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Visual outcome of single piece yellow tinted hydrophobic acrylic intraocular lens: A hospital based prospective observational study

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ABSTRACT

Aim: To evaluate the visual outcome of single piece yellow tinted hydrophobic acrylic intraocular lens (IOL) following phacoemulsification.

Materials and Methods: A single center, hospital based, prospective, observational study. Eligible patients with significant cataract, underwent phacoemulsification with implantation of single piece yellow tinted hydrophobic acrylic IOL. Patients followed up for 6 months. Pre and post-operative assessment of UDVA, CDVA was done and documented in LogMAR values. Contrast sensitivity by Pelli-Robson chart, refraction by Auto refractometer was evaluated pre and post operatively. Post-operative evaluation of glistening and PCO done by slit lamp examination. Glare evaluated by pen-torch contrast sensitivity method. Adverse events documented on regular follow-up.

Results: 132 patients were enrolled in the study. Majority of the subjects (97.7%) achieved expected visual outcome of LogMAR 0.0-0.2 on final follow-up day. Statistically significant improvement in contrast sensitivity noted in 99.2% of our patients. The mean refractive spherical equivalent at 180 days was 0.10±0.81. The incidence of glistening was 3.8% at 180 days follow up. Glare was present in 4.6% subjects on first operative day, 3% on 3rd and decreased to 0.8% on 7th postoperative day. None of our patients complained of glare after 1 month. The incidence of PCO and adverse events was 0.8% and 15.2% respectively, on last postoperative follow-up.

Conclusion: Implantation of single piece yellow tinted hydrophobic acrylic IOL provides expected visual outcome, refractive stability, enhances contrast sensitivity with minimal glistening, glare and adverse events. The square edge design of the hydrophobic lens reduces incidence of posterior capsular opacification.

1. Introduction

Phacoemulsification introduced by Charles Kelman in 1967 revolutionized the concept of cataract surgery which led to the development of foldable intraocular lenses. The first manufacturing of foldable IOL using soft materials such as acrylic, silicone and hydrogel was initiated by Dreifus, Wichterle and Lim.[1]

Acrylic materials due to excellent tissue tolerance have been the material of choice for manufacturing intraocular lenses.[2] Yet acrylic lenses cannot reproduce retinal protection of natural biological lens in preventing photo toxicity of retina by blue light. This paved way for the development of yellow tinted intraocular lenses. The yellow tinted blue blocking intraocular lenses conferred protection to retina by absorption of short wavelength light mimicking natural biological lens.[3] Square edge design of the haptic provided added advantage of reducing incidence

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of posterior capsular opacification.[4]

Modification in the material and design of acrylic intraocular lenses though improved visual acuity, also associated with decrease in contrast sensitivity, vacuolation, glare, posterior capsule opacification and adverse events.[5] Contrast sensitivity is the ability to detect slight changes in luminance between regions which can be affected by the manufacturing material of IOL. Glistenings occur due to accumulation of water vapour in microvoids within IOL, which lead to decrease in contrast sensitivity and visual acuity. Glare refers to photic phenomenon due to light reflected from the optic edges of the intraocular lens. Adverse events are ocular events which occur during the post-operative period till the end of follow-up period.

Supraphob BBY Yellow tinted blue blocking IOL (Appasamy Associates) have been designed to provide good visual acuity, enhance contrast sensitivity, confer retinal protection and reduce posterior capsular opacification. This study aims to evaluate the clinical performance of the single piece supraphob Yellow tinted hydrophobic acrylic intraocular lens by analyzing visual acuity, contrast sensitivity, refractive stability, glistening, glare, adverse events and the influence of square edged design in reducing posterior capsular opacification.

2. Materials and Methods

This was a single center, hospital based, prospective, observational study done at the Institute. Study protocol was reviewed and approved by independent scientific and ethics committee at the Institute. Guidelines of declaration of Helsinki were followed in the conduct of the study.

Patients aged 50 years and above whose visual loss can only be attributed to cataract in an otherwise healthy eye were enrolled in the study. Written informed consent was obtained from eligible subjects. Preoperative UDVA (uncorrected distance visual acuity) & CDVA (corrected distance visual acuity) measured and documented in log MAR (logarithm of minimum angle of resolution) visual acuity values, Contrast sensitivity measured by Pelli-robson chart, Refraction by Topcon Auto refraction, Intraocular pressure measurement with goldmann applanation tonometry, Corneal thickness with ultrasound pachymetry and Keratometry measurements by Topcon KR 8900. Intraocular lens power calculated using Axis Nano. Appropriate SRK II / SRK T or Holladay formula applied depending upon the keratometry and axial length values to calculate intraocular lens power. Surgeon factor considered and accounted while calculating intra-ocular lens power. A standard method of anterior and posterior segment evaluation was followed.

