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Original Article

PENTACAM STUDY OF VAULT CHANGES AFTER TROPICAMIDE 1% AND CYCLOPENTOLATE 1% INSTILLATION IN MYOPIC EYES WITH IMPLANTABLE PHAKIC CONTACT LENS

Mahmoud, M.(*), Abdallah, M. & Abdelrahman, A.
Ophthalmology dept., Faculty of Medicine, Minia Univ., Egypt

*E-mail: drmsalah1982@yahoo.com

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Abstract

Purpose: *to compare the vault changes, anterior segment parameters, and intraocular pressure (IOP) after pharmacological mydriasis by tropicamide 1% and cyclopentolate 1% in moderate-to-high myopic eyes with Implantable Phakic Contact Lens (IPCL).* ***Methods****: a prospective observational study 48 myopic eyes were implanted with IPCL V2.0 (Care group Sight Solutions, India). Pharmacological mydriasis was done by tropicamide 1% and cyclopentolate 1%. The patients were divided into 2 groups, group 1 was dilated by tropicamide1 % and group 2 was dilated by cyclopentolate 1%. The Pentacam was used to evaluate the lens vault, anterior chamber depth (ACD), anterior chamber volume (ACV), pupil size, and endothelium-IPCL (end-IPCL). Also, IOP was evaluated and compared between both groups.* ***Results****: the Pentacam study of both groups revealed significant changes regarding the vault, ACD, ACV, and pupil size with no significant difference in end-IPCL (p-value= 0.884 and 0.880) in groups 1 and 2 respectively. And no significant difference when comparing both groups with each other. Regarding IOP, there was a significant difference in both groups with no significant difference when comparing both groups with each other (p-value=.295).* ***Conclusion****: pharmacological mydriasis in myopic eyes implanted with IPCL results in changes in the vault, ACD, and ACV with no significant difference between tropicamide 1% and cyclopentolate 1%. Both medications caused IOP elevation to a similar value so there was a need to recheck IOP post dilatation preferably at 45 minutes. So mydriasis with either tropicamide 1 % or cyclopentolate 1 % was relatively safe in eyes with IPCL implantation.*

Keywords: *Tropicamide, Cyclopentolate, Mydriasis, IPCL-Pentacam*

1. Introduction

The phakic posterior chamber intraocular lens (pIOL) has several advantages over corneal refractive surgery, including the capacity to correct higher levels of ametropia, decreased induction of postoperative aberrations, retinal image magnification, and improved contrast sensitivity [1,2]. However, because it is an intraocular treatment, it carries a higher risk of consequences, including anterior segment damage, retinal detachment, and infections such as endophthalmitis [3]. The Visian Implantable Collamer lens (ICL - Staar Surgical AG, Nidau, Switzerland) has been shown to be a safe treatment for moderate and high ametropia over a long

period of time, but the cost was a significant issue, particularly in developing nations. The IPCL (Care group Sight Solutions, India) has been created as a cost-effective solution for refractive correction, correcting a wide range of ametropia up to 30.0 D. The V2.0 design features a 380 um central hole that eliminates the requirement for peripheral iridectomy (PI) [4,5]. The central vault is defined as the distance between the back surface of the IPCL and the anterior surface of the crystalline lens. The ideal lens vault has been suggested to be between 250 and 750 µm. Low vault may cause anterior sub-capsular cataract due to the touch between the IPCL and the anterior lens capsule. High vault can cause pupillary blockage and angle-closure glaucoma. So, it is important to plan the IPCL implantation with an ideal vault to avoid complications [6,7]. The vault may change dynamically with the movement of anterior segment structures as under different lighting conditions or accommodation or mydriatic cycloplegic drugs. To anticipate and prevent post-operative complications more effectively, it is necessary to have a better understanding of the effect of vault change and the mechanism behind it [8]. Mydriatic and cycloplegic drops as cyclopentolate and tropicamide are muscarinic receptor antagonists as atropine. They inhibit cholinergic stimulation of the sphincter muscle and ciliary muscle in the iris, they cause pupil dilatation and cycloplegia by inhibiting cholinergic activation of the sphincter muscle and ciliary muscle in the iris. Both cause mydriasis and cycloplegia, however, tropicamide's cycloplegic impact is less efficient than cyclopentolate with changes in the anterior segment parameters as the anterior chamber depth (ACD) and anterior chamber volume (ACV) [9]. The Pentacam system is one of the most widely used commercially available corneal tomography and Scheimpflug imaging systems used in refractive surgery to examine the corneal surface. The technology can create a three-dimensional map of the cornea using a rotating Scheimpflug camera [10]. Our study used the Pentacam to evaluate the anterior segment parameters as the ACD, ACV, vault, endothelium-IPCL (end-IPCL), and pupillary size before and after pupillary dilatation by tropicamide 1% and cyclopentolate 1% and comparing the changes between the 2 mydriatics. Also, IOP was measured and compared with the 2 mydriatics.

