Clinical Research

Trifocal toric intraocular lenses in eyes with low amount of corneal astigmatism

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Abstract

• AIM: To evaluate the refractive and visual outcomes following cataract surgery and implantation of a trifocal toric intraocular lens (IOL) in eyes with low degrees of corneal astigmatism.

• **METHODS:** Twenty-six eyes of 22 patients who underwent implantation a trifocal toric IOL (FineVision PODFT, PhysIOL s.a., Liege, Belgium) were enrolled. Phacoemulsification with femtosecond laser, capsular tension ring insertion and intraoperative aberrometry were performed in all cases. All IOLs used showed a cylinder power of 1.00 D. Main outcome measures were refractive error and corrected-distance visual acuity (CDVA) and uncorrected-distance visual acuity (UDVA) values. Eyes were evaluated at 4mo post-surgery.

• **RESULTS:** Totally 50% of eyes showed a spherical equivalent (SE) within ± 0.13 D and all of them within ± 0.50 D. The mean SE and refractive cylinder were -0.02 ± 0.23 and -0.16 ± 0.22 D, respectively. Vector analysis revealed that 100% of eyes were within ± 0.50 D for the SE and cylindrical components (J0 and J45). Refractive changes were not correlated with keratometric changes (*P*>0.05) showing that the reduction in astigmatism comes from the trifocal toric IOL. Of 81% and 96% of eyes showed UDVA and CDVA of 20/20, respectively. The postoperative mean values of monocular distance Snellen decimal UDVA and CDVA were 0.97 \pm 0.05 and 0.99 \pm 0.02 (about 20/20), respectively.

• **CONCLUSION:** Our study suggests that the use of this trifocal toric IOL in patients with low amount of astigmatism provides accurate refractive outcomes and enables them to achieve excellent visual acuity.

• **KEYWORDS:** toric; trifocal; intraocular lens; phacoemulsification; cataract; astigmatism

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INTRODUCTION

I ntraocular lens (IOL) technology has undergone important advances in the last decade both for ametropia and presbyopia correction. New designs for multifocal IOLs considering diffractive, refractive or hybrid surfaces have appeared in the market in order to provide our patients the best visual quality at different distances^[1-3]. Bifocal, trifocal or extended depth of focus IOLs have been implanted showing good visual outcomes^[4-7]. However, any treatment in our patients requires full correction of both spherical and cylindrical components. Residual refractive errors after a premium IOL surgery, that considers correction of distance, intermediate and near vision, may reduce the benefits of these advances in technology being emmetropia the optimum target^[8].

Different formulae and calculators available in the market have proved to be useful for estimating spherical and cylindrical powers in eyes implanted with premium IOLs reducing postoperative errors^[9]. In this way, it becomes important to note that about 0.50 D of astigmatism is roughly equivalent to 0.25 D of sphere producing a change in high-contrast visual acuity about one logMAR line^[10], however the effect of residual astigmatism may be somewhat greater^[11]. Then, multifocal IOLs should consider the correction of astigmatism in order to provide patients the best visual acuity. A recent review and Meta-analysis^[12] recommends that patients showing regular corneal astigmatism should receive a toric IOL if they want to achieve postoperative spectacle independence for distance viewing.

Several studies show that there about 60% of eyes undergoing cataract surgery have astigmatism up to 1.00 D ($57.76\%^{[13]}$, $59.9\%^{[14]}$ and $58.7\%^{[15]}$). Removing this astigmatism may further improve visual acuity after cataract surgery and

multifocal IOL implantation. As mentioned previously, advanced technology of premium IOLs requires full correction of spherical but also cylindrical errors. Recently low power bifocal toric IOLs have been investigated and two studies show the benefit of using them^[16-17]. However, little attention has been devoted to eyes implanted with toric IOL of low amount of astigmatism specifically with trifocal toric IOLs. Therefore, the purpose of the clinical study is to assess specifically the refractive and visual outcomes in a series of eyes with low astigmatism that received a trifocal toric IOL implantation after cataract surgery with 1.00 D of cylinder.

