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ORIGINAL RESEARCH

Six-Month Visual and Patient-Reported Outcomes of a Biaspheric Trifocal IOL in Asian and European Cataract Patients: A Comparative Study

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Purpose: To compare six-month refractive accuracy, visual performance, and patient-reported outcomes of a bi-aspheric trifocal intraocular lens (IOL) in Asian and European patients.

Methods: In this prospective observational study at Chang Gung Memorial Hospital (Taiwan) and Oftalvist Alicante (Spain), 50 patients (25 Taiwanese, 25 Spanish) received bilateral implantation of the same trifocal IOL during routine phacoemulsification. Visual acuity and defocus curves were measured with Landolt C charts (culturally neutral). Binocular contrast sensitivity was tested under photopic (85 cd/m^2) and mesopic (3 cd/m^2) conditions, with and without glare. Patient satisfaction was evaluated using the Catquest-9SF.

Results: Both groups achieved near-emmetropic outcomes, with 98% of Spanish and 80% of Taiwanese eyes within ±0.50 D of target refraction. Spanish eyes showed significantly lower residual astigmatism (–0.11 ± 0.20 D) than Taiwanese eyes (–0.72 ± 0.41 D; $p < 0.001$), corresponding to superior monocular and binocular acuities at distance, intermediate, and near. Despite this, Taiwanese patients reported comparable or higher satisfaction scores, suggesting cultural factors and visual demands affect perceived quality of vision. Contrast sensitivity for both cohorts fell within or above normative ranges, with minor losses at higher spatial frequencies under mesopic glare.

Conclusion: The bi-aspheric trifocal IOL delivers excellent refractive and functional results in both Asian and European eyes. The divergence between objective metrics and patient-reported satisfaction underlines the necessity of including subjective outcomes in multifocal IOL assessments.

Keywords: trifocal, diffractive, intraocular lens, phacoemulsification, cataract

Introduction

The development of trifocal intraocular lenses (IOLs) has revolutionized cataract surgery, providing surgeons with an excellent tool to enhance visual outcomes for patients seeking to improve intermediate visual acuity. These lenses are designed not only to optimize intermediate vision but also to maintain high levels of visual acuity at both near and far distances. The unique design of trifocal IOLs allows for the distribution of light across three focal points, thereby enabling patients to experience a more comprehensive range of vision. Several review papers have consistently concluded that patients implanted with trifocal IOLs achieve better intermediate visual acuity compared to those with bifocal IOLs.[1–3] The near and distance visual performance, as well as spectacle independence and postoperative refraction outcomes, are comparable between these two types of lenses. Furthermore, trifocal IOLs have demonstrated superior near vision performance and spectacle independence when compared to extended depth-of-focus (EDOF) IOLs. However, they may lead to an increase in photic disturbances, such as halo effects, which can affect the overall visual experience of the patient.[4] Contrast sensitivity and subjective visual quality have been shown to be similar between

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trifocal and EDOF IOL designs, despite the potential for trifocal IOLs to reduce contrast sensitivity and increase photic disturbances due to the distribution of light among three focal points.[4] It is essential to note that while EDOF IOLs aim to extend the depth of focus (DOF), they do not significantly reduce objective dysphotopsia compared to trifocal IOLs.[5]

In recent years, trifocal IOLs have become popular for restoring full-range vision in pseudophakic patients. The Asqelio trifocal IOL (AST VisionCare Inc., Billerica, MA, USA) is a non-apodized, diffractive, bi-aspheric posterior lens designed to boost optical quality. Its two aspheric surfaces sharpen images and raise distance MTF by about 30% versus mono-aspheric models. It allocates 24% of light to an intermediate focus at +2.20 D (3 mm pupil) and, in bench tests, shows minimal MTF loss with decentrations up to 0.25 mm and only slight reductions at larger offsets.[6] Previous clinical studies on this lens have shown good visual and refractive outcomes with the non-toric and toric models, and favorable contrast sensitivity and patient-reported outcomes.[7–12]

The performance and satisfaction of trifocal IOLs may differ by genetics, visual habits, and eye anatomy, yet most presbyopia-correcting IOL studies have examined fairly uniform cohorts. In particular, Asian and European patients, with distinct ocular characteristics and lifestyle demands, have not been directly compared after trifocal implantation. This study therefore evaluates, at six months post-op, binocular visual acuity at distance, intermediate, and near; glare sensitivity; refractive predictability; and patient-reported outcomes in Asian versus European cataract patients implanted bilaterally with the same non-toric, bi-aspheric diffractive trifocal IOL. This study aims to provide valuable insights into the effectiveness and patient satisfaction associated with this specific trifocal IOL design across diverse populations.

Methods

Two parallel clinical studies, one in Taiwan and one in Spain, followed an identical protocol, received Ethics Committee approval, and adhered to the Declaration of Helsinki. All participants provided written informed consent after being fully briefed on the study's procedures and potential risks. Both trials are registered on ClinicalTrials.gov (NCT05065749, NCT04884178).

