



International Journal of Ophthalmology & Vision Research

Original Article

Postoperative Lens Rotation of a 7.0 Mm Optic IOL with Plate Haptics -

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Submitted: 24 September 2021; **Approved:** 06 December 2021; **Published:** 07 December 2021

Cite this article: Pilger D, Bertelmann E, Brockmann T, Duncker T, Duncker GI, Schrecker J. Postoperative Lens Rotation of a 7.0 Mm Optic IOL with Plate Haptics. Int J Ophthal Vision Res. 2021 Dec 07;5(1): 014-020.

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ABSTRACT

Aims: To assess rotational stability and visual performance of a hydrophilic acrylic intraocular lens (IOL) with 7.0 mm optic diameter and cut-out plate haptics.

Methods: In 93 cataractous eyes, an intraocular lens with a 7.0 mm optic was implanted. For assessment of rotational stability all IOLs had a pseudo toric axis marking (but no toric power). The baseline axis of the IOL was documented at the End of Surgery (EoS) with an intraoperative photo or video. The postoperative axis position was determined with digital retro illumination imaging at 1-week, 1-month and 4-months. The difference between baseline axis and the respective postoperative axis position was calculated and evaluated in the postoperative course.

Results: This prospective study enrolled 93 eyes of 65 patients. One week after surgery, median absolute IOL rotation was 1.40° (0.03 to 19.27) and decreased to 0.86° (0.0 to 3.24) between 1-week and 1-month and to 0.73° (0.0 to 11.4) between 1-month and 4-months. The median total IOL rotation between EoS versus 4-month (1.70°; 0.0 to 11.6) was significantly higher than between 1-week vs 4-month (1.02°; 0.06 to 9.77) ($p = 0.003$). Out of 79 images eligible for rotational evaluation from EoS to 4 months, 70 showed <5° rotation and 78 <10°.

Conclusion: This novel IOL with a 7.0 mm optic appears to be position-stable within the capsular bag. Postoperative rotation of the IOL is not clinically relevant in most of the cases and similar to other available modern lenses. Lens rotation most frequently occurs within the first days after surgery.

Keywords: 7.0 mm; Rotation; IOL; Aspira-aXA

INTRODUCTION

Corneal astigmatism of 1.5 diopters or more affects a significant percentage of cataract patients of about 15% to 20% [1-3]. Because of its high prevalence along with the growing patients' expectations, correction of pre-existing astigmatism has become an important aspect of cataract surgery. Although corneal and limbal relaxing incisions are still used, efficient and cost effective for treating low levels of astigmatism, their predictability and visual performance is considered to be lower than the implantation of Toric Intraocular Lenses (tIOLs) [4]. In recent years, the use of tIOLs has become increasingly popular leading to the launch of numerous new tIOL models. The efficacy of a tIOL to reduce astigmatism, however, depends on a stable position in the capsular bag [5]. A systematic review and meta-analysis evaluating the performance of modern tIOLs showed an overall good IOL stability with mean rotation usually smaller than 5.0 degrees [4]. Nonetheless, the authors highlighted that reporting the average of all subjects might not be sufficient as it might hide individual cases with higher degrees of rotation. Furthermore, the method to assess lens rotation may vary considerably between studies making data comparison across studies difficult.

The aim of this prospective study was to assess the rotational stability and visual performance of the Aspira-aXA, a single-piece hydrophilic acrylic IOL with a 7.0 mm optic diameter and plate haptics, and to compare rotational results with other studies. We used an objective technique to assess IOL rotation starting from the End of Surgery (EoS) over a period of 4-months. We deliberately chose the non-toric version of the lens to avoid secondary surgical procedures that are generally required to realign significantly rotated tIOLs.

MATERIAL AND METHODS

This prospective study included 93 eyes of 65 patients who were scheduled for cataract surgery in the Departments of Ophthalmology at the Charité-Medical University Berlin (25 eyes, 16 patients), Institut für Augenheilkunde Halle (30 eyes, 19 patients) and Rudolf-Virchow-Klinikum Glauchau in Germany (38 eyes, 30 patients).

