ORIGINAL ARTICLE

Visual Performance of Two Diffractive Trifocal Intraocular Lenses: A Randomized Trial

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ABSTRACT

PURPOSE: To compare two trifocal intraocular lenses (IOLs), the RayOne Trifocal RAO603F IOL (closed-loop haptic IOL; Rayner Intraocular Lenses Limited) and the AT Lisa tri 839 MP IOL (plate-haptic IOL; Carl Zeiss Meditec AG), concerning optical and capsular bag performance.

METHODS: Patients scheduled for cataract surgery received either a closed-loop haptic IOL or a plate-haptic IOL in the first eye and the other IOL in the second eye. Three months postoperatively, autorefraction and subjective refraction, uncorrected and corrected distance visual acuity at 4 m, 80 cm, and 40 cm, an objective reading test (Salzburg Reading Desk; SRD Vision), a defocus curve, IOL tilt and decentration, a questionnaire about dysphotopsia, and grading of halos with a halometer were performed.

RESULTS: Eighty-eight eyes of 44 patients were included. Visual acuity was comparable between both IOLs. The closed-loop haptic IOL performed better in the defocus curve at -1.50 diopters (D) (0.08 ± 0.10 vs 0.12 ± 0.09 logMAR; $P < .01$). The plate-haptic IOL had better contrast sensitivity without glare under mesopic and photopic conditions in miosis ($P = .0018$ and .002, respectively) and mydriasis ($P = .017$ and .003, respectively). Significant differences were found for less overall subjective disturbance ($P = .047$) and starbursts ($P = .039$) for the plate-haptic IOL, but not for the other positive dysphotopsia symptoms.

CONCLUSIONS: Both trifocal IOLs delivered good and comparable visual function with low degrees of disturbing dysphotopsia. The closed-loop haptic IOL was slightly superior in the defocus curve, whereas the plate-haptic IOL was slightly superior concerning contrast sensitivity and positive dysphotopsia.

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With the increased use of computers and mobile phones, the demand for good spectacle-independent intermediate vision after cataract surgery has also increased. This resulted in adding an intermediate focus in multifocal intraocular lens (IOL) design.[1-6] The advantage of trifocal IOLs compared to enhanced depth of focus IOLs[5,7,8] and monovision concepts is that three foci are used for the different distances.[9-11] However, the distribution of light to three different foci includes several potential disadvantages, such as loss of contrast sensitivity and potentially disturbing positive dysphotopsia, such as halos, glare, and starbursts.[3-5,12]

The aim of this study was to compare two different trifocal IOLs regarding their optical performance and dysphotopsia. Because the optical design of the two IOLs is similar, we chose a bilateral trial design that allowed patients to directly compare the IOLs between their eyes to detect small differences.

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PATIENTS AND METHODS

This randomized, controlled, patient- and examiner-masked single-center trial included patients scheduled for bilateral cataract surgery. The study was approved by the Ethics Committee of the City of Vienna, followed the tenets of the Declaration of Helsinki and all patients signed informed consents prior to participating in the study (Trial Number: NCT03748381).

Inclusion criteria were cataract in both eyes, age of at least 21 years, and corneal astigmatism of less than 1.50 diopters (D) on keratometry (IOLMaster 700; Carl Zeiss Meditec AG). Exclusion criteria were pregnancy, retinal disease, uveitis, amblyopia, a pupil decentration of greater than 1 mm, and any history of ophthalmic surgery or any other ophthalmic pathology that could compromise postoperative visual function.

One week before surgery, clinical slit-lamp examination and optical biometry (IOLMaster 700) were performed. Pupil decentration was estimated at the slit lamp using the first Purkinje reflex as a reference.

Allocation was performed using an online randomization program (www.random.org). In all cases, either a closed-loop haptic IOL (RayOne, Trifocal RAO603F; Rayner Intraocular Lenses Limited) or a plate-haptic IOL (AT Lisa tri 893 MP; Carl Zeiss Meditec AG) was implanted in the first eye to have surgery and the other IOL type was implanted in the second eye. In all cases, the target refraction was emmetropia (-0.50 to +0.25 D). At the patient's request, information concerning the group allocation was given after completing the last study visit.

