

Anatomical and Visual Effects of Implantable Phakic Contact Lens on Correction of Myopia

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Abstract

Purpose: To evaluate the anatomical effects of implantable phakic contact lens (IPCL) (Care Group, India) on anterior segment and its visual outcomes .

Patients and methods: In a prospective interventional case series study, 60 highly myopic eyes of 32 patients were subjected to IPCL implantation in the Ophthalmology Department of Minia University Hospital, Egypt from January 2019 to June 2021. All patients had complete ophthalmic examination and were followed up for 1 year. Pentacam was used for preoperative and postoperative estimation of anterior chamber depth (ACD), anterior chamber angle (ACA), anterior chamber volume (ACV) and IPCL vault in the 1st, 3rd, and 12th months. Assessment of corneal endothelium was done using specular microscope preoperatively and after 12 months. Preoperative and postoperative refraction and visual acuity were measured.

Results: There was a statistically significant decrease in ACD, ACA, and ACV. There was no significant difference between preoperative and postoperative mean intraocular pressure (IOP) by the 12th month ($P=0.163$). The mean preoperative endothelial cell count (ECD) was significantly reduced from 2929.3 ± 248 cells/mm² to 2737.9 ± 303 cells/mm² at the 12th month ($P<0.001$). with a statistically highly significant improvement of mean Log Mar uncorrected visual acuity (UCVA) from 1.48 ± 0.19 preoperatively to 0.46 ± 0.11 by the end of follow up ($P<0.001$) with insignificant difference between preoperative best corrected visual acuity (BCVA) and postoperative UCVA ($P=0.209$). In the 12th month, the mean vault was 240 ± 540 μ m. No sight threatening complications occurred.

Conclusion: Although IPCL induced anatomical changes, it was safe and effective for correction of high myopia.

Introduction:

Surgical procedures performed to correct myopia include laser corneal refractive surgery, clear lens exchange (CLE), and phakic intraocular lens. Laser corneal refractive surgery is an effective method for correcting myopia, but it is not suitable for patients with thin corneas and for patients with high refractive errors. ^[1] Phakic IOLs may have advantages over kerato-refractive surgery because the procedure is reversible and replaceable with another phakic IOL. Phakic IOLs can correct higher levels of ametropia, with lower induction of postoperative aberrations, and retinal image magnification. ^[2-4] Preservation of accommodation is a definite advantage over CLE. ^[5,6]

The safety and efficacy of the Visian implantable collamer lens (ICL, Staar Surgical AG, Switzerland) have been demonstrated for moderate and high ametropia over long-term follow-up. ^[7-10] The disadvantage of the ICL is the high cost of treatment, especially in developing countries. The Implantable Phakic Contact Lens (IPCL V2, India) is as an alternative option with an economic advantage. IPCL V2 is a hydrophilic hybrid acrylic implant, with central hole and six haptic pads for better stability in the ciliary sulcus¹.

Moreover, readily available IPCL can provide correction for myopia up to -30.0 D while ICL can provide correction for myopia up to -18.0 D. [6]

In this study, the efficacy, safety, and the anatomical effects of IPCL V2 on the anterior segment of the eye were evaluated.

Patients And Methods:

This was a prospective interventional case series study which included 60 eyes of 32 patients who underwent IPCL implantation for correction of high myopia. This study was performed in the Ophthalmology Department of Minia University Hospital, between January 2019 and June 2021. The study was approved by the local research ethical committee of Faculty of Medicine, Minia University and was adherent to the tents of Declaration of Helsinki. Detailed informed consent was taken from all patients for inclusion in the study. Inclusion criteria included myopic patients with age between 19 to 39 years, and stable refraction for at least one year. These patients were unsuitable for laser corneal refractive procedures due to thin cornea or high error. Exclusion criteria included patients with endothelial cell density (ECD) $< 2,000$ cells/mm², anterior chamber depth (ACD) < 3 mm, astigmatism > 1.00 D, and patients with keratoconus or other corneal disorders. Also, patients with glaucoma, uveitis, any degree of cataract, myopic CNV, macular hole, previous retinal detachment surgery, intravitreal injections, and any other ocular disorder that may affect visual outcomes, were excluded from the study.

