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OUTCOMES OF IMPLANTABLE PHAKIC CONTACT LENS IN HIGH MYOPES IN A TERTIARY HEALTHCARE CENTER IN WESTERN INDIA- CORRELATION OF CENTRAL VAULT AND INTRAOCULAR PRESSURE.

Ophthalomology

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ABSTRACT

Purpose: To evaluate clinical outcomes and corelation of post-operative vault size and intraocular pressure (IOP). **Methods:** 100 eyes of 50 high myopic patients underwent Implantable phakic contact lenses (IPCL V2.0) implantation using a novel visco-free technique. Both eyes were operated within a span of 1 week using similar technique and by a single surgeon. The clinical outcomes were analysed over 1 month follow up. **Statistical Analysis:** SPSS Software for Windows (version 18.0, SPSS, Inc). **Results:** Majority of study population (90 %) had Visual acuity (VA) of > 6/12, whereas 26 patients (52%) had VA of 6/6 in post-operative period. The pre-operative mean spherical equivalent (MSE) was -13.268 + 4.2606 and post-op mean MSE was -0.825 at 1 month follow up. The Pre-operative MSE values differ significantly from all post-operative MSE values. The IOP analysis displayed comparable mean values for pre-operative and post-operative IOP at day 1, whereas the mean values differed significantly at day 7 and 1 month. The mean post-operative vault size was 706.42 m (range 401-900 m). There was significant positive correlation between vault size and MSE whereas there was no significant correlation between vault and IOP as seen by applying pearson's correlation formula (p value < 0.001) **Conclusion:** Our study is the first study of IPCL V2.0 in Western India carried out in a tertiary healthcare hospital using a novel visco-free IPCL implantation technique. This study shows that Post- operative Vault size is independent of IOP rise and we attribute this rise in IOP majorly to steroid responsiveness in high myopes.

KEYWORDS

Phakic IOL, Implantable contact lens, Vault size, IOP.

INTRODUCTION

Refractive error is the most common cause of low vision in world. Prescribing spectacles for myopia and hypermetropia is routine practice by every ophthalmologist; With advent of technology there are various ways available to treat refractive errors. Cornea based procedures Photo Refractive Keratotomy (PRK), LASIK (Laser Assisted in-situ Keratomileusis), SMILE (Small incision lenticule extraction) have gained popularity over a period of last few years and shown very promising , predictable outcome . Lens based procedures are Refractive lens exchange (RLE) and Phakic intraocular lenses (PIOLs) implantation have emerged to be safe and predictable means of correcting high myopia. [1]

Strampelli and Barraquer introduced PIOLs in the 1950s to correct refractive errors.[2-4] Phakic IOLs provide satisfactory results in refractive surgery for correction of myopia, hyperopia and astigmatism.[2,3] The advantages of this procedure are preservation of accommodation, better quality of vision, potential reversibility of this procedure and stability and predictability of refractive outcome. The potential risks are cataract development,[2-4] sub-clinical intraocular inflammation,[4-6] endothelial cell loss, intraocular pressure (IOP) rise [5,7,8] and risk of retinal detachment.[4,9] To our knowledge, there is no study conducted in tertiary healthcare hospital in western India published on posterior chamber Implantable phakic contact lens, version 2.0 (IPCL V2.0) (Care group, India) (Pubmed Search).

The aim of the study was to assess the clinical outcomes of the IPCL V2.0 implantation in high myopes in Western Indian population.

MATERIALAND METHODS

This prospective interventional case study included 100 eyes of 50 patients with high myopic refractive error (> -6.00 D). IPCL V2.0 implantation procedure was performed at Tertiary healthcare hospital in western India during the period of January 2018 to July 2019. The mean age of the subjects was 23.52 ± 1.92 years. This study was approved by the Institutional Ethics committee and was conducted following the norms of the Declaration of Helsinki. All the patients were subjected to surgery only after comprehensive discussion with them, explaining them the details of the procedure and its benefit and complications and an informed written consent was obtained from all patients. A single experienced surgeon performed all the surgeries. The inclusion criterion was High myopes between the age group of 21 to 50 years with stable refraction for 1 year (less than 0.5 D change) High myopia as per literature, defined as refractive error more than 6 diopters and same operational definition was followed in our study, Anterior chamber depth (ACD) > 3.2 mm measured from corneal epithelium to anterior lens capsule (ALC) and > 2.8mm measured from corneal endothelium to ALC, minimum endothelial density graded according to the age ranging from 2000- 2800 cells/mm3. The exclusion criteria were patients with pathological myopia and macular degeneration, debilitating illness and systemic autoimmune conditions, corneal pathologies like keratoconus, keratoglobus and opacities, refractive surgeries like LASIK, PRK, and cataract surgery, and patients with lenticular opacities were excluded.

