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ORIGINAL PAPER

Quality of vision, patient satisfaction and long-term visual function after bilateral implantation of a low addition multifocal intraocular lens

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Abstract
Purpose The aim of the current study was to compare the quality of vision, contrast sensitivity and patient satisfaction with a biaspheric, segmented, rotationally asymmetric IOL (Lentis Comfort LS-313 MF 15-Oculentis GmbH, Berlin, Germany) as opposed to those of a monofocal IOL.
Methods This prospective single-blind comparative study included two groups of patients affected by bilateral senile cataract who underwent lens extraction and IOL implantation. The first group received a bilateral implantation of a monofocal IOL, and the second group received a bilateral implantation of the Comfort IOL. Twelve months after surgery uncorrected and corrected visual acuity at different distances (30, 50, 70 cm and 4 m), defocus curve and contrast sensitivity were assessed. Patient's satisfaction and spectacle independence were evaluated by mean of the NEI RQL-42 questionnaire.
Results No significant differences were found between the groups in terms of near vision. The group of patients implanted with a Comfort IOL obtained the best results at intermediate distances (50 and 70 cm $P < .001$). Both groups showed an excellent uncorrected distance visual acuity (4 m). No statistically significant differences were found in terms of corrected near, intermediate and distance visual acuity. Concerning contrast sensitivity, no statistically significant differences between the groups were observed at any cycles per degree. The NEI RQL-42 questionnaire showed statistically significant differences between the group for "near vision" ($P = .015$), "dependence on correction" ($P = .048$) and "suboptimal correction" ($P < .001$) subscales.
Conclusion Our findings indicated that the Comfort IOL +1.5 D provides a good intermediate spectacle independence together with a high quality of vision, with a low amount of subjective symptoms and a contrast sensitivity similar to those obtained with a monofocal IOL.

Keywords Multifocal · Comfort IOL · Defocus curve · Pseudophakic presbyopia · Visual quality

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Introduction

With the evolution of cataract surgery, the main goal has shifted from resorting sight to improving visual performance over the greatest variation of distances as possible. Several studies reported that technological advances in multifocal intraocular lens (MIOL) design have resulted in lenses that can maximize best visual outcomes from near to far distances. But, the main drawback of these MIOLs is the incidence and entity of reported side effects, such as halos, glare and loss of contrast sensitivity that in some cases compromised the otherwise excellent visual results [1–4].

In recent years, a MIOL technology based on the concept of refractive rotational asymmetry was introduced in clinical practice [2, 5–7]. Basically, this design splits light into numerous foci only in a specific sector of the lens, while the other part of the lens behaves like a standard monofocal IOL. Therefore, theoretically a higher rate of light concentrates on the furthest focus increasing the contrast sensitivity [6] and reducing subjective symptoms compared to traditional design MIOLs [8, 9]. A recent example of a MIOL that implements this design scheme is the Lentis Comfort LS-313 MF 15 (Oculentis GmbH, Berlin, Germany) with an addition of +1.5 diopters (D). This IOL has an aspheric posterior surface and an anterior single, blended transition zone. In theory, this design should optimize intermediate vision and distance vision restoration, while decreasing the photic phenomena due to an improved twilight vision and optimized depth of focus quality. Based on these features, this MIOL was proposed as an alternative to monofocal IOLs in patients who desire to be as near as possible to spectacle-free without the risk of side effects typically associated with multifocality. The aim of this study was to evaluate whether the visual performance of the Lentis Comfort LS-313 MF 15 can be considered equal to a monofocal IOL in terms of quality of vision.

Patients and methods

This prospective single-blind comparative study comprised 42 consecutive patients affected by bilateral senile cataract who underwent lens extraction and IOL implantation. The Department of Neurological and Movement Sciences of the University Hospital of Verona approved the study and deemed submission/approval by our local ethics committee was not necessary because patient care would not be modified by the study protocol. This study has been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments. Informed consent was provided to all patients before enrollment.

