Evaluation of visual results of hydrophilic diffractive-refractive multifocal intraocular lenses

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PURPOSE: To determine the visual efficacy over a 6-month follow-up period for the Eyecryl Actv DIYHS600ROH, a diffractive-refractive multifocal intraocular lens (IOL).

SETTING: Beyoğlu Eye Research and Training Hospital, Istanbul, Turkey.

METHODS: In this single-centre, observational, retrospective study, we reviewed 13 patients (26 eyes) aged from 41 to 79 years who were treated with a diffractive refractive multifocal IOL (Eyecryl Actv DIYHS600ROH, Biotech Vision Care Pvt. Ltd., India). Near, intermediate and distance visual acuity outcomes were assessed at 1 week and 1, 3 and 6 months after the second eye surgery.

RESULTS: The preliminary results showed an overall reduction in refractive error from preoperative to postoperative. At 6 months, residual sphere was 0.076 dioptres (D) (range 0.75 to –1.25 D) and residual cylinder was 0.61 D (range 0 to –1.75 D). There was also a marked improvement in dynamic visual acuity from the preoperative assessment, which continued until slightly over the 6-month period (re-ANOVA $p<0.001$).

CONCLUSION: The results of this preliminary study showed a marked improvement in distance vision when preoperative best corrected visual acuity (BCVA) was compared with postoperative uncorrected visual acuity (UCVA), as well as improved intermediate and near UCVA.

J Emmetropia 2016; 3: 127-132

Multifocal intraocular lenses (IOLs), which became available in the early 1980s, help to improve unaided functional vision from near to distance by increasing the depth of field. A number of studies have shown that multifocal IOLs provide reliable functional outcomes for distance and near vision[1].They are known, however, to decrease contrast sensitivity compared to monofocal lenses[2], due to the splitting of light into multiple focal points to achieve near, intermediate and distance vision. Since their introduction, changes have been made to multifocal IOL design in order to limit the loss of contrast sensitivity while maximising visual outcomes and spectacle independence, e.g. through apodized diffractive optics that distribute the appropriate amount of light to near and distant focal points under all conditions[2,3].

There are two types of multifocal IOLs: refractive and diffractive. Refractive multifocal IOLs work by splitting and bending light to create two different focal points, and were the first to be commercialised[4]. However, although refractive IOLs have a longer history of use, many ophthalmologists favour diffractive multifocal IOLs because they appear to be associated with a lower incidence of dysphotopic phenomena, such as glare and haloes, in dim lighting[5]. Unfortunately, diffractive multifocal IOLs are associated with a significant loss of light transmission, which may have a considerable impact on contrast sensitivity[4]. One solution may be to use an IOL that combines both diffractive and refractive technologies, gradually decreasing the diffractive steps from the centre to the periphery of the lens. This may not only improve visual performance, but may also help to reduce night-time visual phenomena.

Submitted: 2/24/2016
Revised: 6/22/2016
Accepted: 9/26/2016

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Financial Disclosure: None of the authors have a financial interest in any of the products described herein.

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The Eyecryl Actv DIYHS600ROH is a new multifocal IOL that contains both diffractive and refractive elements. Eyecryl Actv IOLs are diffractive-refractive multifocal IOLs that possess a series of concentric rings with diffractive steps. The spacing between the steps gets progressively closer from the centre of the lens towards the edge. Eyecryl Actv IOLs use this type of design to provide excellent distance and near vision along with good intermediate vision[5].

The aim of this preliminary study was to report clinical visual outcomes with a novel diffractive-refractive multifocal IOL (Eyecryl Actv DIYHS600ROH) implanted bilaterally.

METHODS

This was a retrospective, single-site, observational study investigating patients scheduled to have bilateral cataract surgery and implanted with the study IOL (Eyecryl Actv DIYHS600ROH, Biotech Vision Care Pvt. Ltd., India). All procedures adhered to the tenets of the Declaration of Helsinki and its amendments. The inclusion criteria were age between 50 and 78 years and availability to attend regular postoperative examinations. Exclusion criteria included diseases other than cataract (severe systemic diseases, amblyopia, corneal diseases, uveitis, retinopathy or glaucoma), history of ocular and previous cataract surgery and astigmatism greater than 1 D.

