

Dynamic Assessment of Light-Induced Vaulting Changes of Implantable Collamer Lens With Central Port by Swept-Source OCT: Pilot Study

Felix Gonzalez-Lopez¹, Blas Mompean^{1,2}, Rafael Bilbao-Calabuig¹, Jorge Vila-Arteaga^{3,4}, Jaime Beltran¹, and Julio Baviera¹

¹ Clínica Baviera, Instituto Oftalmológico Europeo, Madrid, Spain

² Department of Ophthalmology, Hospital Torrevieja, Alicante, Spain

³ Hospital La Fe, Valencia, Spain

⁴ Innova Ocular, Valencia, Spain

Correspondence: Felix Gonzalez-Lopez, Department of Refractive Surgery, Clínica Baviera, Melchor Fernández Almagro, 9, 28029 Madrid, Spain. e-mail: felixbavi@hotmail.com, fgonzalez@clinicabaviera.com

Received: 1 February 2018

Accepted: 24 March 2018

Published: 1 May 2018

Keywords: phakic lens; collamer; OCT; dynamic vault; vault range

Citation: Gonzalez-Lopez F, Mompean B, Bilbao-Calabuig R, Vila-Arteaga J, Beltran J, Baviera J. Dynamic assessment of light-induced vaulting changes of implantable collamer lens with central port by swept-source OCT: pilot study. *Trans Vis Sci Tech.* 2018;7(3):4, <https://doi.org/10.1167/tvst.7.3.4> Copyright 2018 The Authors

Purpose: To assess dynamic variations in vault induced by changes in brightness in eyes implanted with phakic collamer intraocular lens (pIOL) with central port for correction of myopia, defining new parameters of vaulting measurement.

Methods: We used a noninvasive Fourier-domain swept-source anterior-segment optical coherence tomography (AS-OCT) system to dynamically evaluate the shifts between the pIOL and anterior chamber structures under changing light conditions. For each eye assessed, we measured vault interval (VI), which we define based on central vault values in maximum mydriasis and in maximum miosis after light-induced changes in pupil diameter, and vault range (VR), which we define as the absolute difference between the VI values.

Results: The pilot study sample comprised 39 eyes (23 patients) previously implanted (mean 107 ± 156 days) with a pIOL. A significant difference in vault value was found when maximum and minimum pupil size was assessed under changing external light conditions ($P < 0.001$). The mean VR from scotopic (0.5 lux) to photopic (18,500 lux) light conditions was $167 \pm 70 \mu\text{m}$.

Conclusions: Vault is continuously affected during movements of the pupil induced by external luminance.

Translational Relevance: Quantifiable dynamic parameters VR and VI obtained with this AS-OCT device describe the position of the pIOL in the posterior chamber of the eye in a more accurate and real way than static vault measurements, and may contribute to improved understanding of the behavior of the pIOL in terms of safety.

Introduction

Achieving appropriate vault is the main challenge after implantation of a posterior chamber phakic intraocular lens (pIOL). Vault has traditionally been measured in static terms, namely, at a specific time and under specific environmental lighting conditions. However, some authors have demonstrated that vault varies both over time and according to specific ocular parameters, such as accommodation and pupil size.^{1–5}

The emergence of 3-dimensional (3D) anterior-segment optical coherence tomography (AS-OCT)

has made it possible to obtain high-precision, dynamic measurements of the anterior ocular structures.^{6,7} The purpose of this study was to measure in vivo changes in postoperative vault in central hole implantable collamer lens (ICL)-implanted eyes resulting from variations in external brightness. This range of variations in vault could have clinically significant repercussions depending on how the pIOL moves toward and away from the crystalline lens. The current study attempts to define these shifts in order to increase the accuracy of the traditional measurement of vault.

