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CLINICAL TRIAL REPORT

One-Year Clinical Outcomes Following Aspheric Toric Monofocal IOL with a Double C-Loop Haptic Design Implantation

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Purpose: This study aimed to evaluate one-year clinical outcomes in cataract patients with pre-existing corneal astigmatism implanted with a biconvex aspheric toric monofocal intraocular lens (IOL) with a double C-loop haptic-design.

Methods: One hundred and eighteen patients (236 eyes) with corneal astigmatism (≥0.75D) were implanted bilaterally with the PODEYE toric IOL and assessed up to 1-year after surgery. Postoperative evaluation included monocular and binocular uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), under both photopic and mesopic lighting conditions, refraction, photopic and mesopic contrast sensitivity (with and without glare), and rotational stability.

Results: At the last postoperative visit, 74.6% and 95.8% of eyes were within ±0.50D and ±1.00D of the target refraction, respectively. About 78.0% and 97.5% of eyes showed a postoperative refractive cylinder of ≤0.50D and ≤1.00D, respectively. The mean manifest spherical equivalent value was 0.16±0.40D, and the mean refractive cylinder value was −0.42±0.33D. 97.5% and 100% of patients had a binocular UDVA and CDVA of ≥20/32, respectively. The mean binocular UDVA and CDVA were 0.01±0.09 and −0.03±0.07 logMAR, respectively. Under mesopic conditions, 79.5% and 89.8% of patients showed a binocular UDVA and CDVA of ≥20/32, respectively. The mean binocular UDVA and CDVA were 0.15±0.11 and 0.10±0.10 logMAR, respectively. Binocular contrast sensitivity function both under photopic and mesopic conditions was good. The mean absolute IOL rotation was 2.52±2.59 degrees with 98.56% of eyes having a rotation of less than 10 degrees.

Conclusion: Bilateral implantation of an aspheric toric monofocal IOL with a double C-loop haptic design in cataract patients with corneal astigmatism provides good visual and refractive outcomes up to 1-year post-surgery.

Keywords: astigmatism, monofocal toric, double C-loop, intraocular lens, cataract

Introduction

Ocular astigmatism, usually present in cataract patients, is a refractive condition that provokes blurred vision. A recent study carried out in eight United Kingdom National Health Service ophthalmology clinics with 110, 468 eyes undergoing cataract surgery reported that 78% of eyes had preoperative corneal astigmatism of ≥0.5 dioptres (D), 42% ≥1.0D, 21% ≥ 1.5D and 11% ≥2.0D.[1] The authors point out that there is significant burden value if the preoperative value is not reduced with monofocal intraocular lenses (IOLs). From a clinical perspective, the visual benefit of accurate <0.5D astigmatism correction would be limited since it has been reported that astigmatism less than this value does not degrade visual acuity.[2] For this reason, post-surgery residual refractive corneal astigmatism of 0.75D should be corrected to reduce the impact on the postoperative visual outcomes, improving the quality-of-life of these patients. Astigmatism-correcting treatment options such as toric IOLs need to be considered during cataract surgery. A systematic review and meta-

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analysis considering 13 randomised clinical trials comparing toric and non-toric IOLs concluded that toric IOLs provided better uncorrected distance visual acuity (UCVA), greater spectacle independence, and lower amounts of residual astigmatism than non-toric IOLs, even when relaxing incisions were used.[3] The authors of this study recommend that patients undergoing age-related cataract surgery who show regular corneal astigmatism should receive a toric IOL if they want to be spectacle independent for distance vision after the surgery.

There are many toric IOLs available in the armamentarium of cataract surgeons during their clinical practice. One of these IOLs is the PODEYE toric IOL (Beaver-Visitec International Inc., Waltham, USA). This lens has an aspheric toric optical surface with a double C-loop and posterior angulated haptic design. Recent retrospective (136 eyes)[4] and prospective (94 eyes)[5] studies involving a short-term follow-up (4–6 months) have concluded that it offers high rotational stability[4,5] and good visual acuity.[5] In an initial publication of our trial,[5] we reported that this IOL is an effective option for improving visual acuity at distance, correcting preoperative corneal astigmatism when implanted bilaterally, and a high percentage of eyes presents small rotation values. We indicated that a large sample with a longer follow-up was desirable to confirm the preliminary outcomes. Thus, the main objective of this article is to provide the 1-year clinical outcomes of the PODEYE toric IOL when implanted bilaterally in cataract patients with pre-existing corneal astigmatism.

Methods

Design

This multicentric prospective open-label study was carried out at 10 centres. The study was approved by the respective Ethics Committees. The study was approved by the respective Ethics Committees: SCMC-AEI Ethics Review Committee (Asian Eye Institute), Eticka Komise Ocni Kliniky Gemin (Zlin, Czech Republic), Ethik-Kommission der Bayerischen Landesärztekammer (München, Germany), Ärztekrammer Berlin (Berlin, Germany), Ärztekammer Sachsen-Anhalt (Halle, Germany), and Hospital Clínico San Carlos (Oftalvist Madrid, Valencia and Alicante, IMO Barcelona and Virgen de Lujan). The study was conducted in line with the Declaration of Helsinki, with all patients providing informed consent. The study was registered with the National Institutes of Health (NCT04778501, NCT04866719, NCT04744467 and NCT04987216).