The study adhered to the tenets of the Declaration of Helsinki and was approved by the local ethics committees. All patients provided

written informed consent before enrollment. Inclusion criteria were uni- or bilateral age-related cataract and expected dilated pupil size of at least 5.5 mm. Exclusion criteria were previous surgery of the eye, uncontrolled glaucoma and any other ophthalmic pathology that could have an impact on postoperative IOL stability or visual function.

The rotational stability investigation was performed with the Aspira-aXA IOL (HumanOptics AG, Erlangen, Germany). The lens is a non-toric, monofocal one-piece IOL made of hydrophilic acrylic with a 7.0 mm optic diameter, cut-out plate haptics with a four-point non-angulated haptic design, an overall IOL-diameter of 11.0 mm and a 360° sharp edge on the posterior surface. All IOLs were manufactured with toric pseudomarkings but no toric power. Refractive power ranged from 11.0 to 26.0 D.

SURGICAL TECHNIQUE

After topical anesthesia a 2.4 mm (Halle), 2.2 mm (Berlin) or 2.0 mm (Glauchau) posterolimbic self-sealing incision was performed. The anterior chamber was filled with a dispersive Ophthalmic Viscoelastic Device (OVD) and a continuous curvilinear capsulorhexis between 5.0 to 6.5 mm was created. After hydrodissection and phacoemulsification, the capsular bag was expanded with an OVD [Berlin: Healon (Johnson & Johnson, New Brunswick, NJ, USA), Halle: Medio-clear (Aivimed, Wiesbaden, Germany), Glauchau: Methylvisc (Rayner, Worthing, West Sussex, UK)] and the IOLs implanted with an injector (HumanOptics Safeloader system with either Accuject 2.0 or 2.2, Mediceal, Switzerland). After IOL placement, the OVD was thoroughly removed from the capsular bag and the anterior chamber. All IOLs showed a symmetrical 360-degree rhexis-IOL overlap at the end of surgery.

PREOPERATIVE AND POSTOPERATIVE EXAMINATIONS

Preoperatively, all patients had a full ophthalmic examination. The Axial Length (AL), Anterior Chamber Depth (ACD) and keratometry measurements were performed with the IOL Master 500 device (Carl Zeiss Meditec AG, Oberkochen, Germany). Monocular manifest refraction and Corrected Distance Visual Acuity (CDVA)

were measured using the standard ETDRS chart (Precision Vision, Woodstock, IL, USA).

Postoperatively, patients were examined 1-week, 1-month and 4-months after surgery. Measurements included funduscopy, tonometry, Scheimpflug tomography, keratometry and Uncorrected and Corrected Distance Visual Acuity (UDVA and CDVA).

POSTOPERATIVE ASSESSMENT OF IOL ROTATION

At the End of Surgery (EoS), a short HD video or an image was recorded via the operating microscope with the patient looking directly into the coaxial light. From the video sequences, a screenshot (which is principally a retro illumination image) with good image quality was selected, which allowed clear identification of the scleral vessels. To assess the rotation of the IOL, further images were taken 1-week, 1-month and 4-months post-surgery using a high-resolution digital retro illumination imaging system. Only good quality images were used for evaluation and within the series of images of one eye at least two images (EoS and at least one follow-up) had to be eligible for evaluation. Rotational stability analysis was performed with Adobe Photoshop CS5 (Adobe Inc., San José, USA). To avoid bias from cyclorotation of the eye or from a tilted head position, we used a modified version of the image analysis technique described by Wolffsohn and Buckhurst [6]. The IOL axis was determined by connecting the two toric pseudomarkings. A reference axis was drawn through two distinctive points of limbal or scleral vessels. For each image, the angle between these two axes was calculated (Figure 1) and compared with chronologically adjacent images (EoS vs 1-week vs 1-month vs 4-months).