During the initial ophthalmological examination, patients were interviewed to assess their principle vision needs in terms of near, intermediate and distant vision and their expectations concerning postoperative spectacles or contact lens use. If they wished to reduce their spectacle dependency they were assigned to the "low add" group that received the Comfort IOL in both eyes. Otherwise, they were added to the "monofocal" group that underwent bilateral implantation of a monofocal IOL (Tecnis 1-piece Abbott Medical Optics, USA). All patients were informed about the characteristics of the IOLs they were to receive, expected performance outcomes in terms of visual acuity, the possibility of becoming partially spectacle independent following surgery and that some optical phenomena such as glare and halos were possible. The final choice was always left to the patient, and they were given the possibility of changing their minds up to the date of surgery. The inclusion criteria were bilateral senile cataract and age between 50 and 70 years. Exclusion criteria were corneal astigmatism greater than 1.00 D, myopia greater than 6.00 D, amblyopia, previous anterior or posterior segment surgery, and history of other ocular pathologies impairing visual function. Before surgery, all patients underwent a complete ophthalmologic examination including manifest refraction, slit-lamp evaluation, tonometry, fundoscopy, corneal topography and pupillometry (C.S.O. Eye-Top topographer-Costruzione Strumenti Oftalmici S.R.L., Scandicci, Italy), and axial length measurement (IOLMaster-Carl Zeiss Meditec, Jena, Germany). All cases were targeted for emmetropia. Evaluations at 12 months postoperatively were all performed by the same ophthalmology (RM) who was blinded to which IOL was implanted.

The main outcome measures concerned the quality of vision. The contrast sensitivity (CS) was assessed binocularly at 3, 6, 12 and 18 cycles per degree (CPD) using a CSV-1000 chart (Vector Vision, Greenville, OH) without dazzle, ensuring the best visual acuity with or without lens correction. To plot the curve, we

converted the results in log units using a specific table for the CSV-1000 [10]. To evaluate satisfaction and spectacle independence, all patients completed the Italian version of the National Eye Institute Refractive Error Quality of LifeInstrument-42 (NEI RQL-42) questionnaire during the 12-month follow-up visit. The survey responses were scored according to the NEI RQL-42 version 1.0 manual, and the answers were converted into a 100-point scale, where higher scores indicated a higher self-reported quality of life. Each subscale consisted of one or more questions and, therefore, each subscale score was the average of those questions specific to that subscale.

The binocular uncorrected distance (4 m) intermediate (50 and 70 cm), and near (30 cm) visual acuity (UDVA, UIVA and UNVA), binocular corrected distance, intermediate and near visual acuity (CDVA, CIVA and CNVA) were measured. The defocus curve for eight different levels of defocus from −.50 to −4 D in steps of .50 D was obtained in all cases. All visual acuities were assessed using standard high contrast logMAR (Early Treatment Diabetic Retinopathy Study).

Statistical analysis

Sample size estimates for the study were based on the primary outcome measure of visual acuity at the 12-month follow-up. For = .05 and = .85, a sample size of 19 patients per group was sufficient to detect mean differences of one standard deviation or greater with Student's *t* test. Twenty-one patients per group were enrolled. Preoperative parameters included sex, age, corrected distance visual acuity, keratometry (K1 and K2) and pupil size (in scotopic, mesopic and photopic). The presence of statistically significant differences in sex and the other parameters was evaluated using the Fisher exact test or two-tailed Student's *t* test for independent samples, respectively. Primary outcome measures were CS and NEI score. Secondary outcomes were uncorrected and corrected visual acuity at 30, 50 and 70 cm and 4 m, defocus curve, spherical equivalent and cylinder. The Mann–Whitney *U* test was applied for a statistical comparison of the mean visual acuity at each defocus value for the two IOLs. All statistical tests were evaluated at a two-sided alpha level of .05. Statistical analysis was performed using SPSS 22.0 (IBM, Armonk, NY). A false discovery rate correction for multiplicity was independently applied to the primary and secondary outcome measures to reduce the risk of a type 2 error (i.e., accept a null hypothesis that is actually false or exclude the presence of a statistically significant result when actually present).

