ARTICLE

Rotational stability and visual outcome after implantation of a new toric intraocular lens for the correction of corneal astigmatism during cataract surgery

Alexander Bachernegg, MD, Theresa Rückl, MD, Wolfgang Riha, MD, Günther Grabner, MD, Alois K. Dexl, MD, MSc

PURPOSE: To evaluate rotational stability and the refractive and visual outcomes of a new aspheric toric intraocular lens (IOL) for correction of preexisting corneal astigmatism during routine cataract surgery.

SETTING: Department of Ophthalmology, Paracelsus Medical University Salzburg, Salzburg, Austria.

DESIGN: Case series.

METHODS: Aspheric Bi-Flex T toric IOLs were monolaterally or bilaterally implanted after phacoemulsification in patients with topographic corneal astigmatism between 1.5 diopters (D) and 4.0 D. Preoperative IOL calculations were performed by laser interference biometry (Haigis formula). Appropriate IOL–torus alignment was facilitated by combined imaging and eye-tracking technology. Refraction and uncorrected distance (UDVA) and corrected distance visual acuities were measured 1 day, 1 week, and 1 and 3 months postoperatively. At each visit, photodocumentation in retroillumination was performed to evaluate torus position and potential toric IOL rotation.

RESULTS: The mean refractive astigmatism decreased from 1.93 D ± 0.90 (SD) (range 0.5 to 4.0 D) to 0.30 ± 0.54 D (range 0.0 to 1.5 D) at 3 months. Patients achieved a mean UDVA of 0.05 ± 0.12 logMAR (range −0.18 to 0.30 logMAR [~20/20]). Intraoperative to 3-month postoperative comparison of IOL axis alignment showed low levels of rotation (mean 2.12 ± 3.45 degrees; range −2 to +5 degrees).

CONCLUSIONS: Implantation of the new aspheric toric IOL was effective, safe, and stable in correcting preexisting regular corneal astigmatism during cataract surgery. Combined imaging and eye tracking seems to be a promising technology to evaluate the correct axis for IOL torus alignment.

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According to numerous estimations, 15% to 29% of cataract patients have more than 1.5 diopters (D) of refractive astigmatism.[1] Several techniques exist to correct corneal astigmatism. These include limbal relaxing incisions,[2] opposite clear corneal incisions,[3] excimer laser refractive procedures,[4,5] femtosecond laser–assisted astigmatic keratotomy,[6,7] and toric intraocular lens (IOL) implantation.[8]

The use of toric IOLs to reduce visually significant corneal astigmatism offers a rational, predictable, and stable method of refractive correction.[9] Implanting a toric IOL allows the correction of not only the refractive spherical equivalent (SE) but also its astigmatic component. The success of a toric IOL can be judged by its ability to reduce refractive astigmatism immediately after surgery as well as by its ability to maintain a stable position in the capsular bag over the longer term. The most frequent cause of IOL rotation after uneventful cataract surgery is capsular bag shrinkage due to fibrosis.[10] The majority of fibrosis occurs within the first 3 months after implantation.[11] Even a small rotational deviation of the toric

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IOL from its intended axis can result in large reduction in the astigmatic correction and potential axis shift. Hence, rotation stability of toric IOLs and accuracy in marking procedures are essential.[A]

The purpose of this study was to evaluate the rotational stability and the refractive and visual outcomes of the new Bi-Flex T aspheric toric IOL (Medicontur Medical Engineering, Ltd., Inc.) for correction of preexisting corneal astigmatism during routine cataract surgery.

PATIENTS AND METHODS

Patient Population

In this prospective interventional case series, consecutive patients had monocular or binocular implantation of the new aspheric toric IOL after phacoemulsification performed by the same surgeon (G.G.). All patients gave written informed consent before enrollment. The study was performed in accordance with the Declaration of Helsinki and approved by an institutional review board (Ethics Committee, County of Salzburg).

Inclusion criteria were senile cataract and preexisting regular topographic corneal astigmatism between 1.5 diopters (D) and 4.0 D. Exclusion criteria were irregular corneal astigmatism, diabetic retinopathy, iris neovascularization, serious intraoperative complications, congenital eye abnormality, glaucoma, pseudoexfoliation syndrome, amblyopia, uveitis, long-term antiinflammatory treatment, advanced age-related macular degeneration, retinal detachment, previous ocular surgery, severe corneal and retinal disease, and a history of eye trauma.