Subjects

The inclusion and exclusion criteria were the same as in our initial report:[5] essentially cataract patients ≥50 years, corneal astigmatism of ≥0.75D and ≤4.25D in both eyes for inclusion; and degenerative visual disorders or previous intraocular or corneal surgery excluding patients, among other criteria. All the patients were bilaterally implanted with the monofocal PODEYE toric IOL, made of hydrophobic acrylic GFY material with an 11.40-mm overall diameter. It presents a double C-loop and a posterior-angulated haptic design and has a biconvex aspheric (−0.11 µm for 5 mm) toric (posterior surface) optic (6.00 mm optical diameter, refractive index = 1.52, Abbe number = 42). The lens is available from +6.00D to +30.00D (0.50D steps) spherical power, and 1.00/1.50/2.25/3.00/3.75/4.50/5.25/6.00D cylindrical power (IOL plane).

Surgical Technique

Standard phacoemulsification cataract surgery was performed through a 2.2 mm incision with a 5.5 mm diameter target for capsulorhexis or femtosecond laser-assisted capsulotomy. Refraction, corrected distance visual acuity (CDVA) and optical biometry using the IOLMaster instrument (700 model in all centers except one that used the 500 model, Carl Zeiss Meditec AG, Jena, Germany) were measured prior to the surgery. With this information, the IOL power (sphere and cylinder) using the Barrett toric formula included in the device or using the online calculator (https://ascrs.org/tools/barrett-toriccalculator) was chosen to achieve a residual spherical equivalent of between −0.2D and 0.1D and the lowest residual cylinder possible.

Study Outcome Parameters

At 4–6 and 11–13 months we measured refraction, including the details of the sphere, cylinder and axis, and calculated the spherical equivalent prediction error and vector analysis. Both monocular and binocular UDVA, and CDVA under

photopic and mesopic (3.5 cd/m^2) conditions were measured using the Clinical Trial Suite (M&S Technologies, Niles, IL, USA). Photopic and mesopic contrast sensitivity, both with and without glare, under binocular conditions were also measured with this instrument. The absolute rotational stability (mean, standard deviation [SD] and range) of the IOLs was obtained between 1-day and 11–13 months post-surgery. To determine the rotational stability of the lenses after implantation, the IOL orientation was recorded as the intended surgical position during surgery using a photograph through the surgery microscope or within one hour after surgery using a photograph through a slit lamp. Additional orientations were measured and recorded at all follow-up visits by taking retro illuminated photographs in mydriasis using the slit lamp. Any adverse IOL events were registered.

Analysis and Sample Size

The data from all the patients was imported into an Excel spreadsheet (Microsoft Corporation, Redmond, USA) for the analysis and all the variables studied were given as the mean ± standard deviation and ranges. The sample size was calculated taking into account the absolute rotation as the primary endpoint and had also been calculated previously in our initial report:[5] a minimum of 70 eyes implanted with a PODEYE toric lens.

Results

Two hundred and thirty-six eyes from 118 patients bilaterally implanted with the PODEYE Toric IOL were analysed in this article; the mean age of the patients was 69.4±4.4 years (range: 51 to 86 years); and 75 were female. The main preoperative characteristics and demographics of the whole sample are given in Table 1. In general, no related adverse IOL events were reported either during the surgery or up to the final follow-up visit.

Refractive Outcomes

Figure 1 shows the refractive accuracy of the surgical procedure for the spherical equivalent prediction error (A) and refractive cylinder (B). Specifically, it shows the distribution at 4–6 and 11–13 months of follow-up. At 4–6 months, 76.7% of eyes were within ±0.50 D and 97.9% of eyes were within ±1.00 D of the target refraction. These values were similar at 11–13 months post-surgery, being 74.6% and 95.8%, respectively. At 4–6 months, 73.3% and 98.3% of eyes had a postoperative refractive

Table 1 Demographic Characteristics of Participants

	Mean ± Standard Deviation	Median (Range)
Number of patients (n)	118	—
Number of eyes (n)	236	—
Gender (female/male)	75/43	—
Age (years)	69.4 ± 4.4	71.0 (51.0 to 86.0)
IOP (mmHg)	15.81 ± 2.83	16.00 (8.00 to 24.00)
Sphere (D)	–0.26 ± 2.97	0.00 (–10.50 to 6.50)
Cylinder (D)	–1.63 ± 1.07	–1.50 (–6.00 to 0.00)
SE (D)	–1.08 ± 3.04	–0.57 (–11.38 to 5.50)
Monocular UDVA (logMAR)	0.58 ± 0.25	0.65 (–0.10 to 0.80)
Monocular CDVA (logMAR)	0.24 ± 0.20	0.20 (–0.14 to 0.80)
K1 (D)	43.02 ± 1.52	43.00 (39.60 to 47.00)
K2 (D)	44.55 ± 1.60	44.39 (40.81 to 49.95)
Axial Length (mm)	24.03 ± 1.40	23.72 (21.69 to 28.22)
Lens Thickness (mm)	4.56 ± 0.50	4.63 (2.43 to 5.52)
ACD (mm)	3.11 ± 0.40	3.12 (2.10 to 4.10)
White to white (mm)	11.92 ± 0.45	11.90 (10.70 to 14.10)
IOL Power spherical (D)	19.7 ± 4.3	20.5 (6.5 to 30.00)
IOL power cylindrical (D)	2.0 ± 1.0	1.5 (1.0 to 6.0)

Abbreviations: IOP, intraocular pressure; D, diopters; SE, spherical equivalent; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; K, keratometry; ACD, anterior chamber depth; IOL, intraocular lens.

