

# Visual and functional outcomes of a new diffractive trifocal intraocular lens with smooth micro phase technology in patients undergoing cataract surgery

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## Abstract

• **AIM:** To assess the refractive and functional outcomes of a novel trifocal intraocular lens (IOL) with smooth micro phase technology.

• **METHODS:** This prospective, single-arm, single-center, observational study included patients who underwent cataract surgery with the implantation of the AT ELANA 841P (Carl Zeiss Meditec, Berlin, Germany) IOL. Visual acuity (VA) at distance, intermediate, and near were evaluated 1- and 3-month postop as well as refractive outcomes. Monocular and binocular defocus curve, binocular contrast sensitivity (M&S® Technologies) and patient satisfaction with the Catquest-9SF questionnaire were measured at 3-month postop.

• **RESULTS:** In total, 46 eyes (23 patients) were bilaterally implanted with the IOL. Mean patient age was 59.86±5.55y. At 1-month postop, monocular corrected VA for distance, intermediate, and near were -0.15±0.09, 0.11±0.10, and 0.15±0.12 logMAR, respectively. These outcomes remained stable at the 3-month follow-up ( $P>0.05$ ). Spherical equivalent (SE) at 1- and 3-month postop remained stable ( $P>0.05$ ). Following surgery, 91% of the eyes at 1mo and 95% of the eyes at 3mo were within ±0.5 D of SE. Monocular defocus curve showed that the lens can be categorized as a steep transition IOL. The contrast sensitivity function revealed high values at low spatial frequencies and decreased values at high spatial frequencies. The results of the Catquest-9SF questionnaire showed that all patients were fairly or very satisfied with their vision after surgery.

• **CONCLUSION:** The AT ELANA 841P IOL offers excellent visual outcomes across distance, intermediate, and near ranges, along with satisfactory contrast sensitivity. Additionally, the lens is associated with high patient satisfaction and minimal visual difficulties during daily activities.

• **KEYWORDS:** cataract surgery; trifocal intraocular lens; Catquest-9SF questionnaire; contrast sensitivity

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## INTRODUCTION

Cataracts remain the primary cause of reversible blindness worldwide<sup>[1-4]</sup>. Cataract surgery, which involves replacing the eye's natural lens with an intraocular lens (IOL), is one of the most frequently performed procedures<sup>[5-7]</sup>. With the evolving demands of modern lifestyles, patients increasingly seek greater visual quality and independence from corrective eyewear across all distances: far, intermediate and near<sup>[8-10]</sup>. To address these expectations, trifocal IOLs were developed, incorporating three focal points to provide seamless vision at multiple distances. This optical performance is achieved through diffractive optics design<sup>[11-13]</sup>.

A recent advancement in this field is the development of the AT ELANA 841P (Carl Zeiss Meditec, Berlin, Germany), a next-generation multifocal IOL that integrates the single-piece C-loop platform of CT LUCIA 621P with the trifocal optic design of the AT LISA tri 839MP. This innovative lens features a diffractive optical structure composed of concentric central diffractive zones enhanced with smooth micro phase technology<sup>[14]</sup>. This design refinement reduces light scatter, effectively minimizing glare and halos.

The objective of this study was to assess the visual, refractive and functional outcomes associated with this novel trifocal IOL.

## PARTICIPANTS AND METHODS

**Ethical Approval** Before participating, all patients were given detailed information about the study's objectives and signed informed consent. The study was performed in accordance with the Declaration of Helsinki and received ethical approval through the IMO Barcelona research committee (approval code: ELANA2023).

**Study Design** This prospective, observational, single-arm study assessed patients undergoing bilateral cataract surgery with the implantation of the AT ELANA 841P IOL. The study ran from December 2023 and March 2024 at the Miranza Begitek clinic in San Sebastián, Spain.

**Participants** The study included patients 50y or older who had bilateral cataracts. Cataracts were at least level 1 of the Lens Opacities Classification System III classification. Inclusion criteria also included a healthy retina and the need for primary IOL implantation.

Patients were excluded if they had preoperative corneal astigmatism greater than 0.75 diopters (D), or other potential ophthalmologic conditions that could affect visual outcomes. Other exclusion criteria included pregnancy, systemic comorbidities, legal constraints, use of vision-impairing medications, or a history of ocular trauma.

**Clinical Protocol** Before surgery, a thorough ophthalmologic examination was performed. The baseline assessment included uncorrected and best-corrected distance visual acuity (UDVA, CDVA) at 6 m, uncorrected and best-corrected intermediate visual acuity (UIVA, CIVA) at 66 cm (+1.50 D) and uncorrected and best-corrected near visual acuity (UNVA, CNVA) at 40 cm (+2.50 D). Subjective refraction, anterior segment optical coherence tomography (MS-39<sup>®</sup>, CSO, Firenze, Italy), slit-lamp examination, intraocular pressure measurements using a Goldman applanation tonometer (CT-80; Topcon, Tokyo, Japan), macular and retinal nerve fiber layer assessments (DRI OCT Triton<sup>®</sup>, Topcon Corp, Tokyo, Japan) and dilated fundus examinations were among the additional tests performed to ensure that none of the exclusion criteria were fulfilled and that all inclusion criteria were satisfied.

Biometric analysis was performed with the IOLMaster 700<sup>®</sup> (Carl Zeiss Meditec, Berlin, Germany) and IOL power calculations were done with the Barret II Universal formula with the manufacturer's an A-constant of 119.5. The first negative IOL power was chosen to address emmetropia.

Postoperative follow-up was scheduled for one and three months after surgery. Every measurement was performed by a qualified optometrist. The 1-month postoperative review included assessments of monocular and binocular uncorrected and corrected visual acuities at three distances (far, intermediate, and near), as well as subjective refraction. For visual and refractive evaluations, only the right eye of each

patient was examined. The 3-month visit included the same assessments, as well as binocular defocus curve (ranging from +2.00 to -4.50 D), and binocular contrast sensitivity function (CSF) test under photopic conditions (85 cd/m<sup>2</sup>) using an M&S Technologies<sup>®</sup> device which measured logarithmically using spatial frequencies of 3, 6, 12, and 18 cycles per degree (cpd). The Catquest-9SF questionnaire was used to evaluate patient-reported outcomes. The nine items in this survey asked about general satisfaction with the visual output created as well as perceived challenges doing particular daily tasks.

