Results of the implantation of an aspheric toric intraocular lens for the correction of astigmatism in cataract surgery

Marta Romero Domínguez, MD; Alfredo Castillo Gómez, MD, PhD; David Carmona González, OD; Carlos Palomino Bautista, MD

OBJECTIVE: The aim of this study was to evaluate correction of astigmatism following implantation of the TECNIS® Toric IOL.

SETTING: University Hospital Quirón, Madrid (Spain)

METHODS: Inclusion criteria were age over 45 years, loss of vision due to cataract, and regular corneal astigmatism > 0.75 diopters. Exclusion criteria included ocular pathology or previous surgery. The cylinder power of the IOL and the position of the axis were determined using an online calculator supplied by the manufacturer. Postoperative evaluation was performed on day 1, 1 week, 1 month and 3 months after surgery. Uncorrected (UDVA) and corrected (CDVA) visual acuity, slit lamp examination, IOL axis, applanation tonometry and funduscopy were all assessed. Intraocular rotation of the IOL was measured with a slit lamp using a scale that overlapped the markings on the anterior side of the IOL.

RESULTS: Fifty-three eyes of 44 patients (25 men and 19 women) were included. Mean age was 62.9 years. At 3 months after surgery, the mean logMAR UDVA was 0.08 ± 0.13 and the mean logMAR CDVA was 0.04 ± 0.13. CDVA was between 20/40 and 20/30 (0.3 - 0.18 logMAR) in 51 eyes (96.23%), only 2 eyes (3.77%) had a CDVA below 20/40 (> 0.3 logMAR).

CONCLUSION: The results of our study show that implantation of the TECNIS® Toric IOL is effective, predictable and stable for the correction of regular corneal astigmatism during cataract surgery.

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Intraocular lenses (IOLs) used in cataract surgery can correct spherical refractive errors. In recent years, new IOL models have been launched which can also correct astigmatism defects\(^1\)-\(^3\).

In a study in 7,500 eyes with cataract, an average corneal astigmatism of 1.0 diopters (D) was obtained and only 4.2% of eyes showed no astigmatism\(^4\). In another study in 4,540 eyes, only 13.2% had no astigmatism, 64.4% had astigmatism between 0.25-1.25 D and 22.2% had ≥ 1.50 D\(^5\). In another study in 1,230 eyes, up to 497 eyes (40.41%) had > 1.0 D of astigmatism\(^6\). This shows the prevalence of this refractive error in the population.

Eyes are not perfect optical systems. When the light conveying the optical information of an object passes through the human eye, it is subject to a series of distortions that cause a worsening of the optical quality and of the visual function. This blurring is the first physical limit of vision. These deformities of light are called optical aberrations, and can be classed as lower- or higher-order aberrations. Lower-order aberrations include the refraction defects traditionally compensated by glasses and contact lenses: positive and negative defocus (myopia and hyperopia respectively) and astigmatism. Higher-order aberrations are spherical aberration, coma, trefoil, tetrafoil, etc.\(^7\).

Different surgical procedures are currently used to correct astigmatism and improve the visual quality of patients, such as controlled positioning of the incision in phacoemulsification surgery, corneal or limbal relaxing incisions and LASIK\(^8\)-\(^12\).
The first toric IOLs were used by Schimizu et al. in 1994 to correct pre-existing astigmatism\(^1\). Toric IOLs reduce postoperative astigmatism, providing greater reversibility and adaptation than other techniques, and are currently considered to be an effective method for the correction of astigmatism\(^2-19\).

This paper presents a prospective observational study aimed at evaluating the correction of astigmatism following implantation of the TECNIS\(^\text{®}\) Toric IOL (Abbott Medical Optics Inc, USA) in a series of patients with corneal astigmatism > 0.75 D undergoing cataract surgery.

**METHODS**

This observational study included 53 eyes from 46 patients aged over 45 with cataract and regular corneal astigmatism greater than 0.75 D that underwent TECNIS\(^\text{®}\) Toric IOL implantation (Abbott Medical Optics Inc, USA) in the University Hospital Quirón in Madrid between January 2012 and January 2013. The study complied with the principles of the Helsinki Declaration.