The closed-loop IOL is an aspheric, diffractive, trifocal IOL made of hydrophilic acrylic material with a total diameter of 12.5 mm, an optic diameter of 6 mm, and a 4.5-mm diffractive trifocal zone. The plate-haptic IOL is an aspheric, diffractive, trifocal IOL made of hydrophilic acrylic material with a hydrophobic surface with a total diameter of 11 mm, an optical diameter of 6 mm, and a 4.34-mm diffractive trifocal zone (outside this zone the diffractive structure changes to bifocal). **Figure A** (available in the online version of this article) illustrates the differences in the trifocal optical designs.

Standard cataract surgery under topical anesthesia was performed by three experienced surgeons and both eyes of a patient had surgery within 2 weeks. A 2.4-mm incision was performed temporally in all cases and no additional relaxing incisions were performed. Implantation of the IOLs was performed with the designated injection systems. As standard procedure in our clinic, intracameral antibiotics (cefuroxime 1.0 mg/0.1 mL normal saline) for endophthalmitis prevention were used at the end of surgery. Postoperative medication was a nonsteroidal anti-inflammatory eye drop (bromfenac gtt [Yellox; Bausch & Lomb]) twice a day for 4 weeks.

Follow-up visits took place 1 week after the first and second eye surgery and 3 and 6 months after the second eye surgery. Slit-lamp examination, autorefraction (Topcon; Topcon Corporation), and subjective refraction were performed at 1 week and 3 months postoperatively. At 3 months postoperatively, additional measurements were unilateral and bilateral uncorrected (UDVA) and corrected (CDVA) distance visual acuity using an Early Treatment Diabetic Retinopathy Study (ETDRS) chart (Precision Vision) at 4 m, unilateral and bilateral uncorrected intermediate visual acuity (UCIVA) and corrected intermediate visual acuity with an ETDRS chart at 80 cm, and unilateral and bilateral uncorrected near visual acuity and corrected near visual acuity with an ETDRS chart at 40 cm. Additionally, reading acuity and reading speed were assessed with the Salzburg Reading Desk using the 75% Michelson contrast and high luminance with IReST Reading Charts (SRD Vision). A defocus curve from -4.00 to +2.00 D in 0.50-D steps was performed unilaterally and bilaterally. For contrast sensitivity testing, the OPTEC 6500 Vision Tester (Stereo Optical Company) was used in miosis (defined as natural pupil conditions, without any medication) and in mydriasis, with and without glare. In addition, decentration of the IOLs with a Purkinje meter[13,14] and a measurement of the halos with the Aston Halometer[15] was performed. The Aston Halometer is a tablet-based device that allows a semi-objective quantification of positive dysphotopsia. The source of glare is a bright LED in the center of a tablet, which is presented to the patient at a distance of 2 m. In the next step, letters with a certain contrast level and at different distances to the source of glare are presented to the patient on the tablet.

At 6 months postoperatively, a subjective evaluation of dysphotopsia was performed. A small but bright LED light was shown to the patient and the eyes were covered in an alternating fashion. The patient was asked to score the disturbance of the light source concerning halos, starburst, and glare using a visual analog scale by comparing both eyes. To help the patients, example images from the Quality of Vision Questionnaire[16] with the dysphotopsia in question were shown. Additionally, the subjective near, intermediate, and distance vision were evaluated subjectively. Only these comparison tests were performed at this visit to avoid overloading the patient with other examinations.

The uncorrected monocular near visual acuity was used for sample size calculation. These data were known for the plate-haptic IOL (0.2 ± 0.2 logMAR).[17,18] Assuming a 0.5 correlation between the groups and using a Wilcoxon signed-rank test and a

