ZEISS CT LUCIA 621P

Treating a wide range of cataract patients
with a unique ZEISS Optic

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Seeing beyond

ZEISS CT LUCIA

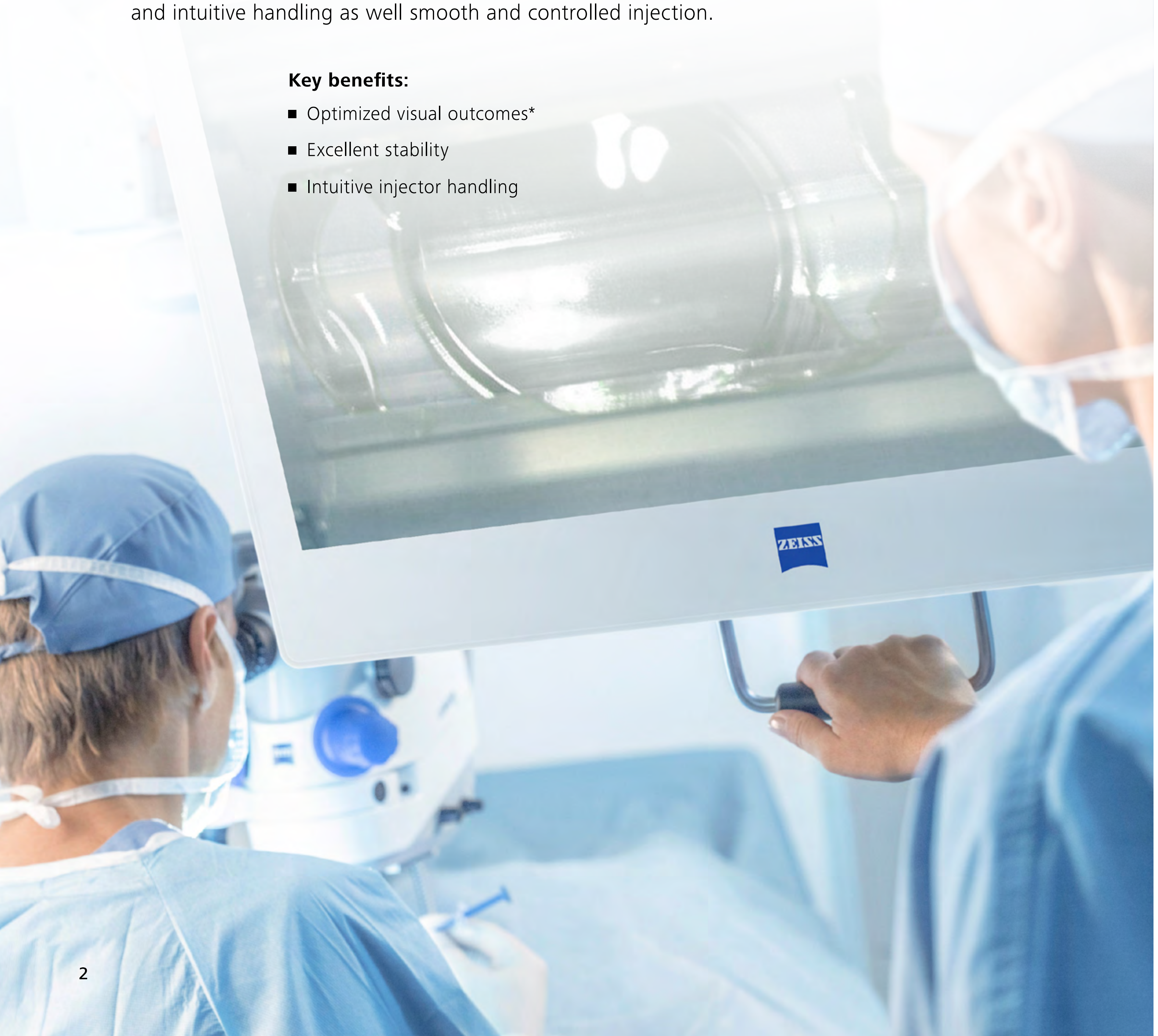
Treating a wide range of cataract patients with a unique ZEISS Optic.

ZEISS CT LUCIA® 621P – an aspheric, monofocal, hydrophobic C-loop IOL with the patented ZEISS Optic (ZO) Asphericity concept. Designed to be less susceptible to decentration* and to confidently deliver optimized visual outcomes*.

The reinforced optic-haptic junction, coupled with step-vaulted C-loop haptics, is designed to enable easy centering while maximizing direct capsular contact, thus optimizing stability and supporting a consistent position in the bag. The CT LUCIA 621P comes in a fully preloaded injector for an easy and intuitive handling as well smooth and controlled injection.

Key benefits:

- Optimized visual outcomes*
- Excellent stability
- Intuitive injector handling



ZEISS CT LUCIA

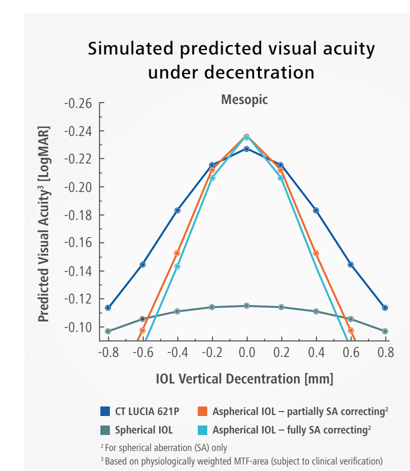
Aspheric C-loop

ZEISS CT LUCIA 621P

- Monofocal
- Aspheric (aberration correcting)
- Hydrophobic acrylic with heparin-coated[1] surface

3 key benefits

OPTIMIZED VISUAL OUTCOMES*



ZEISS Optic

The patented ZEISS Optic (ZO) Asphericity Concept of the ZEISS CT LUCIA 621P is designed to reduce spherical aberration and at the same time optimize visual outcomes in the event of potential lens misalignments.

