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Comparative study of Acrysof ReSTOR multifocal intraocular lenses +4.00 D and +3.00 D: visual performance and wavefront error

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Background: The aim was to evaluate visual performance and wavefront error after implantation of three models of Acrysof ReSTOR multifocal intraocular lenses (MIOLs).

Methods: This prospective comparative six-month study comprised 60 eyes having phacoemulsification and implantation of three diffractive AcrySof ReSTOR MIOLs: SN60D3 +4.00 D spherical MIOL (group 1), SN6AD3 +4.00 D aspheric MIOL (group 2) and SN6AD1 +3.00 D aspheric MIOL (group 3).

Results: The distance visual acuity was at least 0.1 logMAR in 88.8 per cent of group 1, 88.8 per cent of group 2 and 87.5 per cent of group 3. The distance-corrected near vision was 0.02 ± 0.04 logMAR in group 1, 0.02 ± 0.05 logMAR in group 2 and 0.01 ± 0.03 logMAR in group 3 ($p = 0.822$). The distance-corrected intermediate vision was 0.26 ± 0.07, 0.22 ± 0.09 and 0.04 ± 0.05, respectively ($p < 0.001$). The root-mean-square (RMS) of ocular spherical aberration was significantly lower in groups 2 and 3 compared to group 1 ($p = 0.048$).

Conclusion: All diffractive MIOLs provided good vision for far and near. ReSTOR MIOL +3.00 also restored intermediate vision. Aspheric MIOLs +4.00 and +3.00 induced significantly lower spherical aberration compared to spherical MIOL +4.00.

Key words: aberrations, cataract, contrast sensitivity, reading, visual acuity

Multifocal intraocular lenses (MIOLs) were designed to allow vision at different distances, enabling patients to be less dependent on spectacles following surgery.

The first MIOL models, either diffractive or refractive, restored near vision effectively, with good near visual performance in a high percentage of patients.[1,2]

Nevertheless, a degradation of the quality of vision, such as contrast sensitivity decrement and presence of dysphotopsia and halos related to the multifocal vision has been reported as one of the main consequences of MIOL implantation.[1–3]

In addition, the spherical design of the commercially available MIOLs may induce disturbing visual symptoms associated with the increase of spherical aberration.[4]

In the last decade, technical innovations have been introduced in the design of MIOLs to improve visual performance in implanted patients.

Diffractive-refractive MIOLs, such as ReSTOR MIOLs with a central diffractive apodised optic lens consisting of a smooth decrease in step heights from the central zone to the diffractive periphery and a peripheral refractive zone have been manufactured to improve light transmission through the optic lens and reduce light dispersion. Moreover an aspheric profile has been developed for these lenses to reduce the increment of spherical aberration and further improve the quality of vision.

Several studies have demonstrated an improvement of near vision after implantation of the ReSTOR IOLs both with

IOL parameters	ReSTOR SN60D3	ReSTOR SN6AD3	ReSTOR SN6AD1
Profile	Spherical	Aspheric	Aspheric
Addition (D)	+4.00	+4.00	+3.00
Range (D)	+10.00 to +30.00	+10.00 to +30.00	+10.00 to +30.00
Material	Hydrophobic acrylate	Hydrophobic acrylate	Hydrophobic acrylate
Optic zone (mm)	6.0	6.0	6.0
Concentric steps	12	12	9
Overall diameter (mm)	13	13	13
Blue filter	No	Yes	Yes
Light distribution	Approximately 40–90% of light to distance focus	Approximately 40–90% of light to distance focus	Approximately 40–90% of light to distance focus

Table 1. Intraocular lens characteristics

spherical and aspheric profiles and +4.00 dioptres near addition, with low or no significant decrease in the quality of vision compared with monofocal IOLs.[2–8]

Nevertheless with these MIOLs models the quality of intermediate vision was lower compared to that of distance and near vision.

More recently a new aspheric AcrySof ReSTOR IOL with +3.00 D near addition was designed to improve intermediate vision. This IOL demonstrated good far and near vision and better intermediate vision compared to the spherical and aspheric +4.00 D ReSTOR MIOLs.[9–11]

The aim of our study was to assess the efficacy of all three diffractive multifocal intraocular lens models by evaluating the distant, intermediate and near visual performance and to assess at the same time the quality of vision of patients and higher-order aberrations.

PATIENTS AND METHODS

Sixty eyes of sixty patients scheduled for cataract surgery from June 2010 to September 2010 were enrolled in this six-month comparative clinical trial approved by the University Institutional Review Board of the University "G. d'Annunzio", Chieti, Italy. The investigation was conducted in accordance with the 1975 Declaration of Helsinki. Each patient signed the informed consent form.

Inclusion criteria were axial length between 23.0 and 24.0 mm and corneal pre-operative astigmatism less than 1.00 D.

