CT LUCIA from ZEISS

A Scientific Report

Lens properties and specifications

CT LUCIA, the hydrophobic, monofocal C-loop IOL from ZEISS with its patented aspheric ZEISS optics, featuring a 360-degree square–edge design for low PCO rates[1]. ZEISS CT LUCIA® is made with ultra-high purity hydrophobic acrylic and a proprietary cryo-lathing process. Supplied in an easy-to-use, fully preloaded injector system, ZEISS CT LUCIA is available as both a clear UV-blocking and a yellow UV-blocking, blue-light filtering IOL.

ZEISS CT LUCIA 601P

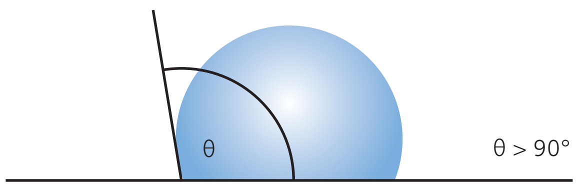
ZEISS CT LUCIA 601PY

BLUEJECT™ (fully preloaded injector system)

Hydrophobic - Hydrophilic

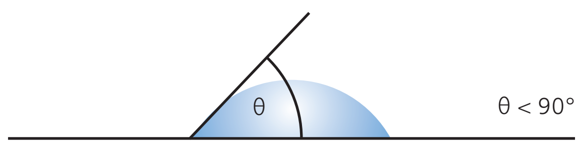
Surface properties

Hydrophobic Drop*



Hydrophobic – contact angle > 90°, tending to repel or be not wetted by water.

Hydrophilic Drop



Hydrophilic – contact angle < 90°, tending to be wetted by water.

** ZEISS CT LUCIA*

Hydrophobic Acrylic

- Copolymer of acrylates/methacrylates
- Covalently bound benzotriazole-class UV absorber
- Refractive index is 1.49 (same as PMMA)
- Exceptional clarity – no glistenings
- Water content: 0.3%
- Heparin coated IOL surface
- Available in yellow and clear
- The IOL comes in a fully preloaded injector system

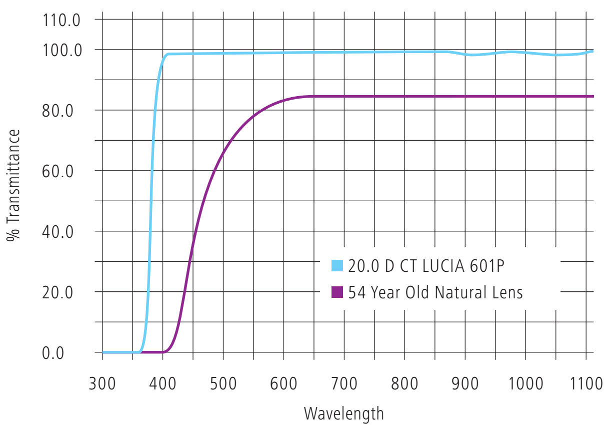
HSM – (Heparin Surface Modification)

"Heparin surface modification results in reduced foreign-body reaction as measured by specular micrography and slit-lamp examination, especially in the early postoperative period."[2]

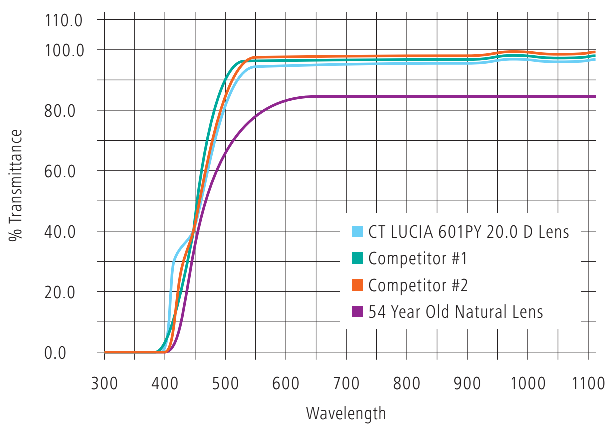
Benefits:

- Heparin coating on the IOL surface results in haptic non-sticking to the optic[3]
- HSM may result in less cell adhesion onto lens surface[4]

Light Transmission Properties



CT LUCIA 601P UV Light Transmission Properties
At least 90% above 410nm, less than 10% below 375nm



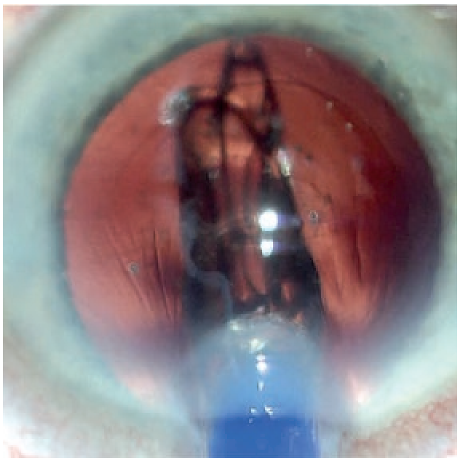
CT LUCIA 601PY UV Light Transmission Properties
At least 90% above 410nm, less than 10% below 400nm

