Original Investigation | CLINICAL TRIAL

Toric vs Aspherical Control Intraocular Lenses in Patients With Cataract and Corneal Astigmatism
A Randomized Clinical Trial

Nienke Visser, MD; Henny J. M. Beckers, MD, PhD; Noel J. C. Bauer, MD, PHD; Sacha T. J. M. Gast, MD; Bart L. M. Zijlmans, MD; Tos T. J. M. Berenschot, PhD; Carroll A. Webers, MD, PhD; Rudy M. M. A. Nuijts, MD, PhD

IMPORTANCE Spectacle independence is becoming increasingly important in cataract surgery. Not correcting corneal astigmatism at the time of cataract surgery will fail to achieve spectacle independency in 20% to 30% of patients.

OBJECTIVE To compare bilateral aspherical toric with bilateral aspherical control intraocular lens (IOL) implantation in patients with cataract and corneal astigmatism.

DESIGN, SETTING, AND PARTICIPANTS A multicenter, hospital-based, randomized clinical trial was conducted. The participants included 86 individuals with bilateral cataract and bilateral corneal astigmatism of at least 1.25 diopters (D) who were randomized to receive either bilateral toric (n = 41) or bilateral control (n = 45) IOL implantation.

INTERVENTIONS Bilateral implantation of an aspherical toric IOL or an aspherical control IOL.

MAIN OUTCOMES AND MEASURES Spectacle independency for distance vision, uncorrected distance visual acuity, refractive astigmatism, contrast sensitivity, wavefront aberrations, and refractive error–related quality-of-life questionnaire.

RESULTS Preoperatively, mean (SD) corneal astigmatism was 2.02 (0.95) D and 2.00 (0.84) D in the toric and control groups, respectively. Four patients (5%) were lost to follow-up. At 6 months postoperatively, 26 (70%) of the patients in the toric group achieved an uncorrected distance visual acuity of 20/25 or better compared with 14 (31%) in the control group ($P < .001$; odds ratio, 5.23; 95% CI, 2.03-13.48). Spectacle independency for distance vision was achieved in 31 patients (84%) in the toric group compared with 14 patients (31%) in the control group ($P < .001$; odds ratio, 11.44; 95% CI, 3.89- 33.63). Mean refractive astigmatism was −0.77 (0.52) D and −1.89 D (1.00) D, respectively. Vector analysis of toric IOLs showed a mean magnitude of error of +0.38 D, indicative of overcorrection. No significant differences were found in contrast sensitivity, higher-order aberrations, or refractive error–related quality of life.

CONCLUSIONS AND RELEVANCE In patients with cataract and corneal astigmatism, bilateral toric IOL implantation results in a higher spectacle independency for distance vision compared with bilateral control IOL implantation. No significant differences were identified in contrast sensitivity, higher-order aberrations, or refractive error–related quality of life following both treatments.

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Author Affiliations: University Eye Clinic, Maastricht University Medical Center, Maastricht, the Netherlands (Visser, Beckers, Bauer, Gast, Berenschot, Webers, Nuijts); Rotterdam Eye Hospital, Rotterdam, the Netherlands (Zijlmans).

Corresponding Author: Nienke Visser, MD, University Eye Clinic, Maastricht University Medical Center, P. Debyelaan 25, 6202 AZ Maastricht, the Netherlands (nienke.visser@mumc.nl).

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In modern cataract surgery, spectacle freedom is becoming increasingly important. Emmetropia can be achieved for patients with myopic or hyperopic refractive errors by selecting the appropriate spherical lens power. However, approximately 20% to 30% of patients who undergo cataract surgery have corneal astigmatism of 1.25 diopters (D) or more.[1,2] Not correcting the astigmatism component at the time of cataract surgery will fail to achieve spectacle independency in these patients.

Toric intraocular lens (IOL) implantation has been shown[3-5] to be a safe and effective treatment option for correcting astigmatism. However, to our knowledge, no randomized clinical trials have compared spectacle independency and quality of vision, including contrast sensitivity or higher-order aberrations, following bilateral toric and control IOL implantation. The main purpose of our study was to compare spectacle independency for distance vision following bilateral toric and control IOL implantation. Secondary outcome measures were uncorrected distance visual acuity, refractive astigmatism, contrast sensitivity, wavefront aberrations, and refractive error-related quality of life.

