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# Alterations in optical higher order aberrations after implantable contact lens for high myopia in Indian eyes

Dr. Dhivya Ashok Kumar<sup>1\*</sup>, Dr. Jayanthi Thangarajan<sup>2</sup>, Dr. Amar Agarwal<sup>3</sup>

<sup>1-3</sup> Dr. Agarwal's Eye Hospital and Eye Research Centre, Ttk Road, Chennai, Tamil Nadu, India

# Abstract

Aim: To evaluate the changes in the higher order aberrations and correlation with visual acuity improvement in eyes operated with implantable contact lens (ICL) for high myopia in Indian population.

**Materials and Methods**: 15 eyes of 10 patients underwent ICL implantation. Main outcomes measured were uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), contrast sensitivity and optical higher order aberrations (HOA). Optical higher order aberrations were measured with Hartmann shack aberro meter postoperatively at 4 weeks.

**Results:** Five patients had ICL implantation in both eyes and 5 patients in one eye. The mean preoperative and postoperative UCVA were  $0.012\pm0.009$  and  $0.762\pm0.359$  respectively. The mean preoperative TRMS and HRMS was  $5.16\pm7.47$  and  $0.11\pm0.8$  respectively at 6mm pupil. The mean postoperative TRMS and HRMS was  $1.17\pm2.42$  and  $0.17\pm0.14$  respectively. There was a significant change (p=0.001) in Z<sup>4</sup><sub>0</sub>, Z<sup>3</sup><sub>-3</sub> (p=0.026) and total trefoil (Z<sup>3</sup><sub>-3</sub> and Z<sup>3</sup><sub>3</sub>) (p=0.009) at 6mm pupil. In eyes with postoperative BCVA of  $\geq 1$  Snellen decimal equivalent, there was significant change in the mean Z<sup>3</sup><sub>3</sub> (p=0.028) and Z<sup>4</sup><sub>0</sub> (p<0.001) at 6mm pupil. In eyes with post-operative BCVA improvement  $\geq 3$  lines, there was significant difference in the Z<sup>4</sup><sub>0</sub> (p=0.014) and (Z<sup>5</sup><sub>-3+</sub> Z<sup>5</sup><sub>3</sub>) (p=0.004) at 6mm pupil. There was no significant change in Z<sup>4</sup><sub>0</sub> at 4mm pupil.

**Conclusion:** ICL implantation produces significant changes in third and fourth optical higher order aberrations. Alteration in spherical aberration was observed to be high at 6mm than at 4mm pupil.

Keywords: aberrations, myopia, pupil, spherical

# Introduction

Since the invention of excimer laser refractive surgery, mild to moderate myopia has been successfully treated. However there are conditions in which excimer laser refractive surgery cannot be performed or is contraindicated <sup>[1, 2]</sup>. Despite the widespread acceptance of LASIK among refractive surgeons, there exists number of potential intraoperative and postoperative complications. The introduction of Phakic intraocular lens has revolutionized the treatment of high myopia in patients in whom LASIK is contraindicated. The Phakic IOLs provide better acuity and quality of vision without the complications of LASIK surgery. Initial studies on phakic intraocular lenses have proven to have good predictability with a low incidence of complications <sup>[3, 4, 5, 6]</sup>. Implantable contact lens (ICL) which is a type of posterior chamber phakic IOL has been shown to provide better visual outcome in high myopes <sup>[3, 6, 7, 8]</sup>. In our study we attempted to analyze the optical higher order aberration (HOA) alterations or induced aberrations in eyes after ICL implantation in Indian eyes.

# **Materials and Methods**

All patients undergoing ICL (Visian, STAAR surgicals) from August 2007 to December 2007 were included. The exclusion criteria were history of glaucoma and uveitis. All patients were informed about the procedure and written consent was taken preoperatively. The preoperative evaluation included the comprehensive slit lamp examination, intraocular pressure measurement with the Goldman applanation tonometer, visual acuity examination with Snellen's distant visual acuity chart. Visual acuity examination included uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA) with spectacles and low contrast visual acuity (LCVA). Contrast sensitivity was taken with digital CSO contrast sensitivity system with spectacle correction in room light conditions. Optical higher order aberrations were calculated from Hartmann shack aberrometer of Zywave station in 6mm and 4mm pupil for comparison. Corneal topography and anterior chamber depth were obtained from Orbscan II. Pupil diameter was measured

using the real time pupillometer in the Hartmann Shack aberrometer. Phakic IOL power calculation was obtained from the software provided from STAAR Surgicals and recorded in respective patient files. UCVA, BCVA, contrast sensitivity and optical higher order aberrations were recorded postoperatively 4 weeks in all patients.

