

Visual Function Outcomes in Tinted versus Non Tinted IOLs in Cataract Patients

ABSTRACT

Aims: To compare the visual function outcomes in tinted versus non tinted IOL in cataract patients.

Study design: Prospective , Randomized, Clinical study .

Place and Duration of Study: Upgraded Department of Ophthalmology Government Medical College Jammu, India between November 2016 to October 2017 .

Methodology: This study included two groups of 100 patients each. 100 patients in group 1 were randomly implanted with tinted IOLs and another 100 patients in group 2 were implanted with non tinted IOLs. Visual functions such as Best Corrected Visual Acuity(BCVA), Colour Vision(CV) and Contrast Sensitivity(CS) were compared after 1st post operative day, 2nd week and 3rd month.

Results: The mean change between the uncorrected visual acuity(UCVA) (day 1) and best corrected visual acuity(BCVA) (3rd month) reveals a non significant change between the two groups, however the mean change in tinted group was more than non tinted groups (76.17 % and (p value 0.101). Pre and Post operative colour vision(CV) remained same in both the groups and mean change in contrast sensitivity(CS) after day 1 and contrast sensitivity(3rd month) also revealed a non significant change , however mean change in tinted group was more i.e. 64.55 % than non tinted group (33.28 percent). (p value 0.283).

Conclusion: The mean change in best corrected visual acuity and contrast sensitivity is statistically insignificant for both the groups.

Keywords: tinted IOL; non tinted IOL; best corrected visual acuity; contrast sensitivity; colour vision .

1. INTRODUCTION

Cataract is a clouding of the normally clear transparent lens of the eye, which may prevent a clear image from forming on the retina. It is one of the leading causes of blindness in the world today, accounting for 50 % of blindness worldwide [1].

[2] defined cataract as any opacity in the lens. [3] defined senile cataract as any cataract that occurs after the age of 50 years and that has no evident cause. It is however more useful to use the term age related because age is the most important factor. Other influences such as environment, toxic, nutritional and systemic factors that affect an individual throughout life have a cumulative effect. Age related cataract is very common and may be a rule in advanced age. Extracapsular cataract extraction with PCIOL implantation remained a popular technique for a long time but the problems faced were –long incision (10-12 mm) multiple sutures & astigmatism.

Today Manual small incision cataract surgery (MSICS) and phacoemulsification are the two most common procedures performed for cataract extraction in India.

Manual SICS has been found to be as safe as phacoemulsification with similar visual rehabilitation outcomes[4].

Few years back, the colour of IOLs was not taken into account while choosing an IOL for patients undergoing surgery for cataract. The patient had a totally transparent IOL implanted, which filtered only UV rays between 200nm and 400 nm.

At present, there are several options of IOLs with filters available. They all attempt to block the passage of blue light to retina, establishing the cut-off at different wavelengths to provide good photo protection. Thus, there are Violet filter lenses that block visible spectrum of wavelength (400-440 nm) and blue filter lenses that block the spectrum between (440-500 nm).

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36 A yellow chromophore has been added in the IOL which absorbs the blue light. Therefore, in addition
37 to blocking UV light wavelengths between 400 and 500 nm are only partially transmitted. The high-
38 frequency blue wavelength light may be more likely to damage the retina through release of free
39 radicals. The AcrySof Natural IOL blocks the unnatural transmission of this blue light and protects
40 retina. The yellow colored lens is also more easily visible inside the cartridge and easier to load and
41 implant.

42 The cut off value considered best for photo protection is around 445 nm [5]. Furthermore, any spectral
43 filter that reduces blue-green phototoxicity causes a percentage decrease in scotopic sensitivity [6].
44 There are no IOLs in the market that offer a good compensation between retinal protection and
45 reduction in the blue light reaching the ocular fundus (photoreception). It is a proven fact that the
46 human crystalline lens turns yellow with age, and this change in colour of the human lens blocks the
47 shorter wavelengths and may contribute in retinal protection as shorter wavelength light may
48 contribute to retinal damage in middle age to elderly patients.

