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Comparison of a trifocal intraocular lens with a +3.0 D bifocal IOL: Results of a prospective randomized clinical trial

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PURPOSE: To compare visual outcomes in patients with cataract surgery and bilateral implantation of a trifocal or bifocal intraocular lens (IOL).

SETTING: University Eye Clinic Maastricht, the Netherlands.

DESIGN: Prospective randomized clinical trial.

METHODS: Eyes with cataract and less than 1.0 diopter (D) of corneal astigmatism were randomized to receive bilateral implantation of Finevision Micro F trifocal IOLs or Acrysof IQ Restor +3.0 bifocal IOLs. Outcome measures were monocular and binocular uncorrected distance (UDVA), uncorrected intermediate (UIVA), and uncorrected near (UNVA) visual acuities; refractive outcomes; binocular defocus curve; contrast sensitivity; reading speed; patient satisfaction; and spectacle independence.

RESULTS: Six months postoperatively, the mean binocular UDVA, UIVA, and UNVA in 56 eyes of 28 patients were $0.01 \log\text{MAR} \pm 0.11$ (SD), $0.32 \pm 0.15 \log\text{MAR}$, and $0.15 \pm 0.13 \log\text{MAR}$ in the trifocal group ($n = 15$) and $0.00 \pm 0.09 \log\text{MAR}$, $0.28 \pm 0.08 \log\text{MAR}$, and $0.12 \pm 0.08 \log\text{MAR}$ in the bifocal group ($n = 13$), respectively. The trifocal group showed a more continuous defocus curve and better results at -1.0 D of defocus ($P < .01$). The mean mesopic contrast sensitivity was higher in the bifocal group ($P = .02$). Complete spectacle independence was reported by 80% of trifocal patients and 50% of bifocal patients. There were no significant differences in refractive outcomes, reading speed, or patient satisfaction.

CONCLUSION: This study showed noninferiority of visual outcomes with the trifocal IOL compared with the bifocal IOL, although the defocus curve was better at an intermediate distance with the trifocal IOL.

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Cataract is an age-related eye disease leading to an impairment of patients' daily functioning as well as optical disturbances such as glare and halos.¹ In 2010, an estimated 95 million people worldwide had cataracts.² Surgical removal of the crystalline lens and replacement with an artificial intraocular lens (IOL) is the only vision-restoring option. After

implantation of a monofocal IOL, reading glasses are usually needed for near vision, whereas multifocal IOLs result in better uncorrected near visual acuity (UNVA) with a reduced overall spectacle dependence.^{1,3,4} Multifocal IOLs function by projecting multiple images on the retina, which may result in unwanted visual phenomena such as contrast reduction,

glare, and halos.^{3–12} Because most multifocal IOLs have only 2 foci, near and far, the quality of intermediate visual acuity might be insufficient for successful functioning in daily life.^{13,14} Trifocal IOLs have been developed to improve vision at intermediate distances.^{13,15} The goal of this randomized clinical trial was to compare the visual outcomes of a new trifocal IOL with those of a commonly used bifocal IOL.

PATIENTS AND METHODS

Patient Selection

A randomized clinical study design was used to compare visual function and patient satisfaction after bilateral IOL implantation in patients treated for age-related cataract. Both patient enrollment and treatment took place at the University Eye Clinic Maastricht. Approval from the medical ethics committee was obtained, and all procedures were conducted according to the Declaration of Helsinki. Written informed consent was obtained from all patients.

Inclusion criteria were bilateral cataract, less than 1.0 diopter (D) corneal astigmatism in both eyes, age over 42 years, and an expected postoperative corrected distance visual acuity (CDVA) of 0.3 logMAR or less. Exclusion criteria were combined ocular procedures, previous ocular surgery, ocular pathology that would limit postoperative visual outcome, suturing of the incision during surgery, and complications during surgery in the first eye.

After enrollment, random allocation of study patients was performed to bilateral implantation of a trifocal IOL (trifocal group) or a bifocal IOL (bifocal group). Patients and investigators were masked.

Surgical Technique

Two experienced surgeons (N.B., R.N.) performed all surgical procedures, which consisted of a standard phacoemulsification technique through a 2.2 mm clear corneal incision. Surgery in the second eye was performed within 2 weeks of the first surgery in each patient. The same type of IOL was implanted in both eyes.

The study used 2 types of IOLs: the Finevision Micro F trifocal IOL (Physiol S.A.) (Figure 1) and the Acrysof Restor IQ +3.0 D bifocal IOL (Alcon Surgical, Inc.) (Figure 2). The

trifocal IOL is a foldable single-piece fully diffractive pupil-dependent aspheric IOL made of a hydrophilic acrylic with an ultraviolet (UV)- and blue-light inhibitor.^{13,15} It has an optic diameter of 6.15 mm, an overall diameter of 10.75 mm, and a 4-point haptic design for stability. It has +3.5 D additional power for near vision and +1.75 D additional power for intermediate vision, consists of 26 diffractive steps, and requires a minimum incision of 1.8 mm. The bifocal IOL is a foldable, single-piece, pupil-dependent aspheric biconvex IOL with a 3.6 mm center and 9 apodized diffractive steps.¹⁵ It is made of a hydrophobic acrylate/methacrylate copolymer with an UV-light and blue-light blocker. The optic diameter is 6.0 mm, and the overall diameter is 13.0 mm. It has +3.0 D additional power for near vision.