The Matlab 7.1 version software was used to generate wavefront maps, the modulation transfer function (MTF), phase transfer function (PTF), point spread function (PSF), and the individual polynomial RMS from the pre-op and post-op file of Zernike coefficients (Zerfiles) at 6mm and 4mm pupil. Zernike polynomial ordering was done based on OSA/VSIA standards<sup>[9, 10]</sup>.

## **Surgical Technique**

Single surgeon (Am A) has performed all the surgeries. Eyelids were cleaned with sponges soaked in povidone–iodine 5% and draping was done. Viscoelastic (OVD) was injected into the anterior chamber. A 2.8mm keratome was used to make a clear corneal incision. Preoperative mydriasis of 8-10mm was obtained in all eyes. ICL (Staar surgical, ICL without central flow) was loaded in the cartridge and injected. In case of toric ICL, the axis marked on the lens was aligned with the preoperative axis as desired. Pilocarpine about 0.3 ml was then injected into the anterior chamber to constrict the pupil. A bimanual irrigation/aspiration cannula was used to remove the viscoelastic. Peripheral iridectomy was done at 11 o'clock position. Wound hydration was done.

## **Statistical Analysis**

SPSS Version 15.1 was used for statistical mean and standard deviation estimation. P<0.05 was taken as significant. Comparisons of means of various prognostic factors were done with paired and unpaired t test (with equal variance assumed). Pearson coefficient was obtained for correlation analysis.

#### Results

Five patients had ICL implantation in both eyes and 5 patients in one eye. Mean preoperative and postoperative spherical equivalent was  $-16.5\pm$  5.3 and  $-0.72\pm$  2.01 respectively. The mean preoperative and postoperative UCVA was 0.012±0.009 and 0.762±0.359 respectively (Table 1). The preoperative BCVA changed from 0.452±0.264 to 0.834±0.414 postoperatively. The mean percentage contrast sensitivity in the preoperative period was  $46\pm16.8\%$  (Table 2) and postoperatively it was  $34.67\pm18\%$ . Low contrast visual acuity (LCVA) also improved from  $0.27\pm0.16$  to  $0.73\pm0.360$  postoperatively. There was a significant change (p<0.001) in the mean preoperative and postoperative visual acuity in uncorrected, best corrected and low contrast visual acuity (Table 1, 2). The mean IOL power used was - $20.18\pm2.78$ . None of the eye had drop in BCVA. There were 10 toric and 5 nontoric ICL implanted. All surgeries were uneventful. No postoperative complications like glaucoma, cataract or corneal edema was seen in any of the eyes. The mean preoperative and postoperative undilated mesopic pupil diameter was  $4.2\pm 0.5$  and  $4.3\pm 0.5$  respectively. No significant change (p=0.197) in undilated pupil diameter was seen in postoperative period.

	Preoperative	Postoperative	Lens	Preoperative	Postoperative
Eye	BCVA	BCVA	Power	UCVA	UCVA
E1	0.5	0.66	-23	0.001	1
E2	0.33	1	-20.8	0.03	1
E3	0.5	1	-20.25	0.03	1
E4	0.05	0.33	-18.5	0.03	0.25
E5	0.03	0.03	-21	0.01	0.03
E6	0.25	0.66	-22.5	0.01	0.33
E7	1	1	-16.5	0.01	1
E8	0.66	1	-16.5	0.01	1
E9	0.66	1	-22.5	0.001	1
E10	0.33	0.33	-23	0.001	0.33
E11	0.16	0.5	-21	0.01	0.5
E12	0.5	1	-23	0.01	1
E13	0.5	1	-22.5	0.01	1
E14	0.66	1.5	-16	0.01	1
E15	0.66	1.5	-15.75	0.01	1
Mean	0.452	0.834	-20.18	0.0122	0.762
SD	0.264	0.414	2.78	0.009	0.359

