

Visual outcomes and patient satisfaction in refractive lens exchange with trifocal intraocular lens in presbyopic hyperopia, emmetropia, and myopia

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Purpose: To compare visual and refractive outcomes and visual function after bilateral refractive lens exchange (RLE) with a trifocal intraocular lens (IOL) in myopic, hyperopic, and emmetropic eyes with presbyopia. **Study Design:** Retrospective comparative case series. **Methods:** Charts of presbyopic patients who underwent RLE with implantation of RayOne Trifocal IOL were retrospectively reviewed. Visual and refractive outcomes were evaluated at 3 months. Patient satisfaction, spectacle independence, and visual disturbance were assessed by patient reported outcomes measures (PROMs) questionnaires. **Results:** A total of 6788 eyes were classified into refractive groups. Mean ($\pm$ standard deviation) visual acuity (logMAR) at 3 months: Group A (emmetropic), binocular uncorrected distance visual acuity (UDVA), 0.01 ± 0.11 ; monocular corrected distance visual acuity (CDVA), 0.01 ± 0.03 ; binocular uncorrected near visual acuity (UNVA) at 40 cm, 0.08 ± 0.07 ; binocular uncorrected intermediate visual acuity (UIVA) at 66 cm, 0.12 ± 0.11 ; postoperative spherical equivalent (SE) (diopters (D)), -0.05 ± 0.29 . Group B (myopic), binocular UDVA, 0.03 ± 0.23 ; monocular CDVA, 0.01 ± 0.02 ; binocular UNVA, 0.07 ± 0.07 ; binocular UIVA, 0.12 ± 0.08 ; SE, -0.05 ± 0.52 . Group C (hyperopic), binocular UDVA, 0.00 ± 0.03 ; monocular CDVA, 0.01 ± 0.02 ; binocular UNVA, 0.08 ± 0.07 ; binocular UIVA, 0.21 ± 0.09 ; SE, -0.08 ± 0.30 . PROMs showed high levels of satisfaction and spectacle independence at all distances with worse results in myopes. Night vision was worse in hyperopes. **Conclusions:** In this retrospective analysis, RayOne Trifocal provided good visual performance at all distances, resulting in excellent levels of spectacle independence and satisfaction despite the preoperative refraction.

Key words: Refractive lens exchange, spectacle independence, subjective satisfaction, trifocal intraocular lens, visual performance

Multifocal intraocular lenses (MIOLs) have been widely used to provide presbyopic patients with good visual acuity (VA) at different distances.^[1] High levels of spectacle independence and significant improvements in quality of vision have been reported, particularly in hyperopic eyes.^[2,3] However, there is some controversy regarding trifocal IOL implantation in presbyopes with emmetropia or high myopia due to their greater visually demanding needs or the presence of some conditions affecting postoperative VA, such as myopic maculopathy.^[4,5]

To this day, few studies have focused on considering specifically the ametropia of the eye in trifocal IOL designs.^[3-6] No previous study has compared visual and refractive outcomes of

RLE with trifocal IOLs in emmetropic, myopic, and hyperopic eyes separately.

The purpose of the current analysis was to provide visual and functional outcomes after bilateral RLE with a trifocal IOL and compare them depending on the preoperative refraction.

Methods

Design

In this retrospective cross-sectional study, data were analyzed from consecutive patients who underwent delayed sequential bilateral RLE with implantation of RayOne Trifocal RAO603F IOL between January 2020 and December 2023. Patients underwent surgery at 22 centers of Clínica Baviera-AIER Eye Hospital Group in Spain by 50 experienced surgeons using the same surgical protocol, instruments, and devices. Informed consent was obtained after detailed information

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regarding the surgical procedure and vision concerns related to MIOLs. Patients signed a specific consent form that covers the anonymous use of the data for research clinical purposes. The study adhered to the tenets of the Declaration of Helsinki and General Data Protection Regulation of the European Union. Institutional review board approval was obtained from the Clinica Baviera Medico-Legal Committee and Ethical Committee of the CEU - Cardenal Herrera University (CEI21/57).

Data were recorded from the central computerized medical file system.

Subjects

Inclusion criteria were: presbyopic patients aged 40 to 65 years with a corrected distance visual acuity (CDVA) of 0.9 decimal or better, who underwent elective RLE and completed at least 3 months of follow-up. Exclusion criteria included: corneal astigmatism >1.00 D, amblyopia or ocular disease affecting prognosis, previous corneal or intraocular surgery, pregnancy, and intraoperative/postoperative complications unrelated to the IOL.