Inclusion criteria were patients 50 years of age or older submitted to cataract surgery and implanted with the Asqelio Trifocal IOL TFLIO130C according to regular clinical practice, patients seeking spectacle-independence following surgery, IOL power between +5.00 D and +34.00 D, transparent intraocular media, except for the cataract prior to surgery, in both eyes, and post-operatory potential visual acuity of 20/25 or better. Exclusion criteria included pre-operative corneal astigmatism >1.00D, lack of informed consent, concurrent participation in other ocular trials or planned eye surgery during the study, significant ocular comorbidities (eg, irregular cornea, prior corneal surgery/trauma, glaucoma, macular disease, optic neuropathies, diabetic retinopathy, uveitis, structural anomalies, etc).

Intraocular Lens

All patients in the Spanish cohort were implanted with the Asqelio Trifocal TFLIO130C model IOL (clear), while the Taiwanese cohort were implanted with the TFLIO130Y model (yellow). The only difference between both models is the blue filter. The Asqelio Trifocal has a bi-aspheric geometry, with a posterior diffractive optic design (15 rings within the central 4.5 mm) in its 6.0 mm in diameter optical zone. It has a total diameter of 13.0 mm and provides an addition for near of +3.30D and +2.20D for intermediate distance. The lens is built in powers ranging from +5.00D to +34.00D in 0.50D increments, C-Loop platform, 360 degrees square edge and with a light distribution among its foci of 50% for distance, 24% for intermediate and 26% for near. It is made of hydrophobic acrylic material (glistening free) with a refractive index of 1.50, UV absorber, Abbe number of 50, water content <0.5% and a spherical aberration of −0.27 microns.

Surgical Procedure

All surgical procedures were carried out according to common clinical practice in the participating centers. The surgical procedure for the Spanish Group consisted on a 2.2 mm limbal incision followed by a standard phacoemulsification using the Centurion® Vision System (Alcon Labs Inc., Fort Worth, TX, USA). After cataract removal and posterior capsule polishing, the capsular bag was filled with sodium hyaluronate 1.0% (Provisc, Alcon, Fort Worth, TX, USA). The spherical IOL power was determined using the ORA system with Verifeye+ (Alcon, Fort Worth, TX, USA) in aphakic

condition. Postoperatively, all patients were prescribed with eyedrops of moxifloxacin 5 mg/mL (Vigamox; Alcon), prednisolone 10 mg/mL (Pred-Forte; Allergan, Inc., Irvine, CA, USA), and diplofenac-Lepori 1 mg/mL in a tapering dose for the first 4 weeks postoperatively. For the Taiwanese Group, the incision size was 2.65 mm, and phacoemulsification was carried with either Centurion® or Infiniti® Vision System (Alcon Labs Inc., Fort Worth, TX, USA). In these either AmVisc® (Bausch&Lomb Inc., Bridgewater, NJ, USA) or DuoVisc® (Alcon Labs Inc., Fort Worth, TX, USA) OVDs were used after cataract removal. Postoperatively, only Tobradex® suspension 5 mL (Novartis Pharmaceuticals Corp., Basel, Switzerland) was prescribed for all patients.

Preoperative and Postoperative Assessment

Pre-operative assessment included slit-lamp exam; logMAR UDVA/CDVA; subjective and objective refraction; IOP; funduscopy; corneal topography; and IOLMaster® 700 biometry. In both centers, the final IOL power selected for implantation followed each site's routine clinical practice. In general, the Barrett Universal II formula was used as the primary reference, and the surgeon considered the degree of agreement among formulas based on the patient's biometric characteristics before making the final selection, therefore Hoffer Q or SRK/T were occasionally used at the surgeon's discretion when the patient's biometric characteristics indicated that an alternative formula might provide a more reliable estimate.

At 6 months post-op, patients underwent refraction and slit-lamp exam plus monocular/binocular logMAR UDVA, CDVA; UIVA/DCIVA at 60 cm; and UNVA/DCNVA at 40 cm under photopic conditions. Visual acuity and monocular defocus curves (+2.00 D to –4.00 D in 0.50 D steps) were recorded via the CTS system (M&S Technologies Inc., Niles, IL, USA), with all results as mean±SD (range). To avoid Roman-alphabet bias in Taiwanese subjects, Landolt C charts were used throughout, precluding direct comparison with Sloan ETDRS-based studies.

Binocular contrast sensitivity (distance-corrected) was measured with/without glare: photopic (85 cd/m^2; 3, 6, 12, 18 cpd) and mesopic (3 cd/m^2; 1.5, 3, 6, 12 cpd) via CTS. Log thresholds were converted to log CS; means ± SD were computed.

