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ORIGINAL ARTICLE

Assessment of Corneal Endothelial changes after Implantable Phakic Contact Lenses (IPCL) In myopic Patients

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Abstract

Background: ***The Implantable Phakic Contact Lens (IPCL) has been established as a substitute for refractive correction as a distinct financial benefit over the Visian Implantable Collamer lens (ICL), with correction of high levels of ametropia up to −30.0 D.***

Aim of the Work: ***To evaluate endothelial changes after implantable Phakic contact lens in moderate and high myopic patients by specular microscope.***

Patients and Methods: ***Twenty eyes of 14 patients were involved in the present interventional prospective clinical study. All eyes were implanted with IPCL V2.0. Corneal endothelium changes using specular microscopy were measured at the preoperative baseline visit, one week, one month, and three months after surgery.***

Results: ***Improvement of visual acuity (VA) from preoperative value (0.26±0.11) to (0.35±0.10) at the last follow-up period, (p<0.001). Spherical equivalent (SE) markedly improved from (-14.83±1.51) preoperatively to (-0.61±0.27) at the last follow-up period (p-value < 0.001). Maximum intraocular pressure (IOP) increases at one week and one month postoperatively but declines by three months postoperatively (p >0.05). Endothelial cell density (ECD) decreased from 3507.20±258.34 preoperatively to 3441.35±261.25 at the end of the follow-up period (p<0.05). Central corneal thickness (CCT) change was insignificant at the last follow-up period (p>0.05). The coefficient of Variation (CV) change was insignificant throughout all visits (p-value>0.05).***

Conclusion: ***IPCL implantation is a safe, reliable, and cosmetically acceptable method for treating moderate to high degrees of myopia when contraindicated corneal refractive surgery.***

Keywords: Corneal Endothelium; Implantable Phakic Contact Lenses; Myopia

1. Introduction

Phakic intraocular lens (IOL) Implantation is considered the primary surgical method for correcting high degrees of refractive defects.[1] One evident benefit of alternative treatment procedures, including clear lens extraction, is the preservation of accommodation.[2] The benefits of phakic IOL implantation are noticeable in cases of higher ametropia because they include improved contrast sensitivity, retinal image magnification, and less induction of postoperative aberrations.[3]

Patients should be aware of several potential complications, including cataracts, loss of corneal endothelium, IOP elevation, phakic posterior chamber intraocular lens rotation and anterior chamber inflammation, even though reports of this technique's effectiveness, safety, and even reversibility as a surgical approach. [4]

The anterior segment characteristics are the most important indicator of whether refractive surgery is appropriate. The most important factors in deciding which patient is a good candidate for posterior chamber phakic IOL surgery and what size lens to use are the white-to-white (WTW) corneal diameter and the anterior chamber depth (ACD). A posterior chamber phakic IOL operation is contraindicated in cases where the value of the ACD is less than 2.80 mm.[5]

Estimating the safety after surgery depends on the central vault, defined as the space between the crystalline lens front surface and the phakic posterior chamber IOL back surface.[6]

The high frequency of opacity of the anterior capsule and cataracts may be attributed to inadequate circulation of aqueous humour or a low vault.[7]

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On the other hand, excessive mechanical contact between the iris and ICL due to a high vault might result in inflammation and elevated intraocular pressure.[8]

Furthermore, a high vault might result in iris atrophy, acute angle-closure glaucoma and pigment dispersion syndrome.[9]

Visian ICL is more expensive than IPCL and cannot correct high degrees of ametropia up to −30.0 D. Therefore, IPCLs have been invented as a substitute for refractive correction. Additionally, V2.0, meant to decrease glare and dispersion while enabling aqueous humour circulation and alignment, replaced V1.0 with an additional centre hole (380µm).[10]

Anterior segment optical coherence tomography (OCT) is a non-invasive technique that can be used to acquire high-resolution anterior segment images for both quantitative and qualitative analysis, which can be used accurately to measure the IPCL central vault and assure its safety. [11,12]

This study uses a specular microscope to assess endothelial changes following IPCL in patients with moderate to high myopia.

