

Correlation of intra ocular pressure and central vault after implantation of ICL/IPCL with a central hole without iridotomy

S Rahman¹, U Kawsar², Z J Ruma³, Z Farhana⁴

Abstract

To compare the intraocular pressure (IOP) values before and a 6 months period after implantation of phakic implantable contact lenses (ICL EVO/EVO+, STAAR Surgical, Switzerland / IPCL V2.0, Care Group, India) with a central hole in it in moderate to high myopic patients, and to measure the central vault in each patient to quantify the risk of increasing IOP.

Material and method : A prospective study was conducted in the department of Glaucoma and Refractive Surgery, Vision Eye Hospital, Dhaka over a period from March 2022 to October 15, 2022. Total of 56 eyes of 30 patients were included. All patients were high to moderate myopic and underwent ICL or IPCL implantation surgery after doing all refractive and preoperative investigations including IOP. We measured IOP and Vault in postoperative days periodically.

Result: The IOP of both eyes with phakic IOL raised temporarily during the first month after surgeries, especially on the 1st and 7th postoperative day, and came down to the previous level after 3 to 6 months. The vault of eyes are variable from patient to patient but did not significantly affect the postoperative IOP.

Conclusion: IOP was more or less same after a 6-month period of ICL/ IPCL implantation. The vault was variable, and patients with extreme variable vaults were excluded for further follow-up to prevent vault-related complications

Keywords: ICL, IPCL, IOP, ACG

Introduction

The implantable Phakic Lens (ICL/IPCL) is a new posterior chamber intraocular lens that can be implanted into the eye, without removing the natural lens. ICL is made from

a material called Collamer copolymer that contains a small amount of purified collagen and IPCL is made from reinforced hybrid acrylic material. It is stable and biocompatible. It has been used for many years in the lenses implanted during eye surgery.

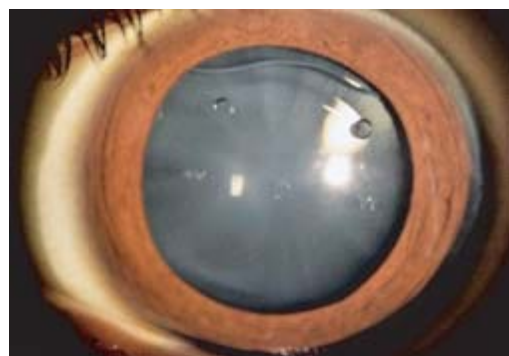


Fig-1a: Implantable phakic Contact lens (In Situ)



Fig-1b: Implantable Collamer lens (In Situ)

ICL/ IPCL is a posterior chamber phakic intraocular lens and has been reported to perform well for the correction of moderate to high ametropia¹⁻⁴. ICL was designed with a 360 μ central hole to allow aqueous humor to flow which did not require additional peripheral iridotomies and may reduce the risk of cataract formation. IPCL is designed with a 380-micron central hole for the same purpose. Achieving an

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appropriate vault is the main concern after the implantation of an implantable phakic lens for surgical correction of high myopia.

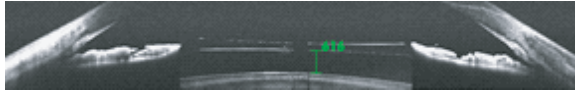


Fig-2a: Vault height



Fig-2b: Vault height

Considering that the presence of the central artificial hole induces a change in the aqueous humor dynamics⁵, the central hole may affect the intraocular pressure (IOP) and the vault of the ICL/IPCL, which play a vital role in determining the safety of the ICL implantation technique. Although several studies have reported the IOP changes after implantation of v4c ICL, most of them described the situations in the middle or late stage postoperatively and are not in great detail^{6,7}. Moreover, the vault is a possible source of IOP changes, and it is uncertain whether there is any correlation between them in v4c(ICL) implanted eyes. In the meantime, new models of ICL EVO, EVO+, and as well as IPCL V2.0 arrived on the market. Therefore, in this perspective and random study, we examine the IOP and vaults in the eyes with these ICL and IPCL early postoperatively, then make further efforts to find out the relationship between IOP and vaults.



