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Astigmatism Management With Toric IOLs – The Importance of Rotational Stability After IOL Implantation

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Introduction

Cataracts, or clouding of the crystalline lens, are highly prevalent in the United States. Starting around age 40 and beyond approximately 18% of the population experience cataracts and in 2010 nearly 25 million people were found to have cataracts.[1] In 2015, nearly 4 million cataract procedures were performed[2] and that number increases each year. Cataract surgery is generally considered a safe and effective procedure for improving a patient's best-corrected visual acuity. Importantly, a growing number of patients expect some level of spectacle independence after the procedure.[3] To achieve this, the correction of astigmatism, even small amounts, is an important component of cataract treatment.[4]

Cataract Surgery, Astigmatism, and Toric IOLs

Preexisting corneal astigmatism is a common factor in postoperative refractive error in patients undergoing cataract surgery. It has been estimated that up to 52% of patients have preoperative corneal astigmatism of 0.75 D or greater and over 71% have 0.50 D or more[5] (Figure 1). It is interesting that given the prevalence of preoperative corneal astigmatism, a relatively low number of toric IOLs are implanted in the US. Since 2010, toric IOLs account for only 6% to 8% of all cataract procedures.[6] This indicates that a large number of patients are undergoing cataract surgery without having their astigmatism addressed. Treating even small amounts of astigmatism can result in notable improvements in vision if corrected accurately.[7]

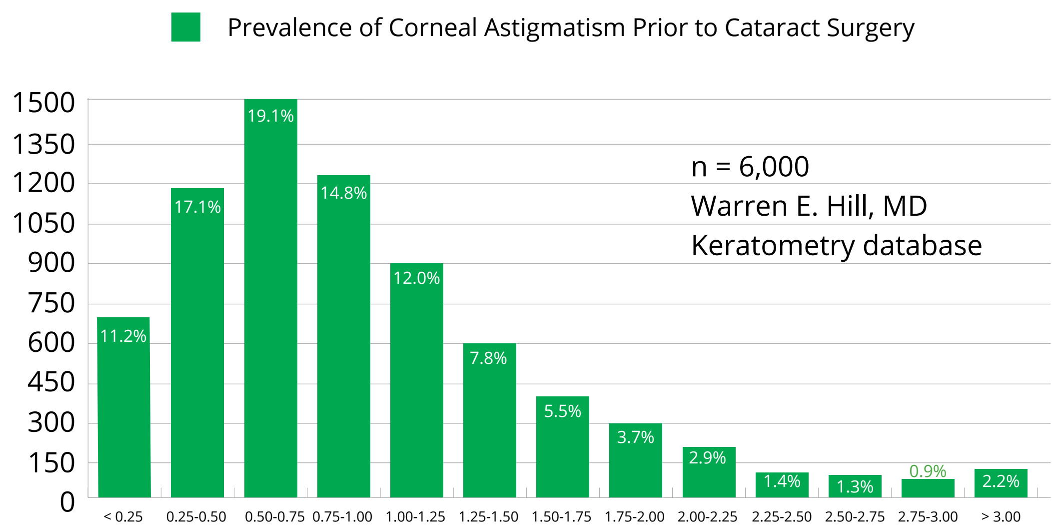


Figure 1: Distribution of Preoperative Corneal Astigmatism

Effects of Astigmatism on Vision

Quality of vision is decreased when astigmatism is not addressed, particularly in context of visual acuity, Low Contrast Visual Acuity (LCVA), and Functional Visual Acuity (FVA). Because traditional visual testing is performed under high contrast conditions, LCVA and FVA are used to more accurately assess an individual's visual performance in relation to certain daily activities such as driving, reading, and computer use. FVA has been linked to postoperative patient satisfaction.[8] A significant decrease in FVA can been observed with astigmatism as low as 0.50 D, cases in which uncorrected visual acuity of 20/20 is measured under high contrast conditions.[9] Testing with increasing amounts of astigmatism showed the ability to achieve 20/20 visual acuity using conventional methods despite decreasing FVA scores (Figure 2). Decreased LCVA with increasing amounts of astigmatism has also been reported.[10]

