

The Tolerance of Refractive Errors of Extended Depth of Focus Intraocular Lens in Patients with Previous Corneal Refractive Surgery

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Abstract

Purpose

To evaluate the tolerance of refractive errors and visual outcomes of extended depth of focus intraocular lens (EDOF IOLs) in patients with previous corneal refractive surgery for myopia.

Methods

Patients from Wuhan Aier Eye Hospital with previous myopia excimer laser correction underwent cataract surgery and implantation of an EDOF IOL. The follow-up period was three months. The uncorrected distance, intermediate, and near visual acuities (UDVA, UIVA, UNVA), corrected distance visual acuity (CDVA), spherical equivalent (SE), defocus curve, optical quality, including modulation transfer functions (MTF) and Strehl ratio (SR), National Eye Institute Visual Functioning Questionnaire-14 for Chinese people (VF-14-CN), spectacle independence, and dysphotopsia were assessed.

Results

At the final visit, UDVA, CDVA, UIVA, and UNVA (logMAR) were 0.07 ± 0.09 , 0.01 ± 0.04 , 0.10 ± 0.08 , 0.20 ± 0.11 , respectively. The mean spherical equivalent (SE) was $\pm 0.75 \pm 0.49D$, where 42% (21 eyes) were within $\pm 0.50D$, 70% (35 eyes) were within $\pm 1.00D$, and 98% (49 eyes) were within $\pm 1.50D$. The defocus curve showed that visual acuity could reach 0.1 in the refractive range of $0 \sim -1.5D$. SR and MTF values of 10, 15, 20, 35, and 30 c/d spatial frequency were measured with a 3 mm pupil diameter after removing the influence of low-order aberrations, which were all higher than the values before the operation. The mean VF-14-CN questionnaire score was 51.02 ± 2.95 out of 56.

Conclusion

The EDOF IOLs have a certain tolerance for refractive errors, and they are recommended for patients with prior myopia excimer laser surgery to achieve satisfactory visual performance.

What Was Learned

1. EDOF IOLs can provide excellent visual outcomes and high patient satisfaction.
2. EDOF IOLs have a certain tolerance to residual postoperative refractive errors.
3. The accurate calculation of IOL power after refractive laser surgery is difficult.

What This Paper Adds

1. EDOF IOLs have a certain tolerance for refractive errors in patients with previous refractive laser surgery.
2. EDOF IOLs can provide improved visual outcomes and a higher quality of life for patients who have undergone refractive laser surgery.

Introduction

Since the excimer laser was first used in corneal refractive surgery, millions of patients with refractive errors have been treated. With aging, many of these patients develop cataracts and presbyopia [1]. Compared with other patients with age-related cataracts, patients with a history of corneal refractive surgery tend to have a stronger desire for independence from spectacles and higher expectations regarding postoperative outcomes [2]. Therefore, functional intraocular lenses (IOLs) that can correct presbyopia may be the appropriate choice for these individuals, including multifocal, extended depth of focus (EDOF) IOLs, and adjustable IOLs [3]. However, accurate IOL power calculation is difficult for patients with prior myopic refractive surgery due to errors in preoperative corneal curvature measurement and postoperative effective lens position estimation [4, 5]. Moreover, it is not uncommon to encounter postoperative refractive error in these individuals. Previous studies have shown that EDOF IOLs have a higher tolerance for refractive errors in comparison to other multifocal or monofocal IOLs because of their unique design. Carones et al. found that EDOF IOLs retained good visual acuity even with an induced astigmatism of -1.50D [6–8]. However, no studies have evaluated the tolerance of EDOF IOLs in patients with previous myopic corneal refractive surgery. This study aims to address this question.

Methods

Patients

The retrospective study enrolled patients who underwent cataract surgery and implantation of an EDOF IOL (Tecnis Symphony, Johnson & Johnson Vision Care, Inc.). All patients had previous myopia excimer laser-assisted in situ keratomileusis (LASIK) correction. The study was approved by the Institutional Review Board of Wuhan Aier Eye Hospital (2021IRBKY1011). All tenets of the Declaration of Helsinki were followed.