STATISTICAL ANALYSIS

Statistical analysis was performed with Analyse-it® software, version 5.65.7 (Analyse-it Software, Ltd., Leeds, UK). Data are presented as mean \pm Standard Deviation (SD), median and range. The non-parametric Wilcoxon test was used to compare IOL rotation over time. The Spearman correlation test was used to analyze potential correlations between IOL rotation and AL, ACD and IOL power. A p-value of 0.05 or less was considered significant.

RESULTS

In total 93 eyes of 65 patients underwent unilateral or bilateral IOL implantation. There were no intra- or postoperative complications. Sixty patients (87 eyes) attended all study visits. Two patients (2 eyes) were not available at the 1-week follow-up. One patient (1 eye) did not attend the 1-month follow-up. For 2 patients (3 eyes) data of the 4-months visit are missing. Preoperative demographic data are displayed in (Table 1).

VISUAL PERFORMANCE

Visual Acuity (VA) improved significantly from preoperative to 1-week postoperatively. Between 1-month and 4-months (Table 2) VA improved further significantly regarding UDVA but not in terms of CDVA. Four months postoperatively 100% of eyes achieved corrected visual acuity better than 20/40 including 60% achieving 20/20 or better. Four months postoperatively, mean deviation from target refraction was 0.08 ± 0.40 D. There was no significant difference between target refraction and achieved spherical equivalent after 1-month or 4-months ($p = 0.262$), (Figure 2). After 4-months, 84% of

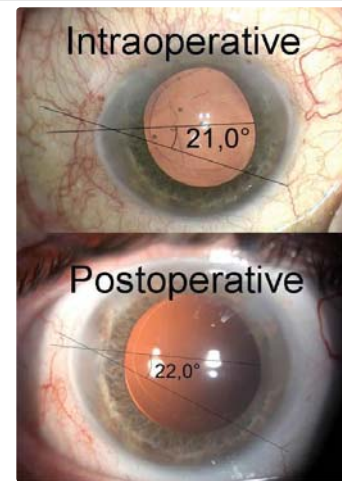


Figure 1: Intraoperative and postoperative image showing the angle between IOL axis and reference axis..

Table 1: Preoperative patient demographics; values are expressed as mean \pm SD and median (range).

Parameter	Mean \pm SD	Median (range)
Age (y)	69.4 \pm 9.10	71.00 (35 to 84)
Gender, n (%) f/m	41 (63%) / 24 (37%)	
AL (mm)	23.50 \pm 0.85	23.46 (21.94 to 26.34)
ACD (mm)	3.14 \pm 0.43	3.09 (2.33 to 4.27)
CDVA (logMAR)	0.30 \pm 0.23	0.22 (0.00 to 1.30)
SE (D)	-0.74 \pm 2.76	-0.44 (-9.13 to 4.13)
Target refraction (D)	-0.15 \pm 0.19	-0.17 (-0.51 to 0.34)
IOL power (D)	22.02 \pm 2.47	22.50 (11.00 to 26.00)
IOP (mmHg)	15.43 \pm 2.94	15.00 (8.70 to 24.00)

AL = Axial Length; ACD = Anterior Chamber Depth; SE = Spherical Equivalent; CDVA = Corrected Distance Visual Acuity; IOP = Intraocular Pressure; SD = Standard Deviation

Table 2: Postoperative monocular visual acuity ($n = 88$ eyes).

Variable	1-month	4-months	p-value
UDVA (logMAR)			
Mean \pm SD	0.03 \pm 0.12	0.01 \pm 0.11	
Median (range)	0.00 (-0.20 to 0.40)	0.00 (-0.20 to 0.52)	0.047
CDVA (logMAR)			
Mean \pm SD	-0.04 \pm 0.10	-0.05 \pm 0.08	
Median (range)	0.00 (-0.20 to 0.30)	0.00 (-0.20 to 0.22)	0.258

UDVA = Uncorrected Distance Visual Acuity; CDVA = Corrected Distance Visual Acuity, SD = Standard Deviation

the eyes achieved a spherical equivalent within ± 0.50 D, 97% within ± 1.00 D and 100% within ± 1.25 D of the target refraction.