Eyes were stratified into three groups based on preoperative refraction: emmetropic (group A; -0.50 D to $+0.50$ D), myopic (group B; ≤ -0.50 D), and hyperopic (group C; $\geq +0.50$ D).

Intraocular lens

The RayOne Trifocal RAO603F is a single-piece, hydrophilic acrylic IOL with an aspheric optic and 16 diffractive steps in a central 4.5 mm zone, across a 6.0 mm optic affording neutral spherical aberration. It provides a $+3.50$ D near add and a $+1.75$ D intermediate add, with a light distribution of 52% for distance, 22% for intermediate, and 26% for near (based on a 3 mm pupil).

Clinical evaluation

Preoperative assessment included slit-lamp biomicroscopy, tear film assessment, fundus examination, corneal topography (Pentacam, Oculus Optikgeräte GmbH), pupillometry, macular optical coherence tomography (Revo, OptalTech), endothelial cell count (SP 3000P, Topcon), refraction, and visual acuities (VAs): CDVA, uncorrected distance, intermediate and near VAs (UDVA, UIVA, UNVA) measured under photopic conditions (~ 85 cd/m²) using a Snellen chart at 4 m for distance (CC-100 Topcon Healthcare) and Precision Vision chart for near vision at 40 cm/intermediate vision at 66 cm. UIVA was not routinely collected at the preoperative visit. Axial length and IOL power calculation were based on IOLMaster measurements (Carl Zeiss AG). Barrett Universal II Formula with A-constant optimized at the network level was used, the target being emmetropia in all cases; second-eye IOL power was fine-tuned using first-eye postoperative refraction.

Surgery

All procedures included a 2.75 mm clear corneal incision (temporal or steepest axis), phacoemulsification, IOL implantation in the capsular bag, and intracameral cefuroxime injection.

Postoperative medication included: moxifloxacin hydrochloride 0.5% QID for 1 week, dexamethasone 0.1% on tapering doses for 4 weeks, and nepafenac 3 mg QD for 8 weeks. The second eye was operated within 1 week of the first eye.

Postoperative assessment

Patients were evaluated at 24 hours, 1 week, 1 month, and 3 months postoperatively. After 3 months, patients were discharged with a recommendation for annual follow-up.

Contrast sensitivity and defocus curve outcomes

Monocular defocus curves were recorded under photopic conditions from -4.00 D to $+1.00$ D defocus levels in 0.50 D increments with residual refractive error corrected.

Contrast sensitivity function (CSF) was tested under photopic conditions using sinusoidal contrast variation stimuli (Topcon CC-100 system). The automated M2 program was used, measuring the contrast threshold for 1.5, 3, 6, 12, and 18 cycles per degree (cpd). CSF function was measured monocularly with residual refractive error corrected, first for distance vision, and then eyes were defocused with -1.25 D and -2.50 D lens to measure CSF at 66 cm (intermediate) and 40 cm (near), respectively.

Patient satisfaction

Patient satisfaction and visual-related difficulty were assessed at discharge using the Catquest-9SF questionnaire, a validated PROM tool designed for quality control regarding appropriateness and outcome of cataract surgery.^[7,8] It has been validated through Rasch analysis and recommended by the European Registry of Quality Outcomes for Cataract and Refractive Surgery.^[9] It consists of nine items (A, B, C1–C7) with four response options coded from 1 (very satisfied/no difficulty) to 4 (very dissatisfied/very great difficulty). Items A and C1–C7 are concerned with difficulty, and item B with satisfaction.

Night vision disturbances and spectacle dependence were assessed using a structured in-house questionnaire previously used in published MIOL studies.^[4,6,10] Spectacle dependence was assessed by asking patients about the need to wear glasses in their daily activities at the three distances (reading, computer, driving). Then, patients were asked to rate levels of alteration of night vision and driving and the quality of vision when performing daily activities on a Likert scale of 1 to 5 (1 = very bad; 5 = very good). Those who responded "bad" or "very bad" were categorized as having postoperative visual impairment. To finish off, the questionnaire inquires about general satisfaction and whether patients would undergo surgery again.

