Visual and optical performance of the Akreos Adapt Advanced Optics and Tecnis Z9000 intraocular lenses

Swedish multicenter study

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PURPOSE: To compare the subjective visual and objective optical performance of 2 aspherical intraocular lenses (IOLs), the Akreos Adapt Advanced Optics (AO) (Bausch & Lomb, Inc.) and the Tecnis Z9000 (Advanced Medical Optics, Inc.).

SETTING: Four university hospitals in Sweden.

METHODS: This study comprised 80 patients, 20 each from 4 university hospital centers in Sweden. All patients had bilateral clear corneal phacoemulsification with implantation of an Akreos Adapt AO IOL in 1 eye and Tecnis Z9000 IOL in the other eye according to a randomization protocol. Preoperatively, 90% contrast Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity was measured and the mesopic pupil sizes were determined. Ten to 12 weeks postoperatively, 12.5% and 90% contrast ETDRS visual acuities and photopic and mesopic Functional Acuity Contrast Test chart contrast sensitivities were determined. Wavefront analysis was performed with the Zywave II aberrometer (Bausch & Lomb, Inc.), and a questionnaire on the subjective quality of vision was completed by each patient.

RESULTS: The Akreos AO IOL and Tecnis Z9000 IOL produced similar high- and low-contrast visual acuities as well as photopic and mesopic contrast sensitivities. The Tecnis Z9000 IOL resulted in lower spherical aberrations of the eye (mean $0.05 \pm 0.13 \mu$ m versus $0.35 \pm 0.13 \mu$ m root mean square, 6.0 mm pupil) (*P*<.001); however, the Akreos AO IOL provided a larger depth of field (mean 1.22 diopter [D] ± 0.48 [SD] versus 0.86 ± 0.50 D, 6.0 mm pupil) (*P*<.001). Patient satisfaction was generally high, although 68.8% of the patients reported some type of visual disturbance postoperatively. Twenty-eight percent of patients reported better subjective visual quality in the Akreos AO eye and 14%, in the Tecnis Z9000 eye (*P*<.0001). Accordingly, 33% perceived more visual disturbances in the Tecnis Z9000 eye and 11%, in the Akreos AO eye (*P*<.0001).

CONCLUSIONS: Maximum reduction of spherical aberration did not maximize subjective visual quality. The higher perceived quality of vision with the Akreos AO IOL could be because of differences in depth of field, IOL material, or IOL design.

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Although aspherical optics have a long history in spectacles¹ and contact lenses,² intraocular lenses (IOLs) were confined to rather primitive spherical optics until a few years ago. In the past, surgical precision was limited and cataract surgeons may have been content with providing freedom from aphakia. With increasingly predictable surgical outcomes, however, both surgeons and patients have increased their demands in terms of postoperative visual quality. As

a consequence, there is less tolerance for dysphotopsia and other visual phenomena associated with optical aberrations. Over time, there has been a reduction in induced astigmatism and decentration of the pupil and IOL³⁻⁷ that today allows us to focus on the properties of IOL optics to further improve results.

The human cornea generally has a positive spherical aberration, which is relatively constant throughout life.⁸ In a young individual, this is largely compensated

for by a negative spherical aberration of the crystalline lens⁹; however, the negative aberration is gradually reduced and often turns into an increasing positive spherical aberration in midlife.⁹ The aging human eye thus has increasing positive spherical aberration¹⁰ and, accordingly, decreasing mesopic contrast sensitivity.¹¹ Implantation of a traditional spherical IOL in such an eye will add to the positive spherical aberration, and despite the superior clarity of the IOL, it may not improve mesopic functional acuity contrast over that in phakic eyes.¹²

