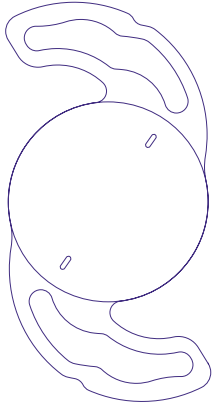


ophtec



# TCT\* Technology & Precizon Toric

Clinical science  
compendium

\* TCT (Transitional Conic Toric) is a unique patented technology by OPHTEC

ophtec.com

# Introduction

At Ophtec we believe that high quality scientific research and evidence is essential to provide the health care community with trustworthy knowledge and experience regarding new technology. In this sense, we are committed to generating and communicating high-quality scientific facts to the eye care professional community.

This clinical science compendium provides a consolidated view of bench studies, scientific papers and presentations from international ophthalmology journals and congresses, involving the Precizon Toric IOL and its patented Transitional Conic Toric (TCT) technology. All this scientific data is the result of research studies conducted to evaluate the performance of the Precizon Toric IOL, and/or the outcomes in patients receiving surgical implantation of the IOL.

A total of nine (9) studies are included: 6 scientific papers from international ophthalmology journals, 1 congress abstracts / presentations reporting clinical data, 1 bench study and 1 literature review.

In addition to exploring this compendium, we encourage you to visit Ophtec's website ([ophtec.com](http://ophtec.com)) to learn more about Ophtec's solution for astigmatism with patented Transitional Conic Toric (TCT) technology.

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# Evaluation of optical performance of 4 aspheric toric intraocular lenses using an optical bench system: Influence of pupil size, decentration, and rotation

Min-Ji Kim, Young-Sik Yoo, Choun-Ki Joo, Geunyoung Yoon.  
*J Cataract Refract Surg.* 2015 Oct;41(10):2274-82.

## OVERVIEW



### Study Design

Experimental optical bench study to evaluate the effect of pupil size and IOL decentration and rotation on the image quality of a Transitional Conic Toric (TCT) IOL and 3 commonly used aspheric toric IOLs.



### Study Site

Bench testing at one site in South Korea.



### Patients

N/A



### Methodology

The IOLs were evaluated using the optical bench metrology system. Spherical aberrations, relative SE and image quality (contrast) of the IOLs were evaluated at different pupil diameters (2.0, 3.0, 4.0 & 4.5 mm). The effect of decentration and rotation on image quality was evaluated at a common pupil size (4.0 mm).



### IOL Type

Transitional Conic Toric (TCT) Precizon Toric, model 565 (Ophtec BV); Bitoric AT Torbi 709M (Carl Zeiss Meditec AG); Posterior toric surface SN6AT4 (Alcon Laboratories Inc.); Anterior toric surface ZCT225 (Abbott Medical Optics, Inc.). TCT & Bitoric IOLs are aberration-free; Posterior & Anterior toric surface IOLs are negatively aspheric.



### Key Endpoints

Relative spherical equivalent (SE); image quality at different pupil diameters; image quality degradation due to decentration and rotation of the IOLs.

## ANALYSIS AND CONCLUSIONS

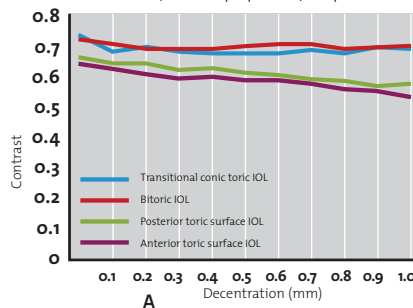
The Precizon Transitional Conic Toric (TCT) IOL demonstrated maximum rotation tolerance compared with the other IOLs.

The Precizon Transitional Conic Toric (TCT) IOL and Bitoric IOL provided superior image quality despite pupil size changes and the presence of decentration.

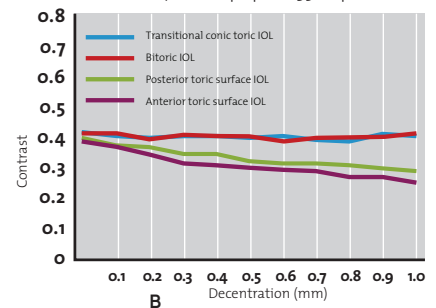
## STUDY RESULTS

- Change in relative SE with pupil size was greater for the aberration-free toric IOLs, since they do not correct the preexisting corneal spherical aberrations.
- The TCT Precizon Toric and Bitoric IOLs showed higher image quality and contrast at both 17.6 & 35.2 cpd. Contrast decreased as pupil size increased for all 4 toric IOLs.
- Contrast reduction rates at 17.6 & 35.2 cpd were lower for the TCT Precizon Toric and the Bitoric IOLs when decentered by 1.0 mm (Fig 1), indicating that aberration-free IOLs tolerate decentration better than negatively aspheric lenses. IOL decentration increases coma aberrations, being this effect greater for IOLs with higher amounts of negative aberrations.
- Rotation-induced contrast reduction at 17.6 & 35.2 cpd was less for the TCT Precizon Toric IOL than that for the other 3 IOLs, indicating the better rotation tolerance of the TCT Precizon Toric IOL (Fig 2).
- A much higher rotation for the TCT Precizon Toric IOL ( $\geq 28^\circ$ ) was needed for a contrast decrease to 0.5 in 17.6cpd than for the other 3 IOLs ( $\geq 16^\circ$  bitoric,  $\geq 14^\circ$  posterior toric surface &  $\geq 12^\circ$  anterior toric surface) (Fig 2).
- Image quality for a 32° rotation at 2 different spatial frequencies was higher for the TCT Precizon Toric (Fig 2).