Routine pre-operative investigations and sterile precautions followed. All surgeries were done by single surgeon. Optikon pulsar minimum stress phacoemulsification machine with 45- degree kelman tip was used for the procedure. All patients underwent clear corneal incision performed with 2.8 mm keratome (optiedge, Appasamy manufacturers). Appropriate nucleus fragmenting and emulsification techniques employed depending upon the density of the nucleus. Following completion of nuclear removal, single piece Supra Phob – BBY yellow tinted hydrophobic acrylic aspheric 360- degree square edged intraocular lens (Appasamy Associates) was inserted utilizing an injector system.

Surgical details including Intra operative Complications were noted. Post-op antibiotic- steroid combination eye drops with cycloplegic medications prescribed. Follow up evaluation was performed on day 1, day 3, day 7, 1 month, 2 months and 6 months post operatively.

Post-operatively uncorrected distance visual acuity and corrected distance visual acuity was recorded in LogMAR values, evaluation of contrast sensitivity was performed by pelli-robson chart, and scored between 0 to 2. Score of 2.0 denotes normal contrast sensitivity of 100%. Less than 1.5 (75%) is consistent with visual impairment and the score of less than 1.0 (50%) represents visual disability.[6,7] Manifest refraction assessed by Topkon KR8900 autorefractometer and documented in spherical equivalent.

The incidence and the severity of glistening were evaluated using slit lamp beam set at 10 X 2 mm^2 with an angle of 30^0, glistening's are graded by the method followed by Tognetto et al.[8] Number of glistening per field at 25x magnification on slit lamp were noted and graded from 0 to 3. Glistening grade 0 (absent); grade 1 (trace); grade 2 (moderate) and grade 3 (severe).

Glare evaluation performed as advocated by TH Williamson et al.[9] After the initial assessment of contrast sensitivity using pelli-robson chart, glare introduced by pen torch held at 20 degrees to visual axis at 30cm directed at pupil and contrast sensitivity subsequently measured under influence of glare. As the pelli-robson chart gives logarithmic measure of contrast sensitivity, the effect of glare upon contrast sensitivity was obtained directly by difference in values before and after introducing glare. Values denote glare disability.

Posterior capsule opacification was evaluated by a grading system, followed by Kruger AJ et al.[10] The 3mm optic zone behind the intraocular lens was assessed for posterior capsular opacification by slit lamp and graded from 0 to 3, grade 0 being absent, grade 1 very mild, grade 2 moderate. Dense white opacities were graded as grade 3.

Adverse events, cumulative or persistent include all ocular complications irrespective of relationship to surgery or intraocular lens. Cumulative adverse events are events occurred at any time through the follow up period of six months. Persistent adverse events are complications noted on immediate post-op period which persist till the end of study period.[11]

Statistical analysis: The collected data was scrutinized using both descriptive and inferential statistics. Chi-square test was used to find out the association between variable, t test and paired t test and repeated ANOVA was used for the comparison. $p<0.05$ was considered to be significant. All the analysis carried out with SPSS version 20 software. [12]

3. Results

A total of 132 eyes were included in the study. Mean age of participants in the study (N = 132) was 59.63 ±6.321 years. 63 patients (47.7%) were males and 69 patients (52.3%) were females. The patients were followed-up for a period of 6 months post surgery.

3.1. Visual and refractive outcomes

Majority of the patients had significant improvement in UDVA and CDVA, on 6 months (day 180) follow-up, chi-square test demonstrated statistically significant difference ($p = 0.000$), indicating good visual outcome. Table 1 shows UDVA and CDVA results in LogMAR in pre-operative and post-operative follow-up period in addition to manifest refraction spherical equivalent (MRSE).

On final follow up 180 days following surgery 129 patients (97.7%) had UDVA and CDVA of LogMAR 0.0 – 0.2 and 3 patients (2.3%) had CDVA of LogMAR 0.3 – 0.8.

