Evaluation of Visual Outcomes and Surgeon Satisfaction with Modified Single-Piece Acrylic Toric Intraocular Lens

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Study Design

Purpose	The purpose of this post-market clinical study is to obtain surgeon feedback on the clinical outcomes achieved in eyes implanted with the TECNIS Toric II IOL.
Study Design	Prospective, multicenter, single-arm study, open-label, post-market clinical study, 8 sites (US)
Study Lens	TECNIS Toric II IOL (Model ZCU 150 to 600)
Subjects	32 subjects were treated bilaterally, and 22 subjects were treated unilaterally, total of 86 eyes

Study Questionnaires

Surgeon Confidence

Controlling IOL Position

Surgeon Satisfaction

IOL Rotational Stability

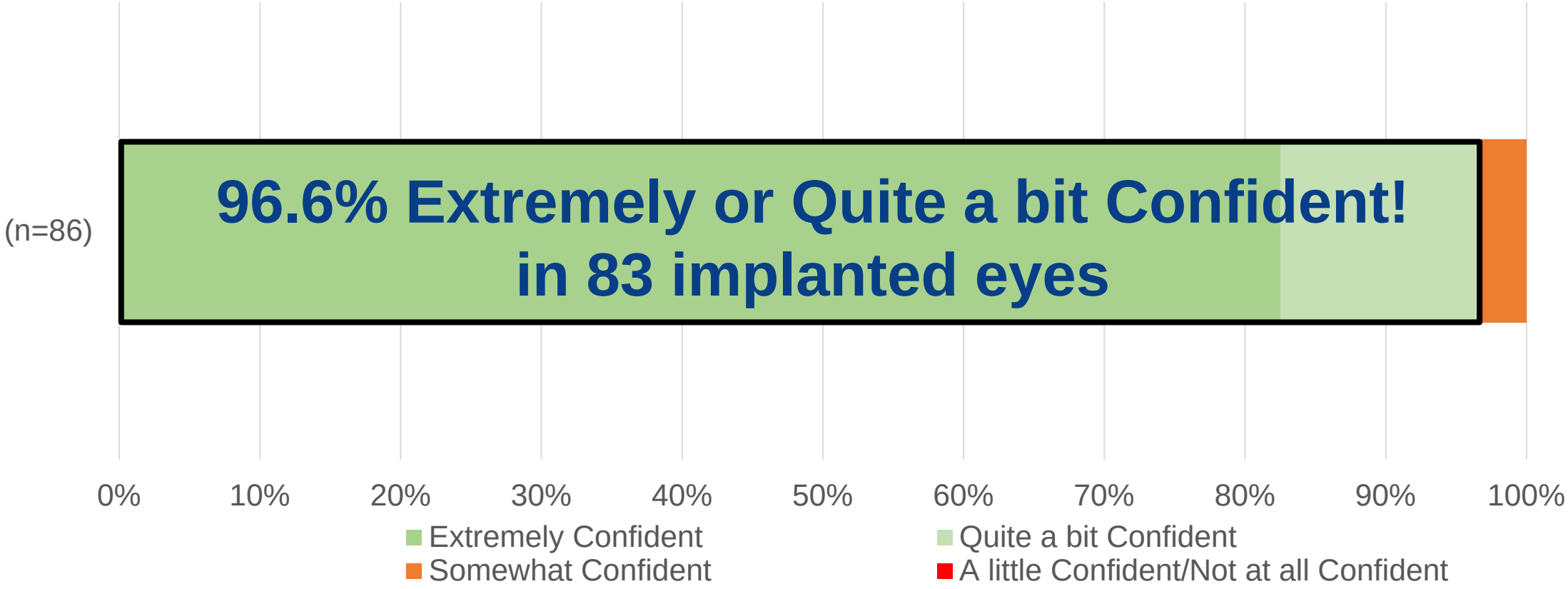