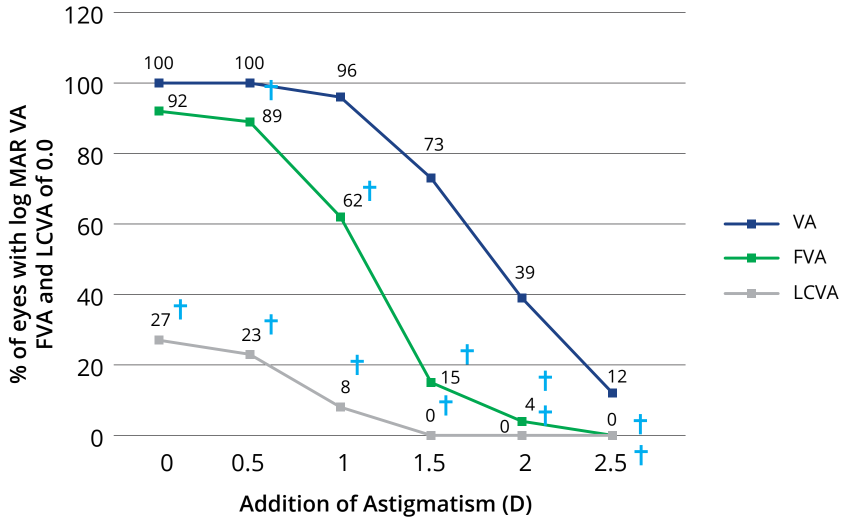


Figure 2: Percentage of eyes with log MAR VA, FVA and LCVA of 0.0 (20/20) with addition of different value of astigmatism (ATR). † Represent statistically significant comparisons of VA with FVA and LCVA (P<0.05)

High contrast visual acuity measurements appear to be good even with up to 1.00D of astigmatism. However, testing measuring FVA and LCVA, more sensitive measures of quality of vision, show a significant drop off between 0.50 D and 1.00 D of astigmatism. Other studies have shown that astigmatism as low as 0.50 D can result in subjects describing their vision as unacceptable.[11] Low amounts of astigmatism can decrease functional vision. This demonstrates that consideration should be given to treating even low amounts of astigmatism.

Treating Astigmatism at the Time of Cataract Surgery

Two methods exist to address astigmatism at the time of cataract surgery, corneal relaxing incisions, created either manually or with a femtosecond laser, and implantation of a toric IOL. It has been demonstrated that using toric IOLs can provide better uncorrected distance visual acuity and greater spectacle independence for distance vision compared to non-toric IOLs with or without limbal relaxing incisions.[12] However, despite the favorable efficacy of toric IOLs, It has been reported that 30% or more patients have more than 0.50 D of postoperative refractive astigmatism.[13] This could be the result of inaccurate cylinder power calculations, incorrect placement of a toric IOL, or postoperative rotation of a toric IOL. As mentioned above, Lee and Chang outline methods that help ensure more accurate outcomes in astigmatic management cases in which toric IOLs are implanted. These methods are highlighted in Figure 3 below.

Accurate pre-operative biometric measurement and IOL power and axis calculations

- Control of ocular surface disease (dry eye) to ensure precise biometric measurement
- Account for the surgeon induced astigmatism (SIA) and posterior corneal astigmatism (PCA)
- Consider the effective lens position (ELP) and IOL spherical equivalent power effect.

Accurate intra-operative toric lens alignment with the axis of astigmatism

Post-operative IOL rotational stability

Both intraoperative misalignment and postoperative rotation will lead to off-target orientation of the IOL.

Figure 3: Critical factors for optimal astigmatism correction with toric IOLs

A number of important factors are involved in achieving an optimal refractive outcome in a toric IOL case. Even with accurate preoperative measurements, accurate cylinder power calculations accounting for SIA and the contribution of the posterior cornea, accurate spherical power calculation, and precise intraoperative placement, if an IOL platform does not demonstrate good postoperative rotational stability, it will be difficult to provide consistent refractive results. Postoperative IOL rotational instability has been reported since the introduction of toric IOLs in the 1990's.[14] Although advancements have been made including improvements in IOL material, IOL design and surgical technique, IOL rotational instability can still be a contributing factor in postoperative refractive surprises.

