

## Prophylactic Effect of Miosis against Early Intraocular Pressure Elevation after V4c Phakic Intraocular Lens Implantation

Zongli Hu<sup>1</sup>, Chunlin Chen<sup>1</sup>, Min Sun<sup>1</sup>, Rongdi Yuan<sup>2</sup> and Jian Ye<sup>1\*</sup>

<sup>1</sup>Department of Ophthalmology, Daping Hospital, Army Medical University, Chongqing, China

<sup>2</sup>Department of Ophthalmology, Xinqiao Hospital, Army Medical University, Chongqing, China

\*Corresponding author: Jian Ye, Department of Ophthalmology, Daping Hospital, Army Medical University, Chongqing, China, Tel: +86 13708385175; E-mail: yejian1979@163.com

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### Abstract

**Purpose:** To confirm the prophylactic effect of miosis against intraocular pressure (IOP) early after V4c phakic intraocular lens (ICL) implantation.

**Design:** Interventional case series.

**Participants:** Forty-six myopia patients scheduled for ICL implantation.

**Methods:** This study was performed in 2 stages. In stage 1 (58 eyes of 29 patients), miosis was conducted immediately postoperative in left eyes, whereas right eyes remained untreated. IOP was compared between right and left eyes at postoperative hours 1, 2, 6, 12 and 24. In stage 2 (34 eyes of 17 patients), miosis was first conducted immediately postoperative in left eyes, and IOP, anterior chamber depth (ACD), angle-opening distance (AOD) and trabecular-iris angle (TIA) were measured in both eyes (right/left eye pupil diameter (PD)) =  $7 \pm 0.5/3 \pm 0.5$  mm). Second, miosis (right) or mydriasis (left) was conducted and these indicators were observed when PD decreased to  $3 \pm 0.5$  mm (right) or increased to  $7 \pm 0.5$  mm (left).

**Results:** In stage 1, IOP was significantly higher in right eyes at postoperative hours 1, 2, 6 and 12 ( $p < 0.01$ ). The prevalence of ocular hypertension was significantly different (Purpose to confirm the prophylactic effect of miosis against intraocular pressure (IOP) early after V4c phakic intraocular lens (ICL) implantation).

**Conclusion:** Miosis lowered postoperative IOP early after V4c ICL implantation, possibly due to a more open angle.

**Keywords:** V4c implantable collamer lens; Miosis; Intraocular pressure; Anterior segment optical coherence tomography (AS-OCT)

### Introduction

The Visian Implantable Collamer Lens (ICL) (STAAR Surgical Co., Monrovia, CA, USA) is widely applied to correct refractive errors in patients with moderate to high myopia. The V4C Model, which has been commercially available since 2011, was designed with a central hole in the optical region to facilitate the flow of aqueous humor. The safety, efficiency and stability of V4c ICLs over time have been confirmed by several studies [1-5]. However, as with any intraocular procedure, complications can occur with V4c ICL implantation, and the most common postoperative complication is intraocular pressure (IOP) elevation. In previous studies, retained viscoelastic [6-8] and a steroid response [6] were considered the most common reasons for increased IOP during the early period and from 2-4 weeks (w) after surgery, respectively. Most studies [6,7,9,10] have focused on evaluating postoperative IOP at least 24 h or 1 w after surgery, and their findings indicate that stable IOP fluctuations occur to lower than 20 mmHg. Few studies have evaluated postoperative IOP in the early period (the first 24 h) after V4c ICL implantation.

We found that postoperative intraocular hypertension (IOP > 21 mmHg) was common (prevalence > 50%) in the first 24 h according to our clinical experience. In 2016, Ganesh [8] observed postoperative IOP after 1, 2, 4 and 24 h and found that the incidence of postoperative intraocular hypertension was 60%, similar to our experience, and that the peak IOP occurred at 1-2 h after operation. In our previous study, we also noticed that postoperative intraocular hypertension was significantly less likely to occur when pupil miosis was performed at the end of surgery. This study was conducted to determine the probable reasons for IOP elevation at 24 h after V4c ICL implantation.

