Study Spotlight: ZEISS CT LUCIA 611P/PY multicenter U.S. clinical trial

Seeing beyond

FDA approval study shows excellent predictability, stability, and visual performance of ZEISS CT LUCIA 611P

Source

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

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Methodology

- Prospective, multicenter, single-arm clinical trial, FDA approval study
- Surgeries were performed at 15 surgical sites across the United States
- Postoperative examination was conducted up to 1-year after surgery
- Used key metrics: e.g., UDVA, CDVA, manifest refraction, PCO, slitlamp examination, Goldmann tonometry, IOL tilt and decentration, IOL glistening and anterior chamber depth (ACD)

Sample Size

339 eyes of 339 patients were implanted of which 310 reached the 12-month visit

Results

The clinical trial demonstrates "…excellent refractive predictability, stability, and visual performance".

Visual Acuity Outcomes

The mean CDVA of patients who attended all postoperative visits was **-0.02 ± 0.09 logMAR at 12 months**, while **33.9%** of patients achieved **CDVA 20/16 or better**.

Prediction Error and Stability

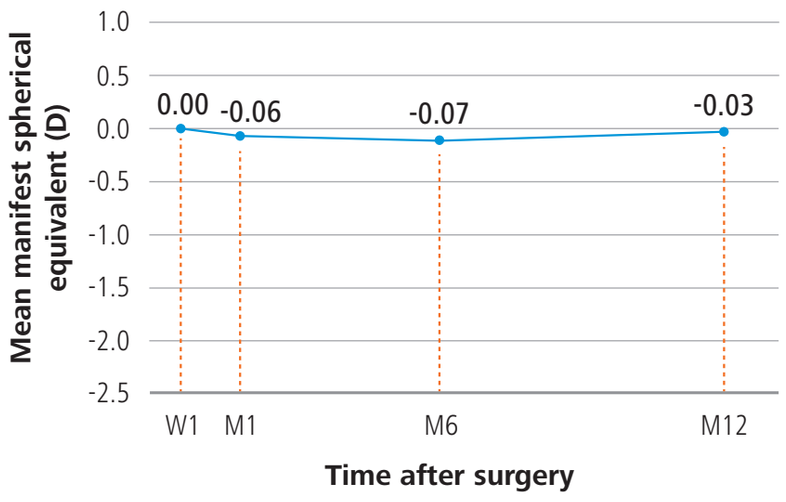
85.8% of eyes achieved a manifest refraction spherical equivalent (MRSE) within ±0.5 D. The CT LUCIA 611P exhibited **excellent refractive stability** in the first post-operative year with insignificant changes in the MRSE.

IOL Material Quality

No finding of glistenings at any visit during the 12 month follow up. The overall rate of Nd:YAG capsulotomy for every implanted subject was 3.25% (11/339)*.

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

Consistent cohort | n = 308 eyes



The study outcomes of CT LUCIA 611P/PY are also applicable to CT LUCIA 621P/PY as both IOLs share the same hydrophobic acrylic material and a very similar optic and haptic design. *4 additional patients were diagnosed with clinically significant PCO, likely to require Nd:YAG capsulotomy.