Results

Table 1 shows the patient characteristics. Statistically significant differences between the two groups were not observed. All surgical procedures were uneventful, and all IOLs were implanted in the capsular bag. The mean interval between surgical procedures of the first and second eyes was 33.8 ± 9.4 days (range 21–43 days). All reported data are those obtained at the 12-month follow-up visit following the second eye surgery. None of the patients were lost during follow-up.

Seven patients [3 (14%) and 4 (19%) for each group] developed a significant posterior capsule opacification, which required a Nd:YAG laser posterior capsulotomy. In no case was IOL tilt or decentration observed either with an intact capsule or after capsulotomy.

Figure 1 shows the contrast sensitivity curves. Albeit the "low add" group results are slightly lower, no statistically significant differences between the groups were observed at any spatial frequency evaluated

Table 1 Preoperative characteristics of the two groups

Parameter	Group		P^a
	Low add	Monofocal	
Sex (M/F)	10/11	9/12	.500
Age (years)	64.9 ± 3.0	66.1 ± 2.7	.205
Preoperative CDVA	.45 ± .19	.46 ± .20	.937
K1 (D)	43.0 ± .4	42.9 ± .4	.309
K2 (D)	43.5 ± .3	43.4 ± .4	.479
Q value	−.20 ± .08	−.19 ± .07	.669
Scotopic pupil size (mm)	5.2 ± .3	5.1 ± .4	.613
Mesopic pupil size (mm)	4.3 ± .1	4.4 ± .1	.201
Photopic pupil size (mm)	3.6 ± .1	3.6 ± .1	.594

CDVA corrected distance visual acuity, *K* keratometry, *D* diopters

[a] Differences in sex were compared using Fisher's exact test. All other statistical comparisons were performed with two-tailed Student's *t* test for independent samples

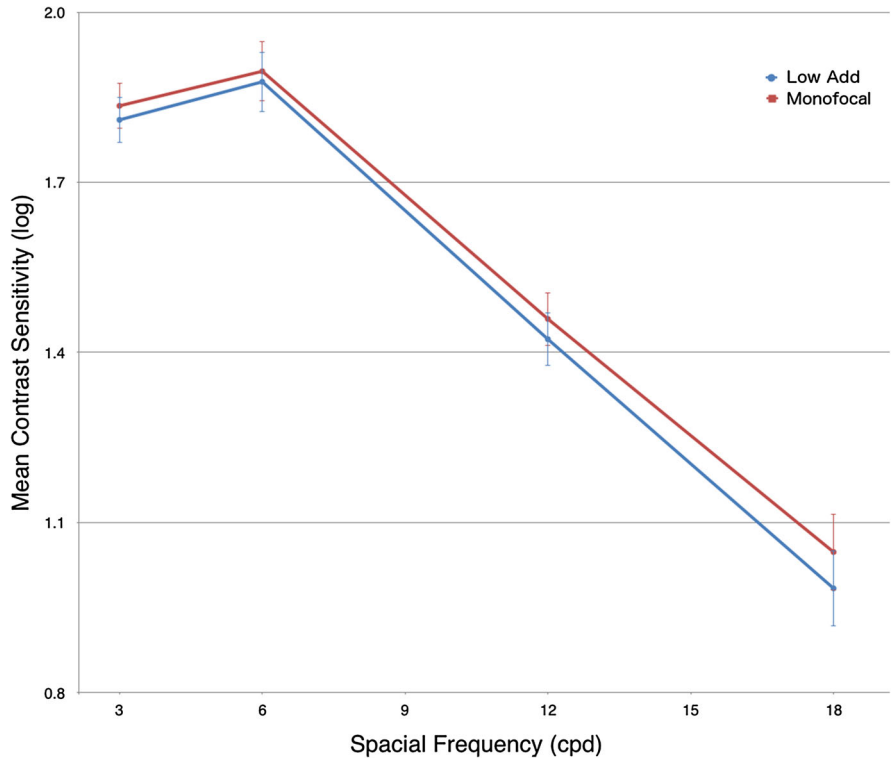

Fig. 1 Contrast sensitivity of the two groups. There were no statistically significant differences between the groups at any CPD

Evaluation of the NEI RQL-42 questionnaire showed statistically significant differences between the groups for the "near vision" ($P = .015$), "dependence on correction" ($P = .048$) and "suboptimal correction" ($P < .001$) subscales (Fig. 2). Statistically significant differences were not found for the other 10 subscales.