The change in mean MRSE between 1st post-operative day and 3rd post-operative day was 0.04 D, change in mean MRSE between 3rd post-operative day and 7th post-operative day was 0.01 D, between 7th post-operative day and post-operative day 30 change in mean MRSE was 0.03 D. The change in mean MRSE was 0.01 D between post-operative day 30 and post-operative day 60 and 0.03 D change in mean MRSE was observed between post-operative day 60 and post-operative day 180, indicating refractive stability.

3.2. Contrast sensitivity

128 patients (97%) had a preoperative score of <1.0 and 4 patients (3%) had a preoperative contrast sensitivity score of 1.0-1.5. Table 2 shows contrast sensitivity measurements in preoperative and postoperative follow-up visits.

Pre-operatively none of the patients had good contrast sensitivity scores of above 1.5. Following cataract removal and intraocular lens implantation contrast sensitivity scores significantly improved. At 180 days, contrast sensitivity scores of 131 patients (99.2%) was between 1.5-2.0. Results indicate that single piece yellow tinted hydrophobic acrylic intraocular lenses significantly improve contrast sensitivity function ($p=0.000$).

3.3. Glistening

Glistenings are micro-vaculations which develop over IOL and affect optical transparency of the IOLs. In our study glistenings were not noticed in any of our subjects till day 60. However 5 patients (3.8%) developed glistenings over IOL at the end of day 180.

3.4. Glare

Glare is subjective response to light stimuli, described as discomfort and disability. Our study utilised pen torch contrast sensitivity method to evaluate glare discomfort. The scoring system for glare was based on TH Williamson et al. [9]

6 of our subjects (4.6%) had glare disability on 1st postoperative day. On 3rd postoperative day 4 subjects (3%) had glare disability. 1 patient (0.8%) had glare disability on 7th postoperative day. None of our subjects had glare disability on postoperative Day 30, Day 60 and Day 180.

3.5. Posterior capsular opacification (PCO)

Design of the IOL influences incidences of posterior capsular opacification. Our study only one patient (0.8%) developed grade II posterior capsular opacification at the end of sixth month.

3.6. Intraoperative phacoemulsification related complications

Posterior capsular Rent (PCR) occurred in only 1 patient (0.8%).

3.7. Adverse events

Adverse events can be considered under cumulative and persistent. In our study cumulative adverse events included corneal edema, subconjuntival haemorrhage, postoperative uveitis and postoperative rise in intraocular pressure. No persistent or serious adverse events encountered in our study. No secondary surgical intervention was required in any of our patients. Distribution of adverse events is depicted in Table 3.

Out of 20 patients having adverse events, 7 patients had multiple adverse events. 4 patients had corneal edema and increase in IOP, 2 patients had corneal edema and sub conjunctival haemorrhage and 1 patient had corneal edema at first postoperative day and uveitis at postoperative day 30.

4. Discussion

Hydrophobic acrylic IOL are commonly used after cataract extraction. The yellow tint incorporated in the IOL helps in retinal protection by filtering blue wavelength light. This mechanism purported to enhance contrast sensitivity and visual outcome. This study evaluated the clinical performance of the yellow tinted hydrophobic IOL by

Table 1: Mean visual andrefractive outcome

Parameter	Pre op	Day 1	Day 3	Day 7	Day 30	Day 60	Day 180	F Value	P value
UDVA in LogMAR Mean±S.D	0.84 ±0.35	0.19 ±0.09	0.16 ±0.06	0.15 ±0.06	0.16 ±0.06	0.15 ±0.05	0.15 ±0.06	396.407	0.000**
CDVA in LogMAR Mean±S.D	0.78 ±0.21	0.13 ±0.13	0.02 ±0.08	0.06 ±0.06	0.08 ±0.09	0.06 ±0.05	0.07 ±0.08	698.430	0.000**
MRSE Mean±S.D	-2.41 ±1.93	0.06 ±0.93	0.10 ±0.89	0.09 ±0.82	0.06 ±0.85	0.07 ±0.85	0.10 ±0.81	100.40	0.000**

Table 2: Contrast sensitivity measurements pre-operative and post-operative

Contrast Sensitivity	Pre op n (%)	Day 1 n (%)	Day 3 n (%)	Day 7 n (%)	Day 30 n (%)	Day 60 n (%)	Day180 n (%)	Chi square	P Value
1.5-2.0	0 (0.0)	118 (89.4)	131 (99.2)	131 (99.2)	125 (94.7)	131 (99.2)	131 (99.2)	931.077	0.000**
1.0-1.5	4 (3.0)	14 (10.6)	1 (0.8)	1 (0.8)	7 (5.3)	1 (0.8)	1 (0.8)		
<1.0	128 (97.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		

