Working-Age Cataract Patients: Visual Results, Reading Performance, and Quality of Life with Three Diffractive Multifocal Intraocular Lenses

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Purpose: To compare the visual outcomes, reading performance, and quality of life (QoL) of working-age cataractous patients bilaterally implanted with 3 different diffractive multifocal intraocular lenses (MIOLs).

Design: Two-center, randomized, prospective, double-masked study.

Participants: Sixty-three consecutive patients (126 eyes) seen at Ophthalmology Section, Palermo and Florence University, Italy, randomized to receive the ReSTOR SN6AD3 (Alcon Laboratories, Inc, Irvine, CA) (20 patients, group A), ReSTOR SN6AD1 (Alcon Laboratories, Inc) (21 patients, group B), or TECNIS ZMA00 (Abbott Medical Optics, Santa Ana, CA) (22 patients, group C) MIOL.

Intervention: Phacoemulsification.

Main Outcome Measures: One-year follow-up differences among the 3 MIOL groups in visual acuity, reading performance by MNREAD (Minnesota Laboratory for Low-Vision Research, University of Minnesota, Minneapolis, MN) reading acuity (RA), critical print size (CPS), and maximum reading speed (MRS) under mesopic and photopic conditions.

Secondary Outcome Measures: Photopic and mesopic contrast sensitivity (CS) by Pelli–Robson test and patient satisfaction by National Eye Institute Refractive Error Quality of Life Instrument-42 (NEI RQL-42) questionnaire.

Results: Mean photopic uncorrected near visual acuity (UNVA), distance-corrected near visual acuity (DCNVA), and corrected near visual acuity (CNVA) did not differ among groups, with a preferred reading distance greater in group B ($P < 0.0005$). Photopic distance-corrected intermediate visual acuity (DCIVA) was best in group B ($P = 0.001$) and better in group C than in group A. Mesopic UNVA and DCNVA were worse in groups A and B compared with group C ($P < 0.0005$ in both cases), with better DCNVA in group B than in group A ($P = 0.031$). Mesopic uncorrected intermediate visual acuity (UIVA) and DCIVA were worst in group A, with better results in group C ($P < 0.0005$ and $P = 0.001$, respectively). Mesopic MNREAD RA was better in group C ($P = 0.02$), and mesopic MRS was higher in groups B and C than in group A ($P = 0.002$). The QoL scores by the NEI RQL-42 test exhibited no differences among groups in 9 over 13 scales. "Near vision" ($P = 0.005$), "symptoms" ($P = 0.001$), and "satisfaction with correction" scale scores ($P = 0.030$) were lowest in group A, and "appearance" scale score was lowest in group B ($P = 0.045$).

Conclusions: Newer-generation aspheric diffractive MIOLs, especially low-add hybrid apodized or full diffractive, are highly suited for working-age cataractous patients in terms of visual outcomes, reading performance, and QoL. Intrinsic optical differences, such as optimization for computer or dim-light working, or night driving, could be useful tools to customize the IOL in each single case. *Ophthalmology 2014;121:34-44 © 2014 by the American Academy of Ophthalmology.*

Today, we are ever more dependent on being able to perform rapidly alternating far and close-up tasks, such as reading from a tablet or mobile phone while watching television or desktop display, following a satellite navigation device while driving, and so on.

Borrowing from the needs of sports, we can say that something similar to a "dynamic vision focusing" as the ability of the eyes to clearly focus on objects quickly and at varying distances is often necessary today, especially in the working-age population.

Presbyopia has an impact on these everyday tasks while the individual is still of working age. Presbyopia is associated with worse vision-targeted health-related quality of life (QoL) compared with younger subjects with emmetropia.[1] Sometimes, in a short time, the development of cataract causes severe deterioration in the quality of sight, which in turn can lead to a further significant reduction in a patient's QoL. Thus, for example, a decrease in reading ability reduces not only the quality of vision but also the QoL.[2,3]

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Since 1997 Food and Drug Administration approval, multifocal intraocular lenses (MIOLs) have been proposed to solve these problems. Despite new-generation MIOLs and later pseudo-accommodating intraocular lenses (IOLs) going through several modifications to improve distance, intermediate, and near vision compared with their predecessors, they are still far from perfect because of unwanted side effects such as glare and halos and inconsistent near vision. Therefore, careful patient selection for each of these technologies is crucial for success and patient satisfaction.[4]

During the last decade, various studies have shown that rotationally symmetric MIOLs, especially those with aspheric full diffractive or hybrid apodized diffractive-refractive optics, provided better distance and near visual outcomes and intraocular optical performances when compared with pseudo-accommodative IOLs or refractive (symmetric or asymmetric) MIOLs with sectorial near addiction.[5–15]

Because simple Snellen acuity and optical outcomes cannot adequately describe the clinical performance of MIOLs, some studies, usually nonrandomized comparative or prospective case series, have analyzed the reading performance or vision-related QoL in different types of pseudo-accommodative IOLs or MIOLs. Mostly used tests are the MNREAD Test (Minnesota Laboratory for Low-Vision Research, University of Minnesota, Minneapolis, MN), the Radner Reading Charts (by the Salzburg Reading Desk), the National Eye Institute Refractive Error Quality of Life Instrument-42 (NEI RQL-42), the National Eye Institute Visual Functioning Questionnaire-25 (NEI VFQ-25), and the Visual Function-14 QoL questionnaire.[2,8,16–22]

The aim of this prospective study was to compare, at 1-year follow-up, the visual outcomes, reading performance, and QoL in cataractous patients of working age who were bilaterally implanted with 1 of 3 types of diffractive third-generation MIOLs. Primary end points were visual results and reading performance under different light conditions. Secondary end points were contrast sensitivity (CS) and QoL. To obtain insight into the clinical outcome and to identify any differences with different IOLs, we evaluated photopic distance logarithm of the minimum angle of resolution (logMAR) acuity; mesopic and photopic near and intermediate (Jaeger) visual acuity; MNREAD eye charts to evaluate maximum reading speed (MRS), critical print size (CPS), and reading acuity (RA) in mesopic and photopic conditions; Pelli–Robson CS test to measure CS in photopic and mesopic conditions; and NEI RQL-42 questionnaire to analyze QoL. To the best of our knowledge, MNREAD reading performance and Pelli–Robson CS results with multifocal IOLs, evaluated under mesopic conditions, have not been reported.

