOL power (D)	22.64±3.44 (6 to 29.50)

Table IPreoperativeDemographicCharacteristicsofParticipantsImplanted with the CTLUCIA621PIOLShown asMeans, StandardDeviations(SD) and Ranges



Figure I Cumulative proportion of eyes having a given uncorrected distance visual acuity (UDVA) and best-corrected distance visual acuity (CDVA) values at I month after surgery (efficacy).



Difference between UDVA and CDVA (Snellen lines)

Figure 2 Change in lines of visual acuity between the postoperative uncorrected distance visual acuity (UDVA) and best-corrected distance visual acuity (CDVA) at 1 month after surgery (efficacy).

CDVA. The postoperative mean values of monocular distance Snellen decimal UDVA and CDVA were 0.64 ± 0.22 (range from 0.10 to 1.0) and 0.89 ± 0.13 (range from 0.60 to 1.0), respectively. For predictability, Figure 3 shows the histogram of postoperative spherical equivalent refraction relative to the intended target refraction. The highest percentage of eyes, 31.11%, was for the range between -0.50 and -0.14D followed by 22.22% for the $\pm0.13D$ range. Ninety percent of the eyes were within ±1.00 D and 73.33% of the eyes within ±0.50 D. The mean postoperative spherical equivalent was $-0.18\pm0.55D$. Figure 4 shows the histogram of postoperative refractive cylinder. Specifically, 37.78% and 76.67% of the eyes showed a value ≤0.50 D and $\le1.00D$, respectively, being the mean postoperative refractive cylinder -0.81 ± 0.50 D.



Figure 3 Histogram of postoperative spherical equivalent refraction (D) at I month after surgery (predictability).



Figure 4 Histogram of preoperative corneal astigmatism (D) and postoperative refractive astigmatism (D) at 1 month after surgery (predictability).

Discussion

Previous clinical and in vitro studies have analyzed some different metrics of previous models of the LUCIA IOL $(601P^{10-15} \text{ and } 611P^{16-21})$, but only one with the new 621P model.²² Then, our purpose in the present study was to provide refractive and visual outcomes in a series of eyes that underwent this implantation after cataract surgery in order to fully describe the clinical outcomes of this new model. Table 2 shows the main characteristics of the different CT LUCIA models.

As we have previously introduced, in addition to the cornea, the visual outcomes of those patients submitted to cataract surgery depend on several factors such as the optical quality of the IOL (spherical and aspherical design) and its position in the capsular bag (effective lens position and postoperative shift). A recent in vitro bench study using

IOL Model	CT LUCIA 601P	CT LUCIA 611P	CT LUCIA 621P
Optic Design	Monofocal, aspheric (aberration correcting)	Monofocal, aspheric (aberration correcting)	Monofocal, aspheric (aberration correcting)
Material	Hydrophobic acrylic with heparin coated surface	Hydrophobic acrylic with heparin coated surface	Hydrophobic acrylic with heparin coated surface
Optic Diameter (mm)	6	6	6
Total Diameter (mm)	13	13	13
Lens Design	Single-Piece	Single-Piece	Single-Piece
Haptic Design	C loop	C loop	C loop
Haptic Angulation	5° angulation	Step vaulted	Step vaulted
Incision Size (mm)	2.2 to 2.6	2.2 to 2.6	2.2 to 2.6
Diopter Range	4.0–34.0D 0.5D increments	4.0–34.0D 0.5D increments	0.0–34.0 D 0.5D increments
Company Labeled A-Constant (refer to <u>www.meditec.com</u> for optimized A-constants)	9.	119.9	120.2
Implantation in	Capsular bag	Capsular bag	Capsular bag
Injector/Cartridge Set	Accuject™ 2.0 Injector Set for diopter range +4.0 to 24.0 D	Blueject™ 2.0 Injector Set for diopter range +4.0 to 24.0 D	BlueSERT™ 2.0 Injector Set for diopter range +0.0 to 24.0 D
	BlueJect™ 2.2 Injector Set for diopter range +24.5 to 30.0 D	Blueject™ 2.2 Injector Set for diopter range +24.5 to 30.0 D	BlueSERT™ 2.2 Injector Set for diopter range +24.5 to 30.0 D
	Blueject™ 2.4 Injector Set for diopter range +30.5 to 34.0 D	Blueject™ 2.4 Injector Set for diopter range +30.5 to 34.0 D	BlueSERT™ 2.4 Injector Set for diopter range +30.5 to 34.0 D
	Soft stop +4.0 to +24.0 D	Soft stop +4.0 to +24.0 D	Soft stop +0.0 to +24.0 D
	Hard stop +24.5 to +34.0 D	Hard stop +24.5 to +34.0 D	Hard stop +24.5 to +34.0 D