The inclusion criteria [9] included patients with a significant bilateral cataract, previous myopic LASIK, seeking spectacle independence, corneal higher-order aberrations (HOAs) up to 0.5 mm, regular corneal astigmatism $\leq 1.5D$, and kappa and alpha angles both < 0.5 mm, without any contraindications of surgical therapy in the preoperative examination or posterior capsular rupture or zonular dialysis during the cataract surgery. Exclusion criteria included previous ocular surgery other than LASIK, active ocular and/or systemic disease, glaucoma, uveitis, diabetes with retinal damage, and any retinal or macular disease.

Examinations

All enrolled patients underwent the following ophthalmologic preoperative examinations: non-contact specular microscopy, intraocular pressure, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction, optical biometry (IOL-master 700, Carl Zeiss Meditec), and ray tracing aberrometry (iTrace, Tracey Technologies). The axial length, keratometry and anterior chamber depth were measured using an IOL-master 700. Corneal tomography (Pentacam HR, Oculus Optikgerate GmbH) was performed to confirm the regularity of the previous ablation and astigmatism. An iTrace was used to measure corneal HOAs, modulation transfer functions (MTFs), and the Strehl ratio (SR).

At the three-month postoperative visit, the following parameters were measured: UDVA and CDVA, uncorrected near visual acuity (UNVA) at 40 cm, and uncorrected intermediate visual acuity (UIVA) at 80 cm using the Early Treatment Diabetic Retinopathy Study charts (ETDRs, Wehen Vision Technology Co., Ltd.) designed for these distances, subjective manifest refraction (spherical equivalent, SE), and the defocus curve with distance-uncorrected vision (logMAR acuity) from + 1.00D to -4.00D in steps of 0.50D. At a pupil diameter of 3 mm, the MTF and SR were measured by iTrace after removing the effects of low-order aberrations. Then, we used questionnaires to assess the quality of life of patients, including the Chinese Visual Function index 14 (VF-14-CN) questionnaire and another short questionnaire about negative visual symptoms, such as halo, glare, and starburst, as well as spectacle independence rate and satisfaction. VF-14-CN is based on 14 uncorrected vision-dependent daily activities, with each item scored on its degree of difficulty as follows: no difficulty (4 score), a little difficulty (3 score), moderate difficulty (2 score), quite difficult (1 score), or impossible to perform the task (0 score). The resulting VF-14-CN score ranged from 0 (worst functional impairment) to 64 (no disability).

Surgical Technique

All surgeries were performed by the same experienced surgeon (Y.W.), who used 0.5% compound tropicamide eye drops to dilate the pupils and obucaine eye drops to maintain topical anesthesia before surgery. Capsulotomies (diameters were all set at 5.5 mm) and lens fragmentation were performed using a LenSx femtosecond laser (Alcon Laboratories, Inc., Fort Worth, Texas, USA). Then, standard phacoemulsification cataract surgery was performed. The EDOF IOL (Tecnis Symphony) was implanted in the capsular bag. The residual viscoelastics were removed, and the position of the lens was adjusted. All incisions were hydrated, and the patients' conjunctival sac was treated with dexamethasone tobramycin ophthalmic ointment.

Lens Power Calculation

A multi-formula average method was utilized for lens power calculation, including three formulas using no previous data from the Haggis-L [10], Barrett True K No-History [11], Shammas No-History [12]. The

target refraction was set to postoperative emmetropia. Then, the average of the results calculated by these formulas was used as the implanted IOL power.

Statistical Analysis

Statistical analysis was performed using SPSS software for Windows (version 23.0, International Business Machines Corp.). Each index was described as the mean \pm standard deviation. A paired t test or paired Wilcoxon test were used for data analysis. Differences were considered statistically significant when the P-value was less than 0.05.