SUBJECTS AND METHODS

Ethical Approval The study was carried out in accordance with the tenets of the Helsinki Declaration and was approved by our Institutional Review Board. All patients signed an informed consent after explaining the objective and consequences of the study.

Totally 26 eyes of 22 patients were retrospectively assessed at the Oftalvist Clinic in Alicante, Spain, between February 2017 and May 2019. The inclusion criteria considered: cataracts, IOL cylinder to be implanted of 1.00 D, age between 45 and 80y and patient's interest to no longer wear any form of spectacle or contact lens correction for distance vision, intermediate and near vision. Exclusion criteria considered: glaucoma, retina or corneal disease, previous corneal or intraocular surgery and pupil alteration.

All eyes were implanted with the Trifocal Toric FineVision PODFT (PhysIOL s.a., Liege, Belgium). The IOL has a double-C-loop haptic design in order to reduce rotation. The diffractive design creates 2 additions for near (+3.50 D) and intermediate distance (+1.75 D). Spherical IOL power ranged from +6.00 to +35.00 D (in 0.50 D steps) and cylinder IOL powers from 1.00 to 6.00 D. In this study all lenses used showed a cylinder power of 1.00 D.

A full pre-operative assessment was carried out in all patients that considered: Snellen decimal monocular uncorrected-distance visual acuity (UDVA) and best-corrected-distance visual acuity (CDVA), refraction, corneal topography (Pentacam, Oculus Optikgeräte GmbH, Wetzlar, Germany) and optical biometry (IOLMaster 700, Carl Zeiss Meditec AG, Jena, Germany). IOL power calculation was based on IOLMaster measurements, considering a 0.2 D surgically induced astigmatism by the incision for the surgeon that performed all procedures. The IOL cylinder power and target axis were calculated with the FineVision Toric Calculator available at http://www.physioltoric.eu considering the option of the Abulafia-Koch (using the *K* values obtained with the IOLMaster 700). The targeted refraction was emmetropia.

Topical anaesthesia was used by the same surgeon (Tañá-Rivero P) using the Catalys Femtosedon Laser System

Table 1	Demograp	hic charac	cteristics of	the diffe	rent partio	ripants
in the st	tudv shown	as means.	standard d	leviation	s and rang	es

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Characteristics	Data
Eyes (n)	26
Age (y)	64.57±7.92 (45 to 76)
Sphere (D)	-0.42±3.94 (5.50 to -9.25)
Refractive cylinder (D)	-0.84±0.37 (-0.50 to -1.25)
Spherical equivalent (D)	-0.84±4.01 (5.25 to -9.88)
DCVA (Snellen decimal)	0.93±0.12 (0.55 to 1.00)
Keratometric cylinder (D)	0.62±0.38 (0.12 to 1.41)
Axial length (mm)	24.26±1.84 (21.66 to 27.94)
Anterior chamber depth (mm)	2.46±0.29 (2.46 to 3.77)
IOL spherical power (D) ^a	21.18±4.67 (11.00 to 29.50)

DCVA: Distance corrected visual acuity; IOL: Intraocular lens ^aAll toric IOLs with a 1.00 D of cylinder; K: Keratometry.

(Johnson&Johnson Vision, Santa Ana, CA, USA) with a 2.2-mm temporally located corneal incision. A 5 mm radius capsulotomy was carried out (centered on the capsular bag). The ORA intraoperative aberrometry with Verifeye+ (Alcon, Fort Worth, TX, USA) was used to refine the axis of the IOL toric after implantation of a capsular tension ring (CTR) with the purpose to improve the stability of the capsular bag.

Statistical Analysis All evaluations were performed 4mo after IOL implantation. Post-operative examination included: refraction and slit-lamp biomicroscopy, and UDVA and CDVA. The analysis of the outcomes was carried out using Excel (version 2016, Microsoft Corporation, Redmond, WA, USA). The Shapiro-Wilk test, evaluated the normality of all data sets and a paired *t* test was applied to assess statistically significant differences in postoperative outcomes. The statistical significance limit was set to a *P* value <0.05 in all cases.