Exclusion criteria were anterior segment pathological alterations, such as chronic uveitis, zonular dialysis, pseudoexfoliation syndrome, glaucoma and diabetes, other ocular pathologies impairing visual function, such as maculopathies or optic nerve diseases, previous anterior or posterior segment surgery and intra-operative or post-operative complications.

All the patients were included if both eyes matched the inclusion and exclusion criteria because of the possibility of a future bilateral implantation.

Patients were implanted with one of three different multifocal AcrySof ReSTOR IOLs and were randomised into three groups: 20 patients received a SN60D3® IOL (+4.00 D addition, spherical design), 20 patients a SN6AD3® (+4.00 D addition, aspheric design) and 20 patients were implanted with a SN6AD1® IOL (+3.00 D addition, aspheric design).

The SN60D3® AcrySof ReSTOR IOL (Alcon Laboratories Inc, Fort Worth, TX, USA) is a single-piece 6.0 mm asymmetric biconvex optic lens of hydrophobic flexible acrylic material with a central 3.6 mm apodised diffractive design and a peripheral refractive area. Apodisation produces a gradual tapering of the diffractive steps from the centre to the outer edge of the lens to create a smooth transition of light between distant, intermediate and near focal points. This is obtained by means of a precise reduction in step heights from 1.3 microns to 0.2 microns. The outer ring of the AcrySof ReSTOR IOL that surrounds the apodised diffractive region is dedicated to focus light for distant vision. The IOL has +4.00 D addition for near.

The SN6AD3 AcrySof ReSTOR IOL model is similar to the spherical model SN60D3 IOL but has a symmetric biconvex design with an anterior aspheric optic lens. The IOL has +4.00 D addition for near.

The SN6AD1 AcrySof ReSTOR IOL has an aspheric optic profile and apodised multifocal structure in the central 3.6 mm optic zone, which consists of nine instead of 12 concentric steps. The IOL has +3.00 D addition for near (Table 1).

In all cases a standardised uneventful small-incision phacoemulsification with IOL implantation was performed by a single surgeon (LM). After a 2.75 mm near clear corneal tunnel was made, a curvilinear capsulorhexis was created. Phacofracture in the capsular bag was followed by automated irrigation/aspiration of the cortical remnants. The IOL was implanted in the capsular bag. The incision was not sutured. Post-operative therapy consisted of ofloxacin 0.3% and dexamethasone 0.2% eye drops four times daily for three weeks.

Patients were examined after surgery over a six-month period.

The main outcome measures were spherical equivalent (SE) subjective refraction, uncorrected distance vision (UDV), distance visual acuity (VA), VA at low contrast (50, 25 and 12.5 per cent) under photopic and mesopic conditions, contrast sensitivity (1.05, 3, 6, 12 and 18 cycles per degree) under photopic and mesopic conditions, distance corrected intermediate vision (DCIV) at 80 cm, distance corrected near vision (DCNV) at 40 cm, corrected near vision acuity (NVA) at 40 cm and defocus curve. The root-mean-square (RMS) of ocular and corneal total higher-order (HOA RMS), coma (RMS Z_3^1), trefoil (RMS Z_3^3) and spherical (RMS Z_4^0) aberrations and Zernike coefficient of fourth-order spherical aberration (Z_4^0) were evaluated in all cases.

At each visit, the posterior capsule was examined after dilating the pupil to establish the presence of posterior capsular opacification (PCO).

The scheduled follow-up times for the main parameters evaluated in the study were set at post-operative 30, 90 and 180 days.

High and low contrast VA and contrast sensitivity evaluation

Uncorrected distance vision and distance VA were measured monocularly in logMAR scale using the Yang vision tester with Sloan letters optotype (SIFI Diagnostic SPA, Treviso, Italy) under photopic conditions (81 candelas/m^2).

Distance VA at low contrast was measured monocularly in logMAR scale using the same optotype by reducing the contrast of letters (50, 25 and 13 per cent of maximal contrast) under photopic (81 cd/m^2) and mesopic (3 cd/m^2) conditions.

Contrast sensitivity at 1.05, 3, 6, 12 and 18 cycles per degree (cpd) under photopic (81 cd/m^2) and mesopic (3 cd/m^2) conditions was evaluated monocularly with correction for distance in place by means of Vistech contrast sensitivity charts displayed by the Yang vision tester.[12]

Distance-corrected near vision and near VA were examined under photopic conditions (81 cd/m^2) at 40 cm using a handheld ETDRS (Early Treatment Diabetic Retinopathy Study) near reading chart.

Distance-corrected intermediate vision was evaluated monocularly under photopic conditions (81 cd/m^2) at 80 cm using the same chart used for near assessment but with an adjustment for distance.