Methods

Study Design

This 2-center, randomized, prospective, double-masked clinical trial enrolled 66 consecutive working-age patients with cataract (132 eyes) who were seen between January 2010 and January 2011 at the Ophthalmology Section of Palermo University Hospital and the Eye Clinic of the University of Florence. Figure 1 shows a flowsheet summarizing patient assignment and outcome measures.

Enrollment and Consent

The study protocol was approved by the Ethics Committees of the Universities of Palermo and Florence, and enrollment and written informed consent were conducted in accord with the tenets of the Declaration of Helsinki. Consecutive patients meeting the inclusion and exclusion criteria in the clinic populations were recruited for this study. The inclusion criteria were bilateral juvenile or senile cataract, visually significant (i.e., visual acuity >0.2 logMAR) in at least 1 eye, corneal astigmatism <1.0 diopter (D), and capability of understanding and signing the informed consent. All patients were of working age and actively engaged. Exclusion criteria were age <18 years or >65 years; pre-cataract myopia or hyperopia >3 D; history of amblyopia; fundus abnormalities that could cause significant vision impairment; previous surgical intraocular procedures; and ocular comorbidities, such as previous trauma, glaucoma, diabetic retinopathy, pseudoexfoliation syndrome, chronic uveitis, corneal opacities, and alpha-antagonist (e.g., tamsulosin) treatment, which might induce floppy iris syndrome.

Intraoperative exclusion criteria were iris pupillary trauma, vitreous loss, and inability to place the IOL in the capsular bag. Patients were informed that they would be randomly allocated to undergo sequential bilateral cataract surgery, with implantation in both eyes of a multifocal diffractive IOL. The potential benefits and drawbacks of multifocal IOLs were explained, including reduced spectacle dependence, better uncorrected near visual acuity (UNVA), and possible glare and halos.

Infrared computerized pupillometry, keratometry by topographic examination (Sirius CSO, Florence, Italy), and immersion ultrasound biometry (OcuScanRxP, Alcon Laboratories, Inc, Ft. Worth, TX) were performed in all cases by 1 experienced examiner (GC or MP). Emmetropic IOL power was determined with the Sanders–Retzlaff–Kraft Theoretical formula, choosing the next available D (plus) for implantation, in all patients.

All patients gave informed consent before randomization. Immediately preoperatively, the patients were randomized to receive bilaterally 1 of the 3 IOL types: the apodized diffractive and refractive Alcon Acrysof IQ ReSTOR SN6AD3 with +4.00 D add (Alcon Laboratories, Inc, Irvine, CA), the apodized diffractive and refractive Alcon Acrysof IQ ReSTOR SN6AD1 with +3.00 D add (Alcon Laboratories, Inc), and the full diffractive AMO TECNIS ZMA00 with +4.00 D add (Abbott Medical Optics, Santa Ana, CA). Randomization used a 1:1:1 block randomization scheme generated by the Statistical Package for the Social Sciences (Windows version 20.0, SPSS, Inc, Chicago, IL). Surgery in the second eye was performed 1 month later, with the same type of IOL implanted in the second eye.

The patients and the medical staff who collected functional data and QoL data (V.B., G.C., M.P.) were masked to the type of lens that each patient received. Patients were observed from the initial preoperative examination until 12 months after surgery in the second eye. The randomization code was maintained only at the central data facility and was not broken until all data analysis was complete (Fig 1).

Intraocular Lenses

The 6-mm acrylic optical surface of the aspheric hybrid diffractive/refractive Alcon ReSTOR SN6AD3 and SN6AD1 IOLs is refractive at the periphery for distance vision and apodized diffractive at the central 3.6 mm of the anterior surface for distance and near vision. The IOLs have 0° angled optics and should add −0.20 μm of spherical aberration to the eye at the 6-mm optical zone. Apodization means that the diffractive steps are greater in the center of the IOL to give a greater proportion of light to near vision