Table 1: Visual Acuity

E: Eye, UCVA: Uncorrected visual acuity, BCVA: Best corrected visual acuity

Table 2: Visual Acuity

	Preoperative	Postoperative	Preoperative	Postoperative
EYE	LCVA	LCVA	CS (%)	<b>CS (%)</b>
E1	0.4	0.66	50	30
E2	0.16	1	50	30
E3	0.16	1	50	30
E4	0.01	0.25	50	30
E5	0.01	0.01	100	100
E6	0.33	0.66	40	30
E7	0.66	1	30	30
E8	0.33	1	30	30

E9	0.33	1	30	30
E10	0.25	0.25	50	30
E11	0.1	0.25	50	30
E12	0.33	1	40	30
E13	0.33	1	40	30
E14	0.33	1	40	30
E15	0.33	1	40	30
Mean	0.27	0.738	46	34.67
SD	0.165	0.365	16.81	18.07

E: Eye, LCVA: Low contrast visual acuity, CS: Contrast sensitivity

# Correlation between the changes in visual acuity

Pearson's coefficient was calculated for correlation analysis. There was a significant correlation between the change in BCVA from preoperative to postoperative period with change in LCVA(r=0.763, p=0.001). Similarly, there was a significant correlation between the change in UCVA from pre to postoperative period with change in LCVA (r=0.8, p<0.001). There was no significant difference in the mean gain in visual acuity in the eyes implanted with toric and non toric ICL.

Alteration of optical higher order aberrations at 6MM pupil The mean preoperative TRMS and HRMS in 6mm pupil was  $5.16\pm7.47$  and  $0.11\pm0.08$  respectively. The mean postoperative TRMS and HRMS in 6mm pupil was  $1.17\pm2.42$  and  $0.117\pm0.14$ respectively. There was a significant change (p=0.001) in Z40 spherical aberration, Z3-3(p=0.026) 6mm pupil (Table 3) after ICL implantation (Fig 1). There was also significant change (p=0.009) observed in the total trefoil (Z3-3 and Z33) (Table 3). The total third order coefficients showed significant change after ICL implantation (p=0.015). On dividing the 15 eyes into two groups based on the postoperative visual acuity, Group I (n=9) consists of eyes with BCVA  $\geq 1$  and Group II (n=6) consists of eyes with BCVA <1; In group 1, there was significant change in

the mean Z33 (p=0.028), spherical aberration (p<0.001). Similarly there was significant change in total trefoil (p=0.003) and total secondary coma (p=0.004). The correlation noted between the change in LCVA and spherical aberration was significant. However the change in the total trefoil and total secondary coma did not show correlation with visual acuity changes in the postoperative period. On comparing the change in HOA in eyes improved  $\geq 3$  lines, there was significant difference in the spherical aberration (p=0.007), secondary trefoil (p=0.026) and total trefoil (Z3-3 and Z33) (p=0.032). No significant correlation was noted between the change in higher order aberrations and postoperative visual acuity. There was significant change in spherical aberration Z40 (p=0.013) and Z51 (p=0.028) in eyes with 2 lines improvement. In eyes with no lines improvement, there was no significant difference in Z40 (p=0.276) and total trefoil (p=0.941). There was no significant difference seen in postoperative optical higher order aberrations in eyes implanted with toric or nontoric ICL. There was no significant change between HOA's in the immediate postoperative period and at 6 months in TRMS (p=0.31), HRMS (p=0.30), Z40 (p=0.617), Z3-3 (p=0.633) and Z33 (p=0.959). There was no correlation between the change in the postoperative pupil diameter and HOA.