Patient Evaluation

Eyes were evaluated at baseline and 1 week, and 1, 3, and 6 months postoperatively (Figure 3). A full ophthalmic examination was performed at every follow-up visit, including manifest refraction, monocular and binocular uncorrected distance visual acuity (UDVA) and CDVA measurements using the Early Treatment of Diabetic Retinopathy Study (ETDRS) chart at different reading distances, slitlamp examination, Scheimpflug photography (Pentacam, Oculus Optikgeräte GmbH), and ophthalmoscopy. A binocular distance-corrected defocus curve was obtained using the ETDRS chart at 4 m, adding lenses from −5.0 to +2.0 D in 0.5 steps. The measurement was performed under photopic (>85 candelas [cd]/m²) and mesopic (~3 cd/m²) conditions 3 months after surgery. Additional contrast sensitivity measurements were performed with a contrast-sensitivity chart (CSV-1000, VectorVision). The contrast-sensitivity chart measured contrast sensitivity at 4 spatial frequencies, each with 8 levels of contrast. When applying the manufacturers' conversion guidelines, individual values could be converted into values suitable for statistical analysis; ie, the area under the log contrast sensitivity function (AULCSF) curve.¹⁶ The uncorrected reading acuity and reading performance were measured at baseline and 3 months postoperatively with the Dutch Radner reading chart¹⁷ (Rotterdam Eye Hospital, Rotterdam, the Netherlands) using the Salzburg Reading Desk (SRD Vision).¹⁸ The Radner reading chart comprises standardized sentences, allowing evaluation in patients with different levels of education. To evaluate vision-related quality of life, the National Eye Institute Refractive Error Correction Quality of Life Instrument-42 (NEI-RQL 42) questionnaire¹⁹ was used preoperatively and 6 months postoperatively. It has 42 questions divided in 13 scales and covering different aspects of vision-related quality of life. Each scale has a score from 0 to 100, with higher scores indicating higher subjective quality of life.^{20,21}

Outcome Measures

The primary outcome measure was the mean binocular distance-corrected visual acuity at intermediate distance (DCIVA) at 70 cm under mesopic (~3 cd/m²) conditions. Secondary outcome parameters were monocular and binocular visual acuities, including DCIVA at 70 cm under photopic conditions, UNVA and distance-corrected near visual acuity (DCNVA) at 40 cm, uncorrected intermediate visual acuity (UIVA) at 70 cm, and UDVA and CDVA at 4 m under photopic and mesopic conditions. Contrast sensitivity was tested monocularly and binocularly under photopic and mesopic conditions, and reading speed was evaluated

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Figure 1. The trifocal IOL.

Figure 2. The bifocal IOL.

70% and 100% contrast levels. Perioperative and postoperative complications were documented.

Sample Size

Calculation of the required sample size was based on the primary outcome parameter of binocular DCIVA at 70 cm under mesopic conditions. A pilot study with the trifocal IOL used in this study found a bilateral DCIVA of 0.12 ± 0.17 logMAR (data on file). To find a clinically significant difference between groups, a difference of 0.2 logMAR was assumed significant. Based on these assumptions, an alpha of 0.05, and power of 0.8, it was calculated that 12 patients were required in each group. While assuming a dropout rate of 15% on the primary outcome measure, this resulted in a total requirement of 28 patients.

Statistical Analysis

Data are provided as the mean $\pm$ standard deviation (SD). The chi-square test was used to compare categorical data and the Student *t* test for scale variables. Linear regression analysis was used to look for possible associations between preoperative values and outcomes 3 months and 6 months after surgery. A *P* value less than 0.05 was considered statistically significant. The statistical analysis was performed using SPSS for Windows software (version 22, International Business Machines Corp.).

RESULTS

The trifocal group included 30 eyes of 15 patients and the bifocal group included 26 eyes of 13 patients. Table 1 shows the preoperative patient characteristics. A statistically significant difference was found in distance-corrected near visual acuity (DCNVA) at patient-preferred distance ($P = .01$) and in pupil size under photopic ($P = .02$) and high mesopic ($P = .01$) conditions. All study patients completed the 6-month follow-up period.

Refraction and Visual Acuity

Table 2 shows the monocular postoperative refraction and visual acuity results 1 month and 6 months. Monocular measurements (photopic and mesopic) at

either timepoint showed no statistically significant differences between the 2 IOL groups.

Table 3 shows the binocular visual acuity and refractive results at 1 and 6 months after surgery. No statistically significant differences were observed under photopic and mesopic circumstances at 1 month or 6 months after surgery.

