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ORIGINAL RESEARCH

Clinical Performance of an Omnidirectional Aberration-Free Trifocal Toric Intraocular Lens

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Purpose: To assess the refractive and visual outcomes at different distances following cataract surgery with implantation of an omnidirectional aberration-free diffractive trifocal toric intraocular lens (IOL).

Methods: A total of 24 patients who underwent bilateral implantation with the TrivaT-aAY IOL were analyzed at 3–4 months post-surgery. Refractive error, monocular and binocular uncorrected and corrected-distance visual acuity (UDVA, CDVA), uncorrected and corrected-distance intermediate visual acuity (UIVA, CDIVA) at 60 cm, uncorrected and corrected-distance near visual acuity (UNVA, CDNVA) at 40 cm, monocular and binocular defocus curve and rotational stability were measured. Patients also completed the Catquest-9SF questionnaire at the last postoperative visit.

Results: The postoperative mean values of binocular logMAR CDVA, CDIVA and CDNVA were −0.06±0.06, 0.05±0.07 and 0.07 ±0.08, respectively. One hundred percent of patients showed a cumulative binocular CDVA ≥20/25, and 95.83% of patients showed a cumulative binocular CDIVA and CDNVA ≥20/32. The mean postoperative spherical equivalent was 0.07±0.26D and 100% and 97.92% eyes were within ±1.00D and ±0.50D, respectively. The mean postoperative refractive cylinder was −0.22±0.29D and 100% and 89.58% eyes showed a value ≤1.00D and ≤0.50D, respectively. The defocus curves showed a wide range of useful vision, with visual acuity values >0.2 logMAR. Mean absolute IOL rotation was 2.19±2.17 degrees and all eyes had a rotation <10 degrees. For the questionnaire, 95.83% of patients reported being quite satisfied to very satisfied with their vision and about 79.17% did not report any difficulty with their vision in their everyday life. Between 83.33% and 95.83% of patients reported no difficulty performing different tasks. No intra- and postoperative complications were reported during the follow-up.

Conclusion: Our study shows that the TrivaT-aAY IOL provides good visual acuities at all distances and refractive outcomes with excellent rotational stability and with high satisfaction among our patients after its implantation.

Keywords: astigmatism, toric, diffractive, trifocal, intraocular lens, cataract

Introduction

One recent advance in cataract and refractive intraocular surgery for presbyopic correction has been the development of trifocal intraocular lenses (IOLs). These lenses have been designed in order to provide the patients with optimal visual acuity at different distances, from far to near. Various publications have compared the outcomes after implantation of bifocal or trifocal IOLs and concluded that patients implanted with trifocal IOLs may achieve better intermediate vision than those implanted with bifocal IOLs, while near and far vision, postoperative refraction or spectacle independence of bifocal IOLs are similar to those of trifocal ones.[1–3]

In addition, it has been published in a multivariate regression analysis considering a large population (17,152 eyes) that low quantities of residual astigmatism can degrade the postoperative visual acuity and, therefore, corneal astigmatism ≥0.50D should be considered in the surgical plan.[4] In a simulated-study by adding different cylindrical lenses (up to 1.50D) in patients implanted with trifocal IOLs, authors concluded that useful visual acuity was achieved when the astigmatism was ≤0.75D, suggesting that this correction is necessary when astigmatism is more than 0.75D.[5] A recent review summarized the visual and refractive outcomes of patients implanted with trifocal toric IOLs.[6] The authors of this review, after encompassing 1404 eyes with three commercially available trifocal toric IOLs in the market, concluded that

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the use of trifocal toric IOLs allows a complete visual restoration over a wide range of distances. We found that the efficacy in refractive correction and visual acuity at different distances, and the patients' quality of vision/satisfaction levels, and photic phenomena were similar between the different IOL models used. Then, it is expected that trifocal toric IOLs may provide full spectacle independence to our patients and should be considered when patients are looking for a presbyopic with astigmatism correction solution.

In this sense, a new omnidirectional aberration-free diffractive trifocal toric IOL named TrivaT-aAY (HumanOptics Holding AG, Erlangen, Germany) has been launched to the market. This lens shows an omnidirectional aberration-free optic design, with the posterior toric surface designed in such a way that both principal astigmatic meridians and every meridian in between are aberration-free. It also shows an achromatics central diffractive element to increase extended focus range and reduces halos and glare. It is expected that this design provides excellent visual acuity at different distances and good rotational stability ensuring accurate astigmatism correction with maximum image quality. Then, the purpose of the current clinical study was to evaluate the postoperative refractive outcomes and visual acuity at different distances in cataract patients with corneal astigmatism implanted with this lens. Defocus curves, rotational stability and patient's satisfaction and quality-of-life questionnaire were also assessed.

Methods

Patients

This was a two-center (Oftalvist Valencia and Oftalvist Alicante) prospective interventional study approved by the Ethics Committee of the Hospital Clínico San Carlos (Madrid, Spain, 22/387-O_P) and was conducted in accordance with the tenets of the Declaration of Helsinki with all Patients providing written informed consent before they were enrolled in the study.

The inclusion criteria considered patients aged between 50 and 90 years submitted to bilateral cataract surgery and implanted with the TrivaT-aAY IOL (HumanOptics Holding AG) according to regular clinical practice (in at least one eye), availability, willingness, and sufficient cognitive awareness to comply with examination procedures, preoperative corneal astigmatism ≥1.00D and clear intraocular media other than cataract. In cases when a toric lens was not considered, the counterpart model non-toric version of the lens (Triva-aAY) was implanted. The exclusion criteria considered those patients unable to comprehend the study requirements, irregular cornea (ie keratoconus, previous corneal refractive surgery, ocular anomalies or pathologies that could reduce visual function or postoperative IOL stability (ie severe amblyopia, macular degeneration), uncontrolled glaucoma, retinal detachment, macular degeneration or retinopathy and non-reactive pupils.