Preoperative Assessment

Before surgery, a complete medical history was taken and all patients had a full ophthalmologic examination including refraction and uncorrected (UDVA) and corrected (CDVA) distance visual acuity measurements. This study used the Early Treatment of Diabetic Retinopathy Study charts. The number of optotypes identified correctly was counted and converted into logMAR values. In addition, intraocular pressure (IOP) (contact Goldman tonometry), corneal topography (Keratron, Optikon Ophthalmic Equipment), and laser interference biometry (IOLMaster, Carl Zeiss Meditec AG) using the Haigis formula[B] were performed. Preoperative images were taken with an SMI-Surgery Guidance unit SG3000 (Sensomotoric Instruments GmbH) for intraoperative imaging and eye tracking to facilitate the appropriate positioning of the toric IOL. Intraocular lens cylinder power and axis placement were calculated using a program available from the IOL manufacturer,[C] taking into account the IOLMaster keratometry readings. One eye was calculated with a target refraction of −3.0 D because the patient requested residual postoperative myopia. All other eyes were calculated for emmetropia. No surgically induced astigmatism was assumed preoperatively because of the corneoscleral tunnel incision used.

Intraocular Lens

The Bi-Flex T toric IOL has an overall diameter of 13.0 mm, double-loop haptics, and an optic diameter of 6.0 mm without haptic angulation. The refractive index of the optic material at 23°C is 1.46. The single-piece IOL is of a hydrophilic acrylic copolymer with integrated covalently bound benzophenone as an ultraviolet filter. The toric component of the IOL is located on the posterior surface of the optic. The torus is marked with 2 marks at the edge of the optic. The toric IOL is available in cylinder powers of 1.5 to 9.0 D. (Toric IOLs with cylinder powers >9.0 D are produced on request.) The IOL is aspheric with neutral asphericity and has a sharp 360-degree edge to prevent migration of lens epithelial cells and therefore prevent posterior capsule opacification.[D]

Surgical Technique

A 5.0 mm continuous curvilinear capsulorhexis was created in all cases. The cataract was removed by phacoemulsification. The toric IOLs were folded and implanted in the bag through a 2.2 mm incision. Sutureless wound closure was performed. After IOL implantation and ophthalmic viscoelastic device (OVD) removal, the toric IOL was rotated to its final position by exactly aligning the toric reference according to the intraoperative imaging and eye-tracking unit.

The SMI Surgery Guidance unit was used to orient the toric IOL. The reference unit took reference measures, including keratometry readings and high-definition images of the eye. The unit's surgery pilot was used to place digital marks on the patient's eye during surgery. The surgery pilot directly displayed the data in the oculars of the microscope. At the end of surgery, an intraoperative picture in retroillumination was taken to document the torus position.

Postoperative Assessment

Postoperative examinations were performed at 1 day, 1 week, and 1 and 3 months. The examinations included UDVA, CDVA, and IOP measurements. A slitlamp examination, subjective refraction, and photography of the IOL in retroillumination were also performed.

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From the Department of Ophthalmology, Paracelsus Medical University Salzburg, Salzburg, Austria.

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Corresponding author: Alois K. Dexl, MD, MSc, Department of Ophthalmology, Paracelsus Medical University Salzburg, Müllner Hauptstraße 48, A-5020 Salzburg, Austria. E-mail: a.dexl@salk.at.

Rotation of the toric IOL was evaluated as follows. First, postoperative photographs were compared with the picture indicating the torus position directly at the end of surgery. Clockwise rotation was counted as positive rotation and counterclockwise as negative rotation. Second, every rotation (clockwise or counterclockwise) was regarded as positive rotation, and the rotation from 1 timepoint to another (end of operation to 1 day; 1 day to 1 week; 1 week to 1 month; 1 month to 3 months) was plotted to check whether there was significant rotation within a particular period. Rotation between the torus position at the end of surgery and the first postoperative visit at 1 day was regarded as misalignment. Rotation between 1 day and the following visits was regarded as toric IOL rotation.