Fig-3a: Implantable collamer lens



Fig-3b: Implantable phakic Contact lens

Methods

This prospective randomized controlled trial was performed in Vision eye hospital. Written informed consent was obtained from all patients after they received a full explanation of the nature and possible consequences of the study.

Patients were selected following these inclusion criteria: a corrected distance visual acuity (CDVA) of 20/40 or better, stable bilateral myopia for at least 1 years, refractive error in the correctable range (from -4.50 to -18.00 diopters [D]), and a clear central cornea. The exclusion criteria included age younger than 16 years, anterior chamber depth (ACD) 2.9 mm, endothelial cell density (ECD) <2000 cell/mm², mesopic pupil >7.0 mm, cataract, history of glaucoma or other ophthalmic diseases.

Each patient underwent bilateral/ unilateral implantation of the posterior chamber phakic implantable lens with a 0.36-mm central hole (ICL EVO) or 0.38-mm central hole (IPCL V2.0) for the correction of moderate to high myopia by the same surgeon.

Preoperative assessment

Before implantation, patients underwent a series of ophthalmologic tests including uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest and cycloplegic refractions, slit-lamp examination, IOP measurement, Central corneal thickness (ultrasound pachymetry), ACD measurement, and dilated fundus examination. All eyes were targeted for emmetropia. Lens power calculation was performed according to the manufacturer's instructions. The size of the ICL was selected based on the horizontal white-to-white diameter measured by a digital caliper, and the anterior chamber depth was measured by Allegro-Ocultyzer-wavelight.

Surgical procedures

Thirty minutes before surgery, corneal markings were done, pupils were dilated with dilating and cycloplegic agents. Under topical anesthesia, a model EVO ICL/V2.0 IPCL was inserted

through a 3.2 mm clear corneal incision with the use of an injector cartridge supplied by manufacturer after injection of visco elastics (Optagel HPMC 2%) into the anterior chamber. The phakic lens was placed in the posterior chamber, and then visco elastics was washed out of the anterior chamber with balanced salt solution, followed by instillation of miotic agent (pilocarpine 2% eye drop). After surgery, antibiotic (0.5% Moxifloxacin eye drops,) and steroidal (difluprednate Eye Drops) drugs were administered topically 6 times daily for 7 days and then gradually tapered.

Postoperative assessment

Postoperative examinations of intraocular pressure by GAT were performed on 1st POD, 7th POD days, after 1 month 3 months 6 months, while vaults were measured by anterior segment OCT (DRI OCT Triton, Topcon Health Care) on 7th POD. The evaluations of uncorrected distance visual acuity, best-corrected distance visual acuity and manifest refraction were also carried out. If the vault is so narrow or so wide, then the patient were instructed to follow up frequently to check the IOP and any cataractous change in phakic lens.

Table 1: Distribution of the patients according to gender (N=30)

Gender	Frequency (n)	Percentage (%)
Male	10	33.3
Female	20	66.7

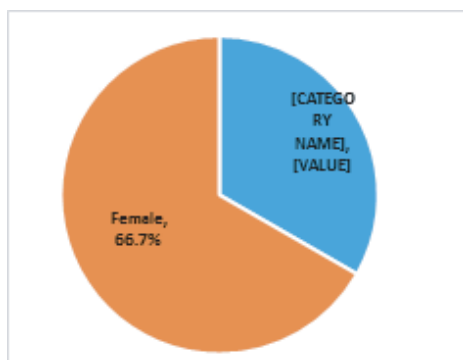


Table 1a (chart): Distribution of the patients according to Gender



Fig-4 a: Slide calipers for measuring white to white



Fig-4 b: Measuring white to white with Slide Calipers

Table 2: Distribution of the eyes according to type (N=54)

Type	Frequency (n)	Percentage (%)
ICL	38	70.4
IPCL	16	29.6

Table 3: ACD level of the eyes (N=54)

