CLINICAL STUDY

Prospective evaluation of a plate haptic toric intraocular lens

M. LEYLAND, E. ZINICOLA, P. BLOOM, N. LEE

Abstract

Purpose **Standard intraocular lenses (IOL) only correct the spherical component of aphakic refractive error. This study describes clinical experience with a foldable, injectable, toric IOL.**
Methods **Keratometric, refractive and visual data were collected on patients listed for cataract surgery. Toric IOLs were offered where keratometric cylinder was greater than 1.5 dioptres. Small-incision phacoemulsification surgery was performed and the IOL implanted with its long axis along the steep corneal axis. Post-operative refractive data were compared with pre-operative and expected refraction using vector analysis software.**
Results **Results of 22 eyes of 16 consecutive patients implanted with toric IOLs are reported. Two IOLs rotated more than 30° in the first 24 h and were re-dialled surgically. Two further IOLs (9%) rotated more than 30° during follow-up. In 21 of 22 eyes (95%) the refractive astigmatism was reduced, with a mean 73% of planned correction (vector analysis) achieved.**
Conclusions **The toric IOL is a useful surgical tool to reduce the refractive effects of pre-existing corneal astigmatism. Design modification to prevent IOL rotation would make results more predictable.**

Key words Cataract, Astigmatism, Toric, Intraocular lens

Intraocular lens (IOL) implantation to correct aphakia is the most commonly performed refractive procedure. Modern IOL power calculation formulae are now sufficiently reliable that predictability of post-operative spherical equivalent is largely limited by the accuracy of biometry measurements.[1] Small-incision cataract surgery has eliminated the problem of unpredictable surgically induced astigmatism.[2] However, pre-existing corneal astigmatism continues to limit post-operative unaided visual acuity because standard IOLs only correct spherical error.

This study describes clinical experience in the United Kingdom with a new, foldable, injectable toric IOL, designed to correct both spherical and astigmatic components of aphakia.

Materials and methods

Twenty-two eyes of 16 consecutive patients with visually significant lens opacities who underwent phacoemulsification with insertion of a plate-haptic silicone toric IOL (Staar Surgical, Monrovia, USA) were included. The lens is 10.8 mm long with a 6 mm optic. The axis of the positive cylinder lies along the long axis of the IOL and is marked by lines on the haptic (Fig. 1). The IOL is available in 0.5 D increments of spherical power from 9.5 to 30.5 D with additional positive cylinder on the front surface of 2 or 3 D. Accordingly, patients were offered a toric IOL if their keratometric cylinder was 1.5 D or greater.

A-scan ultrasound biometry was performed with the Ophthasonic Image 2000 A-scan (Teknar, St Louis, MO) and the KR 7000P Autokeratorefractometer (Topcon, Europe). The autorefractometer was also used to perform corneal topography to exclude abnormal corneas whose keratometry might not be stable. No cases were excluded on this basis.

The IOL spherical power and axis for a given cylindrical add was calculated using the proprietary software, based on the SRK-T formula.[3] In all cases the aim was to undercorrect the cylinder.

The IOL long axis is aligned along the steep corneal axis, i.e. using keratometric rather than refractive data. The axis was identified on the patient's eye with the patient upright, prior to anaesthetic administration (peribulbar in all cases), either by reference to a drawing of the limbal vasculature or with a corneal marker. Clear corneal phacoemulsification was performed using a temporal approach and a 2.8 mm one- or two-step wound. The wound was then enlarged to 3.0 mm with a keratome, and the IOL inserted in the capsular bag. The IOL was aligned along the desired axis, and any

M. Leyland
E. Zinicola
P. Bloom
N. Lee
Hillingdon Hospital NHS Trust
Uxbridge, UK

Mr N. Lee ✉
Eye Unit
Hillingdon Hospital NHS Trust
Pield Heath Road
Uxbridge UB8 3NN, UK
Tel: +44 (0)1895 279223