RESULTS

Totally 26 eyes of 22 consecutive patients, 6 males and 16 females were enrolled in this study. Patients' demographics are shown in Table 1. Mean patient age was $64.57\pm7.92y$ (ranging from 45 to 76y). There were no complications or rotation in any of the cases during surgery and follow-up.

The standard graphs for reporting the outcomes for refraction and vision were created. Figure 1 shows the distribution of spherical equivalent (SE) refraction both before and after surgery. The highest percentage of eyes, 50%, was in the range of ± 0.13 D followed by about 27% in a range of -0.50 to +0.14 D range. All eyes were within ± 0.50 D. Note the change in distribution between pre- and post-surgery. The mean postoperative SE was -0.02 ± 0.23 D (ranging from 0.50 to -0.50 D). Specifically, the analysis of the postoperative refractive cylinder revealed that all eyes showed a value ≤ 0.50 D, being about 73% of eyes ≤ 0.25 D (Figure 2). Similarly, there was a reduction in the distribution



Figure 1 SE refraction (D) before and 4mo after surgery.



Figure 2 Refractive cylinder (D) before and 4mo after surgery.

of the refractive cylinder after surgery. Mean postoperative refractive cylinder (-0.16±0.22 D, ranging from 0 to -0.50 D) was significantly reduced compared to preoperative values (P < 0.05; Table 1). Figure 3 shows the attempted versus achieved plot for the SE (M; Figure 3A) and for J0 (Figure 3B) and J45 (Figure 3C) components of astigmatism. For M, 100% of eyes were within ±0.50 D. For J0 and J45, 100% of eyes were within ± 0.50 D. Figure 4 shows the power vector of the astigmatism as depicted by the 2-dimensional vector (J0, J45) for the refractive (Figure 4A) and keratometric astigmatism values (Figure 4B). It should be considered that the (0, 0) point represents an eye without astigmatism. The distribution of the dots pre- and post-trifocal toric IOL implantation was similar indicting that the changes in refraction were not correlation with the change in keratometry. In fact, the mean change in keratometric astigmatism was 0.04±0.30 D for the vector J0 and -0.02±0.17 D for the vector J45 without statistically significant differences before and after surgery (P>0.05).

Figure 5 shows the cumulative preoperative Snellen CDVA and also the postoperative Snellen UDVA and CDVA. After surgery 81% of eyes showed a UDVA of 20/20 that was the same than CDVA before surgery. This percentage improved to 96% for CDVA postoperatively. Totally 100% of eyes showed UDVA and CDVA of 20/25 after surgery. The postoperative mean values of monocular distance Snellen decimal UDVA



Figure 3 Attempted versus achieved SE (M) (A) and the vector components J0 (B) and J45 (C) of the astigmatism Refraction is shown following the power vector method were S (sphere), C (cylinder) × φ (axis) were converted to power vector coordinates using M = S + C/2; J0 = (-C/2) cos (2 φ); J45 = (-C/2) sin (2 φ).

and CDVA were 0.97 ± 0.05 and 0.99 ± 0.02 , respectively. No statistically significant differences were found between both values (*P*>0.05).

DISCUSSION

It has been published that postoperative residual astigmatism in eyes implanted with multifocal IOLs impairs uncorrected visual acuity^[18-19] and, recently, that SE error also worsens it at various distances in trifocal IOLs being emmetropia the optimum target^[8]. Then, it should be considered that any reduction both in sphere and astigmatism errors after cataract



Figure 4 J0 and J45 astigmatic vectors for refraction (A) and keratometry (B) before and 4mo after surgery Note that some points overlap, especially for refractive astigmatism at 0; 0 (eye without astigmatism).



Figure 5 Cumulative proportion of eyes (percentage) having a specific UDVA and best-CDVA values before and 4mo after surgery.

surgery might provide our patients the best visual performance. We have observed satisfactory refractive and visual acuity outcomes after the surgery. Figure 1 shows the postoperative SE. This graph reveals that the main percentage of eyes showed a postoperative value between ± 0.13 D (50%) and no eye showed a value larger than 0.50 D (all within ± 0.50 D).

