ORIGINAL ARTICLE

Evaluating the Clinical Outcomes of a Wavefront-shaping Presbyopia-correcting IOL Post Bilateral Implantation in an Indian Population

Sudipto Pakrasi, Carreen Pakrasi, Suman Chaudhary

ABSTRACT

Background: **The study aimed at evaluating the clinical performance of wavefront-shaping presbyopia-correcting intraocular lens (IOL) up to 3 months post bilateral implantation in a real-world setting through routine clinical practice.**

Methods: **This ambispective, observational study involved 50 participants who underwent bilateral implantation of a novel wavefront-shaping presbyopia-correcting IOL. For all the participants, subjective refraction and defocus curve were made. The parameters evaluated binocularly 1 and 3 months following second eye surgery include binocular uncorrected near visual acuity (UCNVA) at 40 cm, binocular uncorrected distance visual acuity (UCDVA) at 6 m, binocular uncorrected intermediate visual acuity (UCIVA) at 66 cm. The visual disturbances and contrast sensitivity were assessed based on McAlinden questionnaire and Pelli-Robson's chart respectively.**

Results: **In the present study, the mean age observed was 64.68 ± 7.83years with female dominance (65.38%). After 1-month of 2nd eye surgery, the binocular UCDVA (6/6), UCIVA (N6), and UCNVA (N6) were observed to be 92%, 88% and 76%, respectively, while the same improved at 3-months post-surgery to 100%, 100%, and 96%, respectively. At 3 months, the IOL was very well tolerated and 90% or more of the subjects reported "never" experiencing symptoms. Binocular contrast sensitivity testing revealed the Mean ± SD contrast of 1.63 ± 0.18 and the binocular defocus curve showed consistently good visual acuity between a defocus of -0.5 D and -2.50 D.**

Conclusion: **The study confirmed that bilateral implantation of novel wavefront-shaping presbyopia-correcting IOLs provided a range of vision from distance to functional near in most of the patients with minimal bothersome visual disturbances.**

KEY WORDS

cataract surgery, extended depth of focus IOL, presbyopia, spectacle independence

INTRODUCTION

Patients undergoing cataract surgery usually desire to see without spectacles. Intraocular lenses (IOLs) were devised to meet this expectation, as they offer functional visual acuity, in addition to facilitating better quality of life as most patients who have these lenses do not need to wear spectacles for their everyday activities[1,2].

Cataract surgery may be defined as a refractive treatment, with a strong possibility that patients will not require spectacles for distant vision when a monofocal IOL is implanted. IOLs with a focal or extended depth of focus (EDOF) may be explored for those who want to reduce their dependence on glasses for intermediate (computing) or close (reading) vision[3].

A number of IOLs aimed at treating presbyopia have been developed over the last 20 years. The multifocal IOL, first launched in the 1980s, now delivers good distant, intermediate, and close vision with trifocal technology, resulting in a high frequency of spectacle independence.[4] IOLs with extended-depth-of-focus (EDOF IOLs) are known to have lesser amount of troublesome optical phenomena and provide very good distance and intermediate vision[5,6].

A new presbyopia-correcting AcrySof IQ Vivity® (Alcon Inc., USA) IOL with wavefront-shaping technology (model DFT015, DFT315, DFT415, DFT515) was recently introduced in India. According to the information provided by the manufacturer, the IOL is the first and only EDOF IOL with the wave-front shaping (X-WAVE™) technology which uses innovative wavefront-shaping technology (X-WAVE) that consists of two smooth surface transition elements that stretch and shift the wavefront to provide a continuous extended range of vision, good mesopic contrast sensitivity; and a visual disturbance profile similar to that of a monofocal lens[7].

The objective of this study was to evaluate the clinical performance of wavefront-shaping presbyopia-correcting IOL up to 3 months post bilateral implantation in a real-world setting through routine clinical practice.