**Image contrast according to degree of IOL decentration with the 4.0 mm pupil at 17.6 cpd**

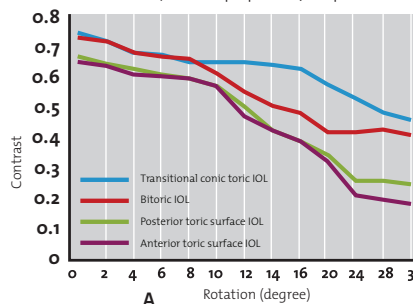


**Image contrast according to degree of IOL decentration with the 4.0 mm pupil at 35.2 cpd**

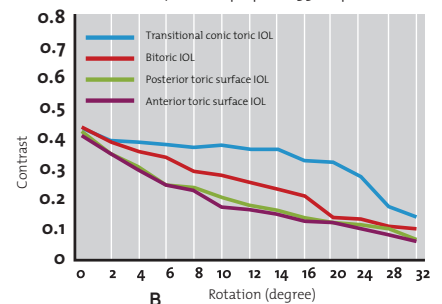


**Figure 1.** Image contrast according to degree of IOL decentration with the 4.0 mm pupil at (A) 17.6 cpd and (B) 35.2 cpd

**Image contrast according to degree of IOL rotation with the 4.0 mm pupil at 17.6 cpd**



**Image contrast according to degree of IOL rotation with the 4.0 mm pupil at 35.2 cpd**



**Figure 2.** Image contrast according to degree of IOL rotation with the 4.0 mm pupil at (A) 17.6 cpd and (B) 35.2 cpd.



# Transitional conic toric intraocular lens evaluation after femtosecond laser-assisted cataract surgery using intraoperative aberrometry

Francisco Pastor-Pascual. Rafael Pastor-Pascual. Robert Montés-Micó, Ramón Ruiz-Mesa. Pedro Tañá-Rivero. *Int Ophthalmol*; 2022 Jan;42(1):177-189

## OVERVIEW



**Study Design**  
Clinical study to assess refractive and visual outcomes following implantation of a Transitional Conic Toric IOL (Precizon Toric) after phacoemulsification with femtosecond laser-assisted cataract surgery (FLACS) using intraoperative aberrometry.



**Study Site**  
One site in Spain.



**Patients**  
One hundred two (102) eyes from seventy (70) patients implanted with the Transitional Conic Toric 565 Precizon IOL after FLACS with capsular tension ring insertion and intraoperative aberrometry. Preexisting corneal astigmatism was between 0.75 and 8 D.



**Methodology**  
Preoperative examination and evaluation of outcomes at 1 year postoperatively. A vector analysis was performed in order to analyze IOL rotation.



**IOL Type**  
Precizon Toric, model 565 (Ophtec BV)



**Key Endpoints**  
1 year postoperatively: refractive error; uncorrected and corrected distance visual acuity (UDVA & CDVA); IOL rotation.

## ANALYSIS AND CONCLUSIONS

**Implantation of the Precizon Toric IOL after FLACS, using intraoperative aberrometry in patients with different amounts of astigmatism, provides good visual acuity, accurate refractive outcomes, and excellent rotational stability.**

Precizon Toric IOL provides robustness in image quality with decentration, due to its Transitional Conic Toric design. Intraoperative aberrometry is an excellent system to control IOL alignment during the surgery.

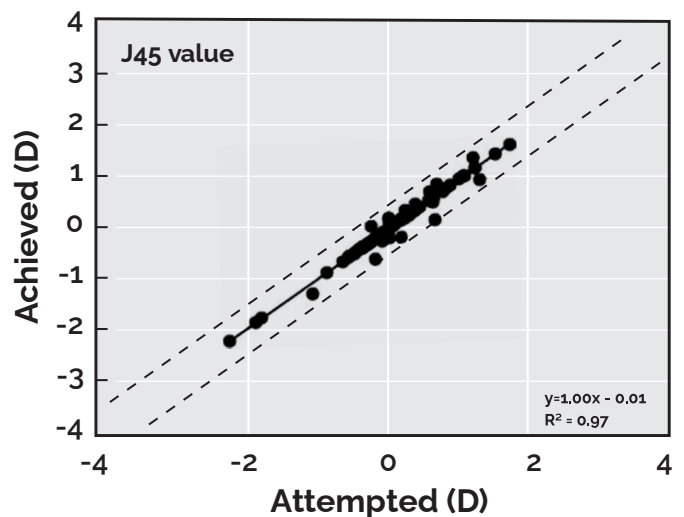
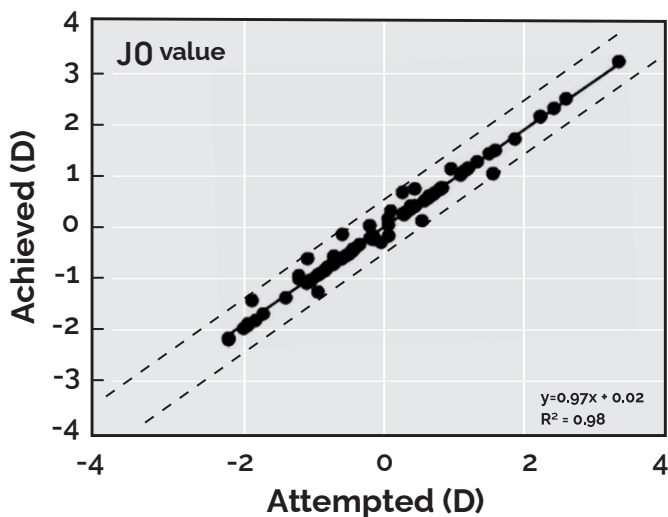
## STUDY RESULTS

### VISUAL & REFRACTIVE OUTCOMES

- At 1 year, mean value of monocular UDVA was  $0.88 \pm 0.17$  (close to 20/20).
- At 1 year, mean SE and refractive cylinder were  $-0.06 \pm 0.29D$  and  $-0.23 \pm 0.37D$ , respectively.

