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ORIGINAL RESEARCH

# Comparing Rotational Stability Over Time Between Four Monofocal Toric Intraocular Lenses

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**Purpose:** To evaluate the rotational stability of four different monofocal toric intraocular lenses (IOLs) from surgery to 4–6 months postoperative.

**Methods:** This was a subset of data from a prospective multi-center randomized clinical study. High resolution retro-illuminated images of eyes implanted with four different toric IOLs were obtained immediately after surgery, and at 1 day, 1 week, 1 month and 4–6 months after surgery. Fixed scleral features were identified in the surgical image. An independent reading center evaluated the orientation of the IOL from all images, based on the angle between the toric axis marks and these fixed scleral landmarks. Rotational stability was determined by calculating differences in orientation between visits.

**Results:** Digital images from 299 eyes implanted with one of the four IOLs were available for analysis. Orientation data were successfully determined in about 90% of images. Biometry and IOL orientation were not significantly associated with IOL rotation. The Vivinex lens showed the lowest absolute rotation, with a mean value less than 1.5 degrees at all time intervals measured, with a maximum standard deviation of 1.4 degrees. The AcrySof lens was next lowest, with an absolute rotation below two degrees for all intervals. Mean absolute rotation for the Tecnis lens was significantly higher than for the other IOLs (>2 degrees for all intervals). For the AcrySof and Vivinex lenses, there were no reported rotations >10 degrees for any interval; 97% or more of results were <5 degrees, compared to 93% for the AT Torbi lens and 90% for the Tecnis lens. Only 6 lenses (4 Tecnis: 8.3%, 2 AT Torbi: 4.3%) had a rotation > 10 degrees at any time point.

**Conclusion:** Rotational stability appeared excellent for the Vivinex and AcrySof toric IOLs, with slightly more variable performance evident with the AT Torbi and Tecnis IOLs.

**Keywords:** toric, Vivinex™, XY1A, XY1-SP, AcrySof™ SN6ATx, Tecnis™ Toric ZCT, AT Torbi™, rotation, Astigmatism

## Introduction

About a third of patients presenting for cataract surgery have corneal astigmatism > 1.0 D,[1] all of whom would be likely to benefit from the implantation of a toric intraocular lens (IOL) to achieve improvement in UDVA (Uncorrected Distance Visual Acuity) and CDVA (Corrected Distance Visual Acuity), respectively. Most manufacturers now include toric IOLs in their product lines, in both monofocal and multifocal designs. Evidence indicates that a toric IOL appropriately oriented in the eye can provide patients who have corneal astigmatism excellent postoperative visual acuity and a significant reduction in their manifest refractive astigmatism.[2]

A key to the success of toric IOLs is their orientation in the eye. The optimal orientation is arguably the orientation that minimizes postoperative refractive astigmatism. Any deviation from this orientation will compromise the



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effectiveness of the toric IOL, with an approximate 3% loss of intended cylinder correction for each degree of misalignment.[3] There are two main components that may affect this optimal IOL orientation. The first is the alignment of the IOL at the time of surgery, and the second is the rotational stability of the IOL. In analyzing toric IOL performance, it is important to distinguish between this toric IOL misalignment and rotational stability.

Toric IOL misalignment occurs at the time of surgery, when the orientation of the toric IOL is not ideal (usually determined postoperatively, based on the patient's refraction). This can be the result of calculation or measurement error, inaccurate alignment marking,[4] surgically induced changes in the cornea that have not been accurately accounted for,[5] or effects from the posterior cornea.[6] Misalignment can be considered an error independent of the toric IOL implanted.

Rotational stability is a measure of any change in orientation of the IOL from its final operative orientation. In other words, rotational stability is not a measure of whether the lens is in the ideal position, but whether the lens stays in the orientation at which it was implanted. The term "IOL rotation" is often misused in the literature, leading to confusing and erroneous conclusions regarding IOL performance.[7] Rotational stability can be affected by material, haptic design, incomplete removal of the viscoelastic at the time of surgery, as well as lens characteristics such as lens thickness and lens or anterior chamber diameter. While detailed analyses of these factors were beyond the scope of the current study, Lin et al provides a good overview of the subject.[8] In addition, it is important to note that rotational stability is not reliably evaluated by examining clinical outcomes. A perfectly stable IOL may be implanted in an incorrect position – stability would be excellent, but the clinical outcome would be compromised.

As early as 1999, surgeons were attempting to use imaging technology to evaluate the rotational stability of toric IOLs.[9] Since that time the technology to evaluate IOL orientation has improved considerably, with high resolution digital photography and computer-assisted measurement systems now available.[10] The use of ocular features such as scleral vessels to better determine the orientation of the lens in the eye, and the orientation of the eye in any captured image (compensating for issues such as head tilt or ocular cyclotorsion), has further improved the ability to accurately determine if IOL rotation has occurred.[11] The combination of identifying fixed scleral features and digital evaluation techniques has demonstrated excellent inter-rater and intra-rater reliability and short-term reproducibility. Digital techniques have been demonstrated to be more precise than those based on manual techniques such as slit-lamp examination.[12]

The study results presented here evaluate the rotational stability of four different monofocal toric IOLs, from the immediate postoperative period to 4–6 months postoperative.