Patient-reported outcomes used Catquest-9SF:[13–15] nine items (A, C1–C7 on difficulty; B on satisfaction) with a 4-point Likert scale (1 = no difficulty/very satisfied to 4 = very great difficulty/very dissatisfied; "cannot decide" treated as missing), where lower scores denote better outcomes. Questionnaires used were the validated versions in both Spanish[16] and Chinese.[17]

Sample Size Rationale and Statistical Analysis

This study pools data from two independent, prospective cohorts (Taiwan and Spain) that followed an identical surgical protocol, visit schedule, and outcome definitions. Because each trial was originally powered for local objectives, we conducted a post hoc power analysis to confirm that the combined sample was adequate for the present comparison. Assuming a clinically relevant between-group difference of 0.10 logMAR in uncorrected distance visual acuity (UDVA) and a pooled standard deviation of 0.12 logMAR (based on pilot data and comparable reports), the standard two-sample formula for means with $\alpha = 0.05$ (two-sided) and 80% power indicated a minimum of 23 eyes per group. Both cohorts exceeded this requirement, contributing 50 eyes (25 patients) each; the merged dataset therefore affords >90% power to detect the predefined effect size, ensuring statistical robustness despite retrospective pooling.

Data were analysed with IBM SPSS Statistics 25.0 (IBM Corp., Armonk, NY, USA) and Microsoft Excel for Mac 16.41 (Microsoft Corp., Redmond, WA, USA). Statistical significance was set at $p < 0.05$. Categorical variables are presented as frequencies and percentages; continuous variables as mean ± standard deviation. Between-group comparisons used the independent-samples *t*-test or Mann–Whitney *U*-test, as appropriate after testing for normality (Shapiro–Wilk).

Results

The data obtained from 100 eyes of 50 patients were included in the present study. Patients were divided into two groups: Taiwanese (25) and Spanish (25). The Taiwanese sample comprised 4 male and 21 female, with a mean age 68.16±7.04 years (range 55 to 83 years). The Spanish sample comprised 4 male, 21 female. Mean age 67.24±7.76 years (range 52 to 84 years). Age differences were not statistically significant ($p>0.05$). Table 1 shows the patients' demographics for the

Table 1 Preoperatory Descriptive Statistics of the Samples Comprising Both Study Groups

	Spain			Taiwan			Mean Diff	P-value
	Mean	SD	Range	Mean	SD	Range		
Age (years)	67.24	7.76	52 to 84	68.16	7.04	55 to 83	0.92	0.332
Sphere (D)	0.70	2.76	5.50 to −5.25	−1.16	3.90	4.75 to −15.25	1.86	0.017*
Cylinder (D)	−0.38	0.37	0.00 to −1.50	−1.20	0.65	0.25 to 3.25	0.81	<0.001*
MRSE (D)	0.51	2.81	−5.50 to 5.50	−1.75	3.85	4.00 to −15.37	2.27	<0.001*
CDVA (LogMAR)	0.82	0.21	0.35 to 1.00	0.38	0.22	0.10 to 0.90	0.44	<0.001*
AL (mm)	23.37	1.11	21.59 to 26.15	23.84	1.08	21.90 to 26.97	0.48	0.008*
ACD (mm)	3.08	0.31	2.55 to 3.82	3.00	0.32	2.48 to 3.75	0.07	0.128
K1 (D)	43.43	1.33	41.09 to 46.35	44.03	1.24	41.50 to 47.00	0.60	0.028*
K2 (D)	43.99	1.35	41.64 to 46.69	44.05	1.25	41.75 to 46.50	0.06	0.410

Note: * indicates statistical significance at the 0.05 level.
Abbreviations: MRSE, Mean refractive spherical equivalent; AL, Axial length; ACD, Anterior chamber depth; K1, Flat corneal meridian curvature; K2, Steep corneal meridian curvature.

patients included in the study, as well as the statistical significance of the differences between both groups. Standard graphs for reporting visual acuity.[18]

Refraction

With regard to refractive predictability, for the spherical equivalent 48% of eyes in the Spanish sample and 30% of eyes in the Taiwanese sample were within the range between ±0.13D. 100% and 98% of eyes were within ±1.00D, and 98% and 80% of eyes were within ±0.50D for the Spanish and Taiwanese groups, respectively. The mean postoperative spherical equivalent was 0.08±0.24 D (ranging from −0.50 to 0.75D) and 0.05±0.44 D (ranging from −1.12 to 0.88D) for the Spanish and Taiwanese groups, respectively (P<0.001). For the astigmatism, 100% and 86% of eyes showed a value ≤1.00D, while 100% and 40% had a cylinder value ≤0.50D for the Spanish and Taiwanese groups, respectively. The mean postoperative refractive cylinder was −0.11±0.20D (ranging from 0 to −0.50D) for the Spanish Group and −0.72 ±0.41D (ranging from 0 to −1.75D) for the Taiwanese group (P<0.001). The slightly larger residual cylinder in the Taiwanese cohort might be partly explained by the larger incision size and differences in the surgical approach.

Visual Acuity and Defocus Curve

For the efficacy of the procedure, Figure 1 was plotted providing the cumulative preoperative CDVA and postoperative UCVA for both groups. It must be reminded that all values were obtained using Landolt C charts, and therefore direct comparison with outcomes from studies using Sloan EDTRS should not be made. Table 2 shows the mean values and statistical significance for the differences between groups for monocular and binocular visual acuities at the different distances analyzed. Differences were significant at all distances in both monocular and binocular conditions (corrected and uncorrected), except for binocular DCNVA (p=0.052). Visual performance was better in the Spanish group except for binocular DCIVA. Figure 2 shows the mean monocular defocus curves for both groups. It may be observed two peaks of visual acuity for each group, one located at vergence 0D and another about −2.00D. Standard deviations were omitted from the plot to avoid excessive cluttering, but they ranged between ±0.09 and ±0.21 for the Spanish group and between ±0.15 and ±0.21 for the Taiwanese group, for the different vergences.

