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ORIGINAL ARTICLE

Analysis of visual outcomes after implantation of aspheric refractive multifocal intraocular lenses

Raffaele NUZZI, Gabriella LALE LACROIX, Daniele ROLLE *, Federico TRIDICO

Unit of Ophthalmology, San Luigi Gonzaga University Hospital, Orbassano, Turin, Italy

*Corresponding author: Daniele Rolle, Unit of Ophthalmology, San Luigi Gonzaga University Hospital, Regione Gonzole 10, Orbassano 10043, Turin, Italy. E-mail: dandan.rolle84@tiscali.it

ABSTRACT

BACKGROUND: The surgical correction of postphacoemulsification aphakia with intraocular lens (IOL) is the most physiological and the most widely used as today. Currently monofocal IOLs are implanted in most cases, but multifocal IOls are also available. The aim of this study was to evaluate visual results and the impact on vision quality of the refractive multifocal IOL (FIL611PV of Soleko) in patients undergoing surgery for bilateral phacoemulsification with IOL implantation.

METHODS: This observational, prospective, single-site study is designed to evaluate the multifocal IOLs FIL611PV (made by Soleko) in patients undergoing phacoemulsification with IOL implantation. Patients were asked to attend at ophthalmologic control visits at 1 day, 7 days, 1 year, 3 months and 6 months after surgery.

RESULTS: The improvement of visual acuity for the three working distances was statistically significant in all cases compared to preoperative status. Binocular uncorrected and corrected visual acuity was better than that monocular, except in the case of natural visual acuity for intermediate distance. The reduction of the additional required to obtain the best binocular visual acuity for near and intermediate distance was statistically significant in both cases. The additional correction required to obtain the best visual acuity for near and intermediate distance resulted lower in case of binocular vision compared to monocular vision.

CONCLUSIONS: Multifocal lenses tested in this study are a viable solution for visual rehabilitation after a cataract extraction surgery that seeks to make phacoemulsification procedure and IOL implantation procedure real refractive measures, in order to improve patient autonomy as much as possible for different working distances. These features are valid depending on the choice of the lens that best suits the patient's visual demands.

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Key words: Cataract extraction - Lenses, intraocular - Phacoemulsification - Vision, ocular.

The surgical correction of post-phacoemulsification aphakia with intraocular lens (IOL) is the most physiological and the most widely used as today.

Currently monofocal IOLs are implanted, in most cases, which generally require the use of glasses for carrying out tasks at intermediate and close up distance.[1, 2]

The more rarely employed multifocal IOLs have been recently developed with the goal of restoring the accommodation capacity of the dioptric system, in addition to the transparency of the lens. These lenses create two or more images of the same object falling on different focal points.[3, 4] Habit and cerebral learning make the subject select images positioned closer to the retina, neglecting other kinds of images.[5, 6] Multifocal lenses provide a certain kind of multifocal vision by exploiting the constructive design of the lens optical portion, which maintains its position relatively unchanged when the subject focuses its attention either on close or long distance objects.[7-9]

Multifocal IOLs are distinguished between:[10-12]

— optical refractive multifocal IOLs. The lens front surface has two or more concentric rings with different curvature radius creating bi- or a multi-focal vision. The performance of the lenses with refractive optics depend on the diameter of the pupil, since the percentage of light that passes through the different optical zones varies depending on the pupillary dynamics;

— optical diffractive multifocal IOLs. On the front/back surface of the lens there are numerous concentric rings, separated from each other by a step of around 2μm in height. These steps diffract light, allowing the creation of two foci regardless of pupil size.

The goal of this study was to evaluate visual results and the impact on both life and vision quality of the refractive multifocal IOL (FIL611PV of Soleko) in patients undergoing surgery for bilateral phacoemulsification with IOL implantation.

Materials and methods

This observational, prospective, single-site study is designed to evaluate the multifocal IOLs FIL611PV (made by Soleko) in patients undergoing phacoemulsification with IOL implantation.

All candidates of the study subscribed written informed consent, specific for multifocal intraocular lens implantation (referring to the one drafted by SOI in 2009). The study was approved by the committee on research ethics at the institution in which the research was conducted.

