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Changes in visual outcomes and ocular morphometrics after foldable myopic and toric intraocular lens implantation: 5 year results.

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Running head: 5 Year Visual and Morphometric Changes in Foldable IF-pIOLs

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Abstract

Purpose: To evaluate the refractive, visual, and morphometric changes after implantation with a foldable iris-fixated phakic intraocular lens (pIOL) to correct myopia or astigmatism.

Setting: University Eye Clinic Maastricht, the Netherlands.

Design: Prospective case series.

Methods: We evaluated patients implanted with the Artiflex Myopia (Toric) iris-fixated pIOL as of January 2004. Measurements were performed annually and reported after 1 and 5 years.

Results: The study included 481 eyes (277 patients; age 39.8±10.9 years [SD]). Five years postoperatively 91% of eyes were within ±1.0 D of target, and the mean myopisation over a 5 year period was 0.22 diopters (p<0.001). The logMAR CDVA increased by a mean 0.015 (p=0.015) over 5 years; 88% of eyes had a CDVA of 20/20 or better and 5.5% lost 2 or more lines of CDVA. Mean UDVA increased by 0.045 logMAR over 5 years (p<0.001); 96% reached an UDVA of 20/40 or more. Anterior chamber depth (ACD) decreased by 0.04 mm (p<0.001), and axial length (AXL) increased by 0.23 mm (p<0.001) over 5 years. Chronic endothelial cell loss showed a 5-year decline of 320 cells/mm² in the myopic and 310 cells/mm2 in the toric subgroups (p<0.001). Cataract resulted in pIOL explantation in 4.0% of eyes (mean survival 59.0±40.0 months); higher preoperative age (hazard ratio [HR], 1.13; p<0.001) and smaller ACD (HR, 6.80; p= 0.035) were risk factors for shorter survival due to cataract formation.

Conclusion: Over 5 years logMAR CDVA and UDVA decreased significantly due to myopisation caused by lenticular changes and AXL elongation.

Introduction

Previous studies have proved implantation with anterior chamber (angle supported, iris-fixated) and posterior chamber phakic intraocular lenses (pIOLs) to be superior to laser refractive surgery in patients with high myopia and myopic patients with thin corneas.[1] The iris-fixated Artiflex Myopia and Artiflex Myopia Toric pIOL were introduced in 2005 and 2007, respectively, as an addition to the rigid iris-fixated Artisan Myopia and Artisan Toric pIOLs (all IOLs by Ophtec B.V., Groningen, the Netherlands). Studies on the rigid myopic and toric iris-fixated pIOLs have shown good results with respect to visual acuity and predictability.[1-3] However, the rigid polymethyl methacrylate (PMMA) material requires a large main incision for implantation of these pIOLs, creating a higher surgically induced corneal astigmatism (SICA). The foldable myopic (toric) iris-fixated pIOLs are composed of a flexible polysiloxane optic and PMMA haptics requiring a much smaller main incision, resulting in less SICA while still achieving good visual acuity, refractive correction, safety and efficacy.[4-8]

Few papers have previously described the results of foldable iris-fixated pIOLs after a follow-up of 5 years or more[9, 10], and no previous report has performed longitudinal analyses describing visual, refractive and morphometric outcomes over time as the current paper.

Methods

Design

From January 2004 to June 2016, 277 patients were implanted with an Artiflex myopic or myopic toric foldable iris-fixated pIOL at the University Eye Clinic Maastricht, Maastricht University Medical Center, Maastricht, the Netherlands. Patients were prospectively evaluated preoperatively, 1 day, 1 week, 1, 3, 6 and 12 months postoperatively in the first postoperative year, followed by annual visits. All surgeries were performed by the same surgeon (RN) under general or local anesthesia. The current study was performed in adherence to the tenets of the Declaration of Helsinki. The Maastricht University Medical Center Institutional Review Board stated that approval was not required for this study.