The mean visual results are reported in Table 2. In terms of UNVA (30 cm), no significant differences were found between the groups. The "low add" group required a lower correction to achieve an optimal near vision; however, this result was not statistically significant. As expected, the "low add" group obtained the best results at intermediated distances ($P \leq .001$ for 50 and 70 cm). Both groups showed an excellent UDVA (4 m). No statistically significant differences were found in terms of CNVA, CIVA and CDVA. The total mean postoperative sphere was $-.010 \pm .14$ D in the low add group and $-.07 \pm .12$ D in the monofocal group. The mean astigmatism was $-.19 \pm .27$ and $-.015 \pm .24$, respectively. Between groups, differences for both parameters were not statistically significant. No patient required an excimer laser enhancement after surgery.

Figure 3 represents the defocus curve. Both groups showed a decreasing mean logMAR with increasing refraction. Nevertheless, in the "low add" group a statistically significant better visual acuity in the range between -1 and -2.5 D has been noted. For the MIOL, the mean intermediate visual acuity was <.1 logMAR at approximately 1 m and 66 cm, whereas the intermediate peak was approximately .2 logMAR for the "monofocal" group. The distance peaks in both groups showed a mean distance visual acuity better than .05 logMAR.

Discussion

Several MIOLs designs were produced in the last decades in order to meet patient desire to obtain spectacle independence. The majority of these lenses are based on the rotational symmetry technology and the concept of refraction, diffraction or their combination. The main drawback of MIOLs is related to the quality of vision, since potential optical side effects such as decreased contrast sensitivity, glare and halos were described [3, 11, 12]. These subjective symptoms

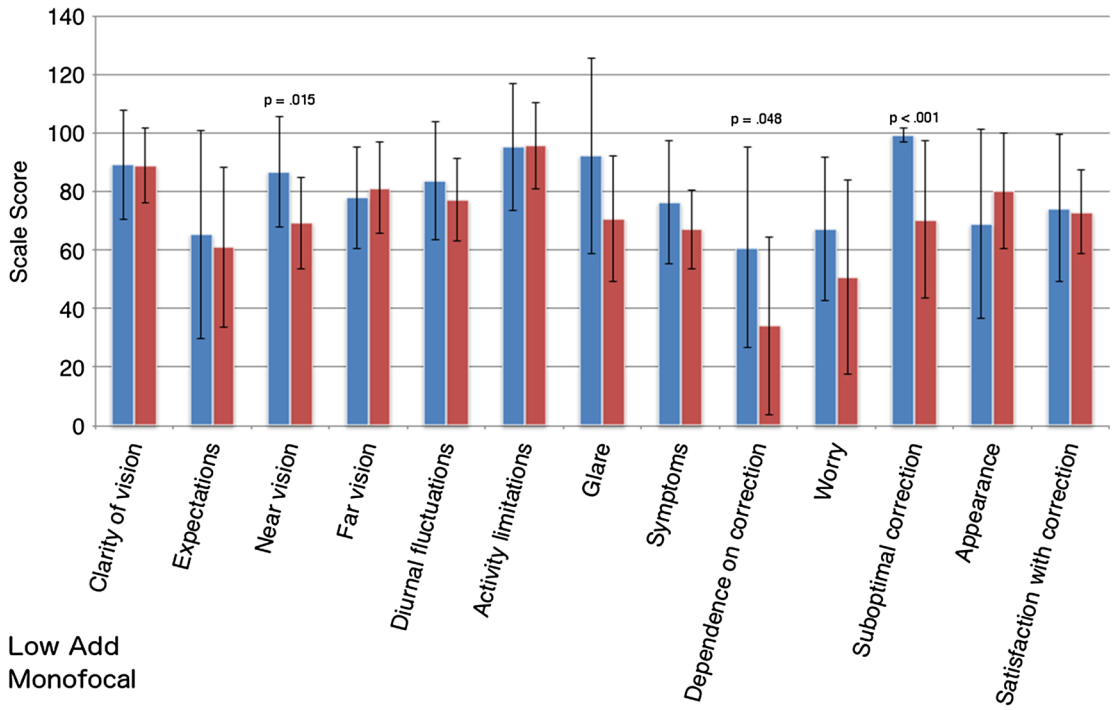

Fig. 2 Spectacle independence and patients' satisfaction between the two groups

Table 2 Mean ± SD of postoperative uncorrected and corrected visual acuity expressed as logMAR, and postoperative SE and cylinder for the two groups