**Surgical Procedure** All surgical operations were carried out under topical anesthetic by a single skilled surgeon (Mendicute J). As all patients had corneal astigmatism <0.75 D, a 2.2 mm near-clear corneal incision was done in the temporal area. There was no need for sutures since the wound healed itself. In surgical mydriasis, capsulorhexis was carried out with a 5 mm diameter, centered in relation to the pupil. The IOL was inserted into the capsular bag following phacoemulsification and posterior capsule polishing, guaranteeing that all viscoelastic material behind the lens had been removed. In every instance, the haptics were vertically oriented. Intracameral cefuroxime was given at the end of the surgery. After a safety check, the second eye was operated on between two days and one month after the first.

**Intraocular Lens** The ELANA IOL (AT ELANA 841P, Carl Zeiss Meditec, Berlin, Germany) is a single-piece IOL made from hydrophobic acrylic material, designed to be glistening free and equipped with a heparin-coated surface. This trifocal diffractive lens incorporates the optic concept of the AT LISA tri 839MP but is structured on a C-loop platform. It features a refined light distribution system aimed at optimizing intermediate (+1.25 D, 80 cm) and near vision (+2.50 D, 40 cm) without sacrificing distance clarity. Furthermore, its design enhances light transmission efficiency, contributing to superior contrast sensitivity under photopic conditions.

The smooth micro phase technology is used in this IOL, which introduces specialized phase zones into the optical surface. This engineering refinement aims to achieve a more precise, shallow-angled design that can reduce light scatter, thereby minimizing glare and halos.

Beyond optical performance, the ELANA IOL integrates a pupil-independent diffractive profile, a neutral aspheric surface to reduce the impact of decentration and tilt, and a refractive index of 1.49. Additionally, it employs lathe-cut manufacturing to create a 360° sharp-edge design with a radius exceeding 3 µm, in order to inhibit early lens epithelial cell migration and lower the risk of posterior capsule opacification. The lens has a diameter of 13 mm and an optic zone of 6 mm.

**Statistical Analysis** The data was gathered using a Microsoft Excel spreadsheet. Quantitative outcomes were reported as

mean, standard deviation (SD), and range (max and min). Qualitative outcomes were provided as a percentage of each category. SPSS software (version 22.0, SPSS Inc., Chicago, IL, USA) was used for statistical analysis. To ascertain statistical normality, the Shapiro-Wilk test was employed. When the quantitative variables were parametric, the Student's *t*-test was used; otherwise, the Wilcoxon test was used. Statistical significance was indicated by a *P*-value of <0.05.

## RESULTS

A total of 23 patients underwent bilateral implantation of the trifocal IOL, with a total of 46 lenses implanted. Of these patients, 16 (69.56%) were female. The mean patient age was  $59.86 \pm 5.55$  y (range: 50 to 68y). Table 1 presents the baseline characteristics. No intraoperative or postoperative complications were observed throughout the study period.

Twenty-three right eyes were assessed at the 1-month follow-up, and 21 right eyes were examined at the 3-month timepoint as two patients were unable to attend. Mean monocular CDVA, CIVA, and CNVA at 1-month after surgery were  $-0.15 \pm 0.09$ ,  $0.11 \pm 0.10$ , and  $0.15 \pm 0.12$  logMAR, respectively, remaining stable without statistical changes until 3mo postop. Table 2 provides the additional visual acuity (VA) findings.

Analysis of the postoperative cumulative distribution of VA revealed that at the 1-month follow-up, 96% of eyes (22 cases) had monocular UDVA and CDVA of 20/25 Snellen or better (Figure 1A). At 3-month following implantation, all eyes (100%) had reached this level (Figure 2A). A detailed breakdown of the cumulative distribution of VA at both time points is provided in Figures 1A and 2A. Regarding visual improvement, 61% of eyes (14 cases) experienced a gain of at least one line in both UDVA and CDVA at one month, while the remaining eyes maintained their initial VA (Figure 1B). At 3-month following surgery, VA remained stable, with no further significant changes observed in UDVA or CDVA (Figure 2B).

The predictability of spherical equivalent (SE) was also consistent, with 91% of eyes within  $\pm 0.50$  D and 100% within  $\pm 1.00$  D at 1mo, and 95% of eyes within  $\pm 0.50$  D at 3mo (Figures 1C, 2C). All eyes (100%) had a postoperative refractive cylinder  $\leq -0.50$  D at 1-month and 3-month (Figures 1D, 2D). At both timepoints, the stability of postoperative subjective refraction (sphere, cylinder, and SE) was comparable ( $P > 0.05$ ; Table 3).

Figure 3 presents the functional classification of the IOL. The monocular defocus curve demonstrated that visual acuity remained better than 0.20 logMAR across a defocus range from -3.00 D and +1.50 D, indicating that the IOL provides a full-range of field (RoF). Additionally, the minimal difference in VA between intermediate and near distances (0.02 logMAR) suggests that the lens can also be categorized as a steep

**Table 1 Baseline characteristics of right eye**

Parameters	Mean $\pm$ SD	Range
AXL (mm)	23.33 $\pm$ 1.01	21.02-25.37
ACD (mm)	3.02 $\pm$ 0.32	2.51-3.76
K1 (D)	43.00 $\pm$ 1.39	39.03-45.13
K2 (D)	43.68 $\pm$ 1.61	39.39-46.50
Central corneal thickness ( $\mu$ m)	547.59 $\pm$ 26.75	504-619
Lens thickness (mm)	4.59 $\pm$ 0.40	3.83-5.38
White to white (mm)	12.12 $\pm$ 0.25	11.50-12.60
Implanted IOL power (D)	23.09 $\pm$ 2.54	16.50-28.50

ACD: Anterior chamber depth; AXL: Axial length; D: Diopters; K: Keratometry; IOL: Intraocular lens; SD: Standard deviation.

transition IOL. Figure 4 illustrates the binocular defocus curve at 3-month following surgery. The curve revealed a peak in VA at 0 D defocus ( $-0.14 \pm 0.07$  logMAR) corresponding to far distance vision. A gradual decline in VA was observed at intermediate distance (66 cm or -1.50 D), reaching  $0.00 \pm 0.08$  logMAR. At -2.00 D of defocus (50 cm), a slight improvement of VA was observed ( $-0.06 \pm 0.08$  logMAR), followed by a final VA of  $-0.01 \pm 0.09$  logMAR at near distance (40 cm or -2.50 D defocus).

