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Effect of Anterior Chamber Depth Changes on Corneal Endothelial Cells after Implantable Phakic Lens Implantation in Myopic Patients

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Abstract

Background: A phakic intraocular lens (pIOL) is a device that internally corrects the phakic eye's refractive error, reducing or eliminating the need for glasses or contact lenses.

Aim and objectives: To determine the impact of anterior chamber depth (ACD) changes on corneal endothelial cells following implantable phakic lens implantation (IPCL V2, Caregroup Sight Solutions, India) in myopic patients after three months of surgery.

Patients and methods: The prospective interventional research was done on 30 eye cases undergoing IPCL implantation for the correction of myopia, and follow-up was done after three months of the surgery at the Ophthalmology Department, AL-HUSSIEN University Hospital.

Results: There was a statistically significant increase in UCVA & BCVA at 3-month follow-up (Paired sample t-test, $P < 0.001$). A statistically significant enhancement was detected in refractive errors at a 3-month follow-up (Paired sample t-test, $P < 0.001$). A statistically significant positive correlation was noticed among ACD and ECD and percentage of hexagonality, and a negative association was observed among ACD and coefficient of variation, where reduction in ACD was associated with endothelial loss, increased CoV and reduced hexagonality at 3-month follow-up (Pearson test, $P < .001$).

Conclusion: The implantation of the pIOL resulted in the attainment of refractive stability, predictability, safety, and effectiveness. A small number of patients had intraoperative and postoperative problems, indicating that this surgical procedure is a secure treatment for correcting extreme myopia.

Keywords: Anterior chamber depth; corneal endothelial cells; myopic patients

1. Introduction

The pIOL offers internal correction for refractive abnormalities in the phakic eye, reducing or eliminating the need for glasses or contact lenses.¹

An implanted collamer lens (ICL) is a type of intraocular lens placed in the eye's posterior chamber. It is made of a soft and flexible gel material, and it is utilized for reversible refractive surgery. ICLs are posterior chamber pIOLs that may be inserted into the ciliary sulcus by a tiny (3.0 mm), self-sealing incision made at the limbal or clear corneal area.²

A novel implanted phakic contact lens (IPCL V2, Caregroup Sight Solutions, and India) has been established as a cost-effective solution for

correcting refractive errors.³

Nevertheless, the intrusive nature of the procedure heightens the likelihood of problems such as the development of cataracts, infections such as endophthalmitis, and the loss of endothelium cells.^{4,5}

The primary cause of cataract development is typically the result of direct contact between the implant and the crystalline lens or an abnormal circulation of aqueous humor leading to inadequate feeding of the lens.⁶

The aim was to determine the effect of ACD changes on corneal endothelial cells after implantable phakic lens implantation (IPCL V2, Caregroup Sight Solutions, India) in myopic patients after three months of surgery.

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2. Patients and methods

The prospective interventional research was done on total of 30 eyes of cases undergoing IPCL implantation for the correction of myopia and follow up was done following three months of the surgery at Ophthalmology department, AL-Hussien University Hospital.

2.1. Inclusion criteria: Age ranging from 20 to 45 years, Consistent refraction throughout the previous year, Patients who are unsuitable for corneal-based laser refractive operations include those with aberrant corneal topography and keratoconus, a projected thin residual stromal bed thickness of less than 300 μ , severe dry eye, a corneal diameter more than 11 mm, and a range of myopia from -5 D to -30D.

2.2. Exclusion criteria: Prior to myopia, it is important to consider a patient's medical history for any other ocular problems such as neuro-ophthalmic diseases, keratectasia, retinal detachment, corneal or lens opacity, glaucoma, and macular degeneration. Furthermore, it is critical to determine whether the patient has a prior ocular surgery, chronic systemic disease, or a history of inflammation or trauma.

2.3. Operational Design

All patients were subjected to the following:

Informed consent, Patients were prospectively evaluated 1 day preoperatively, three months postoperatively. History: Full history taking regarding age, any systemic disease, drug intake or previous intraocular surgery. Visual acuity: Assessment of uncorrected distance visual acuity (UDVA) and best corrected distance visual acuity (CDVA). Visual acuity was assessed utilizing a landolt's C chart and expressed in decimal scoring. IOP assessment with non-contact tonometry – NCT (NT-510 NIDEK technologies, Japan).

Slit-lamp Examination: Examination for tear film abnormalities: Tear meniscus height, tear meniscus floater and Mucous strands.