All patients were subjected to careful history taking and complete ophthalmic examination including measurement of preoperative uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA), anterior segment examination using slit lamp biomicroscopy, measurement of IOP using Goldmann applanation tonometry, cycloplegic refraction and fundus examination. Snellen visual acuity measurements were converted to logarithm of the minimum angle of resolution (log-MAR) equivalents for the purpose of data analysis. Pentacam HR (Oculus, Germany) was used for preoperative measurement of keratometric readings, horizontal white to white diameter (W-W), anterior chamber depth (ACD) from the corneal endothelium to the anterior capsule of the crystalline lens, anterior chamber volume (ACV), anterior chamber angle (ACA) at 9:00 o'clock and 3:00 o'clock, and central corneal thickness (CCT). W-W was double checked by a digital caliper. Preoperative assessment of endothelial cell count (ECD), hexagonal cells, and coefficient of variance (CV) was performed using specular microscopy (Nidek, Japan).

Lens power calculation was performed using the web site: <http://ipcl1.ipcliol.com/ipcl/IPCLStar.aspx> to achieve emmetropia for all eyes.

Surgical procedure:

All surgeries were performed under peribulbar anesthesia. While the surgeon was sitting on the temporal side of the patient's eye, the cartridge was filled by hydroxypropyl methylcellulose (HPMC) and the IPCL was loaded with the 2 holes in the optic and the nearby knob were directed towards the patient's eyebrow

and the anterior surface of IPCL was vaulted upward to ensure proper orientation of the lens while loading in the cartridge and unfolding inside the eye.

Two clear corneal paracentesis were performed and HPMC was injected avoiding overfilling of AC. A clear temporal corneal 2.8 mm incision was performed and the lens was injected slowly through it. While unfolding in AC, proper lens orientation should be carefully observed to continue lens injection. More HPMC was injected above IPCL and the haptics were pushed behind the iris using a blunt flat spatula and an intraocular miotic was injected into AC to constrict pupil over IPCL. Bimanual irrigation/aspiration was done to remove the HPMC followed by hydration of the main wound and the 2 paracenteses.

Postoperatively, patients were examined in the 1st day, 3 days, 1 week, 2 weeks, and every month till the 12th month, and data were collected in the 1st, 3rd, and 12th month visits.

Postoperative evaluation included slit lamp examination to evaluate the IPCL position, iris configuration, and crystalline lens clarity, IOP measurement, UCVA, BCVA, and refraction. Postoperative Pentacam was performed in the 1st, 3rd and 12th months to measure lens vault (distance between central posterior surface of IPCL and anterior surface of the crystalline lens, measured manually), ACA and ACV (both automatically measured by the device's software), and ACD (distance between central corneal endothelium and anterior IPCL surface, measured manually). Postoperative specular microscopy was performed in the 12th month to evaluate ECD, hexagonal cells, and CV.

Statistical method:

The collected data were coded, tabulated, and statistically analyzed using SPSS program (Statistical Package for Social Sciences) software version 25. Descriptive statistics were performed for normally distributed quantitative data with mean, and standard deviation (SD) and for not normally distributed quantitative data, by median and interquartile range (IQR). Data distribution was done by Shapiro Wilk test. Paired Samples T test was used for analysis of parametric quantitative data between each two times, and Wilcoxon Signed rank test was used for non-parametric quantitative data between each two times. Pearson's correlation coefficient was used for correlation between two variants.

Results:

This study included 60 eyes of 32 myopic patients. Bilateral surgery was performed in 28 patients (87.5%) and unilateral surgery in 4 patients (12.5%). Eight patients were males (25%) and 24 were females (75%). The mean age of patients was 28.1±4.3 years (range: 21 - 32 years).

