

Photoc Phenomena and Quality of Vision Following Aspheric Toric Monofocal IOL with a Double C-Loop Haptic Design Implantation

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Purpose: This study aimed to analyse photoc phenomena and quality of vision in cataract patients implanted with a biconvex aspheric toric monofocal intraocular lens (IOL) with a double C-loop haptic design.

Methods: A total of 116 patients (232 eyes) with corneal astigmatism (≥ 0.75 D) were implanted bilaterally with the PODEYE toric IOL. Postoperative evaluation at 11–13 months post-surgery included binocular uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), and posterior capsule opacification (PCO) grading. Specifically, photoc phenomena (halo and glare) and quality of vision (QoV) were assessed at the 4–6 months postoperative visit using a simulator and a validated patient-reported outcomes questionnaire.

Results: Mean binocular UDVA and CDVA were 0.01 ± 0.08 logMAR and -0.03 ± 0.08 logMAR, respectively. Eleven eyes from our cohort of eyes showed mild PCO (4.8%). The size and intensity of halos decreased compared to the preoperative visit, from 29.63 ± 22.52 to 16.27 ± 14.51 , and from 42.47 ± 24.62 to 29.44 ± 24.51 , respectively. A similar trend was found for glare (from 28.38 ± 19.49 to 11.46 ± 13.91 , and from 33.17 ± 23.30 to 22.61 ± 19.36 , respectively). The mean Rasch Score analysis showed different improvements of quality of vision from preoperative to 4–6 months postoperatively for frequency (-26.19 ± 24.65), severity (-22.82 ± 21.32) and bothersomeness (-26.47 ± 26.05).

Conclusion: Bilateral implantation of the PODEYE toric IOL in cataract patients with corneal astigmatism provides good quality of vision. Halo and glare induced by this lens are less intense than those induced by cataracts, thus leading to a subjective reduction in these visual disturbances after surgery.

Keywords: photoc phenomena, quality of vision, monofocal toric, double C-loop, intraocular lens, cataract

Introduction

Ocular astigmatism, which is usually present in cataract patients, is one of the most common refractive conditions presenting with 1.0 dioptres (D) or more.¹ Specifically, a survey by the United Kingdom National Health Service carried out in eight of its ophthalmology clinics, and including 110,468 eyes undergoing cataract surgery, showed that 78% of eyes had preoperative corneal astigmatism of ≥ 0.5 D, 42% ≥ 1.0 D, 21% ≥ 1.5 D and 11% ≥ 2.0 D.² Several systematic reviews and meta-analyses have highlighted the importance of the use of toric intraocular lenses (IOLs) during cataract surgery.^{3,4} Toric IOLs provided better uncorrected distance visual acuity (UDVA), greater spectacle independence and lower amounts of residual astigmatism than non-toric IOLs,³ and correcting for corneal astigmatism using these lenses contributes to spectacle-free vision in the pseudophakic eye.⁴

Different toric IOL models have been designed and used worldwide for cataract surgery in pre-existing astigmatic eyes. One of these lenses is the PODEYE toric IOL (Beaver-Visitec International Inc., Waltham, USA), which comprises

an aspheric toric optical surface with a double C-loop and posterior angulated haptic design. Retrospective and prospective clinical studies^{5–11} with this IOL have shown accurate refractive outcomes, high rotational stability and, therefore, good visual performance at different times post-surgery in eyes with pre-existing astigmatism. However, it has been suggested that patient-reported outcomes studies are needed to evaluate standard and premium cataract surgery options, from initial patient expectations to final patient-reported and visual quality outcomes.¹² Therefore, in order to provide more information about the performance of these lenses, the main purpose of the present study was to analyse photic phenomena and quality of vision in a large sample of cataract patients with pre-existing astigmatism implanted with the PODEYE toric IOL using a glare and hale simulator and a validated quality of vision questionnaire.