Previous reports by our group have described the inclusion criteria, measurements, surgical procedure (including peripheral iridectomy) and postoperative medication used in the current study.[4, 11-13]

Outcome Measures

Refractive and visual outcome measures were based on the 2014 guidelines of the Journal of Refractive Surgery (JRS),[14] describing manifest refractive spherical equivalent (MRSE), target vs. achieved MRSE, change in MRSE, refractive astigmatism, corrected distance visual acuity (CDVA),

change in CDVA, uncorrected distance visual acuity (UDVA), and change in UDVA as outcome measures for refractive surgery. Target induced astigmatism (TIA) vector, surgically induced astigmatism (SIA) vector, difference vector (between TIA and SIA), correction index (SIA divided by TIA), index of success (difference vector divided by TIA) and mean angle of error were calculated using refractive data in eyes implanted with the myopic toric pIOL. Safety indices (postoperative CDVA divided by preoperative CDVA), and efficacy indices (postoperative UDVA divided by preoperative CDVA) were computed, and changes in safety and efficacy indices reported. Additionally, anterior chamber depth (ACD) and axial length (AXL), as well as changes over time were assessed in order to evaluate possible age-related changes in ocular biometry.
Changes in endothelial cell density (ECD) were reported in a previous paper.[13]

Statistical Analysis

Statistical analysis was performed using SPSS for Windows (version 23, IBM Corp, Armonk, NY, USA). The UDVA and CDVA were converted from Snellen values to logarithm of the minimum angle of resolution (logMAR) prior to statistical analysis. Descriptive analyses were performed to compute mean and standard deviation (SD) in primary outcome measures and preoperative characteristics. Vector analyses according to Alpins were performed to assess refractive astigmatism in eyes implanted with the myopic toric pIOL.[15]
Longitudinal changes were analyzed using a linear mixed-model analysis with an eye identification number as a grouping variable and time as a covariate. In each model the best fitted covariance structure was selected using the Bayesian information criterion (BIC). In order to assess long-term changes in the study groups, analyses were performed to separate the short-term from long-term changes results. Longitudinal analyses assessed short-term changes from preoperatively to 12 months postoperatively and long-term changes from 12 months postoperatively until the end of follow-up. Hotelling Trace multivariate analysis of variance (MANOVA) analyses were performed to assess if vectorial change from 1 to 5 years postoperatively was significantly different from zero.
In a subset of patients, longitudinal and cross-sectional analyses on the effect of age on AXL were performed using linear mixed-model analysis (20 eyes, longitudinal data) and analysis of variance (ANOVA) (298 eyes, preimplantation data), respectively. Kaplan-Meier and multivariate Cox regression analyses were performed to measure survival from pIOL implantation to pIOL explantation due to cataract formation. Risk factors for pIOL explantation due to cataract formation were identified using univariate Cox regression analyses. Multivariate analyses were performed to correct for possible correlation between risk factors, while excluding insignificant risk factors. *P* values were considered significant if $P < 0.05$.

Results

The study included 481 eyes of 277 patients; the foldable myopic pIOL was implanted in 293 eyes of 166 patients, and the foldable myopic toric pIOL was implanted in 188 eyes of 111 patients. Table 1 depicts the baseline characteristics of this study population. Mean follow-up was 51 ± 37 months. One eye of 1 patient (0.2%) was implanted with a myopic pIOL one month before turning 18. In 8 eyes of 6 patients (1.7%) the preoperative endothelial cell density (ECD) was lower than 2000 cells/mm^2. This group, with a mean preoperative age of 51.8 ± 3.6 years, had a mean preoperative ECD of 1872 ± 115 cells/mm^2. All patients with a preoperative ECD <2000 cells/mm^2 were extensively informed on the risks of pIOL implantation in case of lower preoperative ECD counts, before opting for surgery.

Predictability

Table 1 shows the mean manifest refraction spherical equivalent (MRSE) and refractive cylinder over time. Target versus achieved MRSE correction 1 and 5 years after implantation is reported in Figure 1A. Figure 1B shows the percentage of eyes within 0.5 D and 1.0 D of intended correction 1 and 5 years after pIOL implantation and Figure 1C shows the percentage of eyes with a MRSE change of > 0.5 D over a 5 year period. The percentage of eyes with a refractive astigmatism within 0.5 D and 1.0 D of zero is reported in Figure 1D.

Single-angle polar plots representing TIA vector, SIA vector, difference vector and correction index 1 and 5 years after toric pIOL implantation are depicted in Figures 2 and 3, respectively. Figure 1E shows the distribution of the angle of error 1 and 5 years after implantation. The mean index of success after 1 and 5 years was 0.26±0.25 and 0.23±0.27, respectively.

