Visual Outcomes Following Bilateral Implantation of Two Diffractive Trifocal Intraocular Lenses in 10 084 Eyes

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• PURPOSE: To investigate refractive and visual acuity outcomes, patient satisfaction, and spectacle independence at 3 months of 2 diffractive (non-toric) trifocal intraocular lenses (IOLs) in a large series of patients.

• DESIGN: Multicenter, retrospective, nonrandomized clinical study.

• METHODS: Patients underwent lens phacoemulsification and were implanted bilaterally with a diffractive trifocal IOL: FineVision Micro F (PhysIOL SA, Liège, Belgium) or AT Lisa tri 839MP (Carl Zeiss AG, Jena, Germany). Surgeries were performed between 2011 and 2015 with at least 3 months of follow-up. Visual and refractive performance, patient satisfaction, and spectacle independence were evaluated.

• RESULTS: A total of 10 084 trifocal IOLs were bilaterally implanted (5802 FineVision in 2901 patients and 4282 AT Lisa in 2141 patients). Three-month mean (± standard deviation) acuity: AT Lisa, binocular uncorrected distance visual acuity (UDVA), −0.01 logMAR ± 0.06; monocular distance corrected visual acuity (CDVA), 0.02 logMAR ± 0.06; binocular uncorrected near visual acuity (UNVA) at 40 cm, 0.05 logMAR ± 0.08; binocular uncorrected intermediate visual acuity (UIVA) at 80 cm, −0.05 logMAR ± 0.14; postoperative spherical equivalent, 0.26 D ± 0.47; cylinder −0.34 D ± 0.38; FineVision Micro F, binocular UDVA, 0.01 logMAR ± 0.05; monocular CDVA, 0.03 logMAR ± 0.06; binocular UNVA, 0.05 logMAR ± 0.08; binocular UIVA, −0.05 logMAR ± 0.12; spherical equivalent, 0.34 D ± 0.50; cylinder −0.39 D ± 0.40. The IOLs were equivalent in achieving spectacle independence; 98% were "satisfied" to "very satisfied" with their IOL performance.

• CONCLUSIONS: In this retrospective study with over 5000 patients, implantation of both trifocal IOL models provided good functional distance, intermediate, and near visual acuity, resulting in high levels of both spectacle independence and patient satisfaction. (Am J Ophthalmol 2017;179:55–66. © 2017 Elsevier Inc. All rights reserved.)

DIFFERENT MULTIFOCAL INTRAOCULAR LENS (MIOL) designs have been used for more than 25 years.[1] Unlike conventional monofocal intraocular lenses (IOLs), which bend light to a single focus point on the retina, MIOLs are designed to help patients to see at varying distances using different points of focus. MIOLs used in clinical practice were either refractive initially, or later diffractive in their optical design. Refractive MIOLs incorporate a lens optic with different optical powers in different parts of the lens, whereas diffractive MIOLs use diffractive steps on the lens to distribute light rays into 2 or more principal foci. Irrespective of the design type, however, all MIOLs involve some form of optical compromise and a process of neuroadaptation for the patient.[2]

Most first-generation multifocal implants incorporated +4.0 diopters (D) addition at the lens plane to minimize the risk of diplopia resulting from the superimposition of simultaneous sharp and defocused images, while still enabling useful near vision. More recently, the introduction of lower near additions in the range of +2.5 D to +3.0 D, and mix-and-match strategies with different near additions, attempted to increase visual acuity at an intermediate distance.[3,4] This improvement in optic lens design, however, has not been sufficient to provide satisfactory intermediate vision for all patients implanted with these bifocal IOLs,[5] prompting manufacturers to develop a new concept—trifocal MIOLs—in an effort to improve quality of vision at all distances. The 3 foci generated by these lenses are obtained by combining 2 bifocal diffractive profiles in 1 surface of the IOL[6] or by using a trifocal diffractive profile combined with a bifocal diffractive optic.[7] Initial studies of trifocal lenses have validated the ability of the eye to use the intermediate focus regardless of lighting conditions and deliver good visual and refractive outcomes.[8–15] For instance, Jonker and associates reported an improvement in intermediate vision obtained with a trifocal lens compared to a reference bifocal implant.[16] Another study correlating optical bench performance with clinical defocus curves in

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Subjective evaluation at discharge of patient with multifocal IOL

1. What was your lifestyle before the TT?

SCORE	3	2	1
Driving:	◯ I used to drive long distances at night	◯ I used to drive at night in the city	◯ I didn't drive frequently at night
Computer:	◯ I used more than 2 hours a day	◯ I used it between 1 and 2 hours a day	◯ I used it less than 1 hour a day
Reading:	◯ I read more than 2 hours a day	◯ I read between 1 and 2 hours a day	◯ I read less than 1 hour a day

