Comparison of Long-Term Rotational Stability of Three Commonly Implanted Intraocular Lenses

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• PURPOSE: To compare rotational stability and its influencing factors in 3 different widely used hydrophobic acrylic intraocular lenses (IOLs) from the end of surgery (EoS) to 4-7 months (6 months) in over 380 eyes.

• DESIGN: Prospective interventional comparative clinical study.

• METHODS: Setting: Department of Ophthalmology, Medical University of Vienna. Patient population: A total of 381 eyes of 199 patients with age-related cataract received an IOL Acrysof SN60WF, Tecnis ZCB00, or Envista MX60 in a consecutive order. Intervention: Implantation of an Acrysof, Tecnis, or Envista IOL randomized to the 0 ± 10, 45 ± 10, 90 ± 10, or 135 ± 10° axis in 1 or both eyes. Baseline measurement was performed with patients supine still on the operating table. Postoperative follow-ups were conducted after 1 hour, 1 week, 1 month, and 6 months. Main outcome measures: Difference of absolute rotation from the EoS to 6 months.

• RESULTS: Absolute rotations from the EoS to 6 months were 1.65 ± 2.1, 2.65 ± 4.1, and 3.18 ± 5.8° for the Acrysof, Tecnis, and Envista group, respectively. Rotational stability was statistically significantly superior in the Acrysof compared with the Envista group (P = .014), but not compared with the Tecnis group (P = .10). No significant difference was found between the Tecnis and Envista groups (P = .761). Maximum values of 15.8, 38.6, and 44.9° were observed for the Acrysof, Tecnis, and Envista group, respectively.

• CONCLUSION: The Acrysof IOL showed the least amount of absolute rotation compared with the Tecnis and Envista IOLs. Outliers possibly requiring secondary intervention were observed in all groups. The amount of rotation was greatest during the first postoperative hour. **(Am J Ophthalmol 2020;220:72–81.**

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ASSESSING THE ROTATIONAL STABILITY IS OF KEY importance for toric intraocular lenses (TIOLs). Decentration and tilt are 2 other aspects of capsular bag performance that are particularly important for aspheric and multifocal intraocular lenses (IOLs). In TIOLs, the refractive error, depending on the power of the torus, is known to increase with the amount of axis misalignment. Consequently, rotational stability is the most important requirement for a TIOL. Early rotation has been found to be the main cause of postoperative TIOL misalignment.[1–3] A recent study of 1273 eyes that retrospectively compared the rotational stability of 2 of the most frequently used IOLs in the United States found early rotation in both IOLs, but delayed or late postoperative rotation after the first postoperative day was not assessed.[4]

In the present study, we compared 3 widely used monofocal IOLs, Acrysof (Alcon, Fort Worth, Texas, USA), Tecnis (Johnson & Johnson Vision, Santa Ana, California, USA), and Envista (Bausch & Lomb, Rochester, New York, USA), with regard to rotational stability as well as decentration and tilt. We used IOLs with rotational symmetric optics to gain faster patient recruitment and exclude dropouts resulting from surgical repositioning in the case of major misalignment.

To the best of our knowledge, this is the first study that compares the long-term rotational stability of these 3 IOLs immediately after the conclusion of the surgery, with the patient still supine on the operation table for a mean follow-up of 6 months in over 380 eyes using sequential imaging examinations.

METHODS

THIS PROSPECTIVE TRIAL INVOLVED 381 EYES OF 199 PAtients (Clinical Trial Number: NCT04345380). Eyes were assigned in consecutive order to 3 groups to receive an Acrysof, Tecnis, or Envista IOL, respectively. All patients provided written informed consent before the study. The studies adhered to the tenets of the Declaration of Helsinki with the approval of the local ethics committee of the Medical University of Vienna (1746/2014). According to the standards for toric IOLs of the American National Standards Institute, at least 100 IOLs are necessary for a valid analysis of rotational stability. To meet these

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requirements, 121 eyes in the Acrysof group, 144 eyes in the Tecnis group, and 116 eyes in the Envista group were included to compensate for the dropouts. These included patients not showing up or failing to contact the patient via mail or phone and eyes with difficulties to identify episcleral or IOL landmarks on the retroillumination photographs because of ill-defined vessels or a small pupil.

Operations were performed between September 2015 and February 2017. The study was conducted at the Department of Ophthalmology and Optometry at the Medical University of Vienna. All operations were performed by 2 experienced surgeons (R.M., C.L.). Inclusion criteria were uni- or bilateral age-related cataract in patients at least 40 years of age and with a dilated pupil width of at least 6.5 mm. Exclusion criteria were corneal abnormalities, pseudoexfoliation syndrome, preceding ocular surgery or trauma, uncontrolled glaucoma, proliferative diabetic retinopathy, history of uveitis, blind fellow eye, uncontrolled systemic or ocular disease, pregnancy, lactation, and pupil width of less than 6.5 mm at follow-up visits.

The primary outcome measure was the absolute (amount of) rotation from the end of surgery (EoS) to the end point of 4-7 months (6 months). The secondary outcome measures were the difference in absolute rotation from the EoS to 1 hour, correlation between absolute rotation from the EoS to 6 months and axial length (AXL), white-to-white corneal diameter (WTW), lens power, and anterior fibrosis intensity as well as differences in long-term rotation within the subgroups' vertical, horizontal, or oblique implantation axis. In addition, decentration and tilt were determined at 6 months.