Results

A total of 50 eyes of 32 patients were enrolled in this study, including 10 males and 22 females. Table 1 summarizes the demographic characteristics. The mean age of these patients was 49.62 ± 5.81 (range, 41 to 62 years). A total of 14 (43.75%) and 18 patients (56.25%) underwent unilateral and bilateral implantation respectively. The mean axial length was 28.66 ± 1.87 mm (range, 25.53 to 34.30 mm), and the mean keratometry was 37.84 ± 2.28 D (range, 31.93 to 41.63D). The preoperative mean UDVA of the patients was 0.95 ± 0.37 . The mean spherical equivalent was -7.17 ± 3.49 D. As shown in Table 1, the mean power of the implanted ZXR00 IOL was 17.58 ± 2.89 D (range, 10.5 to 24D).

Table 1
Demographics of the patients before IOL implantation

Parameters	Number / Mean \pm SD (range)
Number of eyes (N)	50
Number of patients (n)	32
Sex (male/female, n/n)	10/22
Symptoms (n / %)	-
Bilateral	18(56.25%)
Unilateral	14(43.75)
Mean age (Years) \pm SD (range)	49.62 \pm 5.81(41, 62)
Mean pre-UDVA (logMAR) \pm SD (range)	0.95 \pm 0.37(0.20, 1.70)
Mean pre-CDVA (logMAR) \pm SD (range)	0.34 \pm 0.13(0.20, 0.80)
Mean pre-SE (D) \pm SD (range)	-7.17 \pm 3.49(-2.13, -18.26)
Mean axial length (mm) \pm SD (range)	28.66 \pm 1.87 (25.53, 34.30)
Mean keratometry (D) \pm SD (range)	37.84 \pm 2.28(31.93, 41.63)
Mean power implanted IOL (D) \pm SD (range)	17.58 \pm 2.89 (10.5, 24)
CDVA = Corrected Distance Visual Acuity; logMAR = logarithm of the minimum angle of resolution; SD = standard deviation; SE = Spherical Equivalent; UDVA = Uncorrected Distance Visual Acuity.	

Visual And Refractive Outcomes

The mean UDVA of patients three months after surgery was 0.07 ± 0.09 , of which 82% ≤ 0.1 . The mean postoperative CDVA was 0.01 ± 0.04 , UIVA was 0.10 ± 0.08 , and UNVA was 0.20 ± 0.11 . The mean postoperative SE = $\pm 0.75 \pm 0.49$ D. 42% (21 eyes) within ± 0.50 D, 70% (35 eyes) within ± 1.00 D, and 98% (49 eyes) within ± 1.50 D (see Table 2 for details).

Table 2
Visual acuity under the different spherical equivalent after ZXR00 implantation

SE	VA(LogMAR)				N
	UDVA	CDVA	UIVA	UNVA	
≥ 0D	0.05 ± 0.09 (0,0.30)	0.02 ± 0.04(0,0.10)	0.15 ± 0.08(0,0.30)	0.25 ± 0.11(0.10,0.50)	11
-0.50 ~ 0D	0.05 ± 0.10(-0.10,0.20)	0 ± 0.05 (-0.10,0.10)	0.13 ± 0.07(0,0.20)	0.23 ± 0.09(0,0.30)	10
-1.00~-0.51D	0.07 ± 0.09(0,0.30)	0 ± 0.03(-0.10,0)	0.07 ± 0.08(0,0.20)	0.12 ± 0.09(0,0.30)	14
-1.00D	0.09 ± 0.07(0,0.30)	0.02 ± 0.06(-0.10,0.10)	0.07 ± 0.08(-0.10,0.20)	0.12 ± 0.12(0,0.30)	15
CDVA = Corrected Distance Visual Acuity; logMAR = logarithm of the minimum angle of resolution; SE = Spherical Equivalent; UDVA = Uncorrected Distance Visual Acuity; UIVA = Uncorrected Intermediate Visual Acuity;					
UNVA = Uncorrected Near Visual Acuity.					