ROTATIONAL STABILITY

The number of exploitable images varied throughout the follow-



up visits due to partially insufficient mydriasis, non-visibility of peripheral IOL details and/or the scleral/limbal vessels. Nevertheless, in total the images of 91 eyes (63 patients) could be used for the evaluation of rotational stability. The primary axis of implantation was vertically oriented (~ 90°) in 14 eyes and horizontally (~ 0°) in 77 eyes.

(Table 3) shows the absolute IOL rotation over time based on the available data for each of the time points (number of eyes with exploitable images for the respective postoperative visit). One week after surgery, median absolute IOL rotation from EoS was 1.40°. Median rotation was 0.86° between week 1 and 1-month after surgery, and 0.74° between 1-month and 4-months. There were 70 (89%) IOLs showing a rotation ≤5° including 27 (34%) ≤1.0° from EoS to 4-months.

Regarding direction of rotation, only IOLs with rotation >1° were included in the analysis. From 52 IOLs, 17 (33%) had rotated clockwise and 35 (67%) counterclockwise (p = 0.013) after 4-months.

For 5 eyes a rotation of more than 10° was documented. In each case, the rotation occurred in the early postoperative period from EoS to 1-week. These 5 eyes had an AL within 22.28 to 24.43 mm and their IOL powers were 20.5 D to 24.5 D. Planned implantation axis of these cases was at 0° and the OVD used in these cases were all dispersive.

There was no statistically significant correlation between AL, ACD or IOL power and the degree of postoperative IOL rotation. Study center i.e. surgeon was also not statistically significantly correlated to postoperative IOL rotation.

DISCUSSION

In recent years, there has been a growing body of literature reporting on rotational stability of the latest generation tIOLs, with overall good outcomes. A lack of standardization in methods for reporting and evaluating IOL rotation results, however, makes comparison between these studies challenging. For instance, some studies evaluate IOL rotation by measuring the postoperative axis deviation from the intended axis [7]. Since the intraoperative positioning may be inaccurate, the difference between planned and achieved axis is most relevant for reliable outcomes. Furthermore, many studies determine the IOL axis during slitlamp examinations or via retro illumination pictures without compensating for axis alteration, due to either head tilt and/or ocular cyclorotation which can be as high as 11.5° [8]. In our study, we took the aforementioned factors into account to reduce this potential bias as much as possible and analyzed the differences in IOL axis position between baseline (EoS) and adjacent postoperative visits.

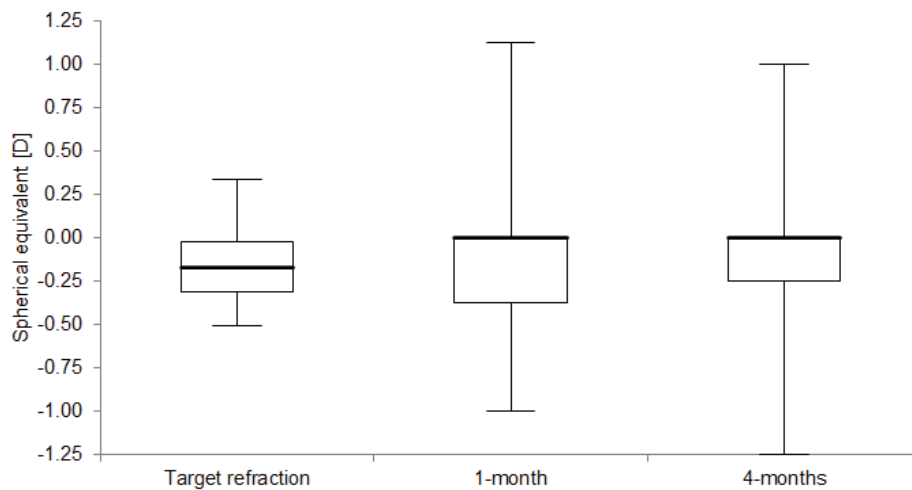


Figure 2: Boxplots showing target refraction and achieved spherical equivalent at all follow-ups (n = 88).

