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Clinical Outcomes of TECNIS Toric Intraocular Lens Implantation after Cataract Removal in Patients with Corneal Astigmatism

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Purpose: To evaluate safety and effectiveness of the TECNIS toric intraocular lenses (IOLs).

Design: Prospective, multicenter, 2-armed, bilateral, 6-month clinical trial following the American National Standards Institute (ANSI) standard for Toric IOLs.

Participants: Subjects implanted with a TECNIS toric IOL (n = 172) or a TECNIS 1-piece control IOL (ZCB00; n = 93).

Methods: Subjects underwent standard cataract surgery with IOL implantation. The randomized control arm consisted of subjects requiring cylinder correction of 0.75 to 1.50 diopters (D) who were implanted with either toric (ZCT150) or nontoric (ZCB00) IOLs. The open-label arm (OLA) consisted of subjects requiring cylinder correction of 1.50 to 3.62 D and implanted with ZCT225, ZCT300, or ZCT400 IOLs.

Main Outcome Measures: Assessments were at 1 day, 1 week, and 1, 3, and 6 months and included uncorrected distance visual acuity (UCDVA) and best-corrected distance visual acuity (BCDVA), manifest refraction, keratometry, adverse events, spectacle use, and photographic documentation of IOL rotational stability.

Results: Mean percent reduction in cylinder (± standard deviation) was statistically significantly greater ($P < 0.0001$) for ZCT150 eyes (74.53±72.25%) versus ZCB00 eyes (31.61±78.73%). In the OLA, mean percent reduction in cylinder was 76.27±33.09%. A UCDVA of 20/20 or better was achieved by 43.6% (44/101) of ZCT150 eyes and by 23.7% (22/93) of ZCB00 eyes ($P = 0.0026$). In the OLA, 38.0% (27/71) achieved 20/20 or better UCDVA. Mean UCDVA was 0.10±0.14 for ZCT150 eyes and 0.16±0.16 for ZCB00 eyes ($P = 0.0009$); in the OLA, mean UCDVA was 0.11±0.12. The BCDVA was 20/40 or better for all eyes. Mean absolute lens rotation between visits for toric eyes pooled was less than 3°. Lens rotation of 5° or less occurred in 92.9% of toric eyes between 1 and 3 months and in 94.1% between 3 and 6 months, exceeding the ANSI standard for stability (≥90% of eyes with ≤5° of rotation between visits). Four lenses (2.3%) were repositioned during the study.

Conclusions: The TECNIS toric IOLs successfully reduce ocular astigmatism and are a safe and effective treatment for cataract patients with corneal astigmatism. *Ophthalmology 2015;122:39-47 © 2015 by the American Academy of Ophthalmology.*

Patients have high expectations for visual rehabilitation after cataract surgery. Standard monofocal intraocular lenses (IOLs) successfully address the spherical component of vision correction; however, approximately 35% of patients with cataracts have 1.00 diopter (D) or more of corneal astigmatism,[1] with 15% to 20% having 1.5 D or more of corneal astigmatism.[1,2] Astigmatism causes a loss of visual acuity of about 1.5 lines per diopter of uncorrected cylinder, such that even low amounts of uncorrected cylinder can reduce uncorrected visual function.[3,4] Patients who have undergone cataract surgery and have had their spherical defocus corrected successfully with an IOL may be unwilling to wear spectacles for residual astigmatism. Wolffsohn et al[4] suggest that most patients are aware of the reduction in visual acuity resulting from residual astigmatism and may restrict their activities accordingly, leading to decreased independence and quality of life.

Although toric IOLs have been designed in the past, it has been difficult to ensure that the IOL would maintain its position after surgery with respect to the corneal steep meridian.[5–7] For example, in a 1994 study, 21% of 47 Nidek Nt-98B toric IOLs (Gamagori, Japan) implanted rotated more than 30° after surgery.[8] A toric IOL loses approximately 3% of its cylinder-correcting power for every 1° of deviation of the IOL axis from the target axis.[9,10] Large amounts of rotation, more than 30° from the targeted axis, lead to a net increase in astigmatism.[8] Additionally, the incision size required for early toric IOLs induces varying degrees of corneal astigmatism, impeding the accurate calculation of the necessary toric IOL power.

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As a result of early toric IOL stability concerns, non–IOL-based astigmatic correction methods, such as limbal or corneal relaxing incisions,[11] photorefractive keratectomy, LASIK,[12,13] or spectacles, have been popular for correcting astigmatism. These approaches have disadvantages, including lack of precision, regression, varied healing responses leading to undercorrection or overcorrection, loss of best-corrected visual acuity, infection, and dry eye.[14,15] With the exception of spectacles, these approaches involve secondary surgical procedures. Wearing spectacles after cataract surgery may be unacceptable to some patients. The ability of toric IOLs to treat the surgical aphakia and pre-existing corneal astigmatism, particularly in cases of higher amounts of corneal astigmatism, provides a substantial advantage.