Defocus Curve

The defocus curve shows a peak between 0D and - 1.5D and a slow downward trend in the refractive range of -2.0D to -4.0D. In the 0 -1. 50D refractive range, visual acuity is stable and could reach more than 0.1 (Fig. 1).

Postoperative Mtf And Sr

Comparison of the preoperative and postoperative MTF of patients with a pupil diameter of 3 mm after removing the influence of low-order aberrations showed that the postoperative MTF values at the six spatial frequencies of 5,10, 15, 20, 25, and 30 c/d were all higher than those before the operation. The differences were statistically significant ($Z=-5.12, -5.478, -5.454, -5.507, -5.508, -5.536$, all $P < 0.001$). Further, postoperative SR was higher than preoperative SR, and the difference was also statistically significant ($Z=-5.478, P < 0.001$) (Table 3).

Table 3
Comparison of MTF and SR before and after ZXR00 implantation

Spatial Frequency, cycle/deg	Preoperative	Postoperative	Z	p
5	0.3407 ± 0.23185	0.6355 ± 0.24338	-5.121	0.001
10	0.1606 ± 0.14161	0.4321 ± 0.22560	-5.478	0.001
15	0.1009 ± 0.08975	0.3084 ± 0.18915	-5.454	0.001
20	0.0681 ± 0.06084	0.2337 ± 0.15996	-5.507	0.001
25	0.0532 ± 0.04588	0.1871 ± 0.13395	-5.508	0.001
30	0.0439 ± 0.03753	0.1518 ± 0.10935	-5.536	0.001
SR	0.0624 ± 0.07732	0.2952 ± 0.26582	-5.478	0.001
MTF = Modulation Transfer Functions; SR = Strehl Ratio.				

Postoperative Questionnaire Survey Results

The VF-14-CN score was 51.02 ± 2.95 points. It is a little difficult for individual patients to do fine work and read small fonts. Fourteen patients often wear glasses when reading, so the near-distance spectacle independence rate is 56.25%. Four patients need to wear glasses often when looking at an intermediate distance, and the intermediate distance spectacle independence rate is 87.5%. Three patients need to wear glasses when looking far away, and the spectacle independence rate is 90.63%. Seven patients felt a mild glare, while five felt a mild glare, which does not affect their vision (Tables 4, 5).

Table 4
Spectacle independence in different distance after ZXR00 implantation

Spectacle independence	Distance	Intermediate	Near
Never/occasionally	29/32	28/32	18/32
50% of time	3/32	4/32	11/32
Frequently	0	0	3/32

Table 5
Distribution of dysphotopsia

Dysphotopsia	Glare	Halo	Starburst
No	23/32	27/32	31/32
Mild	7/32	5/32	0
Moderate	2/32	0	1/32
Severe	0	0	0

Discussion

For ophthalmologists, there are two major challenges in cataract surgery for patients with previous corneal refractive surgery: IOL power calculation and IOL selection [13]. This study explored the tolerance of refractive errors and early clinical outcomes of EDOF IOL implantation in cataract patients with previous myopia excimer laser correction in order to provide a reference for the clinical application of IOLs. The Tecnis Symphony IOL is a single-piece, hydrophobic acrylic, foldable lens with a biconvex, wavefront-designed anterior aspheric surface and posterior achromatic diffractive surface with an echelette design (intended to extend the range of vision by correcting chromatic aberrations) [3, 14]. Currently, there are few reports on the implantation of EDOF IOLs in cataract patients with previous corneal refractive surgery.