Methods

This multicenter randomized clinical trial was conducted at 2 hospitals in the Netherlands: the University Eye Clinic of the Maastricht University Medical Center and the Rotterdam Eye Hospital. Institutional review boards of both participating centers approved the study. Written informed consent was obtained after the nature of the study was explained to the potential participants. The participants did not receive financial compensation. The study adhered to the tenets of the Declaration of Helsinki and good clinical practice guidelines and was registered in a clinical trial register. Patients were included between February 1, 2010, and March 31, 2012.

Participants

Inclusion criteria were age 21 years or older, bilateral age-related cataract, and bilateral regular corneal astigmatism of at least 1.25 D. Exclusion criteria included irregular corneal astigmatism, Fuchs endothelial dystrophy stage 2 or higher,[6] glaucoma-related extensive visual field loss, or an expected postoperative corrected distance visual acuity of less than 20/40. Consecutive patients from the clinical population with cataract and bilateral corneal astigmatism were approached to participate in the study.

Intervention

The test lenses consisted of the AcrySof aspherical toric IOL (model SN6AT3-T9) with cylinder powers from 1.50 to 6.00 D (0.75-D steps). Available spherical powers range from +6.00 to +30.00 D. The spherical power was calculated using optical biometry (IOLMaster; Carl Zeiss Meditec) and the Sanders-Retzlaff-Kraff formula (A-constant, 118.9; goal emmetropia). The toric IOL was calculated using a web-based calculator (http://www.acrysoftoriccalculator.com). The expected surgically induced corneal astigmatism and incision location (superior) were incorporated in the toric IOL calculation. Astigmatism axes measurements obtained by optical biometry and corneal topography (Atlas 9000; Carl Zeiss Meditec, or Keratron Onda; Optikon) were compared. In cases with less than a 5° difference, optical biometry values were used. In cases with more than a 5° difference, manual keratometry (Javal-Schiotz keratometer; Rodenstock) values were used.

The control lens consisted of the AcrySof aspherical IOL model SN60WF. Available spherical powers range from +6.0 to +30.0 D. The design of this IOL is identical to the design of the AcrySof toric IOL. The spherical power was calculated using the SRK/T formula (A-constant, 118.9; target emmetropia).

Surgical Procedure

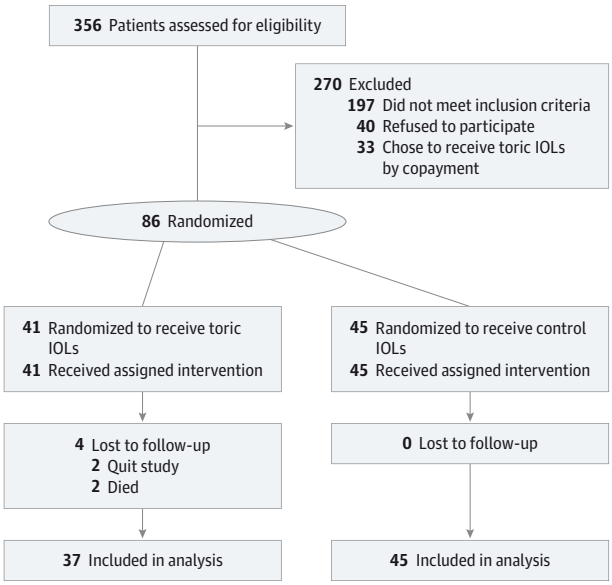
Preoperative and intraoperative marking were performed as previously described.[7] A standard phacoemulsification technique was performed using a superior 2.2-mm limbal incision. Postoperatively, patients received a prescription for a fixed combination eyedrop of tobramycin sulfate, 3 mg/mL, plus dexamethasone, 1 mg/mL (Alcon), and nepafenac, 1 mg/mL (Alcon), in a tapering dose for 4 weeks.