Conjunctival Surface examination: Strings of mucus, Dilated vessels, loss of luster and elasticity of the conjunctiva, Sub-epithelia fibrosis Papillary conjunctivitis sectorial, diffuse episcleritis, Nodular and scleromalacia and keratinization of the conjunctiva.

Anterior chamber examination: For the detection of anterior uveitis in cases with connective tissue disease, a fundus examination is done to exclude any myopia-related or other fundus abnormalities. The endothelial cell count is measured utilizing the Topcon Robo SP-IP98 noncontact specular microscope from Topcon Medical Inc. in Japan, while the ACD is assessed utilizing the pentacam from Sirius in Italy.

2.4. Implantable phakic contact lens power calculation and size selection:

Caregroup Co successfully performed power

calculation for implantable IPCL lenses utilizing an adapted formula. The choice of lens size was assessed concerning the corneal horizontal white-to-white measurement obtained by utilizing pentacam, with a minimum internal ACD of 2.81 mm.

2.5. Surgical technique

Since longer-acting dilating medicines can make it harder to constrict the pupil following the procedure, the pupil was dilated prior surgery with Tropicamide 1% or phenylephrine 2.5%, the recommended dilating agents. Utilizing a combination of lidocaine and marcaine for peribulbar or retrobulbar anesthesia. Place the concave surface of the IPCL into the cartridge while maintaining the alignment ridge or hole on the left leading footplate. Two incisions, one superior and one inferior, were created for paracenteses, and a transparent 3.0 mm keratome (kai by Japan) was utilized to make the incision in the cornea. The anterior chamber was filled with viscoelastic, specifically Hydroxypropyl Methylcellulose USP. Following being inserted into the anterior chamber in a manner that is parallel to the iris plane, the ICL was let to unfold normally. Prior to the lens, more viscoelastic is injected. After that, the iris is placed beneath the haptics footplates. When inserting an intraocular lens (ICL), a Batlle' manipulator can help tuck the haptics under the iris. In most cases, the proximal haptics are placed prior to the leading haptics, which are positioned distant from the incision. For the sake of your lens, it is advised that you stay away from the middle 6.0 mm of the ICL. It is imperative that the surgeon stays away from the cornea and crystalline lens (no fly zone) when doing the operation. Following finishing the case, all viscoelastic was removed. In order to narrow the pupil, a miotic substance like Miochol was injected. Following washing the miochol, make sure the incision is watertight. Antibiotic eye drops (0.5%) of moxifloxacin ophthalmic solution were prescribed for one week following surgery. Steroid eye drops (1% prednisolone) were tapered for four weeks, and antiglaucoma medicine (0.5%) was prescribed for two weeks.

2.6. Post-operative evaluation

All cases undergo:

Specular microscopy: Endothelial cell density (ECD) measurements were done 1 day preoperatively & repeated three months after surgery. Pentacam to evaluate angle of anterior chamber after three months using Pentacam (Sirius, Italy). IOP changes after three months using non-contact tonometry- NCT (NT-510 NIDEK technologies, Japan). Preoperatively, patients underwent a comprehensive evaluation that included the following tests: slit-lamp examination, CDVA and UDVA. The lens vault, as determined by slit lamp biomicroscopy, ought to be around (1.0 to

0.5) times the corneal thickness.