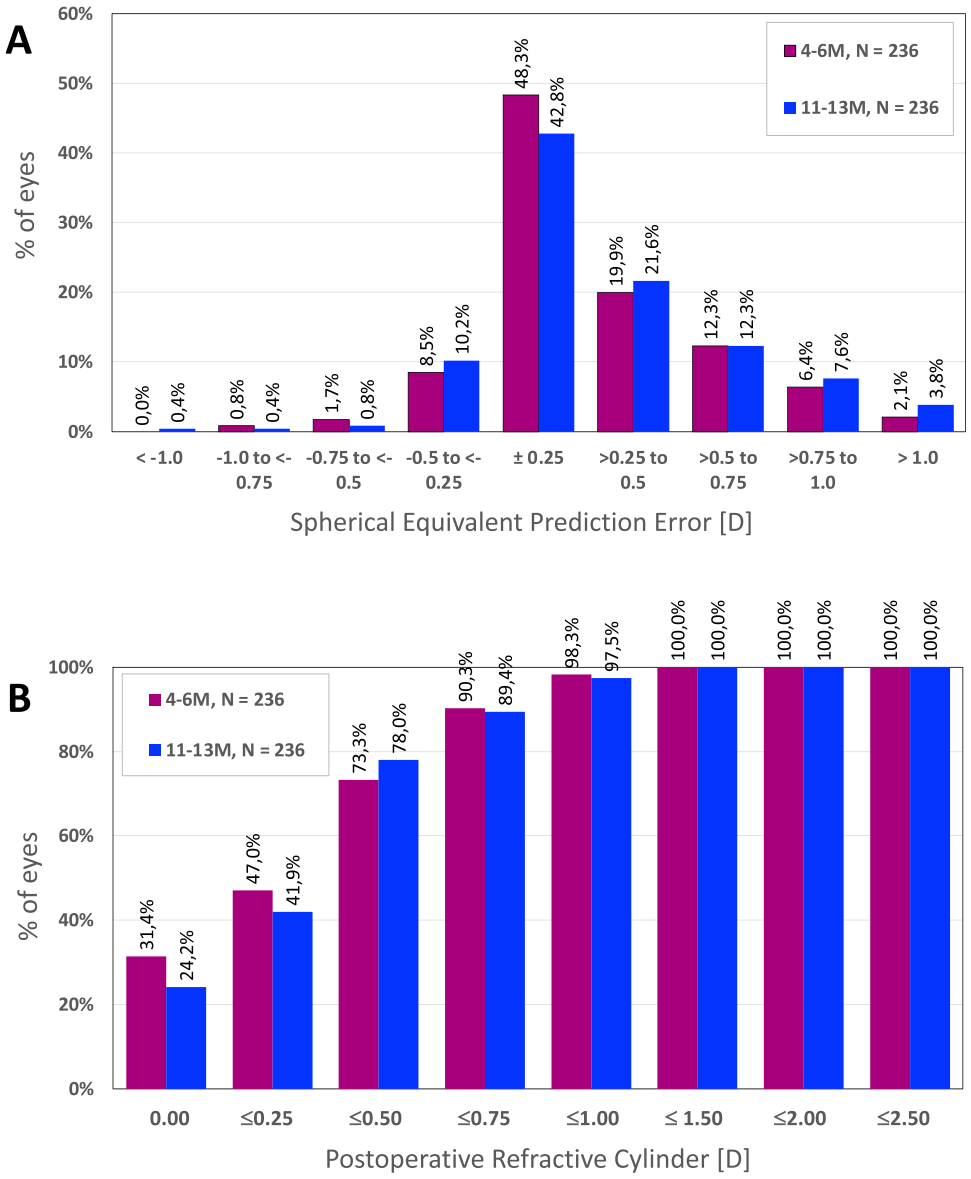

Figure 1 Refraction outcomes: distribution of spherical equivalent prediction error (**A**) and refractive cylinder (**B**) at 4–6 and 11–13 months post-surgery.

cylinder of ≤0.50 D and ≤1.00 D, respectively. These values were also similar at 11–13 months postoperatively, being 78.0% and 97.5%, respectively. The mean manifest refractive spherical equivalent and refractive cylinder values were 0.12±0.39 D and −0.40±0.34 D at 4–6 months, and 0.16±0.40 D and −0.42±0.33 D at 11–13 months, respectively. Less than a quarter of a dioptre was found for the mean manifest refractive spherical equivalent and less than half a dioptre for the refractive cylinder. Figure 2 shows the vector analysis of the preoperative and postoperative data at 4–6 (A) and 11–13 (B) months.