EXCELLENT STABILITY

Reinforced optic-haptic junction

Coupled with step-vaulted C-loop haptics, designed to enable easy centering while maximizing direct capsular contact, thus optimizing stability and supporting a consistent position in the bag.

INTUITIVE INJECTOR HANDLING

Easy to prepare and use

Next to intuitive handling features, the ZEISS CT LUCIA 621P has a heparin-coated[1] surface to allow for a smoother injection and unfolding process.

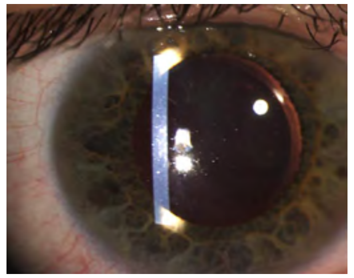
Optimized visual outcomes*

Designed to be less susceptible to decentration*

Every eye is as individual as the patient and typically, the human eye is not optically symmetric, which can lead to IOL decentration.

Does decentration matter?

Yes! Decentrations of varying magnitudes are not uncommon. Generally, IOL decentration occurs due to poor capsular or zonular support, decentered capsulorhexis, asymmetric shrinkage of the capsular bag, misplacement of the haptics of the IOL, or luxation in eyes with pseudoexfoliation. With the patented ZEISS Optic (ZO) Asphericity Concept, the ZEISS CT LUCIA 621P IOLs are designed to reduce spherical aberration and at the same time optimize visual outcomes in the event of potential decentration and lens misalignments.



Slit lamp examination showing a misalignment of the pupil and IOL

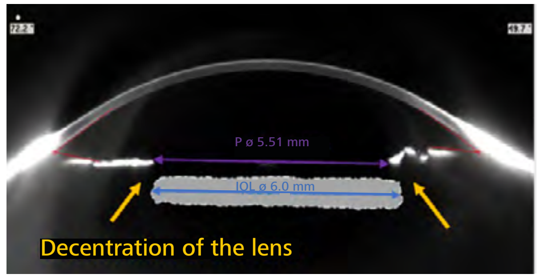


Image of the off-centered position of the IOL

Benefits for you and your patients

With its unique design, CT LUCIA 621P is designed to deliver optimized visual outcomes for a wide range of cataract patients.

What is the secret behind the unique ZEISS Optic?

The ZEISS CT LUCIA 621P offers the best of both worlds: Leveraging a patented asphericity concept to provide optimized visual outcomes for a wide range of cataract patients, while compensating for spherical aberrations. Optical simulations with various aspherical optic designs show that the ZEISS CT LUCIA 621P delivers optimized image quality under photopic (Fig. 1) and mesopic (Fig. 2) conditions, even at larger decentrations.

PHOTOPIC

DECENTRATION / LENS	ZEISS CT LUCIA 621P	Fully SA correcting (IOL)	Partially SA correcting (IOL)
20/20 Perfectly Centered			
20/20 Decentered by 0.6 mm			
20/20 Decentered by 1.0 mm			

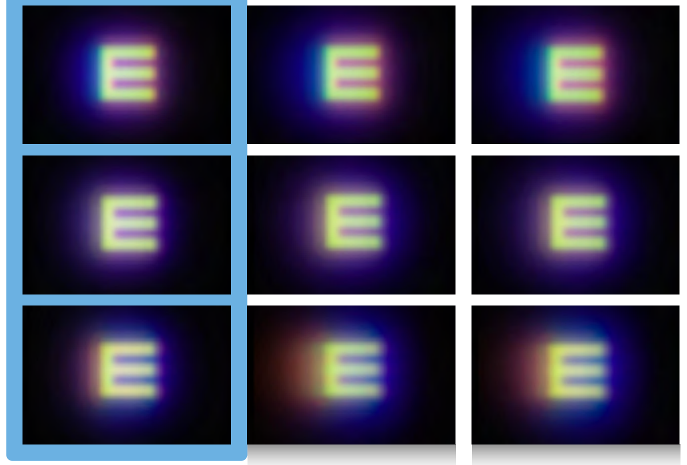


Fig. 1: Table: Optotype simulation for best corrected distance vision under photopic conditions*

MESOPIC

DECENTRATION / LENS	ZEISS CT LUCIA 621P	Fully SA correcting (IOL)	Partially SA correcting (IOL)
20/20 Perfectly Centered			
20/20 Decentered by 0.6 mm			
20/20 Decentered by 1.0 mm			