Uncorrected Distance Visual Acuity

Overall Clinical Outcomes

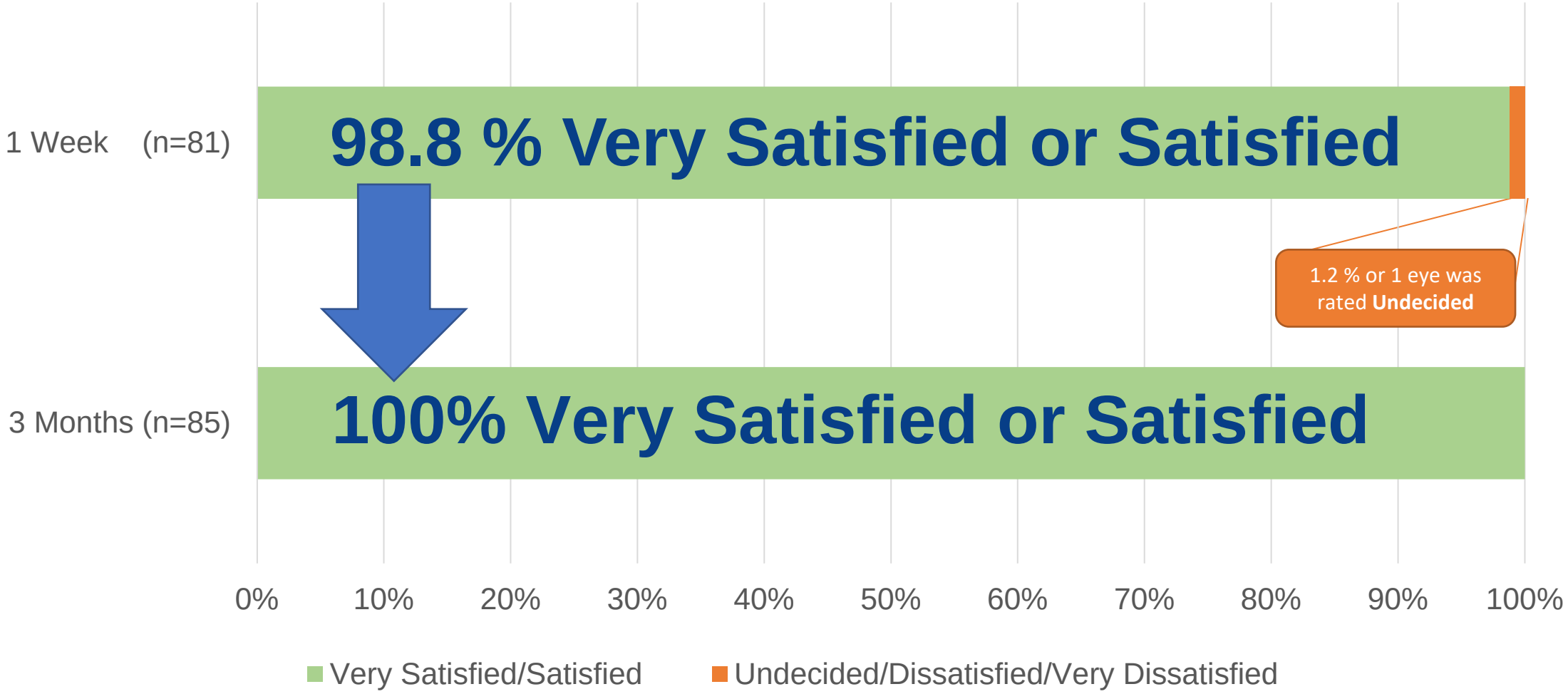
Surgeon IOL Preference

Rotational Stability of study IOL v. preferred IOL prior to the study

Surgeon Confidence in controlling IOL position in Implanted Eyes



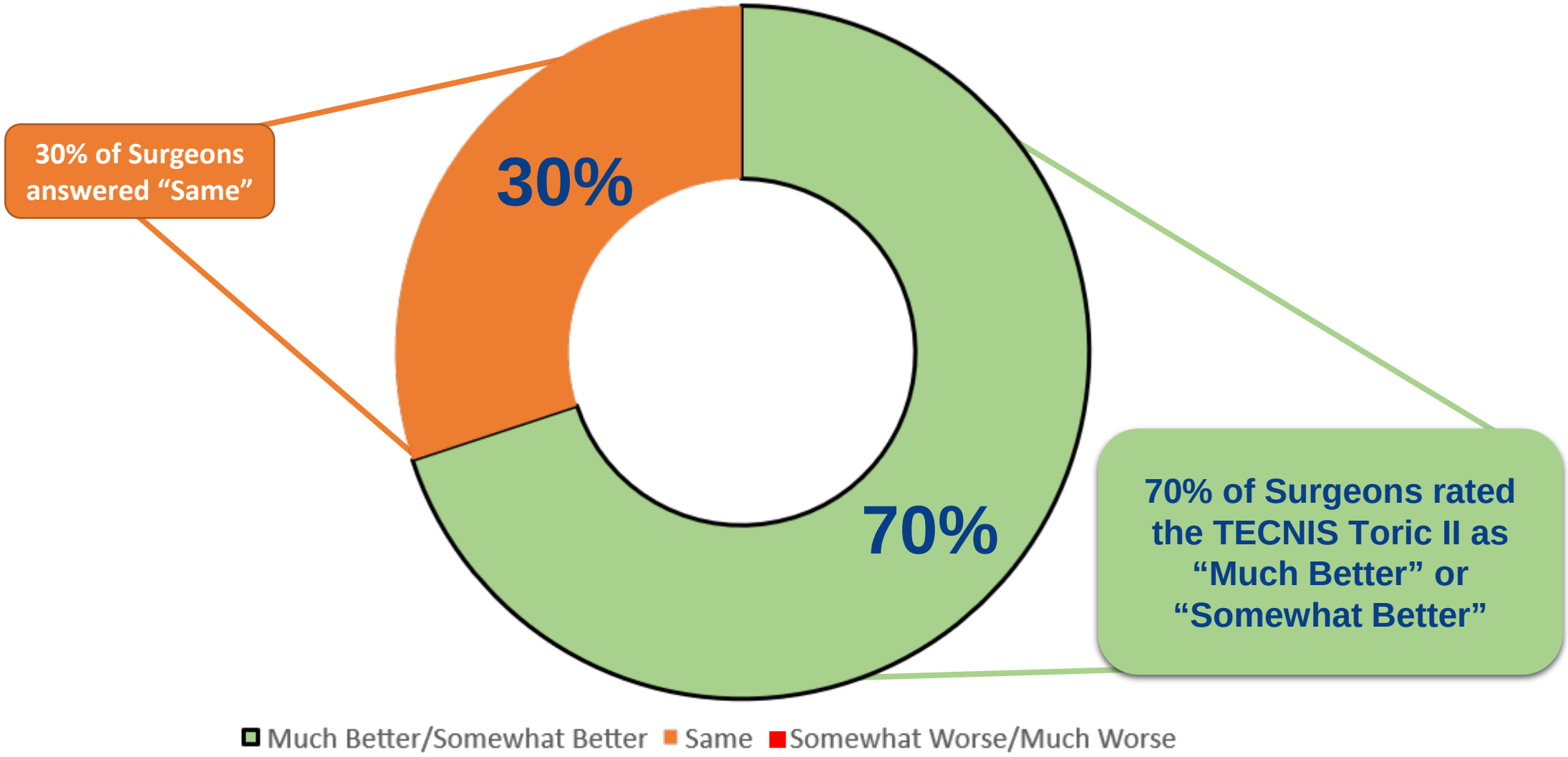
Surgeon Satisfaction of Rotational Stability in Implanted Eyes