Table 3: Absolute IOL rotation over time.

Postoperative time	Absolute IOL rotation (°) Median (range) Mean ± SD	IOL rotation (%)		clockwise/counter-clockwise (>1°)	
		≤ 5°	> 10°	Distribution	p-value*
EoS to 1-week (n=81)	1.40 [0.03; 13.40] 2.37 ± 2.89	91% (n = 74)	6% (n = 5)	19/33	0.070
1-week to 1-month (n=67)	0.86 [0.00; 5.90] 1.32 ± 1.36	97% (n = 65)	-	18/14	0.597
1-month to 4-months (n=67)	0.73 [0.00; 11.40] 1.46 ± 2.02	96% (n = 64)	1% (n = 1)	9/15	0.308
EoS to 4-months (n=79)	1.70 [0.00; 11.60] 2.26 ± 2.24	89% (n = 70)	1% (n = 1)	17/35	0.018

IOL = Intraocular Lens; EoS = End of Surgery; * Binomial test was used to check for significant differences in direction of rotation.



Very few studies have evaluated IOL rotation with an objective technique and using EoS IOL position as baseline (Table 4). Nonetheless, our results are consistent with those of others in showing that significant lens rotation occurs in the very early postoperative period. Kasthurirangan et al. reported 5 cases (3%) of substantial rotation of the Tecnis tIOL 1-day after surgery, ranging from 18° to 45° [9]. After IOL repositioning within 1-month postoperatively, the lenses showed then good stability ≤ 5° of rotation at the 6-months-visit. A study by Garzón et al. showed likewise rotations up to 22° which occurred within the first hour after surgery and remained stable afterwards (tIOLs investigated: AcrySof IQ, enVista, Lentis, ReSTOR) [10]. None of these lenses were repositioned, thus absolute rotation of more than 10° (EoS vs 1-month) was reported in 21.4% of eyes with the AcrySof, 9.5% with the enVista, 14.28% with the Lentis and 17.8% with the ReSTOR. Similarly, we found that all rotations of more than 10° (n = 5) occurred within the first week after surgery. The phenomenon of essential rotation within the early postoperative course might be a consequence of poor friction between the haptic and the capsular bag, possibly due to an incomplete ophthalmic viscoelastic clearance [11]. Another cause might be the different sizes between the capsular bag and IOL diameters, although rotation occurred with all IOL designs and IOL-diameters ranging from 11.0 to 13.0 mm.

Additional risk factors associated with early IOL rotation have been described in the literature, including capsulorhexis size [24], “With The Rule” (WTR) astigmatism [25], IOL design and material [26], axial length superior to 24.0 mm [27, 28] or 25.0 mm [25] and capsular bag shape [28]. Miyake et al. [25] reported rotation of more than 20° within 10 days postoperatively in 6 eyes implanted with the AcrySof IQ toric SN6AT IOL. However, in all cases the eyes had WTR astigmatism, an AL exceeding 25.0 mm and an incomplete coverage of the IOL with the anterior capsule was found in 3 of the 6 eyes [24]. All in all, it is very likely that varying combinations of the above-mentioned factors may account for the early IOL rotation in individual cases. In this study, different OVDs were used in the

capsular bag which could have had an influence on the outcomes since in all cases when IOL rotation superior to 10° was observed, dispersive OVD was used [11].

