Retrospective Chart Review of enVista Toric 0.9D Intraocular Lenses

Retrospective Chart Review

Protocol: BHC-RCR-001

Version: v.2.0

Date: 13-Jan-2022

Study Sponsor
Bausch Health
400 Somerset Corporate Blvd.
Bridgewater, New Jersey 08807

Clinical Research Organization
ethica CRO Inc.
3551 St. Charles Blvd, Suite 501
Kirkland, Quebec H9H 3C4

1 PROTOCOL APPROVAL SIGNATURE PAGE

The following individuals approve this version of Protocol BHC-RCR-001. All changes to this version of the protocol must have a prior written approval and require an amendment or administrative letter.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

2 INVESTIGATOR SIGNATURE PAGE

I agree to:

- Implement and conduct this study diligently and in strict compliance with the protocol, good clinical practices and all applicable laws and regulations.
- Maintain all information supplied by Bausch Health in confidence and, when this information is submitted to an Institutional Review Board (IRB) or another group, it will be submitted with a designation that the material is confidential.

I have read this protocol in its entirety and I agree to all aspects.

Principal Investigator *(Printed Name)*	Signature	Date

3 TABLE OF CONTENTS

4 Background and Study Rationale

Mild amounts of corneal astigmatism are often corrected at the time of cataract surgery with limbal relaxing incisions (LRIs), on-axis incisions or with low-cylinder powered toric IOLs. Leon P. et. al has shown that results from LRIs and toric IOLs significantly decreased refractive astigmatism, but Toric IOLs were more effective and predictable when compared to LRIs. One IOL available in Canada for the correction of mild corneal astigmatism is the enVista Toric IOL. The lowest available cylinder power for enVista Toric IOL is 0.9D. The goal of this retrospective study is to gain a better understanding of the postoperative outcomes in patients implanted with a low-cylinder powered toric IOL (enVista Toric 0.9D) vs non-toric IOLs (enVista).

5 Study Objectives

The primary objective of this study is to evaluate the performance of the enVista Toric 0.9D vs the enVista non-Toric IOL.

6 Study Design and Methods

6.1 General Study Design

The performance of the enVista Toric IOL will be compared with that of the enVista non-Toric (spherical) IOL. At least 384 eyes (n= 192 per lens type) from 3-4 Canadian centers will be investigated.

This is a retrospective chart review for preoperative and postoperative data conducted at least 4 weeks after IOL implantation.

6.1.1 Total Number of Subjects

The study will enroll at least 384 eyes presenting with at least 192 enVista Toric 0.9D IOLs and 192 enVista non-Toric (spherical) IOLs.

It is expected that the medical records of approximately 600 subjects will need to be evaluated in order to identify the required 384 eyes that are eligible for inclusion in this study.

6.2 Study Population

6.2.1 Inclusion Criteria

- Males and Females subjects age 18 or older on the date of the surgery
- Implant of enVista 0.9D Toric IOL or enVista non-Toric (spherical) IOL in at least one eye
- Data available at least 4 weeks after IOL implantation
- Eyes must qualify for the 0.9D toric lens based on the Barrett Toric Calculator (flipped axis must be less than 0.2D) (https://ascrs.org/tools/barrett-toric-calculator)
    - Study eyes were implanted with the 0.9D toric lens
    - Control eyes were not implanted with the 0.9D toric lens and implanted with a spherical (non-toric) equivalent instead

6.2.2 Exclusion Criteria

- History of uncontrolled or clinically significant ocular comorbidities for the treated eye(s) before the surgery (e.g., dry eyes, retinal pathology, etc.)
- BCDVA of 20/25 or worse for the treated eye(s) after the surgery
- Excessive IOL rotation > 10 degrees (Toric IOLs only) for the treated eye(s) after the surgery

7 Study Procedures

7.1 Date Range of the study

Cases will be included in the study if they received an initial enVista IOL on or after 01-Sep-2018.

7.2 Subject Selection

Eligibility will be determined and confirmed at each site by the site Investigator.

7.3 Data Sources

Sources of data include paper medical records and/or EMR systems. Such medical records and systems will be used in order to identify participants who match study defined eligibility criteria.

7.4 Variable Abstraction

The following clinical endpoints to be collected from subject's medical records:

- Subject Demographics and Medical History
  - Include lens calculation data: IOL power selected, predicted residual spherical equivalent refraction, surgically induced astigmatism (SIA), incision angle.
  - If toric IOL: Also include predicted residual cylinder and axis, target axis of placement, and actual axis of placement
- Keratometry (K steep/K flat with axis): Preoperative and Postoperative
- Manifest Refraction (sphere/cylinder/axis): Preoperative and Postoperative
- UCDVA: Preoperative and Postoperative
- BCDVA: Preoperative and Postoperative
- IOL Rotation: If available, also include actual vs. target (Toric IOLs only)
- The presence of any device related adverse events.

8 Statistics

8.1 Primary Effectiveness Endpoint

The primary effectiveness endpoint is the mean reduction in cylindrical power of the eye. Reduction in the cylindrical power of the eye is defined as the difference between the magnitudes of the preoperative keratometric cylinder and the residual refractive cylinder (referenced to the corneal plane).

