Randomized Contralateral Comparison of Visual Outcomes Following Implantation of Two Monofocal Aspherical Intraocular Lenses after Cataract Surgery

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ACKNOWLEDGMENTS/DISCLOSURE

a. Funding/Support: None

b. Financial Disclosures: The authors declare that they have no conflict of interest.

c. Other Acknowledgments: The authors would like to thank the participants who made this study possible and possible and the Deputy of Research of Mashhad University of Medical Sciences. (Code No.: 4452284)

ABSTRACT

Purpose: To compare optical and visual performances of two one-piece aspherical implanted intraocular lenses (IOLs) following phacoemulsification cataract surgery in a contralateral eye study.

Methods: In this prospective randomized parallel-group study, 25 patients with bilateral age-related cataract, were implanted in one eye with the EnVista IOL (MX60, Bausch & Lomb Corporations, Rochester, NY, USA) and the Acrysof IQ IOL (Acrysof IQ SN60WF, Alcon Surgical Laboratories, Fort Worth, TX, USA) in the other eye. Uncorrected and corrected distance visual acuity (UDVA, CDVA), refractive status, higher-orders aberrations (HOAs) in 5 and 6 mm pupil size, contrast sensitivity (CS) with and without glare, color vision status and patient satisfaction were assessed in the two eyes at 1 and 3 months after surgery.

Results: There was no significant difference in CDVA ($P > 0.99$), UDVA ($P = 0.46$), spherical equivalent refractive error ($P = 0.63$), CS with and without glare across different spatial frequencies, color vision and root mean square (RMS) of aberrometric values between the two IOLs after 3 months follow-up. Spherical aberration with 5 and 6 mm pupil sizes ($P= 0.02$) and horizontal coma with a 6 mm pupil size ($P< 0.001$) were lower with the EnVista IOL. Patient's satisfaction showed no cases of dissatisfaction and most patients were highly or moderately satisfied with both IOLs.

Conclusions: The visual and optical performance of eyes implanted with the EnVista IOL or the Acrysof IQ IOL was similar, although the aberration profile differed.

Keywords: Intraocular lens; EnVista; Acrysof IQ; Visual acuity; Contrast sensitivity; Glare.

INTRODUCTION

Cataract, as a leading cause of visual impairment, is a common disease in the elderly and its prevalence increases with age.[1, 2] Nowadays, patients with cataract have a high level of visual and functional expectations from cataract surgery as a lenticular based refractive surgery technique.[3, 4] Despite the improvements in surgical techniques and intraocular lens (IOL) materials, implantation of IOL may yield some functional problems such as the haloes around the lights, photophobia, and glare in surrounding bright environments.[5] However, the severity of these conditions is related to factors such as age, corneal transparency, residual astigmatism, and design of the IOL.[6] Previous studies have shown that contrast sensitivity is a better representative of visual performance compared to visual acuity.[5, 7] Although spherical and cylindrical components of refractive errors adversely influence visual function as a result of producing a blurred retinal image, certain types of induced wave-front aberrations such as spherical aberrations (SA) and coma have a greater impact on contrast sensitivity and visual performance.[8, 9] Hence, the aberrations of an IOL should be considered when aiming to provide excellent visual quality for patients after cataract surgery.

The most suitable type of IOL for a patient with cataract is the lens, which neutralizes or reduces ocular aberrations effectively, in addition to improving visual acuity.[10] For these purposes, aspherical IOLs were developed, of which of the main commercially available types, one induces a negative SA and the other one retains a slight positive SA for the eyes and consequently increases the depth of focus.[5, 7, 11] In the former, the design aims to neutralize the positive SA of the cornea, reducing the total SA of the eye close to zero (aberration-correcting IOLs).[12] One example in this group is Acrysof IQ (SN60WF model, Alcon Laboratories, Fort Worth, TX, USA). It was claimed that Acrysof IQ not only decreases SA and higher-orders aberrations (HOAs), but also improves mesopic contrast sensitivity and finally provides a superior visual function.[11] One example in the latter group is EnVista IOL (MX60 model, Bausch & Lomb, Rochester, NY, USA).