POSTOP	TRMS	HORMS	Z <sup>3</sup> -3	Z <sup>3</sup> -1	Z <sup>3</sup> 1	Z <sup>3</sup> 3	Z <sup>4</sup> -4	Z <sup>4</sup> -2	$Z^{4}_{0}$
E1	0.094	0.0911	-0.004	0.0525	-0.127	0.091	0.242	0.012	-0.09
E2	0.597	0.0963	-0.07	0.04	-0.076	0.285	-0.14	0.009	0.063
E3	0.892	0.1898	0.24	0.2119	-0.148	0.61	-0.12	0.051	0.051
E4	2.22	0.68	0.42	-0.21	0.22	0.03	0.23	0.08	0.33
E5	0.515	0.1251	-0.103	0.2928	-0.017	-0.09	0.018	0.163	0.127
E6	0.063	0.0526	0.113	0.0385	0.147	0.027	-0.02	0	-0.06
E7	0.533	0.196	0.303	0.0266	-0.173	0.631	-0.07	0.026	-0.08
E8	0.464	0.1728	0.365	0.4384	-0.212	-0.16	0.142	-0.01	-0.06
E9	0.169	0.1483	0.149	0.2614	-0.235	0.367	0.089	0.049	0.154
E10	0.351	0.0752	0.102	0.0217	0.068	-0.18	-0.01	-0.09	-0.99
E11	9.719	0.2357	0.73	-0.24	0.1	0.41	-0.01	0.04	0.12
E12	0.464	0.1024	0.065	0.0597	-0.133	0.245	0	-0.04	0.19
E13	0.831	0.2144	0.442	0.0853	-0.191	0.551	-0.06	-0.14	0.038
E14	0.312	0.0963	0.192	-0.082	0.003	0.285	0.065	0	-0.045
E15	0.352	0.1888	0.656	0.0102	-0.063	0.064	0.25	-0.03	-0.06
Mean	1.17	0.117	0.23	0.067	-0.055	0.021	0.041	0.007	0.038
SD	2.42	0.149	0.247	0.179	0.139	0.269	0.126	0.07	0.126

**Table 3:** Post-operative higher order aberration profile at 6mm pupil

TRMS: Total root mean square, HRMS: Higher order root mean square

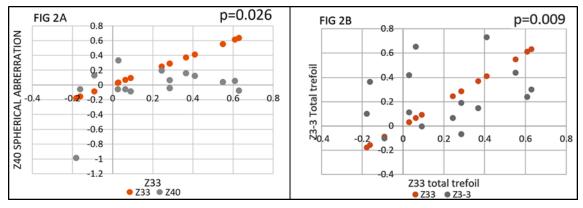


Fig 1: Scatter plot showing the variation in the preoperative and postoperative Z40 (A) and Z3-3 (B)

Efficacy Index: The efficacy as calculated by mean postoperative UCVA divided by mean preoperative BCVA with spectacles was 1.685.

**Safety Index:** The safety index as calculated by mean postoperative BCVA divided by mean preoperative BCVA was 1.845.

**Predictability:** Mean preoperative spherical equivalent was - 16.54D ± 5.31 and range was about – 10.5D to -31.8D. Mean postoperative spherical equivalent was -0.72 ± 2D and the range was -1.25 to -7.25D. Mean preoperative cylinder was -2.06D± 1.04 D and the mean postoperative cylinder was -0.98±1.16D. There was significant negative correlation(r=-0.567, p=0.028) between change in spherical equivalent from preoperative to postoperative period with alteration in Z5-1. 40% of the eyes showed ≥3 lines improvement in Snellen visual acuity. 20% of the eyes showed 2 lines improvement. Nine (60%) out of 15 of the operated eyes obtained postoperative BCVA ≥1 decimal equivalent in Snellen visual acuity. 20% of the eyes showed one line improvement and 20% of the eyes had no change in distant visual acuity.

ICL Position: The mean postoperative AC depth was  $3.01\pm0.15$  mm. The mean postoperative vault seen as in anterior segment OCT was  $0.9\pm0.1$ mm. There was significant positive correlation between AC depth and Vault(r=0.56, p=0.029). There was no significant correlation between ICL vaulting and postoperative

BCVA(r=-0.19, p=0.48). There was no significant difference in postoperative vaulting and postoperative higher order aberrations.

