# Comparative rotational stability of single-piece open-loop acrylic and plate-haptic silicone toric intraocular lenses

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**PURPOSE:** To prospectively compare the early rotational stability of AcrySof SN60T toric intraocular lenses (IOLs) with that in a retrospective series of AA4203 toric IOLs.

**SETTING:** Private practice, Los Altos, California, USA.

**METHODS:** One hundred consecutive eyes with an AcrySof SN60T(3, 4, or 5) toric IOL were compared with a consecutive series of 90 AA4203 (TL or TF) toric IOLs. The same surgeon performed all IOL implantations using an identical surgical technique. In addition to deviation from the desired axis, the change in refractive cylinder was measured 1 month postoperatively.

**RESULTS:** Although surgery was performed during different time periods, the 2 populations had a similar distribution of patient age, axial lengths, and spherical IOL powers. In the AcrySof SN60T group, 90%, 99%, and 100% of the IOLs were aligned at or within 5, 10, and 15 degrees, respectively, of the desired axis and in the AA4203 group, 70%, 90%, and 97%, respectively. The mean IOL rotation was 5.56 degrees $\pm$ 8.49 (SD) in the AA4203 group and 3.35 $\pm$ 3.41 degrees in the AcrySof SN60T group ($P = .0232$). One AcrySof SN60T IOL (1%) and 8 AA4203 IOLs (8.9%) were 15 degrees or more off axis ($P = .01$). No AcrySof SN60T IOL and 3.3% of AA4203 IOLs required surgical repositioning.

**CONCLUSIONS:** Both toric IOLs had good rotational stability and were effective in reducing preexisting corneal astigmatism. Based on the mean axis deviation and the number of IOLs rotating 15 degrees or more, the AcrySof SN60T toric IOL showed statistically better rotational stability.

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Methods for correcting preexisting astigmatism at the time of cataract surgery include incisional astigmatic keratotomy (AK) and toric intraocular lens (IOL) implantation. Toric IOLs avoid potential complications of incisional keratotomy such as perforation and exacerbation of dry-eye symptoms, and they may provide more consistent results. The main disadvantage of toric IOLs is the potential for axis misalignment. Theoretical calculations show that approximately one third of the correction is lost if the IOL is rotated 10 degrees off axis.[1,2] Two thirds of the effect is lost with 20 degrees of rotation, and a net increase in astigmatism will result if the IOL is rotated more than 30 degrees off axis. Therefore, in addition to proper surgical alignment, the postoperative rotational stability of a toric IOL is critical.

At present, 2 approved toric IOL models are available for implantation in the United States. In November 1998, the AA4203 TF (Staar Surgical) became the first toric IOL approved by the U.S. Food and Drug Administration (FDA). Several studies[3–7] confirm that this plate-haptic silicone toric IOL, which is available in 2 astigmatic powers, is effective in reducing preoperative astigmatism. However, the FDA trial and initial clinical studies show a fairly high incidence of early postoperative rotation and surgical

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repositioning.[3–6] These studies evaluated the original AA4203 TF toric model, which measures 10.8 mm in overall length. Subsequently, Staar Surgical introduced a longer (11.2 mm) toric model, the AA4203 TL, for spherical powers less than 24.0 diopters (D). In 2003, I published a study[7] that showed improved postoperative rotational stability with the longer AA4203 TL toric model in a series of 50 consecutive cases. This study was continued until the results in an expanded series of 90 consecutive AA4203 toric IOLs were presented in 2003 (D.F. Chang, MD, "Early Rotational Stability of the Longer Staar Toric IOL," presented at the ASCRS Symposium on Cataract, IOL and Refractive Surgery, San Francisco, California, USA, April 2003). The results showed that as long as the largest available model was used, rotational stability with the AA4203 toric IOL was good and the repositioning rate was reduced to 3.3%.