PROMs completion was $\sim 80\%$ overall (Catquest-9SF $n = 2715$, in-house questionnaire $n = 2477$); analyses are available-case (no data imputation).

Statistical analysis

VA values were converted from decimal to logMAR. For normal distributions, t-tests and ANOVA were used; nonparametric data were analyzed with Wilcoxon and Kruskal–Wallis tests. Fisher's exact test was used for categorical variables. Pairwise comparisons were Bonferroni-corrected. A P value < 0.05 was considered statistically significant. Analyses were conducted using R software (R Core Team, 2021; R Foundation for Statistical Computing, Vienna, Austria).

Results

A total of 6788 IOLs were implanted bilaterally in 3394 patients. Of these, 200 patients were emmetropic (Group A), 140 were myopic (Group B), and 3054 were hyperopic (Group C).

The distribution in terms of age and sex was similar in the three groups, with a majority of women (56.1%) and mean age 55.50 ± 4.80 years.

The mean axial length (mm) was 23.54 ± 0.81 in Group A, 24.89 ± 1.17 in Group B, and 23.03 ± 3.83 in Group C [Table 1].

Visual and refractive performance

Table 1 shows preoperative data; Table 2 summarizes 3-month outcomes. Patients had significantly better mean uncorrected VAs at all distances and CDVA after surgery compared with preoperative values in all groups.

Standard graphs for reporting of refractive outcomes are further referenced in Fig. 1a-e. 92.5% of the eyes in Group A, 94.4% in Group B, and 94.6% in Group C had no loss or gain of lines or a gain of ≥ 1 line of preoperative CDVA compared to postoperative UDVA. Almost all eyes had no change in lines of CDVA.

The percentages of eyes with an SE within ± 0.50 and ± 1 D were 96.1% and 99.3% for Group A, 92.9% and 98% for Group B, and 94.5% and 99% for Group C, respectively.

Visual and refractive changes are illustrated in Fig. 2.

Contrast sensitivity and defocus curve outcomes

Fig. 3 shows monocular defocus curves and CSF data. Mean CSF values were within normal limits at all spatial frequencies and distances (distance, intermediate, near).

Subjective outcomes

PROM results indicated high satisfaction and spectacle independence over all distances across all groups. Higher spectacle dependence in intermediate vision was found in

myopes, and night vision was reported worse in hyperopes. Detailed quality of vision outcomes is shown in Table 3.

Discussion

Refractive lens exchange (RLE) is primarily indicated in presbyopic patients with a refractive error, particularly low to moderate hyperopia, while in emmetropic individuals, it may be considered too aggressive.^[11,12] Its role in myopic eyes remains controversial due to the increased risk of retinal detachment (RD) and the presence of macular abnormalities that may compromise visual outcomes.^[5,11]

Recent studies have nonetheless reported favorable visual and satisfaction outcomes in carefully selected presbyopes with low ametropia or emmetropia seeking spectacle independence, supporting the expanding role of RLE.^[4,6,13-22] However, most prior reports had small samples or grouped refractive errors, limiting insights into differences across refractive profiles.

The present study directly compares visual, refractive, and functional outcomes following bilateral RLE with the RayOne Trifocal IOL according to preoperative refraction. This approach provides new insights for refining patient selection and counseling, particularly for emmetropic and myopic presbyopes, who are increasingly seeking a definitive solution to presbyopia.

Visual acuity and refractive outcomes were favorable across all groups. More than 94% of eyes achieved a postoperative uncorrected distance visual acuity (UDVA) equal to or better than preoperative corrected distance visual acuity (CDVA), with excellent predictability of postoperative spherical equivalent (SE). These findings are consistent with previous reports using this IOL, including a large-scale study with over 5000 RLE eyes and smaller cohorts showing 93–100% of eyes within ± 0.50 D of target refraction.^[23-25]