Table 3: Distribution of adverse events

Adverse events	N	%
Increase in IOP (>21mm Hg)	7	5.30
Corneal (K) –Edema	6	4.55
SCH (Sub conjunctival Haemorrhage)	8	6.06
Uveitis	6	4.55
No Adverse events	112	84.8
Total	132	100

analyzing visual outcome, refractive stability, contrast sensitivity, glare, glistening and the impact of square edge design in reducing PCO.

The FDA data on Intra ocular lenses served as the historical control values for analyzing safety end points and effectiveness of implanted intraocular lenses. Lenses that achieved visual acuity of 20/40 or better in 85% of the operated patients have been approved for implantation by the Ophthalmic Device Section of the FDA.[13] Similar report, FDA Intraocular lens guidance document published in 2013 reported that expected visual outcome was achieved in 96.7% of operated patients.[14] The efficacy of the implanted IOL can be assessed by comparing the visual outcome with that of FDA guidance document. In our study, 129 patients (97.7%) achieved CDVA of LogMAR 0.0-0.2 at 6 month follow-up which exceeds the FDA historical control data and 2013 revised FDA document.[13,14]

The intraocular lens power calculation and design are crucial factors for attaining refractive stability.[15] Refractive stability of intraocular lenses can be studied by the variability in manifest refraction during postoperative period. Less variability in manifest refraction denotes that IOL offers good refractive stability.

In our study the variability of manifest refraction spherical equivalent was maximum between post-operative day 1 to day 3 as depicted in table 1. In further follow-up visits, refractive spherical equivalent remained stable and the mean ± SD of manifest refraction spherical equivalent at day 180 was 0.10±0.81. At 180 day follow up, 81 patients (61.4%) had a spherical equivalence of less than 0.5 D, 37 patients (28%) had ±0.5 to ±1.0 and 14 patients (10.6%) had more than ±1.0 D. kazuno negishi et al evaluated refractive stability of single piece hydrophobic IOL in 50 eyes for 3 months and postulated levels of axial displacement of the IOL affect refractive stability.[16] Hydrophobic materials by virtue of their biomechanical properties are associated with low levels of axial displacement resulting in refractive stability and improved optical performance. Similar conclusions were given by Ning et al, showing negative correlation between anterior chamber depth and post-operative refraction.[17] Manifest refraction measured during the 6 month follow up period was stable in our study and results are comparable to Negishi k et al, indicating refractive stability in yellow tinted hydrophobic IOL. We believe the postulate of hydrophobic material with less axial movement was the factor rendering refractive stability in our study subjects.

Contrast sensitivity is the measure of brightness difference between two points of an image. Yellow lenses mimic biological lenses and provide enhanced contrast

sensitivity. Ravi Nabh et al has successfully employed Pelli-Robson chart in measuring contrast sensitivity owing to its proven reliability and repeatability.[18] In our study contrast sensitivity evaluation was done with Pelli-Robson chart as suggested by Ravi Nabh et al. 128 patients (97%) had pre-operative contrast sensitivity scores of less than 1.0, indicate cataract significantly affects contrast sensitivity. Post –operatively 118 patients (89.4%) had improved contrast sensitivity scores of 1.5- 2.0 on 1st postoperative day and on final evaluation at day 180, 131 patients (99.2%) had contrast sensitivity scores of 1.5 – 2.0. Authors pandita et al, and uchio et al suggests design modifications such as curved anterior surface and asphericity of IOL enhance contrast sensitivity.[19,20] James Wolffsohn suggests selective absorption of short wavelength by yellow IOL improves contrast function.[21] Chin Chiet Ying Alice et al concluded yellow tinted Acrysof IQ lenses enhance contrast sensitivity under different lighting conditions and are comparable with clear negative aberration aspheric IOL.[22]

Our study utilized yellow tinted hydrophobic acrylic aspheric intraocular lenses and we believe that similar factors and design modifications, significantly improved contrast function in our operated patients. Our study was conducted in a standard clinical environment utilizing Pelli-Robson chart. Mainster opines environmental, clinical and photic conditions affect contrast sensitivity.[23] This factor has not been considered in our study and a different environment or lighting state or different method of evaluation by functional acuity charts may have altered the outcome of our study.

