Study Protocol

POST-APPROVAL STUDY OF THE TECNIS® TORIC IOL,

MODELS ZCT300 AND ZCT400

NCT Number: NCT02566083

Version 3.0

Document date: 21 May 2018

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POST-APPROVAL STUDY OF THE TECNIS® TORIC IOL, MODELS ZCT300 AND ZCT400

PROTOCOL NUMBER: TIOL-202-TPAS

SPONSOR: Abbott Medical Optics Inc.
1700 E. Saint Andrew Place
Santa Ana, CA 92705 USA
(714) 247-8200

Investigator Agreement:

As an Investigator, I agree to:

- Implement and conduct this study diligently and in strict compliance with this agreement; the protocol; Good Clinical Practices; 21CFR812 and all other applicable FDA regulations; conditions of approval imposed by the reviewing Institutional Review Board (IRB) or FDA; and all other applicable laws and regulations.
- Supervise all testing of the device where human subjects are involved.
- Ensure that the requirements for obtaining informed consent are met.
- Obtain authorization for use/disclosure of health information (HIPAA authorization).
- Maintain all information supplied by Abbott Medical Optics in confidence and, when this information is submitted to an independent IRB or any other 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.

Investigator Printed Name	Signature	Date
Sub-Investigator Printed Name	Signature	Date
Sub-Investigator Printed Name	Signature	Date

Acknowledged By:

Signature of Sponsor's Representative	Date

Printed Name and Title

TABLE OF CONTENTS

PERSONNEL AND FACILITIES

MEDICAL MONITOR:

[redacted]
Global Medical Director
Abbott Medical Optics Inc.
Santa Ana, CA 92705
[redacted]

SPONSOR:

Abbott Medical Optics Inc.
1700 E. Saint Andrew Place
Santa Ana, CA 92705
Main Number: 714-247-8200
Fax: 714-247-8784

SPONSOR PERSONNEL:

Director Clinical Research, Cataract

[redacted]

Study Manager:

[redacted]
Clinical Research Manager
[redacted]

EMERGENCY TELEPHONE NUMBERS:

[redacted]

Protocol Change History

Version	Section(s)	Page(s)	Description of Change(s)	Rationale for Change(s)
1.0 (31 AUG15/F(A1)	N/A	N/A	Original	N/A
2.0	1.0 Synopsis 8.0 Study Population Attachment A: Informed Consent	5 15 59	Changed number of subject to be enrolled from 435 to 475	Current screen failure rate is 14%; the increase in subject enrollment will ensure the ability to achieve bilateral implantation of 385 subjects.
	10.0 Study Timelines, Table 3	19	Changed expected timelines	Dates were modified to extend enrollment from August 2017 until April 2018. This is necessary to allow time to enroll 40 more subjects due to higher-than-anticipated Screen Failure Rate. All other analyses and reporting dates were modified as well.
	11.3 Preoperative Procedures	21	Removed note for 20/30 or better predicted best-corrected distance visual acuity	Although recommended, there is not an inclusion criteria for potential visual acuity and this note was included in error.
	Footer: Changed footer to comply with current standards	All	Removed dates and placed version number	Improved tracking of versions

3.0	Personnel and Facilities	3	Updated medical monitor information.	Removed Dr. David Tanzer and replaced with current medical monitor, Dr. Joy Domingo.
	1.0 Synopsis 8.0 Study Population	6, 7 15	Changed number of subjects to be enrolled and treated.	The number of subjects required to prove the hypothesis is much smaller than originally calculated.
	20.6 Sample Size	43	Changed sample size calculations	A revised sample size calculation was made following an interim analysis using current rates of severe visual distortions.
	Attachment A: Informed Consent	61	Changed number of subjects enrolled and treated.	Modified to keep consistent with protocol wording,

1.0 SYNOPSIS

STUDY TITLE:

Post-Approval Study of the TECNIS® Toric IOL, Models ZCT300 and ZCT400

Protocol: TIOL-202-TPAS

STUDY TREATMENTS:

Toric Study Lenses:

- TECNIS Toric 1-Piece IOL, Model ZCT300 (and PCT300)
- TECNIS Toric 1-Piece IOL, Model ZCT400 (and PCT400)

The ZCT300 and ZCT400 lens models (as well as PCT300 and PCT400) are intended for cataract patients with pre-existing corneal astigmatism that, when surgically induced astigmatism (SIA) is taken into account, have approximately 2.00 D to 3.62 D of predicted corneal astigmatism to be corrected.

Note: The PCT models (PCT300 and PCT400) are the same IOLs as the ZCT models with the exception that they are provided preloaded in the TECNIS iTec Delivery System. For reference in this protocol, PCT is the same as ZCT.

Control Lens:

- TECNIS Monofocal 1-Piece IOL, Model ZCB00 (and PCB00)

Note: Model PCB00 is the Model ZCB00 IOL preloaded into the TECNIS iTec Delivery System and may also be used as the control lens. For reference in this protocol, PCB00 is the same as ZCB00.

STUDY OBJECTIVE:

The purpose of this post-approval study is to evaluate the rates of visual distortions for the TECNIS Toric IOLs with >2.0 D of cylinder correction at the corneal plane (Models ZCT300 and ZCT400) in a larger population in clinical practice compared to

	a non-toric control IOL and to ensure the continued safety of the approved devices.
CLINICAL HYPOTHESIS:	The rate of severe visual distortions for the TECNIS Toric IOL Models ZCT300 and ZCT400 will be less than 10 percentage points above that for a non-toric control group with the same level of preoperative corneal astigmatism.
OVERALL STUDY DESIGN:	
Structure:	Prospective, multi-center, bilateral, non-randomized, open-label, comparative clinical study
Number of Sites:	Up to 80 sites in the USA
Duration:	Six months; however, any subjects that undergo a lens repositioning procedure due to IOL misalignment or that report a severe visual distortion at six months, will be followed through 1 year postoperatively.
Administration:	Emmetropia will be targeted for both eyes. Surgeons will perform routine small-incision, phacoemulsification cataract surgery and use the AMO-recommended implantation systems for lens implantation.
Visit Schedule:	Subjects will be bilaterally implanted; the second eye is to be implanted within approximately one month after the first eye surgery. Subjects will undergo two postoperative visits at 1 month and 6 months for both eyes together. If a subject experiences a lens repositioning procedure for IOL misalignment or if a subject reports a severe visual distortion at 6 months, the subject will also undergo a final visit at 1 year.
STUDY POPULATION:	
Condition:	Bilateral cataracts with corneal astigmatism of approximately 2.00 D to 3.62 D based on the combination of preoperative keratometric cylinder and the expected effect of SIA.
Number of subjects:	A minimum of 396 subjects will be enrolled to achieve bilateral implantation in approximately 294

subjects: 169 TECNIS Toric ZCT300 and ZCT400 subjects (including a minimum of approximately 30%, or 51, ZCT400 subjects) and 125 control subjects (assumes a 10% drop-out rate for a minimum of 152 toric and 112 control subjects available for evaluation at 6 months). Subjects will choose to be implanted with the same lens in both eyes, either the toric IOLs or the non-toric control IOL.

Inclusion Criteria:

- Minimum 22 years of age
- Bilateral cataracts for which phacoemulsification extraction and posterior chamber IOL implantation have been planned
- Preoperative keratometric cylinder in both eyes that, when taking surgically induced astigmatism into account, have approximately 2.00 D to 3.62 D of predicted corneal astigmatism to be corrected and qualify for implantation of ZCT300 and/or ZCT400 IOLs as determined by the web-based AMO Toric IOL Calculator
    - Most appropriate toric IOL model choice (ZCT300 or ZCT400) based on the associated residual refractive cylinder (lowest) and axis
    - Predicted residual refractive cylinder, based on the AMO Toric IOL Calculator, must be:
        - ≤0.69 D for a ZCT300 IOL
        - ≤0.88 D for a ZCT400 IOL
- Clear intraocular media other than cataract in each eye
- Availability, willingness, ability and sufficient cognitive awareness to comply with examination procedures and study visits
- Ability to understand, read and write English in order to consent to study participation and complete a study questionnaire
- Signed informed consent and HIPAA authorization

Exclusion Criteria:

- Irregular corneal astigmatism
- Any corneal pathology/abnormality other than regular corneal astigmatism
- Previous corneal surgery
- Recent ocular trauma or intraocular surgery that is not resolved/stable or may affect visual outcomes
- Any pupil abnormalities (non-reactive, fixed pupils, or abnormally shaped pupils)

- Subjects with conditions associated with increased risk of zonular rupture, including capsular or zonular abnormalities that may lead to IOL decentration, including pseudoexfoliation, trauma, or posterior capsule defects
- Known ocular disease or pathology that may affect visual acuity or that may require surgical intervention during the course of the study (macular degeneration, cystoid macular edema, diabetic retinopathy, uncontrolled glaucoma, etc.)
- Concurrent participation or participation during 30 days prior to preoperative visit in any other clinical study
- Planned monovision correction
- Patient is pregnant, plans to become pregnant, is lactating or has another condition associated with the fluctuation of hormones that could lead to refractive changes

STUDY ENDPOINTS:

Study endpoints will be evaluated at 6 months postoperatively.

Primary Endpoint:

Rate of severe visual distortions; defined as the percentage of subjects who report a severe visual distortion under overall circumstances at 6 months postoperative for any of the following 5 visual distortion items of interest:

- lines that slant, tilt, split or separate
- flat surfaces appearing curved
- objects appearing further away or closer than they actually are
- objects appearing to have a different size or shape
- physical discomfort related to vision

Other Endpoints:

- Ratings of individual items included on the visual distortion questionnaire
- Rates of IOL repositioning procedures (secondary surgical intervention) due to IOL misalignment
- Rates of other adverse events

VISITS AND PROCEDURES:

All subjects enrolled in the study will sign the IRB-approved informed consent prior to any study-specific testing or administration of the questionnaire. Each subject will choose to receive the same lens type in both eyes, either the TECNIS Toric IOLs (Models ZCT300 and/or ZCT400), or the non-toric control IOL (TECNIS Model ZCB00).

VISIT SCHEDULE: All subjects are intended to have bilateral cataract surgery with the second-eye surgery occurring within approximately 1 month of the first-eye surgery (≤60 days). Two postoperative study visits will be conducted; at 1 month

(30-60 days after the second-eye surgery) and at 6 months (120-180 days after the second-eye surgery) for both eyes together. However, subjects who underwent an IOL repositioning procedure due to IOL misalignment or who reported a severe visual distortion at 6 months will return for a final visit at 1 year (330-420 days after the second-eye surgery) postoperatively.

PREOPERATIVE PROCEDURES: Following informed consent, a subject questionnaire for determination of visual distortions will be administered (Patient Reported Visual Distortion Questionnaire; PRVDQ). Demographic, general preoperative and operative information will be collected from routine cataract evaluation examinations and surgical reports.

POSTOPERATIVE PROCEDURES: At the 1-month visit, a spectacle and/or contact lens prescription will be offered to each subject. If the subject has a spontaneous report of any of the 5 defined visual distortion items of interest or of blurred or hazy vision, the questionnaire will be administered and, for subjects with toric IOLs, keratometry and toric IOL axis measurements will be performed.

At the 6-month visit, the postoperative procedures will include a subject questionnaire (Patient Reported Visual Distortion Questionnaire; PRVDQ) for determination of visual distortions, biomicroscopic slit-lamp examination for any adverse events and, for subjects with toric IOLs, determination of toric IOL axis position and keratometry.

If outside of a scheduled study visit, a subject has a spontaneous report of; 1) any of the 5 defined visual distortion items of interest or 2) blurred or hazy vision at 1 month postoperatively or later, the PRVDQ questionnaire will be administered and, for subjects with toric IOLs, keratometry and toric IOL axis measurements will be performed. Exam details will be documented on an unscheduled visit form.

If a subject reported a severe visual distortion in the questionnaire or experienced an ocular adverse event at any scheduled or unscheduled study visit, uncorrected distance visual acuity, best corrected distance visual acuity, manifest refraction, slit-lamp examination and intraocular pressure measurements will also be performed.

A 1-year examination will be required only if the subject reports a severe visual distortion at the 6-month examination or experienced an IOL repositioning procedure (due to IOL misalignment during the study).

If a serious or device-related adverse event occurs at or prior to the 6-month visit, details of the event will be collected at the time of the event using an adverse event form. If the adverse event is an IOL misalignment resulting in an IOL repositioning procedure, the questionnaire is to be administered prior to the repositioning procedure to collect information regarding visual distortions, and, for subjects with toric IOLs, keratometry and toric IOL axis measurements will be performed prior to the repositioning procedure to collect data regarding the IOL misalignment.

DATA ANALYSIS:

The rate of severe visual distortions as defined by the 5 items listed under primary endpoint will be compared between bilaterally-implanted toric IOL subjects and bilaterally-implanted non-toric control IOL subjects at 6 months. The frequency and proportion of toric and non-toric control subjects with severe visual distortions will be reported. Results between the toric IOL and the non-toric control IOL groups will be evaluated using a non-inferiority approach with a non-inferiority margin of 10%. Assessment of toric IOL axis misalignment will be compared to reports of visual distortions.

The frequency and proportion of secondary surgical interventions due to IOL misalignment, as well as rates for other adverse events or medical and lens findings, will be reported by treatment group. Evaluation at 6 months will include reporting by treatment groups the incidence of all adverse events, including severity for serious adverse events and adverse device effects.