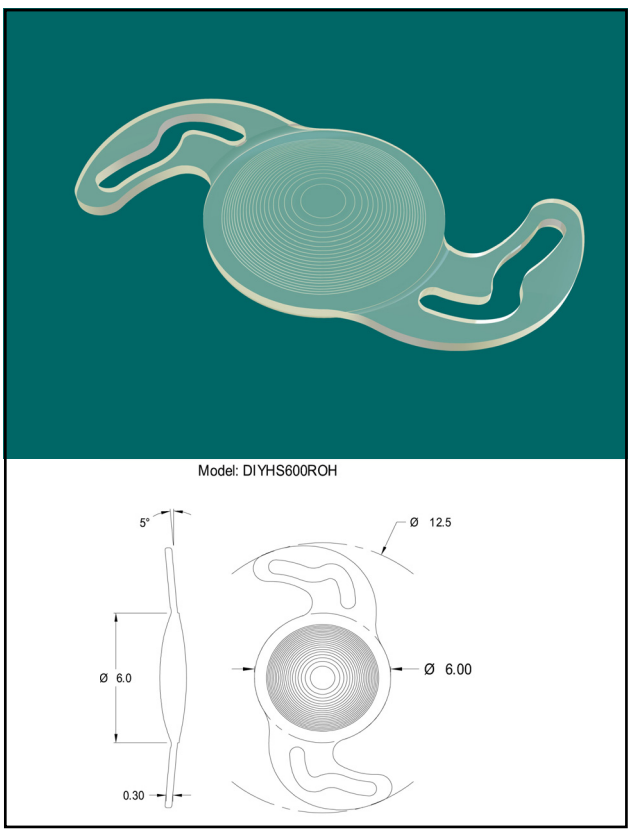

Figure 1. Eyecryl Actv DIYHS600ROH intraocular lens.

Intraocular lens

The Eyecryl Actv DIYHS600ROH is a single-piece, diffractive-refractive multifocal IOL with a 360° square edge and aspheric optics (Figure 1). Composed of hydrophilic acrylic containing a natural chromophore, the Eyecryl Actv DIYHS600ROH has an overall size of 12.5 mm and is available in dioptres ranging from +3.0 D to +32.0 D (in 0.5 D steps)[5].

Surgical technique

All surgeries were performed by the same experienced surgeon (AA) using phacoemulsification with the Infiniti Vision System (Alcon, Fort Worth, TX, USA). After topical anaesthesia with Alcaine 0.05% and a temporal 2.4 mm clear corneal incision, a central continuous curvilinear capsulorhexis approximately 5.5 mm in diameter was created. Phacoemulsification with torsional ultrasound was followed by irrigation and aspiration of the cortex and IOL implantation in the capsular bag. The position of the IOL postoperatively was detected by slit-limp microscopy with maximum pupil dilation. All surgeries were performed with no intraoperative complications.

Measurement outcomes

Standard preoperative measurements including biometry using the IOLMaster® 500 (Carl Zeiss AG, Germany) refraction and visual acuity (ETDRS) were collected on patients scheduled for cataract surgery. Postoperative visual acuity (VA) was assessed regularly over a 6-month period (1 week, 1, 3 and 6 months). Postoperative complications were also noted.

Statistics

Results were expressed as means ± standard deviation/range. Statistical analysis was performed using Statistica advanced statistical 12.0 software (Statsoft Inc., Tulsa, OK, USA). Changes in VA over the 6-month follow-up period were assessed using changes in VA over the 6-month follow-up period were assessed using Friedman analysis. Differences were considered statistically significant when the p-value was <0.05.

RESULTS

Thirteen subjects (26 eyes) with ages ranging from 41 to 79 years (7 male, 6 female) were recruited. Visual outcome results are presented in Table 1.

Near vision

Across the cohort, the 1-week postoperative uncorrected visual acuities (UCVA) were 0.10 ± 0.09 logMAR (range 0-0.2 logMAR, median 0.1 logMAR), which improved to 0.07 ± 0.07 logMAR (range 0-0.2 logMAR, median 0.1 logMAR) at 1 month postoperative follow-up. This slight improvement continued at the 3- and 6-month visits (0.06 ± 0.06 [range 0-0.2, median 0.1 logMAR] and 0.05 ± 0.05

Table 1. Uncorrected visual acuity results (logMAR) during follow-up for the cohort.