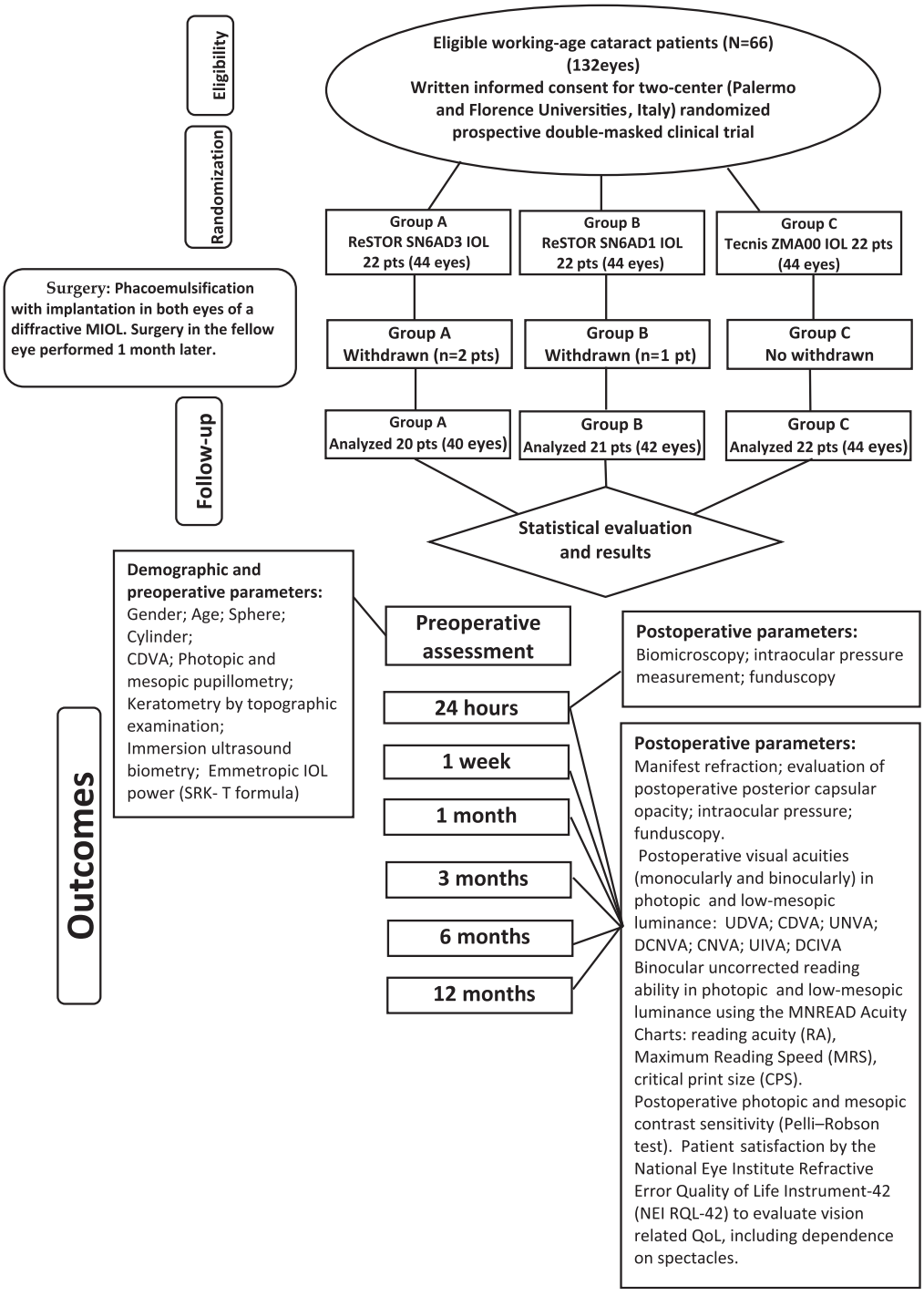

Figure 1. Flowsheet summarizing patient assignment and outcome measures. CDVA = corrected distance visual acuity; CNVA = corrected near visual acuity; CPS = critical print size; DCIVA = distance corrected intermediate visual acuity; DCNVA = distance corrected near visual acuity; IOL = intraocular lens; MIOL = multifocal intraocular lens; MRS = maximum reading speed; NEI = National Eye Institute; QoL = quality of life; SRK-T = Sanders–Retzlaff–Kraft Theoretical formula; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity.

with miotic pupils and to favor distance vision when pupils enlarge. The apodized diffractive 3.6-mm central area of the +4.00 D IOL consists of 12 concentric steps of gradually decreasing height, creating bifocality from near to far and providing +3.20 D of near add at the lens plane. The apodized diffractive 3.6-mm central area of the +3.00 D IOL consists of 9 concentric steps of gradually decreasing height. In addition, the centermost region of the 3.6-mm area is larger than in the +4.00 D add version (0.856 vs. 0.742 mm), creating bifocality from near to far and providing +2.40 D near add at the lens plane.[20,23,24]

The +3.00 D add IOL was designed as an alternative to the +4.00 D add model to provide better intermediate vision or extended reading distance.[24–28] The AMO TECNIS ZMA00 with +4.00 D add has a 6-mm acrylic full diffractive optic. The posterior surface of the IOL contains a diffractive multifocal pattern, with a central 1-mm refractive area, and the anterior surface is a modified prolate refractive zone. The anterior surface is wavefront designed and intended to reduce the total amount of aberration and improve mesopic CS by introducing negative spherical aberration into the eye's optical system. The IOL has a 5° angled optic design and should introduce −0.27 μm of spherical aberration to the eye measured at the 6-mm optical zone. The diffractive pattern is 32 concentric circles with a +4.00 D near add that creates an even split of the light distribution between near and distance vision, regardless of pupil diameter, with approximately +3.00 D at the lens plane.[20,29]

Surgical Procedure

All surgeries were performed by 1 of 2 experienced surgeons (SC or RM). Standard sutureless cataract surgery technique was performed through a temporal 2.6-mm near-clear corneal tunnel incision with a precalibrated knife (Clearcut, Alcon Italia S.P.A., Milan, Italy). Phacoemulsification was performed with the Alcon Infiniti Vision System (Alcon Italia S.P.A.), using the Ozil torsional handpiece in the majority of cases. The IOL implantation was performed using an Unfolder Emerald injector system for TECNIS ZMA00 IOL (AMO Italy, Rome, Italy) or a Monarch II injector for ReSTOR SN6AD IOLs (Alcon Italia S.P.A.).The surgical wound was closed by stromal hydration. All patients received topical ofloxacin (Exocin, Allergan SpA, Rome, Italy) for 3 days preoperatively and tobramycin and dexamethasone ophthalmic suspension (Tobradex, Alcon Italia S.P.A.) for 4 weeks postoperatively.

Outcome Measures

Primary outcomes, evaluated after 1 year, were the differences among the 3 IOL-implanted groups in terms of the photopic distance visual acuity, mesopic and photopic near and intermediate visual acuity, and reading performance by MNREAD Charts RA, CPS, and MRS in mesopic and photopic conditions. Secondary efficacy measures were CS by photopic and mesopic Pelli−Robson CS test, and QoL, evaluated by the NEI RQL-42 questionnaire.

Patients were examined preoperatively and at 24 hours, 1 week, and 1, 3, 6, and 12 months postoperatively. Ophthalmic examination included manifest refraction, biomicroscopy, evaluation of postoperative posterior capsular opacity, intraocular pressure measurement, and fundoscopy.

Postoperative visual acuities were measured both monocularly and binocularly. Uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) were measured in logMAR notation at 100% contrast using Early Treatment of Diabetic Retinopathy Study charts under photopic conditions (CC-100XP LCD System for Chart display, Topcon Europe BV, Milano, Italy) at 5 m. The UNVA, distance-corrected near visual acuity (DCNVA), and corrected near visual acuity (CNVA) were measured using the Federal Aviation Administration Near Vision Acuity Chart (Snellen units converted to logMAR by the Visual Acuity Conversion Chart),[30] with 100% contrast at a mean distance of 35 cm, allowing the patient to hold the chart at the optimum distance for reading the smallest line, with a ±5 cm tolerance, and recording the preferred distance. These acuities were measured in both photopic (85 candelas [cd]/m^2) and low-mesopic (3 cd/m^2) luminance (Luxmeter HD 2302.0, Delta OHM, Tecnopound, Ravenna, Italy). Uncorrected intermediate visual acuity (UIVA) and distance-corrected intermediate visual acuity (DCIVA) were measured at 80 cm in both photopic and mesopic conditions with the same chart.

Binocular uncorrected reading ability was measured under photopic and mesopic conditions using the MNREAD Acuity Charts at 35±5 cm. The logMAR acuities were adjusted for nonstandard viewing distances (i.e., different from 40 cm) by Table A adjustments, on the back page of the MNREAD booklet.[17,24,31] This test is made of charts containing 19 sentences. Each sentence is printed as 3 lines with even left and right margins. The sentences are in different print sizes ranging from 1.3 to −0.5 logMAR, and each of them is 0.1 logMAR units smaller than the previous sentence (i.e., ~80% of the size). Each sentence has 60 characters, which corresponds to 10 standard length words, assuming a standard word length of 6 characters (including a space). Thus, each sentence can be divided into 10 smaller parts, and acuity can be measured to the closest 0.01 logMAR.

