True rotational stability of a single-piece hydrophobic intraocular lens

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ABSTRACT

Background To evaluate rotation and its influencing factors of an aspheric one-piece hydrophobic acrylic intraocular lens (IOL) Vivinex XY1 during 6 months after operation.

Methods In this institutional trial, 122 eyes of 66 patients were implanted with a non-toric aspheric IOL Vivinex XY1 (Hoya Corporation, Tokyo, Japan). IOL alignment was assessed at the end of surgery, 1 hour, 1 week, 1 month and 6 months after implantation. Confounding factors such as axial length, presence of anterior fibrosis and randomised implantation in four different intended axes (0°, 45°, 90°, 135°) were evaluated. Decentration and tilt were measured using a Purkinje metre.

Results Assessment of rotational stability was possible for 103 of 122 implanted IOLs 6 months after eye surgery. The median absolute rotation was 1.1° (range: 0°–5°). Rotation was significantly increased within the first hour after operation compared with later time-points ($p<0.001$). No correlation was found with axial length and rotation (Spearman's $r=0.048$, $p=0.63$). No significant difference was observed regarding different implantation axes ($p=0.75$). Rotation was not influenced by the presence of anterior fibrosis ($p=0.98$).

Conclusion Assessing the true IOL position at the end of surgery is crucial for the evaluation of rotational stability of IOLs. No IOL rotation exceeding 5° could be detected 6 months after surgery.

INTRODUCTION

As modern cataract surgery evolves to minimum-trauma, instant-vision microsurgery, patients' demand for spectacle independence increases. Standard intraocular lenses (IOLs) only correct the spherical portion of the total refractive error and do not correct corneal astigmatism. High corneal astigmatism may cause visually disabling refractive error. Fifteen per cent of patients with cataract have 1.5 dioptres (dpt) or more of corneal astigmatism.[1] Toric IOL (TIOL) correction has been demonstrated to be efficient for a corneal astigmatism of at least 2 dpt and greater.[2]

Exact on-axis positioning of TIOLs is essential for a satisfactory refractive outcome. Efficient and safe use of TIOLs requires not only exact determination of the amount and axis of corneal astigmatism to be corrected and precise primary axis alignment, but also rotational stability of the TIOL. The greater the corrective power, the more important correct alignment and rotational stability are.

To be able to evaluate the TIOLs' rotational stability, it is crucial to start measuring the postoperative IOL axis immediately after implantation. Most of the pertinent studies published did not measure early rotation immediately after IOL implantation. Furthermore, reliable landmarks have to be used for exact and reproducible determination of the IOL axis during the follow-up.

The aim of our study was to investigate the rotational stability of a single-piece hydrophobic acrylic IOL from immediately after implantation to 6 months after surgery.

MATERIALS AND METHODS

One hundred and twenty-two eyes of 66 patients were included in this prospective single-centre trial. Table 1 summarises the preoperative patients' characteristics.

Inclusion criteria were monolateral or bilateral age-related cataract, pupil diameter >6.5 mm in mydriatic conditions, a need for a spherical IOL within 15.00 and 30.00 dpt, and age between 40 and 90 years. Exclusion criteria were previous ocular trauma, corneal abnormalities, pseudoexfoliation syndrome, uncontrolled glaucoma, a history of uveitis, uncontrolled systemic or ocular disease, pregnancy and lactation.

The IOLMaster 700 (Carl Zeiss Meditec AG, Jena, Germany) was used to assess preoperative biometry. The intended axis for lens implantation was randomised into four subgroups: 0°±10°, 45°±10°, 90°±10° and 135°±10°. A randomisation list was generated with the DataInf Randlist V.2.0 software (DataInf, Tuebingen, Germany) before trial start. Sealed envelopes were stored in the operating room. The surgeon was masked to the randomisation until the IOL was unpacked and implanted into a given axis.

The IOL

The Vivinex XY1 IOL (Hoya Corporation, Tokyo, Japan) is a preloaded, one-piece hydrophobic acrylic IOL with a blue light filter, biconvex aspheric optic with a diameter of 6.0 mm and an overall diameter of 13 mm. The haptics are in C-loop configuration. The non-toric version of the IOL was deliberately chosen to exclude possible secondary interventions because of potential misalignment resulting from secondary rotation.