Defocus curve and depth of focus

A defocus curve was obtained by spectacle defocus from +2.00 D to -5.00 D in 0.50 D steps. Non-randomised letter sequence and non-randomised progression of lenses were presented in each eye. All visual acuities were measured by means of the ETDRS scale using Yang vision tester optotype. The cut-off point was chosen as 0.3 logMAR and the depth of focus was calculated as half the values with VA better than 0.3 logMAR at different defocus values.

Ocular wavefront aberration analysis

The higher-order aberrations were measured using the Wasca Wavefront Analyzer aberrometer (Asclepion-Meditec, AG, Jena, Germany) based on the Hartmann–Shack wavefront sensor technique.

The WASCA aberrometer defines and calculates aberrations in terms of Zernike polynomials up to the fourth-order. The third- (Z_3^1, Z_3^{-1}, Z_3^3, Z_3^{-3}) and fourth- (Z_4^0, Z_4^2, Z_4^{-2}, Z_4^4, Z_4^{-4}) order aberrations were expressed as Zernike coefficients and were measured in microns.

The total higher-order wavefront error (from third to fourth) was expressed in RMS (root-mean-square) representing the average of the square root of the wavefront errors, measured in microns. Measurements of aberration were obtained during scheduled follow-up examinations after pupil dilatation with phenylephrine chlorhydrate and tropicamide (Visumidriatic fenilefrina®; Visufarma s.r.l, Rome, Italy) as previously described.[12] For the results across patients to be comparable, a 5.0 mm diameter pupil was used for analysis of all patients. The RMS of the total higher-order aberrations and of single third-order coma (Z_3^1, Z_3^{-1}), third-order trefoil (Z_3^3, Z_3^{-3}) and fourth-order spherical (Z_4^0) aberrations were calculated for each subject at each examination as the mean value of three reliable consecutive measurements.

In addition, the Zernike coefficient of fourth-order spherical (Z_4^0) aberration with a 5.0 mm pupil diameter was calculated for each patient.

Wavefront aberration analysis of total cornea

The total corneal higher-order aberrations were measured by means of the Oculus Pentacam (OCULUS Optikgerate GmbH, Wetzlar, Germany).

It uses Scheimpflug photography to acquire 100 cross-sectional images with 500 measurement points on the anterior and posterior corneal surfaces over a 180-degree rotation. Proprietary software reconstructs corneal topography (anterior and posterior surface) from height data and converts the corneal elevation profile into corneal wavefront data providing analyses of total, anterior and posterior corneal wavefront aberrations using the Zernike polynomials up to the tenth order.

Pentacam software version 1.17.89 was used. The examiner moved the joystick until perfect alignment was achieved and the system automatically captured 100 images of the cornea within two seconds. Scans with blinks or other artefacts were discarded and in accordance with Pentacam software indications were repeated.

All scans were centred on the centre of the pupil.

The RMS of corneal higher-order aberrations of third and fourth order (Z_3-Z_4) and of single third-order coma (Z_3^1, Z_3^{-1}), third-order trefoil (Z_3^3, Z_3^{-3}) and fourth-order spherical (Z_4^0) aberrations and Zernike coefficient of spherical aberration for a 6.0 mm pupil diameter were calculated for each control, for each patient examination as the mean value of three reliable consecutive measurements.

In addition, corneal asphericities (Q) at 6.0, 7.0 and 8.0 mm were calculated for each patient.

Variable	SA60D3 (n = 20)	SN6AD3 (n = 20)	SN6AD1 (n = 20)	p-value[a]
SE (D)	-0.04 ± 0.32	-0.27 ± 0.33	0.03 ± 0.50	0.251
Sphere (D)	0.15 ± 0.21	-0.06 ± 0.21	0.03 ± 0.09	0.099
Cylinder (D)	-0.28 ± 0.59	-0.33 ± 0.59	-0.38 ± 0.68	0.873
UDV (logMAR)	0.13 ± 0.11	0.13 ± 0.27	0.19 ± 0.15	0.317
VA (logMAR)	0.01 ± 0.09	-0.04 ± 0.10	0.03 ± 0.13	0.161
UIV 80 cm (logMAR)	0.29 ± 0.10	0.26 ± 0.05	0.21 ± 0.33*	0.027
DCIV 80 cm (logMAR)	0.26 ± 0.07	0.22 ± 0.09	0.04 ± 0.05*	< 0.001
DCNV 40 cm (logMAR)	0.02 ± 0.04	0.02 ± 0.05	0.01 ± 0.03	0.822

[a] Kruskal–Wallis test; * p = 0.05 Kruskal–Wallis *post hoc* test versus SA60D3.
SE: spherical equivalent, UDV: uncorrected distance vision, VA: distance visual acuity, UIV: uncorrected intermediate vision, DCIV: distance corrected intermediate vision, DCNV: distance corrected near vision.