Parameter	Low add	Monofocal	P^a
UNVA (30 cm)	.54 ± .09	.58 ± .08	.136
UIVA (50 cm)	.24 ± .07	.33 ± .09	<.001
UIVA (70 cm)	.05 ± .05	.20 ± .08	<.001
UDVA	−.01 ± .06	.02 ± .05	.942
CNVA (30 cm)	.01 ± .03	.00 ± .02	.211
CIVA (50 cm)	.02 ± .03	.01 ± .03	.876
CIVA (70 cm)	−.01 ± .02	.00 ± .02	.862
CDVA	−.02 ± .05	−.01 ± .04	.843
SE	−.10 ± .14	−.07 ± .12	.460
Cylinder	−.19 ± .27	−.15 ± .24	.615

UNVA uncorrected near visual acuity, *UIVA* uncorrected intermediate visual acuity, *UDVA* uncorrected distance visual acuity, *CNVA* corrected near visual acuity, *CIVA* corrected intermediate visual acuity, *CDVA* corrected distance visual acuity, *SE* spherical equivalent

[a] *P* values corrected with false discovery rate

can seriously compromise the surgical result and patients' quality of life, making it sometimes necessary to perform an IOL exchange [13]. The rotationally asymmetry technology was developed to overcome this limit. The primary aim of the current study was to compare the quality of vision and patient satisfaction of a rotational asymmetry MIOL with a monofocal IOL.

Contrast sensitivity is the lowest contrast level that could be detected by a patient for a given size target. It is a well-recognized subjective parameter for the assessment of the quality of vision in patient implanted with premium IOLs [10, 14]. In this study, the CS scores showed that the monofocal IOL was superior than the Comfort IOL. However, this difference was not statistically significant at any spatial frequency. The low add group achieved a mean CS higher than 1.7 Log Units at 3 and 6 CPD and higher than 1.4 and .8 LogMar at 12 and 18 CPD, respectively.

These results were consistent with findings reported in other studies using similar IOL designs and even better than certain MIOLs basing on rotational symmetry technology. Pedrotti et al. [15] studied the quality of vision achieved with MIOLs with either a +3 and +2.5 additional power. They found CS values of about .2 Log Units lower than the lens evaluated in this study. Aliò et al. compared the performances of a MIOL with the same technology produced by the same