### Materials and Methods

#### Patients

This study was an interventional case series. Institutional Review Board (IRB)/Ethics Committee approval was obtained prospectively by the Daping Hospital Institutional Review Board, Chongqing, China. The study duration was October 2017 to January 2018, and the setting was the Department of Ophthalmology, Daping Hospital, Army Medical University. The clinical trial registration number is ChiCTR-OON-17012838 (<http://www.chictr.org.cn>). All patients signed consent

forms after explanation of the nature and possible consequences of the study.

The inclusion criterion was stable myopic error ranging from -3.00 D to -12.00 D for 12 m. The exclusion criterion was a history of ocular pathology, such as ocular hypertension, ocular trauma, retinal detachment, glaucoma, cataract, amblyopia or ocular inflammation. Patients with Anterior Chamber Depth (ACD) lower than 2.8 mm and patients over 45 years old were also excluded from this study.

### Groups and interventions

There were 2 stages in this study. In stage 1, 58 eyes of 29 patients were assigned to the following groups: right eyes, which constituted the control group; and left eyes, which constituted the experimental group. Immediately after ICL implantation, miosis was applied in the left eyes through instillation of a miotic agent in the anterior chamber, whereas the right eyes were left untreated. The IOP and rate of ocular hypertension were compared between right and left eyes at 1 h, 2 h, 6 h, 12 h and 24 h postoperatively. In the second stage, 34 eyes of 17 patients were assigned to 2 parts. First, left eyes were treated with a miotic agent after surgery, but right eyes were left untreated. The IOP, ACD, Angle Opening Distance (AOD), Trabecular-Iris Angle (TIA) and vault were measured after surgery when the pupil diameter (PD) was  $7 \pm 0.5$  mm in right eyes and  $3 \pm 0.5$  mm in left eyes. Second, pilocarpine eye drops (5 ml: 25 mg, Freda, China) were applied to induce miosis in right eyes, but compound tropicamide eye drops (1 ml: 5 mg: 5 mg, Santen, Japan) were applied to induce mydriasis in left eyes. The abovementioned parameters were observed and compared when right and left PDs were  $3 \pm 0.5$  mm and  $7 \pm 0.5$  mm, respectively.

### V4c ICL implantation surgical procedure

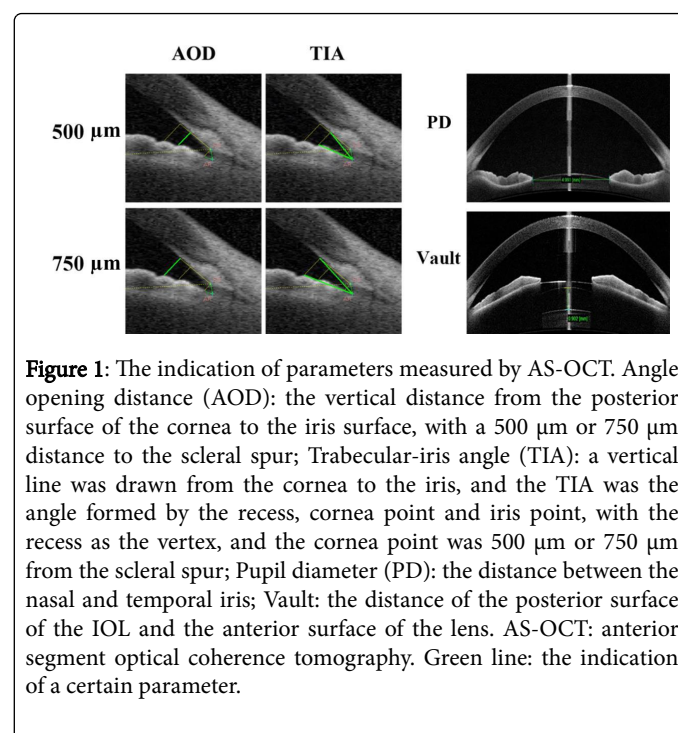
All V4c ICL implantation surgeries were performed by the same ophthalmic surgeon. Compound tropicamide eye drops (1 ml: 5 mg: 5 mg, Santen, Japan) were applied 30 min before surgery to dilate the pupil to  $7 \pm 0.5$  mm. After the application of oxybuprocaine hydrochloride eye drops (20 ml: 80 mg, Santen, Japan), a 3-mm temporal corneal incision and an auxiliary incision at 12:00 were made. The anterior chamber was injected with sodium hyaluronate (Shanghai Kinsson, China), a viscoelastic agent (OVD). The V4c ICL was inserted into the anterior chamber with a Micro-STAAR injector (STAAR Surgical Co., Monrovia, CA, USA) and then placed and positioned in the posterior chamber. OVDs were exchanged with balanced salt solution. A 0.1 ml carbachol injection (2 ml: 0.1 mg, Freda, China), as the miotic agent, was instilled in the anterior chamber of the left eyes. After surgery, prednisolone acetate ophthalmic suspension (5 ml: 50 mg, Allergan, Ireland) and levofloxacin eye drops (5 ml: 24.4 mg, Santen) were administered topically four times daily for 2 w.