At three months postoperatively, most patients achieve satisfactory UDVA, but it is inevitable that there will be a certain degree of refractive error, which will not significantly affect the patient's UDVA. After correcting the refractive error, only one extra line can be seen on the eyesight chart, or the same as with the UDVA. Compared with cataract patients without a history of corneal refractive surgery, those with previous corneal refractive surgery have larger refractive errors after cataract surgery [15, 16]. The reason for this may be the extended range vision design of this IOL. Some reports [6–8] also indicated that the Tecnis Symphony IOL has refractive error tolerance. Compared with the monofocal IOLs on the same platform, the impact of residual refractive error of Tecnis Symphony IOL implantation is limited in postoperative UDVA. Based on this result, this IOL is suitable for patients with previous corneal refractive surgery, as achieving satisfactory results in eyes with a history of corneal refractive surgery is complicated by the lower prediction accuracy of formulas for this population.

In the study, the postoperative UDVA of patients was better than UIVA and UNVA, which is consistent with some studies on the Tecnis Symphony IOL [17–19]. The Tecnis Symphony IOL has a near additional power of + 1.75D. Theoretically, the focal length of the intraocular lens is 57 cm away from the front of the eye, so the patient's visual acuity is lower at 40 cm in front of the eye. This result suggests that patients may need to wear reading glasses when viewing at close distances after surgery, which may affect some jobs that require better near vision. However, according to the follow-up survey results, in most cases this does not affect the patients' life, and they can achieve spectacle independence. In addition, according to some

reports [15, 20, 21], compared with monofocal IOLs, the visual range is wider, but compared with multifocal IOLs, the visual acuity at near and intermediate distances is insufficient. As the defocus curve shows, full vision can be achieved to a certain extent after IOL implantation, meeting the lens removal needs of cataract patients.

The postoperative MTF values of the patients in the five spatial frequencies were all higher than those before the operation, and the SR was also higher than before the operation. MTF and SR are comprehensive evaluation indexes of visual image quality [22]. Studies have shown that IOLs can enable patients to achieve better visual contrast sensitivity [17, 23, 24]. However, the study did not include a control group. Although the achromatic design of this IOL can increase contrast sensitivity, the improvement in the patient's visual quality is also related to cataract removal.

All patients had higher VF-14-CN scores after surgery. In the postoperative follow-up survey, some patients reported that they had difficulties seeing small print and doing fine work, but on the whole they had a good quality of life after surgery. Most patients no longer need to wear glasses at different working distances. However, some people occasionally experience a mild glare and halo, which usually appear at night and do not affect the quality of life and vision. It has been reported [23, 25, 26] that patients with Symphony IOL implantation have a high rate of spectacle independence, and these patients are more satisfied with the operation. Therefore, Symphony IOLs can be considered for cataract patients with previous corneal refractive surgery.

A limitation of this study is that the sample size was too small. In the future, it is necessary to further evaluate the clinical effect of Symphony IOL implantation in cataract patients after corneal refractive surgery with a large sample size, increase the number of indicators, and extend the follow-up time.

Conclusion

In summary, our preliminary findings show that the EDOF IOL has a certain tolerance for refractive errors, and it might provide patients who have undergone LASIK surgery with improved visual outcomes and a higher quality of life.

Abbreviations

IOL: intraocular lens

EDOF IOL: extended depth of focus intraocular lens

UDVA: uncorrected distance visual acuities

UIVA: uncorrected intermediate visual acuities

UNVA: uncorrected near visual acuities

CDVA: corrected distance visual acuity

SE: Spherical equivalent

MTF: Modulation transfer functions

SR: Strehl ratio

VF-14-CN: Visual Functioning Questionnaire-14 for Chinese people

LASIK: Laser-assisted in situ keratomileusis

HOAs: Higher-order aberrations

Declarations

Ethics approval and consent to participate: The study was approved by the Institutional Review Board of Wuhan Aier Eye Hospital(ID:2021IRBKY1011). All enrolled patients were treated in accordance with the tenets of the Declaration of Helsinki. Due to the retrospective nature of the study, the need for informed consent was waived by the Institutional Review Board of Wuhan Aier Eye Hospital.

Consent for publication: Not applicable.