Table 1: Visual and refractive preoperative data

Preoperative	Group A (n=200 patients)	Group B (n=140 patients)	Group C (n=3054 patients)	P*
Sphere (D)				
Mean (SD)	0.38 (0.30)	-2.77 (1.91)	2.22 (1.01)	<0.001
Median (Q1, Q3)	0.50 (0.25, 0.50)	-2.25 (-3.75, -1.25)	2.00 (1.50, 2.75)	
Cylinder (D)				
Mean (SD)	-0.36 (0.34)	-0.50 (0.32)	-0.38 (0.32)	<0.001
Median (Q1, Q3)	-0.50 (-0.50, 0.00)	-0.50 (-0.50, 0.00)	-0.50 (-0.50, 0.00)	
SE (D)				
Mean (SD)	0.20 (0.29)	-3.02 (1.93)	2.04 (0.98)	<0.001
Median (Q1, Q3)	0.25 (0.00, 0.50)	-2.62 (-3.88, -1.50)	1.88 (1.38, 2.50)	
Axial Length (mm)				
Mean (SD)	23.53 (0.81)	24.89 (1.17)	23.03 (3.83)	
Median (Q1, Q3)	23.51 (23.11, 24.05)	24.82 (24.04, 25.71)	22.97 (22.41, 23.49)	<0.001
Range	20.20–25.54	22.56–28.64	20.40–22.30	
UDVA (logMAR)				
Mean (SD)	0.06 (0.07)	0.96 (0.53)	0.51 (0.33)	<0.001
Median (Q1, Q3)	0.05 (0.01, 0.10)	1.00 (0.52, 1.52)	0.40 (0.28, 0.70)	
CDVA (logMAR)				
Mean (SD)	0.01 (0.02)	0.02 (0.02)	0.02 (0.02)	<0.001
Median (Q1, Q3)	0.00 (0.00, 0.02)	0.01 (0.00, 0.03)	0.01 (0.00, 0.03)	

Group A (emmetropic), Group B (myopic), Group C (hyperopic); n (number); D (diopters); SD (standard deviation); Q (quartile); SE (spherical equivalent); UDVA (uncorrected distance visual acuity); CDVA (corrected distance visual acuity); logMAR (log of minimum angle of resolution). *Kruskal–Wallis test

Table 2: Visual and refractive postoperative data

Postoperative	Group A (n=200 patients)	Group B (n=140 patients)	Group C (n=3,054 patients)	P
Sphere (D)				
Mean (SD)	0.07 (0.30)	0.05 (0.54)	0.05 (0.30)	0.347 ^b
Median (Q1, Q3)	0.00 (0.00, 0.25)	0.00 (0.00, 0.25)	0.00 (0.00, 0.00)	
Cylinder (D)				
Mean (SD)	-0.23 (0.28)	-0.21 (0.28)	-0.25 (0.31)	0.600 ^b
Median (Q1, Q3)	0.00 (-0.50, 0.00)	0.00 (-0.50, 0.00)	0.00 (-0.50, 0.00)	
SE (D)				
Mean (SD)	-0.05 (0.29)	-0.05 (0.52)	-0.08 (0.30)	0.059 ^b
Median (Q1, Q3)	0.00 (-0.25, 0.00)	0.00 (-0.25, 0.12)	0.00 (-0.25, 0.00)	
Bin UNVA (logMAR)				
Mean (SD)	0.08 (0.07)	0.07 (0.07)	0.08 (0.07)	0.549 ^b
Median (Q1, Q3)	0.10 (0.00, 0.10)	0.10 (0.00, 0.10)	0.10 (0.00, 0.18)	
Bin UIVA (logMAR)				
Mean (SD)	0.12 (0.11)	0.12 (0.08)	0.11 (0.09)	0.642 ^b
Median (Q1, Q3)	0.11 (0.11, 0.20)	0.11 (0.11, 0.20)	0.11 (0.11, 0.20)	
Bin UDVA (logMAR)				
Mean (SD)	0.01 (0.11)	0.03 (0.23)	0.00 (0.03)	0.659 ^b
Median (Q1, Q3)	0.00 (0.00, 0.01)	0.00 (0.00, 0.01)	0.00 (0.00, 0.01)	
Bin CDVA (logMAR)				
Mean (SD)	0.00 (0.02)	0.00 (0.02)	0.00 (0.02)	0.012 ^b
Median (Q1, Q3)	0.00 (0.00, 0.00)	0.00 (0.00, 0.01)	0.00 (0.00, 0.01)	
Safety Index				
Mean (SD)	1.00 (0.06)	1.01 (0.05)	1.01 (0.06)	0.232 ^b
Median (Q1, Q3)	1.00 (0.98, 1.02)	1.00 (1.00, 1.04)	1.00 (1.00, 1.04)	
Efficacy Index				
Mean (SD)	0.97 (0.10)	0.97 (0.14)	0.98 (0.09)	0.379 ^b
Median (Q1, Q3)	1.00 (0.92, 1.02)	1.00 (0.96, 1.02)	1.00 (0.96, 1.02)	