Surgical technique

All eyes were operated by two experienced surgeons (RM, CL) at the Department of Ophthalmology

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Table 1 Patients' characteristics

Parameter	Values
Age (years)	71.21±9.15 (47–90)
Gender (male/female)	29/37 (n=66)
Axial eye length (mm)	23.46±0.92 (21.32–26.11)
Anterior chamber depth (mm)	3.07±0.48 (1.99–3.94)
White-to-white corneal diameter (mm)	11.94±0.40 (10.90–13.00)
Intraocular lens power (dioptre)	21.33±2.26 (15.50–26.50)

Patient characteristics preoperative presented as mean±SD (range).

at the General Hospital Vienna. After a 2.2 mm posterolimbal incision, the anterior chamber was filled up with a dispersive ophthalmic viscoelastic device (OVD, methylcellulose) (Eyefill HD, Bausch & Lomb, Rochester, USA). A continuous curvilinear capsulorrhexis with a diameter of approximately 5 mm was performed. After hydrodissection, standard phacoemulsification and cortical clean-up, the capsular bag was filled with a cohesive OVD (Provisc, Alcon, Hünenberg, Switzerland), and the IOL was implanted with the optic–haptic junction at one of the four randomised axis depending on the randomisation. OVD residue was carefully aspirated and replaced by balanced salt solution. After the last incision was hydrated, a high-resolution video was taken while the patient was still lying on the operating table to document the IOL position at the end of surgery. During video capture the surgeon moved the conjunctiva with a small swab to differentiate between movable conjunctival and non-movable episcleral vessels or Axenfeld loops. These episcleral vessels or Axenfeld loops were used as typical landmarks for the reference axis.

Follow-up

Follow-up visits were 1 hour, 1 week, 1 month and 6 months after surgery. Retroillumination pictures were taken with a digital colour camera (Kodak DCS720x) at each visit to detect the IOL axis. Additional examinations during the follow-up visits included best-corrected visual acuity (BCVA) with ETDRS charts and ETDRS contrast visual acuity. The aqueous depth (AQD) was evaluated by Visante optical coherence tomography (Carl Zeiss Meditec AG) or the IOLMaster 700 (Carl Zeiss Meditec AG) at the 1-month follow-up visit. It was measured from the corneal endothelium to the anterior surface of the IOL. Lens decentration and tilt were measured using a Purkinje metre (Professor Schaeffel, Tuebingen, Germany) 6 months after surgery. For lens decentration the pupil centre and for lens tilt measurements the fixation axis were used as references.

Assessment of IOL rotation

IOL position was assessed at the end of surgery, 1 hour, 1 week, 1 month and 6 months after surgery. A study group member evaluated the video recorded directly at the end of the operation within the first hour after the operation. A screenshot of the video was taken and non-moving episcleral vessels or Axenfeld loops were marked with Photoshop CS4 V.11.0 (Adobe, San Jose, USA). The IOL axis was measured using the ruler tool for Photoshop. The same principle was followed for measurement during the follow-up visits by marking the identical landmarks.

Two axes were drawn, one between the haptic–optic angles of the lens to assign the IOL axis and one between two typical landmarks. The angle between these two lines was then measured (figure 1). Episcleral landmarks were detected in our pictures to measure IOL rotation independent from head movement or cyclorotation.

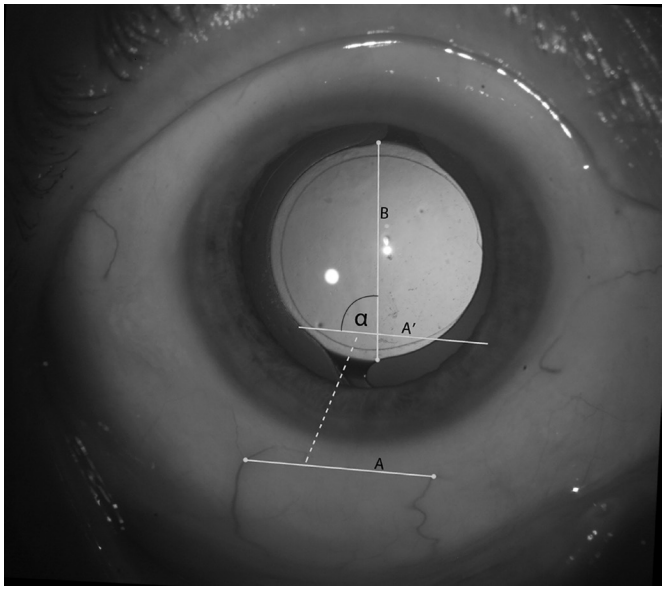

Figure 1 Reference axis A, drafted between two typical landmarks. For example, Axenfeld loops, edges or bifurcations of episcleral vessels are being chosen, which are consistent and non-moving through the entire follow-up. Axis A' is a translation of reference axis A and is shifted until it crosses IOL axis B. IOL axis B is drafted between the two axillar optic–haptic junctions. Alpha identifies the angle between axis A' and IOL axis B. IOL rotation is defined by the difference in angle alpha during follow-up. IOL, intraocular lens.