In addition to its UV blocking feature and soft 360-degree squared edges, which minimize the possibility of postoperative posterior capsular opacity, one of the unique properties of EnVista is the glistening-free feature.[13-15] It was reported that glistening have a significant negative effect on high spatial frequency contrast sensitivity (CS) and visual acuity.[16-18]

Therefore, the current study was designed to compare postoperative changes in visual acuity (VA), contrast sensitivity (CS), higher-orders aberrations (HOAs), color vision, and satisfaction of the patients following implantation of EnVista IOL in one eye and Acrysof IQ IOL in the other eyes using phacoemulsification cataract surgery.

METHODS

This prospective randomized parallel-group design study included 25 patients (50 eyes) diagnosed with bilateral clinically significant age-related cataract and confirmed by a well-experienced corneal specialist (SZ) at the Khatam-Al-Anbia Hospital, Mashhad, Iran. The study protocol was approved by the Ethics Committee of Mashhad University of Medical Sciences, Mashhad, Iran (Code No.: 4452284) and followed the tenets of the Declaration of Helsinki. Those who met the inclusion criteria were approached about taking part in the study. After explaining the aim of this study, the current condition of the eye, the surgical techniques and possible postoperative complications, written informed consent was obtained from all patients.

The inclusion criteria were good general health, age range between 50 to 75 years, axial length between 22 to 25 mm, corneal astigmatism up to 2.00 diopters and preoperative corrected distance visual acuity (CDVA) worse than 20/40. Patients with more than 1 mm difference in axial length between the two eyes, more than 2.00 diopters corneal astigmatism, previous ocular surgery, ocular pathologies such as corneal opacity or irregularity, severe ocular surface disease

or dry eye, amblyopia, glaucoma, pseudoexfoliation syndrome and retinal diseases were excluded from the study.

Along the standard ophthalmic examinations including preoperative uncorrected and corrected distance visual acuity (UDVA & CDVA), refractive assessment using Topocon auto-keratorefractometer (Topcon KR-8800, Topcon Hong Kong Ltd.) and refined by subjective refraction, dilated fundus examination; contrast sensitivity assessed with the CSV 1000E (Vector Vision Inc., Dayton, Ohio, USA) with and without glare in photopic (85 cd/m2) conditions, ocular aberrometry using a Zywave aberrometer (Zyoptix system, Bausch & Lamb, USA), color vision assessment using the Farnsworth-Munsell Dichotomus D-15 test, and the IOL power calculation using the LENSTAR LS900 optical biometer (Haag-Streit AG, Koeniz, Switzerland) with a target correction set to -0.25 D were conducted for each patient.

All cataract surgeries were carried out by an experienced surgeon (SZ) with an identical technique by means of Fritz Ruck Pentasys2 phaco unit (Ophthalmologische Systeme GmbH, Eschweiler, Germany) based on Phaco chop technique through a 2.4 mm clear cornea incision. A similar target refraction -0.25 postoperatively was considered for the two eyes of each patient. The IOL type was randomly selected so that Acrysof IQ IOL was implanted in one eye and the EnVista IOL in the contralateral eye within 4 to 6 weeks of the first eye. Cataract surgery was done sequentially to minimize the risk of postoperative endophthalmitis as much as possible.[19, 20] Therefore due to some social constrains and ethical considerations it was acceptable to perform sequential surgery instead of simultaneous.

The primary characteristics and platforms of the two IOLs which were approved by Food and Drug Administration (FDA) and applied in the current study are presented in Table 1.

Table 1: Characteristics of the two IOLs implanted in the current study.