Defocus Curves

Binocular defocus curves of both groups are shown in Figure 4. When comparing both groups under photopic circumstances, statistically significantly better visual acuity was present in the trifocal group for the defocus levels -1.0 D ($P < .01$) and $+1.0$ D ($P = .02$). Statistically significantly better visual acuity was present in the bifocal group for the defocus levels -5.0 D ($P < .01$), -4.5 D ($P < .01$), and -4.0 D ($P = .01$). When comparing both groups under mesopic circumstances, significantly better visual acuity was present in the trifocal group for the defocus levels -1.0 D ($P < .01$), $+1.0$ D ($P = .02$), and $+1.5$ D ($P = .02$). Statistically significantly better visual acuity was present in the bifocal group for the defocus levels -5.0 D ($P < .01$) and -4.5 D ($P = .01$). At the intermediate range, the defocus curves of the trifocal IOL showed a more continuous performance at the intermediate range under photopic and mesopic conditions.

Contrast Sensitivity

Binocular contrast sensitivity curves with respect to the appropriate age-related cohort under both photopic and mesopic conditions are shown in Figure 5 and Table A (available at <http://jcrsjournal.org>). Binocular measurements of individual contrast sensitivity values (AULCSF) were similar under photopic conditions and significantly better in the bifocal group at a spatial frequency of 6 cycles per degree (cpd) ($P = .01$) under mesopic conditions. As Figure 5 shows, all contrast sensitivity values are within or are only slightly lower

Figure 3. Schedule of postoperative visits.

than the normal age-related cohort. All mean photopic contrast sensitivity (mean AULCSF) results were similar in the trifocal group and the bifocal group ($P > .1$). The mesopic mean binocular contrast sensitivity (mean AULCSF) was significantly higher in the bifocal group ($P = .02$).

Reading Speed

Results of comparative measurements with the Radner reading chart are shown in Table B (available at <http://jcrsjournal.org>). No statistically significant difference was found in the mean reading distance, mean reading speed, or maximum reading speed under 70% and 100% contrast. Comparison of critical print size and visual acuity showed no statistically significant difference between the 2 IOL groups.

Patient-Reported Parameters

Questionnaires were completed by 15 patients (100%) in the trifocal group and 12 patients (92%) in the bifocal group (Figure 6). Six months postoperatively, most patients were pleased with their quality of vision. The occurrence of side effects of multifocal IOLs, such as glare and halos, was similar to preoperative measurements with the NEI-RQL 42 questionnaire.

At 6 months, all patients were spectacle-free for distance, with 12 trifocal patients (80%) and 9 bifocal patients (75%) also reporting spectacle independence at near distance. Patients were also asked to report the duration of daily spectacle use (Figure 7). In the trifocal group, 12 patients (80%) reported complete spectacle independence, and 2 (13%) reported wearing spectacles less than 15% of a day. In the bifocal group, 6 patients (50%) reported total spectacle independence and 5 (42%) reported wearing spectacles less than 15% of a day.

Complications and Intraocular Lens Centration

In 1 eye (3.3%) in the trifocal group, intraoperative IOL exchange occurred because of a damaged haptic. During the follow-up period, there were no potentially sight-threatening complications in either group. No additional interventions in the postoperative period were required.

An IOL decentration of more than 1.5 mm occurred in both eyes of 1 patient (6.6%) in the trifocal group, which did not lead to decreased patient satisfaction. In the bifocal group, 1 eye (3.8%) of 1 patient had IOL decentration of more than 1.5 mm, resulting in glare, halos, and the perception of a shimmer, a vague dark contour in the corner of the eye. This patient did not opt for surgical repositioning of the IOL.

DISCUSSION

To our knowledge, this is the first study to compare the trifocal aspheric Finevision Micro F IOL (introduced in 2011) with a commonly used bifocal IOL, the Restor IQ +3.0 D, in a prospective randomized controlled manner. This trifocal IOL is designed to supply better intermediate visual acuity without impairing near and far vision¹³; however, dividing the light into 3 foci decreases the amount of energy directed to far and near and consequently might affect visual acuity at all distances.²² Preliminary studies of the Finevision IOL have shown a mean UDVA ranging from -0.04 to 0.19 logMAR, a mean UIVA ranging from -0.10 to 0.20 logMAR, and a mean UNVA ranging from 0.00 to 0.26 logMAR.^{23–26} Previous reports after implantation with the Restor IOL showed a mean UDVA ranging from 0.00 to 0.45 logMAR, a mean UIVA ranging from 0.1 to 0.56 logMAR, and a mean UNVA ranging from 0.00 to 0.1 logMAR.^{27–30}

An experimental study²² comparing the Finevision trifocal IOL and the Restor bifocal IOL showed that

Table 1. Baseline measurements.