Clinical evaluations and Scientific studies

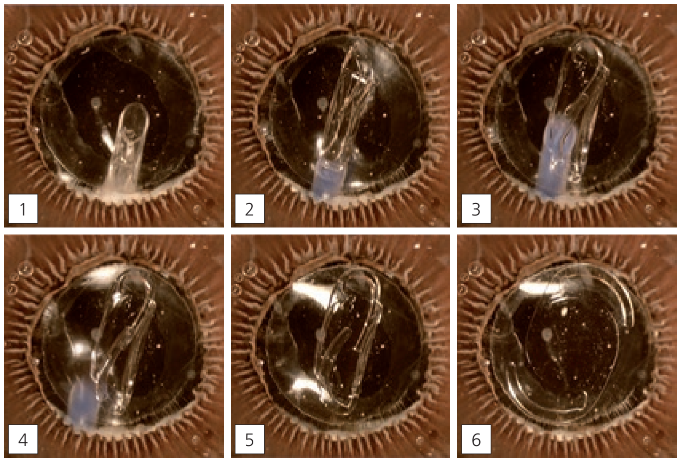
Comparative evaluation regarding the implantation, unfolding and centration behavior of ZEISS CT LUCIA® vs. AcrySof®IQ

During statistical evaluation of clinical implantation data[5], it was identified that the ZEISS CT LUCIA 601P performed smoother during unfolding and faster during centration than other competitive lenses.

Implantation and Unfolding Behavior



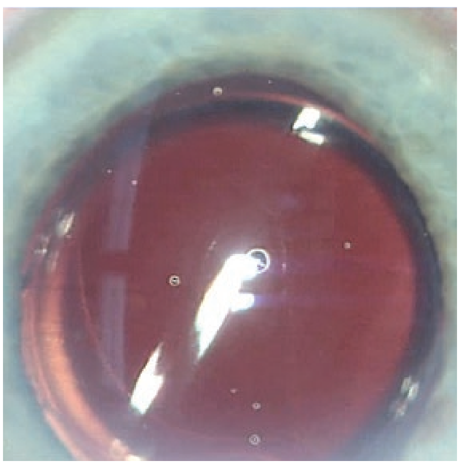
ZEISS CT LUCIA 601P – anterior view [6]



ZEISS CT LUCIA 601P – Miyake-Apple posterior view [6]

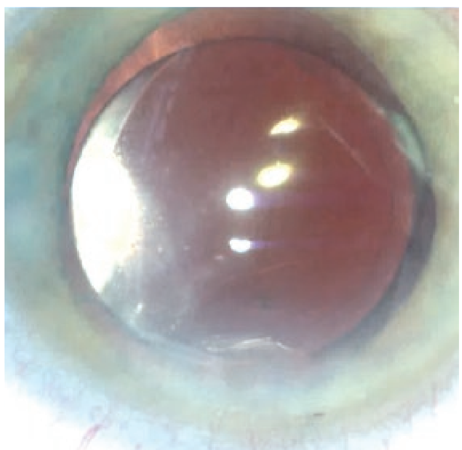
Comparison and time measurement ZEISS CT LUCIA vs. AcrySof®IQ

One sample operation, showing the comparision of an implantation of the ZEISS CT LUCIA 601P in comparision to an implantation of the AcrySof®IQ (SA60AT).



Surgeon anterior view – ZEISS CT LUCIA 601P [6]

00:39 min
(N=1)



Surgeon anterior view – AcrySof®IQ (SA60AT) [6]

01:08 min
(N=1)