### ROTATIONAL STABILITY

- 94.12% (96 eyes) and 100% of eyes showed a SE within  $\pm 0.50D$  and  $\pm 1.00D$ , respectively.
- Vector analysis revealed that 100% of the eyes were within  $\pm 0.50D$  for the J0 and J45 cylindrical components (Fig 1).
- In relation to the rotational stability, the mean toric axis rotation at 1 year was  $1.10^\circ \pm 1.71^\circ$ .
- No patient required IOL realignment during the postoperative follow-up.



**Figure 1.** Attempted versus achieved astigmatic (J0 & J45) components of the power vector analysis. Solid lines represent the best-fit line for each graph. Dotted lines represent the range of  $\pm 0.50D$  for J0 and J45 components.



# Comparison of clinical outcomes of toric intraocular lens, Precizon vs Tecnis: a single center randomized controlled trial

Na Yeon Jung, Dong Hui Lim, Sung Soon Hwang, Joo Hyun, Tae-Young Chung.  
*BMC Ophthalmology 2019; 18(1):292*

## OVERVIEW



**Study Design**  
 Prospective randomized comparative study to evaluate the clinical outcomes of Precizon Toric IOL compared to Tecnis Toric IOL.



**Study Site**  
 One site in South Korea.



**Patients**  
 Forty (40) eyes from forty (40) patients with visually significant corneal astigmatism who underwent cataract surgery with implantation of a toric IOL (Precizon, 20 eyes; Tecnis, 20 eyes).



**Methodology**  
 Preoperative examination and evaluation of outcomes at 1 day, 1 week, 1 month, and 3 months postoperatively. Vector analysis was performed using the Alpins method in order to analyze residual astigmatism.



**IOL Type**  
 Precizon Toric, model 565 (Ophtec BV); Tecnis Toric IOL (Abbott Medical Optics Inc.)



**Key Endpoints**  
 3 months postoperatively: uncorrected and best corrected distance visual acuity (UDVA & BCDVA); uncorrected intermediate visual acuity (UIVA); manifest refraction; residual astigmatism; rotational stability; higher order aberrations.

## ANALYSIS AND CONCLUSIONS

**The Precizon Toric IOL showed a significantly better rotational stability than the Tecnis Toric IOL.**

Both Precizon Toric IOL and Tecnis Toric IOL could be effectively used by cataract surgeons to correct preexisting corneal astigmatism through cataract surgery.

## STUDY RESULTS

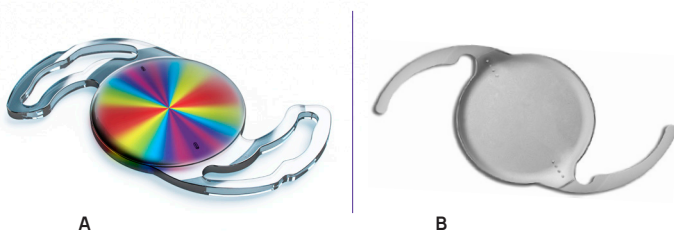
### VISUAL & REFRACTIVE OUTCOMES

- At 3 months, 91% and 83% of eyes in the Precizon and Tecnis groups respectively showed an UDVA of  $\leq 0.1$  logMAR or better.
- UIVA in the Precizon group shows a tendency to be better than in the Tecnis group (not statistically significant difference). This could be related to a higher depth of focus created by the maintenance of the corneal natural positive spherical aberration with the aberration free Precizon Toric IOL.

- At 3 months, 80% and 70% of the eyes in the Precizon and Tecnis groups respectively showed a residual refractive cylinder  $< 0.50$  D.
- No significant difference in refractive outcomes (sphere, cylinder, and spherical equivalent) was found between the two groups.
- Vector analysis showed no statistically significant difference between groups ( $P > 0.05$ ); therefore both toric IOLs showed effective astigmatic correction.

### ROTATIONAL STABILITY

- Mean rotation for the Precizon group was significantly lower ( $P = 0.01$ ) than that in the Tecnis group ( $1.50^\circ \pm 0.84^\circ$  and  $2.56^\circ \pm 0.68^\circ$  respectively) at 3 months.



**Figure 1.** Schematic images of the toric intraocular lens. A: Precizon toric intraocular lens. B: Tecnis toric intraocular lens (b)

	Precizon Toric	Tecnis Toric
UDVA $\leq 0.1$ logMAR (% eyes)	91%	83%
Residual refractive cylinder $< 0.50$ D (% eyes)	80%	70%
Mean rotation	$1.50^\circ \pm 0.84^\circ$	$2.56^\circ \pm 0.68^\circ$



# Transitional conic toric intraocular lens for the management of corneal astigmatism in cataract surgery

Francisco Bandeira, Merce Morral, Daniel Elies, Sergio Eguiza, Spyridoula Souki, Felicidad Manero, Jose L Güell.  
Clin Ophthalmol. 2018 Jun 8;12:1071-1079

## OVERVIEW



### Study Design

Retrospective, non-randomized study to evaluate visual and refractive outcomes of a Transitional Conic Toric intraocular lens (Precizon Toric) for the correction of corneal astigmatism in patients undergoing cataract surgery.



