INTERNATIONAL COUNCIL of OPHTHALMOLOGY

International Council of Ophthalmology
World Ophthalmology Congress
16-19 August, 2024, Vancouver, Canada

A Study to Evaluate the Effect of Intraocular Lens Centration and Tilt on Visual Performance

A. Chokshi[1], R. Shetty [1], H. Schaffner[2], H. Keeton[2], Dontia Orey[1], K. Freidl[1], S.A. Hasan[1], R. Browning[1], O. Gayasaddin[1], M. Lott[1], R. F. Goldfaden [2]

[1]Florida Eye Specialists, Jacksonville, FL, United States
[2]East Coast Institute for Research, Jacksonville, FL, United States

P-CAT-046

INTRODUCTION

Clareon® Vivity®, intraocular lenses (IOLs) feature a hydrophobic acrylic biomaterial and smooth surface that contribute to improved optical lens clarity. Clareon® IOLs illustrated excellent mechanical stability, however no studies have been performed assessing the effects of decentration and tilt of the Clareon® Vivity® and Vivity® Toric lenses on visual outcomes.

Clareon® IOLs have demonstrated excellent mechanical stability. This study was designed to assess the Clareon® family of IOLs, specifically the EDOF lenses known as Vivity and Vivity Toric. Two key parameters measured in this study include decentration and tilt (measured by Tomey Corporation's CASIA2 AS-OCT) and their impact on visual outcomes.

AIM

To evaluate decentration and tilt following Clareon® Vivity®/Clareon® Vivity® Toric IOL implantation and determine their impact on visual performance

METHODS

This was a non-interventional, single center, multi-surgeon, observational study. The study population included adults with cataracts who have undergone bilateral implantation of Clareon® Vivity® or Clareon® Vivity® Toric IOLs (Alcon). Preoperative and operative implantation data were collected through retrospective chart review of 100 implanted individuals (200 eyes). Pre-operative and postoperative (at least one-month post-operation) assessments occurred via examination. Lens decentration and tilt were measured with the CASIA2 AS-OCT (Tomey Corporation).

ELIGIBILITY CRITERIA

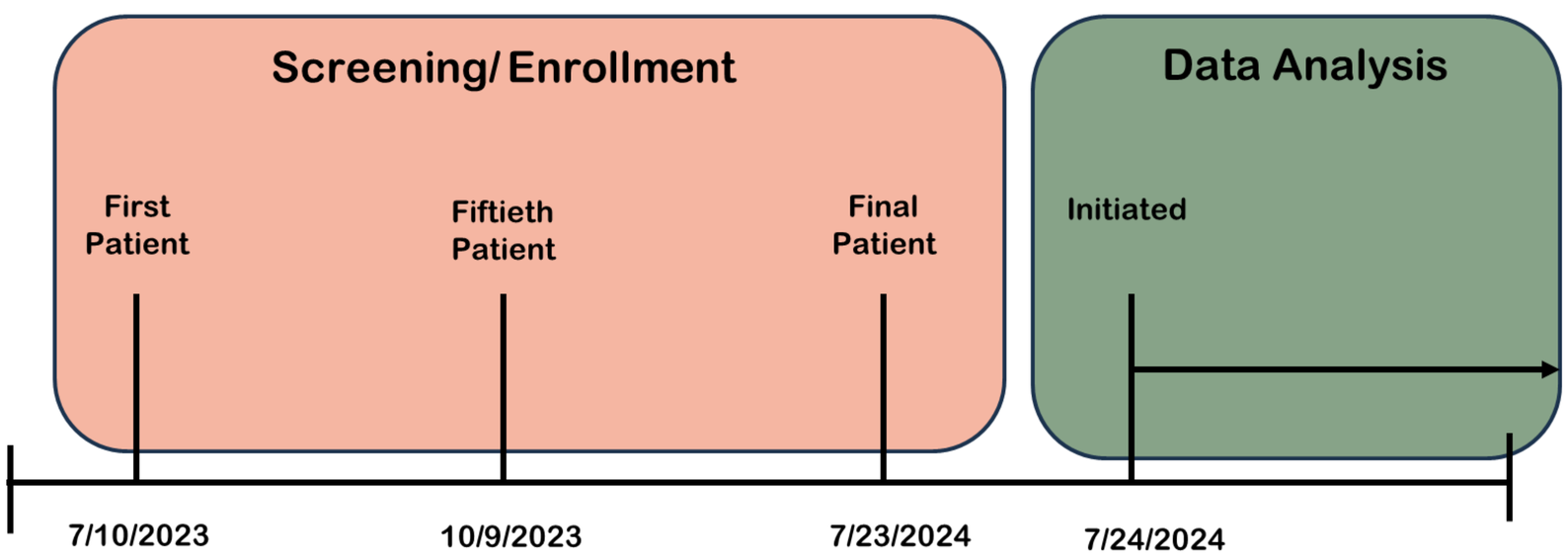
INCLUSION

1. Age ≥ 18 years
2. History of adult cataract and uneventful, refractive cataract surgery with Clareon® Vivity® or Vivity® Toric IOL implantation with MRSE within ±1.00 D
3. Willing to undergo an eye exam with pupil dilation

EXCLUSION

1. Moderate to severe posterior capsule opacification (2+ or more)
2. Yttrium aluminum garnet (YAG) laser capsulotomy within 1 month prior to enrollment
3. Laser-assisted in situ keratomileusis (LASIK) or photorefractive keratectomy (PRK) within the one year prior to IOL implantation or any time after IOL implantation
4. Any previous ocular surgery (excluding YAG, LASIK, PRK)
5. Clinically significant ocular pathology; severe diabetic retinopathy, age-related macular degeneration (AMD), glaucoma, severe dry eye, irregular astigmatism, zonular weakness, pseudoexfoliation, ocular trauma
6. Any additional procedure(s) at the same time as the Vivity implantation including but not limited to microinvasive glaucoma surgery (MIGS)
7. Women who are pregnant at the time of screening (based on self-reported history)
8. Medical or other problems which in the opinion of the investigator will render study participation unsafe

STUDY TIMELINE



ENDPOINTS

PRIMARY

- Monocular BCDVA (4m) (logMAR)

SECONDARY

- Decentration of IOL (mm)
- Tilt of IOL (º)
- Monocular UCDVA (4m) (logMAR)
- Monocular DCIVA (66cm) (logMAR)
- Monocular UCIVA (66cm) (logMAR)
- Manifest refraction/MRSE (D)

EXPLORATORY

- Mean Photopic low contrast (25%) monocular BDCVA (4m) (logMAR)
- Mesopic pupil size (mm)
- HOAs (coma and spherical) of the cornea (µm)

ANALYSIS PLAN

Study exploration: Unadjusted associations between exposures and outcomes of interest. Adjusted associations between exposures and outcomes of interest, in each case following a similar approach

Sample size considerations: based on primary outcome distance-corrected visual acuity (BCDVA)

Sample size justification:

- Two-sided $\alpha<0.05$
- ≥87% power for 200 eyes provide to detect a population effect size of 5 letters (0.1 in logMAR scale) per 1° change in tilt and 4 letters (0.08 in logMAR scale) per 0.1 mm variation in decentration.
- Primary modelling strategy: multiple linear regression with post-op BCDVA (continuous variable) as the dependent or outcome variable and tilt and decentration as the independent variables of interest.

CONCLUSIONS

Current Status: Enrollment was completed on July 23, 2024. Data analysis is underway.

CONTACTS

Rebecca Goldfaden, PharmD, CCRP
E: rg@eastcoastresearch.net

Rajesh Shetty, MD
E: drrshetty1@gmail.com