The Tecnis Z9000 3-piece silicone IOL (Advanced Medical Optics, Inc.), developed by Pharmacia, Inc., was the first commercially available aspherical IOL. It has a negative spherical aberration, aiming to neutralize the positive spherical aberration of the cornea.¹³ Several investigations have found better optical and visual performance with this IOL versus conventional IOLs, particularly under mesopic light conditions with larger pupil sizes.^{8,13-21} However, there have been concerns about the consequences of IOL decentration and tilt with negative spherical aberration, and theoretical calculations and laboratory data suggest that the Tecnis Z9000 may even perform worse than a conventional IOL in cases of significant decentration.²² Other calculations indicate that the Tecnis Z9000 has better optical performance than a conventional IOL only if it is decentered less than 0.4 mm and tilted fewer than 7 degrees,²³ which may not always be possible to achieve in clinical practice. In addition, some positive spherical aberration may provide better depth-of-field and allow for so-called pseudoaccommodation,²⁴ whereas a fully neutralized or negative spherical aberration has no potential benefits of this type. Based on such reasoning, more recently introduced aspherical IOLs have less negative spherical aberration than the Tecnis Z9000 or, as in the case of the Akreos Advanced Optics 1-piece hydrophilic acrylic

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IOL (Akreos AO, Bausch & Lomb, Inc.), are designed to be aberration neutral.

The purpose of this study was to compare the optical and visual performance of Akreos AO and Tecnis Z9000 IOLs through subjective and objective modes of measurement and using a double-masked randomized bilateral implantation study design.

PATIENTS AND METHODS

This prospective double-masked randomized intraindividual multicenter comparison study was approved by the Research Ethics Committee of Umeå University, Umeå, Sweden. Eighty patients with bilateral age-related cataract were included, with 20 patients each from the following 4 Swedish university hospital centers: Umeå, Uppsala, Linköping, and Gothenburg. One surgeon per center performed all the surgeries using clear corneal phacoemulsification and a standardized protocol. Both eyes were operated on the same day or with up to 2 weeks between surgeries. Biometry was performed with the IOLMaster (Carl Zeiss Meditec, Inc.) in 52 eyes and with ultrasound in 28 eyes. Intraocular lens power calculations were performed with the SRK/T formula, aiming for emmetropia in all eyes. The Tecnis Z9000 IOL was implanted in 1 eye and the Akreos AO in the other according to a randomization protocol. Patients with signs of other intraocular diseases, previous trauma or intraocular surgery, a dilated pupil smaller than 4.0 mm, or preoperative astigmatism exceeding 1.5 diopters were excluded. The demographic data recorded included age, sex, and the presence of other ocular or systemic diseases.

Preoperatively, clinical examination of the anterior segment was performed and the 90% contrast best corrected visual acuity (BCVA) was measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) Fast protocol after subjective refraction. Pupil sizes were determined under mesopic conditions using a Colvard infrared pupillometer (Oasis, Inc.). Intraocular pressure (IOP) was measured by Goldmann applanation tonometry. One to 4 days postoperatively, a clinical examination of the anterior segment, including an evaluation of the aqueous flare, was performed and IOP was measured. At 10 to 12 weeks, a similar clinical examination was performed and the uncorrected visual acuity (UCVA) and BCVA were determined at 12.5% and 90% contrast and under photopic (85 cd/m^2) and mesopic (3 cd/m^2) conditions; best corrected contrast sensitivity was determined at 1.5, 3, 6, 12, and 18 cycles per degree (cpd) using Functional Acuity Contrast Test charts according to the manufacturer's instructions. The light intensities were set using a luminometer. Wavefront analysis of the total aberration in all eyes, with and without dilation, was performed with a Zywave II aberrometer (Bausch & Lomb, Inc.). In addition, all patients filled out a questionnaire about their perceived quality of vision. The questionnaire was adapted from Tester et al.,²⁵ with 2 questions added: "Which eye has the best visual quality?" and "In which eye do you perceive most visual disturbance?" Only patients who reported visual disturbance answered the latter question. Those who supervised and recorded all postoperative psychophysical measurements and the responses on the subjective visual quality questionnaire were unaware of the IOL type in the eye.