Figure 2 depicts the distribution of eyes with a specific amount of refractive cylinder with all eyes showing a value ≤ 0.50 D, being about 73% of eyes ≤ 0.25 D. The mean postoperative

values were less than a quarter of diopter both for SE and refractive astigmatism, -0.02 ± 0.23 and -0.16 ± 0.22 D, respectively. Both figures show the reduction in refractive errors after the surgery. This may be also observed in Figure 3 that plots the refractive correction with M and J0 and J45. All eyes showed a post-operative M near emmetropia with high predictability.

Figure 4 (A) shows clearly how the vector components of the refractive astigmatism are minimized and close to 0, 0, what represents an eye without astigmatism. Rotational instability of the lens would have caused larger values of these components. Figure 4B shows how the keratometric astigmatism is randomly spread before and after the trifocal toric IOL implantation showing non-significant differences (P>0.05). The changes in keratometry were minimal showing that the reduction of the astigmatism obtained comes from the implant of the trifocal toric IOL.

In relation to visual acuity outcomes, we have reported an improvement in CDVA after the surgery. Figure 5 shows the cumulative preoperative Snellen CDVA and also the postoperative Snellen UDVA and CDVA. After surgery, 81% and 96% of eyes showed UDVA and CDVA of 20/20, respectively. Mean values for both metrics were similar and about 20/20 (Snellen decimal values of 0.97 ± 0.05 and 0.99 ± 0.02 , respectively, *P*>0.05).

No direct comparison with other studies of trifocal toric IOLs in eyes with low amount of astigmatism was possible because, as far as we are aware, this is the first study that assesses this possibility. However, as introduced, there are two studies using the bifocal AcrySof ReSTOR toric IOL and several using the FineVision PODFT trifocal toric IOL with different amounts of astigmatism, which are interesting to discuss^[16-17]. Table 2 shows the main characteristics of these studies.

Two clinical studies assessed the use of the bifocal toric AcrySof ReSTOR IOL in eyes with low amount of astigmatism (IOL cylindrical power of 1.00 D)^[16-17]. Levitz et $al^{[16]}$ in 2015 reviewed a series of patients (44 eyes) with low degree of corneal astigmatism (from 0.23 to 1.08 D) undergoing the AcrySof ReSTOR SND1T2 bifocal toric IOL implantation to establish the potential benefit of the astigmatic correction in these cases. Preoperative mean cylinder was -0.50±0.43 D and 3mo post-surgery these authors reported that 70.5% of patients obtained a refractive cylinder <0.25 D (significantly reduced, P=0.001). Our results broadly agree with these results (73.08%, ≤0.25 D; Figure 2). They also found 93.3% of patients achieving a postoperative SE within ± 0.50 D. In our study 100% of eyes achieved ± 0.50 D (Figure 1). They used, depending on surgeons choice, either the SRK/T or Holladay II formulas with the Alcon AcrySof Toric Calculator for lens power calculation (with a consistent surgical induced astigmatism value of -0.3 D). The postoperative SE obtained