Insertion ■ Injection ■ Unfolding ■ Centration

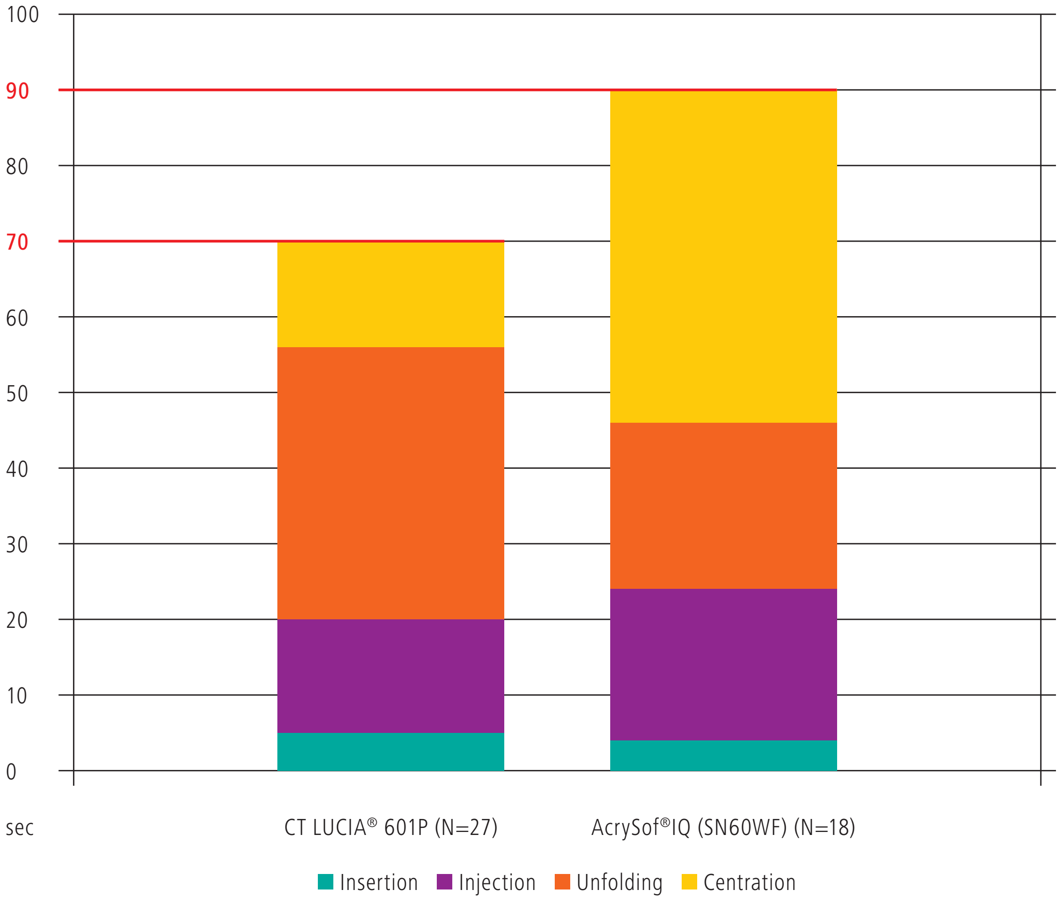
Conclusion

ZEISS CT LUCIA:

- shows a controlled and uncomplicated unfolding of the haptics, as well as a consistent unfolding of the IOL during implantation[5]
- shows faster centration after insertion in the capsular bag with less manipulation required compared to AcrySof®IQ[5]

"ZEISS CT LUCIA shows faster centration after insertion in the capsular bag with less manipulation required compared to AcrySof®IQ" [7]

The graph below shows the average implantation time of a ZEISS CT LUCIA® 601 in comparison to the average implantation time of an AcrySof®IQ (SN60WF) lens. The comparison is based on 27 ZEISS CT LUCIA 601P implantations versus 18 AcrySof®IQ (SN60WF) implantations.

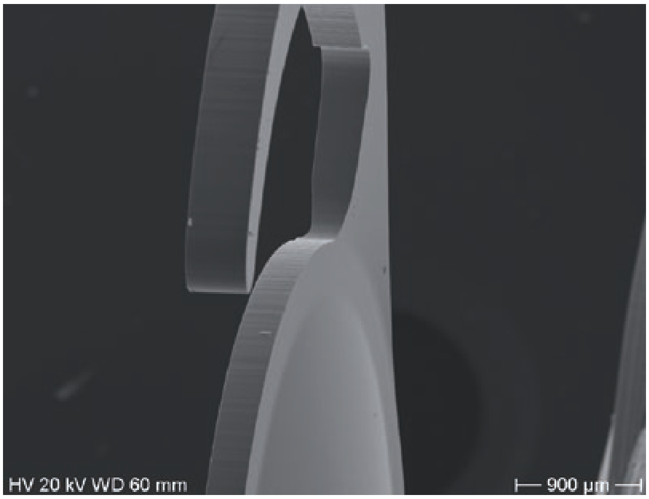


Sophisticated sharp edge design

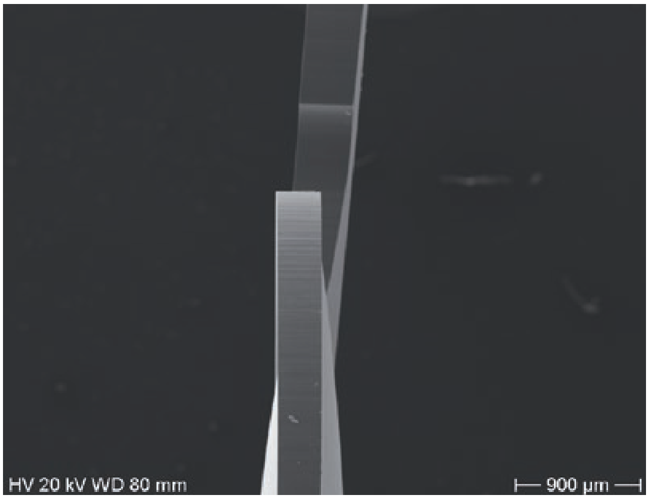
The following images were produced during a test carried out at the Technical University of Berlin using a Scanning Electron Microscope (SEM) that produces images of a sample by scanning with a focused beam of electrons under 3 different resolutions (900µm, 200µm and 80µm), to prove the high quality of sharp edge design of the ZEISS CT LUCIA. The main focus was to visualize the critical areas of the IOL (haptic-optic transition and IOL edges)

The ZEISS CT LUCIA provides a sophisticated 3 µm radius sharp edge design to prevent early cell migration and Posterior Capsular Opacification (PCO)[8]. The proprietary polishing-free lathe cut manufacturing technology provides edge sharpness and edge integrity.