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Table 1. Demographic data (N = 80).				
	Akreos AO, Right Eye Tecnis Z9000,	Right Eye Akreos AO,		
Parameter	Left Eye	Left Eye		
Age (y)				
Mean \pm SD	70.1 ± 6.39	68.0 ± 6.80		
Range	50.0-79.0	55.0-79.0		
General pathology,* n (%)				
No	20 (47.6)	16 (42.1)		
Yes	22 (52.4)	22 (57.9)		
Current treatment, [†] n (%)				
No	19 (45.2)	17 (44.7)		
Yes	23 (54.8)	21 (55.3)		
Ophthalmic history, [‡] n (%)				
No	75 (93.8)	73 (91.3)		
Yes	5 (6.3)	7 (8.8)		
Ophthalmic treatment, [§] n (%)				
No	78 (97.5)	79 (98.8)		
Yes	2 (2.5)	1 (1.3)		

*Including hypertension, mild cardiac disease, and osteoporosis

[†]Generally the medication for the disease in question

⁴Including allergic blepharitis, ocular hypertension (1 case, 1 eye), previous ptosis surgery (1 case, 2 eyes), ectropion, vitreous detachment (1 case, 1 eye), and previous pterygium surgery (1 case, 1 eye) [§]Antiallergic eyedrops (1 case, 2 eyes) and latanoprost (1 case, 1 eye)

Wavefront Data Analysis

Wavefront data were exported from the Zywave II aberrometer as Zernike coefficients fitted up to the 5th order for the maximum pupil size. Through scaling of the coefficients,26 the 4th-order spherical aberration coefficient, Z(4,0), and the root mean square (RMS) value for the total higher-order aberrations (HOAs) (3rd order and up) were calculated with 4.0, 5.0, and 6.0 mm pupils. In addition, RMS values were calculated separately for 3rd-, 4th-, and 5th-order aberrations at all pupil sizes. To compare the depth of field, the Strehl ratio, defined as the area under the modulation transfer function up to 45 cpd normalized to the diffraction-limited case, was used as an image-quality metric. The astigmatism was removed, and the Strehl ratio was calculated as a function of defocus from the Zernike coefficients using Fourier optics. The depth of field was then defined as the defocus interval at which the Strehl ratio was above or equal to 80% of the maximum value. This optical definition of depth of field was used in a similar study by Marcos et al.²

Statistical Analysis

The chi-square test was used for nominal data (sex, presence of general pathology, comparison of the subjective evaluations of eye preference, visual disturbances). An analysis of variance (ANOVA) for crossover design was used for numerical, normally distributed data (visual acuity, contrast sensitivity, total HOA, depth of field). The Wilcoxon rank sum test was used for age, which did not fulfill the criteria for normal distribution. A *P* value of 0.05 was considered statistically significant.

RESULTS

Table 1 shows the patients' demographic data. The anterior segment was normal in all eyes, as was the fundus in eyes that could be evaluated; in 2 eyes, the cataract was too dense to allow a fundus examination. The general pathology and corresponding treatments did not affect the ophthalmic status.

Table 2 shows the preoperative, intraoperative, and early postoperative data. No patient was excluded because of an insufficient dilated pupil diameter. All preoperative preparations, surgical procedures, and postoperative treatments were performed according to the routines. Bilateral surgery on the same day was performed in 52 patients (65%). No significant

