Unilateral Versus Bilateral Refractive Lens Exchange With a Trifocal Intraocular Lens in Emmetropic Presbyopic Patients

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• ABSTRACT

PURPOSE: To compare visual outcomes and patient satisfaction between unilateral and bilateral trifocal diffractive intraocular lens (IOL) implantation in emmetropic patients with presbyopia.

• DESIGN: Retrospective observational case series.

• METHODS: This is a multicenter, multisurgeon study of emmetropic presbyopes who underwent refractive lens exchange (RLE) followed by an implantation of FineVision IOL (PhysIOL). Inclusion criteria were emmetropic eyes, with a sphere between –0.25 and +0.50 diopters (D), cylinder of less than 0.75 D and spherical equivalent (SE) between –0.25 and +0.25 D. In addition, uncorrected distance visual acuity (UDVA) had to be Snellen >0.9 in each eye. A total of 171 eyes of 122 patients were evaluated. This sample was divided into 2 groups depending on whether they have been operated monocularly or binocularly. Visual and refractive performance, patient satisfaction, and spectacle independence were evaluated.

• RESULTS: UDVA and corrected distance visual acuity (CDVA) remained almost unchanged after monocular and binocular surgery. Binocular uncorrected intermediate (UIVA) and near visual acuity (UNVA) were better in those operated binocularly (0.3±0.12 vs 0.22±0.06, $P < .063$, and 0.09±0.08 vs 0.04±0.05, $P < .027$, respectively). Predictability and efficacy were higher in the binocular group, whereas safety was better in the monocular group. Visual dysphotopsia was worse and spectacle independence for all distances was higher in binocular group.

• CONCLUSIONS: Our research shows that RLE with binocular implantation of a trifocal diffractive IOL in presbyopic emmetropic patients is more successful in UNVA than monocular implantation. However, no significant differences were observed in UDVA, UIVA, and patient satisfaction. (Am J Ophthalmol 2021;223:53–59. © 2020 Elsevier Inc. All rights reserved.)

PRESBYOPIA IS THE LOSS OR INSUFFICIENCY OF THE accommodative ability of the eye.[1] It is a normal, physiological, yet irreversible process. Clinically, presbyopia manifests as the inability to focus near objects on the retina. It is one of the most common causes of vision impairment worldwide. With one-third of the world population older than 40 years, the predicted global prevalence of presbyopia is 1.4 billion by 2020 and 1.8 billion by 2050.[2] Presbyopia has been associated with negative impacts on quality of life in people aged 40 years and older because it causes difficulties with reading and with accomplishing near vision activities.[3] In addition, presbyopia usually affects individuals in the prime of their professional and creative lives.

Optical correction of presbyopia may be accomplished through the use of spectacles or contact lenses. The various surgical techniques for the correction of presbyopia include corneal inlays,[4] monovision laser in situ keratomileusis (LASIK),[5] and femtosecond intrastromal presbyopic treatment.[6] These procedures, however, do not target the main cause of presbyopia, namely, crystalline lens deterioration. Nowadays, the most popular option for management of presbyopia is refractive lens exchange (RLE), which involves removing the lens and replacing it with a multifocal intraocular lens (IOL).

Multifocal IOLs aim to provide spectacle independence for both near and distance vision by dividing light into 2 or more foci.[7] In refractive IOLs, the light is bent to form 2 or more retinal images, as a result of differences in optical density and curvature of the IOL. Diffractive IOLs are designed based on the principle of diffraction, where light changes direction or slows down when it encounters an edge of discontinuity. These lenses have rings on the surface. When light particles reach these rings, they are directed toward 2 focal points (bifocal IOLs) or 3 focal points (trifocal IOLs).

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Correction of presbyopia by implanting a multifocal IOL is a widely used approach, although it is performed mostly in patients with refractive error or cataract.[8] The few studies that have assessed RLE with multifocal IOLs in emmetropic patients report on binocular implants[9,10] and on monocular implants.[11] No research has been performed as of this writing on the difference between unilateral and bilateral surgery with trifocal IOLs in emmetropic patients.

The purpose of this study was to compare visual outcomes and satisfaction with unilateral and bilateral trifocal diffractive IOLs in emmetropic patients with presbyopia.

METHODS

IN THIS MULTICENTER, MULTISURGEON STUDY, WE analyzed data from patients who underwent RLE followed by implantation of a FineVision IOL (PhysIOL, Liège, Belgium). The study was performed in accordance with the principles of the Declaration of Helsinki. Institutional review board approval was obtained from the Clinica Baviera Medico-legal Committee before the study began.