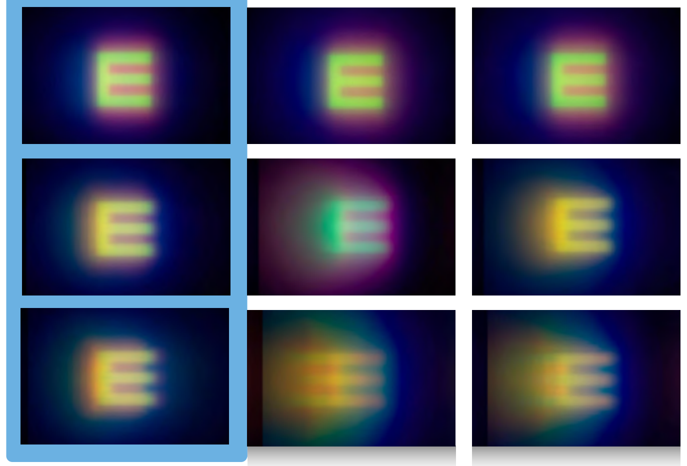


Fig. 2: Table: Optotype simulation for best corrected distance vision under mesopic conditions*

Designed to be less susceptible to decentration for optimized visual acuity and image quality*

Image quality with simulated[4] human cornea

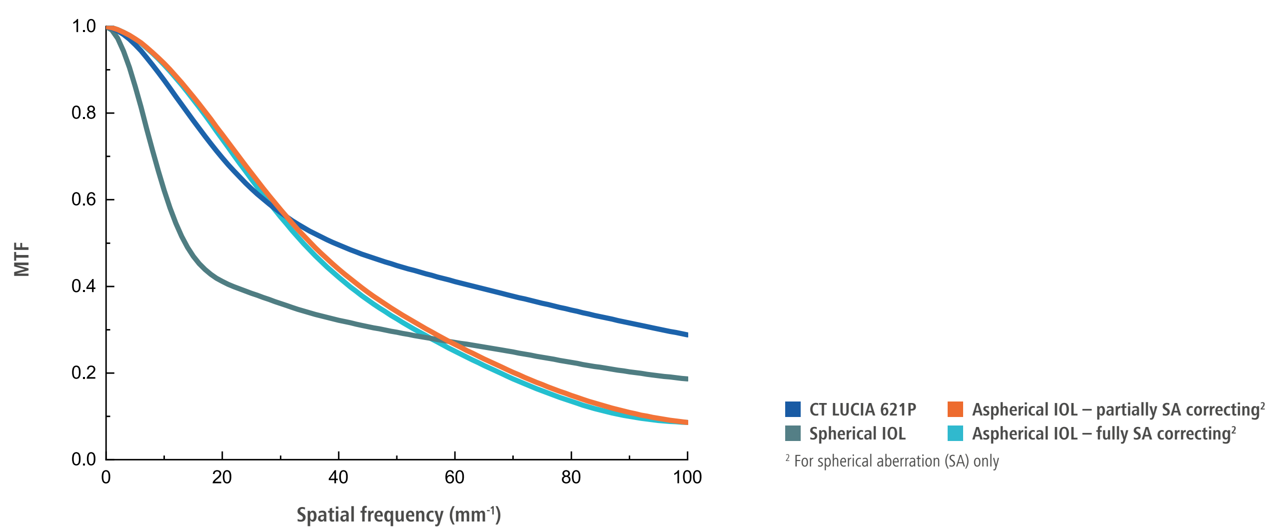


Fig.3: Modulation transfer function (MTF) of various optic designs in an eye model with a simulated human cornea of 4.5 mm aperture and 0.5 mm lens decentration[4]

Simulated predicted visual acuity under decentration*

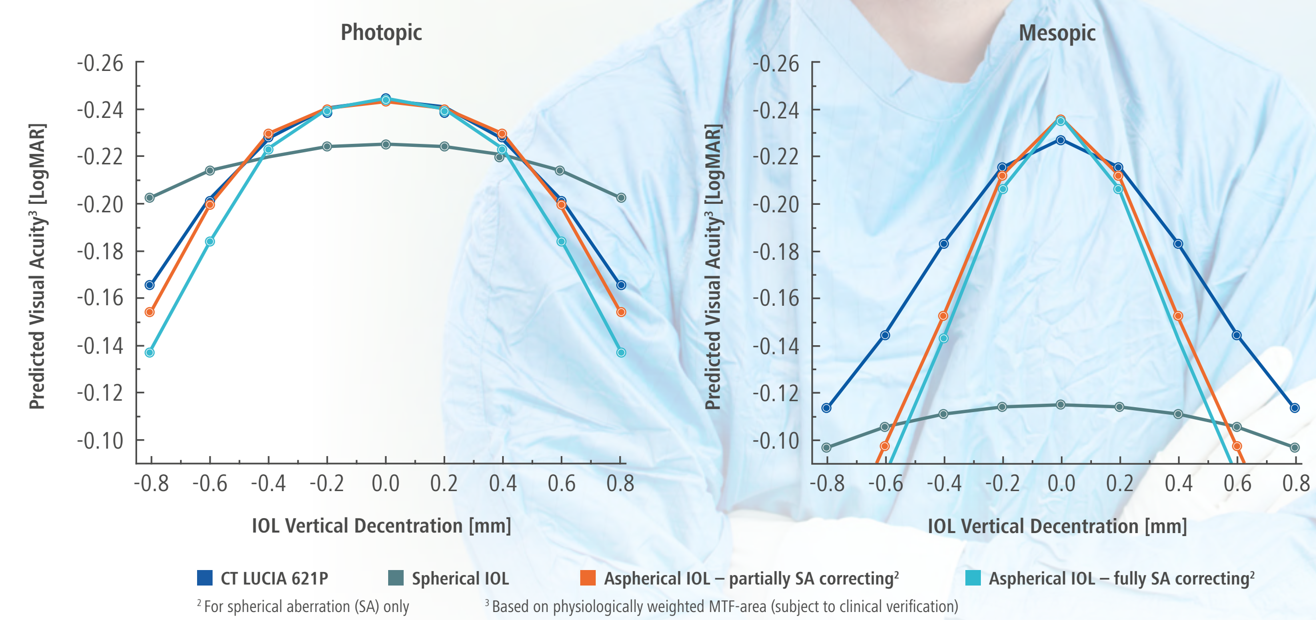


Fig. 4: Influence of decentration on photopic predicted visual acuity.

