


# Effect of Light Conditions and Accommodation on Implantable Phakic Contact Lens Vault by Anterior Segment Optical Coherence Tomography

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**Purpose:** To investigate the dynamic pupil and vault changes in eyes with implantable phakic contact lens (IPCL) under photopic and scotopic settings, as well as during accommodation using the anterior segment optical coherence tomography (AS-OCT).

**Methods:** A prospective observational study included consecutive 36 eyes of myopic patients who underwent IPCL V2.0 implantation. Under photopic and scotopic light settings, as well as during accommodation, all patients were scanned using CASIA OCT (CASIA2; TOMEY, Nagoya, Japan). The pupil size, the vault (distance between the back surface of the IPCL and the anterior lens capsule), ACD-lens (distance between the posterior corneal surface and the anterior lens surface), IPCL-lens (distance between the posterior corneal surface and the anterior IPCL surface), and lens thickness (LT) were the study parameters.

**Results:** The vault was significantly lower under photopic conditions ( $p$ -value<0.001). The pupil size was significantly smaller in photopic conditions ( $p$ -value<0.001). LT ( $p$ -value=0.975) and ACD-lens ( $p$ -value=0.917) were not significantly different between scotopic and photopic conditions, while the ACD-IPCL was significantly larger during photopic conditions ( $p$ -value=0.013). There were significant changes in all parameters between accommodative and non-accommodative conditions.

**Conclusion:** The IPCL vault decreased significantly under photopic light conditions and accommodation.

**Keywords:** IPCL, photopic light, scotopic light, lens accommodation, vault, AS-OCT

## Introduction

The implantable phakic contact lens (IPCL V2.0; Caregroup, Gujarat, India) is a new posterior chamber phakic intraocular lens (pIOL) that can be used to correct refractive problems.<sup>1</sup> It was created as a cost-effective alternative to traditional refractive correction instead of an Implantable Collamer Lens (ICL). Furthermore, the maximal myopic correction attainable with ICL is restricted to  $-18.0$  D, while the IPCL is freely available and can correct a wide range of ametropia up to  $-30.0$  D.<sup>2</sup>

Recently, a new version of the IPCL (IPCL V2.0) with a  $380$   $\mu\text{m}$  central artificial hole became commercially available. This would eliminate the necessity for a peripheral iridectomy (PI) and reduce the risk of cataracts and pupillary block glaucoma.<sup>3</sup>

The space between the back surface of the pIOL and the anterior surface of the crystalline lens is known as the central vault. A suitable vault has been recommended to be between  $250$  and  $750$   $\mu\text{m}$ . The contact between the pIOL and the anterior lens capsule can cause an anterior subcapsular cataract if the vault is insufficient. Excessive vaulting can result in angle closure, pupillary obstruction, or pigmentary dispersion syndrome, all of which can raise intraocular pressure (IOP) and hence increase the risk of glaucoma. As a result, it's critical to measure this distance in order to assure the technique's safety.<sup>4,5</sup>

Using low-coherence interferometry, anterior segment optical coherence tomography (AS-OCT) obtains cross-sectional pictures of the anterior segment without making contact with the cornea.<sup>6</sup> Although previous research has shown that pupil size can influence the vault measures, the dynamic vault alterations associated with dynamic pupil variations in eyes with IPCLs have not been investigated. The current study used AS-OCT to assess dynamic pupil size and vault changes in eyes with IPCL V2.0 in photopic and scotopic situations, as well as in the accommodative and nonaccommodative states.

## Patients and Methods

This is a prospective observational study which included a consecutive 36 eyes of myopic patients who underwent IPCL V2.0 implantation in the Ophthalmology department of Minia University Hospital and International Eye Centre, Minia, Egypt, in the period from March 2021 to December 2021 after obtaining written informed consent from every included patient to participate in the study. The study was designed according to the Declaration of Helsinki and was approved by Minia University Ethical Committee.