Visual distortion findings, adverse events and medical/lens findings at one year will be reported for subjects who experienced a repositioning procedure during the study or for subjects who were reported with severe visual distortions at the 6-month visit.

2.0 BACKGROUND AND PURPOSE OF STUDY

It is estimated that 35% of cataract patients have ≥1.00 diopter of corneal astigmatism[1] with 15%-20% having ≥1.5 D of corneal astigmatism.[1,2] Although there are various modalities to reduce the amount of astigmatism during cataract surgery (e.g., limbal relaxing incisions, etc.), toric IOLs are now commonly used for correction of aphakia and pre-existing ocular astigmatism. On April 15, 2013, Abbott Medical Optics (AMO) received USA FDA approval (P980040/S039) for the TECNIS 1-Piece Toric IOL, Models ZCT150, ZCT225, ZCT300 and ZCT400 for the visual correction of aphakia and pre-existing corneal astigmatism of one diopter or greater.

In the IDE registration trial of the TECNIS 1-Piece Toric IOL (G090251), rotational stability was demonstrated and there were minimal subject complaints of visual distortions; however, there is the potential, particularly in the case of toric IOLs that correct for higher amounts of corneal astigmatism, that patients may experience spatial distortions related to axis misalignment, e.g., whether objects appear tilted or misshapen, etc. As a condition of approval, this post-approval study will be conducted to

evaluate visual distortions of the TECNIS Toric 1-Piece IOLs with ≥2.00 D of cylinder correction at the corneal plane (Models ZCT300 and ZCT400) and to ensure the continued safety of the approved devices.

3.0 STUDY OBJECTIVE

The objective of this post-approval study is to evaluate the rates of severe visual distortions for the TECNIS 1-Piece Toric IOLs with ≥2.0 D of cylinder correction at the corneal plane (Models ZCT300 and ZCT400) in a larger population in clinical practice compared to a non-toric, control IOL, and to ensure the continued safety of the approved devices.

4.0 STUDY DESIGN

This study is a prospective, multicenter, bilateral, non-randomized, open-label, comparative clinical study conducted at up to 80 sites in the USA. Subjects will choose to be bilaterally implanted with either 1) the TECNIS 1-Piece Toric IOLs, Model ZCT300 and/or ZCT400, or 2) the TECNIS Monofocal Model ZCB00 non-toric control IOL, according to subject preference.

5.0 CLINICAL HYPOTHESIS

The rate of severe visual distortions for the TECNIS 1-Piece Toric IOL Models ZCT300 and ZCT400 will be less than 10 percentage points above that for the non-toric control IOL group with the same level of preoperative corneal astigmatism.

6.0 STUDY ENDPOINTS

Study endpoints will be evaluated at 6 months postoperatively.

PRIMARY ENDPOINT

The primary endpoint is the rate of severe visual distortions based on data collected from a self-administered subject questionnaire (PRVDQ).

The rate of severe visual distortions is defined as the percentage of subjects who report a severe visual distortion under overall circumstances at 6 months postoperative for any of the following 5 visual distortion items of interest:

- lines that slant, tilt, split or separate
- flat surfaces appearing curved
- objects appearing further away or closer than they actually are
- objects appearing to have a different size or shape
- physical discomfort related to vision

Distortions will be assessed using the overall circumstance reply at the 6-month visit. The frequency and proportion of subjects reporting one or more of these items as severe will be used to determine the rate of severe visual distortions.

Success criteria: Rates of severe visual distortions for the TECNIS 1-Piece Toric IOL group will be less than 10 percentage points above rates for the non-toric control IOL group.

OTHER ENDPOINTS

- Ratings of individual items included on the visual distortion questionnaire
- Rates of IOL repositioning procedures (secondary surgical intervention) due to IOL misalignment
- Rates of other adverse events

7.0 STUDY PRODUCTS

7.1 INTRAOCULAR LENSES

The TECNIS 1-Piece Toric IOL, Models ZCT300 and ZCT400, and the TECNIS 1-Piece Model ZCB00 non-toric control IOL are posterior chamber, 1-piece, aspheric, hydrophobic acrylic foldable IOLs and are to be implanted in the capsular bag following cataract extraction. Both the TECNIS 1-Piece Toric IOLs and the TECNIS 1-Piece monofocal non-toric IOL, Model ZCB00, have an anterior aspheric optic surface and a spherical posterior optic surface; however, the TECNIS 1-Piece Toric IOLS have an additional toric feature on the anterior optic surface to correct for ocular astigmatism.

The TECNIS 1-Piece Toric IOLs are indicated for the visual correction of aphakia and pre-existing corneal astigmatism of one diopter or greater in adult patients with and without presbyopia in whom a cataractous lens has been removed by extracapsular cataract extraction, and who desire improved uncorrected distance vision, reduction in residual refractive cylinder, and increased spectacle independence for distance. The

ZCT300 and ZCT400 lens models, in particular, are intended for cataract patients with pre-existing corneal astigmatism that, when taking surgically induced astigmatism into account, have approximately 2.00 D to 3.62 D of predicted corneal astigmatism to be corrected (**Table 1**).

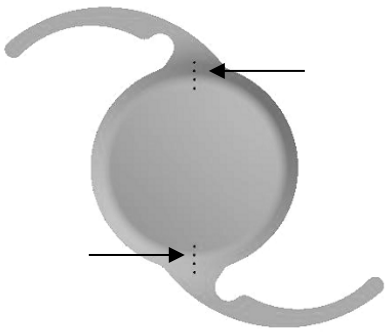
Note: The PCT models (PCT300 and PCT400) are the same IOLs as the ZCT models with the exception that they are provided preloaded in the TECNIS iTec Delivery System. Similarly, Model PCB00 is the Model ZCB00 IOL preloaded into the TECNIS iTec Delivery System and may also be used as the control lens. For reference in this protocol, PCB00 is the same as ZCB00, and the PCT models are the same as the ZCT models.

TABLE 1
TECNIS Toric Models ZCT300 and ZCT400 IOL Astigmatism Correction Range

ZCT IOL Model	Cylinder Power (D)		Correction Range Based on Combined Corneal Astigmatism (Preoperative Kcyl[a] + SIA[b])
	IOL Plane	Corneal Plane	
ZCT300	3.00	2.06	2.00 – 2.75 D
ZCT400	4.00	2.74	2.75 – 3.62 D

[a] Keratometric cylinder
[b] Surgically induced astigmatism

The TECNIS 1-Piece Toric IOLs have two sets of four axis orientation marks 180° apart in the outer periphery of the anterior optic surface (**Figure 1**) to indicate the meridian of the lowest power (flat meridian). These axis orientation marks are for proper alignment of the flat meridian of the IOL with the steep meridian of the corneal curvature.



TECNIS Toric IOL Illustration of Axis Orientation Marks

Table 2 lists the general design characteristics of the non-toric control IOL and the TECNIS 1-Piece Toric IOLs:

TABLE 2
Lens Characteristics of the TECNIS Model ZCB00 and TECNIS Toric Models ZCT300 and ZCT400

CHARACTERISTICS	TECNIS® 1-Piece IOL Model ZCB00 (Control)	TECNIS® Toric 1-Piece IOL Models ZCT300 and ZCT400
Lens Design	1-piece acrylic monofocal with an aspheric anterior surface	1-piece acrylic monofocal with an aspheric anterior surface and a maximum and a minimum radii of curvature perpendicular to each other
Lens Model	Surface-treated SENSAR® soft acrylic (acrylic with covalently bound UV absorber)	Same as Model ZCB00
DIMENSIONAL FEATURES		
Overall Diameter	13.0 mm	Same as Model ZCB00
Optical Center Thickness	0.722 mm (20.0 D Lens)	Same as Model ZCB00
Haptic Angle	No angulation, but offset from the optic body	Same as Model ZCB00
Optic Body Diameter	6.0 mm	Same as Model ZCB00
Haptic Material	Same as optic	Same as Model ZCB00
Haptic Width	0.39 mm	Same as Model ZCB00
Haptic Thickness	0.46 mm	Same as Model ZCB00
Haptic Style	TRI-FIX Design Modified C, integral with optic	Same as Model ZCB00
Other Features	N/A	Axis orientation marks
OPTICAL FEATURES		
Optic Shape	Biconvex	Same as Model ZCB00
Anterior Optic Profile	Aspheric	Aspheric with a maximum and a minimum radii of curvature perpendicular to each other
Posterior Optic Profile	Spherical	Same as Model ZCB00
Optic Edge Design	PROTEC™ squared edge	Same as Model ZCB00
Dioptric Power Range	+5.0 to +34.0 D in 0.50 D increments	Same as Model ZCB00
Cylinder Power Range	N/A	3.00 D, 4.00 D (at the IOL plane)
Refractive Index	1.470 (35° C)	Same as Model ZCB00
Theoretical A-constant[a]	118.8 for ultrasound biometry 119.3 for optical biometry	Same as Model ZCB00

[a] For lens power calculations, the investigator's personalized A-Constant for the TECNIS non-toric ZCB00 IOL is to be used for both the ZCB00 and ZCT IOLs.

7.2 IMPLANTATION SYSTEMS

All lenses are to be implanted using either the UNFOLDER Platinum 1 Series Implantation System (DK7796 handpiece with the Platinum 1 Series cartridge, Model 1MTEC30) or the ONE SERIES Ultra Implantation System (DK7786 [plunger] or the DK7791 [twist] handpieces in combination with the ONE SERIES Ultra cartridge, Model 1VIPR30). Other AMO implantation systems may be used with the lenses if validated for use by AMO.

8.0 STUDY POPULATION

Minimum of 396 subjects will be enrolled to achieve approximately 294 bilaterally-implanted subjects in the study as follows:

- 169 TECNIS Toric ZCT300 and ZCT400 subjects
  - Approximately 30% (51 subjects) to be ZCT400 subjects
- 125 TECNIS Monofocal Model ZCB00 control subjects

Each investigative site is anticipated to treat approximately 10 subjects.

8.1 SUBJECT RECRUITMENT

All subjects will be enrolled from the normal surgical cataract population at the investigative sites. This study will include only subjects intended to undergo bilateral primary phacoemulsification cataract extraction and IOL implantation who have approximately 2.00 D to 3.62 D of corneal astigmatism requiring correction in each eye based on the combination of preoperative keratometric cylinder and the expected effect of SIA. All patients who sign informed consent will be enrolled in the study and subjects that meet the inclusion and exclusion criteria (Section 8.2 and 8.3) in both eyes will be offered treatment in the study. Eligibility criteria may not be waived by the investigator. Any questions regarding patient eligibility are to be discussed with AMO prior to subject treatment. Those subjects who meet the criteria and agree to participate will choose the lens model of their preference for implantation. Subjects will be treated sequentially at each site until the total recruitment goals for each lens model are met. In the case of slower than anticipated enrollment, the use of physician referral networks and IRB-approved advertising may be implemented.

8.2 INCLUSION CRITERIA:

- Minimum 22 years of age
- Bilateral cataracts for which phacoemulsification extraction and posterior chamber IOL implantation have been planned
- Preoperative keratometric cylinder in both eyes that, when taking surgically induced astigmatism into account, have approximately 2.00 D to 3.62 D of predicted corneal astigmatism to be corrected and qualify for implantation of ZCT300 and/or ZCT400 IOLs as determined by the web-based AMO Toric IOL Calculator
  - Most appropriate toric IOL model choice (ZCT300 or ZCT400) based on the associated residual refractive cylinder (lowest) and axis

  - Predicted residual refractive cylinder, based on the AMO Toric IOL Calculator, must be:
    - ≤0.69 D for a ZCT300 IOL
    - ≤0.88 D for a ZCT400 IOL
- Clear intraocular media other than cataract in each eye
- Availability, willingness, ability and sufficient cognitive awareness to comply with examination procedures and study visits
- Ability to understand, read and write English in order to consent to study participation and complete a study questionnaire
- Signed informed consent and HIPAA authorization

8.3 EXCLUSION CRITERIA:

- Irregular corneal astigmatism
- Any corneal pathology/abnormality other than regular corneal astigmatism
- Previous corneal surgery
- Recent ocular trauma or intraocular surgery that is not resolved/stable or may affect visual outcomes
- Any pupil abnormalities (non-reactive, fixed pupils, or abnormally shaped pupils)
- Subjects with conditions associated with increased risk of zonular rupture, including capsular or zonular abnormalities that may lead to IOL decentration, including pseudoexfoliation, trauma, or posterior capsule defects
- Known ocular disease or pathology that may affect visual acuity or that may require surgical intervention during the course of the study (macular degeneration, cystoid macular edema, diabetic retinopathy, uncontrolled glaucoma, etc.)
- Concurrent participation or participation during 30 days prior to preoperative visit in any other clinical study
- Planned monovision correction
- Patient is pregnant, plans to become pregnant, is lactating or has another condition associated with the fluctuation of hormones that could lead to refractive changes

9.0 INVESTIGATOR/SITE SELECTION

The study will be conducted at up to 80 investigative sites in the USA. Initially, 30-40 sites will be targeted; additional sites may be added as necessary to meet enrollment goals. In general, investigative sites will be selected for study participation based on investigator experience with the TECNIS Monofocal Model ZCB00 IOL (having an established personalized A-constant) and toric IOLs, volume of cataract procedures,

and experience conducting clinical studies in accordance with good clinical practices (GCPs) and FDA regulations.