49 However there are few direct experimental measurements that show what this age related yellowing is
50 like. The clearest way to show this process is to determine the spectral transmission of the crystalline
51 lens [7].

52 Weale performed direct measurements of the spectral transmission of the crystalline lens, but only
53 showed the absorbance as a function of age for seven wavelengths and fitted it with a logarithmic
54 equation [8]. As crystalline lens of elderly person is yellowish in order to protect retina. Yellow or
55 orange filters are being incorporated in IOLs so as to imitate this yellowing.

56 It has been a concern that exposure to sunlight may be a risk factor for the development of ARMD
57 (age related macular degeneration).

58
59 Initially intraocular lens implanted during cataract surgery allowed the passage of all the visible light
60 [9]. However, it was found erythropsia [10] (objects appearing with a reddish hue), photic
61 retinopathy (retinal dysfunction which was induced by too much light exposure), and cystoid macular
62 edema [11] (fluid accumulation in the outer plexiform layer and cyst formation a common cause of
63 decreased vision after cataract surgery) occurred in patients with these IOLs.

64 Blue blocking IOLs provide 27-38% less melatonin suppression than a UV only blocking IOL, whereas
65 reduction is 15-16% for violet blocking IOL [6].

66 Our study is an attempt to compare the visual functions (best corrected visual acuity, contrast
67 sensitivity and colour vision) in patients implanted with non-tinted IOLs versus short wavelength blue
68 light blocking yellow tinted IOLs.

69

70 2. MATERIAL AND METHODS

71

72 This prospective, randomized, clinical study was conducted on patients attending the eye OPD of
73 Government Medical College Jammu, India from October 2016 to November 2017 appropriate
74 inclusion and exclusion criteria was applied and any complications if arising due to the procedure were
75 recorded.

76

77 Total of 200 patients were studied and cases were divided into two groups of 100 each.

78 Group-I: comprised of 100 patients who were subjected to manual small incision cataract surgery with
79 yellow tinted posterior chamber intraocular lens implantation.

80 Group-II: comprised of 100 patients who were subjected to manual small incision cataract surgery
81 with non-tinted posterior chamber intraocular lens implantation.

82 Inclusion criteria

83 a. Patients of cataract of grade I, II & III

- 84 b. Patients of either sex.
- 85 c. Both unilateral & bilateral cataract cases.

86

87 **Exclusion criteria**

- 88 a. Patients with coexisting glaucoma, uveitis, subluxated lens, traumatic cataract, corneal
89 opacity, corneal dystrophy, exotropia, esotropia, high myopia
- 90 b. Patients with posterior segment pathology (Retinitis pigmentosa, Retinal Detachment, Age
91 Related Macular Degeneration, Diabetic retinopathy, Hypertensive retinopathy)

92 The study proceeded as follows

- 93 • Detailed history pertaining to visual impairment & relevant medical & surgical history was
94 recorded.

- 95 • Patients were subjected to General Physical Examination to rule out any associated diseases.

- 96 • Each patient underwent detailed ocular examination.

97

- 98 • Pre-operative antibiotic drops & oral antibiotics were given a day before the surgery.

- 99 • Mydriasis was achieved using 1% cyclopentolate and 1% tropicamide with 10%
100 phenylephrine eye drops.

- 101 • 4% xylocaine was instilled topically.

- 102 • All patients were operated using peribulbar block by single surgeon.

- 103 • The eye planned for surgery was cleaned and draped.

104 **Surgical Technique**

105 FOR GROUP 1- Manual small incision cataract surgery through superior sclero-corneal tunnel
106 approach with yellow tinted PCIOL was done.

107 After placing wire speculum & reflecting fornix based conjunctival flap, tenon's & episcleral
108 attachments from sclera was cleaned. A gentle & just adequate cautery was applied.

109 The incision had 3 components:- External sclera incision, Sclero-corneal tunnel ,Internal incision.

110 **External incision**

111 It was a frown shaped, parabolic groove which was convex towards the limbus, 5.5 mm in length &
112 1.5-2 mm behind the limbus. The edges of the frown were 3 mm from the limbus & its centre 2mm
113 from the superior limbus. It was given with a No.15 disposable blade.

