DOI: 10.5152/imj.2018.25993

Manuscript Type: Original Article

Turkish Title: Mor Işığı Filtre Eden Asferik Bir Göz İçi Lensinin Klinik Sonuçları

Turkish Running Head: Mor Filtreli Göz İçi Lens

Title: Clinical Results of a Violet-Light Filtering Aspheric Intraocular Lens

Running Head: Violet-Light Filtering Intraocular Lens

Authors: Dilek Yaşa, Ali Demircan, Banu Acar, Merve Torun, Onur Ölçücü, Ufuk Ürdem, Alper Ağca, Ahmet Demirok

Institutions:

[1]Prof. Dr. N. Reşat Belger Beyoğlu Göz Eğitim ve Araştırma Hastanesi, İstanbul, Türkiye

[2]Bati Goz Hospital, Istanbul, Turkey

[3]Igdir Devlet Hastanesi, Ophthalmoloji Kliniği, Igdır, Türkiye

[4]Kirklareli Babaeski State Hospital, Oftalmoloji Kliniği, Kırklareli, Türkiye

Address for Correspondence: Dilek Yaşa [dilekyasa2@gmail.com]

Cite this article as: Yaşa D, Demircan A, Acar B, Torun M, Ölçücü O, Ürdem U, et al. Clinical Results of a Violet-Light Filtering Aspheric Intraocular Lens. İstanbul Med J 2018; DOI: 10.5152/imj.2018.25993

Received: 25.01.2018

Accepted: 11.06.2018

Abstract/Öz

Introduction: To evaluate the visual and refractive outcomes after implantation of an aspheric yellow chromophore monofocal IOL (Eyecryl Plus ASHFY600, Biotech Vision Care Pvt. Ltd., India)
Methods: Medical records of patients who underwent cataract surgery and implanted with Eyecryl Plus ASHFY600 were retrospectively analyzed. Subjective manifest refraction and visual acuity measurements at 1 week and 1, 3 and 6 months, as well as complications were analyzed.
Results: Fourty-nine eyes of 49 patients were included in the study. At postoperative week 1 visit corrected distance visual acuity (CDVA) improved significantly and it was within an acceptable range. Uncorrected distance visual acuity (UDVA) and CDVA stabilized after month 1 and there was no statistically significant difference between month 1, month 3 and month 6 visits. At 6 months, UDVA and CDVA were 20/25 or better in 79% and 93% of patients respectively. Postoperative spherical equivalent of manifest refraction was within ±1,00 D of emmetropia in 96% of patients.
Conclusion: The IOL was found safe and effective. It provided all patients with clinically significant improvements in UDVA, CDVA and refractive errors similar to non-chromophore lenses.

Keywords: Cataract surgery, emmetropia, violet filtering, visual acuity, yellow chromophore.

Amaç: Sarı kromoforlu, mor ışığı kısmen filtre eden, asferik monofokal bir göz içi lensinin (Eyecryl Plus ASHFY600, Biotech Vision Care Pvt. Ltd., India) klinik sonuçlarını değerlendirmek
Yöntemler: Katarakt cerrahisi geçirip cerrahi sonunda Eyecryl Plus ASHFY600 model intraoküler lens implantasyonu uygulanan hastaların dosyaları retrospektif olarak incelendi. Her hastanın bir gözü çalışma kapsamında değerlendirildi. Birinci hafta, 1. ay, 3. ay ve 6. ay muayenelerindeki subjektif manifest refraksiyon ve görme keskinliği sonuçları ile intraoperatif ve postoperatif komplikasyonlar analiz edildi.
Bulgular: Kırkdokuz hastanın 49 gözü çalışma kapsamına alındı. Ameliyat sonrası 1. hafta muayenesinde en iyi düzeltilmiş uzak görme keskinliği anlamlı derecede artmış ve kabul edilebilir derecedeydi. Dzeltilmemiş ve en iyi düzeltilmiş görme keskinlikleri 1. ay muayenesinde stabilize olmuştu ve 1. ay muayenesi ile 3. ve 6. ay muayeneleri arasında görme keskinlikleri açısından anlamlı fark yoktu. Altıncı ayda düzeltilmemiş ve en iyi düzeltilmiş görme keskinlikleri hastaların sırasıyla %79 ve % 93' ünde 20/25 veya daha iyiydi. Manifest refraksiyonun sferik eşdeğeri hastaların %96'sında ±1,00 D emetropi aralığındaydı. Hiçbir hastada ameliyat esnasında veya sonrasında komplikasyon gelişmedi
Sonuç: Düzeltilmiş ve düzeltilmemiş görme keskinlikleri ve ameliyat sonrası refraktif sonuçlar kromoforsuz lenslerle benzer olarak tespit edilmiştir. Eyecryl Plus ASHFY600 göz içi lensinin implantasyonu etkili ve güvenli olarak değerlendirilmiştir.