Toric Trifocal Intraocular Lens

The TrivaT-aAY IOL model (HumanOptics Holding AG) was used in this study. This is a C-loop, one-piece, foldable, trifocal toric diffractive posterior chamber IOL that presents a 6.0 mm optical diameter and a 12.5 mm total diameter. The optical features show a 3.5 mm central diffractive anterior surface with a refractive optic periphery, toric, aspheric posterior surface with is designed to be aberration-free in an omnidirectional manner. The posterior toric surface of the optic independently corrects astigmatism and is equipped with a 360° lens epithelial cell barrier. Toric markings on the IOL indicate the axis of the plus-cylinder. It shows an intermediate addition of +1.75D and a near addition of +3.50D (at IOL plane). The lens is built in spherical powers ranging from +10.00 to +30.00D in 0.50D steps and cylindrical powers from +1.00 to +6.0D in 0.50D steps. The injector system/cartridge used are the Medicel AccuJect 2.0/2.2–1P LP 604510/604530. It is made from hydrophilic acrylic with a UV-absorber, with a water content of 26% at 35°C, and contains a blue light filter that absorbs the high-energy portion of the light between 400 and 500 nm. Its Abbe number is 56. This IOL was granted CE-mark approval for use in March 2021.

Pre- and Postoperative Examinations

All patients received a complete eye examination before and after the cataract surgery. The following measurements were made before surgery: slit-lamp examination, measurement of logMAR uncorrected and corrected-distance visual acuity (UDVA and CDVA), monocular manifest refraction, intraocular pressure (IOP) measurement, funduscopy, corneal

topography with the Pentacam (Oculus Optikgeräte GmbH, Germany) and biometry with the IOLMaster 700 (Carl Zeiss Meditec AG, Jena, Germany). The Barrett, Kane, and Hoffer Q formulae were used to calculate the IOL power. The target refraction in all cases was emmetropia.

Follow-up visits were carried out at 1 day, 1-week, 1- and 3-4-months post-surgery. This study shows the outcomes found at the last postoperative visit, which included the following examinations: refraction, IOP, slit-lamp biomicroscopy, monocular and binocular logMAR UDVA, CDVA, uncorrected distance intermediate visual acuity (UIVA), corrected distance intermediate visual acuity (CDIVA) at 60 cm, uncorrected distance near visual acuity (UNVA) and corrected distance near visual acuity (CDNVA) at 40 cm. Monocular and binocular defocus curves were measured for each patient using the ETDRS chart positioned at 4 m, under photopic conditions, from +1.00 to –4.00D in 0.50D steps. Patients were asked to complete the Catquest-9SF questionnaire,[7] which has been validated in a Spanish population for trifocal IOLs.[8] An astigmatism vector analysis was also performed with the double-angle tool.[9] Rotational stability was assessed at each of the postoperative visits. All data are shown as the mean ± standard deviation (SD) and ranges. Complications and adverse events were also recorded during the study.

Statistical Analysis and Sample Size

The statistical analysis was carried out using SPSS software (22.0 version, IBM Corp., Armonk, New York, USA). All values are presented as the mean ± SD, and ranges. The sample size estimated for this "pilot" study was calculated according to Sullivan,[10] using the highest standard deviation of the monocular visual acuity defocus curve derived from a previous sample of 16 eyes implanted with the Triva-aA lens. With a standard deviation of 0.24 logMAR at +2.00D defocus, a confidence interval of 95% and a maximum tolerated margin of error of 0.10 logMAR; a minimum of 22 patients was required [$N= [(1.96 \times 0.24)/0.1]^2=22$].

Results

Forty-eight eyes from 24 consecutive patients were analyzed for the current study. Table 1 shows the demographics for the patients included in the study and some preoperative measurements obtained. The mean age was 70.29±5.62 years, ranging from 60 to 81 years, with 16 patients being female (66.67%). There were no complications in any of the cases during surgery and follow-ups.

Refractive and visual acuity outcomes at different distances measured at the last postoperative visit are shown in different standard graphs for this purpose.[11] Figure 1 is plotted to assess the efficacy of the procedure, showing the

Table 1 Demographic Characteristics and Preoperative Measurements of Participants Shown as Means, Standard Deviations (SD) and Ranges

	Values
Patients (n)	24
Sex (male/female)	8/16
Age (y)	70.29±5.62 (60 to 81)
Sphere (D)	1.03±2.04 (−3.25 to 5.50)
Refractive Cylinder (D)	−1.07±0.68 (0 to −2.50)
Spherical Equivalent (D)	0.49±2.06 (−3.50 to 4.50)
CDVA (logMAR)	0.11±0.12 (0 to 0.50)
IOP (mmHg)	16.69±2.22 (10 to 25)
K1 (D)	43.40±1.17 (41.51 to 46.16)
K2 (D)	44.55±1.25 (42.30 to 47.50)
Axial length (mm)	23.13±0.93 (21.25 to 25.15)
ACD (mm)	3.02±0.38 (2.26 to 3.77)
IOL spherical power (D)	22.35±3.14 (15.00 to 29.50)
IOL toric power (D)	1.52±0.59 (1.00 to 3.50)

Abbreviations: CDVA, corrected distance visual acuity; IOP, intraocular pressure; K, keratometry; ACD, anterior chamber depth; IOL, intraocular lens power.