### Study Site

One site in Spain.



### Patients

Ninety-seven (97) eyes of sixty-one (61) patients with preoperative regular corneal astigmatism >0.75D who underwent consecutive phacoemulsification and Precizon Toric IOL implantation.



### Methodology

Preoperative examination and evaluation of outcomes at 1, 3, 6 and 12 months postoperatively. Patients were divided in two groups according to attempted residual refraction: group 1 (29 patients) with emmetropia; group 2 (32 patients) with mild myopia for monovision.



### IOL Type

Precizon Toric, model 565 (Ophtec BV)



### Key Endpoints

Uncorrected and corrected distance visual acuity (UDVA, CDVA); manifest refraction.

## ANALYSIS AND CONCLUSIONS

Precizon Toric IOL is a suitable and safe alternative for astigmatic correction during cataract surgery, with adequate refractive and visual outcomes being our toric IOL of choice in our daily practice.

## STUDY RESULTS

### VISUAL & REFRACTIVE OUTCOMES

- A significant improvement in LogMar UDVA & CDVA was observed in both groups (Tables 1 & 2).
- At 3 months, mean SE in groups 1 and 2 was reduced from  $-0.56 \pm 3.42$  to  $-0.15 \pm 0.42$  and from  $1.07 \pm 3.2$  to  $-0.97 \pm 0.48$ , respectively (Tables 1 & 2).
- At 3 months, mean refractive cylinder was significantly reduced compared to previous keratometric cylinder in both groups, from  $1.98 \pm 1.1$  to  $0.66 \pm 0.54$  and from  $1.84 \pm 0.88$  to  $0.79 \pm 0.63$ , respectively (Tables 1 & 2).
- 67% and 98% of all eyes were within  $\pm 0.50$  D and  $\pm 1.00$  D respectively of attempted spherical correction.
- 81% of the eyes showed  $\leq 1.00$  D of residual cylinder at 3 months.

	Preoperative	3 months post-surgery	p-value
<b>Emmetropia (group 1)</b>			
UDVA (LogMAR)	0.41 ± 0.48	0.12 ± 0.12	0.88
CDVA (LogMAR)	0.13 ± 0.17	0.026 ± 0.06	<0.0001
Cylinder (D)	-1.98 ± 1.11 (-6.79 to -0.93)	-0.66 ± 0.54 (-2.25 to 0)	<0.0001
SE (D)	-0.57 ± 3.43 (-8.75 to +6.38)	-0.15 ± 0.43 (-1.5 to +0.75)	0.35

Table 1. Pre- versus 3-month postoperative data for group 1

	Preoperative	3 months post-surgery	p-value
<b>Mild myopia (group 2)</b>			
UNVA (LogMAR)	-	0.16	-
UDVA (LogMAR)	0.13 ± 0.19 (0 to 0.7)	0.34 ± 0.25 (0 to 1)	0.0003
CDVA (LogMAR)	0.17 ± 0.20 (0 to 0.7)	0.07 ± 0.15 (0 to 0.7)	0.02
Cylinder (D)	-1.84 ± 0.88 (-3.79 to -0.68)	-0.79 ± 0.63 (-1.88 to 0)	<0.0001
SE (D)	1.07 ± 3.20 (-6.5 to +6.38)	-0.87 ± 0.48 (-2.5 to 0)	0.0032

Table 2. Pre- versus 3-month postoperative data for group 2



# Clinical outcomes after implantation of a toric intraocular lens with a transitional conic toric surface

Bettina C Thomas, Ramin Khoramnia, Gerd U Auffarth, Mike P Holzer.  
British J Ophthalmology. 2018 Mar;102(3):313-316.

## OVERVIEW



### Study Design

Unmasked, retrospective and prospective ethics committee controlled clinical trial to evaluate the clinical outcomes after implantation of a toric IOL with a Transitional Conic Toric surface in patients with astigmatism undergoing refractive lens exchange (RLE) or cataract surgery.



### Study Site

One site in Germany.



### Patients

Forty-three (43) eyes of twenty-eight (28) patients with astigmatism implanted with the Precizon Toric IOL after cataract or RLE surgery.



### Methodology

Preoperative examination and evaluation of outcomes at 3 months postoperatively. Power vector analysis was performed to analyze residual astigmatism.



### IOL Type

Precizon Toric, model 565 (Ophtec BV)



### Key Endpoints

3 months postoperatively: uncorrected and corrected distance visual acuity (UDVA & CDVA); manifest refraction; residual astigmatism; rotational stability; patient satisfaction (questionnaire).

## ANALYSIS AND CONCLUSIONS

Precizon Toric IOL with its Transitional Conic Toric surface provided good achievement of target refraction, excellent visual acuities and a very good rotational stability. The IOL was able to reduce subjective astigmatism and led to a high spectacle independency and high patient satisfaction rate.

Compared with other toric IOL models (Agresta and colleagues' systematic review), Precizon Toric shows a better rotational stability and better postoperative UDVA results.

## STUDY RESULTS

### VISUAL & REFRACTIVE OUTCOMES

- At 3 months, median UDVA was 0.06 logMAR.
- Compared with other toric IOLs (Agresta et al systematic review), where most values of UDVA ranged from 0.1 and 0.3 logMAR, postoperative UDVA of the Precizon toric is very good.
- 85%, 98% and 100% of all eyes were within  $\pm 0.50D$ ,  $\pm 0.75D$  and  $\pm 1.00D$  respectively of target refraction (Fig 1).
- At 3 months, the median postoperative subjective cylinder was  $-0.25D$ . The targeted versus achieved astigmatic values are displayed in (Fig 2).