The AcrySof SN60T IOL (Alcon Laboratories, Inc.) became the second FDA-approved toric IOL in September 2005. This toric IOL is available in 3 cylinder powers (1.50 D, 2.25 D, and 3.00 D at the IOL plane) that are intended to correct approximately 1.00 D, 1.50 D, and 2.00 D of astigmatism at the spectacle plane. It shares the same single-piece hydrophobic acrylic platform as the AcrySof SA60AT monofocal IOL. The FDA data and 1 small published series[8] indicate excellent rotational stability of this toric IOL.

This prospective single-surgeon study was performed to analyze the early rotational stability in my first 100 consecutive AcrySof SN60T toric IOL cases and to compare the results with those in the previous large series of 90 consecutive AA4203 toric IOLs using the identical surgical method.

## PATIENTS AND METHODS

Commencing in August 2006, my first 100 consecutive AcrySof SN60T toric IOLs were prospectively analyzed for early rotational stability and postoperative change in refractive cylinder. I performed all cataract operations in a standardized manner. Surgical informed consent was specifically obtained for the toric IOL. The spherical IOL power was calculated in the usual manner for a nontoric IOL, and the appropriate astigmatic power and axis were selected based on preoperative keratometry measurements performed with a RMA 6500 autokeratometer (Topcon). In keeping with the convention for written refractions and eyeglass prescriptions, the intended target axis was rounded off to the nearest 5 degrees.

Before surgery, reference landmarks on the limbus were marked with a disposable ink pen with the patient seated upright on the operating table or in the preoperative holding area. Once the lid speculum was inserted, a sterile ink pen was used to place 2 additional limbal marks denoting the plus axis of astigmatism. This was determined with a Dell astigmatism degree marker (Rhein Medical) aligned with the preplaced reference points. Additional peripheral corneal relaxing incisions were performed at my discretion in cases in which more than 2.00 D of astigmatic reduction was desired.

Phacoemulsification was performed through a 2.6 mm temporal clear corneal incision under topical anesthesia. An intact capsulorhexis was achieved in all cases. The AcrySof SN60T toric IOL was implanted in the capsular bag using the Monarch injector system (Alcon) through the unenlarged phaco incision. A cohesive ophthalmic viscosurgical device (OVD) (sodium hyaluronate 1.0% [Provisc] or sodium hyaluronate 1.6% [Amvisc Plus]), was used in all cases. After the OVD was removed, the toric IOL hash marks were aligned with the inked reference marks and the proper axis was reconfirmed against the chart notes (Figure 1). The eyes were not patched, and patients were not restricted from any physical activity.

The patients were examined on the first postoperative day and at a final visit between 3 weeks and 6 weeks postoperatively. The alignment of the IOL was determined by dilated slitlamp examination at each follow-up visit. The toric IOL axis was measured at a Haig-Streit slitlamp by aligning a thin coaxial slit with the axis marks of the IOL. The degree scale on the top of the slitlamp was used to determine the axis to the nearest 5-degree increment.

Although keratometry was used to select the toric IOL power, the net change in astigmatism was determined by comparing the preoperative and postoperative refractions. This is because refractive cylinder does not always correlate with keratometry readings and the goal was to assess the effective change in the patient's refractive cylinder. If the cataract density precluded an accurate preoperative refraction, the astigmatic correction in the most recent pair of eyeglasses was used. A separate analysis of refractive cylinder reduction was performed for each of the 3 toric IOL powers using only eyes that did not have concurrent astigmatic keratotomy (AK). In addition to the postoperative toric IOL axis alignment, the patient's age, axial length (AL), spherical and toric IOL power, and best corrected visual acuity (BCVA) at the final visit were recorded.