Statistical Analysis

Statistical analysis was performed using SPSS for Windows software (version 15.0, SPSS, Inc.). The mean values and standard deviations were calculated for every parameter. Normal distribution of all data samples was first checked using the Kolmogorov-Smirnov test. Parametric analysis was possible. To analyze the data from preoperative examinations and postoperative examinations and between consecutive postoperative visits in each IOL group, 1-way analysis of variance (ANOVA) for repeated measures was used. If sphericity could not be assumed, Greenhouse-Geisser estimates were used as a correction factor. Post hoc comparisons were performed using the Bonferroni procedure. In all instances, the level of statistical significance was a P value less than .05. For comparisons between the IOL groups, the 1-way ANOVA with Bonferroni post hoc comparison procedure was used when parametric analysis was possible. If variances were not homogeneous (checked by the Levene test), Tamhane post hoc analysis was used. When parametric analysis was not possible, the Kruskal-Wallis test was used to compare the IOL groups, with a P value less than .05 indicating statistical significance. For post hoc analysis, the Mann-Whitney test with Bonferroni adjustment was used to avoid an experimental error rate.

RESULTS

This study enrolled 30 eyes of 20 consecutive patients. Table 1 shows the demographic data and implanted toric IOL powers.

Table 1. Preoperative demographics (20 patients, 30 eyes).

Demographic	Value
Age (y)	
Mean ± SD	63.9 ± 11.1
Range	37, 81
Sex (n)	
Female	12
Male	8
Operated eye (n)	
Right	5
Left	5
Both	10
Refractive astigmatism (D)	
Mean ± SD	1.93 ± 0.90
Range	0.50, 4.00
Topographic astigmatism (D)	
Mean ± SD	2.36 ± 0.50
Range	1.53, 3.28
Keratometric astigmatism (D)	
Mean ± SD	3.29 ± 0.84
Range	1.94, 4.74
MRSE (D)	
Mean ± SD	−1.21 ± 2.83
Range	−6.38, +4.50
UDVA (logMAR)	
Mean ± SD	0.97 ± 0.56
Range	0.10, 2.00
CDVA (logMAR)	
Mean ± SD	0.44 ± 0.31
Range	0.00, 1.30
IOL power (sphere)	
Mean ± SD	18.50 ± 4.58
Range	12.50, 29.00
IOL power (cylinder)	
Mean ± SD	2.98 ± 0.87
Range	1.50, 4.50
Axial length (mm)	
Mean ± SD	23.75 ± 1.67
Range	20.57, 26.51

CDVA = corrected distance visual acuity; IOL = intraocular lens; MRSE = mean refraction spherical equivalent; UDVA = uncorrected distance visual acuity

Visual Acuity

The UDVA data were calculated from the 29 eyes targeted for postoperative emmetropia. All 30 eyes were available for CDVA calculation.

The mean UDVA increased statistically significantly to 0.05 ± 0.12 logMAR (range −0.18 to 0.30 logMAR [~20/22.5]) after 3 months ($P<.01$) (Figure 1, *A*). Postoperatively, the UDVA was 20/25 (0.1 logMAR) or better in 22 eyes (73%) and 20/20 (0.0 logMAR) or better in 17 eyes (56%) (Figure 2).

The mean CDVA increased significantly to −0.01 ± 0.10 logMAR (range −0.18 to 0.22 logMAR [~20/20]) after 3 months $P<.01$) (Figure 1, *B*). The CDVA was 20/32 (0.2 logMAR) or better in 30 eyes (100%), 20/25 (0.1 logMAR) or better in 26 eyes (87%), and 20/20 or better (0.0 logMAR) in 23 eyes (77%) (Figure 2).

There was a 0.5-line difference between the UDVA and the CDVA postoperatively, indicating a good refractive result. The UDVA and CDVA values stayed stable during the 3-month follow-up (Figure 1, *A* and *B*).

Refraction

The mean SE did not significantly change from preoperative values and was −0.16 ± 0.33 D (range

