

## **Title Page**

**TITLE:** Clinical outcomes following implantation of a new hydrophobic acrylic toric IOL during routine cataract surgery

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## **SHORTENED RUNNING HEAD:**

Tecnis Toric IOL

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**SYNOPSIS:** The Tecnis Toric intraocular lens is able to reduce residual astigmatism after routine cataract surgery.

## **Abstract**

**PURPOSE:** To assess clinical outcomes following implantation of the Tecnis Toric intraocular lens (IOL; Abbott Medical Optics) to correct pre-existing corneal astigmatism in patients undergoing routine cataract surgery.

**SETTING:** Four hospital eye clinics throughout Europe.

**METHODS:** This prospective observational study included 67 eyes of 60 patients with at least 0.75 D of pre-existing corneal astigmatism undergoing routine cataract surgery. Phacoemulsification was performed, followed by insertion and alignment of the Tecnis Toric IOL. Patients were examined 4 to 8 weeks post-operatively; uncorrected distance visual acuity (UDVA), best-corrected distance visual acuity (CDVA), manifest refraction and keratometry were measured. Individual patient satisfaction regarding uncorrected vision and the surgeon's assessment of ease of handling and performance of the IOL were also documented. Cylinder axis of the toric IOL was determined by dilated slitlamp examination.

**RESULTS:** 4-8 weeks post-operatively, mean UDVA was  $0.15 \pm 0.17$  logMAR, and 20/40 or better in 88% of eyes. The mean refractive cylinder decreased significantly following surgery, from  $-1.91 \pm 1.07$  to  $-0.67 \pm 0.54$  D; no significant change in keratometric cylinder was observed. Mean absolute IOL misalignment from the intended axis was 3.4 degrees (range 0-12 degrees). The good standard of UDVA achieved resulted in high levels of patient satisfaction.

**CONCLUSIONS:** Implantation of the Tecnis Toric IOL is an effective, safe and predictable method to manage corneal astigmatism in patients undergoing routine cataract surgery.

**KEYWORDS:** astigmatism; cataract surgery; toric IOL; Tecnis; hydrophobic acrylic.

## Introduction

Toric intraocular lenses (IOLs) were conceptualised by Shimizu *et al.* in 1994,<sup>1</sup> to correct pre-existing astigmatism resulting from corneal toricity. Given that approximately 60 % of cataractous eyes have over 0.75 D of corneal astigmatism,<sup>2,3</sup> and uncorrected astigmatism results in reduced visual acuity and increased spectacle dependence,<sup>4,5</sup> predictable and effective toric IOL models are required to provide patients with optimal visual outcomes. Surgical correction of astigmatism is preferable to spectacle prescription, which induces meridional magnification and spatial distortion.<sup>6</sup> Correction of astigmatism on the cornea may be achieved using surgical techniques such as corneal or limbal relaxing incisions, or varying the placement of the incision site.<sup>7,8</sup> However, such techniques are associated with a number of limitations, including poorer predictability in eyes with higher levels of astigmatism, due to variable tissue healing, and long-term mechanical instability.<sup>9,10</sup> Toric IOLs may therefore represent a more stable and predictable method for correction of pre-existing corneal astigmatism.<sup>11</sup>

Several previous studies have reported clinical findings following implantation of various models of toric IOL.<sup>e.g.12-17</sup> Successful visual outcomes rely upon both careful alignment of the toric IOL with its intended axis, and minimal post-operative rotation; approximately 3% of cylinder power is lost for every 1 degree of off-axis rotation.<sup>1</sup> The new Tecnis Toric (Abbott Medical Optics) IOL features 3-point fixation (haptic-lens-haptic) within the capsular bag to stabilise the position of the implant and reduce undesirable rotation.

The purpose of this prospective observational study was to evaluate visual outcomes and patient and surgeon satisfaction with the Tecnis Toric IOL in a non-interventive setting under routine conditions.