114 **Sclero corneal tunnel**

115 Sclero-corneal tunnel was created with a crescent knife.

116 **Internal incision**

The 2.8 mm angled keratome was parallel to the iris to create a side port at 9 o' clock position in the right eye & at 3 o'clock position in the left eye. Anterior chamber was entered with the same keratome and entry will be parallel to the external incision. The keratome was lifted to dip the tip into the anterior chamber with a forward movement. The anterior chamber was deepened with hydroxypropylmethylcellulose and a continuous curvilinear capsulorhexis was initiated and completed using a 26 gauge bent needle through the main incision. Hydrodissection was carried out using a curved cannula connected to BSS bottle with a drip set. The fluid was injected beneath the anterior capsule at one or two places. The nucleus was prolapsed slightly out of the bag. Pressure on posterior lip guided the nucleus out. Cortical cleaning was done using two way simcoe cannula with BSS. Viscoelastic material was injected into capsular bag and yellow tinted PCIOIOL was implanted. Same procedure was repeated for patients in group II.

Measuring Visual Acuity Post operatively

The distant visual acuity was tested with Snellen's test chart. It consists of a series of black capital letters on a white board, arranged in lines, each progressively diminishing in size. The letter on the top line of the chart should be read clearly at a distance of 60 m. Similarly, the letters in the subsequent lines should be read from a distance of 36, 24, 18, 12, 9, 6 and 5 m.

For testing, the patient is seated at a distance of 6 m from the chart, so the rays of light are practically parallel. The chart should be properly illuminated (20 footcandles). The patient is asked to read the chart with each eye separately and the visual acuity is recorded as a fraction, the numerator being the distance of patient from the letters and denominator being the smallest letters accurately read.

Measuring Colour Vision

The colour vision was measured using Ishihara's plates. In this there are patterns of coloured and grey dots which reveal one pattern to the normal individuals and another of colour deficient. The patient is made to identify the patterns on the plates and the results were recorded.

Measuring Contrast Sensitivity

It was measured using Pelli-Robson contrast sensitivity chart. This chart consists of letters that subtend an angle of 3 degree at a distance of 1 m. The letters on chart are organized as triplets, there being two triplets in each line. The contrast decreases from one triplet to the next. The log contrast sensitivity varies from 0.00 to 2.25. While recording, the patient sits 1 m in front of the chart. Patient is made to name each letter starting from the upper left corner and reading horizontally. Patient is made to guess even when he or she believes the letters are invisible. Test concludes when the patient guesses two of the letters incorrectly.

Patients of both the groups were followed up on 1st post op day, 2nd week & 3rd month for visual acuity, contrast visual acuity, colour vision, slit lamp examination & refraction. Any complication if occurred were recorded.

Statistical analysis

Statistical analysis was carried out using SPSS 16 for Windows (SPSS Inc., Chicago, Illinois, USA). The statistical analysis was done and the results were expressed with appropriate charts and tables. Mean and standard deviation were determined for continuous variables. Categorical data were presented with absolute and relative frequencies. In order to detect differences between the two groups, unpaired students t-test was used for continuous variables, while, for categorical variables, the Chi-Square test was used. All tests were two-tailed. A p-value of less than 0.05 was considered statistically significant.

3. RESULTS AND DISCUSSION

The study comprised of the following results

Age

Maximum number of patients (36 and 41) in both tinted and non-tinted IOLs groups were recorded in the age group of 61-70, while minimum number of patients were recorded in the age group of >80 years, respectively. The mean age of the patients in Tinted group was 64.54 years and in non-tinted group it was 66.60 years. The differences between the two groups were found non-significant with p-value of 0.178.

Table 1: Group comparison for age distribution (years)

Age (years)	Number of patients	
	Tinted IOLs (n=100)	Non-tinted IOLs (n=100)
≤50	17	10
51-60	19	18
61-70	36	41
71-80	23	22
>80	5	9
Mean age ± SD	64.54 ± 11.57	66.60 ± 11.16
p-value	0.178	

Sex

With regard to the sex distribution of the patients, the number of males and females in the tinted group was 52 and 48 and in the non-tinted group it was 45 and 55, respectively. Non-significant association was recorded between the two groups with p-value of 0.321.