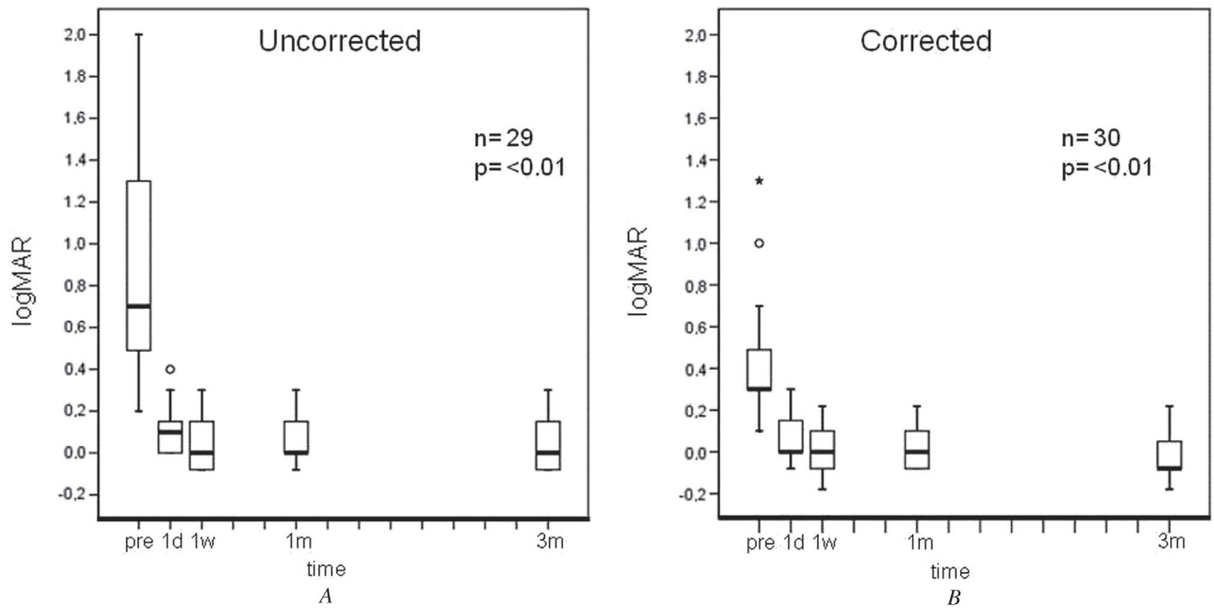

Figure 1. Distance visual acuity (*A*: uncorrected; *B*: corrected) over time after phacoemulsification and toric IOL implantation.

−0.75 to +0.50 D) 3 months postoperatively ($P=.07$) (Figure 3, *A*). Twenty-seven eyes (90%) were within ±0.50 D of emmetropia, and 30 eyes (100%) were within ±1.00 D (Figure 4).

There was no statistically significant difference between the refractive astigmatism at the 3-month visit (mean 0.30 ± 0.54 D) and the calculated residual astigmatism (mean 0.38 ± 0.52 D) ($P=.31$) (Figure 3, *B*). Postoperatively, the refractive astigmatism was 0.50 D or less in 24 eyes (80%), 1.00 D or less in 29 eyes (97%), and 1.50 D or less in 30 eyes (100%) (Figure 5).

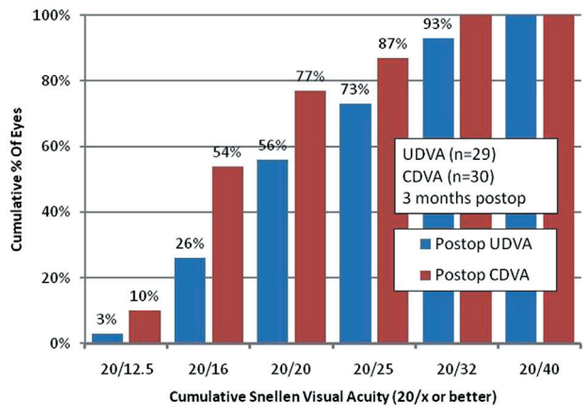

Figure 2. The UDVA and CDVA 3 months postoperatively (CDVA = corrected visual acuity; UDVA = uncorrected visual acuity).

Misalignment and Intraocular Lens Rotation

Analysis of the toric IOL axis position showed a mean rotation of 2.12 ± 3.45 degrees (range −2 to +5 degrees) from the end of surgery to the last follow-up; the difference was not statistically significant (Figure 6, *A*). The magnitude of rotation (regarded as misalignment) could be seen within the first 24 hours, whereas minimal rotation was seen between the 1-day visit and the 3-month visit (Figure 6, *B*).

The median misalignment (ie, absolute difference in toric IOL axis between intended placement at time of surgery and measured IOL axis 1 day after surgery) was 0 degree (range 0 to +5 degrees) (Figure 6, *B*). The alignment was within ±2 degrees of the intended axis in 27 eyes (90%). The median IOL rotation between 1 day and 3 months was also 0 degrees. No IOL rotated more than 2 degrees within this time period (Figure 6, *B*). There were no statistically significant differences in the intended, 1-day, and 3-month IOL axes (repeated-measure ANOVA with Bonferroni post hoc test).

