· Clinical Research ·

# Association between axial length and toric intraocular lens rotation according to an online toric back-calculator

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## Abstract
● **AIM:** To assess the relationship between axial length (AL) and intraocular lens (IOL) rotation among eyes receiving a toric IOL and subsequently entered into an online toric back-calculator database.

● **METHODS:** Retrospective analysis of data collected online *via* astigmatismfix.com, a freely available online toric back-calculator where surgeons enter pre- and post-operative information to help manage residual postoperative astigmatism. Included records were deemed valid with entry of AL and IOL orientation between January 2017 and March 2019. Rotation was determined by a difference of ≥5° between pre-operative intended IOL orientation and actual post-operative IOL orientation. Frequency and magnitude of rotation are presented with means and associated standard deviation (SD). Linear regression models of this association are presented.

● **RESULTS:** Records of 6752 eyes were included in the analysis, of which 74.8% were determined to have a rotated IOL. The magnitude of rotation increased with each millimeter (mm) increase in AL with a mean rotation of 13.3° (SD: 12.8°) for eyes with AL 20-20.9 mm and a maximum mean rotation of 30.6° (SD: 30.3°) among eyes with AL 29-29.9 mm. General linear modeling demonstrated a significant association ($P$<0.0001) with a parameter estimate of 1.19 (standard error: 0.159) and $R^2$ of 0.0083.

● **CONCLUSION:** Analysis from an online database indicates that toric IOLs inserted into eyes with longer AL are more likely to rotate and to rotate more degrees from the target axis. The findings from this study are clinically relevant for surgeons implanting toric IOLs.

● **KEYWORDS:** cataract surgery; toric lens; axial length; rotation

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## INTRODUCTION

Many patients presenting for cataract surgery have preexisting corneal astigmatism. These patients may benefit from implantation of a toric intraocular lens (IOL). In a systematic review and Meta-analysis of eleven randomized clinical trials, Kessel *et al*[1] found that the 707 eyes randomized to toric IOLs were more likely to have better uncorrected distance visual acuity and spectacle independence postoperatively compared to 706 eyes randomized to non-toric IOLs. Additional published systematic review were consistent with this finding that astigmatism correction during cataract surgery improves uncorrected visual acuity[2] and also reduces cost burden of postoperative vision correction[3].

Toric IOLs were first made and used to correct for corneal astigmatism in 1994 and received United States Food and Drug Administration approval in 1998[4]. In a global systematic review, the prevalence of astigmatism ≥1 D was present in 23%-47% of cataract eyes across the 18 included studies[3]. Despite the high rate of preoperative astigmatism, data from two annual American Society of Cataract and Refractive Surgery (ASCRS) clinical surveys report that only 10% of implanted IOLs are toric lenses and, on average, only 20% of patients presenting with astigmatism received toric IOLs[5-6]. The additional cost of a toric IOL is not typically covered by insurance or Medicare which likely contributes to their under-utilization. The added time burden on clinicians due to the additional explanation of risks and benefits associated with toric lenses as well as lack of confidence in ultimate outcomes due to rotational instability may also contribute to the lower rate of toric IOL implantation in patients who qualify for astigmatic correction.

Residual astigmatism post implantation of a toric IOL occurs when the lens has the wrong amount of cylinder power or when axis misalignment occurs due to implantation error or post implantation rotational instability. A significant amount of residual astigmatism can lead to decreased vision and vision-related quality of life. Alignment of the toric lens is more important than with conventional IOLs because small differences in positioning can cause residual astigmatism and blurred vision. It has been reported that ten degrees of misalignment reduces the toric IOL's effectiveness by 30%[7]. Deviations from the intended lens orientation may be a result of inaccurate placement or postoperative rotation. While toric IOL rotation can occur up to one month post-operatively, the majority has been shown to occur within the first hour[8-9]. Determining which patients are at an increased risk of rotational instability can assist physicians in identifying the best candidates for toric IOLs.

A freely available toric back-calculation website (astigmatismfix.com) was designed by Drs. John Berdahl and David Hardten to help surgeons manage postoperative residual astigmatism. The website allows surgeons to enter the patient's postoperative manifest refraction and IOL cylinder power and orientation to determine the ideal location for the IOL and estimated refraction, if the IOL axis is oriented to that location. Axial length (AL) has been shown to be a potential predictor of rotation among toric IOLs in a couple of published studies, but no association was observed in one recent study[8,10-11]. The purpose of the present study was to assess the association between AL and IOL rotation after implantation of toric IOLs among records entered into Astigmatismfix.