2. Patients and methods

This interventional prospective clinical study included twenty eyes selected from the Al-Azhar University Hospital ophthalmic outpatient clinics between (January 2023 and December 2023). The study included myopic patients ranging from moderate to high degrees, whether they have astigmatism or not, who are between the ages of 18 and 40 years, have endothelial cell counts of at least 2,500 cells/mm2 and an ACD of at least 3 mm, have stable refraction (mean spherical equivalent change of - 0.25 diopter or less) for at least a year, and have myopia between -3.00 and -20.00 diobter and astigmatism between 0 and 4.00 diobter. While patients had previous ocular surgery, ocular diseases including glaucoma, uveitis, and cataracts, and patients with systemic diseases including Diabetes mellitus, Rheumatoid Arthritis or other autoimmune diseases and eyes optimal for refractive laser correction were excluded from the study.

Each patient in this study was subjected to the following: Full history taking regarding age, any systemic disease, drug intake or previous intraocular surgery. Visual acuity: Evaluation of best corrected and uncorrected distance visual acuity (UDVA and CDVA). A Landolt's C chart was used to evaluate visual acuity, and the results were presented in decimal scores. The Topcon KR Auto-refractometer was used to measure the cycloplegic and manifest refractions. They were employing a Goldmann application tonometer to measure IOP. Biomicroscopic analysis using a slit light. Fundus dilation examination. They were utilizing (Sirius, CSO, Italy, SN: 16072553) for corneal tomography, the pupil size, and the ACD. Corneal diameter was measured horizontally from white to white using the Zeiss IOL master. ECD was measured using a Topcon SP-1P specular microscope.

IPCL power and size: Based on the manufacturer's recommendations, the power of the IPCL (V2, Caregroup Sight Solutions, India) was determined using a modified vertex formula with an emmetropia target refraction. The formula includes variables such as preoperative manifest spherical and cycloplegic refractions, keratometry power, central corneal thickness, and central ACD. The implanted ICL size was obtained according to the patient's ACD and WTW.

Informed consent: Every patient gave written informed consent after being fully educated about the procedure's risks and specifics.

Surgical procedure: Thirty minutes before surgery, dilate the pupillary with 1% tropicamide and 2.5% phenylephrine hydrochloride. Either peri-bulbar or general anaesthesia. 10% betadine is used for the surgical site, eyelids, and conjunctival cul-de-sac; 5% is used for the two sterilization methods. The hanging of antiseptic curtains. IPCL loading prior to the corneal cut. Clean temporal corneal incision of 2.8 mm. injectable viscoelastic material. Two 90-degree side ports. IPCL insertion. During implantation, the IPCL's landmark must be on the left side to avoid the IPCL turning upside down. The iris covers the footplates. Viscoelastic materials removal. Moisturized wounds. Topical prednisolone acetate 1% and the antibiotic Moxifloxacin are the postoperative treatments—Anti-glaucoma medications in circumstances where IOP is elevated.

Postoperatively: Following surgery, all patients were observed for complications by IOP measurement and assessments of the anterior and posterior segments at the one-, three-, and seven-day visits postoperatively. At one week, 1month, 3 months postoperative: measurement of Visual acuity, measurement of spherical equivalent, IOP measurement by Goldmann applanation tonometer and endothelial cell count measurement using specular microscopy (Topcon sp-1p, Topcon Medical Inc, Japan).

Statistical analysis:

Statistical software for social sciences, version 23.0, was used to analyze the recorded data (SPSS Inc., Chicago, Illinois, USA). The ranges and mean± standard deviation of the quantitative data were displayed. Numbers and percentages were also used to represent qualitative characteristics. Significantity was defined as a P-value ≤ 0.05.

3. Results

Table 1. Distribution of demographic data among patients group.

DEMOGRAPHIC DATA	TOTAL (N=20)
AGE (YEARS)	
RANGE	20-31
MEAN±SD	24.65±3.376
SEX	
FEMALE	14 (70%)
MALE	6 (30%)
EYE SIDE	
LT	9 (45%)
RT	11 (55%)

Table 1 describes the age, sex and the eye side distribution of total study population. Age ranged from 20 to 31 years with mean± SD of 24.65±3.38. As regards sex distribution, there was female predominance with 14 females with percentage 70% and 6 males with percentage 30%; and eye side was 9 patients (45%) were left and 11 patients (55%) were right.