## Methods

The data analyzed here are a subset of the data collected in a study evaluating the clinical performance of four different toric IOLs: Vivinex™ Toric (XY1A, XY1-SP, HOYA Surgical Optics, Singapore), AcrySof™ Toric (SN6AT, Alcon, Fort Worth, TX, USA), Tecnis™ Toric 1 (ZCT, Johnson & Johnson Surgical Vision, Irvine, CA, USA) and AT Torbi™ (709 M/MP, Carl Zeiss Meditec, Jena, Germany). The first 3 lenses are made from hydrophobic acrylic materials and feature c-loop haptics. The AT Torbi is a hydrophilic acrylic IOL with plate haptics.

The study was a prospective, comparative, multicenter (15 sites across the EU), randomized, open-label, monocular design. The study was registered in the German Clinical Trials Register (trial registration number DRKS00015756, registered 10/17/2018). All subjects signed an approved informed consent document. The study was conducted in a manner consistent with good clinical practice and adhered to the tenets of the Declaration of Helsinki. The study was approved by all relevant ethics committees (see Table 1). Data is not available for sharing.

The study included subjects older than 22 years presenting for cataract surgery who were determined to be candidates for a toric IOL. All study subjects had to have corneal astigmatism between 0.70 D and 4.50 D in at least one eye (equivalent to 1.0 to 6.0 D at the IOL plane). Expected postoperative corrected distance acuity had to be 0.2 logMAR or better and the expected postoperative dilated pupil diameter had to be 5.5 mm or greater, to increase the likelihood of identifying the toric markings. Exclusion criteria included strabismus, amblyopia, pupil abnormalities (eg, non-reactive, fixed pupils, or abnormally shaped pupils), the presence of corneal pathology deemed likely to affect topography and subjects with conditions associated with an increased risk of zonular rupture. Any potential subject with acute, chronic, or uncontrolled systemic or ocular disease or illness that was considered likely to increase the operative risk or confound the outcome of the study was also excluded.

**Table 1** Study Investigators and Ethics Approval Information

| Institution/ Address | Investigator | Ethics Committee | Ethics Committee Approval Number |
|---|---|---|---|
| **Charité – Universitätsmedizin Berlin** Augustenburger Platz 113353 BerlinGermany | Prof. Dr. med. Eckart Bertelmann | **Ethikkommission CharitéUniversitätsmedizin Berlin**Charitéplatz 1 10117 Berlin | EA2/161/18 |
| **Klinikum Stuttgart – Katharinenhospital (KH)**Kriegsbergstraße 6070174 StuttgartGermany | Prof. Dr. med. Dr. Katrin Gekeler | **Ethik Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universitätund am Universitätsklinikum Tübingen**Gartenstraße 4772074 Tübingen | 630/2018 |
| **Augen- und Laserklinik Castrop-Rauxel GmbH**Münsterplatz 7D-44575 Castrop-RauxelGermany | Dr. med. Peter Hoffmann | **Ethik-Kommission der Ärztekammer Westfalen-Lippe und der Medizinischen Fakultät der Westfälischen Wilhelms-Universität Münster** Gartenstr. 210–21448147 Münster | 2018–529-b-s |
| **Augen-Zentrum-Nordwest**Domhof 1548683 AhausGermany | Dr. med. Stefanie Schmickler | **Ethik-Kommission der Ärztekammer Westfalen-Lippe und der Medizinischen Fakultät der Westfälischen Wilhelms-Universität Münster** Gartenstr. 210–21448147 Münster | 2018–529-b-s |
| **Universitäts-Augenklinik Heidelberg**Im Neuenheimer Feld 40069120 heidelbergGermany | Prof. Dr. med. Gerd Auffarth | **Ethikkommission Medizinische Fakultät Heidelberg** Alte Glockengießerei 11/169115 heidelberg | S-557/2018 |
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| **Universitätsklinikum des SaarlandesKlinik für Augenheilkunde**Kirrberger Straße 100D-66424 homburg/SaarGermany | Prof. Dr. med. Berthold Seitz | **Ethikkommission der Ärztekammer des Saarlandes** Faktoreistrasse 466111 Saarbrücken | Bu-04/19 |
| **Universitätsklinikum Frankfurt**Theodor-Stern-Kai 760590 Frankfurt am MainGermany | Univ.-Prof.Dr. med. Thomas Kohnen | **Ethikkommission des FB Medizin Universitätsklinikumder Goethe-Universität** Theodor-Stern-Kai 760590 Frankfurt am Main | 19–337 |
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The analysis of rotational stability was based on the technique described by Schartmüller et al,[11] which required a high-resolution retro-illuminated image of the dilated eye (with toric IOL markings visible) to be obtained at the end of surgery, with the patient in the supine position. The reference for IOL alignment was provided by identifying several non-movable landmarks (scleral vessels or Axenfeld loops) on this baseline image. Subsequent images of the toric IOL in the eye were obtained at the 1-day, 1-week, 1-month and 4–6-month visits. High-resolution, retro-illuminated digital photographs of the study eyes with the subjects in the erect position were taken at the slit lamp. Additional measures of interest related to rotational stability were the preoperative biometry (axial length, anterior chamber depth, keratometry), the IOL sphere and toric power, and the planned orientation of the IOL.