2. Methods

A prospective case-series, observantional study was designed on 48 myopic eyes who were implanted with V.20 IPCL from December 2018 to May 2021 in Minia University Hospital and International Eye Centre. The study was conducted after obtaining consent from all the participants in the study with approval of the ethical committee of the faculty of medicine of Minia University (Approval number: 135-2021). The principal inclusion criteria were age >18 years and moderate-to-high myopia who were a candidate for IPCL with ACD 3 mm, normal IOP, normal ocular examination except myopia. The exclusion criteria were young patients (less than 18 years), presence of other ocular comorbidities as keratoconus, cataract, glaucoma, corneal opacity, retinal diseases except for myopic chorioretinal degenerations, and systemic diseases as diabetes mellitus and autoimmune diseases. Data required for IPCL calculations were refraction, keratometric readings, internal ACD, pachymetry, and white to white (WTW) which were measured by Pentacam (Oculus Optikgeräte GmbH, Wetzlar, Germany). The IPCL size was detected upon ACD and WTW. IPCL V 2.0 design was used in our study which had a central

hole of 380 um with no need for PI. Our study was conducted on myopic eyes after 1 month or more of IPCL implantation. Pentacam was done 3 times, first before pharmacological mydriasis, second time 45 minutes after mydriasis by tropicamide 1% and third time 45 minutes after mydriasis by cyclopentolate 1% which was done after one week of tropicamide 1%. The patients were classified into 2 groups: group 1 who were dilated by tropicamide 1% (Mydriacyl®, ophthalmic solution, USP), group 2 who were dilated by cyclopentolate hydroc-hloride 1% (Cicloplejico®, Alcon Cusi, Barcelona, Spain).

2.1. *Pentacam technique (Pentacam HR (Oculus Optikgeräte GmbH, Wetzlar, Germany).*

After entering the patient's data and positioning the chin on a chin rest and forehead against the forehead strap in dim illumination. The patients were asked to blink many times and to fixate their eyes on a black target present in the middle of the blue beam. The operator had focused upon the image and had correctly aligned the corneal vertex. The camera rotated 180◦, and obtained 25 slit images of the anterior eye segment, creating a three-dimensional model of it. The only scans that have been saved are those with a quality factor (QS) >95%. 4 maps refractive and scheimpflug images were used for analysis in our study. The study parameters were: **1)** ACD (Internal): measured from the corneal endothelium to the anterior lens capsule and measured automatically in the 4 maps refractive. **2)** ACV: measured automatically in the 4 maps refractive. **3)** The central vault: measured from the back surface of the IPCL to the anterior lens capsule. **4)** End-IPCL: measured from the corneal endothelium to the anterior surface of the IPCL. The vault and End-IPCL were detected manually in Scheimplug image. **5)** Pupil size: measured automatically in 4 maps refractive or manually in Scheimpflug image. **6)** IOP: measured by the tono-pen (Reichert™ Tono-Pen AVIA® tonopen)

2.2. *Patient and public involvement statement*

Patients or the public were involved in the design, or conduct, or reporting, or dissemination plans of our research

2.3. *Methods of statistical analysis*

The statistical analysis was carried out with the IBM SPSS statistical software version 20 (Chicago, USA). The mean and standard deviation (SD) were utilized for quantitative data, while number and percent were employed for qualitative data. The independent sample t-test was used to compare the quantitative data. The Pearson Bivariate correlation test was used for analysis of the correlation between the study parameters. If the probability (p) was less than 0.05, the test was declared significant.