Intraocular pressure:

Regarding IOP "mmHg", there was a highly statistically significant difference between pre-operative with after 1week and after 1m, with p-value <0.001. Also highly statistically significant changes between 1 week and after 1m and after 3m, with p-value <0.001, as well as a statistically significant between after 1m and after 3m, with p-value <0.05; while the rest time have insignificant difference, with p-value (p>0.05).

Table 2. Comparison between different times according to their IOP (mmHg) in patients group.

FOLLOW UP	IOP (MMHG)				
	RANGE		MEAN±SD		
PREOPERATIVE	12-16		14.15±1.14		
AFTER 1 WEEK	15-23		18.15±2.08		
AFTER 1 MONTH	13-19		15.60±1.73		
AFTER 3 MONTHS	12-17		14.50±1.28		
DIFFERENCE BETWEEN TIME INTERVAL					
FOLLOW UP	MD±SE	CHANGE%	T-TEST	P-VALUE	SIG.
PREOP. - 1 W	4.00±0.43	28.3	9.320	0.000	HS
PREOP. - 1 M	1.45±0.36	10.2	4.040	0.001	HS
PREOP. - 3 MS	0.35±0.20	2.5	1.161	0.260	NS
1 W - 1 M	-2.55±0.23	-14.0	10.860	0.000	HS
1 W - 3 MS	-3.65±0.36	-20.1	10.007	0.000	HS
1 M - 3 MS	-1.10±0.35	-7.1	3.168	0.005	S

Using: Paired sample t-test

NS: Non significant; S: Significant; HS: Highly significant

Endothelial cell count:

Regarding Endothelial cell count / Cell Density (CD) (cells/mm2), there was a statistically significant difference between pre-operative with after 1week, after 1m and after 3m, with p-value (p<0.05); also statistically significant difference between 1 week with (after 1m and after 3m), with p-value (p<0.05), as well as a statistically insignificant change between (after 1m and after 3m), with p-value (p>0.05) as shown in Table 3 & Figure 1 .

Table 3. Comparison between different times according to their endothelial cell count / cell density (cells/mm2) in patients group.

FOLLOW UP	ENDOTHELIAL CELL COUNT / CELL DENSITY (CD) (CELLS/MM²)					
	RANGE		MEAN±SD			
PREOPERATIVE	2988-3885		3507.20±258.34			
AFTER 1 WEEK	2934-3834		3456.90±261.33			
AFTER 1 MONTH	2926-3825		3447.60±261.40			
AFTER 3 MONTHS	2918-3818		3441.35±261.25			
DIFFERENCE BETWEEN TIME INTERVAL						
FOLLOW UP	MD±SE	CHANGE %	T-TEST	P-VALUE	SIG.	
PREOP. - 1 W	-50.30±2.70	-1.4	2.239	0.035	S	
PREOP. - 1 M	-59.60±2.87	-1.7	2.494	0.019	S	
PREOP. - 3 MS	-65.85±3.07	-1.9	2.571	0.013	S	
1 W - 1 M	-9.30±0.55	-0.3	2.018	0.042	S	
1 W - 3 MS	-15.55±0.83	-0.4	2.252	0.023	S	
1 M - 3 MS	-6.25±0.39	-0.2	1.924	0.097	NS	

Using: Paired sample t-test

NS: Non significant; S: Significant; HS: Highly significant

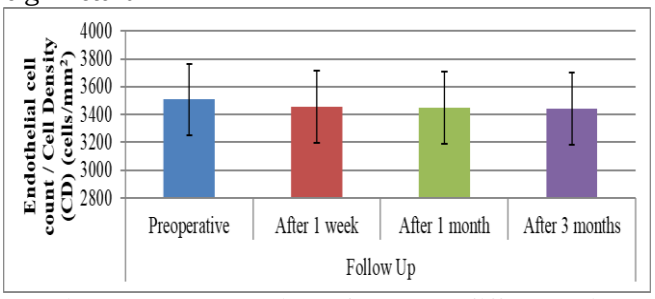

Figure 1. Comparison between different times according to their endothelial cell count / cell density (cells/mm2) in patients group.