Table 2 Mair	Characteristics	of the Differen	t CT LUCIA Models
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computed tomography to assess the geometry of different monofocal C-loop haptic design with identical overall length and optic diameter revealed clear differences between IOLs.²² One of the IOLs analyzed in this study was the CT LUCIA 621PY. These authors found variability in analyses of haptic angle of contact and capsular bag contact between the lenses assessed at all well sizes, but both values were consistently greatest for the CT LUCIA 621PY, which had the lowest percentage change in these values between the smallest and largest diameter wells. These authors pointed out that an IOL with a design that maintains a consistent relationship and contact with the capsular bag independent of native size would be expected to confer intraocular positional stability, limit posterior capsule opacification development, and provide predictable visual outcomes after cataract surgery. These should be assessed in clinical studies.

In this sense, in the current study, we have found good visual acuity outcomes with 80% of eyes with a CDVA of 20/25 or better after the surgery (see Figure 1), being the monocular mean postoperative CDVA 0.89 ± 0.13 (ranging from 0.60 to 1.0). Note that all eyes showed the same or better difference between UDVA and CDVA post-surgery (Figure 2). In relation to predictability (related to the positional stability of the lens in the capsular bag), we found excellent

refractive outcomes with 90% of eyes with a spherical equivalent within ± 1.00 D (Figure 3) and a mean value less than a quarter of diopter (-0.18 \pm 0.55D). For the astigmatism, the mean postoperative refractive cylinder was similar than corneal astigmatism reported before the surgery (-0.81 \pm 0.50 D versus 0.81 \pm 0.40 D) with 76.67% of eyes with a value ≤ 1.00 D (Figure 4). Our results support the conclusion of the in vitro bench study previously indicated showing the good visual acuity outcomes.

It has been reported that the 611P model is equipped with the ZO asphericity concept, which means that the power of the IOL is higher in the center and then varies toward the periphery (flatter lens surface at intermediate distance from the lens axis and a steepening at the peripheral region of the lens).¹⁶ As introduced, this design may offer more robustness to decentration and tilt, and with the thicker optic-haptic junction, it is expected to provide a better centering and alignment, improving refractive predictability and stability.¹⁶ The possible reduction of incidence of higher-order aberrations due to the variability of corneal shapes may benefit patients implanted with this lens. Our results, with the 621P model, with the same C-loop haptic design than the 611P (see Table 2), support this suggestion taking into account the good predictability outcomes: mean spherical equivalent value was <0.25D ($-0.18\pm0.55D$). According to the manufacturer, the optic was engineered based on the realistic Liou–Brennan eye model, which is optimized for a pupil size typically found in cataract patients. The central zone induces positive spherical aberration to increase decentration for an improved image quality, and the peripheral zone induces positive spherical aberration to increase decentration tolerance. Thus creates an ideal balance between aberration correction and neutral effects. Unfortunately, as introduced, there are no peer review clinical publications showing visual and refractive outcomes of the CT LUCIA 621P IOL to compare with the present research. However, we consider it interesting to discuss the clinical outcomes reported in publications using previous models.