Table 2. Preoperative, intraoperative, and early postoperative

Parameter	Tecnis Z9000	Akreos AO	P Value
Mesopic pupil,			.11
undilated (mm)			
Mean \pm SD	4.19 ± 1.01	4.25 ± 1.04	
Range	2.50 to 6.50	2.50 to 6.50	
Mesopic pupil,			.24
dilated (mm)			
Mean \pm SD	5.70 ± 0.92	5.75 ± 0.93	
Range	4.00 to 7.50	4.00 to 7.50	
Preop IOP (mm Hg)			.22
Mean \pm SD	16.5 ± 2.7	16.7 ± 2.8	
Range	10 to 22	10 to 24	
Preop SE (D)			.40
Mean \pm SD	$+0.4 \pm 2.2$	$+0.3 \pm 2.3$	
Range	-6.0 to $+5.0$	-7.0 to $+4.5$	
Preop 90% BCVA			.63
(logMAR)			
Mean \pm SD	0.24 ± 0.16	0.26 ± 0.19	
Range	0.00 to 0.90	-0.04 to 0.96	
Preop axial length (mm)			.28
Mean \pm SD	23.17 ± 0.84	23.20 ± 0.85	
Range	21.38-25.04		
Incision site, n (%)			_
Nasal	14 (18.2)	19 (25.0)	
Temporal	37 (48.1)	35 (46.1)	_
12 o'clock	26 (33.8)	22 (28.9)	_
Postop aqueous			_
flare, n (%)			
0	41 (51.3)	38 (47.5)	
1+	38 (47.5)	41 (51.3)	_
2+	1 (1.3)	1 (1.3)	_
Postop IOP (mm Hg)	- (1.0)	- (1.0)	_
Mean \pm SD	17.0 ± 4.4	17.2 ± 4.7	
Range	8 to 32	10.2 ± 4.7 10 to 41	

surgical complications were registered; thus, no patient was excluded for this reason. At 1 to 4 days, slight corneal edema was noted in 4 eyes and a slight fibrinoid reaction in 1 eye. A few cases presented with postoperative IOP spikes that did not require intervention. The Tecnis Z9000 eyes and Akreos AO eyes did not differ significantly in any recorded variable.

Table 3 shows the 10- to 12-week data. Some deviations from the desired postoperative refraction were seen with both IOLs at the final visit, but there was no difference between the IOLs. There were no significant differences in UCVA, BCVA (12.5% or 90%), or photopic and mesopic contrast sensitivity between the 2 IOLs (ANOVA) (Figure 1, *A* and *B*). The slitlamp examinations showed slight posterior capsule opacification in 3 eyes (1 Tecnis Z9000, 2 Akreos AO), mild cornea guttata in 2 eyes (1 and 1, respectively), slight upward decentration of the IOL in 1 eye (Akreos AO), and a vitreous strand in 1 eye (Tecnis Z9000); all other eyes were normal.

The level of total HOA was significantly lower in the Tecnis Z9000 eyes at all pupil sizes (P < .01, ANOVA) (Figure 2 A). The difference was more evident when the spherical aberration was quantified selectively (P < .001, ANOVA) (Figure 2, B). Thus, the depth of field, assessed by the Strehl ratio, was larger in Akreos AO eyes than in Tecnis Z9000 eyes, a difference that increased with increasing pupil size (4.0 mm, P = .17; 5.0 mm, P = .002; 6.0 mm, P < .001; ANOVA) (Figure 2, C).

Tables 4A and 4B show the results of the patient questionnaire. Patient satisfaction was generally high; 72.5% indicated they were very satisfied with the results; 25.0%, satisfied, and 2.5%, neutral. Still, 68.8% of patients reported some type of visual disturbance (light-caused glare/increase in eye sensibility/unwanted

Table 3. Data from the 10- to 12-week postoperative visit in patients with an Akreos Adapt AO IOL in 1 eye and Tecnis Z9000 IOL in the other eye.				
Parameter	Tecnis Z9000	Akreos AO	P Value	
SE (D)			.40	
Mean \pm SD	$+0.06 \pm 0.72$	$+0.20 \pm 0.64$		
Range	-2.9 to $+2.0$	-1.9 to $+2.0$		
90% BCVA (logMAR)			.98	
Mean \pm SD	-0.06 ± 0.09	-0.06 ± 0.09		
Range	-0.24 to 0.30	-0.26 to 0.26		
90% UCVA (logMAR)			.26	
Mean \pm SD	0.08 ± 0.18	0.11 ± 0.21		
Range	-0.18 to 0.72	-0.20 to 0.96		
12.5% BCVA (logMAR)			.19	
Mean \pm SD	0.10 ± 0.11	0.12 ± 0.12		
Range	-0.14 to 0.44	-0.16 to 0.44		
BCVA = best corrected visual acuity; SE = spherical equivalent; UCVA = uncorrected visual acuity				