IOL characteristics	EnVista	Acrysof IQ
Type	single-piece	single-piece
Material specifications	Ultraviolet blocking Hydrophobic acrylic Glistening-free	Ultraviolet and blue light filtering Acrylate/Methacrylate Copolymer
Total diameter (mm)	12.50	13.00
Optic diameter (mm)	6.00	6.00
Angle (degrees)	0	0
Refractive index	1.54	1.55
Optic configuration	Biconvex Equal front and back asphericity	Biconvex Aspherical posterior surface
Manufacturer	Bausch & Lomb	Alcon

Visual acuity was recorded in decimal notation and converted to logarithm of minimum angle of resolution (LogMAR) for the analytical purpose. Contract sensitivity was measured at a test distance 2.5 meters and at 4 spatial frequencies (3, 6, 12, and 18 cycle per degree (cpd)). The CS values were transformed into logarithmic values (based on Vector Vision instruction). Color vision status was evaluated with Farnsworth-Munsell Dichotomus D-15 test at a testing distance of 50 cm on a black background under an illuminance level of 270 lux.[21]

More than one single-place error was considered as failure criterion. For aberrometry analyses, the root-mean-square (RMS) values of total higher orders aberrations (HOA), spherical (SA, Z400), horizontal and vertical coma aberrations and HOA without SA in both pupil sizes 5 and 6 millimeter were recorded in microns using a Zywave aberrometer. In addition to the refractive status (SE: spherical equivalent) and visual assessments (UDVA, CDVA, CS with and without

glare in photopic conditions and color vision assessment), the patient's satisfaction of the visual outcome was investigated subjectively using a 5-point question based on their current visual status (0: very satisfied, 1: satisfied; 2: neutral, 3: dissatisfied, 5: very dissatisfied)[22] one and three months after surgery. Aberrometric measurements were performed 3 months postoperatively.

Similar test conditions were used for all patients by a well-qualified examiner (NM) who was masked as to which IOL had been implanted in each eye.

Twenty-five patients (50 eyes) were included for the statistical analysis. The sample size was calculated based on a preceding pilot study in which visual function of 10 eyes in each group were assessed. Based on the mean and standard deviation of contrast sensitivity at spatial frequency 3 at a distance of 3 m (variable calculating with the highest sample size), a 2-sided significance level (alpha) 0.05 and power (i.e. probability of detection) 0.80 or 80%, the sample size was calculated for each group was 22 eyes. Considering the subject dropout rate of 15%, the sample size increased to 25 patients. Data were analyzed in the SPSS software (version 16.0, SPSS, Inc.). The data was assessed using the Kolmogorov-Smirnov test and as this showed it was significantly different from a normal distribution, the Mann-Whitney U test was used to compare the mean values of optical and visual parameters between the two IOL groups. The distribution of color vision dysfunction in the two groups was assessed using the Chi-square test. A p-value less than 0.05 was considered significant statistically.

RESULTS

The mean age of 25 patients was 66±4.1 years (age range 57 to 73 years), with 18 being male.

Mean UDVA, CDVA, SE one and three months after surgery separately in the two groups are presented in Table 2. (Table 2)

Table 2: Mean Visual and refractive parameters separately in the two groups 1 and 3 months postoperatively. (n= 50 eyes) (UDVA: Uncorrected distance visual acuity, CDVA: Corrected distance visual acuity, SE: Spherical equivalent, cpd: cycles per degree, CI: Confidence interval, SD: standard deviation)

Variables		**Mean±SD (95% CI)**		**P-value**
		EnVista (n= 25 eyes)	**Acrysof IQ (n= 25 eyes)**	
UDVA (LogMAR)	**1 m**	0.04±0.05 (0.02 to 0.06)	0.11±0.14 (0.05 to 0.17)	0.004
	3 m	0.04±0.05 (0.02 to 0.06)	0.06±0.11 (0.55 to 0.64)	0.46
CDVA (LogMAR)	**1 m**	0.0±0.02 (-0.01 to 0.01)	0.0±0.02 (-0.01 to 0.01	0.78
	3 m	0.0±0.0 (0.0)	0.0±0.0 (0)	>0.99
SE (D)	**1 m**	-0.24±0.42 (-0.41 to -0.07)	-0.38±0.78 (-0.70 to -0.06)	0.24
	3 m	-0.24±0.56 (-0.47 to -0.01)	-0.34±0.62 (-0.67 to -0.15)	0.63

There was no significant difference in refractive and visual acuity outcomes between the two IOLs at 1 and 3 months after cataract surgery.