Group A (emmetropic), Group B (myopic), Group C (hyperopic); n (number); D (diopters); SD (standard deviation); Q (quartile); SE (spherical equivalent);

Bin (binocular); UNVA (uncorrected near visual acuity); UIVA (uncorrected intermediate visual acuity); UDVA (uncorrected distance visual acuity);

CDVA (corrected distance visual acuity); logMAR (log of minimum angle of resolution). ^bKruskal-Wallis test

Table 3: Outcomes of patient satisfaction questionnaires

Vision dissatisfaction	Group A	Group B	Group C	P
Far ^a	0.0%	6.8%	1.2%	<0.001 ^c
Intermediate ^a	1.2%	6.8%	0.9%	0.013 ^c
Near ^a	0.0%	6.8%	1.1%	<0.001 ^c
Night vision ^b	2.4%	2.3%	3.5%	0.011 ^c
Night driving ^b	13.6%	12.2%	9.1%	0.318 ^c
Spectacle dependence ^b				
Far	0.0%	0.0%	0.3%	0.984 ^c
Intermediate	1.2%	4.5%	0.4%	<0.001 ^c
Near	2.4%	7%	1.7%	0.064 ^c
Satisfaction				
Not satisfied ^a	0.0%	2.3%	0.1%	0.031 ^c
Would not repeat ^b	7.0%	4.7%	1.9%	0.007 ^c

Group A (emmetropic), Group B (myopic), Group C (hyperopic);

^aCatquest-9SF, ^bIn-house questionnaire, ^cFisher exact test

Contrast sensitivity (CS) results were within normal ranges across spatial frequencies and distances. Unlike other diffractive IOLs, the RayOne Trifocal did not show significant CS drop-offs at near or intermediate distances, and performance

was comparable to our exceeding previous reports.^[20,23,24,26] The defocus curve revealed a broad range of functional vision, with peak performance between 40 and 66 cm and maintained acuity above 0.3 logMAR until 20 cm.

In hyperopic patients, visual and refractive outcomes were highly predictable, consistent with earlier studies showing favorable safety and efficacy indices.^[17] Emmetropic patients achieved similarly positive results. These outcomes support existing evidence that RLE with a trifocal IOL is an effective option in presbyopic emmetropes desiring spectacle independence, especially when accommodative reserve is minimal.^[4,6,14,15]

In myopic patients, although RLE is generally avoided between the ages 40 and 65 in the absence of cataract due to the increased risk of RD, our study contributes meaningful data to this limited body of evidence. Only a few prior studies have evaluated trifocal IOLs in myopic eyes, typically with small sample.^[5,18,19] We included 140 patients with low to high myopia, making this one of the largest reported cohorts of myopic presbyopes undergoing RLE with a trifocal IOL. Similarly, in our previous large-scale study of 5226 RLE eyes with the same IOL, approximately 10% were also myopic (≤ -1.00 D).^[25] These findings not only support the consistent performance