Visual Acuity Outcomes and IOL Rotation

Figure 3 depicts the cumulative proportion of eyes (for monocular conditions) and patients (for binocular conditions) with given photopic UDVA and CDVA logMAR values at the two follow-ups. About 70.8% and 93.6.4% of eyes presented monocular UDVA and CDVA values of ≥20/25 (≤0.10 logMAR) at 4–6 months, and 69.5% and 86.9% at 11–13 months, respectively. Under binocular conditions, these values increased to 90.7% and 99.2% at 4–6 months, and 88.1% and 92.4% at 11–13 months, respectively. In detail, at 4–6 months, the mean monocular UDVA and CDVA values were 0.07±0.12 and 0.00±0.08 logMAR, respectively; and 0.01±0.09 and −0.03±0.07 logMAR for binocular conditions,

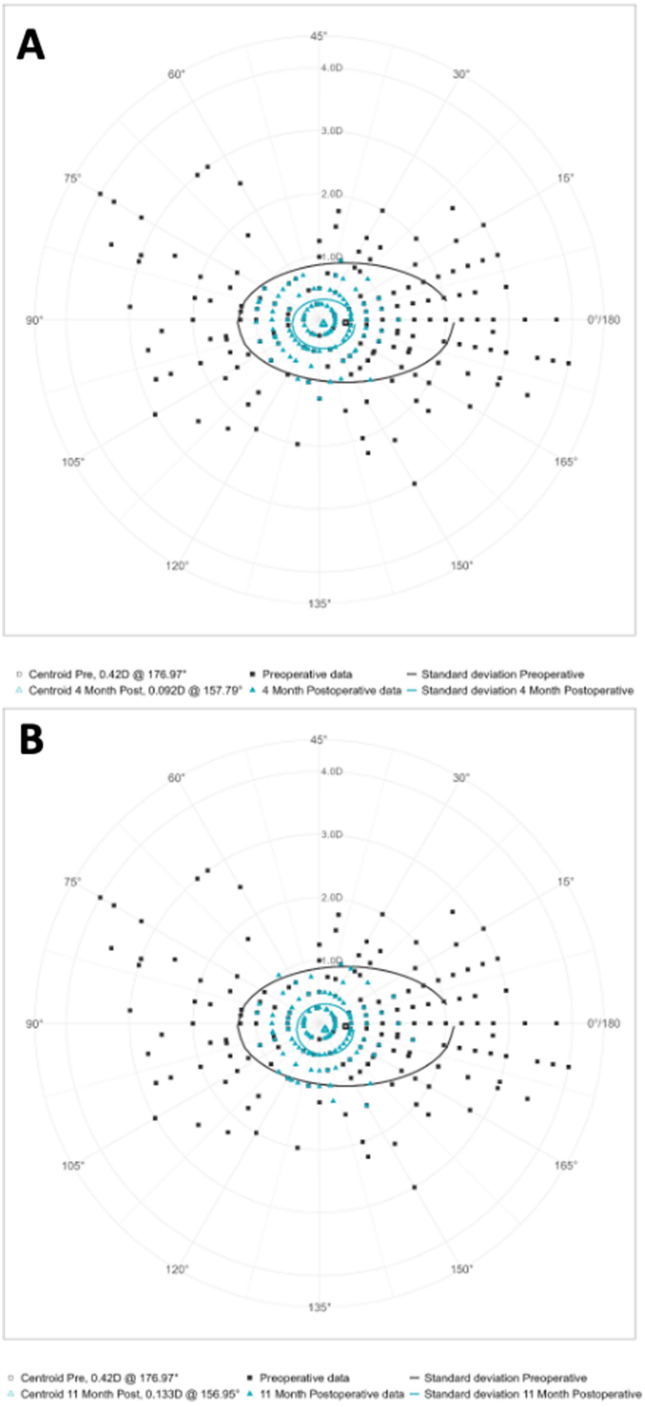

Figure 2 Vector analysis with preoperative and postoperative data at 4–6 (**A**) and 11–13 (**B**) months post-surgery. Centroids with standard deviations are also shown.

respectively. These values changed to 0.08±0.11 and 0.01±0.09 monocularly, and 0.01±0.08 and −0.02±0.08 binocularly, respectively, at 11–13 months post-surgery.

Figure 4 represents the cumulative proportion of eyes (for monocular conditions) or patients (for binocular conditions) with given monocular and binocular mesopic logMAR UDVA and CDVA values. About 60.6% and 81.8% of eyes presented a monocular UDVA and CDVA of ≥20/32 (≤0.20 logMAR) at 4–6 months, and 59.7% and 79.2% at 11–13 months, respectively. These percentages, for patients (binocular conditions), increased to 80.5% and 90.7%, at 4–6 months and 79.5% and 89.8% at 11–13 months post-surgery, respectively. At 4–6 months, the mean values of monocular