Fig. 5: Influence of decentration on mesopic predicted visual acuity.

The ZEISS Optic was engineered based on the realistic Liou-Brennan eye model[4], which is optimized for a pupil size typically found in cataract patients.

Central zone with negative spherical aberration to balance corneal aberration for an improved image quality (Fig. 3)

Peripheral zone with alteration of aberration correction* designed to compensate for decentration (Fig. 4, 5)

Optimized balance between aberration correction and neutral effects (Fig. 6)

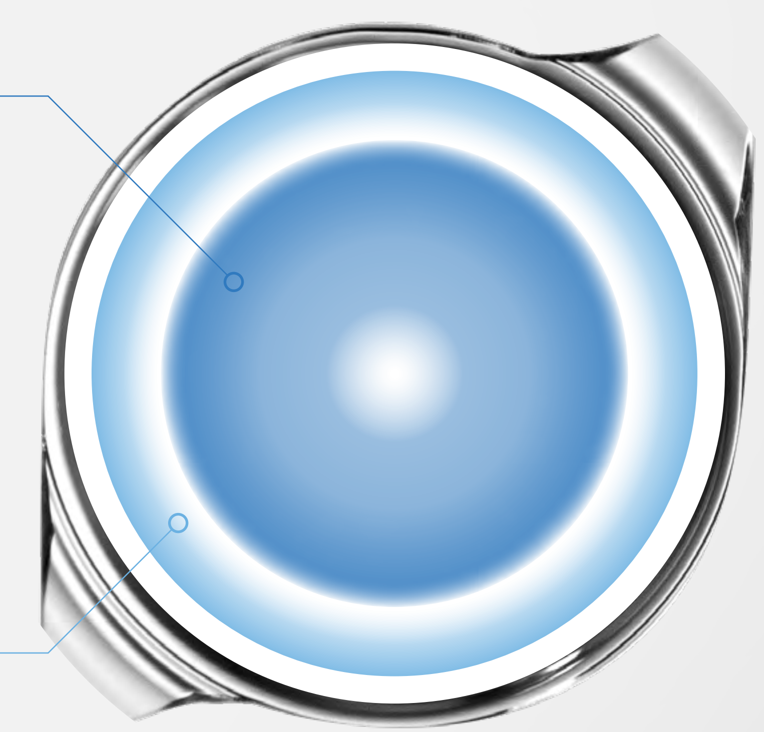


Fig. 6: Aberration profile of the ZEISS CT LUCIA 621P with non-uniform power distribution (schematic visualization, image not to scale)
*** Gradual transition from negative to positive spherical aberration offsetting each other to simulate a neutral effect*

Excellent stability

ZEISS CT LUCIA 621P IOLs feature a reinforced optic - haptic junction, coupled with step-vaulted C-loop haptics. They are designed to enable easy centering while maximizing direct capsular contact, thus optimizing stability and supporting a consistent position in the bag.

> *The CT LUCIA lens has a stiffer and thicker, and therefore much more rigid optic-haptic junction. And you can even feel it as a surgeon at the end of the surgery, when you do irrigation-aspiration, or the last steps of the surgery, that the lens is very stable and there is no shifting to the anterior chamber. And, therefore, this is very beneficial.*
>
> ***Dr. Borkenstein, Graz, Austria***[5]

> *I appreciate the reproducibility in unfolding the haptics in the bags and also the stability in the first part of the injection, and the proximity of finding the lens exactly in the same place in which I left it.*
>
> ***Dr. di Carlo, Turin, Italy***[5]

The sophisticated edge design of the ZEISS CT LUCIA

"… most researchers agree that the best IOL is one that has a sharp edge for the entire 360 degrees of the posterior surface of its optic."[6]

Sophisticated edge design

The ZEISS CT LUCIA 621P provides a 3 µm radius sharp-edge designed to reduce early cell migration and posterior capsule opacification. CT LUCIA 621P is manufactured using Lathe-cut technology.

The following images were produced at the Technical University of Aalen, Germany using scanning secondary electron microscope (SEM) analysis with ZEISS Sigma 300 VP secondary electron contrast (image size 3072 x 2304 pixels) to visualize the sharp-edge design of the ZEISS CT LUCIA 621P (Fig. 7 a – d).

