



# Clinical Investigation of the Rotational Stability of a Modified Single-Piece Acrylic Toric Intraocular Lens

Kevin M. Miller, MD

Srividhya Vilupuru, OD, PhD; Cameron Sefton, OD, MS; Wuchen Zhao, MS; Devi Priya Janakiraman, OD, FAAO

***Financial Disclosures:***

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# Introduction

**TECNIS Toric Monofocal IOL**



**TECNIS Toric II Monofocal IOL**



- The haptics of the TECNIS® Toric II IOL are squared and frosted to provide greater friction within the capsular bag and improved rotational stability.
- The new haptics demonstrated improved rotational stability in comparison to the original haptic design in a Proof of Concept (POC) study.

# TECNIS® TORIC II Intraocular Lens

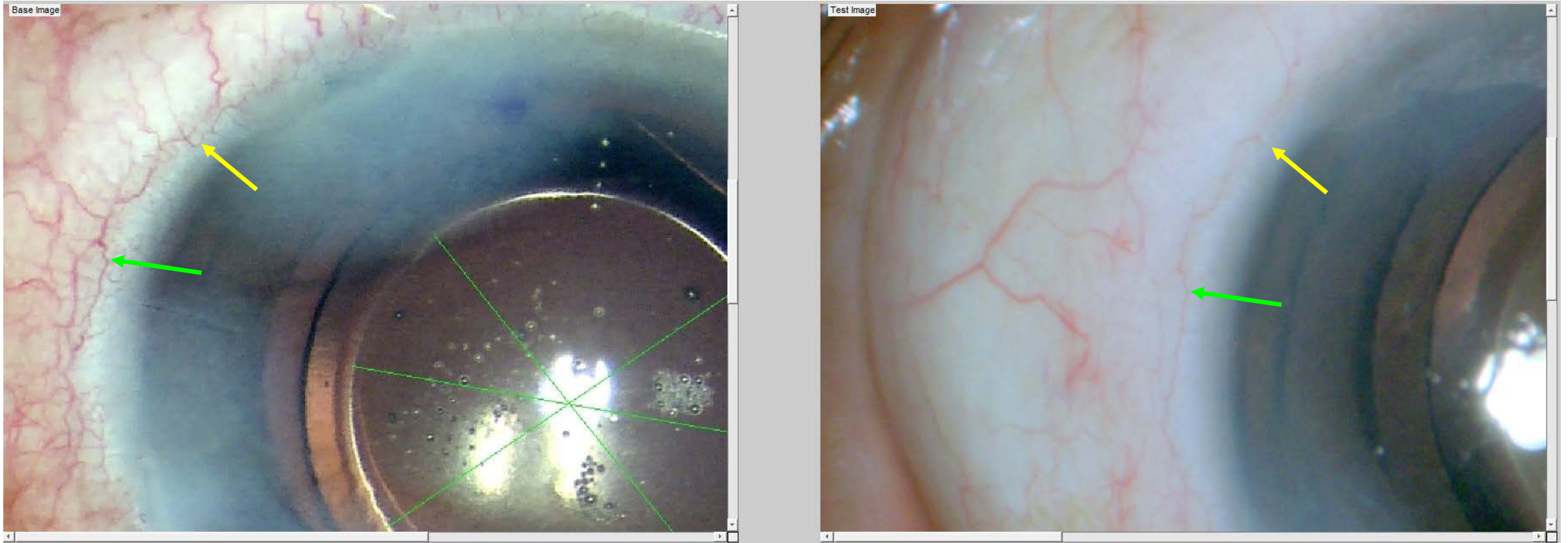
<b>Purpose</b>	To evaluate the rotational stability of the TECNIS Toric II IOL by comparing the absolute change in toric axis orientation from the conclusion of surgery to several postoperative visits using a photographic method
<b>Study Design</b>	<ul style="list-style-type: none"><li>• Prospective, multicenter, single-arm, open-label clinical study</li><li>• 8 sites (USA)</li></ul>
<b>Study Lens</b>	TECNIS Toric II IOL, (Models ZCU 1.50 D to 6.0 D)
<b>Subjects</b>	<ul style="list-style-type: none"><li>• 106 subjects were implanted with the study lens in at least 1 eye</li><li>• 73 subjects were treated bilaterally; 43 subjects were treated unilaterally (total of <b>189 eyes</b>)</li></ul>
<b>Key Study Endpoints</b>	<ul style="list-style-type: none"><li>• Absolute IOL rotation in degrees</li><li>• Percentage of eyes with <math>\leq 5^\circ</math> rotation</li><li>• Uncorrected distance visual acuity (UDVA)</li><li>• Postoperative manifest refraction</li><li>• Residual postoperative manifest refractive cylinder</li></ul>