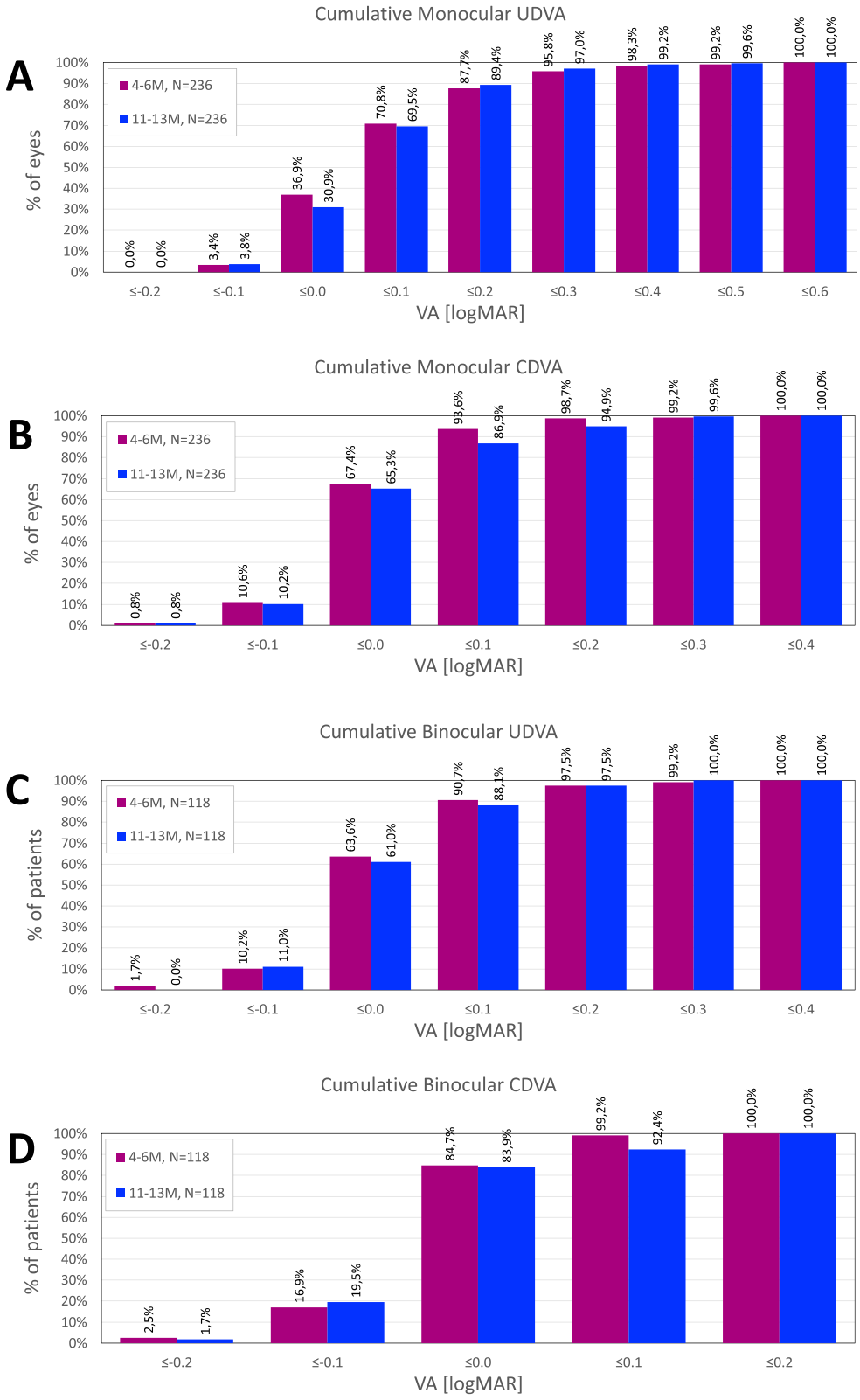

Figure 3 Cumulative proportion of eyes (**A** and **B**)/patients (**C** and **D**) having a given photopic monocular and binocular logMAR uncorrected-distance visual acuity (UDVA) and best corrected-distance visual acuity (CDVA) value at 4–6 and 11–13 months post-surgery.

UDVA and CDVA were 0.21±0.15 and 0.14±0.11 logMAR, respectively; and 0.14±0.11 and 0.09±0.10 logMAR, for binocular conditions, respectively. At 11–13 months, these values were 0.21±0.13 and 0.15±0.11 for monocular conditions and 0.15±0.11 and 0.10±0.10 for binocular conditions, respectively.

In relation to IOL rotation (n=208 eyes), we found a mean absolute rotation of 2.52±2.59 degrees (ranging from 0 to 12 degrees), and 98.56% of eyes had a rotation of <10 degrees.

Contrast Sensitivity

Figure 5 shows the mean and standard deviation values for the photopic and mesopic binocular contrast sensitivity functions with glare (B and D) and without glare (A and B) at both 4–6 and 11–13 months post-surgery. Similar log contrast sensitivity values were found at 3, 6, 12, and 18 cycles per degree spatial frequencies for the two post-operative visits, being, as expected, slightly worse in mesopic conditions (low lighting) as well as when measured with a glare source.

Discussion

A systematic review and meta-analysis with trial sequential analysis has recently concluded that for cataract patients toric IOLs are an effective method for correcting astigmatism and the preferred choice for astigmatism correction in cataract patients when compared with femtosecond laser-assisted astigmatic keratotomy.[6] This approach for correcting corneal astigmatism enhances the patient's vision after the surgical intervention and the evidence-based use points out that toric IOLs contribute to spectacle-free vision in pseudophakic eyes.[7] Some considerations such as accurate preoperative measurements, a good IOL cylinder power calculation and a good surgical procedure are important aspects for achieving excellent refractive outcomes.[7] In the current clinical trial, we studied the outcomes obtained when the PODEYE toric IOL was implanted bilaterally in cataract patients presenting corneal astigmatism.