Patients underwent surgery at any of the 22 surgical centers of Clinica Baviera in Spain. The procedures were performed by 51 experienced surgeons using the same surgical protocol, instruments, and devices. Before surgery, patients received detailed information regarding the procedure and concerns about their vision after trifocal IOL implantation. They provided written consent for their surgical procedure and for review of their anonymous medical records for research purposes. All procedures took place between February 2013 and December 2018, and only patients with at least 3 months of follow-up were included in the analysis. Routine preoperative and postoperative outcomes and complications were collected and analyzed. Data were recorded from the central computerized medical records system at Clinica Baviera, which contains the medical records and surgical data of the patients evaluated.

The inclusion criteria were age 46-60 years and candidates for RLE followed by implantation of a trifocal IOL. Patients were required to have emmetropic eyes, that is, eyes with a sphere of between –0.25 and +0.50 diopters (D), cylinder of less than 0.75 D, and a spherical equivalent (SE) of between –0.25 and +0.25 D. In addition, uncorrected distance visual acuity (UDVA) had to be Snellen >0.9 in each eye.

The exclusion criteria were amblyopia, previous corneal surgery, clinically significant corneal endothelial dystrophy, history of corneal disease, history of retinal detachment, neuro-ophthalmic disease, pregnancy, and intraoperative or postoperative complications not related to the IOL design that may have impaired visual outcomes (intraoperative posterior capsule rupture with anterior vitrectomy, postoperative retinal detachment, and cystoid macular edema).

TABLE 1. Average Age and Proportion per Sex of Patients for Each Study Group Implanted Monocularly or Binocularly

Demographics Data	Group 1	Group 2	*P* Value[a]
No. of patients	73	48	
No. of eyes	73	96	
Sex (%)			
Male	53.42	47.92	
Female	46.58	52.08	.684[a]
Age, mean ± SD	53.21 ± 3.21	53.02 ± 2.71	.679[b]

[a]χ^2 test.
[b]Yuen test for trimmed means of independent samples.

The sample was divided into 2 groups depending on whether the procedure had been performed on the nondominant eye only (Group 1) or on both eyes (Group 2). The decision of whether to operate on one or both eyes depended on the surgeon. Visual and refractive performance, patient satisfaction, and spectacle independence were evaluated.

• **PREOPERATIVE ASSESSMENT:** Before surgery, all patients underwent a full ophthalmologic examination including refractive status, monocular uncorrected distance visual acuity (UDVA), monocular corrected distance visual acuity (CDVA), binocular uncorrected intermediated visual acuity (UIVA), and binocular uncorrected near visual acuity (UNVA), all of which were tested under photopic conditions (at approximately 85 cd/m^2). They also underwent corneal topography, 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 (IOL Master; Carl Zeiss Meditec AG, Jena, Germany). The IOL power was selected based on the surgeon's experience. The target for all eyes was emmetropia.

• **SURGERY:** The surgical RLE 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, implantation of the IOL in the capsular bag, and intracameral injection of cefuroxime. Side ports were hydrated in all cases, and the main incision was hydrated if necessary. Postoperative topical therapy included a combination of antibiotics, corticosteroids, and topical NSAID drops (moxifloxacin hydrochloride [0.5% 4 times a day for 1 week], dexamethasone [0.1% 4 times a day for 1 week, 3 times a day for 1 week, twice a day for another week, and once a day for the last week], and nepafenac [3 mg once a day for 8 weeks]). The second eye was operated on within 2 weeks of the initial procedure.

• **POSTOPERATIVE ASSESSMENT:** The patient had a scheduled follow-up assessment within 24 hours of the

TABLE 2. Preoperative Range and Mean Sphere, Cylinder, Spherical Equivalent, Uncorrected and Corrected Distance Visual Acuity for Each Study Group Implanted Monocularly or Binocularly

	Group 1 (n=73)		Group 2 (n=98)		
Preoperative Data	Range (Min/Max)	Mean ± SD	Range (Min/Max)	Mean ± SD	*P* Value[a]
Sphere (D)	–0.25/0.5	0.13 ±0.13	–0.25/0.5	0.09 ± 0.12	.246
Cylinder (D)	–0.75/0	–0.22 ± 0.22	–0.75/0	–0.17 ± 0.23	.446
Spherical equivalent (D)	–0.25/0.25	0.03 ± 0.13	–0.25/0.25	0.03 ± 0.06	.786
UDVA (logMAR)	0/0.05	0.01 ± 0.01	0/0.05	0.01 ± 0.02	.278
CDVA (logMAR)	0/0.06	0± 0	0/0.1	0 ± 0.01	.473

CDVA = corrected distance visual acuity, UDVA = uncorrected distance visual acuity.
[a]Yuen test for trimmed means of independent samples.

surgery and again at 1 week, 1 month, and 3 months after surgery. Residual refractive error was corrected with laser enhancement therapy. Patients were then discharged and asked to return for routine follow-up visits every year thereafter. The results were registered from the last available follow-up visit.