Anterior segment parameters by Pentacam: (table 1)

ACD and ACA was significantly reduced at all postoperative follow-up visits in comparison with preoperative value ($P<0.001$) with no significant difference between the different follow-up time points.

Mean preoperative ACV was $194.7 \pm 23.7 \text{ mm}^3$ and was significantly decreased to $127.2 \pm 20.7 \text{ mm}^3$, $126.9 \pm 21.9 \text{ mm}^3$, and $127.9 \pm 21.3 \text{ mm}^3$ in the postoperative 1st, 3rd and 12th months, respectively ($P < 0.001$).

By the end of the follow up, the lens vault ranged from 240 to 540 μm with no statistically significant change throughout the different follow-up visits (Figure 1).

In comparison with preoperative values, postoperative mean CCT was significantly increased in the 1st and 3rd months ($P < 0.001$) and ($P = 0.013$) respectively but it was significantly reduced in the 12th month ($P = 0.001$).

Table 1: Anterior segment parameters by Pentacam:

	Preoperative	1 st month	3 rd month	12 th month
	N=60	N=60	N=60	N=60
Angle				
<i>Range</i>	(34.9-50.7) °	(18-33.9) °	(17-33.9) °	(16.8-33.6) °
<i>Mean ± SD</i>	(42.2±4.2) °	(25.8±4.2) ° (A)	(25.1±3.9) ° (A)	(25.8±4.5) ° (A)
AC depth				
<i>Range</i>	(3000-3450) μm	(2055-2600) μm	(2030-2700) μm	(2080-2700) μm
<i>Mean ± SD</i>	3205.3±133.5 μm	2364.7±162.9 μm (A)	2374.7±194.3 μm (A)	2371.3±187 μm (A)
AC volume				
<i>Range</i>	139-216 mm^3	94-176 mm^3	96-176 mm^3	93-173 mm^3
<i>Mean ± SD</i>	194.7±23.7 mm^3	127.2±20.7 mm^3 (A)	126.9±21.9 mm^3 (A)	127.9±21.3 mm^3 (A)
Central corneal thickness				
<i>Range</i>	(478-590) μm	(473-599) μm	(476-592) μm	(476-585) μm
<i>Mean ± SD</i>	523.7±35.3 μm	533.6±36.8 μm (A)	531.3±39.5 μm (A)	518.9±34.4 μm (A)
Vault				
<i>Median</i>		420 μm	410 μm	420 μm
<i>IQR</i>		(330-520) μm	(270-525) μm	(240-540) μm

- Paired samples T test for parametric quantitative data between each 2 times.

- (A): significant difference in comparison with preoperative value (P value < 0.05).

- IQR: interquartile range.

Mean preoperative IOP was 13.7 ± 1.8 mmHg which was increased to 17.2 ± 2.3 mmHg in the 1st month and to 15.9 ± 4.5 mmHg in the 3rd month. This was a statistically significant difference ($P < 0.001$ and $P = 0.025$, respectively). There was no significant difference between preoperative and postoperative mean IOP by the 12th month ($P = 0.163$). Four eyes (6.66 %) had an elevated IOP (26-30 mmHg) that were treated with topical IOP-lowering medications (a combination of timolol and brimonidine) until the 2nd month, then IOP was controlled without medication. There was insignificant correlation between postoperative elevation of IOP and the reduction of ACD and ACA at different follow-up visits (Table 2).

Table 2: Correlation between IOP change and changes of ACA and ACD at postoperative follow-up.