Toric IOL Rotational Instability

Incidence and amount of postoperative toric IOL rotation

With improvements in toric IOL design and materials, postoperative lens rotation is rare. If a lens rotates, the average amount of rotation is usually less than 5 degrees.[12] However, when postoperative rotation does occur, the percentage of cases for which rotation is more than 10 degrees can range up to 20% depending on IOL model.[13]

Time course of postoperative Toric IOL rotation

Postoperative IOL rotation is typically analyzed by assessing changes in orientation from the baseline, typically Day 1 postoperatively. It had been accepted that the greatest rotation occurred in the early postoperative period, typically within the first month postoperatively.[15] However, a recent prospective study examining the Tecnis* Toric platform demonstrated that the greatest rotation occurred within one hour after surgery. Further, IOL orientation was highly stable after the first postoperative day. In this study some misalignment was due to intraoperative misalignment.[16] However, the study did not incorporate a digital marking system.

** Tecnis is a trademark of Abbott Medical Optics Inc.*

Potential cause of toric rotational instability

Numerous factors have been identified that might affect the likelihood of postoperative toric IOL rotation as outlined in Figure 4.

Patient or surgeon related:

- Long axial length/large capsular bag
- Large capsulorhexis size or poor centration
- Weak zonules
- Orientation of intended toric IOL axis (vertical axis)
- Preoperative astigmatism (power)
- Incomplete removal of ophthalmic viscosurgical devices (OVD)
- Change in intraocular pressure

IOL model related:

- IOL material
    - Adhesion to capsular bag (strongest with Hydrophobic acrylic, followed by hydrophilic acrylic, PMMA and silicone
    - Thickness due to difference in refractive index
- IOL design
    - IOL overall diameter
    - Haptic design (plate or loop haptic)

Many of these factors are interrelated

Figure 4: Potential factors leading to postoperative Toric IOL rotation

Previous studies suggested that different IOL models might have different rotational stability, possibly related to IOL material or design. For example, The STAAR* toric IOL TL model was found to have better rotational stability than TF model. Both toric lenses are made of same silicone material with same optic design except the overall IOL length (TL- 11.2 mm; TF- 10.8 mm).[17] A retrospective study using the surgeon inputted data at the astigmatismfix.com website, compared the rates of significant misalignment (≥5 degree) in four most frequently used IOL models in US. It was found that the Tecnis* Toric was 2.5 times more likely to be misaligned than the Alcon AcrySof® Toric ($p<0.0001$). The rates of misorientation were calculated to be 1.86% for the Tecnis* Toric compared to 0.75% for the Alcon AcrySof® Toric. It was also reported that the Tecnis* Toric IOL appeared more likely to be misaligned in a counterclockwise direction.[18] One important note about this study is that based on the information supplied to astigmatismfix.com, it could not be determined if misalignment was the result of inaccurate intraoperative lens placement or postoperative lens rotation.

** STAAR is a trademark of STAAR Surgical.*

The Impact of Postoperative Toric IOL Rotation

Postoperative toric IOL rotation results in unexpected postoperative astigmatism, which affects postoperative visual acuity, functional visual acuity, quality of vision, and patient satisfaction. A toric IOL has its maximum astigmatic correction effect when aligned with the patient's axis of astigmatism. Any misalignment will results in more postoperative refractive astigmatism than expected. Misalignment will also result is a shift in the axis of postoperative refractive astigmatism, occasionally resulting in oblique astigmatism.

Theoretical calculations and clinical studies have demonstrated that every degree of misalignment reduces a toric IOL's effectiveness by approximately 3.3%. If a toric IOL is misaligned by 30 degrees, the effectiveness of the lens will theoretically be reduced by 100%.[19] Table 1 shows the theoretical values of residual astigmatism may occur with toric IOL rotation or misalignment with the theoretical toric IOL powers at the corneal plane.

Astigmatism at Corneal Plane (D)	OFF AXIS 5°	OFF AXIS 10°	OFF AXIS 20°	OFF AXIS 30°
0.75	0.12	0.25	0.50	0.74
1.00	0.17	0.33	0.66	0.99
1.50	0.25	0.50	0.99	1.49
2.00	0.33	0.66	1.32	1.98
3.00	0.50	0.99	1.98	2.97
4.00	0.66	1.32	2.64	3.96

Table 1: Theoretical Calculation of the Residual Astigmatism with Toric IOL Misalignment

It is important to note that in addition to an effective reduction of cylinder power, toric IOL misalignment also results in astigmatism being created at a different axis. This is a crossed cylinder effect cause by a misalignment of the toric IOL cylinder axis with respect to the corneal axis of astigmatism. Figure 5 demonstrates the cross cylinder effect in an eye with 2.00 D of against the rule corneal astigmatism.