• **PATIENT SATISFACTION QUESTIONNAIRE:** Patient satisfaction, night vision disturbance, and spectacle dependency were assessed according to the time of discharge from the clinic. This questionnaire, used previously in patients implanted with multifocal IOLs,[12] was based on our clinical experience and patients' demands. Patients rated their quality of vision on a scale of 1 to 5 (1 = very bad; 5 = very good) and the night vision disturbance based on questions that compare vision before and after the treatment. Those who described their quality of vision as "bad" or "very bad" were considered to experience visual disturbance after surgery. To assess spectacle dependency, patients were asked about the need to wear spectacles for near, intermediate, and far vision.

• **INTRAOCULAR LENS:** The IOL implanted was FineVision Micro F, a trifocal IOL made of hydrophilic acrylic material. The optic combines 2 diffractive structures that are adjusted to offer a +3.5 D addition for near vision and +1.75 D for intermediate vision. The single piece, 4-loop haptic 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 aperture of the pupil (apodization).

• **STATISTICAL ANALYSIS:** Categorical variables were compared between the groups using either Pearson χ^2 test or Fisher exact test, depending on the frequencies expected within the cells. For continuous variables, we calculated 20% trimmed means and winsorized standard deviations to reduce the effect of some outliers on the general trend. We also performed the Yuen test for independent samples, which assesses differences between the trimmed means as described in Wilcox (2011).[13] All calculations were made using R Core Team (2019). Visual acuity was converted from Snellen chart to logarithm of minimal angle of resolution (logMAR) value for statistical purposes. The results are expressed as the mean ± standard deviation. A *P* value of less than .05 was considered statistically significant.

RESULTS

A TOTAL OF 169 EYES FROM 121 PATIENTS (59 FEMALES AND 62 males) were included in this study, with no loss to follow-up prior to 3 months. One eye was operated on in 73 cases (Group 1), and both eyes were operated on in 48 cases (Group 2). Patients' demographic data are shown in Table 1.

Table 2 shows preoperative data, illustrating the similarity between both groups. Table 3 displays postoperative data. Postoperative sphere, cylinder, and spherical equivalent were slightly lower in Group 2. None of the findings were statistically significant. Patients had significantly better binocular UNVA in Group 2, whereas there was no significant difference in UDVA, CDVA, and UIVA between the groups.

Predictability and efficacy were higher in the binocular group, whereas safety was better in the monocular group. In Group 1, 95.38% of patients reached the emmetropic range after surgery (±0.50 SE), in comparison with 100% of patients in Group 2. The safety index was 1 in both groups. The efficacy index was 0.98 in Group 1 and 0.99 in Group 2. In our sample, 2 patients lost 2 or more lines of CDVA, owing to an epiretinal membrane and a fibrillar vitreous, respectively. Efficacy and safety are shown in Figure. Bioptics were necessary in 10 eyes (13.7%) in Group 1 and 13 eyes (13.27%) in Group 2 (Table 4).

The subjective quality of vision and the patient's satisfaction were evaluated using a postoperative questionnaire,

TABLE 3. Postoperative Range and Mean Sphere, Cylinder, Spherical Equivalent, Uncorrected and Corrected Distance Visual Acuity, Binocular Uncorrected Intermediate and Uncorrected Near Visual Acuity for Each Study Group Implanted Monocularly or Binocularly