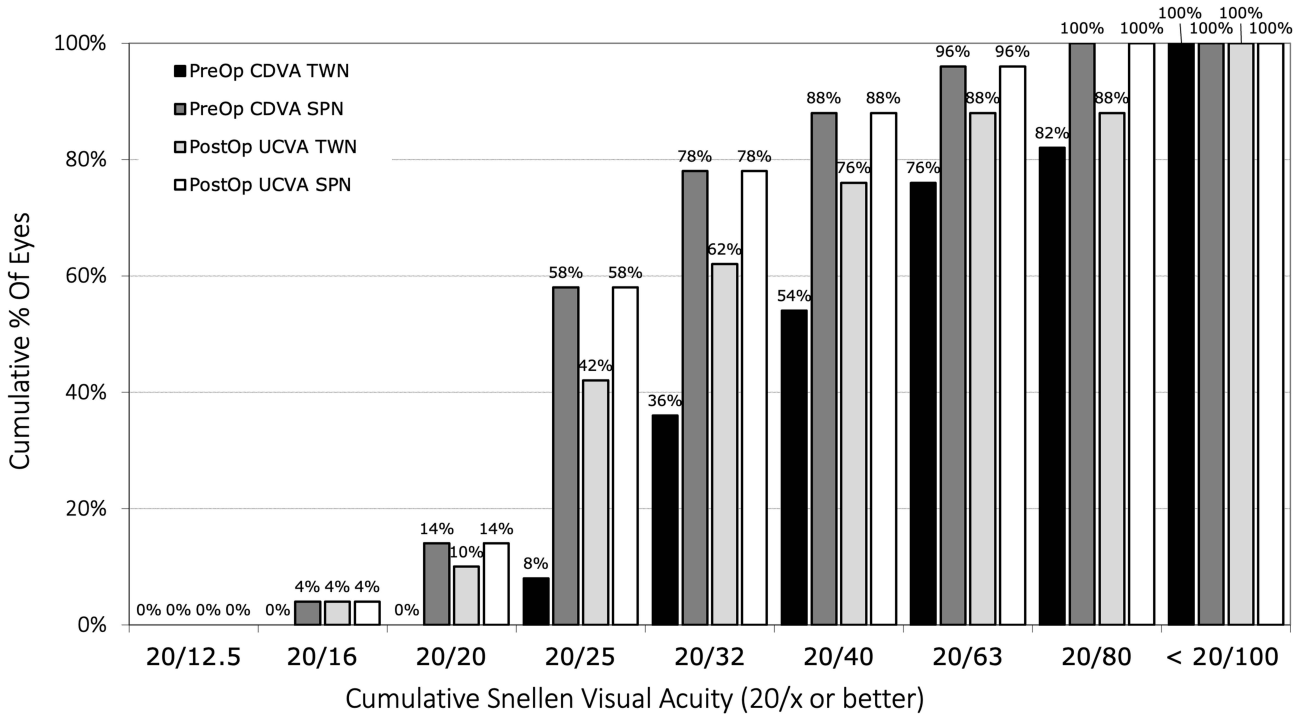

Figure 1 Cumulative proportion of patients' preoperative best-corrected distance visual acuity (CDVA) and postoperative uncorrected distance visual acuity (UCVA) at 6 months after surgery for both study groups.

Contrast Sensitivity

Figure 3 shows the mean binocular contrast sensitivity function determined under photopic conditions (85 cd/m^2) with glare (lower left) and without (upper left) and under mesopic conditions (3 cd/m^2) with glare (lower right) and without (upper right). Since the CTS system lacks reference ranges of normality for healthy subjects under mesopic conditions, both with and without glare, the normal ranges for non-operated eyes over 60 years of age established by Escaf et al[19] using the Functional Acuity Contrast Test (FACT) were used.[8] The results show that contrast sensitivity was either within or above normal levels under both photopic and mesopic conditions, both with and without glare, for both groups. The only exception to this was mesopic contrast sensitivity for 12 cpd with glare in both groups, 12 cpd without glare for the Taiwanese group, and 6 and 12 cpd under photopic conditions with glare for the Spanish Group. In these cases, the mean values fall just below the normal

Table 2 Monocular and Binocular Visual Acuity Outcomes (logMAR)

	Spain			Taiwan			P-value
	Mean	SD	Range	Mean	SD	Range	
Monocular UDVA	0.13	0.15	−0.10 to 0.58	0.25	0.24	−0.10 to 1.00	0.002*
Binocular UDVA	0.05	0.13	−0.10 to 0.50	0.17	0.19	0.00 to 0.80	<0.001*
Monocular CDVA	0.08	0.10	−0.10 to 0.38	0.17	0.18	−0.10 to 0.70	0.002*
Binocular CDVA	0.01	0.07	−0.10 to 0.20	0.11	0.17	−0.10 to 0.49	<0.001*
Monocular UIVA	0.19	0.16	0.00 to 0.70	0.26	0.20	−0.20 to 0.70	0.021*
Binocular UIVA	0.08	0.14	−0.10 to 0.54	0.15	0.17	−0.10 to 0.49	0.008*
Monocular DCIVA	0.17	0.16	0.00 to 0.70	0.24	0.18	−0.10 to 0.80	0.023*

(*Continued*)

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Table 2 (Continued).