Methods

Study Design and Patients

This was a prospective multicentre (10 sites) open-label study undertaken at different sites located in the Czech Republic (Gemini Eye Clinic), Philippines (Asian Eye Institute), Spain (IMO, Virgen de Lujan and Oftalvist Alicante, Valencia and Madrid), and Germany (Augenzentrum Erding, Augentagesklinik Spreebogen, Medicum Wittenberg). The study was designed to adhere to the Declaration of Helsinki, with all patients providing informed consent, and was approved by the Ethics Committees of the different centres [SCMC-AEI Ethics Review Committee (2021–008; Asian Eye Institute), Eticka Komise Ocní Kliniky Gemin (2024–04; Zlin, Czech Republic), Ethik-Kommission der Bayerischen Landesärztekammer (mb21053; München, Germany), Ärztekammer Berlin (Eth-MZ 28/21; Berlin, Germany), Ärztekammer Sachsen-Anhalt (070/21 II; Halle, Germany), and Hospital Clínico San Carlos (21/230-EC_P; Oftalvist Madrid, Valencia and Alicante, IMO Barcelona and Virgen de Lujan)] and registered at the National Institutes of Health with numbers NCT04778501, NCT04866719, NCT04744467 and NCT04987216. All patients were implanted bilaterally with the monofocal PODEYE toric IOL. The PODEYE toric IOL (hydrophobic acrylic GFY material, Abbe number of 42 and refractive index of 1.52), has a double C-loop and a posterior-angulated haptic design (Figure 1). It has a biconvex aspheric toric (posterior surface) optic ($-0.11 \mu\text{m}$ for 5 mm), with a 6.00 mm optical diameter and an 11.40 mm overall diameter. The spherical power ranges from 6.00D to 30.00D in 0.50D steps, and the cylindrical power at the IOL plane can be selected from the following values: 1.00/1.50/2.25/3.00/3.75/4.50/5.25/6.00D. Optical biometry with the IOLMaster instrument (Carl Zeiss Meditec AG, Jena, Germany) was used, and the IOL power, mainly calculated

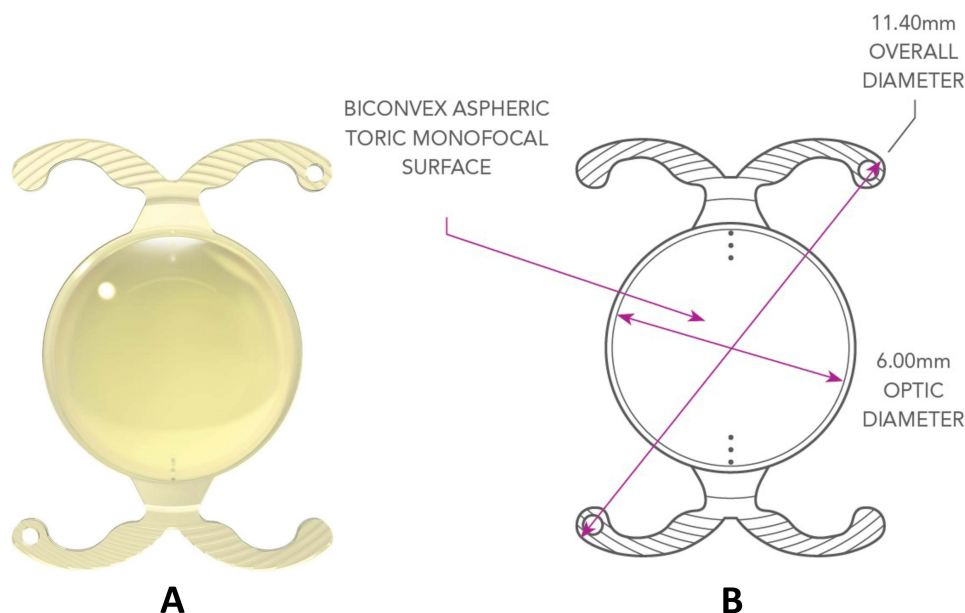


Figure 1 PODEYE toric intraocular lens (A) photography; (B) design). Courtesy of Beaver-Visitec International, Inc. [BVI].

using the online calculator for the Barrett toric formula, was chosen to achieve a residual spherical equivalent of between -0.2D and 0.1D and the lowest residual cylinder possible.