The inclusion criteria were patients younger than 40 years of age with stable myopia higher than  $-8.0$  D, myopic patients less than  $-8.0$  D, but not candidates for corneal refractive surgery, an endothelial cell count (ECC) greater than 2,500 cells/ $\text{mm}^2$  (Topcon Corp, Tokyo, Japan), anterior chamber depth (ACD) greater than or equal to 3 mm, estimated from the endothelium to the anterior lenticular surface (Pentacam, HR; Oculus Optikgeräte GmbH, Wetzlar, Germany). IOP less than 21 mmHg by Goldmann applanation tonometer (AT 900; Haag-Streit, Zug, Switzerland) with normal fundus examination except myopic chorioretinal degenerations by Volk 90 D lens (Volk, Mentor, Ohio, USA). Patients younger than 18 years of age and older than 40 years, shallow ACD less than 3 mm and any ocular pathological problem such as glaucoma, chronic uveitis, diabetic retinopathy, or cataract were excluded from the study. Also, patients with chronic systemic diseases such as collagen vascular diseases or diabetes mellitus were excluded.

## IPCL V2.0 Design, Power, and Size Calculation

The IPCL V2.0 is a hydrophilic acrylic copolymer single-piece PC pIOL. It can be injected through a 2.8 mm incision. It has a wide range of power from  $+15.0$  to  $-30.0$  D with astigmatic correction up to 10.0 D. It has six haptic, it has a central opening of about 380  $\mu\text{m}$  designed to decrease light scattering and glare and to facilitate aqueous humor circulation to eliminate the need for PI. The data needed for power calculation were refraction, keratometric readings, pachymetry, and ACD which were measured by Pentacam. The size of the IPCL was selected according to the ACD and horizontal white to white (WTW) using IOL Master (Carl Zeiss Meditec, Jena, Germany).

## AS-OCT Technique

All patients were examined 1 month or more after surgery (not before 1 month), to confirm stability of refraction and topical steroid withdrawal. All patients had no or postoperative complications.

After entering patient's data and accurate patient poisoning on the AS-OCT instrument, one eye from each patient was examined with CASIA OCT (CASIA2; TOMÉY, Nagoya, Japan) under different lighting conditions 1 month or more after the operation. Scans were obtained in the horizontal meridian and each scan was measured twice with the aid of the Light Intensity Meter (Pro'skit MT-4617, China) to measure the light intensity of the room. The measurements were taken after 5 minutes of the light on and off to give a chance for the adaptation to occur.

## The Scotopic Measurement (0.5 LUX)

The lights of the patient room were turned off with light only coming from the OCT screen while the measurement was performed.

## The Photopic Measurement (1,500 LUX)

After turning the lights of the patient room on, the light reflex (5 seconds from a distance of 15 cm) was induced by shining a penlight into the contralateral eye to induce miosis in the examined eye due to the consensual reflex.

## The Accommodative Measurement

In dim illumination, the patients fixated on an accommodative target image in the OCT device internal target while looking through a 0.00-diopter (D) lens for the first 5 seconds and a  $-5.00$  D lens (stimulate the physiologic accommodation) for the next 5 seconds. The patients were asked to specifically focus on the internal fixation target to achieve an accommodative state.

The study parameters were the pupil size, the vault (the distance between the back surface of the IPCL and the anterior lens capsule), anterior chamber depth (ACD)-lens (the distance between the posterior corneal surface and the anterior lens surface), IPCL-lens (the distance between the posterior corneal surface and the anterior IPCL surface), and the lens thickness (LT). All measurements were expressed in millimeters, except the vault, which was in micrometers.

## Methods of Statistical Analysis

Data were collected, revised, verified, coded, then entered into a PC for statistical analysis done by using IBM SPSS (Chicago, IL) statistical package version 20. Mean and standard deviation (SD) were used for quantitative data. The Independent sample *t*-test was used for comparison of the quantitative data. For all tests, probability (*p*) was considered non-significant if  $\geq 0.05$  and significant if  $< 0.05$ .