Figure 5 illustrates the CSF assessed at 3-month follow-up. The binocular CSF demonstrated strong performance at low spatial frequencies, with values of  $-2.33 \pm 0.10$  log units at 3 cpd and  $-2.21 \pm 0.26$  log units at 6 cpd. Conversely, at higher spatial frequencies (12 and 18 cpd), a moderate decline in contrast sensitivity was observed, reaching  $-1.97 \pm 0.21$  log units and  $-1.27 \pm 0.68$  log units, respectively. A similar trend was noted in monocular measurements, reflecting a consistent pattern across testing conditions.

Table 4 shows the CATQUEST-9SF answers of 21 patients at 3-month postop. In response to question A, 9 patients (42.86%) reported no difficulty at all in their life after the surgery and 12 patients (57.14%) had some difficulty. In response to question B, all patients (100%) reported that they were fairly or very satisfied with their vision after surgery. The remaining answers are displayed in Table 4.

## DISCUSSION

Numerous presbyopia-correcting IOLs, including multifocal and extended depth-of-focus IOLs, have been developed and commercialized over the last decade to address patient desire for spectacle independence and thus, increase their quality of life<sup>[15-21]</sup>.

To the best of our knowledge, this was the first study reporting the visual, refractive, and functional outcomes of ELANA IOL over a 3-month follow-up period. The results of this study showed a mean monocular CDVA of  $-0.11 \pm 0.07$  logMAR, CIVA  $0.13 \pm 0.14$  logMAR and CNVA  $0.21 \pm 0.12$  logMAR, respectively. Moreover, the IOL can provide a binocular UDVA of  $-0.13 \pm 0.08$  logMAR, UIVA of  $0.03 \pm 0.12$  logMAR

**Table 2 Visual acuity (logMAR) at 3-month following IOL implantation**

			mean±SD (range)
Visual acuity	1-month postop.	3-month postop.	<i>P</i>
Monocular (right eye)			
UDVA	-0.08±0.11 (-0.30/0.14)	-0.04±0.07 (-0.18/0.04)	0.022
UIVA	0.11±0.17 (-0.18/0.44)	0.13±0.15 (-0.10/0.36)	0.968
UNVA	0.16±0.14 (-0.12/0.40)	0.21±0.13 (0.00/0.46)	0.096
CDVA	-0.15±0.09 (-0.30/0.10)	-0.11±0.07 (-0.24/0.00)	0.051
CIVA	0.11±0.10 (-0.06/0.32)	0.13±0.14 (-0.10/0.40)	0.982
CNVA	0.15±0.12 (-0.06/0.46)	0.21±0.12 (0.06/0.46)	0.079
Binocular			
UDVA	-0.17±0.09 (-0.30/0.10)	-0.13±0.08 (-0.30/-0.02)	0.083
UIVA	0.01±0.11 (-0.30/0.20)	0.03±0.12 (-0.14/0.30)	0.883
UNVA	0.08±0.11 (-0.10/0.32)	0.11±0.11 (-0.02/0.32)	0.478
CDVA	-0.19±0.08 (-0.30/0.06)	-0.15±0.07 (-0.28/-0.06)	0.083
CIVA	0.05±0.11 (-0.28/0.20)	0.06±0.11 (-0.08/0.26)	0.899
CNVA	0.10±0.12 (-0.06/0.36)	0.13±0.11 (0.00/0.36)	0.586

IOL: Intraocular lens; CDVA: Best-corrected distance visual acuity; CIVA: Best-corrected intermediate visual acuity; CNVA: Best-corrected near visual acuity; UDVA: Uncorrected distance visual acuity; UIVA: Uncorrected intermediate visual acuity; UNVA: Uncorrected near visual acuity. *P*<0.05 was considered statistically significant.

**Table 3 Refractive outcomes at 1- and 3-month following IOL implantation**

			mean±SD (range)
Refractive data	1-month postop.	3-month postop.	<i>P</i>
Spherical equivalent (D)	0.02±0.37 (1.00/-0.75)	0.08±0.44 (1.50/-0.50)	0.391
Sphere (D)	0.13±0.37 (1.00/-0.75)	0.19±0.43 (1.50/-0.50)	0.386
Cylinder (D)	-0.22±0.25 (0.00/-0.50)	-0.23±0.25 (-0.50/0.00)	0.763

IOL: Intraocular lens; D: Diopters; SD: Standard deviation. *P*<0.05 was considered statistically significant.

**Table 4 Percentage of answers for the difficulties of different daily-life tasks at 3-month following IOL implantation**