Outcome Measures

Preoperatively, the following examinations were conducted: slit-lamp examination, funduscopy, Goldmann applanation tonometry, visual acuity, objective refraction (Topcon TRK-1P; Topcon Medical Systems), and subjective refraction. Uncorrected (UDVA) and corrected (CDVA) distance visual acuity were assessed using the 100% contrast Early Treatment Diabetic Retinopathy Study (ETDRS) chart (Precision Vision) at 4 m. The ETDRS scores were determined as follows: the log score of the last row where the patient correctly identified all 5 letters was recorded (eg, 0.10 log row), and 0.02 log units were then subtracted for every letter that was correctly identified beyond the last row (eg, 0.10 log row +3 letters on the 0.00 log row = 0.10 − (3 × 0.02) = 0.04 logMAR [Snellen equivalent, 20/25]). Corneal topography was performed using Atlas (Carl Zeiss Meditec) or Keratron Onda (Optikon) equipment. Both devices are Placido-disk videokeratoscopes and determine the anterior corneal curvature in the central 3.0-mm zone. Preoperative and postoperative measurements were always performed with the same device. In addition, manual keratometry (Javal-Schiotz keratometer) and biometry (IOLMaster) were performed. Contrast sensitivity was measured using the CSV-1000 contrast test (Vector vision Inc) under photopic conditions (85 cd/m^2) and at a 2.5-m testing distance. We compared our values with those obtained for a population with normal vision with a mean age of 64 years.[8]

Wavefront aberrometry was performed (Keratron Onda or iTrace [Tracey Technologies Corp]). The Keratron Onda is a combined Hartmann-Shack aberrometer and Placido-disk videokeratoscope. The iTrace is a combined ray-tracing aberrometer and Placido-disk videokeratoscope. Preoperative and postoperative measurements were always performed with the same device. Head positioning and eye alignment were carefully checked before each measurement. Natural pupil dilation was obtained in all participants under mesopic light condition (<1 lux). Aberrations were exported for a 3.5-mm pupil as Zernike coefficients ($Z_{x,x}$).[9] Root mean square values were calculated for lower-order astigmatism ($Z_{2\pm2}$), coma-like aberra-

Figure 1. Flowchart



Flowchart of patient screening and follow-up. IOLs indicates intraocular lenses.

tions ($Z_{3\pm3}+Z_{5\pm5}$), spherical-like aberrations ($Z_{2,0}+Z_{4,0}+Z_{6,0}$), and higher-order aberrations ($Z_{3,-3}$ up to $Z_{7,7}$).

Spectacle use for distance vision was evaluated using a questionnaire. Patients rated spectacle use on a scale of 1 to 5: always (1), usually (2), half of the time (3), sometimes (4), and never (5). Refractive error–related quality of life was evaluated using the National Eye Institute Refractive Error Quality of Life (RQL-42) questionnaire,[10] which is self-administered. Each subscale is scored from 0 to 100; a higher score indicates a better quality of life.

At 1 week and 1 month postoperatively, the UDVA and CDVA were determined and slitlamp examination was performed in mydriasis to assess toric IOL alignment. Toric IOL alignment was measured using a slitlamp with a rotating slit. Accurate head positioning and horizontal eye alignment were ensured before each measurement, and patients were asked to fixate at a distance. At 3 and 6 months postoperatively, full examinations were performed.

Sample Size

Sample size calculation was based on estimated spectacle independency following bilateral toric or control IOL implantation based on the studies of Holland et al[4] and Lane et al[11]: estimated spectacle independence of 80% following toric IOL implantation and 45% following control IOL implantation. Sample size calculation was performed using the PS: Power and Sample Size Calculation Software[12] based on an α value of .05 and a power of 90%, resulting in a sample size of 38 patients per group. Including an expected 10% of participants lost to follow-up, the total sample size was calculated as 86 patients. Four patients in the toric group were lost to follow-up (**Figure 1**). The last recorded UDVAs in these patients was 0.04 logMAR, 0.04 logMAR, 0.12 logMAR, and 0.22 logMAR (Snellen equivalents, 20/25, 20/25, 20/25, and 20/32, respectively). The last patient was found to have a macular pucker. No patients in the control group were lost to follow-up.