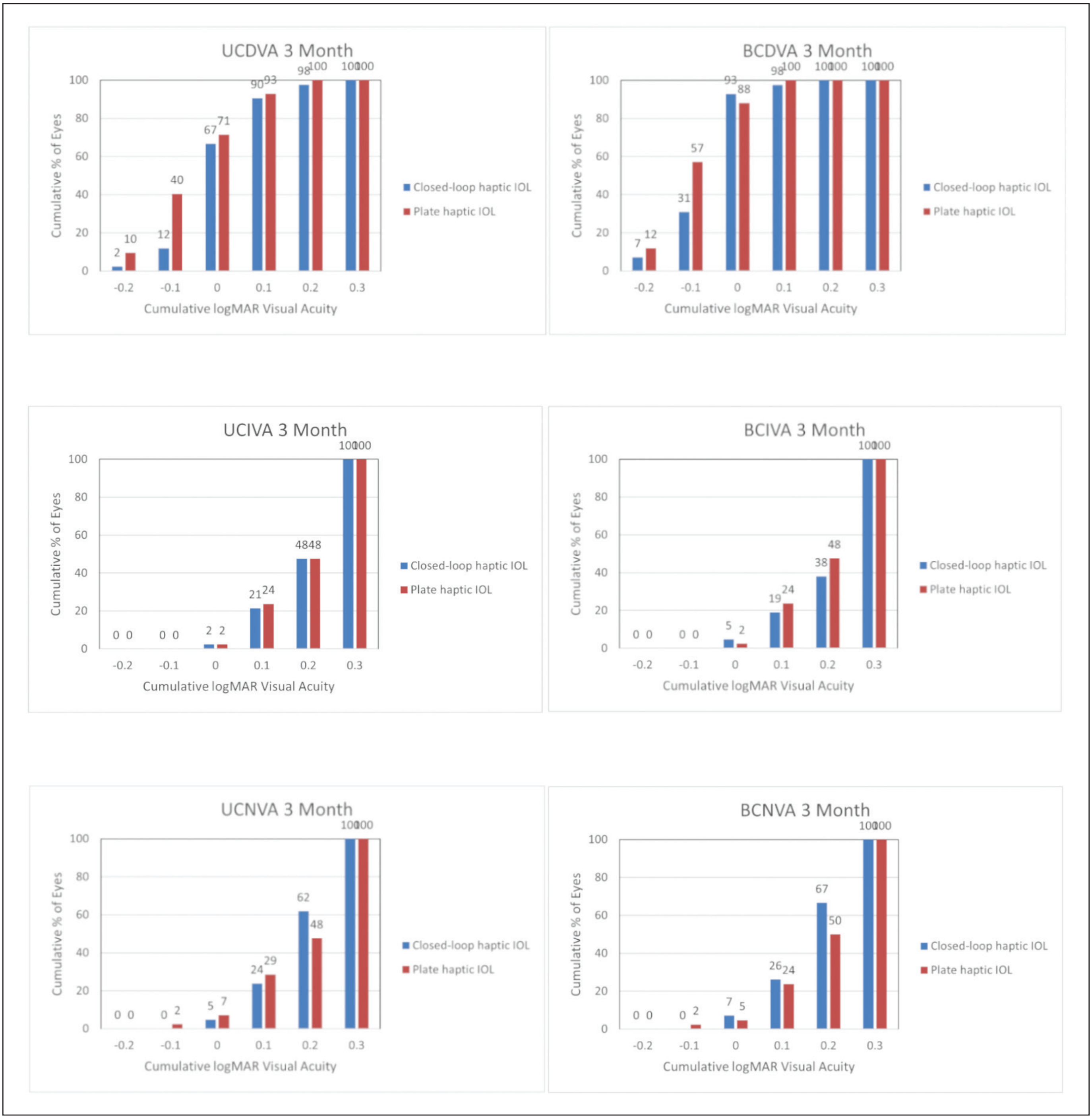

Figure 1. Uncorrected and corrected visual acuity at distance (4 m) (UCDVA and BCDVA), intermediate (80 cm) (UCIVA and BCIVA), and near (40 cm) (UCNVA and BCNVA) for the closed-loop (blue) and plate-haptic (red) trifocal intraocular lenses (IOLs) at 3 months after surgery.

drop-out rate of 25%, a total of 88 eyes of 44 patients was needed. For descriptive statistical analysis, IBM SPSS software (version 21; SPSS, Inc) was used. The Mann-Whitney *U* test was used to determine significance. A *P* value of less than .05 was considered statistically significant.

RESULTS

Altogether, 88 eyes of 44 patients were included in the study and 2 patients were lost to follow-up due to compliance problems. In some cases, patients were not able to perform all examinations at a follow-up visit, as mentioned below. The preoperative data of both groups are listed in **Table A** (available in the online version of this article).

Three months postoperatively, visual acuity at distance, intermediate, and near showed no significant differences between the IOLs (**Table B,** available in the online version of this article, and **Figure 1**). Defocus curves (**Figure 2**) were available for 41 patients and showed no relevant differences between both IOLs at distance (*P* = .071) and near (*P* = .180) vision. However, performance in the intermediate range (at -1.50 D) for the closed-loop haptic IOL showed a statistically significantly better visual acuity of 0.08 ± 0.10 logMAR (range: 0.34 to -0.10 logMAR) compared to 0.12 ± 0.09 logMAR (range: 0.30 to -0.10) (*P* = .008) with the plate-haptic IOL.