		IOP increase	
		r	P value
1 st follow-up	ACA decrease	0.347	0.061
	ACD decrease	-0.284	0.128
2 nd follow-up	ACA decrease	0.181	0.337
	ACD decrease	0.033	0.864
3 rd follow-up	ACA decrease	0.261	0.163
	ACD decrease	-0.253	0.178

- Pearson's correlation

- *: Significant level at P value < 0.05

- IOP = intraocular pressure

- ACA= anterior chamber angle

- ACD = anterior chamber depth

Specular microscopy: (table 3)

Mean preoperative ECD was significantly decreased by the end of follow up ($P < 0.001$) with a percentage of decrease of $6.52 \pm 6.71\%$. There was also a statistically significant decrease in hexagonal cells ($P = 0.033$) and increase in CV ($P = 0.040$). A statistically insignificant negative correlation ($r = -0.285$) was found between the decrease in endothelial cell density and the decrease in ACD ($P = 0.126$).

Table 3: Comparison between preoperative and postoperative endothelial cell density, hexagonal cells and CV.

		Preoperative	12 th month	P value
		N=60	N=60	
Endothelial cell density (cell/mm ²)	Range	(2503-3377)	(2193-3268)	<0.001*
	Mean ± SD	2929.3±248.1	2737.9±303.1	
Hexagonal cells	Range	(57-73)	(61-72)	0.033*
	Mean ± SD	66.9±2.8	65.5±4.8	
CV	Range	(24-37)	(24-35)	0.040*
	Mean ± SD	28.4±2.6	29.8±3.9	

- Paired samples T test for parametric quantitative data between each 2 times.

- *: Significant level at P value < 0.05.

- CV= coefficient of variance.

IPCL was implanted upside down in 2 eyes (3.33%) and were managed by removal of IPCL, reloading, and reinjection in the proper orientation.

Throughout the study, no sight threatening complications occurred such as cataract, permanent glaucoma, endophthalmitis, or retinal detachment.

Visual acuity and refraction:

The mean Log-Mar UCVA significantly improved from 1.48±0.19 preoperatively to 0.46±0.11 postoperatively by the end of follow up (P<0.001) (Figure 2).

There was a statistically insignificant difference between the mean preoperative BCVA and postoperative UCVA (P=0.209) by the end of the 12th month. There was no statistically significant difference between mean postoperative UCVA and postoperative BCVA by the 12th month.

Cumulative Snellen postoperative UCDA shows that 7% had UCVA 6/18, 47% had UCVA 6/12, 40% had UCVA 6/9, and 6% had UCVA 6/6. Figure (3 A)

As regard changes in Snellen lines of CDVA, 66.7% showed no changes, whereas 26.7% gained one or more lines, and 6.7% lost one or more lines (Figure 3 C).

As regard refraction, spherical equivalent decreased from (-11: -16D) preoperatively to (-0.5: +1D) postoperatively with a statistically highly significant difference (P<0.001). There was no significant

change in postoperative refraction throughout the follow up visits.

Post-operative spherical equivalent refraction at last follow up showed that 27% of patients became emmetropic, 7% became -0.25 D, 27% became -0.5D, 13% became +0.25 D, 20% became +0.5 D and 7% became +1D postoperative (Figure 3 B).

Discussion:

Phakic IOLs offer a very good option for the treatment of high myopia with preservation of accommodation and a minimal impact on higher-order aberrations. Corneal endothelial damage has been a major concern in cases of anterior chamber phakic IOL implantation but not with posterior chamber phakic IOLs such as ICL and IPCL. [11-13]

In this study, we used IPCL V2 which had a central hole, and 6 peripheral holes, making preoperative laser iridotomy unnecessary. Also, absence of a central hole might cause a disturbance in the aqueous circulation, resulting in an increased incidence of cataract. [14]

This study included patients with myopia of (-11: -16D) with a cylinder value not exceeding 1 D due to our limited access to the toric design of IPCL in our hospital. Patients were required to have a normal endothelial cell density for age and an anterior chamber depth ≥ 3 mm to avoid postoperative corneal endothelial damage, iatrogenic cataract and/or glaucoma. Finally, all patients with any other type of ocular pathology were excluded to avoid any confusing factors of the visual outcomes. Evaluation of anterior segment parameters relied on Pentacam HR due to its high accuracy and reliability. The “Enhanced Dynamic Range” was used to prolong the exposure time per Scheimpflug image to enhance visualization of IPCL. [15]