The results were compared with those in a retrospective consecutive series of 90 consecutive AA4203 toric IOLs implanted between March 1999 and May 2002. Only the

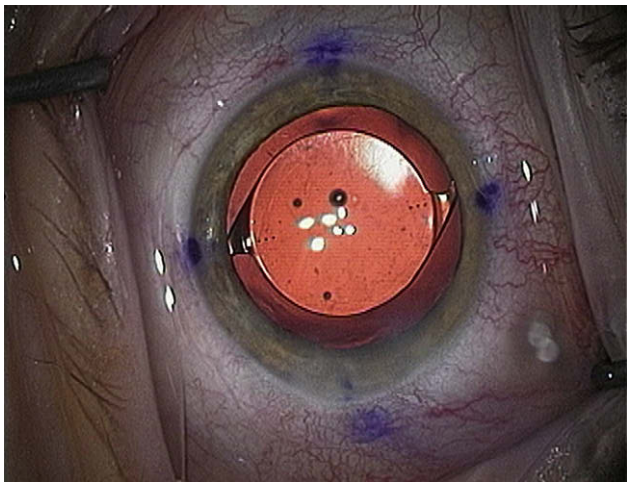

**Figure 1.** Surgeon's view from temporal position of an AcrySof SN60T5 toric IOL aligned at axis 90 degrees in a right eye. The pen marks on the limbus denote the 90-degree axis and the original 3 o'clock and 9 o'clock limbal reference points.

**Table 1.** Patient characteristics in 2 consecutive series of toric IOL implantation.

| Characteristic | Percentage | |
|---|---|---|
| | AA4203 (n = 90) | AcrySof SN60T (n = 100) |
| Age <65 y | 40 | 50 |
| AL >24.5 mm | 56 | 60 |
| IOL power <19.0 D | 61 | 70 |

AL = axial length; IOL = intraocular lens

shorter toric model (AA4203 TF) is manufactured above 23.50 D. For all other powers, only the longer toric model (AA4203 TL) was used. These cases had been performed using an identical surgical technique, and the target axis had been determined and marked preoperatively in an identical manner. Postoperative IOL axis determination had also been performed using an identical technique and at the same 2 time intervals.

## Statistical analysis

Statistical analysis was performed using SAS software (PC version 9.1.2, SAS Institute, Inc.). Summary statistics, such as means, standard deviations, and percentages, were presented to describe the study population and subgroups. The primary outcome variable was IOL rotation measured by slitlamp beam. Unsatisfactory rotation was assessed by the percentage of eyes that had IOL rotation of 15 degrees or more at the postoperative follow-up visit. Between-group comparison was performed using the Student *t* test for numeric variables and the Pearson chi-square test for categorical variables. All tests were 2-sided with a 95% confidence level.

## RESULTS

One hundred consecutive AcrySof SN60T toric IOLs were implanted from August 2006 to January 2008. The mean age of the patients was 63.4 years ± 13.88 (SD) (range 16 to 87 years); 50% of the IOLs were implanted in patients younger than 65 years. The mean AL was 24.89 ± 1.64 mm (range 21.72 to 30.34 mm), with 60% of eyes having an AL greater than 24.5 mm. The mean spherical IOL power was 17.0 D (range 6.0 to 30.0 D); 70% of IOLs had a power less than 19.0 D.