### **Patients and Methods**

This prospective observational study included 67 astigmatic eyes of 60 patients undergoing routine cataract surgery with implantation of the Tecnis Toric IOL. Surgery took place at four hospital departments across Europe between January and March 2011. The research was approved by the local ethics committees and adhered to the tenets of the Declaration of Helsinki. Informed consent was obtained from all patients prior to participation.

Patients with cataract, scheduled for routine phaco-emulsification cataract surgery and IOL implantation, with at least 0.75 D of pre-operative regular corneal astigmatism were enrolled in the study. As the study was a non-interventional trial, patient selection was not limited beyond the indications of the product (i.e. adults with cataract and corneal astigmatism, listed for routine cataract surgery).

#### *Pre-operative assessment*

All patients underwent a complete ophthalmic examination prior to cataract surgery, which included manifest refraction; best corrected logMAR visual acuity (BCVA); axial length measurement with the IOLMaster (Carl Zeiss Meditec Inc., Dublin, CA) and dilated slitlamp examination. Keratometry was largely measured automatically with the IOLMaster, although manual keratometry was permitted. Corneal topography was optional to exclude irregular astigmatism. In incidences where

topography was not available, previous ophthalmic history was examined, along with a comparison of refractive and corneal astigmatism; eyes with a significant disparity between these values were excluded from the study. The IOL manufacturer's web-based tool ([www.TecnisToricCalc.com](http://www.TecnisToricCalc.com). Accessed July 7<sup>th</sup> 2012) was used to determine the required cylindrical power of the IOL and the axis of placement in the eye from pre-operative keratometry and biometry data, preferred incision location and the surgeon's estimated surgically-induced corneal astigmatism (e.g. 0.4 D).

### *Intraocular lens*

The Tecnis Toric 1-piece IOL, launched in 2010, incorporates a proprietary wavefront-designed toric aspheric optic to compensate for corneal spherical aberration and correct astigmatism. The optic is 6.0 mm in diameter and features a 360° squared edge with frosting to reduce migration of lens epithelial cells (LECs) and reduce possible edge glare effects. Overall length of the IOL is 13.0 mm, and the C-loop haptics, offset to the optic, provide 3-point fixation (Tri-fix) within the capsular bag to maintain good centration and confer rotational stability. The hydrophobic acrylic material has a high Abbé value of 55 (compared to 47, 43 and 37 for the natural crystalline lens and the Hoya and Alcon acrylic IOL materials, respectively); reduced longitudinal chromatic aberration improves optical quality and can increase contrast sensitivity.<sup>18</sup> Available parameters for the Tecnis Toric are now +5.00 to +34.00 D spherical equivalent, in 0.50 D steps, and 1.00, 1.50, 2.25, 3.00 and 4.00 D cylinder powers. At the time of the study in 2011, the maximum available cylinder power was 3.00 D. Cylinder axis marks (4 dots) on the anterior surface of the IOL denote the meridian with the lowest power.

.....Insert Figure 1 here.....

### *Surgical technique*

Prior to surgery, topical anaesthetic eye drops (e.g. benoxinate 0.4 %) were instilled to the operative eye, and with the patient sitting upright with their head in the vertical position to avoid cyclorotation, a single use ophthalmic marking pen was used to mark the corneal limbus at the 12 and 3 o'clock positions. Each surgeon used their preferred marking technique; either free-hand or with a Bakewell Bubble Level (Mastel Inc.). Intraoperatively, these marks enabled determination of the required axis of IOL orientation, using the individual surgeon's preferred instrument e.g. Mendez ring with a Nujits toric axis (America Surgical Instruments Corp.). Following phacoemulsification, a foldable Tecnis Toric IOL was inserted into the capsular bag using the Unfolder Platinum 1 series implantation system (Abbott Medical Optics). Gross alignment of the IOL with its intended axis was achieved by rotating the IOL as it unfolded. Following careful removal of all ophthalmic viscosurgical device (OVD, which may cause undesirable rotation of the implant if not fully removed) from the capsular bag, the IOL was rotated to the correct axis to complete surgery.<sup>19</sup>

### *Post-operative assessment*

In addition to the routine post-operative management offered by individual surgeons, patients were assessed 4 to 8 weeks following implantation of the Tecnis Toric IOL. At this visit, manifest refraction, logMAR uncorrected (UCVA) and corrected (CDVA) visual acuities were recorded, and keratometry was performed using the IOLMaster.