Small-incision cataract surgery techniques now allow the creation of nearly astigmatically neutral phacoemulsification incisions,[16] and advanced intraocular designs and materials have improved the stability and predictability of IOLs. As such, these innovations have made toric IOLs a feasible method for the correction of corneal astigmatism in patients requiring cataract extraction and implantation of an IOL.

The TECNIS toric IOLs (Abbott Medical Optics, Inc, Santa Ana, CA) are 1-piece, hydrophobic acrylic, aspheric, biconvex, clear optic IOLs and are similar to the TECNIS ZCB00 1-piece IOL with the addition of cylindrical correction. The haptics of the TECNIS toric IOLs are offset to maximize contact between the posterior surface of the IOL and the posterior capsule. The bioadhesiveness of the lens material enables adherence to the capsular bag for improved positional stability.[17]

This is a report on the safety and effectiveness of the TECNIS toric IOLs in cataract patients with pre-existing corneal astigmatism from the Investigational Device Exemption registration clinical trial. The results were submitted to the United States Food and Drug Administration as part of the requirements for United States approval of the TECNIS toric astigmatism-correcting IOLs.

Methods

Study Design

The Clinical Evaluation of a 1-Piece Intraocular Lens study (ClinicalTrials.gov identifier, NCT01098812) was a multicenter, bilateral, 2-armed clinical investigation conducted at 14 sites in the United States and Canada. The study was designed in accordance with the American National Standards Institute (ANSI) standard for toric IOLs, Z80.30-2010. One arm of the study was a randomized, comparative, double-masked evaluation (randomized control arm [RCA]) of the TECNIS toric ZCT150 IOL and the nontoric control IOL, the TECNIS 1-piece (ZCB00) IOL. The second arm was an open-label, noncomparative evaluation (open-label arm [OLA]) of the TECNIS toric ZCT225, ZCT300, and ZCT400 IOLs. The study protocol was approved by the ethics committee or institutional review board at each site and adhered to the tenets of the Declaration of Helsinki and all applicable regulatory and legal requirements. All patients provided written informed consent; additionally, United States patients provided Health Insurance Portability and Accountability Act authorization and Canadian subjects provided Canadian Health Information Protection Act authorization before any study-specific procedures were undertaken.

Study Subjects

Patients were eligible for the study if they had pre-existing corneal astigmatism and cataracts for which uncomplicated phacoemulsification surgery and IOL implantation were planned. Eligible patients had preoperative regular corneal astigmatism requiring correction of 0.75 to 3.62 D at the corneal plane in 1 or both eyes, required a spherical equivalent lens power between +15.0 and +28.0 D, and had a projected postoperative best-corrected distance visual acuity (BCDVA) of 20/30 or better. Exclusion criteria included irregular corneal astigmatism; pharmacologically dilated pupil size less than 5.5 mm or pupillary abnormalities; or any ocular or systemic medications, pathologic features, abnormalities, or diseases that would affect corneal topography, visual acuity, or operative risk.

Study Lenses

The control lens, the ZCB00, is a 1-piece hydrophobic-acrylic aspheric lens with a 6.0-mm biconvex optic and an overall length of 13.0 mm. The study lenses, models ZCT150, ZCT225, ZCT300, and ZCT400, have the same design as the control lens with the addition of a toric optic on the anterior IOL surface. Cylinder power and recommended corneal astigmatism correction for each toric lens model are listed in Table 1. Two sets of dots located 180° apart at the center of the optic–haptic junctions designate the flat meridian of the IOL for alignment with the steep meridian of the cornea (Fig 1).

Preoperative Assessments

Preoperative assessments included medical history, Snellen visual acuities, manifest refraction, keratometry, pupil size, slit-lamp examination, intraocular pressure, axial length, spectacle independence, and toric IOL calculations. All keratometry was performed using the IOLMaster (Carl Zeiss Meditec, Inc, Dublin, CA). Pupil size was measured using a pupillometer, pupil gauge card, or millimeter gauge rule; dilated pupil size was measured to ensure the pupil dilated sufficiently to photograph the implanted lens. A web-based toric calculator (TECNIS Toric Calculator; Abbott Medical Optics, Inc) from the study sponsor was used to determine the appropriate choice of toric IOL power and axis, target

Table 1. Cylinder Power and Corneal Astigmatism Correction Ranges for Each TECNIS Toric Intraocular Lens Model

Intraocular Lens Model	Cylinder Power (D)		Correction Ranges Based on Combined Corneal Astigmatism (Preoperative Keratometric Cylinder [D] Plus Effect of Surgically Induced Astigmatism*)
	Intraocular Lens Plane	*Corneal Plane*†	
ZCT150	1.50	1.03	0.75–1.50
ZCT225	2.25	1.55	1.50–2.00
ZCT300	3.00	2.00	2.00–2.75
ZCT400	4.00	2.74	2.75–3.62

D = diopters.
*The recommended corneal astigmatism correction ranges are based on the preoperative corneal astigmatism and the predicted effect of surgically induced astigmatism.
†The corresponding cylinder values at the corneal plane have been calculated based on the average pseudophakic eye.