	Spain			Taiwan			P-value
	Mean	SD	Range	Mean	SD	Range	
Binocular DCIVA	0.20	0.85	−0.10 to 0.58	0.15	0.19	−0.10 to 0.70	0.016*
Monocular UNVA	0.20	0.17	0.00 to 0.70	0.28	0.18	0.00 to 0.80	0.017*
Binocular UNVA	0.11	0.14	−0.02 to 0.50	0.21	0.15	0.00 to 0.60	<0.001*
Monocular DCNVA	0.18	0.15	0.00 to 0.60	0.26	0.19	0.00 to 0.80	0.034*
Binocular DCNVA	0.10	0.12	−0.02 to 0.50	0.17	0.19	0.00 to 0.60	0.052

Note: * indicates statistical significance at the 0.05 level.
Abbreviations: UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; UIVA, uncorrected distance intermediate visual acuity; DCIVA, distance-corrected intermediate visual acuity; UNVA, uncorrected distance near visual acuity; DCNVA distance-corrected near visual acuity.

range. Again, as with the defocus curve, standard deviations were omitted from the plot to avoid excessive cluttering, but they ranged between ±0.21 and ±0.41 for the Spanish group and between ±0.21 and ±0.40 for the Taiwanese group. Differences in contrast sensitivity were significant between both groups for all spatial frequencies and under all conditions, except for 1.5, 3 and 6 cpd under mesopic conditions with glare (p-values of 0.991, 0.364 and 0.205, respectively), and for 3cpd under photopic conditions, both with and without glare (p-values of 0.731 and 0.986, respectively).

Patient Reported Outcomes

In relation to the patient reported outcomes, the Catquest-9SF shows that although the clinical outcomes are significantly better for the Spanish cohort, Taiwanese patients report greater satisfaction with the outcomes than the Spanish group, although the differences are not significant (p>0.05), except for the item related to engaging into activites/hobbies (Table 3). In any case, both groups report satisfaction with the outcomes and no difficulty in performing any of the tasks included in the questionnaire. The average score for the whole sample of patients was 1.72±0.74 for satisfaction with vision after surgery.

Discussion

The purpose of the present study was to assess and compare the outcomes of patients implanted with the bi-aspheric trifocal diffractive Asqelio IOL in two different populations, Asian (Taiwanese) and European (Spanish). Previous investigations conducted solely on European populations have consistently demonstrated good refractive accuracy, excellent intermediate and near visual acuities, and high patient satisfaction with this trifocal lens design.[7–12]

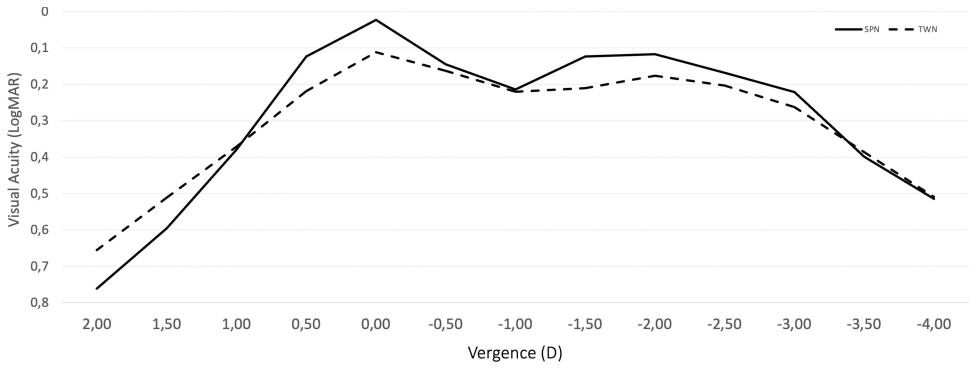

Figure 2 Mean defocus curve for each of the study groups, Spanish (solid lines) and Taiwanese (dashed line).