Measurement*	Mean $\pm$ SD		P Value
	Trifocal IOL	Bifocal IOL	
Age (y)	62.6 $\pm$ 8.7	64.0 $\pm$ 8.8	.68
Preoperative data			
Spherical equivalent (D)	0.47 $\pm$ 2.72	0.82 $\pm$ 2.46	.90
Astigmatism (D)	-0.94 $\pm$ 0.48	-0.91 $\pm$ 0.48	.80
Corrected monocular visual acuity (logMAR)			
CDVA at 4 m	0.06 $\pm$ 0.16	0.04 $\pm$ 0.10	.72
DCIVA at 70 cm	0.39 $\pm$ 0.18	0.37 $\pm$ 0.12	.61
DCNVA at 40 cm	0.24 $\pm$ 0.30	0.11 $\pm$ 0.10	.03 [†]
DCNVA at PP	0.21 $\pm$ 0.24	0.08 $\pm$ 0.11	.01 [†]
Pupil size (mm)			
Photopic	5.66 $\pm$ 0.71	5.19 $\pm$ 0.72	.02 [†]
Mesopic high	3.76 $\pm$ 0.70	3.30 $\pm$ 0.48	.01 [†]
Mesopic low	4.75 $\pm$ 1.10	4.40 $\pm$ 0.76	.18
Radner reading test (binocular) [‡]			
70% contrast			
Reading distance (cm)	39.4 $\pm$ 12.0	41.9 $\pm$ 11.3	.64
Mean reading speed (words/min)	145.3 $\pm$ 32.9	144.6 $\pm$ 38.5	.96
Maximum reading speed (words/min)	176.9 $\pm$ 48.8	196.3 $\pm$ 38.5	.32
Reading visual acuity (logRAD)	0.19 $\pm$ 0.20	-0.02 $\pm$ 0.27	.10
SWRVA	0.71 $\pm$ 0.26	0.87 $\pm$ 0.23	.13
100% contrast			
Reading distance (cm)	39.6 $\pm$ 11.9	40.6 $\pm$ 11.8	.86
Mean reading speed (words/min)	141.8 $\pm$ 39.7	168.0 $\pm$ 37.3	.12
Maximum reading speed (words/min)	186.7 $\pm$ 63.8	236.1 $\pm$ 52.4	.06
Reading visual acuity (logRAD)	0.12 $\pm$ 0.15	0.06 $\pm$ 0.15	.36
SWRVA	0.75 $\pm$ 0.23	0.88 $\pm$ 0.20	.15

CDVA = corrected distance visual acuity; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; PP = patient-preferred distance; SWRVA = Snellen visual acuity at critical print size

*Except for Radner reading test data, n = 30 eyes for trifocal IOL and n = 26 eyes for bifocal IOL

[†]Statistically significant ($P < .05$)

[‡]Trifocal IOL = 12 patients; bifocal IOL = 11 patients

the image quality at near and far distance was better with the bifocal IOL, whereas the trifocal IOL provided better image quality at intermediate distance. Another available trifocal IOL, the AT Lisa tri 839MP (Carl Zeiss Meditec AG), showed similar results to the Finevision IOL.^{23-26,31}

In the present study, the refractive results in both study groups were in accordance with those in previous studies of diffractive bifocal and trifocal IOLs.^{27,28,30,32} The present study did not find any statistically significant difference in postoperative refraction between the 2 groups. For visual acuity, our study did not find any differences between binocular and monocular UDVA and UNVA. Binocular UIVA was 0.3 logMAR without any intergroup difference. Comparing binocular UIVA with monocular UIVA showed better results in the binocular group, illustrating an important role for binocular summation in achieving good visual acuity.

Our results with the Finevision IOL differ from those in other clinical studies. Cochener et al.²⁵ and Vryghem and Heireman²⁶ reported better binocular UIVA outcomes (0.10 ± 0.15 logMAR and 0.05 ± 0.08 logMAR, respectively), whereas our results showed a binocular UIVA of 0.32 ± 0.15 logMAR. A possible explanation for this difference in outcomes is that in our study, visual acuity was assessed with the ETDRS charts (direct representation in logMAR values), whereas Cochener et al.²⁵ and Vryghem and Heireman²⁶ used Parinaud optotypes with subsequent conversion to logMAR values. Conversion of Parinaud optotypes to logMAR notation could lead to better results in the described studies. Our results in the bifocal group were in accordance with those in studies with similar study populations that assessed visual acuity at comparable distances.^{5,28} Because of variations in the age of study populations, different tests, and variable distances used for

Table 2. Postoperative monocular refractive results and visual acuities at 1 month and 6 months.