2. Evaluate your vision after the treatment

	Very bad	Bad	Medium	Good	Very good
SCORE	1	2	3	4	5
Distant vision	◯	◯	◯	◯	◯
Intermediate Vision (computer)	◯	◯	◯	◯	◯
Near vision (reading)	◯	◯	◯	◯	◯

3. Evaluate your night driving after the treatment

	SCORE
◯ Night driving is the same or better than before treatment	4
◯ Night driving is worse than before treatment but it is not a problem for me	3
◯ Night driving is much worse than before treatment and I feel unsafe	2
◯ I have stopped driving because I don't feel safe	1

4. Evaluate your vision at night after the treatment

	SCORE
◯ Night vision is the same or better than before treatment	3
◯ Night vision is worse than before treatment	2
◯ Night vision is much worse than before treatment	1

5. Do you still depend on glasses after the treatment?

	Never	Sometimes	Nearly Always
SCORE	3	2	1
I use glasses for distant vision	◯	◯	◯
I use glasses for intermediate vision (computer)	◯	◯	◯
I use glasses for near vision (reading)	◯	◯	◯

6. Considering all the items related to the treatment, as a general conclusion you feel:

	SCORE
◯ Very satisfied with the result	4
◯ Satisfied with the result	3
◯ Less satisfied with the result	2
◯ Unsatisfied with the result	1

7. Would you repeat the treatment with the same procedure?

◯ Yes
◯ No

FIGURE 1. Questionnaire that was given to the patient, with the scores attributed marked in red.

FIGURE 2. AT Lisa tri 839MP intraocular lens.

FIGURE 3. FineVision Micro F intraocular lens.

varifocal and trifocal intraocular lenses showed inferior results for a trifocal IOL compared with a bifocal rotationally asymmetric refractive implant, but noted that the results were nevertheless satisfactory.[17] These outcomes were somewhat inconsistent with the results of a previously published study of defocus curves by Wolffsohn and associates.[18] Recently, findings from our own research group also showed that bilateral implantation of trifocal IOLs provided a better range of visual acuities at near and intermediate distances with better defocus curve profiles than mix-and-match bifocal IOLs.[19] Finally, a clinical trial comparing the FineVision Micro F and AT Lisa tri 839MP IOLs in 30 patients who underwent bilateral implantation with the same lens found that both trifocal MIOLs were associated with excellent distance, intermediate, and near visual outcomes at 3 months.[20]

Nevertheless, despite the very good results obtained with the latest generation of MIOLs, many surgeons remain reluctant to implant these lenses. Visual symptoms such as glare and haloes, reduced contrast sensitivity, and night vision problems are all known complications of multifocal implants and have served to hamper wider acceptance of these IOLs.[21]

This paper explores the retrospective analysis of over 10 000 trifocal implantations performed in the Baviera Clinics in Spain, since the first trifocal IOL was implanted in 2011 by our group.

METHODS

IN THIS MULTICENTER, MULTISURGEON STUDY, DATA WERE analyzed from patients who underwent clear lens or cataract surgery and implantation with 1 of 2 trifocal IOLs: the FineVision Micro F (PhysIOL SA, Liège, Belgium) or the AT Lisa tri 839MP (Carl Zeiss AG, Jena, Germany). The study was performed in accordance with the principles of the Declaration of Helsinki. Institutional review board approval was obtained from the Clínica Baviera medicolegal committee prior to study commencement.

Patients underwent surgery in any of the 24 surgical centers of Clínica Baviera, Spain, by 47 different experienced surgeons, using the same surgical protocol, instruments, and devices. Each surgical center implanted 1 or both types of non-toric trifocal IOL. Preoperatively, patients received detailed information regarding the surgical procedure and vision concerns after trifocal IOL implantation, and provided written consent for their surgical procedure and for anonymous medical records and data revision for investigation purposes. All surgeries took place between October 2011 and May 2015, and only patients with at least 3 months of follow-up were included in the analysis. Eyes with any significant intraoperative or postoperative complication not related to the IOL were excluded from the analysis. Data were recorded from the central

TABLE 1. Average Age and Proportion per Sex of Patients for Each Study Group Implanted With 1 of 2 Diffractive Trifocal Intraocular Lenses

	IOL		
	AT Lisa[a] (N = 4282 Patients)	FineVision[b] (N = 5802 Patients)	*P* Value
Age (y) ± SD (range)	57.74 ± 7.94 (20–85)	57.72 ± 7.95 (23–88)	.895
Sex	61.07% women; 38.93% men	59.10% women; 40.90% men	.046

IOL = intraocular lens.
[a]AT Lisa tri 839 (Carl Zeiss AG, Jena, Germany).
[b]FineVision Micro F (PhysIOL SA, Liège, Belgium).