Longitudinally, the MRSE decreased significantly ($p < 0.001$) by 0.043 D each year. On vector analyses the toric pIOL group supported a change in refractive cylinder of 0.41±0.53 D at 9° from 1 to 5 years postoperatively ($p = 0.024$).

Safety

Mean logMAR CDVA over time is portrayed in Table 1. Figure 4A shows the change in Snellen CDVA lines from preoperatively to 1 and 5 years postoperatively. Five years after implantation 205 eyes (98%) and 185 eyes (88%) had a CDVA of ≥20/40 and ≥20/20, respectively.

The logMAR CDVA increased significantly by 0.003 each year ($p = 0.015$), causing a significant decrease in safety index of 0.007 each year ($p = 0.043$)(Table 1).

Efficacy

LogMAR UDVA 1 and 5 years after implantation is reported in Table 1. Cumulative Snellen UDVA 1 and 5 years after implantation is shown in Figure 4B. The postoperative UDVA was compared to the preoperative CDVA in order to compute the efficacy indices after 1 and 5 years, as reported in Figure 4C, and Table 1. Annually the logMAR UDVA increased significantly ($p < 0.001$) by 0.009, resulting in a significant decrease in efficacy index of 0.016 each year ($p < 0.001$).

Ocular Biometry

Mean pre- and postoperative ACD is summarized in Table 1, with longitudinal analyses showing a statistically significant annual decrease in ACD of 0.014 mm ($p < 0.001$).

Subgroup analyses were performed describing longitudinal changes in 20 eyes that were measured using optical biometry prior to pIOL implantation, as well as prior to combined pIOL explantation and cataract surgery at a later date. The mean preoperative AXL was 27.21 ± 1.38 mm in this subgroup, and analyses showed a statistically significant increase in AXL of 0.046 mm each year ($p < 0.001$). Secondary cross-sectional ANOVA analyses were performed to assess correlations between age and preoperative AXL measured with optical biometry in a larger subgroup of 298 eyes. Mean preoperative AXL was 26.79 ± 1.26 mm in this subgroup, with results indicating an annual increase in AXL of 0.016 mm ($p = 0.018$).

Complications and Interventions

Table 2 shows the complication profile on all eyes implanted with myopic (toric) pIOLs in the current study, and presents an overview of reasons for additional surgery, pIOL exchange and pIOL explantation. Rhegmatogenous retinal detachments (RRD) did not occur after cataract surgery in any patient.

Risk Factors

After excluding insignificant risk factors, the Cox regression multivariate analyses registered higher preoperative age (Hazard Ratio [HR] = 1.13/year [95% Confidence Interval (CI) 1.06-1.20], $p < 0.001$) and smaller ACD (HR = 6.80/mm [95% CI 1.14-40.58], $p = 0.035$) as significant risk factors for a shorter survival due to cataract formation.

Discussion

The current study presents visual acuity and refractive outcomes five years after foldable iris-fixated pIOL implantation. The main finding of this study is a slight deterioration of all visual and refractive parameters that can be attributed to age-related increase in crystalline lens thickness and AXL

elongation. Linear mixed-model analyses were performed to test for significant changes over time (e.g., annually). Albeit a similar trend, a previous study by our group showed greater changes in AXL, visual acuity and refraction after implantation with rigid pIOLs in high myopes that warrants additional research in order to validate these changes in epidemiological studies.[16]

Five years after implantation the MRSE, and percentage of eyes within 0.5D and 1.0D of target refraction were similar to previous studies with a follow-up of 6 months to 6 years.[4-7, 9, 10, 17-20] Vector analyses indicated a significant change in refractive cylinder from 1 to 5 years postoperatively, but the mean values after 5 years showed excellent results. The mean difference vector was 0.34 D at 8° (0.00 D being the preferred result) and the mean correction index was 1.03 (1.0 being the preferred result). The correction index results are similar to two previous studies using double angle polar plots to describe a significant reduction in refractive cylinder after 6 months and 1 year.[4, 8]

The logMAR CDVA, percentage of eyes with ≥20/40 and ≥20/20 vision, with ≥2 Snellen CDVA lines lost, and safety index 5 years after implantation were similar or superior to the results of previous studies with a maximum follow up of 6 years.[4-7, 9, 17-20]