Measurement	Postoperative Visit					
	1 Month (Mean $\pm$ SD)		P Value	6 Month (Mean $\pm$ SD)		P Value
	Trifocal*	Bifocal [†]		Trifocal*	Bifocal [†]	
Spherical equivalent (D)	0.08 $\pm$ 0.39	0.10 $\pm$ 0.32	.84	0.03 $\pm$ 0.52	0.11 $\pm$ 0.25	.46
Astigmatism (D)	-1.02 $\pm$ 0.60	-0.67 $\pm$ 0.47	.02 [‡]	-0.90 $\pm$ 0.61	-0.66 $\pm$ 0.42	.11
Photopic visual acuity (logMAR)						
Uncorrected						
UDVA at 4 m	0.12 $\pm$ 0.15	0.07 $\pm$ 0.11	.16	0.09 $\pm$ 0.16	0.08 $\pm$ 0.11	.88
UIVA at 70 cm	0.44 $\pm$ 0.14	0.44 $\pm$ 0.12	.35	0.45 $\pm$ 0.18	0.41 $\pm$ 0.15	.46
UNVA at 40 cm	0.21 $\pm$ 0.16	0.15 $\pm$ 0.11	.11	0.25 $\pm$ 0.17	0.20 $\pm$ 0.09	.19
UNVA at PP	0.19 $\pm$ 0.16	0.13 $\pm$ 0.10	.78	0.20 $\pm$ 0.17	0.19 $\pm$ 0.10	.77
Distance-corrected						
CDVA at 4 m	-0.01 $\pm$ 0.09	-0.04 $\pm$ 0.07	.17	0.01 $\pm$ 0.11	0.02 $\pm$ 0.08	.93
DCIVA at 70 cm	0.39 $\pm$ 0.11	0.42 $\pm$ 0.13	.97	0.43 $\pm$ 0.15	0.42 $\pm$ 0.14	.89
DCNVA at 40 cm	0.13 $\pm$ 0.11	0.09 $\pm$ 0.09	.12	0.19 $\pm$ 0.14	0.17 $\pm$ 0.08	.53
DCNVA at PP	0.10 $\pm$ 0.13	0.11 $\pm$ 0.11	.11	0.14 $\pm$ 0.14	0.16 $\pm$ 0.08	.55
Mesopic visual acuity (logMAR)						
Uncorrected						
UIVA at 70 cm	0.63 $\pm$ 0.15	0.56 $\pm$ 0.15	.14	0.69 $\pm$ 0.14	0.71 $\pm$ 0.12	.52
UNVA at 40 cm	0.39 $\pm$ 0.20	0.34 $\pm$ 0.17	.27	0.48 $\pm$ 0.13	0.54 $\pm$ 0.13	.12
Distance-corrected						
DCIVA at 70 cm	0.62 $\pm$ 0.13	0.55 $\pm$ 0.18	.08	0.69 $\pm$ 0.14	0.73 $\pm$ 0.13	.31
DCNVA at 40 cm	0.31 $\pm$ 0.17	0.31 $\pm$ 0.13	.81	0.46 $\pm$ 0.12	0.52 $\pm$ 0.14	.08

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

*Trifocal = 30 eyes at 1 month and 29 eyes at 6 months

[†]Bifocal = 26 eyes at both visits

[‡]Statistically significant ($P < .05$)

intermediate visual acuity measurements, a direct comparison of the results in our trifocal group with findings in other studies is not possible.

The trifocal IOL used in this study is designed to improve depth of focus and thus to provide good visual acuity, not only at far and near distances but also intermediate. Our study results showed photopic pseudoaccommodation (depth of focus) of roughly -3.5 D to +1.75 D in the trifocal group and -3.75 D to +1.5 D in the bifocal group. Under mesopic circumstances, pseudoaccommodation was roughly -3.5 to +1.75 D in the trifocal group and -3.75 to +1.25 D in the bifocal group. Both IOLs performed well at the diopters of defocus representing distance (0.0 D) and near (-2.5 D) visual acuity. The trifocal group had a more continuous performance, with a statistically significantly better performance at -1.0 D in all lighting conditions than the bifocal group ($P < .01$). Although performance with the trifocal IOL was better at this point of defocus, no difference was found in binocular UIVA or

DCIVA under photopic and mesopic conditions between the bifocal group and the trifocal group. Measurement of intermediate visual acuity took place at 70 cm, similar to -1.4 D of defocus, a range in which the results in this study showed no statistically significant difference between IOL types. With this knowledge, it can be argued that measuring visual acuity at 1 m would probably show a substantially better performance with the trifocal IOL.

A decrease in contrast sensitivity is a well-known side effect of diffractive multifocal IOLs. Our results showed statistically significantly better binocular results in the bifocal group for both the AULCSF at 6 cpd ($P = .01$) and the mean AULCSF ($P = .02$). In our study, the binocular contrast sensitivity in both groups appeared similar or slightly lower than in the age-related cohort and similar to previous reports about these IOLs (Figure 5).^{3-12,23,24} Even though use of the AULCSF enables us to compare contrast sensitivity function results with other tests

Table 3. Postoperative binocular visual acuities at 1 month and 6 months.