### Outcome measures

AS-OCT measurements were performed by a single technician at a horizontal stage of 0-180°, and both nasal and temporal data were recorded. The analyzed parameters included the PD, ACD, AOD500, AOD750, TIA500, TIA750 and vault. The measurement and definition of these parameters are described as follows: 1) ACD: the distance from the vertex of the posterior surface of the cornea to the front of the lens; 2) AOD: the vertical distance from the posterior surface of the cornea to the iris surface; 3) TIA: a vertical line drawn from the cornea to the iris, defined as the angle formed by the recess, cornea point and

iris point, with the recess as the vertex; 4) PD: the distance between the nasal and temporal iris; and 5) vault: the distance from the posterior surface of the intraocular lens (IOL) to the anterior surface of the lens. The definitions and representations of AOD, TIA, PD and vault are shown in Figure 1. These parameters were measured before surgery and when the PD was approximately 3 mm or 7 mm in right or left eyes after surgery.

A noncontact tonometer (TX-20 full auto tonometer, Cannon, Japan) was used to detect the IOP by a single skilled technician, with 3 parallel measurements taken at each time point. Intraocular hypertension was defined as an IOP > 21 mmHg.



**Figure 1:** The indication of parameters measured by AS-OCT. Angle opening distance (AOD): the vertical distance from the posterior surface of the cornea to the iris surface, with a 500 μm or 750 μm distance to the scleral spur; Trabecular-iris angle (TIA): a vertical line was drawn from the cornea to the iris, and the TIA was the angle formed by the recess, cornea point and iris point, with the recess as the vertex, and the cornea point was 500 μm or 750 μm from the scleral spur; Pupil diameter (PD): the distance between the nasal and temporal iris; Vault: the distance of the posterior surface of the IOL and the anterior surface of the lens. AS-OCT: anterior segment optical coherence tomography. Green line: the indication of a certain parameter.

### Statistical analysis

Statistical analysis was performed by SPSS version 22.0 software (IBM, USA), and continuous variables are presented as the mean ± standard deviation (SD). Continuous variables were analyzed by Student's t-test or one-way ANOVA, and comparisons were performed by the least significant difference (LSD) method. A Chi square test was used to compare the differences in qualitative data. The sample size for this study was based on an earlier study, and the required eyes per group was at least 10 with  $\alpha=0.05$  and  $\beta=0.1$ . A P value < 0.05 was considered statistically significant.

### Results

A total of 46 patients were enrolled in this study, including 25 males and 21 females, with an average age of  $23.43 \pm 4.33$  years old. All surgeries were performed uneventfully, with no significant complications. A miotic agent was applied in all left eyes at the end of surgery to achieve a PD of  $3 \pm 0.5$  mm.

### Pupil sizes and early postoperative IOP

In stage 1, IOP fluctuations were monitored in 58 eyes of 29 participants after surgery. On admission, the PD in right and left eyes was  $3.23 \pm 0.79$  mm and  $3.26 \pm 0.79$  mm, respectively, with no

significant difference ( $t=-0.140$ ;  $p=0.890$ ). The mean IOP before surgery was  $15.51 \pm 2.77$  mmHg in right eyes and  $14.58 \pm 3.04$  mmHg in left eyes, with no significant difference ( $t=1.222$ ;  $p=0.227$ ). The IOPs at 1 h, 2 h, 6 h, 12 h and 24 h postoperatively are shown in Table 1.