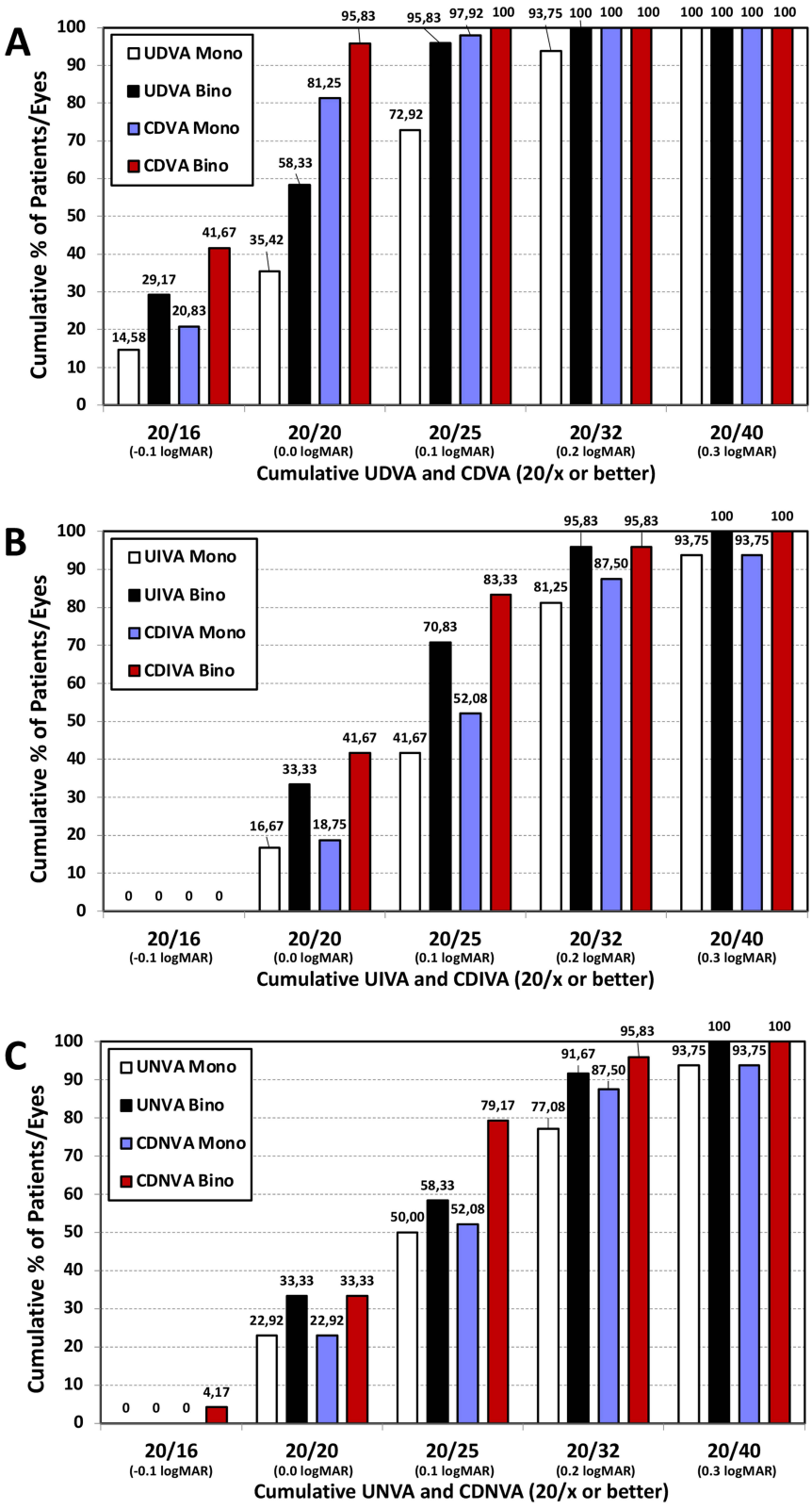

Figure 1 (**A**) cumulative proportion of patients/eyes having a given photopic monocular and binocular uncorrected distance visual acuity (UDVA) and best-corrected distance visual acuity (CDVA). (**B**) cumulative proportion of patients/eyes having a given photopic monocular binocular uncorrected distance intermediate visual acuity (UIVA) and corrected distance intermediate visual acuity (CDIVA). (**C**) cumulative proportion of patients/eyes having a given photopic monocular binocular uncorrected distance near visual acuity (UNVA) and corrected distance near visual acuity (CDNVA). All the outcomes were depicted for the values obtained at the last postoperative visit (3–4 months).

Table 2 Visual Acuity Outcomes (logMAR) of Patients Implanted with the TrivaT-aAY Intraocular Lens Shown as Means, Standard Deviations (SD) and Ranges at 3–4 Months of Follow-Up

	Monocular	Binocular
UDVA	0.06±0.09 (−0.10 to 0.28)	−0.01±0.08 (−0.14 to 0.14)
CDVA	−0.01±0.06 (−0.10 to 0.14)	−0.06±0.06 (−0.16 to 0.06)
UIVA (60 cm)	0.13±0.11 (−0.06 to 0.38)	0.07±0.08 (−0.06 to 0.26)
CDIVA (60 cm)	0.11±0.10 (−0.06 to 0.38)	0.05±0.07 (−0.06 to 0.26)
UNVA (40 cm)	0.13±0.11 (−0.02 to 0.38)	0.09±0.08 (−0.04 to 0.28)
CDNVA (40 cm)	0.11±0.09 (−0.02 to 0.38)	0.07±0.08 (−0.10 to 0.28)