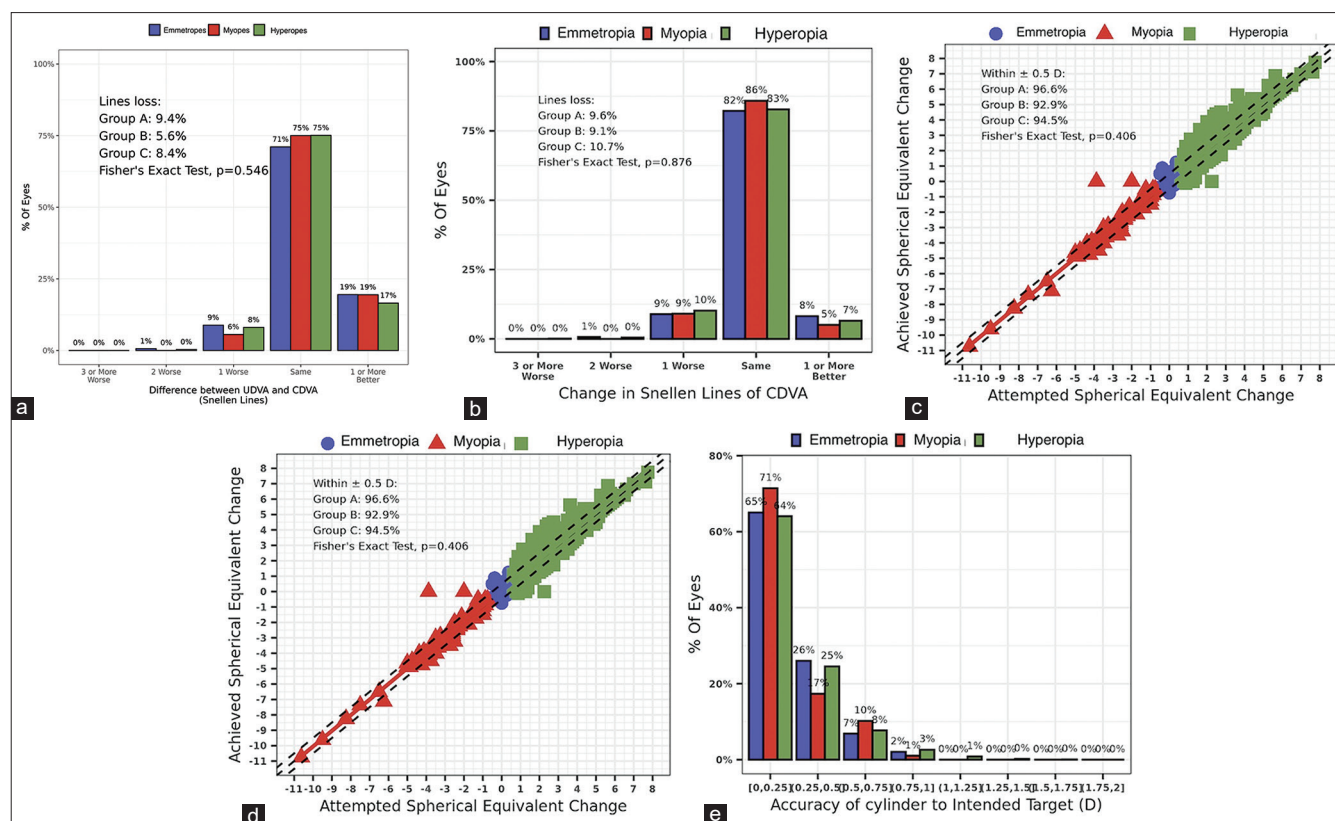


Figure 1: Standard graphs for reporting of visual (a, b) and refractive (c-e) outcomes. Comparison between groups