Anahtar Kelimeler: Emetropi, görme keskinliği, katarakt cerrahisi, mor ışık, sarı kromofor.

Introduction

Ultraviolet light (below 400 nm) does not provide useful vision and it can lead to retinal damage so Ultraviolet-blocking intraocular lenses have been dominant in cataract surgery after 1980s (1). These lenses are now standard of care and effectively block most of the radiation belo 400 nm. In addition, it has been suggested that increasing the absorption spectrum of the IOL to violet or further to blue spectrum may result in better contrast sensitivity and better protection against retinal phototoxicity and associated age-related macular degeneration (AMD) (2).

Although a blue or violet-light-filtering IOL may help prevent phototoxic damage thought to contribute to the pathogenesis of age-related macular degeneration, it has been suggested by some researchers that such lenses may also result in impaired scotopic vision and color perception (3). However, major differences in the absorption capacities were observed in the violet and blue light range among commercially available violet or blue light filtering IOLs depending on the material properties of each IOL (4). Thus, it is not correct to think all these lenses as a homogenous subgroup. Filtering properties of each IOL and corresponding clinical effects must be tested individually.

Eyecryl Plus ASHFY600 is a hydrophobic acrylic, aspherical intraocular lens and through its unique Natural Yellow Chromophore filters 400 nm to 440 nm of light spectrum only not to affect quality of scotopic vision and there are no published studies describing clinical outcomes following implantation of this lens.

In this study, we retrospectively analyzed the visual and refractive results after implantation of Eyecryl Plus ASHFY600.

Methods

This study followed the tenets of the Declaration of Helsinki, and approval was obtained from the local Ethics Committee. Medical records of patients who underwent cataract surgery and implanted with Eyecryl Plus ASHFY600 were retrospectively analyzed. Patients with a history of diabetes, pre-existing retinal or other ocular pathology were excluded from the analysis. Only one eye of each patient was included in the study.

Uncorrected and corrected visual acuity testing and routine preoperative and postoperative ocular examinations were performed at 1 week, and 1, 3, and 6 months postoperatively. At the pre-operative visit, uncorrected distance visual acuity (UDVA), best corrected distance visual acuity (CDVA), manifest refraction, corneal topography, biometry, ocular health evaluation, and other standard preoperative testing were performed. At 1-week visit UDVA, CDVA and manifest

refraction was performed. At 1 month, 3 months and 6 months visits UDVA, CDVA, uncorrected near visual acuity (UCNVA) and distance corrected near visual acuity (DCNVA) measurements were performed. A back-illuminated 19" LED LCD monitor chart with a decimal notation (CC-100 XP, Topcon, Tokyo, Japan) was used for UDVA and DCVA visual acuity measurements. The visual acuities were converted to logMAR for statistical analysis and converted back to Snellen/decimal notation for presentation. UNVA and DCNVA were measured using a Jaeger test chart at 40 cm.

Surgical Technique: All surgeries were performed using phacoemulsification with the Infiniti Vision System (Alcon Laboratories Inc., Fort Worth, Texas, United States) and R-Evolution (Optikon 2000 SpA, Rome, Italy). After topical anesthesia (Proparakain hydrochloride 0.5%) a temporal clear corneal incision (2.75 mm) was made. A central, continuous, curvilinear capsulorhexis, approximately 5.5 mm in diameter was created. Phacoemulsification was performed using torsional or longitudinal ultrasound, followed by irrigation and aspiration of the cortex. The IOL was then implanted in the capsular bag.

Intraocular Lens: The Eyecryl Plus ASHFY600 IOL is a hydrophobic acrylic lens with a natural chromophore to filter 400 nm to 440 nm of Violet-Blue light spectrum only not to affect quality of scotopic vision. It has a single piece, aspheric optic and a 360-degree square edge. The optic was designed with negative spherical aberration to compensate for the cornea's positive spherical aberration. The IOL has "C" loop haptics with an overall diameter of 13.00 mm and an optic size of 6.00 mm. The Abbe value is 49 in order to reduce chromatic aberrations, and the refractive index is 1.48. (5)

Statistical Analysis

Statistical analysis was performed using Statistical Analysis Software (SPSS 20®). Mean (±Standard deviation) was reported for continuous variables. Median (minimum, maximum) was reported for near visual acuity (Jaeger). Following tests of normality (Shapiro-Wilks) Friedman analysis and Wilcoxon Signed Ranks Test were used to evaluate for differences in visual acuity at the follow-up visits.