Complications

Due to the learning curve, 2 trial IOLs had a partially broken double-loop haptic after placement in the posterior chamber with the injector (Medicontur Medjet B injector; Medicontur Medical Engineering. Ltd., Inc.); no secondary procedure was required within the follow-up. No eye had other intraoperative or postoperative complications, and no patient required

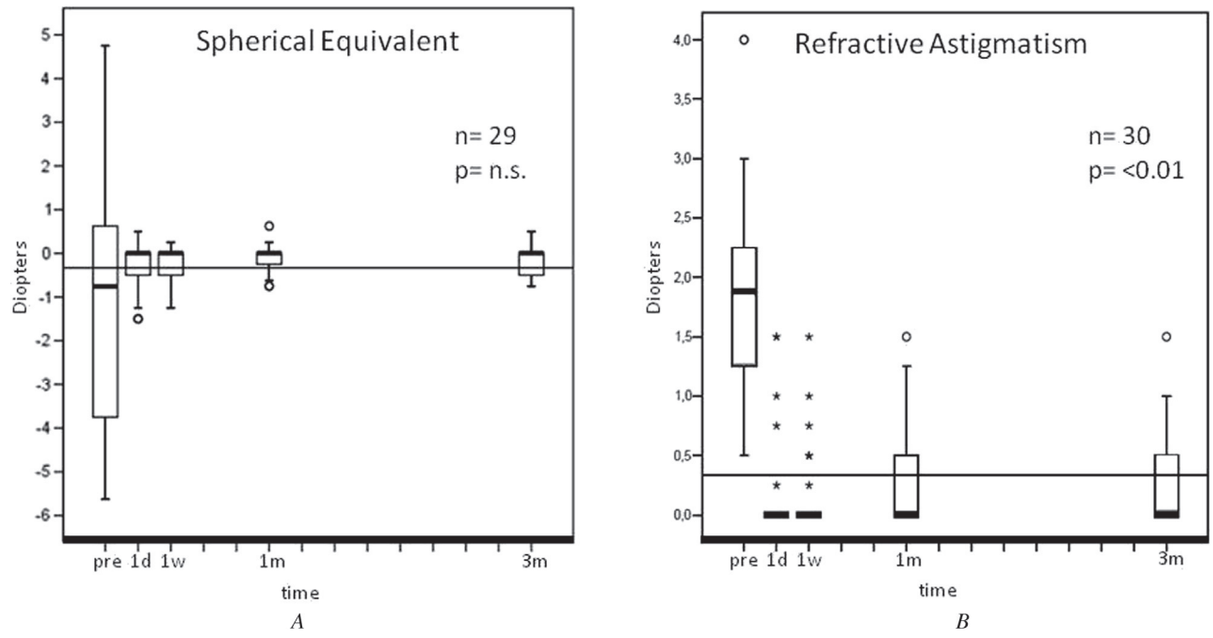

Figure 3. Stability of SE (*A*) and refractive astigmatism (*B*) over time after phacoemulsification and implantation of the trial toric IOL. The horizontal line in *A* indicates the calculated mean postoperative target refraction (SE). The horizontal line in *B* indicates the calculated mean postoperative residual refractive astigmatism (cylinder).

a secondary procedure because of rotational instability or torus misalignment. In addition, no eye required a neodymium:YAG (Nd:YAG) capsulotomy up to the last postoperative visit.

DISCUSSION

Corneal astigmatism is frequent in cataract patients[1] and contributes significantly to the refractive outcomes of surgery. The use of toric IOLs is one of many surgical options to correct corneal astigmatism and provide improved visual outcomes. Because of the unpredictability of surgical methods that flatten the cornea,[12] stable and effective toric IOLs implanted in the capsular bag during routine cataract surgery (requiring no modification of the cornea) are an important advancement in modern cataract surgery. Precise measurement, IOL calculation, IOL placement, and IOL rotational stability are mandatory for success.