**Table 1** The Demographic and Preoperative Data

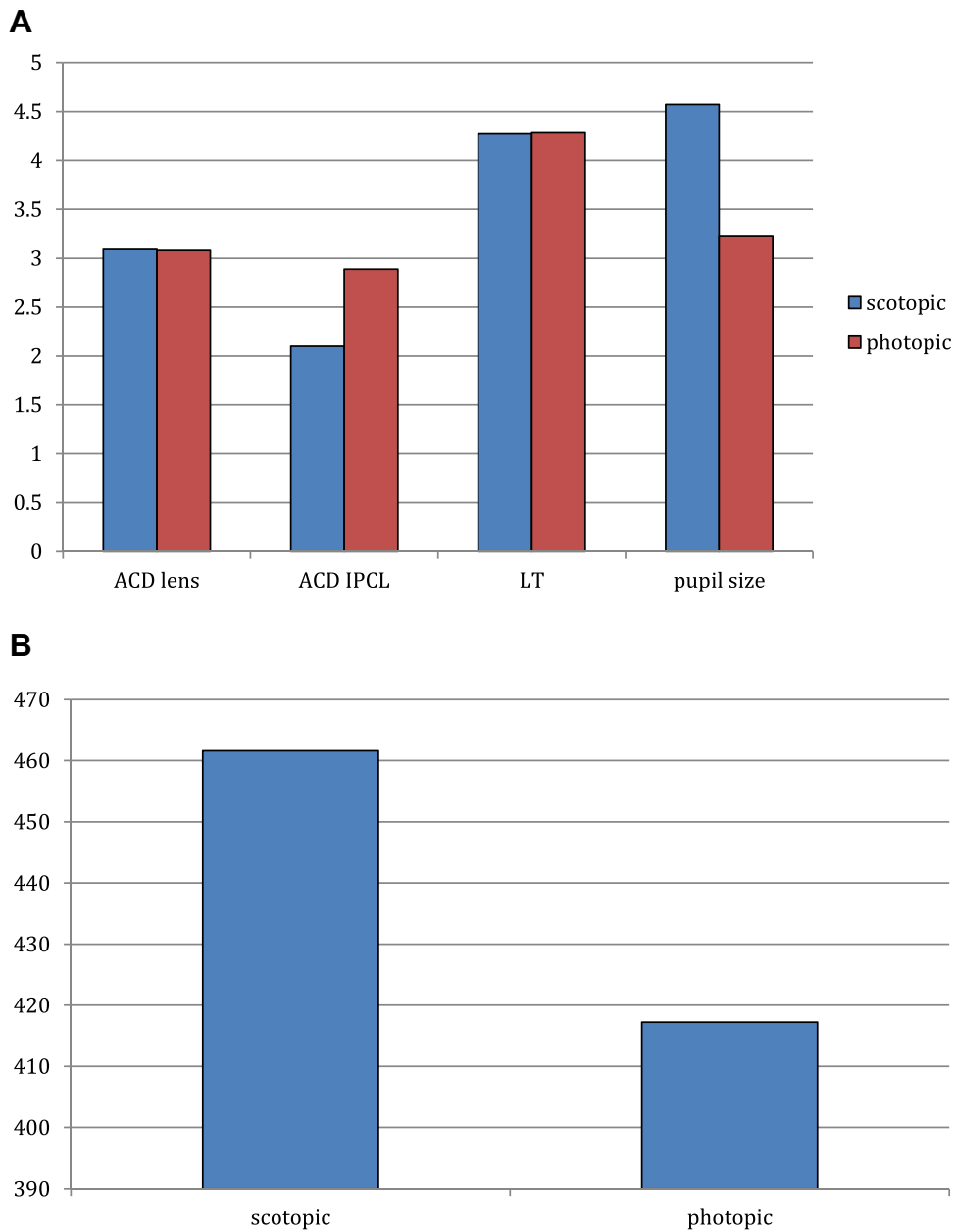
	Mean $\pm$ SD	Range
Age	26 $\pm$ 5.8	19–37
Sex: N (%)		
Males	20 (55.5%)	
Females	16 (44.5%)	
IOP	13.1 $\pm$ 0.97	12–16
SPH	$-10.2\pm 2.4$	$-15$ to $-6$
CYL	$-1.5\pm 0.23$	$-1.5$ to $-0.5$
UCDVA	1.04 $\pm$ 0.09	1–1.3
BCDVA	0.06 $\pm$ 0.08	0–0.2