The mean logarithm of CS without and in the presence of glare source at different spatial frequencies are represented in Table 3.

Table 3: Mean logarithm of CS with and without glare at different spatial frequencies 1 and 3 months postoperatively in the two groups. (n= 50 eyes) (cpd: cycles per degree, CI: Confidence interval, SD: standard deviation)

Variables		**Without Glare**			**With Glare**		
		Mean ± SD (95% CI)		**P-value**	**Mean ± SD (95% CI)**		**P-value**
		EnVista (n= 25 eyes)	**Acrysof IQ (n= 25 eyes)**		**EnVista (n= 25 eyes)**	**Acrysof IQ (n= 25 eyes)**	
3 cpd	**1 m**	1.62 ± 0.33 (1.47 to 1.73)	1.54 ± 0.31 (1.40 to 1.65)	0.77	1.51 ± 0.32 (1.36 to 1.61)	1.46 ± 0.33 (1.32 to 1.58)	0.84
	3 m	1.87 ± 0.15 (1.81 to 1.93)	1.77 ± 0.15 (1.72 to 1.83)	0.59	1.70 ± 0.12 (1.66 to 1.75)	1.69 ± 0.15 (1.62 to 1.75)	0.26
6 cpd	**1 m**	1.79 ± 0.34 (1.64 to 1.91)	1.79 ± 0.33 (1.64 to 1.91)	0.26	1.68 ± 0.40 (1.52 to 1.84)	1.61 ± 0.45 (1.42 to 1.78)	0.86
	3 m	2.05 ± 0.16 (1.99 to 2.11)	2.00 ± 0.14 (1.95 to 2.06)	0.67	1.93 ± 0.15 (1.87 to 1.99)	1.97 ± 0.14 (1.92 to 2.03)	0.80
12 cpd	**1 m**	1.46 ± 0.36 (1.31 to 1.59)	1.44 ± 0.45 (1.25 to 1.60)	0.49	1.40 ± 0.45 (1.22 to 1.56)	1.27 ± 0.42 (1.09 to 1.42)	0.99
	3 m	1.72 ± 0.20 (1.64 to 1.80)	1.67 ± 0.16 (1.60 to 1.72)	0.73	1.66 ± 0.17 (1.59 to 1.72)	1.61 ± 0.21 (1.53 to 1.69)	0.30

18 cpd	**1 m**	1.00 ± 0.43 (0.83 to 1.15)	0.95 ± 0.41 (0.79 to 1.10)	0.64	0.92 ± 0.40 (0.76 to 1.07)	0.86 ± 0.40 (0.68 to 1.00)	0.40
	3 m	1.23 ± 0.20 (1.15 to 1.31)	1.21 ± 0.23 (1.12 to 1.30)	0.72	1.22 ± 0.17 (1.15 to 1.28)	1.19 ± 0.22 (1.10 to 1.27)	0.89

The Mann-Whitney U test showed no statistically significant difference in CS in all spatial frequencies between EnVista and Acrysof IQ IOLs with and without glare.

The mean aberrometry data separately for the eyes implanted with EnVista and Acrysof IQ IOLs three months after surgery are presented in Table 4.

Table 4: Mean aberrometric data (µm) in 5 and 6 millimeters pupil sizes at 3 months postoperatively separately for two IOL groups. (n= 50 eyes) (HOA: High order aberrations, RMS: Root mean square (RMS), Spherical Z400: Forth order's spherical aberration, HOA W/O Z40: HOA without forth order's spherical aberration)

IOLs / **Aberrations & Pupil Size**		**Mean ± SD (95% CI)**		**P-value**
		EnVista (n= 25 eyes)	**Acrysof IQ (n= 25 eyes)**	
Spherical Z400	**5 mm**	0.06 ± 0.09 (-0.02 to 0.11)	0.12 ± 0.08 (0.08 to 0.15)	0.02
	6 mm	0.18 ± 0.19 (0.09 to 0.27)	0.31 ± 0.18 (0.22 to 039)	0.02
Horizontal coma	**5 mm**	0.09 ± 0.18 (-0.18 to -0.02)	0.04 ± 0.07 (0.01 to 0.07)	0.20