The patients read the chart aloud beginning with the largest characters and continued to read the sentence at each character size. The time required for reading and the frequency of mistakes were recorded.

The RA is the smallest print that the patient can read without making significant errors and was calculated (in logMAR) counting the number of sentences that the patient read and the number of words that the patient read incorrectly, and using the following formula: RA = 1.4 − (sentences × 0.1) + (errors × 0.01).

The reading speed was measured in words per minute, which correlates the reading time (in seconds) of each sentence with the number of words per minute. The MRS was the number of words per minute corresponding to the sentence read without mistakes at the higher speed.

The CPS, measured in logMAR, is the smallest print that the patient can read with maximum speed; the characters' size of the sentence at which the reading speed starts to cut indicates the CPS.

Postoperative CS was determined binocularly at 3 m with the best distance correction using the Pelli−Robson test in photopic and mesopic conditions. The test chart consists of 8 lines of 6 letters each, and each line contains two 3-letter sets at different CS levels. Reading from left to right and top to bottom, log CS (measured as logCS units) increases in 0.15 log steps from 0.05 to 2.30. All letters in the test are the same size, subtending 5° of visual angle at a distance of 3 m, with a line width of 1°.[32,33]

Patients' satisfaction was assessed by the NEI RQL-42 to evaluate vision-related QoL, including dependence on spectacles. All of the 42 items in the NEI-RQL are grouped into 13 scales covering specific aspects of QoL. Each of the 13 subsets is composed of 1 to 7 items, the scores of which are averaged to yield the final score for that subset. Each scale has a score from 0 to 100. A higher score on the NEI RQL-42 scales indicates a higher self-reported QoL.[21,22,34–36] A subgroup of patients using a computer at work was also analyzed.

Statistical Analysis

A power calculation showed that a sample size of 20 in each group would have 80% power to detect a difference of 1 line of logMAR acuity with a significance of 0.05 (2 tailed) and an expected proportion of withdrawals of 5%.

All continuous data are expressed as a mean ± standard deviation of the mean. Statistical analysis of quantitative data, including descriptive statistics, was performed for all the items. Categoric variables were compared using the Pearson's chi-square test. When parametric analysis was possible, univariate analysis of variance with Bonferroni post hoc comparison was used to compare the results among the 3 IOL groups.

When parametric analysis was not possible, the Kruskal–Wallis test was used to compare the IOL groups. For post hoc analysis, the Mann–Whitney test with the Bonferroni adjustment was used to avoid the experimental error rate. Data were analyzed with Epi Info software (version 6.0, Centers for Disease Control and Prevention, Atlanta, GA) and SPSS version 20.0 (SPSS, Inc). All P values were 2 sided, and P values less than 0.05 were considered statistically significant.

Results

Sixty-six patients of working age were enrolled in the study. Three patients withdrew after randomization or during the postoperative period. Therefore, 63 of them (126 eyes) were available for analysis in the 3 groups and for the whole follow-up (Table 1). Thirty-seven patients underwent surgery at the Ophthalmology Section of Palermo University Hospital, and 26 patients underwent surgery at the Eye Clinic of the University of Florence, Italy. Group A included 20 patients (40 eyes) implanted with the pupil-dependent Alcon ReSTOR SN6AD3 IOL, group B included 21 patients (42 eyes) implanted with the pupil-dependent Alcon ReSTOR SN6AD1IOL, and group C included 22 patients (44 eyes) implanted with the pupil-independent AMO TECNIS ZMA00 IOL. Table 1 summarizes the preoperative conditions of the groups of eyes analyzed in the study. As shown, there were no significant intergroup differences in age, sex, preoperative sphere, and cylinder. Preoperative photopic and mesopic pupil diameters and CDVA were comparable among groups. The percentage of patients using computer at work did not differ in the 3 groups.

No intraoperative complications occurred in any eye. No clinically significant cystoid macular edema, prolonged intraocular pressure increase, or corneal edema was observed. During the 12-month follow-up, no clinically significant IOL decentration (i.e., >0.5 mm) was observed. In all eyes, the posterior capsule maintained adequate transparency for optimal posterior pole biomicroscopy.

Table 2 shows the 12-month postoperative photopic and mesopic pupil diameters, refraction, preferred reading distance, and binocular visual outcomes by IOL group. No differences were found in terms of mean pupillary diameters and spherocylinder correction in the 3 groups.

All patients achieved a binocular UDVA of ≥0.010 (i.e., >20/25 Snellen ratio), with CDVA mean values <0.00 logMAR (i.e., >20/20 Snellen ratio) in the 3 groups, without significant difference ($P = 0.900$ and $P = 0.344$, respectively). Mean photopic UNVA, DCNVA, and CNVA were ≤0.05, ≤0.04, and ≤0.04, respectively, and did not differ in the 3 groups ($P = 0.398$, $P = 0.341$, and $P = 0.260$, respectively), with a preferred reading distance greater in group B than in the other 2 groups ($P < 0.0005$) and greater in group C than in group A ($P < 0.0005$). Photopic UIVA and DCIVA exhibited a trend or were better in group B than in the other groups and better in group C than in group A ($P = 0.001$; group A vs. B $P < 0.0005$; group B vs. C $P = 0.035$, and group A vs. C $P = 0.006$). Mesopic UNVA and DCNVA were worse in groups A and B than in group C ($P < 0.0005$ in both cases), with no difference between the former 2 groups regarding mesopic UNVA, whereas a better mesopic DCNVA performance was found in group B than in group A ($P = 0.031$). No differences were found relating to mesopic CNVA among groups ($P = 0.249$). With respect to mesopic UIVA and DCIVA, the worst performance was found in group A than in the other 2 groups, with better results in group C ($P < 0.0005$ and $P = 0.001$, respectively). Figure 2 graphically shows the uncorrected visual acuities in all groups.

Photopic MNREAD RA at the best patient-preferred reading distance did not differ in the 3 groups ($P = 0.835$). The same parameter under mesopic conditions was higher in group C ($P = 0.02$) than in the remaining groups. The photopic MRS was similar among groups ($P = 0.279$), whereas the mesopic MRS value tended to be higher in groups B and C than in group A ($P = 0.002$). No statistical differences were found in the 3 groups relating photopic and mesopic MNREAD CPS ($P = 0.890$ and $P = 0.348$, respectively) (Table 3).