Three widely used IOL platforms were investigated. The nontoric version of all IOLs was chosen to exclude possible dropouts due to secondary interventions resulting from postoperative rotation. The nontoric and toric versions of the IOL platforms investigated are equivalent in design. The Acrysof SN60WF (Alcon) is a 1-piece monoplanar aspheric acrylic hydrophobic IOL with modified L-loop haptics and no angulation and a square edge interrupted at the optic-haptic junction. Its overall diameter is 13.0 mm and optic diameter 6.0 mm. The Tecnis ZCB00 (Johnson & Johnson Vision) is a 1-piece aspheric hydrophobic acrylic IOL with C-loop haptics and a posterior optic offset for 3-point fixation and a 360-degree square edge. Its overall diameter is 13.0 mm and optic diameter 6.0 mm. The Envista MX60 (Bausch & Lomb) is a 1-piece aspheric hydrophobic acrylic IOL with fenestrated modified C-loop haptics and a posterior optic offset and a 360-degree square edge. Its overall diameter is 12.5 mm and optic diameter 6.0 mm.

• **PREOPERATIVE EVALUATION:** One to 2 weeks before cataract surgery the patients were examined for biometry with the IOL Master 700 (Carl Zeiss Meditec AG, Jena, Germany), visual acuity with an autorefractor keratometer Nidek ARK-1 (Nidek Co Ltd, Tokyo, Japan), and with a slit lamp (Haag-Streit, Koeniz, Switzerland) including a fundus examination. The SRK/T and Haigis formulas were used to determine the IOL power.

• **SURGICAL TECHNIQUE:** Manual standard phaco surgery was performed in all eyes. Most patients received bilateral surgery on 1 occasion. An envelope with the preoperatively randomized axis was opened before surgery. A 2.2 mm self-sealing temporal posterior limbal incision was made, and the anterior chamber filled with an ophthalmic viscoelastic device (OVD). Two temporal paracenteses were made. A curvilinear capsulorhexis with a target diameter of 5.0-5.5 mm was created, and hydrodissection performed. Phacoemulsification was followed by irrigation/aspiration and IOL implantation into the capsular bag. As an OVD, a dispersive OVD (Eyefill HD; Bausch & Lomb) was used to ease needle capsulorhexis and protect the endothelium during phacoemulsification, but was then replaced by a cohesive OVD (Provisc; Alcon) for loading the IOL into the cartridge and expanding the capsular bag before IOL implantation to optimize IOL-capsule adherence. The cohesive OVD used for IOL implantation was then thoroughly aspirated from the bag with special attention paid to the capsular equator and the retrolental space. Preoperatively, primary axis positioning of the IOLs was randomly assigned to 0 ± 10, 90 ± 10, 45 ± 10, or $135 \pm 10^{\circ}$ to also allow evaluation of a possible influence of horizontal, vertical, or oblique positioning in an oval capsular bag on rotation. After hydration of the incisions, a video clip was made and the conjunctiva gently moved with a swab to allow detection of nonmoveable episcleral vessels to be used as the reference vessels during the follow-up examinations.

• **DETERMINATION AND FOLLOW-UP OF AXIAL POSITION:** Baseline measurements were taken using a technique described earlier[1]: two nonmoveable episcleral vessel landmarks were identified while watching the video clip recorded at the end of the surgery. A suitable screenshot was selected and subsequently a line was drawn between the 2 episcleral landmarks to be used as the reference for the follow-up examinations. This reference line was then crossed with the IOL axis line connecting the optic-haptic junctions. The meridional position of the IOL was defined as the angle between the reference and the IOL axis lines. Rotation of the IOL at the consecutive follow-up visits was determined by measuring the change in the angle. Follow-up visits were scheduled after 1 hour, 1 week, and 1 month with a long-term follow-up visit after 4-7 months (6 months) when capsular sealing and fibrosis were completed.[5] At each follow-up visit, retroillumination pictures were taken with a high-definition digital camera DCS720x (Kodak, Rochester, New York, USA). These pictures were used to compare the actual IOL axis with the IOL axis at the EoS. At the 6-month follow-up, tilt and decentration were measured in addition using a Purkinje meter (Prof Schaeffel, Tuebingen, Germany).[6] The

TABLE 1. Baseline Demographics

	Acrysof	Tecnis	Envista	All
Age, y	72.95 ± 6.81	69.25 ± 9.12	70.72 ± 8.66	70.89 ± 8.42
	74 [51; 86] n = 63	68 [41; 86] n = 76	73 [47; 86] n = 60	72 [41; 86] n = 199
Sex (female/male)	(35/28) n = 63	(46/30) n = 76	(37/23) n = 60	(118/81) n = 199
ACD, (mm)	3.04 ± 0.32	3.14 ± 0.38	3.12 ± 0.34	3.10 ± 0.35
	3.03 [2.25; 3.91] n = 121	3.15 [2.31; 3.84] n = 144	3.12 [2.12; 3.86] n = 116	3.1 [2.12; 3.91] n = 381
AXL (mm)	23.53 ± 1.07	23.74 ± 1.31	23.66 ± 1.28	23.65 ± 1.23
	23.42 [21.25; 26.40] n = 121	23.50 [21.81; 27.62] n = 144	23.54 [21.13; 27.84] n = 116	23.49 [21.13; 27.84] n = 381
WTW (mm)	11.95 ± 0.36	12.02 ± 0.41	11.94 ± 0.43	11.97 ± 0.40
	12.0 [11.0; 12.8] n = 121	12.1 [11.2; 13.2] n = 144	12.0 [10.8; 12.8] n = 116	12.0 [10.8; 13.2] n = 381
Lens power, (dpt)	21.82 ± 2.60	21.79 ± 3.24	21.50 ± 3.02	21.71 ± 2.98
	22.0 [14.5; 28.0] n = 121	22.0 [10.0; 28.5] n = 144	22.0 [11.0; 30.0] n = 116	22.0 [10; 30] n = 381

ACD = anterior chamber depth; AXL = axial length; WTW = white-to-white corneal diameter.
Baseline demographics preoperatively. Values presented as means ± standard deviations and median [range].

