Early rotational stability of the longer Staar toric intraocular lens

Fifty consecutive cases

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Purpose: To determine whether rotational stability is improved with the longer Staar toric intraocular lens (IOL).

Setting: A private practice, Los Altos, California, USA.

Methods: Staar Surgical manufactures toric plate-haptic IOLs under +24.0 diopters (D) in 2 lengths. Fifty consecutive eyes requiring toric IOL spherical powers less than +24.0 D received the longer toric IOL (TL; 11.2 mm) using a specific surgical protocol. The IOL axis was recorded at 1 day, 1 week, and a final follow-up visit. Five additional eyes requiring powers greater than +24.0 D received the shorter toric IOL (TF; 10.8 mm), which is the only available length in these powers. Results were compared with those in an initial consecutive series of 6 eyes having implantation of the TF IOL with a power less than +24.0 D before the TL model became available.

Results: Rotational stability of all 50 TL IOLs and the 5 TF IOLs of higher dioptric powers was excellent. One IOL rotated as much as 20 degrees off axis. The repositioning rate was zero in both groups. In the initial 6 eyes receiving the shorter toric IOL in powers below +24.0 D, the repositioning rate was 50%.

Conclusions: The longer toric IOL had excellent early rotational stability. Rotational and repositioning rates with the TL IOL were superior to those in a previous series of the TF IOL. Adequate overall length is a critical factor in the rotational stability of plate-haptic toric IOLs, and the longer IOL should be used when available.

J Cataract Refract Surg 2003; 29:935–940 © 2003 ASCRS and ESCRS

In November 1998, the Staar AA4203 toric intraocular lens (IOL) became the first toric lens approved by the U.S. Food and Drug Administration (FDA). Subsequent studies confirmed that this silicone, plate-haptic, toric IOL, which is available in 2 astigmatic powers, is effective in reducing preoperative astigmatism.[1–4] The original FDA studies analyzed the Staar TF model, which has a 10.8 mm overall length. Subsequently, Staar Surgical introduced a longer, 11.2 mm TL toric model for spherical powers less than +24.0 diopters (D). Both the 10.8 mm and 11.2 mm lengths are available in this power range.

Rotational stability is crucial to the success of toric IOL design. The most common complication reported with the Staar toric IOL is misalignment requiring surgical repositioning.[1] The IOL size relative to the capsular bag diameter is therefore of greater importance with toric designs than with nontoric IOLs. Studies suggest that although late postoperative rotation of plate-haptic IOLs is unusual, early postoperative rotation is more likely.[5]

Accepted for publication September 17, 2002.

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The author has no financial or proprietary interest in any material or method mentioned.

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Published by Elsevier Inc.

0886-3350/03/$–see front matter
doi:10.1016/S0886-3350(02)01843-6

Both the FDA trials and earlier clinical studies[1–3,5,6] analyzed the rotational stability of the shorter TF toric IOL only. For Staar toric IOLs under +24.0 D, 2 lengths are available. This study analyzed the early rotational stability of the longer TL toric IOL using a specific surgical protocol.

Patients and Methods

Beginning in February 1999, an initial consecutive series of 6 eyes of 4 patients had implantation of the 10.8 mm TF IOL in powers ranging from +16.0 to +20.0 D. Sodium hyaluronate 3.0%–chondroitin sulfate 4.0% (Viscoat®) was used in all cases. Three of the 6 TF IOLs required surgical realignment within the first 2 weeks postoperatively. Therefore, the 11.2 mm TL toric IOL, which became available in March 1999, was used exclusively thereafter for spherical powers below +24.0 D.

From March 1999 to May 2002, 50 consecutive TL toric IOLs were implanted in 50 eyes of 37 patients. These patients had been deemed less suitable for limbal relaxing incisions because of a younger age or higher degrees of astigmatism. The powers used ranged from +9.5 to +23.5 D. Only the shorter TF IOL is manufactured in powers above +23.5 D. During this same period, 5 additional TF toric IOLs were implanted in powers ranging from +24.0 to +27.0 D.