	Group 1			Group 2			
Postoperative Data	n	Range (Min/max)	Mean ± SD	n	Range (Min/max)	Mean ± SD	*P* Value[a]
Sphere (D), mean ± SD	65	–0.5/1.25	0.06 ± 0.12	84	–0.75/0.75	0.01 ± 0.1	.102
Cylinder (D), mean ± SD	65	–1/0	–0.26 ± 0.23	84	–1.25/0	–0.17 ± 0.23	.164
Spherical Equivalent (D), mean ± SD	65	–0.5/0.88	–0.06 ± 0.18	84	–1.38/0.38	–0.05 ± 0.11	.867
UDVA	68	0/0.7	0.01 ± 0.02	94	0/0.4	0.01 ± 0.02	.457
CDVA	59	0/0.22	0.01 ± 0.02	80	0/0.12	0 ± 0	.260
Bin. UIVA	26	0/0.48	0.3 ± 0.12	38	0/0.48	0.22 ± 0.06	.063
Bin. UNVA	48	0/0.3	0.09 ± 0.08	45	0/0.18	0.04 ± 0.05	.027

CDVA = corrected distance visual acuity, UDVA = uncorrected distance visual acuity, Bin. UIVA = binocular uncorrected intermediated visual acuity, Bin. UNVA = binocular uncorrected near visual acuity.

[a]Yuen test for trimmed means of independent samples.

which was completed by 50 patients in Group 1 (68.49%) and 31 patients in Group 2 (63.26%). No spectacle dependence was recorded in any patient in Group 2, whereas in Group 1, only a few patients needed spectacles for intermediate vision (2%) and near vision (6%). The results are shown in Table 5. Patient satisfaction is detailed in Table 6.

DISCUSSION

RLE IS WIDELY USED, ALTHOUGH IT IS PERFORMED MAINLY IN patients with refractive error.[8] Replacing the clear lens with a multifocal IOL in emmetropic patients is the extreme application of this surgery. Many surgeons would consider RLE to be controversial in an emmetropic presbyopic patient.

Few studies have analyzed multifocal IOL results in emmetropic patients.[9–11] To our knowledge, this is the first study to compare monocular and binocular implantation.

In terms of visual outcomes, our retrospective study demonstrated that both monocular and binocular implantation provided good distance, intermediate, and near visual outcomes. The main difference observed between the groups was that binocular surgery offers better results in UIVA and UNVA than monocular surgery, probably because both eyes are involved in intermediate and near vision.

This finding is consistent with the results of previous studies on emmetropic presbyopes. Levinger and associates[11] also examined emmetropic patients (n=26) who received a FineVision Multifocal IOL in their nondominant eye and reported a UDVA of 0.18±0.32, UNVA 0.02±0.10, and UIVA of 0.17±0.21 logMAR. Venter and associates[10] examined emmetropic patients with presbyopia who underwent bilateral implantation of a Lentis Mplus LS-313 MF30 IOL. Preoperative UDVA changed from –0.04±0.06 preoperatively to –0.04±0.11 logMAR postoperatively. Mean UNVA was 0.13±0.14 logMAR monocularly and 0.10±0.12 logMAR binocularly. UIVA was not reported. Alfonso and associates[9] examined bilateral RLE with AcrySof ReSTOR Natural (SN60D3) in 46 emmetropic eyes and reported a mean UDVA and UNVA of 0.95±0.09 and 0.95±0.07, respectively.

The same IOL platform has been used in many studies, although not with emmetropic patients. Cochener and associates[14] reported similar results for UDVA, UIVA, and UNVA, with FineVision IOL (monocular 0.01, 0.08, and 0.00; binocular 0.01, 0.06, and 0.00). They also reported better UIVA with binocular surgery. Sheppard and associates[15] found that binocular CDVA was better than monocular CDVA (0.06 vs 0.08), although they also reported lower monocular UDVA (0.19) with the same IOL. Vryghem and associates[16] compared monocular and binocular implantation and recorded monocular UDVA, UIVA, and UNVA of 0.06, 0.05, and 0.11; the binocular values were –0.04, –0.10, and 0.02. Even better results were reported by Bilbao-Calabuig and associates,[12] who recorded monocular UDVA, UIVA, and UNVA of 0.06, –0.01, and 0.08 and binocular values of 0.01, –0.05, and 0.05 in the largest sample as of this writing (n=5,802 patients). Both Vryghem and associates and Bilbao-Calabuig and associates also confirm better UIVA and UNVA with binocular surgery.