Schaeffel Purkinje meter cannot distinguish between left and right eyes. Negative decentration or tilt values stand for temporal decentration or tilt in right eyes and nasal decentration or tilt in left eyes. To match the symmetry of left and right eyes, values assessed from left eyes were converted to be compatible with right eye values. Therefore, nasal and temporal tilt will be reported for both eyes in the same figure. Visual acuity assessment as well as anterior segment and fundus biomicroscopy was conducted at every follow-up.

• **STATISTICAL ANALYSIS:** Descriptive statistics such as means, medians, standard deviation, quartiles, and interquartile range for continuous variables and absolute and relative frequencies for categorical variables were computed.

The primary objective was to compare the 3 lens types with respect to differences in IOL rotation from the EOS to the study end after 6 months. The primary objective was assessed using a linear mixed model, with the difference in rotation as the dependent variable and the lens type as an explanatory variable. A random patient intercept was included in the model to account for the correlated measurements of 2 eyes within the same patient. The overall null hypothesis that there is no difference in the means of the rotation differences was tested using a type III analysis of variance with Kenward-Roger's method to determine the degrees of freedom. As the overall null was rejected, pairwise comparisons were conducted. Pairwise *P* values are based on the *t*-distribution using Kenward-Roger degrees of freedom. Because of the outliers in the primary endpoint and thereof resulting nonrobustness of the mean, we conducted a sensitivity analysis in which we excluded the outliers (differences in rotation greater than 10°) and repeated the primary analysis.

The first secondary objective was to compare the 3 lens types with respect to differences in rotation from the EoS to 1 hour after surgery. The first secondary objective was assessed analogously to the primary objective, without a sensitivity analysis. The second secondary objective was to assess the correlation between (1) lens power/lens thickness, (2) axial eye length, (3) intensity of anterior capsule fibrosis, and (4) WTW and absolute rotation from the EoS to the end of the study after 6 months. In all 4 cases, the repeated measure correlations by Bland and Altman as implemented in the rmcorr R package were used.[7,8] Unless otherwise stated, missing observations were excluded from the respective analyses, leading to different sample sizes for most analyses.

The analysis was conducted using R 3.6.3. *P* values <.05 were considered statistically significant throughout, and no multiplicity correction was applied.

RESULTS

• **ROTATIONAL STABILITY:** Of the 381 eyes included in the study, 311 met the criteria for the primary objective: 104 of the 121 in the Acrysof group, 106 of the 144 in the Tecnis group, and 101 of the 116 in the Envista group.

Thirty-three eyes were lost to follow-up because of no show-up of or inability to contact the patient: 10 in the Acrysof, 19 in the Tecnis, and 4 in the Envista group. Thirty-seven eyes could not be analyzed because of difficulties in appropriately identifying the episcleral or IOL landmarks: 7 in the Acrysof, 19 in the Tecnis, and 11 in the Envista group.

Baseline demographics are shown in Table 1.

TABLE 2. Detailed Rotational Stability Results

Observation Period	Acrysof	N = 121	Tecnis	N = 144	Envista	N = 116	All	N = 381
End of surgery to 1 hour	1.0 [0.1; 17.6] 1.6 ± 2.6	113	1.2 [0.0; 39.9] 1.9 ± 3.8	123	1.35 [0.0; 48.3] 2.5 ± 5.2	104	1.2 [0.0; 48.3] 2.0 ± 4.0	340
1 hour to 1 week	0.9 [0.0; 27.2] 1.2 ± 2.6	113	1.0 [0.0; 37.0] 1.7 ± 3.5	121	0.8 [0.0; 10.6] 1.3 ± 1.5	99	0.9 [0.0; 37.0] 1.4 ± 2.7	333
1 week to 1 month	0.6 [0.3; 5.2] 0.8 ± 0.8	111	0.7 [0.0; 3.3] 0.9 ± 0.7	116	0.7 [0.0; 5.2] 1.1 ± 1.1	98	0.7 [0.0; 5.2] 0.9 ± 0.9	325
1 month to 6 months	0.5 [0.3; 3.6] 0.5 ± 0.5	103	0.5 [0.3; 3.6] 0.9 ± 0.7	105	0.6 [0.0; 5.6] 1.0 ± 1.1	100	0.5 [0.0; 5.6] 0.8 ± 0.8	308
End of surgery to 6 mo	1.1 [0.0; 15.8] 1.65 ± 2.1	104	1.75 [0.1; 38.6] 2.65 ± 4.1	106	1.5 [0.0; 44.9] 3.18 ± 5.8	101	1.4 [0.0; 44.9] 2.49 ± 4.3	311

Absolute intraocular lens (IOL) rotation in degrees for all IOLs. Values presented as median [range] and means ± standard deviations. N = number of valid observations within this period. Data are presented for every IOL in detail.

Detailed results including absolute means and medians of rotation for all time windows are shown in Table 2. There was a significant difference in the means of rotation from the EoS to the end of the study after 6 months with respect to lens type (P = .043). Pairwise comparisons yielded a significant difference in overall rotation between the Acrysof and Envista groups (P = .014), but no significant difference between the Acrysof and Tecnis groups (P = .10) and the Tecnis and Envista groups (P = .39). When excluding the outliers with more than 10-degree rotation, again a significant overall difference was observed (P = .01), with pairwise comparison yielding a significant difference between the Acrysof and Tecnis groups (P = .005) and the Acrysof and Envista groups (P = .015), but no significant difference between the Tecnis and Envista groups (P = .761).