# Aberration profile at 4MM Pupil

The mean preoperative TRMS in 4mm pupil was 3.81±2.5 and the postoperative mean was 0.38±0.18. There was significant change in TRMS (P<0.001). The mean preoperative HRMS was 0.03±0.01 and the mean postoperative HRMS was 0.04±0.01. There was no significant difference in preoperative and postoperative HRMS in 4mm (p=0.155). At 4mm there was no significant change in spherical aberration Z40 (p= 0.18). But there was significant change in Coma x (p=0.035), Z4-4(p=0.028) and total secondary coma Z5-1+ Z51. In eyes with postop BCVA  $\geq 1$ , there was significant change in Z3-3 (p=0.025), Z33 (p=0.032) and Z40 (p<0.001) (table 3). There was significant change in the 3rd order coefficients (p=0.016) and 4th order coefficients (p=0.005). There was no significant correlation with change in visual acuity. In eyes with more than three lines improvement there was significant change in Z40 (p=0.006). There was significant change in 3rd order as well. Table 4 shows the difference in the alteration of HOA's at 4mm and 6 mm pupil.

Table 4: Alteration of HOA's at 4mm and 6 mm pupil	l
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		61	nm	4mm		
		Preop	Postop	Preop	Postop	
Overall group (n=15)	$Z^{3}$ 1	-0.042±0.15	-0.05±0.13	-0.007±0.06	$-0.04 \pm 0.04$	
Overall group (n=15)	$Z^{3}-3+Z^{3}-3$	0.145±0.12	$0.45 \pm 0.405$	$0.05 \pm 0.06$	0.11±0.107	
Overall group (n=15)	Total 3 <sup>rd</sup> Order	0.136±0.24	0.46±0.33	0.05±0.12	0.09±0.12	
Overall group (n=15)	$Z^{4}_{0}$	-0.108±0.124	0.038±0.12	-0.017±0.04	$-0.00004 \pm 0.02$	
Overall group (n=15)	$Z^{4}$ -4	0.005±0.13	0.04±0.12	-0.005±0.01	$0.008 \pm 0.02$	
Overall group (n=15)	$Z_{-1}^{5} + Z_{1}^{5}$	0.027±0.09	0.03±0.06	$-0.002 \pm 0.008$	0.003±0.009	
BCVA ≥1 (n=9)	$Z^{3}$ -3	$0.08 \pm 0.09$	0.26±0.21	$0.022 \pm 0.03$	$0.08 \pm 0.06$	
BCVA ≥1 (n=9)	$Z_{3}^{3}$	0.06±0.103	0.32±0.25	0.013±0.03	$0.09 \pm 0.07$	
BCVA≥1 (n=9)	$Z^{3}_{-3} + Z^{3}_{-3}$	$0.15\pm0.12$	-0.0006±0.007	$0.03\pm0.04$	0.17 ±0.07	
BCVA ≥1 (n=9)	$Z^{4}_{0}$	-0.12±0.12	0.02±0.09	-0.02±0.02	0.005±0.01	
BCVA $\geq 1$ (n=9)	$Z_{-1}^{5} + Z_{1}^{5}$	$-0.004 \pm 0.05$	-0.0006±0.007	0.019±0.05	0.002±0.006	
$\geq$ 3 lines of improve(n=7)	$Z^{3}-3+Z^{3}3$	$0.15 \pm 0.086$	0.523±0.365	-0.05±0.055	0.105±0.079	

$\geq$ 3 lines of improve(n=7)	$Z^{4}$ 0	-0.063±0.101	$0.057 \pm 0.152$	-0.01±0.034	0.017±0.021			
$\geq$ 3 lines of improve(n=7)	Z <sup>5</sup> -3 +Z <sup>5</sup> 3	0.003±0.014	-0.02±0.014	$0.0009 \pm 0.005$	0.0026±0.015			
BCVA: Best corrected visual acuity, HOA: Higher order aberrations								

#### Discussion

Phakic intraocular lenses (IOLs) have proved to be a good alternative for surgical correction of myopic, hyperopic and astigmatic refractive errors of the eye. The optical function of an IOL depends on its exact location. For instance, the distance from the corneal apex to the IOL, distance from the IOL centre to the crystalline lens or to the nodal point which determines the final power required for optimal correction. Centeration of the ICL and absence of tilt is one of the factors for excellent postoperative results. There have been many studies on the visual outcome, positioning, long term results and complications of phakic IOL <sup>[3-8]</sup>. So far there are no reports on analyzes of alternations in higher order aberrations with posterior chamber phakic IOL namely ICL. To our knowledge this is the first study on the evaluation of alterations or induced changes in the higher order aberrations after implantation of ICL in Indian eyes.