	Uncorrected near visual acuity (UNVA)	Uncorrected intermediate visual acuity (UIVA)	Uncorrected distance visual acuity (UDVA)	Corrected near visual acuity (CNVA)	Corrected intermediate visual acuity (CIVA)	Corrected distance visual acuity (CDVA)
1-week	0.10 ± 0.09	0.14 ± 0.06	0.07 ± 0.01	0.06 ± 0.10	0.10 ± 0.09	0.05 ± 0.10
1-month	0.07 ± 0.07	0.12 ± 0.07	0.05 ± 0.07	0.05 ± 0.07	0.10 ± 0.10	0.02 ± 0.05
3-months	0.06 ± 0.06	0.09 ± 0.05	0.04 ± 0.05	0.02 ± 0.09	0.07 ± 0.10	0.00 ± 0.09
6-months	0.05 ± 0.05	0.08 ± 0.05	0.04 ± 0.05	0.02 ± 0.09	0.07 ± 0.10	0.00 ± 0.09
***p*-value**	0.003	<0.001	0.11	<0.001	0.05	<0.001

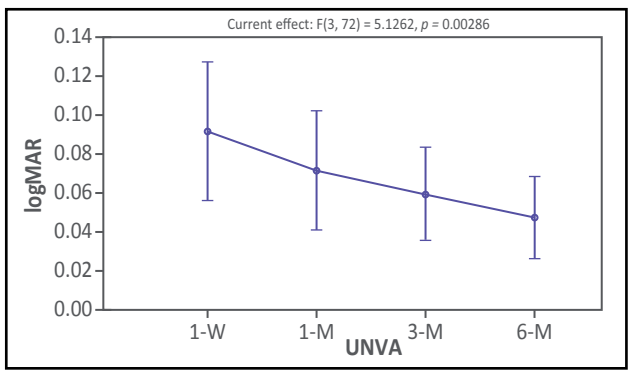

Figure 2. Improvement in uncorrected near visual acuity (UNVA) during follow-up in the cohort.

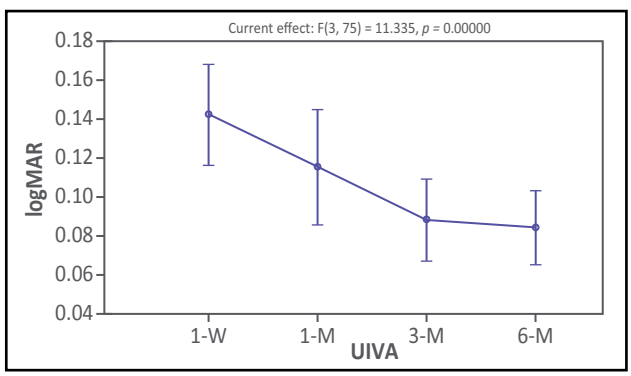

Figure 3. Improvement in uncorrected intermediate visual acuity (UIVA) during follow-up in the cohort.

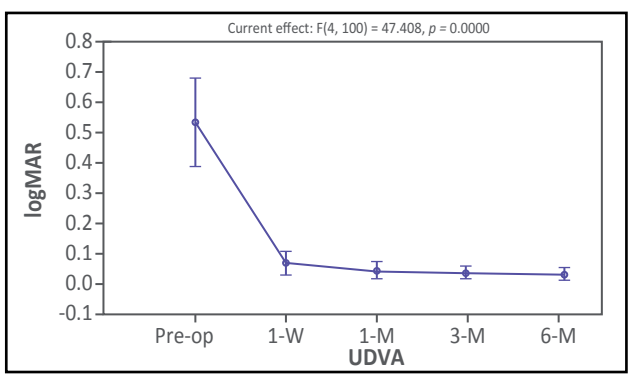

Figure 4. Improvement in uncorrected distance visual acuity (UDVA) as compared to pre-op best corrected visual acuity (BCVA) across the cohort.

[range 0 0.1, median 0.0 logMAR], respectively). These findings are presented in Figure 2.

Intermediate vision

The uncorrected intermediate VA (UIVA), as presented in Figure 3, showed improvements postoperatively, following the same trend as near vision. The 1-week UIVA (0.14 ± 0.06 logMAR; range 0-0.3, median 0.1 logMAR) improved slightly at the 1 month visit (0.12 ± 0.07 logMAR; range 0-0.2, median 0.1 logMAR), with marked improvements at the 3- and 6-month visits (0.09 ± 0.05 logMAR [range 0-0.2, median 0.1] and 0.08 ± 0.05 logMAR [range 0-0.1, median 0.1], respectively).

Distance vision

As shown in Figure 4, the study sample showed a general and marked improvement in distance vision when preoperative best-corrected VA (BCVA) was compared with uncorrected distance VA (UDVA) for each follow-up visit. The 1-week postoperative UDVA showed a marked improvement from preoperative BCVA (0.07 ± 0.01 logMAR [range 0-0.4, median 0.05 logMAR] as compared to 0.53 ± 0.36 logMAR [range 0.2-1.3, median 0.4]) which continued at the 1-month visit (0.05 ± 0.07 logMAR; range 0-0.3, median 0.0), 3-month visit (0.04 ± 0.05 logMAR; range 0-0.1, median 0.0) and 6-month visit (0.04 ± 0.05 logMAR; range 0-0.1, median 0.0).