Detailed absolute rotation results are shown in Figure 1 (EoS to 6 months) and Figure 2 (absolute rotation EoS to 1 hour, 1 hour to 1 week, 1 week to 1 month, and 1-6 months). Differences in absolute rotation for the horizontal ($0 \pm 10^\circ$), oblique (45 ± 10 and $135 \pm 10^\circ$), and vertical ($90 \pm 10^\circ$) primary axis positioning groups are shown in Table 3. When excluding the IOL rotation of less than 1° to account for possible measurement noise, a statistically significant difference was found regarding clockwise or counterclockwise rotation for the entire study group. Counterclockwise rotation, if occurred, was most pronounced in the 135-degree group (Table 4).

No correlation was found between lens power (r = 0.077; P = .37), axial length (r = −0.06; P = .48), intensity of anterior capsule fibrosis (r = 0.058; P = .51), and WTW (r = 0.012; P = .89) on the one side and absolute rotation from the EoS to 6 months on the other.

• **EARLY IOL ROTATION:** No significant difference in the means of the rotations from the EoS to 1 hour after surgery with respect to lens type was observed (P = .238); hence no pairwise comparisons were conducted. Maximum rotation within the first hour was 17.6° for the Acrysof, 39.9° for the Tecnis, and 48.3° for the Envista group. Figure 3 shows a representative case of early rotation from the EoS to 1 hour.

• **INTERMEDIATE AND LATE IOL ROTATION:** Frequencies of intermediate rotation from 1 hour to 1 week and late postoperative IOL rotation beyond 1 week of more than 5, 10, and 15° are shown in Table 5.

• **LENS DECENTRATION AND TILT:** Decentration and tilt for all IOLs are shown in Figure 4.

The mean horizontal decentration was 0.11 ± 0.21 mm for the Acrysof, 0.03 ± 0.25 mm for the Tecnis, and 0.02 ± 0.21 mm for the Envista group. The mean vertical decentration was −0.03 ± 0.33 mm for the Acrysof, −0.15 ± 0.24 mm for the Tecnis, and −0.09 ± 0.18 mm for the Envista group. The mean horizontal tilt was −4.87 ± 2.0° temporal for the Acrysof, −4.67 ± 2.70° for the Tecnis, and −4.58 ± 2.62° for the Envista group. The mean vertical tilt was −2.89 ± 2.31° for the Acrysof, −2.24 ± 1.65° for the Tecnis, and −1.97 ± 1.58° for the Envista group.

DISCUSSION

ROTATIONAL BEHAVIOR AS WELL AS DECENTRATION AND tilt is gaining ever more importance because of the market's increasing demand for premium IOLs and the widespread use of aspheric-correcting IOLs. A clinical survey of the American Society of Cataract and Refractive Surgeons reported that approximately 22% of patients with clinically prominent astigmatism received a toric IOL in the United States in the 2018. In addition, 9% of all patients received presbyopia-correcting IOLs (American Society of Cataract and Refractive Surgeons 2018 Survey). The growing use of IOLs to correct astigmatism and presbyopia increases the