In this study, mean vault at the 1st postoperative month ranged from 330-520 μm and did not significantly change throughout the rest of follow up. Similarly, Bianchi found no difference in vault measurements between the 3rd and 6th postoperative months. [16] However, Vasavada et al., found that the IPCL vault decreased with time, with significant reduction at 3 years postoperatively, compared to the 1st month. [17]

This study showed that there was a significant elevation of mean IOP in 1st and 3rd month follow-up visits compared to baseline but remained within the normal range. In the 12th month, there was no significant difference between preoperative and postoperative IOP values. Vasavada et al, demonstrated that the mean postoperative IOP was not significantly different from preoperative level at any of the follow-up visits. [17] Bianchi reported that the IOP values remained similar at baseline and 1 day and 6 months after surgery. A slight increase of IOP occurred in the 1st day postoperatively, which decreased at the end of study, but IOP values were always in the normal IOP range. They reported that there was no statistically significant difference in IOP values between baseline and 6 months after surgery. [16]

In our study, 4 eyes had an elevated IOP and were treated by cessation of steroid eye drops and instillation of topical combination of timolol and brimonidine until the 2nd month after which IOP was controlled without any medication. The mechanism of IOP elevation was postulated to be due to steroid response. No eye developed permanent increased IOP requiring treatment until the last follow-up.

ACD and ACA were significantly decreased at the 1st month compared to baseline and remained stable thereafter till the end of follow up. There was insignificant correlation between postoperative elevation of IOP and the reduction of ACD and ACA at different follow-up visits.

In the current study, there was a transient increase in CCT in the 1st and 3rd months that subsequently decreased to values below baseline by the 12th month follow-up visit. Similarly, Bianchi found a decreased CCT at 6 months that was statistically insignificant. [16] While the transient early increase in CCT could be explained by temporary dysfunction of corneal endothelium in response to inevitable intraoperative surgical trauma and early postoperative IOP spikes, the decrease in CCT below baseline values may need further investigation to clarify its possible causes.

In this study, mean ECD was significantly reduced ($P < 0.001$) in the 12th month. Studies of ICL demonstrated a mean ECD loss ranging from 0.3% to 7.8%^{18,19}. Vasavada et al, reported a mean percentage loss in ECD of $9.73\% \pm 6.72\%$ with IPCL after 3 years. [17]

This study showed a significant improvement in the postoperative refraction and UCVA till 12 months of follow-up. This agreed with Vasavada et al who found a significant improvement in UDVA at 3 years postoperatively. [15] Also, Vasavada et al, and Bianchi demonstrated a significant decrease in postoperative spherical equivalent after IPCL implantation to a value within 1 D of emmetropia. [15,17]

The 2 eyes where the IPCL was implanted upside down, experienced a significant drop in ECD postoperatively compared to baseline (from 2678 cell /mm² to 2195 cell /mm² and from 2972 cell /mm² to 2374 cell /mm²). So, great care should be taken to ensure that IPCL is implanted properly. A great tip to avoid this intraoperative complication is to make sure that HPMC in the cartridge is free of air bubbles not to confuse the surgeon with the orientation of holes in the optic.

None of the studied eyes developed lens opacity of any degree. Not only slit-lamp examination was used for evaluation of postoperative lens clarity, but also all Scheimpflug images obtained using the “Enhanced Dynamic Range” function was carefully evaluated to ensure lens clarity at all follow-up visits. Fernandes et al., demonstrated that cataract was the major postoperative complication in eyes who had a vault of $< 200 \mu\text{m}$ after ICL implantation. [18] One eye (3.3%) in Vasavada et al series developed anterior subcapsular cataract. [17]

Although IPCL was more economically viable, it had results not less than what were demonstrated with ICL. Sachdev et al compared both IPCL and ICL, and demonstrated that both implants were safe,

predictable and had refractive stability. [20] This agreed with our study in which all eyes showed significant improvement in refraction and UCVA without significant complications.