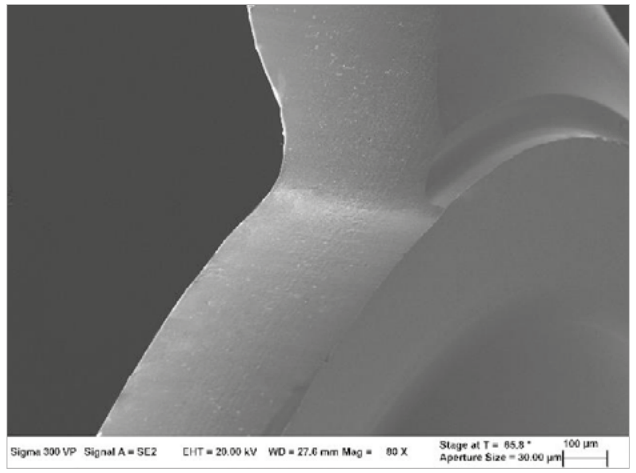


Fig. 7 a

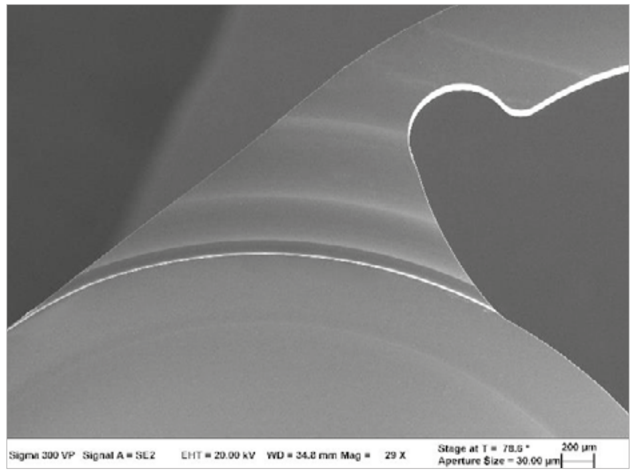


Fig. 7 b

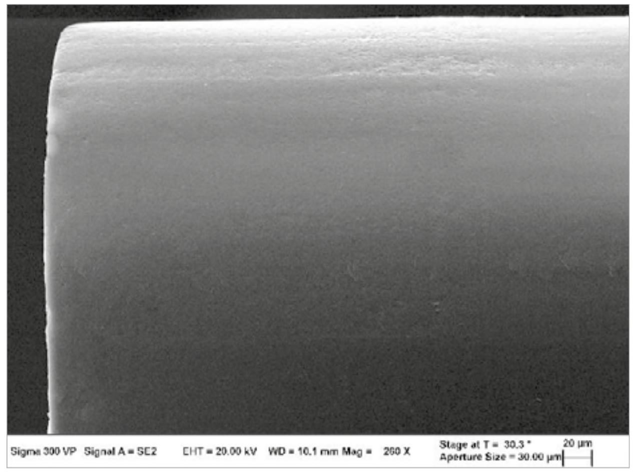


Fig. 7 c

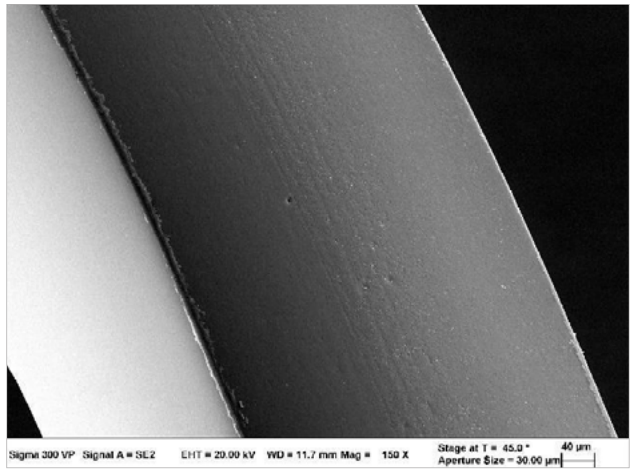


Fig. 7 d

Fig. 7 a – d: The ZEISS CT LUCIA 621P optic-haptic-junction and images of the sharp-edge (Scanning secondary electron microscopic analysis (SEM) with ZEISS Sigma 300 VP secondary electron contrast)

Excellent stability

Proven in practice

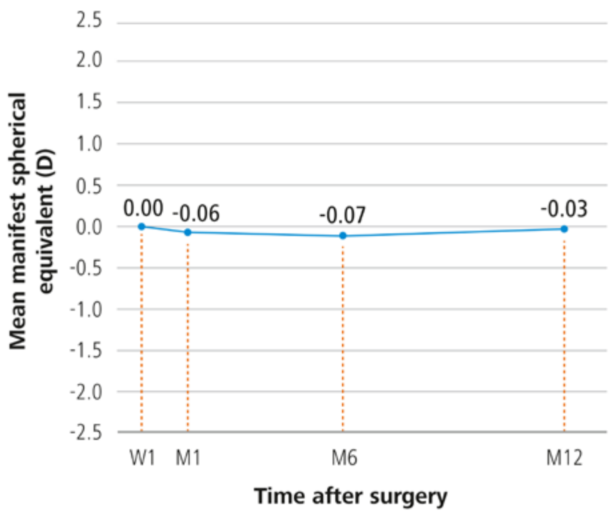
For US FDA premarket approval of CT LUCIA 621P, a US clinical trial[a] using the CT LUCIA 611P[b] as study device was performed in a multicentric setting by 23 US surgeons over 15 sites. The evaluation included 339 eyes with cataracts. The age of the patients in this cohort ranged from 40 to 93 with average reported preoperative refractive astigmatism of -0.84 ± 0.66 D (-5.25 D, 0.00 D).