Eyes/IOP	bo	1 h po	2 h po	6 h po	12 h po	24 h po
Right	$15.510 \pm 2.774$	$23.307 \pm 9.238$	$25.448 \pm 9.338$	$17.638 \pm 4.673$	$14.314 \pm 2.918$	$13.028 \pm 2.937$
Left	$14.576 \pm 3.042$	$15.507 \pm 7.520^{**}$	$14.693 \pm 4.286^{***}$	$13.431 \pm 4.358^{**}$	$12.228 \pm 2.993^{**}$	$11.631 \pm 3.214^*$

Note: IOP: Intraocular Pressure

bo: Before Operation; po: Post Operation

\*/\*\*/\*\*\*: The difference was significant between 2 groups ( $p<0.05$ ;  $p<0.01$ ;  $p<0.001$ )

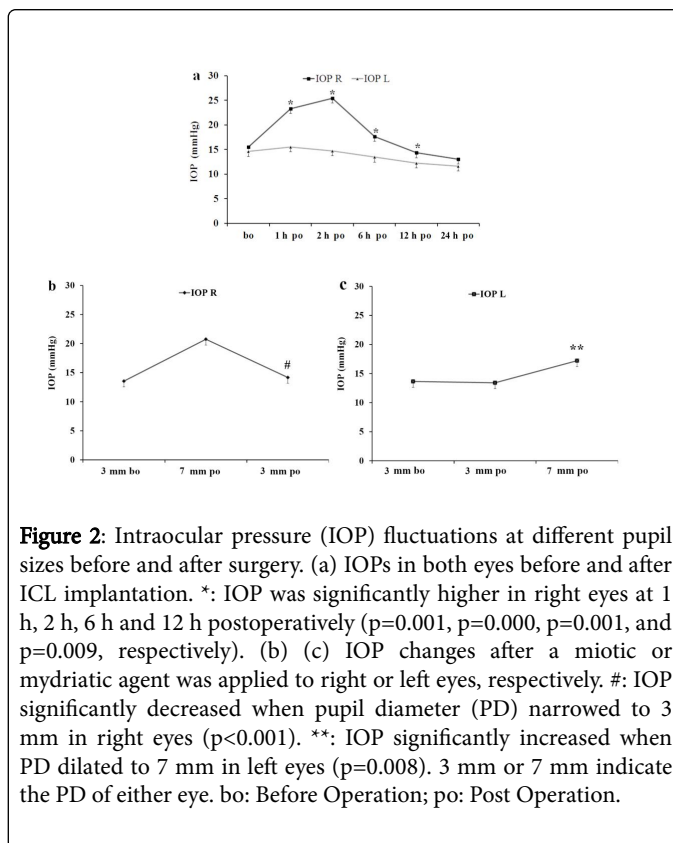
**Table 1:** Early postoperative IOPs after ICL implantation in right and left eyes.

In stage 1, at 1 h, 2 h, 6 h and 12 h postoperatively, the IOP in right eyes was significantly higher than that in left eyes ( $p=0.001$ ,  $p=0.000$ ,  $p=0.001$ , and  $p=0.009$ , respectively) (Figure 2a). Ocular hypertension was observed in 18 right eyes (18/29, 62.069%) and 6 left eyes (6/29, 20.690%), reflecting a significant difference ( $\chi^2=10.235$ ,  $p=0.003$ ). In stage 2, when PD was  $7 \pm 0.5$  mm and  $3 \pm 0.5$  mm in right and left eyes, respectively, IOPs were significantly different ( $t=3.858$ ;  $p=0.001$ ) at  $20.75 \pm 6.08$  mmHg and  $13.41 \pm 4.96$  mmHg, respectively. The mean IOP decreased to  $14.165 \pm 3.300$  mmHg when PD narrowed to  $3 \pm 0.5$  mm in right eyes ( $p<0.001$ ) and increased to  $17.21 \pm 4.29$  mmHg when PD dilated to  $7 \pm 0.5$  mm in left eyes ( $p=0.008$ ). Ocular hypertension was observed in 5 left eyes (29.41%) after pupil dilation. The observed fluctuations in IOPs after miosis or mydriasis are shown in Figures 2b and 2c.

