Original Research Article

Efficacy of phakic intraocular lens in high myopic patients

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Abstract

Background: High myopia is usually associated with sight-threatening pathologies that are irreversible. A supplementary IOL (phakic IOL) implanted allows the crystalline lens to retain its function and may possibly protect against vitreo-retinal side effects of CLE. It could even improve the natural properties of the eye's optical system. **Aim:** To evaluate efficacy of phakic IOL in high myopic patients from western India. **Material and Methods:** 45 phakic foldable phakic intraocular lens of calculated power were implanted during study period. Efficacy index (postoperative un corrected visual acuity (UCVA) preoperative best spectacle-corrected visual acuity [BSCVA]), Safety index (postoperative BSCVA/preoperative BSCVA) and any complications were assessed during follow up period of 6 months. **Results:** Mean spherical equivalent was –14.89±4.62D preoperatively suggestive of high myopic population. After implantation of Phakic IOL, it significantly decreased to -0.25± 0.95D, -0.45±0.80 D, -0.49±0.72 D, -0.68±1.52 D at 1st week, 4th week, 3rd month and 6th month respectively. There was a significant improvement in the mean values of BCVA Log MAR and UCVA Log MAR from preoperative to postoperative period. **Conclusion:** Phakic intraocular lens seems to be predictable, safe, stable and effective refractive surgical modality for patients with high myopia provided meticulous patient selection and surgical planning is taken care.

Key Word: High myopia, Phakic intraocular lens, efficacy index, safety index

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INTRODUCTION

Myopia (near sightedness) is the most common cause of correctable visual impairment in the developed world in adults and children[1-5] and is a leading cause of preventable blindness in developing countries.[6] Approximately one in six of the world's population is myopic.[7] This represents a substantial burden worldwide. Individual studies show variations in the prevalence of myopia and high myopia between regions and ethnic groups, and there continues to be uncertainty regarding increasing prevalence of myopia. High myopia (RE>-6.00) is usually associated with sight-threatening pathologies that are irreversible.[8] Correction options include eyeglasses, contact lenses, or refractive surgery. A supplementary IOL (phakic IOL) implanted between the cornea and the lens, fixated in the angle or enclavated to the mid-peripheral iris with a claw or placed in the posterior chamber, gives rise to a condition called duophakia.[9] It allows the crystalline lens to retain its function and may possibly protect against vitreo-retinal side effects of CLE. It maintains and potentially could even improve the natural properties of the eye's optical system to enhance the quality of the retinal image, allowing excellent vision even in dim light conditions.[10-12] The lens is removable and exchangeable, permitting potential reversibility to the preoperative condition[13,14] The drawbacks of phakic IOLs are related to the risk of an intraocular operative procedure. There are very few studies on phakic IOLs conducted in Indian population and no prospective study reported till date in Western Indian population. A study was therefore conducted at a

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tertiary eye care hospital to evaluate efficacy of phakic IOL in high myopic patients from western India.

MATERIAL AND METHODS

This prospective observational clinical study included all patients who underwent phakic intraocular lens implantation having high myopia at Tertiary eye care centre.

Ethical consideration: Approval of the study protocol was granted by the hospital ethics committee and the protocol was compiled in accordance with the guidelines of the Declaration of Helsinki. Informed consent was taken from each participant before inclusion

Sample size: 45 eyes in the study group depending on previous study and in our institute approximately 45 phakic intraocular lenses were implanted during one year. Sample size was calculated by using below formula: $n_B=[(p_A(1-p_A][(z_\alpha+z_{1-\beta})/(p_A)]^2$

- *nB* = Sample size in the case group, ($n_A=kn_B$; k=1 for equal number of subjects)
- proportion p_A= 0.02
- α is Type I error =5%; z_α =1.64 one sided
- β is Type II error, 1−β is power; $z_{1-\beta}$=0.84 for 1−β=80% i.e. Sample size n=45

Inclusion criteria

Patients with -

- age between 18 and 40 years
- anterior chamber depth >2.8 mm
- intraocular pressure <21 mmHg
- Best corrected visual acuity of operating eye >20/40
- myopia >-6.00 D

Exclusion criteriai

Patients with -

- Lack of corneal transparency
- Cataract
- Lens subluxation
- Glaucoma or narrow angle
- Anterior chamber depth < 2.8 mm
- Uveitis
- Retinal problems