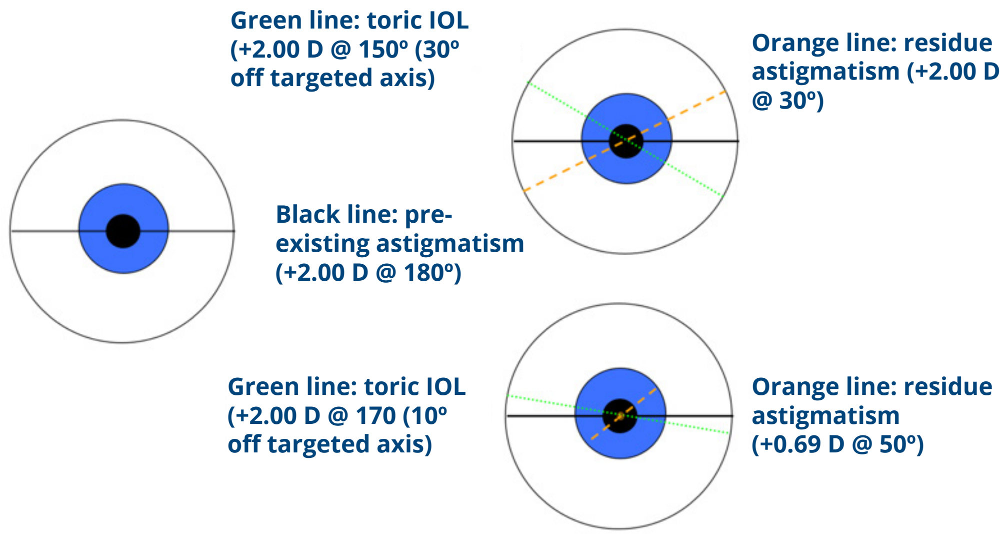


Figure 5: Example of toric IOL rotation in a case with preexisting corneal astigmatism (+2.00D @ 180°)

If the toric IOL with 2.00 D of cylinder at the corneal plane positions 30° off axis (150°), the resultant refractive astigmatism will be 2.00 D, axis 30°. If the lens positions 10° off axis, the resultant residual astigmatism is 0.69 D, axis 50. In both cases, astigmatism shifts from against the rule to oblique. It is known that WTR and ATR astigmatism produce a smaller loss of visual acuity than oblique astigmatism, due to the fact that most scenes contains more horizontal or vertical contours and edges, which produce less clinical blur in WTR or ATR astigmatic patients than in patients with oblique astigmatism.[20] It is possible, but not proven, that astigmatic patients might be more sensitive and can't easily neurologically adapt when the astigmatism is switched from WTR or ATR to oblique astigmatism.

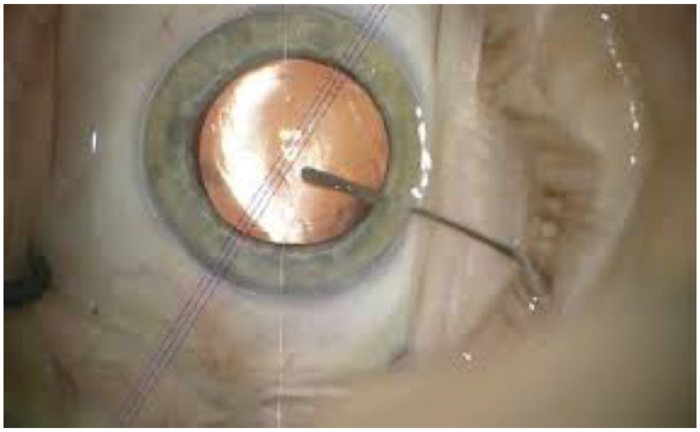
Comparison of Toric IOL Rotational Stability Across Platforms