Table 2: Sex distribution

Sex	Number of patients	
	Tinted IOLs (n=100)	Non-tinted IOLs (n=100)
Male	52	45
Female	48	55
p-value	0.321	

Pre-operative visual acuity

Perusal of the data presented in Table 3 shows that out of 100 patients in tinted group, the highest number of patients (41) were recorded in 4/60-6/60 range which was followed by >6/60 (30 patients) and the lowest number of patients were recorded in ≤3/60 (29 patients). Similarly in the non-tinted group, the maximum (44 patients) and minimum (22 patients) were recorded in 4/60-6/60 and >6/60 range, respectively. The two groups were non-significantly associated with each other with p-value of 0.421.

Table 3: Pre-operative visual acuity

Visual acuity	Number of patients	
	Tinted IOLs (n=100)	Non-tinted IOLs (n=100)
≤3/60	29	34
4/60-6/60	41	44
>6/60	30	22
p-value	0.421	

Uncorrected visual acuity (day1)

The data demonstrated below shows that out of 100 patients in tinted IOL group maximum patients (61) recorded a UCVA between (6/36-6/12) similarly in non-tinted group maximum patients (57) also recorded a UCVA between (6/36-6/12).

Table 4: Uncorrected visual acuity (day 1)

Uncorrected visual acuity	Number of patients	
	Tinted IOLs (n=100)	Non-tinted IOLs (n=100)
≤6/60	22	26
6/36-6/12	61	57
6/12 -6/6	17	17
p-value	0.793	

Uncorrected visual acuity week 2

Data presented in Table 5 indicated that the two groups viz., tinted and non-tinted IOLs were significantly associated with each other with p-value of <0.0001. Maximum number of patients (63) in the tinted group were recorded in 6/36-6/12 range and the minimum number of patients (12) were recorded in >6/60 range. In non-tinted group no patient was recorded in >6/60 range, however, maximum number of patients (56) were recorded in 6/12 -6/6 range.

Table 5: Uncorrected visual acuity week 2

Uncorrected visual acuity	Number of patients	
	Tinted IOLs (n=100)	Non-tinted IOLs (n=100)
≤6/60	12	0
6/36-6/12	63	44
6/12 -6/6	25	56
p-value	<0.0001	

Best Corrected Visual Acuity 3rd month:-

The data below shows that out of 100 patients in tinted IOL group maximum (71) showed BCVA in the range of (6/12-6/6) and in non tinted group maximum (60) patients also showed BCVA in the range of (6/12-6/6).

Table 6: Best Corrected Visual Acuity 3rd month

BCVA 3 rd month	Number of patients	
	Tinted IOLs (n=100)	Non-tinted IOLs (n=100)
≤6/60	0	0
6/36-6/12	29	40
6/12 -6/6	71	60
p-value	0.104	

Change between Uncorrected visual acuity (day 1) and BCVA (3rd month)

The data with regard to change between uncorrected visual acuity (day 1) and best corrected visual acuity (3rd month) is presented in Table 7 and perusal of the data presented in the table reveals non-significant change between the two groups, however the maximum change per cent (100.0% and 100.0%) in tinted and non-tinted groups were recorded in ≤6/60 range, while the minimum change per cent (52.46% and 29.82%) was recorded in 6/36-6/12 range, respectively. Mean change in tinted IOL group was more than non tinted group.