Visual Acuity	Postoperative Visit					
	1 Month (Mean $\pm$ SD)		P Value	6 Month (Mean $\pm$ SD)		P Value
	Trifocal*	Bifocal [†]		Trifocal*	Bifocal [†]	
Photopic visual acuity (logMAR)						
Uncorrected						
UDVA at 4 m	0.01 $\pm$ 0.08	−0.02 $\pm$ 0.07	.76	−0.01 $\pm$ 0.11	0.00 $\pm$ 0.09	.79
UIVA at 70 cm	0.33 $\pm$ 0.10	0.32 $\pm$ 0.12	.50	0.32 $\pm$ 0.15	0.28 $\pm$ 0.08	.08
UNVA at 40 cm	0.11 $\pm$ 0.11	0.10 $\pm$ 0.08	.42	0.15 $\pm$ 0.13	0.12 $\pm$ 0.08	.31
UNVA at PP	0.09 $\pm$ 0.12	0.07 $\pm$ 0.07	.52	0.12 $\pm$ 0.12	0.10 $\pm$ 0.08	.77
Distance-corrected						
CDVA at 4 m	−0.07 $\pm$ 0.05	−0.07 $\pm$ 0.08	.26	−0.04 $\pm$ 0.09	−0.05 $\pm$ 0.06	.79
DCIVA at 70 cm	0.29 $\pm$ 0.11	0.32 $\pm$ 0.13	.94	0.31 $\pm$ 0.11	0.24 $\pm$ 0.08	.33
DCNVA at 40 cm	0.03 $\pm$ 0.09	0.05 $\pm$ 0.07	.65	0.08 $\pm$ 0.08	0.11 $\pm$ 0.08	.45
DCNVA at PP	0.03 $\pm$ 0.11	0.01 $\pm$ 0.07	.63	0.07 $\pm$ 0.10	0.08 $\pm$ 0.06	.60
Mesopic visual acuity (logMAR)						
Uncorrected						
UIVA at 70 cm	0.56 $\pm$ 0.14	0.48 $\pm$ 0.16	.18	0.58 $\pm$ 0.14	0.60 $\pm$ 0.12	.75
UNVA at 40 cm	0.31 $\pm$ 0.16	0.24 $\pm$ 0.17	.29	0.36 $\pm$ 0.11	0.42 $\pm$ 0.10	.19
Distance-corrected						
DCIVA at 70 cm	0.52 $\pm$ 0.15	0.47 $\pm$ 0.13	.35	0.58 $\pm$ 0.12	0.59 $\pm$ 0.12	.92
DCNVA at 40 cm	0.25 $\pm$ 0.14	0.19 $\pm$ 0.12	.22	0.34 $\pm$ 0.13	0.41 $\pm$ 0.10	.11

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

*Trifocal = 15 eyes at both visits

[†]Bifocal = 13 eyes at both visits

using spatial frequencies (ie, FACT, Ophtec Vision tester),^{33,34} a substantial number of studies still use other outcome measures, which limits comparability of outcomes.³ Under photopic conditions, no statistically significant difference between the 2 groups was measured; however, under mesopic conditions, performance in the bifocal group was statistically significantly better at 6 cpd ($P = .01$) and in general ($P = .02$). However, it is unlikely that this is also clinically relevant because the results of the NEI-RQL

questionnaire showed that 99% of trifocal patients and 95% of bifocal patients were not limited by their visual function during daily activities.

Near visual acuity measurements with standardized charts cannot fully represent the actual performance at near distance. Thus, assessment of the reading performance during real reading tasks was measured in this study. Similar preoperative performances were found in both groups. Postoperatively, there were no statistically significant differences

Figure 4. A: Mean binocular photopic defocus curve 3 months postoperatively. B: Mean binocular mesopic defocus curve 3 months postoperatively (IOL = intraocular lens).

Figure 5. A: Mean binocular photopic contrast sensitivity 3 months postoperatively. B: Mean binocular mesopic contrast sensitivity 3 months postoperatively (IOL = intraocular lens).

between the groups in reading speed, reading acuity, or critical print size measured at 70% and 100% contrast levels. Compared with the results described by Rasp et al.,³⁵ our study found better reading acuity and speed but similar or slightly lower critical print size. A possible explanation is that our study population was younger than that described by Rasp et al.

Spectacle independence, a desired outcome of cataract surgery with multifocal IOLs, was high and in line with results in previous studies.^{26,29,36} This resulted in a high degree of patient satisfaction in both groups 6 months postoperatively, results that are in accordance with findings in other studies of the trifocal IOL^{23,26} and the bifocal IOL²⁷; however, because those studies used different questionnaires, it was not possible to make direct comparisons regarding patient satisfaction or the occurrence of side effects (eg, glare and halos). The questionnaire used in this study

imposed several limitations; most important, it did not assess spectacle use or vision at the intermediate distance specifically. However, the secondary results in our study imply high spectacle independence, with 80% of trifocal patients and 50% of bifocal patients reporting complete spectacle independence. This suggests a good quality of vision at all distances.

A previous report¹³ suggested that 1.0 mm of decentration of the trifocal IOL theoretically could shift the energy balance toward far vision, with negative effects for near and intermediate visual acuity. Our study did not confirm those findings; the 1 patient with more than 1.5 mm of IOL decentration expressed no complaints.

Despite the randomized nature of this study, there were significant preoperative differences between the study groups. One was that the mean DCNVA at the patient-preferred distance was better in the bifocal group. Another was that pupil size was larger in the

Figure 6. Mean vision-related quality-of-life scores 6 months postoperatively (NEI-RQL 42 questionnaire). A score of 100 refers to the best quality of life.

Figure 7. Patient-reported spectacle use 6 months postoperatively.

trifocal group under photopic and high mesopic conditions. However, a linear regression analysis showed no correlation between preoperative differences and outcomes 3 and 6 months postoperatively. Furthermore, the difference in pupil size is not expected to be clinically relevant because the difference was less than 0.5 mm. Also, the difference in visual acuity at the patient-preferred distance normalized during the follow-up period.

In conclusion, the Finevision Micro F trifocal IOL and the Acrysof Restor IQ +3.0 D bifocal IOL were safe and provided good uncorrected near and far visual acuity, with similar contrast sensitivity function and reading performance. The defocus curves for photopic and mesopic conditions showed similar results, with the trifocal IOL showing more continuous results at all ranges from -2.5 D to 0.0 D and statistically significantly better visual acuity at -1.0 D. Despite considerably lower intermediate visual acuity measurements (at 70 cm) with both IOLs, the patients reported a high overall satisfaction with quality of vision and vision-related quality of life. Complete spectacle independence was higher in the trifocal group than in the bifocal group.