Inclusion criteria were:

— age >50 years;

— patients affected by bilateral cataract;

— eyes with maximum regular corneal astigmatism of 1.0 D;

— eyes without maculopathy;

— no means opacifications apart of lens cataract;

— patients/eye with pupillary diameter ≤5.2 mm in mesopic ambient illumination.

Exclusion criteria are:

— previous ocular surgery;

— irregular astigmatism;

— amblyopia;

— neural/neuromuscular diseases (ictus, myasthenia, etc.);

— open-angle/narrow-angle glaucoma with IOP decompensation;

— intra-operative complications.

Recruited patients underwent complete ophthalmologic evaluation 90 days before the surgery, with data collection; keratometric values acquisition performed with the Javal keratometer by the same operator (keratometric values were obtained from the average of three consecutive measurements); tomography corneal data capture with Oculus Pentacam device with detection of central corneal thickness values, anterior chamber depth and breadth of the iris-corneal angle; ultrasound biometry acquisition with contact method; manifest refraction examination and long-distance visual acuity measurement (both natural and corrected performed with ETDRS charts), as well as visual-acuity for intermediate distance (UNIVA and BCIVA) and close distance (UCNVA and BCNVA) (with Jaeger tables); Lang II test and Amsler test execution; detection of intraocular pressure with Goldmann applanation tonometer; slit-lamp examination of the anterior segment and fundus oculi after mydriasis induction; photopic pupil size measurement at the slit lamp (values detected were represented by the average of three consecutive measurements); mesopic pupil size measurement at the slit lamp with SCBL (Slit lamp-based Cobalt Blue Light) method (mesopic pupil diameter values were represented by the average of three consecutive measurements); orthoptic evaluation; evaluation of ocular dominance for distance and near.

Each patient received prophylactic preoperative treatment consisting of Moxifloxacin droplets (5 mg/mL; 1 drop 3 times daily in both eyes for 3 days before the surgery).

Therefore, each patient underwent cataract extraction surgery by phacoemulsification (procedures performed by the same operator).

Patients were asked to attend at ophthalmologic control visits at 1 day (t1), 7 days (t2), 1 year (t3), 3 months (t4) and 6 months after surgery (t5).

At each of the last three check-ups the following evaluations were performed: examination of the manifest refraction and visual acuity measurement (both natural and corrected) for long-distances (UNDVA and BCDVA) (with the ETDRS charts), for intermediate distance (UCIVA and BCIVA) and near (UCNVA and BCNVA) (with Jaeger tables); intraocular pressure detection with Goldmann applanation tonometer; slit-lamp examination of the anterior segment and the fundus of the eye, if necessary, after pharmacological mydriasis; acquisition of keratometric values by Javal keratometer performed by the same operator (keratometric values were obtained from the average of three consecutive measurements); Oculus Pentacam corneal topography with detection of central corneal thickness values, anterior chamber depth and breadth of the iris-corneal angle; optical coherence tomography (OCT) of the macula; measurement of photopic size of the pupil as measured at the slit lamp (the value of photopic pupil diameter was obtained with the average of three consecutive measurements); mesopic pupil size measurement at the slit lamp with SCBL (slitlamp-based Cobalt Blue Light) method (the value of the mesopic pupil diameter was obtained with the average value obtained by three consecutive measurements). During the one-month and 6-months follow-up after surgery carried orthoptic assessment and evaluation of ocular dominance for distance and near were assessed as well.

The procedures in the study concerning conduction and documentation were in conformity with the ethical principles set out in the Helsinki Declaration and its revisions. The study data were analyzed using the Student *t*-test for paired data. Correlations were evaluated using Pearson correlation coefficients. They were recruited sixteen patients (seven males and nine females), mean age 70.87 years (±7.15).

Results

In the following results for measurements taken during the visit of recruitment (t0) and the follow-up at six months (t5) are shown.

The results regarding visual acuity monocular are shown in Table I. The improvement of visual acuity for the three working distances was statistically significant in all cases compared to preoperative status (Table II).