According to the study authors, the results of the clinical trial demonstrate the "excellent refractive predictability, stability, and visual performance"[a] of CT LUCIA 611P[b] postoperatively after 12 months:

Refractive Stability Over Time
The CT LUCIA 611P[b] exhibited excellent refractive stability in the first post-operative year with **minimal and insignificant changes in the manifest refraction spherical equivalent** (MRSE).

Refractive stability over time – changes in MRSE at W1, M1, M6 and M12

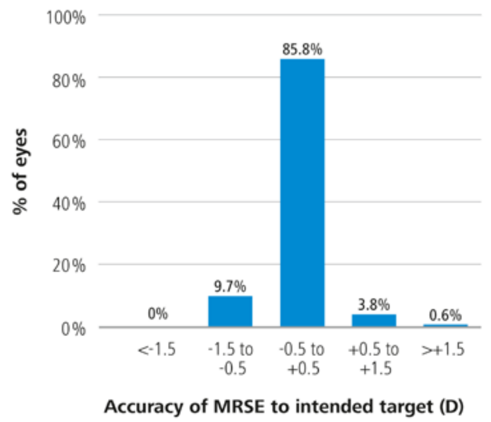
Consistent cohort | n = 308 eyes



Refractive Predictability
When comparing achieved and targeted refraction, it was found that **85.8%** of eyes achieved a **manifest refraction spherical equivalent (MRSE) within ±0.5 D** of the targeted refraction (emmetropia). 96.8% were within ±1.00 D of targeted refraction.
Note: Preoperative refractive astigmatism (on average -0.84 D within patient cohort) was not corrected during surgery: this may partly explain the percentage of patients outside ±0.5 D and ±1.0 D SE.

Predictability of MRSE – Difference between target and achieved MRSE at 12 months postoperative by class

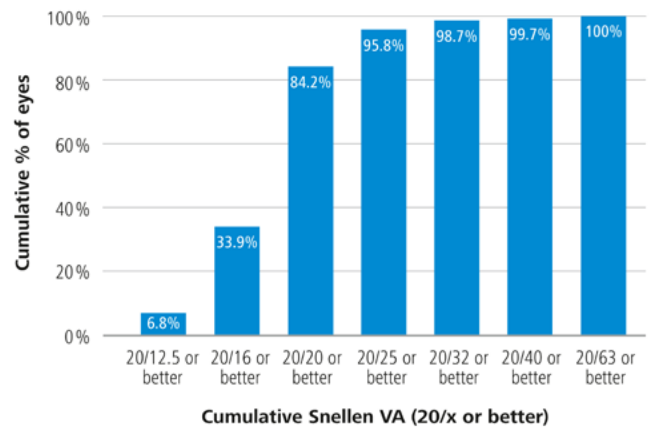
12 months postop | n = 310 eyes ±0.50D: 85,8% | ±1.00D: 96.8%



Visual Acuity Outcomes
The ZEISS CT LUCIA 611P[b] achieved corrected distance visual acuity (CDVA) that improved from **mean CDVA** of 0.26 ± 0.22 (≈20/36) logMAR at baseline to **-0.02 ± 0.09 (≈20/19) logMAR at 12 months**. Postoperative CDVA of 20/25 or better was achieved in 95.8% (297/310) of eyes, while 84.2% and 33.9% of patients achieved CDVA of 20/20 and 20/16 or better, respectively.

Postoperative corrected distance visual acuity (CDVA) at 12 months by class

12 months postop | n = 310 eyes



IOL Material Quality
Posterior Capsule Opacification (PCO) related Nd:YAG Capsulotomy Rate: Nd:YAG capsulotomy was not performed in 96.8% (328/339) of subjects in the study. The **overall rate of Nd:YAG capsulotomy** for every implanted subject was **3.2%** (11/339). **11 of 15 clinical sites had no cases** of Nd:YAG capsulotomy.

IOL Glistenings: The CT LUCIA 611P[b] was **glistening-free** with no findings of glistening at any visit during the 12 month investigation. CT LUCIA 621P is of same material as CT LUCIA 611P[b].

Conclusion

The ZEISS CT LUCIA 611P[b] provides high optical quality helping surgeons to fulfill patients' expectations of predictable and impressive visual performance.

a Schallhorn SC, Bonilla M, Pantanelli SM. Outcomes of a multicenter U.S. clinical trial of a new monofocal single-piece hydrophobic acrylic IOL. J Cataract Refract Surg. 2022 Oct 1;48(10):1126-1133. Quote referenced from page 1133.
b The results of the ZEISS CT LUCIA 611P US IDE study are applicable to the ZEISS CT LUCIA 621P IOL. Bench studies have demonstrated equivalent performance between the CT LUCIA 621P IOL and the CT LUCIA 611P IOL.

Intuitive injector handling

Surgeons' experiences with ZEISS CT LUCIA 621P

The fully preloaded injection system of the ZEISS CT LUCIA 621P has been designed to make handling easy and intuitive for the target users. The design simplifies the surgical workflow, providing a smooth preparation process that enables implantation of the lens in an easy and efficient manner.

It is a three-step designed, fully preloaded injector system, and, I guess, for rookies and for high-volume surgeons, very beneficial in daily routine.