The orientation of the IOL at the surgical visit was recorded as the angle between the axis marks of the IOL and the identified landmarks of the eye. The orientation of the IOL at subsequent visits was determined in the same manner, where the IOL landmarks had to first be identified (using the surgical image as a reference). The IOL orientation at all visits was determined by an independent reading center (Li Wang, MD, PhD, Department of Ophthalmology, Baylor College of Medicine, Houston, Texas, USA) using a semi-automated software system (MATLAB version R2019a, MathWorks, Natick, MA, USA). For any image where the lens orientation could not be determined, a reason was provided. With this orientation data, the degree of rotation of the IOL at any visit interval could be calculated, with clockwise rotations considered to be positive. Changes in lens orientation were calculated for any two visits when a usable image was available for both visits.

The data was analyzed using linear regression techniques for multiple continuous variables, while analysis of variance (ANOVA) was used to analyze categorical factors. Statistical significance was set to $p = 0.05$.

## Results

A total of 299 eyes were implanted with one of the four toric IOLs included in the study. Table 2 summarizes the availability of evaluable images at the surgical visit and each of the postoperative visits. The lowest and highest percentage of follow-up (across all visits) is provided at the end of the table, to indicate that the percentage follow-up was consistently high and not materially different between the IOLs. Table 3 summarizes the availability of rotation data between visits – it differs from Table 2 in that the rotation data calculation required an evaluable image at both visits. As with Table 2, the percentage follow-up is included, showing that 85–98% of eyes had calculated rotation data across the

**Table 2** Availability of Imaging Results

| | | **Images Analyzed at Given Time Point** | | | | | **Follow up Rate** | |
|---|---|---|---|---|---|---|---|---|
| Lens Model | Total eyes | Surgery | 1 Day | 1 week | 1 Month | 4–6 Months | Lowest | Highest |
| Vivinex | 162 | 153 | 154 | 158 | 153 | 158 | 94% | 98% |
| AcrySof | 41 | 38 | 38 | 38 | 38 | 37 | 90% | 93% |
| Tecnis | 47 | 41 | 46 | 44 | 46 | 45 | 87% | 98% |
| AT Torbi | 46 | 44 | 40 | 42 | 44 | 45 | 87% | 98% |

**Table 3** Availability of Calculated Rotation Data

| | | **Visit Comparisons*** | | | | | **Follow up Rate** | |
|---|---|---|---|---|---|---|---|---|
| **Lens Model** | **Total eyes** | **V0 - V1** | **V0 - V2** | **V0 - V3** | **V0 - V4** | **V3 - V4** | **Lowest** | **Highest** |
| Vivinex | 163 | 145 | 149 | 144 | 150 | 149 | 88% | 92% |
| AcrySof | 41 | 35 | 35 | 36 | 37 | 36 | 85% | 90% |

(*Continued*)

**Table 3** (Continued).

| | | Visit Comparisons* | | | | | Follow up Rate | |
|---|---|---|---|---|---|---|---|---|
| **Lens Model** | **Total eyes** | **V0 - V1** | **V0 - V2** | **V0 - V3** | **V0 - V4** | **V3 - V4** | **Lowest** | **Highest** |
| Tecnis | 46 | 40 | 39 | 41 | 41 | 45 | 85% | 98% |
| AT Torbi | 46 | 39 | 40 | 42 | 43 | 43 | 85% | 93% |

**Note**: * V0 = surgery, V1 = 1 day, V2 = 1 week, V3 = 1 month, V4 = 4–6 months.

visits. Again, the follow-up percentages were not materially different between the IOLs. The major factors that influenced being able to obtain the IOL orientation at a given visit were pupil size (ie, toric axis markings could not be located) and image quality.

The 259 eyes with rotation data for the operative to 1-day visit were analyzed using multiple linear regression to determine if biometry had any significant effect on results. Variables included axial length, anterior chamber depth, mean keratometry, keratometric astigmatism, IOL sphere power and IOL toric power. Results indicated none of the biometric variables investigated was statistically significantly associated with the operative to 1-day rotation for any of the IOLs implanted ($p > 0.11$ in all cases). A factorial ANOVA including IOL and category of astigmatism (against the rule, with the rule, oblique) showed no statistically significant effect of astigmatism orientation on results ($p = 0.38$). A more detailed correlation analysis showed that axial length was not significantly correlated with IOL rotation or absolute IOL rotation for any of the time periods investigated, for any IOL. For example, Figure 1 shows the Vivinex IOL results by axial length for the surgery to 1 week period. IOL sphere power was also not significantly correlated with IOL rotation or absolute rotation, except in one instance (AcrySof lenses, absolute rotation from surgery to 1 week, $p < 0.05$), but this result was not considered clinically relevant (all rotations were <4 degrees). Figure 2 shows the Vivinex IOL results by IOL power for the surgery to 1 week period.