3. Results

3.1. *Demographic and preoperative data*

The included patients (28 males and 20 females) had range of age of 18-38 years, as listed in tab. (1), in addition, the preoperative data were summarized in tab. (2)

Table 1: Demographic data

Age (years)	**Range** **Mean ± SD**	**18-38** **26.00 ± 5.950**
Sex	**Male** **Female**	**28 (58.3 %)** **20 (41.7%)**

Table 2: Preoperative data

	Range	Mean ± SD
Sphere (D)	**-6.0 - -16.0**	**-10.812 ± -2.6770**
Cylinder (D)	**00 - - 2.00**	**-1.0313 ± .38807**
UCDVA (Log MAR)	**1.0 – 1.3**	**1.038 ± .1003**
BCDVA (Log MAR)	**0 - 0.2**	**.033 ±. 0753**
IOP (mmHg)	**11-15**	**12.96 ± .944**

3.2. *Study groups*

3.2.1. Group 1

There were significant changes regarding the pupil size, the vault, ACD, ACV, and IOP with no significant difference in end-IPCL (p-value= 0.884), tab. (3)

Table 3: Group1

	Before mydriasis	After mydriasis	p-value
Pupil size (mm)	**2.9±.28**	**6.6±.24**	**<0.001**
Vault (µm)	**459.9±39.3**	**516.3±27.5**	**<0.001**
ACD (mm)	**3.0±.05**	**3.1±.11**	**<0.001**
End-IPCL (um)	**2404.9±97.1**	**2402.2±84.4**	**0.884**
ACV(mm^3)	**121.1±6.5**	**155.5±15.8**	**<0.001**
IOP (mmHg)	**14.0±.74**	**15.7±.72**	**<0.001**

3.2.2. ***Group 2***

There were significant changes regarding the pupil size, the vault, ACD, ACV, and IOP with no significant difference in end-IPCL (p-value= 0.880), tab. (4)

Table 4: Group 2

	Before mydriasis	After mydriasis	p-value
Pupil size (mm)	**2.9±.28**	**6.7±.26**	**<0.001**
Vault (µm)	**459.9±39.3**	**517.08±28.0**	**<0.001**
ACD (mm)	**3.0±.05**	**3.17±.11**	**<0.001**
End-IPCL (um)	**2404.9±97.1**	**2402.1±82.8**	**0.880**
ACV(mm^3)	**121.1±6.5**	**156.0±16.6**	**<0.001**
IOP (mmHg)	**14.0±.74**	**15.9±.82**	**<0.001**

3.3. *Comparison of both groups*

No significant differences had been detected between group 1 and group 2, as could be listed tab. (5) & could be seen fig. (1)

Table 5: Comparison of groups 1and 2

	Group 1	Group 2	p-value
Pupil size (mm)	**6.6±0.24**	**6.7±.26**	**0.241**
Vault (µm)	**516.3±27.5**	**517.08±28.0**	**0.895**
ACD (mm)	**3.1±.11**	**3.17±.11**	**0.823**
End-IPCL (um)	**2402.2±84.4**	**2402.1±82.8**	**0.996**
ACV(mm^3)	**155.5±15.8**	**156.0±16.6**	**0.901**
IOP (mmHg)	**6.6±0.24**	**15.9±.82**	**0.295**