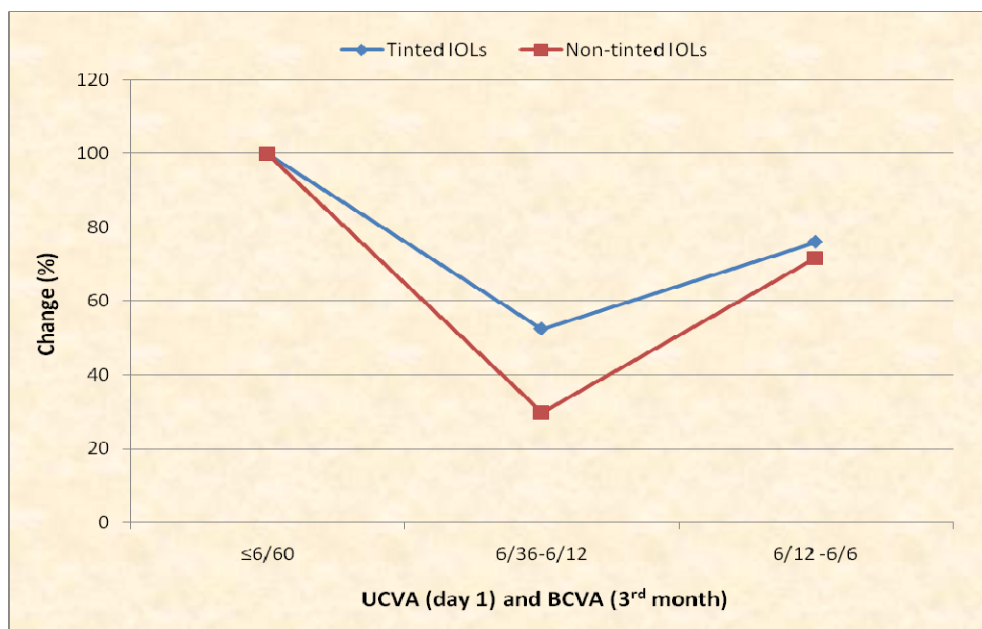
Table 7: Change between Uncorrected visual acuity (day 1) and BCVA (3rd month)

Visual acuity	Number of patients					
	Tinted IOLs (n=100)			Non-tinted IOLs (n=100)		
	UCVA (day 1)	BCVA (3 rd month)	Change (%)	UCVA (day 1)	BCVA (3 rd month)	Change (%)
≤6/60	22	0	100.00	26	0	100.0
6/36-6/12	61	29	52.46	57	40	29.82
6/12 -6/6	17	71	76.05	17	60	71.66
Mean Change	76.17			67.16		
p-value	0.101					

221

222

Fig.1



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224

225 Preoperative colour vision

226 The pre operative colour vision remained normal in both tinted and non tinted IOL group as shown by
227 the table below.

228 Table 8:

Preoperative colour vision	Number of patients	
	Tinted IOLs (n=100)	Non-tinted IOLs (n=100)

Normal	100	100
Defective	0	0
p-value	0.104	

229
230

231 Preoperative contrast sensitivity

232 Perusal of the data presented in Table 9 revealed that the two groups were non-significantly
233 associated with one another (p-value = 0.221). In tinted group maximum number of patients (48) were
234 recorded in 0.90 – 1.65 log units range which was closely followed by 0.0 – 0.75 log units range (47
235 patients), while minimum number of patients (5) was recorded in 1.80 – 2.25 log units range. Similarly,
236 the maximum (54 patients) and minimum number of patients (9) with regard to contrast sensitivity
237 were recorded in 0.0 – 0.75 log units and 1.80 – 2.25 log units, respectively

238 **Table 9: Preoperative contrast sensitivity**

Preoperative contrast sensitivity	Number of patients	
	Tinted IOLs (n=100)	Non-tinted IOLs (n=100)
0.0 – 0.75 log units	47	54
0.90 – 1.65 log units	48	37
1.80 – 2.25 log units	5	9
p-value	0.221	

239
240

241 Post operative contrast sensitivity day 1:

242 In the table below the maximum patients having post operative contrast sensitivity on day 1 in tinted
243 group were in the range of (1.80-2.25 log units) and minimum below 1.05 log units similarly in the non
244 tinted group the maximum patients fell under the range of (1.80-2.25 log units) and minimum below
245 1.05 log units.