METHODS

The present ambispective, observational study was carried out at Medanta Institute of Education and Research, Gurugram for duration of six months. This study was conducted on 50 participants of either gender with non-traumatic cataracts with Nuclear Sclerosis Grade I to IV cataracts as per LOCS III criteria were included in the study. The patients underwent bilateral implantation of a novel wavefront-shaping presbyopia-correcting IOL (toric and non-toric) (AcrySof IQ Vivity®, Alcon Inc., USA). Ethical clearance was obtained by the institutional

Received on February 16, 2023 and accepted on March 1, 2023
Division of Ophthalmology, Medanta The Medicity
Gurugram, India
Correspondence to: Sudipto Pakrasi
(e-mail: sudiptopakrasi@gmail.com)

Table 1: Distribution of subjects according to age and gender

Age	Age ranges (years)	Number of subjects (%)
	40-49	2 (4%)
	50-59	9 (18%)
	60-69	26 (52%)
	70-79	12 (24%)
	80-89	1 (2%)
	Mean ± SD	64.68 ± 7.83
	Median (Min, Max)	65.50 (41, 88)
Gender	Female	33 (66%)
	Male	17 (34%)

study review board (Ref#1351/2021). Adult subjects (18 years or older), who were willing to participate and provided written informed consent were included in this study. The exclusion criteria comprised subjects who were participating in another investigational drug or device study at the same time, corneal refractive surgery post-Vivity IOL implantation, manifest refraction (spherical equivalent) > 0.75 D postoperatively, pregnancy at the time of enrolment and patients with any pre-existing ocular co-morbidities/prior refractive surgery.

For all the participants, subjective refraction and defocus curve were made. The parameters evaluated binocularly 1 and 3 months following second eye surgery include binocular uncorrected near visual acuity (UCNVA) at 40 cm, binocular uncorrected distance visual acuity (UCDVA) at 6 m, binocular uncorrected intermediate visual acuity (UCIVA) at 66 cm. The visual disturbances were assessed by McAlinden questionnaire at 3 months and binocular contrast sensitivity testing was carried out using Pelli-Robson's chart[8,9].

STATISTICAL ANALYSES

Data was analyzed using R software (version 4.1.2) and Microsoft Excel. Categorical variables were represented by frequency and percentage. Continuous variables were represented in Mean ± SD/ Median (Min, Max) form. Friedman test was used for visual acuity comparison, wherein p values ≤ 0.05 were considered significant.

RESULTS

In the present study, the age of 50 subjects ranged from 41-88 years with mean age 64.68 ± 7.83years. Out of 50 subjects, more than 50% were above 60 years, and female dominance was observed with a gender ratio of 1: 1.89 (Table 1).

About 92% of the subjects had post-operative binocular UCDVA of 6/6 at1-month follow-up, after 2nd eye surgery, and all subjects had post-operative binocular UCDVA of 6/6 at 3 months follow-up, after 2nd eye surgery (Table 2).

Out of 50 subjects, 14% had N5, 76% had N6, and 10% had N8 binocular UCNVA in 1-month post-operatively after 2nd eye surgery, whereas 96% had N6 binocular UCNVA and 4% had N8 binocular UCNVA at 3 months post operatively after 2nd surgery (Table 2).

Table 3 represents the summary of the quality of vision questionnaire (QoV). At3 months, the IOL was very well tolerated. For glare, halos, and starbursts, 90% or more of subjects reported a frequency of "not at all", similarly 90% or more of subjects reported severity of "never" and 92% or more of subjects reported a degree of bother of "not at all".

The distribution of binocular contrast sensitivity testing using Pelli-Robson's chart is presented in Table 4.

The binocular defocus curve showed consistently good visual acuity between a defocus of -0.5 and -2.50 D (Figure 1), similar to the outcomes of the USFDA study with the curve touching 0 logMAR (20/20) for distance, 0.1 logMAR (20/25) for intermediate and close to 0.2 logMAR (20/32) for near.[10]

Table 2: Distribution of BUCDVA, BUCIVA and BUCNVA at 1-month and 3 months post-operatively after 2nd eye surgery

Binocular UCDVA	Number of subjects (%)	
	1 month	3 months
6/6	46 (92%)	0
6/9	4 (8%)	50 (100%)
Binocular UCIVA	**Number of subjects (%)**	
	1 month	**3 months**
N5	2 (4%)	0
N6	44 (88%)	50 (100%)
N8	4 (8%)	0
Binocular UCNVA	**Number of subjects (%)**	
	1 month	**3 months**
N5	7 (14%)	0
N6	38 (76%)	48 (96%)
N8	5 (10%)	2 (4%)

DISCUSSION

To minimize postoperative dissatisfaction, awareness of the numerous alternatives for presbyopia correction, as well as patient selection, is critical. Understanding the fundamental distinctions that distinguish different technologies is helpful in predicting and analysing clinical results[11].