**Notes:** The demographic and preoperative patients' data including the spherical error (SPH), cylindrical error (CYL), uncorrected distance visual acuity (UCDVA), and best corrected distance visual acuity (BCDVA).

**Table 2** The Scotopic and Photopic Measurements

	Scotopic	Photopic	<i>p</i> -value
Vault ( $\mu$ m)	461.6 $\pm$ 51.0	417.2 $\pm$ 25.6	$< 0.001$
ACD-Lens (mm)	3.09 $\pm$ 0.20	3.08 $\pm$ 0.19	0.917
ACD-IPCL (mm)	2.10 $\pm$ 0.29	2.89 $\pm$ 0.31	0.013
LT (mm)	4.27 $\pm$ 0.60	4.28 $\pm$ 0.61	0.975
Pupil size (mm)	4.57 $\pm$ 0.94	3.22 $\pm$ 0.41	$< 0.001$

**Notes:** Notice the change in the pupil size, the vault, anterior chamber depth (ACD)-lens (the distance between the posterior corneal surface and the anterior lens surface), IPCL-lens (the distance between the posterior corneal surface and the anterior IPCL surface), and the lens thickness (LT). All measurements expressed in mm, except the vault, in  $\mu$ m.



**Figure 1** The difference between the scotopic and photopic conditions in the ACD-lens, ACD-IPCL, LT, pupil size (A) and the vault (B).

## Results

### Patient’s Data

Our study included 36 myopic eyes of 20 males and 16 females with a range of age from 19–37 years. Ten patients had bilateral surgery while 16 patients had unilateral IPCL implantation (nine right eye and seven left eye). The preoperative data, including the spherical error (SPH), cylindrical error (CYL), uncorrected distance visual acuity (UCDVA), and best corrected distance visual acuity (BCDVA) are expressed in Table 1.

### The Scotopic and Photopic Measurements

The vault was significantly lower under photopic conditions ( $p$ -value<0.001). The pupil size was significantly smaller in photopic conditions ( $p$ -value<0.001). LT ( $p$ -value=0.975) and ACD-lens ( $p$ -value=0.917) were not significantly different

**Table 3** The Accommodative and Non-Accommodative Conditions

	Accommodative	Non-Accommodative	p-value
Vault ( $\mu\text{m}$ )	475.3 $\pm$ 76.7	525.3 $\pm$ 74.7	0.022
ACD-Lens (mm)	3.09 $\pm$ 0.32	3.92 $\pm$ 0.62	0.035
ACD-IPCL (mm)	2.04 $\pm$ 0.38	2.88 $\pm$ 0.45	0.042
LT (mm)	4.01 $\pm$ 0.37	3.06 $\pm$ 0.32	0.039
Pupil size (mm)	4.03 $\pm$ 0.89	4.85 $\pm$ 0.964	0.028

between scotopic and photopic conditions, while the ACD-I PCL was significantly larger during photopic conditions ( $p$ -value=0.013) (Table 2 and Figure 1).

## The Accommodative Condition

There were significant changes in all parameters between accommodative and non-accommodative conditions (Table 3 and Figure 2).

