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Case Report

Influence of corneal spherical aberration, anterior chamber depth, and ocular axial length on the visual outcome with an extended depth of focus wavefront-designed intraocular lens

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Abstract

Purpose: The purpose of the study was to evaluate which ocular parameters have an impact on visual results obtained after an extended depth of focus (EDF) wavefront-designed intraocular lens (IOL).

Setting: The study was conducted in three Italian centers (private practice in Lucca and two ambulatory surgical centers in Pisa and in Rome) from 01/09/2014 to 30/09/2015.

Design: The study population included 178 eyes of 91 patients who had cataract surgery and implantation of an EDF wavefront - designed IOL (Mini Well Ready - SIFI Med Tech S.r.l.).

Methods: Preoperative and postoperative refractive corneal spherical aberration (SA), ocular axial length, or anterior chamber depth were measured.

Results: The majority of patients were spectacle-independent for near, intermediate, and distance vision and no one reported disturbing halos or glare. No overall significant differences were observed when stratifying anterior chamber depth (ACD) and ocular axial length (AL) by uncorrected distance visual acuity (UCDVA); p = 0.465 and 1.000 respectively, corrected distance visual acuity (CDVA); p = uncorrected near visual acuity (UCNVA); p = 1.000 and 0.728 respectively; p = 1.000 under both parameters and halos; 1.000 under both parameters. Still, there was a statistically significant difference when stratifying SA with 5 mm only by UDVA (p = 0.040).

Conclusion: These results are consistent with similar outcomes in the scientific literature as measured with tests of visual acuity, either with or without optical correction. We also demonstrated that these IOLs can be used in myopic and hyperopic eyes, although it may be useful to evaluate the preoperative corneal SA to achieve better results.

Introduction

Until twenty years ago, the main objective of cataract surgery was visual rehabilitation, which is the process of restoring functional ability and improving quality of life and independence. Today, thanks to technological evolution, cataract surgery has become a refractive procedure too, one that can eliminate the dependency on glasses.

The use of refractive or diffractive multifocal intraocular lenses (IOLs) has also allowed to correct presbyopia and improve patients' quality of life [1-7]. The possible disadvantages associated with the use of these lenses are optical quality reduction, the presence of only 2 or 3 visual foci (bi - or trifocal), and the appearance of glares and halos, especially in night vision [8-10].

To overcome this, a new class of multifocal IOLs – the Extended Depth of Focus (EDOF) lenses – has recently been introduced [11-15]. These IOLs have been designed to

achieve continuous vision at all distances, with minimal visual disturbances.

In the context of this therapeutic option, we run a clinical study to evaluate whether preoperative corneal spherical aberration, ocular axial length, or anterior chamber depth have an impact on visual results obtained using an EDOF wavefront-designed IOL.

Patients and methods

This observational, retrospective study was conducted in 3 Italian sites (surgery was done in two ambulatory surgical centers in Pisa and in Rome; follow-up visits were done in these two ambulatory centers and in private practice in Lucca). As a non-interventional study, there was no clinical trial registration requirement. The study was conducted in accordance with good clinical practice (GCP) and the tenets of the Declaration of Helsinki were observed.

All patients that fulfilled the inclusion criteria from 01/09/2014 to 30/09/2015 were included in the study. Informed consent was obtained from all subjects enrolled, after an explanation of the nature of the study.

Inclusion criteria were: Patients who had had cataract surgery and implantation of an EDOF wavefront-designed IOL (Mini Well Ready - SIFI Med Tech S.r.l., Italy).

Fu Y, Kou J, Chen D, et al. Influence of angle kappa and angle alpha on visual quality after implantation of multifocal intraocular lenses. J Cataract Refract Surg. 2019;45(9):1258–1264. doi: 10.1016/j.jcrs.2019.04.003. Preoperatively, all patients had a full ophthalmologic assessment. Uncorrected distance visual acuity (UCDVA) and best-corrected distance visual acuity (BCDVA) were evaluated with the logarithm of the minimum angle of resolution (logMAR) charts; uncorrected near visual acuity (UCNVA) and best-corrected near visual acuity (BCNVA) were evaluated with Jaeger chart at 40 cm. Corneal topography, tomography, and aberrometry, anterior chamber tomography, slit lamp examination, Goldmann tonometry, dilated funduscopy and retinal optical coherence tomography were completed.