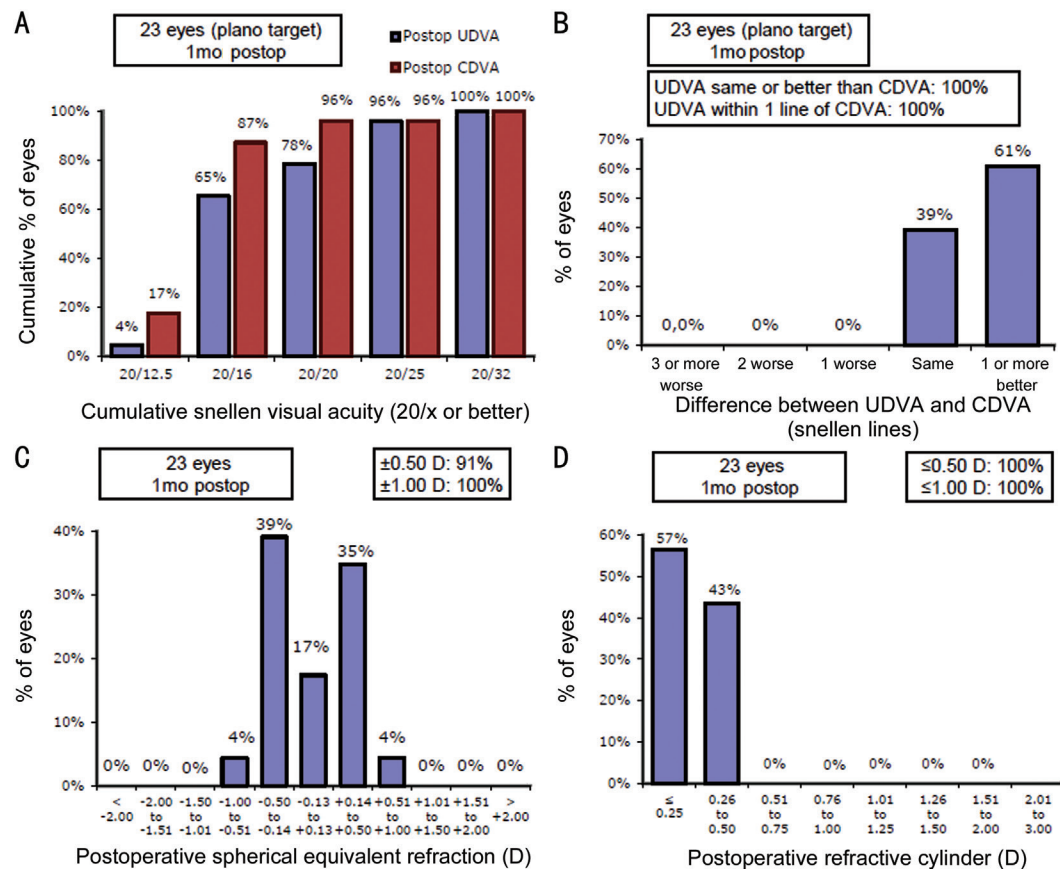
CATQUEST-9SF	A, C: very great difficulty; B: very dissatisfied			
	A, C: great difficulty; B: fairly dissatisfied	A, C: some difficulty; B: fairly satisfied	A, C: no difficulty; B: very satisfied	
Question A. Do you find that your sight at present in some way causes you difficulty in your everyday life	0	0	57.14	42.86
Question B. Are you satisfied or dissatisfied with your sight at present	0	0	47.62	52.38
Question C1. Do you have difficulty with reading text in the newspaper because of your vision	0	0	57.14	42.86
Question C2. Do you have difficulty with recognizing the faces of people you meet because of your vision	0	0	42.86	57.14
Question C3. Do you have difficulty with seeing the prices of goods when shopping because of your vision	0	4.76	66.67	28.57
Question C4. Do you have difficulty with seeing to walk on uneven surfaces, e.g. cobblestones because of your vision	0	0	19.05	80.95
Question C5. Do you have difficulty with seeing handicrafts, woodwork etc. because of your vision	0	4.76	76.19	19.05
Question C6. Do you have difficulty reading subtitles on TV because of your vision	0	0	28.57	71.43
Question C7. Do you have difficulty with seeing to engage in an activity/hobby that you are interested in because of your vision	0	9.52	57.14	33.33

IOL: Intraocular lens.

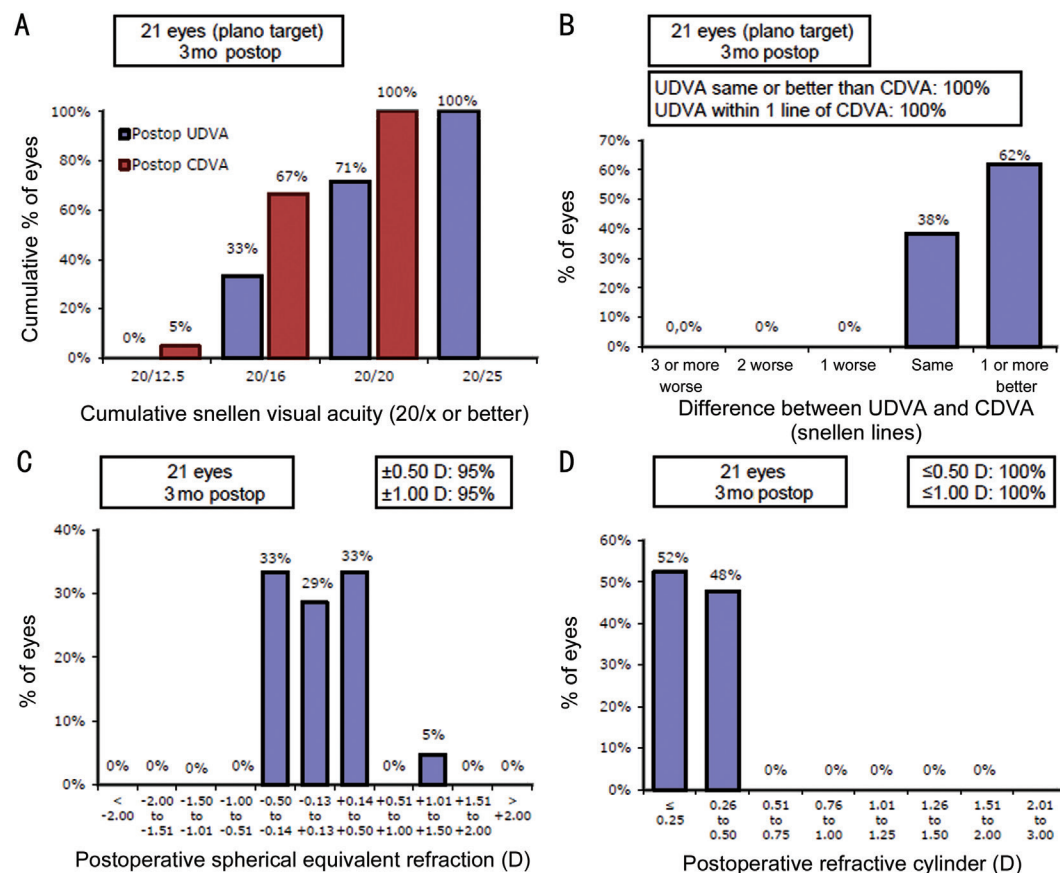
and UNVA of 0.11±0.11 logMAR at 3-month follow-up. No statistical difference was observed between 1-month and 3-month follow-up visit, except for UDVA (*P*=0.022). We consider this statistical difference between 1-month and 3-months in UDVA as not clinically relevant due to the difference of less than 0.05 logMAR value. Since no other

monocular or binocular distance, intermediate and near VAs are significantly different between these 2 timepoints, we can consider no VA change was observed during both timepoints. Overall, both monocular and binocular VAs reported in this study showed that ELANA IOL can provide good vision at all distances, including intermediate and near distance which