Materials and Methods

The sample for this prospective observational pilot study comprised 39 eyes from 23 patients who underwent uneventful implantation of spherical central hole pIOLs (Visian ICL V4c and EVO+ models) performed by the same experienced surgeon (FG-L) for treatment of myopia at Clinica Baviera (Madrid, Spain). The EVO+ design introduces an increased optical zone with an expanded diameter range (5.0–6.1 mm) in spherical powers of –0.5 diopters (D) to –14.0 D. It maintains the 360- μ m hole in the center of the optic and intrinsic vaulting design of its predecessor, the V4c model. The pIOLs are available in four sizes (12.1, 12.6, 13.2, and 13.7 mm).

All patients gave their written informed consent for the surgical procedure and for the use of their personal data in medical and scientific research. Data collection fulfilled Spanish legal requirements, and the Medico-Legal Committee of Clinica Baviera approved the study.

Study Outcome Parameters

Dynamic vault was assessed using a commercially available 3D swept-source AS-OCT (Fourier Domain OCT CASIA SS-1000; Tomey Corp, Nagoya, Japan). The OCT device has a swept-source laser wavelength of 1310 nm with an axial resolution of <10 μ m (in tissue), a transverse resolution of 30 μ m, and a scan rate of 30,000 A-scans per second.⁷

A dynamic examination of the anterior pole was performed in all eyes using the “angle analysis” protocol, which comprised 128 radial B-scans, each with 512 A-scans (scan length, 16 mm). The system operated at a very high scanning speed (8 frames/sec) and produced high-resolution images. The results were recorded in an OCT video as a sequence of frames lasting 15 seconds. The intensity of the light of the examination room was 0.5 lux, as measured using a PCE-MLM1 Light Meter (PCE Instruments, Meschede, Germany). Once the recording had started, the eye focused on an internal dot during imaging, while the fellow eye was exposed to a shining penlight (intensity, 18,500 lux) for 5 seconds, followed by ocular occlusion for 5 seconds. The eye under examination was centered automatically using the active eye tracker of the OCT system. Thus, the consensual pupillary light reflex enabled miosis and mydriasis in the study eye. A video recording of the pupil was obtained simultaneously in the corneal plane. Freezing one frame when the pupil reached its

minimum size subsequently processed the images acquired. The measurements taken from the image were pupil size in the iris plane, vault, anterior chamber depth (ACD) from the corneal endothelium, distance between the endothelium and the anterior surface of the pIOL (ACD-ASpIOL), angle-to-angle distance (ATA), crystalline lens rise (CLR), and the chamber angle formed between the iris root and the rear face of the cornea in the first 500- μ m area (trabecular-iris angle 500). Pupil size and white-to-white distance in the corneal plane were also measured. The same procedure was followed to obtain measurements at the time of maximum mydriasis (Fig. 1).

Our approach enabled us to propose two new parameters, vault interval (VI) and vault range (VR). VI is based on central vault values measured in maximum mydriasis and miosis and expressed in microns after light-induced changes in pupil diameter; VR is defined as the difference between the two values obtained after measurement of VI, which is expressed as an absolute value in microns. Therefore, once these measurements were collected, the VI and VR were established for each eye by taking the vault obtained in maximum miosis as the lower value and the vault obtained in maximum mydriasis as the higher value.

The differences obtained for each eye were analyzed, as were the groups established according to the vault value in maximum miosis, ACD, CLR in miosis, and spherical power, model, and according to the size of the ICL.

Statistical Methods

Outcomes reported in the clinical records were entered into an Excel spreadsheet (Microsoft Corp, Redmond, WA). Data were analyzed using Stata 11 (2009, Stata Statistical Software: Release 11; Stata-Corp, College Station, TX). Descriptive statistics were obtained. The results were expressed as mean \pm standard deviation. To analyze differences between miosis and mydriasis, we applied either the *t*-test for dependent samples or the Wilcoxon signed-rank test, depending on whether the assumption of normality of differences was satisfied. The differences between the groups were tested using the Mann-Whitney *U* test when the distribution of the differences between miosis and mydriasis was not normal; otherwise, the *t*-test was used. Assessing skewness and kurtosis tested normality. All *P* values were adjusted after multiple comparisons (3 groups tested against each other) using a Bonferroni correction. The differences