This study showed that although IPCL induced remarkable anatomical changes in the anterior segment parameters, it was both safe and effective for correction of high myopia.

Limitations of this study included the relatively small sample size, the non-comparative design, and the need for a longer follow-up period.

Declarations:

Conflict of Interest

The authors declare that there is no conflict of interest.

Financial Support

All authors declare that there are no financial conflicts of interest to disclose.

The study conducted ethically in accordance with regulation of Helsinki Declaration. Study registration number is: R000051823,Trial ID:UMIN000045383)

Statement of Ethics

The study was has granted ethical approval from Local Research Ethics Committee, Faculty of Medicine, Minia University Hospitals. Approval NO.336:11/2019.

Informed consent

Written informed consent form was gained from all participants in the study.

Funding source

All authors declare that there are no funding source to disclose.

Data Availability

Data is available upon request from author.

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Figures

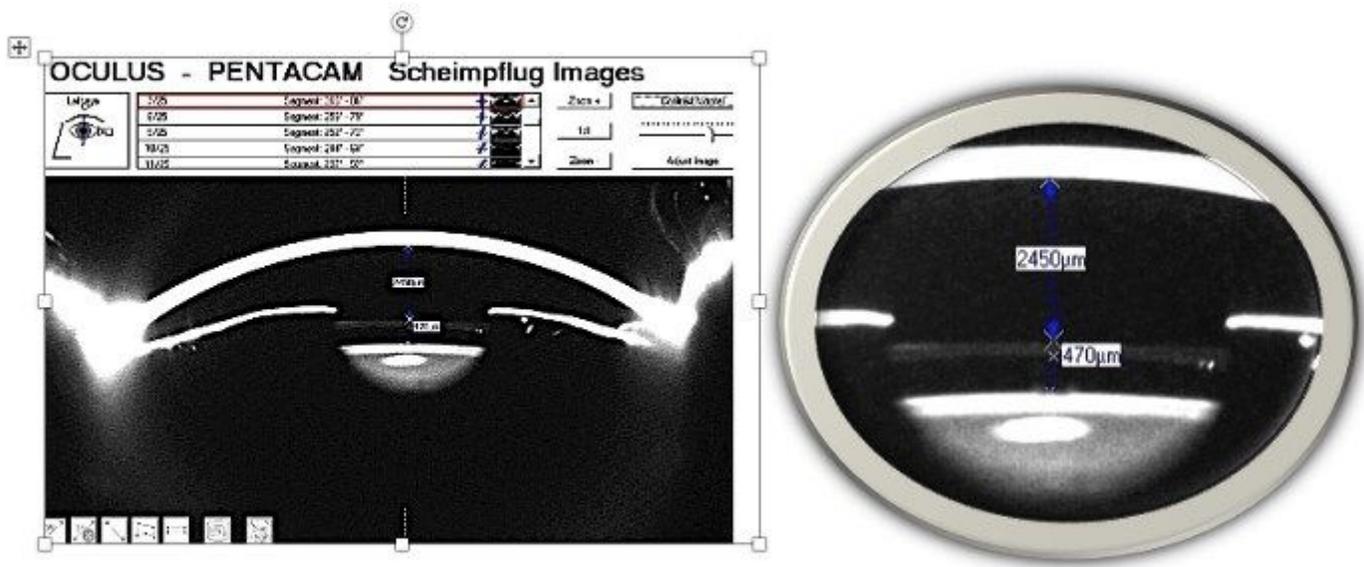


Figure 1

Enhanced dynamic Scheimpflug image showing measurement of IPCL vault and postoperative AC depth.