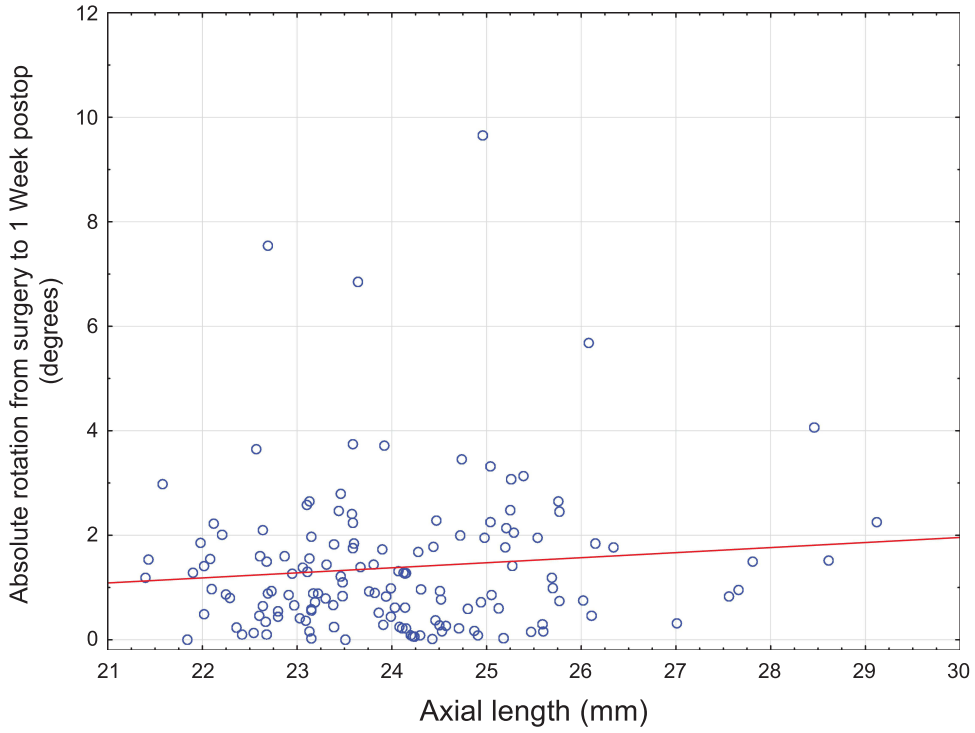


**Figure 1** Scatterplot of absolute rotation (surgery to 1 week) by axial length, Vivinex IOLs.


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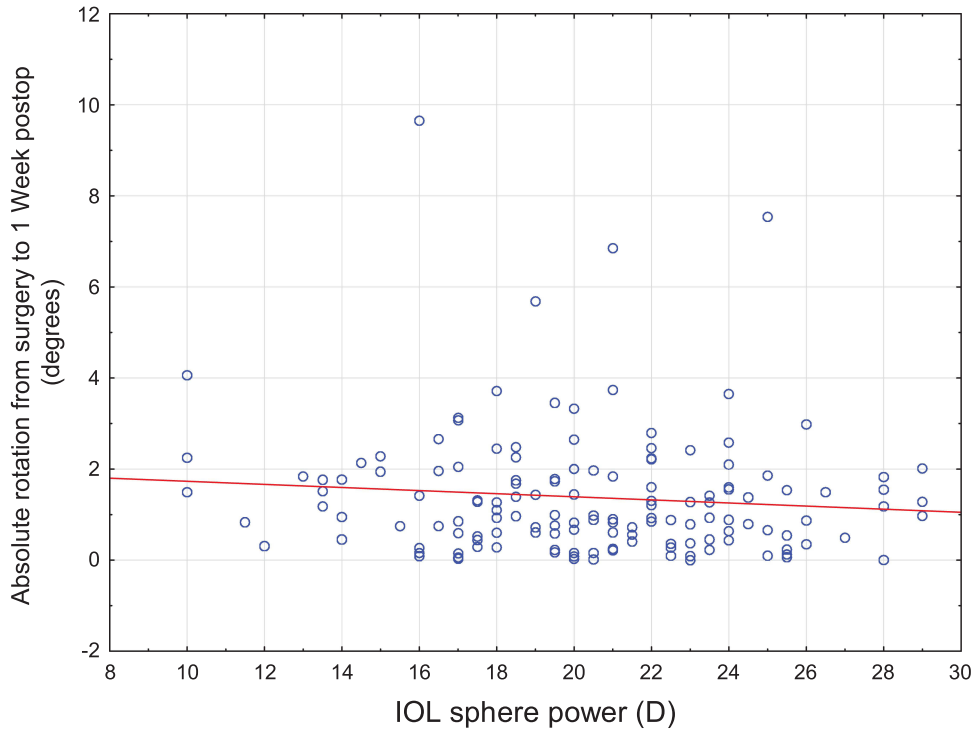