WHAT WAS KNOWN

- Diffractive bifocal IOLs improve near and far uncorrected visual acuity, while intermediate visual acuity can be insufficient.

WHAT THIS PAPER ADDS

- The trifocal and bifocal IOLs provided similarly good uncorrected near, far, and intermediate visual acuity.
- Although a trifocal IOL might provide more spectacle independence, patients reported high levels of satisfaction with the bifocal IOL and the trifocal IOL.

REFERENCES

1. Nijkamp MD, Dolders MGT, de Brabander J, van den Borne B, Hendrikse F, Nuijts RMMA. Effectiveness of multifocal intraocular lenses to correct presbyopia after cataract surgery; a randomized controlled trial. *Ophthalmology* 2004; 111:1832–1839
2. Pascolini D, Mariotti SP. Global estimates of visual impairment: 2010. *Br J Ophthalmol* 2012; 96:614–618
3. Calladine D, Evans JR, Shah S, Leyland M. Multifocal versus monofocal intraocular lenses after cataract extraction. *Cochrane Database Syst Rev* 2012; (9):CD003169. Summary Available at: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003169.pub3/pdf/abstract>. Accessed May 20, 2015
4. Javitt JC, Steinert RF. Cataract extraction with multifocal intraocular lens implantation; a multinational clinical trial evaluating clinical, functional, and quality-of-life outcomes. *Ophthalmology* 2000; 107:2040–2048
5. Kohnen T, Allen D, Boureau C, Dublneau P, Hartmann C, Mehdorn E, Rozot P, Tassinari G. European multicenter study of the AcrySof ReSTOR apodized diffractive intraocular lens. *Ophthalmology* 2006; 113:578–584
6. Vingolo EM, Grenga P, Iacobelli L, Grenga R. Visual acuity and contrast sensitivity; AcrySof ReSTOR apodized diffractive versus AcrySof SA60AT monofocal intraocular lenses. *J Cataract Refract Surg* 2007; 33:1244–1247
7. Steinert RF, Aker BL, Trentacost DJ, Smith PJ, Tarantino N. A prospective comparative study of the AMO ARRAY zonal-progressive multifocal silicone intraocular lens and a monofocal intraocular lens. *Ophthalmology* 1999; 106:1243–1255
8. Hunkeler JD, Coffman TM, Paugh J, Lang A, Smith P, Tarantino N. Characterization of visual phenomena with the Array multifocal intraocular lens. *J Cataract Refract Surg* 2002; 28:1195–1204
9. Montés-Micó R, Alió JL. Distance and near contrast sensitivity function after multifocal intraocular lens implantation. *J Cataract Refract Surg* 2003; 29:703–711
10. Alfonso JF, Fernández-Vega L, Baamonde MB, Montés-Micó R. Prospective visual evaluation of apodized diffractive intraocular lenses. *J Cataract Refract Surg* 2007; 33:1235–1243
11. Pepose JS, Qazi MA, Davies J, Doane JF, Loden JC, Sivalingham V, Mahmoud AM. Visual performance of patients with bilateral vs combination Crystalens, ReZoom, and ReSTOR intraocular lens implants. *Am J Ophthalmol* 2007; 144:347–357
12. Montés-Micó R, España E, Bueno I, Charman WN, Menezo JL. Visual performance with multifocal intraocular lenses; mesopic contrast sensitivity under distance and near conditions. *Ophthalmology* 2004; 111:85–96
13. Gatineau D, Pagnouille C, Houbrechts Y, Gobin L. Design and qualification of a diffractive trifocal optical profile for intraocular lenses. *J Cataract Refract Surg* 2011; 37:2060–2067
14. Alfonso JF, Fernández-Vega L, Puchades C, Montés-Micó R. Intermediate visual function with different multifocal intraocular lens models. *J Cataract Refract Surg* 2010; 36:733–739
15. Gatineau D, Houbrechts Y. Comparison of bifocal and trifocal diffractive and refractive intraocular lenses using an optical bench. *J Cataract Refract Surg* 2013; 39:1093–1099
16. Eppig T, Filser E, Goepfert H, Schroeder AC, Seitz B, Langenbacher A. Index of contrast sensitivity (ICS) in pseudophakic eyes with different intraocular lens designs. *Acta Ophthalmol* 2015; 93:e181–e187