Overall, there was a reduction in refractive error from the preoperative visit to each postoperative visit. At 1-month postoperatively, the mean residual sphere was –0.07 D (range 0.5 to –0.75), with a mean residual cylinder of –0.63 D (range 0 to –1.75 D). At 3 months postoperatively, the residual sphere had improved to 0 D (range 0 to 0.05 D) and at 6 months, residual sphere was 0.076 D (range 0.75 to –1.25 D) and residual cylinder was 0.61 D (range 0 to –1.75 D).

Adverse events

There were no serious adverse events as a consequence of the IOL. After cataract extraction and in-the-bag IOL implantation, the pupils of all patients were

Table 2. Published studies describing outcomes following implantation of diffractive/diffractive-refractive multifocal IOLs.

IOL	Study	Follow-Up (Months)	UDVA (± SD)	UIVA (± SD)	UNVA (± SD)	CDVA (± SD)	DCIVA (± SD)	DCNVA (± SD)	CNVA (± SD)
AcrySof ReSTOR, SA60D3	Rekas and Zelichowska[6]	6	0.9 ± 0.1	_	_	_	_	_	_
AcrySof ReSTOR, SA60D3	Alfonso et al.[7]	6	0.060 ± 0.006	_	0.013 ± 0.010	0.034 ± 0.004	0.352 ± 0.040 (70 cm) 0.321 ± 0.031 (60 cm) 0.223 ± 0.038 (50 cm) 0.101 ± 0.033 (40 cm)	0.011 ± 0.012	_
AcrySof Natural ReSTOR, SN60D3	Alfonso et al.[7]	6	0.073 ± 0.0015	_	0.014 ± 0.012	0.019 ± 0.002	0.401 ± 0.042 (70 cm) 0.356 ± 0.030 (60 cm) 0.273 ± 0.041 (50 cm) 0.109 ± 0.031 (40 cm)	0.035 ± 0.013	_
AMO Tecnis ZM500	Cillino et al.[8]	12	_	0.69 ± 0.04	0.72 ± 0.18	_	0.90 ± 0.22	0.78 ± 0.12	0.84 ± 0.12
Zeis AcriLisa 366D	Alió et al.[9]	3	0.06 ± 0.05	_	0.12 ± 0.11	0.00 ± 0.01	_	0.10 ± 0.12	0.07 ± 0.07
AcrySof ReSTOR, SN6AD1	Wang et al.[10]	6	−0.02 ± 0.13	_	0.21 ± 0.17	−0.16 ± 0.04	_	_	0.01 ± 0.03
Acriva Reviol BB MF 613/ MFM 611	Wang et al.[10]	6	−0.05 ± 0.10	_	0.18 ± 0.14	−0.14 ± 0.07	_	_	0.03 ± 0.10
AcrySof ReSTOR, SN6AD3	Wang et al.[10]	6	0.00 ± 0.13	_	0.12 ± 0.14	−0.16 ± 0.04	_	_	0.00 ± 0.0
Acriva UD Reviol BB MFM 611	Wang et al.[11]	6	−0.05 ± 0.13	_	0.15 ± 0.14	−0.16 ± 0.05	_	_	0.01 ± 0.02
Acriva UD Reviol BB MF 613	Wang et al.[11]	6	0.02 ± 0.14	_	0.20 ± 0.17	−0.13 ± 0.08	_	_	0.02 ± 0.07

Data provided as mean ± standard deviation; UDVA, uncorrected distance visual acuity; UCIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity; CDVA, corrected distance visual acuity; DCIVA, distance-corrected intermediate visual acuity; DCNVA, distance-corrected near visual acuity; CNVA, corrected near visual acuity.
NB: All visual acuities (VAs) are expressed as LogMAR, except for Cillino et al. and Rekas and Zelichowska, which are Snellen VAs.

round and showed good responsiveness to light; there was no case of iris trauma. One patient was diagnosed with postoperative macular oedema and treated accordingly with ketorolac eye drops. The oedema resolved progressively leaving a VA of logMAR 0.00 (Snellen 20/20).