The use of toric IOLs to correct corneal astigmatism is frequently complicated by rotation of the IOL in the capsular bag.[9] Rotation occurs in the early postoperative period, before the anterior and posterior leaves of the capsule fuse. Several mechanisms may result in undesirable postoperative IOL rotation. These include incomplete OVD clearance, which causes reduced friction between the haptics and the capsular bag,[13]

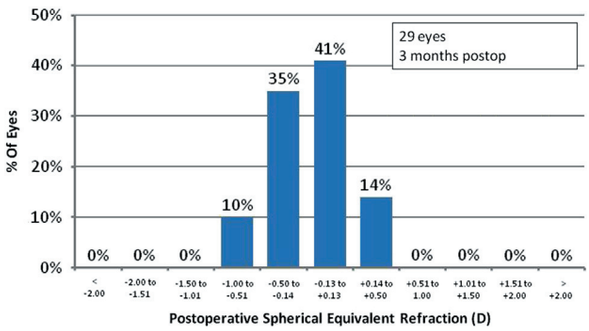

Figure 4. Spherical equivalent 3 months postoperatively.

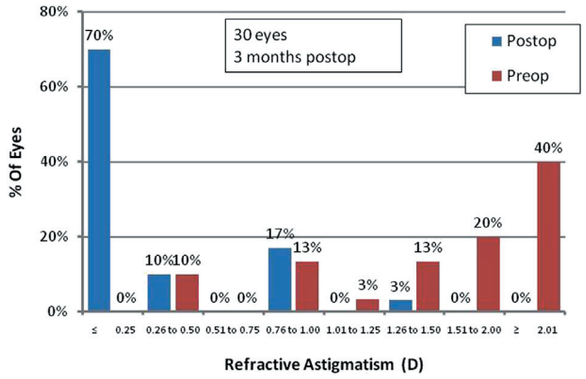

Figure 5. Preoperative and postoperative refractive astigmatism.

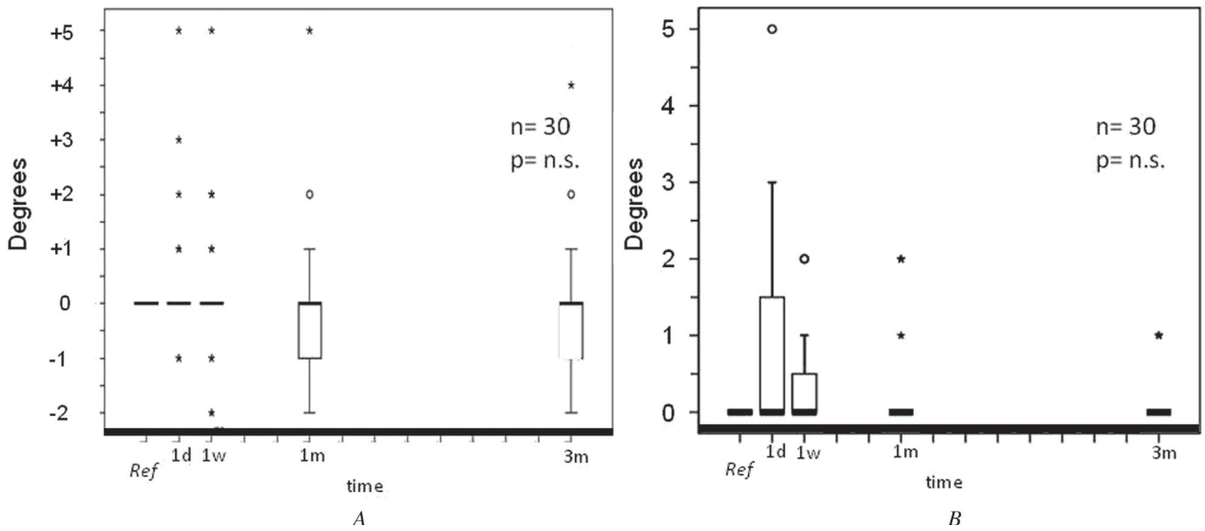

Figure 6. *A*: Intraocular lens rotation in relation to the torus position at the end of surgery (rotation clockwise was regarded as positive and counterclockwise as negative). *B*: Rotation between different follow-up visits (every rotation was regarded as positive whether rotation was clockwise or counterclockwise).

and early postoperative IOP fluctuations[14]; both are linked to rotational instability. Capsulorhexis size and IOL design and material are other influencing factors.[15] With time, postoperative capsule shrinkage compresses the IOL haptics and may cause rotation of IOLs of certain designs and materials.