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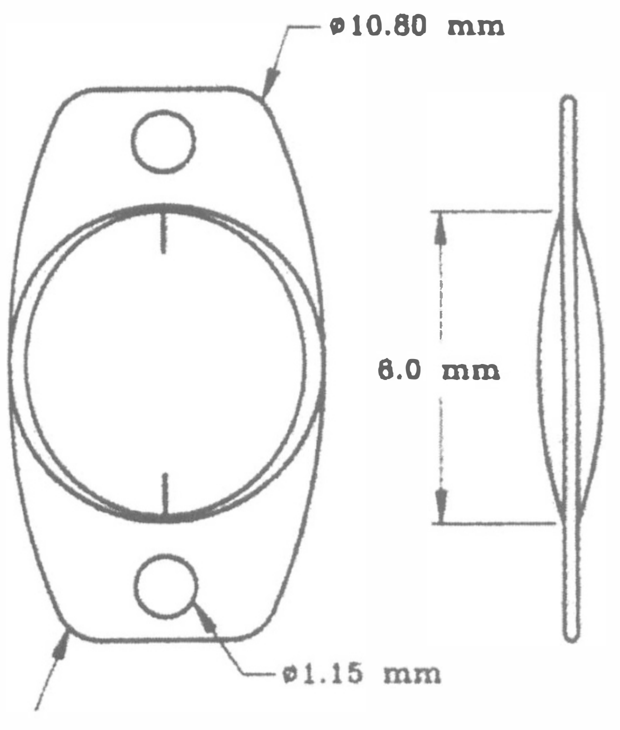

Fig. 1. *The Staar toric IOL (AA-4203TF). It is an injectable, plate-haptic silicone IOL with 6 mm optic diameter and 10.8 mm overall length. Hash marks indicate the positive axis along the long axis of the IOL (the optic has its steeper radius of curvature at 90° to this).*

rotation that occurred during aspiration of viscoelastic material was corrected prior to completion of the procedure.

Vector analysis of surgically induced and intended refractive change was performed using the 'Vector Inspector' program (Mr J. Stevens, Moorfields Eye Hospital).

Post-operative assessment

Each patient was examined on day 1 post-operatively and then again at 1, 2 and 8 weeks post-operatively. LogMAR visual acuity was obtained at each visit. Keratometry was performed at 1 week and 8 weeks post-operatively. The axis of the IOL was measured at the slit-lamp following mydriasis. The axis of the slit-beam was aligned along the IOL axis and the angle of rotation recorded.

Full subjective refraction was obtained pre-operatively and following the 8 week clinic visit.

Table 1. *Change in refractive status following surgery*

	Corneal astigmatism	Refractive ametropia	Refractive astigmatism
Pre-operative	2.97D (0.88)	3.3D (2.2)	3.2D (1.1)
Post-operative	2.66D (1.05)	0.85 (0.65)	0.85D (0.66)

Values are the mean (SD).
There was no significant change in corneal astigmatism. Mean refractive astigmatism was reduced to 27% of the pre-operative level ($p<0.001$).

Table 2. *Vector analysis: actual versus predicted refractive change*

	Absolute axis error (deg)	Magnitude of cylinder error (D)	Magnitude of SIRC as % of IRC
Vector analysis	7.0 (6.8)	−0.83 (0.99)	0.79 (0.22)

Values are the mean (SD).
SIRC, surgically induced refractive change; IRC, intended refractive change.
The minus sign indicates a mean undercorrection of cylinder magnitude. The SIR averaged 79% of the IRC.

Results

The mean age of the patients was 77 years (range 44–86 years); 9 were female and 7 were male. Mean pre-operative vision was 1.45 LogMAR (SD 0.64, Snellen equivalent 2/60) unaided and 0.78 logMAR (SD 0.70, Snellen 6/36) best corrected. Mean post-operative vision was 0.27 (SD 0.25, Snellen 6/11) unaided and 0.1 logMAR (SD 0.14, Snellen 6/7.5) best corrected.

Simple refractive results and keratometry changes are given in Table 1 and Fig. 2. All but one patient experienced a reduction in the magnitude of cylinder. Two dioptre cylinder toric IOLs produced a mean cylinder reduction of 1.68 D, compared with 2.68 D for 3.5 D IOLs ($p = 0.02$). Results of vector analysis of surgically induced refractive change compared with intended refractive change are summarised in Table 2.