Abbreviations: UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; UIVA, uncorrected distance intermediate visual acuity; CDIVA, corrected distance intermediate visual acuity; UNVA, uncorrected distance near visual acuity; CDNVA, corrected distance near visual acuity.

cumulative postoperative binocular logMAR UDVA and CDVA (A), UIVA and CDIVA (B), and UNVA and CDNVA (C), respectively. Specifically, Table 2 shows the detailed mean visual acuity outcomes for monocular and binocular conditions at distance, intermediate and near vision. At far vision (Figure 1A), 58.33% of patients showed a binocular UDVA of 20/20 or better compared to 95.83% for CDVA. These values increased to 95.83% and 100% for a cumulative value of 20/25 or better, respectively. The postoperative mean values for binocular UDVA and CDVA were −0.01±0.08 and −0.06±0.06 logMAR, respectively (about 20/20). At intermediate vision (60 cm, Figure 1B), 33.33% of patients showed a binocular UIVA of 20/20 or better compared to 41.67% for CDIVA. These percentages increased to 70.83% and 83.33% for a cumulative value of 20/25 or better, respectively. The postoperative mean values for binocular UIVA and CDIVA were 0.07±0.08 and 0.05±0.07 logMAR, respectively. At near vision (Figure 1C), 33.3% of patients showed a binocular UNVA of 20/20 or better and the same percentage for CDIVA. These values increased to 58.33% and 79.17% for a cumulative value of 20/25 or better, respectively. The postoperative mean values for binocular UNVA and CDNVA were 0.09±0.08 and 0.07±0.08 logMAR, respectively. Figure 2 shows the change in lines of visual acuity between the postoperative monocular and binocular UDVA and CDVA at 3–4 months post-surgery. All eyes and patients showed the same or better postoperative UDVA than the postoperative CDVA.

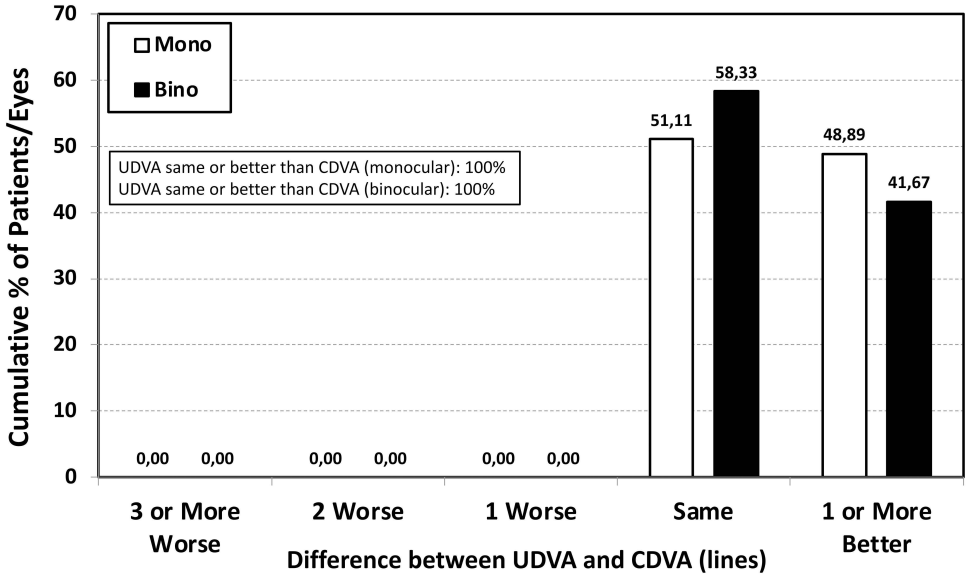

Figure 2 Change in lines of visual acuity between the photopic monocular and binocular postoperative uncorrected distance visual acuity (UDVA) and best-corrected distance visual acuity (CDVA) at 3–4 months after the surgery.

In order to assess the predictability of the surgery, Figure 3A shows the distribution of postoperative spherical equivalent refraction relative to the intended target refraction. The highest percentage of eyes (54.17%) was for the range ±0.13D, followed by 27.08% for the +0.50 to +0.14D range. All eyes were within ±1.00D and 97.92% of eyes within ±0.50D. The mean postoperative spherical equivalent refraction value was 0.07±0.26D (ranging from −0.38 to 0.75D). Figure 3B shows the distribution of the postoperative refractive cylinder. Specifically, 89.58% of eyes showed a value ≤0.50D and all eyes a value ≤1.00D. The mean postoperative refractive cylinder was −0.22±0.29D, ranging from 0.00 to –1.00D. The double-angle plots of preoperative corneal astigmatism and postoperative refractive astigmatism at 3–4 months given in Figure 4 evidence a mean absolute preoperative corneal astigmatism of 1.15±0.45D and a mean absolute postoperative refractive astigmatism of 0.22 ±0.29D. The centroid decreased from 0.10±1.24D at 2 degrees to 0.01±0.37D at 163 degrees following cataract surgery at the last postoperative visit. At 3–4 months post-surgery, the TrivaT-aAY IOL had a mean absolute rotational stability of 2.19±2.17 degrees (range: 0 to 6 degrees). Note that no significant rotation was reported in any of the eyes during follow-up, as all eyes had a rotation of <10 degrees.