## Discussion

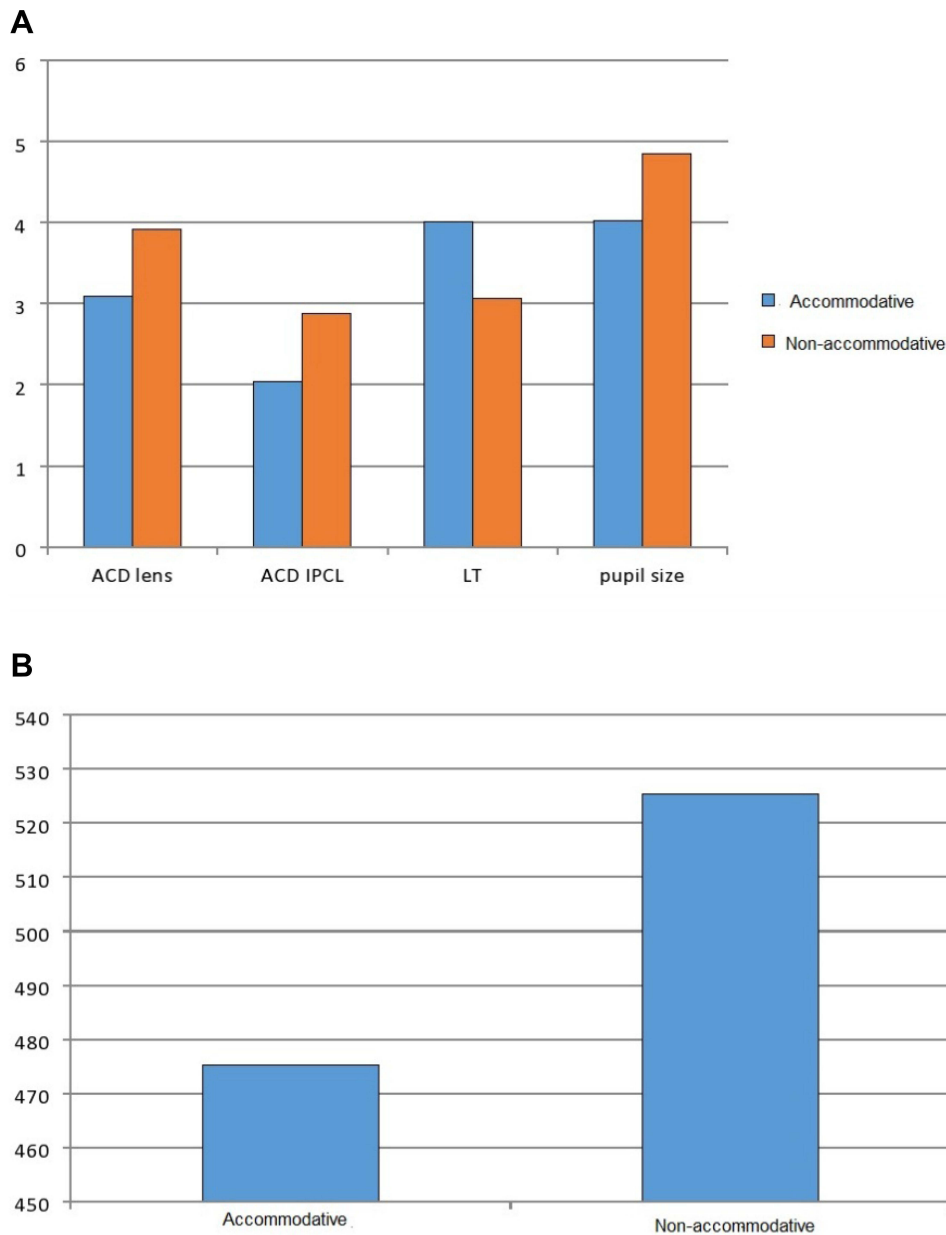
The pIOL are a well-established alternative in myopic patients who are not fit for corneal refractive surgery. The most commonly used lenses are the ICL and IPCL. IPCL is a good alternative to ICL due to the economic burden of ICL (nearly twice IPCL). Cataract and glaucoma are the main postoperative complications, so the sizing of the lens was a very important issue that depends on WTW and ACD to avoid postoperative complications.<sup>7</sup>