Statistical analysis

Statistical analysis was performed using SPSS V.23.0.0.3. Descriptive statistics are presented as mean±SD or as median (range). Continuous values between multiple groups were compared using the one-way analysis of variance (ANOVA) followed by the least significant difference (LSD) test. The binomial test was used to compare counter-clockwise and clockwise rotated IOLs. To account for possible measurement noise, we excluded all IOLs with rotation <1.0° from binomial analysis. To correlate between specific patient characteristics and IOL rotation, Spearman's correlation coefficient was used. A p value of less than 0.05 was considered statistically significant in all tests.

RESULTS

Rotational stability

Of the 122 eyes included in the study, overall IOL rotation measurement was possible in 103 (84%). Mydriatic conditions were insufficient to detect the optic–haptic junction and therefore the IOL axis B in five eyes. Seven patients (14 eyes) did not show up at the 6-month follow-up visit for reasons unknown. Bilateral surgery was performed in 45 patients. To show that the IOL rotation of both eyes was intraindividually independent, we calculated the intraclass correlation coefficient (ICC) between both eyes in the same patient, showing no correlation between both eyes of the same patient (ICC=0).

Within the 6 months of follow-up, no IOL rotated more than 5° from its initial axis. The mean rotation of 103 lenses after 6 months was 1.5°±1.2° (range: 0°–5.0°). Table 2 shows detailed rotation data through all time-steps.

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Table 2 Detailed rotation data and distribution of clockwise versus counter-clockwise rotation

	Absolute IOL rotation in degree			Absolute number of IOLs rotating clockwise:counter-clockwise (>1.0°)	
Observation period	Median (range)	Mean±SD	≤5° (%)	Distribution	P value
End of surgery to 1 hour	1.3 (0–3.9)	1.5±0.96	100	30:38	0.396
1 hour–1 week	1.0 (0–4.5)	1.2±0.9	100	35:20	0.058
1 week–1 month	0.9 (0–4.4)	1.1±0.8	100	34:17	0.024*
1 month–6 months	1.0 (0–4.3)	1.1±0.8	100	36:15	0.005*
End of surgery to 6 months (n=103)	1.2 (0–5.0)	1.5±1.2	100	46:14	<0.001*

Rotational data within different time-steps. Binomial test was used to identify significant differences in direction of rotation. A statistically significant difference was observed for the full observational period from end of surgery to 6 months, from 1 week to 1 month and from 1 month to 6 months. IOLs with rotation under 1.0 degree were not reported in this table.
*Statistically significant.
IOL, intraocular lens.

IOL rotation within the first hour after surgery was significantly higher compared with all other time-points (figure 2) (p<0.001; one-way ANOVA followed by the LSD test).

After 6 months 42 (41%) IOLs showed <1.0° rotation, 46 (45%) IOLs rotated clockwise and 14 (14%) counter-clockwise (p<0.001; binomial test).

There was no significant difference in rotation among the four subgroups of 0°±10° (n=26), 45°±10° (n=25), 90°±10° (n=28) and 135°±10° (n=23) (p=0.75; one-way ANOVA). There was no correlation between axial length of the eye and rotation of the IOL after 6 months (Spearman's r=0.048, p=0.63) (figure 3). No correlation was found between white-to-white corneal diameter and rotation after 6 months (Spearman's r=−0.081, p=0.41).

Visual outcome

The mean postoperative BCVA at 6 months was −0.01±0.08 logarithm of the minimum angle of resolution (logMAR) and 0.34±0.14 logMAR for contrast vision.

Capsular bag performance

Assessment of the AQD was possible for 82 IOLs (76%). The mean postoperative depth was 4.17±0.42 mm. The absolute median decentration was 0.17 (0.0–0.78) mm horizontal and 0.15 (0.0–0.64) mm vertical with respect to the dilated pupil centre. Absolute median tilt was 4.73° (0.9°–13.3°) horizontal and 2.93° (0.0°–13.5°) vertical.

The presence of anterior fibrosis was graded into four levels ranging from 0 for no fibrosis to 3 (+++) for severe fibrosis. After 6 months, 6 IOLs showed no fibrosis (6%), 70 IOLs slight (+) fibrosis (65%), 22 IOLs moderate (++) fibrosis (21%) and 9 IOLs heavy (+++) fibrosis (8%). There was no significant difference in rotation within the strength of anterior fibrosis (p=0.98; one-way ANOVA).