TABLE 2. Preoperative Mean Keratometry, Selected Intraocular Lens Power, and Axial Length for Each Study Group Implanted With 1 of 2 Diffractive Trifocal Intraocular Lenses

	IOL		
	AT Lisa[a] (N = 4282 Patients)	FineVision[b] (N = 5802 Patients)	*P* Value
K (D) ± SD (range)	43.55 ± 1.5 (37.45–49.5)	43.56 ± 1.47 (37.5–50)	NS, *P* = .743
IOL power (D) ± SD (range)	22.39 ± 4.33 (1.5–32)	23.06 ± 3.79 (10–35)	*P* < .001
Axial length (mm) ± SD (range)	23.1 ± 1.47 (19.36–30.5)	22.92 ± 1.20 (19.5–29.41)	*P* < .001

D = diopter; IOL = intraocular lens; K = keratometry; NS = not significant.
[a]AT Lisa tri 839 (Carl Zeiss AG, Jena, Germany).
[b]FineVision Micro F (PhysIOL SA, Liège, Belgium).

computerized medical file system from Clínica Baviera. The system contains all the medical records and surgical data from all the patients evaluated in Clínica Baviera.

Routine preoperative and postoperative outcomes and complications were collected and analyzed. Patient satisfaction data derived from the Clínica Baviera satisfaction questionnaire were also included.

Inclusion criteria included patients aged 21–70 years who required bilateral cataract or refractive lens exchange, followed by trifocal IOL implantation. Patients were required to have 1.5 D or less of regular preoperative astigmatism determined by autokeratometry. Exclusion criteria were planned multiple refractive procedures, amblyopia, previous corneal surgery, clinically significant corneal endothelial dystrophy (eg, Fuchs dystrophy), history of corneal disease (eg, herpes simplex, herpes zoster keratitis), history of retinal detachment, neuro-ophthalmic disease, pregnancy, and intraoperative or postoperative complications, not related to the IOL design, that may have impaired visual result (eg, intraoperative posterior capsule rupture with anterior vitrectomy, postoperative retinal detachment, or chronic cystoid macular edema).

• **PREOPERATIVE ASSESSMENT:** Preoperatively, all patients had a full ophthalmologic examination including refractive status, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), uncorrected intermediate visual acuity (UIVA) at 80 cm, uncorrected near visual acuity (UNVA) at 40 cm (visual acuities were tested under photopic conditions, at approximately 85 cd/m^2), corneal topography (Orbscan II; Bausch & Lomb, Houston, Texas, USA), slit-lamp and eye fundus evaluation, endothelial cell count analysis (SP 3000P; Topcon, Capelle aan den Ijssel, Netherlands), and optical biometry measurements by partial coherence interferometry (PCI) (IOLMaster; Carl Zeiss Meditec AG, Jena, Germany), and/or immersion ultrasonic biometry (Ocuscan RPX; Alcon). IOL power selection was performed according to the experienced surgeon criteria. The target for all eyes with both types of IOL was emmetropia.

• **SURGERY:** The technique included a 2.75-mm incision in the temporal or steepest meridian, a capsulorrhexis diameter of approximately 5.0 mm, hydrodissection, phacoemulsification, irrigation/aspiration of cortical remnants, IOL implantation in the capsular bag, and intracameral injection of cefuroxime. The side ports were hydrated in all cases; main incisions were hydrated only if necessary. Postoperatively, topical therapy included a combination of antibiotic and steroidal agents (tobramycin 0.3% and dexamethasone

TABLE 3. Visual Acuity and Refractive Outcomes for Each Study Group Implanted With 1 of 2 Diffractive Trifocal Intraocular Lenses