Randomization

Consecutive patients were randomized using an online program (TenAlea; FormsVision BV). Patients' sex, age, and highest calculated toric IOL power for both eyes were used as stratification factors. The surgeon received the assigned randomization by e-mail. The patient and investigator performing the postoperative examinations were masked for treatment allocation. Slitlamp examination was performed by a second examiner. Randomization was revealed after 6 months of follow-up.

Data Management and Statistics

Data were collected in an online data management system (Macro; InferMed) and analyzed using Excel software (Microsoft Office 2007; Microsoft Corp). LogMAR scores were calculated to the approximate Snellen equivalent. Surgically induced corneal astigmatism was calculated as the vector change between preoperative and postoperative corneal astigmatism (measured by corneal topography).[13] The effectiveness of astigmatism correction by toric IOLs was determined using the Alpins method of vector analysis.[14]

Statistical analyses were performed using SPSS, version 16.0, for Windows (SPSS Inc). Data were analyzed using an intention-to-treat analysis. The variables showed normal distribution and allowed us to use parametric tests. Continuous data were analyzed using independent unpaired, 2-tailed *t* tests (mean differences with 95% CIs). Dichotomous variables were analyzed using χ^2 tests (*P* value and odds ratio [OR] with 95% CI).

Results

Participant Flow and Patient Characteristics

Eighty-six patients were enrolled in this study: 41 in the toric group and 45 in the control group (Figure 1). Patient characteristics are reported in **Table 1**.

Visual Acuity

At 6 months postoperatively, 26 of 37 patients (70%) in the toric group achieved a UDVA of 20/25 (0.1 logMAR) or better compared with 14 of 45 patients (31%) in the control group ($P < .001$; OR, 5.23; 95% CI, 2.03-13.48) (**Figure 2**A). A CDVA of 20/25 or better was achieved in 33 of 37 patients (89%) and 41 of 45 patients (91%) in the toric and control groups, respectively ($P = .77$; OR, 0.81; 95% CI, 0.19-3.47) (Figure 2B). Within both groups, no significant changes were identified in UDVA and CDVA between 1, 3, and 6 months postoperatively (eTable 1 in the Supplement).

Astigmatism

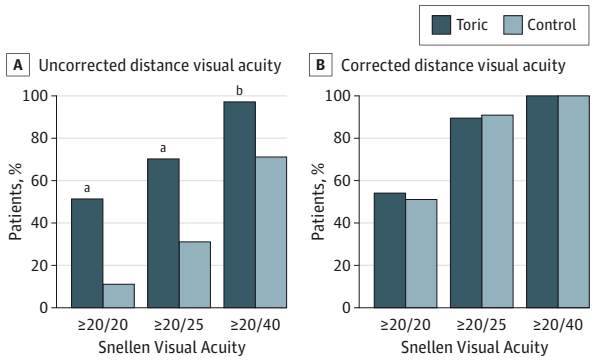
Preoperatively, no significant difference was identified in the amount of corneal astigmatism between groups. The mean corneal astigmatism was 2.02 (0.95) D and 2.00 (0.84) D in the toric

Table 1. Preoperative Patient Characteristics

Characteristic	Toric Group (n = 41)	Control Group (n = 45)
Eyes, No.	82	90
Age, mean (range), y	74 (50 to 88)	74 (49 to 87)
Women, No. (%)	21 (51)	21 (46)
CDVA, mean (SD) [range], logMAR		
Monocular	0.34 (0.35) [0.00 to 3.00]	0.34 (0.36) [0.04 to 3.00]
Binocular	0.22 (0.16) [0.00 to 0.72]	0.19 (0.15) [−0.04 to 0.64]
Corneal astigmatism, mean (SD) [range], D	2.02 (0.95) [1.20 to 6.15]	2.00 (0.84) [1.23 to 5.54]
Refractive astigmatism, mean (SD) [range], D	−2.27 (1.15) [−0.50 to −7.00]	−2.28 (1.21) [0.00 to −6.25]

Abbreviations: CDVA, corrected distance visual acuity; D, diopters.