All patients were examined thoroughly for Pre-Op and Post-Op best corrected visual acuity (BCVA) at Day 1, 7 and 30, Undilated Autorefraction (AR) and dilated cycloplegic AR, cycloplegic retinoscopy (CDR), Topography, Anterior chamber Depth (ACD), Pre-Op Intraocular pressure (IOP) and Post-Op IOP, Vault size calculation and complications on all the follow-ups. All patients were subjected to pre-operative evaluation, Unaided Visual Acuity (UVA) and BCVA was measured using Snellen's Chart, an estimate of refractive error was gauged using Auto kerato-refractometer (TOPCON KR-800) and was later confirmed using CDR and AR. All patients were evaluated for Keratometry (K) and Pachymetry on Scheimpflug topographer (TOMEY TMS 5), IOP measurement using Non-Contact air-puff tonometry (TOPCON CT-1) and, anterior chamber angle width, Anterior Chamber depth, Lens thickness and W to W and S to S were measured using Ultrasound biomicroscopy (UBM Plus, Keeler, USA) and IOL Master 700 (Zeiss). The Post-operative IPCL Vault was measured by Anterior Segment Optical coherence topography (AS-OCT) (Zeiss, Cirrus HD-OCT 5000/500). Follow-up of the aforementioned variables was done at 1, 7, and 30 days postoperatively, together with IPCL vault measurements. The IPCL V2.0 vault was estimated clinically relative to CCT (1.00x) using slit beam, and the central vault of the IPCL V2.0 over the crystalline lens was objectively evaluated with AS-OCT at 1, 7, and 30 days postoperatively. Using the image analysis software program with this device, without cycloplegia, an experienced Doctor calculated the amount of the central vault of the IPCL V2.0 over the crystalline lens as the distance between the posterior surface of the IPCL V2.0 and the anterior surface of the crystalline lens.

We calculated the IPCL V2.0 power (modified vertex calculation formula) by entering patients' ACD, manifest refraction spherical equivalent (MRSE), back vertex distance, and K readings on Care Group online calculator and ordering system (OCOS). For the IPCL V2.0 proper sizing, the system requires data entry by the user, for W-W measurement, ACD, CCT, beside the birth date, and any history of previous intervention like IOL implantation. ICL size was determined by the manufacturer nomogram (OCOS) in all cases, without making any changes to the assigned surgeon.

All procedures were performed by a by a single surgeon under topical anesthesia using Proparacaine 0.5%.

Surgical procedure

IPCL V2.0 (Care Group Sight Solution LLP, India) implantation was performed by a novel technique without using the viscoelastic substance for AC maintenance thus reducing the post-operative risk of trabecular meshwork clogging by viscoelastic remnants and reducing the time of surgery by eliminating the need for thorough AC wash. Two sideports were created using 1.1 MVR blades at 180 degrees apart and a temporal tunnel 3.2 mm clear cornea incision was created, and the anterior chamber was maintained with the help of AC maintainer tubing plugged to one of the sideports. The IPCL V 2.0 was loaded into the cartridge with minimal viscoelastic substance (Hydroxypropyl Methyl Cellulose Ophthalmic solution, Appavisc PFS, Appasamy) and Ringer Lactate solution in 20:80 proportion respectively and injected very slowly to allow controlled slow lens unfolding; then an IPCL dialer was used to tuck the footplate haptics of the lens within the posterior chamber in the ciliary sulcus. No peripheral iridectomy was needed, as Central Hole in IPCL V2.0 ensures dynamic regular aqueous flow between posterior and anterior chambers. Postoperatively, patients were prescribed Moxifloxacin 0.5% w/v + Dexamethasone 0.1 % w/v eye drops starting 8 times daily for 1 week and tapered for 1 month.