Glistenings are fluid filled microvacuoles ranging from 10 to 20 μ in diameter, occurs due to the accumulation of water vapour in microvoids within the IOL material. It may lead to diffraction of light and produce scattering effect causing reduced contrast sensitivity. Lesser size and lower density of glistening do not significantly alter contrast function where as higher grades of glistening severity result in reduced contrast functions. Joseph colin reported incidence and severity are directly proportional to duration of follow up.[24] In our study, only 3.8% of study subjects have a traceable glistenings at 6 month follow-up. Studies conclude that longer follow-up duration increases glistening severity and our 6 month follow-up period explains the lesser grade of glistenings. Longer duration of follow-up might increase the glistening severity and may alter visual and contrast function.

Glare is subjective discomfort upon exposure to light source which cause reduced visual function. Authors Deepak Pandita et al and Uchio concludes that yellow chromophores imbued in the IOL absorb blue spectrum of light resulting in reduced glare.[19,20] Similar hypothesis was postulated by Yuan z based on Rayleigh's law where the intensity of scatter radiation is inversely proportional to fourth power of wave length, thus filtering of blue light resulting in reduced glare.[25]

On immediate postoperative day glare disability was present in 4.6% of our operated cases, which declined to 3% by day 3 and none of our patients had glare discomfort by 1 month. Similar decrease in glare disability was reported by Yuan Z who attributed such reduction of glare disability to patient adaptation.[25] Our study reflects many of the theoretical postulations of yellow tinted IOL absorbing blue spectrum reducing glare disability and improving contrast function.

Posterior capsule opacification is a common complication. One of the objectives of this study was to investigate whether posterior square design in single piece hydrophobic acrylic yellow tinted IOLs implanted in our patients offered any substantial advantage in reducing the incidence and severity of PCO. The incidence of PCO in our study was 0.8% (1 patient) and severity was grade 2 at 6 month follow-up.

Hydrophobic acrylic lenses have low incidence rate of PCO due to their high biocompatibility, low surface roughness and high water contact angle.[26] Square edge design modification results in 360 degree apposition of optic – haptic junction to posterior capsule thereby preventing epithelial cellular migration and proliferation from equatorial region reducing PCO formation. Yellow tinted IOL implanted in our patients comprise the biocompatible properties of the hydrophobic material combined with square edged design might have contributed to the lower incidence of posterior capsular opacification estimated in our study group.

Historical control report on Intra ocular lens published by FDA is considered as an assessment tool for the safety and effectiveness of intraocular lenses.[11] This report iterated adverse events, cumulative or persistent, as a study tool to assess safety profile of the intraocular lens. Cumulative adverse events occurred during any point of follow up while persistent adverse events are present from immediate postoperative period till the end of study period.

Cumulative adverse events in our study group were 15.2%, which can be primarily attributed to inflammatory changes in immediate postoperative period, which mitigated during the period of follow-up. 7 patients (5.3%) had multiple adverse events. None of patients had persistent adverse event or vision threatening complications. No secondary surgical intervention was required in any of our patients. The historical control value to assess the safety of an intraocular device should exceed control value of 96.7% as defined by FDA.[14] In our study, 97.7% and 2.3% of our operated patients achieved expected visual outcome of LogMAR 0.0-0.2 and LogMAR 0.3-0.8 respectively. The results suggest the safety profile of the supraphob BBY hydrophobic intraocular lens meets the safety standards as established by FDA.

Limitation in our study was the short duration of follow up for 6 month post operatively. A longer duration of follow up would have yielded more information. Also contrast functions were studied in standard clinical environment and subjectively assessed. Different lighting conditions and evaluation with advanced technical equipment might provide better functional assessment of the contrast function. Similarly glistening, glare and posterior capsular opacification was assessed by subjective methods. Technical methods would have improved the accuracy of the results.

5. Conclusion

In conclusion our study suggests that Supra phob single piece yellow tinted hydrophobic acrylic blue blocking intraocular lens provides expected visual outcome, refractive stability and contrast sensitivity with less incidence of glistening, glare and adverse events. The study also highlights that the square edge design incorporated in the intraocular lens reduces the incidence of posterior capsular opacification.

6. Source of Funding

Nil.

7. Conflicts of Interest

There are no conflicts of interest.

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