Table 2. Visual parameters for the three groups of lenses at six months after surgery, expressed as mean ± SD

Capsular biocompatibility assessment

Digital photographs using retro-illumination were obtained with a Tomey video slitlamp to evaluate posterior capsular opacification.

All digital images were transferred to a personal computer and stored on a hard disk for later evaluation. All findings were analysed by the same observer. The intensity of central posterior capsular opacification (behind the IOL optic) was subjectively scored from zero to 4: 0 = none, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe, as previously described.[13]

Statistical analysis

This study was designed to show the differences in post-operative vision and visual acuity between three different lenses. The main outcome was the difference between groups in the mean change from pre-operative to post-operative value of distance-corrected intermediate vision. Assuming a difference of at least two logMAR lines (10 letters) with a standard deviation of 0.15 between groups, 20 patients in each group were required for an 80 per cent power and 0.05 alpha level.

In all patients, the post-operative follow-up of the parameters evaluated in the study was set at six months.

The main parameters evaluated included: the visual parameters (spherical equivalent, sphere, cylinder, uncorrected distance vision and distance VA at high contrast, VA at low contrast, distance-corrected near vision, near VA, uncorrected intermediate vision, distance-corrected intermediate vision, contrast sensitivity), the aberration parameters (HOA RMS, coma RMS, trefoil RMS, spherical RMS and Zernike coefficient of spherical aberration) and topographic parameters (Q).

The demographic parameters evaluated were age and gender.

The visual parameters (expressed as logMAR), the aberrometric and topographic parameters were summarised as mean and standard deviation (SD) in the tables and as mean and standard error (SE) in the figures. The qualitative variables were summarised as frequency and percentage. The results were reported separately for each of the three lenses (SA60D3, SN6AD3 and SN6AD1). The Shapiro–Wilk test was performed to verify normal distribution.

Kruskal–Wallis test was applied for assessing the comparison of the quantitative variables between three groups and Kruskal–Wallis *post hoc* analysis was used to determine whether there were pairwise differences.

Defocusing curves comparing three IOLs were obtained plotting the mean of VA with respect to 15 different values of defocus (from +2.00 D to -5.00 D).

All statistical tests were evaluated at an alpha level of 0.05. Statistical analysis was performed using SPSS® Advanced Statistical 11.0 software (SPSS Inc, Chicago, IL, USA).

RESULTS

Demographic characteristics

In the SN60D3 group, the mean age was 64.4 ± 6.11 years (range 60 to 74 years), in the SN6AD3 group it was 67.6 ± 5.32 years (range 60 to 74 years) and in the SN6AD1 group the age was 66.8 ± 5.54 years (range 60 to 73 years).

The mean ages were not statistically different among the three groups.

Visual and refractive outcomes

At six months the mean spherical equivalent, astigmatism, sphere, uncorrected distance vision and VA did not show statistically significant differences among the three groups (Table 2).

The distance VA at low contrast progressively decreased from 50 to 12.5 per cent contrast in the three groups with lower values under mesopic conditions compared to photopic conditions (Figure 1). The distance VA at all percentages of contrast in photopic and scotopic conditions was not significantly different among the three groups.

The distance-corrected near vision was 0.02 ± 0.04 logMAR in the SN60D3 group, 0.02 ± 0.05 logMAR in the SN6AD3 group and 0.01 ± 0.03 logMAR in the SN6AD1 group (p = 0.822). The near VA was 0.0 logMAR in 100 per cent of cases in all three groups.

The uncorrected intermediate vision and distance-corrected intermediate vision were respectively 0.29 ± 0.10 and 0.26 ± 0.07 in the SN60D3 group, 0.26 ± 0.05 and 0.22 ± 0.09 in the SN6AD3 group and 0.21 ± 0.05 and 0.04 ± 0.05 in the