***Dr. Borkenstein, Graz, Austria*[5]**

Surgeons' evaluations: In total 11 doctors & 9 nurses in Germany, France, Spain, Italy, Portugal, Sweden & Austria were involved[5]

Dr. Adam + resident – Paris, France, **Dr. Amaro + nurse –** Lisbon, Portugal, **Dr. Borkenstein –** Graz, Austria, **Dr. Cuttitta –** Palermo, Italy, **Dr. di Carlo + nurse –** Turino, Italy, **Dr. Hettlich + nurse –** Minden, Germany, **Dr. Johansson + nurse –** Kalmar, Sweden, **Dr. Loqvist + nurse –** Elskistuna, Sweden, **Dr. Merkoudis + nurse** – Elskistuna, Sweden, **Dr. Monnet + resident –** Paris, France, **Dr. Roldan + nurse –** Seville, Spain

Report on performance in surgery

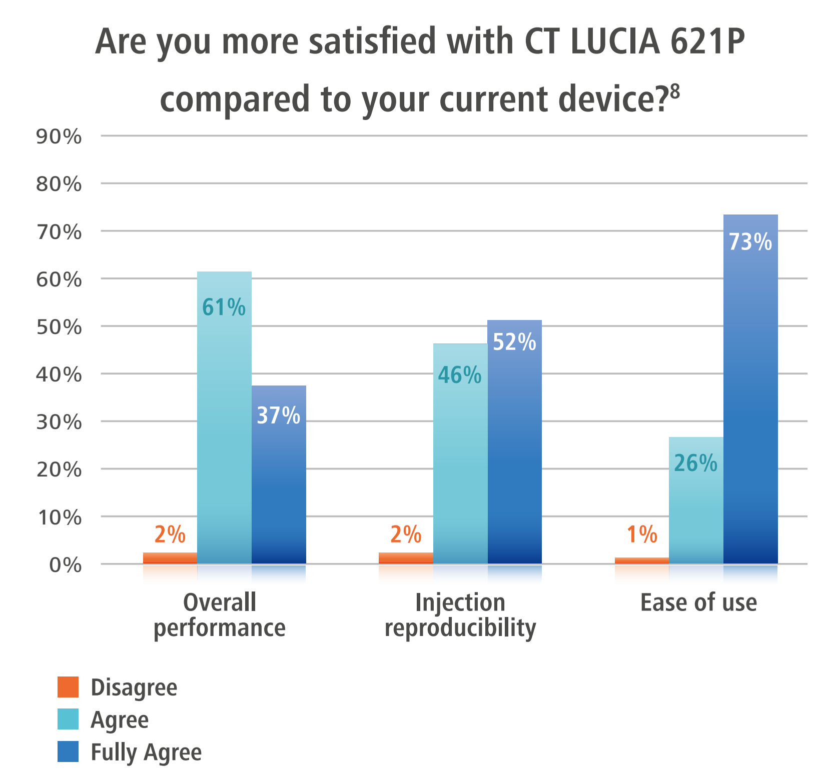
ZEISS CT LUCIA 621P

Easy to handle

Intuitive injector preparation for scrub nurse indicating where to stop while preparing the injector.

Smooth and controlled injection

The preloaded ZEISS CT LUCIA 621P has a heparin-coated[1] surface for smooth injection and unfolding.



Excellent performance

98% of the testing surgeons and nurses agreed that the overall performance of the CT LUCIA 621P is preferred over other injectors of choice, even over market leading injectors.

Particularly advantageous was the homogenous injector force, resulting in a high percentage of reproducibility and ease to implant the lens in the bag.[8]

Treating a wide range of cataract patients with a unique ZEISS Optic.

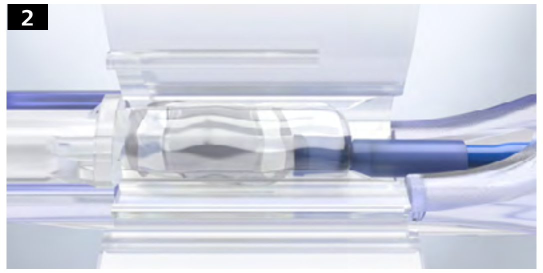
ZEISS CT LUCIA 621P

Preparing the CT LUCIA 621P

1

Verify that the lens is centered and secure in the IOL chamber.

2

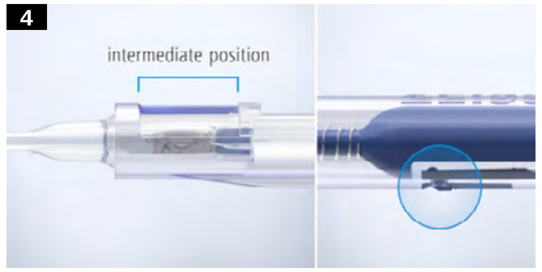


Cover the whole lens and blue plunger tip with a **generous** amount of ophthalmic viscoelastic. Avoid touching the lens and blue plunger tip.

3

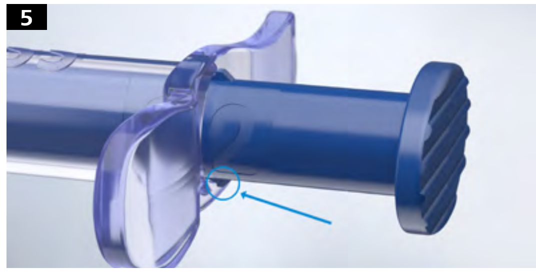
Close the wings of the IOL chamber. **IMPORTANT:** Allow the lens to remain in this position until the surgeon is ready to implant it into the eye.