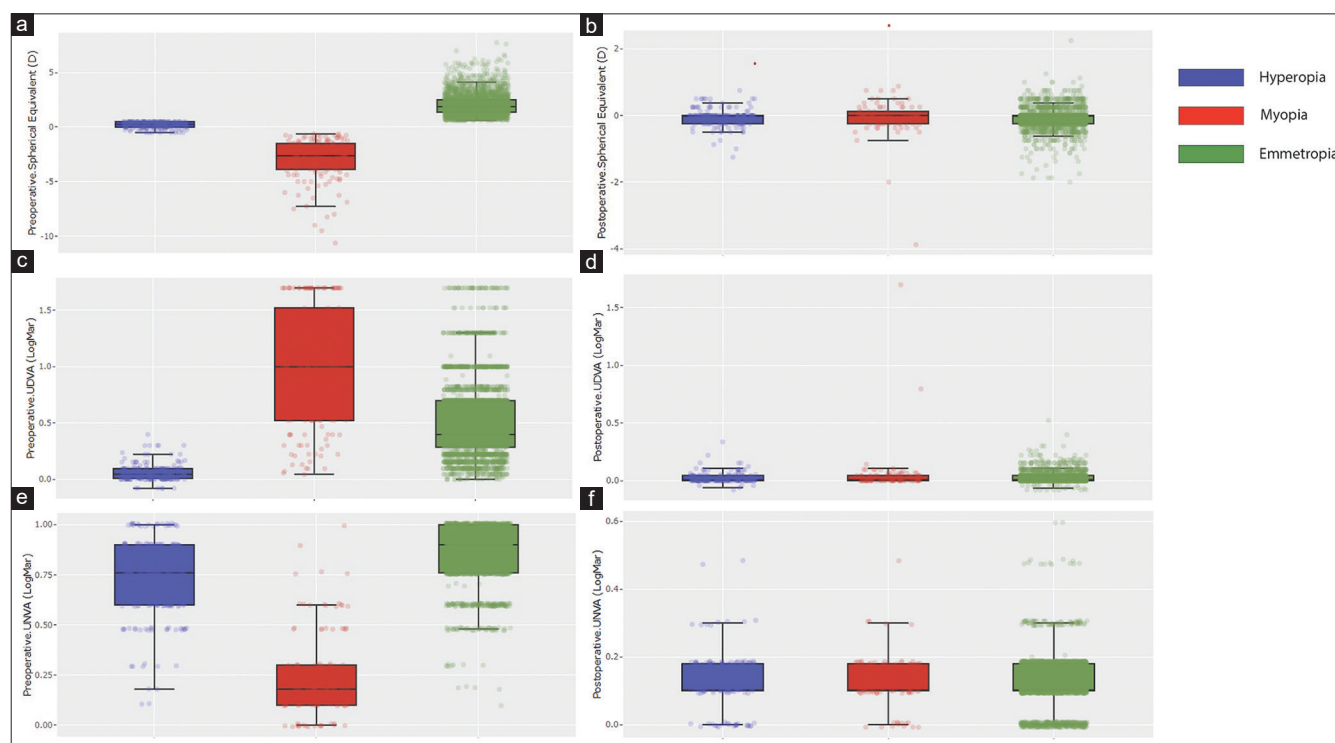


Figure 2: Box plots showing changes in spherical equivalent (a, b), uncorrected distance visual acuity (UDVA) (c, d) and uncorrected near visual acuity UNVA (e, f) in emmetropic, myopic, and hyperopic patients

of the RayOne Trifocal IOL across refractive profiles but also add valuable evidence on an understudied population where

careful case selection and individualized counseling are especially important.