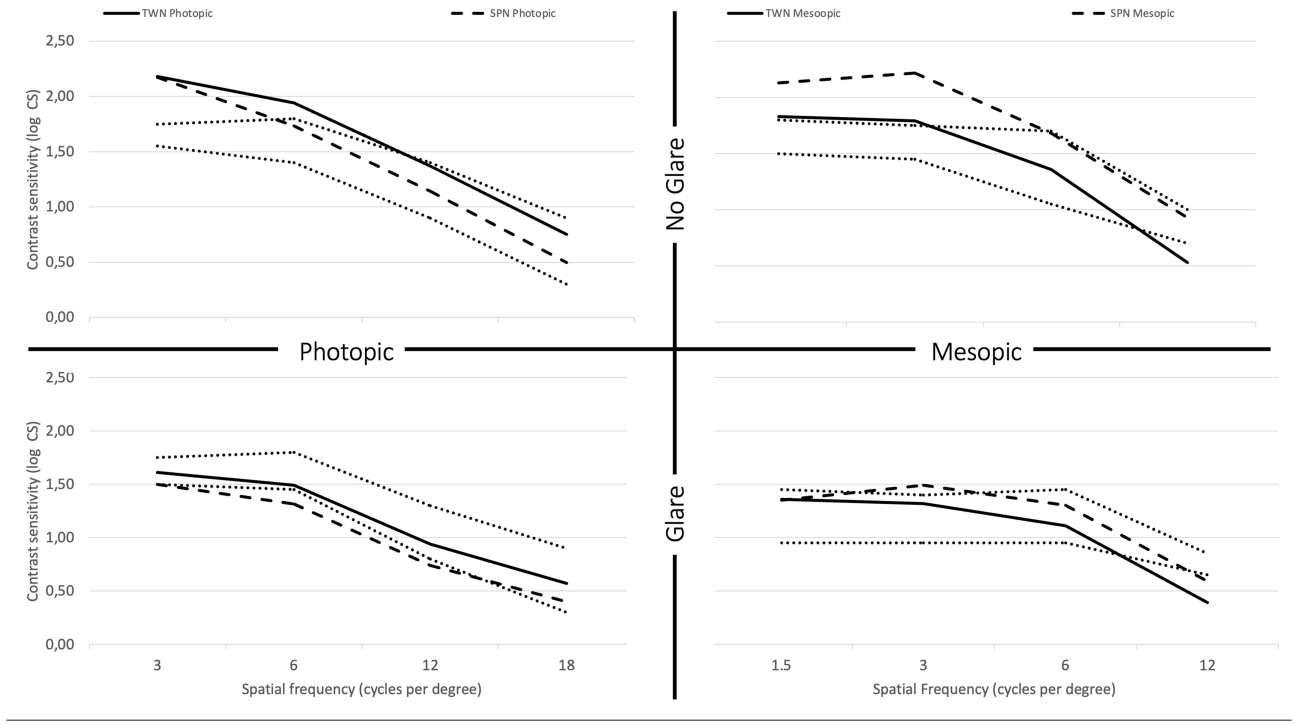

Figure 3 Contrast sensitivity function determined under photopic conditions (85 cd/m^2) with (lower left) and without induced glare (upper left) and under mesopic conditions (3 cd/m^2) with (lower right) and without induced glare (upper right) for Taiwanese (solid lines) and Spanish (dashed line) groups. Dotted lines delimit the normal range for non-operated eyes above 60 years of age using the Functional Acuity Contrast Test (FACT).[17]

Palomino-Bautista et al[7] assessed 25 patients bilaterally implanted with the Asqelio trifocal IOL at 3 months. Postop spherical equivalent was +0.05 ± 0.23 D (cylinder 0.01 ± 0.023 D). Mean UDVA, CDVA, CDIVA and CDNVA ranged from −0.05 to 0.04 logMAR. Absolute DOF averaged 3.35 ± 0.80 D. Binocular satisfaction ≥8/10 was reported by 72%, and mean halo bothersome was 4.36/10, reflecting significant visual gains at all distances. The predictable outcomes allow good visual acuity at different distances and good patient satisfaction rates.

Cano-Ortiz et al[8] evaluated 25 patients bilaterally implanted with the Asqelio trifocal IOL at 3 months. Mean spherical equivalent was +0.21 ± 0.37 D (residual cylinder –0.20 ± 0.35 D), with 84% within ±0.50 D and 100% within ±1.00 D. Nearly all eyes achieved CDVA ≥20/20 (98%) and ≥20/25 (100%). Binocular UDVA, UIVA and UNVA averaged –0.02 ± 0.09, 0.06 ± 0.08 and 0.11 ± 0.07 logMAR; CDVA, DCIVA and DCNVA were –0.06 ± 0.08, 0.02 ± 0.09 and 0.06 ± 0.07 logMAR. Defocus tolerance was 3.64 ± 0.70 D (≤0.1 logMAR from +1.00 to –2.75 D). Spectacle independence was 100% for distance, 96% intermediate, 88% near; ≥80% were very/completely satisfied at all but near

Table 3 Summary of Patient-Reported Difficulties and Satisfaction with Their Vision as per Catquest-9SF for Both Groups

	Mean±SD	Response Frequencies (%)					p-value
		R1	R2	R3	R4	R5	
Do you find that your sight at present in some way causes you difficulty in your everyday life?	1.44±0.87	8	0	20	72	0	0.093
	1.09±0.29	0	0	9	91	0	
Are you satisfied or unsatisfied with your current vision?	1.60±0.82	4	8	32	56	0	0.102
	1.86±0.62	0	14	59	27	0	

(*Continued*)

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Table 3 (Continued).

