COMPARING TWO HYDROPHOBIC MONOFOCAL IOLS
A focus on handling and implantation behavior

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The vast majority of patients undergoing cataract surgery today receive a monofocal intraocular lens (IOL), and results with these implants are excellent overall. However, there are many material and design issues that affect the intraoperative delivery and clinical performance of any IOL. Therefore, IOL manufacturers have continued to refine and update their technologies with the aim of improving surgical handling and clinical outcomes.

In 2016, Carl Zeiss Meditec AG (Jena, Germany) introduced the CT LUCIA 611P/PY IOL as a successor to the CT LUCIA 601P. The CT LUCIA 611P/PY retained all of the desirable material and optical characteristics of the previous lens but was designed with modifications to the optic-haptic junction to optimize centration and postoperative stability.

Specifically, the CT LUCIA 611P/PY IOL is a single-piece, hydrophobic acrylic monofocal lens with a heparin-coated[1] surface that comes preloaded in the BLUEJECT™ injector (Carl Zeiss Meditec AG). The IOL features the patented ZO (ZEISS Optic) asphericity design (Carl Zeiss Meditec AG), also referred to as a non-constant aberration aspheric optic. This approach provides improved vision by more closely representing the optics of the human eye. Furthermore, the IOL has a 6.0 mm optic with a 360° square edge design that inhibits lens epithelial cell migration. Step-vaulted haptics of the CT LUCIA 611P/PY maximize optic contact with the capsular bag to further limit the development of posterior capsule opacification.

We have implanted the CT LUCIA 611P/PY over the past 4 years with excellent results, and it is our preferred monofocal IOL. However, we were interested in conducting a formal comparative study to document its handling and clinical outcomes. For this purpose, we chose to compare the CT LUCIA 611P/PY to another commonly used single-piece hydrophobic acrylic monofocal IOL, the TECNIS-1 ZCB00 (Johnson & Johnson Surgical Vision). We were particularly interested in evaluating our intraoperative experience with the two IOLs. We hypothesized we would find differences between the two IOLs associated with material differences and because the CT LUCIA 611 P/PY comes preloaded while the TECNIS-1 IOL must be manually folded and loaded into an injector system.

Clinical study design

Our IRB-approved clinical trial included the first eye of 100 patients representing two consecutive cohorts. The first 50 eyes received the CT LUCIA 611P/PY and the next group of 50 eyes were implanted with the TECNIS-1 IOL. Although patients enrolled in the study were not randomized to IOL assignment, the two study groups were well-matched with respect to age and preoperative biometric characteristics.

One surgeon (Dr. Sri Ganesh) performed all of the procedures using the same technique and phacoemulsification unit. A video shows implantation of the preloaded CT LUCIA 611P/PY (Figure 1). The TECNIS-1 IOL was delivered using the UNFOLDER Platinum 1 Series Screw-Style Inserter (Johnson & Johnson Surgical Vision). Emmetropia was the refractive target for all cases. Intraoperative evaluations included measurement of unfolding time. Difficulties with injection or other delivery complications were also noted. In addition, clinical outcomes were recorded at follow-up examinations scheduled at 1 day, 2 and 6 weeks, and 6 and 12 months after surgery.

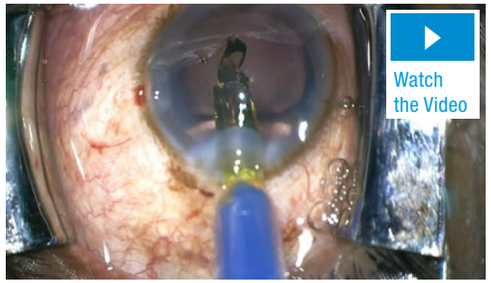

Figure 1. Implantation of the preloaded CT LUCIA 611P/PY

Clinical study results

We found that the mean intraoperative unfolding time was significantly shorter (p= 0.00) for the CT LUCIA 611P/PY IOL compared to the TECNIS-1 (12.93 ± 3.80 vs 35.16 ± 10.50 seconds, respectively). Otherwise, all surgeries were completed uneventfully without complications.

No complications were encountered in either study group during follow-up to 1 year, and no eye needed Nd:YAG laser capsulotomy to treat PCO. Refractive outcomes were excellent in both groups, and assessments of visual function and quality, including uncorrected and best corrected distance visual acuity, contrast sensitivity, Objective Scatter Index, and modulation transfer function, were similar in the two groups.

Mean total higher order aberrations, coma, and spherical aberration were also similar comparing eyes implanted with the CT LUCIA 611P/PY and TECNIS-1 IOLs. However, mean internal spherical aberration and internal coma values, which derive from the IOL, were significantly higher in the TECNIS-1 group.

Discussion

Comparison of the intraoperative handling of the CT LUCIA 611P/PY and TECNIS-1 IOLs was a focus of our study, and the results showed a benefit of the preloaded CT LUCIA 611 P/PY IOL for reducing unfolding time and problems with IOL delivery. Not only does the need for additional manipulation during implantation raise the possibility of causing IOL damage, but it can also increase the risk for additional complications, including damage to the capsular bag, that can compromise a successful outcome.

Cases of improper unfolding related to adhesion of the haptics to the optic have been described with acrylic IOLs and have been suggested to be related to insufficient OVD in the injector cartridge or improper IOL loading.[2] Theoretically, differences in unfolding behavior between the two IOLs might also reflect differences in material and surface coating. Faster unfolding of the CT LUCIA 611P/PY relative to the TECNIS-1 may also be enabled by the higher glass transition temperature of the CT LUCIA's hydrophobic acrylic material (13.8º C vs 11-12º C).

The findings in our study are consistent with those reported for the CT LUCIA 611P/PY by other cataract surgeons.[3-5] In a study including 29 eyes followed up to 6 months after surgery, Stepanov et al. concluded that the CT LUCIA 611P/PY was safe and easy to implant.[3] In addition, they found it had good in-the-bag centration and patients benefited with stable refractive outcomes and visual acuity. Borkenstein and Borkenstein reported outcomes for a series of 54 patients (96 eyes) followed for up to 1 year after implantation of the CT LUCIA 611P/PY.[4] They also highlighted the IOLs centering in the bag and its positional and refractive stability along with an encouragingly low rate of PCO and attributed the performance of the CT LUCIA 611P/PY to the construction of its optic-haptic junction. In a separate study focusing on eyes with pseudoexfoliation syndrome that are at risk for IOL decentration, the same investigators again reported that the CT LUCIA 611P/PY had excellent refractive stability during follow-up of 10 months after cataract surgery.[5]

Looking ahead

We have been very satisfied with the results achieved using the CT LUCIA 611P/PY. Consistent with its history of continually improving its surgical technology, Carl Zeiss Meditec AG more recently introduced the CT LUCIA 621P. Available in Europe since October 2020 and coming soon to the Asia-Pacific region, the CT LUCIA 621P comes preloaded in a new single-use injector system (BLUESERT™), but the IOL itself is made of the same material as 611P/PY with same design features.

Trusted colleagues who have been implanting the CT LUCIA 621P are very enthusiastic about the performance of the new injector system. Because of their feedback and our experience with the CT LUCIA 611P/PY, we are now looking forward to implanting the CT LUCIA 621P that represents the next generation of a time-tested hydrophobic acrylic monofocal IOL platform.

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Dr. Brar and Dr. Ganesh are paid consultants to Carl Zeiss Meditec AG. The study described in this article was an investigator-initiated trial conducted by them independently.

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