17. Maaijwee K, Mulder P, Radner W, Van Meurs JC. Reliability testing of the Dutch version of the Radner reading charts. *Optom Vis Sci* 2008; 85:353–358. Available at: http://journals.lww.com/optvissci/Fulltext/2008/05000/Reliability_Testing_of_the_Dutch_Version_of_the.12.aspx. Accessed May 20, 2015
18. Dextl A, Schlögel H, Wolfbauer M, Grabner G. Die Entwicklung einer neuen Methode zur Bestimmung der Leseschärfe – Das “Salzburg Reading Desk (SRD)” [The development of a new method for the evaluation of reading acuity – The “Salzburg Reading Desk (SRD)”]. *Spektrum Augenheilkd* 2009; 23:435–438
19. Hays RD, Mangione CM, Ellwein L, Lindblad AS, Spritzer KL, McDonnell PJ; for the NEI-RQL Research Group. Psychometric properties of the National Eye Institute-Refractive Error Quality of Life instrument. *Ophthalmology* 2003; 110:2292–2301
20. Nichols JJ, Mitchell GL, Saracino M, Zadnik K. Reliability and validity of refractive error-specific quality-of-life instruments. *Arch Ophthalmol* 2003; 121:1289–1296. Available at: <http://archophth.jamanetwork.com/article.aspx?articleid=415657>. Accessed May 20, 2015
21. Nichols JJ, Twa MD, Mitchell GL. Sensitivity of the National Eye Institute Refractive Error Quality of Life instrument to refractive surgery outcomes. *J Cataract Refract Surg* 2005; 31:2313–2318
22. Montés-Micó R, Madrid-Costa D, Ruiz-Alcocer J, Ferrer-Blasco T, Pons AM. In vitro optical quality differences between multifocal apodized diffractive intraocular lenses. *J Cataract Refract Surg* 2013; 39:928–936
23. Sheppard AL, Shah S, Bhatt U, Bhogal G, Wolffsohn JS. Visual outcomes and subjective experience after bilateral implantation of a new diffractive trifocal intraocular lens. *J Cataract Refract Surg* 2013; 39:343–349
24. Alió JL, Montalbán R, Peña-García P, Soria FA, Vega-Estrada A. Visual outcomes of a trifocal aspheric diffractive intraocular lens with microincision cataract surgery. *J Refract Surg* 2013; 29:756–761
25. Cochener B, Vryghem J, Rozot P, Lesieur G, Heireman S, Blanckaert JA, Van Acker E, Ghekiere S. Visual and refractive outcomes after implantation of a fully diffractive trifocal lens. *Clin Ophthalmol* 2012; 6:1421–1427. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3437955/pdf/ophth-6-1421.pdf>. Accessed May 20, 2015
26. Vryghem JC, Heireman S. Visual performance after the implantation of a new trifocal intraocular lens. *Clin Ophthalmol* 2013; 7:1957–1965. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3794849/pdf/ophth-7-1957.pdf>. Accessed May 20, 2015
27. Lane SS, Javitt JC, Nethery DA, Waycaster C. Improvements in patient-reported outcomes and visual acuity after bilateral implantation of multifocal intraocular lenses with +3.0 diopter addition: multicenter clinical trial. *J Cataract Refract Surg* 2010; 36:1887–1896
28. de Vries NE, Webers CAB, Montés-Micó R, Ferrer-Blasco T, Nuijts RMMA. Visual outcomes after cataract surgery with implantation of a +3.00 D or +4.00 D aspheric diffractive multifocal intraocular lens: comparative study. *J Cataract Refract Surg* 2010; 36:1316–1322
29. Kohnen T, Nuijts R, Levy P, Haefliger E, Alfonso JF. Visual function after bilateral implantation of apodized diffractive aspheric multifocal intraocular lenses with a +3.0 D addition. *J Cataract Refract Surg* 2009; 35:2062–2069
30. Ang RE, Martinez GA, Cruz EM, Tiongson AA, Dela Cruz AG. Prospective evaluation of visual outcomes with three presbyopia-correcting intraocular lenses following cataract surgery. *Clin Ophthalmol* 2013; 7:1811–1823. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3788698/pdf/ophth-7-1811.pdf>. Accessed May 20, 2015
31. Madrid-Costa D, Ruiz-Alcocer J, Ferrer-Blasco T, García-Lázaro S, Montés-Micó R. Optical quality differences between three multifocal intraocular lenses: bifocal low add, bifocal moderate add, and trifocal. *J Refract Surg* 2013; 29:749–754
32. Mojzis P, Peña-García P, Liehneova I, Ziak P, Alió JL. Outcomes of a new diffractive trifocal intraocular lens. *J Cataract Refract Surg* 2014; 40:60–69
33. Hitchcock EM, Dick RB, Krieg EF. Visual contrast sensitivity testing: a comparison of two F.A.C.T. test types. *Neurotoxicol Teratol* 2004; 26:271–277
34. Boxer Wachler BS, Krueger RR. Normalized contrast sensitivity values. *J Refract Surg* 1998; 14:463–466
35. Rasp M, Bacherneegg A, Seyeddain O, Ruckhofer J, Emesz M, Stoiber J, Grabner G, Dextl AK. Bilateral reading performance of 4 multifocal intraocular lens models and a monofocal intraocular lens under bright lighting conditions. *J Cataract Refract Surg* 2012; 38:1950–1961
36. Maxwell WA, Cionni RJ, Lehmann RP, Modi SS. Functional outcomes after bilateral implantation of apodized diffractive aspheric acrylic intraocular lenses with a +3.0 or +4.0 diopter addition power; randomized multicenter clinical study. *J Cataract Refract Surg* 2009; 35:2054–2061

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