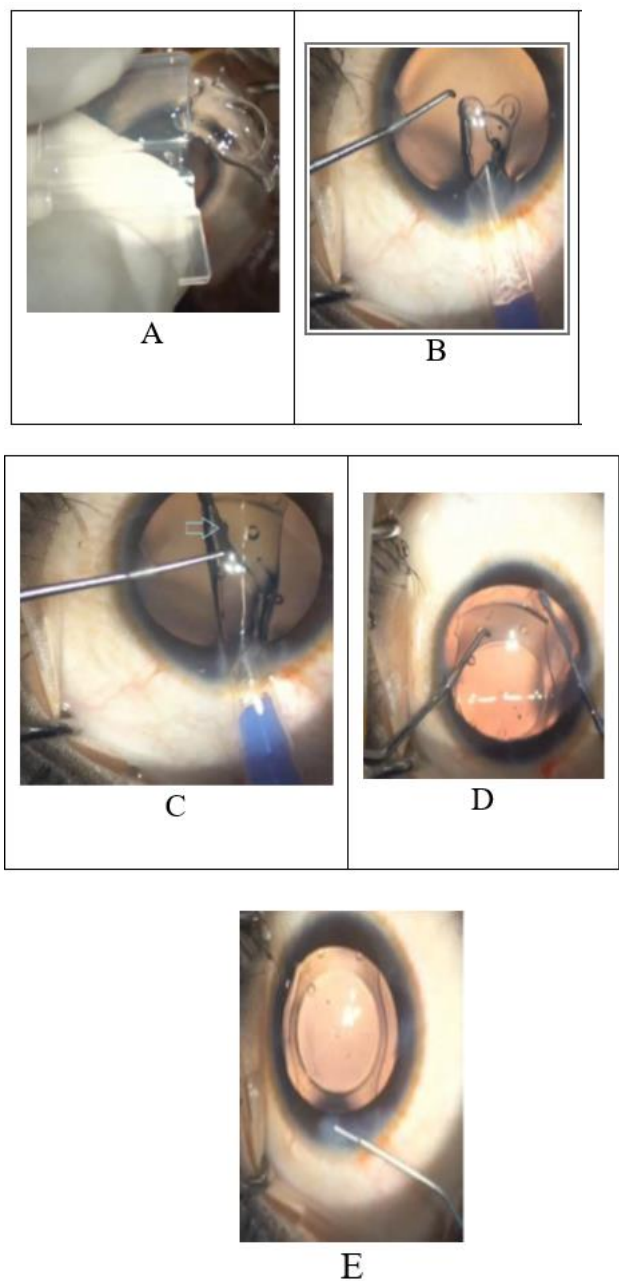


Figure 1. showed surgical technique: A) Loading of IPCL, B) Implantation through 3.0 mm incision, C) Important land mark should be to the left during implantation. Viscoelastic (Hydroxypropyl Methylcellulose USP) was used to fill the anterior chamber, D) footplates tucked under the iris, D) Hydration of the wound.

3. Results

The mean age of enrolled cases was 34.1 ± 7.1 years, ranging between 22 and 45 years. 12 (44%) patients were males, while 15 (56%) were females. The female to male ratio in our study group was 1.3, 11 (41%) patients, the phakic lens implantation was performed on the right side, 13 (48%) patients had their left eye operated on, and three (11%) patients underwent bilateral implantation. [Table 1](#)

Table 1. Baseline Demographic Data (N = 27 patients, 30 eyes)

VARIABLES	NO.	%
AGE, YEARS	34.1 ± 7.1 (Range, 22– 45)	
LESS THAN 30	7	25.9
30 – 40	12	44.4
MORE THAN 40	8	29.6
GENDER		
MALE	12	44.4
FEMALE	15	55.6
SIDE		
RIGHT	11	40.7
LEFT	13	48.1
BILATERAL	3	11.1

There was a statistically significant increase in UCVA and BCVA at 3-month follow-up (Paired sample t test, $P < 0.001$). [Table 2](#)

Table 2. Visual Acuity (N = 27 patients, 30 eyes)

VARIABLES	MIN	MAX	MEAN	SD
UCVA				
PREOPERATIVE	0.01	0.07	0.04	0.02
3-MONTH FOLLOW-UP	0.10	1.00	0.56	0.30
P VALUE*	< 0.001			
BCVA				
PREOPERATIVE	0.20	0.97	0.63	0.24
3-MONTH FOLLOW-UP	0.40	0.98	0.70	0.18
P VALUE*	< 0.001			

* PAIRED SAMPLE T TEST

There was a statistically significant improvement in refractive errors at 3-month follow-up (Paired sample t test, $P < 0.001$). [Table 3](#)

Table 3. Refractive Error (N = 27 patients, 30 eyes)

VARIABLES	MIN	MAX	MEAN	SD
SE REFRACTION (D)				
PREOPERATIVE	-	-	-	5.28
3-MONTH FOLLOW-UP	23.38	6.56	15.72	1.30
P VALUE*	< 0.001			
CYLINDER (D)				
PREOPERATIVE	-3.73	-	-2.10	1.05
3-MONTH FOLLOW-UP	-2.85	0.26	-1.32	0.86
P VALUE*	< 0.001			

There was no statistically significant variance was observed between preoperative and postoperative IOP (Paired sample t test, $P = 0.184$). [Table 4](#)

Table 4. Intraocular Pressure (N = 27 patients, 30 eyes)

VARIABLES	MIN	MAX	MEAN	SD
IOP (MMHG)				
PREOPERATIVE	8	15	10.9	2.4
3-MONTH FOLLOW-UP	7	15	11.1	2.4
P VALUE*	0.184			

There was a statistically significant reduction in anterior all chamber measurements were observed at 3-month follow-up (Paired sample t test, $P < 0.001$). [Table 5](#)

Table 5. Anterior Chamber Measurements (N = 27 patients, 30 eyes)