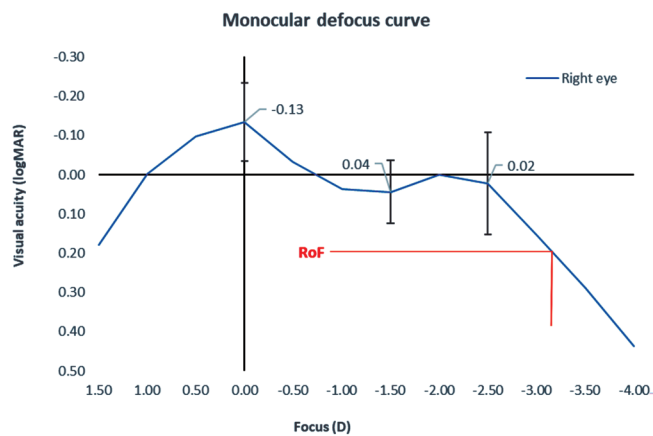




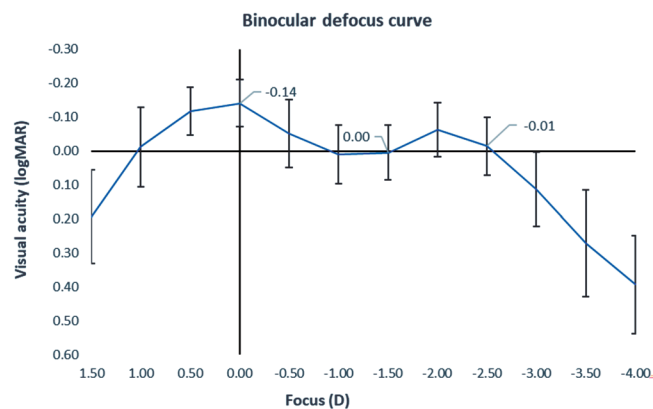
**Figure 1** Visual acuity, spherical equivalent and refractive cylinder at 1-month following IOL implantation ( $n=23$ ) CDVA: Best-corrected distance visual acuity; D: Diopter; UDVA: Uncorrected distance visual acuity.



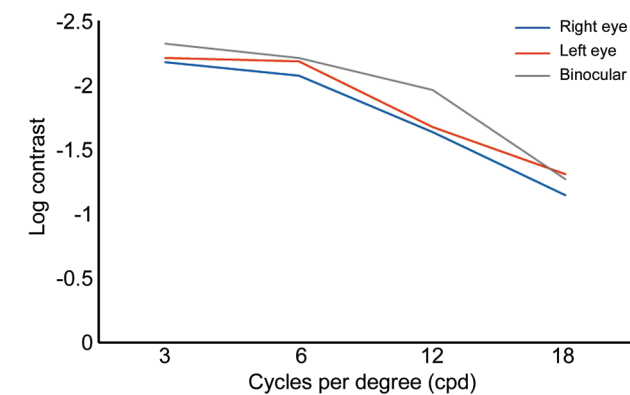
**Figure 2** Visual acuity, spherical equivalent and refractive cylinder at 3-month following IOL implantation ( $n=21$ ) CDVA: Best-corrected distance visual acuity; D: Diopter; UDVA: Uncorrected distance visual acuity.



**Figure 3 Monocular defocus curve (logMAR) at 1-month following IOL implantation (n=23 patients)** The red lines indicate the range of field (RoF) for visual acuity of 0.2 logMAR. IOL: Intraocular lens.



**Figure 4 Binocular defocus curve (logMAR) at 3-month following IOL implantation (n=21 patients)** IOL: Intraocular lens.



**Figure 5 Contrast sensitivity function under photopic conditions at 3-month following IOL implantation** IOL: Intraocular lens.

corresponds to the distance where most daily life activities can be performed.

ELANA IOL has the same diffractive pattern as AT LISA tri 839 MP. The monocular and binocular VAs reported in this study are similar to the acuities reported for AT LISA tri 839 MP in other studies<sup>[22-24]</sup> (Table 5), showing that both IOLs have similar visual performance. Distance VAs (*i.e.* monocular and binocular UDVA and CDVA) reported in this study for ELANA IOL are also in a similar range to those reported in other studies conducted on AcrySof IQ or Clareon PanOptix

IOL (Alcon), which represents one of the most extensively studied trifocal IOLs in literature<sup>[25-27]</sup> (Table 5). However, intermediate and near VAs (*i.e.* monocular and binocular UIVA, UNVA, CIVA and CNVA) reported for ELANA IOL are generally slightly lower than the ones reported for AcrySof IQ or Clareon PanOptix IOLs<sup>[25-27]</sup>. Similar intermediate and near visual acuity observations can be made between ELANA IOL and other trifocal IOLs, although with some differences observed, including Acriva Trinova (VSY Biotechnology)<sup>[27]</sup>, FineVision (BVI International)<sup>[28]</sup> and Liberty 677CMY (Medicontour). These differences in performance could be explained by the fact that the ELANA intermediate focal plane is optimized for 80 cm, and the present study used 66 cm to evaluate the performance at intermediate distance. Compared to the RayOne (Rayner), monocular uncorrected and corrected VAs reported for the ELANA IOL were found to be better at all distances, except for CNVA<sup>[24]</sup> (Table 5). The ELANA IOL has neutral spherical aberration; therefore, it is less sensitive to misalignment, including decentration and tilt, which could explain the better results obtained in this study when compared to other IOLs.

In this present study, the mean postop. SE was  $0.08 \pm 0.44$  D, which represents an excellent value considering that A-constant optimization data was not available for IOL power calculation. Achieving a postop SE close to the target can positively impact patient satisfaction and prove the predictability and efficacy of the IOL. The SE reported for ELANA IOL is within the range of SEs (from  $-0.14 \pm 0.36$  to  $0.13 \pm 0.32$  D) reported for AT LISA tri 839 MP in two other studies<sup>[22-23]</sup> (Table 5). Additionally, the SE reported for ELANA IOL is similar than the ones reported in other studies for Clareon and AcrySof IQ PanOptix<sup>[25-27]</sup>, Acriva Trinova<sup>[27]</sup> and FineVision<sup>[28]</sup>. Moreover, we found that 95% of eyes achieved a prediction of  $\pm 0.50$  D at 3-month follow-up which appears to be higher than other percentages reported for PanOptix<sup>[26]</sup> (81%) or FineVision<sup>[28]</sup> (83.3%). However, our group achieved a prediction of 100% of eyes within  $\pm 0.50$  D with Clareon PanOptix<sup>[25]</sup>, but these results were measured at 6mo follow-up and not 3-month follow-up as per this present study.