Binocular uncorrected visual acuity (Table III) was better than that monocular (comparisons carried out with the visual acuity of right eye (see Table I), and this difference was statistically significant in all cases (P<0.05), ex-

TABLE I.—*Monocular visual acuity outcomes.*

Visual acuity (logMAR - Jaeger)	Pre-operative exhamination t0)	6 months follow-up (t5)
	FIL611PV	FIL611PV
UCDVA OD	0.75 (0.38)	0.39 (0.29)
UCDVA OS	0.71 (0.36)	0.32 (0.24)
UCIVA OD	7.57 (3.89)	3.27 (0.7)
UCIVA OS	6.5 (2.36)	3.31 (0.70)
UCNVA OD	8 (3.39)	3.53 (0.24)
UCNVA OS	7.5 (3.28)	3.56 (0.89)
BCDVA OD	0.30 (0.16)	0.10 (0.08)
BCDVA OS	0.37 (0.18)	0.07 (0.05)
BCIVA OD	3.67 (1)	///
BCIVA OS	3.44 (0.88)	///
BCNVA OD	3.90 (1.37)	3 (///)
BCNVA OS	3.54 (0.93)	3 (///)

UCDVA: uncorrected distance visual acuity; UCIVA: uncorrected intermediate visual acuity; UCNVA: uncorrected intermediate visual acuity; BCDVA: best corrected distance visual acuity; BCIVA: best corrected intermediate visual acuity; BCNVA: best corrected near visual acuity; OD: right eye; OS: left eye.

TABLE II.—*Statistical significance of comparison between pre-operative and post-operative visual acuity.*

Visual acuity	Difference between preoperative time and (t0) – 6 months follow-up (t5) (P-value)
	FIL611PV
UCDVA	P<0.001
UCIVA	P<0.001
UCNVA	P<0.001

TABLE III.—*Binocular visual acuity at 6 months follow-up (OO, both eyes).*

Binocular visual acuity (logMAR - Jaeger)	6 months follow-up (t5) FIL611PV
UCDVA OO	0.29 (0.25)
UCIVA OO	3 (0)
UCNVA OO	3 (0)
BCDVA OO	0.06 (0.1)

TABLE IV.—*Comparison of additional correction for intermediate and near distance between t0 and t5.*

Additional correction for intermediate and near distance (D)	Preoperative exhamination (t0)	6 months follow-up (t5)
	FIL611PV	FIL611PV
Intermediate additional	2.12 (0,66)	0.90 (0.51)
Near additional	2.75 (0,69)	0.91 (0.49)

TABLE V.—*Entity of additional in monocular and binocular vision for Intermediate and near distances at t5.*

	Monocular additional (D)	Binocular additional (D)
	FIL611PV	FIL611PV
Intermediate distance	1.51 (0.71)	0.90 (0.51)
Near distance	1.51 (0.71)	0.91 (0.49)

TABLE VI.—*Corneal and irido-corneal angle characteristics comparison between preoperative and postoperative time.*

	Preoperative exxhamination	6 months follow-up
	FIL611PV	FIL611PV
Corneal astygmatism RE (D)	0.57 (0.38)	0.65 (0.41)
Corneal astygmatism LE (D)	0.74 (0.81)	0.75 (0.53)
CCT RE (μm)	554.83 (25.65)	551.53 (23.12)
CCT LE (μm)	557.41 (29.40)	549.42 (15.79)
ACD RE (mm)	2.89 (0.35)	4.67 (0.68)
ACD LE (mm)	2.87 (0.39)	4.47 (0.80)
Angle RE (°)	31.74 (6.04)	42.26 (6.33)
Angole LE (°)	32.19 (4.54)	41.7 (6.61)

cept in the case of the comparison of mono/binocular natural visual acuity for intermediate distance (UCIVA) (0=0.164).

Even the binocular corrected visual acuity for long distance (Table III) was better than that monocular (comparisons carried out with the visual acuity of right eye (Table I). This difference is however not statistically significant (P>0.05) (comparisons were performed only for the BCDVA because for the intermediate and close up distances no patient required the use of lenses in binocular vision).

The need of additional lenses in order to achieve the best binocular visual acuity was reduced for both near and intermediate distance (Table IV).

The reduction of the additional required to obtain the best binocular visual acuity for near and intermediate distance was statistically significant in both cases (P<0.001 for both the vision at intermediate distance, both for close viewing distances).

The additional required to obtain the best visual acuity for near and intermediate distance resulted lower in case of binocular vision compared to monocular vision (Table V). This decrease was in both cases statistically significant (P<0.05).