Pupil dilation of operative eyes was achieved by topical application of tropicamide 1.0 % (with phenylephrine 2.5 % if necessary) and the toric axis measured at the slitlamp using a thin coaxial slit, rotated until it overlapped the axis markings on the IOL. Post-operative determination of the axis of the IOL was performed on 61 eyes.

As well as clinical findings, patients were questioned regarding post-operative experiences of optical/ visual disturbances (e.g. arcs of light; haloes; ghosting; day glare; night glare) and asked to rate their satisfaction with their level of unaided vision on a scale of 1-5, where 1 = not at all happy and 5 = very happy. Surgeons used similar scales of 1-5 to rate ease of use of the Tecnis Toric IOL calculator, ease of lens implantation, achievement of target refraction, and overall satisfaction with the IOL. Surgeons documented these satisfaction scores for all of the eyes treated in the study. All data were entered into online case report forms (CRFs).

#### *Data analyses and statistics*

Pre- and post-operative  $J_0$  and  $J_{45}$  cylindrical vectors (refractive and keratometric) were computed, using an Excel worksheet (2010 version, Microsoft Corp.) as follows:<sup>20</sup>

$$J_0 = -(\text{cylinder}/2)\cos(2*\text{axis}) \quad \text{Equation 1}$$

$$J_{45} = -(\text{cylinder}/2)\sin(2*\text{axis}) \quad \text{Equation 2}$$

SPSS for Windows (version 18.0, SPSS Inc.) was used for statistical analysis. Following a Kolmogorov-Smirnov test for normality, if parametric analysis was possible, a paired *t*-test was performed for comparison of parameters between pre- and post-operative visits. The Wilcoxon rank-sum test was used where data were not normally distributed to identify significant changes between pre- and post-operative



values. A *P* value of 0.05 or less was considered statistically significant. Linear regression analysis was used to analyse the association between the intraoperative axis and the level of post-operative misalignment from the intended axis.

## **Results**

67 eyes of 60 patients were enrolled in the study. The patient demographics and pre-operative data are summarised in Table 1.

.....Insert Table 1 here.....

### *Complications*

There were no intraoperative complications. One eye developed post-operative cystoid macular oedema and a second patient experienced a hypersensitivity reaction to the topical antibiotic and steroid medication, which caused significant facial and ocular redness, with a reduction in visual acuity. These patients did not attend the 4-8 week post-operative assessments as they were receiving alternative ophthalmic care (so could not be included in statistical analyses), however the final CDVAs in these eyes were both 0.1 logMAR.

### *Visual Outcomes*

Table 2 summarises the pre- and post-op, operative refractive data, UCVA and CDVA values. At the 4 to 8 week visit, mean UCVA was approximately 20/30, which improved slightly with refractive correction to approximately 20/25. The UCVA was

20/40 (0.3 logMAR) or better in 87.7 % of eyes (Figure 2). The post-operative CDVA was 20/40 (0.3 logMAR) or better in 95.4 % of eyes, 20/30 (0.18 logMAR) or better in 76.9 %, and 20/20 (0.0 logMAR) or better in 46.2 %.

.....Insert Table 2 here.....

.....Insert Figure 2 here.....

### *Refractive outcomes*

Four to eight weeks post-operatively, 62 eyes (95%) had a mean spherical equivalent (SE) within  $\pm 1.00$  D of emmetropia. The level of refractive astigmatism decreased significantly following Tecnis Toric IOL implantation ( $P < 0.001$ ; Table 2). Figure 3 illustrates the pre- and post-operative  $J_0$  and  $J_{45}$  refractive cylinder vectors; the origin (0, 0) of Figure 3 represents an eye with nil refractive astigmatism. Post-operatively, a concentration of data points around the origin is present, compared to the pre-operative spread. There was a significant reduction in the magnitude of the refractive  $J_0$  vector ( $P = 0.002$ ) following implantation of the Tecnis Toric IOL. The mean  $J_{45}$  vector did not change significantly ( $P = 0.703$ ), however, this would be expected given that the magnitude of the mean  $J_{45}$  vector was minimal both pre- and post-operatively ( $0.04 \pm 0.58$  D, and  $-0.02 \pm 0.25$  D, respectively), and not significantly different to zero (pre-operative:  $P = 0.528$ ; post-operative:  $P = 0.870$ ). The keratometric  $J_0$  and  $J_{45}$  vectors did not change significantly between the pre- and post-operative visits ( $J_0$ :  $P = 0.484$ ;  $J_{45}$ :  $P = 0.982$ ).