Availability of data and materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: Hansong Zheng and Yong Wang conceived of and designed this study. Yong Wang performed the surgeries and contributed to the data acquisition. Hansong Zheng performed the patient follow-up and data collection, the data analysis and rechecking, and drafted the initial manuscript. Qian Tan, Suowang Zhou, Wenjing Luo, Julio Ortega-Usobiaga, Li Wang, and Yong Wang revised the manuscript critically for important intellectual content. This manuscript has been read and approved by all the authors, and each author believes that the manuscript represents honest work.

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Figures

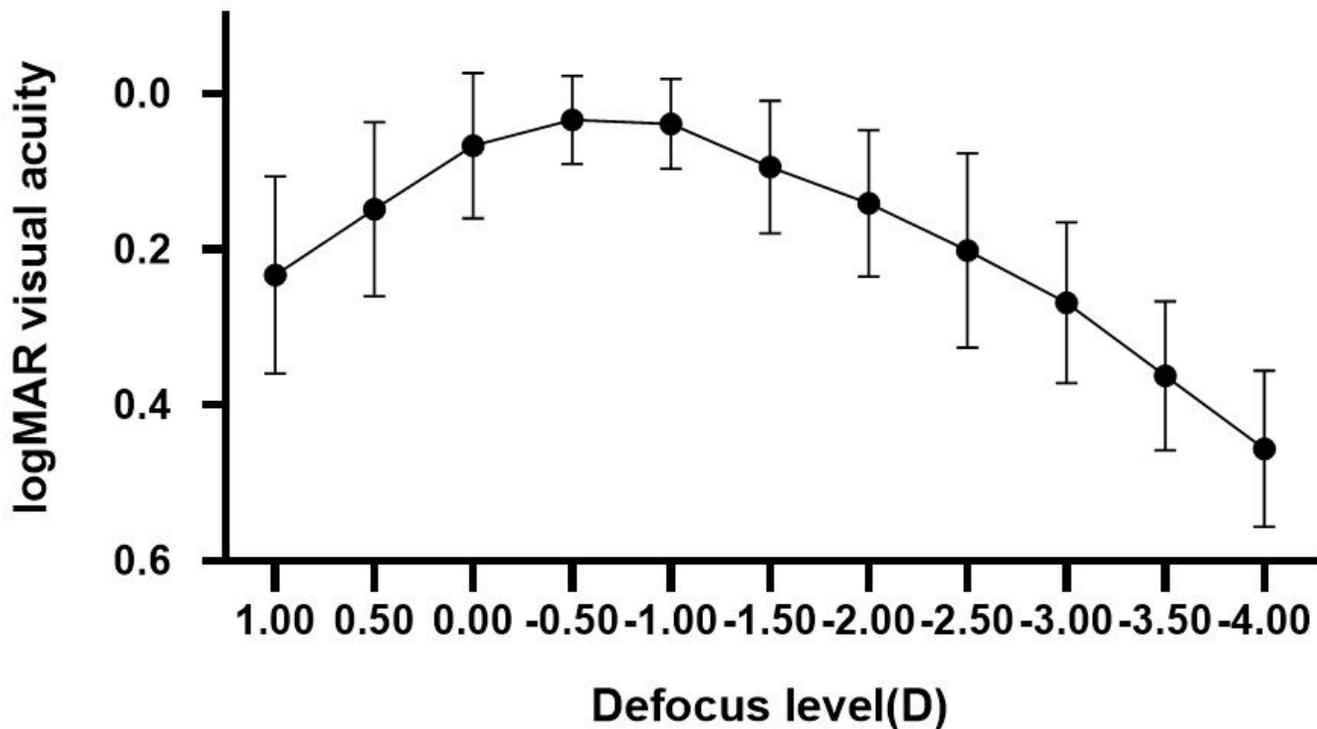


Figure 1

Defocus curve of EDOF IOL at 1 month. D = diopters. logMAR=logarithm of the minimum angle of resolution.