Statistical analysis:

SPSS 15 software was used for data analysis. Data were presented as mean ± SD for normally distributed data and medians (quartiles) for abnormally distributed data. Variables were analyzed with baseline values using analysis of variance (ANOVA) for repeated measures. Pearson correlation analysis was performed for normally distributed data; value less than 0.001 was considered statistically significant.

Results

100 eyes of 50 patients with age group between 21 to 50 years were studied (22 Men and 28 women, mean age 23.52 years with Standard Deviation (SD) 1.92). Majority of study population (90 %) had Visual acuity (VA) of > 6/12, whereas 26 patients (52%) had VA of 6/6 in post operative period. (Table 1).

Table 1: Pre-op & Post-op Visual Acuity Table with Percentage

Bcva	Pre Op	Percentage (%)	Post Op	Percentage (%)
6/6	8	16	26	52
6/9 To 6/12	18	36	19	38
6/18 To 6/24	17	34	5	10
6/36 To 6/60	7	14	0	0
Less Than 6/60	0	0	0	0
Total	50	100	50	100

The pre op mean spherical equivalent (MSE) was -13.268 + 4.2606 and post-op mean MSE was -0.825 at 1 month follow up. The Pre-operative MSE values differ significantly from all post-operative MSE values. There is no statistical difference among post-operative MSE values. (Table 2)

Table 2: Post Hoc Analysis for ANOVA- MSE

MSE				
	Day	N	Subset for alpha = 0.05	
			1	2
Tukey B	0	50	-13.268	
	1	50		-0.444
	7	50		-0.560
	30	50		-0.825
Means for groups in homogeneous subsets are displayed.				

The mean Keratometry (Kf) was 44.1094 with SD 1.58 (range 41.50 to 47.50), mean keratometry (Ks) was 44.41 with SD 1.566 (range 41.47 to 48.97). The mean pachymetry was 512.98 + SD 36.56 m (range 426 to 601m). The mean S to S was 12.03 and mean W to W was 12.06. The mean anterior chamber depth (ACD) was 3.40 + 0.314 (range 2.86 to 3.97). The mean pre- operative IOP was 13.62 + 2.687 and mean post-op IOP at 1 month was 16.08 + 4.232. The post HOC analysis for ANOVA IOP displayed comparable mean values for pre op and post op IOP at day 1, whereas the mean values differed significantly at day 7 and 1 month. (Table 3) {Figure 1}

Table 3: Post Hoc Analysis for ANOVA-IOP

IOP				
	Day	N	Subset for alpha = 0.05	
			1	2
Tukey Ba	0	50	13.62	
	1	50	13.52	
	7	50		16.80
	30	50		16.08
Means for groups in homogeneous subsets are displayed.				

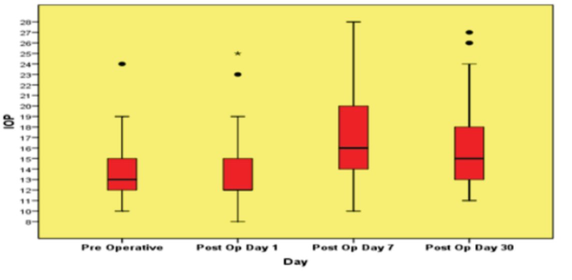

Figure 1: Boxplot showing Mean IOP in Pre & Post-Operative Period

The mean post operative vault size was 706.42 m (range 401-900 m). There was significant positive correlation between vault size and MSE whereas there was no significant correlation between vault and IOP as seen by applying pearson's correlation formula. (Table 4)

Table 4: Correlation of Vault with MSE & IOP values

	Pearson's Correlation Coefficient (r)	p value
MSE preoperative	0.318	0.025
MSE POD1	0.122	0.397
MSE POD7	0.369	0.008
MSE POD 30	0.316	0.025
IOP preoperative	0.125	0.387
IOP POD1	0.029	0.841
IOP POD7	0.063	0.662
IOP POD30	0.079	0.584