Study Outcome Parameters

Binocular UDVA and corrected distance visual acuity (CDVA) under photopic conditions were measured at 11–13 months using the Clinical Trial Suite (M and S Technologies, Niles, IL, USA) at 4 m in logMAR scale, along with photic phenomena and quality of vision. The photic phenomena of halo and glare were measured at 4–6 months using a simulator that presented a simulated image of car headlights and traffic lights (Eyeland Design Network GmbH, Germany). Patients were asked to adjust the halo and glare level in a simulated image to the amount of such photic phenomena they perceived. Based on this image, patients adjusted the halo and glare levels on analogous scales from 0 to 100 according to their perception. The higher the value, the worse the perceived outcome, thereby indicating greater severity of halo or glare symptoms reported by the patients. This test was performed pre- and postoperatively, with the preoperative outcomes serving as a baseline measurement. The McAlinden Quality of Vision (QoV) questionnaire¹³ was used to assess visual symptoms at the same follow-up. It includes questions about glare, halos, starbursts, hazy vision, blurred vision, distortion, seeing multiple images, fluctuating vision, difficulty focusing and difficulty perceiving distance or depth, with scores ranging from 0 to 100 (higher scores indicate poorer vision quality). Photographs are used to simulate visual symptoms (ie, glare and halos), and patients are asked to report how often they experience the symptom (frequency), how severe they find the symptom (severity) and how bothered they are by the symptom (bothersomeness). For analysis, all answers are grouped together under the rating scales frequency, severity and bothersomeness. Subjective PCO grading was performed after pupil dilation at up to 11–13 months of follow-up.¹⁴ Any adverse IOL events were registered. Data from all patients were imported into an Excel spreadsheet (Microsoft Corporation, Redmont, USA) for complete analysis and the different variables studied were given as the mean $\pm$ standard deviation, 95% confidence interval (CI), median and ranges. Sample size was previously calculated.⁷

Results

A total of 232 eyes from 116 patients implanted bilaterally with the PODEYE Toric IOL were analysed in this study. In general, no related adverse IOL events were reported either during surgery or up to the final follow-up visit. At the 11–13 months visit, mean binocular UDVA was 0.01 ± 0.08 logMAR (95% CI: 0.00, 0.02; range: -0.16 to 0.26 logMAR) and mean binocular CDVA was -0.03 ± 0.08 logMAR (95% CI: -0.04 , -0.01 ; range: -0.26 to 0.20 logMAR). Significant opacities were only reported for the posterior capsule. Eleven eyes from our cohort of eyes implanted with this toric IOL showed mild PCO (4.8%).

Halo and Glare Outcomes

Table 1 shows photic phenomena, halo and glare (type, size and intensity) outcomes registered using the visual simulator in our cohort of patients both preoperatively ($n = 109$ patients) and at 4–6 months post-PODEYE toric IOL implantation ($n = 116$ patients). The results post-surgery show that the size and intensity of halos decreased compared to the preoperative visit (from 29.63 ± 22.52 to 16.27 ± 14.51 and from 42.47 ± 24.62 to 29.44 ± 24.51 , respectively). A similar trend was found in relation to glare (from 28.38 ± 19.49 to 11.46 ± 13.91 and from 33.17 ± 23.30 to 22.61 ± 19.36 , respectively). Note that not all the patients reported preoperative outcomes.

Quality of Vision (QoV) Questionnaire

Table 2 shows the QoV questionnaire outcomes obtained before ($n = 115$ patients) and at 4–6 months after PODEYE toric IOL implantation ($n = 115$ patients). The mean Rasch Score analysis showed different improvements in quality of vision for the three categories evaluated: frequency, severity and bothersomeness. Specifically, the mean changes from preoperative to 4–6 months postoperatively were -26.19 ± 24.65 (95% CI: -30.77 , -21.62), -22.82 ± 21.32 (95% CI: -26.78 , -18.87) and -26.47 ± 26.05 (95% CI: -31.31 , -21.64), respectively.

Table 1 Halo and Glare Outcomes Obtained Preoperatively and Postoperatively at 4–6 Months After PODEYE Toric Intraocular Lens Implantation

	Preoperatively	4–6 Months Postoperatively
Halo Size		
Number of patients	109	116
Mean $\pm$ standard deviation	29.63 $\pm$ 22.52	16.27 $\pm$ 14.51
95% confidence interval	(25.36, 33.91)	(13.60, 18.94)
Median	29.00	13.00
Min, Max	0.00, 100.00	0.00, 67.00
Halo Intensity		
Number of patients	109	116
Mean $\pm$ standard deviation	42.47 $\pm$ 24.62	29.44 $\pm$ 24.51
95% confidence interval	(37.79, 47.14)	(24.93, 33.95)
Median	50.00	28.50
Min, Max	0.00, 100.00	0.00, 100.00
Glare Size		
Number of patients	109	116
Mean $\pm$ standard deviation	20.38 $\pm$ 19.49	11.46 $\pm$ 13.91
95% confidence interval	(16.68, 24.08)	(8.90, 14.02)
Median	15.00	6.50
Min, Max	0.00, 92.00	0.00, 79.00
Glare Intensity		
Number of patients	109	116
Mean $\pm$ standard deviation	33.17 $\pm$ 23.30	22.61 $\pm$ 19.36
95% confidence interval	(28.74, 37.59)	(19.05, 26.17)
Median	35.00	20.00
Min, Max	0.00, 84.00	0.00, 64.00