**Figure 2** Scatterplot of absolute rotation (surgery to 1 week) by IOL sphere power, Vivinex IOLs.

A Chi-squared test showed that the occurrence of counterclockwise vs clockwise rotation was not statistically significantly different for any of the lenses ($p > 0.05$) between the operative and 1 day visit. To avoid the effects of positive and negative rotation values "cancelling out", the absolute IOL rotation was analyzed. Figure 3 shows the mean

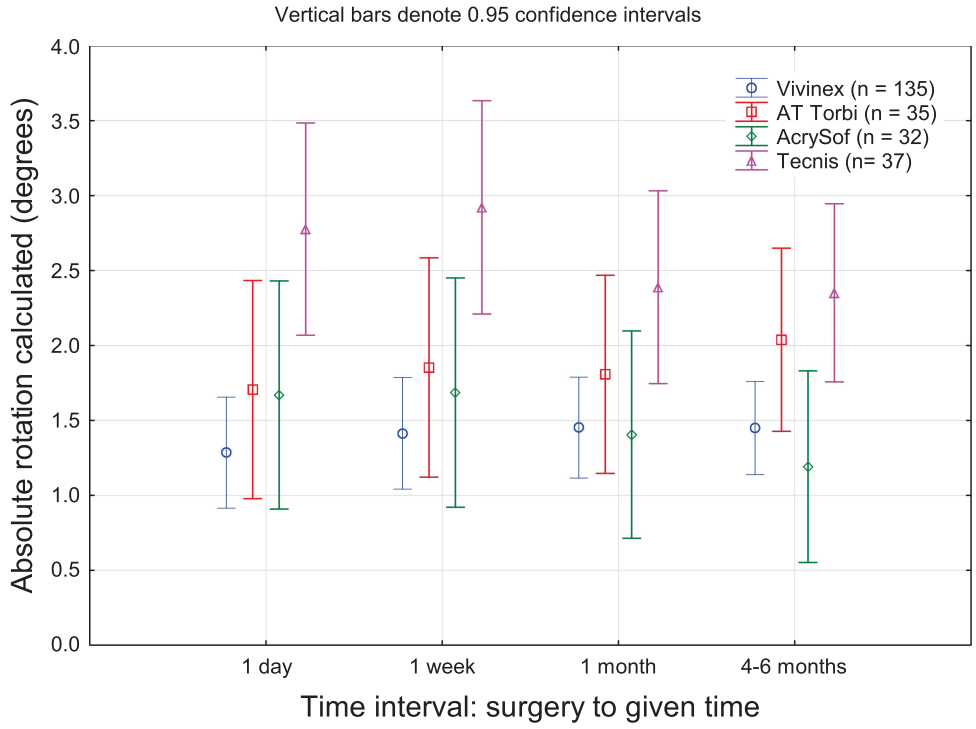


**Figure 3** Mean calculated absolute rotation from baseline at each time period by IOL type.

absolute rotation by time and IOL. A repeated measures analysis of variance for the absolute rotation by time and IOL showed a statistically significant difference by IOL ($p = 0.007$), driven primarily by the Tecnis lens (post-hoc testing with Tukey's Honestly Significant Difference test). The Vivinex lens had the lowest absolute rotation observed, with a mean less than 1.5 degrees for all time intervals measured. The AcrySof lens was next lowest, with a mean absolute rotation below two degrees. The Vivinex lens also showed the lowest variability in results, evident in the smaller 95% confidence interval shown.

Figures 4 and 5 show the distribution of the absolute measured rotation in the early postoperative period (surgery to one day postop, and surgery to one week postop, respectively). There was a statistically significant difference in absolute measured rotation by IOL between surgery and 1-day postop, and surgery and 1-week postop ($p < 0.01$ in both cases), driven by the difference between the results for the Vivinex and Tecnis lenses (post-hoc testing with Tukey's Honestly Significant Difference test).

Stability in the longer postoperative period was also of interest. Figure 6 shows the distribution of the absolute measured rotation between the 1 month and 4–6-month visits by IOL. There was a statistically significant difference in absolute measured rotation by IOL ($p = 0.02$), driven by the difference between the results for the Vivinex and AT Torbi lenses (post-hoc testing with Tukey's Honestly Significant Difference test). However, the mean difference in absolute rotation between these two lenses was less than 0.5 degrees (Vivinex: $0.6 \pm 0.55$, AT Torbi: $1.0 \pm 0.89$). There was only one lens that rotated more than 5 degrees in this time interval, a Tecnis lens that exhibited more than 20 degrees of rotation between the surgical and one-day visits; this lens was observed to have rotated 5 degrees back towards the targeted alignment at the 6-month visit.