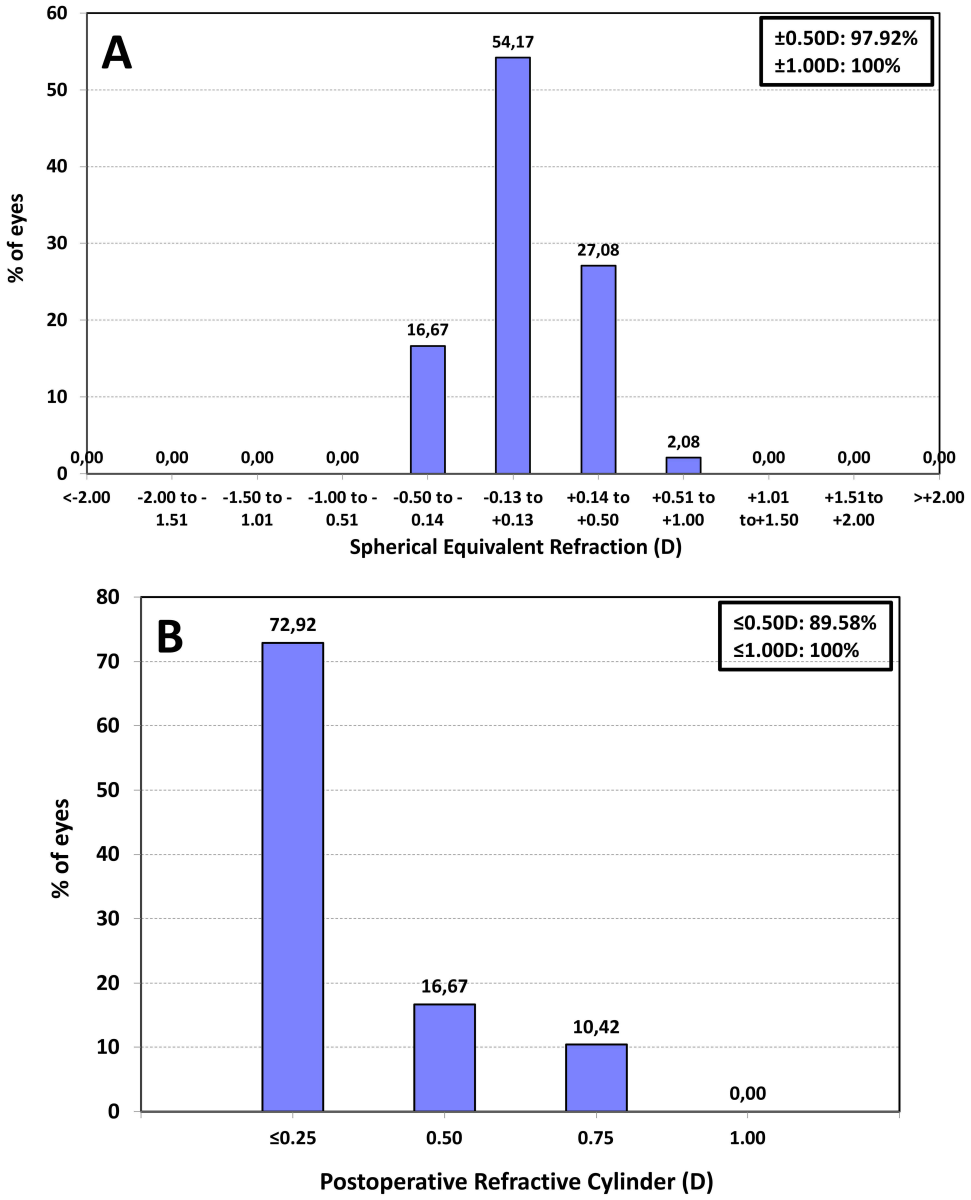

Figure 3 (**A**) Histogram of the postoperative spherical equivalent refraction (D), and (**B**) refractive cylinder (D), at 3–4 months after the surgery.