9.1 INVESTIGATOR QUALIFICATIONS

AMO will select ophthalmic surgeons who have completed a residency in ophthalmology and are licensed to practice medicine and perform surgery in the state where the investigator conducts the study. Each site will have one principal investigator; some sites may have additional implanting sub-investigators.

Investigators for this clinical study will be selected from surgeons who are experienced in small incision, phacoemulsification and toric IOL implantation in cataract patients. Additionally, investigators should have established their personalized A-Constant for the TECNIS Monofocal Model ZCB00 IOL. It is preferable that the investigator have experience with the TECNIS Toric ZCT IOLs. Surgical cataract volume will be evaluated to ensure the ability to adequately enroll subjects. It is preferable that sites also have experience conducting clinical studies in accordance with GCPs and FDA regulations. All sites will be required to have adequate staff support for reporting and subject follow-up.

9.2 INVESTIGATOR OBLIGATIONS

Investigators are required to fulfill the following obligations:

- Conduct the study in accordance with the relevant and current protocol. Investigator will only make changes to a protocol after notifying and obtaining approval from AMO, the FDA, and the Institutional Review Board (IRB), except when necessary to protect the safety, rights or welfare of subjects
- Personally conduct and supervise the study
- Maintain a list of appropriately qualified persons to whom the investigator has delegated significant study-related duties
- Be responsible for protecting the rights, safety and welfare of subjects under the investigator's care
- Maintain confidentiality as required by HIPAA or similar laws and regulations
- Shall not obtain written informed consent of any subject to participate or allow any subject to participate before obtaining IRB approval and approval from the FDA
- Document in each subject's case history that informed consent was obtained prior to participation in the study as required by 21CFR812

- Report to AMO any adverse experiences and/or device defects or malfunctions that occur during the course of the study in accordance with applicable laws and regulations
- Maintain adequate and accurate records in accordance with applicable laws and regulations and make available all study documents and subject medical records for inspection by either AMO, duly authorized regulatory agencies (e.g., FDA) and/or the IRB
- Submit progress reports on the study to AMO and the reviewing IRB at regular intervals, but no less often than yearly as required by 21CFR812.150
- Ensure the IRB that is responsible for initial and continuing review of the study complies with applicable laws and regulations
- Report all changes in research activity and all unanticipated problems involving risks to patients to the IRB and AMO
- Submit a final report to AMO and reviewing IRB within 3 months after termination or completion of the study or the investigator's part of the study
- Provide sufficient accurate financial information to AMO to allow AMO to submit complete and accurate certification or disclosure statements as required by 21CFR54. Promptly update this information if any relevant changes occur during the course of the study or for up to one year following completion of the study
- Comply with all other obligations of clinical investigators and requirements according to all applicable FDA regulations (e.g., 21CFR812), all other applicable laws and regulations and all conditions of approval imposed by the reviewing IRB and FDA
- Ensure that all associates, colleagues and employees assisting in the conduct of the study are adequately informed about the protocol, the study devices, their study-related duties and functions and agree to fulfill their obligations in meeting the above commitments.

9.3 INVESTIGATOR APPROVAL

It is the responsibility of the investigator to obtain prospective approval of the study protocol, protocol amendments or changes, informed consent forms and other relevant documents (e.g., advertisements) from the IRB. All correspondence with the IRB should be retained in the Investigator Study Files/Notebook. Copies of IRB approvals should be forwarded to AMO.

The investigator is required to report to AMO within five working days any withdrawal of approval by the reviewing IRB for his/her participation in the study.

Study sites will obtain IRB approval and fulfill any other site-specific regulatory requirements. Prior to the start of subject enrollment, the following documents must be signed and returned to AMO:

- Confidentiality Agreement
- Clinical Trial Agreement
- Investigator Agreement/Protocol Signature Page
- Financial Disclosure Form
- Signed and dated copy of investigator's current curriculum vitae
- Copy of the investigator's current medical license

By signing the study documents, the investigator agrees to conduct this study according to the obligations above and all other applicable regulatory and legal requirements.

10.0 STUDY TIMELINE

This study will be initiated following the validation activities of the subjective study questionnaire (estimated time of 9 months) and FDA approval of both the questionnaire and this protocol. Initially, 30-40 sites will be targeted for study participation; however, up to 80 sites may be included as needed to meet enrollment goals. The expected study timeline is presented in **Table 3**

TABLE 3
Expected Study Timeline

Study Activity	Expected Timing
Begin IRB approvals, site initiations and subject enrollment	AUG 2015: Following FDA approval of the study questionnaire
Complete Site IRB approvals and initiations (30-40 sites)	APR 2016: 8 months (~5 sites/month)
Complete subject enrollment	APR 2018: 30 months from study start (1 subject/site/~3 months)
Complete subject follow-up	OCT 2018: 6 months APR 2019: 12 months[a]
Complete primary-analysis, 6-month clinical study report	JAN 2019: 3 months following completion of 6-month exams
Complete 1-year clinical study report	JUL 2019: 3 months following completion of 1-year exams

[a] An additional 6 months may be necessary depending upon the number and timing of subjects returning for 1 year visits (due to reports of severe visual distortions at 6 months or the occurrence of an IOL repositioning procedure)

11.0 EXPERIMENTAL PLAN

11.1 OVERVIEW

This study will be conducted in accordance with U.S. Code of Federal Regulations, the Declaration of Helsinki and all other applicable laws and regulations.

This study is a prospective, multicenter, bilateral, non-randomized, open-label, comparative clinical study conducted at up to 80 sites. Subjects will choose to be implanted with the same lens type in both eyes, either the toric IOLs or the non-toric control IOL. Second-eye surgeries are to be performed within approximately 1 month (no more than 60 days) of the first-eye surgery, as second-eye cataract surgeries are typically performed within 2 months of the first-eye surgery. Subjects will be examined postoperatively at 1 and 6 months following the second-eye surgery. If a subject requires a lens repositioning procedure due to IOL misalignment or if a subject reports a severe visual distortion at 6 months, the subject will undergo a final visit at 1 year. Additional visit schedule details are provided in Section 11.2 Visit Schedule.

At the 1-month visit, a spectacle and/or contact lens prescription will be offered to each subject. If the subject has a spontaneous report of any of the 5 defined visual distortion items of interest or of blurred or hazy vision, the questionnaire will be administered and, for subjects with toric IOLs, keratometry and toric IOL axis measurements will be performed.

At the 6-month visit, the postoperative procedures will include a subject questionnaire for determination of visual distortions, biomicroscopic slit-lamp examination for any adverse events and, for subjects with toric IOLs, determination of toric IOL axis position and keratometry.

If outside of a scheduled study visit, a subject has a spontaneous report of; 1) any of the 5 defined visual distortion items of interest or 2) blurred or hazy vision at one month postoperatively or later, the PRVDQ questionnaire will be administered and, for subjects with toric IOLs, keratometry and toric IOL axis measurements will be performed. Exam details will be documented on an unscheduled visit form.

If a subject reported a severe visual distortion in the questionnaire or experienced an ocular adverse event at any scheduled or unscheduled study visit, uncorrected distance visual acuity, best corrected distance visual acuity, manifest refraction, slit-lamp examination and intraocular pressure measurements will also be performed.

A 1-year examination will be required only if the subject reports a severe visual distortion at the 6-month examination or experienced an IOL repositioning procedure (due to IOL misalignment during the study). The PRVDQ will be administered at this visit, followed by uncorrected distance visual acuity, best corrected distance visual acuity, manifest

refraction, slit-lamp examination and intraocular pressure measurements. For subjects with toric IOLs, keratometry and toric IOL axis measurements will also be performed.

If a serious or device-related adverse event occurs at or prior to the 6-month visit, details of the event will be collected at the time of the event using an adverse event form. If the adverse event results in an IOL repositioning procedure due to misalignment, the questionnaire should be administered prior to the procedure to collect information regarding visual distortions, and for subjects with toric IOLs, keratometry and toric IOL axis measurements will be performed prior to the repositioning procedure to collect data regarding the IOL misalignment.

A chart summary of all examination procedures required at each study visit is provided in Appendix A.

11.2 VISIT SCHEDULE

The study visit schedule for all study subjects is outlined below in **Table 4**. Additional visits may be conducted at the discretion of the investigator; however routine follow-up visits without reports of ocular adverse event(s) or spontaneous reports of visual distortion(s) are not considered study visits. Note that second-eye surgeries are intended to be performed within approximately 1 month (≤60 days) of the first-eye surgery.

TABLE 4
Study Visit Schedule

Visit	Eyes Evaluated	Exam	Visit Window
1	Both Eyes	Preoperative Exam	N/A
First Eye Surgery			N/A
Second Eye Surgery			Within approximately 1 month (≤60 days) of 1st eye surgery
2	Both Eyes	1 month	30-60 days postoperative from 2nd implant
3	Both Eyes	6 months	120-180 days postoperative from 2nd implant
4[a]	Both Eyes	1 year[a]	330-420 days postoperative from 2nd implant

[a] The 1-year exam is only required if a severe visual distortion was reported by the subject at the 6-month visit or if the subject underwent an IOL repositioning procedure during the study as a result of axis misalignment.

11.3 PREOPERATIVE PROCEDURES

All subjects enrolled in the study must sign the current IRB-approved informed consent document. The informed consent must be signed and dated before any study-specific testing is performed and this must be documented in the source documents. An

Authorization for Use/Disclosure of Health Information Form (HIPAA authorization) must also be signed for study enrollment.

Study-specific preoperative testing for this protocol includes the administration of the subject questionnaire assessing visual distortions (Appendix B), as well as any other preoperative procedures that are not already performed during the investigator's routine cataract evaluation for astigmatic patients (e.g., potential visual acuity). To ensure subjects in both lens groups meet eligibility criteria, documentation via the AMO Toric IOL Calculator options of ZCT300 and/or ZCT400 for each eye of each subject is required. As toric IOL calculations are not generally performed for non-toric IOL surgeries, the use of the AMO Toric IOL Calculator may be considered study-specific for subjects who choose to be implanted with the control, non-toric IOL.

Preoperative data will be collected on the preoperative case report form (CRF) and includes the following:

- Informed consent documentation (including subject lens selection)
- Subject demographic information
- Ocular history, including presence of ocular pathology for each eye
- Potential best-corrected distance visual acuity for each eye Uncorrected distance visual acuity (Snellen) for each eye
- Best corrected distance visual acuity (Snellen) for each eye
- Manifest refraction (Snellen) for each eye
- Keratometry for each eye
- Intraocular pressure for each eye
- Ocular medications
- Cataract type and density for each eye
- Dilated fundus exam results for each eye (recommended)
- Medical and lens findings from a biomicroscopic slit-lamp exam for each eye
- Axial length, spherical equivalent IOL power and spherical equivalent targeted refraction (emmetropia, within ±0.50 D) for each eye using the investigators preferred biometry method
- A-constant used for spherical equivalent IOL power determination
- Surgeon-estimated surgically induced astigmatism (SIA) and planned incision location

- Documentation of the AMO Toric IOL Calculator choice of ZCT300 and/or ZCT400 for each eye and corresponding residual refractive cylinder and axis for each eye (including control eyes)
  - Investigator to determine the most appropriate toric IOL model (ZCT300 or ZCT400) based on the associated residual refractive cylinder (lowest) and axis
  - Predicted residual refractive cylinder, based on the AMO Toric IOL Calculator, must be:
    - ≤0.69 D to receive a ZCT300 IOL
    - ≤0.88 D to receive a ZCT400 IOL
- Subject Questionnaire (Appendix B)

LENS POWER CALCULATIONS AND IOL SELECTION:

For lens power calculations, the investigator's personalized A-Constant for the TECNIS monofocal ZCB00 lens is to be used for both the ZCB00 and Toric ZCT IOLs. The spherical equivalent lens power, as determined by the investigator's standard biometry methods, should be calculated to achieve emmetropia (± 0.50 D) at distance for all eyes. Intentional overcorrection or under-correction (i.e., monovision or outside ± 0.50 D) should NOT be planned for either eye; however, surgeons may adjust the targeted refraction as necessary to achieve emmetropia based on their surgeon factor, study subject experience and/or subject first-eye outcomes.

In order to verify subject eligibility and to optimize toric IOL selection and axis placement, investigators will use the web-based AMO Toric IOL Calculator (www.TecnisToricCalc.com) to determine the appropriate TECNIS Toric IOL model (ZCT300 and/or ZCT400 for this study) for each eye. Note that the AMO Toric IOL calculator provides toric IOL options based on predicted astigmatism, i.e., the vector sum of pre-existing corneal astigmatism and the expected effect of SIA. For this study, subjects are to have corneal astigmatism that, when taking SIA into account, have approximately 2.00 D to 3.62 D of predicted corneal astigmatism to be corrected and qualify for implantation of a ZCT300 and/or ZCT400 IOL in both eyes by the web-based AMO Toric IOL Calculator. Therefore, toric IOL calculations are to be performed for all subjects in this study, regardless of whether they choose to be implanted with the TECNIS Toric IOLs (Models ZCT300/ZCT400) or the TECNIS non-toric control IOL, Model ZCB00. The investigator will determine the toric lens model that is most appropriate for each eye (based on associated residual refractive cylinder and axis) regardless of the choice of IOL type by the subject. For all subjects, the toric IOL model

selections chosen by the investigator via the AMO Toric IOL Calculator are to be printed and maintained as source documentation.