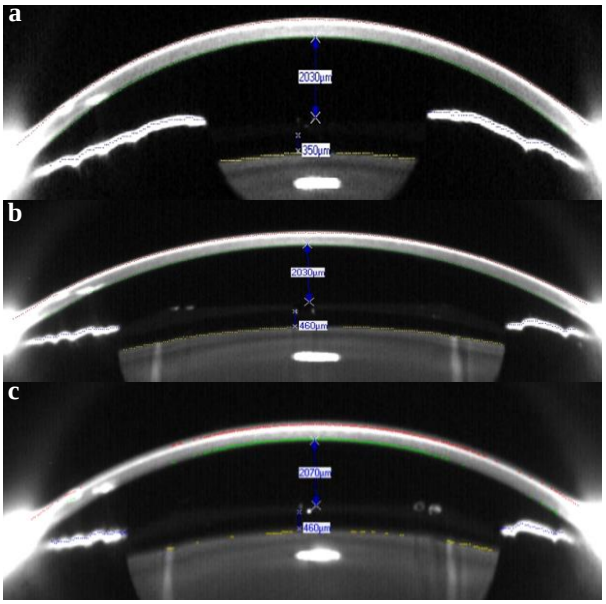

Figure 1: Scheimpflug image; before mydriasis, **b.** after tropicamide 1% and **c.** after cyclopentolate. The end –IPCL was measured between the posterior corneal endothelium and the IPCL; the vault was measured as the central distance between the posterior IPCL surface and the anterior crystalline lens capsule.

3.4. *Correlation between the pupil size, the vault, ACD, End-IPCL and ACV*

In group 1, there was positive mild correlation between the vault with ACD (r= 0.409, p=0.004) and ACD with ACV (r=0.445, p=0.002), tab. (6). While among group 2, there was positive mild correlation between the vault with ACD (r= 0.433, p=0.002) and ACD with ACV (r=0.412, p=0.004), tab. (7). In both groups, the pupil size has no correlation with the vault.

Table 6: Correlation between the pupil size, the vault, ACD, End-IPCL and ACV in group 1

		Pupil size	Vault	ACD	End-IPCL
Pupil size	**Pearson Correlation**				
	Sig. (2-tailed)				
Vault	**Pearson Correlation**	**0.044**			
	Sig. (2-tailed)	**0.768**			
ACD	**Pearson Correlation**	**0.314***	**0.409****		
	Sig. (2-tailed)	**0.029**	**0.004**		
End-IPCL	**Pearson Correlation**	**-0.182-**	**0.159**	**0.286***	
	Sig. (2-tailed)	**0.216**	**0.279**	**0.049**	
ACV	**Pearson Correlation**	**0.172**	**0.093**	**0.445****	**-0.231-**
	Sig. (2-tailed)	**0.242**	**0.530**	**0.002**	**0.114**

Table 7: Correlation between the pupil size, the vault, ACD, End-IPCL and ACV in group 2

		Pupil size	Vault	ACD	End-IPCL
Pupil size	**Pearson Correlation**				
	Sig. (2-tailed)				
Vault	**Pearson Correlation**	**0.004**			
	Sig. (2-tailed)	**0.978**			
ACD	**Pearson Correlation**	**0.165**	**0.433****		
	Sig. (2-tailed)	**0.263**	**0.002**		
End-IPCL	**Pearson Correlation**	**-0.110-**	**0.192**	**0.278**	
	Sig. (2-tailed)	**0.459**	**0.192**	**0.055**	
ACV	**Pearson Correlation**	**0.111**	**0.039**	**0.412****	**-0.280-**
	Sig. (2-tailed)	**0.454**	**0.795**	**0.004**	**0.054**