The patients' age, axial length, and IOL power are shown in Figures 1 to 3, respectively. Forty-two percent of the IOLs were used in patients younger than 65 years. Most patients receiving the TL toric IOL were myopic. Seventy percent of the patients had axial lengths greater than 24.5 mm. Seventy-eight percent received IOLs with spherical powers less than +19.0 D.

A single surgeon (D.F.C.) performed all cataract surgeries in a standardized manner. The astigmatic power and axis were determined by the preoperative keratometry. Surgical informed consent was obtained specifically for the toric IOL. Only +3.50 D toric lenses were used. In IOL powers lower than +24.0 D, only the TL model was implanted. The TF model was used when the TL model was unavailable (≥+23.5 D).

Before surgery, the 6 o'clock limbus was marked with a disposable ink pen with the patient seated upright on the operating table. Once the lid speculum was inserted, a disposable ink pen was used to place 2 limbal marks denoting the plus astigmatism axis. This was determined with a Mendez-style degree marker aligned with the 6 o'clock reference point.

Phacoemulsification was performed using topical anesthesia through a temporal clear corneal incision. An intact capsulorhexis was achieved in all cases. The toric IOL was inserted using the supplied injector. Cohesive viscoelastic material—sodium hyaluronate 1.0% (Provisc® or BioLon®)—was used in all cases. When the viscoelastic material was removed, the irrigation/aspiration instrument tip was routinely placed behind the IOL to minimize retention of the

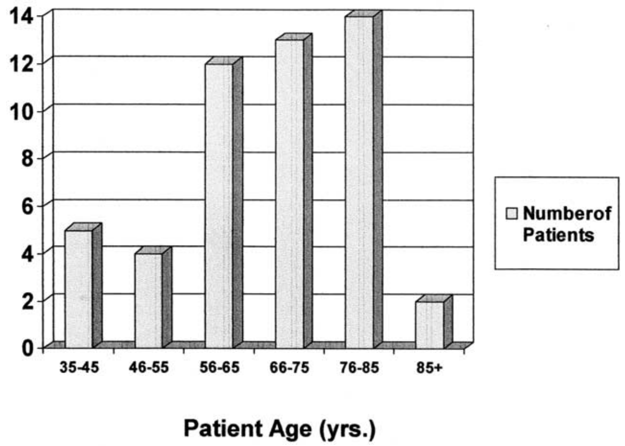

Figure 1. (Chang) Age distribution, TL toric IOL.

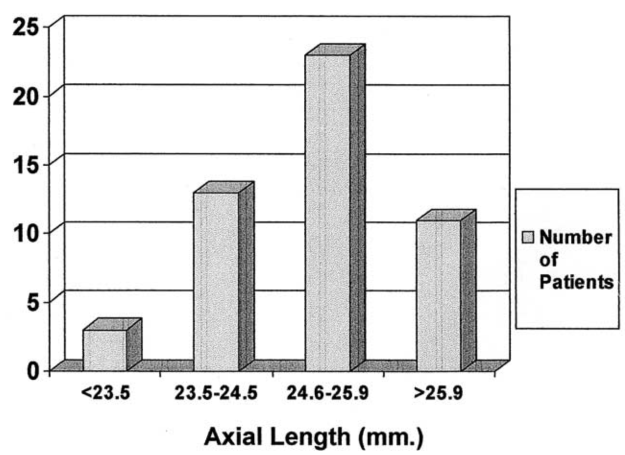

Figure 2. (Chang) Axial length distribution, TL toric IOL.

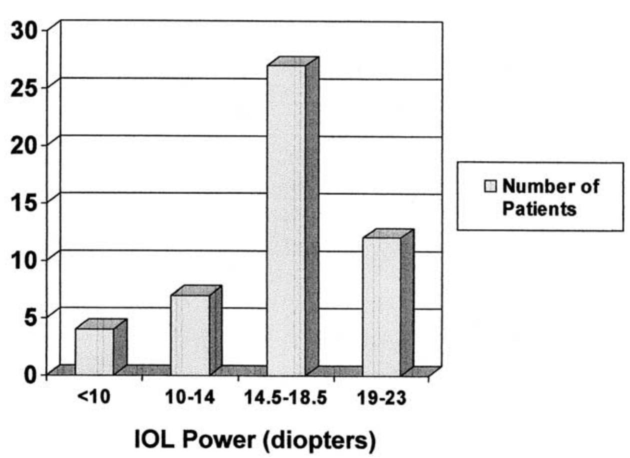

Figure 3. (Chang) Intraocular lens power distribution, TL toric IOL.