Results

Forty-nine eyes of 49 patients were included in the study. The average age of all patients was 68.2 years, with a range of 40-84 years.

Visual Acuity: The visual outcomes are presented in Table 1 and Figure 1. There was a statistically significant improvement in uncorrected distance visual acuity (UDVA) and CDVA from 1 week to 1 months (Table 1, p=0,007). UDVA and CDVA stabilized after month 1 and there was no statistically significant difference between month 1, month 3 and month 6 visits (Table 1). At 6 months median DCNVA was J3 (Table 2). UDVA and CDVA were 20/25 or better in 79% and 93% of patients respectively at month 6 (Figure 1).

Refractive Outcomes: The mean spherical equivalent of the manifest refraction (SE) was significantly reduced from the preoperative visit to the 6-month visit (Table 3, p <0.001). Mean SE was stable across the 1-, 3-, and 6-month visits, and there were no statistically significant differences between the postoperative visits. At 6 months, the SE was within ±0.50 D of emmetropia in 36 of 49 eyes (74 %) and within ±1.00 D in 47 of 49 eyes (96 %) (Figure 2). At 6 months, the refractive cylinder was 0.50 D or less in 30 (61.22%) of 49 eyes and 1.00 D or less in 42 eyes (85.71%) (Figure 3).

Complications

No preoperative or postoperative complications in our cohort. No patients lost any lines of DCVA.

Discussion

This retrospective study assessed the refractive and visual outcomes in cataract surgery patients implanted with the hydrophobic aspheric ASHFY600 IOL. The results revealed good visual acuity at 6 months postoperative. Specifically, mean UDVA, CDVA and SE improved significantly over the postoperative period to a UDVA, CDVA and SE of 0.83±0.19, 0.97±0.08, and -0.15±0.57 D respectively at 6 months postoperative.

In our study %74 of the eyes were within ±0,50 D of emmetropia and 96% (47/49) were within ±1,00 D of emmetropia and UCDVA was 20/25 or better in 79% of the eyes. The Royal College of Ophthalmologists Cataract Surgery Guidelines state that with appropriate formula selection, optical axial length measurement, and optimization of IOL constants a refractive outcome within ±1,00 D of the target should be achieved at ≥85% of the eyes.(6) Gale et al. (7) have set the refractive benchmark of more than 55 % within ±0.50 D and Hahn et al. (8) has set the refractive benchmark of more than 80 % within ±0.50 D. Our refractive results are comparable with these results and benchmarks in the literature.

In our study 7 of 49 (%14) eyes had astigmatism more than 1.00 D postoperatively and UCVA was relatively lower in these eyes. A 2.75-mm temporal clear corneal incision was used in all patients and this may have resulted in astigmatism of more than 1.00 D in the eyes which already have

astigmatism close to 1.00 D. Placement of the incision site on the steep corneal meridian or implantation of a toric IOL may have reduced the amount of post-operative astigmatism and increase UCDVA.

UNVA and DCNVA were not satisfactory. However, we consider it reasonable that a monofocal IOL does not result in a satisfactory near vision. Although the intraocular lens is monofocal, it is noteworthy that a significant number of patients had distance corrected near visual acuity of J3 or more. Relatively better near vision in these eyes may be due to the aspheric nature of the intraocular lens, pseudoaccomodative mechanisms such as a small pupil size (which is frequently seen in this age group) or a combination of these factors. Also, it must be underlined that reading speed was not assessed, thus these results may not reflect functional near vision accurately.

Retrospective nature and lack of a control group are weaknesses of our study. However, this study adequately shows the safety and efficacy ASHFY600 IOL. Close and frequent follow up all consecutive patients implanted with the intraocular lens and presence of all the patients in all follow up-visits are major strengths of this study.

In conclusion, this preliminary study shows that ASHFY600 IOL provides excellent UDVA, CDVA and refractive stability.

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as: Yaşa D, Demircan A, Acar B, Torun M, Ölçücü O, Ürdem U, et al. Clinical Results of a Violet-Light Filtering Aspheric Intraocular Lens. İstanbul Med J 2018; DOI: 10.5152/imj.2018.25993

REFERENCES

1. Mainster MA, Sparrow JR. How much blue light should an IOL transmit? Br J Ophthalmol. 2003;87:1523-9.

2. Symes RJ, Cuthbertson FM. Blue-blocking intraocular implants should be used routinely during phacoemulsification surgery - Yes. Eye. 2012;26:1397-9

3. Zhu X, Zou H, Yu Y and et all. Comparison of Blue Light-Filtering IOLs and UV Light-Filtering IOLs for Cataract Surgery: A Meta-Analysis. PLoS ONE. 2012; doi:10.1371/journal.pone.0033013.