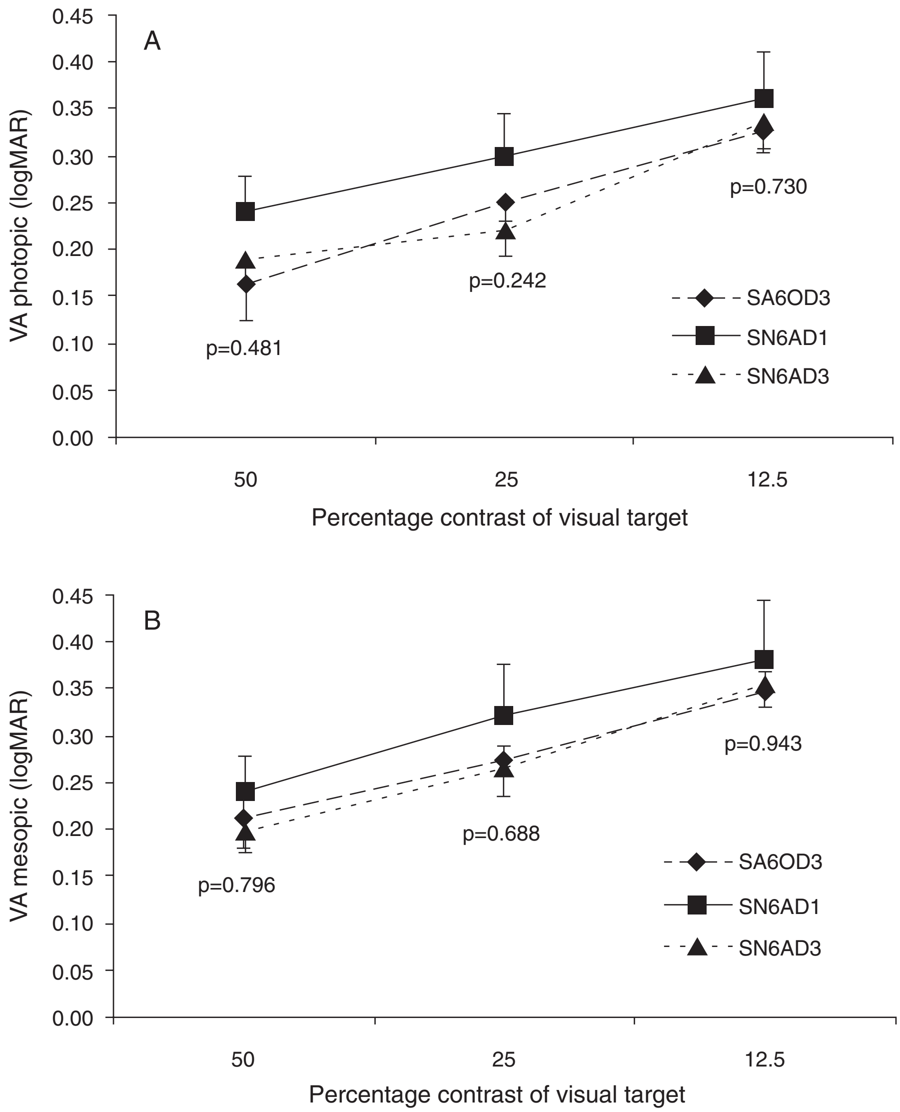

Figure 1. Distance visual acuity (VA) at 50, 25 and 12.5 per cent of contrast in photopic (A) and mesopic (B) conditions for the three groups of lenses. Values are mean and standard error of logMAR VA. The p-values are the results obtained with Kruskal–Wallis test for comparison between groups.

SN6AD1 group. Significant differences among groups were observed for uncorrected ($p = 0.027$) and distance-corrected ($p < 0.001$) intermediate vision.

The defocus curve showed a good functional capacity for distant and near vision, with a slight visual decline in the middle distances with some differences in the three groups for intermediate and near distances (Figure 2). Near vision at 40 cm was comparable in the three groups and at 33 cm was significantly better in the SN60D3 and SN6AD3 groups compared to the SN6AD1 group ($p = 0.005$). Intermediate vision was significantly better at 66.6 cm ($p = 0.05$) and at 50 cm ($p = 0.006$) in the SN6AD1 group compared to groups SN60D3 and SN6AD3.

The depth of focus was 3.00 D in the SN60D3 group and 2.50 D in the SN6AD3 and SN6AD1 groups. The amplitude of functional vision (0.3 logMAR or better) was 2.50 D in the SN60D3 group (from optical infinity to 25 cm) with a functional vision worse than 0.3 logMAR from 100 cm to 50 cm and 2.00 D in the SN6AD3 group (from optical infinity to 25 cm) with a functional vision worse than 0.3 from 100 cm to 50 cm and at 28.5 cm and 2.00 D in the SN6AD1 group with a functional vision worse than 0.3 from 100 cm to 66 cm and from 33 to 25 cm.

Contrast sensitivity

The mean values of contrast sensitivity at all spatial frequencies under photopic and mesopic conditions were not significantly different among the three groups. Under photopic conditions at 1.05 cpd, 18 per cent of patients of the SN60D3 group, none of the patients of the SN6AD3 group and 13 per cent of the SN6AD1 group were below the normal range, at 3.0 cpd, nine per cent of the SN60D3 group, and none of the SN6AD3 and SN6AD1 groups, at 6.0 cpd, 55 per cent of the SN60D3 group, 22 per cent of the SN6AD3 group and 25 per cent of the SN6AD1 group, at 12.0 cpd, 36 per cent of the SN60D3 group, 22 per cent of the SN6AD3 group and 13 per cent of the SN6AD1 group and at 18.0 cpd, 64, 33 and 38 per cent, respectively (Figure 3).