- The power vector analysis shows a deviation of target versus achieved astigmatic power of 0.10 and a reduction of astigmatism by approximately 83%.

### ROTATIONAL STABILITY

- 1 week postoperatively median axis deviation was  $2^\circ$ . Three months postoperatively it was  $3^\circ$ .
- Compared with other toric IOLs (Agresta et al systematic review), where most values of axis deviation were around  $3.5^\circ$ , Precizon Toric shows better stability.

- At 3 months, the values of axis deviation were as follows: 65% eyes within  $0^\circ-5^\circ$ , 26% eyes within  $6^\circ-10^\circ$ , and 7% within  $11^\circ-16^\circ$ . Interestingly, the residual subjective astigmatism was in median  $-0.25D$  in all three groups. A possible explanation could be that the **transitional conic toric surface is indeed more tolerant for axis misalignment** as shown in optic bench experiments.

### PATIENT SATISFACTION

- At 3 months, visual disturbances were in median 'none' or 'mild', which is an expected result for a monofocal IOL. Glasses independency was very good.

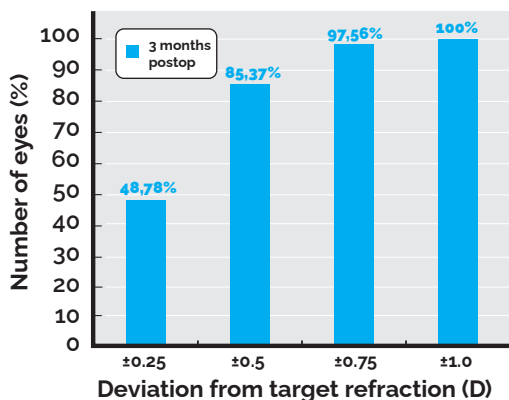


Figure 1. Deviation from target refraction 3 months postoperatively.

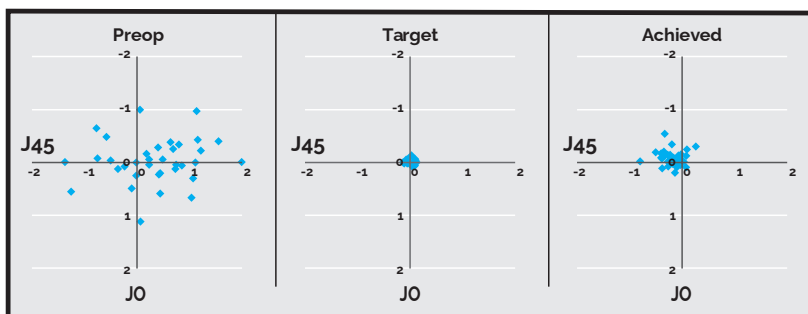


Figure 2. Power vector analysis of preoperative (subjective), targeted (as calculated by the Ophtec toric calculator) and achieved (subjective) astigmatic values (n=41 eyes).



# Clinical outcomes after cataract surgery with a new transitional toric intraocular lens



Tiago B Ferreira, Tos T J M Berendschot, Filomena J Ribeiro. *J Refract Surg.* 2016 Jul 1;32(7):452-9.

## OVERVIEW



**Study Design**  
Prospective interventional case series to evaluate the visual outcomes of patients who underwent cataract surgery with implantation of a transitional toric monofocal intraocular lens.



**Study Sites**  
Two sites in Portugal.



**Patients**  
Fifty-one (51) eyes of thirty-nine (39) patients with cataract and regular keratometric astigmatism between 1D & 4.50D implanted with the Precizon Toric IOL after phacoemulsification.



**Methodology**  
Preoperative examination and evaluation of outcomes at 1 & 4 months postoperatively. Vector analysis was performed using the Alpíns method in order to analyze residual astigmatism.



**IOL Type**  
Precizon Toric, model 565 (Ophtec BV)



**Key Endpoints**  
4 months postoperatively: uncorrected and corrected distance visual acuity (UDVA & CDVA); spherical equivalent (SE) refraction; astigmatism outcomes; rotational stability; higher order aberrations (HOA).

## ANALYSIS AND CONCLUSIONS

The implantation of the Precizon Toric IOL in patients with cataract and corneal astigmatism provided excellent visual outcomes, predictability of refractive results and astigmatic correction, excellent rotational stability, and good optical quality and performance.

## STUDY RESULTS

### VISUAL & REFRACTIVE OUTCOMES

- At the 4-months, mean UDVA was 0.06 ± 0.1 logMAR.
- UDVA was 20/32 or better in 98% of eyes and 20/25 or better in 90% of eyes.
- Mean SE refraction was -0.19 ± 0.38 D, with 86% of eyes within ±0.50 D and 98% within ±1.00 D of the attempted correction (**Fig 1**).
- Refractive astigmatism was within ±1.00 D of the attempted correction in 100% of eyes and within ±0.50 D in almost 60% (**Fig 2**).

### VECTOR ANALYSIS RESULTS

- Correction index was 0.94, 0.75 & 0.73 (ideal value = 1) for eyes with ATR, WTR & oblique astigmatism respectively.
- The index of success (ideally 0), was 0.33 ± 0.27 D.

### ROTATIONAL STABILITY

- Excellent rotation stability at 4 months, with a mean toric IOL axis rotation of 1.98° ± 1.78°.
- The difference between 1-day and 4-month follow-up was not statistically significant (P = .789).
- No eye required secondary surgery for IOL rotation.