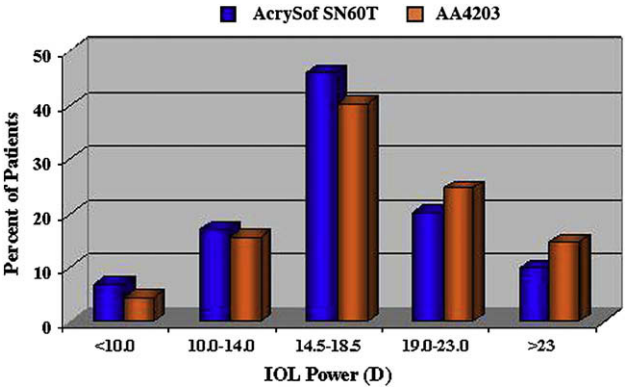


**Figure 3.** Comparative IOL spherical power distribution of cases.

The retrospective review included all 90 consecutive AA4203 toric IOLs implanted by the same surgeon from March 1999 to February 2003. Of 90 total eyes, 80 received the AA4203 TL model. The remaining 10 eyes received the shorter AA4203 TF model because it was the only model available in powers of 24.0 D or greater. Only the +3.50 D AA4203 toric IOLs were used. The mean patient age was 67.2 ± 13.38 years (range 29 to 89 years), the mean AL was 24.73 ± 1.74 mm (range 21.35 to 29.00 mm), and the mean IOL power was 18.0 D (range 9.5 to 29.0 D). Table 1 shows the comparative percentages between the 2 series of cases in patients younger than 65 years, with an AL less than 24.5 mm, and with an IOL power less than 19.0 D. Figures 2 to 4 show a more detailed comparison of patient age, AL, and IOL dioptric power in the 2 series of toric IOLs. Both series had a large number of younger cataract patients, and the majority of eyes in both series were myopic with a longer AL and lower diopter IOL power.

The BCVA by 1 month postoperatively was at least 20/40 in 94% in the AcrySof SN60T IOL series and

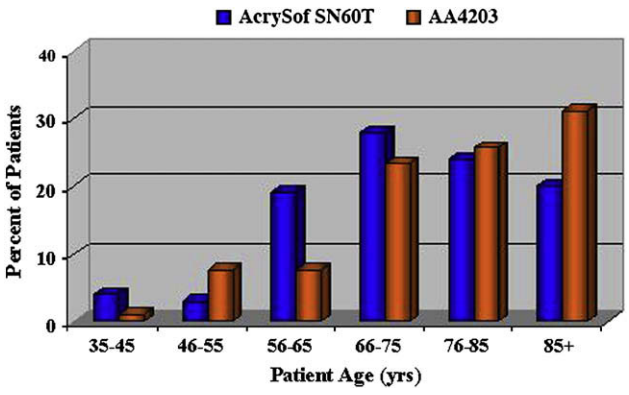


**Figure 2.** Comparative age distribution of cases.

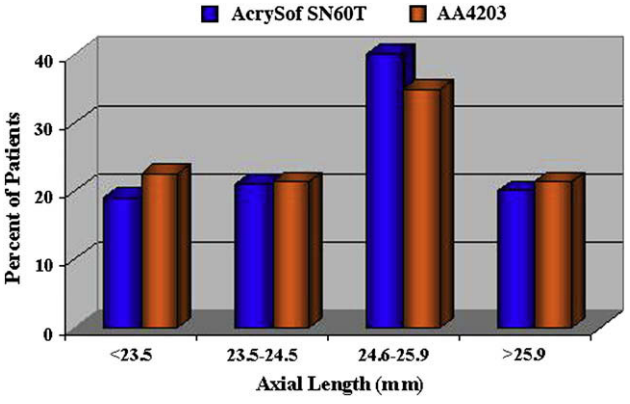


**Figure 4.** Comparative AL distribution of cases.

**Table 2.** Postoperative BCVA and preoperative and postoperative cylinder in 2 consecutive series of toric IOL implantation.

| Parameter | AA4203 IOL | AcrySof SN60T IOL |
|---|---|---|
| BCVA ≥20/40 (%) | 92 | 94 |
| Mean preop cylinder (D) | 3.68 | 2.48 |
| Mean postop cylinder (D) | 0.92 | 0.53 |

BCVA = best corrected visual acuity

92% in the previously reported retrospective AA4203 IOL series. In both series, the cause of reduced BCVA was macular degeneration or amblyopia. In the AcrySof SN60T series, the mean preoperative refractive cylinder was 2.48 D and the mean postoperative mean refractive cylinder was 0.53 D. In the AA4203 IOL series, the mean preoperative and postoperative cylinder was 3.68 D and 0.92 D, respectively (Table 2).