METHODOLOGY

Preoperative assessment: Preoperatively every patient underwent complete ophthalmological examination. This included testing uncorrected visual acuity for distance, best corrected visual acuity for distance, undilated and cycloplegic refraction, manifest refraction, slit lamp biomicroscopy, contact tonometry, pachymetry, topography, anterior segment OCT, mesopic pupil measurement and fundoscopy. Routine laboratory investigations were done. According to patient's co-operation either topical or peribulbar anaesthesia was given. Under all aseptic precaution painting and draping was done. Wire speculum was applied. Thorough conjuctival wash was given. Temporal clear corneal incision was taken. Viscoelastic was instilled and then foldable phakic intraocular lens of calculated power was implanted just in front of natural clear lens in the sulcus. Viscoelastic was removed with irrigating solution. Intracameral antibiotic (moxifloxacin) was given. Paracentesis and entry ports were hydrated. Betnesol-n eye drop was instilled and eye was patched. Postoperatively, topical antibiotics, topical steroid in tapering dose, oral acetazolamide or topical timolol eye drop for 7 days were given. Anterior segment OCT was done whenever suboptimal vault was noted. Patients were followed up at 1 day, 1 week, 4 week, 3 month and 6 month. At every follow up visit, following parameters were assessed: Uncorrected visual acuity (UCVA), Best corrected visual acuity (BCVA), Refraction (retinoscopy, Jackson cross cylinder, worth four dot test, duochrome test, astigmatic fan test), Ccontrast sensitivity, Acceptance of patient, Spherical equivalent (SEQ), Intraocular pressure (IOP), Gonioscopy in suspect patient and in patients with very high vault distance, Anterior segment examination in details. Dilated detailed fundus examination. Efficacy index (postoperative UCVA/preoperative best spectacle-corrected visual acuity [BSCVA]), Safety index (postoperative BSCVA/preoperative BSCVA) and complications if occurred were assessed.

Statistical analysis: Data analysis was done by descriptive statistics as mean, standard deviation, percentage etc. Student's t-test of difference between two means were applied to compare the vision improvement from pre to postoperative follow up. The significance levels were 0.05, considered as significant. Statistical software namely "SYSTAT" version 12 was applied to analyses the data.

RESULTS

This prospective, clinical study was conducted in tertiary eye care hospital on 45 eyes of 30 patients fulfilling the inclusion criteria. Out of the 45 eyes, 32 were of Females and 13 were of males. Mean age of male subjects were 24.17±6.22 years and mean age of females were 21.35±5.25 years. Mean age of total subjects were 22.07±6.54 years. 60% of the subjects [27 subjects] belonged to 18 - 25 years age group. 28.88% subjects [13 subjects] belonged to age group between 25 to 30 years. 11.12% of the subjects [5 subjects] belonged to age above 30 years. 12 out of 45 patients had myopia greater than -12D, 26 patients had refractive error between -10 to -18 D while 7 patients had refractive error between -6 to –10D.

20 patients had no or less than -1.00D cylinder, while 17 out of 45 and 8 out of 45 patients had cylinder of –1 to –3 D and greater than – 3D cylinder respectively. There was a significant improvement in the mean values of BCVA Log MAR and UCVA Log MAR from Preoperative to Postoperative 6 monthsi(p=0.001). There was significant difference of 0.127±0.07 and 1.37±0.06 respectively between preoperative and 6th month postoperative BCVA Log MAR and UCVA Log MAR visual acuity. There was a significant decrease in the mean values of Spherical equivalent (D) from Preoperative(-14.89±4.62) to Postoperative 6 months(p=0.001). After implantation of Phakic IOL, it was significantly decreased to -0.25±0.95D, -0.45±0.80D, 0.49±0.72D, -0.68±1.52D at 1st week, 4th week, 3rd month and 6th month respectively. Values of manifest refraction postoperatively and the values were -0.45±0.64D, 0.47±0.61D, -0.49±0.63D, -0.49±0.64D on day 1, 1 month, 3 month and 6th month respectively. These values were calculated excluding single surprising case of sudden ciliary body rotation. The mean preoperative IOP was 14.07 ± 1.89 mm Hg. At postoperative 1st day the IOP was 14.22±2.36 mm Hg, at 1st week it was 14.73±1.78 mm Hg, at 4th week the IOP was 17.33±5.91 mm Hg, at 3 months it was 14.82±1.89 mm Hg and at 6 months it was 14.98±1.94 mm Hg which is well within normal range of IOP and doesn't suggest any postoperative IOP rise. By applying Student's Paired't' test there is no significant increase in the mean values of IOP from Preoperative to Postoperative 6 months. There were 8 cases (17.78%) above > 6/12 and 20 cases (44.4%) had BCVA above 6/12 to 6/7.5 and 17 cases (37.78%) had 6/6 BCVA.