Borkenstein and Borkenstein¹⁰ prospectively analyzed 42 eyes implanted with the CT LUCIA 601P in 28 pseudoexfoliation syndrome patients. They found a CDVA of -0.05 ± 0.13 logMAR after the surgery. The target refraction using the Haigis formula within $\pm 0.5D$ was reached by 92.9% and by 100% within $\pm 1.0D$ of all cases, respectively and patient satisfaction was very high, and no halos or glare were reported in any case. Our results showed 90% eyes within ±1.00D. Authors concluded that the implantation of this lens was safe in complicated cases as pseudoexfoliation. Nguyen et al¹¹ in an in vitro study evaluated the power, modulation transfer function, light transmission and light scattering of the CT LUCIA 601PY before and after power adjustment by a femtosecond laser. They found that the power adjustment in this lens produced an accurate change in dioptric power while not significantly affecting the quality of the lens. Labuz et al¹² analyzed glistening formation and light scattering in different hydrophobic-acrylic IOLs, obtaining mean values of 85±86 microvacuole (MV)/mm² and 8.4±0.4 µm for glistening number and size, respectively, and 1.09±0.99 deg²/sr for straylight, for the CT LUCIA 601P model. They found that the density of microvacuoles decreased from the center to the periphery in this model. De Giacinto et al¹³ analyzed the surface properties of the CT LUCIA 601P and other hydrophobic acrylic lenses using atomic force microscopy and surface contact angle measurements with the sessile drop method was performed to assess lens wettability. They found that the CT LUCIA 601P lens had the lowest contact angle (48.75 ± 4.91 degrees) of all IOL models evaluated. Tandogan et al¹⁴ used an accelerated laboratory method to develop glistenings in several IOLs and measure MV density and size (Mivata grading) using an image analysis program. The found a mean glistening density [MV/mm²] and a mean Miyata grading (in brackets) of 11.6 ± 5.7 (0) for the Vivinex XY1, 264.4 ± 110.3 (2.6) for the SN60WF, 6.0 ± 2.8 (0) for the Tecnis ZCB00, 2.2 ± 0.7 (0) for the Avansee PN6A, 851.4±59.4 (3+) for the Aktis SP NS-60YG and 71.0±71.6 (1) for the CT LUCIA 601P. They concluded that while all tested lenses showed glistening with this method, the Aktis and SN60WF showed the highest MV density, followed by the CT LUCIA 601P. In comparison, the Vivinex, Tecnis, and Avansee lenses showed far fewer number of glistening. Liu et al^{15} compared the visual performance after the implantation of three aberration-correcting aspherical intraocular lenses: LUCIA 601P, CT ASPHINA 509M and the AMO Tecnis ZCB00. 26 eyes were implanted with the LUCIA 601P model and found at 3 months post-surgery mean UDVA of 0.11±0.12 LogMAR and CDVA 0.03±0.06 LogMAR. Mean spherical equivalent and cylinder were -0.02 ± 0.66 D and -0.30 ± 0.61 D, respectively. Note that out mean spherical equivalent was -0.18 $\pm 0.55D$. These authors compared three groups of eyes implanted with the three lenses considering that the LUCIA lens shows a non-constant aberration, the ASPHINA lens a spherical aberration of $-0.18 \,\mu\text{m}$, and the Tecnis lens a spherical aberration of -0.27 µm. They found no statistically significant differences in UDVA and CDVA between groups (p ≥ 0.83). Wavefront aberrations and contrast sensitivity were also reported and the root-mean-square for total ocular coma was statistically significantly lower in the LUCIA group (p=0.03) and spherical aberration was statistically significantly lower in the Tecnis group (p<0.01). Comparing higher order aberration values among the three groups no statistically significant differences were found (p=0.85) and, neither for contrast sensitivity under both photopic and mesopic lighting conditions (p \ge 0.05). In this study authors carried out an analysis of intraocular stray light with better values in the LUCIA group (p=0.04). Authors argued that the lower intraocular stray light may be related with that this lens does not produce glistenings of any grade¹⁶ compared to the other models.² These authors concluded that the implant of a non-constant aberration IOL in cataract surgery patients provided lower coma and better intraocular straylight than with the spherical aberration –0.18µm and –0.27µm IOLs despite equivalent postoperative levels of visual acuity and contrast sensitivity.