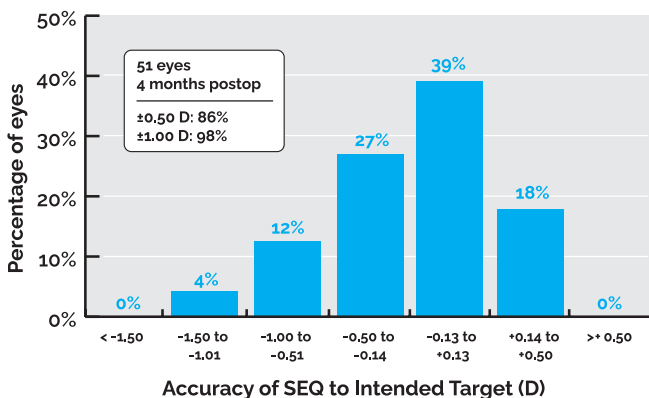


Figure 1. Accuracy of SEQ correction.\*

\*Graph and label numbers do not coincide 100% probably due to rounding reasons.

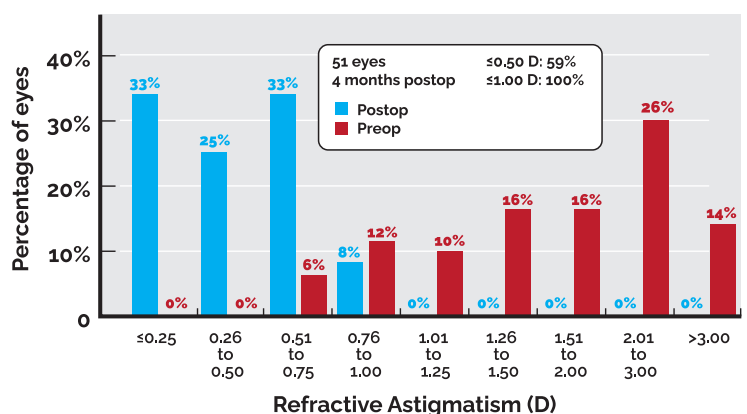


Figure 2. Distribution of refractive astigmatism at 4 months postoperatively.\*

# Astigmatism management in cataract surgery with Precizon toric intraocular lens: a prospective study



Carolina Vale, Carlos Menezes, J Firmino-Machado, Pedro Rodrigues, Miguel Lume, Paula Tenedório, Pedro Menéres, Maria do Céu Brochado. Clin Ophthalmol. 2016 Jan 19;10:151-9.

## OVERVIEW



### Study Design

Prospective noncomparative clinical study to evaluate the visual and refractive outcomes and rotational stability of the aspheric Precizon toric IOL for the correction of corneal astigmatism in cataract surgery.



### Study Sites

Two sites in Portugal.



### Patients

Forty (40) eyes of twenty-seven (27) patients with corneal astigmatism >1.0 D implanted with the Precizon Toric IOL after phacoemulsification surgery.



### Methodology

Preoperative examination and evaluation of outcomes at 1, 3 & 6 months postoperatively. Vector analysis was performed using the Alpins and Goggin method in order to analyze residual astigmatism.



### IOL Type(s)

Precizon Toric, model 565 (Ophtec BV)



### Key Endpoints

6 months postoperatively: uncorrected and corrected distance visual acuity (UDVA & CDVA); subjective refraction; IOL rotation; patient satisfaction.

## ANALYSIS AND CONCLUSIONS

**Precizon toric IOL revealed very good rotational stability and performance regarding predictability, efficacy, and safety in the correction of regular corneal astigmatism associated with cataract surgery.**

Vector analysis results indicated that Precizon toric IOL had better alignment compared to other types of IOLs and that it was very effective in reducing astigmatism at the intended meridian of treatment.

Precizon toric IOL resulted in a very high level patient satisfaction.

## STUDY RESULTS

### VISUAL & REFRACTIVE OUTCOMES

- At 6 months, median UDVA was 0.02 logMAR. UDVA was 0.1 logMAR or better in 95% of the eyes.
- Mean SE was  $-0.02 \pm 0.30$  D ( $P < 0.001$ ) with 97.5% of the eyes within  $\pm 0.50$  D of emmetropia.
- Mean postop refractive cylinder was  $0.24 \pm 0.27$  D ( $P < 0.001$ ) with 95% and 100% of the eyes with  $\leq 0.50$  D &  $\leq 1.00$  D of refractive astigmatism at 6 months (Fig 1).

### ROTATIONAL STABILITY

- The mean IOL rotation was very low:  $2.43^\circ \pm 1.55^\circ$ .
- During follow-up, IOL rotation was  $\leq 4^\circ$  in 90% of the eyes (no more than  $6^\circ$ )
- IOL rotation occurred mainly within the 1st week after surgery ( $P < 0.0125$ ) and minimal rotation was observed afterwards (Fig 2).

### VECTOR ANALYSIS RESULTS

- Absolute angle of error was  $1.90^\circ \pm 0.69^\circ$ .
- Correction index was  $0.95 \pm 0.19$  and index of success was  $0.12 \pm 0.14$ D (close to ideal values 1 & 0 respectively).
- Magnitude of error was  $-0.10 \pm 0.28$  (ideal value = 0)

### PATIENT SATISFACTION

- Satisfaction with visual acuity and quality of vision was rated as very good by all the patients.