Table VI shows the relative changes in corneal astigmatism, corneal thickness (both found not statistically significant), the width of iris-corneal angle and anterior chamber depth (the latter statistically significant) detected with tomograph Oculus Pentacam between time t0 and time t5.

Discussion

As today, the available literature concerning IOLs implanted in this study is very poor.

Results obtained with the FIL611PV lenses show that these IOLs are able to obtain good performance in terms of visual acuity for the three working distances considered (far, intermediate and near).

However, some clarifications are necessary: FIL611PV lenses did not provide high performances in natural vision for distance: This could be largely due to tendency of FIL611PV multifocal lenses to induce myopia, especially in photopic conditions, in the postoperative period, equal to approximately -1.08D in conditions of monocular vision, with a non-statistically significant reduction to -0.90 diopters binocularity conditions. Such refractive result is precisely linked to the constructive design of the lens (which like all the multifocal lens has refractive performance directly dependent on the diameter of the pupil),[13-15] with the optical zone for near the center of the optical plate, which penalizes the performance under miosis conditions. These findings appear to be due to the con-

structional design of the lens and not to the surgical technique that, as is clear from the biometric data detected with tomograph Oculus Pentacam, did not significantly influenced corneal astigmatism, while modified, as it was natural to expect, two other variables such as the size of the irids-corneal angle and anterior chamber depth.

Patients with implanted FIL611PV lens refer difficulties in depth perception, in the distance vision, which often appears unsatisfactory/distorted/blurred (these facts were probably attributable to induced ametropy and were not adequately compensated by binocularity). Moreover, occurrence of halos and relative disturb were common and sometimes eddy images responsible for monocular diplopia were referred.

The natural visual acuity for intermediate and near distances was optimal, especially in binocular vision conditions (multifocal lenses have allowed to "save" 0.51 diopters of addition to obtain the binocular BCIVA and about 0, 87 diopters to obtain the binocular BCNVA). All this is in accordance with what stated by the manufacturer (which reports for the lenses an additional potential of approximately +3.00 D for multifocal lenses FIL611PV) and with what is reported by patients in the satisfaction questionnaires, which show a significant spectacle dependence only for distance.

The performance in terms of uncorrected visual acuity for the three working distances were improved in case of binocular implantation. Compared to the visual acuity measured in monocular condition the gain in binocular vision resulted of about a line of optotype.

From literature data analysis, emerges a not complete accordance to the findings from this study, compared with data reported in the literature.

More detailed literature data report a minimal discomfort in the distance vision for multifocal lenses.[16-18] From our data a rather more difficult vision and an increased dependence on glasses appeared for long-distance in patients implanted with multifocal lenses FIL611PV. Most likely this is due to construction design of the multifocal lens FIL611PV, which unlike the other diffractive multifocal lenses, such as Restor, the AMO Tecnis and the AcriTec TwinSet, adopts a refractive geometry with an optical zone to near located in the central lens portion, which induces a myopia especially in photopic conditions.[19-23]

In agreement with the data of the literature, halos and glare perceptions are a quite frequently feature associated with the use of multifocal lenses, either refractive or diffractive.[24-26]

The difficulty in reading small fonts reported in literature for the AMO Tecnis multifocal lenses and AcriTec TwinSet [27-31] was not been confirmed by our lenses FIL611PV, which much like the Restor, proved very promising performance in natural vision from intermediate / close, also in monocular vision.[32-38]

Concerning intermediate distance,[39-41] in agreement with the results of Literature, multifocal lenses FIL611PV have met the expectations and needs of our patients, with the advantage of greater spectacle independence.

Conclusions

In agreement with the literature data, multifocal lenses tested in this study are a viable solution for visual rehabilitation after a cataract extraction surgery that seeks to make phacoemulsification procedure and IOL implantation procedure real refractive measures in order to improve patient autonomy as much as possible for different working distances. These features are valid depending by the choice of the lens that best suits the patient's visual demands. If in fact the Restor lenses seem to guarantee the patient best visual performance in all working distances, Soleko lenses offer an alternative at a more reasonable cost, more oriented to favor the vision for intermediate -close distance. Just from the valuation of these features (that our study, even if small and worthy of further development, has allowed to highlight) it depends patient satisfaction relying to the physician in order to get the solution that best suits their needs.

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