Reading speed (words per minute) was available for 32 patients and showed no significant differences between IOLs. The median words per minute for the closed-loop haptic IOL versus the plate-haptic IOL were 136.0 ± 49.8 versus 147.5 ± 50.5 (*P* = .730) (mean: 143.1 vs 148.3; range: 234 vs 279, min: 55 vs 59) and the median reading speed in seconds was 7.0 ± 3.0 versus 6.9 ± 3.1 (*P* = .679) (mean: 7.6 vs 7.4; max: 16.3 vs 16.3, min: 4.4 vs 3.7), respectively.

Contrast sensitivity showed good and comparable values for both IOLs (**Table 1**). The plate-haptic IOL showed statistically significantly better contrast sensitivity under photopic and mesopic conditions in miosis (*P* = .018 and .002, respectively) and mydriasis (*P* = .017 and .003, respectively) without glare.

Positive dysphotopsia measurements with the Aston Halometer were not found to be statistically significant between the two IOL types concerning halos (**Figure 3**) (*P* = .798). Six months postoperatively, visual analog scale testing for subjective comparison of the 2 eyes when looking at a bright light source was available for 23 patients (others were lost to follow-up)

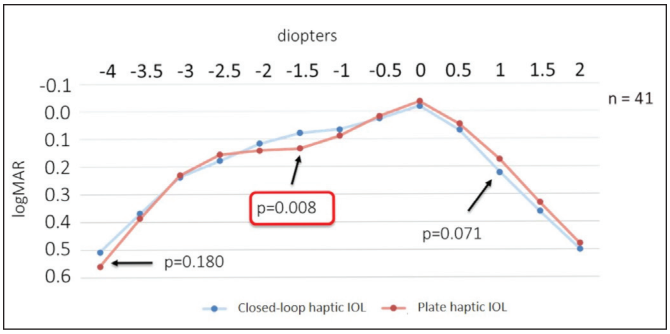

Figure 2. Defocus curve of the closed-loop haptic (blue) plate-haptic (red) intraocular lenses (IOLs) at 3 months after surgery.

and showed a statistically significantly lower overall disturbance (*P* = .047) and less intense starbursts (*P* = .039) for the plate-haptic IOL (**Figure 4**).

Tilt and decentration of both IOLs were similar. The median tilt of the closed-loop haptic IOL versus the plate-haptic IOL on the x-axis was -0.92 ± 3.44° versus -1.18 ± 3.81° (mean: -0.67 vs -1.61°; max: 11.35 vs 6.84°; min: -6.31 vs -9.89°) (*P* = .520) and the median tilt of the y-axis was 1.81 ± 2.62° versus 2.34 ± 1.71° (mean: 1.48 vs 2.29°; max: 6.81 vs 5.10°; min: -5.31 vs -0.79°) (*P* = .164). The median decentration on the x-axis was 0.06 ± 0.29 vs 0.09 ± 0.24 mm (mean: -0.00 vs 0.10 mm; max: 0.45 vs 0.75 mm; min: -0.89 vs -0.42 mm) (*P* = .254) and the median decentration on the y-axis was 0.09 ± 0.30 vs 0.24 ± 0.26 mm (mean: 0.16 vs 0.21 mm; max: 0.68 vs 0.75 mm; min: -0.62 vs -0.62 mm) (*P* = .208), respectively.

DISCUSSION

To our knowledge, this is the first study comparing two trifocal IOLs in a bilateral study design allowing within-subject comparison. Visual acuity testing at distance, intermediate, and near showed good results

TABLE 1

Contrast Sensitivity (Mean ± SD)

	Photopic		Mesopic	
Parameter	**Closed-Loop Haptic IOL**	**Plate-Haptic IOL**	**Closed-Loop Haptic IOL**	**Plate-Haptic IOL**
Miosis	13.9 ± 5.9	17.8 ± 7.4	9.0 ± 4.5	12.1 ± 4.7
P	.018 (n = 42)		.002 (n = 42)	
Miosis + glare	14.3 ± 6.4	16.7 ± 7.0	4.6 ± 4.6	5.2 ± 5.1
P	.222 (n = 42)		.575 (n = 42)	
Mydriasis	9.4 ± 5.8	13.0 ± 7.1	6.9 ± 4.3	10.2 ± 4.6
P	.017 (n = 39)		.003 (n = 40)	
Mydriasis + glare	6.6 ± 5.8	9.7 ± 7.4	0.2 ± 1.0	1.3 ± 2.5
P	.052 (n = 39)		.052 (n = 40)	