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First author, year	Sample (eyes)	Age (y)	Follow-up (mo)	Preoperative corneal astigmatism (D)	Axial length (mm)	IOL spherical power (D)	IOL cylindrical power (D)	IOL power calculation
Low amount of astigmatism (AcrySof ReSTOR SND1T2)								
Levitz ^[16] , 2015	44	NA	3	0.47 ± 0.19 (0.23 to 1.08)	NA	NA	1.00	SRKT or Holladay II with AcrySof toric Calculator
Hao ^[17] , 2019	17	NA	9	NA (0.50 to 1.00)	NA	NA	1.00	Hoffer-Q (< 22 mm), Holladay (22-25 mm) and SRK/T (>26 mm) with AcrySof toric Calculator
Different amounts of astigmatism (FineVision PODFT)								
Gundersen ^[20] , 2016	22	62.1±7.5 (51 to 72)	б	2.11±1.11 (1.04 to 5.19)	24.43±1.49 (22.66 to 27.11)	NA	NA	Using Fine Vision Toric Calculator
Nistad ^[21] , 2017	145	NA	3	$NA (>0.75)^{a}$	NA	NA	NA	Haigis
Vandekerckhove ^[22] , 2018	37	63.3±9.5 (43 to 80)	12	NA (0.83 to 3.28)	23.95±1.43 (22.05 to 27.59)	19.01±4.20 (9 to 26)	1.90±0.88 (1 to 3.75)	SRK/T, Hoffer Q, Holladay I or Haigis with FineVision Toric Calculator
Poyales ^[23] , 2019	52	57.3±3.9 (49 to 64)	б	3.18±0.40 (2.45 to 3.88)	23.58±1.32 (21.11 to 25.38)	20.79±3.32 (20.5 to 25)	2.40±0.49 (1 to 6)	NA
Poyales ^[24] , 2019	29	62.0±12.8 (NA)	3	$NA~(>1.00)^{a}$	NA	19.81±5.79 (9.5 to 32.5)	2.43±0.49 (1 to 6)	Barret Toric
Ribeiro ^[9] , 2019	51	68±8 (50 to 82)	б	1.91 ± 0.76 (0.90 to 4.41)	23.40±1.54 (20.11 to 28.36)	22.07±3.91 (11.50 to 33)	2.40±1.11 (1 to 6)	SRK/T (>22 mm) and Hoffer-Q (≤22 mm) with 5 calculators ^b
Values: mean±standard deviat Pentcam and Holladay with C	ion (rang assini.	ge); NA: not available	s; ^a Value fro	om the inclusion criteria (1	egular corneal a	stigmatism); ^b Standard tor	ic, Physiol toric wit	h Abulafia-Kock formula, Barret, Holladay with

was -0.04±0.32 D (ranging from 0.75 to -0.75 D). In our study we have obtained a mean value of -0.02±0.23 D (ranging from 0.50 to -0.50 D) using the FineVision Toric Calculator with the Abulafia-Koch formula. In relation to visual acuity outcomes, they reported that 68.2% of patients achieved UDVA 20/20 and, in our study, this value was even higher (81%; Figure 5). Levitz *et al*^[16] finally concluded that patients with low amounts</sup>of astigmatism may benefit from the excellent outcomes of a single treatment with multifocality and astigmatism correction. Hao *et al*^[17], in a small sample (17 eyes) with</sup>the same IOL model but with a longer follow-up, showed a residual astigmatism of -0.18±0.07 D. Unfortunately SE was not reported. These authors calculated IOL power considering the following formulae: Hoffer-Q for axial lengths of <22 mm, Holladay between 22 and 25 mm, and SRK/T for axial lengths of >26 mm with the AcrySof Toric Calculator. They showed that the visual acuity improved from UCVA (0.08 logMAR) to CDVA (0.01 logMAR) concluding that this lens improves patients' visual quality and satisfaction.

Different clinical studies have reported the outcomes of the trifocal toric FineVision PODFT IOL^[8,20-24], however, these studies included eyes with different amounts of astigmatism (>0.75 to 5.19 D) using several cylindric powers (from 1.00 to 6.00 D). Our study, specifically, focuses in eyes with low amount of astigmatism implanting IOLs with a cylindrical power of 1.00 D.

Gundersen and Potvin^[20] assessed the outcomes of 22 eves implanted with the FineVision PODFT IOL 3mo post-surgery with a preoperative corneal astigmatism from 1.04 to 5.19 D. They indicated that this lens effectively reduced astigmatism with a mean refractive cylinder of -0.30±0.26 D. They used the FineVision Toric Calculator. In another study, Nistad et al^[21] analysed, with a large sample (145 eyes) and the same followup, the use of a CTR to reduce refractive shift in patients with the FineVision non-toric and toric models. They used the Haigis formula reporting postoperative SE values of 0.33±0.46 D and 0.12±0.44 D, for the group with and without a CTR, respectively. They concluded that placing a CTR with the toric IOLs appeared to reduce refractive stability, although not significantly. One year later, Vandekerckhove^[22] assessed 37 eyes implanted with lenses with an IOL cylinder from 1 to 3.75 D in order to compare the rotational stability of the monofocal and trifocal toric models. The spherical power of the IOL was calculated using several formulas considering the eye's characteristics (i.e. axial length and anterior chamber depth): SRK/T, Hoffer Q, Holladay I, or Haigis, and for the IOL (cylinder power and axis) FineVision Toric Calculator was used. A CTR was used in all eyes and patients were assessed up to 1y of follow-up. This author showed a postoperative cylinder of -0.41±0.35 D (from 0 to 1.00 D) with 65% of eyes