Table 1: BVCA pre and postoperatively

BCVA	Preoperative No. (%)	Postoperative No. (%)			
		1 day	4 weeks	3 months	6 months
<6/12	8 (17.78%)	2 (4.44)	2 (4.44)	2 (4.44)	2 (4.44)
6/12 to 6/7.5	20 (44.4%)	5 (11.11)	5 (11.11)	5 (11.11)	5 (11.11)
6/6	17 (37.78%)	38 (84.44)	38 (84.44)	38 (84.44)	38 (84.44)
Total	45 (100%)	45 (100%)	45 (100%)	45 (100%)	45 (100%)

There were 12 cases (26.66%), 7 cases (15.57%), 6 cases (13.34%) and 8 cases (17.78%) above <6/12 UCVA at day 1, week 1, week 4, 3 month and postoperative 6 month respectively. There were 13 cases (28.88%), 18 cases (40.0%), 19 cases (42.62%) had 6/12-6/7. 5 UCVA at follow up visit day 1. (Table2).

Table 2: Postoperative UCVA

UCVA	Postoperative 1 day	Postoperative 1 week	Postoperative 1 month	Postoperative 3 months	Postoperative 6 months
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
<6/**12**	12 (26.66)	7 (15.57)	6 (13.34)	6 (13.34)	8 (17.78)
6/12 - 6/7.5	13 (28.88)	18 (40.0)	19 (42.62)	19 (42.62)	19 (42.62)
6/6	20 (44.44)	20 (44.44)	20 (44.44)	20 (44.44)	18 (40.0)

Table 3 shows values of mean axis at postoperative day 1, 1 month, 3 month, and 6 months.

Table 3: Mean postoperative axis

Postoperative follow up	Mean axis value (degrees) Mean±SD
Day1	54.38±54.13
1 month	54.131±54.06
3 months	54.29±53.97
6 months	53.37±53.96

The mean values of postoperative cylinder were 0.078±0.18D, 0.043±0.15D, 0.071±0.18D, and 0.071±0.18D on 1 week, 1 month, 3 months and 6 months respectively.

Table 4: Mean cylinder value (postoperative)

Postoperative follow up	Mean cylinder value Mean±SD
1 week	0.078±0.18
1 month	0.043±0.15
3 months	0.071±0.18
6 months	0.071±0.18

Efficacy index was calculated after conversion of visual acuity from Snellen's chart to LogMAR chart. LogMAR values decreased simultaneously from 1st postoperative day [0.86±0.015] to 6th month [0.29±0.06] which signified that there was significant gain in visual acuity.

Table 5: Distribution of efficacy index at postoperative follow up

Efficacy Index (Post-op UCVA/ Pre-op BCVA) Postoperatively	Mean ± SD
1 day	0.86±0.015
1 week	0.67±0.019
4 weeks	0.30±0.032
3 months	0.29±0.06
6 months	0.29±0.06

By applying Student's Paired 't' test there is a significant increase in Safety Index (Preop BCVA/Postop BCVA) at postoperative 1 day, 1 week, 4 weeks, 3 months and 6 months. (p=0.001).

Table 6: Distribution of safety index postoperative follow up

Safety index (post-op BCVA / pre-op BCVA Postoperative	Mean ± SD
1 day	1.18±0.87
1 week	1.19±0.46
4 weeks	1.21±0.43
3 months	1.26±0.66
6 months	1.29±0.66

Average WTW diameter was found to be 10.98 ± 0.0.19 mm in our tertiary eye care. The sizing and horizontal placement of posterior chamber PIOL is very crucial and error in measuring the horizontal white-to-white can lead to the PIOL rotation if the PIOL is smaller and then it has to be replaced or an increased vaulting leading to shallow anterior chamber and possibility of angle closure. During our observation we did not performed any replacement surgery. The vaulting of the PIOL at 1 month, 3 months and 6 months was found to be 0.96 CCT, 0.84 CCT, and 0.76 CCT in this study which is considered safe for avoiding adverse effects of excess or too less vaulting. Regarding complications, at day 1, one case (2.22%) had Descmets membrane fold and 1 case (2.22%) had pupillary block. At the postoperative week 1 only 1 case (2.22%) had DM folds. At postoperative 4 week 6 cases (13.33%) were steroid responder. At postoperative month 3 no one had any complication. At follow up visit 6 month, 2 cases (4.44%) had delayed ciliary body rotation.