The degree of absolute rotation in individual eyes was categorized in 5-degree increments. Results, by IOL and visit interval, are shown in Table 4. The AcrySof and Vivinex lenses were the only lenses with no rotations greater than 10 degrees reported at any visit interval. Furthermore, rotations within 5 degrees for AcrySof and Vivinex were 97% in contrast to only 90% and 90.7% for the Tecnis and AT Torbi lenses, respectively. Only six lenses exhibited rotation > 10 degrees in any of the visit intervals analyzed. One subject with a Tecnis lens had an absolute rotation > 20 degrees at 3 of their 5 visits, and one subject with an AT Torbi lens had an absolute rotation > 20 degrees between the operative and 1-week visits.

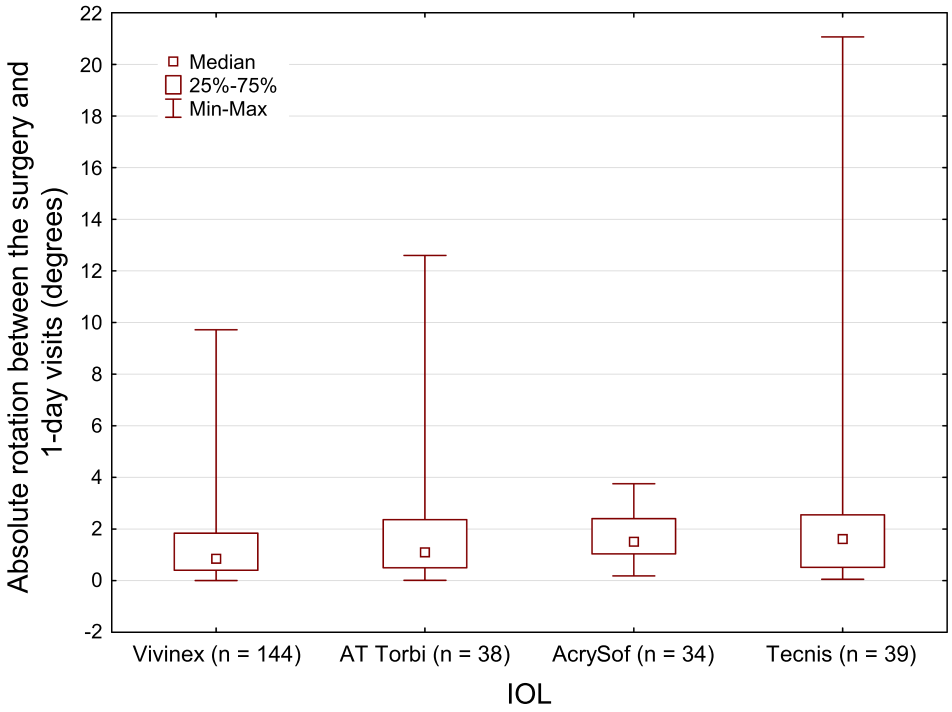


**Figure 4** Box-whisker plot of the absolute rotation calculated between the surgical and 1-day visits by IOL.


https://doi.org/10.2147/OPTH.S522728

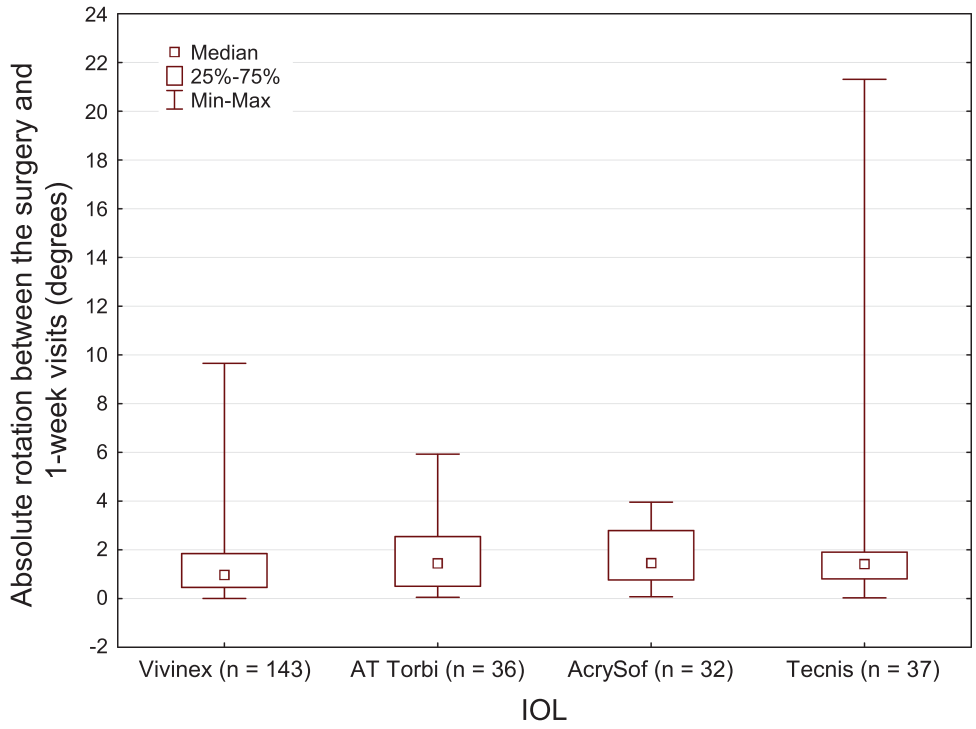


**Figure 5** Box-whisker plot of the absolute rotation calculated between the surgical and 1-week visits by IOL.

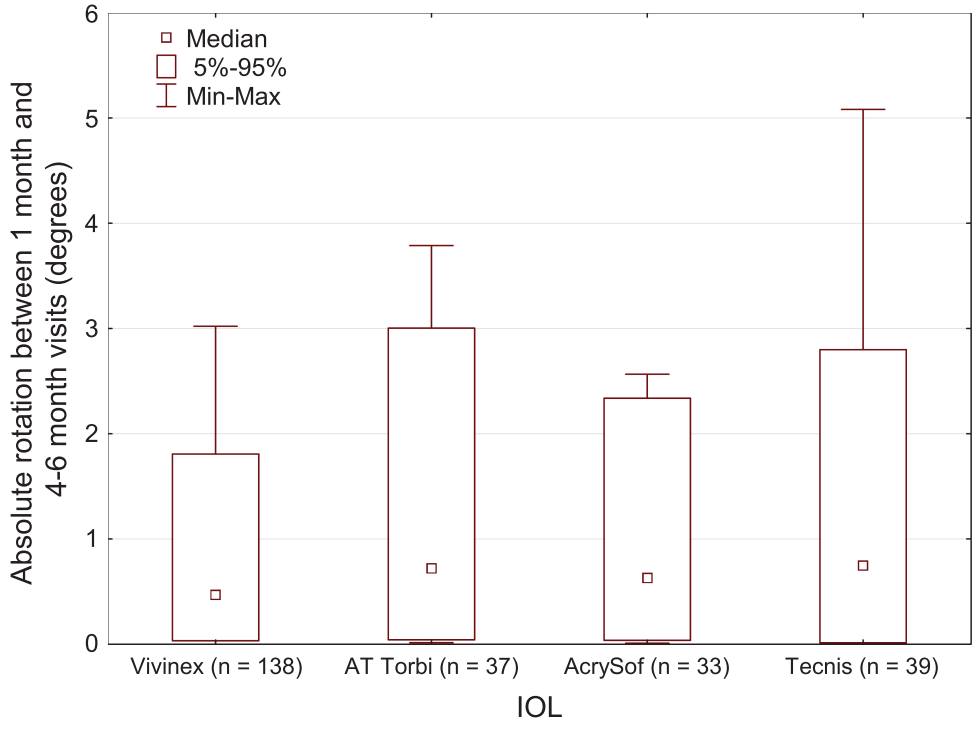


**Figure 6** Box-whisker plot of the absolute rotation calculated between the 1 month and 4–6 month visits by IOL.