8.2 Hypotheses

The null hypothesis (H_0) is that the mean reduction in cylindrical power of the eye for the toric group (μ_T) is less than or equal to the mean for the sphere control group (μ_C). The alternative hypothesis (H_1) is that the mean reduction in cylindrical power of the eye for the toric IOL group is greater than the mean for the control group.

$$H_0: \mu_T \leq \mu_C$$
$$H_1: \mu_T > \mu_C$$

8.3 Statistical Methods

Continuous variables will be summarized by treatment using the sample size, mean, standard deviation, minimum, and maximum. Categorical variables will be summarized by treatment using frequencies and percentages. Missing data will not be imputed.

The preoperative keratometric cylinder (D) will be calculated as the difference between the preoperative steep and flat keratometric powers (both in diopters). The postoperative manifest refraction cylinder (PMRC) will be referenced to the corneal plane assuming a vertex distance of 13 mm as follows.

$$PMRC \quad \left| \frac{1000(Sph + Cyl)}{1000 \quad 13\,(Sph + Cyl)} \quad \frac{1000\,Sph}{1000 \quad 13\,Sph} \right|$$

Where:

- PMRC = the postoperative manifest refractive cylinder at the corneal plane (D)
- Sph = the postoperative manifest refraction sphere at the spectacle plane (D)
- Cyl = the postoperative manifest refraction cylinder at the spectacle plane (D)

Reduction in the cylindrical power of the eye (D) will be computed as the preoperative keratometric cylinder minus the PMRC and summarized using continuous summary statistics by treatment. The statistical hypotheses will be tested using a two-sample t-test assuming unequal variances. If the one-sided p-value is less than 0.025 (or, equivalently, the two-sided p-value is less than 0.05 and the treatment difference is greater than zero), then the null hypothesis will be rejected and the toric IOL will be statistically successful in this outcome. A two-sided 95% confidence interval around the treatment difference will be reported.

8.4 Sample Size and Power

A sample size of 192 eyes in each group will have 90% power to detect a difference in means of 0.25 D assuming that the common standard deviation is 0.753 D using a two-group Satterthwaite t-test with a 2.5% one-sided significance level.

9 Study Administration

9.1 Data Collection and Management

Paper source document worksheets will be created to capture all study related data. Data recorded in these worksheets will be entered into an electronic Case Report Form (Dacima eCRF) by qualified site personnel.

Access to the eCRF will be password restricted to designated and appropriately trained site personnel.

Subject identifiers will not be entered into the eCRF. Subjects will be identified by a subject number that will be sequentially assigned to each eligible medical record (i.e., subject).

9.2 Confidentiality

All data and records generated throughout the course of the study will be kept confidential in alignment with local, provincial and federal policies and the site personnel will be the only ones to have access to the study data and records for the purposes of conducting the study.

All data will be stored within a password protected electronic data capture system which is secured by a firewall. Paper copies of data will be limited in nature to only copies of charts which were not available in EMR systems. These documents will be stored in a locked filing cabinet, the key to which will remain with the PI and designated CRC.

9.3 Records Retention

Essential documents (including but not limited to study-related correspondence [including emails], subject records, subject privacy documentation, and copies of eCRFs should be retained and available for audit by the Sponsor's auditor and regulatory authorities until at least 2 years after completion or termination of the study. These documents should be retained for a longer period, however, if mandated by the applicable regulatory requirements, by conditions imposed by the IRB, or by an agreement with the Sponsor. It is the responsibility of the Sponsor to inform the PI when these documents no longer need to be retained.

The Sponsor must be notified in writing if the PI chooses to store the records at a different physical address than the site address or if the PI wishes to relinquish ownership of the data so that mutually agreed-upon arrangements can be made for transfer of ownership to a suitably qualified, responsible person.

Any and all linkage to subject identifiers will be destroyed after data have been cleaned and analyzed.

9.4 Informed Consent

9.4.1 Waiver of Consent

A waiver of informed consent may be applicable as per the following:

- the research involves no more than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research could not practicably be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation.

10 Study Finances

10.1 Funding Source

A separate financial agreement (Clinical Study Agreement) will be made between the Sponsor and the PI at each site.

The study is covered under a Bausch Health liability insurance policy. The certificate of insurance will be provided upon request.

11 Study Reportable Events

11.1 Reportable Events

Any breach or suspected breach of confidentiality will be considered to be a reportable event and will be reported to the IRB as it poses a risk to subjects who participated in the study.

12 Publication Plan

Bausch Health, as the Sponsor, has a proprietary interest in this study. Authorship and manuscript composition will reflect joint cooperation among multiple PIs and sites and Bausch Health personnel. Authorship will be established prior to the writing of the manuscript. As this study involves multiple sites, no individual publications will be allowed prior to completion of the final report of the multicenter study except as agreed with Bausch Health.

All information, including but not limited to information regarding the intraocular lenses or the Sponsor's operations supplied by the Sponsor to the PI and not previously published, along with any data generated as a result of this study are considered confidential and remain the sole property of the Sponsor. The PI agrees to maintain this information in confidence and will use the information only to perform the study.

The Sponsor or its designate is responsible for preparing a clinical study report.

The Sponsor or its designate is responsible for publicly registering this study on http://www.clinicaltrials.gov prior to initiating enrolment.