DISCUSSION

This 6-month preliminary study evaluating visual outcomes following implantation of a novel diffractive–refractive multifocal IOL showed significant improvements in near, intermediate and distance VA. The results suggest that near vision improves substantially from 1-week postoperatively (0.10 log MAR; range 0-0.2 logMAR) to 0.06 (range 0-0.2) and 0.05 (range 0-0.1) logMAR at 3 and 6 months, respectively. This trend was also evident for intermediate vision: the 1-week VAs (0.14 logMAR; range 0-0.3) improved markedly at the 3- and 6-month visits (0.09 logMAR [range 0-0.2] and 0.08 logMAR [range 0-0.1], respectively).

Distance VA with the implanted IOL drastically improved from 0.53 logMAR (range 0.2-1.3) to 0.07 logMAR (range 0-0.4) at 1 week. This continued further at the 1-month visit (0.05 logMAR; range 0-0.3), 3-month visit (0.04 logMAR; range 0-0.1) and 6-month visit (0.04 logMAR; range 0-0.1).

Since there are no other published studies describing clinical outcomes following implantation of the Eyecryl Actv DIYHS600ROH, it is difficult to put our findings within the context of others. Additionally, data describing clinical outcomes following use of a multifocal IOL with both diffractive properties is scant, although a number of studies have evaluated visual outcomes following implantation of diffractive multifocal IOLs. These results compare well with those reported in this current study using a diffractive-refractive IOL (summarised in Table 2).

In a study by Rekas and Zelichowska[6], ten patients underwent implantation of the AcrySof ReSTOR, SA60D3 (Alcon), a diffractive multifocal IOL. Six months after surgery, UDVA ≥1.0 was achieved in 55% of operated eyes (6/11), and best corrected in 91% (10/11). Uncorrected near VA (UNVA) was achieved in all patients 2-6 months after surgery.

Alfonso et al.[7] evaluated visual outcomes similar to those of the present study alongside patient satisfaction in 325 patients who had bilateral implantation of the SA60D3 IOL (AcrySof ReSTOR, Alcon) and 335 patients who had bilateral implantation of the SN60D3 IOL (AcrySof Natural ReSTOR). The results showed that both IOLs provided good visual performance at distance and near under photopic and mesopic conditions. Intermediate vision with both models was reduced compared with distance and near vision.

At the 6-month postoperative visit, binocular best corrected distance VAs with the ReSTOR IOL and the Natural ReSTOR IOL were 0.034 logMAR ± 0.004 (SD) and 0.019 ± 0.020 logMAR, respectively (approximately 20/20). Binocular best distance-corrected near VAs were 0.011 ± 0.012 logMAR and 0.035 ± 0.013 logMAR, respectively.

In a consecutive case series study, patients received bilateral implantation of one of four IOLs, including a multifocal diffractive pupil-independent IOL (Tecnis ZM500, AMO)[8]. At one year postoperatively, 87.5% of patients had achieved spectacle independence. UNVA was 20/32 or better, and UIVA was 20/30 or better.

In a prospective, comparative, non-randomized, consecutive case series study by Alió et al.[9], 38 of 83 eyes were implanted with the diffractive Acri.LISA 366 D IOL; all other eyes were implanted with a refractive multifocal IOL. There were significant improvements in UDVA, CDVA, and UNVA at 3 months, similar to those of our study.

Finally, Wang et al. published two papers retrospectively comparing visual and optical performances of diffractive IOLs with different near additions (AcrySof ReSTOR SN6AD1 +3.00 D, Acriva Reviol BB MF 613 or BB MFM 611 +3.75 D, and AcrySof ReSTOR SN6AD3 +4.00 D)[10] and haptic designs (Acriva Reviol BB MFM 611 and a modified-C haptic multifocal IOL model, Acriva Reviol BB MF 613)[11]. For the first study[10], Wang et al. reported visual outcomes with the AcrySof ReSTOR IOLs similar to the current study IOL, demonstrating better UNVA.

The current findings also compare well with those found using the +3.75 addition Acriva IOL. In the second paper[11], the authors showed that using the Acriva +3.75 D IOL resulted in slightly better UDVA than our study lens, but our near VA findings show much better visual outcomes. This may be due to the haptic design of the IOL, as Wang alludes to an influence on visual outcomes. The authors understand that this is a preliminary study and that a larger medium-to-long-term follow-up study evaluating patient satisfaction, contrast sensitivity and corneal aberration would provide further evidence of success with this IOL. Nevertheless, this study does present promising findings with this novel diffractive-refractive multifocal lens that warrants further investigation.

In conclusion, the Eyecryl Actv DIYHS600ROH shows significant improvements in distance, intermediate and near VAs over a 6-month follow-up, whilst maintaining good contrast sensitivity.

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