TECNIS Toric II Monofocal IOL



# IOL Rotation Measurement

*Analysis of lens rotation between Operative and Postoperative photos*

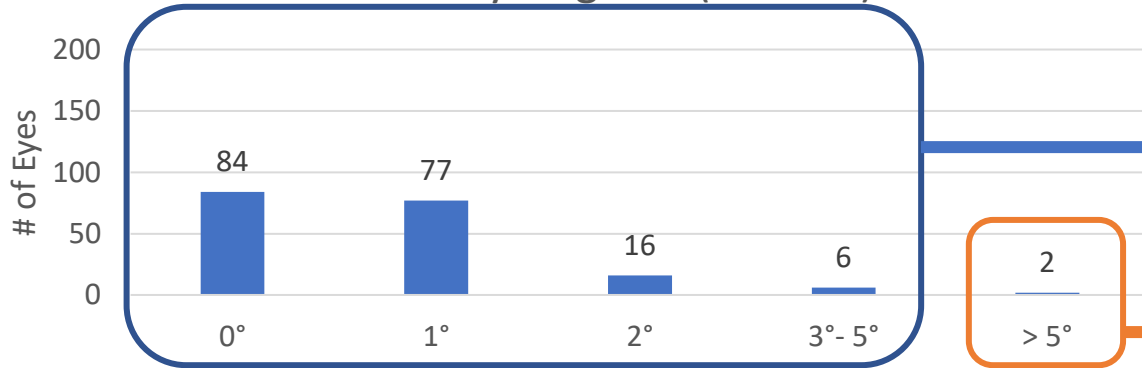


- Two Independent analysts determined IOL rotation using custom image analysis software.
- IOL axis orientation was compared between intraoperative and postoperative photos utilizing limbal and iris landmarks.

# Absolute IOL Rotation

1 Day

Lens Rotation by Degrees (n = 185)



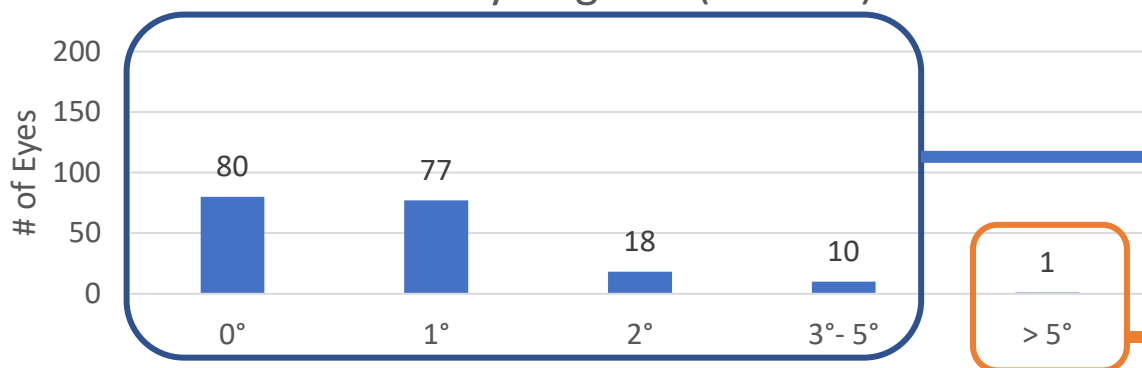
Mean absolute rotation:  $0.83^\circ \pm 1.01^\circ$

**183 eyes or 98.9% of eyes rotated  $\leq 5^\circ$**

Absolute IOL Rotation for these 2 eyes were  $5.7^\circ$  and  $8.3^\circ$

1 Week

Lens Rotation by Degrees (n = 186)