All patients were submitted to the implantation of the same type of IOL. The IOL used for this study is an EDOF wavefront-designed IOL (Mini Well Ready - SIFI MedTech S.r.l., Italy). This IOL is a progressive aspheric, single-piece lens made of a hydrophilic-hydrophobic copolymer, which is specific for the surgical technique of mini-incision. This IOL has an overall diameter of 10.75 mm, a 6.0 mm optic, an equivalent addition of +3.00D, and is available in powers of 0.0 D to 30.0 D.

The wavefront-engineered optic is designed to introduce an appropriate spherical aberration at the pupil's center and to control high-order aberrations (HOA) at the pupil's periphery in order to increase the depth of focus and generate a progressive multifocality.

The optic consists of three zones, a 2 mm central zone with positive spherical aberration (SA), a 1 mm middle zone with negative SA, and an outer aspheric monofocal zone.

All surgeries were performed using a standard technique of sutureless phacoemulsication through a 2.2 mm incision. All patients were submitted to the implantation of the same type of IOL. Anterior capsulorhexis of approximately 5.0 mm in diameter was created and the IOL was implanted into the capsular bag.

The study focused on three pre-operative parameters: anterior chamber depth (ACD), ocular axial length (AL) and corneal spherical aberration with a pupil of 5 mm (SA).

For all measurements, the same anterior chamber O.C.T. (MS-39, C.S.O. S.r.l.), optical biometer (AL-Scan, Nidek co. LTD) and aberrometer (Osiris, C.S.O. S.r.l.) were used.

Preoperative and postoperative refractive corneal spherical aberration (SA), ocular Axia.

We studied 178 eyes of 91 patients who had cataract surgery and implantation of Outcome parameters were the BCDVA and UCDVA, UCNVA, and presence of halos and glares (asking the patient to quantify these problems using a scale where 0 was the highest discomfort and 10 no discomfort) for each eye after 5 - 6 weeks after surgery.

The ophthalmological examinations were performed before and 1 day, 1 week, 1, 3, 6, 9 and 12 months after surgery. The preoperative examination included measurements of uncorrected (UDVA) and corrected (CDVA) distance visual acuity, uncorrected (UIVA) and distance-corrected (DCIVA) intermediate visual acuity measured at 70 cm, uncorrected (UNVA) and distance-corrected (DCNVA) near visual acuity measured at 30 cm, manifest refraction, intraocular pressure, slit lamp anterior segment examination, optical biometry, keratometry and retina evaluation under pupil dilation.

Patients were asked about the severity of photic phenomena. The intensity of glare and halo. l length or anterior chamber depth were measured.

Outcomes

The visual outcomes of every analyzed parameter were divided into 3 groups.

The ACD groups were:

i. From 1.99 to 2.85 mm (41 eyes)

ii. From 2.86 to 3.35 mm (47 eyes)

iii. From 3.36 to 4.16 mm (47 eyes).

The AL groups were:

i. From 21,28 to 22,70 mm (48 eyes)

ii. From 22,71 to 23,70 mm (68 eyes)

iii. From 23,71 to 27,88 mm (62 eyes).

The SA groups were:

I. From 0,00 to -0,10 μ (50 eyes)

II. From -0,11 to -0,16 μ (87 eyes)

III. From -0,17 to -0,32 μ (41 eyes).

The corneal diameter considered was the same for all eyes: 5 mm.