4. Discussion

In Upper Egypt, refractive errors are a common cause of vision impairment in adolescents. Myopia is more common in this region than it is in other parts of Egypt and other countries. To avoid ametropic amblyopia, early detection and correction are critical [11]. The pIOL are a well-established alternative in 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 [4,12]. 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 suitable vault is necessary to avoid these complications. The vault could be assessed by many instruments as high-frequency ultrasound biomicroscopy, scheimpflug imaging instrument, and anterior segment optical coherence tomography (OCT). Also, it could be measured clinically by the slit-lamp 0.5 to 1.5 times the corneal thickness (CT, 250 to 750 μm) [13,14]. Cycloplegic agents have become essential diagnostic and therapeutic components for ocular examination. They are important for refraction and fundus examination in myopic patients to detect vitreoretinopathies which increase with age [15] in today's clinics, cyclopentolate and tropicamide are the most widely utilized mydriatic drugs. Although tropicamide's cycloplegic action is not as effective as cyclopentolate, it is widely used for pupillary dilation since it acts faster and has fewer adverse effects [16, 17]. Regardless of refractive status, topical treatment of cycloplegic eye drops causes small but significant alterations in the ACD, ACV, and anterior segment angle parameters in healthy persons. Furthermore, during biometric evaluation and phakic intraocular lens implantation, reduced values of ACD and anterior segment angle parameters in hyperopic persons following administration of cycloplegic drops should be taken into account [18]. Forty-eight myopic eyes were included in our study, IPCL V.20 design was used with no need for PI. The patients were examined after 1 month or more of IPCL implantation to ensure the stability of refraction and withdrawal of topical steroid which may lead to an increase of IOP. We included patients with myopic IPCL with no intraoperative or postoperative complications. Pentacam was done at first followed by tropicamide 1% instillation and Pentacam and IOP were evaluated after 45 minutes. The same imaging and IOP were assessed after 1 week but cyclopentolate 1% was used instead of tropicamide 1%. From the Pentacam, we used 2 maps, the 4 maps refractive to evaluate automatically the internal ACD (from the corneal endothelium to the anterior lens capsule), and ACA and pupil diameter. The scheimpflug image (enhanced depth imaging) to evaluate end-IPCL distance, lens vault and pupil diameter which were measured manually. Our results revealed significant changes between the undilated and dilated eyes in both groups regarding the ACD, ACA, vault, and pupil diameter while there were no significant differences in the end-IPCL. In group 1, there was positive mild correlation between the vault with ACD ($r= 0.409$, $p=0.004$) and ACD with ACV ($r=0.445$, $p=0.002$). While in group 2, there was positive mild correlation between the vault with ACD ($r= 0.433$, $p=0.002$) and ACD with ACV ($r=0.412$, $p=0.004$). In both groups, the pupil size has no correlation with the vault. These changes were attributed to the crystalline lens zonules relaxation due to relaxation of the ciliary and sphincter

muscles with shift of the iris lens diagram posteriorly leading to increase in the central vault. When comparing both groups, there were no significant changes in the study parameters, and this indicates the safety of both mydriatics on the lens vault. To the best of our knowledge, no previous studies on the effect of mydriasis on anterior segment parameters in myopic patients with IPCL but other studies as a study by Bianchi GR et al, which was a prospective case-series study was 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 one and 2 years after surgery were compared, and the differences between the scotopic and the photopic condition was evaluated and showed that the vault difference observed between the scotopic and the photopic condition was 98.4 ± 48.4 µm, (p-value= 0.001) [19]. A study by Yi Z et al. on the postoperative ACD, end-ICL distance, and vault before and after mydriasis in eyes with implanted ICL V4 and V4c and found a significant increase in the vault [20]. Also, a study by Gargallo-Martinez, B et al. who studied the vault before and after cyclopentolate instillation in thirty-nine eyes of 39 patients who underwent Visian ICL and concluded that cyclopentolate may change the mean central vault in eyes with pIOL implantation [21]. The changes in the anterior segment parameters following mydriatic cycloplegics were studied by previous studies as Tasci YY et al. who concluded that cyclopentolate and tropicamide did not make a significant change in most of the anterior segment parameters (K1, K2, AL, CCT, WTW) and therefore did not affect the third-generation IOL calculation; however, there was a significant change in ACD [9]. Also, a study by Alghamdi WM et al. who used the Pentacam to assess the anterior segment parameters following cyclopentolate 1% and 0.5% and showed that cyclopentolate 1% had significant changes in ACA and ACV among the hyperopia and myopic groups compared to 0.5% [22]. Also, a study by Higashiyama T et al. employed swept-source OCT (SSOCT) to detect changes in the anterior segment of the eye after cycloplegia in pediatric patients and found that the ACD was increased in comparison to the decrease in lens thickness after cycloplegia [23]. AS-OCT was used in other studies to assess the central vault of other posterior chamber phakic IOLs as ICL as Lee et al. [24] who compared the 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 (p-value =0.532 for V4 ICL and p-value =.415 for V4c ICL). During accommodation, however, both groups experienced significant reductions in ACD, endo-ICL distance, and pupil size. Gonzalez-Lopez et al. [25] 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 ± 208 µm, whereas in scotopic conditions it increased to 540 ± 252 µm, generating a difference of 167 ± 70 µm. Regarding correlation between the pupil size and the vault, our study showed that no significant difference in the vault measurement with the pupil size in both groups. So the vault could be measured in the dilated and undilated pupil. These results agreed with Srirampur A et al., who used the AS-OCT to measure the ICL vault in relation to the pupil size, and showed that no statistically significant difference

