Original Article

Effect of pupil size on posterior chamber phakic intraocular lens vault measurements

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Purpose: The aim of this study was to measure the implantable collamer lens (ICL) vault changes with anterior segment optical coherence tomography (AS-OCT) after the implantation of the Visian posterior chamber phakic ICL with a central hole (V4c) in relation to the pupil size. **Methods:** This retrospective observational pilot study included 32 eyes of 16 patients, who underwent V4c ICL implantation. ICL vault was measured with AS-OCT in undilated and fully dilate state of the pupil. Primary outcome measure was the change in the vault of V4c ICL at the maximum and minimum pupil size. **Results:** Median (IQR) undilated and post-dilated vault measurement was 393.00 (335.50–493.50) microns and 421.00 (338.50–503.75) microns, respectively, which was not statistically significant (P = 0.44). **Conclusion:** No statistically significant difference was observed between the undilated and post-dilated ICL vault measurements. Hence, the postoperative vault can be measured either in resting, undilated state or fully dilated state of the pupil and would be similar irrespective of the pupil size.

Key words: Implantable collamer lens, pupil size, vault

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The implantable collamer lens (ICL) is often the first choice for surgical correction for high myopia.[1,2] The ICL (STAAR Surgical, Nidau, Switzerland) is a posterior chamber phakic intraocular lens (IOL), which is widely used and accepted for the correction of high myopia.[3] Introduction of V4C ICL was a marked improvement over the Visian posterior chamber phakic ICL without a central hole (ICL V4), which has been associated with an increased incidence of cataract and increased intraocular pressure (IOP) postoperatively. The central hole of 0.36 mm size in V4C ICL improves aqueous humor circulation, preventing these complications.[4] An appropriate vault (distance between the posterior surface of ICL surface and anterior surface of crystalline lens surface) after ICL implantation is generally 0.5–1.5 times the central corneal thickness (CCT), which is around 250–750 microns. Patients with a low vault after V4 ICL implantation are at an increased risk of development and progression of cataract postoperatively, whereas those with a high vault after V4 ICL implantation are at an increased risk of postoperative IOP elevation.[5] Hence, the measurement of postoperative vault is an important parameter in the evaluation in the ICL patients. Previous studies have reported that the factors that can influence ICL vault measurement are pupil size, measurements under photopic and scotopic conditions, and in the accommodative and nonaccommodative states.[6] But till now there has been no uniform consensus on whether the vault has to be measured in a dilated or resting, undilated pupillary state in the postoperative period. Hence, we decided to undertake this study where the postoperative vault was measured on anterior segment optical coherence tomography (ASOCT) both in the resting state and full dilated state of the pupil.

The aim of this study was to evaluate the vault changes in the eyes with ICL V4 C, both in the resting state and full dilatation state of the pupil, using AS-OCT.

Methods

This study was reviewed and approved by the Institutional Review Board (IRB). All patients provided informed consent to participate in the study and the study procedures adhered to the tenets of the Declaration of Helsinki. All patients had undergone V4C ICL implantation at our institute, from January 2017 to December 2018.

Indications for ICL implantation included myopic eyes that were not suitable for laser refractive surgery, stable refraction for at least 1 year prior to the surgery, age of 19 years or older, no preexisting ocular pathologic features, no previous ocular surgery, IOP between 10 and 21 mm Hg, anterior chamber depth (ACD) of more than or equal to 2.8 mm measured with Sirius topographer (SCHWIND eye-tech GmbH, Kleinostheim, Germany), and a clear crystalline lens. ACD was defined as the distance between corneal endothelium and anterior capsule of the lens. All the eyes included in the study had a myopic refractive error. Twenty-three of the 32 eyes underwent

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ToricV4C ICL implantation and 9 eyes underwent nontoric V4C ICL implantation. The rotation of the ICL was done as advised by the manufacturer.