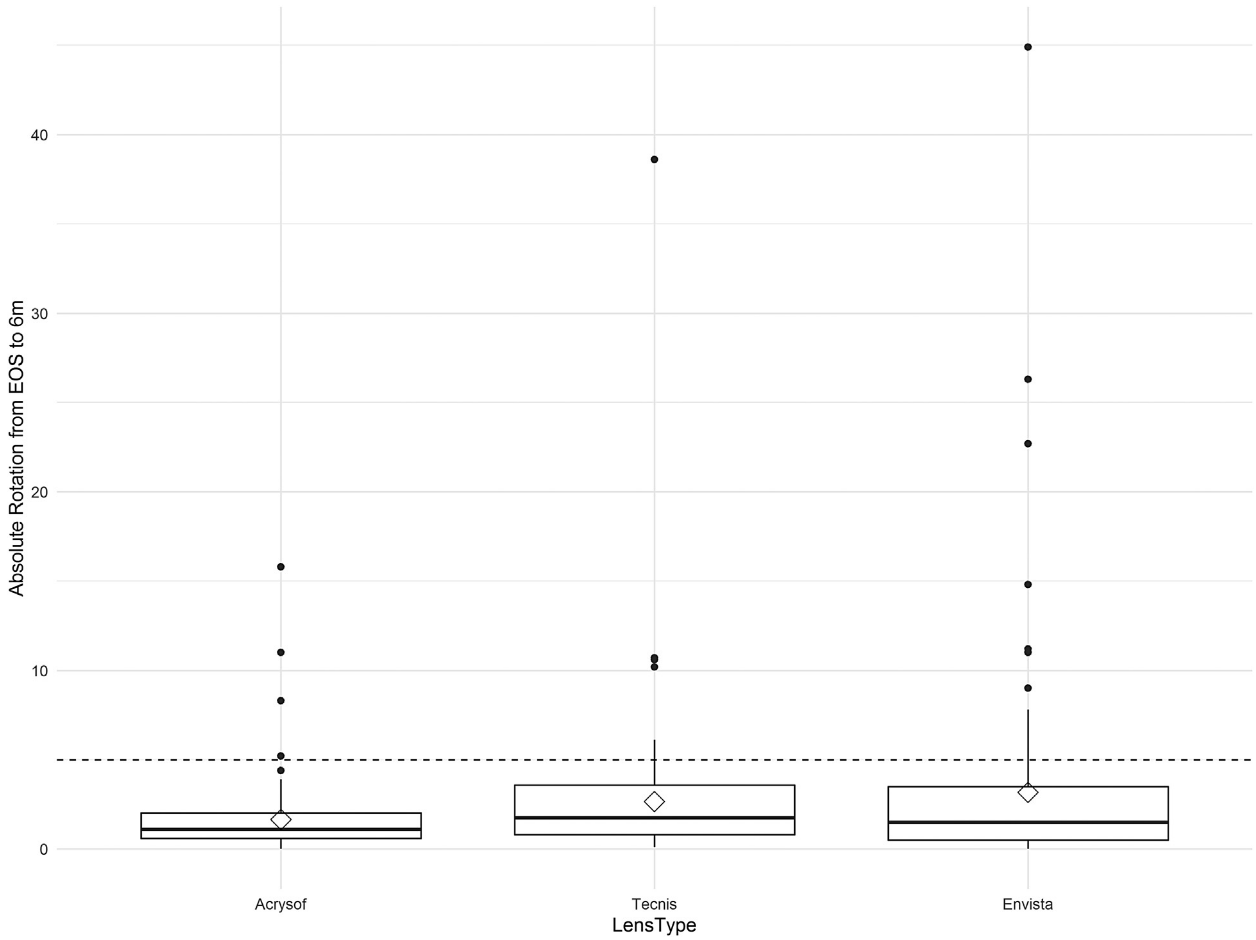

FIGURE 1. Boxplots for all 3 groups showing the absolute rotation in degree from the end of surgery (EoS) to 6 months postoperatively.

demand for different specifications of IOLs. The IOLs investigated in the present study are among the most commonly implanted in the United States and worldwide.

Astigmatism correction with TIOLs depends on 3 factors: correct assessment of the amount and axis of corneal astigmatism including the posterior surface, precise intraoperative positioning of the TIOL, and IOL rotational stability.[2] To the best of our knowledge, our study is the first to compare the rotational stability of the Acrysof, Tecnis, and Envista IOLs postoperatively with more than 100 eyes in each group, randomizing primary axis positioning, starting with axis baseline measurements on the operating table and using a standardized objective method compensating for head tilt or cyclotorsion. We used the nontoric platform of the IOLs for faster patient recruitment and to avoid dropouts due to major secondary rotation requiring surgical repositioning.

When considering all the IOLs included in the study, we found a statistically significant difference in rotational stability between the Acrysof and Envista IOLs ($P = .014$) but not between the Tecnis and Acrysof ($P = .10$) or between the Tecnis and Envista IOLs ($P = .39$). When excluding outliers with *greater* than 10 degrees of absolute rotation, we found a significant difference between the Acrysof and Tecnis ($P = .005$), as well as between the Acrysof and Envista ($P = .015$) IOLs. The absolute median amount of rotation observed in all groups was below 2°. This indicates a safe use for astigmatism treatment in the vast majority of IOLs in all 3 groups under best conditions. However, particularly with higher power cylinder TIOLs, even minor deviations from the corneal astigmatic axis may markedly decrease the corrective potential of the TIOL and additionally cause a hyperopic and astigmatic axis shift.[9] Considering the unavoidable error in primary TIOL alignment with the target axis, the secondary rotation of less than 5° may be disregarded and the percentage of rotations exceeding 5° can be used as a suitable score for the rotational stability of IOL platforms.

Outliers have to be considered, because these substantially interfere with the intended correction and may create the need for a secondary surgical intervention. Outliers above 5° were observed with all 3 IOLs. The differences