	Mean $\pm$ SD	Min – max
ACD (mm)	3.36 $\pm$ 0.67	2.80-6.40

Table 4: Vertical and horizontal white to white distance of the eyes (N=54)

White to white (mm)	Mean $\pm$ SD	Min – max
Vertical	10.96 $\pm$ 0.43	10.15 – 12.00
Horizontal	11.30 $\pm$ 0.38	10.25 – 12.00

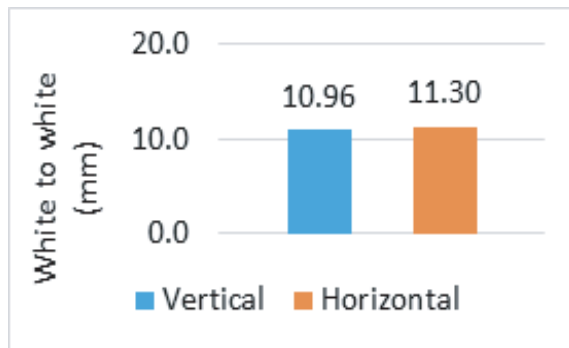


Table 4a (chart): Vertical and horizontal white-to-white distance of the eyes

Table 5: IOP before and after surgery of the eyes (N=54)

IOP (mmHg)	Mean $\pm$ SD	Min - max
Before surgery	12.54 $\pm$ 1.51	10 – 15
1 st POD	15.89 $\pm$ 1.95	12 – 21
7 th POD	15.07 $\pm$ 5.42	10 – 36
After 1 month	13.70 $\pm$ 1.62	10 – 17
After 3 months	12.81 $\pm$ 1.47	10 – 16
After 6 months	12.61 $\pm$ 1.14	10 – 15
p-value (before vs after 6 months)	0.727	

Paired sample t test was done

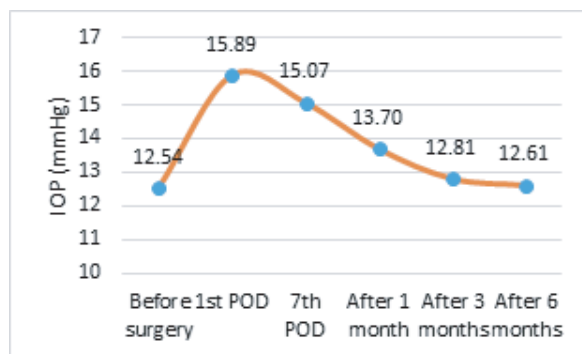


Table 5a (chart) : IOP before and after surgery of the eyes

Table 6: Vault level of the eyes (N=54)

	Mean $\pm$ SD	Min - max
Vault (μ m)	450.93 $\pm$ 147.25	210 - 770

Discussion

This trial was planned to find out the IOP changes and its correlation with vaults after implantation of phakic IOL with a central hole, without iridotomies. Indeed, this preoperative, randomized study largely decreased the variability introduced by inter-individual differences and differences in surgeons that linked to outcome measures. It also allowed a better statistical evaluation with each patient serving as his own control. Thus, for an identical number of cases, this methodology allowed us to define small quantitative differences more clearly. Furthermore, concerning the important problem of risks for the patient, because the long-term outcome of both ICL and IPCL was unknown, our choice of performing a bilateral study balanced the potential risk for the patient.

In the present study, we observed 56 eyes of 30 patients where males were 10 and females were 20 in number. It is demonstrated that IOP was mildly elevated in 1st and 7th POD. But after 1 month IOP was declined and on 3th to 6th month it was near to preoperative evaluation. Values of intraocular pressure were stable during 6 months of follow ups. In the study, 56 eyes were implanted with the ICL and IPCL.