With respect to the postoperative binocular CS by the Pelli–Robson test, no differences among groups were present under photopic or mesopic conditions ($P = 0.410$ and $P = v0.460$, respectively), but mesopic CS was significantly worse than photopic CS ($P < 0.0005$) (Table 3).

Figure 3 and Table 4 show the postoperative vision-related QoL scale scores by NEI RQL-42 test in the MIOL groups. In 10 over 13 subset scales the mean score was high, usually >90, in all

Table 1. Preoperative Characteristics of Patients

	Group A RESTOR SN6AD3 (Alcon Laboratories, Inc, Irvine, CA) +4.00 D IOL	Group B RESTOR SN6AD1 (Alcon Laboratories, Inc) +3.00 D IOL	Group C TECNIS (Abbott Medical Optics, Santa Ana, CA) ZMA00 IOL	P Value
Patients, N	20	21	22	
Eyes, N	40	42	44	
Gender (M/F)	9/11	11/10	10/12	0.067*
Age (y)†	53.7 (3.2)	55.2 (2.3)	54.2 (2.8)	0.297‡
Sphere (D)†	0.60 (2.0)	0.50 (2.2)	0.65 (1.8)	0.836‡
Cylinder (D)†	−0.50 (0.55)	−0.67 (0.42)	−0.55 (0.60)	0.511‡
CDVA (logMAR)†	0.31 (0.22)	0.30 (0.24)	0.28 (0.26)	0.791‡
Pupil diameter (photopic)† (mm)	2.8 (0.4)	2.7 (0.6)	2.9 (0.5)	0.419‡
Pupil diameter (mesopic)† (mm)	3.9 (0.4)	4.1 (0.3)	4.0 (0.5)	0.331‡
Using computer at work, N (%)	10 (50%)	11 (52%)	13 (59%)	0.077*

CDVA = corrected distance visual acuity; D = diopter; IOL = intraocular lens; logMAR = logarithm of the minimum angle of resolution.
*Chi-square test.
†Mean (± standard deviation).
‡Univariate analysis of variance test.

Table 2. Postoperative Pupil Diameter, Refraction, Reading Distance, and Visual Acuity Results (Mean ± Standard Deviation) for the Three Groups At 12-Month Follow-up

	Group A RESTOR SN6AD3 +4.00 D IOL	Group B RESTOR SN6AD1 +3.00 D IOL	Group C TECNIS ZMA00 IOL	*P* Value[†]	*P* Value Post Hoc Comparison[*]		
					A-B	A-C	B-C
Pupil diameter (mm)							
Photopic	2.8 (0.4)	2.8 (0.6)	3.0 (0.5)	0.467			
Mesopic	3.9 (0.4)	4.0 (0.3)	4.1 (0.4)	0.281			
Sphere (D)	0.08 (0.40)	0.10 (0.30)	0.07 (0.50)	0.871			
Cylinder (D)	−0.20 (0.30)	−0.23 (0.42)	−0.26 (0.32)	0.707			
Preferred reading distance (cm)	32.0 (1.0)	39.5 (1.3)	34.4 (0.9)	<0.0005	<0.0005	<0.0005	<0.0005
UDVA (logMAR)	0.010 (0.08)	0.008 (0.05)	0.006 (0.08)	0.900			
CDVA (logMAR)	−0.09 (0.10)	−0.12 (0.05)	−0.11 (0.03)	0.344			
UNVA (logMAR)							
Photopic	0.05 (0.08)	0.02 (0.04)	0.05 (0.06)	0.398			
Mesopic	0.31 (0.12)	0.25 (0.07)	0.14 (0.05)	<0.0005	NS	<0.0005	<0.0005
CNVA (logMAR)							
Photopic	0.04 (0.05)	0.01 (0.05)	0.035 (0.05)	0.260			
Mesopic	0.08 (0.09)	0.06 (0.08)	0.03 (0.08)	0.249			
DCNVA (logMAR)							
Photopic	0.04 (0.08)	0.015 (0.04)	0.04 (0.06)	0.341			
Mesopic	0.27 (0.10)	0.21 (0.07)	0.11 (0.09)	<0.0005	0.031	<0.0005	<0.0005
UIVA (logMAR)							
Photopic	0.16 (0.12)	0.09 (0.12)	0.11 (0.04)	0.201			
Mesopic	0.36 (0.09)	0.29 (0.07)	0.25 (0.05)	<0.0005	0.008	<0.0005	0.036
DCIVA (logMAR)							
Photopic	0.15 (0.07)	0.07 (0.05)	0.10 (0.04)	0.001	<0.0005	0.006	0.035
Mesopic	0.36 (0.12)	0.29 (0.07)	0.24 (0.06)	0.001	0.027	<0.0005	0.016

CDVA = corrected distance visual acuity; CNVA = corrected near visual acuity; D = diopter; DCIVA = distance corrected intermediate visual acuity; DCNVA = distance corrected near visual acuity; IOL = intraocular lens; logMAR = logarithm of the minimum angle of resolution; NS = not significant; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity.
*Bonferroni post hoc comparison.
[†]Univariate analysis of variance test.

groups, with relatively lower values in the "glare," "worry," and "appearance" scales. No differences were found among groups in 9 over 13 scales. Significant differences were found in "near vision" ($P = 0.005$), "symptoms" ($P = 0.001$), and "satisfaction with correction" scale scores ($P = 0.030$), which were lowest in group A, and "appearance" score ($P = 0.045$), which was lowest in group B.

Table 4 shows the 2 NEI RQL-42 test scale scores exhibiting differences in the computer users subgroup. "Clarity of vision" and "near vision" were reported as best in group B ($P < 0.0005$ in both cases) than in the remaining groups, and better in group C than in group A.

Discussion

Many surgeons have concerns about using multifocal IOLs to correct presbyopia. This is partly due to the work overload that MIOL use implies and partly due to the notion that even the latest generation of diffractive MIOLs have been associated with photic phenomena, such as glare or halos, or difficulties in some light conditions. These can negatively affect daily-life activities, limiting the patient's ability to perform them and thus affecting the patient's QoL, as stated by Alió et al.[14] This problem can be more significant in working-age patients, who, as stated earlier, often have to perform rapidly alternating far and close-up tasks or sustain long work at near to intermediate distance.