.....Insert Figure 3 here.....

### *IOL alignment*

No eye required additional surgery to rotate and reposition the IOL axis during the course of the study. Mean absolute IOL misalignment at the 4-8 week visit was 3.4 degrees (range 0 to 12 degrees). Nine eyes (14.7 %) had misalignment >5 degrees, 1 eye (1.6 %) had misalignment >10 degrees. Linear regression analysis revealed no significant association between intraoperative axis position and post-operative alignment ( $P = 0.27$ ).

### *Subjective experiences*

#### Patients

On a scale of 1 to 5 (where 1 = not at all happy, and 5 = very happy), 22 patients (37.9 %) were very happy with their unaided vision post-operatively, and 32 (55.2%) were happy (4 out of 5). Although all subjects were at least moderately happy (3 out of 5) with their post-operative unaided vision, patient satisfaction was significantly associated with post-operative UDVA ( $y = 4.834 - 2.481x$ ;  $r = 0.564$ ;  $r^2 = 0.318$ ;  $P < 0.001$ ). Optical or visual disturbances were rarely reported by patients attending the post-operative visit; 2 subjects (3%) reported daytime glare, both giving scores of 3 out of 5 for post-operative satisfaction with vision.

#### Surgeons

Also using a 1 to 5 scale to describe their experience related to each subject, the 4 ophthalmic surgeons described use of the Tecnis Toric online calculator as easy (4 out of 5) or very easy (5 out of 5) in 56 subjects (96.6 %). Regarding ease of IOL

implantation; ease of alignment and achievement of target refraction, surgeons scored 4 or 5 out of 5 in 94.8% (55 patients); 96.5 % (56 patients) and 98.3% (57 patients), respectively. In terms of overall refraction with the Tecnic toric IOL, surgeons were satisfied or very satisfied in 93.1% (54 patients).

## **Discussion**

Use of toric IOLs during cataract surgery is one of several surgical options to correct corneal astigmatism and provide improved visual outcomes. The variability in healing responses associated with surgical flattening of the cornea results in a level of unpredictability regarding final outcomes,<sup>9,10</sup> thus stable and effective toric IOLs implanted into the capsular bag during routine cataract surgery and requiring no modification of the cornea, are an important advancement in modern cataract surgery. The present study, to the best of our knowledge, is the first to describe application of the Tecnis Toric IOL in a cohort of patients undergoing routine cataract surgery.

The results of the present study indicate that the Tecnis Toric IOL is an effective means of treating corneal astigmatism  $\geq 0.75$  D, with a statistically significant mean reduction in refractive astigmatism of  $1.24 \pm 1.20$  D. Post-operative refractive astigmatism ranged from 0.00 to -2.25 D (mean  $-0.67 \pm 0.54$  D); the single eye with a -2.25 D post-operative cylindrical refraction had a pre-operative -4.75 D refractive cylinder and 3.80 D of corneal toricity. Tecnis Toric IOLs now feature cylinder powers of 1.00, 1.50, 2.25, 3.00 and 4.00 D (equivalent to 0.69, 1.03, 1.54, 2.06 and 2.74 D at the corneal plane, respectively). The broad range of cylinder powers allows

application of the IOL in the majority of cataract patients with significant corneal astigmatism.