Before surgery, all patients signed an informed consent form describing the risks, complications, and techniques involved in the procedure.

Inclusion criteria were age older than 45 years with loss of vision due to cataract and regular corneal astigmatism ≥ 0.75 D. Exclusion criteria were irregular corneal astigmatism, corneal pathologies, glaucoma, pseudoexfoliation, retinopathy or macular degeneration, previous history of ocular inflammation and previous intraocular or corneal surgery.

Preoperative evaluation consisted of a complete eye examination including uncorrected distance visual acuity (UDVA), best corrected distance visual acuity (CDVA), keratometry (Topcon Corporation, Tokyo, Japan), subjective refraction, applanation tonometry, slit lamp examination, ophthalmoscopy with pupillary dilation, corneal topography (Topcon Corporation, Tokyo Japan), Optical Coherence Tomography (OCT) of the macula (Stratus\(^\text{®}\), Carl Zeiss Meditec, Jena, Germany) and optical biometry (IOL Master\(^\text{®}\), Carl Zeiss Meditec, Jena, Germany).

The cylinder power of the toric IOL and the correct positioning of the axis were determined using an online calculator supplied by the manufacturer (www.tecnistoriccalc.com). Patient age, surgically induced astigmatism (SIA), (which according to our statistical data was 0.15 D; axis 180\(^\circ\)), preoperative keratometry (corneal topography Topcon Corporation, Tokyo, Japan), preoperative corneal astigmatism, spherical equivalent of the IOL and axial length (IOL Master, Carl Zeiss Meditec, Jena, Germany) were considered for the calculation. The biometric formula was chosen according to the following algorithm: for less than 21 mm axial length the Holladay II formula was used, between 22 and 27 mm the Haigis formula was used and in eyes with an axial length exceeding 27 mm the SRK-T formula was used.

The TECNIS\(^\text{®}\) Toric IOL is a biconvex IOL with a toric aspherical anterior surface (Figure 1) made of a foldable hydrophobic acrylic material. The optic has a diameter of 6.0 and a total length of 13.0 mm. It has a frosted 360\(^\circ\) double-square edge to reduce migration of epithelial cells and glare caused by the edge of the lens. The special offset arrangement of the haptics provides three fixation points in the lens capsule to maintain good stability. The IOL is available between +5 and +34 diopters with increments of 0.5 D and a cylinder power of 1.0, 1.5, 2.25, 3.0, and 4.0 D. (Table 1). The marks indicating the flat axis of the IOL appear as four points on the anterior surface of the lens.

![Figure 1. Toric intraocular lens used in the study.](image-url)

All surgeries were performed by the same surgeon (ACG) using topical anesthesia. With the patient sitting at the slit lamp, the corneal limbus was marked at 0\(^\circ\) and 180\(^\circ\). Later, with the patient supine, the corneal meridian was marked with a Mendez ring. Phacoemulsification was performed with a micro coaxial technique using a 2.2 mm temporal incision. The IOL was inserted into the capsular bag with an implantation system (Abbott Medical Optics Inc, USA). The IOL was rotated from −10\(^\circ\) to −15\(^\circ\) of the final position. After complete elimination of the viscoelastic, the IOL was rotated to its finally alignment determined by earlier calculations. The correct position of the IOL was reviewed with a Mendez ring, and finally the incision was hydrated. In cases of bilateral surgery, both eyes underwent surgery within one week.
Postoperative evaluation was performed 1 day, 1 week, 1 month and 3 months after surgery. UDVA, CDVA, slit lamp examination, IOL axis, applanation tonometry and funduscopy were assessed. The intraocular rotation of the IOL was measured using the scale of a slit lamp by assessing the overlap of the scale with the IOL toric marks.