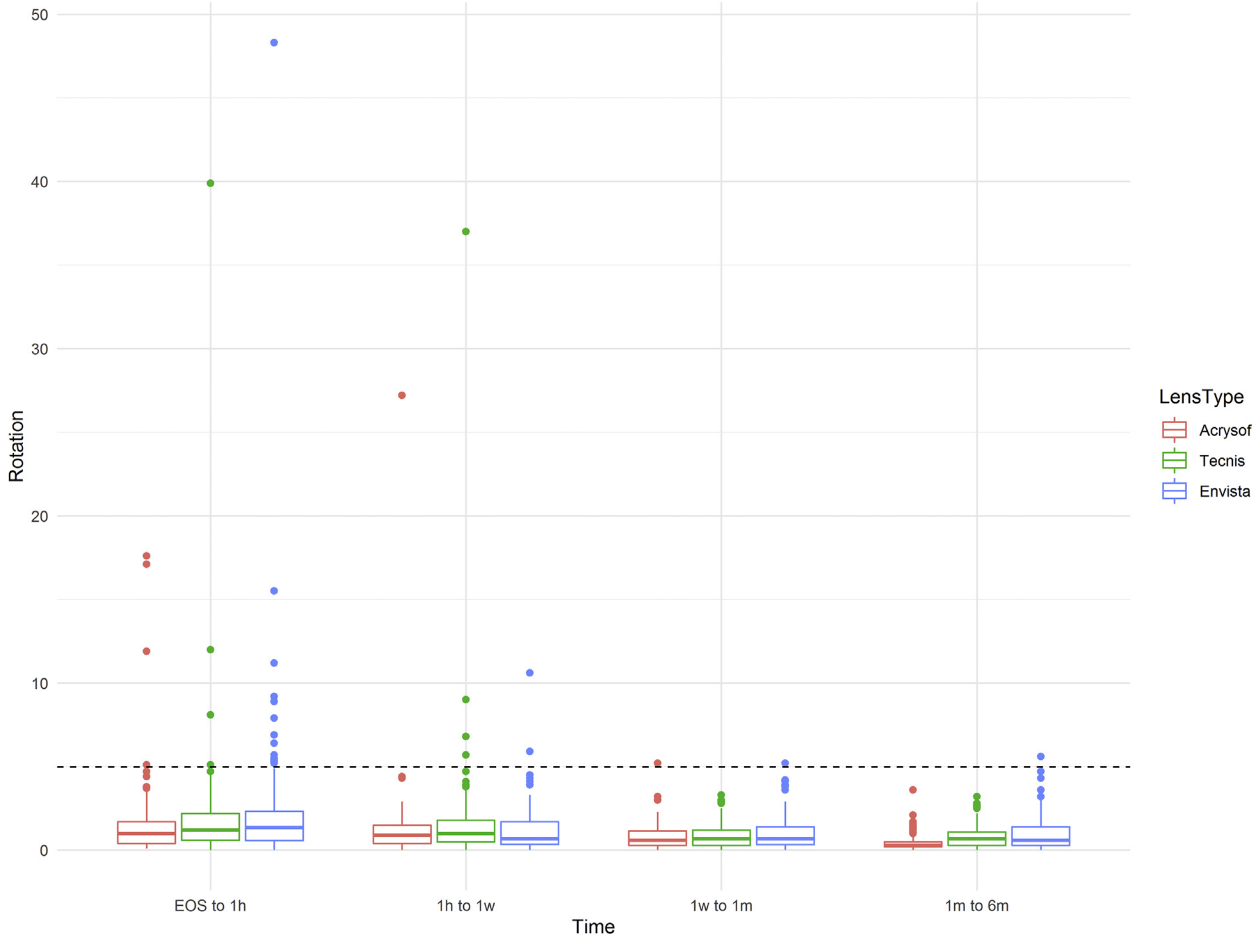

FIGURE 2. Boxplots showing the absolute rotation in degree for all groups from the end of surgery (EoS) to 1 hour, from 1 hour to 1 week from 1 week to 1 month, and from 1 month to 4-7 months (6 months).

in rates of IOLs rotating more than 5° could influence a surgeon's choice of which TIOL to implant. The percentage of implanted IOLs that rotated more than 5° from their initial axis was 4.8% of the Acrysof, 7.5% of the Tecnis, and 13.9% of the Envista group. A rotation of more than 10° from the EoS to 6 months was observed in a corresponding 1.9%, 3.8%, and 5.9%.

Studies found a maximum rotation from 1.8 to 95°[10–17] in the Acrysof and 8 to 45.32° in the Tecnis IOL.[16,18–22] In our study, 1 Acrysof IOL rotated 17.6° after 1 hour and 27.2° from 1 hour to 1 week in the same direction. In total, this IOL showed 44.8 degrees of rotation during the first week. Unfortunately, this patient was lost to follow-up after 1 week so that this outlier is not included in the overall 6-month results. Based on the results of the present study, it can be assumed that the lens would have been stable thereafter. For the Tecnis IOL, a maximum rotation of 45.32° agrees with the results in our study, where the maximum rotation of the Tecnis IOL was 44.9°. Because of the toric version of the IOL implanted in some of the studies, secondary repositioning interventions biased the true long-term rotational stability results of the IOL.

A study that investigated the toric versions of the Acrysof and Envista IOL, in which an overall of 56 eyes in the Acrysof and 21 in the Envista group were observed, reported a maximum rotation of 18° for the Acrysof IOL and a maximum rotation of 22° for the Envista IOL. Rotation was found to be greatest within the first hour. Even though the most prominent axis offset after 1 hour was observed in the Envista group, it was observed to be the most stable IOL after 1 hour. This is because the researchers did not use the absolute values to calculate the mean rotation.[3] Absolute values have to be used because rotation can occur in both clockwise and counterclockwise directions.

In a study by Lee and Chang[4] investigating the postoperative rotational stability of the Acrysof and Tecnis TIOLs in 1273 eyes, mean absolute rotation rates of 2.72 and 3.79° were found for the Acrysof and Tecnis IOLs, respectively. We observed mean absolute rotations of 1.65 and 2.65°, respectively. Unlike in that earlier study, we investigated rotational stability over a time span of 4-7 months performing longitudinal follow-ups. Of the 311 IOLs that completed the entire follow-up, 14 IOLs rotated more

TABLE3. Rotation Separated to Their Primary Implantation Axis

Observation Period All Groups	Horizontal Group 0 ± 10 Degrees	N = 96	Oblique Group 45 ± 10 Degrees 135 ± 10 Degrees	N = 180	Vertical Group 90 ± 10	N = 105
End of surgery to 6 months	3.22 ± 5.15 1.7 [0.1; 44.9]	77	2.37 ± 4.45 1.2 [0.0; 38.6]	147	2.05 ± 2.44 1.4 [0.0; 15.8]	87
Numbers of IOLs rotating more than 10° (%)	3 (3.9%)	77	5 (3.4%)	147	4 (3.8%)	87

Absolute rotation of intraocular lenses (IOLs) from the end of surgery to 6 months separated by their primary implantation axis.