Note: Because lenticular astigmatism in the crystalline lens may influence the determination of the amount of astigmatism to be corrected, it is vital that corneal astigmatism (keratometry readings) and not refractive cylinder data be used for toric IOL calculations.

11.4 OPERATIVE PROCEDURES

The investigator should use his or her standard, small-incision, phacoemulsification cataract extraction surgical technique. All lenses should be folded for implantation and inserted into the capsular bag using one of the insertion systems indicated in the labeling. **No additional refractive procedures are to be performed on any study eyes during the initial surgeries or prior to completion of the 6-month study exam** (e.g., LRI, AK, OCCI, etc.).

TECNIS TORIC IOLS ONLY:

Using the reference marks made prior to surgery with the subject sitting upright, an axis marker is to be used immediately prior to or during surgery to mark the intended axis of lens placement (post-incision steep corneal meridian) as indicated by the AMO Toric IOL Calculator.

Following lens insertion, the TECNIS 1-Piece Toric ZCT IOL is to be precisely aligned with the intended axis of placement using the imaginary line formed by the axis orientation marks at each of the haptic/optic junctions of the IOL, identifying the flat meridian of the optic. Carefully remove all viscoelastic from the capsular bag. Special care should be taken to ensure proper positioning of the TECNIS 1-Piece Toric IOL at the intended axis following viscoelastic removal and/or inflation of the capsular bag at the end of the surgical case. Residual viscoelastic and/or over-inflation of the bag may allow the lens to rotate, causing misalignment of the TECNIS 1-Piece Toric IOL from the intended axis.

Operative case report forms will collect the following information:

- Date of surgery
- Operative eye
- IOL model, power and serial number
- Incision location

- Surgical complications
- Other surgical procedures
- IOL placement (e.g., within capsular bag, proper alignment, etc.)
- Wound closure (e.g., suture required)
- Adverse events

11.5 POSTOPERATIVE PROCEDURES

Postoperatively, all subjects will be examined at the 1- and 6-month study visits. If a subject requires a lens repositioning procedure due to IOL misalignment or if a subject reports a severe visual distortion at 6 months, the subject will also undergo a final visit at 1 year.

At the 1-month visit, a spectacle and/or contact lens prescription will be offered to each subject. If the subject has a spontaneous report of any of the 5 defined visual distortion items of interest or of blurred or hazy vision, the questionnaire will be administered and, for subjects with toric IOLs, keratometry and toric IOL axis measurements will be performed.

Primary 6-month postoperative data collection consists of administration of a subject questionnaire for determination of visual distortion reports, biomicroscopic slit-lamp examination for any adverse events, and for subjects with toric IOLs, determination of toric IOL axis position and keratometry.

If outside of a scheduled study visit, a subject has a spontaneous report of; 1) any of the 5 defined visual distortion items of interest or 2) blurred or hazy vision at one month postoperatively or later, the PRVDQ questionnaire will be administered and, for subjects with toric IOLs, keratometry and toric IOL axis measurements will be performed. Exam details will be documented on an unscheduled visit form.

If a subject reports a severe visual distortion or has experienced an ocular adverse event at any scheduled or unscheduled study visit, uncorrected distance visual acuity, best corrected distance visual acuity, manifest refraction, slit-lamp examination and intraocular pressure measurements will be performed.

If a serious or device-related adverse event occurs at or prior to the 6-month visit, details of the event will be collected at the time of the event using an adverse event form. If the

adverse event results in an IOL repositioning procedure due to misalignment, the questionnaire should be administered prior to the procedure to collect information regarding visual distortions, and, for subjects with toric IOLs, keratometry and toric IOL axis measurements will be performed prior to the repositioning procedure to collect data regarding the IOL misalignment.

If correction is required during the study postoperatively, spectacles or contact lenses will be prescribed; however, no additional refractive procedures (LRI, AK, etc.) are allowed until after completion of the 6-month study visit. This is particularly important for non-toric control subjects who will likely have residual refractive cylinder for which they may need to wear correction until completion of the 6-month study exam. If a subject is required to return for a 1-year exam (due to a severe visual distortion at 6 months or an IOL repositioning procedure during the study), a refractive enhancement (LRI, AK, etc.) may be performed prior to the 1-year exam but must be reported on the 1-year CRF.

The postoperative case report form will collect the following information (Appendix A):

- Confirmation of offering of spectacle and/or contact lens prescription: 1-month visit only
- Questionnaire (Appendix B): 6-month and 1-year visits; also at 1-month or unscheduled visits only if there is a spontaneous report of visual distortion or prior to an IOL repositioning procedure at that visit.
- Keratometry, for toric IOLs only: 6-month and 1-year visits; also at 1-month and unscheduled visits if there is a spontaneous report of visual distortion or prior to an IOL repositioning procedure at that visit.
- Toric IOL axis measurement by dilated slit-lamp examination ,for toric IOLs only (Refer to Appendix C for measurement instructions): 6-month and 1-year visits; also at 1-month and unscheduled visits if there is a spontaneous report of visual distortion or prior to an IOL repositioning procedure at that visit.
- Medical and lens findings from biomicroscopic slit-lamp exam: 6-month and 1-year visits and may be performed at the 1-month and/or unscheduled visits if an ocular adverse event occurred at such visit or if a severe visual distortion is noted. Findings of aqueous cells and flare, corneal edema, posterior capsule striae, posterior capsular opacification and IOL glistenings are to be rated using the standardized grading scales provided in Appendix D.
- Ocular medications

- Dilated fundus exam, if medically indicated
- Occurrence of Nd:YAG capsulotomy(ies)
- Occurrence of any adverse events
- If an ocular adverse event or a severe visual distortion is noted at any postoperative study visit, the following additional information should be collected:
  - Monocular uncorrected distance visual acuity (Snellen)
  - Binocular uncorrected distance visual acuity (Snellen), 6-month and 1-year visits only
  - Manifest refraction (Snellen) for each eye
  - Monocular best corrected distance visual acuity (Snellen)
  - Binocular best corrected distance visual acuity (Snellen), 6-month and 1-year visits only
  - Intraocular pressure

11.6 UNSCHEDULED VISIT(S) FOR ADVERSE EVENT OR SPONTANEOUS REPORT OF VISUAL DISTORTION(S)

A visit is considered an unscheduled study visit when it occurs other than at the specified 1- or 6-month study visits AND at which an ocular adverse event is reported OR if the subject has a spontaneous report of any of the 5 defined visual distortion items of interest (lines that slant, tilt or separate, flat surfaces appearing curved, objects appearing further away or closer than they actually are, objects appearing to have a different size or shape or physical discomfort related to vision as defined in Section 6.0) or of blurred or hazy vision at 1 month postoperatively or later. For example, if the subject is seen for a routine (non-study) 3-month follow-up visit and there are no ocular adverse events or any spontaneous reports of visual distortion(s) of interest or of blurred or hazy vision at 1 month postoperatively or later, this would NOT be captured on an unscheduled visit form. If however, the subject commented on a visual distortion as listed above or an ocular adverse event was noted at this visit, this visit would be captured on an unscheduled visit form.

During the study period, if a serious or device-related adverse event occurs, per Section 12.0, details of the event are to be captured on an adverse event CRF and the exam details are to be captured on the appropriate visit CRF (i.e., 1-month, 6-month, 1-year or unscheduled). The event will be followed up as necessary and details captured on adverse event follow-up CRFs until resolution.

If the event results in an IOL repositioning procedure (secondary surgical procedure), the PRVDQ questionnaire is to be administered and, for subjects with toric IOLs, keratometry and toric IOL axis measurements are to be performed PRIOR to the IOL repositioning procedure for evaluation of visual distortions arising from IOL misalignment.

If a subject reports a visual distortion at an unscheduled visit, the PRVDQ questionnaire is to be administered, and, for subjects with toric IOLs, keratometry and toric IOL axis measurements are to be performed.

Data to be collected on adverse event and/or unscheduled visit forms (due to ocular adverse event or spontaneous report of visual distortion) include, as applicable:

- Adverse event, date of onset and classification
- Prognosis and treatment
- Questionnaire - in the event of a spontaneous report of visual distortion or prior to an IOL repositioning procedure
- Manifest refraction (Snellen),if performed
- Uncorrected and best-corrected distance visual acuity (Snellen), if performed
- Keratometry, for toric IOLs only- in the event of a spontaneous report of visual distortion or prior to an IOL repositioning procedure
- Intraocular pressure, if performed
- Toric IOL axis measurement by dilated slit-lamp examination, for toric IOLs only (Refer to Appendix C for measurement instructions) - in the event of a spontaneous report of visual distortion or prior to an IOL repositioning procedure
- Slit-lamp examination for medical and/or lens findings (e.g., IOL rotation), if performed
- Dilated fundus exam, if performed
- Ocular medications

11.7 SUBJECT FOLLOW-UP AND DISCONTINUATION

Every attempt will be made to gather complete follow-up data for all treated subjects. If a subject has a confirmed report of severe visual distortion(s) per the questionnaire, prior to the 6-month exam, every effort is to be made to ensure that subject returns for the 6-month exam. The investigative site shall make a minimum of at least three attempts

(phone calls/emails and/or letters) to locate missing subjects. It is the responsibility of the investigator to provide complete follow-up data to AMO for each subject.

SUBJECT FOLLOW-UP

To minimize subjects lost to follow-up, subjects will be provided compensation for their time and participation in the study at the 1- and 6-month postoperative exams. Additionally, sites will be compensated for completion of the 1- and 6-month exams and will be provided frequent listings of upcoming 1- and 6-month subject examinations as well as follow-up reminder cards to send to the subjects. It is anticipated that at least 90% of subjects will be available for the 6-month study visit (i.e., no more than a 10% lost-to-follow-up rate at 6 months postoperatively).

SUBJECT DISCONTINUATION

The investigator should notify AMO prior to discontinuing a subject from the study. If a subject is discontinued from the study, the investigator will, if at all possible, have the subject return for a final study visit. An Exit CRF is to be completed for each subject exiting the study indicating the reason for early termination.

Subjects should be discontinued from the study only if irretrievably lost to follow-up or for unavoidable reasons such as subject moved/unable to locate, subject uncooperative/refuses to return, subject died, subject ill/unable to travel, subject institutionalized. The site shall document at least three attempts (phone calls/emails and/or letters) to locate lost-to-follow-up subjects. Patients who would be traveling, relocating or otherwise unavailable for postoperative follow-up visits should not be chosen for this clinical study. In the event of unplanned subject relocation, efforts must be made by the investigator to secure follow-up information (i.e., slit-lamp examination, etc.) from the subject's new physician.

A subject may be discontinued from the study if complications occur during the first-eye surgery and the planned study lens is not implanted; however, the eye will be followed until the resolution of the complication prior to discontinuing the subject from the study. If a complication occurs during the second-eye surgery and the planned study lens is not implanted in the second eye, the subject is to be followed according to the protocol for the first eye (although data may be analyzed separately), and the second eye will be followed for safety until resolution of the complication.

In the event of a lens removal or other serious adverse event, the subject may be exited from the study; however, efforts must be made by the investigator to follow the subject until resolution of the adverse event.

12.0 ADVERSE EVENTS AND PRODUCT COMPLAINTS

12.1 ADVERSE EVENT AND COMPLAINT DEFINITIONS

ADVERSE EVENT (AE)

Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the IOL or the implantation procedure.

All adverse events will be recorded in the subject's case report forms. An adverse event form will be completed by the investigative site for any adverse device effect (ADE) or serious adverse event (SAE).

NOTE: Findings typical of early postoperative healing (e.g., corneal edema, cells and flare, elevated intraocular pressure, etc.) will not be considered an ocular adverse event in the first postoperative month.

ADVERSE DEVICE EFFECT (ADE)

An adverse event that is believed to be, probably or possibly related to the IOL or the use of the IOL.

PRODUCT COMPLAINT/DEVICE DEFICIENCY

Any alleged deficiency related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution. Product complaints can pertain to any marketed AMO device being used in the study as well as the study device, if marketed in another region. The investigator is to assess whether the deficiency could have led to a serious adverse event without suitable action or intervention or under less fortunate circumstances.

SERIOUS ADVERSE EVENT (SAE)

A serious adverse event is any (ocular or non-ocular) untoward occurrence which may or may not be related to the use of the study device that:

- results in death
- is sight- or life-threatening

- requires in-patient hospitalization or prolongation of existing hospitalization (a planned hospitalization for a pre-existing condition is not considered an SAE)
- results in permanent impairment of a body structure or body function, or
- necessitates medical or surgical intervention to prevent permanent impairment to a body structure or function
- led to fetal distress, fetal death, congenital abnormality or birth defect

STUDY-SPECIFIC ANTICIPATED SERIOUS ADVERSE EVENTS

The following is a list including, but not limited to, ocular adverse events that are anticipated and must be reported to AMO for this study. Any events that are unlikely but anticipated (i.e. endophthalmitis) will be reported to the FDA.