In the current study, we paid particular attention to the removal of the ophthalmic viscoelastic at the end of surgery and a centered capsulorhexis with a maximum diameter of 6.5 mm to cover the rim of the 7.0 mm-optic circularly. We found no correlation between the extent of IOL rotation and the primary placement of the axis (horizontal vs. vertical) but observed that none of the IOLs implanted vertically (~ 90°) had a rotation of more than 10°. In this study, we did not randomly assign the IOLs to their primary axis positioning which could have given insight on whether primary positioning influences rotation. Anatomical factors as well as gravity might have an impact on IOL rotation, as reported with a plate haptic IOL [28]. Schartmüller et al found no evidence that primary axis had an influence on the amount of rotation though the authors found a greater balance in rotation orientation when IOLs with C-loop haptics were placed at 135° [15]. With our current data, we did not find a tendency to such a causal relationship.

When considering the mean rotation of the current IOL from EoS to 4-months (2.26° ± 2.24°, median: 1.70°, range: 0.00° to 11.60°) our results are in line with other tIOL models for which the baseline IOL position was EoS or 1-day postoperatively. In a study including 156 eyes, Waltz et al. found a mean rotation of 2.7° ± 5.5° for the Tecnis tIOL at the 6-months visit [23]. Marques et al. found a mean IOL rotation of 3.18° ± 3.28° for the Tecnis ZMT IOL (n = 60) [22]. In a comparative study, Draschl et al. reported a mean IOL rotation of 2.4° ± 1.85° for the Podaye (n=40) and 1.6° ± 1.61° for the hydrophilic Pod Ay 26P (n = 40) at the 3-months visit [29]. Schartmüller et al. compared three lenses for 6-months and found a mean IOL rotation of 1.65° ± 2.10° (Acrysof), 2.65° ± 4.10° (Tecnis) and 3.18° ± 5.80° (Envista) [15]. Most recently, Wendelstein et al. published rotational data on the Aspira-aXA [13]. Similar to our results, main rotation occurred in the early postoperative period, with only one eye exceeding 10° and

Table 4: Summarizes studies reporting IOL rotation published between 2015 and 2020 which used an IOL axis baseline documented at the end of surgery (EoS) and compared it with 3-months or 6-months postoperatively. Methods used to assess IOL axis were documentation via Retro Illumination Photography (RP). Rotation data is reported as relative frequencies (≤ 5°, ≤ 10°, > 10°). Data is reported in the form of degrees either in mean ± standard deviation or in median [minimum; maximum].

Year	First Author	IOL	Eyes	Baseline		Follow up to		Rotation in degrees			Percentages if data were ≥ 3 months		
								1-month	3/4 months	≥ 6-months	≤ 5°	≤ 10°	> 10°
2021	Schrecker [12]	Aspira-aXA	55	EoS	RP	1.5-y	RP	1.8 [0-13.4]		1.4 [0-10.9]	92	96	4
2021	Wendelstein [13]	Aspira-aXA	74	EoS	RP	4-mo	RP		2.34 ± 2.39		85	98	2
2021	Schartmüller [5]	Rayner RAO800C	122	EoS	RP	4-mo	RP		5.53 ± 10.46		76	89	11
2020	Sandoval [14]	Tecnis Symphony Toric	103	1-d	RP	3-mo	RP	-1.20 ± 2.10	-1.09 ± 1.70		97		3
2020	Schartmüller [15]	Acrysof SN60WF	104	EoS	RP	6-mo	RP			1.65 ± 2.10	95	98	2
		Tecnis ZCB00	106	EoS	RP	6-mo	RP			2.65 ± 4.10	93	96	4
		Envista MX60	101	EoS	RP	6-mo	RP			3.18 ± 5.80	86	94	6
2020	Zhu [16]	AcrySof Toric	31	EoS	RP	3-mo	SL		8.00 ± 3.60		36	74	26
		AT Torbi 709M	31	EoS	RP	3-mo	SL		4.42 ± 3.24		58	90	10
2020	He [17]	Tecnis toric	64	EoS	RP	3-mo	SL	7.42 ± 11.32	7.48 ± 11.90		55	88	12
2019	Savini [18]	Mini Toric Ready	63	1-d	RP	6-mo	RP			1.6 ± 3.1		92	8
2019	Schartmüller [19]	Vivonex XY1	103	EoS	RP	6-mo	RP			1.5 ± 1.2	100		
2018	Gundersen [20]	Tecnis Simfony	52	EoS	RP	3-mo	RP		2.0 [0-16]		87	96	4
2016	Gyöngyössi [21]	Torica-aA	34	1-d	RP	6-mo	RP			1.99 ± 1.88	94	100	
2016	Marques [22]	Tecnis ZMT	60	EoS	RP	6-mo	RP			3.18 ± 3.28		100	
2015	Waltz [23]	Tecnis ZCB00	156	1-d	RP	6-mo	RP			2.7 ± 5.5	94	97	3