DISCUSSION

The key components of successful astigmatism correction by IOL implantation are precise measurement and calculation of the power and axis of corneal astigmatism together with correct

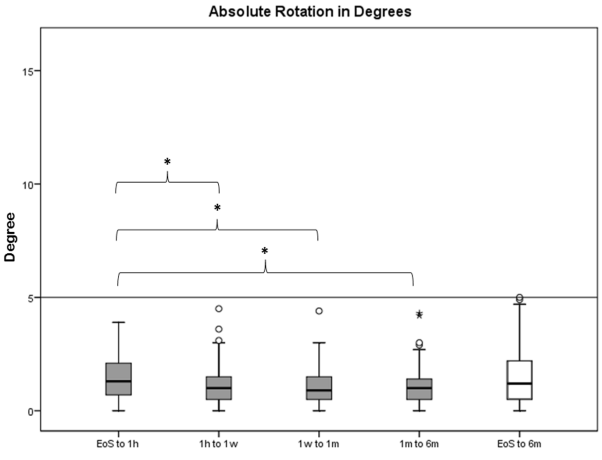

Figure 2 Absolute rotation in degrees from time-point to time-point. *Within the first hour, rotation was statistically significantly increased compared with all other time-points (p<0.001; one-way analysis of variance followed by least significant difference test). EOS, end of surgery; 1h, 1 hour; 1w, 1 week; 6 m, 6 months.

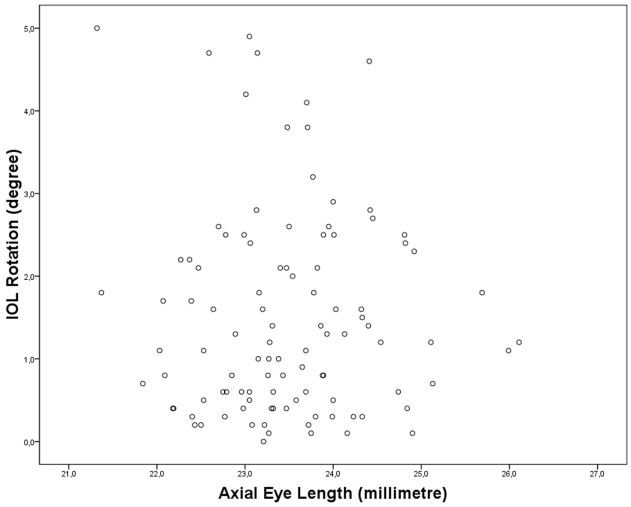

Figure 3 No correlation was found between the axial eye length and the absolute intraocular lens (IOL) rotation after 6 months (Spearman's r=0.048, p=0.63).

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primary alignment of the TIOL axis. However, rotational stability and centration are equally important. The corrective power of a TIOL decreases in a linear manner with its rotational offset. An axis shift will induce iatrogenic astigmatism and an axis change.[3 4] According to the TIOL standards of the American National Standards Institute, axis change must not exceed 5° in 90% of at least 100 IOLs on two consecutive visits 3 months apart.

Rotational stability of the IOL has to be investigated separately from the calculation and primary positioning of the implant. Studies have assessed rotational IOL stability, using different time-points for measuring the baseline and measurement methods. The time-point at which baseline has been measured ranges from after 1 hour, within 24 hours, after 1 or 2 weeks, to even after 3 months.[5–11] In some studies the intended axis was simply used as the baseline instead of the actual axis at which the IOL was positioned.[12 13]

The method used for measuring the IOL axis is crucial. Some studies have used the reticule of the slit-lamp or an eyepiece to measure the angle and evaluate the axis.[14–16] Others have captured retroillumination pictures or digital slit-lamp images and assessed the axis on a screen.[6 17] However, cyclorotation or inclined head position can cause a rotational error due to changing assessment conditions. A study by Viestenz *et al*[4] including 400 eyes found a cyclorotation of 2.3°±1.7° by taking consecutive fundus photographs at least 6 months apart and measuring the axis of two characteristic markers. The difference in angle after 6 months was supposed to be the autorotation angle. Another prospective study showed that head tilt caused an error up to 4.4° in the same eye when no correction was made for changes in head position. Rotation was measured by taking two retroillumination photographs on the same day or 2 days apart and comparing the IOL axis position. Head tilt was corrected by using characteristic iris or vessel markings, and the mean difference between the measurements was found to be 0.04°±0.29° with a maximum of 0.8°. The same photographs were used to evaluate the rotation without using characteristic markers. The mean difference between the two measurements was 0.07°±1.35° with a maximum of 4.4°. These findings show the importance of correcting for head tilt.[18] However, the iris structure or iris vessels are questionable reference markers when the pupil is dilated.