Data were analyzed using SPSS for Windows version 19.0 (IBM, Armonk, NY, USA). The normality of data samples was assessed using the Kolmogorov-Smirnov test. When parametric analysis was possible, preoperative and postoperative data and consecutive postoperative visits were analyzed using the paired Student’s t test, while the Wilcoxon signed rank test was used to assess the importance of these differences when parametric analysis was not possible. One-way ANOVA with post-hoc Bonferroni analysis was used to compare independent groups (IOL model), while the Kruskal-Wallis test with post-hoc Mann-Whitney and Bonferroni correction was used when parametric statistics could not be applied. In addition, the Chi-square test was used to compare percentages between consecutive visits. For all statistical tests, a p-value inferior to 0.05 was considered statistically significant.

Preoperative and postoperative astigmatism was analyzed as a two-dimensional vector (J0 and J45), where J0 is the result of $-(\text{cylinder}/2) \cos(2 \times \text{axis})$, and J45 = $-(\text{cylinder}/2) \sin(2 \times \text{axis})$.

**RESULTS**

Fifty-three eyes of forty-four patients (56.8% males, 43.2% females) were included in the study. Mean age was 62.9 ± 10.2 years (range 45-88 years) (Table 2).

<table>
<thead>
<tr>
<th>Lens model</th>
<th>ZCT100</th>
<th>ZCT150</th>
<th>ZCT225</th>
<th>ZCT300</th>
<th>ZCT400</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cylinder power-plane of the lens</td>
<td>1.00 D</td>
<td>1.50 D</td>
<td>2.25 D</td>
<td>3.00 D</td>
<td>4.00 D</td>
</tr>
<tr>
<td>Cylinder power-corneal plane</td>
<td>0.69 D</td>
<td>1.03 D</td>
<td>1.54 D</td>
<td>2.06 D</td>
<td>2.74 D</td>
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<tr>
<td>Corneal astigmatism correction range</td>
<td>0.50-0.75 D</td>
<td>0.75-1.50 D</td>
<td>1.50-2.00 D</td>
<td>2.00 D-2.75 D</td>
<td>&gt; 2.75 D</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n)</td>
<td>44</td>
</tr>
<tr>
<td>Age (mean ± SD)</td>
<td>62.9 ± 10.2</td>
</tr>
<tr>
<td>Sex (male/female)</td>
<td>25/19</td>
</tr>
<tr>
<td>Eyes (n)</td>
<td>53</td>
</tr>
<tr>
<td>Preoperative sphere (D, mean ± SD)</td>
<td>−0.11 ± 3.30</td>
</tr>
<tr>
<td>Range</td>
<td>+4.0 to −12.0</td>
</tr>
<tr>
<td>Preoperative cylinder (D, mean ± SD)</td>
<td>−1.95 ± 0.75</td>
</tr>
<tr>
<td>Range</td>
<td>−0.75 to −3.75</td>
</tr>
<tr>
<td>Preop keratometry</td>
<td>k1 (mean ± SD) 42.77 ± 1.85</td>
</tr>
<tr>
<td></td>
<td>k2 (mean ± SD) 44.33 ± 1.73</td>
</tr>
<tr>
<td>IOL diopter power (D, mean ± SD)</td>
<td>20.2 ± 2.85</td>
</tr>
<tr>
<td>Range</td>
<td>14.0-26.5</td>
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<td>Toric lens model</td>
<td>ZCT150 (n) 18</td>
</tr>
<tr>
<td></td>
<td>ZCT225 (n) 16</td>
</tr>
<tr>
<td></td>
<td>ZCT300 (n) 19</td>
</tr>
</tbody>
</table>

n = sample size, SD = standard deviation
Preoperative mean of sphere and cylinder was $-0.11 \pm 3.30 \, \text{D (range +4 to –12 D)}$ and $-1.95 \pm 0.75 \, \text{D (range –0.75 to –3.75 D)}$, respectively. Six eyes (11.32%) had preoperative astigmatism of less than 1 D, in 32 eyes (60.38%) this was between 1 and 2 D, and in 15 eyes (28.30%) it was higher than 2 D. The ZCT150 model (cylinder power 1.5 D) was implanted in 18 eyes (34%), the ZCT225 model (cylinder power 2.25 D) in 16 eyes (30.2%) and the ZCT300 model (cylinder power 3.0 D) in 19 eyes (35.8%).