	IOL		
	AT Lisa[a] (N = 4282 Patients)	FineVision[b] (N = 5802 Patients)	*P* Value
Preoperative clinical information			
Monocular UDVA (logMAR), ± SD (range)	0.75 ± 0.55 (0 to 2)	0.72 ± 0.51 (0 to 2)	.006
[Snellen]	[20/125]	[20/100]	
Monocular UIVA (logMAR), ± SD (range)	0.72 ± 0.61 (0 to 2)	0.73 ± 0.45 (0 to 2)	.352
[Snellen]	[20/100]	[20/100]	
Monocular UNVA (logMAR), ± SD (range)	0.71 ± 0.21 (0 to 1.10)	0.72 ± 0.23 (0 to 1.10)	.028
[Snellen]	[20/100]	[20/100]	
Monocular CDVA (logMAR), ± SD (range)	0.16 ± 0.12 (-0.1 to 2)	0.18 ± 0.12 (-0.1 to 2)	<.001
[Snellen]	[20/32]	[20/32]	
Postoperative outcomes at 3 months			
Postoperative follow-up (mo), ± SD (range)	3.18 ± 0.47 (3.03–3.97)	3.29 ± 0.41 (3.03–3.97)	<.001
Monocular UDVA (logMAR), ± SD (range)	0.04 ± 0.08 (-0.15 to 0.70)	0.06 ± 0.08 (-0.10 to 0.82)	<.001
[Snellen]	[20/20]	[20/25]	
Binocular UDVA (logMAR), ± SD (range)	-0.01 ± 0.06 (-0.20 to 0.3)	0.01 ± 0.05 (-0.18 to 0.52)	<.001
[Snellen]	[20/20]	[20/20]	
Monocular UNVA (logMAR), ± SD (range)	0.07 ± 0.10 (0.00 to 0.76)	0.08 ± 0.10 (0.00 to 1.00)	<.001
[Snellen]	[20/25]	[20/25]	
Binocular UNVA (logMAR), ± SD (range)	0.05 ± 0.08 (0.00 to 0.06)	0.05 ± 0.08 (0.00 to 0.76)	1.000
[Snellen]	[20/25]	[20/25]	
Monocular UIVA (logMAR), ± SD (range)	0.00 ± 0.17 (-0.3 to 0.6)	-0.01 ± 0.15 (-0.3 to 0.7)	.002
[Snellen]	[20/20]	[20/10]	
Binocular UIVA (logMAR), ± SD (range)	-0.05 ± 0.14 (-0.3 to 0.7)	-0.05 ± 0.12 (-0.3 to 0.6)	1.000
[Snellen]	[20/16]	[20/16]	
Monocular CDVA (logMAR), ± SD (range)	0.02 ± 0.06 (-0.18 to 0.7)	0.03 ± 0.06 (-0.08 to 0.52)	<.001
[Snellen]	[20/20]	[20/20]	
Spherical equivalent (D), ± SD (range)	0.26 ± 0.47 (-1.25 to 3)	0.34 ± 0.50 (-1.25 to 4.63)	<.001
Cylinder (D), ± SD (range)	-0.34 ± 0.38 (-2.5 to 0)	-0.39 ± 0.40 (-3.25 to 0)	<.001

CDVA = corrected distance visual acuity; D = diopter; IOL = intraocular lens; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity.
[a]AT Lisa tri 839 (Carl Zeiss AG, Jena, Germany).
[b]FineVision Micro F (PhysIOL SA, Liège, Belgium).

0.1% 4 times a day for 1 month and moxifloxacin hydrochloride 0.5% 4 times a day for 1 week). The second eye was operated on within 2 weeks of the initial procedure.

• **POSTOPERATIVE ASSESSMENT:** Patients had a scheduled follow-up assessment within 24 hours of the surgery, and then 5–7 days, 1 month, and 3 months postoperatively. Patients were then discharged and asked to return for routine follow-up visits every year thereafter.

• **PATIENT SATISFACTION QUESTIONNAIRE:** Figure 1 shows the patient satisfaction questionnaire that was used.

• **INTRAOCULAR LENSES:** The FineVision Micro F and AT Lisa tri 839MP are both trifocal IOLs made of 25% hydrophilic acrylic materials.

The AT Lisa tri 839MP is a trifocal, diffractive lens with a +3.33 D near add and +1.66 D intermediate add at the IOL plane. The single-piece plate haptic lens has an overall diameter of 11.0 mm and an optical zone of 6.0 mm. The optical zone is trifocal in the center over 4.34 mm and then bifocal from 4.34 mm to 6 mm. The lens is available in a diopter range from 0.0 to +32.0 D, in 0.5-D increments (Figure 2).

The FineVision Micro F optic combines 2 diffractive structures that are adjusted to offer the +3.5 D addition for near vision and +1.75 D addition for intermediate vision. The single-piece 4-loop haptics lens has a total diameter of 10.75 mm, an optic body diameter of 6.15 mm, and 5 degrees of haptic angulation. By varying the height of the diffractive step, the amount of light distributed to the near, intermediate, and distant foci is adjusted according to the pupil aperture (apodization). The lens is available in spherical powers from +10.0 D to +35.0 D in 0.5-D increments (Figure 3).

• **STATISTICAL ANALYSIS:** The statistical calculations were performed using R software version 3.2.1. Preoperative outcomes were compared with postoperative results using a paired test.

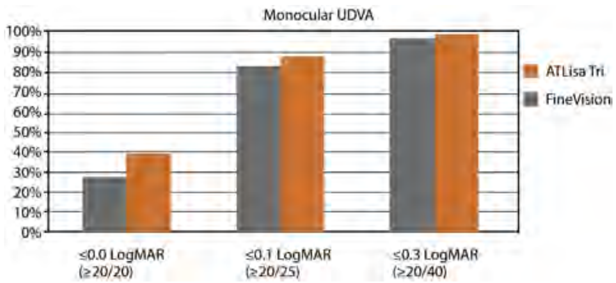

FIGURE 4. Distribution of the postoperative monocular uncorrected distance visual acuity (UDVA) with respect to the chosen intraocular lens.