Different methods can be used to accurately determine the position of a toric IOL. Weinand et al.[16]

Table 2. Publications reporting rotational stability after implantation of a toric IOL.

			Mean ± SD						Mean ± SD (Range)
				Preop Cylinder (D)					
Study*	Year	IOL Model (Manufacturer)	Postop UDVA (LogMAR)	Refractive	Keratometric	Topographic	Postop Refractive Cylinder (D)	FU (Mo)	Eyes/ Patients (n)	IOL Rotation (°)
Current	2013	Bi-Flex T (Medicontur)	0.05 ± 0.12	1.93 ± 0.90	3.29 ± 0.84	2.36 ± 0.50	0.30 ± 0.54	3	30/20	2.12 ± 3.45 (+4, −2)
Alberdi[21]	2012	T-flex 573T&623T (Rayner)	0.10 ± 0.12	2.81 ± 0.87	NR	NR	0.52 ± 0.63	3	27/22	3.11 ± 3.57 (0, 12)
De Silva[20]	2006	MicroSil 611TU (Humanoptics)	0.32 ± 0.24	3.52 ± 1.11	3.08 ± 0.76	NR	1.23 ± 0.90	6	21/14	NR
Entabi[23]	2011	T-flex 623T (Rayner)	0.28 ± 0.23	3.35 ± 1.20	3.98 ± 1.89	NR	0.95 ± 0.66	4	33/25	3.4 ± NR (0, 12)
Hoffmann[24]	2011	Acrysof toric (Alcon)	0.20 ± 0.11	3.49 ± 1.31	3.55 ± 0.73	3.50 ± 0.78	0.67 ± 0.32	3	40/30	0.23 ± 1.9 (0, 5)
Mendicute[8]	2009	Acrysof toric (Alcon)	0.11 ± 0.15	1.75 ± 0.71	NR	NR	0.62 ± 0.46	3	20/20	3.53 ± 1.97 (0, 8)
Sheppard[22]	2013	Tecnis toric 1-piece (Abbott)	0.15 ± 0.17	1.91 ± 1.07	2.21 ± 0.91	NR	0.67 ± 0.54	1–2	67/60	3.4 ± NR (0, 12)
Chua[25]	2012	AA4203-TF/TL (Staar)	NR	NR	NR	1.68 ± 0.52	0.54 ± 0.54	3	26/NR	9.42 ± 7.80 (NR)
Chua[25]	2012	AcrySof toric (Alcon)	NR	NR	NR	1.60 ± 0.27	0.52 ± 0.36	3	24/NR	4.23 ± 4.28 (NR)

FU = follow-up; IOL = intraocular lens; NR = not reported; UDVA = uncorrected distance visual acuity
*First author

and Becker et al.[17] analyzed digital and conventional photographs taken preoperatively and postoperatively through the slitlamp and operating microscope. Analyzing photographs in retrograde illumination has become widely used in evaluating the centration and axial positioning of a toric IOL. It is reasonable to consider that misalignment of fewer than 5 degrees might be attributed to observational errors when a slitlamp photographic technique is used for axis measurement; these errors might be related to reasons other than IOL rotation (reference marking and reading, preoperative keratometry readings), as mentioned in the literature.[18,19]

In this study, the SMI Surgery Guidance unit SG3000 was used to align the toric IOL to the correct position. The equipment was developed to increase precision and objective evaluation outcomes of cataract surgery, mainly the refractive part. The equipment provides automated visual guidance for the surgeon without manual markers. Based on a preoperative reference image, the unit allows automatic registration and control of the eye position under the surgical microscope.

The low level of rotation in the present study (mean 2.12 ± 3.45 degrees; range −2 to +5 degrees) is in agreement with results in relatively recent reports of postoperative toric IOL stability. Table 2 is a summary of published data on toric IOL rotation.[8,20–25] Mendicute et al.[8] found a mean IOL rotation of 3.6 degrees in 30 eyes with the Acrysof SN60T IOL (Alcon Laboratories, Inc.) at 12 weeks; 97% of the IOLs rotated less than 10 degrees. Entabi et al.[23] report rotation of 3.4 degrees (range 0 to 12 degrees) at 16 weeks with the T-flex 623T IOL (Rayner Intraocular Lenses, Ltd.). Hoffmann et al.[24] found postoperative rotation of 0.23 degree with higher power toric IOLs. Chua et al.[25] report rotational stability of 4.23 degrees. Approximately 1 degree of off-axis rotation results in a loss of up to 3.3% of cylinder power for each degree of rotation.[15] Thus, in the present study, we can attribute 0.06 ± 0.02 D to the mean rotation of 2.12 ± 3.45 degrees (mean toric IOL cylinder power 2.98 ± 0.87 D). Most IOL rotation was seen within the first 24 hours after implantation, and we believe this misalignment may have been the result of inadequate clearing of the OVD trapped behind the IOL, causing minor positional IOL instability.