The aim of the current study was to compare at 1-year follow-up the visual outcomes, reading performance, and CS under different light conditions, and QoL in working-age cataractous patients bilaterally implanted with 1 of 3 types of diffractive third-generation MIOLs. On the basis of the mechanism of the 3 MIOLs, as described in the "Intraocular Lenses" section, all should provide similar photopic distance visual acuity, even if the wider refractive centermost region could favor the TECNIS and the ReSTOR +3.00 group. All groups achieved good to excellent binocular UDVA and CDVA with no significant intergroup difference. This depends on miotic pupils under photopic conditions, in which both the full diffractive TECNIS MIOL and the diffractive/refractive ReSTOR MIOLs behave similarly, with 41% light distribution for far focus and 41% light distribution for near focus, whereas the remaining 18% is lost to higher-order scattering.[16,37]

The mean photopic UNVA, DCNVA, and CNVA were good in all 3 groups, with statistically greater, and often more comfortable for working purposes, preferred reading distance in group B (ReSTOR +3.00 MIOL), which is a widely recognized characteristic of a low-add optic design.[24–26] The statistically greater reading distance in group C compared with group A, even if small and clinically less significant, can depend on the discussed slightly

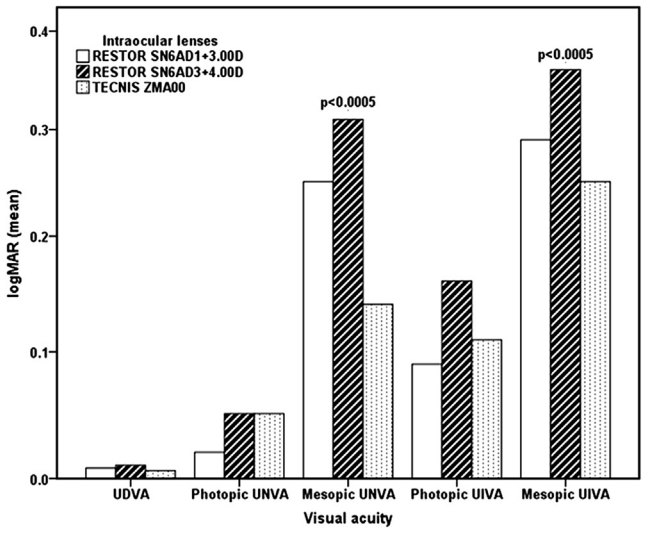

Figure 2. Uncorrected visual acuities in all groups. logMAR = logarithm of the minimum angle of resolution; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity.

different lens-plane add power (3.00 vs. 3.20 D), on the position of diffractive surface, posterior in TECNIS MIOL and anterior in the ReSTOR MIOL, and on the 5° angled optic design of the TECNIS MIOL, which positions the optic further back in the eye.

With respect to the photopic intermediate visual acuities (photopic UIVA and DCIVA), these were better with the ReSTOR +3.00 MIOL, whereas the worst results were found with the ReSTOR +4.00 type. This finding is in agreement with previous studies.[38] The behavior of these parameters in group C (TECNIS +4.00 MIOL), worse than in group B but better than in group A, could again indicate that the angled posteriorly diffractive optic, pushing the near point further out compared with an anterior diffractive multifocal lens, provides better functional intermediate vision than the latter.

The mesopic near visual acuities, both mesopic UNVA and DCNVA, were better in group C because of the full diffractive surface, which maintains the 41%/41% light distribution regardless of pupil diameter, whereas the apodized diffractive/refractive surface of the other 2 MIOL groups progressively unbalances light distribution to favor distance vision when pupils enlarge, as discussed in the "Intraocular Lenses" section. A better functional value of mesopic DCNVA was found in group B than in group A (0.21 vs. 0.27 logMAR). Likewise, mesopic UIVA and DCIVA were best with the TECNIS MIOL (group C), followed by the ReSTOR +3.00 add. The anterior prolate TECNIS surface with its enhanced asphericity (−0.27 vs. −0.20 μm) could hypothetically play a role in the mesopic visual acuity results. With respect to the binocular reading ability with diffractive multifocal IOLs, a few recent studies using the Radner Reading Charts with the patient sitting at the Salzburg Reading Desk found that diffractive MIOLs significantly improved reading performance, better than that obtained with a refractive multifocal or monofocal IOL.[18,19,39] Moreover, when tested under low-light conditions, patients with the TECNIS MIOL had better RA and reading speed with respect to ReSTOR +4.00 MIOL.[16,40]

In our study, because of the lack of Radner Charts in Italian, we used the MNREAD Acuity Charts, characterized by good repeatability and differing from Radner for the varying length and position of the words.[41,42] In our patients, according to photopic near acuity findings, the reading ability at the best patient-preferred reading distance was good in all groups with bright light. Under mesopic conditions, the RA and MRS were better mainly in group C

Table 3. Postoperative Photopic and Mesopic MNREAD Reading Acuity, Critical Print Size, Maximum Reading Speed, and Pelli–Robson Contrast Sensitivity Results (Mean ± Standard Deviation) for the Three Groups at 12-Month Follow-up

Variable	Group A RESTOR SN6AD3 +4.00 D IOL	Group B RESTOR SN6AD1 +3.00 D IOL	Group C TECNIS ZMA00 IOL	*P* Value†	*P* Value Post Hoc Comparison*		
					A-B	A-C	B-C
RA (logMAR)							
Photopic	0.03 (0.1)	0.022 (0.07)	0.025 (0.07)	0.835			
Mesopic	0.11 (0.1)	0.097 (0.1)	0.033 (0.1)	0.02	NS	0.017	0.040
MNREAD CPS (logMAR)							
Photopic	0.35 (0.2)	0.35 (0.2)	0.34 (0.1)	0.890			
Mesopic	0.50 (0.2)	0.49 (0.2)	0.41 (0.1)	0.348			
MRS (words per minute)							
Photopic	248 (24.0)	263 (26.0)	253 (28.1)	0.279			
Mesopic	220 (24.0)	247 (28.5)	250 (34.3)	0.002	0.002	0.002	NS
CS (logMAR)							
Photopic	1.80 (0.1)‡	1.78 (0.1)‡	1.76 (0.1)‡	0.410			
Mesopic	1.40 (0.1)‡	1.42 (0.1)‡	1.45 (0.2)‡	0.460			

D = diopter; IOL = intraocular lens; logMAR = logarithm of the minimum angle of resolution; SD = standard deviation; NS = not significant.
*Bonferroni post hoc comparison.
†Univariate analysis of variance test.
‡Intragroup comparison between mesopic and photopic condition $P < 0.0005$ in all cases.