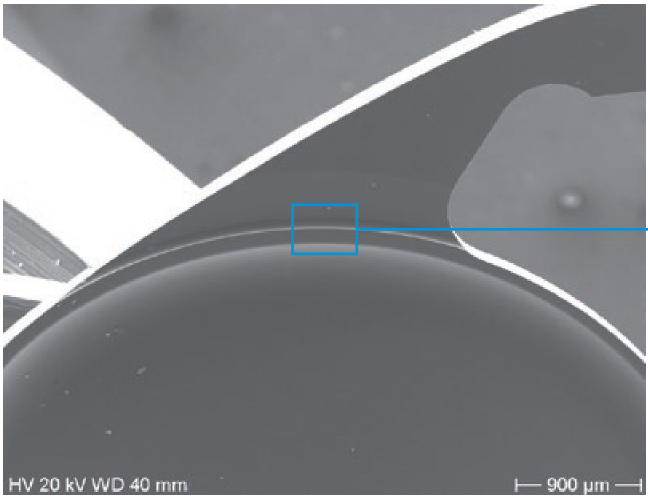
Scanning Electron Microscope (SEM) images 900µm



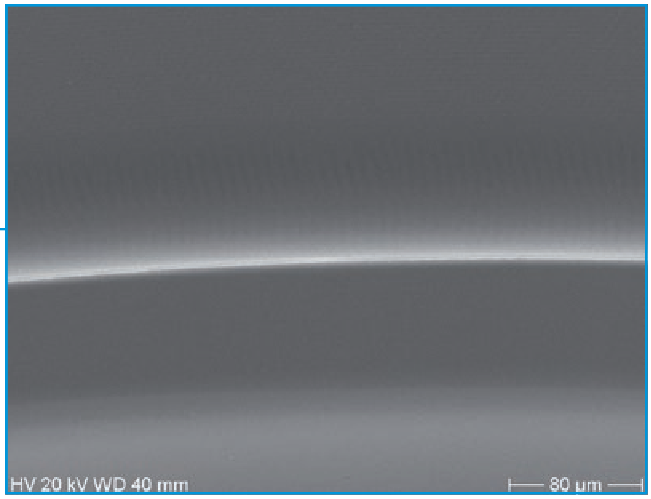
1. 900µm resolution angulated anterior picture of CT LUCIA - haptic-optic transition



2. 900µm resolution side view picture of CT LUCIA 601P - IOL body



3. 900µm resolution frontal posterior picture of CT LUCIA - haptic-optic transition

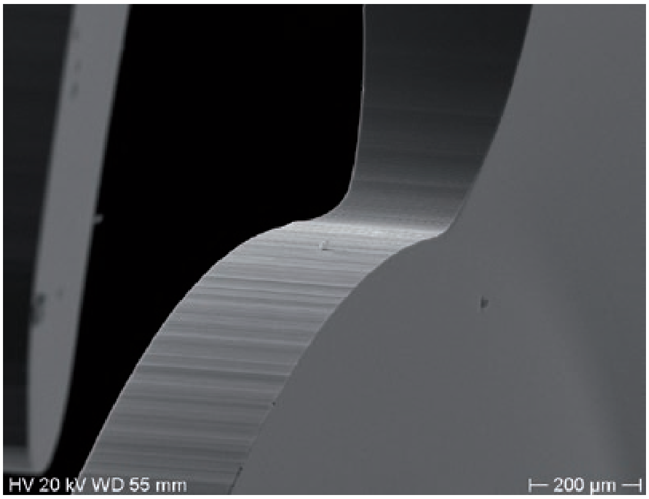


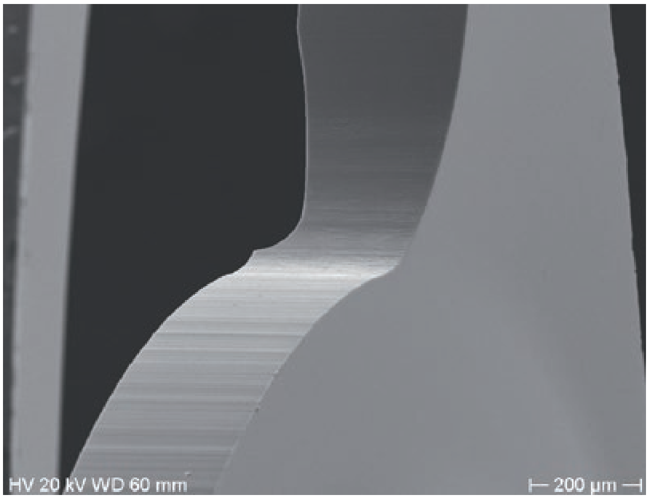
4. Magnified view of CT LUCIA haptic-optic transition

Sharp edge design of the CT LUCIA 601P

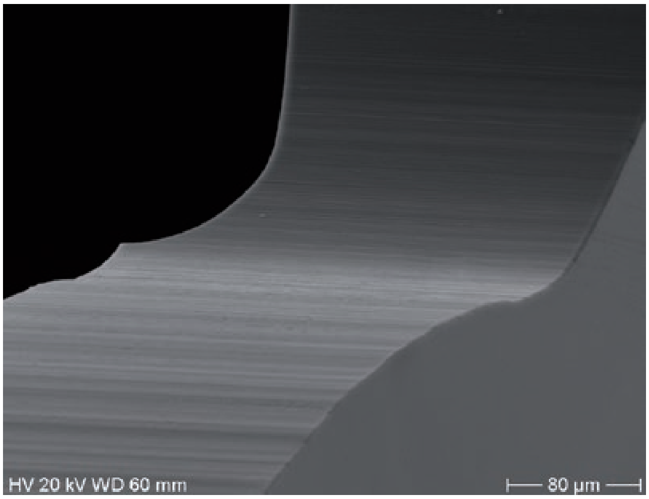
"… most researchers agree that the best IOL is one that has a sharp edge for the entire 360 degrees of the posterior surface of its optic." [9]