Uncorrected distance visual acuity is an important parameter of success for patients and can be significantly improved by implanting toric IOLs. In our study, the mean UDVA was 20/40 or better in 30 eyes (100%) and all patients had CDVA of 20/25 or better. Chang[26] studied implantation of the 1-piece acrylic toric Staar TF/TL IOL (Staar Surgical Co.) and obtained a CDVA of 20/40 or better in 92% of eyes. In a study by Sun et al.[27] using the toric Staar TF in 130 patients, 84% of eyes achieved a CDVA of 20/40 or better. The UDVA in the present study (mean 0.05 ± 0.12 logMAR) compares with reports of outcomes with other toric IOLs. De Silva et al.[20] found a mean UDVA of 0.32 ± 0.24 logMAR after implantation of the Microsil 6116TU (Humanoptics AG). Mendicute et al.[8] report a mean UDVA of 0.11 ± 0.15 logMAR, with 93% of eyes achieving 20/40 or better. Other studies[21,22] also had good UDVA outcomes with different IOLs. In the present study, the difference between the mean UDVA (+0.05 ± 0.12 logMAR [~20/25]) and the mean CDVA (−0.01 ± 0.10 logMAR [~20/20]) postoperatively was 0.5 line, indicating a very good refractive result.

Some studies of foldable toric IOLs found significant surgically induced astigmatism (SIA),[28,29] while others did not.[30] Surgically induced astigmatism is dependent not only on incision width but also on incision location (clear corneal, limbal, scleral) and architecture. We used 2.3 mm corneoscleral incisions, and they proved to be astigmatically neutral. Therefore, SIA was not taken into account when calculating the toric IOL power.

In our study, 2 partially broken double-loop haptics could be seen directly after IOL injection into the posterior chamber; this had no noticeable influence on postoperative UDVA and CDVA. No patient required a secondary procedure because of rotational instability or torus misalignment. In addition, no eye required an Nd:YAG capsulotomy up to the last postoperative visit.

We have been implanting the Bi-Flex T toric IOL (1.5 to 4.5 D of cylinder) at our clinic since May 2011. It is a single-piece hydrophilic acrylic toric IOL with marks indicating the plus axis of the cylinder. We believe that the present study is the first to describe application of this toric IOL in a cohort of consecutive patients having routine cataract surgery. Our results indicate that implantation of this IOL model is safe, effective, predictable, and stable in correcting corneal astigmatism during routine cataract surgery. The available range of cylinder powers allows application of this toric IOL in the majority of cataract patients with significant corneal astigmatism. The Bi-Flex T toric IOL was stable in the capsular bag after 1 day, with minimal rotation from 1 day to 3 months. The difference between the mean UDVA (+0.05 ± 0.12 logMAR) and the mean CDVA (−0.01 ± 0.10 logMAR) postoperatively was a 0.5 line, indicating a good refractive result.

WHAT WAS KNOWN

- Approximately 60% of cataractous eyes have more than 0.75 D of corneal astigmatism.
- Stable and effective toric IOLs implanted in the capsular bag during routine cataract surgery are therefore an important requirement for modern cataract surgery, allowing correction of corneal astigmatism during cataract surgery.

WHAT THIS PAPER ADDS

- The new Bi-Flex T hydrophilic acrylic toric IOL effectively and predictably managed corneal astigmatism during routine cataract surgery.
- The difference between the mean UDVA ($+0.05 \pm 0.12$ logMAR) and the mean CDVA (-0.01 ± 0.10 logMAR) postoperatively was a 0.5 line, indicating a good refractive result. The mean IOL rotation was 2.12 ± 3.45 degrees over the 3-month follow-up.

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First author:
Alexander Bachernegg, MD

From the Department of Ophthalmology, Paracelsus Medical University Salzburg, Salzburg, Austria