In our study we used the axis position at the very end of surgery as the primary baseline for possible axis change. We implanted non-TIOLs for faster patient recruitment. The angle of the connecting lines between two Axenfeld vessels on the sclera and between the haptic–optic junctions of the IOL was used for precise and reliable determination of the axis position. To allow for this, the pupillary diameter had to be at least 6.5 mm at the end of surgery and during the follow-up measurements. The dropout rate for insufficient mydriasis was 5%.

Our results demonstrate the relevance of baseline measurement timing. We found that IOL rotation, when observed, occurred statistically significantly more often during the first hour after surgery than in the period from 1 hour to 1 week, 1 week to 1 month and 1 month to 6 months. Therefore, it is highly important to define the baseline axis on the operating table directly at the end of surgery.

Studies on similar lenses have reported comparable median values of rotation.[5 9]

However, in contrast to those studies, none of our consecutive eyes rotated over the 5° level that could require a secondary repositioning intervention.

In another study including 93 IOLs (NY-60), similar in design to the IOL evaluated in our study, the mean absolute rotation between 1.93° and 2.32° has been shown. These results are comparable with ours. Nevertheless, three IOLs had to be repositioned because of excessive rotation.[19] A lower overall diameter of 12.5 mm of the NY-60 IOL could explain these findings since the overall diameter seems to influence early rotation. A hydrophobic acrylic lens with a 12.0 mm diameter was found to have rotated slightly more than a 13.0 mm diameter lens in a study of 60 eyes.[20] This is in accordance with the low rotation we observed in our study assessing true rotation of a 13.0 mm diameter IOL.

Similar studies have found a significant, although feebly, correlation between axial eye length and rotation.[7 11] These findings could be explained through the interaction between IOL diameter and a possibly larger capsular bag in long eyes.[11] Analysis of rotation in 13.5 mm diameter IOLs has found no association between axial eye length and rotation.[21 22] We did not find any correlation between axial length and rotation in spite of the fact that—other than the studies quoted—we took the position of the lens at the end of the surgery as the reference axis. A possible explanation is that the haptics of the Vivinex IOL are also frosted at the anterior and posterior surfaces.

An investigation of the influence of decentration and tilt on higher order aberrations in an eye model found that decentration of 0.5 mm or more statistically significantly influenced the optical quality of aspheric IOLs, while tilt only had a minor effect on higher order aberrations.[23] We measured both decentration and tilt with a Purkinje metre described previously.[24] The majority of IOLs in our study were centred within the 0.5 mm margin with respect to the centre of the pharmacologically dilated pupil. In both eyes IOLs were slightly decentred superotemporally. A previous study showed that the centre of the pharmacologically dilated pupil tends to shift inferonasally.[25] Taking this centroid shift of the dilated pupil into account, the IOL in our study may be centred even better in photopic conditions.

Anterior capsule fibrosis potentially influences rotational stability. IOLs have shown a better rotational stability in eyes with pronounced anterior fibrosis.[11] In our study, the percentage of IOLs with moderate or severe fibrosis was low and we observed no statistically significant difference in rotation associated with the degree of fibrosis. Regarding the direction of rotation, one would expect IOLs to only rotate clockwise, but 28% of our IOLs had rotated counter-clockwise after 6 months. When excluding those IOLs with an amount of under 1.0°, still 23% showed such counter-clockwise rotation.

In conclusion, we show that IOL rotation should be measured immediately from the end of surgery onwards with a reliable and precise method. On this premise, we found the Vivinex IOL to have good rotational stability with no rotation exceeding 5° detected.

Contributors Concept and design of the study: SS, CL and RM. Data acquisition: DS, SS, CL and LS. Data analysis/interpretation: DS, SS, LS, CL and RM. Drafting the manuscript: DS. Critical revision of manuscript: SS, LS, CL and RM. Statistical analysis: DS. Administrative, technical or material support: DS, SS, LS, CL and RM. Supervision: CL and RM. Final approval: DS, SS, LS, CL and RM.

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Patient consent Obtained.

Ethics approval This prospective study at the Department of Ophthalmology of the Medical University Vienna was approved by the local ethics committee (EK 1436/2014).

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