4. Mainster MA. Violet and blue light blocking intraocular lenses: photoprotection versus photoreception. Br J Ophthalmol. 2006;90:784-92.

5. EyeCryl Plus (Natural Yellow Hydrophobic Series) Technical Specifications for Model ASHFY600. http://www.biotechvisioncare.com/home/ophthalmic/cataract_products/intraocular_lenses/hydrophobic_lenses.shtml. Accessed 10 Aug 2017.

6. The Royal College of Ophthalmologists Cataract Surgery Guidelines. [Online] 2010. https://www.rcophth.ac.uk/wp-content/uploads/2014/12/2010-SCI-069-Cataract-Surgery-Guidelines-2010-SEPTEMBER-2010.pdf. Accessed 10 Aug 2017.

7. Gale RP, Saldana M, Johnston RL and et all. Benchmark standards for refractive outcomes after NHS cataract surgery. Eye. 2009;23:149-52.

8. Hahn U, Krummenauer F, Kölbl B and et all. Determination of valid benchmarks for outcome indicators in cataract surgery: a multicenter, prospective cohort trial. Ophthalmology. 2011;118:2105-12.

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as: Yaşa D, Demircan A, Acar B, Torun M, Ölçücü O, Ürdem U, et al. Clinical Results of a Violet-Light Filtering Aspheric Intraocular Lens. İstanbul Med J 2018; DOI: 10.5152/imj.2018.25993

Table 1. Uncorrected and distance corrected visual acuities during follow-up for the cohort

	Preoperative (n=49) Mean±SD	1 week (n=49) Mean±SD	1 month (n=49) Mean±SD	3 months (n=49) Mean±SD	6 months (n=49) Mean±SD	p*
UDVA (Decimal)	N/A	0.72±0.24	0.81±0.20	0.83±0.18	0.83±0.19	0.03**
CDVA (Decimal)	0.33±0.15	0.89±0.19	0.98±0.07	0.97±0.08	0.97±0.08	<0.001†

UDVA: Uncorrected Distance Visual Acuity; CDVA: Corrected Distance Visual Acuity; SD: Standard Deviation
*: Global p value (overall all groups comparison)
**: 1 week-1 month: p=0,007; 1 week-3 month: p=0,004; 1 week-6 month: p=0,002; 1 month-3 month: p=0,470; 3 months-6 months, p=0,962 (Wilcoxon signed ranks test)
† : Preoperative - 1 week: p<0.001; 1 week-1 month: p<0,001; 1 week-3 month: p=0,001; 1 week-6 month: p=0,002; 1 month-3 month: p=0,751; 3 months-6 months, p:0,314 (Wilcoxon signed ranks test)

Table 2. Uncorrected and distance corrected visual acuities during follow-up for the cohort

	1 month (n=49) Median (Min-Max)	1 month (n=49) Median (Min-Max)	6 months (n=49) Median (Min-Max)
UCNVA (Jaeger)	13 (3-14)	13 (3-14)	13 (3-14)
DCNVA (Jaeger)	3 (3-19)	3 (3-13)	3 (3-13)

UCNVA: Uncorrected near visual acuity; DCNVA: Distance corrected near visual acuity; min: minimum, max: maximum
UCNVA**:** 1 month-3 month: p=0,220; 1 month-6 month: p=0,180; 3 months-6 months, p=0.750 (Wilcoxon signed ranks test). DCNVA: 1 month-3 month: p=0,420; 1 month-6 month: p=0,285; 3 months-6 months, p=0.670 (Wilcoxon signed ranks test)

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as: Yaşa D, Demircan A, Acar B, Torun M, Ölçücü O, Ürdem U, et al. Clinical Results of a Violet-Light Filtering Aspheric Intraocular Lens. İstanbul Med J 2018; DOI: 10.5152/imj.2018.25993

Table 3: Spherical equivalent of manifest refraction during follow up for the cohort

	Preoperative (n=49) Mean±SD	1 week (n=49) Mean± SD	1 month (n=49) Mean± SD	3 months (n=49) Mean± SD	6 months (n=49) Mean± SD	p*
SE (Diopters)	-1.60±2.21	0.15±0.56	-0.14±0.55	-0.14±0.55	-0.15±0.57	<0.001

SE: Spherical equivalent of manifest refraction; SD: Standard Deviation.
*: Global p value (overall all groups comparison)