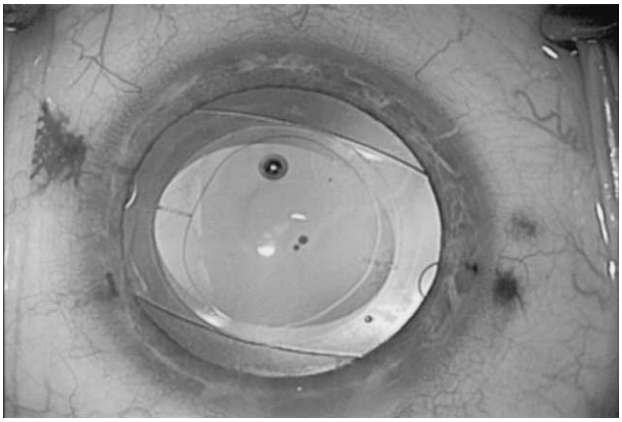

Figure 4. (Chang) Surgeon's view from the temporal position of a TL +3.50 D toric plate-haptic IOL aligned at the 75-degree axis in a right eye. The pen marks on the limbus denote the 75-degree axis and the original 6 o'clock limbal reference point.

Table 1. Distribution of final alignment relative to the desired axis in 50 consecutive cases of TL toric IOL implantation.

	Axis Misalignment (Degrees)			
Eyes	**≤5**	**10**	**15**	**20**
Number	36	9	4	1
Percentage	72	18	8	2

Table 2. Distribution of the reduction in refracted cylinder preoperatively and postoperatively.

	Decrease in Cylinder (D)			
Eyes	**≥2.50**	**≥2.00**	**≥1.50**	**≥1.00**
Number	30	37	45	50
Percentage	60	74	90	100

material behind the optic. The IOL hash marks were then aligned with the inked reference marks, and the proper axis was reconfirmed against the chart notes (Figure 4). As the chamber was formed, an effort was made to avoid overinflating the globe and to err on the side of leaving the eye slightly softer than usual. The eye was not patched, and patients were not restricted from any physical activity.

The patients were checked on the first postoperative day and 1 week and approximately 1 month postoperatively. The IOL alignment was determined by dilated slit-lamp examination at each follow-up. Operative repositioning was considered for any IOL that had rotated 30 degrees or more off axis.

Results

In the initial series of 6 TF toric IOLs, 3 lenses remained within 15 degrees of the initial alignment. Three lenses required repositioning because of excessive rotation (30 degrees, 70 degrees, and 85 degrees) that was immediately apparent on the first postoperative morning. In each case, review of the operative videotape confirmed that proper intraoperative alignment had been achieved. After the secondary alignment procedures, all 3 IOLs had good, stable alignment (within 5 degrees of the desired axis) and no further surgery was required.

In the series of 50 eyes receiving the longer TL toric IOL, no lens required repositioning over a minimum follow-up of 1 month. The alignment on the first postoperative day was stable. One IOL rotated 10 degrees between 1 and 6 days postoperatively. No other cases of measurable rotation occurred after the first postoperative day.

At the final recorded postoperative visit, 72% of the IOLs were within 5 degrees of the intended axis, 90% were within 10 degrees, and 98% were within 15 degrees (Table 1). One lens was 20 degrees off axis, which was the maximum misalignment in this series. Of the 5 TF toric lenses implanted in spherical powers ranging from +26.0 to +27.0 D, 2 were 10 degrees off axis and 3 were within 5 degrees of the intended axis.

The best corrected visual acuity (BCVA) postoperatively was 20/40 or better in 92% of eyes. The remaining eyes had a BCVA from 20/50 to 20/80 because of amblyopia or macular degeneration. The mean preoperative refractive cylinder was 3.68 D ± 1.38 (SD). The mean postoperative refractive cylinder was 0.92 ± 0.87 D. The mean decrease in refractive cylinder was 2.76 ± 1.20 D. Table 2 shows the number and percentage of eyes according to the amount of cylinder reduction achieved.