Borkenstein and Borkenstein¹⁶ reported clinical outcomes of 96 eves of 54 patients who underwent implantation of the CT LUCIA 611P model at 1-year post-surgery. In this model the optic-haptic junction was completely redesigned and changed (wider and stiffer) in comparison to the predecessor CT LUCIA 601 lens (see Table 2). According to the manufacturer, the CT LUCIA 601P was the first generation with a different haptic design, angulated by 5° and with Accuject injector. The CT LUCIA 611P platform shows different changes where the angulation was removed and the haptic design as the injector were changed. Borkenstein and Borkenstein¹⁶ indicated that in theory, the optic design should make the IOL more insensitive to decentration and tilt, and given that the profile of the optic-haptic junction is thicker and more expanded, there should be more stiffness to the IOL, which would result in better centering and alignment properties in the capsular bag, thus improving refractive predictability and long-term results regarding refractive stability. They found a mean 0.02 logMAR CDVA (range from 0.14 to -0.10 logMAR) with 94.8% of all subject eyes with 0.10 logMAR or better. In our case 80% of eyes showed an CDVA of 20/25 or better. The spherical equivalent within ± 0.50 D was reported in 88 of 96 patients (91.7%) and within ± 0.75 D in 96.9%. The percentages in our study were 90% within ± 1.00 D and 73.33% within ± 0.50 D. The target refraction ± 1.00 D was achieved in 100% of subject eyes and no glistenings were reported in any case. In addition, no intraoperative or postoperative adverse events were observed. They concluded that these results demonstrate the safety and efficacy of the lens. In addition, authors pointed out that because of the new designed thicker and stiffer optic-haptic junction regarding improved characteristics of the lens (stability in the capsular bag), some special attention has to be addressed to the slightly different behavior of the lens during implantation and unfolding process. Same authors analyzed this model in 15 eyes of 15 patients with severe cases of pseudoexfoliation syndrome, phacodonesis and small pupils.¹⁷ Both 601P and 611P models have the same optical design but in the latter model, as we have indicated previously, the haptics are wider and stiffer, and then this model may be considered a better choice in patients where stability of the capsular bag is compromised. 3 months postoperatively, the mean manifest spherical equivalent was -0.35 D (from 0.00 to -1.00 D) and all eves were within ± 0.50 D of their preoperative target. Mean CDVA was 0.02 logMAR at the 3 months postoperative visit. Authors found that in 6 cases (40%) decentration or tilt was detected but these patients did not complain of any subjective visual symptoms or discomfort at any time of the follow-up. No significant refractive shift or refractive surprise occurred during the follow-up of 10 months, and no intraoperative adverse events were noted. These authors concluded that this model provided good surgical performance, excellent refractive stability, and predictable outcomes in challenging cases. Our results, using the 621P model, which has the same haptics design of the 611P, also support this conclusion. According to the manufacturer, the CT LUCIA 621P changed the injector, further optimized the asphericity of the optic to be more forgiving with decentration and increase diopter range. Ling et al¹⁸ published a study about the evaluation of Nd:YAG capsulotomy rates carried out for posterior capsule opacification (PCO) in 200 eyes implanted with the CT LUCIA 611P IOL. They reported 3.5% and 8.5% at 1 and 2 years, respectively. In this sense, Wormstone et al¹⁹ assessed the CT LUCIA 611PY/capsular bag biomechanical interactions following cataract surgery in a human in vitro graded culture capsular bag model. These authors concluded that throughout culture the lens appeared stable in its position and capsular bag modifications did not change this. They proposed that the lens optic edge shows an enhanced barrier function, which is likely to provide better PCO management in patients. Yildirim et al.²⁰ in a laboratory study, assessed the resistance to MV (glistening) formation analyzing the number of microvacuoles per square mm in the central part of different lenses. Results revealed mean glistening numbers with the highest in the SN60WF lens (66.0±45.5 MVs/mm²), followed by the CT LUCIA 611P (30.7±8.4 MVs/mm²), 800C (2.0±3.6 MVs/mm²), Vivinex XY1 (2.7±2.4 MVs/mm²) and the Tecnics ZCB00 (0.9±0.6 MVs/mm²). This study shows that the resistance to glistening formation differs depending on the hydrophobic acrylic copolymer composition of the IOL material. These authors indicated that there were differences with the values obtained previously in another study $(85\pm86 \text{ MVs/mm}^2)^{12}$ and to explain this difference considered that there was an improvement in the manufacturing process between the 601P and the 611P models,

which lead to a higher resistance to glistening formation. And, finally, Hienert et al²¹ carried out a study to compare the dynamics of axial IOL position and stability in the capsular bag after fellow-eye implantation of the CT LUCIA 611P and the CT ASPHINA 409MP IOLs. 100 eyes of 50 patients were analyzed up to 6 months post-surgery using the IOLMaster 700 biometer. They found statistically significant differences in postoperative anterior chamber depth with an overall IOL shift of 0.25 ± 0.16 mm for the ASPHINA lens and 0.14 ± 0.09 mm for the LUCIA 611P IOL (p<0.001). Notwithstanding, no significant differences were found in refraction or visual acuity between groups, reporting a mean UDVA of 0.06 ± 0.14 logMAR and a mean spherical equivalent of $-0.32\pm0.48D$ for the LUCIA 611P model. In our results, with the 621P model, these values were 0.64 ± 0.22 for UDVA (Snellen decimal) and $-0.18\pm0.55D$ for the spherical equivalent.

We have to consider that our study has two main limitations. First, there was no clinical direct comparison with other available aspheric IOLs in the market, but previously published literature was used to compare outcomes reported. And, second, despite of previous models of this lens have been assessed with long follow-ups showing good safety outcomes, the follow-up time in our study was short- and long-term effect of this specific IOL model should be further studied. Then, future prospective studies should include other models of lenses and longer follow-up where wavefront aberrations and contrast sensitivity should be measured.

Conclusion

Our study shows that the CT LUCIA 621P IOL provides satisfactory visual acuity and good accuracy in the postoperative refractive error. This lens with a non-constant aberration aspheric design may be considered as a valid choice for patients in a standard-routine cataract surgery practice. Future studies should include the analysis of wavefront aberrations and contrast sensitivity under different lighting conditions, and a comparison with other aspheric IOL models available in the market.

Data Sharing Statement

Data are not available for sharing.

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Disclosure

The authors report no conflicts of interest in this work.

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