For refractive accuracy, at 11–13 months of follow-up, we found that 74.6% of eyes were within ±0.50D and 95.8% of eyes were within ±1.00D of the target refraction (see Figure 1A) with a mean manifest refractive spherical equivalent of <0.25 (0.16±0.40D). Two previous studies, one retrospective (n=136 eyes)[4] and one prospective (n=94 eyes)[5] at 4–6 months, also analysed this IOL model. Chassain et al[4] looked at the target refraction for emmetropia or mild to moderate myopia (monovision). For monovision in emmetropic eyes, they considered a target of 0D for dominant eyes and −1.0D for non-dominant eyes; for myopic eyes these values were −0.50D and −1.50D, respectively; and for hyperopic eyes they were 0.00/-0.50D. Their results revealed a manifest refractive spherical equivalent of −0.67±0.56D, −1.07±0.44D and −0.17±0.17D for the cohort, myopic eyes, and for eyes with a myopic target of >-0.50D, respectively. They reported that the mean value was −0.30±0.54D at 4–6 months with 70% and 92% of eyes within ±0.50D and ±1.00D of the target refraction. Ang et al[5] at the same follow-up time found 78.2% and 98.9% of eyes within ±0.50 D and ±1.00D of the target refraction, respectively. Our results, for this follow-up period, broadly agree with both studies, with 76.7% of eyes within ±0.50 D and 97.9% of eyes within ±1.00 D of the target refraction (see Figure 1A). These percentages were similar at 1-year post-surgery (74.6% and 95.8%, respectively), showing the stability of the procedure. In fact, the mean manifest refractive spherical equivalent values were 0.12±0.39 D and 0.16±0.40 D at the two follow-up visits. Note that Chassain et al[4] reported a mean refractive prediction error of −0.30±0.46D and Ang et al[5] of 0.09±0.35D, both at 4–6 months. For the refractive cylinder, our results revealed that 78.0% and 97.5% of eyes showed a postoperative refractive cylinder of ≤0.50D and ≤1.00D, respectively, at the last visit, being similar to the 4–6 months follow-up (73.3% and 98.3%, respectively), and similar to those obtained by Chassain et al[4] (84.1% and 98.1%, respectively) and Ang et al[5] (78.2% and 98.9%, respectively). Figure 2, both at 4–6 (A) and 11–13 months (B) shows the reduction in the distribution of points in the vector analysis after the surgery showing the reduction of astigmatism (0,0 value represents and eye free of astigmatism).

Good refractive outcomes obtained in our cohort of patients allow us to expect excellent visual performance since uncorrected refractive astigmatism inherently degrades visual acuity. Binocular UDVA and CDVA values better than 20/25 (≤0.10 logMAR) were found in 88.1% and 92.4% of our patients at the last follow-up visit (see Figure 3C and D) with mean values of 0.01±0.08 and −0.02±0.08 logMAR, respectively. These outcomes are in agreement with those reported at 4–6 months by Chassain et al[4] with a mean logMAR CDVA value of −0.08±0.08 (100% of eyes with a cumulative