the majority having a rotation less than 5°. Our rotational values from EoS to 4 months are similar to their findings with $2.18^\circ \pm 2.23^\circ$ in a cohort of 52 eyes.

The positive results of the study IOL may result from several design aspects of the new lens. The large optic size goes along with an increased center thickness, which might prevent from optic deformation [13]. Additionally, plate haptic lenses were shown to be more rotationally stable [16] and this lens has a four-point non-angulated plate haptic design which provides a greater area of contact between IOL and capsular bag.

The major limitations of the present study are the loss of rotation data. Furthermore, where patients were bilaterally implanted with the lens, we included both eyes in the evaluation, which might have caused bias, although by including only one eye per individual in the analysis would have led to a potential “waste” of information. It would also have been interesting to include an additional documentation of the IOL axis within the first postoperative hours. However, this was not possible in some of the study centers.

In terms of distance visual acuity, excellent results (comparable to all modern IOL) were achieved with the study IOL. Mean CDVA after one month was -0.04 ± 0.10 and there were no significant changes over the follow-up period. No significant differences were found between target refraction and postoperative spherical equivalent. After 4 months there were 84% of eyes within ± 0.5 D and 97% within ± 1.0 D.

The data of the present article confirm those of Wendelstein et al [13] showing good rotational stability of the Aspira-aXA in the capsular bag 4-month after surgery. The authors used the same method as ours for the assessment of IOL rotation, but the time-point EoS-1 day was additionally analysed. They found a median absolute IOL rotation of 1.42° ($n=52$; $\text{mean}=2.18 \pm 2.23^\circ$) within 1 day after surgery which was significantly higher compared to all later intervals (median $< 1.0^\circ$; $p=0.001$). At the 4 months follow-up, IOL rotation was within 5.0° in 85% of the eyes ($n = 40$) and within 10.0° in 98% ($n = 46$) of the eyes. The only eye with an IOL rotation of ≥ 10.0 degrees (EoS vs. 1 day) had an axial length of 26.45 mm. Nonetheless, the authors pointed out that since the IOL in the contralateral eye rotated only by 2.57° for the same time-point, myopia could be excluded as a favorizing factor for the rotation. Furthermore, they did not find any correlation between axial length and absolute IOL rotation.

Very few studies have investigated long-term stability of IOLs since usually they do not rotate significantly beyond 3-month postoperatively when the shrinkage of the capsular bag is completed. In a very recent article by Schrecker et al [12] which includes the same patients as in the current study (Glauchau center) but over a 1.5-year follow-up period, results confirm the long-term stability of the lens with no significant changes in IOL rotation between the first postoperative week and last visit.

In summary, the examined Aspira-aXA IOL provides excellent visual performance with high rotational stability. This offers best preconditions for future applications as a toric model and of course within the scope of diagnostic and therapy of retinal pathologies on the basis of their 7-mm-optic.

ACKNOWLEDGEMENTS

Daniel Pilger is a participant in the BIH-Charité Clinician

Scientist Program funded by the Charité-Universitätsmedizin Berlin and the Berlin Institute of Health. This study was supported by HumanOptics.

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