



Research Article

Visual Outcomes with Binocular Implantation of the Extended Monofocal Non-Diffractive Intraocular Lens

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Abstract

Aim: To evaluate the performance of a new Extended Depth Of Focus (EDOF) Evolux Intraocular Lenses (IOLs), an extended monofocal IOL with a non-diffractive profile designed to improve intermediate vision while providing distance vision comparable to monofocal IOLs, in terms of Visual Acuity (VA) at various distances and contrast sensitivity .

Materials and methods: Twenty five patients (50 eyes) were included in this retrospective case series. Every patient underwent bilateral implantation of Evolux IOLs after cataract surgery. Preoperative and postoperative parameters evaluated included axial length, IOL power, refractive error in terms of spherical equivalent (SE) and VA for various distances. Patients were reviewed periodically after surgery. At 1 month after surgery, Contrast Sensitivity (CS) was assessed.

Results: The study included 14 (56%) male and 11 (44%) female patients. Significant improvement in VA was observed at all distances. When assessing unocular VA, near VA > N8 was seen in 80% of eyes, intermediate VA > 6/9 was seen in 54% eyes and distance VA > 6/6 was seen in 96% eyes. Binocular VA at 1 month showed 92% of patients with near vision comparable to N8 or better and 96% with distance vision of 6/6 or better. The mean CS was 0.07 ± 0.02. At 1 month, the mean SE was -0.33 ± 0.46

Conclusion: This study shows that extended monofocal Evolux iols with non-diffractive optical profile safe, effective and stable providing excellent distance vision, intermediate vision and better near vision compared to standard monofocal IOLs.

Keywords: Enhanced Monofocal; Extended Depth of Focus; Intraocular Lens; Evolux Lens

Introduction

The extended depth of focus intraocular lenses with a hydrophobic non-diffractive profile designed to improve intermediate vision and to provide comparable distance vision to standard monofocal IOLs. Conventional monofocal iols only allow a restoration of distance vision and limit visual performance at intermediate distance. Enhanced monofocal IOLs aim to provide improved depth of focus compared with standard monofocal lenses, but without an increase in dysphotopsia effects.

Functional vision is visual ability at a range of distances needed to perform activities of daily living. In today's world, many activities need the use of devices that mandate clear intermediate and near vision [1]. Besides the professional activities, as age advances, recreation and leisure also demand adequate vision at these distances [2].

The existing multifocal IOLs and Extended Depth of Focus (EDOF) IOLs have their own drawbacks and enhanced monofocal IOLs aim to overcome these and provide better vision and contrast over a wider spectrum. It has been shown that enhanced monofocal IOLs match EDOF IOLs, with more correction of functional near vision compared to monofocal IOLs and no compromise in visual quality [3].

Multifocal IOLs work by splitting the entering beam of light and projecting onto the retina at the same time. This occasionally leads to complaints of glare. On the other hand, EDOF IOLs work by elongating the area of focus and thereby improve vision at intermediate distances while minimising deleterious effects on va for distance [4,5]. In extension, the novel enhanced monofocal IOL employs an innovative optical design based on optimization of spherical aberration technology for effective optical performance.

Material and Methods

Institutional ethics committee clearance was obtained, the tenets of declaration of Helsinki were followed and a retrospective study was conducted. This was a case series of 25 consecutive patients who had bilateral implantation (50 eyes) of the novel non-diffractive Evolux IOL.

This study excluded patients whose eyes had other eye disorders such as glaucoma, corneal opacities, retinal problems or optic nerve head lesions. There were few patients who had bilateral Evolux IOL implantation but were not able to follow up after 3 weeks. They were also excluded. All eyes included in the study had their data analysed retrospectively. Information gathered from medical records were Visual Acuity (VA) for distance with the Snellen's chart, VA for intermediate at 45 cm and for near at 30 cm with hand held near vision charts. Refractive error was noted as Dioptres (D) from the auto-refractor. Data on axial length, IOL power, IOL offset and corneal curvature were obtained from the optical biometry reports. Contrast sensitivity data was gathered with the Pelli Robson chart at a distance of 6 m.

For the purpose of data analysis and statistical calculations, SPSS software was used. Demographic details were noted. Improvement in VA over the follow up visits was compared with the paired t-test.

Results

In total 25 normal binocular vision subjects 14 (56%) males and 11(44.0%) females aged 60 ± 18.50 years were studied. Baseline data pertaining ocular and refractive status is tabulated in Table 1. When assessing the BCVA for each eye individually, we noted a significant improvement at week 1, week 2 and month 1 for distance, intermediate and near. The same is shown in Table 2 and Fig. 1.