Table 1: Patient demographics and Undilated and Dilated ICL vault measurements

Gender	8 Females (50%), 8 Males (50%)
Age in years (Mean±SD)	23.88±3.09
Pre Operative SE (D) (Mean±SD)	- 9.85±4.40
3 months Postoperative SE (D) (Mean±SD)	0.02±0.25
Undilated ICL Vault (microns) Median (IQR)	393.00 (335.50-493.50)
Dilated ICL Vault (microns)	421.00 (338.50-503.75)

Eyes with preexisting ocular pathologies such as glaucoma, pigment dispersion syndrome, and pseudoexfoliation of the lens capsule were excluded from the study.

Implantation of the V4C ICL was performed through a 3.2 mm self-sealing clear corneal incision with an injector. Hydroxypropyl methylcellulose was used as the viscoelastic substance. With a hook, both haptics of the ICL were carefully placed beneath the iris, achieving a horizontal orientation. After removal of the remaining viscoelastic substance, corneal wound closure was performed by stromal hydration.

Postoperatively all the AS-OCT measurements (Optovue, Fremont, California) were performed by a single operator in the mesopic condition, with the patient fixing at a fixating target. The patients were asked to specifically focus on the internal fixation target to achieve an accommodative state. All the examinations were performed in a common setting

Table 2: Patient details showing preoperative refractive error, vault measurement in undilated and dilated state of the pupil

Gender	EYE	Age in years	Preoperative Spherical error in Diopters	Preoperative Cylinder error in Diopters	Preoperative Spherical equivalent in Diopters	V1 in Microns	V2 in Microns
F	RE	21	-7.50	-1.5×180	-8.25	700.00	666.00
F	LE	21	-6.00	-1.5×180	-6.75	356.00	310.00
M	RE	20	-8.00		-8	396.00	353.00
M	LE	20	-9.00		-9	485.00	495.00
F	RE	25	-4.50		-4.5	384.00	434.00
F	LE	25	-4.50		-4.5	368.00	410.00
M	RE	30	-16.00	-1.5×160	-16.75	656.00	696.00
M	LE	30	-13.50		-13.5	566.00	567.00
M	RE	28	-9.00	-0.5×180	-9.25	337.00	347.00
M	LE	28	-7.50	-1.5×170	-8.25	344.00	356.00
M	RE	24	-7.75		-7.75	322.00	371.00
M	LE	24	-7.75		-7.75	390.00	399.00
M	RE	25	-6.50	-0.5×180	-6.75	127.00	176.00
M	LE	25	-6.50	-0.5×180	-6.75	266.00	143.00
F	RE	25	-10.00		-10	331.00	415.00
F	LE	25	-10.00		-10	381.00	436.00
F	RE	28	-9.75	-0.75×180	-10.125	294.00	313.00
F	LE	28	-9.75	-0.75×180	-10.125	269.00	285.00
F	RE	26	-9.25	-1.75×15	-10.125	498.00	509.00
F	LE	26	-9.25	-1.75×180	-10.125	470.00	495.00
F	RE	21	-4.25	-0.75×180	-4.625	390.00	307.00
F	LE	21	-3.25	-1×150	-3.75	470.00	418.00
F	RE	19	-12.00	-4×10	-14	424.00	469.00
F	LE	19	-10.00	-2.5×180	-11.25	405.00	424.00
M	RE	21	-14.50	-2.5×40	-15.75	492.00	502.00
M	LE	21	-15.50	-2.5×140	-16.75	694.00	622.00
M	RE	24	-19.00	-2×40	-20	461.00	579.00
M	LE	24	-20.00	-3×140	-21.5	533.00	495.00
F	RE	22	-7.00	-1×10	-7.5	981.00	792.00
F	LE	22	-8.00	-1×170	-8.5	790.00	746.00
M	RE	23	-6.00	-3×5	-7.5	217.00	310.00
M	LE	23	-4.50	-2.5×170	-5.75	276.00	306.00

V1: Vault in microns in undilated resting state of the pupil. V2 : Vault in microns in Dilated state of the pupil