Figure 2. Visual Acuity

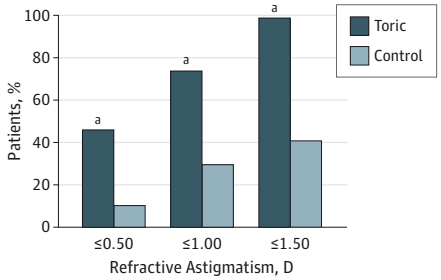


Cumulative postoperative binocular uncorrected (A) and corrected (B) distance visual acuity at 6 months postoperatively.

[a] $P < .001$.

[b] $P = .002$.

Figure 3. Residual Refractive Astigmatism



Cumulative postoperative residual refractive astigmatism at 6 months postoperatively. D indicates diopters.

[a] $P < .001$.

and control groups, respectively. At 6 months postoperatively, surgically induced corneal astigmatism was −0.12 (0.72) D at 115° in the toric group and −0.12 (0.45) D at 94° in the control group. The mean magnitude of refractive astigmatism at 6 months postoperatively was −0.77 (0.52) (range, 0 to −2.00) D in the toric group and −1.89 (1.00) D (range, 0 to −4.50) D in the control group (mean difference, 1.12 D; 95% CI, 0.87 to 1.37). As shown in **Figure 3**, 55 of 74 eyes (74%) in the toric group had refractive astigmatism of 1.0 D or less compared with 27 of 90 eyes (30%) in the control group ($P < .001$; OR, 6.75; 95% CI, 3.39 to 13.46). **Table 2** reports the vector analysis of the effectiveness of astigmatism correction using toric IOLs. The mean magnitude of error was +0.38 D, indicative of an astigmatism overcorrection. Twenty-six of 74 eyes (35%) showed an overcorrection of 0.5 D or more, and 16 of 74 eyes (22%) showed an overcorrection of 1.0 D or more.

Spectacle Independence

At 6 months postoperatively, 31 of 37 patients (84%) in the toric group compared with 14 of 45 patients (31%) in the control group reported never using spectacles for distance vision ($P < .001$; OR, 11.44; 95% CI, 3.89 to 33.63). Thirty of 45 patients (67%) in the control group reported always using spectacles for distance vision compared with 5 of 37 patients (14%) in the toric group. The remaining patients reported sometimes using spectacles for distance vision.

Contrast Sensitivity

Preoperatively, contrast sensitivity levels were similar in the toric and control groups but lower compared with the population with normal vision at all spatial frequencies (eFigure in the Supplement). At 6 months postoperatively, contrast sensitivity improved at all special frequencies in both groups up to values for a population with normal vision. No significant differences were identified between the toric and control groups (eFigure in the Supplement).

Wavefront Aberrometry

Aberrometry data for a 3.5-mm pupil were available in 51 eyes in the toric group and 73 eyes in the control group. Regarding total ocular aberrations, root mean square of lower-order astigmatism was lower in the toric group compared with the control group. No significant differences were identified in root mean square of coma-like aberrations, spherical-like aberrations, or total higher-order aberrations (eTable 2 in the Supplement).

Refractive Error–Related Quality of Life

At 6 months postoperatively, no significant differences were identified between the toric and control groups for any of the subscales, including far vision, dependence on correction, and

satisfaction with correction (eTable 3 in the Supplement). Far vision was rated 82 and 83 on a scale of 0 to 100 for the toric and control groups, respectively.

Complications and Misalignment

In the toric group, a small anterior capsule tear occurred, which still allowed toric IOL implantation. In the control group, a zonulolysis (n = 1) and a large anterior to posterior capsule tear (n = 1) occurred. In the latter patient, a 3-piece IOL (AcrySof MN60AC) was implanted in the sulcus. Postoperative complications in the toric group included high intraocular pressure (n = 1), cystoid macular edema (n = 1), macular pucker (n = 1), and posterior vitreous detachment with a retinal defect (n = 1). In the control group, high intraocular pressure (n = 2), cystoid macular edema (n = 2), anterior uveitis (n = 1), and posterior vitreous detachment without retinal defect (n = 1) occurred.