VARIABLES	MIN	MAX	MEAN	SD
ACD (μM)				
PREOPERATIVE	3.00	4.00	3.42	0.31
3-MONTH FOLLOW-UP	2.40	3.40	2.88	0.30
P VALUE*	< 0.001			
ACV (MM^3)				
PREOPERATIVE	180	200	190.97	6.56
3-MONTH FOLLOW-UP	125	153	140.40	7.91
P VALUE*	< 0.001			
ACA (DEG)				
PREOPERATIVE	30	41	35.60	3.36
3-MONTH FOLLOW-UP	20	30	26.17	3.05
P VALUE*	< 0.001			

There was a statistically significant positive association was observed among ACD & ECD and percentage of hexagonality and a negative association was observed among ACD & coefficient of variation, where reduction in ACD was associated with endothelial loss, increased CoV and reduced hexagonality at 3-month follow-up (Pearson test, $P < .001$). Table 6

Table 6. Correlation Analysis (N = 27 patients, 30 eyes)

VARIABLES	DEPTH OF ANTERIOR CHAMBRE	
	Correlation Coefficient	P value*
ENDOTHELIAL CELLS		
ECD (CELL/ MM^2)	0.981	< 0.001
COV	0.702	< 0.001
HEXAGONALITY, %	0.859	< 0.001

* PEARSON TEST

4. Discussion

For the correction of medium to high myopia, pIOL is an option. They maintain the cornea's original prolate shape and help maintain accommodation.⁷

The main results of this study were as follows:

Our current study showed that the mean age of enrolled cases was 34.1 ± 7.1 years, ranging between 22 and 45 years. Patients were classified into three groups: less than 30 ($n = 7$), between 30 and 40 ($n = 12$), and more than 40 ($n = 8$). 12 (44%) patients were males, while 15 (56%) were females. The female-to-male ratio in our study group was 1.³

Also, our results supported Shajari et al., who determined whether implantation of an iris-fixed pIOL affected the central corneal ECD in the eyes

after alterations in the ACD. The study included 52 patients (95 eyes). The age of patients ranged from 20 – 49 (20 men, 32 women). Women were more common than males.⁸

There were 11 (41%) patients, the phakic lens implantation was performed on the right side, 13 (48%) patients had their left eye operated on, and three (11%) patients underwent bilateral implantation.

Also, our results were supported by Shajari et al., who reported that the operation was performed on 41 right eyes and 54 left eyes of 52 patients.⁸

Regarding Visual Acuity, the mean preoperative UCVA and BCVA were 0.04 ± 0.02 and 0.63 ± 0.24 , correspondingly. At 3-month follow-up, the mean UCVA and BCVA elevated to 0.56 ± 0.30 and 0.70 ± 0.18 , correspondingly. Contrasted with preoperative values, a statistically significant increase was observed in UCVA & BCVA at 3-month follow-up ($P < 0.001$).

Also, our results supported Shajari et al., who reported that Prior to intervention, the decimal UDVA was worse for all patients. While seventy-two eyes (76%) had a UDVA of 0.8 or higher four years following pIOL implantation, seventy-four eyes (78%) achieved a CDVA of 0.8 or higher prior to surgery. In six eyes (6% of the total), one Snellen line was lost in CDVA. Forty-four eyes (46%) showed no change in CDVA after four years, whereas forty-five eyes (47%) showed an increase of one or more lines of CDVA. One or more lines were lost in no eye.⁸

A year and four years later, the same cohort was also studied by Benedetti et al. and Yuan et al. Also, after the first year, ECD drops significantly, and it drops down more. Based on these findings, it can be concluded that both surgical and pIOL implantation significantly impact ECD negatively.^{9,10}

Regarding the refractive error, the mean preoperative spherical equivalent (SE) and cylinder were -15.72 ± 5.28 and -2.10 ± 1.05 diopters, respectively. At 3-month follow-up, the mean SE and cylinder increased to -1.82 ± 1.30 and -1.32 ± 0.86 diopters, respectively. Compared to preoperative values, a statistically significant improvement was observed in refractive errors at 3-month follow-up ($P < 0.001$).