Central corneal thickness:

Regarding Central Corneal Thickness (CCT) (µm), there was a statistically significant difference between pre-operative with (after 1week and after 1m), with p-value (p<0.05); also statistically significant difference between (1 week with after 1m and after 3m), with p-value (p<0.05), as well as a statistically significant between (after 1m and after 3m), with p-value (p<0.05); while the rest time have insignificant difference, with p-value (p>0.05) as shown in Table 4 & Figure 2.

Table 4. Comparison between different times according to their central corneal thickness (CCT) (µm) among patients group.

FOLLOW UP	CENTRAL CORNEAL THICKNESS (CCT) (µM)				
	RANGE		MEAN±SD		
PREOPERATIVE	489-593		545.50±34.69		
AFTER 1 WEEK	494-597		549.45±34.34		
AFTER 1 MONTH	491-595		546.25±34.94		
AFTER 3 MONTHS	489-593		545.55±34.65		
DIFFERENCE BETWEEN TIME INTERVAL					
FOLLOW UP	MD±SE	CHANGE %	T-TEST	P-VALUE	SIG.
PREOP. - 1 W	3.95±1.24	0.7	3.178	0.005	S
PREOP. - 1 M	0.75±0.22	0.1	3.470	0.003	S
PREOP. - 3 MS	0.05±0.03	0.0	1.000	0.330	NS
1 W - 1 M	-3.20±1.22	-0.6	2.629	0.017	S
1 W - 3 MS	-3.90±1.22	-0.7	3.190	0.005	S
1 M - 3 MS	-0.70±0.21	-0.1	3.390	0.003	S

Using: Paired sample t-test

NS: Non significant; S: Significant; HS: Highly significant

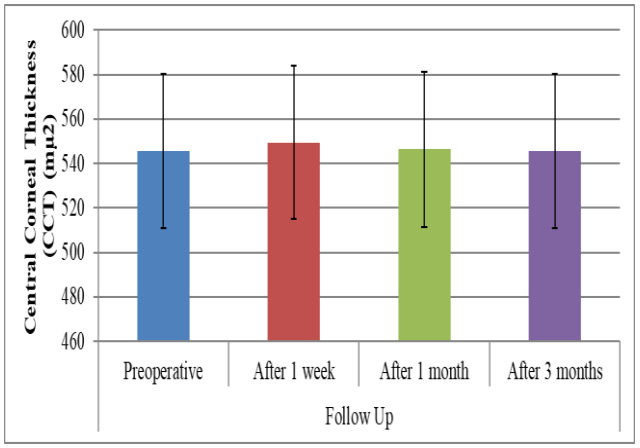

Figure 2. Comparison between different times according to their central corneal thickness (CCT) (μm) in patients group.

Co-efficient of Variation (CV):

Regarding Co-efficient of Variation (CV) (%), there is no statistically significant difference between different time, with p-value (p>0.05) as shown in Table 5 & Figure 3.

Table 5. Comparison between different times according to their Co-efficient of Variation (CV) (%) in patients group.

FOLLOW UP	CO-EFFICIENT OF VARIATION (CV) (%)				
	Range	Mean±SD			
PREOPERATIVE	28-39	34.85±3.54			
AFTER 1 WEEK	28-38.5	34.66±3.31			
AFTER 1 MONTH	27-39	34.62±3.24			
AFTER 3 MONTHS	29-39	34.58±3.15			
DIFFERENCE BETWEEN TIME INTERVAL					
FOLLOW UP	MD±SE	Change %	t-test	p-value	Sig.
PREOP. - 1 W	-0.19±0.33	-0.5%	0.581	0.568	NS
PREOP. - 1 M	-0.23±0.17	-0.7%	0.319	0.600	NS
PREOP. - 3 MS	-0.27±0.13	-0.8%	0.091	0.802	NS
1 W - 1 M	-0.04±0.03	-0.1%	0.678	0.428	NS
1 W - 3 MS	-0.08±0.07	-0.2%	0.807	0.449	NS
1 M - 3 MS	-0.04±0.02	-0.1%	0.568	0.487	NS