There were no operative complications. Two IOLs had rotated > 30 ° on the day 1 examination. They were returned to theatre and dialled under topical local anaesthetic; both were subsequently stable. IOL rotation after the first day was common, but in most cases minor (Fig. 3). Three IOLs (14%) rotated more than 15°, 2 more than 30° (9%). In only one case was more than 5° rotation noted after 2 weeks post-operatively. There was no predilection to a particular direction of rotation. IOLs

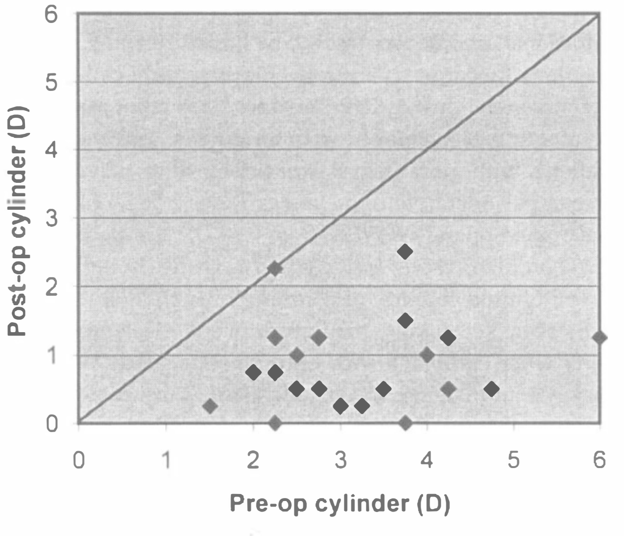

Fig. 2. *Scatter plot of pre-operative versus post-operative refractive astigmatism. The line indicates no change; below the line indicates reduced cylinder.*

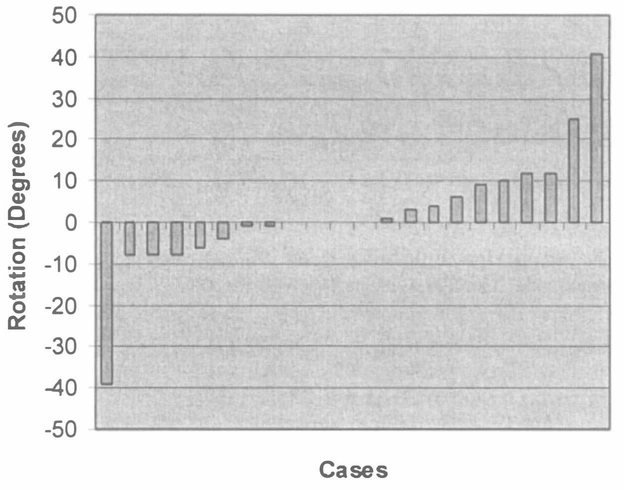

Fig. 3. *IOL rotation at last review (1 column/case). Minus numbers indicate anticlockwise rotation (8 anticlockwise, 4 no movement, 10 clockwise). Mean magnitude of rotation was 8.9° (SD 11.6°). Follow-up 4–83 weeks, median 16 weeks.*

placed 45° either side of vertical were no more likely to move than those placed 45° either side of horizontal (mean rotation 8.93° and 8.75° respectively, $p = 0.97$).

Discussion

Pre-existing corneal astigmatism was effectively reduced for most cases described in this paper, resulting in improved unaided visual acuity and reduced image distortion from spectacle correction. It has long been felt unwise to attempt to alter long-standing astigmatism in elderly people because of the risk that they might not adapt to an alteration in spectacle-induced meridional distortion.[4] Subjective visual outcomes were not addressed in this study, and would anyway have been coloured by the improved vision resulting from cataract surgery. Only a randomised trial with a non-toric IOL control group could answer this question.

Corneal astigmatism detected prior to cataract surgery is usually treated, if at all, by on-axis surgery with additional arcuate keratotomy or limbal relaxing incisions for larger cylinders. This approach, called 'keratolenticuloplasty' by Kershner,[5] has comparable results to those achieved with toric IOLs. Thirty-one patients with more than 2 D of pre-existing astigmatism (mean pre-operative refractive cylinder 2.56 D) had a mean post-operative cylinder of 0.68 D,[5] compared with 3.2 D and 0.85 D respectively in this study. In individual cases, unpredictability of coupling ratio following astigmatic keratotomy may result in spherical equivalent error when combined with simultaneous cataract surgery and IOL implantation.[6] Arcuate keratotomy requires additional surgical steps and skills and is best performed with topical anaesthesia to allow patient fixation on the operating light. With the toric IOL, the operation and anaesthesia are unchanged, and the possible complications of corneal incisional surgery (e.g. perforation, corneal oedema, infection, glare[7]) are avoided. Clearly, use of the toric IOL precludes use of a multifocal IOL; thus corneal approaches to reducing astigmatism are necessary if multifocality is required. Additionally, the magnitude of cylinder correction possible is limited by the availability of only two IOL-cylinder powers, whereas corneal surgery may offer a wider range of possible treatment effects.