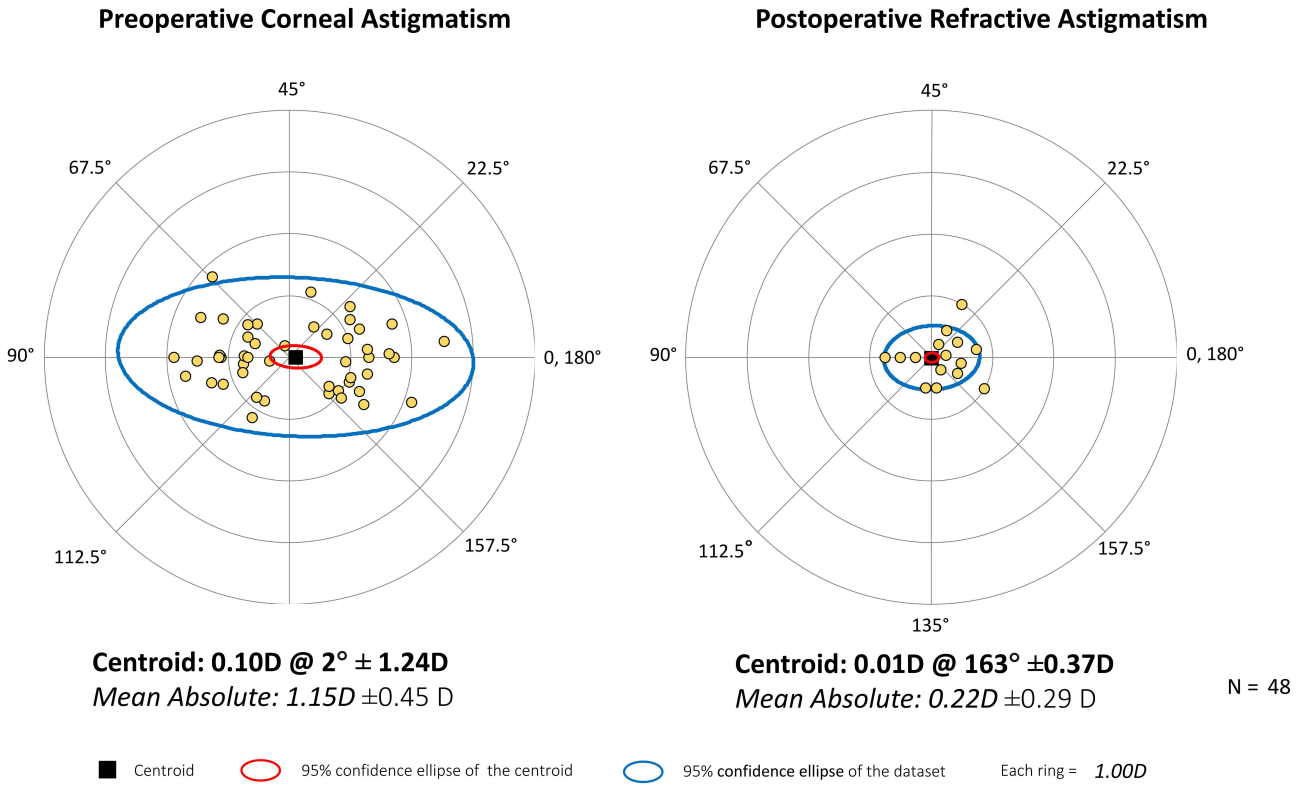

Figure 4 Double-angle plots of preoperative corneal astigmatism and postoperative refractive astigmatism at 3-4-months after the surgery. Centroids, mean absolute values with standard deviations, and 95% confidence ellipses of the centroid and dataset are also shown.

Figure 5 shows the mean high-contrast photopic monocular and binocular defocus curves. In both situations, there is a peak in visual acuity for distance vision (vergence of 0D), followed by a steady reduction as the negative vergence increases in magnitude (intermediate and near vision). The depth-of-focus was defined as the range of lens powers that

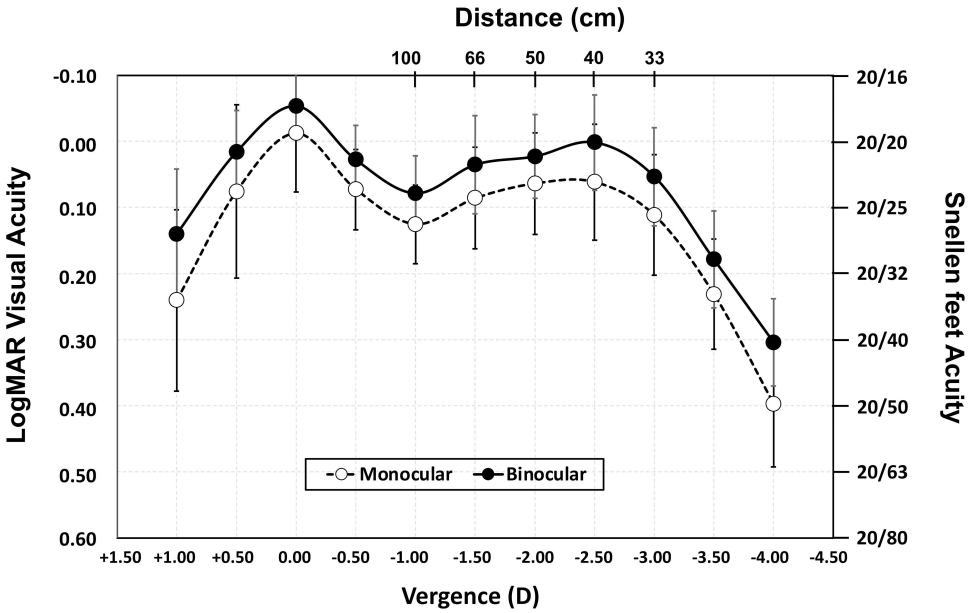

Figure 5 Mean, high-contrast, photopic, monocular and binocular logMAR visual acuities with best correction for distance, as a function of chart vergence at 3–4 months after the surgery. Error bars represent the standard deviation. The right Y-axis shows the Snellen feet acuity and the upper X-axis shows distance values (cm).

Table 3 Outcomes of Patient Reported Difficulties with Their Vision Assessed Using the Catquest-9SF Questionnaire. Response Coding: R1 [Yes, Very Great Difficulty; Very Unsatisfied (for Question 2)], R2 [Yes, Great Difficulty; Quite Unsatisfied (for Question 2)], R3 [Yes, Some Difficulty; Quite Satisfied (for Question 2)], R4 [No, No Difficulty; Very Satisfied (for Question 2)], R5 (Cannot Decide). SD: Standard Deviation

	Mean±SD	Response Frequencies (%)				
		R1	R2	R3	R4	R5
Do you find that your sight at present in some way causes you difficulty in your everyday life?	3.79±0.41	0.00	0.00	20.83	79.17	0.00
Are you satisfied or dissatisfied with your present vision?	3.67±0.56	0.00	4.17	25.00	70.83	0.00
Do you have difficulty…						
…Reading text in newspapers?	3.79±0.59	0.00	8.33	4.17	87.50	0.00
…Recognizing the faces of people you meet?	3.92±0.28	0.00	0.00	8.33	91.67	0.00
…Seeing the prices of goods when shopping?	3.92±0.28	0.00	0.00	8.33	91.67	0.00
…Seeing to walk on uneven surfaces?	3.96±0.20	0.00	0.00	4.17	95.83	0.00
…Seeing to do handicrafts, woodwork etc.?	3.83±0.38	0.00	0.00	16.67	83.33	0.00
…Reading subtitles on TV?	3.96±0.20	0.00	0.00	4.17	95.83	0.00
…Seeing to engage in an activity/hobby?	3.96±0.20	0.00	0.00	4.17	95.83	0.00

achieved a mean acuity of 20/32 or better (from 0D of vergence), and for our results it spanned about 3.50 D. The graphs show clearly better visual outcomes for binocular conditions.