A recent study[21] compared the rotational stability of the Alcon AcrySof® IQ Toric Platform versus the Tecnis* Toric Platform. It also compared the need for a secondary surgical procedure to reposition a lens that had rotated postoperatively. It was a large study involving 1273 consecutive eyes. The AcrySof® IQ toric groups was comprised of 626 eye while the Tecnis* Toric group was comprised of 647 eyes. The study was conducted by two surgeons at the same practice. Surgeries were performed at the same surgery center. This reduced the risk of introducing inter-surgeon or inter-surgery center variables that might have confounded the results. Additionally, postoperative refractions were performed by the same Optometrist for Dr. Chang's cases and by Dr. Lee for his cases. This reduced the risk of introducing variables that might have confounded the refractive results. Similar to the study examining Tecnis* toric IOLs listed above, postoperative toric lens orientation was evaluated in the immediate postoperative period (at least one-hour after surgery), either on the day of surgery, or day 1 postoperatively, depending on the time of surgery. The study showed that the Alcon AcrySof® IQ toric rotated less than the Tecnis* Toric. The difference in postoperative IOL rotations of ≤ 5°, ≤ 10°, and ≤ 15° were statistically significant. In addition, the mean postoperative IOL rotation was lower for the Alcon AcrySof® IQ Toric as compared to the Tecnis* Toric.

The study also demonstrated that eyes implanted with the Tecnis* Toric were approximately twice as likely to require a secondary surgical procedure to reposition, 3.1% vs 1.6%, but this difference was not statistically significant ($p = 0.10$).

The authors reported additional results that, although were not listed as endpoints of the study, might have provided some insight into the differences in rotational stability of the two toric IOL platforms. First, greater axial length and lower spherical equivalent IOL power were found to be two predictors of larger amounts of IOL rotation, greater than 10 degrees ($P=0.023$) and greater than 5 degrees ($P=0.011$) respectively. Second, It was also noted that rotation of greater than 10 degrees occurred more often in cases with WTR astigmatism (P=0.005). However, for with the rule eyes, The AcrySof® IQ still demonstrated superior stability (≤ 5° rotation, 91.2% for AcrySof® , 81.4% for Tecnis*, p=0.002; ≤ 10° rotation, 96.7% for AcrySof® IQ, 91.2% for Tecnis* p=0.013) Third, the Tecnis* Toric showed a strong predisposition to rotate in a counterclockwise direction and large Tecnis* postoperative rotations were usually counterclockwise. Fourth, the authors hypothesized that the Tecnis*' increased tendency to rotate might be related to the of the material or design features of lens platform. Finally, despite the differences in rotational stability, and mean postoperative rotation, overall refractive outcomes were similar between two groups.

One of the unique aspects of this study was that it was possible to attribute a malpositioned lens to postoperative rotation as rather than to inaccurate intraoperative lens placement. Accurate lens placement was achieved and quantified through the use of Intraoperative Wavefront Aberrometry (ORA™ System with VerifEye+™, Alcon Laboratories, Ft Worth, Texas) and a digital registration system (Callisto, Carl Zeiss Meditec, Dublin, CA). Use of these systems ensured, if lenses were malpositioned at the first postoperative visit, the postoperative position of the lens was the result of lens rotation, not inaccurate lens placement. This was critical in assessing rotational stability. Once the lens was in place, an image could be captured and used in the comparison to lens position at the first postoperative visit. Figure 6 demonstrates the Callisto* system being used to position a toric IOL.



**Callisto is a trademark of Carl Zeiss Meditec, Inc.*

Figure 6: Callisto* Image

Conclusion

Rotational instability of toric IOL is an obstacle to achieve refractive success for cataract patients with corneal astigmatism. This is independent from the surgeon's ability to obtain accurate biometric measurements, utilize digital marking/registration, and intraoperative aberrometry to ensure precise initial alignment. In order to achieve the desired refractive outcome and increase patient satisfaction, it is critical to use a platform that has clinically proven rotational stability. The AcrySof® IQ toric IOL was demonstrated to offer superior rotational stability compared with the Tecnis* toric IOL. Additionally, the mean absolute rotation was significantly lower for many cases with AcrySof® IQ toric IOL versus the Tecnis* Toric IOL. Overall, confidence in the stability of an implanted toric IOL is key in achieving the best possible visual outcome, including spectacle independence, for cataract patients with astigmatism.

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