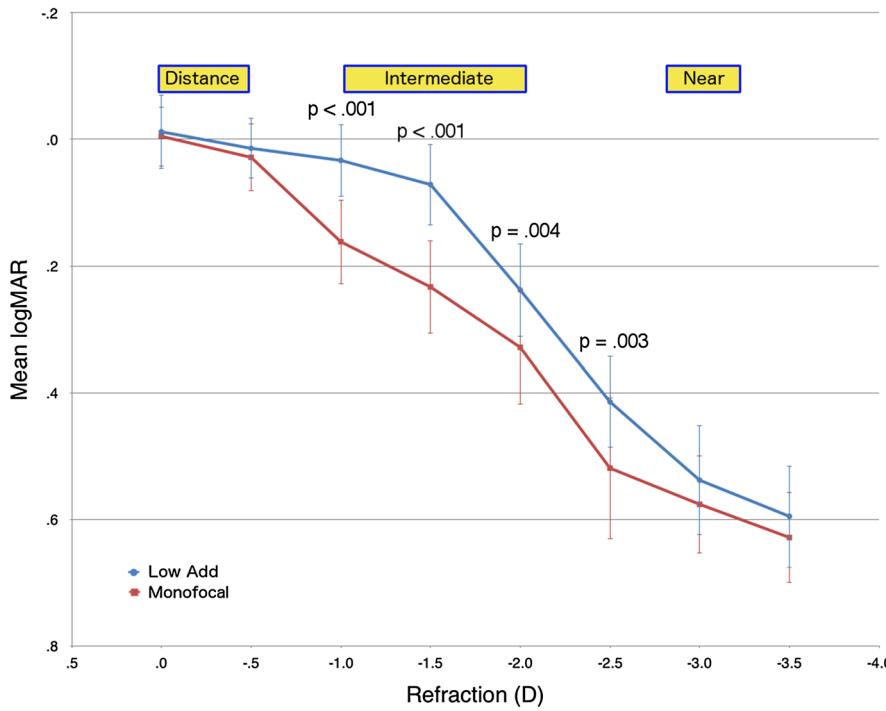

Fig. 3 Defocus curve of the two groups

company with a single optic accommodating IOL. The latter obtained better CS values in photopic condition while the results were similar in terms of mesopic CS, modulation transfer function and postoperative intraocular aberrations [16]. Further studies with a larger number of patients will be required to elucidate this concept.

Previous studies evaluated the patient's satisfaction and spectacle independence by mean of the Visual Function-14 questionnaire, the National Eye Institute Visual Functioning Questionnaire and the Activity of Daily Vision Scale [14, 17]. In the current study was used the NEI RQL-42 questionnaire because it comprises items that evaluate glare symptoms and night driving, which are related to the impact of spherical aberration on the patient's quality of life [18]. The statistically significant better results of the MIOL in terms of "near vision," "dependence on correction" and "suboptimal correction" were actually expected and consistent with the visual acuity and defocus outcomes. Interestingly, statistically significant differences were not observed between the groups in terms of "clarity of vision," "glare" and "symptoms." This result can be attributed to the structure of the lens, designed to distribute a low amount of light for the intermediate foci.

The visual acuity was considered a secondary outcome. Both groups achieved excellent vision for far while the low add group obtained best results at intermediate distances. Both IOLs were limited in the near vision restoration. The defocus curve confirms this outcome. This was expected, since several studies highlighted how decreasing the MIOL additional power yields good results at intermediate distances by increasing the range of focus. In 2009, Maxwell et al. showed how a +3.0 D IOL yielded better results at 40 cm compared to a +4.0 D IOL, whereas near and distance visual acuity were similar. Thereafter the IOL technology developed up to lenses with a +2.5 and +1.5 D [18–20]. These lenses render necessary a slight correction for near but allow a good spectacle-free vision for those activities characterizing the routinely life (e.g., using a computer and reading a watch).

This study has limitations to be mentioned. First of all, the results are possibly biased by the lack of aberrometry data. The evaluation of all the low-order aberration related to the lens structure could explain differences between the 2 groups in terms of CS [21]. Even if minimal, the higher score achieved by the monofocal IOL could make the difference in such activities as night driving. Another limitation is the

lack of a comparison with a group implanted with an extended range of vision (ERV) or other new generation multifocal IOLs. This comparison would be critical in assessing the real effectiveness of the Lentis Comfort LS-313 MF 15 in achieving an adequate intermediate visual acuity without penalizing the quality of vision. Ruiz-Mesa et al. recently published encouraging results after the implantation of an ERV and a trifocal IOL. In both cases, they found a good CS and a low perception of halos [22]. Their results agree with those found by Gatinel et al. [23] who firstly described the optical qualities of an ERV IOL and showed similar visual quality outcomes compared to a last generation trifocal lens. Further limitations were the relatively long time-gap between surgeries and the limited number of patients. Multicenter studies with a larger sample size will be required to confirm the results of this study.

In summary, our findings indicated that the Comfort IOL +1.5 D provides a good intermediate spectacle independence together with a quality of vision comparable to that of a monofocal IOL with a low amount of subjective symptoms and a similar CS. Thus, this lens should be considered a valid option for patients who request good intermediate vision but are worried about possible side effects in terms of visual quality.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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