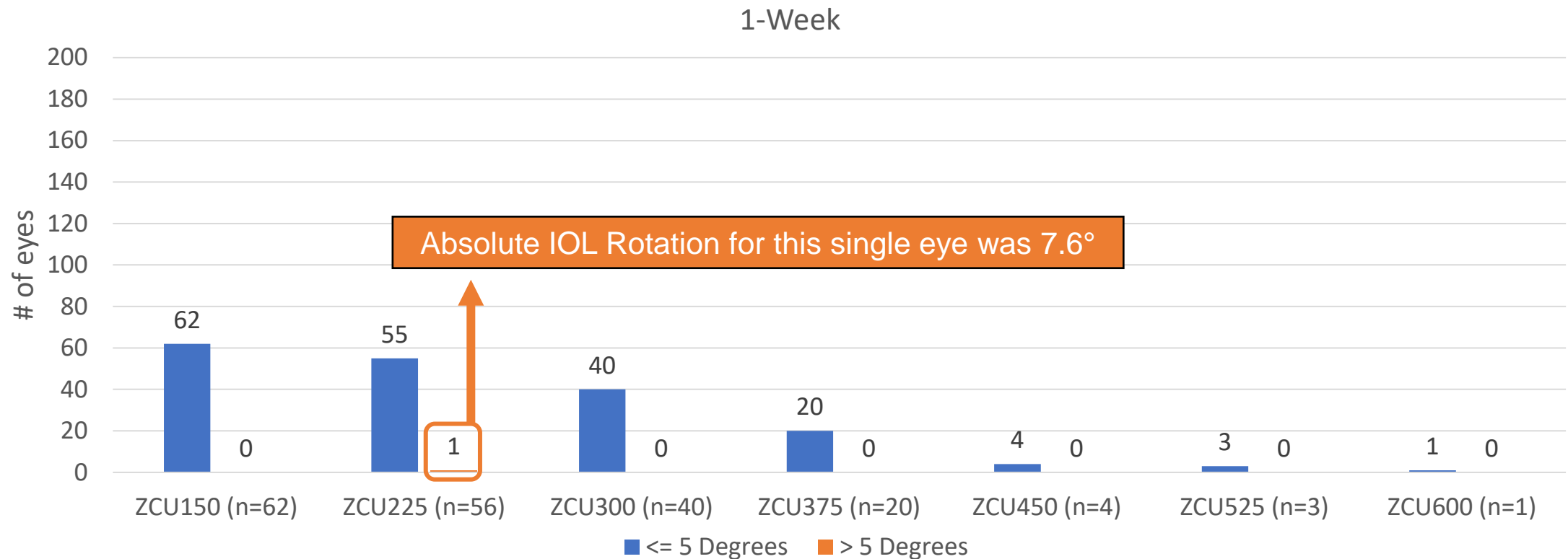
Mean absolute rotation:  $0.85^\circ \pm 0.93^\circ$

**185 eyes or 99.5% of eyes rotated  $\leq 5^\circ$**

Absolute IOL Rotation for this single eye was  $7.6^\circ$  (One eye reduced from  $5.7^\circ$  at 1-day to  $4.9^\circ$  at 1-week)