Our research revealed satisfactory outcomes in relation to the safety index (1 in both groups), with most eyes maintaining CDVA. The efficacy index was favorable (0.98 and 0.99) and predictability was good, with 95.38% and 100% of eyes being within the 0.50 D range in SE. Predictability

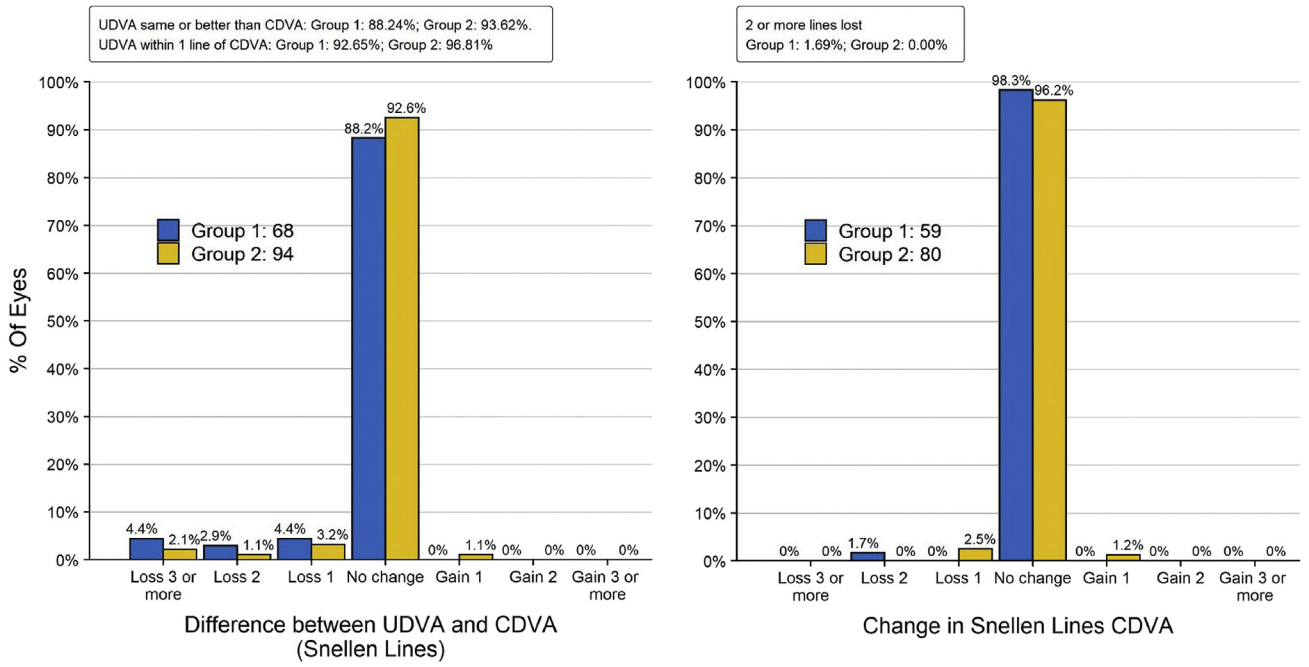

FIGURE. Preoperative corrected distance visual acuity versus postoperative uncorrected distance visual acuity. Preoperative versus postoperative corrected.

TABLE 4. Predictability, Safety, Safety Index, Efficacy, Efficacy Index, and Percentage of Bioptics for Each Study Group Implanted Monocularly or Binocularly

Predictability, Safety and Efficacy	Group 1	Group 2	*P* Value
Predictability (±0.50 D), n (%)	62 (95.38)	84 (100)	.081[a]
Safety (% eyes) (postop CDVA – preop CDVA ≥2 lines)	58 (98.31)	78 (97.5)	>.99[a]
Safety index (postop CDVA/preop CDVA), mean ± SD	1 ± 0.01	1 ± 0.01	0.943[b]
Efficacy (% eyes) (postop UDVA ≥ preop CDVA)	60 (88.24)	88 (63.24)	0.358[c]
Efficacy index (postop UDVA/preop CDVA) mean ± SD	0.98 ± 0.03	0.99 ± 0.05	0.540[b]
Bioptics (%)	10 (13.7)	13 (13.54)	>.99[c]

CDVA = corrected distance visual acuity, UDVA = uncorrected distance visual acuity.
[a]Fisher exact test.
[b]Yuen test for trimmed means of independent samples.
[c]χ^2 test.

and efficacy were higher in the binocular group, whereas safety was better in the monocular group.

Safety, efficacy, and predictability are critical, even more, in emmetropic patients. In our sample, 2 patients lost 2 or more lines of CDVA, owing to an epiretinal membrane and a fibrillar vitreous, respectively. The patient with the fibrillar vitreous had a complete ophthalmologic evaluation and that was the only pathology detected. He had very fluctuating visual acuities depending of the vitreous movement. The worst visual acuity measurement was registered. Other patients who have lost 2 or more lines of UDVA were due to residual myopia. Those patients were comfortable with the UNVA improvement and refused to have a bioptics enhancement.