The IPCL vault was defined as the distance between the back surface of the IPCL and the anterior lens capsule. The low vault had the risk of cataract formation, the high vault had the risk of glaucoma. So a suitable vault is necessary to avoid these complications and it is important to measure this distance to ensure the safety after IPCL implantation. The vault could be assessed by many instruments such as high-frequency ultrasound biomicroscopy, Scheimpflug imaging instrument, and AS-OCT. Also, it could be measured clinically by the slit-lamp at 0.5–1.5-times the corneal thickness (CT, 250–750  $\mu\text{m}$ ), but the vault is not static and affected by the pupillary size and lens condition.<sup>8,9</sup>

Accommodation has an effect on anterior segment parameters in normal subjects without IPCL implantation, according to a study by Mitsukawa et al,<sup>10</sup> who used swept-source AS-OCT to analyze changes in the crystalline lens during accommodation and found that the ACD, anterior, and posterior curvature of the lens decreased, and LT increased significantly during 5.0 D accommodative stimulation.

Thirty-six myopic eyes were included in our study implanted with IPCL V2.0. We selected cases with no intraoperative or postoperative complications and AS-OCT was done 1 month or more after IPCL implantation to confirm stability of refraction and withdrawal of topical steroid. Our aim was to evaluate the dynamic vault changes with changes in the pupillary size under different light and lens conditions as the vault was not static to assess long-term safety of the IPCL, for example, driving a car at night (scotopic) and suddenly another car shining the light (photopic) and watching TV with light of the room off (scotopic) and suddenly the room light turned on (photopic). Also, the vault changes with accommodation as during reading. The scotopic and photopic light conditions were assessed with the aid of Light Intensity Meter for better estimation of the light intensity. Our results showed significant changes in the vault, pupillary size, and ACD-IPCL with no significant difference in the LT and ACD-lens, this indicated the safety of examination of patients with IPCL with OCT. Regarding the accommodation, there were significant changes in all study parameters with no complications.

While reviewing the literature, we found a study by Bianchi et al,<sup>11</sup> which was a prospective case-series study performed on 44 eyes (22 patients) operated with IPCL V2.0 under three different lighting conditions (mesopic/scotopic/photopic). The central vault was measured with an OCT. The results obtained 1 and 2 years after surgery were compared, and the differences between the scotopic and the photopic conditions were evaluated and it was shown that the vault difference observed



**Figure 2** The differences between the accommodative and non-accommodative conditions in the ACD-lens, ACD-IPCL, LT, pupil size (A) and the vault (B).

between the scotopic and the photopic conditions was  $98.4 \pm 48.4 \mu\text{m}$  ( $p\text{-value}=0.001$ ). Our results about the vault agreed with this study, but our study did not include the mesopic light condition and we included the accommodation.

The effect of varied light situations and accommodation was investigated with ICL and summarized in Table 4.

Our study concluded that the AS-OCT was a valuable tool for evaluation of dynamic IPCL vault under photopic and scotopic light conditions and accommodation which showed that the vault had significant changes with frequent changes in the pupil size and accommodation as during daily activities such as the reading and watching TV in dim illumination. So it is better to examine the dynamic vault not the static one.

The limitations of our study were the small number of patients and we did not examine patients with variable postoperative periods. Also, not all light conditions and accommodations power were examined.