	6 mm	-0.17 ± 0.34 (-0.35 to -0.04)	0.09 ± 0.14 (0.02 to 0.15)	<0.001
Vertical coma	**5 mm**	0.03 ± 0.10 (-0.01 to 0.07)	0.02 ± 0.18 (-0.05 to 0.10)	0.81
	6 mm	0.10 ± 0.19 (0.02 to 0.20)	0.10 ± 0.29 (-0.03 to 0.23)	0.91
HOAs RMS	**5 mm**	0.38 ± 0.07 (0.28 to 0.55)	0.32 ± 0.08 (0.29 to 0.36)	0.44
	6 mm	0.68 ± 0.60 (0.50 to 0.99)	0.59 ± 0.13 (0.54 to 0.65)	0.49
HOA W/O Z_4^0	**5 mm**	0.36 ± 0.33 (0.26 to 0.52)	0.28 ± 0.09 (0.24 to 0.32)	0.29
	6 mm	0.63 ± 0.60 (0.44 to 0.92)	0.49 ± 0.15 (0.41 to 0.56)	0.32

Spherical aberration in both pupil diameters was more positive in eyes implanted with Acrysof IQ IOL than in eyes with Envista IOL. There was a significant difference between the two IOLs in SA with 5 (P= 0.02) and 6 (P= 0.02) mm pupil, and horizontal coma with 6 mm pupil diameter (P< 0.001). While there was no statistically significant difference across other postoperative aberrometry data between two IOLs in both pupil analysis sizes. (P> 0.05)

Color vision status improved during postoperative assessments from 1 to 3 months with both IOLs. The eyes with color dysfunction in Acrysof IQ and Envista groups were 10 and 8 eyes one month, and 3 and 2 eyes three months after surgery, respectively. Chi-square test did not show significant differences in the distribution of eyes with color defect in one (P= 0.26) and three (P= 0.56) months in the two IOL groups postoperatively.

Assessing patient satisfaction using a 5-item questionnaire indicated that there have been no cases of dissatisfaction 3 months after surgery, and approximately all patients were highly or moderately satisfied with both IOLs. Satisfaction with the Envista (Acrysof IQ) IOL 1 month after surgery was 72% (70%) very satisfied, 24% (26%) satisfied and 4% (4%) with neutral which was 48% (49%) very satisfied and 52% (51%) satisfied 3 months after surgery without a statistically significant change between the two IOLs. (P> 0.05)

DISCUSSION

The results of the present study demonstrated no statistically significant difference in most optical and visual parameters assessed between the EnVista and Acrysof IQ IOLs, except for their in eye aberrations. A contralateral eye study was conducted to minimize physiological variation, increasing the sensitivity to detect differences. A possible limitation of the current study may appear no including preoperative assessments; however, accurate determination of visual parameters such as VA, CS, refraction and aberrometric data is not possible due to the interference of crystalline lens opacity in the measurements. As a result, preoperative data were not included in this study.

Many studies have investigated the quality of visual performance after cataract surgery with various kinds of IOLs, showing improvement in visual outcomes as expected after cataract removal.[23-26]

Monofocal IOL can be designed as spherical and aspherical IOLs. Aspherical IOLs produce negative or zero SA, leading to a smaller amount of postoperative SA as compared to spherical IOLs.[10, 27] The advantages of aspherical IOLs over their spherical counterparts have been demonstrated in some studies.[24, 28] Although, there have been a few studies comparing visual

function against one-piece aspherical hydrophobic IOLs,[29, 30] the current study was designed to investigate the postoperative visual performance in patients who underwent cataract surgery and were implanted contralaterally with two aspherical IOLs, EnVista and Acrysof IQ.