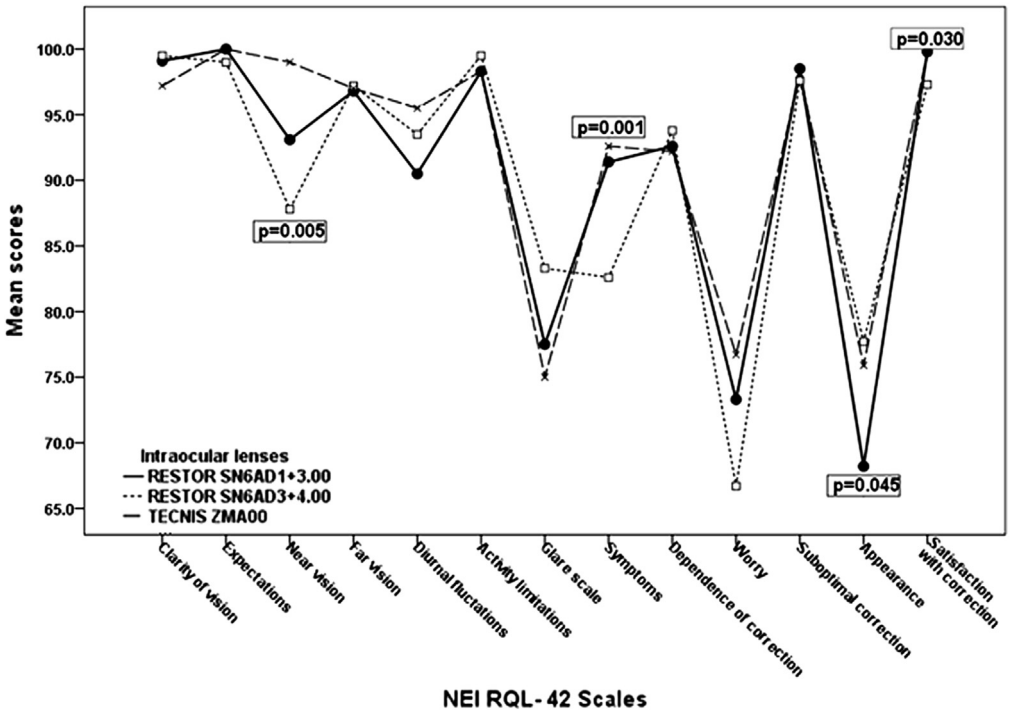

Figure 3. Comparison of mean scale scores of the National Eye Institute Refractive Error Quality of Life Instrument-42 (NEI RQL-42) for vision-related quality of life (QoL) among 3 multifocal intraocular lenses (MIOLs) groups at 12-month follow-up.

(TECNIS) and partly in group B (ReSTOR +3.00), confirming the mesopic advantage especially with the full diffractive MIOL. The lack of difference dealing with mesopic CPS could be ascribed to the low repeatability of this parameter, as previous authors noted.[41,42]

We chose the Pelli–Robson CS test, which uses letters instead of sine-wave gratings, because of its simplicity and reliability. Moreover, because the test distance of 3 m corresponds to a spatial frequency of approximately 3 cpd, this region of peak sensitivity could give important information even to differentiate among multifocal IOLs, as reported in previous studies.[13,33] We have to acknowledge that our mono-frequency CS analysis, which ignores the higher frequencies, may be inadequate to differentiate a multifocal IOL CS response from both a phakic or monofocal one and from different multifocals, especially under mesopic light, even if there is wide variability among various studies.[9,13,14]

For instance, some studies showed sine-wave grating CS curve reduction, especially at higher spatial frequencies and in mesopic conditions, with MIOLs compared with monofocal or pseudo-accommodative IOLs, whereas others found a reduction at all or only at lower frequencies.[8,13,18,43–45]

With respect to differences in CS among MIOLs, one study failed to disclose any difference between an apodized and a full diffractive MIOL.[18] Another study found better photopic CS at higher frequencies, but no differences in mesopic conditions, when comparing a refractive asymmetric MIOL with sectorial near addiction with a full diffractive MIOL.[14]

In our patients, the photopic binocular Pelli–Robson distance CS was not <1.76 logCS units in all groups and favorably compared with previous studies using the same test, in regard to both phakic age-matched subjects and pseudophakic patients implanted with a TECNIS MIOL or a monofocal IOL.[33,46,47]

Moreover, distance mesopic logCS, even if significantly reduced with respect to the photopic one, as previously described with MIOLs,[48] did not differ among groups. This indicates that the mesopic distance logCS with the full diffractive TECNIS MIOL did not differ from the hybrid ReSTOR MIOLs, denying any contrast enhancement by the purely refractive peripheral zone in the latter. This could depend on various factors, such as cortical binocular enhancement with the aspheric full diffractive multifocal IOL, limited frequency analysis with the Pelli–Robson test, and sample size nontargeted on a secondary outcome such as CS.

Previous studies have judged the NEI RQL-42 as the most applicable measurement for the surgical correction of refractive error, because other functional status instruments such as the NEI VFQ-25, Visual Function-14, and Short Form Health Survey-36 were not designed to distinguish individuals with corrected refractive error from emmetropic individuals who have normal vision without correction. Moreover, the instrument seems to be useful for comparisons of people with different types of correction for refractive error.[21,34]

The vision-related QoL, evaluated by scores from 13 scales grouping the NEI RQL-42 items, indicate an overall high satisfaction in all groups. The relatively lower values in the "glare" and "worry" scales, relating night starbursts, halos, and glare with difficulty to see or worrying and thinking about eyesight, respectively, have been described in previous studies on keratorefractive or MIOL

Table 4. Postoperative Vision-related Quality of Life Scores (Mean ± Standard Deviation) by National Eye Institute Refractive Error Quality of Life Instrument-42 Test at 12-Month Follow-up in the Three Multifocal Intraocular Lens Groups and Significant Differences for the Computer Users Subgroup