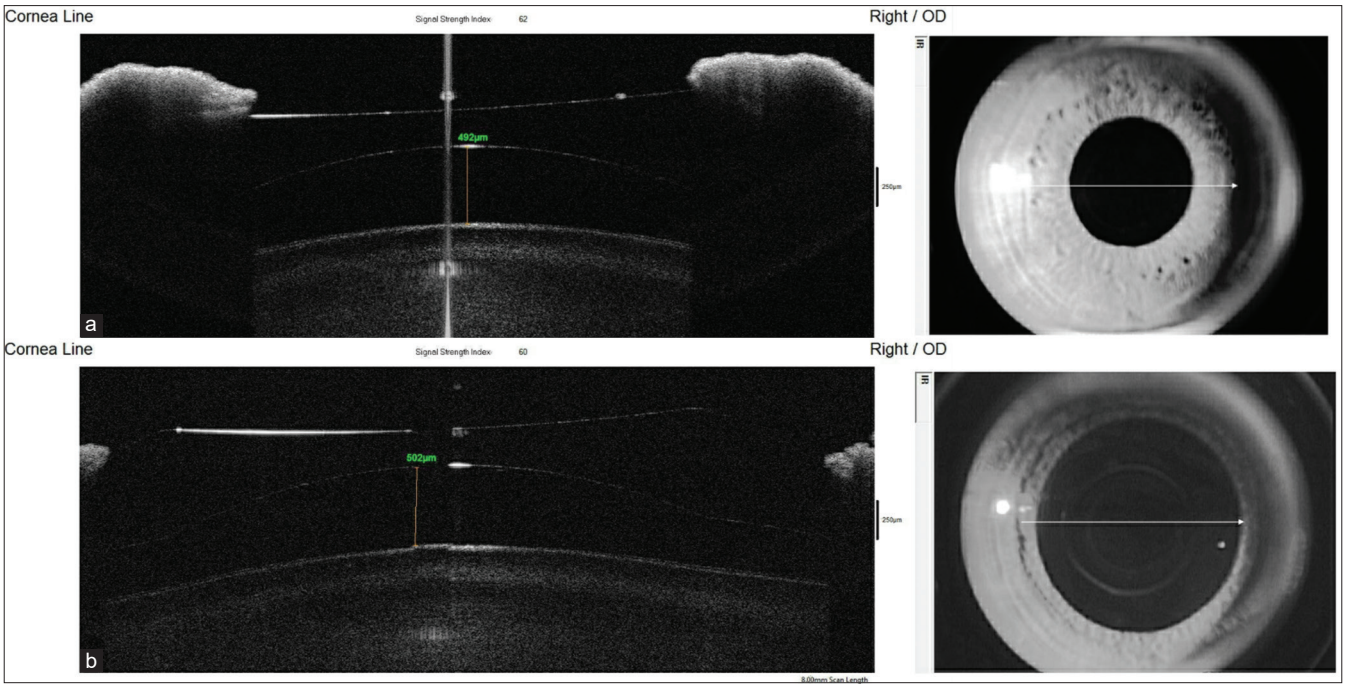

Figure 1: (a): Postoperative ICL vault in resting state of the pupil (3 mm size). (b): Postoperative ICL vault in dilated state of the pupil (8 mm size)

with common lighting conditions. The undilated pupil size was around 3 mm in all the eyes. Dilated pupil size was 8 mm after instilling one drop of mydriatic (phenylephrine hydrochloride5%, Drosyn Eye Drops, FDC Limited, India). The size of the pupil was measured on the Sirius topographer by the same operator.

The AS-OCT images obtained while the pupil was at its resting state and at its maximum sizes were identified under each measurement condition, and each anterior segment parameter was manually measured on these images. All the AS-OCT measurements were done after at least 6 months after the ICL surgery. The examined parameters included the pupil size and ICL vault. The vault was defined as the distance between the posterior surface of the ICL and the anterior surface of the crystalline lens.

Statistical analysis

Data were analyzed using the software STATA version 11.1 (Stata Corp., College Station, Texas) and Origin version 7.0 (OriginLab Corporation, Northampton, Massachusetts). Quantitative data were represented as either mean and standard deviation or median and interquartile range (IQR). Student's *t* test was used to compare the variables. In cases when the data were not normally distributed Wilcoxon signed rank test was used to compare two groups. A value of $P < 0.05$ was considered statistically significant. Normality test was performed using the Shapiro–Wilk test.