Results similar or superior to studies with a follow-up of up to 6 years were reported regarding logMAR UDVA, percentage of eyes with ≥20/40 and ≥20/20 vision, and efficacy index, 5 years after implantation with the myopic (toric) pIOL.[4-7, 9, 17, 19, 20]

In line with previous studies describing an annual decrease in ACD of 0.011 to 0.018 mm, our study showed an annual decrease in ACD of 0.014 mm that can be attributed to the ageing lens resulting in increased lens thickness.[21-23] Ageing initially results in a hyperopic shift followed by a myopic shift when patients develop nuclear cataract. It is likely that the myopisation observed in this study is partly due to an advanced myopic shift, considering high myopia is both a reason for pIOL implantation and a risk for cataract formation at a younger age.[23-26] We divided patients in two age groups – 33 years or younger at implantation or older than 33 years at implantation – and assessed changes in SE, logMAR UDVA and logMAR CDVA in these groups (data on file). Results did not show significant differences between groups except for changes in logMAR CDVA over time. LogMAR CDVA changed significantly in the older age group by 0.004 per year ($p = .031$) as opposed to 0.002 per year ($p = .220$) in the younger group. It was not possible to conclude if this change was caused by cataract formation. Additional analyses were performed, following the results of a previous study by our group, to assess the possibility of annual AXL increase in an adult population with high myopia.[16] The results of the abovementioned study showed high rates of myopisation that could in part be attributed to changes in axial length. Two subsets of patients were analyzed to evaluate the hypothesis posed in the previous study. The first subset of patients included 20 eyes that had

received optical biometry AXL measurements prior to pIOL implantation, and prior to combined pIOL explantation and cataract surgery at a later date. The second subset was analyzed using a cross-sectional (ANOVA) analysis in order to evaluate the possibility of a correlation between age and AXL in 298 eyes measured using optical biometry prior to pIOL implantation. Both analyses showed a statistically significant increase in AXL that would result in an AXL increase of 0.23 mm and 0.08 mm over 5 years, respectively. These slight but statistically significant changes were much less than the previous report on rigid iris-fixated pIOLs and would require additional population based studies to evaluate the presence and significance of AXL changes in an adult population.[16]

Retinal detachment occurred in 4 eyes (0.8%) implanted with the myopic (toric) pIOL in the current study after a mean follow-up of 2.5 years. A previous posterior vitreous detachment was described after pIOL implantation and prior to retinal detachment in another two eyes. These eyes did not report vitreous detachment prior to retinal detachment. Previous studies on foldable iris-fixated myopic (toric) pIOLs did not report any cases of retinal detachments, whereas studies on rigid pIOLs showed RRD rates of 0.25% to 1.09% after a follow up of up to 10 years.[2, 4-7, 16, 17, 20, 27] Myopia of -3.0 D or stronger is well defined as a significant risk-factor for increased rates of RRD, a relevant criterion in the highly myopic population described in this study (ie, MRSE -9.89±2.79 D).[1, 28-30] Cataract surgery is a second known risk-factor for RRD, attributed to changes in volume of the vitreous as well as the inflammatory reaction after surgery. The results of this study are in line with the data of pseudophakic patients, but the position of the pIOL anterior to the crystalline lens does not create volumetric changes. [29, 30] In our opinion, the higher RRD rates are likely the result of the highly myopic configuration, and less likely attributed to inflammation or volumetric changes. Presence of a posterior vitreous detachment was assessed and reported when the patient reported relevant complaints. Therefore it was not possible to report reliable numbers on posterior vitreous detachments – indicating possible volumetric changes - prior and after pIOL implantation. No previous study reported the occurrence of other complications such as a macular hole, non arteritic anterior ischemic optic neuropathy (NA-AION), or additional laser refractive correction in patients with foldable pIOLs. Additional laser refractive correction (photorefractive keratotomy) was required in 9 eyes (3.1%) in the current study, comparable to data on rigid pIOLs in a previous report by our group.[16] This is the only study describing faulty packaging as a reason for iris-fixated pIOL exchange. Lens exchange was described in one paper where 0.34% of eyes required this procedure in order to obtain an optimal correction, results that were only mildly different to the rate of pIOL exchanges performed in the current study (4 eyes, 0.8%).[6]