Vault (μ m) 450.93 $\pm$ 147.25 210 - 770 mean IOP in 30 patients after ICL implantation were 12.66 $\pm$ 1.14 mm of Hg in R/E and 12.56 $\pm$ 1.16 mm of Hg which was not significantly different regarding the preoperative value. Gonzalez-Lopez et al. reported that no eye in their series of 100 eyes had an IOP > 30 mm Hg at any post operative measurement⁸. Before the surgery, the mean IOP in our study was 12.45 $\pm$ 1.50 in R/E and 12.64 $\pm$ 1.55 mm of Hg in L/E and after 6 month it was 12.66 $\pm$ 1.14 in R/E and 12.56 $\pm$ 1.16 in L/E. So ultimately IOP was mostly same as before the surgery. During 1st POD to 6 months, the IOP

showed an analogous trend and had no significant difference statistically. 1 eye had an IOP over 32 mmHg. The same patient's another eye the IOP was 34 mm of Hg. Other 2 eyes we found 34 and 25 mm of Hg respectively. We added Anti Glaucoma medication (Timolol Maleate 0.5%+ Brimonidine Tartrate 0.2% fixed combination eye drop: one drop 12 hourly for 6 weeks) All patients were steroid responder and after reducing the doses of steroids, IOP were declined. Consistent with other studies^{9,10}, we attribute the increase in IOP during the first month after surgery to the effect of postoperative inflammation and topical steroids. As we use Difluprednate eye drops 6 times daily for 7 days, and reduce dose onward. This steroid-related increases in IOP were most obviously 1 weeks after surgery correspondingly. Furthermore, with the decrease in the dosage of the drug and the intraocular inflammation, the IOP gradually went down to nearly preoperative levels.



Fig-5: IPCL



Fig-6: ICL

At the end of our study, only 4 eyes had more than a 5 mmHg increase in IOP over the preoperative value. However, this increases were not considered clinically relevant (within normal limit of IOP range). In most of the cases after topical steroid treatment, no eye required further hypotensive treatment to maintain IOP. Thus, it can be seen that the effects of conventional drugs and mild inflammation are proximal on EVO ICL and IPCL V2.0. Despite the absence of peripheral iridotomy, normal aqueous flow seems to occur as a result of the central hole. Hence, the EVO ICL and IPCL V2.0 could maintain physiologic IOP levels under normal circumstances during the follow up period.

The evaluated IOP was not caused by vault difference. In another study, Gonzalez-Lopez⁸ found that obstruction of the trabecular meshwork or even of the central hole by residual viscoelastic material may be the main cause of this increase. Postoperative trabeculitis may also have affected early changes in IOP. Nevertheless, the reduction of surgical trauma and intraoperative time limited the degree of impact of the inflammation on IOP. In our study, we also found elevated IOP in early post operative period due to residual visco elastic material and post operative trabeculitis. Therefore, we consider the fluid circulation function of central hole is less effective than that of peripheral iris incision, especially when the aqueous humor is mixed with the viscoelastic agent or a lot of inflammatory cells and pigments.

The results of vaults in this study showed that in EVO ICL and IPCL V2.0, some vaults were narrow over the crystalline lens, suggesting that with the time course of this lenses, there may chance of cataract formation. And some vaults were wide suggesting that with time course there may chance of angle closure glaucoma.

There are many factors affecting IOP. However, our results showed no significant correlation between the vault and the IOP.

One main concern about these Phakic IOL is

the possibility of pupillary block caused by obstruction of the central hole which would affect IOP extremely. But no cases of pupillary block were observed in our study. The limitation of this study is that the sample data were limited. Only by increasing the number of implantations will we know whether the central hole ensures the free flow of aqueous humor in all possible clinical situations.

During the course of follow up there has not been any persistent increase of IOP among patient in our study. Elevation of IOP could happen in the early post-operative period due to residual visco elastic in the anterior chamber or because of angle closure due to positions of ICL / IPCL haptics and development of pupillary block.

The distance between the posterior ICL surface and anterior crystalline lens pole is termed the 'vault', which is crucial regarding the incidence of anterior subcapsular cataract formation. The ideal post operative vault must create a space over the entire anterior crystalline lens surface, whilst poor vault (< 250 micrometers) increases risk of cataract development excessive vault (>750micrometer) may result in pupillary block angle closure glaucoma⁵. Phakic IOL vault is determined by patient age, white to white measurement and Lens shape/ design.