SD = standard deviation; IOL = intraocular lens

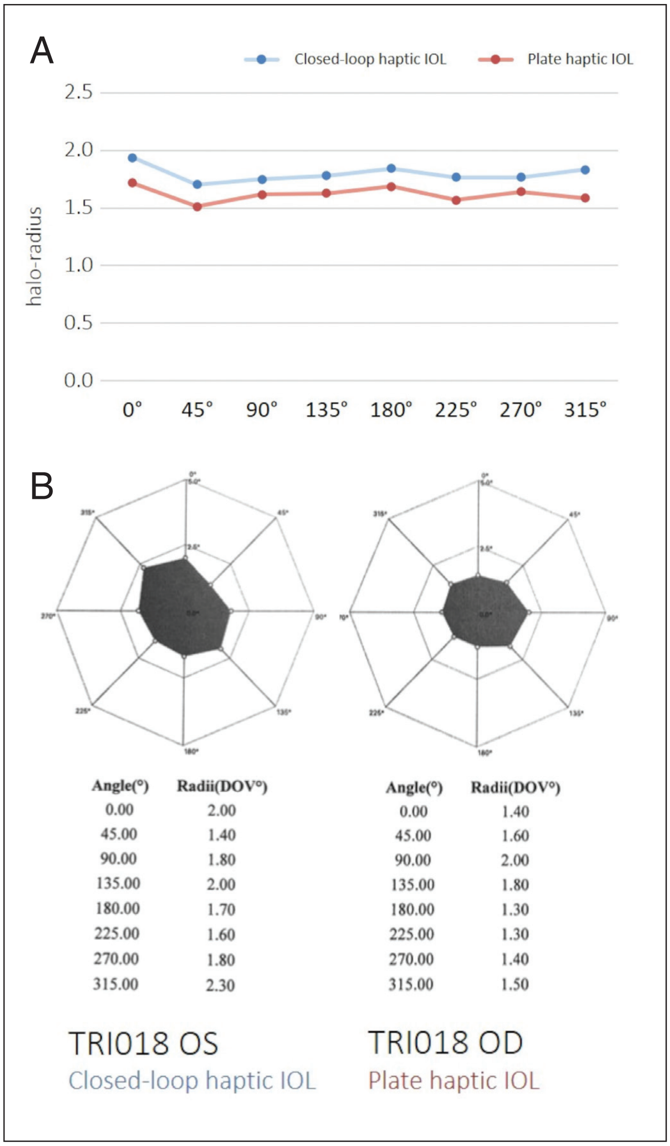

Figure 3. (A) Halo radius at 0° to 315° measured with the Aston Halometer (Aston University) by the closed-loop (blue) and plate-haptic (red) trifocal intraocular lens (IOL) at 3 months after surgery. (B) Example for the closed-loop haptic Halometer result and one plate-haptic Halometer result. DOV = degrees of view; OD = right eye; OS = left eye

for both IOLs and no significant differences. Although there is no direct comparison between these two trifocal IOLs available in the literature, both IOLs investigated showed good visual acuity results in other studies.[12,17,19,20] Mencucci et al,[12] Marques and Ferreira,[18] and Ferreira and Ribeiro[19] also showed that these IOLs provide good visual outcomes at all distances.

Concerning the defocus curve, the closed-loop haptic IOL performed better at -1.50 D. Kretz et al[17] tested the plate-haptic IOL in a separate study and found slightly better visual outcomes for the plate-haptic IOL at all diop-

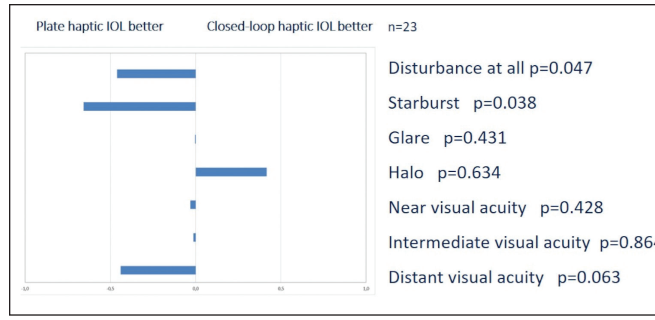

Figure 4. Subjective comparison of dysphotopsia using a visual analogue scale (0 to 10) at 6 months after surgery. Relative difference between intraocular lens (IOL) types: 0 depicts equal performance for both IOLs, left of 0-line = better performance of the plate-haptic IOL and right of 0-line = better performance of the closed-loop IOL.