Shajari et al. reported the average SE following four years was $-0.42 \text{ D} \pm 0.47$ (SD), with a range of -1.75 to $+0.88 \text{ D}$. Following the procedure, the SE ranged from $\pm 0.5 \text{ D}$ in 68 eyes (72%), $+0.5$ to $+1.0 \text{ D}$ in 2 eyes (2%), -0.5 to -1.0 D in 19 eyes (20%), and -1.0 to -2.0 D in 6 eyes (6%). Absolute astigmatism decreased by 0.71 D following four years.⁸

Bouheraoua et al. reported that the mean prior to surgery and final SE was -13 ± 4.10 and -0.75 ± 0.74 diopters (D), correspondingly.¹¹

Regarding intraocular pressure, the mean preoperative IOP was 10.9 ± 2.4 mmHg, ranging from 8 to 15 mmHg. At 3-month follow-up, the mean IOP was 11.1 ± 2.4 mmHg, ranging from 7 to 15 mmHg. No statistically significant variance was detected among before- and after-surgery IOP (Paired sample t-test, $P = 0.184$).

Our results were supported by Shajari et al., who reported the average and range of IOP before surgery. Following the operation, the average IOP was 15.22 ± 2.66 mm Hg (range 9 to 24 mm Hg) at one year, 15.06 ± 2.53 mm Hg (range 7 to 23 mm Hg) at two years, 14.69 ± 2.6 mm Hg (range 8 to 26 mm Hg) at three years, and 15.30 ± 2.39 mm Hg (range 9 to 25 mm Hg) at four years.⁸

In anterior Chamber Measurements, the ACD reduced from 3.4 ± 0.3 μm (range, 3 to 4) preoperatively to 2.88 ± 0.3 μm (range, 2.4 – 3.4) at three months. The mean preoperative anterior chamber volume (ACV) was 191 ± 6.7 mm³, ranging from 180 to 200 mm³. At 3-month follow-up, the mean ACV decreased to 140 ± 7.9 mm³, ranging from 125 and 153 mm³. The mean preoperative anterior chamber angle (ACA) was 35.6 ± 3.4 degrees, ranging from 30 to 41 degrees. At 3-month follow-up, the mean ACA decreased to 26.2 ± 3.1 degrees, ranging from 20 to 30 degrees. A statistically significant reduction in anterior all chamber measurements was observed at the 3-month follow-up (Paired sample t-test, $P < 0.001$); the mean preoperative ECD was 2819 ± 516 cell/mm², ranging from 2008 to 3825 cell/mm². At 3-month follow-up, the mean ECD decreased to 2748 ± 518 cell/mm², ranging from 1968 to 3790 cell/mm². No statistically significant variance was detected before or after surgery ECD (Paired sample t-test, $P = 0.207$).

Our results supported Doors et al. reported that Preoperative ECD (cells/mm²) Mean \pm SD 2664 ± 337 Range 1588 to 3753. Post-operative after six months was 2663 ± 351 . There was no significance between preoperative and post-operative regarding ECD. At 2, 5 and seven years, the ECD decreased significantly by 1.28% G, 8.46%, 3.25% G, 8.24%, and 5.02% G, 10.40%, respectively.¹²

In their research, Jonker et al. found that the myopic group saw a yearly decrease of 64 cells/mm² due to chronic EC loss ($P < .001$, standard error 3.58) while the toric group experienced a fall of 62 cells/mm² ($P < .001$, standard error 3.77). The myopic group experienced a total chronic EC loss of 10.5% from 6 months to 5 years after surgery, whereas the toric group saw a loss of 10.2%. An ECD decline of at least 25% happened in 4.4% and 4.3% of eyes after five years, whereas 3.0% and 0.0% of eyes, respectively, reported an ECD

below 1500 cells/mm². In 3.1% and 0% of eyes, correspondingly, pIOL transplantation was necessary because of EC loss. Over five years, patients utilizing the foldable myopic (toric) pIOL saw a chronic EC loss of around 10%. Significant EC loss led to pIOL explantation in 3.1% of eyes.¹³

Bouheraoua et al. found that pIOL implantation was a stable and successful operation after five years of follow-up. Ophthalmologists can utilize the offered model to help with patient selection and follow-up by predicting EC loss following pIOL implantation.¹¹

Reductions in ACD, volume, and angle have been associated with endothelial loss at the 3-month follow-up, as demonstrated by a statistically significant positive association among ECD anterior chamber evaluations and endothelial loss (Pearson test, $P < .001$).

Yaşa et al. found that pIOL implantation, a surgical method for correcting excessive myopia, is safe and effective. In the first several days following surgery, ECD loss levels out.¹⁴

4. Conclusion

With the implantation of the pIOL, refractive stability, predictability, safety, and efficacy were all attained. The infrequent occurrence of intraoperative and postoperative complications renders this surgical procedure a risk-free approach to managing high myopia.

Disclosure

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Authorship

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