The vault will vary with time and optical parameters such as accommodation and pupil size. In our study we found the lowest vault size was 289 micrometer and highest vault was 770 micrometer. Mean vault size was 432.76+138.32 micrometer in R/E and (472.00+157.17) micrometer in left eye.

But with the elevation of IOP was not associated with vault size.

ICL/IPCL implantation offers outstanding benefits, postoperative complications have been reported, most of which were associated with the vault (distance between the posterior ICL/IPCL surface and anterior crystalline lens surface) inappropriateness^{11, 12}. A low vault may lead to mechanical contact with the lens or inadequate aqueous humour circulation,

accounting for the high incidence of anterior capsular opacity and cataract formation^{13,14}. Conversely, a high vault can cause excessive mechanical contact between the ICL and iris, leading to inflammation and increased intraocular pressure^{15,16}. Additionally, the occurrence of pigment dispersion syndrome, iris atrophy, and acute angle-closure glaucoma has been associated with a high vault^{17,18, 19}.

Many factors can influence the vault after ICL /IPCL implantation. Lee et al.²⁰ found that horizontal compression of the ciliary sulcus is a key factor in vault formation, but it could not effectively predict vault. Trancon et al.²¹ and Zeng et al.²² believed that the anatomy of the crystalline lens could affect vaulting after surgery. Additionally, many studies have found that changes in pupil size are closely associated with changes in vaulting^{23,24,25}. Unfortunately, insufficient studies exist to integrate these factors to predict postoperative vaulting.

Conclusion

Our study shows that, after ICL/IPCL implantation, the IOP were elevated temporarily during early postoperative period, and after 3 to 6 month the IOP was significantly declines as pre operative period indicating that the former is more vulnerable to viscoelastic agent, post operative trabeculitis and aqueous humor turbidity. We assessed vault height of all patients to see if there was any role in increasing IOP. Since the vault size were variable in different eyes, the narrower and wider vault height have risk factors of developing PACG and cataract, patients with vault height outside the normal range were advised to come for regular check up according to our protocol in order to avoid vault related complications.

Although longer observation in a large number of patients is required to assess the long-term effect of implantation of current phakic IOL models, we agree with other authors^{7,26,27} that this new surgical approach, which does not require additional iridectomies.