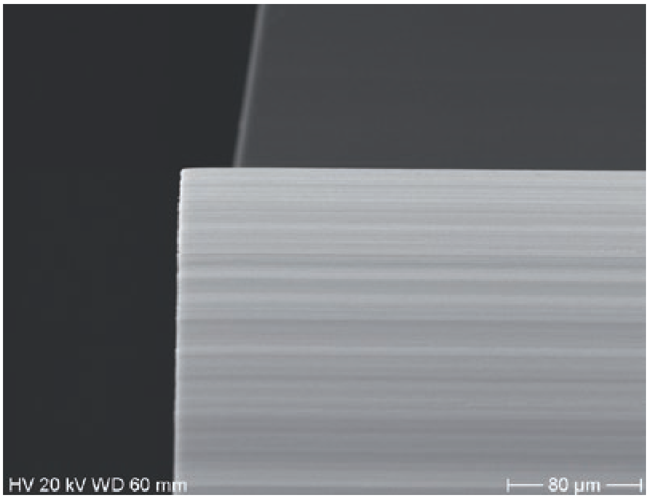
Scanning Electron Microscope (SEM) images 200µm



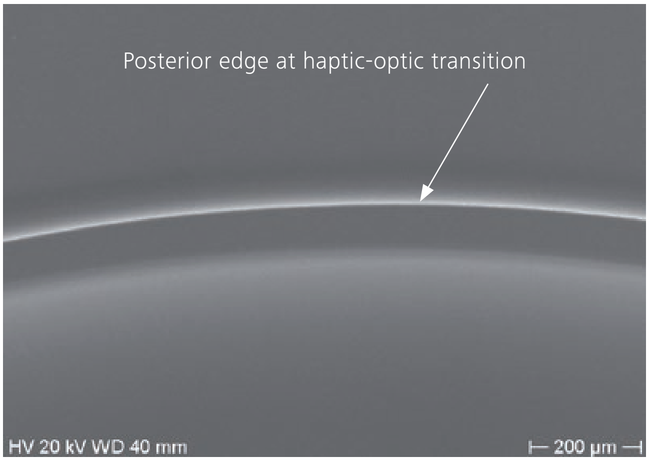


Scanning Electron Microscope (SEM) images 80µm

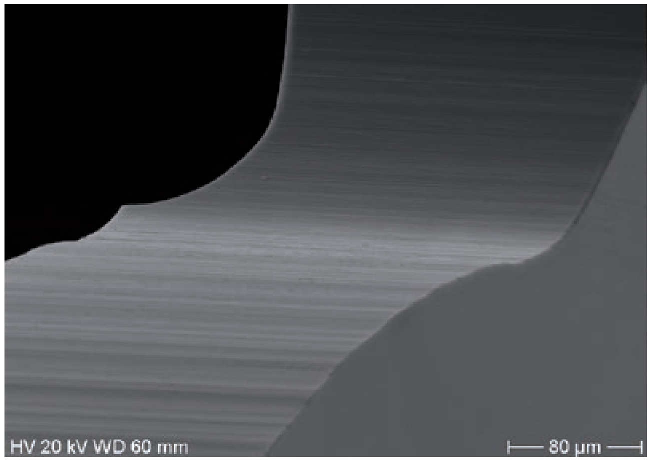




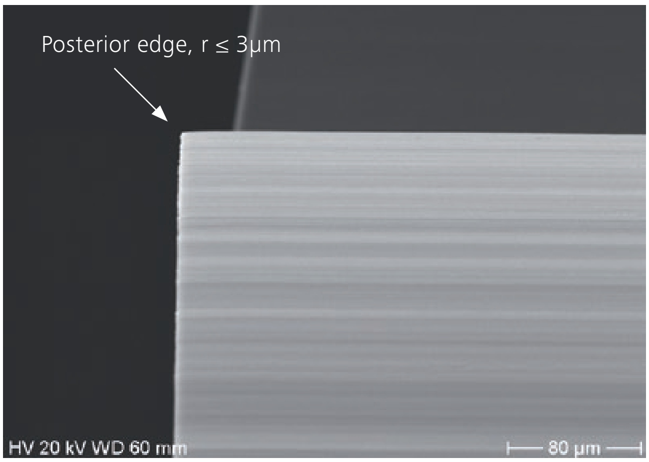
Posterior edge design – CT LUCIA 601P



4. 200µm resolution fontal posterior picture of CT LUCIA - haptic-optic transition