	Mean±SD	Response Frequencies (%)					p-value
		R1	R2	R3	R4	R5	
Do you have difficulty…							
…Reading text in newspapers?	1.36±0.76	4	4	16	76	0	0.801
	1.41±0.78	5	5	18	73	0	
…Recognizing the faces of people you meet?	1.36±0.99	12	0	0	88	0	0.097
	1.00±0.00	0	0	0	100	0	
…Seeing the prices of goods when shopping?	1.08±0.28	0	0	8	92	0	0.143
	1.36±0.77	5	5	14	77	0	
…Seeing to walk on uneven surfaces?	1.12±0.60	4	0	0	96	0	0.348
	1.00±0.00	0	0	0	100	0	
…Seeing to do handicrafts, woodwork etc.?	1.44±0.82	4	8	16	72	0	0.119
	1.14±0.69	0	9	5	77	0	
…Reading subtitles on TV?	1.20±0.65	4	0	8	88	0	0.854
	1.23±0.60	0	9	5	86	0	
…Seeing to engage in an activity/hobby?	1.44±0.92	4	4	12	80	0	0.015
	1.00±0.00	0	0	0	100	0	

Notes: For each item, upper row corresponds to Spanish group answers, and lower row for the Taiwanese group. Response coding: R1 (Yes, extreme difficulty), R2 (Yes, great difficulty), R3 (Yes, some difficulty), R4 (No, no difficulty), R5 (Cannot decide) for difficulties and R1 (very unsatisfied), R2 (fairly unsatisfied), R3 (fairly satisfied), R4 (very satisfied), R5 (Cannot decide). SD: standard deviation.

(56%). Over half experienced halos often, though only 16% found them very bothersome. The trifocal IOL delivered excellent multi-distance vision, high satisfaction and strong spectacle independence.

Tañá-Rivero et al[9] assessed 25 patients bilaterally implanted with the Asqelio trifocal IOL at 6 months. Photopic contrast sensitivity (85 cd/m^2) was normal or above without glare and slightly below normal with glare; mesopic sensitivity (3 cd/m^2) remained within or above norms except at 12 cpd with glare. Glare significantly reduced binocular sensitivity across all spatial frequencies ($p < 0.05$). On Catquest-9SF, 88% were satisfied/very satisfied, with no reported difficulty in daily tasks. Visual-symptoms scores showed no notable issues in frequency, intensity, or bothersomeness. The authors conclude this trifocal IOL delivers strong contrast sensitivity in bright and dim light and high patient satisfaction with minimal visual disturbances.

Tañá-Sanz et al[10] evaluated 24 bilaterally implanted Asqelio trifocal IOL patients at 6 months. Mean binocular photopic CDVA, CDIVA (60 cm), CDNVA (40 cm) and mesopic CDNVA were −0.01, 0.03, 0.02 and 0.19 logMAR. All eyes achieved CDVA/CDNVA ≥ 20/25 and CDIVA ≥ 20/32; absolute DOF averaged 4.50 D and mean SE was +0.05 ± 0.30 D (93.75% within ±0.50 D). Contrast sensitivity stayed within normal limits except at 12 cpd under mesopic glare. On Catquest-9SF, 87.5% were satisfied and most reported no difficulty with daily activities. Although 33% experienced halos often, only 17% found them bothersome. Overall, the trifocal IOL delivered excellent multi-distance vision and high patient satisfaction.

Tañá-Sanz et al[11] evaluated 30 patients with the Asqelio trifocal toric IOL at 3 months. Mean binocular photopic CDVA, CDIVA (60 cm), CDNVA (40 cm) and mesopic CDNVA were –0.04 ± 0.06, 0.02 ± 0.08, 0.02 ± 0.07 and 0.22 ± 0.11 logMAR. All eyes achieved ≥20/25 CDVA and ≥20/32 CDIVA/CDNVA; DOF was 3.25 D. Mean SE was –0.08 ± 0.26 D (95% within ±0.50 D), cylinder –0.22 ± 0.27 D (91.7% ≤ 0.50 D). Rotation averaged 0.25 ± 0.65° (<5° in all), contrast sensitivity remained normal, and 96.7% of patients were satisfied with minimal visual symptoms.

All these studies were carried out on European populations, consistently describe refractive predictability, very good visual acuity across distances, and high patient satisfaction, particularly at intermediate and near ranges, and no direct comparative analysis with Asian populations has been reported until now. When comparing the present results with these reports, the Spanish cohort in this study shows outcomes that are consistent with previously published European data. The findings here reported suggest that this IOL provides a satisfactory range of vision across both cohorts. Nevertheless, the Taiwanese cohort demonstrated slightly higher residual astigmatism and marginally reduced acuity at certain focal points, but overall followed the same performance pattern as the European studies, indicating that the optical behaviour of this lens remains stable across different anatomical and biometric characteristics.

One of the observations in this study is the higher mean residual astigmatism found in the Taiwanese cohort relative to the Spanish group. Several factors may explain this outcome, including differences in incision size (2.65 mm vs 2.2 mm) and phacoemulsification devices used (Centurion® or Infiniti® vs Centurion® alone). Although these surgical differences allowed each site to follow its standard clinical practice, they likely contributed to the between-group disparity in residual cylinder. Future studies might incorporate a more standardized surgical protocol or analyze surgically induced astigmatism to better understand the precise role of incision size and phaco machine selection.