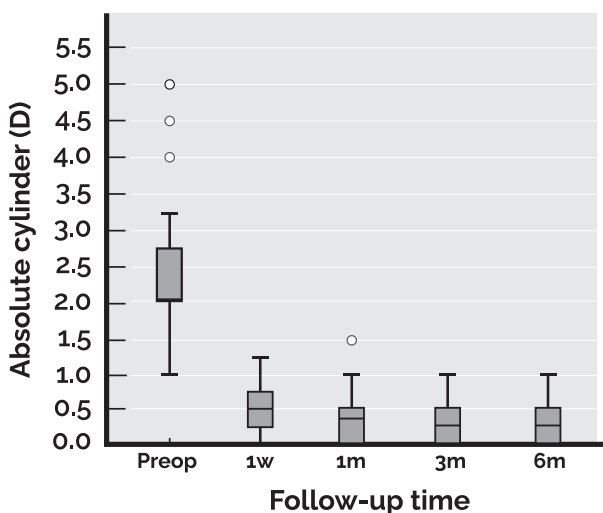


Figure 1. Astigmatism shift during the follow-up.

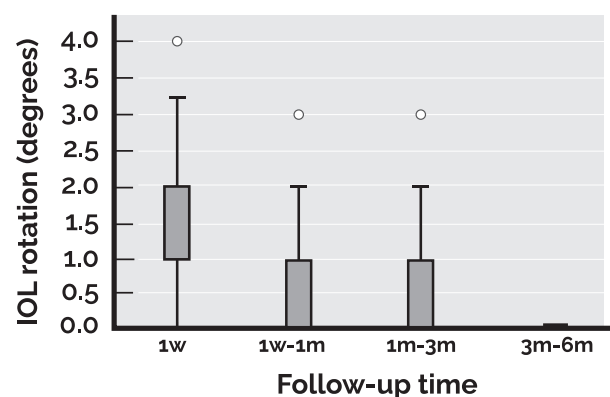


Figure 2. Absolute IOL rotation between observation periods.

# Evaluation of a new toric IOL optic by means of the ORA system: the effect of IOL misalignment on cylinder reduction

Erik L. Mertens. Presented at the XXXII Congress of the European Society of Cataract & Refractive Surgeons (ESCRS); September 13-17, 2014; London, UK. Data on File 2014.

## OVERVIEW



**Study Design**  
Prospective, randomized, comparative study to intraoperatively compare the effect of misalignment of the Precizon™ Toric and Lentis Toric IOLs on refraction by means of the ORA system and to compare postoperative outcomes.



**Study Site**  
One site in Belgium.



**Patients**  
Twenty (20) eyes with cataract and pre-existing corneal astigmatism who underwent routine cataract surgery with bilateral implantation of a two different toric IOL models (10 eyes each subgroup).



**Methodology**  
Intraoperative assessment and evaluation of outcomes at 1 month postoperatively. Intraoperative wavefront aberrometry (ORA system) was used to assess the effect of 10°, 5° and 0° misalignment on cylinder reduction.



**IOL Type(s)**  
Precizon Toric, model 565 (Ophtec BV); Lentis Toric (Oculentis GmbH Berlin Germany).



**Key Endpoints**  
Intraoperative refraction measured with ORA system.  
1 month postoperatively: uncorrected and corrected distance visual acuity (UDVA & CDVA); refraction; IOL misalignment.

## ANALYSIS AND CONCLUSIONS

The new Precizon™ Toric IOL performed significantly better in astigmatism correction and was less sensitive to misalignment in respect to the Lentis Toric IOL.

## STUDY RESULTS

- Average rotation was 1,6° with the Precizon Toric IOL and 2,2° with the Lentis Toric IOL.
- A deliberate misalignment of 10° resulted in a lower average under correction for the Precizon Toric than for the Lentis Toric IOL (18% vs 33%) (Table 1).
- A deliberate misalignment of 5° resulted in a lower average under correction for the Precizon Toric than for the Lentis Toric IOL (9% vs 15%) (Table 1).

**Precizon Toric vs Lentis Toric IOL**  
Cylinder Loss Per Degree Of Rotation

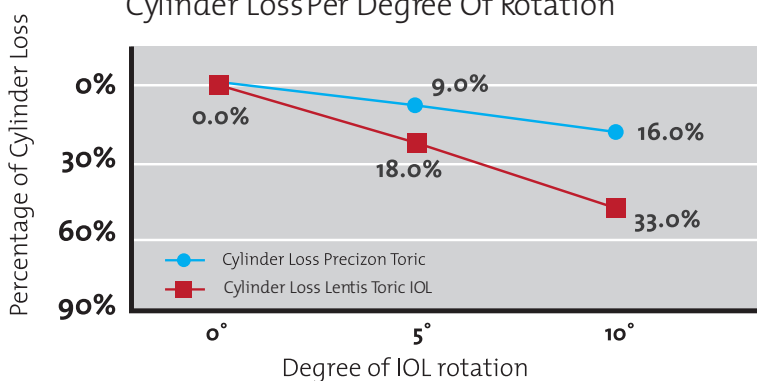


Figure 1. Cylinder loss per degree of rotation for Precizon Toric IOL and Lentis Toric IOL.

Degrees of misalignment	10° rotation	5° rotation
Precizon™ under correction - loss of effect	18%	9%
Lentis Toric IOL under correction - loss of effect	33%	15%

EXAMPLE: Effective Loss of Cylinder Power

	Precizon™ @ 10°	Lentis IOL @ 10°	Precizon @ 5°	Lentis IOL @ 5°
4D cy IOL	.72D loss	1.32D loss	.36D loss	.6D loss
10D cy IOL	1.8D loss	3.3D loss	.9D loss	1.5D loss

Table 1. Cylinder loss at 10 and 5 degrees of rotation for Precizon Toric IOL and Lentis Toric IOL.