ter steps except a reduced effect at approximately -2.00 D. However, in that study the defocus curve was tested binocularly. Martínez de Carneros-Llorente et al[20] had similar outcomes to ours, also showing a slight reduction of acuity at -1.50 D for the plate-haptic IOL. Reading speed was similar between both IOLs. To our knowledge, this study is the first to test reading speed for these IOLs.

The plate-haptic IOL had significantly better contrast sensitivity under photopic and mesopic conditions, and under miosis and mydriasis without glare. Previous studies have shown that the plate-haptic IOL performs well concerning contrast sensitivity. Kretz et al[17] showed a good contrast sensitivity for the plate-haptic IOL except for mesopic condition with glare. Mencucci et al[12] showed that the EDOF IOL used in their study had better contrast sensitivity compared to the plate-haptic IOL. Contrast sensitivity of the plate-haptic IOL was comparable with our results.

Patients had halos in both groups, but no statistically significant difference was detectable. Other studies typically assess halos using questionnaires.[17,20] Using a device such as a halometer to quantify the halo data may be more objective than using a questionnaire only.[15]

Tilt and decentration was comparable between IOLs. Crnej et al[13] showed that tilting and decentration are seen more commonly in three-piece IOLs compared to one-piece or plate-haptic IOLs. It should be taken into account that the control IOL was different compared to our study.

One of the limitations of our study is the size of the study population. To show small differences between IOL types, a larger population would have been necessary. However, we believe that our study was powered sufficiently to spot a clinically relevant difference, which we did not find between these IOL types. On the other hand, the bilateral design is powerful to find even small differences between IOL types for dysphotopsia because the patients were able to assess these directly under the same conditions. It is well accepted that the perception of dysphotopsia is variable between patients and this factor has been neutralized with our study design.

Our study showed that both trifocal IOL types delivered a good and comparable outcome. Visual acuity showed good results in all distances. Contrast sensitivity showed comparable data with existing studies. There were low degrees of disturbing dysphotopsia and good capsular bag performance after surgery. Both IOLs are a good choice for trifocal IOLs with a satisfying performance.

AUTHOR CONTRIBUTIONS

Study concept and design (JH, HZ, OF); data collection (JH, KS, MR, HZ); analysis and interpretation of data (JH, KS, NH); writing the manuscript (JH); critical revision of the manuscript (KS, NH, MR, HZ, OF); statistical expertise (NH); administrative, technical, or material support (MR); supervision (JH, HZ, OF)