The increase in spherical aberration after LASIK has been confirmed by many studies and has also been shown to be related to the amount of myopia being corrected <sup>[11-14]</sup>. It has already been shown that the spherical aberration and coma are the major differences between postoperative LASIK and Phakic IOL higher-order aberrations <sup>[15]</sup>. However Buhren et al showed change in higher order aberrations after Ophtec Artisan IOL implantation <sup>[16]</sup>. They concluded that after implantation of the Artisan lens, HOA's increased slightly. Particularly induction of Z3-3 and Z40 contribute to the increase of HOA and they also concluded that the induction of trefoil Z3-3 was a result of the incision, whereas the increase of spherical aberration was due to the implant. However we did not get any such correlation with incision. Though there was significant change (p=0.006) in Sim K value in Orbscan II corneal topography. There was no correlation between the changes in the HOA and Sim K.

However there was significant change (p=0.026) seen in the mean cylinder (preop -2.06±1.04 decreased to -0.98±1.16 postoperatively) which did not correlate with the change in HOA's especially Z40 (r=0.066, p=0.816). In a normal eye, the cornea also exhibits positive spherical aberration, which is compensated by negative spherical aberration of the natural lens. But in phakic IOL eye, there are chances the optic of the IOL can induce spherical aberrations. Tehrani et al have analysed the change in higher order aberrations over a time period of 12 months and reported that there was a statistically significant reduction in Z40 in the first postoperative week, but the decrease was not significant thereafter [17]. However in our study, we did not obtain significant change in aberration profile between immediate and 6 months postoperative follow up. Sasivimon et al studied the HOA's changes in eves with Verisyse IOL, Array lens and post LASIK [18]. He noted that the higher order aberrations after implantation of the Verisyse IOL increased moderately both with a 4-mm and 6-mm pupil, but that increase was not statistically significant. Chung SH et al also noted small increase in HOAs under photopic conditions and with reduction in contrast <sup>[19]</sup>. But in our 15 eyes of 10 patients we noted improvement in contrast sensitivity seen well with significant change in LCVA.

In our prospective study of 15 eyes of 10 ICL patients, we observed significant change (p=0.001) in mean spherical aberration at 6mm pupil. There was significant change in mean Z40 from preop (-0.108 $\pm$ 0.12) and postop (0.038 $\pm$ 0.12). There was a significant change (p=0.009) seen in the total trefoil (Z3-3 and Z33) from before to after ICL implantation. Table 4 shows the difference in the alteration of HOA's at 4mm and 6 mm pupil. There were also changes seen in the point spread function, Modulation Transfer Function and Phase transfer

Function. We observed that Z40 was the common Zernicke coefficient at 6mm pupil which significantly altered in both subgroups, namely the eyes with mean postoperative BCVA≥1 decimal equivalent and eyes with improvement  $\geq$  three lines in Snellen distant visual acuity charts. The next common modes were the third order coefficients (table 4) which showed significant change. The changes in HRMS after ICL implantation at 6mm pupil was significant (p=0.012) but it was not significant (p=0.155) at 4mm pupil. And moreover the mean postoperative pupil size in our patients was 4.3±0.5mm and thus we expect that the effect of change of aberration on visual acuity to be less as compared to the effect at 6mm pupil. Similarly, though there was significant change in spherical aberration at 6mm pupil (p=0.001) and there was no change in spherical aberration at 4mm pupil. Though ICL implantation is one of the promising alternatives for the correction of high myopia as it preserves corneal curvature, with good postoperative optical qualities especially in cases requiring high ablation, alternations in the higher order aberrations are still observed. It has also been shown that adverse effect of aberrations that were induced or those that which was not entirely eliminated by refractive surgery on visual quality can be minimized by avoiding them near the center of the Zernike tree <sup>[20]</sup>. Understanding how residual aberrations interact to affect visual function will be important in optimizing ultimate visual outcomes. There are various factors affecting the HOA's like pupil size and diurnal variation apart from the changes induced by ICL <sup>[21-24]</sup>. However further study with variable pupil size and aberration analysis with the help of adaptive optics might be required to completely understand the answer behind the alterations of aberrations and visual performance in phakic IOL.

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