Discussion

It is well known that toric IOLs were developed to enhance the reduced visual acuity caused by cataracts and to correct pre-existing corneal astigmatism during the same surgical procedure. Previous literature concerning the clinical outcomes of the PODEYE toric IOL supports the use of this lens for this purpose.^{5–11} With regard to binocular visual acuity outcomes, our findings agree with these studies, thus showing that this lens offers good visual performance. Specifically, since this has not been evaluated and reported previously, we focused on the photic phenomena that patients implanted with this IOL model may report post-surgery. To that end, we used a visual simulator and a validated patient-reported outcomes questionnaire.

Table 2 Quality of Vision (QoV) Questionnaire Outcomes Obtained Preoperatively and Postoperatively at 4–6 Months After PODEYE Toric Intraocular Lens Implantation

	Preoperatively	4–6 Months Postoperatively	Change from Preoperatively
Frequency			
Number of patients	115	115	
Mean $\pm$ standard deviation	46.14 $\pm$ 18.61	19.66 $\pm$ 18.35	–26.19 $\pm$ 24.65
95% confidence interval	(42.70, 49.58)	(16.27, 23.05)	(–30.77, –21.62)
Median	45.00	15.00	–26.50
Min, Max	0.00, 93.00	0.00, 67.00	–80.00, 46.00
Severity			
Number of patients	115	115	
Mean $\pm$ standard deviation	38.95 $\pm$ 17.02	15.83 $\pm$ 16.47	–22.82 $\pm$ 21.32
95% confidence interval	(35.80, 42.09)	(12.78, 18.87)	(–26.78, –18.87)
Median	39.00	13.00	–22.00
Min, Max	0.00, 100.00	0.00, 59.00	–73.00, 46.00
Bothersomeness			
Number of patients	115	115	
Mean $\pm$ standard deviation	41.10 $\pm$ 21.20	14.29 $\pm$ 16.92	–26.47 $\pm$ 26.05
95% confidence interval	(37.18, 45.01)	(11.16, 17.41)	(–31.31, –21.64)
Median	42.00	0.00	–28.00
Min, Max	0.00, 100.00	0.00, 71.00	–86.00, 57.00

Halo and glare outcomes are shown in Table 1 indicating size and intensity pre- and post-surgery (4–6 months). The size and intensity of both visual phenomena decreased after PODEYE toric IOL implantation. Other studies using the same visual simulator but analysing different cohorts have been published.^{15,16} For example, Kretz et al¹⁵ assessed 28 cataract patients (56 eyes) after trifocal toric AT LISA tri toric 939MP (Carl Zeiss Meditec, Jena, Germany) implantation at 3 months postoperatively. Their analysis with the halo and glare simulator revealed the presence of halos with a mean size of 50.67 ± 15.69 (median: 53; range: 31 to 75) and a mean intensity of 54.89 ± 17.86 (median: 62; range: 33 to 79). With regard to glare, the mean size and intensity were 39.67 ± 3.51 (median: 40; range: 0 to 49) and 44.67 ± 15.01 (median: 36; range: 14 to 68), respectively. The mean values reported for the two visual phenomena in terms of both size and intensity were higher than those reported in our study. It should be considered, however, that the diffractive profile of the trifocal toric lens may play a significant role in comparison to the monofocal aspheric surface of the PODEYE toric. The optical principle of diffractive surfaces means that the light is distributed between different foci, thereby creating a superimposition of the retinal images. This creates the perception of halos reported by patients. Glare, in turn, can arise due to scattering of the light from the diffractive steps. Savini et al¹⁶ investigated the clinical performance of an enhanced depth-of-focus (EDOF) IOL in comparison with a diffractive bifocal IOL. These authors studied 20 patients implanted with the Mini Well IOL (Sifi, Catania, Italy) and 37 patients implanted with the AcrySof ReSTOR SV25T IOL (Alcon Labs, Fort Worth, TX, USA) at 4–8 weeks post-surgery and found that halos had a mean size of 34.8 ± 22.08 and a mean intensity of 38.50 ± 16.47 with the Mini Well IOL. In contrast, the mean halo size and intensity were significantly higher with the diffractive bifocal AcrySof ReSTOR IOL (53.57 ± 23.67 ($P = 0.0439$) and 54.76 ± 20.53 ($P = 0.0222$),