**Table 4** Table Summarizing the Reported Literature on ICL

Study	Patients and Methods	Results
Xiong, Y et al., 2021 <sup>12</sup>	68 eyes from 68 patients who had Myopic EVO ICLs implanted and 60 eyes from 60 patients who had Toric EVO ICLs implanted. The ACD, pupil size, and vault were assessed 1 week after the operation using a Visante OCT under various lighting circumstances	No significant differences in the ACD were seen in either group between mesopic and photopic settings. Under photopic conditions, both groups showed a considerable reduction in vault and pupil size
Petternel et al., 2004 <sup>13</sup>	Partial coherence interferometry was used to compare the pupil size and vault in eyes with a V3 or V4 ICL under photopic and mesopic conditions	A significant light-induced change in ACD-lens, but ACD-ICL was significantly increased by 0.10 mm, whereas vault was significantly decreased by 73 $\mu$ m.
Lee et al., 2014 <sup>14</sup>	The Visante OCT was used to compare ACD, pupil size, and postoperative vaulting in eyes implanted with V4c and V4 ICL under photopic and mesopic conditions 1 month after surgery	They found no significant differences in ACD between photopic and mesopic conditions in either group, and significant decreases in vaulting and pupil size under photopic conditions in both groups.
Lindland et al., 2012 <sup>15</sup>	investigated the anterior chamber anatomy under mesopic (2 lx) and photopic (257 lx) circumstances	The shift from mesopic to photopic vision resulted in a 1.8 mm decrease in pupil size, a decrease in ACD-lens, an increase in ACD-ICL, and a 35 $\mu$ m decrease in vault.
Lee et al., 2015 <sup>16</sup>	Compare vaulting and movement variations during accommodation in 35 eyes (18 patients) with the V4 ICL and 51 eyes (26 patients) with the V4c ICL. The Visante OCT was used to assess ACD, posterior corneal surface-to-ICL distance (endo-ICL distance), pupil size, and postoperative vaulting	In eyes with the V4 or V4c ICL, ICL vaulting did not alter significantly during accommodation. During accommodation, however, both groups experienced significant reductions in ACD, endo-ICL distance, and pupil size.
Gonzalez-Lopez et al., 2018 <sup>17</sup>	conducted an experimental evaluation with low (0.5 LUX) and high (18500 LUX) light intensity in 39 eyes of myopic patients, using an anterior segment OCT and measuring different anterior chamber parameters, including the ICL vault values	They found that in photopic conditions the mean vault was $374 \pm 208 \mu$ m, whereas in scotopic conditions it increased to $540 \pm 252 \mu$ m, generating a difference of $167 \pm 70 \mu$ m
Kato et al., 2019 <sup>18</sup>	the vault of the ICL was evaluated under different lighting conditions	they found a mean value of $476.1 \pm 219.6 \mu$ m under photopic conditions, which grew to $521.1 \pm 220 \mu$ m under scotopic conditions and concluded that the vault can be significantly lowered by light-induced pupil constriction and accommodation in eyes with ICL
Srirampur A et al., 21 <sup>19</sup>	Included 32 eyes from 16 patients who had V4c ICLs implanted. The ICL vault was measured using AS-OCT in both its undilated and completely dilate states	The undilated and post-dilated ICL vault measurements showed no statistically significant difference. As a result, the postoperative vault can be measured in the pupil's resting, undilated, or completely dilated state, and the results will be equivalent regardless of pupil size
Zhu, Y et al., 2019 <sup>20</sup>	Investigated the effect of pharmacological mydriasis on 45 eyes of 24 patients with ICL V4 implantation and 128 eyes of 65 patients with ICL V4c implantation using Mydrin-P (Santen, Japan). Pentacam (Oculus, Wetzlar, Germany) was used to assess the ACD and vault.	Significant vault and ACD increases generated by mydriasis were observed in both the ICL V4 and V4c groups at 1, 3, and 6 months postoperatively

## Human and Animal Rights

No animals were used in this research. All human research procedures followed were in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013.

## Data Sharing Statement

The raw data (Excel sheet) that support the findings of this study are available upon request from the corresponding author.

## Ethics Approval and Consent to Participate

This study was approved by the Institutional Review Board and Research Ethics Committee of Minia University, Egypt under approval no. (134-2021). All patients signed their written informed consent to participate.

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## Disclosure

The authors declare no conflicts of interest for this work, financial or otherwise.

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