Table 3 compares the percentage of patients in each toric IOL series with varying degrees of axis misalignment. Ninety percent of the AcrySof SN60T IOLs and 73% of the AA4203 IOLs were within 5 degrees of the target axis; 99% and 91%, respectively, were within 10 degrees. The mean rotational misalignment was 5.56 ± 8.49 degrees in the AA4203 IOL series and 3.35 ± 3.41 degrees in the AcrySof SN60T series; the difference was statistically significant ($P$ = .0232). One AcrySof SN60T IOL (1.0%) and 8 AA4203 IOLs (8.9%) were 15 degrees or more off axis ($P$ = .01) (Figure 5). No AcrySof SN60T IOL was repositioned; 3 AA4203 IOLs (3.3%) required repositioning.

Table 4 shows the distribution of toric IOL powers in the AcrySof SN60T series. Most eyes (85%) received either of the 2 higher toric powers. Seventy-one eyes did not receive concurrent limbal relaxing incisions, including 21 eyes receiving the T4 model and 39 eyes receiving the T5 model. The mean decrease in refractive cylinder in the latter 2 groups was 1.32 D and 2.03 D, respectively.

**Table 3.** Final toric IOL axis alignment in 2 consecutive series of toric IOL implantation.

| | Number (%) | |
|---|---|---|
| Alignment of IOL | AA4203 (n = 90) | AcrySof SN60T (n = 100) |
| ≤5 degrees from target | 66 (73) | 90 (90) |
| ≤10 degrees from target | 82 (91) | 99 (99) |
| ≤15 degrees from target | 87 (97) | 100 (100) |

IOL = intraocular lens

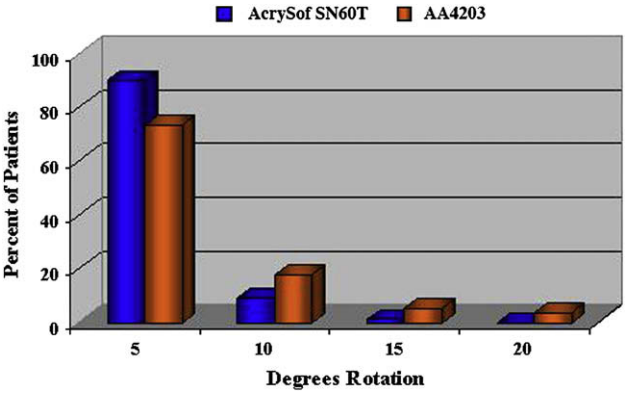


**Figure 5.** Comparative percentages of patients with 5 degrees or less, 10 degrees, 15 degrees, and 20 degrees or more of axis deviation.

## DISCUSSION

Clinical studies of the shorter 10.8 mm AA4203 TF toric IOL report a significant rate of early postoperative rotation (Table 5).[3–6] In the FDA trial of the TF model, 24% of patients had more than 10 degrees of rotation from the intended axis, 12% had more than 20 degrees, and 8% had more than 30 degrees. In series of 130 AA4203 TF toric IOLs by Sun et al.,[3] 25% of IOLs rotated more than 20 degrees, 7% rotated 40 degrees or more, and 9.2% were repositioned surgically. Ruhswurm et al.[4] report a smaller series of 37 AA4203 TF toric IOLs in which 19% rotated 10 degrees or more off axis. In a series of 22 AA4203 TF toric IOLs by Leyland et al.,[5] 23% of IOLs were more than 15 degrees off axis and 18% were more than 30 degrees off axis. Till et al.[6] published a mixed series of AA4203 TF IOLs (63%) and AA4203 TL IOLs (37%); 14% rotated more than 15 degrees off axis. The rotation rates were similar between the TF and TL IOL subgroups. The IOL repositioning rate would have been 9%; however, only 5% had surgical repositioning because 4 patients returned too late to have a reoperation.