images). Better subjective visual quality in the Akreos AO eye was reported by 28% of the patients, whereas 14% preferred the Tecnis Z9000 eye (P < .0001, chi-square test) (Figure 3, A). Accordingly, 33% perceived more visual disturbances in the Tecnis Z9000 eye and 11% perceived more disturbances in the Akreos AO eye (P < .0001, chi-square test) (Figure 3, B) table 4A-B summarize and characterize the visual disturbances and light induced problems reported.

Table 5 shows the results of the wavefront data analysis.

DISCUSSION

Our study found that in patients who were randomized to have implantation of an Akreos AO in 1 eye

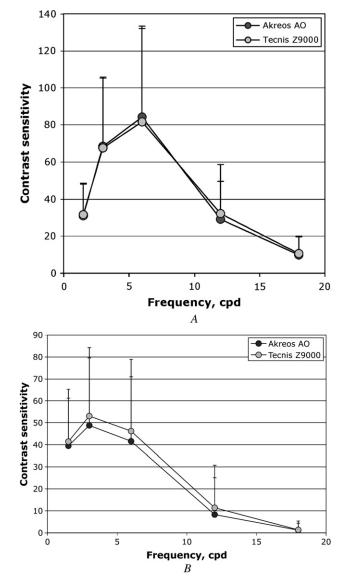


Figure 1. Photopic (*A*) and mesopic (*B*) contrast sensitivities at 1.5, 3, 6, 12, and 18 cpd after bilateral implantation of Akreos AO and Tecnis Z9000 IOLs, respectively (N = 80), means \pm SD. The contrast sensitivities do not differ significantly at any frequency.

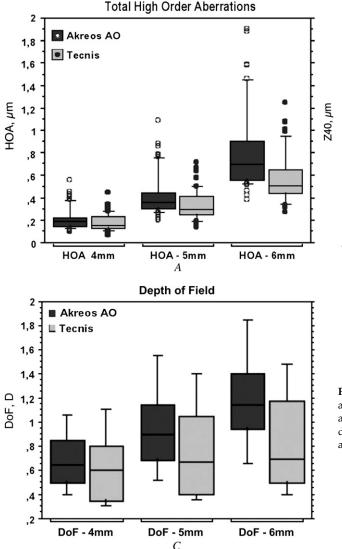


Figure 2. Box plot of the total HOAs (*A*) and spherical aberrations (*B*) after IOL implantation showing individual values, medians, and 1st and 3rd quartiles (HOA = higher-order aberration. C: Box plot of depth of field assessed by the Strehl ratio showing medians and 1st and 3rd quartiles (DoF = depth of field).

and a Tecnis Z9000 IOL in the other, the Tecnis Z9000 vielded significantly fewer HOAs. Still, twice as many patients preferred the visual quality in the eye with the Akreos AO IOL, and accordingly, 3 times more patients perceived visual disturbance in the eye with the Tecnis Z9000. The design of this study, with bilateral surgery and randomized implantation of the 2 IOLs, was chosen to minimize the effects of factors other than the IOLs such as ocular dominance or refraction deviations, which could affect the outcomes. The double-masked design also likely minimized bias, particularly in the results of the patient questionnaires. The patients' awareness of having different IOLs in the right eye and left eye may have increased their awareness of minor differences between the eyes. Still, more than half the patients reported no difference between the eyes, which is probably because of the patients' high level of overall satisfaction with the

surgical results, visual improvement, and IOL performance. The differences in eye preference and visual disturbance between the 2 IOLs favored the Akreos AO. This is interesting considering the results of the wavefront analysis, in which the total HOA, in particular the spherical aberration, was significantly lower in eyes with the Tecnis Z 9000 IOL. From this, it would appear that maximum reduction of spherical aberration does not correlate with the perceived visual quality of the eye having surgery. The Akreos AO eyes had a larger depth-of-field, determined by the Strehl ratio, which may contribute to a higher perceived visual quality, although other factors (eg, differences in IOL design, material, edge design) may also have affected the results.