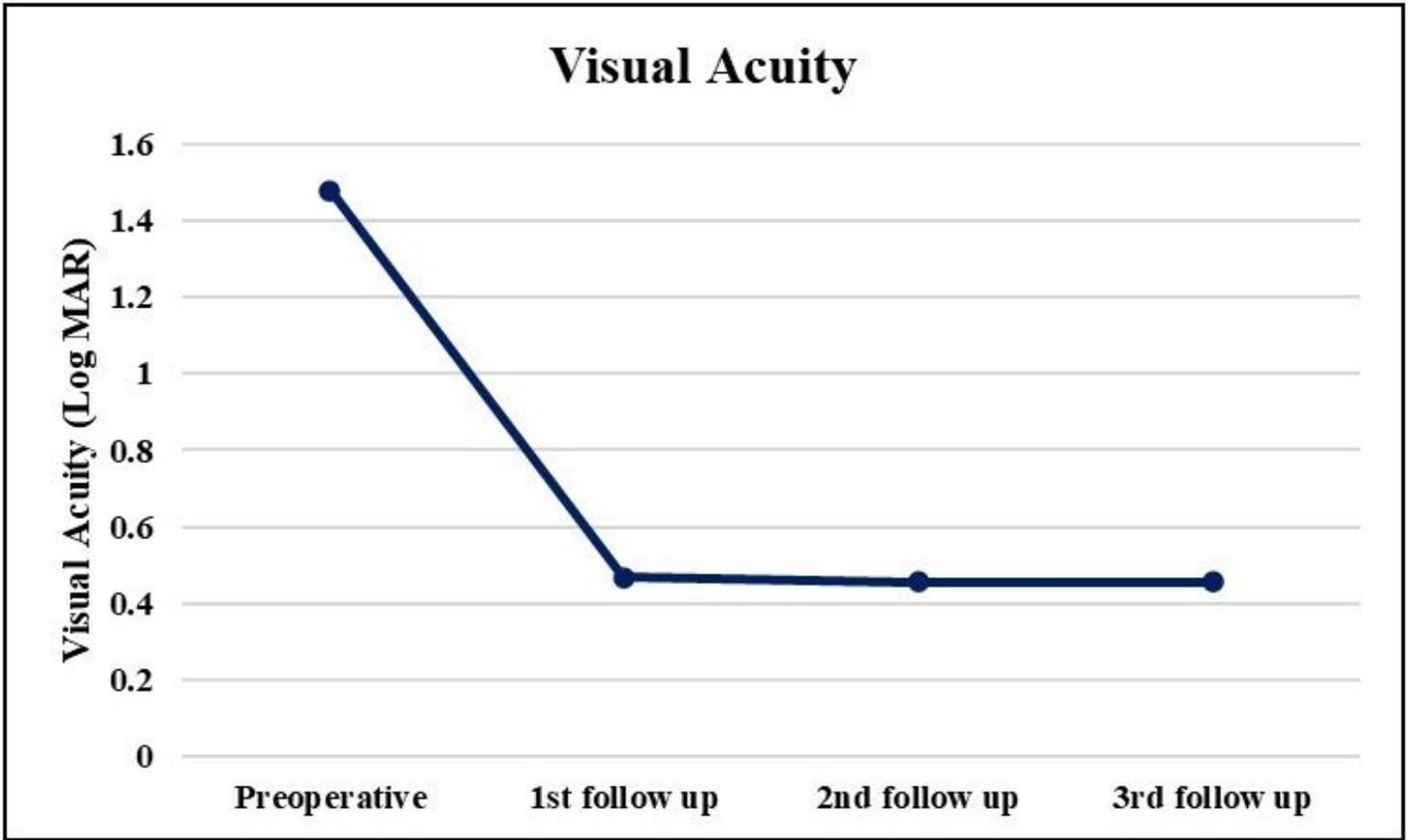


Figure 2

Comparison between preoperative and postoperative Log Mar UCVA.