DISCUSSION

In this study, we evaluated post-operative spherical, astigmatic and MSE values, UCVA, BCVA, IOP, ACD, ACA, IPCL VAULT and intraoperative and post-operative complications after IPCL V2.0 implantation in ciliary sulcus. The Mean spherical value decreased significantly, and UCVA increased significantly in postoperative follow-up examinations. We preferred IPCL V2.0 with a central hole in our patients to provide aqueous humour passage in order to avoid any intervention to iris in future. The model was chosen as per the white-to-white (WTW) and S to S distance of the patients on UBM. Tang, et al & Shimizu, et al reported that implanting phakic posterior chamber IOL with a central hole (ICL V4c) in patients with moderate to high myopia is safe and effective.[10] [11] It appears likely that the presence of the central hole does not significantly affect these visual and refractive outcomes. Yaşa et al. reported that the mean preoperative SE of the patients was -13.41 ± 3.22 D, and the mean age of the patients was 32.0 ± 7.0 years.[12] Yang et al. reported that the mean preoperative SE of the patients was -12.08 ± 2.44 D, and the mean age of the patients was

33.15 ± 9.28 years.[13] In our study, the mean preoperative SE of the patients was -12.57 d ± 3.53 D, and the mean age of the patients was 23.52 ± 1.92 years.

At the end of the postoperative one month, Yang, et al. asserted that the visual acuities of all patients were over 6/12; 60% of them reached 6/6 visual acuity, and the refractive power of all patients within ± 1.00 D.[13] Yaşa et al. reported that, at the end of the postoperative one month, the visual acuities of all patients were better than 6/9, and 93% of the patients' refractive powers were within ± 1.00 D.[12] In our study, at the end of the postoperative one month, the mean visual acuities of the 90 % of patients were 6/12, and 52% of patients had mean visual acuities of 6/6, the mean refractive power of patients was -0.825 ± 0.8642 D. Thus, signifying the safe and predictable outcome of IPCL V 2.0 implantation in ciliary sulcus.

Eldanasoury, et al. stated that smaller ACD and aqueous depth are significantly correlated with more endothelial cell loss.[14] Minimum ACD of 3.35 mm or aqueous depth of 2.75 mm is recommended for better long-term endothelial safety. [15] In our study, the patient's ACD preoperatively was more than 3.2 mm, postoperative ACD values decreased significantly when compared to preoperative values, however, no significant endothelial cell loss was seen on 1 month follow-up. In addition, the Anterior chamber depth and anterior chamber angle width is greatly affected by post operative vault size. The phakic intraocular lenses (pIOLS) are known to decrease the ACD and angle width. The thicker periphery of highly powered pIOLs causes anterior chamber narrowing because of an iris forward shift; these factors result in excessive vault. In study by Sherif Eissa et al, Despite the statistically significant decrease in AC angle width following V4C ICL implantation, mean Pentacam AC angle width 18 months following surgery showed no correlation with increase in IOP.[16] Our study showed findings consistent with Eissa et al. Hence, the ideal postoperative vault must not only create space over the whole anterior crystalline lens surface, but also, should not be high enough to narrow the angle width. The recommended amount of vault equal to 1.0 to 1.5 central corneal thicknesses on slitlamp examination, corresponds approximately to a value between 400 to 600 m.[17] For this to be achieved, the appropriate IPCL V2.0 must be selected. Underestimating the IPCL V2.0 diameter is frequently associated with poor vault (< 250 m). This increases the risk for cataract development, which is caused by pIOLs–crystalline lens contact or by disturbances in aqueous flow, which interferes with lens nutrition and thus results in metabolic disturbances to the crystalline lens.[11,17] On the other hand, excessive vault (>900 m)[18] can cause angle closure, pupillary block glaucoma, or pigmentary dispersion glaucoma and is often associated with an oversized pIOLs.[19] Moreover, the sheer dynamicity of anterior segment makes it more vulnerable to complications of IPCL V2.0 placement. The IPCL V2.0 central hole avoids central anterior crystalline opacity since aqueous humor can flow through the lens, justifying the central hole for aqueous flow a significant addition in factors reducing the IOP and cataractous lens changes.[20]

Although, in our study the mean age group of patients was 23 years, the factors such as accommodation and biometric ocular changes did not affect the variation of vault size much.[17] Thus, achieving a satisfactory vault is important for safe and successful IPCL V2.0 implantation.