with a refractive cylinder ≤ 0.50 D. In relation to visual acuity he reported a mean UDVA of 0.13 logMAR. He stated that the trifocal lens reduces refractive astigmatism providing good visual acuity, showing the trifocal toric lens better rotational stability than the monofocal one due to the higher frictional coefficient of its surface. Our results confirm this conclusion taking into account the good astigmatic components outcomes (J0, J45), which are related with any possible rotation of the lens. Recently, two studies of the same group^[23-24], reported the outcomes of 52 and 29 eyes with a 3mo of follow-up. The first study, focusing on stability and visual outcomes of 3 trifocal IOLs, analyzed eyes with preoperative corneal astigmatism from 2.45 to 3.88 D using lenses with a cylindrical power from 1 to 6 D^[23]. For the FineVision PODFT IOL, they found an UDVA of 0.04±0.02 logMAR, a CDVA of 0.03±0.02 logMAR (ranging from -0.05 to 0.1), and a mean SE of -0.17±0.10 D (ranging from -1.25 to 0.75 D). In the second one^[24], they analyzed 29 eyes (with the same follow-up) using the Barret toric formula to compare the spherical and toric models of the FineVision IOL. For the FineVision PODFT lens, the mean SE was -0.09±0.27 D (ranging from -1.00 to 0.5 D) with 93% and 100% of eyes within ± 0.50 and ± 1.00 D of the target refraction, respectively. Specifically, for the refractive cylinder, 86% of eyes had 0.50 D or less of residual astigmatism. UDVA and CDVA were 20/20 or better in 59% and 81% of eyes, respectively, and changed to 93% and 98% of eves for 20/25 or better. And, finally, Ribeiro et al^[9] retrospectively analysed a series of 51 eyes with a preoperative corneal astigmatism from 0.90 to 4.42 D and an IOL cylinder from 1 to 6.00 D. They used the SRK/T for eyes with axial length >22 mm and the Hoffer-Q for eyes ≤ 22 mm with 5 calculators (Table 2). They concluded that the Abulafia-Koch regression formula and the Barret toric calculators yielded lower astigmatic prediction errors compared to standard toric calculators (using only anterior keratometry data).

Our results broadly agree with these authors showing the good visual acuity and refractive outcomes. It should be noted that these studies were carried out in samples with a wide range of astigmatism but the postoperative outcomes were similar. In our study, the use of the FineVision Toric Calculator with the Abulafia-Koch formula showed excellent refractive outcomes of predictability (Figures 1-3). Were performed our series using femtosecond laser (capsulotomy centered), CTR insertion and intraoperative aberrometry. With this procedure we aimed to avoid possible IOL decentration and/or tilt that may affect the refractive and consequently visual outcomes in our patients. However, some controversy exists about the use of intraoperative aberrometry as an alternative method to accurately calculate IOL^[25-27]. In our series, using this technology, the outcomes were highly predictable. The main

limitation of the current study is its small sample, however, considering the low amount value of astigmatism and the consistent predictability, it seems that the current outcomes are noteworthy. Despite of this, further studies with larger samples and longer follow-up using the same technology would be desirable to confirm these outcomes.

In conclusion, patients with low astigmatism who were submitted to phacoemulsification for cataract surgery with a trifocal toric IOL implantation showed a significant reduction in their refractive astigmatism with an improvement in their visual acuity. The findings of the present study demonstrate that this lens is highly predictable in eyes with small amount of astigmatism and patients may benefit from them.

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