Ocular and corneal wavefront error

Post-operatively RMSs of corneal and total ocular higher-order aberrations and of coma and trefoil aberrations were not significantly different in the three groups. The RMS of ocular spherical aberration was significantly lower in the SN6AD3 group (0.07 ± 0.05 μm) and SN6AD1 group (0.05 ± 0.03 μm) compared to the SN60D3 group (0.12 ± 0.05 μm) ($p = 0.048$). The RMS of corneal spherical aberration was significantly lower in the SN60D3 group compared to the SN6AD3 and SN6AD1 groups (Table 3).

Capsular biocompatibility

No patient showed central posterior capsular opacification and no Nd-YAG (neodymium-yttrium aluminum garnet) capsulotomy was performed in any patient.

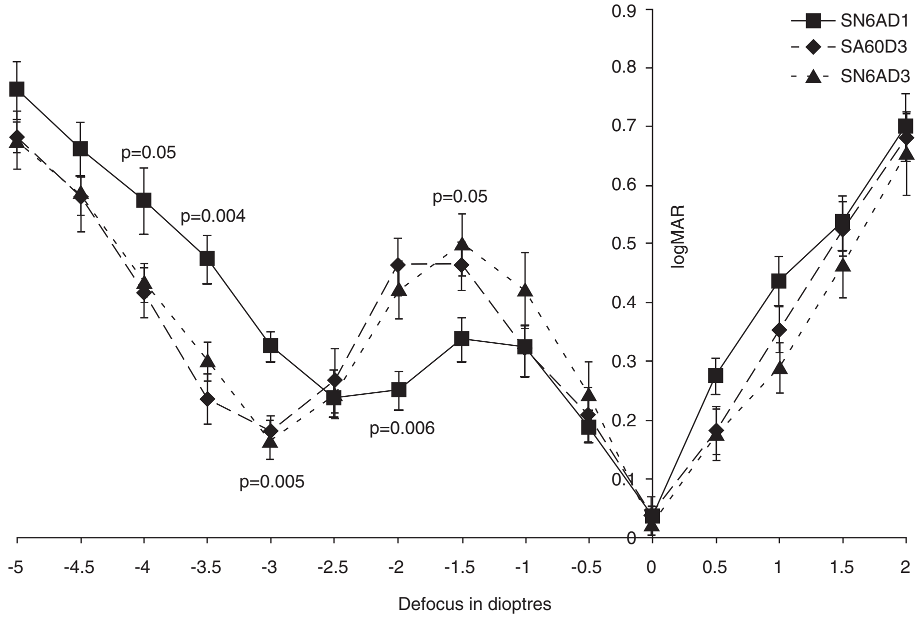

Figure 2. Visual acuity (VA) at different levels of defocus for the three groups of lenses. Values are mean and standard error of logMAR VA. The p-values are the results obtained with Kruskal–Wallis test for comparison between groups at each value of defocus.

Variable	SA60D3 (n = 20)	SN6AD3 (n = 20)	SN6AD1 (n = 20)	p-value[a]
Q (6.0 mm)	-0.25 ± 0.16	-0.08 ± 0.09	-0.10 ± 0.17	0.083
Q (7.0 mm)	-0.29 ± 0.13	-0.13 ± 0.09	-0.18 ± 0.16	0.062
Q (8.0 mm)	-0.36 ± 0.10	-0.19 ± 0.09*	-0.27 ± 0.13	0.013
Corneal				
RMS HOA (Z_3-/Z_4-) (6.0 mm)	0.10 ± 0.05	0.10 ± 0.02	0.12 ± 0.03	0.251
RMS Z_3^1 (6.0 mm)	0.05 ± 0.05	0.03 ± 0.02	0.04 ± 0.02	0.404
RMS Z_3^3 (6.0 mm)	0.03 ± 0.03	0.03 ± 0.03	0.03 ± 0.02	0.993
RMSZ_4^0 (6.0 mm)	0.05 ± 0.02	0.08 ± 0.02	0.09 ± 0.04*	0.010
Ocular				
RMS HOA (Z_3-/Z_4-) (5.0 mm)	0.31 ± 0.11	0.30 ± 0.14	0.32 ± 0.10	0.917
RMS Z_3^1 (5.0 mm)	0.16 ± 0.05	0.12 ± 0.07	0.10 ± 0.02	0.064
RMS Z_3^3 (5.0 mm)	0.18 ± 0.09	0.23 ± 0.11	0.29 ± 0.11	0.161
RMS Z_4^0 (5.0 mm)	0.12 ± 0.05	0.07 ± 0.05	0.05 ± 0.03*	0.048

[a] Kruskal–Wallis test; * p = 0.05; Kruskal–Wallis *post hoc* test versus SA60D3.