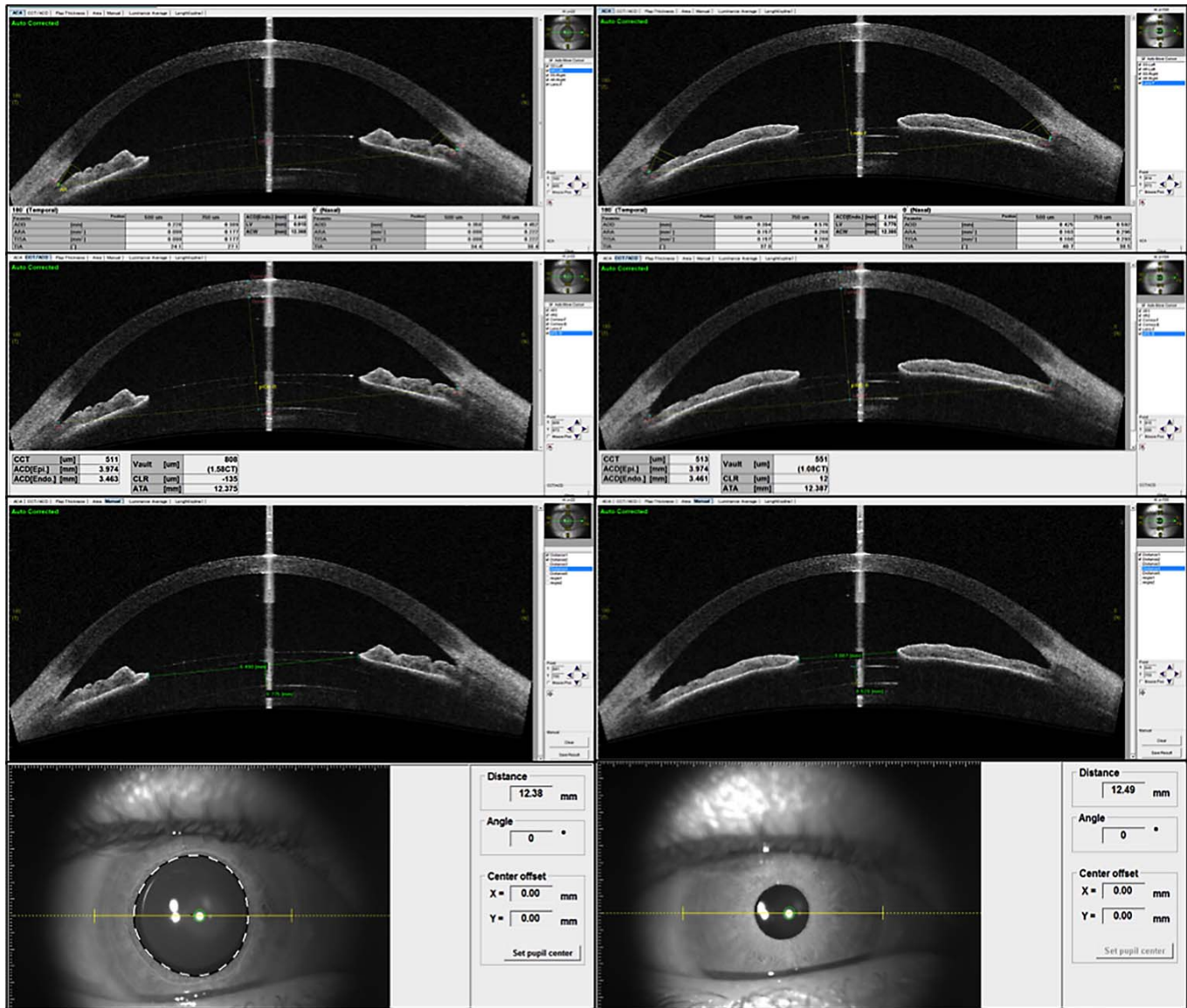


Figure 1. Imaging of the anterior segment in maximum mydriasis (*left column*) and miosis (*right column*) induced by changes in external brightness conditions. The image was taken using Fourier-domain swept-source optical coherence tomography after placement of a Visian implantable V4c collamer lens (size, 13.2; –6 diopters).

were considered statistically significant when the P value was less than .05.