AcrySof Vivity is a new and first of its kind of non-diffractive (X-wave technology) Extended Depth of focus intraocular lens from Alcon built on the Acrysof platform. It is claimed to provide distance vision comparable to its respective monofocal (AcrySof IQ), additionally providing superior intermediate and near vision than the monofocal. The AcrySof IQ Vivity IOL is a single-piece, hydrophobic aspheric posterior chamber IOL with blue-light filter and ultraviolet protection[3]. It has a total length of 13 mm and an optical zone of 6 mm with a new optical principle in the central 2.2 mm of the IOL to increase the depth of focus[2].Being a non-diffractive design, the lens may also be devoid of the visual disturbances typically associated with other diffractive multifocals, trifocals, and EDoFs[4,7].

Previously, EDOF IOLs were thought to be less effective than trifocal IOLs in correcting various vision distances, especially for close vision. However, EDOF IOLs are less influenced by visual discomfort observable in low luminance and night settings. Because of the technological properties of the IOL, AcrySof IQ Vivity is managed similarly to monofocal IOLs, as opposed to trifocal IOLs, which require greater pre-operative work up for successful implantation and better patient satisfaction. Furthermore, compared to diffractive trifocal IOL technology, the postoperative visual problems were significantly reduced with EDOF IOL technology[4,7].

The present study marked improvement for long and intermediate vision. A 6/6 binocular UCDVA and N6 binocular UCIVA were noted following the 2nd eye surgery in all patients, 3 months after implantation of the AcrySof IQ Vivity IOL. Similarly, Baur *et al*. implanted a patient with AcrySof IQ Vivity IOL and observed good functional results for long and intermediate distances[12]. In an interventional prospective case series of early real-world experience, Arrigo *et al*. observed that the AcrySof IQ Vivity IOL provided remarkable distance and intermediate vision[13]. In accordance with this, Thomas Kohnen noted a considerable improvement in the binocular UCDVA and binocular UCIVA after implantation of AcrySof IQ Vivity IOL[2]. In another real real-world study, Hovanesian et al. noticed that the AcrySof IQ Vivity extended the depth of focus IOLs and provided a comparable range of uncorrected vision to previous multifocal implant[14].

Arrigo *et al*. observed that patients implanted with the AcrySof IQ Vivity IOL required some spectacle for near vision[13], whereas the clinical results from prospective clinical trials revealed the ability of the AcrySof IQ Vivity IOL to offer an extended depth of focus, with improvements in near visual acuity[15]. Similar to this, in this study, most of the patients had N6 binocular UCNVA at 3 months post-operatively

Table 3: Summary of Quality of Vision Questionnaire (QoV)

	How Severe		How Bothersome		How often	
	Sub Category	Number of Subjects (%)	Sub Category	Number of Subjects (%)	Sub Category	Number of Subjects (%)
Glare	Never	50 (100%)	Not at All	50 (100%)	Not at All	46 (92%)
	Sometimes	0	Occasional	0	Minimal	2 (4%)
	Often	0	Moderate	0	Moderate	2 (4%)
	Very Often	0	Severe	0	Severe	0
Halos	Never	46 (92%)	Not at All	47 (94%)	Not at All	45 (90%)
	Sometimes	4 (8%)	Occasional	2 (4%)	Minimal	2 (4%)
	Often	0	Moderate	1 (2%)	Moderate	3 (6%)
	Very Often	0	Severe	0	Severe	0
Starbursts	Never	45 (90%)	Not at All	46 (92%)	Not at All	50 (100%)
	Sometimes	5 (10%)	Minimal	3 (6%)	Minimal	0
	Often	0	Moderate	1 (2%)	Moderate	0
	Very Often	0	Severe	0	Severe	0

Table 4: Distribution of contrast sensitivity

Variable	Mean ± SD	Median (Min, Max)
Contrast sensitivity	1.63± 0.18	1.60 (0.9, 1.80)

after the 2nd surgery. McCabe *et al*. evaluated the effectiveness and safety of the DFT015 intraocular lens (IOL) (AcrySof IQ Vivity Extended Vision) and found that DFT015 was effective in providing a continuous range of vision with superior intermediate and near vision, which was consistent with the oservations of the present study[16].