The good standard of UDVA achieved in the study resulted in a high level of patient satisfaction with their uncorrected vision (93.1 % of subjects were happy or very happy), and a statistically significant association between these two factors was identified. The UDVA achieved in the present study (mean  $0.15 \pm 0.17$  logMAR, with 88 % of eyes equivalent to 20/40 or better) compares favourably with reports of outcomes with alternative toric IOLs. DeSilva *et al.*<sup>14</sup> reported that 79 % of eyes achieved 20/35 or better UDVA following implantation of the HumanOptics MicroSil 6116TU; Alió *et al.*<sup>21</sup> found UDVA of at least 20/40 in 76% of eyes with moderate to high astigmatism implanted with the Acri.Comfort 646 TLC and with various Acrysof toric models, Bauer *et al.*<sup>17</sup> found UDVA of at least 20/25 in 75-85% of eyes. Mendicute *et al.*<sup>13</sup> identified a mean UDVA of  $0.16 \pm 0.18$  logMAR, with 93 % of eyes achieving 20/40 or better, although the investigators excluded patients with macular degeneration and other ocular diseases which could reduce visual acuity. In the present study, which sought to investigate the routine application of the Tecnis Toric IOL, such exclusions were not made; all patients listed for routine cataract surgery with a minimum of 0.75 D of corneal astigmatism were eligible to participate, thus the sample included several patients with early age-related macular degeneration and one amblyope (CDVA 0.3 logMAR in this eye).

Post-operative rotational stability is vital to confer the best possible visual results with toric IOLs. The Tecnis Toric IOL demonstrated low levels of deviation from the target axis 4-8 weeks after implantation. Several mechanisms may result in undesirable

post-operative IOL rotation; incomplete clearance of OVD causing reduced friction between the haptics and the capsular bag,<sup>22</sup> and early post-operative intraocular pressure (IOP) fluctuations<sup>23</sup> are both linked to rotational instability. Post-operative capsular shrinkage compresses IOL haptics, and may cause rotation of certain designs and IOL materials. C-loop haptic IOLs have previously been associated with high levels of post-operative rotation; Shimizu *et al.*<sup>1</sup> reported >10 degree rotation in 41 % of eyes 12 weeks post-operatively with a PMMA toric IOL. Whilst the Tecnis Toric features C-loop haptics, its rotational stability is likely to result from factors relating to both its design and material. The Tri-Fix 3-point fixation system (as the haptics are offset), and angled haptics that resist compression, enable close contact between the IOL optic and posterior capsule [Nixon, DR. *Clinical evaluation of an investigational 1-piece acrylic monofocal IOL. Presented at the ASCRS Symposium on Cataract IOL and Refractive Surgery. 5<sup>th</sup> April, 2008, Chicago, IL*]. Furthermore, the hydrophobic acrylic Tecnis IOL material can form bioactive bonds with fibronectin,<sup>24</sup> an extracellular protein, resulting in a sandwich-like structure where a single layer of lens epithelial cells binds with the IOL and the posterior capsule.<sup>24,25</sup> Such attachment may improve the rotational stability of the IOL and reduce the incidence of posterior capsular opacification.

The low level of misalignment reported in the present study (mean 3.4 degrees, range 0-12 degrees) is in agreement with relatively recent reports of post-operative toric IOL stability. Mendicute *et al.*<sup>13</sup> observed mean IOL rotation of 3.6 degrees in 30 eyes implanted with the Alcon Acrysof SN60T at 12 weeks, with 97% of the IOLs rotating <10 degrees; Chang<sup>26</sup> compared the Staar 4203TL/TF and the Alcon Acrysof SN60T at 1 month, finding mean rotations of  $5.6 \pm 8.49$  and  $3.4 \pm 3.4$

degrees, respectively; Entabi *et al.*<sup>15</sup> reported rotation of 3.4 degrees (range 0-12 degrees) at 16 weeks with the Rayner T-flex 623T. A limitation of the present investigation is that the follow-up period of 4-8 weeks did not permit long-term assessment of IOL stability. However, previously published studies indicate that the vast majority of IOL rotation occurs in the early post-operative period, before fusion of the anterior and posterior capsule. Kim *et al.*<sup>27</sup> and Ahmed *et al.*<sup>16</sup> both identified minimal rotation of the Acrysof toric, which is also composed of a hydrophobic acrylic material, between 1 and 3 months post-operatively.