Statistical analysis

We studied the mean, median, standard deviation (SD), and interquartile range (IqR), to understand if ACD, AL, and SA could influence visual outcomes. The data analyzed are expressed as the mean ± standard deviation (SD) and a *p* value of less than 0.05 was considered statistically significant. We report also median +/- IqR to additionally assess skewness. Summary statistics are computed overall and stratified separately by each pre-specified, exogenously defined, subgroup definition (UCDVA, CDVA, etc.). Differences among subgroups are evaluated by Kruskal-Wallis non-parametric tests, and p-values are Bonferroni adjusted to take into account multiplicity issues. Adjusted significance levels are reported, so that $p < 0.05$ can be interpreted directly as the (global) significance of the result. Analyses were done using R software (R development core team, Vienna, Austria) version 3.3.3.

Surgical technique

All patients were operated on by two different surgeons. A manual small incision cataract surgery was performed for all eyes. The corneal tunnel (2,2 mm) was performed on the steepest meridian, so as not to determine an increase in astigmatism.

An EDOF wavefront-designed IOL, Mini Well Ready, was implanted in every case.

This IOL is a progressive aspheric, single-piece lens made of a hydrophilic-hydrophobic copolymer, which is specific for the surgical technique of mini-incision. This IOL has an overall diameter of 10.75 mm, a 6.0 mm optic, an equivalent addition of + 3.00 D and is available in powers of 0.0 to 30.0 D.

The wavefront-engineered optic is designed to introduce an appropriate spherical aberration at the pupil's center and to control high-order aberrations (HOA) at the pupil's periphery in order to increase the depth of focus and generate a progressive multifocality.

The optic consists of three zones, a 2 mm central zone with positive spherical aberration (SA), a 1 mm middle zone with negative SA, and an outer aspheric monofocal zone.

Results

We included 178 eyes of 91 patients who had cataract surgery and implantation of an EDOF wavefront-designed IOL in two Italian sites from 01/09/2014 to 30/09/2015. Patients' characteristics at baseline are as follows: the average age of patients was 67.58 +/- 8.88 and 41 patients were female.

Overall, the use of Multifocal Wavefront-designed IOLs has shown excellent visual outcomes with minimal disturbances in all 178 eyes studied.

The UCDVA was of 0,12 ± 0,13 LogMAR, the BCDVA 0,01 ± 0,05 LogMAR, the UCNVA 2,62 ± 1,17 Jaeger character, for single eye at 40 cm and the glares and halos were 8,79 ± 1,24.

No overall significant differences are observed when stratifying by ACD by UCDVA, CDVA, UCNVA, and Halos (Table 1). Similarly, no significant differences were observed when stratifying by ocular axial length (AL) (Table 2).

When stratifying by corneal SA of 5 mm, once again no significant differences are observed when comparing groups defined by CDVA, UCNVA, and Halos. On the contrary, there was a statistically significant difference when stratifying SA with 5 mm only by UDVA, with $p = 0.040$ (Table 3).

Table 1: Outcomes in all eyes.

UCDVA	0,12 ± 0,13 LogMAR
BCDVA	0,01 ± 0,05 LogMAR
UCNVA	2,62 ± 1,17 Jaeger character, for single eye at 40 cm
Glares and Halos	8,79 ± 1,24

Table 2: Anterior Chamber Depth.

	Group	UCDVA	BCDVA	UCNVA	Halos-Glares
I 41 eyes	Mean	0,13	0,02	2,49	8,78
	SD	0,14	0,06	1,07	1,15
	Median	0,10	0,00	2,00	9,00
	IqR	0,20	0,00	1,00	2,00
II 90 eyes	Mean	0,09	0,02	2,42	8,84
	SD	0,12	0,05	1,07	1,21
	Median	0,00	0,00	2,00	9,00
	IqR	0,10	0,00	1,00	2,00
III 47 eyes	Mean	0,12	0,02	2,72	8,72
	SD	0,16	0,07	1,33	1,35
	Median	0,10	0,00	3,00	9,00
	IqR	0,18	0,00	2,50	2,00

Table 3: Ocular Axial Length.