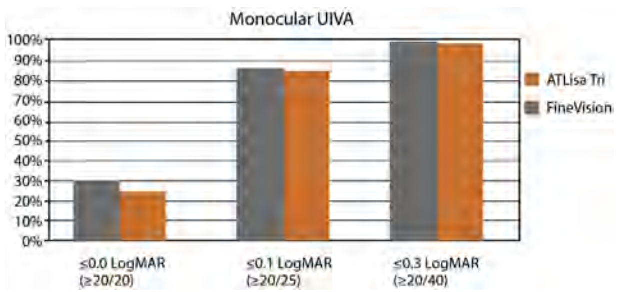

FIGURE 5. Distribution of the postoperative monocular uncorrected intermediate visual acuity (UIVA) with respect to the chosen intraocular lens.

Age, sex, and IOL power were compared between groups. The normality of the cohorts was tested with a Kolmogorov-Smirnov test. Fisher exact test was used to assess the sex balance of the 2 IOL groups (AT Lisa and FineVision). Age difference and lens power difference were assessed using *t* test for equal variances.

To compare outcomes before and after surgery of each group, normality was first tested using the Kolmogorov-Smirnov test. When normality was not achieved, a nonparametric test—the Wilcoxon rank sum test—was used for paired data.

The same methods were used to compare outcomes before and after surgery between groups. The results are expressed as the mean ± standard deviation. A P value of less than .05 was considered statistically significant.

RESULTS

A TOTAL OF 10 256 TRIFOCAL IOLS WERE UNEVENTFULLY implanted between May 2011 and May 2015. Of these, 10 084 trifocal IOLs of 5048 patients (5802 FineVision IOLs and 4282 AT Lisa tri IOLs) completed 3 months of follow-up and were eligible for inclusion in the analysis (86 patients were excluded from the study; 42 had incomplete data recording and 44 failed to complete at least 3 months of follow-up). The age and sex of the groups are shown in Table 1. Their distributions were similar in both groups of IOLs, with a majority of women and a relatively young mean age for a lens surgery series, explained by the fact that many patients received intervention primarily for refractive purposes rather than for age-related cataracts.

The mean keratometry, the selected IOL power, and the axial length in both groups of IOLs are presented in Table 2.

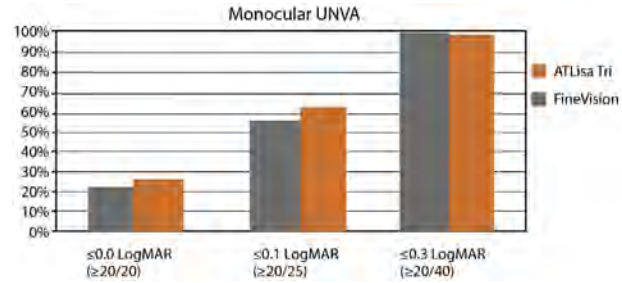

FIGURE 6. Distribution of the postoperative monocular uncorrected near visual acuity (UNVA) with respect to the chosen intraocular lens.

• **VISUAL ACUITY AND REFRACTIVE OUTCOMES:** Visual outcomes available at 3 months postoperatively are shown in Table 3. Patients had significantly better mean uncorrected visual acuities at all distances and CDVA after surgery compared with preoperative values.

Postoperative spherical equivalent and cylinder were minimally lower with AT Lisa tri than with FineVision. Postoperative uncorrected visual acuities were thus significantly better, albeit only marginally, with the AT Lisa tri at far (both monocularly and binocularly) and at near (only monocularly). Intermediate monocular visual acuity was marginally but significantly better with the FineVision, whereas intermediate binocular visual acuity did not show any significant difference between groups.

Figures 4, 5, and 6 show the distribution of the uncorrected visual outcomes at far, intermediate, and near vision distance, respectively. Uncorrected monocular visual acuity was 20/40 or better (≤0.3 logMAR) at 4 m, 80 cm, and 40 cm, respectively, in 98%, 98%, and 98% of eyes implanted with AT Lisa Tri and in 96%, 99%, and 99% of eyes implanted with FineVision Micro F.

Uncorrected monocular visual acuity was 20/25 or better (≤0.1 logMAR) at 4 m, 80 cm, and 40 cm, respectively, in 87%, 83%, and 62% of eyes implanted with AT Lisa Tri and in 83%, 86%, and 57% of eyes implanted with FineVision Micro F.