At three months after implantation of the IOL, the logMAR UDVA mean is $0.08 \pm 0.13$ (20/20 - 20/25) and the logMAR best-corrected distance visual acuity (BCDVA) mean was $0.04 \pm 0.13$ (20/20 - 20/25). The BCDVA was between 0.3 and 0.18 logMAR (between 20/40 and 20/30) in 51 eyes (96.23%), only 2 eyes (3.77%) reached a BCDVA > 0.3 logMAR (less than 20/40) (Table 3).

A significant reduction in refractive astigmatism after implantation of the toric IOL was found in all patients ($p < 0.05$) (Table 3). Figure 2 shows the astigmatic component as a two-dimensional vector ($J_0$ and $J_{45}$). The central zone (0.0) represents an eye without refractive astigmatism. The preoperative measurements show scattered data, whereas data are concentrated around the central zone (0.0) after implantation of the toric IOL. The magnitude of the refractive vector $J_0$ was reduced from $-0.05 \pm 0.71 \, \text{D}$ to $+0.01 \pm 0.15 \, \text{D}$ at three months ($p = 0.18$); $J_{45}$ was reduced from $-0.16 \pm 0.77 \, \text{D}$ to $+0.04 \pm 0.18 \, \text{D}$ at three months ($p = 0.16$). There were no statistically significant differences between the pre- and postoperative keratometric $J_0$ and $J_{45}$ values ($p = 0.54$ for $J_0$ and $p = 0.72$ for $J_{45}$).

None of the eyes required further surgery to reposition the axis of the IOL within three months of follow-up. The average rotation was $3.1 \pm 2.8$ degrees (range 0° to 12°). Stratified for the toric IOL model, we obtained an average rotation of $2.8 \pm 3.9$ degrees for ZCT150 (range 0° to 10°), of $3.5 \pm 2.4$ degrees for ZCT225 (range 0° to 12°) and $3.1 \pm 4.6$ degrees for ZCT300 (range 0° to 12°). The linear regression analysis showed no significant relationship between the intraoperative position of the axis and the postoperative alignment at three months ($p > 0.05$).

There were no intraoperative or postoperative complications.

**DISCUSSION**

The use of toric IOLs during cataract surgery is a valid surgical option to correct corneal astigmatism. Limbal or corneal relaxing incisions and excimer laser treatment can also be used.

Astigmatism has a significant impact on visual function and visual quality. Currently, several models of toric IOL are available with a wide range of spheres and cylinders that allow them to be used in most patients with cataract and astigmatism.
In our study, at three months after surgery, mean logMAR UDVA was 0.08 ± 0.13, with 96.3% of patients (51 eyes) achieving a visual acuity of 20/40 or better (≤ 0.3 logMAR). Mean logMAR CDVA was 0.04 ± 0.13. With respect to the toric IOL model, the best results were obtained with ZCT225, where 100% (16) of the eyes achieved a logMAR UDVA of ≤ 0.30. The results were comparable with other studies, considering that patients with previous ocular pathologies such as irregular corneal astigmatism, glaucoma, macular degeneration, amblyopia and previous surgeries were excluded. Sheppard et al. reported that 88% of eyes with the TECNIS® Toric IOL reached a UDVA of 20/40 (0.3 logMAR) or better and 95.4% reached a CDVA of 20/40 (0.3 logMAR) or better; it should be noted that this study did not exclude patients with other eye diseases, and thus included several patients with incipient macular degeneration and one patient with amblyopia. De Silva et al. reported that 79% of eyes reached a UDVA of 20/35 or better after MicroSil® 6115TU IOL implantation. Alio et al. achieved a visual acuity of 20/40 in 76% of eyes implanted with the Acry. Comfort® 646 TLC (Acri.Tec GmbH, Hennigsdorf, Germany). Mendicute et al. obtained a UDVA of 20/40 or better in 93% of eyes after implantation of the AcrySo® toric IOL (Alcon, Fort Worth, USA). In this study, other ocular pathologies with decreased visual acuity were excluded. Holland et al. showed in their parallel group study that 40.7% of patients with the toric AcrySo® IOL obtained a UDVA of 20/20 compared to 19.4% in the control group with the spherical AcrySo® IOL. Bauer et al. reported a UDVA of 20/25 in 75%-85% of patients implanted with the AcrySo® toric IOL.

