# CLINICAL INVESTIGATION OF ROTATIONAL STABILITY OF THE TECNIS™ TORIC II INTRAOCULAR LENS

## OBJECTIVE

To evaluate the rotational stability of the **TECNIS™** Toric II Intraocular Lens.

## STUDY DESIGN

IOL rotation was assessed in this study with a novel measurement method. Two independent analysts assessed rotational stability by measuring axis misalignment, which is defined as an absolute difference between intended IOL axis of orientation (immediately at the end of the surgery) and follow-up visit(s) by a custom-developed and validated photographic based method.

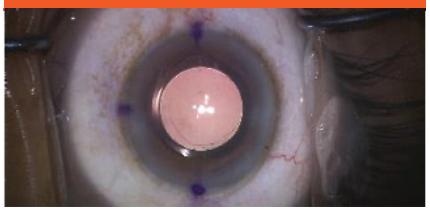
## PROTOCOL OVERVIEW

| | |
|---|---|
| TREATMENTS | **TECNIS™** Toric II IOL (Models ZCU 150, 225, 300, 375, 450, 525, 600) |
| OBJECTIVE | To evaluate the rotational stability of the **TECNIS™** Toric II IOL in approximately 200 eyes. |
| CLINICAL HYPOTHESIS | **TECNIS™** Toric II IOL will demonstrate ≤ 5° change from the intended IOL axis (immediately postop) in 90% of eyes with preoperative corneal astigmatism at 1-week postoperative |
| STRUCTURE | Prospective, multicenter, single-arm, open-label |
| DURATION | Follow-ups at 1 day, 1 week and 3 months post-op |

## Novel Rotation Measurement Method

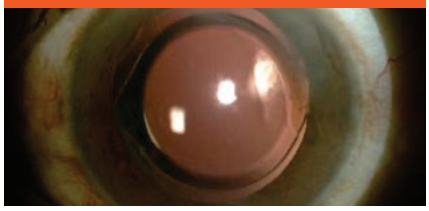
**Surgical visit**

Digital photography through surgical microscope of lens in final position

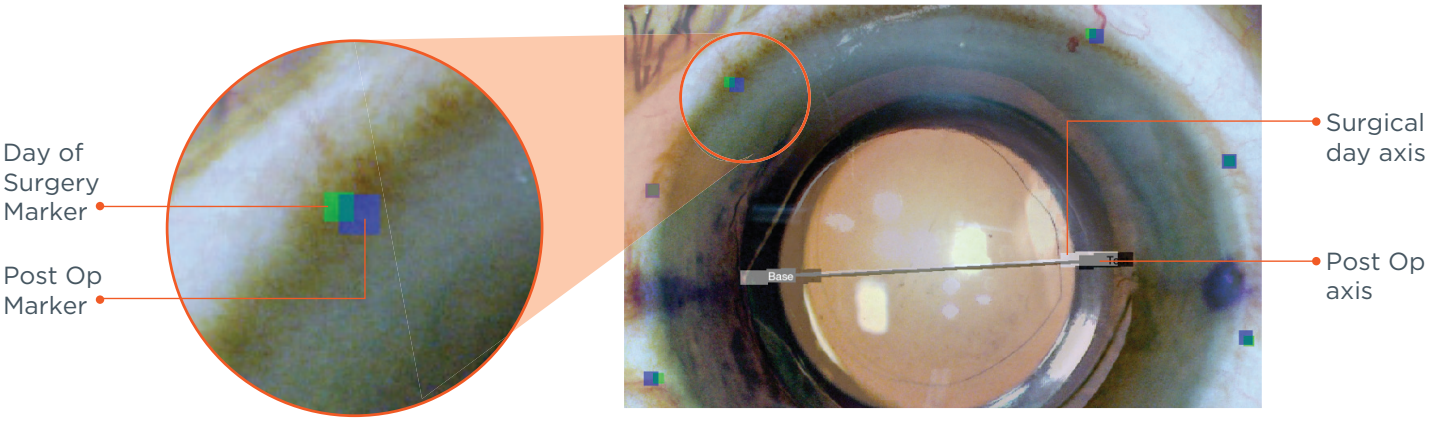


**Postoperative visits (1D, 1W, 3M)**

Digital photography of lens including axis markings through slit lamp



1. Photographs taken on the day of surgery and at post-op visits (1 day, 1 week, 3 months).
2. Day of operation and post-op photographs overlaid by manual selection of matching scleral vessel and iris details
3. Change in axis between surgical visit and post-op visit measured to assess any IOL rotation



## RESULTS

### IOL Rotation by Degree at 3-Months Using Photographic Method

Proportion Within 5 Degrees | Absolute Axis Difference (Postop Minus Op)
All Toric II Eyes with Valid Axis Data

| Category | n | % |
|---|---|---|
| **<= 5 Degrees** | 185 | 100 |
| **> 5 Degrees** | 0 | 0 |
| **TOTAL** | **185** | **100** |

Values rounded to the nearest degree prior to placing in the category.
Used the absolute value of the averaged data of signed delta for the two analysts.
Only includes eyes with data for both analysts and where differences between analysts were not greater than 3 degrees.

## CONCLUSION

### TECNIS™ Toric II Platform Delivers Exceptional Rotational Stability[1]

**100%**
**of surgeries had**
**≤ 5 DEGREES**
**rotation at 3-months[1]**

**Mean rotation of TECNIS™ Toric II was**
**0.94° ± 0.712°**
**at 3-months[1]**

[1] Based on data from 200 eyes after 3 months post-operative follow-up in a post-market prospective, multicenter, single-arm, open-label study in the U.S. Outcomes differ from the pivotal investigation data in the product labeling and was collected using different measurement methods, study design and clinical conditions.

**REFERENCE:** DOF2021CT4019. - Clinical Investigation of Rotational Stability of the **TECNIS™** Toric II IOL - Steele Study - NXGT-202-QROS. 20 Aug. 2021.

For healthcare professionals only. Please reference the Instructions for Use for a complete list of Indications and Important Safety Information and contact our specialists in case of any question.

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