Mean toric IOL misalignment at 6 months postoperatively was 3.6° (3.2). A misalignment of more than 10° occurred in 4 eyes. In one of these eyes, an IOL repositioning was performed to correct a 17° misalignment. After IOL repositioning, the UDVA improved from 20/40 to 20/20 Snellen. Other patients were satisfied and did not wish to undergo IOL repositioning.

Discussion

To our knowledge, this is the first randomized clinical trial comparing spectacle independency for distance vision following bilateral toric IOL implantation and bilateral control IOL implantation. Spectacle independency was achieved in 84% of the patients with toric IOLs compared with 31% of the patients with control IOLs. Holland et al[4] reported spectacle independency in approximately 60% of patients with toric IOLs compared with 36% of patients with control IOLs. However, patients in this study underwent unilateral toric or control IOL implantation, which does not allow for an accurate evaluation of spectacle independency. Lane et al[11] offered patients from the study population of Holland et al fellow-eye implantation with the same IOL (toric or control IOL), allowing bilateral examination of spectacle independency. Almost all patients (97%) with toric IOLs were spectacle independent for distance vision compared with half of the patients in the control group. However, a selection bias may have occurred in patients who wished to undergo fellow-eye implantation with the same type of IOL.

We found a better UDVA and lower refractive astigmatism following toric IOL implantation compared with control IOL implantation. We found a UDVA of 20/25 or better in 70% of the patients in the toric group and 31% in the control group. Previous studies[4,15-17] reported a UDVA of 20/25 or better in approximately 60% to 80% of patients with toric IOLs. Regarding refractive astigmatism, the correction index of 1.20 and magnitude of error of +0.38 D demonstrate a general overcorrection of astigmatism using AcrySof toric IOLs. This overcorrection has also been demonstrated by Goggin et al[18] and is related to the manufacturer's underestimation of the IOL cylinder power at the corneal plane.

Table 2. Alpins[14] Vector Analysis of the Effectiveness of Astigmatism Correction Using Toric Intraocular Lenses

Characteristic	Data
Target-induced astigmatism, mean (SD), D	2.00 (0.93)
Surgically induced astigmatism, mean (SD), D	2.38 (1.19)
Difference vector, mean (SD), D	0.75 (0.51)
Magnitude of error, mean (SD), D	0.38 (0.61)
Angle of error, mean (SD), degrees	0 (15)
Absolute angle of error, mean (SD), degrees	11 (10)
Correction index	1.20
Index of success	0.42

Abbreviation: D, diopters.

We found no substantial differences in the quality of vision following toric or control IOL implantation. Quality of vision was evaluated using contrast sensitivity (CSV-1000 chart), aberrometry, and refractive error–related quality of life. At 6 months postoperatively, contrast sensitivity had improved in both groups up to values for a population with normal vision. Two studies[19,20] compared contrast sensitivity levels under similar illumination levels following toric IOL implantation or corneal relaxing incisions. However, a direct comparison of our results with these studies is not possible owing to different contrast sensitivity tests and different testing distances. No previous studies have compared contrast sensitivity values between toric and control IOLs.

Wavefront analysis allows for a detailed evaluation of imperfections in the optical system of the eye. Different measurement techniques, including Hartmann-Shack, ray-tracing, and automated retinoscopy, are available but may not be used interchangeably.[21] To minimize this effect, we measured patients preoperatively and postoperatively with the same device. Both devices used in this study use light wavelengths in the infrared spectrum and therefore do not require pupil dilation. In addition, the application of mydriatic agents may cause differences in wavefront analysis.[22,23] Mencucci et al[24] compared aberrometry (OPD-Scan II; Nidek) following toric or control IOL implantation and found a higher Strehl ratio, which indicates a better image quality. We identified no differences in higher-order aberrations following toric or control IOL implantation.