## SUBJECTS AND METHODS

**Ethical Approval** Patient information is not collected in the database. The University of North Carolina, Office of Human Research Ethics was contacted regarding this study and determined that it did not constitute as human subjects research as defined under federal regulation and further Institutional Review Board approval was unnecessary.

Astigmatismfix was launched in 2012. From January 2017 through March 2019, several optional fields, including AL, were available for surgeons to enter. This study included records from the database during this timeframe in order to include records that had AL data. Entries were filtered *via* criteria in Table 1 to remove erroneous and non-sensical data. Entries labeled as duplicates or theoretical (options that users select when making entries) were eliminated. In a further attempt to eliminate any duplicate entries representing a single patient, if there were multiple entries made by the same person on the same calendar day, only the first entry was used, and subsequent entries were eliminated. This validation process for the dataset has been described and used previously as other publications have utilized this source of data[7,12-15].

**Table 1 Filtering criteria**

| Laterality | Right/left eye |
|---|---|
| Intended IOL axis | 0 to 180° |
| MRx sphere | -6 to 6 D |
| MRx cylinder | 0.5 to 6 D |
| MRx axis | 0 to 180° |
| IOL cylinder power | 0 to 10 D |
| IOL spherical equivalent | 5 to 34 D |
| IOL axis | 0 to 180° |

IOL: Intraocular lens; MRx: Manifest refraction.

In addition to the filtering process, records were excluded if they were missing data elements for AL, the primary explanatory measure for this study. The main outcome was degrees of rotation, which was measured as the smallest absolute change between the original intended axis and current post-operative axis. The database also includes data regarding laterality of eye, residual refractive astigmatism, and anterior chamber depth (ACD), in addition to other fields not included in the present analysis.

**Statistical Analysis** Data entries were downloaded from the online website into Excel and imported into SAS version 9.4 for analysis (Cary, North Carolina, USA). The amount of rotation was analyzed as a continuous variable bounded between zero and 90°. Since amount of rotation can be defined differently, the frequency of rotation was summarized at three different cut-point levels: ≥5°, ≥10°, and ≥15°. AL was grouped into ten categories of one-millimeter unit each from 20.0 to 29.9 mm for tables and box plots. Mean, standard deviation (SD), and median rotations were presented by one-millimeter category of AL for all eyes and a sub-analysis of eyes with ≥5° of rotation.

Univariate and multivariable linear regression modeling were utilized to examine the association between the independent variable AL and rotation as the outcome, both as continuous variables. Rotation was also evaluated after log-transformation (base e with an anchor at 1) in order to normalize the data and to assess improvement in model fit. Multivariable modeling included residual refractive astigmatism and ACD as potential confounding variables.

## RESULTS

The initial data set following the filtering process contained 28 712 records. After excluding records that did not contain AL data, 6752 (23.5%) records were included in the final analytic dataset. The median residual refractive astigmatism was 1.5 D with an interquartile range of 1.25 to 2.25 D (Table 2). The overall rate of rotation ≥5° was 74.8% for all eyes in the dataset with a range of 67.2% for eyes with ALs in the ≥21.0 to <22.0 mm category to a maximum of 84.8% in eyes with ALs ≥28.0 to <29.0 mm (Table 3). The same trend was observed with rotation at cut-points of ≥10° and ≥15°.

As presented in Table 4, most of these records had ALs between 22.0 and 27.0 mm (88.9%), however, there were some records with ALs at the most extreme categories of 20.0 to <21.0 mm (*n*=78) and 29.0 to <30.0 mm (*n*=24). The mean and median rotation increased as AL category increased. Median rotation ranged from a minimum of 10.0° for eyes with AL 21.0 to <22.0 mm to a maximum of 28.5° for eyes with AL 29.0 to <30.0 mm. The variability of mean rotations were large across all categories of AL as demonstrated in the Figure 1 box plots. A sub-analysis of eyes that rotated ≥5° is also shown in Table 4. Mean and median summary measures demonstrate a similar consistent increase in rotational magnitude for longer AL categories.

A scatter plot of AL and magnitude of rotation is shown in Figure 2 with an estimated prediction line indicated in red. Univariate linear regression modeling resulted in a parameter estimate of 1.19 (SE: 0.159) with a high level of significance ($P$<0.0001) and low $R^2$ of 0.0083. When rotation was log-transformed (base e with anchor at 1), the parameter estimate was 0.09 (SE: 0.010) with a high level of significance ($P$<0.0001) and an $R^2$ of 0.0126. Multivariable modeling including residual refractive astigmatism and ACD as continuous variables did not change the *P*-value or appreciably change the parameter estimate or $R^2$.