• **SUBJECTIVE OUTCOMES:** The outcomes to the questionnaire are shown in Table 4. Overall, the FineVision MIOL

TABLE 4. Outcomes of Patient Satisfaction Questionnaire After Bilateral Implantation With 1 of 2 Diffractive Trifocal Intraocular Lenses

	IOL		
	AT Lisa[a] (N = 4282 Patients)	FineVision[b] (N = 5802 Patients)	*P* Value
Q1 (Driving): Which was your lifestyle before treatment?	2281 eyes	3595 eyes	NS W = 4657800, *P* = .951
I used to drive for long distance	46.47%	45.54%	
I used to drive in the city	28.87%	26.87%	
I did not drive frequently at night	24.66%	27.59%	
Q1 (Computer): Which was your lifestyle before treatment?	2132 eyes	3821 eyes	A<F W = 4518600, *P* = .042
I used it less than 1 hour a day	42.78%	39.99%	
I used it between 1 and 2 hours a day	23.17%	24.79%	
I used it more than 2 hours a day	34.05%	35.22%	
Q1 (Reading): Which was your lifestyle before treatment?	2333 eyes	3623 eyes	NS W = 4566600, *P* = .181
I read less than 1 hour a day	48.66%	45.07%	
I read between 1 and 2 hours a day	29.86%	34.00%	
I read more than 2 hours a day	21.48%	20.94%	
Q2 (Distance vision): Evaluate your vision after treatment	2333 eyes	3939 eyes	A>F W = 4899100, *P* < .001
Very bad	0.43%	0.36%	
Bad	1.29%	0.56%	
Medium	6%	8.63%	
Good	48.18%	51.41%	
Very good	44.11%	39.05%	
Q2 (Intermediate vision): Evaluate your vision after treatment (Intermediate vision) (Computer)	2253 eyes	3849 eyes	NS W = 4777100, *P* = .051
Very bad	0.44%	0.47%	
Bad	0.80%	0.62%	
Medium	5.42%	7.01%	
Good	49.00%	51.36%	
Very good	44.34%	40.53%	
Q2 (Near vision): Evaluate your vision after treatment (Near vision) (Reading a book)	2299 eyes	3895 eyes	NS W = 4671200, *P* = .782
Very bad	1.22%	0.72%	
Bad	0.78%	0.87%	
Medium	7.79%	7.19%	
Good	37.76%	40.44%	
Very good	52.46%	50.78%	
Q3: Evaluate your night driving after treatment	2054 eyes	3306 eyes	A>F W = 4793100, *P* = .03
Night driving is better than or the same as before treatment	58.23%	59.17%	
Night driving is worse than before treatment but this is not a problem for me	33.11%	32.97%	
Night driving is much worse than before treatment and I feel unsafe	6.33%	5.75%	
I have stopped driving because I don't feel safe	2.34%	2.12%	
Q4: Evaluate your night vision after treatment	2271 eyes	3839 eyes	NS W = 4737000, *P* = .141

Continued on next page

TABLE 4. Outcomes of Patient Satisfaction Questionnaire After Bilateral Implantation With 1 of 2 Diffractive Trifocal Intraocular Lenses (*Continued*)

	IOL		
	AT Lisa[a] (N = 4282 Patients)	FineVision[b] (N = 5802 Patients)	*P* Value
Night vision is the same as or better than before treatment	72.88%	70.46%	
Night vision is worse than before treatment	24.75%	27.35%	
Night vision is much worse than before treatment	2.38%	2.19%	
Q5 (Distance): Do you still depend on glasses after treatment for distance vision?	2305 eyes	3884 eyes	A<F W = 4612500, *P* = .04
Never	98.52%	99.38%	
Sometimes	0.95%	0.46%	
Always	0.52%	0.15%	
Q5 (Intermediate): Do you still depend on glasses after treatment for intermediate vision?	2257	3832	NS W = 4625300, *P* = .291
Never	98.32%	98.12%	
Sometimes	1.06%	1.46%	
Always	0.62%	0.42%	
Q5 (Near): Do you still depend on glasses after treatment for near vision?	2273	3841	A<F W = 4534400, *P* < .001
Never	92.48%	94.85%	
Sometimes	5.94%	4.17%	
Always	1.58%	0.99%	
Q6 General evaluation	2339	3941	A>F W = 4951200, *P* < .001
Very satisfied with the result	66.78%	60.19%	
Satisfied with the result	31.47%	37.99%0	
Less satisfied with the result	1.75%	1.42%	
Unsatisfied with the result	0.00%	0.41%	
Q6: Would you have surgery again?	2333	3926	A>F W = 4714500, *P* = .006
Yes	98.07%	96.82%	
No	1.93%	3.17%	

IOL = intraocular lens; NS = non significant.
[a]AT Lisa (A) tri 839 (Carl Zeiss AG, Jena, Germany).
[b]FineVision Micro F (PhysIOL SA, Liège, Belgium).

offered higher spectacle independence, whereas the AT Lisa tri scored higher for overall patient satisfaction.