TABLE 4. Direction of Rotation of Intraocular Lenses

Direction of rotation from the EoS to 6 mo (IOL rotation of more than >1°)	0 ± 10°	45 ± 10°	90 ± 10°	135 ± 10°	All
Clockwise/Counterclockwise EoS to 6 m	38/17	26/14	38/20	22/21	124/72
Binomial test[a]	$P = .006$	$P = .081$	$P = .025$	$P = 1.0$	$P < .001$

Direction of rotation from the end of surgery (EoS) to 6 months (6 m) for the initial implantation axis subgroups of 0 ± 10, 45 ± 10, 90 ± 10, and 135 ± 10°.

Only IOLs rotating more than 1° are included.

[a]Binomial test: testing hypothesis that proportion of clock- and counterclockwise rotation is 50%.

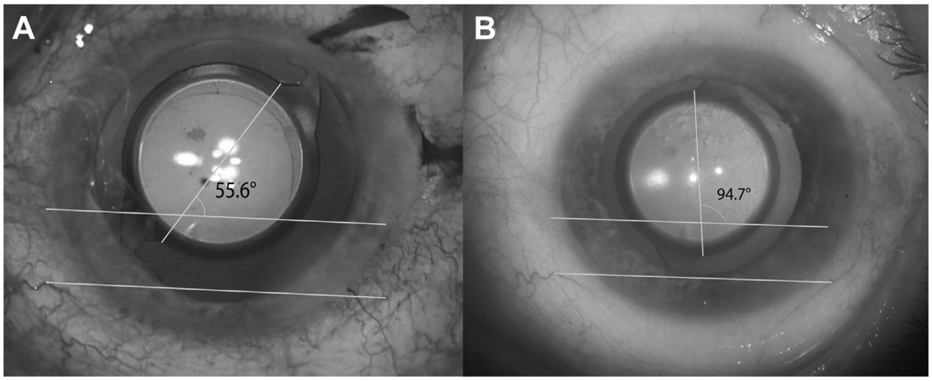

FIGURE 3. Representative case of a Tecnis intraocular lens (IOL), rotating 39.1° counterclockwise from the end of surgery (A) to 1 hour (B). The same reference line between 2 critical landmarks (loops of episcleral vessels) is shifted until it crosses the IOL line (axillar optic/haptic junctions) in both pictures.

than 5° after the 1-hour follow-up, even though they had rotated less than 5° within the first hour.

This finding underlines the necessity of long follow-up periods to analyze the true postoperative axis position. The same earlier study showed that astigmatism with the rule was more often associated with IOL rotation of more than 10° than oblique astigmatism or astigmatism against the rule. The authors opined that gravity or haptic orientation could be the explanation.[4] To exclude the potential bias by implanting all IOLs on the same axis in our study, we randomized IOL implantation to 4 different subgroups. We did not observe a higher number of IOLs rotating more than 10° in any of our horizontal (0 ± 10°), oblique (45 ± 10 and 135 ± 10°), or vertical (90 ± 10°) subgroups.

The sequential imaging examinations in our study allowed assessing late rotation of the IOLs. Although IOL rotation was mostly pronounced within the first hour after the operation, intermediate and late rotation beyond 1 hour after operation was quite rare. In total, only 2.1% of all 3 IOLs rotated more than 5° from 1 hour to 1 week and only 0.6% from 1 week to 1 month. These results indicate that severe late rotation is unusual but not impossible.

TABLE 5. Frequencies of IOLs Rotating More Than 5, 10, and 15 Degrees.

IOLs Rotating More Than 5/10/15 Degrees (%)	Acrysof	N = 121	Tecnis	N = 144	Envista	N = 116	All	N = 381
EoS to 1h	3.5/2.6/1.8%	113	4.1/1.6/0.8%	123	12.5/3.8/1.9%	104	6.8/2.6/1.5%	340
1h to 1w	0.9/0.9/0.9%	113	3.3/0.8/0.8%	121	2.0/1.0/0.0%	99	2.1/0.9/0.6%	333
1w to 1m	0.9/0.0/0.0%	111	0.0/0.0/0.0%	116	1.0/0.0/0.0%	98	0.6/0.0/0.0%	325
1m to6m	0.0/0.0/0.0%	103	0.0/0.0/0.0%	105	1.0/0.0/0.0%	100	0.3/0.0/0.0%	308
EoS to 6m	4.8/1.9/1.0%	104	7.5/3.8/0.9%	106	13.9/5.9/3.0%	101	8.7/3.9/1.6%	311

Frequencies of intraocular lenses (IOLs) rotating more than 5, 10, and 15° within the timeframes of the end of surgery (EoS) to 1 hour (1h), 1 hour to 1 week (1w), 1 week to 1 month (1m), 1 month to 4-7 months (6m), and the EoS to 6 month.