### Pupil sizes and anterior chamber angle structures

No significant differences were observed between right and left eyes in the TIA500, TIA750, AOD500, AOD750 or ACD before surgery ( $p=0.907$ ;  $p=0.559$ ;  $p=0.679$ ;  $p=0.677$ ;  $p=0.875$ ). The observed changes in these parameters and vault after ICL implantation are shown in Table 2.

After ICL implantation, when PD was  $7 \pm 0.5$  mm and  $3 \pm 0.5$  mm in the right and left eyes, respectively, there were significant differences in the ACD, TIA500, TIA750, AOD500, AOD750 and vault between the two eyes ( $p=0.01$ ,  $p<0.001$ ,  $p=0.001$ ,  $p=0.001$ ,  $p=0.03$ , and  $p<0.001$ , respectively) (Figures 3-5). When PD narrowed to  $3 \pm 0.5$  mm in right eyes, TIA500, TIA750, AOD500, AOD750 and ACD significantly increased ( $p=0.001$ ,  $p=0.004$ ,  $p=0.03$ ,  $p=0.001$ , and  $p=0.009$ , respectively). When PD dilated to  $7 \pm 0.5$  mm in left eyes, ACD, TIA500, TIA750, AOD500 and AOD750 significantly decreased ( $p=0.001$ ,  $p=0.001$ ,  $p=0.001$ ,  $p=0.005$ , and  $p=0.01$ , respectively).

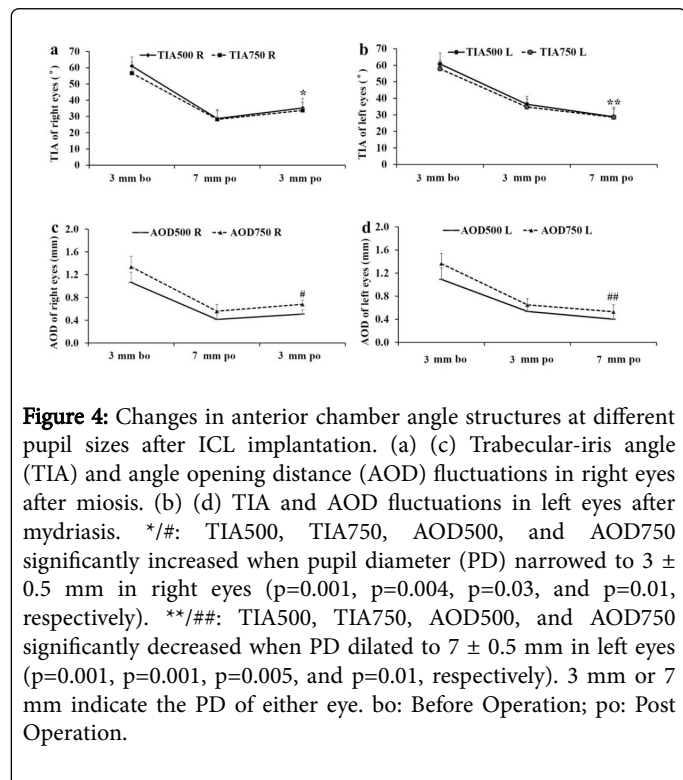
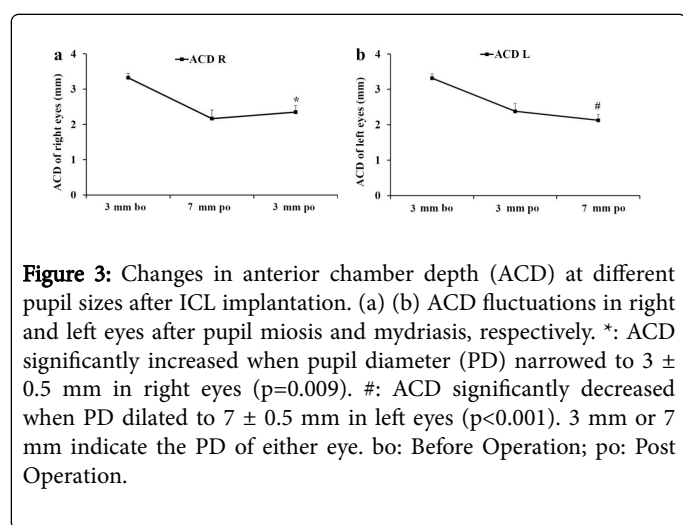