246

247 **Table 10: Post-operative contrast sensitivity day 1**

Post-operative contrast sensitivity day 1	Number of patients	
	Tinted IOLs (n=100)	Non-tinted IOLs (n=100)
≤1.05 log units	10	3
1.20 – 1.65 log units	37	43

1.80 – 2.25 log units	53	54
p-value	0.121	

Post operative contrast sensitivity 2nd week:-

In the table 11 below the maximum patients having post operative contrast sensitivity on 2nd week in tinted group were in the range of (1.80-2.25 log units) and minimum below 1.05 log units similarly in the non tinted group the maximum patients fell under the range of (1.80-2.25 log units) and minimum below 1.05 log units.

Table 11: Post-operative contrast sensitivity 2nd week

Post-operative contrast sensitivity 2 nd week	Number of patients	
	Tinted IOLs (n=100)	Non-tinted IOLs (n=100)
≤1.05 log units	2	0
1.20 – 1.65 log units	31	37
1.80 – 2.25 log units	67	63
p-value	0.271	

Post operative contrast sensitivity 3rd month

In the table below the maximum patients having post operative contrast sensitivity on 3rd month in tinted group were in the range of (1.80-2.25 log units) and minimum below 1.05 log units similarly in the non tinted group the maximum patients fell under the range of (1.80-2.25 log units) and minimum below 1.05 log units.

Table 12: Post-operative contrast sensitivity 3rd month

Post-operative contrast sensitivity 3 rd month	Number of patients	
	Tinted IOLs (n=100)	Non-tinted IOLs (n=100)
≤1.05 log units	0	0
1.20 – 1.65 log units	16	26
1.80 – 2.25 log units	84	74
p-value	0.082	

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267 **Change between contrast sensitivity (day1) and contrast sensitivity(3rd month)**

268 The data with regard to change between contrast sensitivity (day 1) and contrast sensitivity (3rd
 269 month) is presented in Table 13 and Fig 2. perusal of the data presented in the table reveals non-
 270 significant change between the two groups, however the maximum change per cent (100.0% and
 271 100.0%) in tinted and non-tinted groups were recorded in ≤1.05 log units range, while the minimum
 272 change per cent (36.90% and 27.03%) was recorded in 1.80-2.25 log units range, respectively.

273 **Table 13: Change between contrast sensitivity (day 1) and BCVA (3rd month)**

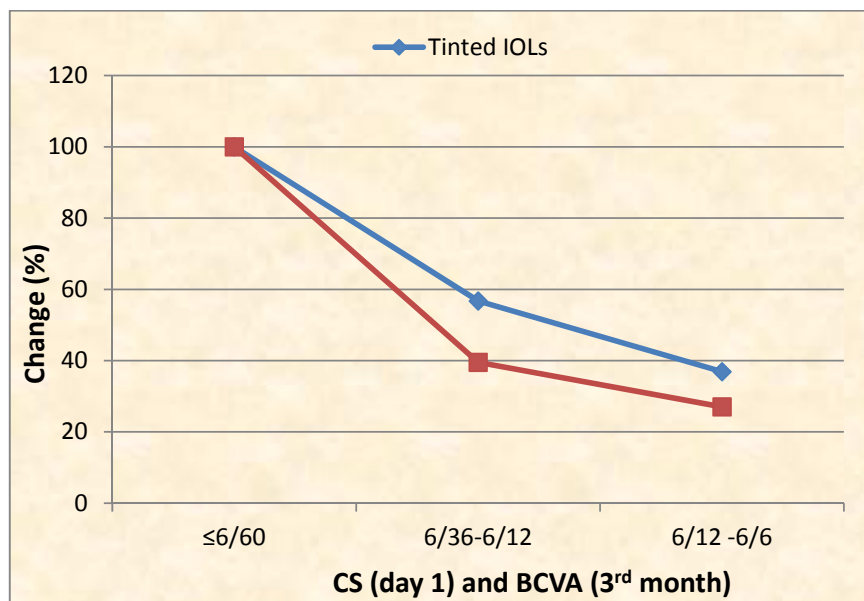
Contrast sensitivity	Number of patients					
	Tinted IOLs (n=100)			Non-tinted IOLs (n=100)		
	CS (day 1)	CS (3 rd month)	Change (%)	CS (day 1)	CS (3 rd month)	Change (%)
≤1.05 log units	10	0	100.00	3	0	100.0
1.20 – 1.65 log units	37	16	56.75	43	26	39.53
1.80 – 2.25 log units	53	84	36.90	54	74	27.03
Mean Change	64.55			33.28		
p-value	0.283					