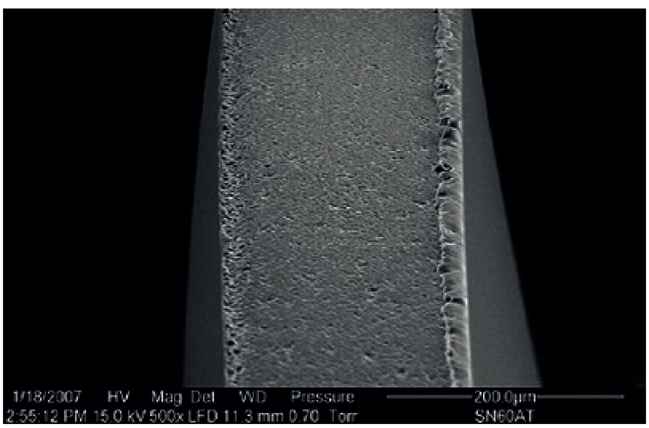


5. 80µm resolution angulated anterior picture of CT LUCIA - haptic-optic transition

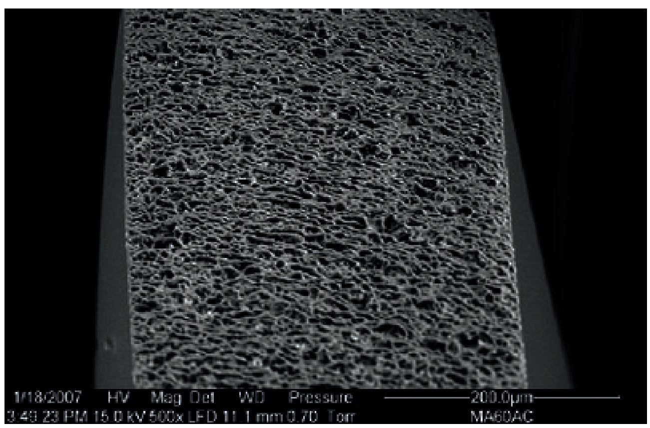


6. 80µm resolution side view picture of CT LUCIA 601P - IOL body

Competitive edge design – Alcon AcrySof®



Scan of Alcon AcrySof® (SN60AT) IOL [10]

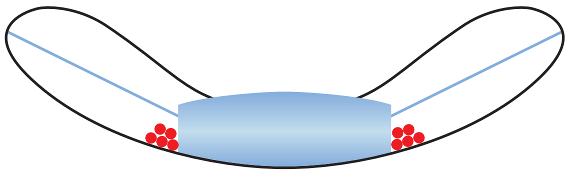


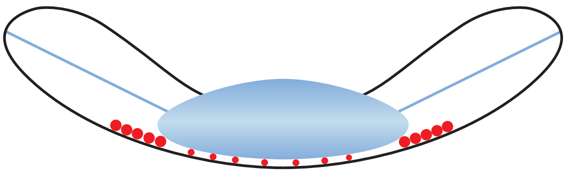
Scan of Alcon AcrySof® (MA60CT) [11]

PCO - Posterior Capsular Opacification:

Posterior capsular opacification (PCO) is the most frequent complication of cataract surgery. Advances in surgical techniques, intraocular lens (IOL) materials, and designs have reduced the PCO rate; however, it remains a significant problem resulting in suboptimal outcome of cataract surgery.[12]

Edge design comparison





* ZEISS CT LUCIA

Square Edge*
Square Edge **inhibits** the migration of lens epithelial cells (LEC)

"When a square-edged IOL is implanted, lens epithelial cells are blocked from migrating past the barrier, preventing PCO development." [13]

"The square edge of the optic can block the lens epithelial cells from growing across the posterior capsule. This effect has been well-demonstrated in hydrophobic acrylic, silicone and PMMA lenses." [14]

Round Edge
Round Edge **allows** the migration of lens epithelial cells (LEC)

"When a round-edged IOL is implanted, lens epithelial cells can migrate past the barrier, and onto the posterior capsule where they can proliferate, obscuring the patient's vision." [13]

Glistening Study

Definition

Acrylic foldable IOLs have grown in popularity due to stable clinical results and a low incidence of posterior capsular opacification. One concern of these lenses is the potential to form glistenings. As documented extensively in peer-reviewed literature, glistenings commonly occur in certain hydrophobic acrylic IOL materials, and clinical significance has been reported to range from none to a significant loss in visual acuity and contrast sensitivity.

Glistenings are fluid accumulation in the microvacuoles of the optic, which are likely caused by temperature changes rather than material changes. The AcrySof® lens material (Alcon, Fort Worth, Texas) is particularly susceptible to develop such glistenings. Incidence rates have been published ranging between 11% to 60%.[14]

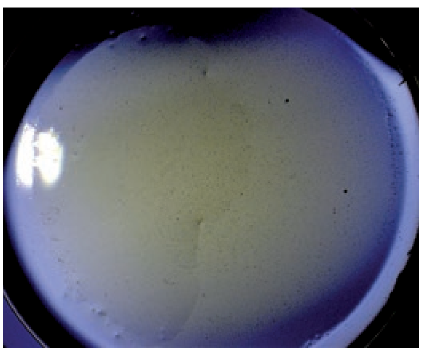
Controversy exists regarding the true impact of glistenings on functional vision. While some papers report that glistenings have no influence on visual functions[15], there are also reports that argue that glistenings lead to visual function deterioration[16], affect contrast sensitivity in particular at high spatial frequencies[17], generate more night vision disturbances[18], and in some extreme cases, explantations due to severe glistenings has been reported[18].