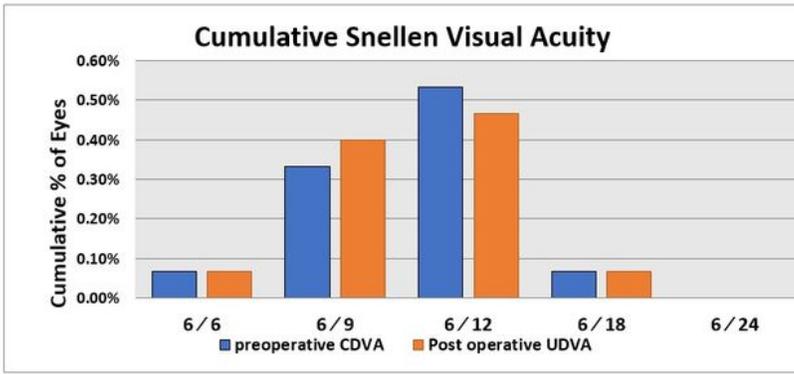


Figure 3 (A):

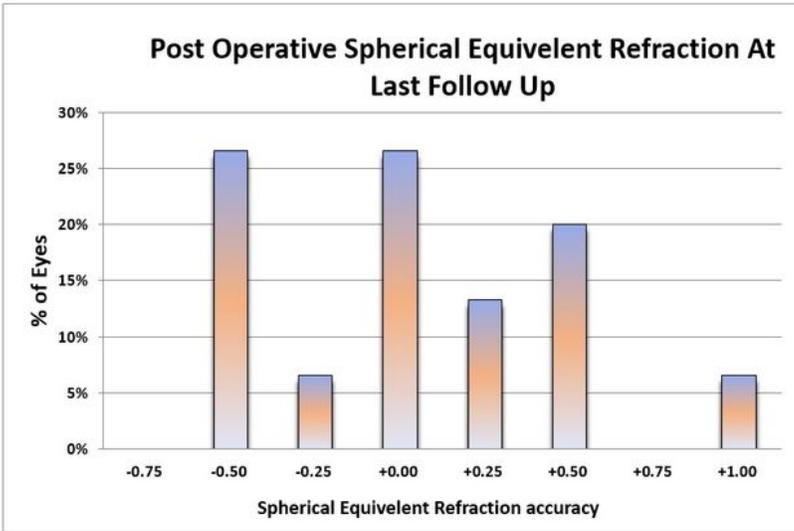


Figure 3 (B):

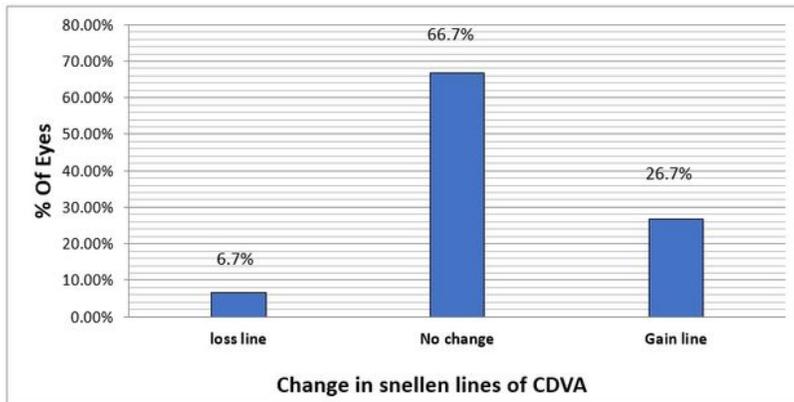


Figure 3 (C):

Figure 3

3 (A): Cumulative Snellen visual acuity preoperative CDVA & Post-operative UCVA.

3 (B): Post-operative spherical equivalent refraction.

3 (C): changes in Snellen lines of CDVA.