In contrast, I reported improved rotational stability in a consecutive series of 50 eyes using only the longer

**Table 4.** Mean decrease in refractive cylinder in Acrysof SN60T toric IOL cases according to IOL model used.

| | Number | | |
|---|---|---|---|
| IOL Model | Patients | Without LRI | Mean Decrease in Cylinder (D) |
| T3–T5 | 100 | 71 | 1.80 |
| T3 | 15 | 11 | 1.95 |
| T4 | 23 | 21 | 1.32 |
| T5 | 62 | 39 | 2.03 |

IOL = intraocular lens; LRI = limbal relaxing incisions

**Table 5.** Selected data in published studies of the AA4203 TF IOL compared with data in the Chang AA4203 TL IOL series.[7]

| Series* | AA4203 TF IOL | AA4203 TL IOL (Chang[7]) |
|---|---|---|
| FDA trial | 12% >20 degrees | 1% >20 degrees |
| Sun[3] | 25% >20 degrees | 1% >20 degrees |
| Ruhswurm[4] | 19% >10 degrees | 9% >10 degrees |
| Leyland[5] | 18% >30 degrees | 1% >30 degrees |
| Till[6,†] | 14% >15 degrees | 3% >15 degrees |

*First author
†Of the IOLs, 37% were the TL model

11.2 mm AA4203 TL toric IOL.[7] These results suggest that the plate-haptic IOL must be sufficiently long relative to the size of the capsular bag to resist early rotation. My expanded series of 90 eyes used only the longer AA4203 TL model when it was available (80 eyes) and the shorter TF model when it was the only available model for powers more than 24.0 D (10 eyes). Table 5 compares the rotational stability data in this expanded series with selected data in previous series using the shorter TF. The previous studies that used only the shorter AA4203 TF toric IOL may have created a misperception of higher misalignment rates than would have occurred if the longer TL model had been used.

The FDA trial of the AcrySof SA60T toric IOL compared 244 patients against a control group of 250 patients with the nontoric AcrySof SA60AT IOL (Available at: http://www.fda.gov/cdrh/pdf/p930014s015.html. Accessed August 1, 2008). The former found excellent rotational stability with a mean rotation of less than 4 degrees from the initial alignment 12 months postoperatively. Rotational misalignment was 10 degrees or less in 97% of patients and 5 degrees or less in 81% of patients. No IOL rotated more than 15 degrees off axis. Mendicute et al.[8] published the first clinical series of AcrySof SN60T toric IOLs. In a consecutive series of 30 eyes (15 patients), the mean toric IOL axis rotation was 3.63 ± 3.11 degrees and 96.7% of eyes had less than 10 degrees of IOL rotation. The mean refractive cylinder decreased from −2.34 D to −0.72 D postoperatively. Zuberbuhler et al.[9] subsequently reported a larger series of AcrySof SN60T toric IOLs in 44 eyes (33 patients). The mean toric IOL axis rotation was 2.2 ± 2.2 degrees, and 95% of IOLs were within 5 degrees of the targeted axis.

The current study of the rotational stability of the AcrySof SN60T toric IOL had nearly identical results to the aforementioned 3 series, with a mean rotation of less than 4 degrees, 99% of IOLs having 10 degrees or less rotation, and 90% having 5 degrees or less rotation. This study also found that the mean change in refractive cylinder was exactly what would be predicted based on well-aligned placement of the T4 and T5 models (Table 4). The sample size of the T3 group was probably too small to provide a reliable measure of the mean improvement in cylinder.

I believe that this is the first study to compare the early postoperative rotational stability of the 2 FDA-approved toric IOL platforms using a standardized surgical technique with a single surgeon. Although the 2 consecutive series were conducted at different times, the surgical technique and study methods were identical. The same method was used to mark the astigmatic axis during surgery and to measure it postoperatively. Use of the same-sized temporal clear corneal incision would have been expected to produce similar amounts of surgically induced astigmatism. The same anesthesia and phaco technique were used, and a dispersive OVD was avoided in both groups. I was using only 1 toric IOL platform during each period in which the 2 series were compiled. Specifically, when the AcrySof SN60T toric IOL became available in 2006, I switched to using this toric IOL model exclusively because of a preference for the single-piece hydrophobic acrylic design. Therefore, both study populations incorporated all patients in my practice in whom a toric IOL was indicated during the 2 time periods.