Patients were also asked to complete the Catquest-9SF questionnaire at the last postoperative visit. Table 3 summarizes the patient-reported limitations in certain activities of daily living and satisfaction with the present vision. Mean score for the first question was 3.79±0.41 with 79.17% of patients not reporting any difficulty with their vision in their everyday life. Note that almost all patients (95.83%) reported being quite satisfied to very satisfied with their present vision. In relation to difficulties carrying out different specific tasks defined in Table 3, in general between 83.33% and 95.83% of patients reported no difficulty performing these tasks. Mean values ± SD for each task are shown in this table.

Discussion

As we have previously introduced, a review paper has been published summarizing the outcomes in terms of visual acuity at different distances and refraction accuracy of patients implanted with trifocal toric IOLs.[6] This study specifically focus on the outcomes reported for the AT LISA tri toric 939MP IOL (Carl Zeiss Meditec, involving 3 articles and 313 eyes), the FineVision toric POD FT IOL (BVI, with 7 articles studying 370 eyes) and the AcrySof IQ PanOptix toric IOL (Alcon Labs, involving 11 articles and 721 eyes). In general, the outcomes revealed that the use of trifocal toric IOLs allows a full visual restoration over a wide range of distances. To date, no clinical studies have been performed using the diffractive trifocal toric TrivaT-aAY IOL, then, we cannot compare our findings with previous outcomes; however, we can compare them with published literature on the other models indicated. Therefore, our purpose was to analyze the outcomes in terms of visual acuity at different distances, refraction, rotational stability and patient-reported satisfaction and quality-of-life questionnaire when this lens was implanted after cataract surgery, and, when possible, to compare with other models' outcomes at the same follow-up.

Our results revealed good monocular and binocular visual acuity outcomes at far, intermediate and near vision distances. The mean values, SD and ranges are shown in Table 2. At distance, 58.33% of patients showed a binocular UDVA ≥20/20 compared to 95.83% for CDVA (see Figure 1A). These percentages increased to 95.83% and 100% for a cumulative value of ≥20/25, respectively. The mean values for binocular UDVA and CDVA were −0.01±0.08 and −0.06 ±0.06 logMAR, respectively. Our results are in agreement with those of other authors using other lenses. For example,

outcomes for the AT LISA tri toric 939MP IOL at 3 months of follow-up were reported by Kretz et al[12] (56 eyes) and Paredes et al[13] (337 eyes) who found mean values for binocular CDVA of −0.04 and 0.00 logMAR, respectively. Similarly, for the FineVision toric POD FT IOL Poyales and Garzón[14] (29 eyes) found a mean value of −0.03 logMAR and for the AcrySof IQ PanOptix toric IOL Kohnen et al[15] (50 eyes) a mean value −0.11 logMAR, both binocularly and at the same follow-up. In relation to the safety of the procedure, all eyes and patients showed the same or better postoperative UDVA than the postoperative CDVA (Figure 2). At intermediate vision, 33.33% of patients showed a binocular UIVA ≥20/20 compared to 41.67% for CDIVA as shown in Figure 1B). As expected, these percentages were higher for a cumulative value of ≥20/25: 70.83% and 83.33%, respectively. Our mean values for binocular UIVA and CDIVA were 0.07±0.08 and 0.05±0.07 logMAR, respectively. Kohnen et al[15] found a mean binocular CDIVA of 0.11 logMAR at the same intermediate distance (60 cm). At near vision (see Figure 1C), 33.33% of patients showed binocular UNVA and CDNVA ≥20/20. These percentages increased to 58.33% and 79.17% for a cumulative value ≥20/25, respectively. In our series, the mean values for binocular UNVA and CDNVA were 0.09±0.08 and 0.07±0.08 logMAR, respectively. Kretz et al.[12] Poyales and Garzón[14] and Kohnen et al[15] found a mean value of binocular CDNVA of −0.03 logMAR, 0.11 logMAR and 0.00 logMAR for the AT LISA tri toric 939MP IOL, FineVision toric POD FT IOL and the AcrySof IQ PanOptix toric IOL, respectively.

If we focus now on the predictability outcomes shown in Figure 3, we may observe the good outcomes obtained with a mean postoperative SE and refractive cylinder of 0.07±0.26D and −0.22±0.29D, respectively. Mojzis et al[16] reported mean values of −0.50±3.30D and −0.35±0.27D and Paredes et al[12] of −0.01±0.08D and −0.03±0.14D for the SE and cylinder, respectively, with the AT LISA tri toric 939MP IOL. Poyales and Garzón[14] found mean values of −0.18±0.27D and −0.19±0.36D, for the FineVision toric POD FT IOL and Kohnen et al[15] of 0.12±0.38D and −0.21±0.23D, for the AcrySof IQ PanOptix toric IOL, respectively. Mojzis et al,[16] Poyales and Garzón[14] and Kohnen et al[15] found 83.3%, 93% and 88% of eyes with an SE within ±0.50D, respectively. These values changed to 80%, 86% and 96% for a refractive astigmatism ≤0.50D, respectively. Our results revealed also showed good outcomes with 100% of eyes within ±1.00D and 97.92% within ±0.50D, and specifically for astigmatism, 89.58% of eyes showed a value ≤0.50D and 100% eyes a value ≤1.00D. The correction of astigmatism after the surgery may be also observed in Figure 4 with the double angle plot. This figure shows how the dots are concentrated around the (0,0) value, which represent an eye free of astigmatism. This specifically supports the accuracy of the procedure for the correction of the corneal astigmatism shown in our cohort.