Table 3. *Summary of results of studies on IOL rotation*

Author	IOL type	Rotation
Shimizu *et al.*[8]	Three-piece PMMA C-loops (toric)	21% >30° at 3 months
Werblin[9]	Three-piece PMMA J-loop (spherical)	4% >30° 'early'
Patel *et al.*[10]	Plate-haptic silicone 10.3 mm (spherical)	24% >30° at 2 weeks (no significant rotation after 2 weeks)
	Three-piece silicone C-loops Polypropylene	9% >30° at 2 weeks
Grabow[11]	Plate-haptic silicone 10.8 mm (toric)	5% >30° at 6 months
Current study	Plate-haptic silicone 10.8 mm (toric)	18% >30° at 3–6 months

The results of the current study are comparable with those of previous studies.

There are a number of reasons why post-operative refraction may differ from that predicted. These include biometric error, keratometric changes, anterior chamber depth prediction error and rotation of a toric IOL. The latter has been addressed by a number of authors (Table 3).[8–10]

Assuming IOL stability and no corneal curvature changes, the post-operative axis of astigmatism would be unchanged from the pre-operative keratometric axis (any lenticular component to refractive astigmatism having been removed by cataract surgery). IOL rotation results in axis shift and reduced efficacy of astigmatic correction. The relationship is non-linear. At 30° of rotation the cylinder remains the same size but is shifted 30°.[12] A planned under-correction is much less likely to cause a significant change in cylinder axis in the event of IOL rotation. Assuming a planned 80% correction of pre-existing cylinder, the mean IOL rotation of 8.9° in this series would result in 65% correction of magnitude with a 23° shift in axis.[12] The actual mean (vector) refractive axis error of 7° in this series is likely to be acceptable to most surgeons (and patients). Four eyes, however, had IOL rotation of more than 30° (including those detected and dialled on the first post-operative day).

To improve refractive predictability it is necessary to consider the forces that might act upon an IOL and cause it to rotate.[10] Gravity, eye movement and capsular bag changes such as fibrosis and epithelial proliferation act on the IOL. The IOL resists these forces as a result of haptic tension, and friction between the optic and/or the haptic and the capsular bag. The forces amenable to intervention relate to haptic tension and haptic/optic adhesion to the capsular bag. The excellent study by Patel *et al.*[10] suggests that capsular fibrosis contributes to late anticlockwise rotation of loop haptic IOLs, while capsular adhesion either side (and through the fenestration) of symmetrical plate haptic IOLs accounts for their late stability. From their data it would seem that designs with symmetrical haptics are most likely to be successful in the long term. Modifications to improve early stability should be considered. Staar have modified their toric IOL range with the introduction of the AA-4023TL for lower dioptric powers (9.5–21 D). The overall length is increased to 11.2 mm on the assumption that these are likely to be larger eyes with larger capsular bags, and the increased length is intended to increase haptic friction with the capsular equator. Interestingly, Patel *et al.*[10] found no relationship between axial length and IOL rotation, despite using a plate-haptic IOL of only 10.5 mm overall length. The haptic surface has also been modified ('frosted') to increase friction, though this raises concerns over enhanced bacterial and biofilm adhesion.[13]

Conclusions

Refractive astigmatism was markedly reduced in most of the cases in this series. The few unsuccessful cases result from early IOL rotation. Results could be improved by careful observation over the first 2 weeks post-operatively, with operative reintervention as required. IOL design adaptations may further improve rotational stability.

The toric IOL is a valuable addition to the tools available to the cataract surgeon. A randomised trial in comparison with combined cataract extraction and corneal refractive surgery would be necessary to establish their relative merits.

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