Because this was not a prospective randomized study, other confounding variables affecting IOL rotational stability might have been present in the 2 study populations. The most significant variable might have been capsular bag size because early postoperative IOL rotation is more likely to occur in larger diameter bags. Studies show that capsular bag diameter tends to correlate with increasing AL, meaning that early rotation might be more likely in longer myopic eyes.[10,11] On a percentage basis, however, the age distribution, AL and IOL powers were surprisingly similar between the 2 study populations. This may reflect my preference for using toric IOLs in younger patients in whom AK is less reliable and effective. In my experience, younger patients with high myopia who require cataract surgery frequently have significant corneal astigmatism.

Considering the similar distribution of ALs and IOL powers in the 2 study populations, the results suggest that the AcrySof SN60T toric IOL has better rotational stability than the longer AA4203 TL toric IOL. The AcrySof SN60T toric IOL was statistically better in mean rotation (3.35 degrees versus 5.56 degrees) and the number of IOLs rotating 15 degrees or more off axis (1% versus 9%). In addition, no AcrySof SN60T toric IOL required surgical repositioning, while 3.3% of AA4203 toric IOLs did. An advantage of having reliable rotational stability is the ability to combine simultaneous AK incisions at the time of surgery for higher amounts of astigmatism that exceed the available toric IOL powers.[12]

A likely reason for the improved rotational stability of the AcrySof SN60T toric IOL is the stronger tendency

for its hydrophobic acrylic material to adhere to the capsule. This "tackiness" is in contrast to the slippery surface of a plate-haptic silicone IOL, which has been shown to be far less adherent to the posterior capsule in animal studies.[13] Combining a silicone toric IOL with a different haptic design improved rotational stability in 1 small series, however.[14] Additional clinical advantages of the AcrySof SN60T toric IOL are its more popular single-piece acrylic design and the presence of a truncated posterior optic edge.[15]

In this series of 100 AcrySof SN60T toric IOLs, there were no cases in which the IOL rotated by as much as 5 degrees between the 1-day and 1-month postoperative visits. This study did not evaluate the incidence of later postoperative rotation because previous trials found excellent long-term rotational stability of toric IOLs.[3,6,9,16] Strenn et al.[10] used capsular tension ring measurements to document a reduction in the mean capsular bag diameter between 1 day and 1 week postoperatively, suggesting rapid shrinkage of the capsular bag after surgery. This would suggest a very short and early window of opportunity for a toric IOL to rotate postoperatively.

In the FDA study, there were no cases of late postoperative rotation (up to 12 months) of the AcrySof SN60T toric IOL. Weinand et al.[17] used a precise photographic method to measure the amount of postoperative rotation between 2 serial examinations (1 day postoperatively and 6 months later) in 23 eyes with the nontoric AcrySof SA60AT IOL. The mean axis rotation was 0.7 degrees and did not exceed 2 degrees in any eye, confirming that this IOL design, which the SN60T IOL shares, does not rotate after the first postoperative day. This also raises the possibility that any off-axis alignment of the AcrySof SN60T toric IOL at 1 day may have resulted from inaccurate surgical alignment rather than from rotation occurring immediately postoperatively.

In conclusion, both the AcrySof SN60T toric IOL and the AA4203 TL toric IOL are effective at reducing preexisting corneal astigmatism, with acceptably low rates of IOL misalignment and surgical repositioning. The AcrySof SN60T toric IOL was particularly stable, with 90% aligned within 5 degrees of the astigmatic axis and only 1% rotating more than 10 degrees off axis. None of the 100 consecutively implanted AcrySof SN60T IOLs required surgical repositioning. This represents a statistical improvement over results in a retrospective series of 90 consecutive AA4203 toric IOLs implanted with the identical surgical technique by the same surgeon.

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