**Figure 2:** Intraocular pressure (IOP) fluctuations at different pupil sizes before and after surgery. (a) IOPs in both eyes before and after ICL implantation. \*: IOP was significantly higher in right eyes at 1 h, 2 h, 6 h and 12 h postoperatively ( $p=0.001$ ,  $p=0.000$ ,  $p=0.001$ , and  $p=0.009$ , respectively). (b) (c) IOP changes after a miotic or mydriatic agent was applied to right or left eyes, respectively. #: IOP significantly decreased when pupil diameter (PD) narrowed to 3 mm in right eyes ( $p<0.001$ ). \*\*: IOP significantly increased when PD dilated to 7 mm in left eyes ( $p=0.008$ ). 3 mm or 7 mm indicate the PD of either eye. bo: Before Operation; po: Post Operation.

Eyes/PD	R			L		
	3 mm bo	7 mm po	3 mm po	3 mm bo	3 mm po	7 mm po
TIA500 (°)	$61.03 \pm 5.65$	$28.69 \pm 5.52$	$35.18 \pm 5.95$	$60.78 \pm 6.65$	$36.26 \pm 4.91$	$31.48 \pm 6.40$
TIA750 (°)	$56.67 \pm 6.81$	$28.19 \pm 5.24$	$33.69 \pm 4.78$	$57.86 \pm 4.77$	$34.74 \pm 4.92$	$28.53 \pm 5.09$
AOD500(mm)	$1.06 \pm 0.18$	$0.42 \pm 0.10$	$0.51 \pm 0.07$	$1.09 \pm 0.20$	$0.54 \pm 0.09$	$0.45 \pm 0.11$

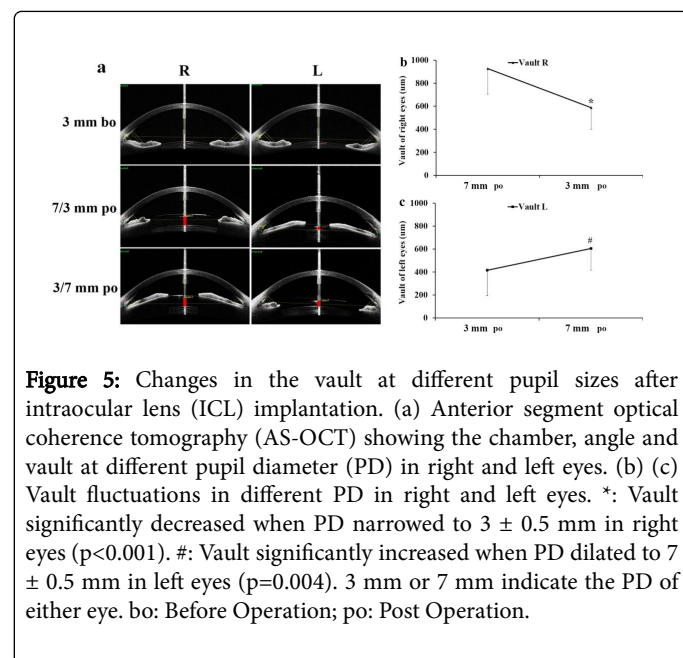
<b>AOD750(mm)</b>	1.34 ± 0.18	0.56 ± 0.12	0.68 ± 0.07	1.36 ± 0.16	0.65 ± 0.11	0.53 ± 0.12
<b>ACD (mm)</b>	3.32 ± 0.13	2.16 ± 0.24	2.35 ± 0.19	3.32 ± 0.12	2.38 ± 0.23	2.13 ± 0.17
<b>Vault (µm)</b>	---	927.18 ± 222.06	587.59 ± 188.55	---	415.23 ± 223.15	604.76 ± 193.97
<b>PD (mm)</b>	3.46 ± 0.72	6.98 ± 0.43	3.13 ± 0.44	3.51 ± 0.61	2.89 ± 0.51	7.13 ± 0.53