Despite the design of this study and the rather large number of patients, we found no differences between the IOLs in low-contrast visual acuity or contrast **Table 4A.** Summary of subjective reports of visual disturbances and light-induced problems at the 10- to 12-week postoperative visit in patients with an Akreos Adapt AO IOL in 1 eye and a Tecnis Z9000 IOL in the other eye.

	Percentage			
Visual Disturbance	None	Minimal	Annoying	Debilitating
Light-induced glare	46.3	38.5	18.6	2.5
Unwanted images	75.0	21.3	3.8	0
Increased eye sensibility	52.5	28.8	18.8	0
Evaluation of				
light-induced				
problems				
Driving into	42.3	32.1	24.4	1.3
sunset/sunrise				
Bright sunny	47.5	26.3	26.3	0
day at noon				
Brightly lit	81.3	13.8	5.0	0
environment				
Oncoming	39.0	41.6	18.2	1.3
headlights at night				

Table 4B. Description of light-induced problems.				
	Perce	Percentage		
Description	No	Yes		
Halos around lights	90.0	10.0		
Generalized light sensitivity	50.0	50.0		
Central flash of light	89.9	10.1		
Arcs of light	93.8	6.3		

sensitivity. Because many studies have found such differences in favor of the Tecnis Z9000 IOL versus conventional spherical IOLs,^{13–18,28} our findings indirectly indicate that the Akreos AO IOL might also provide better optical performance than a spherical IOL in these respects. To confirm this would require a study directly comparing the Akreos AO IOL with a corresponding spherical IOL.

Apart from a slight upward decentration of 1 Akreos AO IOL, no clinically apparent decentration was noted in our study. Although patients with pseudoexfoliation, who have a larger risk for IOL decentration, were not excluded from the study, preoperative signs of zonular insufficiency or IOL dislocation were exclusion criteria. Because the 5th-order aberrations (corresponding to the trefoil) were equal between the 2 IOLs, and the 3rd-order aberrations (corresponding to the coma) were higher in Akreos AO eyes at larger pupil sizes, the hypothesis that the Akreos AO IOL should be less sensitive to changes in position within the eye could not be proved from our results. Conversely,

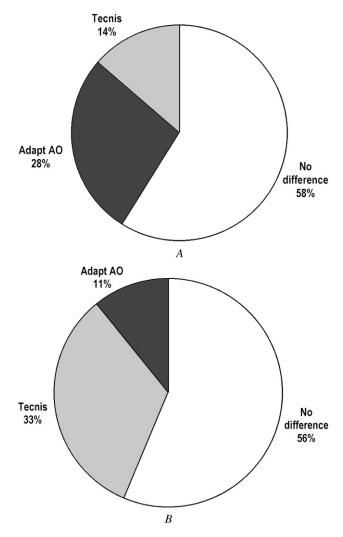


Figure 3. *A*: Pie chart of the subjective preference for a certain eye after IOL implantation. *B*: Pie chart of which eye was perceived as having more pronounced visual disturbances after IOL implantation.

the Tecnis Z9000 IOL did not appear to decenter or tilt to a degree that would affect optical performance as the total level of HOA and 3rd-order aberrations was generally lower with the Tecnis Z9000 IOL. We did not perform a separate analysis of corneal aberrations; however, the study's bilateral randomized design makes it unlikely that surgically induced differences in corneal aberrations contributed significantly to the results. In addition, because the total aberrations of the eye directly affect the image quality of the retina, it is relevant to measure them from the patient's perspective.