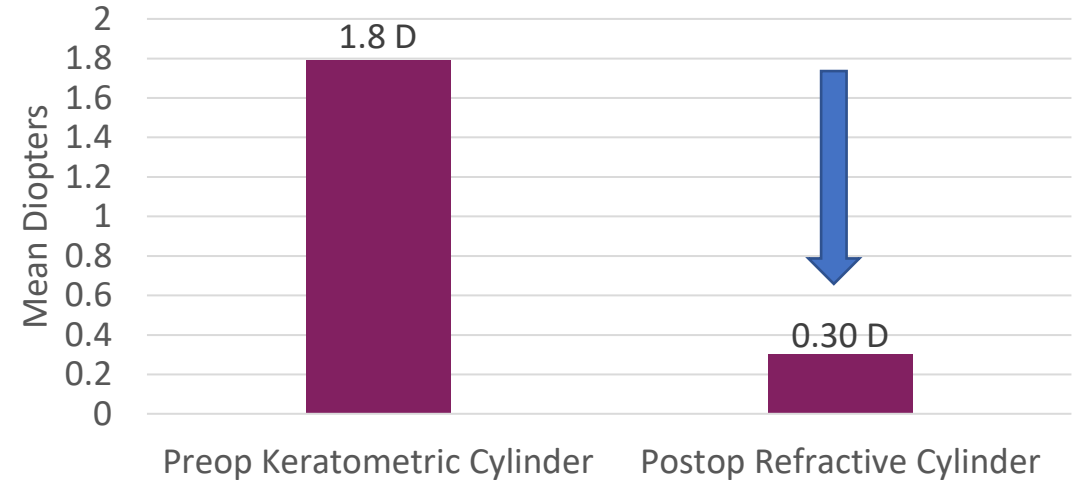
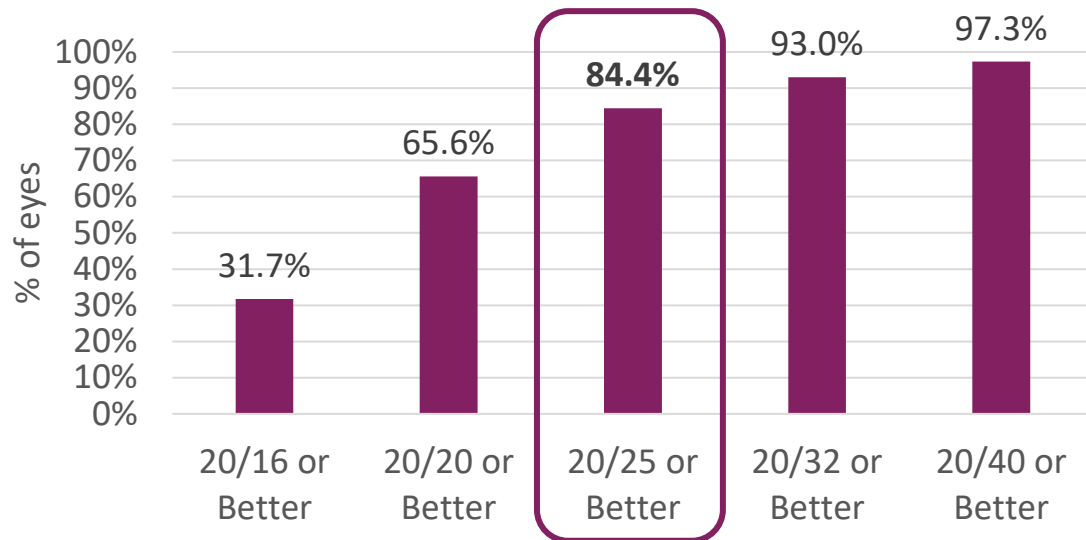
# IOL Rotation by Model

- Postoperative rotation of  $10^\circ$  results in residual astigmatism increasing by  $\sim 1/3$ rd of the correcting cylinder power<sup>1</sup>
  - e.g.,  $10^\circ$  rotation of a 3.0 D toric IOL will result in  $\sim 1$ D of residual astigmatism
- At the 1-week visit, 1 eye implanted with model ZCU 2.25 rotated by  $7.6^\circ$ .



<sup>1</sup>Till JS, Yoder PR, Wilcox TK, Spielman JL. Toric intraocular lens implantation: 100 consecutive cases. *Journal of Cataract & Refractive Surgery*. 2002;28(2):295-301.

# Uncorrected Distance Visual Acuity & Refraction



- Mean UDVA at 1 Week was  $0.03 \pm 0.14$  logMAR (~20/20 Snellen acuity).
- Mean manifest refraction spherical equivalent (MRSE) was  $-0.24 \text{ D} \pm 0.45 \text{ D}$ .
- Mean difference between target and achieved postoperative MRSE was  $-0.04 \text{ D} \pm 0.44 \text{ D}$ .

# Conclusions

- TECNIS Toric II platform delivers excellent rotational stability over the full dioptric range (ZCU150 to ZCU600).
- Eyes implanted with the TECNIS Toric II IOL demonstrated minimal rotation, low residual refractive astigmatism, and excellent UDVA.