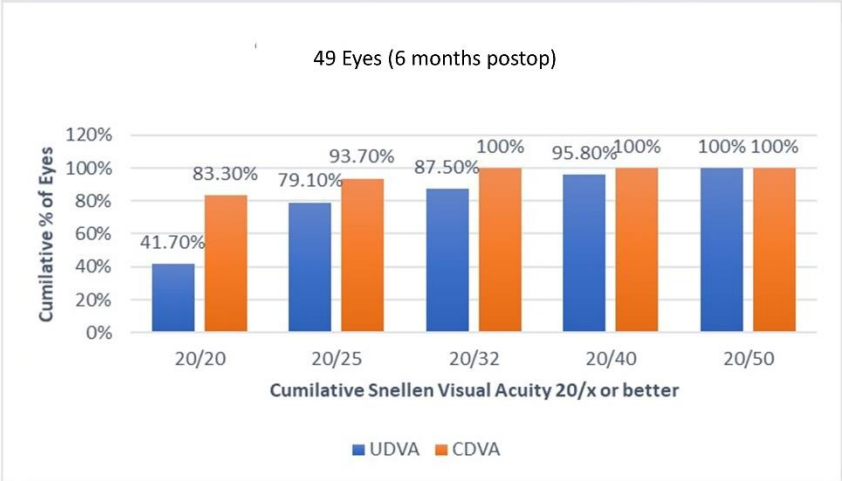

Figure 1. Cumulative monocular UDVA and CDVA at 6 months postoperatively

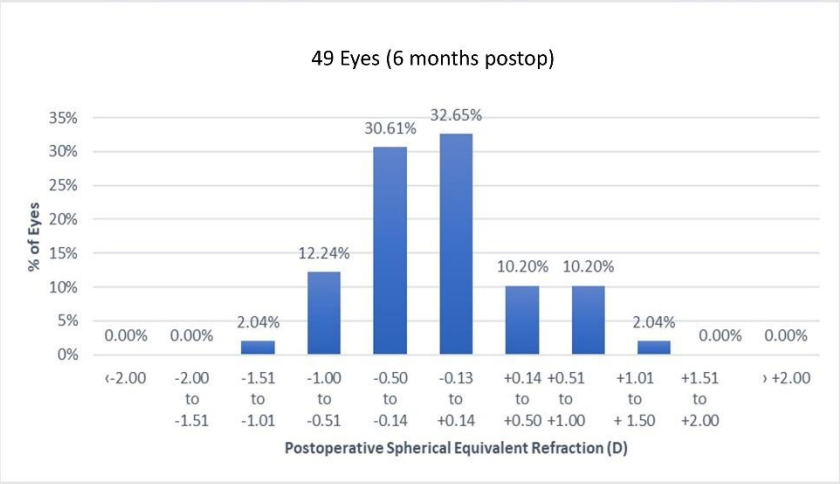

Figure 2. Predictability of refraction at the 6-month visit

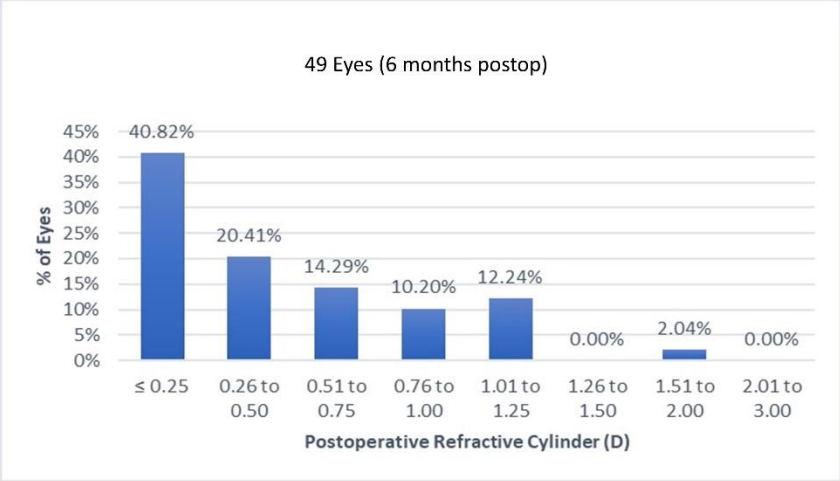

Figure 3. Residual refractive cylinder at 6-month visit

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as: Yaşa D, Demircan A, Acar B, Torun M, Ölçücü O, Ürdem U, et al. Clinical Results of a Violet-Light Filtering Aspheric Intraocular Lens. İstanbul Med J 2018; DOI: 10.5152/imj.2018.25993