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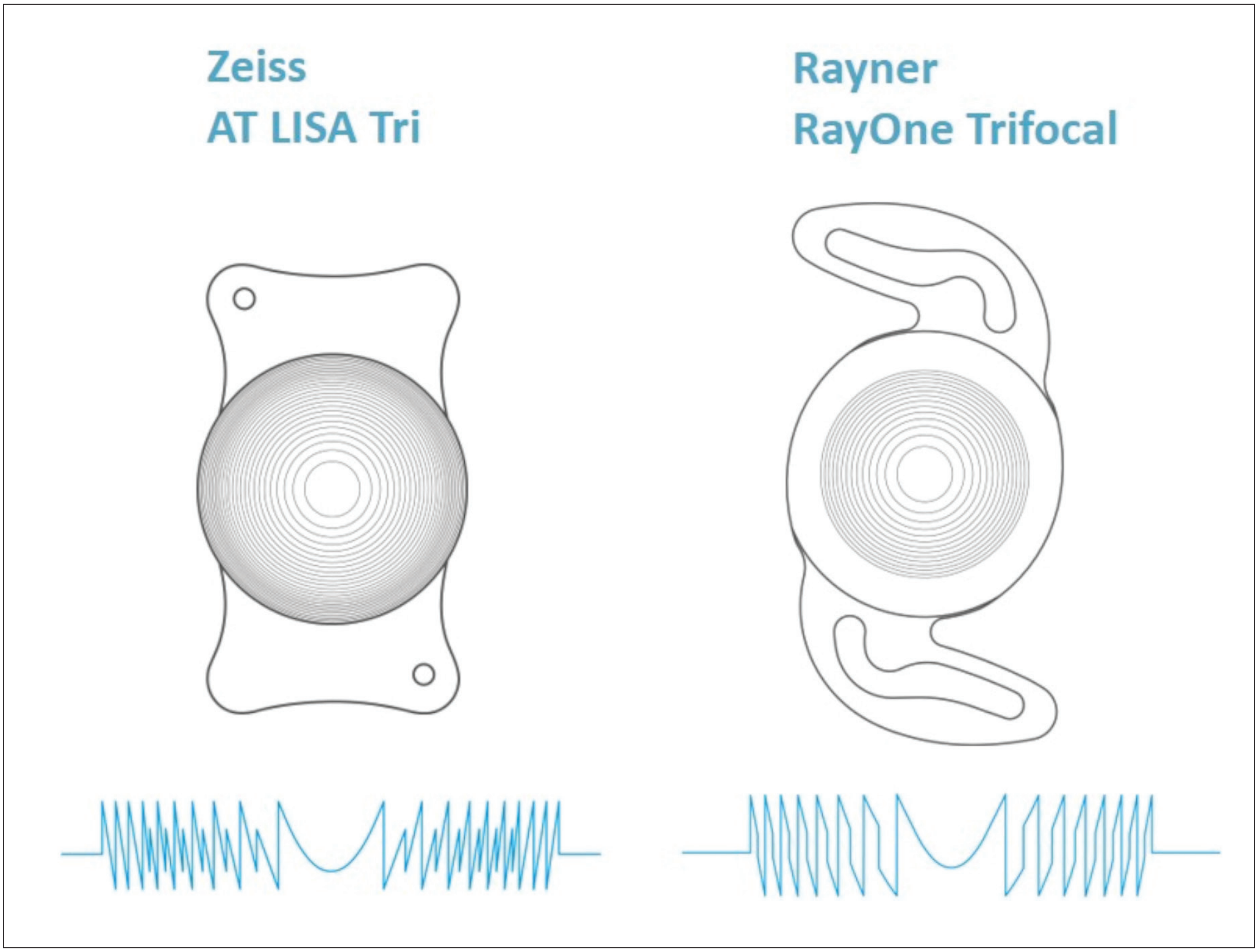

Figure A. Difference in trifocal intraocular lens (IOL) design: (left) the plate-haptic IOL and (right) the closed-loop haptic IOL. Reprinted with permission from Rayner Intraocular Lenses Limited, United Kingdom).

TABLE A

Preoperative Data of Both Groups

Parameter	Closed-Loop Haptic IOL		Plate-Haptic IOL
Axial length (mm)			
Mean ± SD	23.33 ± 0.85		23.33 ± 0.85
Median	23.19		23.19
Range	26.00 to 21.77		26.06 to 21.76
P		.98	
Mean keratometry (mm)			
Mean ± SD	7.72 ± 0.24		7.71 ± 0.23
Median	7.77		7.73
Range	8.19 to 7.18		8.11 to 7.17
P		.79	
Astigmatism magnitude (D)			
Mean ± SD	0.58 ± 0.40		0.52 ± 0.30
Median	0.47		0.56
Range	1.49 to 0.00		1.17 to 0.00
P		.69	
IOL power implanted (D)			
Mean ± SD	21.36 ± 2.86		21.36 ± 2.73
Median	21.50		22.00
Range	25.50 to 13.00		25.00 to 13.00
P		.93	

IOL = intraocular lens; SD = standard deviation; D = diopters

TABLE B

Visual Acuity at Distance, Intermediate, and Near 3 Months Postoperatively

Parameter	Closed-Loop Haptic IOL	Plate-Haptic IOL	*P*
UDVA (logMAR), median ± SD			
Distance	0.00 ± 0.09	0.00 ± 0.11	.120
Intermediate	0.26 ± 0.10	0.26 ± 0.10	1.00
Near	0.21 ± 0.09	0.26 ± 0.12	.429
CDVA (logMAR), median ± SD			
Distance	-0.01 ± 0.07	-0.08 ± 0.08	.134
Intermediate	0.28 ± 0.10	0.26 ± 0.10	.549
Near	0.02 ± 0.10	0.25 ± 0.11	.289

IOL = intraocular lens; UDVA = uncorrected distance visual acuity; SD = standard deviation; CDVA = corrected distance visual acuity