When the foldable myopic pIOL was first introduced in a clinical trial in 2003, the optic-haptic junction and the vault between the junction and the iris-plane was shaped differently.[6] During the

clinical trial with the first pIOL model a higher incidence (4.8%) of iris pigment precipitates was reported, which was believed to be caused by compression of the iris between the pIOL and the crystalline lens. This was most likely caused by the lower vault between optic-haptic junction and iris in the initial model (0.13 mm), as compared to the rigid iris-fixated pIOL (0.20 mm). The optic-haptic junction was altered to create a higher (0.20 mm) vault between junction and iris that is similar between the rigid and foldable iris-fixated pIOLs.[6]

In the current study all results of the 27 eyes of the 14 patients implanted with the initial myopic model were combined with the 266 eyes of the 152 patients implanted with the second, improved, myopic model, because lens type (1 or 2) did not have a significant influence on any of the outcome measures described in the current paper (data on file).

Recommendation

The slight myopisation and decrease in visual acuity shown in this study are likely caused by a combination of nuclear cataract formation and slight AXL elongation over time. More extensive AXL elongation, as well as corresponding cases of myopic macular degeneration, were reported in a previous paper by our group.[16] Prior to implantation with a foldable iris-fixated pIOL, patients with (high) myopia should be informed by their refractive surgeon about the possible changes in refraction and visual acuity. Phakic IOLs should not be considered a permanent solution for refractive errors, and regularly be followed up to monitor safety and efficacy.

WHAT WAS KNOWN

- Foldable iris-fixated phakic intraocular lenses provide excellent visual and refractive results in highly myopic patients, as well as lower rates of surgically induced astigmatism.

WHAT THIS PAPER ADDS

- Phakic intraocular lenses should be considered a long-term correction for refractive errors, rather than a permanent solution.
- Annualized changes in refractive error, visual acuity and axial length in a large group of patients implanted with foldable iris-fixated phakic intraocular lenses.

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Figure legends

Figure 1. Results in Eyes 1 and 5 years after Implantation with an Iris-Fixated Foldable Myopic (Toric) Foldable Phakic Intraocular Lens, Showing; **A.** Target versus Achieved Manifest Refraction Spherical Equivalent (MRSE) Correction; **B.** Bar Graph Showing the Accuracy of the Manifest Refractive Spherical Equivalent (MRSE); **C.** Change in Manifest Refraction Spherical Equivalent (MRSE) postoperatively; **D.** Bar Graph Showing Refractive Astigmatism prior to Surgery and postoperatively; **E.** Bar Graph Showing the Refractive Astigmatism Angle of Error.
Diopters (D), Standard Deviation (±SD), Counterclockwise (CC/wise), clockwise (C/wise).

Figure 2. Single-Angle Polar Plots Representing Target Induced Astigmatism (TIA) Vector, Surgically Induced Astgimatism (SIA) Vector, Difference Vector and Correction Index, One Year after Implantation with Iris-Fixated Foldable Toric Phakic Intraocular Lens (116 eyes).
Diopters (D), standard deviation (SD), number of eyes (n).

Figure 3. Single-Angle Polar Plots Representing Target Induced Astigmatism (TIA) Vector, Surgically Induced Astgimatism (SIA) Vector, Difference Vector and Correction Index, Five Years after Implantation with Iris-Fixated Foldable Toric Phakic Intraocular Lens (63 eyes).
Diopters (D), standard deviation (SD), number of eyes (n).

Figure 4. Results in Eyes 1, and 5 Years after Implantation with an Iris-Fixated Foldable Myopic (Toric) Phakic Intraocular Lens, Showing; **A.** Change in Snellen Lines of Corrected Distance Visual Acuity (CDVA); **B.** Snellen Preoperative Corrected Distance Visual Acuity (CDVA) and Uncorrected Distance Visual Acuity (UDVA); **C.** Difference in Snellen Lines Between Postoperative Uncorrected Distance Visual Acuity (UDVA) and Preoperative Corrected Distance Visual Acuity (CDVA).