In the present study, the binocular defocus curve showed consistently good visual acuity between a defocus of -0.5 and -2.50 D, in accordance with the results of Fernández-Vega-Cueto *et al*. who noted that the mean visual acuity was better than 0.2 logMAR between +1.00 and -2.00 D of defocusin individuals who had bilateral implantation of AcrySof IQ Vivity IOL[17]. Thomas Kohnen, after implantation of the AcrySof IQ Vivity IOL noted that visual acuity was continuously good over the monocular/binocular defocus curve[2].

Rementerı´a-Capelo *et al*. observed promising results, with a higher patient satisfaction rate, and minimal difficulties in day-today activities after implantation of the Vivity IOL in individuals with coexisting ocular pathologies[18]. As per literature, AcrySof IQ Vivity IOL is safe and severe visual abnormalities (such as starbursts, halos, and black patches) were uncommon[7,15]. In line with this, in the present study the IOL was very well tolerated and most of the subjects reported "never" experiencing any symptoms like glare, halos and starbursts. Similarly, Arrigoet al. observed that the AcrySof IQ Vivity IOL provided a higher satisfaction rate and tolerability to AcrySof IQ Vivity IOL[13]. In accordance with this, Hovanesian *et al*. noticed a significantly lesser rate of glare and halo in patients treated with the AcrySof IQ Vivity IOL compared to multifocal IOLs[14]. Fernández-Vega-Cueto *et al*. evaluated in vitro optical quality and halo formation in subjects who had bilateral implantation of AcrySof IQ Vivity IOL, and observed that the overall halo formed was low in intensity[17]. The present study revealed higher values of safety findings starbursts 92%), halos (94%), and glare (100%), of as compared to the results of Bala *et al*. with the proportion of patients who reported "not bothered at all" by individual visual disturbances at 6 months, starbursts (72.6%), halos (75.5%), and glare (73.6%), respectively all assessed using the Quality of Vision questionnaire as in the present study[19].

In the present study, the visual acuity dropped from N5 to N6 from 1 month to 3 months in 14% subjects. The possible explanation for this could be the presence of some amount of residual astigmatism < 0.5D which could not be corrected or some cataract patients may have developed post operative dry eye symptoms leading to a drop in VA outcomes over the previous visit. Another possible contributing factor could be the use of a trial frame in the testing process of visual acuity instead of phoropter. Pantoscopic tilt, optical centering and inter-pupil distance significantly affected the optics of the trial lenses and hence the VA outcomes[20].

Findings from the present study are encouraging and these must of course be confirmed and complemented by further clinical research with a larger number of samples from multiple centers.

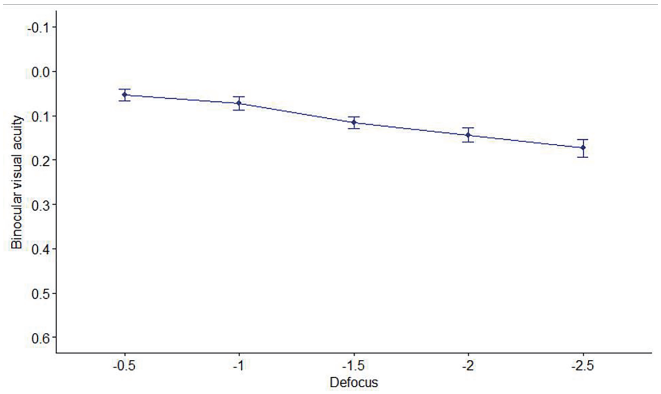

Figure 1: Defocus curve

The limitations of the present study are outweighed by its strengths, including the fact that it was a ambispective, observational study. Findings from the present study are encouraging and these must of course be confirmed and complemented by further clinical research with a larger number of samples from multiple centers.

CONCLUSION

In conclusion, the observations from this study confirm that bilateral implantation of novel wavefront-shaping presbyopia-correcting IOLs provided a range of vision from distance to functional near in most of the patients with minimal bothersome visual disturbances. Bilateral implantation of AcrySof IQ Vivity IOL could be a better option for individuals undergoing cataract surgery and desiring independence from optical aids.

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