- Endophthalmitis/Intraocular infection
- Hypopyon
- Hyphema
- Lens dislocation
- Cystoid macular edema
- Pupillary block
- Retinal detachment/tear
- Persistent corneal edema
- Persistent iritis
- Persistent elevated IOP requiring treatment
- Tilt, decentration or axis misalignment resulting in secondary surgical intervention (e.g. repositioning)
- Visual symptoms requiring secondary surgical intervention
- Residual refractive error resulting in a secondary surgical intervention
- Residual lens remnants resulting in a secondary surgical intervention

NOTE 1: Conditions resulting in anterior chamber taps in the first postoperative week, suture removal and/or Nd:YAG capsulotomy are not considered adverse events for this study.

NOTE 2: For those subjects who are required to return for the 1-year study exam, conditions resulting in refractive enhancements performed after the 6-month postoperative exam are also not considered adverse events for this study and are to be reported as non-adverse event secondary surgical procedures.

NOTE 3: Raised IOP requiring treatment, corneal edema and iritis will only be considered serious if persistent at the final study visit (120-180 days postoperative or 330-420 days postoperative if 1-year visit is required) or sight-threatening at the time of occurrence. Treatment merely to hasten the resolution of such conditions (and not intended to prevent permanent damage to the eye) will not be reported.

UNANTICIPATED ADVERSE DEVICE EFFECT (UADE)

An unanticipated adverse device effect is defined as any serious adverse device effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem or death was not previously identified in nature, severity or degree of incidence in the study protocol, risk management file or existing product labeling; or any other unanticipated serious problem associated with a device that relates to the rights, safety or welfare of subjects.

12.2 ADVERSE EVENT REPORTING REQUIREMENTS

All adverse events, regardless of severity and whether or not attributed to the IOLs, are to be reported to AMO and recorded on the CRFs supplied. All serious adverse events, whether anticipated or unanticipated, and all adverse device effects shall be reported using an adverse event case report form and forwarded to AMO. Adverse events are also to be reported to the reviewing IRB as per their reporting requirements. If required, adverse events will be reported to the appropriate regulatory agencies (e.g., FDA, etc.) according to all applicable laws and regulations. Specific instructions on notification procedures to AMO are included in Appendix E, Adverse Event Reporting.

In addition to adverse event reporting, Investigators are required to notify AMO of a product complaint, device defect or malfunction within a timely manner. Any device deficiency that could have led to a serious adverse event without suitable action or intervention, or under less fortunate circumstances, must be reported to the sponsor immediately (no later than 48 hours after detection). Device deficiencies that could have let to a serious adverse event should also be reported to the investigators IRB as per their reporting requirements.

ADVERSE DEVICE EFFECT (ADE)

An adverse device effect is to be reported to AMO in a timely manner by submitting a completed Adverse Event CRF. The investigator must report the ADE to the investigator's IRB as per their reporting requirements.

SERIOUS ADVERSE EVENT (SAE)

In the event of a serious adverse event, which may or may not be related to use of the study device, the investigator must notify AMO immediately (within 48 hours after detection) by phone and by submitting a completed Adverse Event CRF. The

investigator must report serious adverse events to the investigator's IRB as per their reporting requirements.

UNANTICIPATED ADVERSE DEVICE EFFECT (UADE)

If during the study a serious adverse event occurs that may reasonably be regarded as product related and was not previously identified in nature, severity, or degree of incidence in the study protocol, risk management file, or existing product labeling, the investigator is to report the UADE to AMO within 48 hours, and to the investigator's IRB as soon as possible (and no later than 10 working days after learning of the event).

12.3 ADVERSE EVENT FOLLOW-UP

For every serious or device-related adverse event, i.e., ADE, SAE and UADE, appropriate measures should be undertaken to treat and/or monitor the subject until resolution occurs. The investigator should keep AMO closely informed as to the outcome, thereby allowing AMO to comply with the appropriate regulatory reporting requirements. An Adverse Event Update CRF should be completed each time the subject returns for follow-up until resolution of the event, i.e., of an ADE, SAE or UADE. Additionally, the investigator may need to supply to AMO written reports (e.g., from outside specialist evaluations) related to these adverse events until resolution of the adverse event. Any subject who is withdrawn from the study due to an adverse event will be followed until the outcome is determined.

12.4 RELATIONSHIP TO STUDY DEVICES

The investigator should be alert to adverse events that may be related to the study devices; in this case, the TECNIS Toric IOLs, Models ZCT300 or ZCT400, and the control TECNIS 1-piece monofocal IOL, Model ZCB00. An attempt should be made in every case to determine if the event may be device-related. The following definitions are to be used as guidelines to determine the relationship between the event and the study devices or use of the device (implantation procedure):

Definitely related:	There is a definite causal relationship between the study device or implantation procedure and the adverse event.
Probably related:	There is a reasonable possibility of a causal relationship between the study device or implantation procedure and the adverse event.

Possibly related: The adverse event has not been determined to be related to the study device or implantation procedure, but no other cause has been definitively identified and the device cannot be ruled out as a possible cause.

Unlikely to be related: The possibility of a potential causal relationship between the adverse event and the study device or implantation procedure could exist but the adverse event is most likely explained by causes other than the study device or implantation procedure.

Not related: There is no possibility of a causal relationship between the adverse event and the study device or implantation procedure.

If an adverse event is believed to be definitively, probably or possible related to the study device, the event will be considered device-related. The investigator's determination of causal relationship between the adverse event and the IOLs and/the implantation procedure will be recorded on the Adverse Event case report form.

13.0 PROTOCOL CHANGES AND PROCEDURES

Any deviation from the protocol done to protect the life or physical well-being of a subject in an emergency must be reported to AMO and the reviewing IRB as soon as possible, but no later than five working days after the deviation occurred. A Protocol Deviation form is to be completed by the investigator for each protocol deviation, defined as any deviation from the study plan and/or procedures (e.g., an exception to the inclusion/exclusion criteria). Unless it is an emergency, if the investigator desires to modify any procedure and/or deviate from the design of the study, he or she must contact and obtain consent from AMO regarding the proposed changes prior to implementation. Any modifications (including additional data collection) require approval by the FDA as well as approval by the IRB.

14.0 ETHICS REVIEW AND PATIENT WELFARE

14.1 INSTITUTIONAL REVIEW BOARD (IRB)

It is the responsibility of the investigator to obtain prospective approval of the study protocol, protocol amendments or changes, informed consent forms and other relevant documents (e.g., advertisements) from the IRB. All correspondence with the IRB should be retained in the Investigator Notebook. Copies of IRB approvals should be forwarded to AMO.

The investigator is responsible for notifying the IRB of reportable adverse events as well as any other circumstance in which additional procedures outside the protocol were conducted to eliminate apparent hazards to subjects.

14.2 INFORMED CONSENT

The current version of the IRB-approved study informed consent must be signed and dated by each study subject prior to any study-specific examinations being performed. The approved informed consent is to be signed and dated by the subject as well as by the person who conducted the informed consent discussion. The signed informed consent will be maintained by the investigator as a permanent part of the subject's medical records. A signed and dated copy is to be provided to the subject. The investigator will provide AMO written acknowledgement on the preoperative case report form that a signed agreement of informed consent has been obtained and is in the investigator's possession for each subject. As required by 21CFR812 Part G, the site shall document in the source documents that informed consent was obtained prior to participation in the study for each subject enrolled. A sample informed consent form is provided in Attachment A.

NOTE: The informed consent process also includes obtaining the subject's signature on an Authorization for Use/Disclosure of Health Information for Research Form. A sample Authorization for Use/Disclosure of Health Information for Research Form is provided in Attachment B.

15.0 DOCUMENTATION

15.1 SOURCE DOCUMENTS

Source documents must be kept for all study subjects. Source documents may include a subject's medical records, hospital charts, clinic charts, the investigator's subject study files (including original subject case report forms), as well as results of any diagnostic tests or procedures, photographs or instrument printouts.

Each site is expected to adhere to the clinic's own standard documentation requirements for medical charts/clinic notes. However, for the purposes of this clinical study, the medical charts/clinic notes must also include, at a minimum, the following data that will be considered source data and will be reviewed by AMO:

- Subject's name and study identification number
- Subject's contact information
- Study title and/or protocol number of the study and the sponsor name, Abbott Medical Optics (AMO)
- Document in each subject's case history that informed consent was obtained prior to participation in the study as required by 21CFR812
- Dates of all subject visits and surgeries throughout the duration of the study
- Concomitant medications
- Corrected and uncorrected distance visual acuities
- Manifest refraction
- Keratometry (e.g., IOL master or topography printouts)
- Toric IOL Calculator output for each eye
- Occurrence and status of any operative complications, postoperative medical or lens findings and adverse events
- The date the subject completed the study; or if the subject was discontinued prior to completing the study, the date the subject exited the study and the reason for discontinuation
- If the subject was lost to follow-up, documentation of a minimum of three attempts to locate subject (phone, email and/or letter)

The study protocol should be used as a guide for the points of data that are required for the study.

15.2 SUBJECT CONFIDENTIALITY

Subjects will be assigned a unique subject number and code at the time of enrollment as a means of identification on study documents. Subject confidentiality will be maintained by recording only the subject number and code (e.g., subject initials) on case report forms. Subject names may possibly be disclosed to AMO, the IRB or regulatory agencies during inspection of study records. All reasonable precautions will be taken to maintain confidentiality of medical records and personal information to the extent permitted by applicable laws and regulations.

15.3 CASE REPORT FORM COMPLETION

An electronic data capture system using electronic case report forms will be used for this study. Case report forms are to be completed in accordance with instructions provided to the site prior to study start.

The investigator is responsible for ensuring that data are properly recorded on each subject's case report forms and related documents. Prior to database lock, the investigator will verify completeness and accuracy of data submitted to AMO.

16.0 MONITORING PROCEDURES

AMO will perform three types of monitoring to ensure compliance with regulations: data monitoring, administrative monitoring and medical oversight.

16.1 DATA MONITORING

In order to ensure a well-controlled clinical trial, AMO will follow specific data monitoring procedures.

Subject data will be transmitted via case report forms from the investigative site to AMO. Requests for data clarification will be handled through this same data management system.

To minimize data omissions and inconsistencies on clinical reports and to ensure that data are accurately transcribed to computer data files, AMO will follow internal data processing procedures that include automated and manual quality control checks to identify any data discrepancies. Any such items will be resolved and documented as needed on the case report forms at the investigative site and entered into the data management system at AMO.

16.2 ADMINISTRATIVE MONITORING

Administrative monitoring procedures will ensure that subjects, study product, including IOLs, and forms can be traced and will allow monitoring of investigator progress and compliance.

LENS ACCOUNTABILITY

As both study lens types, the TECNIS Toric ZCT300 and ZCT400 IOLs and the TECNIS Model ZCB00, are commercially available, supply records for study lenses will solely be the responsibility of the site and managed by their customary methods. However, documentation of the lenses that are implanted in study subjects will be maintained. AMO will periodically monitor IOL implant logs to ensure compliance and traceability.

SITE MONITORING

Prior to performing any study implants, the requirements of the study and reporting mechanisms will be explained to each investigator either personally at the investigative site or at a group investigator meeting. When necessary, a pre-study site qualification visit may also be performed to assess the adequacy of the site to perform the study for sites that have not previously worked with AMO or have undergone significant changes, or have not been visited in the past year. At a minimum, a study initiation visit will be performed at all sites.

Throughout the duration of the study, site visits to monitor compliance to the protocol will be made at each investigative site by an AMO representative. Sites will be visited at least once a year during the study or more often if needed, depending upon site enrollment progress, data collection and case report form completion, study exam visit compliance, occurrence of adverse events, etc. During a routine site visit, AMO will review informed consent documents and eligibility, and the data on study case report forms against subject charts and other source documents to ensure complete and accurate reporting. The subject files will also be reviewed to ensure that all adverse events have been reported in a timely manner. Additionally, AMO will review documents to verify that the minimum items for source documentation have been documented in the subject medical charts. Refer to Section 15.1 Source Documents for a list of items that are required for source documentation. Subject records will be reviewed at each site in accordance with an approved monitoring plan. Training on study-specific procedures may also be conducted during or outside of monitoring visits. Upon study completion, a final close-out visit to each site will be conducted to monitor the last of the subject data records and finalize any outstanding study issues.

16.3 MEDICAL OVERSIGHT

The medical monitor will be available throughout the clinical study to review study results and to answer any questions from investigators. The specific responsibilities of the medical monitor are to review and assess any reports of serious or device-related adverse events and, if necessary, to discuss these with the reporting investigator(s). The medical monitor, as well as any other qualified personnel designated by AMO, shall also review any reports on the progress of the study.

17.0 PUBLICATIONS

Refer to the Clinical Trial Agreement for information regarding AMO publication policies.

18.0 RECORDS RETENTION

All study-related correspondence, subject records, consent forms, Authorization for Use/Disclosure of Health Information Forms, records of use of study products and original case report forms should be maintained on file by the investigative site.

The investigator must maintain and have access to the following essential documents for a minimum of two years from the date of study completion or five years from the date of regulatory submission, whichever is longer, or until AMO informs the site as to when these documents no longer need to be retained:

- All case report forms
- All adverse event information (adverse event forms, follow-up letters, etc.)
- IRB and regulatory approval documentation
- Study agreements
- Study correspondence
- Site visit documentation
- Protocol(s) and the reason for any deviations from the protocol
- Subject log(s)
- Study lens implantation logs
- Completed subject informed consent forms and Authorization for Use/Disclosure of Health Information forms
- Subject medical chart/clinic notes

AMO requires written notification from the site if the investigator wishes to relinquish ownership of the study documents so that mutually agreed-upon arrangements can be made for transfer of ownership to a suitably-qualified, responsible person.