Method

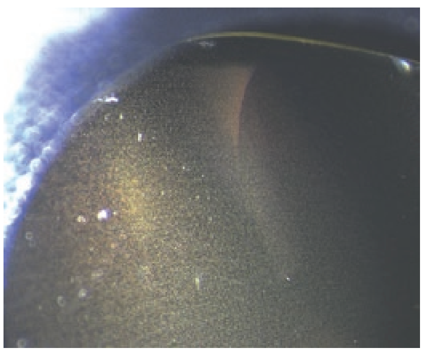
For the assessment of the glistening properties of IOL materials, a commonly employed method uses rapid temperature changes in order to provoke glistening formation (see for example Pagnoulle et al., JCRS 2012, 38:1271–1277). This was not the method of choice in the present investigation. Glistenings induced by rapid temperature fluctuations may be transient, and disappear again after a certain equilibration time at the target temperature. Hence this method (using temperature fluctuations) may not adequately reproduce the situation of long term implantation in the eye. Therefore, we chose to incubate the IOLs continuously at 35 °C in BSS, for a total period of two years, as a model of the situation in the eye. IOLs are stored in special lens holders and submerged fully in a Balanced Salt Solution (BSS). The samples are kept at 35°C in a water bath. The BSS solution is exchanged every four weeks. A total of 60 CT LUCIA 601PY IOLs are incubated, and a total of 20 AcrySof®IQ (SN60WF) IOLs.

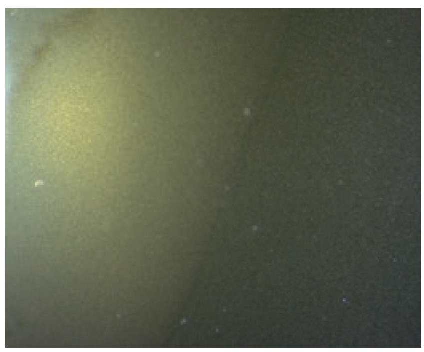
Glistenings are evaluated by a subjective observation method, using a slit lamp. Severity of Glistenings is graded as:
0: no glistenings, 1: 1 – 10 Glistenings per IOL, 2: 11 – 50, 3: 51 – 100, 4: more than 100

ZEISS CT LUCIA 601PY
No glistening after 24 months



AcrySof®IQ (SN60WF)
Increased glistening after 24 months





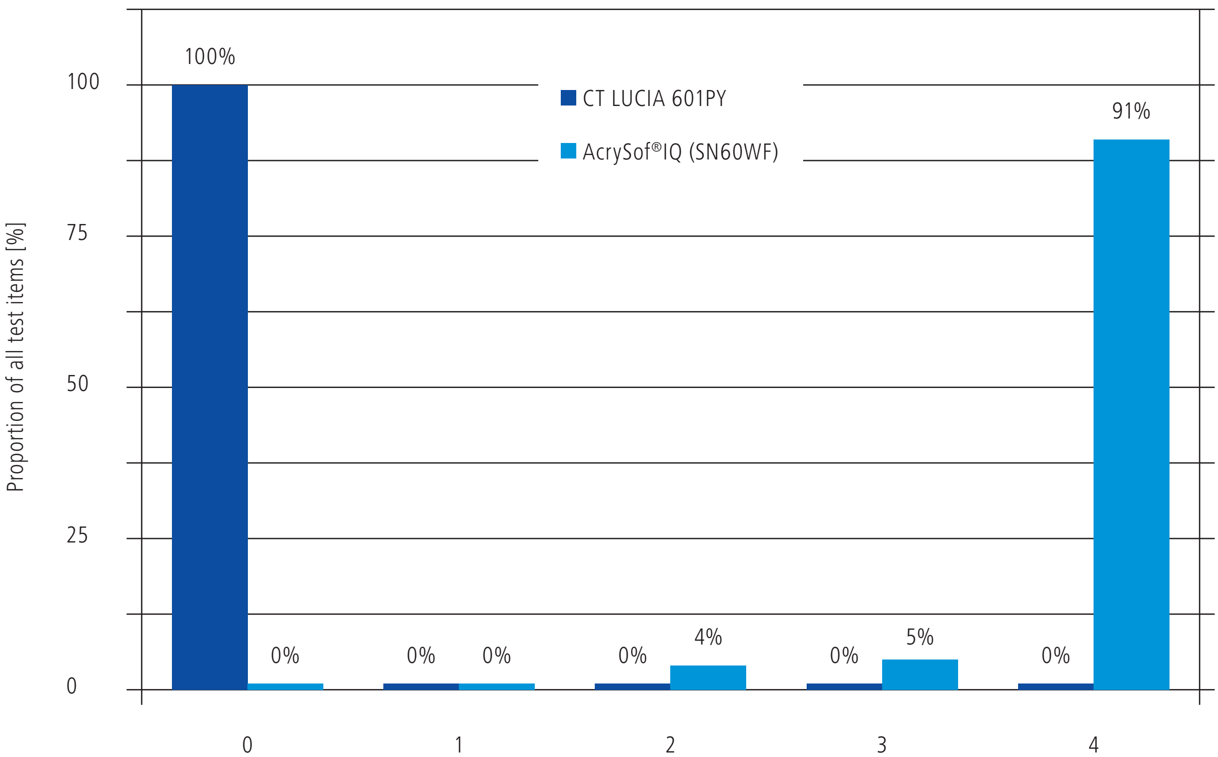
The following factors may influence the formation of glistening on IOL material: IOL manufacturing technique, IOL packaging / storage, Patient-associated conditions (leading to breakdown of the blood-aqueous barrier), ocular medications