Variable	Group A RESTOR SN6AD3 +4.00 D IOL	Group B RESTOR SN6AD1 +3.00 D IOL	Group C TECNIS ZMA00 IOL	P Value†	P Value Post Hoc Comparison*		
					A-B	A-C	B-C
Scale 1							
Clarity of vision	99.5 (5.5)	99.1 (4.6)	97.2 (4.1)	0.363			
	78.0 (2.5)‡	99.6 (4.6)‡	94.2 (4.1)‡	<0.0005‡	<0.0005‡	<0.0005‡	0.006‡
Scale 2							
Expectations	99.0 (4.1)	100 (2.5)	100 (2.5)	0.565			
Scale 3							
Near vision	87.8 (9.2)	93.1 (8.2)	99.0 (11.2)	0.005	NS	0.0009	NS
	83.1 (6.2)‡	99.8 (9.6)‡	90.2 (2.2)‡	<0.0005‡	<0.0005‡	0.0009‡	0.002‡
Scale 4							
Far vision	97.2 (6.5)	96.8 (8.7)	97.0 (5.6)	0.903			
Scale 5							
Diurnal fluctuations	93.5 (8.1)	90.5 (8.5)	95.5 (8.5)	0.251			
Scale 6							
Activity limitations	99.5 (2.5)	98.3 (2.9)	98.3 (6.5)	0.535			
Scale 7							
Glare scale	83.3 (16.1)	77.5 (25.5)	75.0 (26.3)	0.458			
Scale 8							
Symptoms	82.6 (9.7)	91.4 (6.2)	92.6 (8.3)	0.001	0.0013	0.0009	NS
Scale 9							
Dependence on correction	93.8 (6.1)	92.6 (2.5)	92.2 (6.5)	0.540			
Scale 10							
Worry	66.7 (32.3)	73.3 (25.8)	76.7 (34.7)	0.510			
Scale 11							
Suboptimal correction	97.6 (1.8)	98.5 (2.5)	98.1 (2.0)	0.386			
Scale 12							
Appearance	77.7 (16.3)	68.2 (13.3)	75.9 (11.5)	0.045	0.047	NS	0.048
Scale 13							
Satisfaction with correction	97.3 (4.5)	99.8 (2.5)	99.8 (2.5)	0.030	0.035	0.029	NS

IOL = intraocular lens; NS = not significant.
*Post hoc comparison by the Mann–Whitney test with the Bonferroni adjustment.
†Kruskal–Wallis test.
‡Computer users subgroup scale scores (mean ± standard deviation) with a significant difference among the 3 groups at 12-month follow-up.

implantation surgery and can be justified by the intrinsic characteristics of type of correction and by the surgery itself.[21,35,36] The lower score of the "appearance" scale in all 3 groups is more difficult to explain, probably relating to small sample size, if you want to deny a sharper vision of the patient's own aged face.

No differences were found among groups in 9 over 13 scales. In particular, results of scale 2, relating "expectations," and scale 9, relating "dependence on correction," which includes reading in different conditions and night driving, did not differ among groups, with a mean score not <99.0 and 92.2, respectively ($P = 0.565$ and $P = 0.540$). Some differences among the 3 groups exist regarding "near vision" scale, with a poorer result in group A, which could arise from computer working–related difficulties. Again, the lower "satisfaction with correction" score in group A could confirm that this hybrid +4.00 add MIOL performs less satisfactorily for the current needs of near and computer work activity. The poorer result in group A with respect to the other 2 groups relating the "symptoms" scale could be minimally due to headache, soreness, or tiredness related to uncomfortable near or intermediate vision, but also could be biased from the small sample size, because symptoms such as burning, itching, or tearing are hardly dependent on a particular MIOL. The latter explanation could be true relating the "appearance" scale score, which was lowest in group B.

With respect to the computer users subgroup, the supremacy of the ReSTOR low-add +3.00 MIOL is confirmed in terms of "clarity of vision" and "near vision" scales. The reported refractive error QoL score seems clinically adequate (i.e., >90.0), even with the TECNIS full diffractive MIOL, but not as much with the ReSTOR high-add +4.00 MIOL.

Pepose et al,[8] using the NEI RQL-42, found significantly more QoL night glare–related problems with MIOLs than with the accommodative Crystalens AT-45 IOL (Eyeonics, Aliso Viejo, CA), although it should be noted that the study deals with older-generation refractive ReZoom (American Medical Optics, Santa Clara, CA), and hybrid diffractive +4.00 add spherical ReSTOR IOLs (Alcon Laboratories, Fort Worth, TX) which are less efficient in

terms of mesopic CS.[8,13] The QoL with multifocal IOLs recently was analyzed by a simplified, less specific questionnaire for refractive correction than the NEI RQL-42: the NEI VFQ-25. These studies, using hybrid apodized +4.00 add ReSTOR, full diffractive Acri.LISA, or Acri.Smart (Carl Zeiss Meditec, Jena, Germany) monofocal IOLs, confirm that the implantation of a multifocal diffractive IOL had a positive effect on the patient's QoL. Moreover, postoperatively, patients could easily perform several daily tasks at near and intermediate distances with less night-driving limitation with a full diffractive IOL than with apodized multifocal and monofocal IOLs.[18,19]

With respect to the cited studies, in our patients, significant differences in terms of refractive QoL between new-generation hybrid diffractive and full diffractive MIOLs are lacking, and the subset scores relating reading and night driving are higher and comparable to those found by previous studies with pseudo-accommodative IOLs, where problems related to contrast, haloes, or glare are obviously absent. This finding can be due to sample characteristics or environmental conditions, but, keeping in mind that QoL is a multifactorial process and not dependent on purely visual performance only, the younger mean age (~10 years less than in previous studies), which can provide a faster and complete neuroadaptation, prompted by the working-age lifestyle, also could be a significant factor.

In our sample, a good near photopic visual acuity was found with all 3 lens types, with a more comfortable reading distance with the ReSTOR +3.00 and, depending on the patient's preference, the TECNIS MIOL. In unusual conditions of working or reading under dim light, the TECNIS MIOL has an edge, or, alternatively, a worker wearing TECNIS MIOL can face a wider range of dim to intermediate illumination levels. On the contrary, a ReSTOR IOL wearer, especially with the +4.00 add model, can find it difficult to perform near tasks under dim light. These differences can be more striking in a relatively younger sample of working-age patients, as in our study, in whom an effective pupillary response is still present. Our reading ability results confirm that the low-addition ReSTOR +3.00 MIOL allows a more comfortable reading distance under bright light and that when working-age patients demand a functional reading performance even under dim light, a good compromise can be represented by the TECNIS MIOL. In working-age subjects, diffractive MIOLs generally meet the demand for a dynamic glass-free way of life.

In conclusion, our study indicates that newer-generation aspheric MIOLs, both low-add hybrid apodized and full diffractive, are highly suited for working-age patients in terms of visual outcomes, reading performance, and QoL. Intrinsic optical differences, such as optimization for computer or dim light working, or night driving, can be useful tools to customize the IOL in each case.

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Footnotes and Financial Disclosures

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