respectively). These values are in agreement with those reported previously by Kretz et al¹⁵ with the trifocal diffractive toric IOL. In contrast, when glare was evaluated by Savini et al¹⁶ no statistically significant differences were reported for glare size (4.40 ± 8.69 for the Mini Well IOL and 8.52 ± 14.54 for the AcrySof ReSTOR IOL) or intensity (15.70 ± 26.33 for the Mini Well IOL and 13.81 ± 23.70 for the AcrySof ReSTOR IOL).

The outcomes of the QoV questionnaire are shown in Table 2. This table shows different improvements in quality of vision for the three categories evaluated (frequency, severity and bothersomeness). Al-Shymali et al¹⁷ assessed patient dissatisfaction outcomes using the QoV questionnaire in 15 dissatisfied patients following multifocal IOL implantation by IOL exchange with another multifocal IOL using another optical profile. Postoperatively, the mean Rasch score values for frequency, severity and bothersomeness were 35.87 ± 29.40 , 34.20 ± 32.26 , and 32.33 ± 35.97 , respectively. In another study, Al-Shymali et al¹⁸ also assessed patient dissatisfaction outcomes using the same questionnaire in 16 patients following multifocal IOL implantation, in this case by IOL exchange with a monofocal IOL. Postoperatively, the mean Rasch score values for frequency, severity and bothersomeness were 34.46 ± 16.33 , 28.46 ± 14.09 , and 28.85 ± 16.22 , respectively, when the multifocal IOL was exchanged with a monofocal IOL. These authors found no statistically significant difference in quality of vision after the exchange between both types of groups (multifocal and monofocal IOLs).¹⁹ The corresponding values in our study were lower than those reported by these authors (about 20 for frequency, and about 15 for severity and bothersomeness; see Table 2), thereby highlighting the good quality of vision obtained in our cohort of patients. Note that photic phenomena increase after trifocal IOL implantation. A review of multifocal versus monofocal IOLs found that photic phenomena are 3.5-times more likely to occur with the former than with the latter.²⁰ This study finds that multifocal IOLs improve near vision compared to monofocal IOLs, despite uncertainty about the exact size of the benefit. Whether these gains justify side effects like glare and halos remain a matter of individual patient experience.

PCO is a postoperative complication that can directly contribute to asymmetric contraction of the capsular bag, thereby leading to rotational instability of toric IOLs.²¹ Therefore, in addition to the reduction in quality of vision, PCO should also be taken into account, specifically in toric IOLs, in order to avoid any rotation that may reduce visual performance. It is well known that there is a difference in PCO rate between hydrophobic and hydrophilic lenses. A meta-analysis of randomized controlled trials reported lower PCO rates for hydrophobic versus hydrophilic IOLs at one and two years of follow-up, as well as significantly lower rates of Nd:YAG capsulotomy.²² A prospective multicentre (16 sites in USA) study analysing 342 patients implanted with the Clareon hydrophobic IOL (SY60CL, Alcon Labs, Fort Worth, TX, USA) reported a PCO rate of 5.4% at one-year post-surgery.²³ Our study showed a comparable performance at the same post-operative follow-up period (4.8%).

We need to consider that our study has several limitations. First, neither additional patient-reported outcome questionnaires nor other IOL groups were included to evaluate potential differences. Second, given the short follow-up period of our study, longer-term data are needed to validate these initial results. And third, other factors such as the size of capsulorhexis, size of the pupil, type of cataract and the multicenter study may affect and should be considered. Future studies should further explore, with a larger sample, how these perceptions evolve over time across a broader range of questionnaires and IOL models.

Conclusions

The results of this study suggest that bilateral PODEYE toric IOL implantation provides high-quality vision in patients with pre-existing corneal astigmatism undergoing cataract surgery. Although photic phenomena are a known side-effect of IOLs, the halo and glare induced by the PODEYE toric IOL are lower than those induced by cataracts, thereby leading to a subjective reduction in visual disturbances after surgery.

Data Sharing Statement

Data of this trial are not available for sharing.

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