Results

The results are extracted from an interim report of the observation after a total incubation time of twenty-four months.[19]

The ZEISS CT LUCIA showed no glistenings (Grade 0) over the entire duration of the subjective observation method, in comparison to AcrySoft®IQ, which developed a glistening severity of "4" in 91% of the observed cases. [19]

Results of Glistening study after 24 months



Glistening Grade

Conclusion

The ZEISS CT LUCIA has excellent no-glistening results thanks to its ultra-high purity hydrophobic acrylic and a proprietary cryo-lathing process.

When changing your IOL makes a big difference.

ZEISS CT LUCIA

References

[1] Bosc JM, Rosca G. Clinical results with the EC-1Y; satisfaction after 1 year. Powerpoint

[2] Trocme SD, Li H. Effect of heparin-surface-modified intraocular lenses on postoperative inflammation after phacoemulsification. Ophthalmology. 2000;107:1031-1037.

[3] Data on file, Review R&D injector testing, 2014

[4] J Cataract Refract Surg. 1997 Apr;23(3):440-6.Heparin eye drops to prevent posterior capsule opacification. Mastropasqua L1, Lobefalo L, Ciancaglini M, Ballone E, Gallenga PE.

[5] David J Apple International Laboratory for Ocular Pathology, International Vision Correction Research Centre (IVCRC), Department of Ophthalmology, University of Heidelberg, Chairman: G.U. Auffarth, MD, PhD, FEBO., Comparative evaluation regarding the implantation, unfolding and centration behavior of ZEISS CT LUCIA® vs. AcrySof®IQ, Heidelberg 2015. Study not published. Data on file.

[6] Video footage, CT LUCIA Study Results - The David J Apple International Laboratory for Ocular Pathology International Vision Correction Research Centre (IVCRC), Department of Ophthalmology, University of Heidelberg, Chairman: G.U. Auffarth, MD, PhD, FEBO. Study not published. Data on file.

[7] During the statistical evaluation of implantation times, comparing the ZEISS CT LUCIA and the AcrySof® (SN60WF), the ZEISS CT LUCIA performed with a total implantation time of 70 seconds versus the AcrySof® (SN60WF) with 90 seconds. The ZEISS CT LUCIA showed a faster centration after insertion in the capsular bag with less manipulation required, compared to AcrySof® (SN60WF). The measured implantation steps included: insertion, injection, unfolding and centration. Details of the evaluation can be viewed as part of the supporting research, carried out by the David J Apple International Laboratory for Ocular Pathology, International Vision Correction Research Centre (IVCRC), Department of Ophthalmology, University of Heidelberg, Chairman: G.U. Auffarth, MD, PhD, FEBO. Study not published. Data on file.

[8] Data on file

[9] Review of Ophthalmology, IOL Design Closes Off PCO, 01/2003

[10] EuroTimes,Vol 13, Issue 3, March 2008

[11] EuroTimes 2014, EMERGING MONOFOCAL INTRAOCULAR LENSES IN EUROPE, Page 6.

[12] Indian Journal of Ophthalmology, 2013 Jul; 61(7): 371–376.

[13] International Vision Correction Research Centre (IVCRC), The David J Apple International Laboratory for Ocular Pathology, Department of Ophthalmology, University of Heidelberg, Chairman: G.U. Auffarth, MD, PhD, FEBO, Instructional course on the use of the CT LUCIA Family, ESCRS 2015

[14] Eye World 2011, EW Supplement: Customizing cataract and corneal refractive surgery, Identifying the best acrylic IOL materials and assessing the visual significance of glistening, by William Trattler, M.D.

[15] Chang A, Kugelberg M. Glistenings 9 years after phacoemulsification in hydrophobic and hydrophilic acrylic intraocular lenses. J Cataract Refract Surg. 2015 Jun;41(6):1199-204. doi: 10.1016/j.jcrs.2014.09.038. Epub 2015 Jun 19.

[16] Henriksen BS, Kinard K1, Olson RJ. Effect of intraocular lens glistening size on visual quality. J Cataract Refract Surg. 2015 Jun;41(6):1190-8. doi: 10.1016/j.jcrs.2014.09.051.

[17] Christiansen G, Durcan FJ, Olson RJ, Christiansen K. Glistenings in the AcrySof intraocular lens: pilot study. J Cataract Refract Surg 2001; 27: 728–733

[18] Rullo J, C Lloyd J. Clinically significant deterioration in the quality of vision as a result of subsurface nanoglistenings in a hydrophobic acrylic intraocular lens. J Cataract Refract Surg. 2014 Feb;40(2):336-7. doi: 10.1016/j.jcrs.2013.12.010.

[19] Data on file

CE 0297

CT LUCIA 601P / 601PY
CT LUCIA 201P

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