Results

A total of 32 eyes of 16 patients (8 men [50%] and 8 women [50%]) were enrolled in this study. The mean age of participants was 23.88 ± 3.09 years (range, 19–30 years). Mean spherical equivalent (SE) of refractive error was –9.85 ± 4.40 diopters (D) before surgery. Three months postoperatively SE was + 0.02 ± 0.25 D ($P < 0.001$). Twenty-nine eyes had postoperative uncorrected visual acuity of 6/9 or better. Three eyes had postoperative best-corrected visual acuity of 6/18, as they were amblyopic [Table 1]. Median (IQR) undilated and dilated vault was 393.00 microns (335.50–493.50) and 421.00 microns (338.50–503.75), respectively, but the difference was not statistically significant ($P = 0.44$) [Table 2, Fig. 1a and b]. Considering the correlation factor between fellow eyes, vault measurements were averaged between both the eyes and then repeated measurement analysis. Similar results were obtained, median (IQR) undilated and dilated vault was 440.75 (366.38–505.63) microns and 450.25 (371.75–498.00) microns, respectively, but the difference was not statistically significant ($P = 0.31$)

Discussion

The vault is considered as an important index to evaluate the safety after ICL implantation. Although most of the postoperative patients can obtain ideal vault, excessive or insufficient vaults cannot be avoided.[7,8] Hence, regular measurement of the vault in the postoperative period is of paramount importance to predict any complications beforehand such as anterior subcapsular cataract in shallow vault and glaucoma in high vaults. There was never a uniform consensus whether to measure the postoperative vault in resting state or full dilated state of the pupil. To address this, we undertook a pilot study to measure the central vault measurements in our patients who underwent Vc4 ICL surgery, both in resting state and dilated state of the pupil.

However, the accommodative reaction of pupil in response to the light can affect the amount of ICL vaulting. Studies evaluating changes in vaulting of the ICL under differing lighting conditions showed a significant decrease in central vaulting under photopic conditions.

Petternel *et al*. have reported no significant measurement changes between the ICL and the crystalline lens were detected

during subjective accommodation and after application of pilocarpine.[9] However, under photopic conditions, with constriction of the pupil, the distance between the ICL and the crystalline lens was significantly reduced. This study was done in older versions of the ICL without a central hole (V3 and V4 models).

Lee *et al*. compared the changes in the vault in eyes implanted with V4c ICLs and V4 ICL under photopic and mesopic conditions and reported a significant decrease in the vault under photopic conditions in the eyes implanted with V4c ICL.[10]

This study measured the vault under undilated resting state and dilated states of the pupil. In both the cases, there is no statistically significant difference between the postoperative vault. The main idea of undertaking this study was to evaluate the vault changes in relation to the size of the pupil as there has always been a dilemma whether to measure the vault in a dilated or undilated, resting state of the pupil.

All the vault measurements were done after 6 months of the ICL surgery, as vault of the ICL decreased until 3 months postoperatively but remained stable from 3 months to 1 year postoperatively as evaluated by Kojimia *et al*.[11]

A majority of the eyes in our series had toric ICL implantation. As the maximum intraoperative rotation allowed by the manufacturer is never more than 21°, we believe that the vault measurements in nontoric and toric groups can be comparable even though the sulcus measurements vary in vertical and horizontal meridians.[12]

The strength of our study is that this is first study that compared the V4c ICL vault measurements in resting state and fully dilated state of the pupil. There was always a confusion whether to measure the vault in the resting state or a dilated state of the pupil, in the postoperative period.

However, there are limitations to this study, including its retrospective nature. First, the sample size was relatively small. Second, this study performed assessments only under resting state and undilated states of pupil. Future studies should include various light and accommodation levels to better understand the anatomical position of V4C ICL in all conditions.

Conclusion

We conclude that the vault measurements in resting state and full-dilated state of the pupil in eyes with V4C ICL were not statistically significant. As there is no difference in the vault measurements in relation to the postoperative pupil size, the vault can be measured either in resting state or dilated state of pupil.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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