was observed between the undilated and post-dilated ICL vault measurements [26]. In both normal and open-angle glaucoma, cycloplegic mydriasis can produce an increase in IOP. Previous research on the effects of tropicamide and cyclopentolate on IOP in cataract patients revealed a considerable increase in IOP 4–6 hours after cycloplegia with 2.5 % phenylephrine and 1 % tropicamide. Furthermore, pupil dilatation with 1% cyclopentolate induces an increase in IOP of up to 20 mmHg. IOP rise after cycloplegic mydriasis has been linked to decreased aqueous outflow due to decreased traction on the trabecular meshwork due to ciliary muscle paralysis, as well as iris pigment release into the anterior chamber and trabecular meshwork occlusion. The other factor that causes IOP to rise is pupillary obstruction [27-29]. The results of our study showed significant changes in IOP values before and after mydriasis and no significant changes between tropicamide 1% and cyclopentolate 1%. (P-value= .295). This indicates careful follow up of IOP in these patients preferably after 45 minutes of mydriasis. To the best of our knowledge, no previous studies on the effect of pharmacological mydriasis on IOP in patients with IPCL but many studies on the effect of IPCL on IOP comparing the pre and postoperative IOP as ELkareem et al. who showed that the mean preoperative IOP was 14.7±2.6 mmHg and at 12 months postoperatively, it was 14.9±2.5 mmHg, a statistically nonsignificant change (P= 0.14). The mean IOP was stable and did not show significant changes during the postoperative follow-up period. This stability in IOP can be attributed to the existence of a 380-µm central opening in the IPCL that can maintain the normal aqueous flow between the posterior and anterior chambers without the need for PI, thus decreasing the incidence of pupillary block glaucoma [4]. There were previous studies on the effect of mydriatic cycloplegic on IOP as Adediji AK et al., Hung, Kuo-Chi et al., Kim J.M., et al. which resulted in dilatation of the pupil significantly and incidentally elevated IOP in normal subjects preferably at 45 minutes [27-29]. Our study had some limitations as the small number of patients. We did not differentiate the postoperative period as 1, 3, and 6 months. Also, we did not evaluate 0.5% of the concentration of cyclopentolate and tropicamide.

5. Conclusion

In conclusion, posterior segment evaluation is mandatory at regular intervals in moderate to high myopia, so we need pupillary dilation for this issue either by tropicamide 1% or cyclopentolate 1%. We demonstrated significant changes in anterior segment parameters in myopic eyes with IPCL following pupillary dilatation with tropicamide 1 % and cyclopentolate 1% without significant changes between both drugs. This indicted the safety of both drugs in pupillary dilatation in patients with implanted IPCL. Also, IOP increased after pupillary dilatation by both drugs, this indicated careful follow up of IOP after mydriasis preferably after 45 minutes.

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