Our results also revealed an excellent rotational stability of the lens after the surgery with a mean value of 2.19±2.17 degrees with all eyes with a rotation of <10 degrees. The mean values obtained by different authors at the same follow-up were: 5.80±8.47 degrees[16] (mean angle of error using the Alpins method) and <1 degrees[17] for the AT LISA tri toric 939MP IOL, 1.89±3.31 degrees[18] for the Finevision Toric POD FT IOL, 1.59±2.15 degrees[18] and 2.0±2.7 degrees[19] for the AcrySof IQ PanOptix toric IOL. Kohnen et al[15] found that 98% of eyes rotated <5 degrees when the AcrySof IQ PanOptix toric IOL was implanted.

At the visual acuity threshold of 0.20 logMAR (20/32), the binocular depth-of-focus obtained was about 3.50D (see Figure 5). For monocular condition, this value was slightly lower. The best visual acuity was found at distance vision (0D of vergence) followed by a steady reduction as the negative vergence increases in magnitude (intermediate and near vision). Note that between 0D and –3.50D of vergence, the curve showed a wide range of useful vision that may be considered suitable to obtain a high level of spectacle independence. This correlates with the visual acuities obtained at distance, intermediate and near vision (see Table 2). Ackerman et al[20] in a sample of 254 patients implanted with the AcrySof IQ PanOptix toric IOL at 3 months of follow-up reported that this lens achieved good visual acuity across all distance with mean visual acuity greater than 0.1 logMAR for defocus levels between −2.50D and +1.00D with the exception of −1.00D and −0.50D steps.

The results of the Catquest-9SF questionnaire showed that 95.83% of patients reported being quite satisfied to very satisfied with their vision after surgery. Our results agree with those found by Rementeria-Capelo et al[21] also used the Catquest 9SF questionnaire and obtained at 3 months after the AcrySof IQ PanOptix toric IOL implantation mean values >3 for the first two questions of the test related to the difficulties in patients' everyday life and satisfaction with their sight at present. The outcomes for difficulties in daily activities were also > about 3.5. Our mean values (see Table 3) were

always >3.7. Kohnen et al[15] used another test (NEI VFQ-25) and found mean values of 1.97, 1.92, 2.02, and 2.12 for all daily, far, intermediate, and near distance activities, respectively. They also found that of the 25 patients of their sample, 76% reported halos, 52% glare, 16% starbursts, 8% ghosting, and 8% distorted vision. Ackerman et al[20] included a quality of vision questionnaire at the 3 months follow-up and indicated that the most frequent and severe phenomena were starbursts, halos and glare. They indicated that the impact of the phenomena on daily activities is of equal importance however and the responses indicated only glare was described to be "quite a bit" bothersome (2 patients). Mohaseb et al,[19] using the same lens, obtained that 81% of patients reported needing spectacles rarely or never postoperatively, whereas 96%, 94%, and 79% at distance, intermediate, and near, respectively, reported needing spectacles rarely or never postoperatively. Also, they found that 24% of patients experienced glare, halos, or starbursts. Even though this percentage of patients reported dysphotopsias, the vast majority did not find them troubling because 91% were satisfied or very satisfied with their vision. We did not ask our patients about dysphotopsia phenomena but according to the high levels of satisfaction and the fact that no difficulties were found in our cohort, it seems that if dysphotopsia had occurred, there were no disturbances.

In a recent study published by our group[22] with the diffractive trifocal non-toric Triva-aXAY IOL in 23 patients at 6 months post-surgery, we also found good visual acuities at different distances (100%, 86.96% and 95.65% of patients with binocular CDVA, CDIVA and CDNVA ≥20/25, respectively) and excellent refractive accuracy (all eyes within ±1.00D, and 91.30% of eyes within ±0.50D, with a mean postoperative spherical equivalent of –0.14±0.29D). This study showed that 95.65% of patients reported being quite satisfied to very satisfied with their vision and about 74% did not report any difficulty with their vision in their everyday life. We concluded that the use of this lens with a 7 mm optic and plate cut-out haptics seemed to be an excellent option to be considered in patients aiming to be spectacle-independent at different distances.

Finally, we want to consider some limitations of our study, being for example the sample size of our series. Note that we have calculated it but is always desirable to increase the number of eyes/patients in a cohort in order to support the findings encountered. Also, we have not compared directly with another group implanted with other trifocal toric available in the market. Notwithstanding, we have compared with previous clinical studies that reported outcomes with other models. Future studies should add more eye/patients, other models and longer follow-ups to fully analyze the performance of the lens.

Conclusion

In conclusion, our outcomes show that the diffractive trifocal toric TrivaT-aAY IOL implanted in astigmatic cataract eyes provides excellent visual performance at different distances, with good rotational stability and refractive outcomes. We have also obtained a high percentage of satisfied patients measured with the patient-reported outcomes questionnaire. Thus, our results demonstrate that its implantation was effective, predictable and safe, being a good surgical solution to those patients with cataracts and astigmatism aiming to be spectacle independent.

Data Sharing Statement

Data are not available for sharing.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

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