References

- Alfonso JF, et al. Posterior chamber collagen copolymer phakic intraocular lenses to correct myopia: five-year follow up. *J Cataract Refract Surg.* 2011;37(5):873–80.
- Kamiya K, et al. Four-year follow-up of posterior chamber phakic intraocular lens implantation for moderate to high myopia. *Arch Ophthalmol.* 2009;127(7):845–50.
- Sanders DR, et al. United States Food and Drug Administration clinical trial of the Implantable Collamer Lens (ICL) for moderate to high myopia: three-year follow up. *Ophthalmology.* 2004;111(9):1683–92.
- Schallhorn S, et al. Randomized prospective comparison of visiantoric implantable collamer lens and conventional photorefractive keratectomy for moderate to high myopic astigmatism. *J Refract Surg.* 2007;23(9):853–67.
- Kawamori T, Uozato H, Shimizu K. Fluid dynamics simulation of aqueous humour in a posterior-chamber phakic intraocular lens with a central perforation. *Graefes Arch ClinExpOphthalmol.* 2012;250(6):935–9.
- Higuera-Esteban A, et al. Intraocular pressure after implantation of the Visian Implantable Collamer Lens With CentraFLOW without iridotomy. *Am J Ophthalmol.* 2013;156(4):800–5.
- Shimizu K, et al. Intraindividual comparison of visual performance after posterior chamber phakic intraocular lens with and without a central hole implantation for moderate to high myopia. *Am J Ophthalmol.* 2012;154(3):486–94. e1.
- Gonzalez-Lopez F, et al. Intraocular pressure during the early postoperative period after consecutive implantations of posterior chamber phakic intraocular lenses with a central hole. *J Cataract Refract Surg.* 2013;39(12):1859–63.
- Chen LJ, et al. Metaanalysis of cataract development after phakic intraocular lens surgery. *J Cataract Refract Surg.* 2008;34(7):1181–200.
- Huseynova T, et al. Comparative study of 2 types of implantable collamer lenses, 1 with and 1 without a central artificial hole. *Am J Ophthalmol.* 2014;157(6):1136–43.
- Fernandes P, Gonzalez-Mejome JM, Madrid-Costa D, Ferrer-Blasco T, Jorge J, Montes-Mico R. Implantable collamer posterior chamber intraocular lenses: a review of potential complications. *J Refract Surg.* 2011;27:765–76.
- Matarazzo F, Day AC, Fernandez-Vega Cueto L, Maurino V. Vertical implantable collamer lens (ICL) rotation for the management of high vault due to lens oversizing. *IntOphthalmol.* 2018;38:2689–92.
- Gimbel HV, LeClair BM, Jabo B, Marzouk H. Incidence of implantable collamer lens induced cataract. *Can J Ophthalmol.* 2018;53:518–22.
- Guber I, Mouvet V, Bergin C, Perritaz S, Othenin-Girard P, Majo F. Clinical outcomes and cataract formation rates in eyes 10 years after posterior phakic lens implantation for myopia. *JAMA Ophthalmol.* 2016;134:487–94.
- Alfonso JF, Lisa C, Abdelhamid A, Fernandes P, Jorge J, Montes-Mico R. Three-year follow-up of subjective vault following myopic implantable collamer lens implantation. *Graefes Arch ClinExpOphthalmol.* 2010;248:1827–35.
- Repplinger B, Kohnen T. Intraocular pressure after implantation of an ICL with aquaport. Development of intraocular pressure after implantation of an ICL (model V4c) with aquaport without iridotomy. *Ophthalmology.* 2018;115:29–33.
- Chun YS, Park IK, Lee HI, Lee JH, Kim JC. Iris and trabecular meshwork pigment changes after posterior chamber phakic intraocular lens implantation. *J Cataract Refract Surg.* 2006;32:1452–8.
- Ye C, Patel CK, Momont AC, Liu Y. Advanced pigment dispersion glaucoma secondary to phakic intraocular collamer lens implant. *Am J Ophthalmol.* 2018;10:65–7.
- Shipper I. Surgical management of acute angle-closure glaucoma after implantation of a toric ICL. *J Cataract Refract Surg.* 2007;33:563–4.
- Lee DH, Choi SH, Chung ES, Chung TY. Correlation between preoperative biometry and posterior chamber phakicvisian implantable collamer lens vaulting. *Ophthalmology.* 2012;119:272–7.
- Trancon AS, Manito SC, Sierra OT, Baptista AM, Serra PM. Determining vault size in implantable collamer lenses (ICL): preoperative anatomy and lens parameters. *J Cataract Refract Surg.* 2020;46:728–36.
- Zeng QY, Xie XL, Chen Q. Prevention and management of collagen copolymer phakic intraocular lens exchange: causes and surgical techniques. *J Cataract Refract Surg.* 2015;41:576–84.
- Lee H, Kang DSY, Choi JY, Ha BJ, Kim EK, Seo KY, et al. Analysis of pre-operative factors affecting range of optimal vaulting after implantation of 12.6-mm V4c implantable collamer lens in myopic eyes. *BMC Ophthalmol.* 2018;18:163.
- Kato S, Shimizu K, Igarashi A. Vault changes caused by light-induced pupil constriction and accommodation in eyes with an implantable collamer lens. *Cornea.* 2019;38:217–20.
- Chen X, Miao H, Naidu RK, Wang X, Zhou X. Comparison of early changes in and factors affecting vault following posterior chamber phakic implantable collamer lens implantation without and with a central hole (ICL V4 and ICL V4c). *BMC Ophthalmol.* 2016;16:161.
- Lee H, et al. Effect of Accommodation on Vaulting and Movement of Posterior Chamber Phakic Lenses in Eyes With Implantable Collamer Lenses. *Am J Ophthalmol.* 2015;160(4):710–6. e1.