19.0 TERMINATION OF THE STUDY

The clinical study will be suspended in the event of unexpected high levels of complications and/or the occurrence of adverse events that are unexpected in nature and/or severity. The clinical study will be suspended by AMO if any of the following conditions occur:

- In the event of severe and alarming adverse events that have not been previously anticipated in nature and/or severity.

- The Medical Monitor, upon review and evaluation of the clinical data and/or adverse event reports, finds the level of single or total complications and/or adverse events unacceptable for continuation of the study.
- The FDA or IRBs, upon review of clinical study data and/or adverse event reports, find the level of complications and/or adverse events unacceptable for continuation of the study.
- Unacceptable clinical performance of the study lens(es) (i.e., unacceptable incidence, bother or intensity of subjective visual distortions, etc.) as deemed by AMO and/or the Medical Monitor.

If the study is suspended, an evaluation of causality will be made to determine the relationship to the study lens(es). If causality is shown not to be related to the study lens(es), the study may be resumed in accordance with the IRB and FDA. The study will be terminated if causality is shown to be related to the study lens(es).

The investigator or AMO may stop a subject's participation at any time. Additionally, AMO may stop the study at any time for reasons it determines appropriate. However, no suspension of the study will be made to disadvantage the study subjects. Following suspension of the study for any reason, all study subjects who have already received at least one study lens will continue to be followed through completion of the study visit schedule.

20.0 DATA ANALYSIS AND REPORTING

Outcomes for subjects implanted with the TECNIS Toric IOLs, Models ZCT300 and ZCT400, will be compared to those implanted with the TECNIS Model ZCB00 control IOL at 6 months postoperatively. The number and proportion of subjects who did and did not have 6-month data available will be presented for toric and non-toric control IOL groups. Demographic data (age, sex, gender) will also be presented for both groups. Visual distortion findings, adverse events and medical/lens findings at one year will be reported for subjects who experienced a repositioning procedure during the study or for subjects who were reported with severe visual distortions at the 6-month visit. The primary endpoint is the rate of severe visual distortions defined as the proportion of subjects who report a severe visual distortion under overall circumstances at 6 months for any of the 5 visual distortion items of interest. The frequency and proportion of subjects reporting one or more of these items as severe will be used to determine the rate of severe visual distortions.

20.1 ANALYSIS POPULATIONS

For the primary endpoint of the rate of severe visual distortions (under overall circumstances) and for most visual distortion endpoints, the primary analysis population will be subjects bilaterally implanted with either the toric IOLs or the control lenses. An additional analysis for the rate of severe visual distortions based on the 5 items used for the primary endpoint will be performed that includes all bilateral subjects and those with only one eye implanted (i.e., having a phakic or cataractous fellow eye or having another IOL in the fellow eye due to surgical complications prior to lens implantation). The rates of severe visual distortions (based on the 5-item evaluation), will also be stratified by subjects in the lower-cylinder group (those eligible for the ZCT300) and the higher-cylinder group (those eligible for the ZCT400). Control subjects will be included in the lower- or higher-cylinder group based on the toric lens they would have required if they had chosen a toric IOL. Subjects who are eligible for the ZCT300 in one eye and the ZCT400 in the fellow eye will be placed in the ZCT400 group for analysis. .

For other safety endpoints, the primary analysis will consist of the safety population of all eyes implanted with either a toric or control IOL and with available data at the time of analysis. Any operative complications or additional procedures will also be presented for first and second eyes of toric and control subjects. Reporting of cumulative complications (occurring at any time postoperatively) will include data from all study eyes (first and second) implanted.

20.2 PRIMARY ENDPOINT ANALYSIS

The primary endpoint is the rate of severe visual distortions (under overall circumstances) as measured by the 5 defined visual distortion items at 6 months postoperative. The frequency and proportion of bilateral subjects with severe visual distortions will be presented for toric IOL and control IOL subjects. Any subject with missing data for visual distortion symptoms at the 6-month visit will have the last reported value carried forward, if the subject had an earlier visit. Results for severe visual distortions will be evaluated using a non-inferiority approach with a non-inferiority margin of 10%. The upper limit of the 90% confidence interval of the difference in severe visual distortion rates (toric minus control) will be used to evaluate this endpoint.

The null hypothesis, H_0, is: pToric – pControl $\geq$ 0.10

The alternate hypothesis, H_1, is: pToric – pControl < 0.10

With p=proportion reporting severe visual distortions

A logistic regression analysis for severe visual distortions will be performed with age, sex, race, and cylinder subgroup as well as age by IOL group and sex by IOL group as covariates to evaluate the influence of these variables.

To evaluate if toric IOL axis misalignment relative to keratometry are associated with severe visual distortions, descriptive statistics for IOL axis misalignment will be reported for toric subjects with and without severe visual distortions. In this study, axis misalignment is defined as the difference between the toric IOL axis marker location from the slit-lamp evaluation and the steep meridian from the postoperative keratometry measurement. This measurement is intended to evaluate toric IOL misalignment as a possible reason for severe visual distortions experienced by a subject at a specific postoperative time point. This axis misalignment measurement is not a measure of toric IOL rotational stability, but a measure of toric IOL alignment relative to post-surgical keratometry steep meridian, as it is known that cataract surgery can induce changes in the cornea.

The frequency and proportion for the rate of severe visual distortions will also be presented for those in the low- and high-cylinder subgroups for toric and control subjects.

20.3 OTHER VISUAL DISTORTION ENDPOINT ANALYSES

In addition, the number and percent of subjects with each response will be reported for the individual visual distortion items from the questionnaire and will also be reported by IOL group.

20.4 OTHER ENDPOINT ANALYSES

The frequency and proportion of medical and lens findings and adverse events will be presented for first and second eyes of toric and control subjects. The severity of all serious adverse events and adverse device effects, such as IOL repositioning procedures, through 6 months postoperatively will also be presented.

20.5 ADDITIONAL ANALYSES AND DATA CONVENTIONS

For categorical data, frequencies and proportions will be computed. Descriptive statistics will include sample size (N), mean, standard deviation (SD), minimum (Min) and maximum (Max) as appropriate.

20.6 SAMPLE SIZE

A sample size of a minimum of 396 enrolled subjects to achieve bilateral implantation of approximately 294 subjects: 169 TECNIS Toric ZCT300 and ZCT400 and 125 control subjects is reflective of the number of subjects enrolled on the date of this protocol revision (3.0).

A two-group large-sample normal approximately test of proportions with a one-sided 0.05 signficance level using only 37 evaluable toric subjects and 27 evaluable control subjects will have a greater than 90% power to detect a rate of severe visual distortions for toric subjects as being 10 percentage points or greater than that for control subjects. This assumes severe visual distortion rates of 1% for both the toric and control subjects. Therefore, the sample size proposed for a minimum of 396 enrolled subjects, assuming a 10% drop out rate for a minimum of 152 toric and 112 control subjects available for evaluation at 6 months, is sufficient to demonstrate non-inferiority in the rate of severe visual distortions (the primary endpoint of this study) between the two study groups in a larger population in clinical practice and thereby demonstrate the continued safety of the toric IOLs.

20.7 DATA REPORTING REQUIREMENTS

Interim status study reports will be provided to FDA every 6 months from the date of study initiation for the first 2 years and annually thereafter according to the guidance document entitled “Procedures for Handling Post-Approval Studies Imposed by PMA Order,” dated June 15, 2009.

A primary-analysis, complete 6-month study report will be provided to FDA approximately 3 months following completion of the last 6-month study visit. Any 1-year data collected to date will be included.

A final study report will be provided to FDA approximately 3 months following completion of the last 1-year study visit. Note that the primary-analysis, 6-month report and the final report may be submitted at the same time depending upon when the last 6-month and 1-year exams are completed.

Interim and final study reports will include general enrollment and accountability items including the number of active sites, the number of subjects enrolled, implanted and discontinued and the number of postoperative examinations completed. Enrollment rates and subject follow-up will be compared to anticipated, target study timelines (Section 10.0 Study Timeline).

21.0 REFERENCES

1. Ferrer-Blasco, T. et al. Prevalence of corneal astigmatism before cataract surgery. J Cataract Refract Surg 2009; 35: 70-75

2. Hoffer KJ. Biometry of 7,500 cataractous eyes. Am J Ophthalmol 1980;90:360-368

APPENDIX A
SUMMARY OF EXAMINATIONS FOR EACH VISIT

Examination **X= To be performed** **A= To be performed if a subject reports a severe visual distortion or experienced an ocular adverse event at this visit** **B= To be performed if a visual distortion is spontaneously reported prior to 6 month exam or prior to a required IOL repositioning (adverse event)** **O = Only if medically indicated**	**Preoperative Both eyes**	**Op 1 1st eye**	**Op 2 2nd eye**	**Unscheduled Visit**	**1 Month Both eyes**	**6 Months Both eyes**	**1 Year[a] Both eyes**
Ocular history, inclusion/exclusion criteria	X						
Informed consent	X						
Potential visual acuity	X						
Targeted refraction/IOL power calculations[b]/axial length	X						
Lens power/serial number/operative procedures		X	X				
Manifest refraction (Snellen)	X			A	A	A	X
UCDVA-photopic, monocular (Snellen)	X			A	A	A	X
UCDVA-photopic, binocular (Snellen)						A	X
BCDVA-photopic, monocular (Snellen)	X			A	A	A	X
BCDVA-photopic, binocular (Snellen)						A	X
Offer spectacle and/or contact lens prescription					X		
Keratometry	X			B[d]	B[d]	X[d]	X[d]
Intraocular pressure	X			A	A	A	X
Biomicroscopic slit-lamp exam[c]	X			A	A	X	X
Toric IOL axis measurement at dilated slit-lamp exam[d],				B[d]	B[d]	X[d]	X[d]
Dilated fundus exam	X			O	O	O	O
Adverse events		X	X	X	X	X	X
Ocular medications	X			X	X	X	X
Subject questionnaire	X			B	B	X	X

[a] Examination at 1 year is to be conducted ONLY if a subject reported a severe visual distortion at 6 months or if the subject experienced an IOL repositioning procedure (due to IOL misalignment) during the study.
[b] Includes documentation of toric IOL calculations showing ZCT300 and/or ZCT400 IOLs as toric choices for each eye
[c] Includes determination of medical and lens findings/complications, including lens rotation
[d] For Toric IOLs only

APPENDIX B
STUDY QUESTIONNAIRE

Patient Reported
Visual Distortions Questionnaire
(PRVDQ)

This questionnaire asks about the severity of visual distortions OVER THE LAST 7 DAYS. If your vision is different between eyes, please respond with how you see with both eyes in general. For each question, please indicate if you have experienced the "visual distortion" under these 3 circumstances:

A. When NOT wearing corrective glasses (including reading glasses) or contacts

B. When WEARING corrective glasses (including reading glasses) or contacts.

C. Overall (taking all things into account)

Please read each question carefully and answer as honestly as you can without the help of anyone. There are no right or wrong answers.

For ALL questions, please mark an ☒ in the box that best describes your answer.

Blurred vision at all distances may be described as a lack of vision sharpness resulting in the inability to see fine detail.

Q1. Please rate the severity of **blurred vision at all distances** you experienced over the LAST 7 DAYS…

	Did not experience	Mild	Moderate	Severe	Does not Apply
a When **not** wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b When **wearing** corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c Overall (taking all things into account)	☐ 0	☐ 1	☐ 2	☐ 3	

Hazy vision may be described as looking through fog or smoke.

Q2. Please rate the severity of **hazy vision** you experienced over the LAST 7 DAYS…

	Did not experience	Mild	Moderate	Severe	Does not Apply
a When **not** wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b When **wearing** corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c Overall (taking all things into account)	☐ 0	☐ 1	☐ 2	☐ 3	

Double vision may be described as seeing a single object as two slightly overlapping or separate objects.

Q3. Please rate the severity of double vision you experienced over the LAST 7 DAYS…

	Did not experience	Mild	Moderate	Severe	Does not Apply
a When not wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b When wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c Overall (taking all things into account)	☐ 0	☐ 1	☐ 2	☐ 3	

Straight lines may appear to slant, tilt, split or separate.

Q4. Please rate the severity of seeing lines that slant, tilt, split or separate you experienced, over the LAST 7 DAYS…

	Did not experience	Mild	Moderate	Severe	Does not Apply
a When not wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b When wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c Overall (taking all things into account)	☐ 0	☐ 1	☐ 2	☐ 3	

Lines or edges of an object may appear to have dark bumps or spikes.

Q5. Please rate the severity of seeing lines or edges of an object with dark bumps or spikes you experienced over the LAST 7 DAYS…

	Did not experience	Mild	Moderate	Severe	Does not Apply
a When not wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b When wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c Overall (taking all things into account)	☐ 0	☐ 1	☐ 2	☐ 3	

Flat surfaces may appear curved.

Q6. Please rate the severity of flat surfaces appearing curved you experienced over the LAST 7 DAYS…

	Did not experience	Mild	Moderate	Severe	Does not Apply
a When not wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b When wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c Overall (taking all things into account)	☐ 0	☐ 1	☐ 2	☐ 3	

Objects may appear to be a different color or shade of the same color than you know they actually are.