4



Advance the lens to the intermediate position. Gently push the plunger forward until an audible 'click' is heard.
IMPORTANT: The lens should be implanted immediately.

5



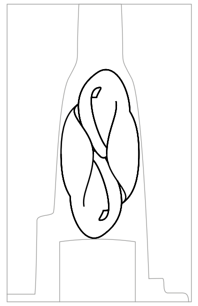
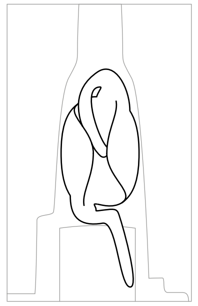
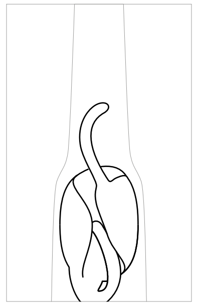
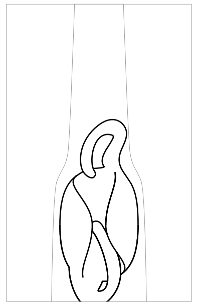
Before implantation, please check to ensure that the IOL is correctly oriented.
Injection: With loading chamber wings facing upwards, slowly advance the lens until it has been released from the injector.
If delivery is incomplete, apply additional force to the thumb flange to release the lens.

6 Carefully position the lens in the capsular bag.

7 Discard the device. Do not reuse the injector.

Implantation recommendations

General advice: Before implantation, please check to ensure that the IOL is correctly oriented.

Possible haptic configuration	Possible IOL behaviour	Recommendation	CT LUCIA 621P injection picture	Drawing
Both haptics are tucked into the optic (ideal scenario).	Correct position (no risk).	Proceed.		
Plunger overriding trailing haptic.	The haptic could become pinned between the cartridge and the plunger cushion, and the IOL could become stuck in the injector tip. There is a risk that the haptic might tear.	Do not proceed.		
Leading haptic twisted.	The leading haptic may become twisted and may point downward and/or to the right; the optic may begin to roll counter-clockwise and even roll upside down.	Rotate the injector clockwise (bevel to the left) to ensure the leading haptic is correctly positioned in the capsular bag and proceed as normal.		
Leading haptic is looped but not over the optic.	Haptic can swing out and is slightly off-axis but pointing in the correct direction.	Proceed.		

Technical specifications

ZEISS CT LUCIA 621P

	CT LUCIA® 621P – fully preloaded
Optic Design	Monofocal, aspheric (aberration correcting)
Material	Hydrophobic acrylic with heparin-coated[1] surface
Optic Diameter	6.0 mm
Total Diameter	13.0 mm
Haptic	Step vaulted
Lens Design	Single-piece
Incision Size	2.2 – 2.6 mm (depending on diopter)
Diopter Range	From 0.0 to +34.0 D, 0.5 D increments
Company Labeled A-Constant[2]	120.2
ACD[2]	6.29
Abbe Number	51
Refractive Index	1.49
Implantation in	Capsular bag
Injector/Cartridge Set	BLUESERT™ 2.2 Injector for diopter range 0.0 to +24.0 BLUESERT 2.4 Injector for diopter range +24.5 to +30.0 BLUESERT 2.6 Injector for diopter range +30.5 to +34.0

[1] The heparin coating on the lens surface has no pharmacological, immunological or metabolic action.
[2] For optimized A Constants and ACD Constants refer to IOLCon: https://iolcon.org/lensesTable.php. Last retrieved 2019-02-28

* The data is taken from a simulation. The transferability of the results of such a simulation to patients with an actual implanted intraocular lens has not yet been scientifically proven. Whether the simulated impressions correspond to the actual visual impressions must be clarified in future invasive studies.

[1] The heparin coating on the lens surface has no pharmacological,immunological or metabolic action.
[2] For spherical aberration (SA) only.
[3] Based on physiologically weighted MTF-area (subject to clinical verification).
[4] The Liou-Brennan eye model contains features of the biological eye that were not considered in previous eye models, as the distribution of a gradient refraction index and a decentered pupil. Furthermore, it has great reliability since it takes into account the mean value of empirical measurements of the in vivo eye in order to define size and parameters such as anterior and posterior curvature of cornea, lens, axial length, etc.
Hwey-Lan Liou and Noel A. Brennan: "Anatomically accurate, finite model eye for optical modeling", Journal of the Optical Society of America A, Vol. 14, Issue 8, pp. 1684-1695 (1997)
[5] The statements of the doctors presented reflect only their personal opinions and do not necessarily reflect the opinions of an institution with which they are affiliated. The doctors shown have a contractual or other financial relationship with Carl Zeiss Meditec and have received financial support.
[6] *Review of Ophthalmology*, "IOL Design Closes Off PCO", 01/2003
[7] Based on cohort data collected from Dr Cuttitta (University of Palermo, Italy) after implantation of CT LUCIA 621P IOLs in sixty eyes. Internal report on CT LUCIA 621P data collection (Dr Cuttita) - Version 1.1 dated 19.11.2019
[8] CT LUCIA 621P – Surgeon evaluation report (Apr-Sep 2019) - Report on surgery Performance CT LUCIA 621P injector. Results are based on 521 implantations.
[9] For optimized A Constants and ACD Constants refer to IOLCon: https://iolcon.org/lensesTable.php. Last retrieved 2019-02-28

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