**Table 2 Characteristics of the eyes in the analytic dataset** *n*=6752

| Characteristics | *n* (%) |
|---|---|
| Laterality | |
| Right eye | 3510 (52.0) |
| Left eye | 3242 (48.0) |
| Residual refractive astigmatism category | |
| 0.5-1.00 D | 1555 (23.0) |
| 1.01-2.0 D | 3288 (48.7) |
| >2.0 D | 1909 (28.3) |
| Residual refractive astigmatism continuous (D) | |
| Mean (SD) | 1.88 (1.07) |
| Median (IQ range) | 1.5 (1.25-2.25) |
| Axial length (mm) | |
| Mean (SD) | 24.3 (1.55) |
| Median (IQ range) | 24.1 (23.2-25.2) |

D: Diopter; SD: Standard deviation; IQ: Interquartile.

**Table 3 Frequency of rotation ≥5°, ≥10°, and ≥15° by axial length category** *n* (%)

| Axial length (mm) | Rotation ≥5° | Rotation ≥10° | Rotation ≥15° |
|---|---|---|---|
| 20.0 to <21.0 | 53 (68.0) | 43 (55.1) | 32 (41.0) |
| 21.0 to <22.0 | 197 (67.2) | 150 (51.2) | 110 (37.5) |
| 22.0 to <23.0 | 652 (69.1) | 520 (55.1) | 405 (42.9) |
| 23.0 to <24.0 | 1281 (73.0) | 1044 (59.5) | 812 (46.3) |
| 24.0 to <25.0 | 1287 (76.2) | 1080 (63.9) | 849 (50.2) |
| 25.0 to <26.0 | 853 (78.1) | 740 (67.8) | 613 (56.1) |
| 26.0 to <27.0 | 415 (79.2) | 360 (68.7) | 297 (56.7) |
| 27.0 to <28.0 | 217 (83.1) | 190 (72.8) | 163 (62.4) |
| 28.0 to <29.0 | 78 (84.8) | 61 (66.3) | 49 (53.3) |
| 29.0 to <30.0 | 18 (75.0) | 16 (66.7) | 13 (54.2) |
| Total | 5051 (74.8) | 4204 (62.3) | 3343 (49.5) |

## DISCUSSION

The primary finding of this study is that AL is significantly and positively associated with rotational instability in regards to both frequency and magnitude. Implantation of a toric IOL can provide spectacle freedom for patients with preoperative corneal astigmatism, however, a concern of toric IOLs is rotational stability. While surgeon practice has typically taken AL into consideration when selecting and counseling patients prior to preoperative lens selection, there is a general lack of data to inform such decisions and conversations, especially surrounding toric IOLs. This study lends insight into the relationship between rotation and AL and may help direct the decision-making process for both lens selection as well as setting expectations for post-operative outcomes and potential for needed secondary interventions to enhance outcomes.

To date, this is the largest study to assess the association between AL and toric IOL rotational stability. The linear regression models indicate that AL and rotation are highly associated ($P$<0.0001), however, the $R^2$ is low which indicate that only about 1 percent of the variability in rotation is explained by AL. The data show a very consistent direct relationship of rotation increasing with each level of AL when rotation is measured in terms of both magnitude and frequency. Rotation was highly variable and bounded between 0 and 90, and there were many eyes not close to the regression line which resulted in a low $R^2$. Therefore, the association between these variables is weak, but the significant *P*-value indicates that we are confident that the slope of the association is positive. Given the variability remaining in the outcome with this dataset, AL alone could not be used to identify subjects who are more likely to rotate.