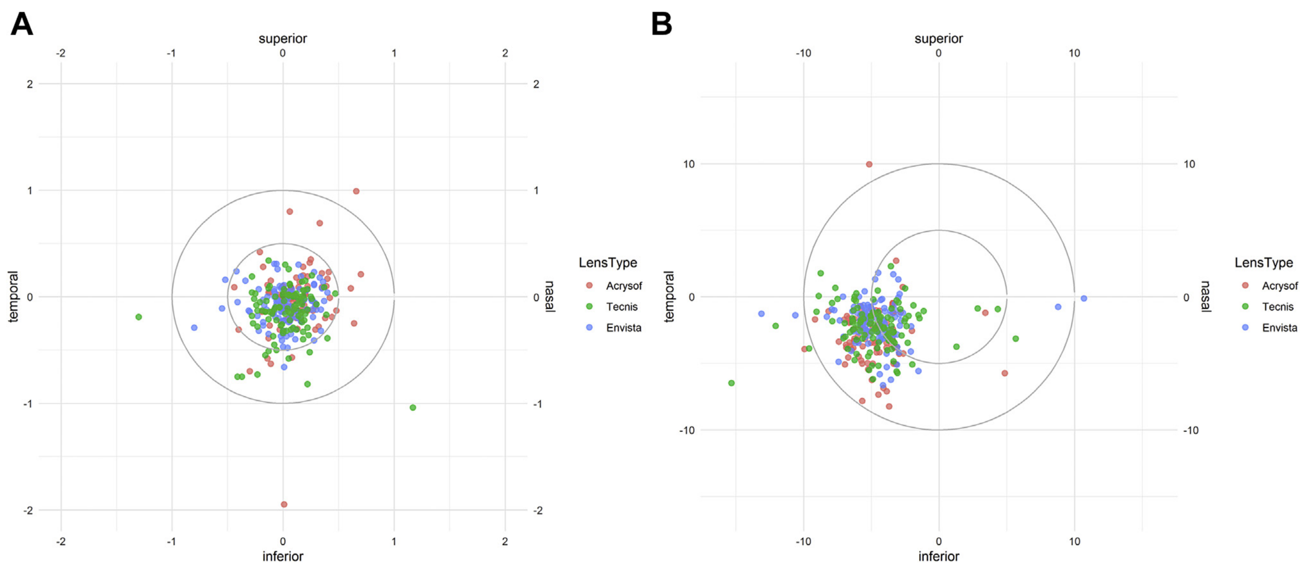

FIGURE 4. (A) Superior, nasal, inferior, and temporal decentrations for all intraocular lenses. (B) Superior, nasal, inferior, and temporal tilts for all intraocular lenses. To match the symmetry of the right and the left eye, values observed for the left eye were converted to be compatible with those for the right eye and are shown in the figure.

However, in individual eyes, lower amounts of rotation within the different timeframes summed up to more than 5° and consequently could have decreased uncorrected visual acuity when using a TIOL even though apparently stable within the early postoperative phase.

In a recently published study including over 100 eyes, we investigated the rotational stability of the Vivinex XY1 IOL (Hoya Corporation, Tokyo, Japan) with an overall diameter of 13.0 mm and frosted anterior and posterior haptic surfaces. None of the IOLs rotated more than 5° within the first hour and subsequently.[1] The Acrysof and Tecnis IOLs in the present study feature the same overall diameter of 13.0 mm but showed less rotational stability in the early postoperative phase. The fully frosted haptics of the Vivinex IOL could favor early postoperative stability and thus avoid outliers compared with the Acrysof and Tecnis IOLs. Comparable stability was observed after the 1-week follow-up.

Peripheral capsule bag contraction may play a decisive role in postoperative rotational stability. Capsule leaf fusion starting from the periphery of the capsular bag embeds the haptics and provides rotational stability even with primary unstable IOLs. Individual variability in timing may explain for differences in rotational stability after the first postoperative hour.

Although the IOLs in our study statistically significantly more often rotated clockwise, a considerable percentage of IOLs (37%) rotated counterclockwise. Interestingly, if counterclockwise rotation occurred, it was most pronounced in IOLs initially placed at the 135-degree axis (Table 4). The balanced proportion of clockwise and counterclockwise rotation at 135-degree axis might contribute to gravity. In contrast to that, IOLs placed at 45° did not show a considerable higher percentage of clockwise rotation compared with the 0- and 90-degree subgroup.

For decentration and tilt measurements, the Schaeffel Purkinje meter was used, which has been proven to have very good reliability and reproducibility.[23] The optical performance of IOLs with a high asphericity has been shown to be more susceptible to decentration and tilt, whereas aspherically neutral IOLs are most tolerant in this regard.[24] The Acrysof IOL has a negative asphericity of -0.20 μm, less than the Tecnis IOL with -0.27 μm, whereas the Envista IOL has an aspheric aberration-free optic profile more robust to decentration and tilt. An in vitro study showed the superiority of the Acrysof spherical aberration-correcting IOL over the Envista IOL, when the average spherical aberration of the cornea was added to an eye model.[25]

The results of tilt in our study are in accordance with an earlier study investigating the crystalline lens and IOL tilt measured by anterior segment optical coherence tomography. Both crystalline lens and IOL showed a tendency to tilt toward the inferotemporal direction.[26] Decentration was generally low and mostly within 0.5 mm. Unlike tilt, the IOLs in our study showed no tendency to decenter toward a specific direction as reported in a recent publication.[27]

A limitation of the present study design is the unaddressed influence of rotation in a TIOL on uncorrected distance visual acuity. Because of the use of spherical IOLs instead of TIOLs, it could not be determined. However, the clear aim of the study was to determine the rotational stability of 3 IOL platforms as such. Uncorrected distance visual acuity also reflects the biometric error as well as decentration and tilt, which, though clinically relevant, makes it a very crude determinant for rotational stability as an anatomical parameter.

In conclusion, this is the first study to compare the long-term rotational stability of 3 well-established IOLs starting at the very end of the surgery with the patient still supine on the table and applying a standardized high-precision measurement method independent from head tilt and cyclotorsion by using nonmoveable episcleral landmarks. We could show that the Acrysof IOL showed a statistically significantly better rotational stability than the Tecnis and Envista IOLs when excluding the rotation of more than 10°. Sequential imaging examinations showed rare but not impossible late rotation of all 3 IOLs.

Rotation was independent of axial eye length and WTW distance. A posterior IOL optic offset did not substantially improve rotational stability. Regardless of the generally low absolute values of rotation, outliers resulting in possible unsatisfying uncorrected vision and the possible need for a secondary surgical intervention were observed in all 3 groups.

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