# Optimizing outcomes with toric intraocular lenses



Manpreet Kaur, Farin Shaikh, Ruchita Falera, Jeewan S Titiyal. *Indian J Ophthalmol.* 2017 Dec; 65(12):1301-1313.

## OVERVIEW



### Study Design

Review to provide a comprehensive overview of toric IOLs.



### Study Site

Multiple sites worldwide



### Patients

Multiple samples from 5 to 256 eyes. See table.



### Methodology

Comprehensive literature search was performed in MEDLINE using "toric intraocular lenses," "astigmatism," and "cataract surgery" as keywords. Relevant references cited in those articles were also searched. All articles were reviewed since the first use of toric IOLs in 1992.



### IOL Type(s)

Toric IOLs found on literature review.



### Key Endpoints

N/A

## ANALYSIS AND RESULTS

**Precizon Toric outcomes are better or similar to other Toric IOLs.**

Light Adjustable Lens outperforms other Toric IOLs, but the sample is too small.

## STUDY RESULTS

TYPE OF IOL	AUTHORS	STUDY DESIGN	SAMPLE SIZE	FOLLOW-UP	IOL MISALIGNMENT/ROTATION	UDVA			RESIDUAL ASTIGMATISM	TARGET REFRACTION		VISUAL QUALITY
						LogMAR UDVA	>20/25	>20/40		WITHIN ± 1 D	WITHIN ± 0.5 D	
ACRYSOF TORIC	Kim et al.	Prospective observational	30	13.3 ± 5.0 months	3.45° ± 3.39° (range 0° - 10.3°)	0.33 ± 0.18	73.3%		-0.28 ± 0.38 D	100%	86.7%	
	Koshy et al.	Prospective	30	6 months	2.66° ± 1.99°	0.20 (range 0.60 - 0.20)			-0.80 D (range -1.75 - 0.00 D)			
	Holland et al.	Randomized clinical trial	256	12 months	< 4° (range 0° - 20°)		63.4%	92.2%	≤ 1.00 D in 88.0%			61% had spectacle independence for distance vision
	Mendicute et al.	Randomized prospective clinical study	20	3 months	3.53° ± 1.97° (range 0° - 8°)	0.11 ± 0.15	70%	95%	-0.62 ± 0.46 D	100%	90%	Higher order aberration, contrast sensitivity similar to OCCI
	Miyake et al.	Prospective observational	378	2 years	4.1° ± 3.0°	0.35 ± 0.38			-0.67 ± 0.90 D (73 eyes)			
	Mendicute et al.	Prospective observational	30	3 months	3.63° ± 3.11° (range 0° - 12°)	0.16 ± 0.18	66.6%	93.3%	-0.72 ± 0.43 D	96.7%	90%	
	Mingo-Botin et al.	Prospective randomized comparative	20	3 months	3.65° ± 2.96°	0.13 ± 0.10	55%	95%	0.61 ± 0.41 D			Better mesopic contrast sensitivity with glare in the toric IOL. Spectacle independence in 85%.
PRECIZON TORIC IOL (OPHTEC)	Thomas et al.	Retrospective + prospective	43	3 months	Median 3° (range 0° - 16°)	0.06 (range -0.10 - 0.72)			-0.25 D (range -1.50 - 0.00)	100%	85.37%	Spectacle independence in majority for distance. 73% happy with outcomes
	Ferreira et al.	Prospective	51	4 months	1.98° ± 1.78° (range 0° - 7°)	0.06 ± 0.1	82%	98%			86%	Very good quality of vision and patient satisfaction
	Vale et al.	Prospective	40	6 months	2.43° ± 1.55° (range 0° - 6°)	Median 0.02 - 0.06 (range 0.16 - -0.10)	95%	100%	0.24 ± 0.27 D	100%	97.5%	
HUMAN OPTIC MICROSIL	De Silva et al.	Prospective	21	6 months	5° (range 0° - 15°)	0.32 ± 0.24	35%	85%	1.23 ± 0.90 D (range 0.25 - 3.50 D)			
RAYNER T-FLEX	Entabi et al.	Prospective observational	33	4 months	3.44° (range 0° - 12°)	0.28 ± 0.23	< 20%	69.7%	0.95 ± 0.66 D	87.8%		
STAAR	Ruhswurm et al.	Retrospective	37	20.3 ± 16.6 months	18.9% cases-rotation up to 25°	0.61 ± 0.29	≈ 20%	48.6%	0.84 ± 0.63 D	78.4%	48.6%	
TECNIS ZCT	Lubinski et al.	Prospective	27	6 months	11° ± 2.4° (range 0° - 8°)	0.19 ± 0.12		92.6%	-1.42 ± 0.88 D	100%		Mean patient satisfaction score of 9.7 ± 0.47
MORCHER	Rozema JJ et al.	Prospective	59	6 months	1.27° ± 0.76°							
	Tamignon et al.	Prospective	52	12 months		0.85 ± 0.21						
LIGHT-ADJUSTABLE LENS	Chayet et al.	Prospective	5	9 months		Range (0.0 - 0.1)	100%		-0.50 D		100%	
ACRI-COMFORT	Alió et al.	Prospective	21	3 months	-1.75° ± 2.93°	0.65 ± 0.22		76.1%	-0.45 ± 0.63 D			Mean index of success 0.11 ± 0.15

Table 1: Visual and anatomical outcomes after toric intraocular lens implantation