Previous published studies on this specific topic have examined rotational stability for one specific type of lens or compared two different lens models. Lee and Chang[8] determined eyes implanted with AcrySof (Alcon) toric IOLs (*n*=626) had greater rotational stability than the TECNIS toric IOL (Johnson & Johnson) (*n*=647), and rotational magnitude for both lenses was associated with AL ($P$<0.01 for both) but an estimate of the magnitude of association and goodness of fit statistics were not provided. Zhu *et al*[16] studied 75 patients implanted

**Table 4 Average amount of rotation by category of axial length for all eyes and eyes that rotated ≥5°**

| Axial length (mm) | All eyes | | | Eyes ≥5° rotation | | |
|---|---|---|---|---|---|---|
| | Number of records | Mean rotation degrees (SD) | Median rotation degrees | Number of records | Mean rotation degrees (SD) | Median rotation degrees |
| 20.0 to <21.0 | 78 | 13.3 (12.8) | 11.5 | 53 | 19.0 (11.8) | 16.0 |
| 21.0 to <22.0 | 293 | 17.3 (21.1) | 10.0 | 197 | 25.1 (21.7) | 18.0 |
| 22.0 to <23.0 | 944 | 17.7 (21.0) | 11.0 | 652 | 25.1 (21.4) | 17.0 |
| 23.0 to <24.0 | 1754 | 18.5 (20.0) | 13.0 | 1281 | 25.0 (19.8) | 19.0 |
| 24.0 to <25.0 | 1690 | 19.9 (20.1) | 15.0 | 1287 | 25.8 (19.5) | 20.0 |
| 25.0 to <26.0 | 1092 | 21.3 (20.3) | 16.0 | 853 | 26.9 (19.5) | 21.0 |
| 26.0 to <27.0 | 524 | 21.6 (20.1) | 17.0 | 415 | 26.9 (19.2) | 21.0 |
| 27.0 to <28.0 | 261 | 24.0 (20.2) | 20.0 | 217 | 28.6 (19.2) | 23.0 |
| 28.0 to <29.0 | 92 | 21.8 (20.0) | 15.6 | 78 | 25.5 (19.6) | 18.0 |
| 29.0 to <30.0 | 24 | 30.6 (30.3) | 28.5 | 18 | 40.6 (28.6) | 30.5 |
| Total | 6752 | 19.6 (20.3) | 14.0 | 5051 | 25.8 (19.9) | 20.0 |

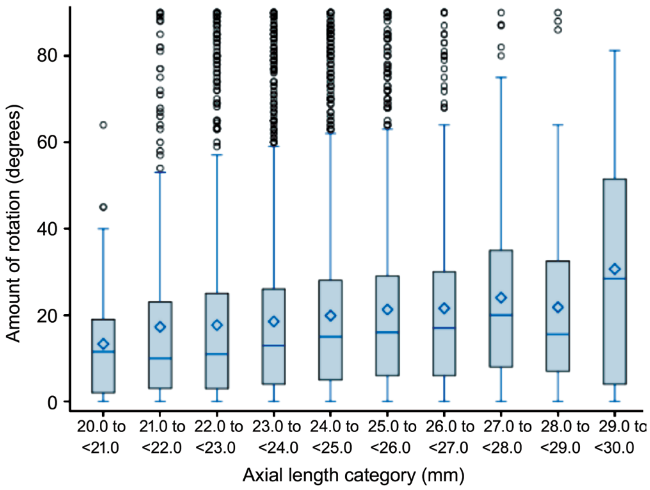


**Figure 1 Box plots of rotation by category of axial length.**

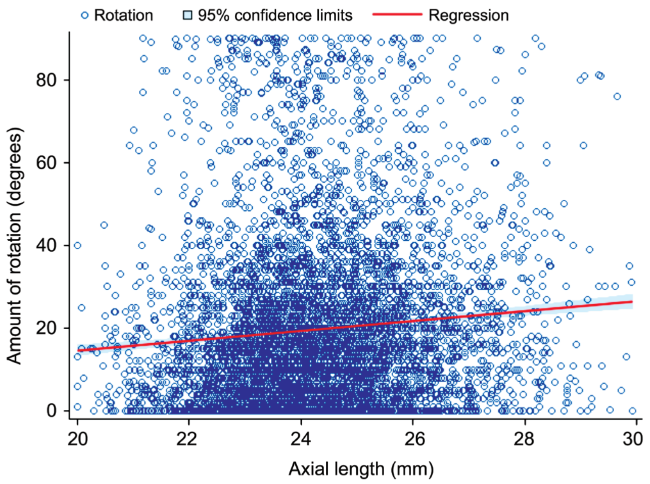


**Figure 2 Scatter plot and prediction line of amount of rotation and axial length.**

with AcrySof toric IOLs and found a Pearson's correlation coefficient of 0.335 ($P$=0.003) between AL and degrees of rotation. There is also one recent study that concluded no significant association between rotation and AL, however, this study examined AL only as a categorical variable with two large categories for the 65 patients (≤24 mm or >24 mm) opposed to the much more precise categories and the continuous variable regression analysis presented in our study[11]. Our current study may have large variability of rotation in respect to AL due to the fact that included records are much more heterogeneous regarding both the patients' eyes and the performing surgeons compared to the results shown by Zhu *et al*[16]