Acrysof IQ is an aspherical IOL which yields a negative SA to the eyes to neutralize positive SA of the cornea.[11] Basic studies have shown that the positive SA of the human visual system increases with age.(22) The modified prolate anterior surface of the Acrysof IQ was optimized for neutralizing the average level of positive SA.[12] On the other hand, EnVista is an aberration-free aspherical IOL to retain minor positive SA for the eyes to maximize the depth of focus.[15] A unique feature of EnVista, stated by its manufacturer, is called glistening-free property.[13-15, 31] Glistenings are micro-vacuoles that appear within an IOL material, and are commonly seen in hydrophobic acrylic IOLs. They may cause forward-scattering of the light going to the eye, and accordingly degrade visual function. *In-vitro* studies have not revealed that glistenings significantly reduce optical quality,[32] or induce light scattering by IOL.[33] Similar to these results, the current study does not show a significant difference in the RMS of total HOAs between AcrySof IQ and EnVista IOLs.

The EnVista IOL (aspheric IOL with no aberration) showed statistically less aberrations compared to Acrysof IQ IOL (aspheric IOL with negative SA) in terms of spherical aberration; this concurs with the results of Denoyer and colleagues in comparing the SofPort Advanced Optics IOL with zero SA and the Tecnis Z9000 IOL with negative SA. [34] However, they reported a better quality of near vision in the eyes with zero SA implanted IOLs six months after surgery.

No difference in CDVA between the two IOLs at 1 and 3 months after cataract surgery in the present study concurs with a previous study by Yadav and colleagues, who compared two kinds of aspherical IOLs one with negative aberration (AcrySof IQ) and another with neutral aberration (Acriol EC) and found no significant difference in the mean postoperative CDVA at 1, 3, 6 and 12 months postoperatively.[35] Other studies also reported improved postoperative UCVA and CDVA

in both IOL groups at the end of 3 months with no statistical difference between the two groups.[29, 36]

A unique feature of the current study was the measurement of CS both with and without a glare source. Notwithstanding there was no significant difference in CS measurements in both IOLs with and without glare postoperatively. Better marginal CS findings in the eyes implanted with the EnVista IOL compared to Acrysof IQ group may be attributed to the glistening-free feature of EnVista IOL. One advantage of IOLs with zero SA is that their postoperative decentration does not exaggerate existing aberrations, while, decentration of IOLs with negative SA may produce coma aberration.[37, 38] Another explanation for slightly better performance with EnVista IOL using CS measurement may be related to higher SA values and horizontal coma aberration in 6 mm pupil in Acrysof IQ group. Such a difference in SA between Tecnis Z9000 IOL and Acrysof MA60BM IOL has previously been reported with greater SA with Acrysof lens. [29, 39]

Color vision assessment showed no difference between the two IOLs, but the distribution of color vision inaccuracy in the Acrysof IQ lens was slightly higher. Acrysof IQ is a blue light-filtering IOL and blue light-filtering IOLs may have a negative impact on contrast acuity as well as blue/yellow foveal threshold.[40] However, the effect of blue light-filtering IOLs on color vision status showed no significant difference between blue light-filtering IOLs and traditional IOLs, [41-43] which confirm the results of the current study. Such a lack of difference was also reported in eyes implanted with a UV-filtering IOL (AcrySof SA60AT; Alcon) and a blue light-filtering IOL (AcrySof SN60AT) in terms of color vision testing and contrast sensitivity.[44]

Patient satisfaction implanted with both IOLs was high at the first follow-up. This remarkable early satisfaction, despite incomplete visual recovery and some degrees of ametropia, was probably related to the opacity extraction and a considerable increase in the patient's visual quality than preoperative visual function. Nonetheless, longer satisfaction may change due to postoperative complications especially posterior capsular opacity (PCO) formation.[45] Both IOLs resulted in a

significant enhancement in the visual function of the patients. Our findings affirm the previous studies regarding the benefits of cataract surgery, which found great improvement in visual performance.[31] In conclusion, presenting both EnVista and Acrysof IQ lenses may be considered as a suitable option for patients who desire to have a good visual quality with minimal visual complications after cataract surgery.

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