For all eyes there were 4 secondary surgical interventions. One (AcrySof) involved repositioning a dislocated haptic and 3 (Tecnis) involved realignment of the IOL. Two of these latter cases were related to IOL rotation, while one was related to an axis transcription error in surgical planning. There were no other serious adverse device effects reported.

**Table 4** Categorized Distribution of Absolute Rotation Data

| Lens Model | Window | ≤5 Degrees | >5 and ≤10 Degrees | >10 and ≤15 Degrees | >15 and ≤20 Degrees | > 20 Degrees |
|---|---|---|---|---|---|---|
| Vivinex | V0 - V1 | 97.2% | 2.8% | | | |
| Vivinex | V0 - V2 | 97.3% | 2.7% | | | |
| Vivinex | V0 - V3 | 97.2% | 2.8% | | | |
| Vivinex | V0 - V4 | 97.3% | 2.7% | | | |
| Vivinex | V3 - V4 | 100.0% | | | | |
| AcrySof | V0 - V1 | 100.0% | | | | |
| AcrySof | V0 - V2 | 100.0% | | | | |
| AcrySof | V0 - V3 | 100.0% | | | | |
| AcrySof | V0 - V4 | 97.3% | 2.7% | | | |
| AcrySof | V3 - V4 | 100.0% | | | | |
| Tecnis | V0 - V1 | 90.0% | 2.5% | 2.5% | 2.5% | 2.5% |
| Tecnis | V0 - V2 | 87.2% | 2.6% | 7.7% | | 2.6% |
| Tecnis | V0 - V3 | 90.2% | 4.9% | 2.4% | | 2.4% |
| Tecnis | V0 - V4 | 90.2% | 4.9% | 2.4% | 2.4% | |
| Tecnis | V3 - V4 | 97.8% | 2.2% | | | |
| AT Torbi | V0 - V1 | 89.7% | 7.7% | 2.6% | | |
| AT Torbi | V0 - V2 | 92.5% | 5.0% | | | 2.5% |
| AT Torbi | V0 - V3 | 92.9% | 4.8% | 2.4% | | |
| AT Torbi | V0 - V4 | 90.7% | 4.7% | | 4.7% | |
| AT Torbi | V3 - V4 | 100.0% | | | | |