**Table 2:** Anterior chamber angle structures and vault in different pupil sizes after surgery.



The images of AS-OCT at different PDs are shown in Figure 5a. The vault was higher in dilated pupils and lower in narrowed pupils. After surgery, the vault was significantly different (t=6.705; p<0.001)

between right and left eyes at 927.17 ± 222.06 µm and 415.23 ± 223.15 µm when PD was 7 ± 0.5 mm and 3 ± 0.5 mm. In right eyes, when PD narrowed to 3 ± 0.5 mm, the vault decreased to 587.59 ± 188.55 µm (p<0.001). In left eyes, the vault increased to 604.76 ± 193.97 µm when PD dilated to 7 ± 0.5 mm (p=0.004), as shown in Figures 5b and 5c.



## Discussion

With regard for postoperative IOP management after V4 ICL implantation, there is a lack of research on the effect of miosis or anterior angle on early postoperative IOP at 24 h. There is some controversy surrounding the use of miosis after V4c ICL implantation surgeries [11-15]. Some studies applied miosis following ICL implantation, while others have suggested allowing the pupil to remain in mydriasis after surgery. The mechanism underlying these effects remains unclear.

According to Ganesh et al. [8], IOP peaks primarily occurred 2 h after surgery, similar to our results. In the study by Ganesh and colleagues, no miotic agent was used during or after surgery, and dorzolamide was topically applied to all patients to prevent ocular hypertension. In our study, although a miotic agent was applied at the end of surgery, regardless of its effect on pupil contraction or its ability to lower IOP, no other IOP-lowering agent is conventionally applied after surgery. In this study, IOP peaks and ocular hypertension were mostly observed within 1 or 2 h after the operation, when the PD was over 3 mm. In contrast, increased IOPs have rarely been reported in

other studies after 24 h postoperatively [9,10]. This difference is likely due to differences in observation time points.

Regarding the relationship between the pupil size and anterior angle, a narrowed pupil resulted in a more open angle. In our results, a miotic agent effectively increased the TIA, AOD and ACD, while pupil dilation caused a reduction in angle parameters. A miotic agent was necessary during conventional V4 ICL implantation because of peripheral iridotomy before or during surgery. In V4c ICL implantation, the use of a miotic agent remains controversial, and there is a lack of studies concerning miotic agent application. In a recent prospective study in 2016 [16], the TIA and AOD500 were measured 1 m after V4c ICL implantation, and the angle was narrowed by 34%-42%, which was maintained for 3 m. In the present study, the angle was narrowed by 52.990% in right eyes and 40.335% in left eyes at 1 h postoperatively, indicating that a miotic agent applied in surgery might result in a more open angle.

In our study, a narrowed pupil was related to a lower vault, and a dilated pupil was related to a higher vault. In a series of cross-sectional studies in 2014 and 2015, Lee H [17,18] made comparisons between V4 and V4c to explore the relationships between lighting conditions and accommodations with the vault. These authors found significant decreases in vaulting and PDs under photopic conditions and a narrow pupil size 1 m after operation, with a more obvious change after V4c ICL implantation. However, no changes were observed in the vault under the condition of accommodation. In our study, the vault was positively related to pupil size, in agreement with previously discussed results.

The limitation of our study is that we measured IOP and anterior chamber parameters only within 24 h after operation. Whether these parameters remain stable over time in patients remains unknown. Thus, future studies with longer follow-up periods and larger populations are needed to determine the long-term relationships between miotic agent application and IOP, angle structures and the vault after V4c ICL implantation. The potential effect of early postoperative IOP on visual acuity or the optic nerve must also be explored.

## Conclusion

In conclusion, miosis was effective in preventing ocular hypertension in the early postoperative period after V4c ICL implantation. The maintenance of postoperative IOP was likely due to a more open anterior angle with a smaller pupil.

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