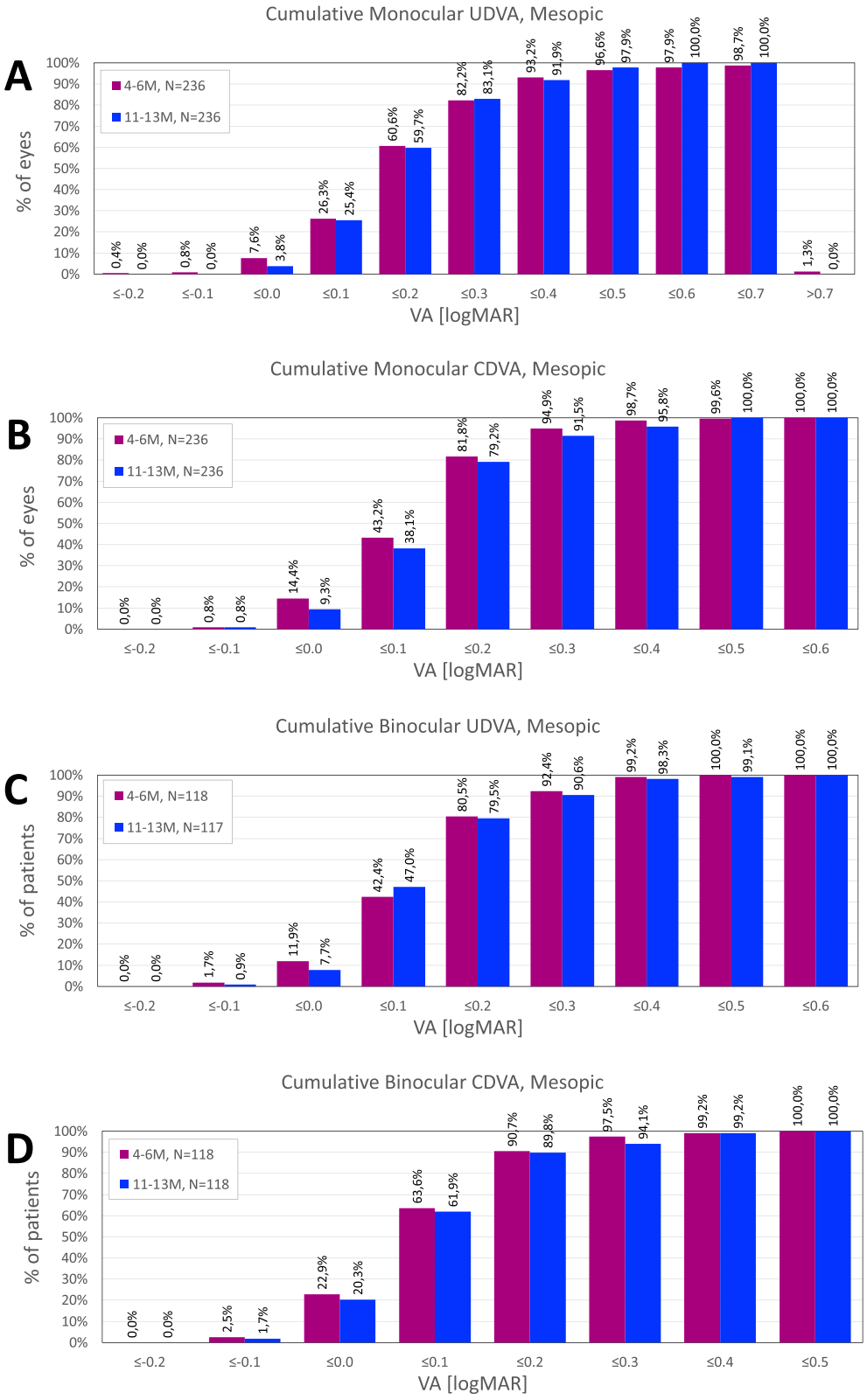

Figure 4 Cumulative proportion of eyes (**A** and **B**)/patients (**C** and **D**) having a given mesopic monocular and binocular logMAR uncorrected-distance visual acuity (UDVA) and best corrected-distance visual acuity (CDVA) value at 4–6 and 11–13 months post-surgery.

monocular CVDA of ≤0.20 logMAR), and Ang et al[5] with a mean logMAR CDVA value of −0.02±0.07 (100% of eyes with a binocular cumulative CDVA of ≤0.10 logMAR). When the visual acuity was measured in reduced lighting conditions (mesopic, Figure 4) the percentages of the cumulative and mean values for visual acuity were slightly worse, as expected. Note that 79.5% and 89.8% of patients presented a binocular UDVA and CDVA of ≥20/32 (≤0.20 logMAR) at 11–13 months, respectively (Figure 4C and D), with mean values of 0.15±0.11 and 0.10±0.10 logMAR, respectively. The outcomes obtained by Ang et al[5] at 4–6 months were similar: 78.7% and 83.0%, with mean values of 0.15±0.11 and 0.12±0.11 logMAR, respectively. The good visual acuity findings correlate with good contrast sensitivity, specifically for the highest spatial frequency (18 cpd, see Figure 5). The values reported are in agreement with those found in our preliminary outcomes at 4–6 months[5] (ie, mean photopic logCS at 18 cpd of −1.02[5] and −1.08 in the present study at the same follow-up time). The differences between the graphs plotted in Figure 5 correlate with the variation in lighting conditions, with or without glare, during the measurements. As can be seen in this figure, the outcomes obtained for the short and long follow-ups are practically the same, indicating that the visual performance this lens offers patients is maintained over time.

The correct alignment of the toric IOL is one of the most important parts of the postoperative management of this type of lens. Our mean postoperative absolute IOL rotation was 2.52±2.59 degrees (n=208 eyes). Previous studies with small samples and shorter follow-up periods (4–6 months) report mean postoperative IOL rotations of 2.05±2.17 degrees (n=136)[4] and 1.22±2.21 degrees (n=94).[5] The first study showed that, except for one outlier with 15 degrees of rotation, the IOL rotation was ≤10 degrees, and the second study reported that 97.87% of eyes had a rotation of <10 degrees. Our current study indicates that 98.56% of eyes have a rotation of <10 degrees; this is an excellent outcome and similar to those reported in the two preceding studies. Different samples may play a role in the mean values obtained by Chassain et al[8] in another study using the Ankoris toric IOL (BVI Inc., Waltham, USA), which has the same C-loop design but which is made of a different material (hydrophobic vs hydrophilic), reported a similar absolute mean rotation: 2.16±1.95 degrees. An in silico laboratory study (computer simulation) analysing the biomechanical stability of IOLs with different