DISCUSSION

In our study, the mean postoperative UCVA(log MAR) was 0.35-0.28 at the end of the respective observation. Preoperatively, none of the patients in our study had UCVA better than 6/60. Majority of the patients had UCVA 6/120 or worse. Postoperatively, it was observed that a significant number of the total patients improved to UCVA of 6/6, being 40% at 6 months. In Lackner *et al* study, the mean UCVA(logMAR) increased from 0.04±0.04 preoperatively to 0.42±0.27 at 1 month.[15] Considering the proportion of patients who had postoperative UCVA in range of 6/6 to 6/12, 28.88% of the patients had UCVA in that range at day1, 40% at 1 month, 42.22% at 3 months and 42.22% at 6 months, thereby indicating a significantly good visual outcome of the refractive procedure. BCVA should be improved postoperatively than preoperative value for most of the refractive surgery. In the study conducted by Risto *et al*,[16] the preoperative BCVA was 20/40 (6/12) or better in 63.2% eyes and 20/20 (6/6) or better in 23.9% eyes. The mean follow up period was 24 months. at final follow up, the BCVA was 20/40 (6/12) or better in 94.7% eyes and 20/20 (6/6) or better in 39.5% eyes. A gain of one line of BCVA was seen Bhandari study[17] in 10% and 11.76% eyes in V4b and V4c groups, respectively (p ¼ 0.08), while no change in BCVA was seen in 90% and 88.24% of eyes (p ¼ 0.07). We found that there is significant improvement in BCVA postoperatively. This is also due to removal of minification factor of glasses. We found that in our study, preoperatively 37.77% of the total patients had BCVA of 6/6, 44.44% of the total patients had BCVA in the range of 6/7.5 to 6/12. The proportion of patients who attained a postoperative BCVA of 6/6 was 84.44% at 6 months which is significant. Out of the remaining patients, 11.11% of the total had BCVA in range of 6/7.5 to 6/12 after 6 months. Comparing the preoperative UCVA and BCVA, it was observed that none of the patients had UCVA 6/6, whereas 37.77% of the total patients had BCVA as 6/6 which indicates that prior to undergoing the surgical procedure, we had expected that 37.77% patients had the potential to attain 100% vision irrespective of the vision being attained with or without additional visual aids postoperatively. After the surgical procedure, we observed that 40% of the total patients had attained UCVA of 6/6 after 6 months of follow up and 84.44% of the patients had BCVA of 6/6 at 6 months. Every patient had been consoled about the

limitations of the PIOL power to be implanted in their eye and the need for postoperative visual correction by additional methods if their refractive error was not corrected by PIOL implantation alone i.e. in eyes in which refractive error was more than the available power of PIOL that could be implanted. Similar to Bhandari study no patient had lost even a single line. Efficacy index is postoperative UCVA/ preoperative BCVA. In a study by Pothireddy *et al*[18] in India, the efficacy index was 1.04 twelve months postoperatively. Efficacy is also measured in terms of gain in visual acuity. It was found to be 0.80 in Baikoffs study.[19] Our study measure this index after conversion of Snellen's visual acuity into LogMAR acuity chart. Our study got consistent efficacy index at 1 month, 3 month and 6 months also. There was gain of 2 to 3 lines in all 8 subjects whose preoperative visual acuity was below 6/12. We also got gain of 1 to 2 lines in 21 patients which was very efficacious. Efficacy is also measured in terms of mean preoperative spherical equivalent, mean improvement in UCVA. Alio *et al*[20] study also got good efficacy index of 1.19. In a study by Pothireddy *et al*[18] in India, the and the efficacy index was 1.04 twelve months postoperatively. Most of the studies showed good efficacy index for treating high myopic patients. The mean value of axis of ICL at day 1 was 54.39±54.13 degrees, at 1 month was 54.31 ± 54.02 degrees, at 3 months was 54.285± 53.97 degrees and at 6 months it was 54.37±53.96 degrees .Thus there is no significant variation in the axis of the implanted PIOL on four subsequent visits indicating the rotational stability of the lens. The mean value of expected spherical equivalent as calculated for each PIOL implanted was considered as ± 0.50 D in our study. As calculated on 1st week, the value was -0.25 ±0.95 D that indicates the predictability of ICL. The mean SEQ at 1 month was -0.45 ± 0.0.80 D, at 3 months was-0.49±0.72 D, and at 6 months was -0.68± 1.52 D which indicates that the procedure was stable as the SEQ values were almost similar as assessed at each visit.

CONCLUSION

Phakic intraocular lens seems to be predictable, safe, stable and effective refractive surgical modality for patients with high myopia provided meticulous patient selection and surgical planning is taken care.

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