Discussion

The Staar silicone toric IOL is manufactured in 2 astigmatic powers and 2 lengths. The +3.5 D power corrects approximately 2.3 D of astigmatism at the spectacle plane, while the +2.0 D power corrects approximately 1.4 D at the spectacle plane. A disadvantage of any toric IOL design is the potential for misalignment with the astigmatic axis. Theoretical calculations show that approximately one third of the correction is lost if the lens is rotated 10 degrees off axis.[6] Two thirds of the effect is lost with 20 degrees of rotation, and a net increase in astigmatism will result if the lens is rotated more than 30 degrees off axis. Thus, in addition to proper surgical alignment, early and late rotational stability of toric IOLs is important.

Shimizu and coauthors[7] report late rotation of a conventional 3-piece IOL with polypropylene loop haptics. By 3 months postoperatively, 25% of the 47 IOLs had rotated 20 degrees or more off axis and 21% had rotated 30 degrees or more. The lenses always rotated counterclockwise. Sanders and coauthors[6] evaluated the early rotational stability of 10.4 mm plate-haptic IOLs; 9% had shifted 15 degrees or more by 1 week postoperatively.

Patel and coauthors[5] used serial digital photography to compare the rotation of plate-haptic and 3-piece foldable IOLs. Both designs showed a tendency toward early postoperative rotation. By 2 weeks postoperatively, 41% of the 3-piece and 38% of the plate-haptic IOLs had rotated more than 10 degrees. However, severe rotation was more likely with the plate-haptic IOLs, with 24% rotating more than 30 degrees compared with 5% of the 3-piece IOLs.

Patel and coauthors then analyzed the amount of late rotation (between 2 weeks and 6 months postoperatively). Late rotation was far less likely with the plate-haptic IOL ($>$10 degrees in 14%) than with the 3-piece IOLs ($>$10 degrees in 37%). These data suggest that the plate-haptic design, perhaps because of its edges, better resists the delayed torsional forces of capsular bag contraction. However, early rotation was a more significant problem with this design. Presumably, before initial capsule bag shrinkage, the shorter overall IOL length allows rotation. The 10.4 mm plate-haptic design used by Patel and coauthors is shorter than the 2 toric IOLs used in the present study. The plate-haptic IOL in Patel and coauthors' study also lacked the large fixation fenestrations on the haptic, which are used in current designs.

Clinical studies of the 10.8 mm Staar AA4203 TF toric IOL found a significant rate of early rotation. In the FDA trial of the shorter TF IOL, 24% of patients had more than 10 degrees of rotation from the desired axis, 12% had more than 20 degrees, and 8% had more than 30 degrees.

Three additional published clinical series exclusively evaluating the shorter Staar TF toric IOL have been published. In a series of 130 TF toric IOL implantations by Sun and coauthors,[1] 25% of IOLs rotated more than 20 degrees and 7% rotated 40 degrees or more; 9.2% of eyes had secondary repositioning. In a smaller series of 37 eyes, Ruhswurm et al.[2] evaluated the TF toric IOL. The rotation rate was much lower, with only 19% of eyes positioned 10 degrees or more off axis and 1 (3%) requiring repositioning. They found that IOL rotation was associated with increasing axial length. In a series of 22 eyes with a TF toric IOL by Leyland and coauthors,[3] 18% of eyes had rotation greater than 30 degrees and 23%, greater than 15 degrees.

Till and coauthors[4] report a mixed series of TF (63%) and TL (37%) toric IOL implantations. This was the first published report to include data on the TL IOL. Fourteen percent of all IOLs (TL and TF) were more than 15 degrees off axis. The repositioning rate would have been 9%; however, because 4 patients returned too late to have a reoperation, only 5% had IOL repositioning. The rotation rates were similar between the TF and TL IOL groups. There was no mention of the criteria used by the 2 different surgeons for implanting the longer or shorter toric IOL. The authors also did not mention at what point the TL IOL became available during the study.