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275

276

277 Fig.2



DISCUSSION

Few studies on post operative visual outcomes of tinted and non tinted IOLs were performed worldwide .However no such studies were performed in our set up here. These studies had wide range of outcomes as will be discussed and compared to the present study. Maximum number of patients (36 and 41) in both tinted and non-tinted IOLs groups were recorded in the age group of 61-70, while minimum number of patients were recorded in the age group of >80 years, respectively. The mean age of the patients in Tinted group was 64.54 ± 11.57 years and in non-tinted group it was 66.60 ± 11.16 years. The differences between the two groups were found non-significant with p-value of 0.178. Mean age of patients reported by [12] was 70.9 ± 6.4 with range of 58-85 years for both the groups which is comparable to the present study in terms of mean age. [13] reported a mean age of 72 ± 6 years in both the groups in their study on effects of tinted IOLs on visual quality .This can be attributed to geographical variations.[12] reported that there were 50 females and 24 males in their study ($p=0.5$) which is statistically non significant as in the present study.[13] reported that there were 30 females and 21 males in their study which was statistically non significant.[14] reported a total of 12 males and 13 females in the tinted group and 7 females and 20 males in the non tinted group which was also statistically insignificant as in the present study.[12] reported no significant differences between mean change in best corrected visual acuity at 1st day and 3rd month for both tinted and non tinted group ($p=0.8$) and ($p=0.5$) respectively. These results are comparable to the present study. [13] reported a pre operative BCVA of $0.3 + 0.1$ logMAR for non tinted group and $0.3 + 0.2$ logMAR ($p=0.23$) for tinted group. And 3 months after surgery of $0.02 + 0.1$ logMAR ($p=0.84$) for both the groups. Hence there was a statistically significant change in their study.[14] found no statistically significant results for change in best corrected visual acuity in their study ($p=0.1$). [14] reported no statistical difference in mean BCVA 0.01 ± 0.1 logMAR ($p=0.432$) in tinted and 0.02 ± 0.02 logMAR ($p=0.475$) in non tinted group.[15] also reported no significant differences in change in BCVA in both the groups ($p=0.40$).

[12] reported no difference in pre and post operative colour vision both remaining normal. [13] also reported no difference in this parameter as it remained normal in both the groups.[15] reported a better colour perception in non tinted group as compared to tinted group.[16] found no difference in colour vision and it remained normal in both the groups.

[12] reported no statistically significant change in mean contrast visual acuity in both tinted and non tinted group ($p=0.47$). [13] also found no statistically significant change in contrast sensitivity in both photopic and mesopic illumination conditions ($p=0.43$) and ($p=0.92$).

[17] found that blue filtering tinted IOLs had worse contrast sensitivity ($p=0.0004$) and foveal threshold ($p=0.008$) compared to non tinted IOLs which is different to the present study. This may be because it is measured at different illumination levels unlike in the present study. [14] found no statistically significant difference in mean contrast visual acuity in both the groups ($p=0.42$). [15] reported no significant change in contrast acuity from day 1 to 3rd post operative month ($p=0.2$) which is comparable to the present study.

4. CONCLUSION

The present study concludes that the change in mean visual acuity and contrast sensitivity is statistically insignificant. However, because studies have shown that short wavelength blue light has phototoxicity for retinal pigment epithelial cells so the blue light absorbing tinted IOLs could prevent age related macular degeneration. Therefore their use is recommended for eyes at high risk to develop ARMD such as eyes with drusens or atrophy of retinal pigment epithelium in the macula. Although no statistically significant effect of tinted IOLs on visual function was found in the present study.

CONSENT

A written informed consent was obtained from all patients who participated in the study after explaining the whole procedure and possible complications.

ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. The ethical approval number for the present study is IEC/Thesis/Research/T9B/2016/294.

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