**Note**: V0 = surgery, V1 = 1 day, V2 = 1 week, V3 = 1 month, V4 = 4–6 months.

## Discussion

The analysis here was specifically related to evaluating the rotational stability of different toric IOLs. As the data shows, rotational stability of all lenses was very good. For both the Vivinex and AcrySof lenses there were no rotations >10 degrees in any time interval investigated; 97% or more of the lenses from these two companies rotated ≤5 degrees. Rotational stability of the Tecnis and AT-Torbi IOLs was slightly worse, with several lenses of each IOL model exhibiting rotations > 10 degrees.

Schartmüller et al applied the technique they pioneered, and the one used in the current study (described previously),[11] to a rotational stability study of a non-toric version of the Vivinex IOL over a 6-month period.[13] They reported that no IOL rotated more than 5 degrees, which appears consistent with the results found in the current study. Mean absolute rotations reported over the time periods they evaluated were 1.5 degrees or less, again consistent with the current study. Haptic design, lens diameter and material were not modified; these appear to be the primary factors associated with IOL rotational stability. The addition of a toric design element to the Vivinex platform had no apparent impact. As previous authors have noted, axial length does not appear correlated to IOL stability.[14]

Schartmüller et al also evaluated the rotational stability of the non-toric versions of the AcrySof and Tecnis IOLs in a separate study, using the same technique.[15] Their results appear quite similar to those found for these lenses in the current study. Mean absolute rotation results were slightly better for the AcrySof than the Tecnis toric, consistent with the findings in the current study. However, they found slightly more outliers (rotations > 10 degrees) for the AcrySof lens than were found in the current study. Koshy et al reported higher levels of rotation for the toric version of the AcrySof lens than were


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found in the current study.[16] While their study incorporated digital photography, head positioning was performed manually, to the best of the examiner's ability, and there was no compensation for cyclotorsion.

Rotational stability of the AT Torbi lens was previously evaluated by Shi et al[17] and Bascaran et al.[18] In both studies there were significantly higher rotations reported than were found in the current study. However, their evaluations were based on slit lamp microscopy. Head tilt and cyclotorsion would add considerable variability to the orientation measurements with that methodology.

The results in Table 4 and Figures 4–6 corroborate previous observations that rotation primarily occurs in the early postoperative period.[15,17] One known contributing factor to very early rotation is lack of adhesion to the capsule because of retained ophthalmic viscosurgical device (OVD). Thorough irrigation and aspiration of OVD is important to rotational stability.[19] The changes from 1 to 3 months were less frequent and lower magnitude than those from the surgical visit to 1 day, particularly for the Tecnis and AT Torbi lenses, where more rotations >5 degrees were observed.

There are some limitations to the current study. First, IOL orientation could not be determined in about 10% of all images due to image quality or pupil size issues. Second, outliers or extreme values for IOL rotation are rare, and the subject numbers in the current study were limited – a larger data set would be helpful to corroborate the findings here. Third, while some basic biometric characteristics were evaluated for correlation to rotational stability, data for more detailed analyses (eg capsular bag size, anterior capsule coverage,[20] change in lens position[21] or capsular bend[22]) were not available. Detailed surgical information such as viscoelastic choice, or wound closure technique was also not available for analysis. Finally, the study included the original design of the Tecnis toric IOL. Since this study was conducted, the rotational stability of the Tecnis lens was a recognized concern. The lens was redesigned to improve its performance. Stability data for the new lens are available in the literature and appear to be better than for the original design.[23,24] In addition, Alcon has developed a new material (Clareon™) and is migrating their IOL portfolio to this material. Results from a recent study indicate that the rotational stability of the Clareon toric IOL is consistent with its predecessor, demonstrating very good postoperative rotational stability.[25]

## Conclusion

High resolution digital photography and computer-assisted analytical techniques are an excellent method to evaluate the rotational stability of toric IOLs, provided that stable ocular landmarks are available for reference. These two requirements appear necessary for reliable measurement of rotational stability, a similar conclusion to that of Viestenz et al and Wolffsohn et al in earlier studies.[26,27] Using such techniques, results here indicate that toric IOLs are very rotationally stable once implanted. The Vivinex and the AcrySof lenses demonstrated the best overall rotational stability, with 97% of all measurements showing less than 5 degrees of rotation, and all measurements showing less than 10 degrees of rotation, from baseline orientation at the time of surgery.

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