Using: Paired sample t-test

NS: Non significant; S: Significant; HS: Highly significant

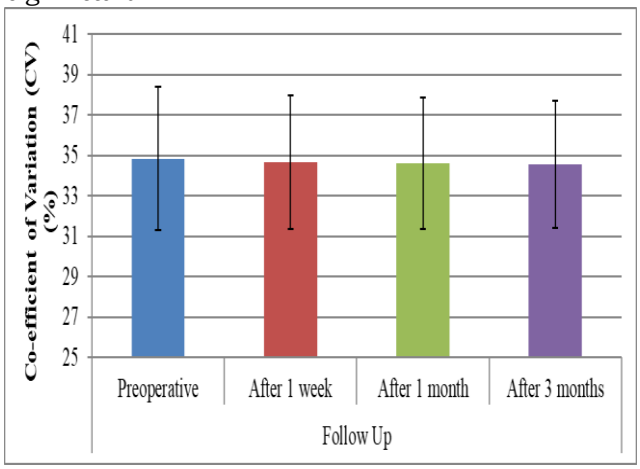

Figure 3. Comparison between different times according to their Co-efficient of Variation (CV) (%) in patients group.

Hexagonality of cells (HEX):

Regarding Hexagonality of cells (HEX) (%), there is no statistically significant difference between time interval, with p-value (p>0.05) as shown in Table 6 & figure 4.

Table 6. Comparison between different times according to their hexagonality of cells (HEX) (%) in patients group.

FOLLOW UP	HEXAGONALITY OF CELLS (HEX) (%)				
	Range	Mean±SD			
PREOPERATIVE	61-74	66.25±3.78			
AFTER 1 WEEK	60-74	65.95±4.09			
AFTER 1 MONTH	60-75	65.92±4.22			
AFTER 3 MONTHS	60-75	65.92±4.24			
DIFFERENCE BETWEEN TIME INTERVAL					
FOLLOW UP	MD±SE	Change%	t-test	p-value	Sig.
PREOP. - 1 W	-0.30±0.14	-0.45	1.661	0.107	NS
PREOP. - 1 M	-0.33±0.19	-0.50	1.791	0.077	NS
PREOP. - 3 MS	-0.33±0.20	-0.50	1.688	0.099	NS
1 W - 1 M	-0.03±0.02	0.0	0.132	0.896	NS
1 W - 3 MS	-0.04±0.02	0.0	0.175	0.863	NS
1 M - 3 MS	0.00±0.02	0.0	0.018	0.986	NS

Using: Paired sample t-test

NS: Non significant; S: Significant; HS: Highly significant

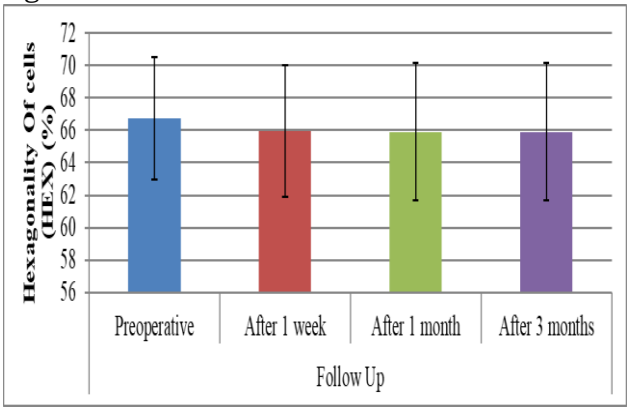

Figure 4. Comparison between different times according to their hexagonality of cells (HEX) (%) in patients group.