DISCUSSION

THIS RETROSPECTIVE STUDY OF A LARGE SERIES OF PAtients demonstrated that in terms of visual outcomes, the AT Lisa tri 839MP and the FineVision Micro F were equivalent in achieving spectacle independence after lens phacoemulsification. Both IOLs provided excellent distance, intermediate, and near visual outcomes. Although the AT Lisa tri demonstrated slightly better refractive outcomes, this could perhaps be explained by the use of initially better optimized A-constants with the AT Lisa tri (previous experience with the same plate-haptic platform with a bifocal model) than the FineVision lens (with a relatively newer tetraloop platform design).

Regarding biometric parameters, although the mean axial length of eyes implanted with FineVision was significantly shorter, and thus mean IOL implanted power was significantly higher, the differences were clinically irrelevant. This could be explained by the larger power range available for low diopters with the AT Lisa tri IOL model, and the larger range available for high diopters with the

TABLE 5. Summary From Published Studies of the Effectiveness of the FineVision Micro F (PhysIOL SA, Liège, Belgium) Diffractive Trifocal Intraocular Lens

	Binocular LogMAR Visual Acuities					
	Eyes (N)	CDVA	DCIVA	DCNVA	20/40 or Better (≤0.3 LogMAR)	20/25 or Better (≤0.1 LogMAR)
Lesieur[24]	20	0.00 ± 0.01	P2.29 ± 0.49[a]	P1.8 ± 0.261[a]	100% (CDVA)	87% (CDVA)
Vryghem et al[11]	50	-0.07 ± 0.08	-0.13 ± 0.14	0.02 ± 0.05		
Sheppard et al[10]	30	0.06 ± 0.08				
Alió et al[12]	40	0.05 ± 0.06	0.17 ± 0.09	0.16 ± 0.13		
Cochener et al[8]	94	0.01 ± 0.07	0.06 ± 0.08	0.00 ± 0.03	100% for CDVA and DCNVA, >95% DCIVA	>90% for CDVA and DCNVA, >70% DCIVA
Marques et al[9]	20	-0.02 ± 0.07	0.04 ± 0.07	0.03 ± 0.06	100% for CDVA and DCNVA, 97% DCIVA	97% CDVA, 93% DCNVA, 67% DCIVA
Carballo-Alvarez et al[25]	44	-0.05 ± 0.05	0.15 ± 0.1	0.06+0.10		
Kretz et al[14]	28	-0.08 ± 0.077	0.048 ± 0.152	0.03 ± 0.165	100% for CDVA, UNVA, UIVA	100% CDVA, 77% UNVA and 49% UIVA
Cancino et al[26]	66	0.00 ± 0.01	0.01 ± 0.04			
Moyal et al[27]	16	0.00 ± 0.07	0.06 ± 0.06			

CDVA = corrected distance visual acuity; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity.

[a]Parinaud optotest. P2 is equivalent to Jaeger 1, P3 is equivalent to Jaeger 2.

FineVision IOL. Although this is a possible bias, we consider that this fact should not alter considerably the main outcomes of the study; the proportion of implanted lenses out of the common range of IOL power (from 10 to 32 D) for both lenses is very low: only 81 of 5082 eyes (1.4%) implanted with PhysIOL's Micro F had a power lens larger than 32 D, and only 52 eyes of 4282 (1.2%) implanted with the AT Lisa tri had a power lens below 10 D. These numbers, among such a substantial series of 10 084 eyes, could justify the statistical differences reported, but should not significantly bias the results.

In this series of over 10 000 eyes, a very high percentage (98%) of patients stated that they were "satisfied" to "very satisfied" with the performance of their implanted trifocal IOL. There were very few dissatisfied patients and a low incidence of complaints relating to dysphotopic phenomena such as glare, haloes, or ghost images that are commonly found with MIOLs.

Although reported night vision was not optimal, the majority of patients did not identify it as crucial and gave far more emphasis to spectacle independence obtained with the surgical procedure. Before the implantation of a trifocal IOL a very thorough and honest discussion with the patient should be carried out, focusing specially on the drawbacks of this technology. This includes a certain worsening in night vision quality, especially in patients without significant cataracts. In fact, coach or truck drivers, or professionals who would need accurate and prolonged night vision, should be clearly advised against receiving this type of implant. Realistic expectations being given to the patient in preoperative assessment is one of the keys to success with any type of multifocal IOL. This approach could explain why although around 40%-42% of our patients reported a worsening in night driving vision 3 months after the surgery, this was a problem for only 6%, and exclusively 2% of the patients had to stop driving, with similar scores obtained for both types of trifocal lenses.

Issues of dry eye and lack of comfort with the lens in mesopic conditions were identified as the principal causes of dissatisfaction among those patients who said they were less satisfied or dissatisfied with their implants.