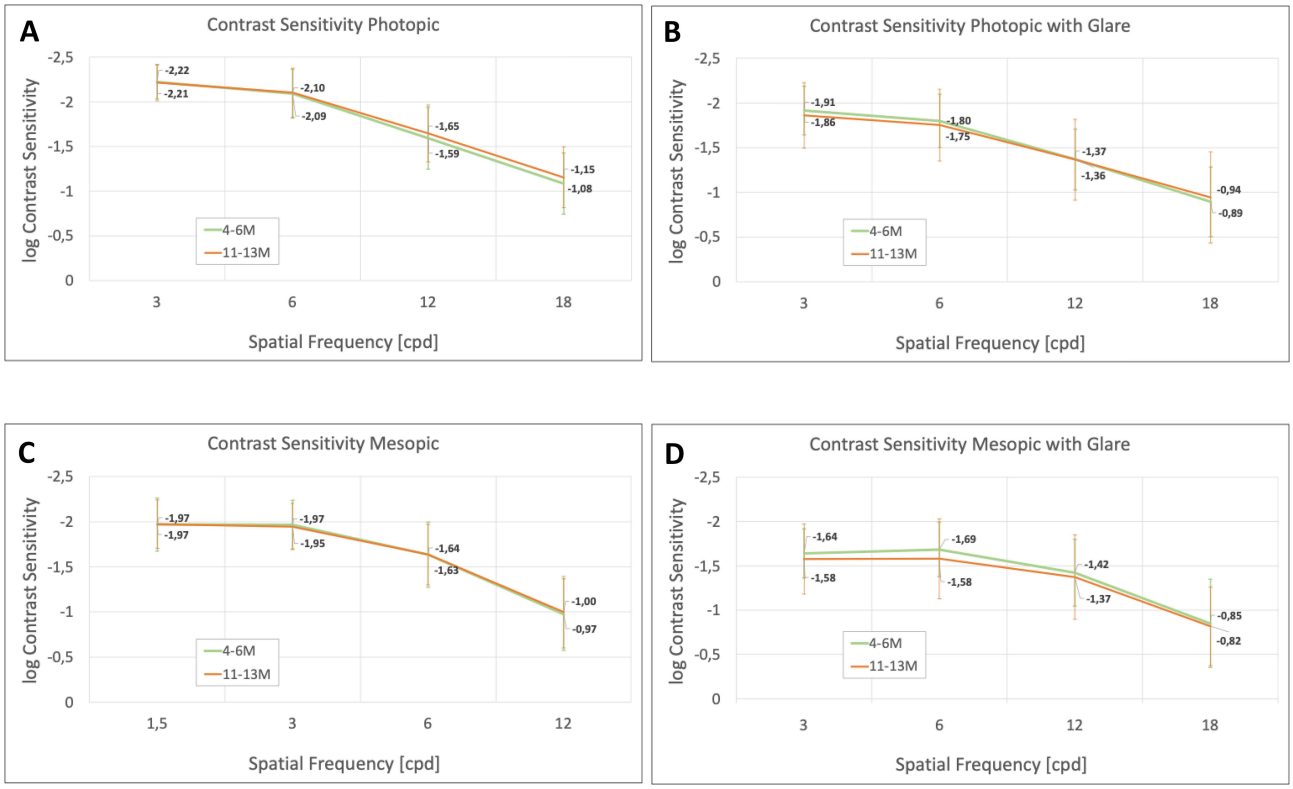

Figure 5 Mean photopic (n=115) and mesopic (n=118) binocular contrast sensitivity function with glare (**B** and **D**) and without glare (**A** and **B**) at 4–6 and 11–13 months post-surgery.

haptic designs (four-loop and double C-loop manufactured by BVI Inc.) found that despite these lenses showing statistically significant variations (displacement, tilt and rotation), the differences cannot be considered clinically relevant, thereby suggesting that all of them yield excellent stability in those terms.[9] One of the specific features of this lens is the good manoeuvrability since the lens allows it to be rotated in both senses, clockwise and counter-clock wise, facilitating the alignment of the toric IOL with the desired axis.

A recent systematic review and single-arm meta-analysis study evaluated the rotational stability of different toric IOLs according to lens model and haptic design.[10] This study considered 51 published studies involving 4863 eyes and showed that the pooled mean absolute rotation of all the toric IOLs was 2.36 degrees, with a 95% CI: 2.08–2.64, and concluded that commercially available modern toric IOLs exhibit exceptional rotational stability. The authors reported that the rotation depends on many aspects of the lens material and design. It has been reported that a misalignment of less than 10 degrees can lead to a minimal to moderate loss of cylindrical correction, with the highest cylindrical correction loss occurring at 10 and 20 degrees, taking into account the fact that the image quality and the amount of rotation is non-linear.[11] The previous study[10] found, specifically, that the pooled mean absolute rotation of the FineVision POD FT (BVI Inc., Waltham, USA) was 1.53 degrees (95% CI: 1.2–2.04). This diffractive trifocal toric IOL has the same haptic design as the PODEYE Toric IOL. The authors also analysed other toric models available on the market and found significant differences between them ($p<0.01$); however, the pairwise *t*-test with Bonferroni adjustment and additional Tukey-Kramer and Scheffé's tests did not reveal significant differences between any 2 pairs. The authors suggest that this may be due to the sheer number of comparisons from the different number of sub-groups considered, meaning each test does not have enough power to detect statistically significant differences. Specifically, they reported that the FineVision POD FT IOL exhibits exceptional rotational stability despite using hydrophilic lens material with its double-loop haptics. The ISO11979-7:2018 indicates that the absolute value of rotation should be less than 10 degrees in 90% of the eyes implanted.[12] In our cohort, the outcomes obtained broadly fulfil this criterion since our percentage for this value was 98.56%. Some risk factors for toric IOL rotation have been published: biological parameters (ie, axial length, capsular bag dimensions, and direction of corneal astigmatism); toric IOL characteristics (ie, size, shape and material design); surgical factors (ie, manual marking and computer navigation and continuous curvilinear capsulorhexis); anterior capsular opacification degree or neodymium:YAG laser posterior capsulotomy.[13] Based on these considerations, surgeons should take into account all these factors to minimise postoperative toric IOL rotation and to provide good refractive and hence visual acuity outcomes. Our study includes a large sample of eyes with 1 year of follow-up, and despite the fact that further rotation is not expected after 6 months post-surgery it is always desirable to report the outcomes for longer follow-ups in order to confirm the good rotational stability.

Conclusions

The results of this study suggest that bilateral PODEYE toric IOL implantation provides good refractive and visual outcomes in patients with pre-existing corneal astigmatism undergoing cataract surgery. The PODEYE toric IOL presents very good rotational stability with a mean absolute rotation of less than 2.6 degrees.

Data Sharing Statement

Data of this trial are not available for sharing.

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Disclosure

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Detlef Holland reports study fee from physiol, outside the submitted work.

The authors report no other conflicts of interest in this work.

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