Table 3. Aberrometric and asphericity parameters for the three groups of lenses at six months after surgery, expressed as mean ± SD

DISCUSSION

Multifocal IOLs provide greater independence from spectacles than monofocal IOLs.[2]

Recent AcrySof ReSTOR hybrid diffractive-refractive models with spherical and aspheric design and +3.00 or +4.00 near additions have proven to enable vision for several distances in several studies.

The AcrySof ReSTOR +4.00 both with aspheric and spherical designs demonstrated good results for far and near with distant and near VA of 0.0 logMAR or better in the majority of studies.[5,8]

Because of the diffractive design of ReSTOR +4.00 lenses, as in the other diffractive IOLs, two principal focal points are created with a decline of visual capacity for intermediate distances.

The intermediate vision was reported to vary between 0.20 to 0.30 logMAR at 50 cm and between 0.30 and 0.40 logMAR at 60 and 70 cm with the spherical model. The aspheric model showed better results for intermediate vision.[5,11]

The aspheric AcrySof ReSTOR +3.00 demonstrated overlapping results compared to the ReSTOR +4.00 for far vision.

For near vision, the preferred working distance was greater for the ReSTOR +3.00 with better near VA at 40 cm compared to ReSTOR +4.00.[11] For closer distances, such as 30 cm near VA was better for ReSTOR +4.00 compared to ReSTOR +3.00.

According to published studies intermediate VA varied from -0.12 to 0.07 logMAR at 50 cm, from 0.02 to 0.16 at 60 cm and from 0.11 to 0.19 at 70/80 cm.[5,11]

In our study, the three groups showed good far and near VA without statistically significant differences between the lenses. The percentage of patients with distance VA of 0.1 logMAR or better was 88.8 per cent for groups 1 and 2 and 87.5 per cent for group 3 and 0.3 logMAR or better in all patients in all three groups.

The near vision with distance correction at 40 cm was 0.0 logMAR in all three groups and at the defocus curve at a closer

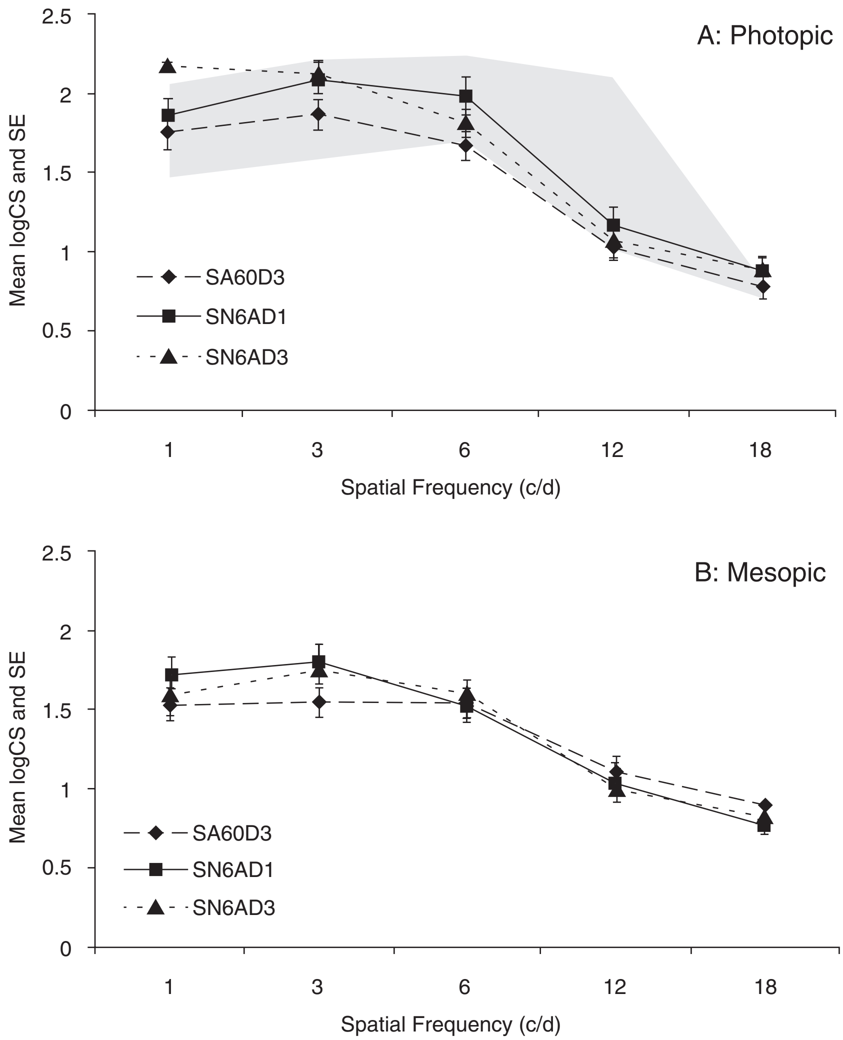

Figure 3. Contrast sensitivity functions for the three groups of lenses expressed as logCS and standard error: photopic (85 cd/m^2) (A) and mesopic (5 cd/m^2) (B). The grey area represents the normal range.

distance of 33 cm, near vision was significantly better in the aspheric and spherical MIOLs +4.00 compared to MIOLs +3.00 ($p = 0.005$).