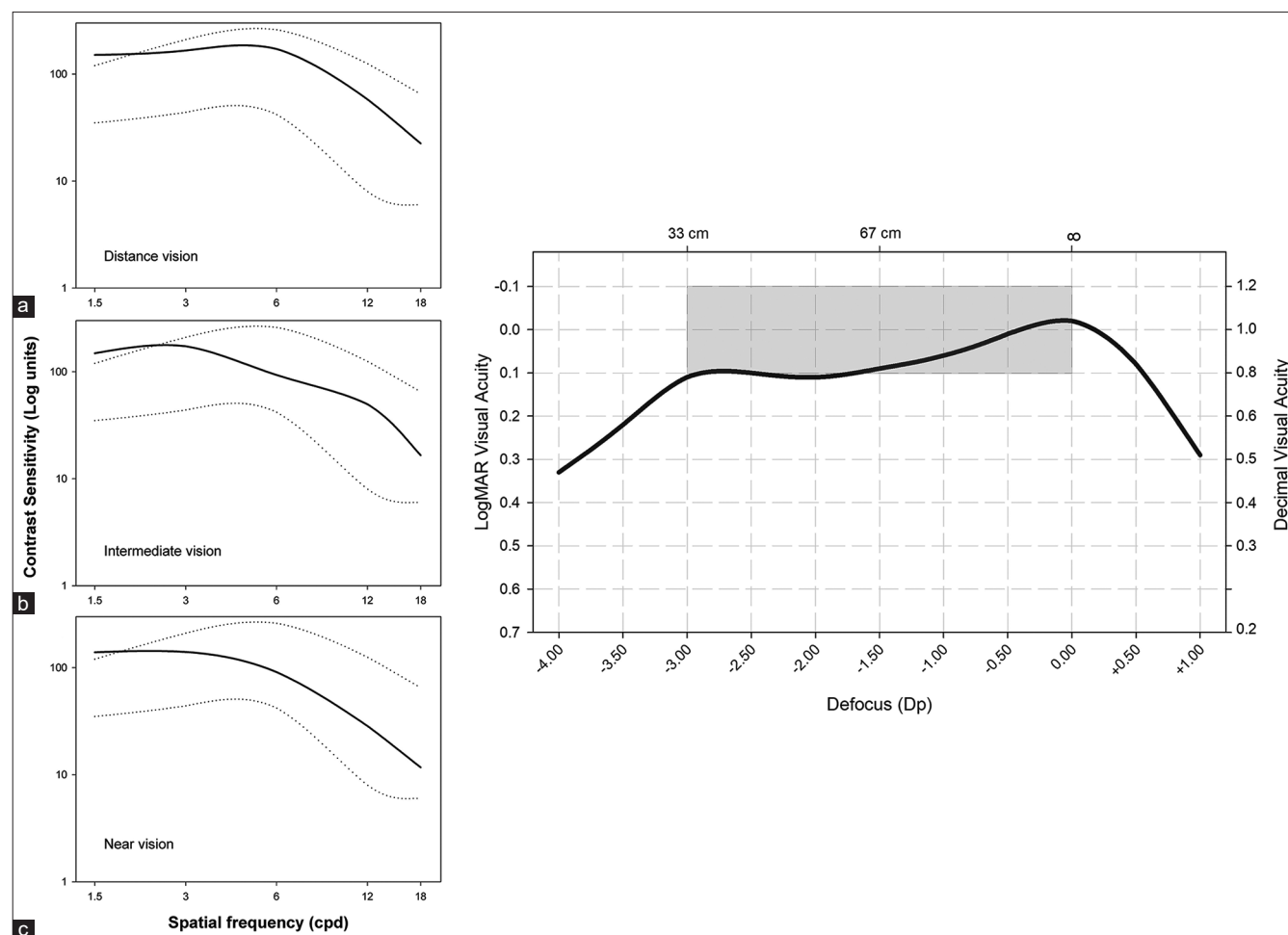


Figure 3: Mean monocular contrast sensitivity function (CSF) (left) for distance vision (a), intermediate vision (b), and near vision (c). Defocus curve obtained at the three distances (right)

Subjective outcomes were also favorable. PROMs indicated high satisfaction and spectacle independence across all groups. However, some group-specific differences emerged. Myopic patients reported slightly lower satisfaction and greater dependence on glasses for intermediate tasks. Clinically, this may impact satisfaction in individuals accustomed to unaided intermediate-range activities such as computer use or reading at arm's length. Surgeons should proactively explore these expectations during counseling to improve alignment between perceived needs and outcomes. In contrast, hyperopic patients reported more frequent night vision disturbances, echoing previous findings.^[17] These differences highlight the need for personalized preoperative counseling. This may reflect individual variability in neuroadaptation or increased sensitivity to dysphotopsias, a known limitation of multifocal IOLs. Given the potential impact on nighttime tasks—particularly driving—this risk should be clearly explained to ensure hyperopic patients have realistic expectations.

Interestingly, Venter reported more photic phenomena in emmetropic presbyopes compared to ametropes with the same IOL, likely due to the absence of preoperative optical aberrations.^[16] Hawker also noted that patients who never wore glasses preoperatively may be more prone to postoperative dissatisfaction.^[27] In our cohort, dissatisfaction was rare—0%

in emmetropes, 2.3% in myopes, and 0.1% in hyperopes—yet approximately 7% of emmetropes stated they would not repeat the procedure. This finding underscores the importance of managing expectations, particularly in emmetropes.

Limitations of this study include its retrospective nature and multicenter design, which may introduce variability despite standardized protocols. Follow-up was limited to 3 months; thus, longer-term outcomes are needed to evaluate neuroadaptation. Preoperative UIVA was not routinely collected; therefore, change scores for intermediate vision could not be computed. RD, cystoid macular edema (CME), and Nd:YAG laser capsulotomy were not systematically recorded at this time point, and extended surveillance is planned. Although PROMs used were validated and culturally adapted, they remain subjective, and approximately 20% of patients did not complete the questionnaires.^[7,9] The visual disturbances questionnaire, while used in prior studies, is not a formally validated instrument.^[4,6,10,17,25,28] Other studies have used tools like the McAlinden Quality of Vision Questionnaire to assess dysphotopsia.^[24,29] Finally, potential contributors to dissatisfaction—such as angle kappa, pupil size, residual refractive error—could not be consistently analyzed due to incomplete data. Future prospective studies with more granular data are needed.

Conclusions

This is the first study to compare trifocal IOL outcomes in RLE according to ametropia in a large cohort. Future research should explore the interaction between refractive error, optical performance, and subjective quality of vision using real-world data, advanced analytics, or AI-supported PROMs platforms such as RayPRO.

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