The follow-up in this study was 10 to 12 weeks, which precludes analysis of long-term performance of the 2 IOLs. The study was long enough for patients to adjust their spectacles when necessary but short enough to minimize the risk that later changes in the

Aberration		Mean \pm SD		
	Pupil (mm)	Tecnis Z9000	Akreos AO	P Value
RMS higher order (µm)	4.0	0.18 ± 0.07 (0.06 to 0.44)	0.22 ± 0.09 (0.10 to 0.55)	<.01
RMS 3rd order (µm)	4.0	$0.17 \pm 0.07 (0.05 \text{ to } 0.43)$	$0.19 \pm 0.10 \ (0.06 \ { m to} \ 0.53)$.09
RMS 5th order (μm)	4.0	0.02 ± 0.01 (0.00 to 0.06)	0.02 ± 0.01 (0.00 to 0.07)	.68
Z(4,0) (μm)	4.0	$0.01 \pm 0.02 (-0.05 \text{ to } 0.08)$	0.07 ± 0.02 (0.00 to 0.17)	<.001
Depth of focus (D)	4.0	$0.63 \pm 0.37 (0.20 \text{ to } 2.35)$	0.72 ± 0.33 (0.30 to 1.75)	.17
RMS higher order (µm)	5.0	0.33 ± 0.13 (0.13 to 0.72)	0.43 ± 0.18 (0.20 to 1.09)	<.01
RMS 3rd order (µm)	5.0	0.30 ± 0.12 (0.10 to 0.67)	0.35 ± 0.18 (0.11 to 1.02)	<.01
RMS 5th order (µm)	5.0	$0.06 \pm 0.03 (0.01 \text{ to } 0.20)$	0.06 ± 0.04 (0.00 to 0.20)	.83
Z(4,0) (μm)	5.0	$0.03 \pm 0.06 (-0.11 \text{ to } 0.21)$	$0.17 \pm 0.06 \ (0.00 \ {to} \ 0.41)$	<.001
Depth of focus (D)	5.0	$0.78 \pm 0.47 (0.20 \text{ to } 2.75)$	0.97 ± 0.41 (0.40 to 2.20)	<.01
RMS higher order (µm)	6.0	0.58 ± 0.22 (0.27 to 1.25)	$0.82 \pm 0.37 \ (0.38 \text{ to } 1.91)$	<.01
RMS 3rd order (µm)	6.0	0.50 ± 0.20 (0.13 to 1.10)	$0.64 \pm 0.36 \ (0.21 \text{ to } 1.73)$	<.01
RMS 5th order (µm)	6.0	$0.14 \pm 0.09 (0.03 \text{ to } 0.49)$	$0.15 \pm 0.09 (0.04 \text{ to } 0.49)$.40
Z(4,0) (μm)	6.0	$0.05 \pm 0.13 (-0.17 \text{ to } 0.43)$	0.35 ± 0.13 (0.09 to 0.84)	<.001
Depth of focus (D)	6.0	$0.86 \pm 0.50 (0.20 \text{ to } 2.45)$	$1.22 \pm 0.48 \ (0.45 \text{ to } 2.65)$	<.001

posterior capsule or IOL position would influence the results. Previous studies had longer follow-up times and data on, for example, posterior capsule opacification (PCO) and long-term centration of sharp-edged IOLs.^{29,30} The evaluation of long-term IOL stability and PCO rates was not the scope of the present study.

In summary, the Akreos AO IOL and Tecnis Z9000 IOL gave similar high- and low-contrast visual acuities as well as photopic and mesopic contrast sensitivities. However, the Tecnis Z9000 IOL yielded significantly less total HOA, in particular less spherical aberration. The Akreos AO IOL, on the other hand, provided a larger depth of field. Whether the latter contributes to the fact that more patients preferred their Akreos AO eye or whether other differences between the 2 IOLs are responsible remains to be elucidated.

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