We assessed refractive error–related quality of life using the RQL-42 questionnaire, which was developed to measure the effect of refractive error correction on vision-related functioning and well-being.[10] This questionnaire has recently been used to evaluate multifocal IOLs, phakic IOLs, and laser refractive surgery.[25-27] However, McAlinden et al[28] administered the RQL-42 questionnaire to 100 patients who underwent laser refractive surgery and demonstrated insufficient psychometric properties for all 13 subscales. One previous study[24] used the RQL-42 to compared toric and control IOLs. Mencucci et al[24] found a higher score for subscales of clarity of vision, far vision, and satisfaction with correction in patients with toric IOLs. In the present study, we identified no substantial differences between toric and control IOLs for any of the subscales of the RQL-42. Aside from the

limitation of this questionnaire, this finding may be related to a limitation of our study. In the Netherlands, patients have the option to choose toric IOL implantation by means of co-payment. Therefore, patients with a definite preference for spectacle independence were not included in this study.

Another possible limitation of the present study is its use of a superior incision in all patients. In most patients, this type of incision will be on axis, thereby reducing corneal astigmatism. However, in patients with against-the-rule astigmatism, a superior incision may increase astigmatism. In the toric group of the present study, this outcome was compensated for in the toric IOL calculation; however, there was no compensation in the control group. We chose to use a superior incision in all patients because this is the standard of care for most ophthalmologists in the Netherlands and therefore results in a fair comparison of treatments. In addition to the present study, a previous study[29] has shown that the surgically induced corneal astigmatism of a superior 2.2-mm incision is only approximately −0.1 D.

Mean toric IOL misalignment was approximately 4°, which is comparable to the value reported in previous studies.[3-5,18] The mean absolute angle of error was 11°, which indicates a substantial overall misalignment of treatment. Toric IOL outcomes may be further optimized by incorporating IOL sphere power and estimated lens position in the IOL calculation.[30] In addition, incorporating the effect of the posterior corneal surface may further increase the efficacy of toric IOLs.[31,32] Implementation of eye-tracking technology may improve the accuracy of toric IOL alignment.[7]

Conclusions

In patients with cataract and corneal astigmatism, bilateral toric IOL implantation results in a higher spectacle independency for distance vision compared with bilateral control IOL implantation. No significant differences were identified in contrast sensitivity, higher-order aberrations, or refractive error-related quality of life following both treatments.

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Study concept and design: Webers, Nuijts.
Acquisition, analysis, or interpretation of data: Visser, Beckers, Bauer, Gast, Zijlmans, Berenschot, Nuijts.
Drafting of the manuscript: Visser, Nuijts.
Critical revision of the manuscript for important intellectual content: Beckers, Bauer, Gast, Zijlmans, Berenschot, Webers, Nuijts.
Statistical analysis: Visser, Berenschot.
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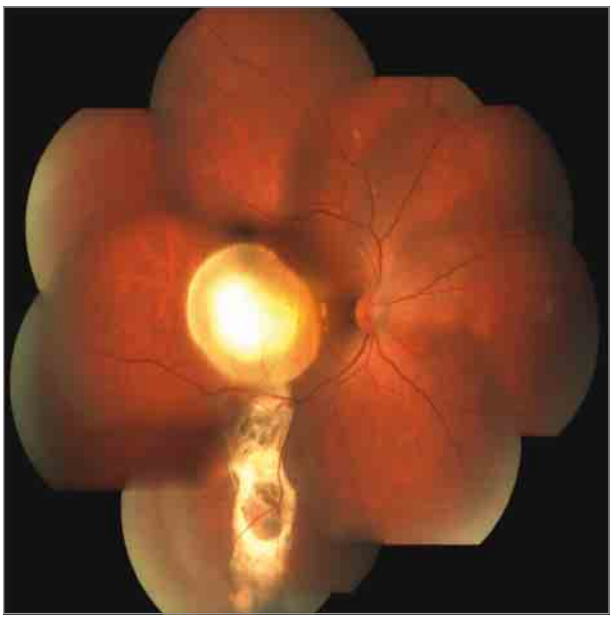
OPHTHALMIC IMAGES

Bug Inside The Eye
Ocular Cysticercosis

Neha Mohan, MS; Krushna Gopal Panda, BSc Optom; Tapas Ranjan Padhi, MS



A 53-year-old man presented with a macular subretinal cystoid abnormality with a whitish central shadow showing contractions during an examination, suggestive of a scolex, and subretinal gliosis extending inferiorly. Ocular cysticercosis was surgically removed, with visual acuity 5 months after surgery of 20/400.