One difference between groups that must be addressed is the type of intraocular lens implanted in each cohort: a clear IOL (TFLIO130C) in Spain versus a blue-light–filtering IOL (TFLIO130Y) in Taiwan. While neither group reported any lens-related difficulty, the possibility that the yellow tint contributed subtly to the overall disparity between groups could be considered. However, extensive evidence indicates that visual performance is largely unaffected by the presence of a yellow tint, suggesting that any influence of this difference is likely minimal.[20–23]

A further important consideration is the use of Landolt C charts to measure visual acuities and defocus curves in both cohorts. This choice was made to ensure a culturally neutral test for the Taiwanese patients, where some patients may be less familiar with the Roman letters employed by standard EDTRS charts. Although this strategy minimizes bias arising from alphabet recognition, it also makes direct comparisons with all the published studies aforementioned difficult. Indeed, there is evidence suggesting that Landolt C charts can yield slightly lower acuity values than EDTRS charts,[24,25] with differences of up to approximately one logMAR line.

Tañá-Rivero et al[12] compared monocular defocus curves in 49 Asqelio trifocal IOL eyes at 6 months using ETDRS versus Landolt C charts. ETDRS charts yielded significantly better through-focus acuity; Landolt C charts underestimated performance. Thus, although within-study comparisons remain valid, absolute logMAR values here should not be directly compared to ETDRS-based studies due to this methodological discrepancy. Investigators interpreting our results should bear in mind this methodological discrepancy.

Cerviño et al[6] measured the optical quality of this lens in vitro using an optical bench and the effect of decentration on the MTF. They showed that there was a slight effect in this metric with decentration (being robust to small decentrations, for 0.25 mm), being greater as decentration level increases, but the DOF provided by the trifocal lens was preserved. In a recent study identifying risk factors associated with IOL decentration after cataract surgery a mean IOL decentration magnitude after uneventful phacoemulsification reported was 0.27±0.15 mm.[26] Then, taken into account this mean value and the robustness in the MTF of the Asqelio trifocal lens, we may argue that this lens can provide good visual quality when implanted. This is correlated with the clinical outcomes found in both populations studied here.

Interestingly, although one group showed marginally better clinical results (less astigmatism or slightly sharper acuity), patient-reported outcomes did not reflect these differences, echoing earlier studies. This gap implies that satisfaction depends on more than clinical metrics, factors like lifestyle expectations, visual demands, and tolerance for minor disturbances, highlighting the importance of gathering patient feedback.

Regarding patient-reported outcomes, this study provides one of the first comparisons of satisfaction with this trifocal lens across populations with distinct cultural backgrounds. While no prior studies have evaluated the Asqelio trifocal IOL outside Europe, investigations of other multifocal and trifocal IOLs in diverse geographic settings have shown that cultural differences, personality, visual demands, lifestyle habits, and tolerance to visual phenomena can significantly influence subjective satisfaction independently of objective clinical outcomes.[27,28] The pattern observed in this study, where the Taiwanese group reported equal or greater satisfaction despite slightly less favourable refractive and visual results, is consistent with these broader findings. Incorporating this context helps explain the divergence between

objective measurements and subjective satisfaction and underscores the importance of evaluating patient-reported outcomes when assessing presbyopia-correcting technologies in diverse populations.

This study has several strengths, including its bilateral implantation design, the use of identical protocols across two culturally and anatomically distinct populations, and the comprehensive assessment of both objective visual performance and patient-reported outcomes. Nonetheless, some limitations should be acknowledged. Monocular analyses were conducted using standard independent-samples methods despite the inclusion of both eyes, which may introduce within-subject correlation; however, this does not affect the interpretation of our primary endpoints, which were inherently binocular. Differences in surgical technique between centers, as well as the use of clear versus blue-filter IOL models, may also have contributed to some between-group variability. Finally, cultural and lifestyle differences between the two populations may influence subjective satisfaction independently of objective outcomes, an aspect that deserves further exploration in future studies.

In conclusion, our study shows that the Asqelio Trifocal IOL provides favorable visual and refractive outcomes in both Asian and European populations. The present findings offer valuable insights into the performance of a bi-aspheric trifocal diffractive IOL in diverse patient populations and highlight areas for further investigation to optimize refractive outcomes and patient satisfaction. Future research might also explore the toric model of this IOL in populations with higher astigmatism, and include a broader range of patient-reported outcome measures to capture differences in lifestyle and visual expectations across diverse cultures.

Data Sharing Statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Ethical Statement

This study was conducted in accordance with the principles of the Declaration of Helsinki and its subsequent amendments. The data analyzed in this manuscript were derived from two previously approved clinical studies. The first study was reviewed and approved by the CEIm Hospital Clínico San Carlos (approval number: 21/592-O_P), and the second study was reviewed and approved by the Chang Gung Memorial Hospital IRB (approval number: 202100157A3).

The current analysis used anonymized data and did not require additional ethical approval.

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Disclosure

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