Because the haptics of the pIOL rest in the ciliary sulcus, the ideal overall diameter of pIOL depends on the ciliary sulcus diameter. Thus, it is desirable to obtain a direct measurement of the sulcus-to-sulcus and WTW length using new imaging technologies such as UBM.[18] [24] In the present study, the pIOL diameter was chosen according to the UMB, and we could accurately predict the exact position of the pIOL in the sulcus and negating the need to replace IPCL V2.0. The mean post operative vault in our study was 706.42 mm. In the present study, although 41 eyes (82%) had a vault between 500 mm to 800 mm and 8 eyes (16%) had a vault of more than 800 mm, no IPCL V2.0 was replaced, thus signifying the predictability when calculated using UBM.[18] Patients with higher degrees of myopia tended to have higher vault.[25] We found statistically significant positive corelation between Vault and MSE values. (Table 4) The pIOLS implantations are vulnerable to complications.

Cataract development is another complication of phakic IOL implantation in young patients. [26] We did not encounter any cataract formation in our patients in follow-up examinations.

Glaucoma may develop after pIOLs implantation due to the pupillary block and pigment dispersion. Yaşa, et al. & Yang et al reported that glaucoma developed in a patient related to steroid usage.[12] [13] Navarrete Argüello, et al. found the effect of an ICL on IOP fluctuations not to be statistically significant.[27]. While Eissa et al. [16] reported an increase in IOP with V4c lens and attributed the elevated IOP following ICL implantation to the coincident decreased AC angle width at the same time points., Kohlaas M et al [28] found no significant changes in IOP. Our study was consistent with Kohlaas et al, although there was gradual rise in IOP, there was no significant corelation between post-operative IOP and vault contradictory to other authors.[16]

During the past decade, several authors have reported cases of pupillary block, a complication that carries a potential risk for loss of vision. To prevent pupillary block, conventional laser iridotomies or intraoperative peripheral iridectomy were done, causing discomfort for the patient and difficulties for the surgeon. Peripheral iridectomies can cause complications. In our study we used IPCL V2.0 with a central hole for better aqueous dynamics thus negating the complications of iridectomy. This model obviated the surgical manoeuvre, reducing surgical time and eliminating potential associated complications. This approach may also have had a positive impact on the changes in IOP after surgery. In a pilot study, Shimizu et al [11] did not find a significant increase in IOP during the early postoperative period (3 to 6 hours).

Similarly, We saw late rise in IOP over 1 month follow up period and there was significant correlation between pre-op and post-op IOP with comparable pre-op and POD 1 values.(Table 3) However, rise in IOP was observed over consecutive follow ups with slight fall over the period. We attribute this rise to post operative inflammation and topical steroids. [24] [29] In their analysis of highly myopic eyes, Jimenez-Alfaro et al. [24] reported a statistically significant increase in IOP 1 month after surgery that normalized by 3 months in all patients after steroid treatment was stopped.

In our study, at the first reading, the mean IOP was 13.52 mmHg, while a rise in mean IOP by 3.30 mmHg was observed in further follow ups. Consistent with other authors,[28] we attribute the increase in IOP during the first month after surgery to the effect of postoperative inflammation and topical steroids.We consider neither the obstruction of the trabecular meshwork nor the central hole clogging by residual OVD material to be the main cause of this increase, but steroid responsiveness to be the main culprit. Our study implemented a novel technique of visco-free IPCL V2.0 implantation under Ringer lactate solution, thus minimizing the OVD obstruction of central hole and trabecular meshwork. The minimal surgical trauma, reduced intraoperative time, and absence of intraoperative iridectomy minimized the degree of impact of the inflammation on IOP. We used topical dexamethasone 0.1%, which is known for its lesser effects on IOP as compared to prednisolone 1%. Nevertheless, during the first month after surgery, 19 eyes required temporary topical hypotensive treatment. After stopping topical steroid treatment, no eye required further hypotensive treatment to maintain IOP.

There were no major inadvertent complications during the surgeries. 1 patient had iritis and 1 patient had retinal detachment on 3 month follow up.

Limitations

One of the limitations of our study was a small sample size and short period of follow up which is insufficient to study long term complications like cataract, decreasing vault size and endothelial cell loss over time.[30]

CONCLUSION

In summary, our study is the first study of IPCL V2.0 in Western India carried out in a tertiary healthcare hospital using a novel visco-free IPCL implantation technique. This study shows that postoperative Vault size is independent of IOP rise in these patients in short term and we attribute this rise in IOP majorly to steroid responsiveness. However, long-term follow-up of AC angle width should be performed to detect potential angle closure.

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