In our study, UDVA was similar to or better than preoperative CDVA in 88.24% and 93.62% of patients in Groups 1 and 2, respectively. Two or more lines lost in CDVA were recorded in 1.69% in Group 1 and in no patients in Group 2. This also agrees with the results provided by Levinger and associates,[11] who found that CDVA was maintained by 92% of patients and that 1 line of binocular CDVA was lost in 8%. Venter and associates[10] reported that 2.2% lost 2 lines, 18% lost 1 line, and 14.3% gained 1 line or more of CDVA. Alfonso and associates[9] reported an efficacy and

TABLE 5. Outcomes of Visual Disturbance After Surgery for Each Study Group Implanted Monocularly or Binocularly

Visual Disturbance	Group 1, % (n = 50)	Group 2, % (n = 31)	*P* Value[a]
Night	0	6.45	.093
Night driving	2	9.68	.362
Near	6	3.23	.263
Intermediate	6	16.13	.062
Far	12	12.9	.569

[a]Fisher exact test.

TABLE 6. Outcomes of Patient Satisfaction for Each Study Group Implanted Monocularly or Binocularly

Patient Satisfaction	Group 1, % (n = 50)	Group 2, % (n = 31)	*P* Value[a]
Unsatisfied	6	3.23	.564
Would have surgery again	92	93.55	.284

[a]Fisher exact test.

safety index of 1.00 and 1.03, respectively. In this study, 10.9% of patients lost 1 line of CDVA, 37.1% gained 1 or more lines of CDVA, and 52.2% remained unchanged.

Spectacle independence was more common in the binocular group for all distances. No patients in Group 2 required spectacles, whereas in Group 1, only a few patients needed spectacles for intermediate vision (2%) and near vision (6%). Cochener and associates[14] reported comparable results, with 7% of patients requiring additional near correction. Vryghem and associates[16] also reported spectacle independence in 100% of cases for distance and 80% for near vision. Subjective intermediate and near vision were poorer in Group 1 (16.1% and 3.2%), leading to higher dissatisfaction rates (6% vs 3.23%). The fact that only one eye was operated on in Group 1 means that there is a single chance to achieve good results; the other emmetropic eye can be used to compare for far vision. In addition, in Group 2, both eyes work together in near and intermediate vision and might have better subjective vision. Nevertheless, in both groups, a similar number of patients would undergo the surgery again.

Multifocal lenses are associated with dysphotopsia and can affect quality of life.[17,18] This is approximately 3.5 times more common with multifocal than monofocal IOLs.[19] The most frequently reported findings were halos, glare, starburst, and hazy vision. In our study, patients in whom both eyes were treated reported more visual symptoms at nighttime, probably because those operated on monocularly have the fellow eye with normal vision and no added lens that can distort their vision; consequently, visual phenomena might be hidden by the nonoperated eye. This observation is consistent with the results reported by Levinger and associates,[11] who found that dysphotopsia was rare, probably because surgery was monocular.

Venter and associates[10] reported a higher incidence of glare, halo, and starburst in emmetropic presbyopic patients than in ametropic patients with the same multifocal IOL. The main reason might be that emmetropic patients never experience aberrations from spectacles or contact lenses, and the induction of unwanted optical side effects with multifocal IOLs might be more bothersome. As Hawker and associates[20] also pointed out, patients not wearing spectacles before surgery have a greater risk of refractive disappointment and complaints.

Our study is subject to limitations. First, it is retrospective and was restricted to an analysis of available cases with completed follow-up. Second, we included data gathered from multiple surgical centers (n=22), where procedures were performed by several different surgeons (n=51), and visual acuity measurements were obtained by several technicians. However, both surgeons and optometrists followed the same protocols for patient treatment.

As a retrospective and multicenter study, our sample is subject to the known limitations of selection bias between groups because it is not randomized and data are missing from some patient satisfaction surveys. Furthermore, the satisfaction questionnaire was not a validated model, and more sophisticated functional visual tests, such as contrast sensitivity evaluation, defocus curves, or reading speed, were not performed and could be part of further studies.

In conclusion, our research shows that RLE with binocular implantation of a trifocal diffractive IOL in presbyopic emmetropic patients is more successful in UNVA than monocular implantation. However, no significant differences were observed in UDVA, UIVA, and patient satisfaction.

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