The monocular defocus curve presented in this study reports a VA of  $-0.13 \pm 0.10$  logMAR at 0 D (far vision), of  $0.04 \pm 0.08$  logMAR at -1.50 D (intermediate vision) and of  $0.02 \pm 0.13$  at -2.50 D (near vision). This defocus curve corresponds to the optical function measured *in vitro* in a previous study<sup>[14]</sup>. This is due to the simulated VA of the referenced study<sup>[29]</sup> being comparable to achievable defocus, highlighting the importance of preclinical *in vitro* studies and postoperative clinical outcomes. Our VA values in monocular defocus curve are similar in three focuses compared with one study conducted on AT LISA tri 839 MP<sup>[23]</sup> and are better than

Table 5 Description of main visual and refractive outcomes reported in this study for ELANA IOL and other studies conducted on trifocal IOLs at 3-month follow-up

VA	AT ELANA 841P (present study)	AT LISA tri 839 MP		Clareon PanOptix		AcrySof IQ PanOptix Bayhan <i>et al</i> <sup>[27]</sup>	Acriva Trinova Bayhan <i>et al</i> <sup>[27]</sup>	Fine Vision Bellucci <i>et al</i> <sup>[28]</sup>	Liberty 677CMY Cano-Ortiz <i>et al</i> <sup>[30]</sup>	RayOne Hienert <i>et al</i> <sup>[24]</sup>
		Webers <i>et al</i> <sup>[22]</sup>	Majzis <i>et al</i> <sup>[23]</sup>	Mendicute <i>et al</i> <sup>[25]</sup>	Suzuki <i>et al</i> <sup>[26]</sup>					
Monocular photopic visual acuities (logMAR)										
UDVA	-0.04±0.07 (6 m)	N/A	-0.04±0.10 (N/A) <sup>a</sup>	0.00±0.11 (4 m)	0.06±0.11 (6 m) <sup>b</sup>	-0.05±0.12 (5 m)	0.05±0.13 (N/A)	0.04±0.12 (N/A)	0.05±0.08 (N/A)	0.00±0.09 (4 m) <sup>a</sup>
UIVA	0.13±0.15 (66 cm)	N/A	0.11±0.10 (66 cm) <sup>a</sup>	0.26±0.10 (80 cm)	0.12±0.14 (66 cm) <sup>b</sup>	0.01±0.13 (60 cm)	0.06±0.12 (60 cm)	0.07±0.15 (60 cm)	0.11±0.10 (66 cm)	0.26±0.10 (80 cm) <sup>a</sup>
UNVA	0.21±0.13 (40 cm)	N/A	0.19±0.11 (33 cm) <sup>a</sup>	0.26±0.12 (40 cm)	0.18±0.12 (40 cm) <sup>b</sup>	0.01±0.11 (40 cm)	0.05±0.11 (N/A)	0.06±0.13 (N/A)	0.14±0.11 (40 cm)	0.21±0.09 (40 cm) <sup>a</sup>
CDVA	-0.11±0.07 (6 m)	N/A	-0.06±0.09 (N/A) <sup>a</sup>	-0.08±0.08 (4 m)	-0.02±0.08 (6 m) <sup>b</sup>	-0.13±0.09 (5 m)	-0.07±0.07 (N/A)	-0.07±0.06 (N/A)	-0.03±0.07 (N/A)	-0.01±0.07 (4 m) <sup>a</sup>
CIVA	0.13±0.14 (66 cm)	N/A	0.08±0.10 (66 cm) <sup>a</sup>	0.26±0.10 (80 cm)	0.11±0.14 (66 cm) <sup>b</sup>	-0.02±0.13 (60 cm)	0.04±0.08 (60 cm)	0.04±0.11 (60 cm)	0.14±0.12 (66 cm)	0.28±0.10 (80 cm) <sup>a</sup>
CNVA	0.21±0.12 (40 cm)	N/A	0.14±0.10 (33 cm) <sup>a</sup>	0.25±0.11 (40 cm)	0.15±0.11 (40 cm) <sup>b</sup>	-0.02±0.10 (40 cm)	0.05±0.10 (N/A)	0.05±0.07 (N/A)	0.12±0.11 (40 cm)	0.02±0.10 (40 cm) <sup>a</sup>
Binocular photopic visual acuities (logMAR)										
UDVA	-0.13±0.08 (6 m)	-0.05±0.07 (4 m)	N/A	N/A	N/A	-0.12±0.10 (5 m)	0.00±0.10 (N/A)	-0.02±0.09 (N/A)	-0.04±0.08 (N/A)	N/A
UIVA	0.03±0.12 (66 cm)	0.01±0.03 (66 cm)	N/A	N/A	N/A	-0.05±0.10 (60 cm)	0.04±0.10 (60 cm)	0.05±0.12 (N/A)	0.06±0.09 (66 cm)	N/A
UNVA	0.11±0.11 (40 cm)	0.04±0.07 (40 cm)	N/A	N/A	N/A	-0.04±0.09 (40 cm)	0.00±0.10 (N/A)	0.01±0.09 (N/A)	0.12±0.12 (40 cm)	N/A
CDVA	-0.15±0.07 (6 m)	N/A	N/A	N/A	N/A	-0.16±0.09 (5 m)	N/A	N/A	-0.08±0.06 (N/A)	N/A
CIVA	0.06±0.11 (66 cm)	N/A	N/A	N/A	N/A	-0.08±0.09 (60 cm)	N/A	N/A	0.09±0.12 (66 cm)	N/A
CNVA	0.13±0.11 (40 cm)	N/A	N/A	N/A	N/A	-0.07±0.09 (40 cm)	N/A	N/A	0.10±0.11 (40 cm)	N/A
SE (D)	0.08±0.44	0.13±0.32	-0.14±0.36	N/A	-0.05±0.24 <sup>b</sup>	0.02±0.39	-0.16±0.31	-0.36±0.36 (objective); -0.07±0.41 (subjective)	N/A	N/A
Within ±0.50 D	95%	N/A	N/A	N/A	100% <sup>b</sup>	81%	N/A	83.3%	N/A	N/A
Monocular defocus curves values in photopic conditions (logMAR)										
VA at 0 D	-0.13±0.10	N/A	-0.09±0.09 <sup>a</sup>	~-0.03	N/A	N/A	N/A	N/A	N/A	~-0.01
VA at -1.5 D	0.04±0.08	N/A	~-0.04 <sup>a</sup>	0.12±0.09	N/A	N/A	N/A	N/A	N/A	0.08±0.10
VA at -2.5 D	0.02±0.13	N/A	~-0.08 <sup>a</sup>	~0.15	N/A	N/A	N/A	N/A	N/A	~-0.17
Binocular defocus curves values in photopic conditions (logMAR)										
VA at 0 D	-0.14±0.07	-0.08	N/A	N/A	-0.04 <sup>b</sup>	~-0.17	-0.08	-0.07	N/A	N/A
VA at -1.5 D	0.00±0.08	0.06	N/A	N/A	0.01±0.10 <sup>b</sup>	~-0.07	0.07	0.03	N/A	N/A
VA at -2.5 D	-0.01±0.09	0.02	N/A	N/A	0.03±0.07 <sup>b</sup>	~-0.10	0.02	0.01	N/A	N/A

