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



Authors

Steven C. Schallhorn, MD, Michael Bonilla, Seth M. Pantanelli, MD, MS



Publication

Journal of Cataract & Refactive Surgery: October, 2022

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