Surgeon Satisfaction of Uncorrected Distance Visual Acuity in Implanted Eyes

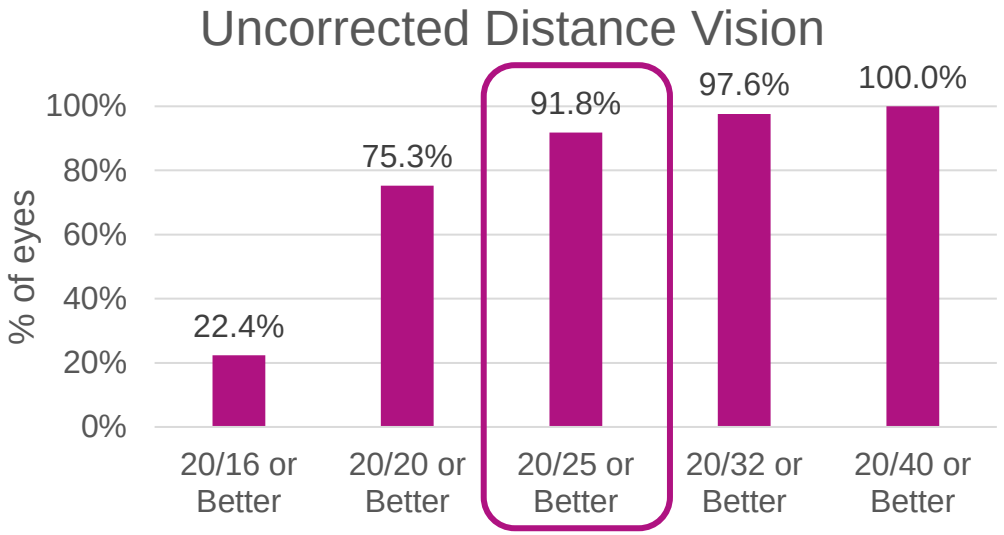
Surgeon Satisfaction of Overall Clinical Outcomes in Implanted Eyes

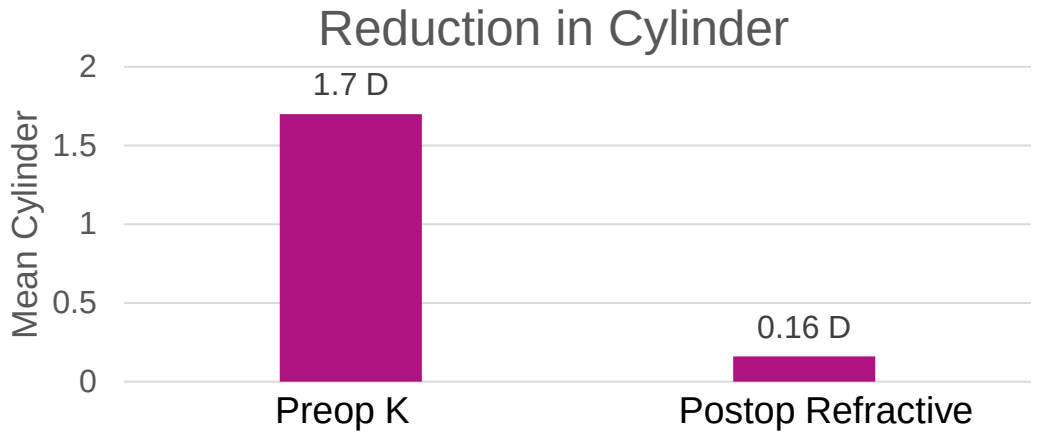
Rotational Stability of the study lens compared to the Surgeons' preferred monofocal toric IOL prior to study



(n = 10)

Visual Acuity & Refraction





91.8% of implanted eyes achieved 20/25 or better

- Mean UCDVA at 3 Months
  - 0.01 ± 0.09 logMAR
  - 20/20 Snellen Acuity
- Mean manifest refractive spherical equivalent is -0.23 D ± 0.41 D
- Mean difference between planned vs. manifest spherical equivalent refraction is 0.10 D ± 0.44 D

Conclusions

- Eyes implanted with the TECNIS Toric II IOL demonstrate high levels of:
  - Surgeon confidence in controlling the lens position.
  - Surgeon satisfaction with rotational stability, uncorrected visual acuity and overall clinical outcomes.
- Eyes implanted with the TECNIS Toric II IOL with the ***squared and frosted haptics design*** demonstrate low residual refractive astigmatism and excellent uncorrected vision.