Unocular best corrected VA for near, intermediate and distance at 1 week, 2 week and 1 month is shown in Table 2. There was significant improvement of VA in all distances. The same can be seen by representation of of continuous data as a box whisker plot (Fig. 1) and contrast no changes seen shown in the Fig. 2.

Parameter	N
Age - mean (SD; range)	60 ± 18.50 (38 – 82)
Gender - n (%)	Males 14 (56%), females 22 (44.0%)
Axial length - mean (SD; range)	23.06 ± 1.50
Estimated power - Mean(SD)	20.78(1.56)
IOL power - mean (SD; range)	20.86 ± 0.50
Target refraction spherical - mean (SD; range)	0.11 ± 0.50
Target refraction cylinder - mean (SD; range)	0.36 ± 0.75

Table 1: Binocular vision.

There was appreciable vision improvement 1 month after surgery when checked unioocularly and binocularly. During single eye VA tests, near VA \geq N8 or better was seen in 40 eyes (80%), intermediate VA \geq 6/9 was seen in 27 eyes (54%) and distance VA \geq 6/9 was seen in 47 (94%) eyes. When VA was checked for both eyes simultaneously, near VA \geq N8 or better was seen in 23 patients (92%) and distance VA of 6/6 was seen in 24 patients (96%). When assessing refractive status after IOL impalnation, the residual Spherical error (SE) was within 0.50D. This SE was correlated with the target refraction that was aimed for and no association was made out ($p > 0.05$) (Fig. 2). CS was 1.65 ± 0.02 . The CS shows $p > 0.76$, statistically no significant difference in contrast sensitivity between unioocular and binocular conditions.

	First wk	Second wk	First month
Unioocular uncorrected VA (logMAR)			
Near	0.31 ± 0.50 (N8)	0.31 ± 0.50 (N8)	0.44 ± 0.52 (N10)
Intermediate	-0.94 ± 0.48 (20/32)	-0.94 ± 0.48 (20/32)	0.92 ± 0.46 (20/32)
Distance	0.02 ± 0.24 (6/9)	0.02 ± 0.24 (6/9)	0.06 ± 0.20 (6/6P)
Binocular uncorrected VA (logMAR)			
Near	0.3 ± 0.22 (N6)	0.2 ± 0.20 (N6)	0.2 ± 0.20 (N6)
Intermediate	0.9 ± 0.33 (20/25)	0.89 ± 0.37 (20/25)	0.89 ± 0.37 (20/25)
Distance	0.06 ± 0.09 (6/6)	0.0 ± 0.08 (6/6)	0.0 ± 0.08 (6/6)

Table 2: Improvement after the timeline.

At 1 month 40 eyes (80%) had intermediate UCVA of 0.2 ± 0.20 logMAR. When comparing eyes that had uncorrected intermediate vision of ≥ 0.87 to eyes and distance vision of $\log \geq 0.0$ at 1 month, there was no difference between 1 week and 1 month of distance ($p > 0.19$), 1 week and 1 month of intermediate $p > 0.84$ and 1 week and 1 month of near $p > 0.61$.

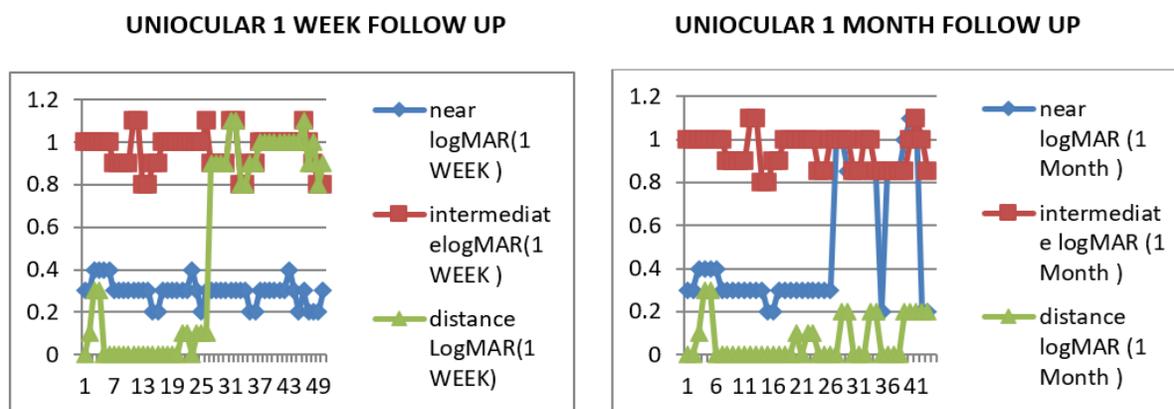


Figure 1: Unioocular vision.