Q7. Please rate the severity of objects appearing to be a different color or shade of the same color than you know they actually are over the LAST 7 DAYS…

	Did not experience	Mild	Moderate	Severe	Does not Apply
a When **not** wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b When **wearing** corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c Overall (taking all things into account)	☐ 0	☐ 1	☐ 2	☐ 3	

Objects may appear to project or stand out from the background in an unusual way.

Q8. Please rate the severity of objects appearing to project or stand out from the background in an unusual way you experienced over the LAST 7 DAYS…

	Did not experience	Mild	Moderate	Severe	Does not Apply
a When **not** wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b When **wearing** corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c Overall (taking all things into account)	☐ 0	☐ 1	☐ 2	☐ 3	

Objects may appear to be further or closer than they actually are, making it difficult to judge distance.

Q9. Please rate the severity of objects appearing further or closer than they actually are over the LAST 7 DAYS…

	Did not experience	Mild	Moderate	Severe	Does not Apply
a When not wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b When wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c Overall (taking all things into account)	☐ 0	☐ 1	☐ 2	☐ 3	

Objects may appear distorted causing their size or shape to look different than you know they actually are.

Q10. Please rate the severity of objects appearing to have a different size or shape than you know they actually are over the LAST 7 DAYS…

	Did not experience	Mild	Moderate	Severe	Does not Apply
a When not wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b When wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c Overall (taking all things into account)	☐ 0	☐ 1	☐ 2	☐ 3	

Visual distortions may cause physical discomfort such as nausea (feeling sick to your stomach), dizziness and/or headache.

Q11. Please rate the severity of physical discomfort related to vision you experienced over the LAST 7 DAYS…

	Did not experience	Mild	Moderate	Severe	Does not Apply
a When **not** wearing corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
b When **wearing** corrective glasses or contacts (including reading glasses)	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
c Overall (taking all things into account)	☐ 0	☐ 1	☐ 2	☐ 3	

Q12. Over the LAST 7 DAYS, have you experienced any other visual distortions not described above?

☐ Yes (if yes, please describe): _____

☐ No

APPENDIX C

TORIC IOL AXIS MEASUREMENT AT SLIT LAMP

The following instructions are to be followed for the measurement of the toric IOL axis in both eyes.

1. Dilate each eye with 2.5% phenylephrine prior to measurement. Tropicamide (1%) may be used in addition, at the Investigator's discretion.
2. Allow sufficient time to achieve adequate pupillary dilation to facilitate direct visualization of alignment marks.
3. At the slit lamp, adjust the slit-lamp beam to be as narrow as possible and align the beam with the four axis orientation marks (4.5, 5.0, 5.5 and 6.0 mm diameter) on one side of the toric IOL.
    a. It is important to align the beam with at least two of the four orientation marks for an accurate measurement.
    b. Ensure the subject's head is oriented vertically in the slit lamp with proper head position and alignment of eye with the slit lamp.
4. Read the angle of the toric IOL axis markers based on the narrowed slit-lamp beam from the angular scale on the slit lamp.
5. Record this angle in degrees for each eye on the appropriate postoperative case report form.

APPENDIX D
SLIT-LAMP EXAM RATINGS

A. RATINGS OF AQUEOUS CELLS AND FLARE

For consistency across study sites, the SUN (Standardization of Uveitis Nomenclature) Working Group Grading Scheme is to be used for grading of anterior chamber cells and flare as reported in: Standardization of uveitis nomenclature for reporting clinical data. Results of the first international workshop; The standardization of uveitis nomenclature (SUN) working group. Am J Ophthalmol 2005;140:509-516.

CELLS

Grade	Cells in Field* *Field is a 1x1 mm slit beam
0	<1
0.5+	1-5
1+	6-15
2+	16-25
3+	26-50
4+	>50

FLARE

Grade	Description
0	None
1+	Faint
2+	Moderate (iris and lens details clear)
3+	Marked (iris and lens details hazy)
4+	Intense (fibrin or plastic aqueous)

B. RATINGS OF CORNEAL EDEMA

Corneal edema should be classified according to the haziness of the epithelium, the number of microcysts observed and the clouding of the stroma.

None	**0**	Normal transparency: a. No epithelial or sub-epithelial haziness b. No microcysts c. No stromal cloudiness
Trace	**+1**	a. Barely discernable localized epithelial or sub-epithelial haziness and/or b. 1 to 20 microcysts and/or c. Barely discernable localized stromal cloudiness
Mild	**+2**	a. Faint but definite localized or generalized epithelial, sub-epithelial or stromal haziness/cloudiness and/or b. 21-50 microcysts
Moderate	**+3**	a. Significant localized or generalized epithelial, sub-epithelial or stromal haziness/cloudiness and/or b. 51-100 microcysts
Severe	**+4**	a. Definite widespread epithelial or stromal cloudiness, giving dull glass appearance to cornea or numerous coalescent bullae (please note the number and location of bullae) and/or b. >100 microcysts or bullae and/or c. Numerous striae (please note the number and location of striae or folds)

APPENDIX D (CONTINUED)
SLIT-LAMP EXAM RATINGS

C. POSTERIOR CAPSULE STRIAE GRADING SCALE

The following five-point grading scale is to be used for rating striae in the posterior capsule:

None	**0**	None
Trace	**+1**	One detectable, barely noticeable striae
Mild	**+2**	One or two prominent striae
Moderate	**+3**	Three or more prominent striae, but visibility of retina is not impacted
Severe	**+4**	Three or more prominent striae affecting visualization of retina

D. POSTERIOR CAPSULE OPACIFICATION (PCO) GRADING SCALE

Below is the five-point grading scale to be used for PCO determination:

None	**0**	Normal posterior capsule with no area of opacity. Red reflex bright.
Trace	**+1**	Some loss of transparency involving the posterior capsule. Red reflex fairly bright
Mild	**+2**	Mild loss of transparency with cloudiness extending through most of the posterior capsule. There may be a few Elschnig's pearls in the posterior capsule. Red reflex mildly diminished.
Moderate	**+3**	Moderate loss of transparency with difficulty visualizing the retina. There may be multiple Elschnig's pearls in the posterior capsule. Red reflex markedly diminished.
Severe	**+4**	Posterior capsule very opaque with inability to view the retina. The posterior capsule may have confluent Elschnig's pearls and fibrous scarring. Red reflex barely visible.

E. IOL GLISTENINGS

Use the following scale to grade IOL glistenings using a slit beam 2.0 mm wide and 10.0 mm long:

None	**0**	No glistenings visible
Rare	**+0.5**	<10 glistenings visible
Trace	**+1**	10-19 glistenings visible
Mild	**+2**	20-29 glistenings visible
Moderate	**+3**	30-39 glistenings visible
Severe	**+4**	≥40 glistenings visible

APPENDIX E
ADVERSE EVENT REPORTING INSTRUCTIONS

Adverse Device Effect (ADE)

In the event of an ADE, the investigator must notify AMO preferably within 48 hours and no later than 10 working days of first becoming aware of the event by completing the Adverse Event Form and submitting it to AMO.

Serious Adverse Event (SAE)

In the event of a sight- or life-threatening incident or serious adverse event, which may or may not be related to use of the study device, **the investigator must notify AMO immediately (no later than 48 hours after detection)** by phone and/or email and by submitting a completed Adverse Event Form as follows:

a. Contact the following AMO personnel by phone:

AND

b. Complete an Adverse Event Form and submit to AMO.

Unanticipated Adverse Device Effect (UADE)

For an adverse event that may reasonably be regarded as product related and was not previously expected in nature, severity, or degree of incidence in the study protocol, risk management file or existing product labeling, the investigator must report the event to AMO within 48 hours of detection after learning of the event using the same reporting method as for SAEs.

Device Defect or Malfunction without an Adverse Event

In the event of a complaint of study device defect or malfunction, the investigator must notify AMO preferably within 48 hours and no later than 10 working days of first becoming aware of the event by completing the information about the device on the Operative CRF and submitting it to AMO.

ATTACHMENT A
SAMPLE STUDY INFORMED CONSENT

NOTE: This sample informed consent is intended for submission to IRB upon FDA approval of protocol and is not to be used for participant enrollment. Only a current IRB-approved consent is to be used for subject enrollment.

SAMPLE ONLY - NOT TO BE USED FOR SUBJECT ENROLLMENT

SAMPLE
Informed consent

Research Subject Information and Consent Form

SPONSOR:	Abbott Medical Optics Inc. 1700 E. Saint Andrew Place Santa Ana, CA 92705
STUDY TITLE:	Post-approval study of the TECNIS® Toric 1-Piece Intraocular Lens, Models ZCT300 and ZCT400
STUDY NUMBER:	TIOL-202-TPAS
STUDY DOCTOR:	_____
Doctor's Phone Number:	_____
Subject Number:	_____

INTRODUCTION

You are being invited to participate in a clinical research study sponsored by Abbott Medical Optics Inc. (AMO). This document describes the study and your role in it. Your doctor has reviewed the study and has agreed to participate as an investigator. He or she will answer any questions that you have about this study or this consent document. Please read this document carefully and ask any questions you have regarding the information that it contains.

PURPOSE OF THIS RESEARCH STUDY

The purpose of this study is to evaluate the rate of visual distortions and ongoing safety of the TECNIS Toric intraocular lenses (IOLs), Models ZCT300 and ZCT400. You have been invited to participate in this research study because you have a certain level of astigmatism and are scheduled to undergo cataract surgery with IOL implantation in both of your eyes.

Cataracts occur when the natural lens of the eye becomes cloudy and eventually can interfere with vision. Cataract surgery involves the removal of the clouded lens by a surgical technique called phacoemulsification, and this must be performed before an IOL can be placed in your eye. The IOLs will be implanted into your eyes to help restore vision and are intended to remain in your eyes permanently; however, the IOLs can be surgically repositioned, replaced or removed if necessary. Standard or "monofocal, non-toric" IOLs provide predominantly far vision only and do not correct astigmatism.

Astigmatism is a condition where the cornea (front surface) of the eye is not curved uniformly like a sphere, but is shaped more like a football. With astigmatism, the light rays passing through the cornea do not focus on a single point of the retina. This may cause objects both near and far away to appear blurred and even broadened or elongated. An IOL designed to reduce astigmatism is called a "toric" IOL.

In this study, you will have the option to choose which type of lens you would like to be implanted with in both of your eyes: either toric IOLs or standard IOLs. Both types of

IOLs in this study have been approved by the FDA and are made of the same acrylic material, the same 1-piece monofocal lens design and have the same TECNIS aspheric front surface for improved vision quality. The only difference between the toric lenses and the standard lens is the toric surface to correct for astigmatism. The toric IOLs in this study are designed for eyes with higher amounts of astigmatism and are called the TECNIS Toric IOLs, Models ZCT300 and ZCT400. If you choose to be implanted with the toric lenses, the amount of astigmatism you have in your eyes will determine which toric IOL model is best for each of your eyes. The standard IOL in this study is called the TECNIS 1-piece IOL, Model ZCB00. The table below compares the three lenses in this study:

Lens Model	General Design	Amount of Astigmatism Correction
TECNIS 1-Piece Monofocal Model ZCB00 (Standard)	1-Piece, acrylic material	None
TECNIS Toric Model ZCT300	1-Piece, acrylic material with toric feature	2.00 to 2.75 diopters
TECNIS Toric Model ZCT400	1-Piece, acrylic material with toric feature	2.75 to 3.62 diopters

Approximately 396 enrolled and 294 treated from up to 80 investigative sites in the USA to participate in this study. If you qualify for the study, you will be able to choose which lens type you prefer (“toric” or “standard”) and your Study Doctor will help you decide.

The TECNIS Toric IOLs were previously studied for safety and effectiveness in a clinical study of 269 subjects. In the previous study, 174 subjects were implanted with the TECNIS Toric IOLs and 55 of these were implanted with the TECNIS Toric IOL Models ZCT300 and ZCT400. The TECNIS Toric IOLs are marketed in the US, Europe and other countries worldwide.

INCLUSION CRITERIA

To be considered for enrollment in this study, you must:

- be at least 22 years old
- have cataracts in both eyes
- have a certain degree of astigmatism in both eyes
- sign this written informed consent
- be willing and able to comply with examination procedures
- understand, read and write English to complete informed consent and questionnaires
- be available for study follow-up visits

EXCLUSION CRITERIA

You will not be eligible to participate in the study if:

- you are currently participating in any other clinical study or have participated in a clinical study during the last 30 days

- you have a certain disease/illness such as poorly-controlled diabetes
- you have certain ocular conditions such as uncontrolled glaucoma
- you are taking medication that may affect your vision
- you are pregnant, plan to become pregnant during the study, or are breastfeeding

Both of your eyes must qualify to be eligible to participate in this study. Your Study Doctor will inform you if you do not meet the criteria to participate in this study.

DURATION OF PARTICIPATION

The duration of participation is approximately 6 months with a minimum of two study visits after the surgeries. If you experience a secondary surgical procedure to reposition your IOL(s) or have certain visual distortions you will need to return at 1 year as well. Your personal doctor will be informed of your participation in this study only with your permission.