	Preop	1y Follow-Up	5y Follow-Up
Patient Characteristics			
Age, y			
Mean ± SD	39.8 ± 10.9	NR	NR
Range	17.9 to 63.4	NR	NR
Ratio male/female, %	36/64	NR	NR
Number of eyes	481	375	210
Predictability			
MRSE, D			
Mean ± SD	-8.98 ± 2.79	-0.19 ± 0.52	-0.35 ± 0.22
Range	-20.50 to -1.50	-4.75 to 1.38	-2.25 to 1.25
Refractive cylinder, D			
Mean ± SD	-2.32 ± 0.88	-0.57 ±0.46	-0.76 ± 0.52
Range	-5.25 to -1.00	-2.00 to 0.00	-2.50 to 0.00
Safety			
CDVA, logMAR			
Mean ± SD	0.003 ± 0.10	-0.06 ± 0.11	-0.05 ± 0.09
Range	-0.24 to 0.60	-0.20 to 0.70	-0.30 to 0.40
Safety index			
Mean ± SD	NA	1.20 ± 0.27	1.17 ± 0.24
Range	NA	0.17 to 2.67	0.40 to 2.40
Efficacy			
UDVA, logMAR			
Mean ± SD	NA	0.02 ± 0.14	0.05 ± 0.15
Range	NA	-0.20 to 1.30	-0.18 to 0.70
Efficacy index			
Mean ± SD	NA	1.02 ± 0.28	0.96 ± 0.28
Range	NA	0.04 to 2.67	0.20 to 2.00
IOP, mmHg			
Mean ± SD	15.4 ± 2.9	15.4 ± 3.2	15.9 ± 3.0
Range	8.0 to 24.0	8.0 to 28.0	10.0 to 23.0
ACD[#], mm			
Mean ± SD	3.25 ± 0.34	3.31 ± 0.34	2.98 ± 0.26
Range	2.68 to 4.47	2.79 to 4.47	2.32 to 3.67

Table 1. Preoperative Characteristics and Results One and Five Years after Implantation with the Foldable Iris-Fixated Myopic (Toric) Phakic Intraocular Lens (mean ± standard deviation [SD]).

Years (y), manifest refraction spherical equivalent (MRSE), diopters (D), logarithm of the minimum angle of resolution (logMAR), corrected distance visual acuity (CDVA), uncorrected distance visual acuity (UDVA), intraocular pressure (IOP), anterior chamber depth (ACD), axial length (AXL).

Not applicable (NA), not reported (NR)

[#]Measured from the corneal endothelium.

	No. eyes [patients]	Ratio, %	Time, months (range)
Complications			
Intraoperative iris hemorrhage	10 [10]	2.1	NA
Retinal detachment	4 [3]	0.8	29.9±36.3 (range 2.9 to 92.4)
Acute glaucoma	2 [1]	0.4	1 day and 27 days
Macular hole	1 [1]	0.2	55.9
NA-AION	1 [1]	0.2	7.1
Secondary Surgical Intervention			
Laser Refractive Correction			
PRK	15 [14]	3.1	13.3±14.4 (range 1.2 to 61.2)
pIOL Refixation			
Traumatic subluxation	1 [1]	0.2	24.6
Insufficient enclavation	2 [2]	0.4	71.5 and 141.4
Decentration	2 [2]	0.4	3.7 and 3.7
pIOL Exchange			
Undercorrected	1 [1]	0.2	9.4
Overcorrected	3 [3]	0.6	11.5±6.6 (range 2.3 to 17.4)
Incorrect labelling[a]	2 [1]	0.4	1.1 and 4.6
pIOL Explantation			
Cataract	19 [14]	4.0	59.0±40.0 (range 4.7 to 130.7)
EC-loss	9 [5]	1.9	85.6±25.7 (range 42.5 to 126.6)
High IOP	1 [1]	0.2	15.4
Excessive pigment on pIOL	1 [1]	0.2	6.4

Table 2. Overview of Sight Threatening Events, Secondary Surgical Interventions, Phakic Intraocular Lens Exchanges and Explantations in Eyes Implanted with a Foldable Iris-Fixated Myopic (Toric) Phakic Intraocular Lens (n = 481)(mean ± standard deviation [SD]).
Months (mo), non arteritic anterior ischemic optic neuropathy (NA-AION), photorefractive keratectomy (PRK), endothelial cell (EC) loss, intraocular pressure (IOP).
[a]Cylindrical axis was reported incorrectly on the packaging of the foldable toric pIOL. Modified quality control functions have been administered by the supplier, no further complications have occurred since.