Several papers have now been published in the scientific literature that explain and assess the underlying optical outcomes of multifocal (bifocal and trifocal) IOLs.[6,8–12,14,15,22–28] The outcomes published with the FineVision Micro F and the AT Lisa tri IOLs are listed in Tables 5 and 6, respectively. As noted in the introduction, the clinical outcomes of all of these studies confirmed the ability of the human eye to use the 3 available foci of these new lens designs. The results of this series of over 5000 patients add further weight to this evidence.

To the best of our knowledge, this is the first study to amass such substantial data in such a large series of patients, not just for trifocal IOLs but for multifocal lenses in general.

The current study clearly has limitations. First, it is retrospective and was restricted to an analysis of available cases with completed follow-up. Second, the study also included data gathered from multiple surgical centers (n = 24) with different surgeons (n = 47) and many different technicians who performed visual acuity measurements. However, surgeons and optometrists followed the same protocols for patient management and a large number of cases were included in this analysis, which should (to some degree) compensate for these variations. Follow-up was limited to 3 months because that is when patients are usually discharged after an uneventful procedure. As a retrospective and multicenter study, this series does have the known limitations of selection bias between groups in the conditions of patients, in the type of implanted IOL that was not randomized, and in the lack of some data for some patient satisfaction surveys. Furthermore, the satisfaction questionnaire was a nonvalidated model, and more sophisticated functional visual tests such as contrast sensitivity evaluation or defocus curves were not considered as a result of the large patient sample studied. Nevertheless, it is a very large series, and the authors believe that if any bias exists this would be the same for both groups, and that therefore the study outcomes are reliable. The demonstrated results helped us, as a large refractive surgery group, in the decision to shift from bifocality to trifocality with our MIOL implanted patients. By the end of 2016, more than 34 000 trifocal IOLs had been implanted in Clinica Baviera in Spain.

Overall, the data may go some way toward reassuring surgeons of the consistently high refractive and visual acuity outcomes that can be obtained with the latest-generation trifocal IOLs. For patients who request spectacle independence after cataract surgery, trifocal lenses offer a very high chance of achieving that goal. In this study, over 98% of patients achieved spectacle independence for both distance and intermediate vision, and over 92% never used glasses for near vision.

Comparing the visual performance of the 2 trifocal IOLs in this study, both designs provided very good distance, intermediate, and near visual outcomes in lens surgery patients. Although there was a statistically significant difference in the visual acuity scores, the difference was 0.01 logMAR, which is clinically insignificant. Other recent studies have found similar results. Carson[29] and Ruiz Alcocer,[30] for instance, showed very little difference between the IOLs in optical bench performance, and Marques and associates reported that both trifocal IOLs provided comparable distance, intermediate, and near vision in a clinical setting.[9] With this in mind, the decision to choose one IOL over another may depend on other criteria such as surgeon preferences, patient-specific factors, or posterior capsule opacification scores, rather than just refractive or visual acuity outcomes. Regarding this issue, in a recently published study from our research group, eyes implanted with the FineVision Micro F IOL required significantly fewer neodymium–yttrium-aluminum-garnet capsulotomies than those with the AT Lisa tri 839MP

TABLE 6. Summary From Published Studies of the Effectiveness of the AT Lisa tri 839 (Carl Zeiss AG, Jena, Germany) Diffractive Trifocal Intraocular Lens

		Binocular LogMAR Visual Acuities							
	Eyes (N)	UDVA	CDVA	UIVA	DCIVA	UNVA	DCNVA	20/40 or Better (≤0.3 LogMAR)	20/25 or Better (≤0.1 LogMAR)
Kretz et al[15a]	76	0.05		0.05		0.05			100% for UDVA, UIVA, and UNVA
Mendicute et al[28]	208	0.03 ± 0.09		0.10 ± 0.15		0.15 ± 0.14		99% for UDVA, 98% for UIVA, and >92% UNVA	100% (CDVA), 77% UNVA, and 49% UIVA
Marques et al[9]	30	0.00 ± 0.01	−0.03 ± 0.04	0.13 ± 0.42	0.09 ± 0.04	0.13 ± 0.05	0.05 ± 0.04	97% for UDVA and UIVA and 100% for UNVA	100% UDVA, 50% for UIVA, and 67% for UNVA

CDVA = corrected distance visual acuity; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity.

[a]No SD values given in the Kretz paper.

during the first years after implantation (14% vs 35%, respectively), after 3–4 years of follow-up.[31] As Coleman noted, the ability to track patient outcomes in "big data" studies provides a welcome opportunity for further research arising from cataract surgery.[32] In this study of over 10 000 cases with 47 different surgeons, similar outcomes to smaller cohorts could be demonstrated in terms of efficacy, indicating that implantation of trifocal IOLs provides very high levels of spectacle independence and patient satisfaction after lens surgery.

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