STUDY PROCEDURES

You will be screened preoperatively by your Study Doctor to ensure that you are a good candidate for this study. If you are enrolled and qualify, you will be able to choose which lens type you prefer (the TECNIS Toric IOLs or the TECNIS standard IOL). If you choose to be implanted with toric IOLs, your doctor will determine which lens model (ZCT300 or ZCT400) will be best for each of your eyes.

During surgeries, the IOLs will be folded and inserted into your eyes, following routine cataract extraction. Your second eye will undergo surgery within approximately 1 month after the surgery on your first eye. Your estimated recovery time after surgery is expected to be the same regardless of which IOL type you receive.

You will have a minimum of 2 postoperative study visits through approximately 6 months following the surgery for your second eye. If you experience an ocular adverse event prior to the 6-month visit, you will be asked to return for evaluation(s) by your study doctor. In certain cases, you may also be asked to return for a visit at 1 year if you experience a secondary surgical procedure to reposition your IOL(s) or have certain visual distortions. The study visits are outlined in the table below:

Study Visit	Exams	Eyes Evaluated
1	**Preoperative Exam**	**Both Eyes**
	Operative	1st Eye
	Operative	2nd Eye
As needed	Unscheduled visit(s) if an ocular adverse event occurs	Either Eye
2	**1 Month**	**Both Eyes**
3	**6 Months**	**Both Eyes**
4	1 Year (possible)	Both Eyes

Each study visit will consist of routine procedures that are commonly performed during preoperative, operative and postoperative visits for this type of surgery. Your doctor may also ask you to return for additional study or routine follow-up visits at his or her discretion. Prior to surgery and at the 6-month visit, you will be asked to complete a questionnaire related to the occurrence of any visual distortions. If you experience certain visual

distortions or have had a secondary surgical procedure to reposition your IOL(s), you will be asked to return at 1 year to complete the questionnaire again.

If you experience significant complications during the study in either of your eyes, regardless of which lens type you choose, the lens(es) may be surgically removed. In this case, you will be asked to return for routine follow-up exams as needed.

Please understand that missing study exams can have a negative effect on the integrity and reliability of the study and may reduce the scientific value of your contributions to the study. You are therefore encouraged not to miss any scheduled visits.

During the course of the study, no additional surgical procedures to enhance your vision (such as LASIK or limbal relaxing incisions) are to be performed on your eyes after IOL implantation. If you require correction for your vision, you will be asked to wear glasses or contact lenses for the duration of the study. A spectacle and/or contact lens prescription will be offered to you at the 1-month visit.

Your Study Doctor or a member of the study staff will answer any questions you may have about the surgery, follow-up tests and procedures.

REASONABLY FORESEEABLE RISKS OR DISCOMFORT TO THE PATIENT

GENERAL CATARACT SURGERY AND IOL IMPLANTATION RISKS
Regardless of which IOL type you receive, there are risks and possible complications for the basic procedure of cataract surgery and IOL implantation. Some complications of this surgery in general, although rare, may include:

- worsening of vision
- hemorrhage (bleeding)
- loss of corneal clarity
- inflammation
- infections
- pupil size or shape changes
- retinal detachment
- glaucoma
- swelling in the back of the eye
- secondary surgical procedure to reposition, remove or replace the IOL(s)

These complications may occur whether or not an IOL is implanted and may result in poor vision, total loss of vision, or loss of the eye. Additionally, there may be other unforeseeable risks that may also be associated with cataract surgery and implantation of an IOL.

TORIC IOL RISKS: Toric IOLs are primarily intended to provide far vision, and you will most likely need to wear glasses for near vision. If the toric IOLs are not placed in your eyes in the correct position or rotate at a later time, you may possibly experience visual distortions such as:

- objects appearing distorted in shape
- objects appearing tilted
- flat surfaces appearing curved
- queasiness related to your vision

Additionally, you may need to undergo a second surgical procedure to reposition the toric IOL if it is no longer in the correct position.

STANDARD IOL RISKS: Standard (monofocal) IOLs are primarily intended to provide far vision, and you will most likely need to wear glasses for near vision. The standard monofocal IOL is not designed to correct astigmatism. If you choose to receive this IOL, you may need to wear spectacles (glasses) for the duration of the study to correct your astigmatism. Following study completion, contacts may be worn or you may undergo a surgical procedure such as a Limbal Relaxing Incision (LRI) to correct the astigmatism if needed. Additionally, some patients report optical visual symptoms with monofocal IOLs as well.

TECNIS ASPHERIC SURFACE RISKS: Both the TECNIS monofocal and TECNIS Toric IOLs have the TECNIS aspheric surface designed to improve vision in low-light conditions. However, there is a possibility you may not experience improved vision in low-light conditions as the surface was designed for the “average” eye and may not improve vision for all people and also depends on achieving complete correction postoperatively.

MEDICAL BENEFITS

You may or may not receive any direct medical benefit from being in this study. Your condition may get better, it may get worse, or it may stay the same. The information that is obtained during this study may be useful scientifically and thus be helpful to others requiring the same treatment

ALTERNATIVE TREATMENTS

You understand that you may decide not to have a cataract operation at all. However, if you decide to participate in this study, you understand that there are alternative toric IOLs available for restoring useful vision and reducing astigmatism. Additionally, other treatments and procedures to reduce astigmatism are available to you such as spectacles (glasses), contact lenses, and surgical procedures such as LRI and LASIK. You should discuss the potential risks and benefits of the additional treatments and procedures available to you with your Study Doctor.

CONFIDENTIALITY

Information from this study will be given to AMO. “AMO” includes any persons or companies that are contracted by AMO to have access to the research information during and after the study.

The information will also be given to the U.S. Food and Drug Administration (FDA). It may be given to governmental agencies in other countries as well. Medical records that identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by AMO and may be looked at and/or copied for research or regulatory purposes by:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- The governing Institutional Review Board (IRB)

Absolute confidentiality cannot be guaranteed because of the potential need to give information to these parties. The results of this research study may be presented at meetings or in publications, but your identity will not be disclosed. All reasonable

precautions will be taken to keep your medical records and personal information private to the extent permitted by applicable laws and regulations.

A description of this clinical study will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time; however, there may be some delay in posting study information.

PHOTOGRAPHY RELEASE INFORMATION

Photographs may be taken of your eye(s) during the study. These photographs will be of your eye(s) only and will not show your face. If you do not wish to have the photographs taken, you may still participate in the study. AMO may use the photographs to evaluate results of the study and/or for general research, education, or informational purposes. As the photographs are part of the study records, they will also be available for review by health regulatory agencies (such as the Food and Drug Administration), or governing IRB, that is entitled to view study records. AMO may also use these photographs for advertising, publicity, and promotional purposes with your consent. AMO will own the copyright of the photographs. When the photographs are used for any purposes indicated above, you release AMO from any claims or actions due to their publication or distribution.

COST TO YOU

You and/or your insurance company will be responsible for all usual and customary fees related to your cataract surgeries, the IOLs implanted and any glasses or contacts that may be needed postoperatively.

PAYMENT FOR PARTICIPATION

You will be compensated for your time and participation in this study. Compensation will be provided to you by way of a Visa or American Express gift card at the completion of each of the study visits as follows:

Exams	Eyes Evaluated	Compensation
Preoperative Exam	Both Eyes	$50
1-Month Postoperative Exam	Both Eyes	$50
6-Month Postoperative Exam	Both Eyes	$100
Total Compensation		$200

Abbott Medical Optics (AMO), the company sponsoring the study, is paying for the compensation listed above. The Study Doctor is being paid by AMO to conduct this study.

I

N CASE OF RESEARCH INJURY

If, during your participation in the study, you are injured as a direct result of the use of the study device(s) or study treatment, AMO agrees to pay reasonable medical expenses necessary to treat the injury; provided you have followed the direction of the study doctor and to the extent that these expenses are not covered by a third party, private or government insurance or programs. AMO makes no commitment to provide compensation except as described above.”.

LEGAL RIGHTS

You do not lose any legal rights by signing this consent form.

WHOM TO CONTACT

You may contact the Study Doctor or study staff at the phone number listed on the first page of this consent document:

- for answers, questions, concerns or complaints about this research study,
- to report a research-related injury, or
- for information about the study procedure.

If you need immediate medical attention, please go to the nearest emergency room.

You may contact the Institutional Review Board if you:

- would like to speak to someone not related to the research,
- have questions, concerns, or complaints regarding the research study, or
- have questions about your rights and welfare as a research subject.

<IRB NAME>
<ADDRESS>
<PHONE NUMBER>
<EMAIL>

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is entirely voluntary. You may refuse to participate or may withdraw from this study at any time without penalty or loss of any rights or benefits to which you are otherwise entitled. Your Study Doctor or AMO may also stop your participation in the study at any time. AMO may stop the study at any time for reasons they determine to be appropriate.

If you decide to withdraw from the study, you should contact your Study Doctor immediately. If you withdraw or are removed from the study, you may be asked to return for final tests and procedures to be done for your safety. Please also understand that if you agree to participate in the study, you may not receive the study lens you chose if something happens during your first cataract procedure. In this case, you will receive an alternate, marketed lens during your surgery and you will be withdrawn from the study. You may not be withdrawn from the study if something happens during your second cataract procedure. You may continue to be followed for your first study eye until study completion.

NON-PREGNANCY

Although there is no known risk to an unborn baby or infant, you should not participate in the study if you are pregnant, plan to become pregnant during the study or are breastfeeding because these conditions could change your vision.

NEW INFORMATION

Your Study Doctor will inform you of any new information about the study that may develop during the course of this research and may influence your willingness to participate in the study.

SAMPLE ONLY - NOT TO BE USED FOR SUBJECT ENROLLMENT

INFORMED CONSENT SIGNATURE PAGE

STUDY TITLE: Post-approval study of the TECNIS Toric 1-Piece Intraocular Lens, Models ZCT300 and ZCT400

STUDY NUMBER: TIOL-202-TPAS

Study Participant Initials:_____ Study Participant ID Number:_____

You will be given a signed and dated copy of this consent form for your records prior to your participation in the study.

BY SIGNING BELOW, YOU ACKNOWLEDGE THAT:

1. You have read all sections of this Informed Consent Form.
2. You are able to understand and complete a questionnaire in English.
3. You have had your questions about the study and your participation in it answered.
4. You voluntarily consent to participate in this research study and follow your Study Doctor's instructions.
5. Should you decide not to participate, discontinue or withdraw from the study at any time, there is no penalty to you.
6. You authorize the release of your medical records for research or regulatory purposes to AMO, the Study Doctor, the FDA, DHHS agencies, and the governing Institutional Review Board (IRB).
7. By signing this consent form, you have not waived any of the legal rights which you otherwise would have as a study participant in a research study.

I choose to receive the following lens type in both of my eyes (choose one):

☐ **TECNIS Toric IOL (Models ZCT300 and/or ZCT400)**

☐ **TECNIS Monofocal IOL Model ZCB00 (non-toric IOL)**

By placing your initials in the space provided below, you are also agreeing to the following use of the photographs by AMO:

_____ for advertising, publicity, and promotional purposes.

Study Participant's Name (Please print) _____

Signature _____**SAMPLE DOCUMENT DO NOT SIGN**____ Date _____

Legal Representative's Name (Please print)_____

Signature _____**SAMPLE DOCUMENT DO NOT SIGN**____ Date _____

Name/Signature of person who conducted informed consent discussion:

Name (Please print) _____

Signature _____ Date _____

FEMALE PARTICIPANTS: Please affirm by your signature below that either you are not pregnant at this time or are taking precautions not to become pregnant during this study.

Affirmation of study participant regarding non-pregnancy:

Signature_____ Date _____

SAMPLE ONLY - NOT TO BE USED FOR SUBJECT ENROLLMENT

ATTACHMENT B

SAMPLE AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FORM

SAMPLE ONLY - NOT TO BE USED FOR SUBJECT ENROLLMENT

Authorization for Use/Disclosure of Health Information

Only minimal medical/health information may be collected for research-related purposes. This disclosure form pertains to your release of such information to Abbott Medical Optics Inc.

What is the purpose of this form? You are being asked to sign this form so that we may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

What health information do the researchers want to use? They may use medical information and personal identifiers including past, present and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research study.

Why do the researchers want my health information? The researchers want to use your health information as part of the research study described to you in the Informed Consent document.

Who will disclose, use and/or receive my health information? The technicians and staff working on this research study; the governing Institutional Review Board and its staff; the sponsor of this research, its employees and agents contracted by it to analyze study data; and outside regulatory agencies, such as the Food and Drug Administration.

How will my health information be protected once it is given to others? Your personal health information may no longer be protected by HIPAA (Health Insurance Portability and Accountability Act) once it is disclosed to the study sponsor (AMO) by the study doctor. However, AMO will take reasonable measures to keep your personal health information confidential.

How long will this Authorization last? Unless withdrawn, your HIPAA authorization has no expiration date, since information collected for research purposes continues to be analyzed for many years.

Can I cancel the Authorization? You may cancel this Authorization at any time by notifying your doctor, in writing, at the address on the first page of the Informed Consent Document (please reference the research protocol number). If you cancel this Authorization, the investigator and researchers will not collect any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Can I see my health information? You have a right to request to see your health information. However, to ensure scientific integrity of the research, you will not be able to review the research information until after the research study has been completed.

Signature of Subject: _____ Date: _____

Signature of Legal Representative: _____ Date: _____

Signature of Witness: _____ Date: _____