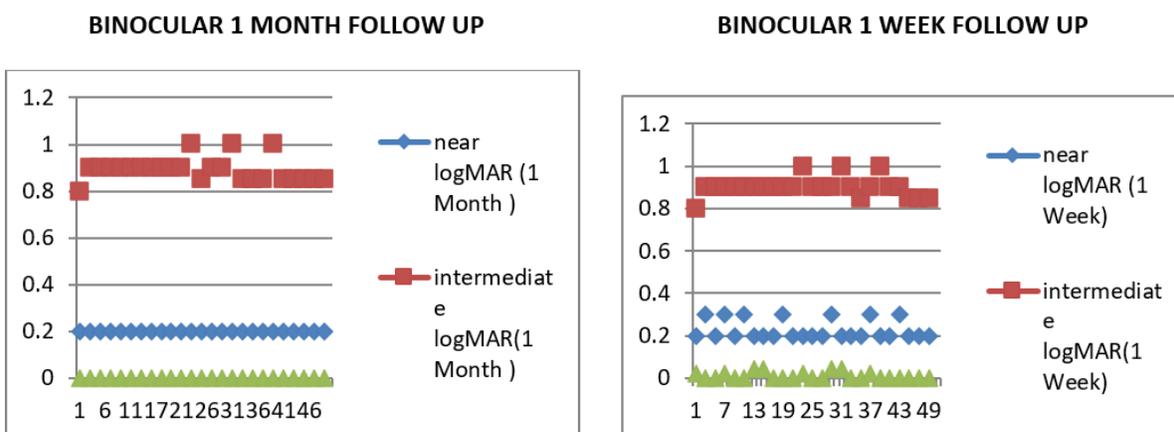


Figure 2: Binocular vision.

Discussion

Cataract surgery has now evolved into a refractive procedure and patients expect better VA at various distances. The standard monofocals have their disadvantages when intermediate and near VA is desired. To bridge this deficiency, multifocal IOLs, trifocal IOLs, EDOF IOLs and extended monofocal lenses have been introduced. We have provided the first report of real world outcomes with the novel extended monofocal Evolux lenses. This IOL is designed to create an elongated single focus area from far to intermediate distances unlike monofocal in which light is focussed on a single point. They have an innovative optical design with monofocal periphery and spherical aberration distribution of opposite signs in the 4.5 mm central optical zone thereby providing optimisation of spherical aberration technology for an effective and manageable optical performance.

In general, no adverse events or reactions were observed after IOL implantation. The IOL satisfied other main outcome measures such as proper positioning, absence of macular changes. These were studied clinically at all visits. More importantly, this IOL appears to perform well in distance and intermediate range of vision as it has been designed to address this concern. Most IOLs currently in vogue that aim to provide intermediate vision do so from distance to 60 cm and the performance of the novel Evolux IOL was noted to be good even up to 45 cm. Significant VA improvement was noted at all distances. Besides, we also noted that contrast sensitivity has not been compromised while providing vision at different distances. Both unocular CS and binocular CS have been well maintained 1 month after implantation of this IOL.

Pedrotti and colleagues demonstrated the comparison of visual outcomes between an aspheric monofocal IOL and an EDOF IOL [5]. As with the results of our study, their conclusion was that EDOF IOL provides better intermediate and near vision while maintaining the contrast sensitivity and thereby the visual quality.

Our study results correlate with those provided by Now et al. Techis Symphony is the IOL studied by them. It was noted that the spectacle independence for various tasks was comparable to the outcomes of our study. This study does have a few limitations. Only 25 patients (50 eyes) were studied. We had a shorter follow up. Future studies can address these issues along with having a control group using another EDOF type IOL. Visual function questionnaires would also aid in collecting patient's subjective opinions about their perceptions.

Conclusion

Our novel study on the clinical outcomes highlights the visual outcomes obtained with extended monofocal hydrophobic nondiffractive Evolux IOL. We were able to clinically demonstrate that this IOL is effective in optical performance and as safe as monofocal IOL.

Conflict of Interest

The authors declare no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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No author has a financial or proprietary interest in any material or method mentioned.

Ethical Approval

The study was approved by the Institutional Ethics Committee.

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