The differences in the early rotational rates in these studies of the TF toric IOL may be explained by several factors. Differences in surgical techniques or viscoelastic material use may have had an influence. More important, the distribution of longer, myopic eyes may have been significantly different among the 4 study populations. More patients with larger capsular bags would be expected to increase the rotation rate of the smaller TF IOL. Studies show that capsular bag diameter correlates with increasing axial length; thus, early rotation is more likely in longer, myopic eyes.[8,9] However, the relationship is not linear enough to provide a reliable preoperative estimate for a given individual.[8–11]

Strenn and coauthors[8] demonstrated with capsular tension ring measurements that the mean capsular bag diameter 1 day postoperatively was 11.1 mm in myopic eyes. There was a measurable reduction in diameter at the 1-week visit, consistent with early capsular bag shrinkage. This suggests that until the initial capsular bag contraction starts to occur during the first few days, a plate-haptic IOL may rotate if its overall length is too short relative to the bag diameter. This mechanism is different from that of late postoperative rotation of any bag-fixated IOL design, which would be secondary to the compressive forces of delayed capsule fibrosis.

The preliminary experience with the shorter TF IOL in 6 consecutive myopic patients in the present study provides additional confirmation that significant misalignment can occur within the first 24 hours postoperatively. Repositioning was necessary in 50% of the 6 eyes. One myopic patient had severe rotation (>70 degrees) in both eyes, suggesting that this individual may have had a particularly large capsular bag diameter.

This is the first published study specifically evaluating the early rotational stability of the longer 11.2 mm plate-haptic design. It is also the first to demonstrate a negligible early rotation rate with any toric IOL. This implies that the length of the plate-haptic toric IOL is the most critical factor in early rotational stability. Previous studies using shorter toric IOLs may have fostered a misperception of higher early rotation rates than would be found with the current technology. Although this was not a prospective, randomized study of the 2 IOL lengths, the difference in the repositioning rates between the TF and TL lenses (3 of 6 and 0 of 50, respectively) would have been highly statistically significant.

The operative technique included several measures recommended by the manufacturer to maximize immediate contact between the posterior capsule and the posterior IOL surface. Because dispersive viscoelastic materials such as Viscoat and hyaluronate 3.0% (Vitrax®) are more likely to coat the IOL surface, cohesive viscoelastic materials were used. Irrigation/aspiration of the viscoelastic material was performed behind the IOL to minimize the separation of the posterior capsule from the IOL optic. For the same reason, an attempt was made to avoid inflating the capsular bag with a balanced salt solution at the conclusion of surgery. Leaving the globe slightly underinflated may allow the capsular bag to collapse around the IOL sooner. Although some suggest that implanting the lens upside down improves stability, this was not investigated in this study.

This study did not look at whether these operative measures independently affected early rotational stability. Also, it did not seek to analyze the incidence of late postoperative rotation because previous studies indicate long-term rotational stability of shorter plate-haptic IOLs.[1,5] No occurrence of late postoperative rotation was found in this series of patients, of whom 61% were examined at or past 6 months postoperatively.

Corneal limbal relaxing incisions have become a popular method for reducing congenital astigmatism at the time of cataract surgery.[12–14] However, this technique is less effective for higher degrees of astigmatism and, as with all incisional keratotomy, is less effective in younger patients.[14] The current study included many younger patients and patients with very high degrees of congenital astigmatism (mean preoperative cylinder 3.68 D). The results demonstrate the efficacy of +3.50 D toric IOLs in cases in which limbal relaxing incisions are less reliable.

Conclusion

Previous clinical studies primarily analyzed the shorter TF toric IOL model, which was the first to be manufactured by Staar Surgical. In this consecutive series of 50 eyes requiring spherical powers less than +24.0 D, the longer TL toric IOL demonstrated excellent early postoperative rotational stability. No IOL required repositioning. The TF model was stable in 5 smaller eyes requiring spherical powers of +24.0 D and above, powers in which the TL lens is unavailable. Given the potential for larger and variably sized capsular bag diameters in eyes with medium to long axial lengths, the longer TL toric lens should be selected when it is available (powers <+24.0 D).

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