The TECNIS® Toric IOL is effective in reducing refractive astigmatism. The preoperative sphere and cylinder mean was −0.11 ± 3.30 D (range +4 to −12 D) and −1.95 ± 0.75 D (range −0.75 to −3.75 D), respectively, and went down to a postoperative sphere of +0.06 ± 0.32 D (range −0.50 to +0.75) and an astigmatism of −0.36 ± 0.32 D (range −1 to 0.0). Sheppard et al. reported a preoperative mean sphere of +0.20 ± 2.54 D and a preoperative mean astigmatism of −1.91 ± 1.07 D which were reduced to a postoperative mean sphere of +0.24 ± 0.66 D and a postoperative mean astigmatism of −0.67 ± 0.54 D. Mendicute et al. reported a preoperative mean sphere of +1.26 ± 1.85 and mean astigmatism of −2.34 ± 1.28 and a postoperative mean sphere of −0.12 ± 0.44 D and mean astigmatism of −0.72 ± 0.43.

The rotational stability of toric IOL is crucial for good refractive results. In fact, rotation is a major issue of toric IOLs. In general, toric IOL rotations less than 10° changed the eye’s refraction less than 0.50 diopters. Rotation occurs most frequently in the early postoperative period, before anterior and posterior capsule fuse together. Factors influencing postoperative rotation are fluctuations in intraocular pressure, incomplete removal of the viscoelastic, capsular contraction, capsulorhexis size and optic and haptic design of the IOL. IOLs with C-shaped haptics show a higher rate of postoperative rotation. Shimizu et al. reported that 41% of operated eyes presented a rotation of more than 10°. Although the TECNIS® Toric IOL has C shaped haptics, it shows low deviation levels from the theoretical axis, due to its design with three fixing points and offset haptics giving 360° contact with the capsular bag. Its acrylic hydrophobic material binds with fibronectin, giving additional stability.

The TECNIS® Toric IOL has a high stability in the capsular bag. In our study, the average rotation was 3.1 ± 2.9° (range 0°-12°). Stratifying for the toric IOL model, we obtained an average rotation of 2.8 ± 3.9° for ZCT150, of 3.5 ± 2.4° for ZCT225 and 3.1 ± 4.6° for ZCT300. The results are similar to those obtained in other studies. No secondary procedure to reposition the IOL axis was necessary in any eye.

Sheppard et al. noted a rotation of 3.4° in 67 eyes implanted with the TECNIS® Toric IOL; no patient required a secondary procedure to reposition the IOL. Mendicute et al. obtained an average rotation of 3.63 ± 3.11° in 30 eyes operated with the AcrySo® Toric IOL, with a rotation of less than 10° in 96.7%. Holland et al. had an average rotation of 4° (range 0°-20°) for the AcrySo® Toric IOL in 256 patients. Entabi et al. observed a rotation of 3.4° (range 0°-12°) with the T-flex® IOL (Rayner Intraocular Lenses Ltd, Hove, UK) at 16 weeks.

In conclusion, the results of our study show that implantation of the TECNIS® Toric IOL for the correction of regular corneal astigmatism during cataract surgery is effective, predictable and stable. Studies with a larger sample size and longer postoperative follow-up are necessary to evaluate the efficacy and safety of this IOL.

REFERENCES


First author:
Marta Romero Domínguez, MD
Quiron University Hospital Madrid,
Madrid, Spain