No complications related to the new toric IOL model were observed in the present study. In summary, a significant reduction in refractive astigmatism, resulting in good UDVA and high levels of patient and surgeon satisfaction were measured. The Tecnis toric IOL is based on the same platform as the Tecnis Aspheric IOL and has the advantage of a proprietary aspheric optic design to correct spherical aberration. The IOL is available in a broad range of cylinder powers and data from the present study indicate good post-operative alignment with the intended axis. Hence, the Tecnis Toric IOL appears to be an effective and predictable method of managing corneal astigmatism during routine cataract surgery.

## **WHAT WAS KNOWN**

Approximately 60 % of cataractous eyes exhibit over 0.75 D of corneal astigmatism. Stable and effective toric intraocular lenses implanted into the capsular bag during routine cataract surgery are therefore an important requirement for modern cataract surgery, allowing correction of corneal astigmatism without modification of the cornea.

## **WHAT THIS PAPER ADDS**

The new Tecnis toric 1-piece hydrophobic acrylic intraocular lens is an effective and predictable method of managing corneal astigmatism during routine cataract surgery. The IOL is associated with high levels of patient and surgeon satisfaction.



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## Figure Legends

**Figure 1.** Diagram of the Tecnis Toric IOL used in the study. The dotted lines indicate the meridian with the lowest power

**Figure 2.** Post-operative UDVA (uncorrected distance visual acuity) with the Tecnis Toric IOL. n = 65 eyes.

**Figure 3.** Pre- and post-operative  $J_0$  and  $J_{45}$  cylindrical vectors. n = 65 eyes implanted with the Tecnis Toric IOL during routine cataract surgery.

Parameter	Value
<b>Patients (n)</b>	60
<b>Eyes (n)</b>	67
<b>Age (y)</b>	
Mean $\pm$ SD	74.1 $\pm$ 9.6
Range	46- 92
<b>Sex, n (%)</b>	
Male	22 (36.7)
Female	38 (63.3)
<b>Pre-operative refractive sphere (D)</b>	
Mean $\pm$ SD	+0.20 $\pm$ 2.54
Range	-7.00 to +6.00
<b>Pre-operative refractive cylinder (D)</b>	
Mean $\pm$ SD	-1.91 $\pm$ 1.07
Range	-0.50 to -4.75
<b>Pre-operative keratometry (D) <math>\pm</math> SD</b>	
K1 (steep)	45.24 $\pm$ 1.96
K2 (flat)	42.91 $\pm$ 1.90
<b>Axial length (mm)</b>	
Mean $\pm$ SD	23.48 $\pm$ 1.10
Range	21.60 to 26.80
<b>Mean IOL power (D) <math>\pm</math> SD</b>	
Sphere	21.68 $\pm$ 2.60
Cylinder	2.50 $\pm$ 0.54

**Table 1.** Patient demographics and pre-operative data. IOL = intraocular lens.

	Mean $\pm$ SD		P value
	Pre-op	4-8 wk post-op	
UCVA (logMAR)	-	0.15 $\pm$ 0.17	-
CDVA (logMAR)	0.41 $\pm$ 0.26	0.09 $\pm$ 0.15	<0.001*
Refractive sphere (D)	0.20 $\pm$ 2.54	0.24 $\pm$ 0.66	0.901
SE (D)	-0.70 $\pm$ 2.38	-0.10 $\pm$ 0.59	0.034*
Refractive cylinder (D)	-1.91 $\pm$ 1.07	-0.67 $\pm$ 0.54	<0.001*
Range	-0.50 to -4.75	0.00 to -2.25	
Keratometric cylinder (D)	-2.21 $\pm$ 0.91	-2.06 $\pm$ 0.90	0.084
Range	-0.78 to -5.55	-0.45 to -5.55	

**Table 2.** Mean pre- and post-operative visual acuity and refraction. \* indicates a statistically significant difference between pre- and post-operative values at the  $\alpha = 0.05$  level.