The associated mechanism between toric IOL rotation and AL is not necessarily a direct cause. Rather, it is thought that increased AL is associated with a larger capsular bag diameter which in turn allows for more rotational instability. There currently isn't a widely available way to directly measure the capsular bag dimensions *in vivo*, with ultrasound biomicroscopy being largely unavailable and/or cost prohibitive in many settings. However, the association between AL and capsular bag diameter was shown to be true in a postmortem study measuring lens diameter and also an *in vivo* study which measured the capsular bag indirectly *via* a capsular tension ring[17-18]. The capsular bag diameter theory was established in earlier toric studies which evaluated rotational stability in toric IOLs with plate-haptics and found increased rotation both in longer eyes and when shorter diameter IOLs were used[19]. Today, the majority of toric IOLs used are on single-piece acrylic platforms, and their maximum haptic diameters (13.0 mm)[20-21] are much wider than most capsular bags (9.83-10.88 mm)[18]. However, it is possible that IOLs aren't completely unfolded to their maximum diameter prior to the end of the case which allows for rotational instability in the acute post-operative period, especially for those with longer ALs (*i.e.,* larger capsular bags). This would partially explain why the majority of IOL rotation has been shown to occur within the first hour post-operatively[8-9]. Additionally, the design of intraocular lenses are intended to address the average capsular bag diameter. The outward force of haptics on the capsular bag is influenced by the size of the capsular bag diameter. Thus, larger bags experience less force from the unfolded haptics compared to average or smaller bags and may therefore lead to more rotational instability during the early post-operative period. Past attempts at using capsular tension rings to further stabilize implanted lenses in high AL eyes has been met with inconsistent results[8,10]. It is also possible that zonular instability or mechanistic details of the capsular bag other than diameter may also be playing a role in toric IOL instability in longer eyes.

Regarding the clinical significance of these findings, we can again say with certainty that when toric IOLs are placed in eyes with longer ALs they have higher frequency of rotating away from the intended axis, and that they typically rotate further from the intended axis compared to eyes with shorter ALs. As an example, the least stable AL groups (28.0 to <29.0 mm AL and 27.0 to <28.0 mm AL) are 1.3 times more likely to rotate ≥5° and 1.4 times more likely to rotate ≥15° than the most stable AL group (21.0 to <22.0 mm AL). While post-operative rotation with modern toric IOLs has improved compared to past IOL designs, there remains an issue with clinically significant rotation in some patients and, as we show in this current analysis, rotation is more likely in eyes with longer ALs. Our findings will help guide physicians and patients about expectations and the higher potential for rotation of toric IOLs in eyes with longer ALs. Our findings will also help in improving pre-operative counseling of patients on the potential need for secondary interventions in the event an IOL rotates to a level that influences visual outcomes, which again is shown to be more likely in eyes with longer ALs.

This online toric back calculator system has a primary purpose of assisting surgeons with lens orientation post-operatively and is not ultimately designed for research. As a result, there are several limitations to this study. It is unknown whether the lens rotated or was inserted incorrectly, however, it is unlikely that surgeon error would differ by AL and impact our findings. AL was an optional field captured for only slightly over two years, therefore, there were many records entered into Astigmatismfix that were not included in the analysis due to missing data. In addition, our dataset includes post-operative eyes that are much more likely to have rotated compared to all toric IOLs implanted during cataract surgery (75 rotated ≥5° in our dataset, simply because this set or eyes entered into the calculator have residual astigmatism to start with)[1,8]. It has been estimated that data from Astigmatismfix only represents about 1 of all toric IOLs implanted, and therefore findings from the present study may not represent all toric IOLs[12]. Finally, since data do not include patient information, there is no way to validate data or account for the correlation of patients potentially having two eyes included in the analysis.

The main strength of our study is the large number of records available for analysis. The large number of records allows for the ability to include eyes with extremes of the measurement spectrum and to determine summary measures of rotation at each specific unit level of AL. We conclude that rotational instability is positively and significantly associated with AL. Additional studies with validated patient data would strengthen findings from this study. Finally, new technologies that could help address enhanced stability of toric lenses across the spectrum of ALs and capsular bag diameters may enhance surgeon confidence and patient acceptance, ultimately leading to more broad adoption of astigmatic correction at the time of cataract surgery.

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