	Group	UCDVA	BCDVA	UCNVA	Halos-Glares
I 48 eyes	Mean	0,14	0,04	2,44	8,71
	SD	0,17	0,10	1,07	1,17
	Median	0,05	0,00	2,00	9,00
	IqR	0,20	0,00	1,00	2,00
II 68 eyes	Mean	0,08	0,01	2,42	8,97
	SD	0,09	0,03	1,07	1,11
	Median	0,10	0,00	2,00	9,00
	IqR	0,12	0,00	1,00	2,00
III 62 eyes	Mean	0,11	0,01	2,72	8,68
	SD	0,14	0,03	1,33	1,39
	Median	0,10	0,00	2,00	9,00
	IQR	0,18	0,00	2,00	2,00
p		1,00	0,728	1,000	1,000

All *p* - values are reported in Tables 1- 3, together with the mean, median, SD and IqR for each subgroup.

In conclusion for SA 5 mm we can see that UDVA groups 1 and 3 have a slightly larger mean and median than group 2, where the median (as formally compared by the Kruskall-Wallis test) in groups 1 and 3 is 0.1 vs a median of 0.0 in group 2.

Discussion

Nowadays cataract surgery has become a precise and safe surgical procedure, and the use of multifocal IOLs in selected cases has also allowed for correcting presbyopia. These lenses can be diffractive or refractive and consist of multiple zones of lens power that produce 2 or 3 visual foci, allowing for enhanced vision in both near and far vision.

The use of multifocal IOLs may be associated with the appearance of some visual disturbances, such as reduction of the optical quality and the vision of glares and halos, especially with low brightness.

To overcome these problems a new class of lenses – the EDOF lenses – has been studied.

The Mini Well Ready is an EDOF wavefront-designed IOL with a "continuum of foci". Compared to the common multifocal IOLs, this lens has 3 different optical zones, 2 concentric central zones with spherical aberrations of opposite signs (internal positive and external negative), and a monofocal periphery.

Dominguez Vincent A, et al. [16] performed a study to evaluate the optical quality of 3 multifocal lenses: the Mini Well Ready IOL and the AT Lisa trifocal diffractive IOL (both by Carl Zeiss Meditec AG) and the Fine-vision full diffractive trifocal IOL (PhysIOL SA). The authors showed that the progressive multifocal aspheric IOL provided a greater depth of focus between intermediate and near vision and better optical quality than trifocal IOLs at distant vision focus for a large aperture of the pupil.

Another study compared 2 EDOF lenses [17]. The Mini Well Ready and the TECNIS Symphony (both by Abbott Laboratories,). The results suggested that both designs might enlarge the depth of focus. Nevertheless, the Mini Well showed better optical quality than the TECNIS Symphony at far vision with a 4.5 mm aperture and larger defocus tolerance than the diffractive lens at near-distance vision.

In our study, the use of Mini Well IOL has shown excellent visual outcomes, but the aim of our work was to assess whether certain preoperative parameters (ACD, AL, and SA) could influence the visual outcomes.

We have found that ACD and AL, in the range we have studied, do not seem to have an impact on the visual results. Instead, a significant difference as far as stratification of SA 5 mm by UDVA is examined, where the results in group 2, from -0,11 to -0,16 μ, are slightly better.

In conclusion, this lens offers good visual quality at all distances with minimal risk of glare and halos. Still, physicians need to carefully evaluate the preoperative corneal SA to achieve better results.

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Conflict of interest

The authors have no financial interest in any of the issues contained in this article and have no proprietary interest in the development of marketing or materials used in this study.

Ethics statements

Signed informed consent was obtained from all subjects after they were informed of the procedures and possible side effects.

The study was conducted in accordance with good clinical practice (GCP) and the tenets of the Declaration of Helsinki were observed.

What was known

- There is a wide variety of surgical solutions for presbyopic patients, with the ability to provide good vision at different distances;
- Light scattering and an increased level of high-order aberrations (HOAs) are factors related to patient dissatisfaction following cataract surgery with multi-focal IOL implantation.

What this paper adds

- It helps to predict the behavior of a multifocal IOL prior to implantation.
- Preoperative workup including the patients' visual needs and inherent ocular anatomy allows us to achieve superior outcomes.

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