4. Discussion

High degrees of refractive defects have traditionally been corrected surgically using phakic intraocular lenses (IOLs). Even in the absence of peripheral iridectomy, the implantation of a recently designed Hole ICL has shown significant improvements in safety, effectiveness and steadiness for correcting moderate-to-high myopia errors, indicating the possibility of this procedure as a surgical alternative for the care of such eyes.[13]

ICLs are posterior chamber pIOLs placed in the ciliary sulcus and inserted through a tiny, self-sealing limbal/clear corneal incision (approximately 3.0 mm). Unlike the exchange of refractive lenses, ICL implantation does not obstruct natural accommodation or increase the risk of retinal detachment above the background rate for untreated individuals with extreme

myopia. It also has a favourable safety profile. [14]

The current study has been carried out using IPCL (V2, Caregroup Sight Solutions, India) design. Special concern has been made for evaluating the corneal endothelial changes that may occur after PC IOL Implantation using specular microscopy.

Regarding IOP, IOP elevation during the first month postoperatively attributed to retained viscoelastic, topical steroid usage and postoperative inflammation, while returning to the normal preoperative values at the last follow-up period.

According to Bianchi et al.[10] there are insignificant changes in IOP values at baseline, one day, and six months following IPCL V2.0 implantation.

Zhou et al.[15] investigated ICL V4c and found an insignificant increase in IOP at 1, 6, and 12 months postoperatively.

These two studies support our study in that the IOP remains similar to the preoperative values with the new version of the ICL (which has a central hole) by the end of the follow-up period.

Regarding Endothelial cell density, evaluated using specular microscopy, Found that CD decreased from 3507.20±258.34 preoperatively to (3456.90±261.33 at one week, 3447.60±261.40 at 1 month&3441.35±261.25 at three months postoperatively), showing maximum loss occurred during the first week postoperative (-50.30±2.70), the least loss occurred between the first month and the end of the follow-up period (three months) (-6.25±0.39). The p-value at three months was 0.023 (<0.05), indicating significant loss.

Bianchi et al.[10] also found that ECC decreased by 2.9% in patients with IPCL V2.0 implants, with a statistically significant difference, P = 0.03, at six months of follow-up. These findings support our results.

Igarashi et al.[16] investigated ICL V4c and found a statistically insignificant difference between pre-and postoperative results regarding the ECC loss (P > 0.05).

Regarding Central corneal thickness, evaluated using specular microscopy, there was a statistical increase in the central corneal thickness during the first week, changing from (545.50±34.69 preoperatively) to (549.45±34.34 at one week postoperatively), returning to statistically insignificant difference between preoperative and three months with(p>0.05).

Bianchi GR et al. [10] found that CCT decreased by 0.87% after IPCL V2.0 implantation without a statistically significant difference (P = 0.35) at six months of follow-up.

The Coefficient of variation, evaluated using specular microscopy, found insignificant changes between preoperative and all visits with (p>0.05) (34.85±3.54 preoperative to 34.66±3.31 at one week, 34.62±3.24 at one month & 34.58±3.15 at three months postoperatively).

Edelhauser et al.[17] conducted over a four years period; the CV decreased throughout the study, decreased from (35.8 ± 7.3 baseline) to (35.8 ±5.7 at three months)& to (34.3 ± 6.1 at the last visit) with (p≤0.001).

Regarding the Hexagonality of cells, there was a statistically insignificant change in Hx% from (66.25±3.78 preoperatively) to (65.92±4.24 at the end of three months) with (p<0.05).

Edelhauser et al.[17] conducted over four years, The Hx% was as follows: (55.8 ± 7.2 preoperatively) changed to (55.1±6.7 at three months) and increased by the end of the follow-up period to (57.5 ±6.2) which was statistically significant increase with (p≤0.001).

Edelhauser et al.[17] support our study regarding the decrease in the Coefficient of variation and the insignificant change in the Hx of cells during the first three months of their follow-up period.

4. Conclusion

IPCL implantation is a successful, cosmetically accepted, and secure method of correcting myopia ranging from moderate to high degrees when corneal refractive surgery is contraindicated. The rate of complications was insignificant throughout all follow-up periods. However, a bigger sample size and long-term monitoring are necessary.

Implementing new versions of ICL (with central Hole) offered excellent outcomes even in the absence of peripheral iridectomy for correcting moderate to high myopia, indicating its feasibility as a surgical option for correcting such refractive error.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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