<sup>a</sup>The authors did not specify if these are monocular or binocular values, we considered them as monocular values; <sup>b</sup>These outcomes have been measured at 6-month follow-up, not 3-month follow-up like the other values reported. IOL: Intraocular lens; N/A: Not assessed in the study; CDVA: Best-corrected distance visual acuity; CIVA: Best-corrected intermediate visual acuity; CNVA: Best-corrected near visual acuity; D: Diopter; IOL: Intraocular lens; SE: Spherical equivalent; UDVA: Uncorrected distance visual acuity; UIVA: Uncorrected intermediate visual acuity; UNVA: Uncorrected near visual acuity; VA: Visual acuity.

the ones reported in another study conducted on AT LISA tri 839 MP and RayOne<sup>[24]</sup>. FineVision IOL only achieved similar results at -1.50 and -2.50 D<sup>[28]</sup> (Table 5). The binocular defocus curve values obtained for ELANA IOL at 0, -1.50 and -2.50 D are better than the ones reported in other studies for AT LISA tri 839 MP<sup>[22]</sup>, Clareon PanOptix<sup>[25]</sup>, AcrySof IQ PanOptix<sup>[27]</sup>, Acriva Trinova<sup>[27]</sup>, and Liberty 677CMY<sup>[30]</sup> (Table 5). However, Suzuki *et al*<sup>[26]</sup> achieved better VA at -1.50 and -2.50 D focus for Clareon PanOptix than our study, but not for 0 D focus. Although they are differences of 0.10 logMAR with our study in intermediate and near distances, we obtained values of 0 logMAR that are really good and sufficient to give independence in intermediate and near tasks.

The CSF reported for ELANA IOL in this present study was  $-2.33 \pm 0.10$  log units at 3 cpd, and  $-2.21 \pm 0.26$  log units at 6 cpd,  $-1.97 \pm 0.21$  log units at 12 cpd and  $-1.27 \pm 0.68$  log units at 18 cpd. These results are difficult to compare with literature because the technique used in this study (M&S<sup>®</sup> technologies) to measure CSF are not the one commonly used (CVS-1000). We used M&S<sup>®</sup> technologies in a previous study to assess CFS of Clareon PanOptix<sup>[25]</sup>. In this previous study, similar CFS values were found for PanOptix, *i.e.*  $-2.20 \pm 0.24$  log units at 3 cpd,  $-2.19 \pm 0.22$  log units at 6 cpd,  $-1.68 \pm 0.32$  log units at 12 cpd and  $-1.30 \pm 0.34$  at 18 cpd<sup>[25]</sup>. These good CSF results for ELANA IOL can be explained by its new enhanced light transmission technology.

In addition, this present study showed that 100% of patients had no difficulty or only some difficulty in their everyday life due to their sight, and 100% of patients were fairly or very satisfied with their vision after surgery. These rates are better than the ones reported in another study for AcrySof IQ PanOptix (94% and 97%, respectively) and for Clareon PanOptix (96% and 85%, respectively). The excellent patient satisfaction and ease in performing daily life tasks provided by ELANA IOL can be explained by its good contrast sensitivity and defocus curve and by the proved optic design of the previous AT Lisa Tri 839MP.

Nevertheless, it is worth noting that all these comparisons to other studies are only observations, and only randomized comparative trials conducted simultaneously on ELANA IOL and other trifocal IOLs can confirm these differences/similarities in terms of visual and refractive performance. Overall, our results suggest that ELANA IOL improves near, intermediate and distance vision in presbyopic patients, with an excellent rate of patient satisfaction.

However, this study presents some limitations. First, this is a single-arm study, so we did not make a direct comparison with other trifocal IOLs. The results presented in this study could vary in other centers or with other surgeons. Second, the population size and follow-up time was small. Other clinical

studies are therefore needed on a higher population size and a longer follow-up time to confirm these preliminary results as well as the need for multicentric studies to corroborate the results. Finally, for this study we used the first A-constant of 119.5 given by ZEISS before ELANA IOL appeared in the market. Thus, further studies with an optimized A-constant should be done to confirm our findings.

In conclusion, the results of this study showed that AT ELANA 841P IOL can provide good visual performance for distance, intermediate, and near vision, with adequate trifocal defocus curve, contrast sensitivity and low visual difficulties for daily life tasks.