The distance-corrected intermediate vision at 80 cm was better in group 3 (0.04 ± 0.05) compared to group 1 (0.26 ± 0.07) or 2 (0.22 ± 0.09) ($p < 0.001$) and at the defocus curve distance-corrected intermediate vision was significantly better at 66.6 cm ($p = 0.05$) and at 50 cm ($p = 0.006$) in group 3 compared to groups 1 and 2.

The quality of vision after MIOL implant has been another important issue in the last decades because after MIOLs implant visual disturbances such as reduced contrast sensitivity, degradation of night vision and halos were reported.[1,2]

Some technical innovations such as aspheric design of the optic, hybrid diffractive-refractive profile and apodisation of diffractive steps were introduced to improve optical quality of the IOL and thus visual performance of patients implanted with MIOLs.

ReSTOR MIOLs particularly with aspheric profile showed good quality of vision in terms of contrast sensitivity and subjective symptoms comparable to monofocal IOLs.[5,11,13–17]

No significant differences in quality of vision were observed between ReSTOR +3.00 and +4.00, both with aspheric profiles.[11]

In our study, the mean values of contrast sensitivity at all spatial frequencies under photopic and mesopic conditions were not significantly different among the three groups and were within normal range. Nevertheless, under photopic condition at 6.0, 12.0 and 18.0 cpd a higher percentage of patients with spherical ReSTOR +4.00 were below the normal range compared to aspheric ReSTOR +4.00 and +3.00.

A low amount of spherical aberration with the spherical and aspheric ReSTOR +4.00 and, more recently, with the aspheric +3.00 with lower values of spherical aberration for the aspheric compared to the spherical design have been reported.[11,13,17–19]

In our study, the three groups did not differ for RMS of corneal and total ocular higher-order aberrations, coma and trefoil aberrations. The RMS of ocular spherical aberration was significantly lower in the aspheric IOL groups compared to the spherical IOL group. A lower value of corneal spherical aberration in the spherical MIOL group implied an even higher value of internal spherical aberration in the spherical group compared to the other two groups.

The good visual performance of the three IOLs without significant differences of vision quality as shown by the results of low-contrast VA and contrast sensitivity is probably related to an equal amount of total ocular higher-order aberrations even though the spherical aberration was significantly different between spherical and aspheric groups.

Some authors evidenced a higher amount of third-order aberrations, when aspheric IOLs were decentred compared to spherical IOLs, demonstrating a limitation of correcting spherical aberration with aspheric IOLs, when correct positioning of the IOL was not obtained because of decentration and/or tilt.[20–23]

In our study, the aspheric SN6AD3 and SN6AD1 IOL groups showed a slightly higher value of ocular third-order trefoil aberrations compared to the SN60D3 IOL group but it was not statistically significant.

We did not evaluate lens decentration and tilt and thus we cannot establish a correlation between eventual IOL misalignment and third-order aberrations.

The main limitations of the study are related to the lack of control groups implanted with monofocal spherical and aspherical IOLs to better highlight differences in visual and optical performance compared to MIOLs and the lack of the measurement of IOL tilt/decentration, so as to relate the higher-order aberration pattern particularly of third-order to IOL position and the lack of randomisation of the defocus curve measurements that would make more reliable evaluation of the amplitude of pseudo-accommodation.

Moreover, there have been some concerns regarding the accuracy of measurements of higher-order aberrations with the Hartmann–Shack (H-S) sensors in eyes implanted with a MIOL. It has been pointed out that diffractive IOL zones may be under-sampled and/or inadequately reconstructed using conventional H-S technology.[24,25]

This limitation of Shack–Hartmann wavefront sensors for the measurement of higher-order aberrations is thought to be imposed by the density of the sampling distribution of the instruments' lenslet array. In our study the aberrometer was a Wasca wavefront analyser aberrometer with 1,452 lenslets for 9.0 mm of analysis —the highest number of lenslets among the commercially available ocular wavefront sensors, as previously clarified.[26] Moreover, our results confirm that these aspheric MIOLs analysed in the study, created to induce low spherical aberrations, are related to a lower amount of spherical aberration compared to the spherical model, thus demonstrating a reliable analysis of symmetrical spherical aberration.

In conclusion, ReSTOR MIOLs +4.00 and +3.00 provided good distant and near vision with better vision at intermediate distances for +3.00 compared to +4.00. All three lenses showed good quality of vision and the ReSTOR +4.00 with aspheric profile and +3.00 revealed lower spherical aberration error compared to the spherical +4.00.

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