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## REFERENCES

- 1 Vision Loss Expert Group of the Global Burden of Disease Study, GBD 2019 Blindness and Vision Impairment Collaborators. Global estimates on the number of people blind or visually impaired by cataract: a meta-analysis from 2000 to 2020. *Eye (Lond)* 2024;38(11):2156-2172.
- 2 Flaxman SR, Bourne RRA, Resnikoff S, *et al.* Global causes of blindness and distance vision impairment 1990-2020: a systematic review and meta-analysis. *Lancet Glob Health* 2017;5(12):e1221-e1234.
- 3 Cicinelli MV, Buchan JC, Nicholson M, *et al.* Cataracts. *Lancet* 2023;401(10374):377-389.
- 4 GBD 2019 Blindness and Vision Impairment Collaborators, Vision Loss Expert Group of the Global Burden of Disease Study. Causes of blindness and vision impairment in 2020 and trends over 30 years, and prevalence of avoidable blindness in relation to VISION 2020: the Right to Sight: an analysis for the Global Burden of Disease Study. *Lancet Glob Health* 2021;9(2):e144-e160.
- 5 Segers MHM, Behndig A, van den Biggelaar FJHM, *et al.* The European registry of quality outcomes for cataract and refractive surgery: benefits and lessons of a multinational registry. *NEJM Catal Innov Care Deliv* 2024;5(11).
- 6 Usmani B, Iftikhar M, Latif A, *et al.* Epidemiology of primary ophthalmic procedures performed in the United States. *Can J Ophthalmol* 2019;54(6):727-734.
- 7 Rossi T, Romano MR, Iannetta D, *et al.* Cataract surgery practice patterns worldwide: a survey. *BMJ Open Ophthalmol* 2021;6(1):e000464.



- 8 Daka Q, Henein C, Fang CEH, *et al.* Effectiveness of intraocular lenses designed to correct presbyopia after cataract surgery: an overview of systematic reviews. *Br J Ophthalmol* 2025;bjo-2025-327363.
- 9 Katz JA, Karpecki PM, Dorca A, *et al.* Presbyopia—a review of current treatment options and emerging therapies. *Clin Ophthalmol* 2021;15:2167-2178.
- 10 Kohnen T, Biller ML, Lwowski C, *et al.* Treatments for presbyopia. *Dtsch Arztebl Int* 2025;122:501-507.
- 11 Simpson MJ, Gatinel D, Faria-Ribeiro M, *et al.* Design concepts for advanced-technology intraocular lenses. *Biomed Opt Express* 2025;16(1):334-361.
- 12 Werner L. Intraocular lenses: overview of designs, materials, and pathophysiologic features. *Ophthalmology* 2021;128(11):e74-e93.
- 13 Ribeiro F, Dick HB, Kohnen T, *et al.* Evidence-based functional classification of simultaneous vision intraocular lenses: seeking a global consensus by the ESCRS Functional Vision Working Group. *J Cataract Refract Surg* 2024;50(8):794-798.
- 14 Łabuz G, Yan W, Khoramnia R, *et al.* Optical-quality analysis and defocus-curve simulations of a novel hydrophobic trifocal intraocular lens. *Clin Ophthalmol* 2023;17:3915-3923.
- 15 Li J, Sun B, Zhang Y, *et al.* Comparative efficacy and safety of all kinds of intraocular lenses in presbyopia-correcting cataract surgery: a systematic review and meta-analysis. *BMC Ophthalmol* 2024;24(1):172.
- 16 Tavassoli S, Ziaei H, Yadegarfar ME, *et al.* Trifocal versus extended depth of focus (EDOF) intraocular lenses after cataract extraction. *Cochrane Database Syst Rev* 2024;7(7):CD014891.
- 17 Scheepers MA, Bunce CB, Michaelides M, *et al.* Clinical outcomes of a trifocal compared with an extended depth of focus IOL following bilateral cataract surgery. *Can J Ophthalmol* 2023;58(5):393-400.
- 18 Zamora-de La Cruz D, Bartlett J, Gutierrez M, *et al.* Trifocal intraocular lenses versus bifocal intraocular lenses after cataract extraction among participants with presbyopia. *Cochrane Database Syst Rev* 2023;1(1):CD012648.
- 19 Gil MA, Varón C, Cardona G, *et al.* Visual acuity and defocus curves with six multifocal intraocular lenses. *Int Ophthalmol* 2020;40(2):393-401.
- 20 Cochener B, Boutilier G, Lamard M, *et al.* A comparative evaluation of a new generation of diffractive trifocal and extended depth of focus intraocular lenses. *J Refract Surg* 2018;34(8):507-514.
- 21 Karam M, Alkhowaiter N, Alkhabbaz A, *et al.* Extended depth of focus versus trifocal for intraocular lens implantation: an updated systematic review and meta-analysis. *Am J Ophthalmol* 2023;251:52-70.
- 22 Webers VSC, Bauer NJC, Saelens IEY, *et al.* Comparison of the intermediate distance of a trifocal IOL with an extended depth-of-focus IOL: results of a prospective randomized trial. *J Cataract Refract Surg* 2020;46(2):193-203.
- 23 Mojzis P, Peña-García P, Liehneova I, *et al.* Outcomes of a new diffractive trifocal intraocular lens. *J Cataract Refract Surg* 2014;40(1):60-69.
- 24 Hienert J, Stjepanek K, Hirschall N, *et al.* Visual performance of two diffractive trifocal intraocular lenses: a randomized trial. *J Refract Surg* 2021;37(7):460-465.
- 25 Mendicute J, Lauzirika G, Illarramendi I, *et al.* Visual, refractive, functional, and patient satisfaction outcomes after implantation of a new trifocal diffractive intraocular lens. *Clin Ophthalmol* 2024;18:2785-2795.
- 26 Suzuki T, Ota Y, Suzuki H, *et al.* Visual outcomes following high water-content hydrophobic acrylic trifocal intraocular lens implantation. *BMC Ophthalmol* 2024;24(1):469.
- 27 Bayhan HA, Taşçı YY, Aslan Bayhan S, *et al.* Comparison of two presbyopia-correcting trifocal intraocular lenses: a prospective study. *Türk J Ophthalmol* 2024;54(2):63-68.
- 28 Bellucci C, Mora P, Tedesco SA, *et al.* Comparison of objective and subjective visual outcomes between pentafoveal and trifocal diffractive intraocular lenses. *J Refract Surg* 2024;40(9):e604-e613.
- 29 Alarcon A, Canovas C, Rosen R, *et al.* Preclinical metrics to predict through-focus visual acuity for pseudophakic patients. *Biomed Opt Express* 2016;7(5):1877-1888.
- 30 Cano-Ortiz A, Sánchez-Ventosa Á, Villalba-González M, *et al.* Clinical and patient reported outcomes of an optimized trifocal intraocular lens. *J Clin Med* 2024;13(14):4133.