Results

Descriptive

The study sample comprised 39 eyes (20 right, 19 left) from 23 patients (14 women, 9 men) implanted with spherical pIOLs with a central port (22 Visian ICL model V4c, 17 model EVO+). The mean age of the patients was 35 ± 6 years (range, 24–49 years).

Eyes had a mean baseline preoperative spherical equivalent of -7.68 ± 3.17 D (range, -1.75 to -15.63 D). The time between surgery and OCT was 107 ± 156 days (range, 3–621 days). Lens size was distributed as follows: 12.1 mm in 3 eyes, 12.6 mm in 11 eyes, 13.2 mm in 23 eyes, and 13.7 mm in 2 eyes.

Clinical Outcomes

Mean pupil size in the iris plane under photopic conditions was 2.95 ± 0.47 mm (range, 2.33–4.11 mm), with a mean vault value under maximum miosis of 374 ± 208 μ m (range, 85–963 μ m). Mean pupil size

Table 1. Changes in Vault and Anterior Chamber Structures Under Different Light Conditions

Characteristic	Photopic	Scotopic	Change Scotopic-Photopic	P
ACD (endo), mm	3.33 ± 0.17 (2.95–3.73)	3.32 ± 0.17 (2.95–3.69)	0.00 ± 0.02 (–0.02 to 0.05)	0.079 ^a
ACD-ASpIOL, mm	2.73 ± 0.23 (2.22–3.09)	2.59 ± 0.24 (2.03–3.04)	0.15 ± 0.12 (–0.48 to 0.28)	<0.001 ^b
Vault, μm	374 ± 208 (85–963)	540 ± 252 (133–1329)	–167 ± 70 (–366 to –48)	<0.001 ^a
Pupil size (iris plane), mm	2.95 ± 0.47 (2.33–4.11)	5.49 ± 0.86 (3.63–7.09)	–2.54 ± 0.75 (–3.93 to –1.17)	<0.001 ^a
Pupil size (corneal plane), mm	3.30 ± 0.51 (2.60–4.64)	6.40 ± 0.85 (4.79–8.02)	–3.10 ± 0.70 (–4.38 to –1.70)	<0.001 ^a
ATA, mm	12.21 ± 0.35 (11.45–13.05)	12.13 ± 0.39 (11.26–13.07)	0.08 ± 0.12 (–0.19 to 0.34)	<0.001 ^a
TIA 500 (temporal), deg	37 ± 6 (19–51)	32 ± 8 (17–50)	4 ± 7 (–12 to 18)	<0.001 ^a
TIA 500 (nasal), deg	37 ± 9 (12–52)	32 ± 7 (19–48)	5 ± 8 (–9 to 34)	<0.001 ^b
WTW, mm	12.09 ± 0.45 (11.33–13.20)	12.10 ± 0.46 (11.44–13.31)	–0.01 ± 0.13 (–0.27 to 0.37)	0.628 ^a
CLR, μm	125 ± 144 (–185 to 441)	64 ± 139 (–247 to 274)	60 ± 66 (–70 to 248)	<0.001 ^a

TIA 500, trabecular-iris angle in the first 500 μm; WTW, white-to-white. Values expressed as mean ± SD (range, minimum–maximum).

^a Dependent *t*-test.

^b Wilcoxon matched-pairs signed-rank test.

in the iris plane under scotopic light conditions was 5.49 ± 0.86 mm (range, 3.63–7.09 mm), and the mean vault value in maximum mydriasis was 540 ± 252 μm (range, 133–1329 μm). The mean VR was 167 ± 70 μm (range, 48–366 μm; Fig. 2). The mean change in

pupil size was 2.54 ± 0.75 mm (range, 1.17–3.93 mm). Table 1 shows changes in vault and anterior chamber structures under different light conditions.

We compared changes in vault under scotopic and photopic light conditions in different subgroups

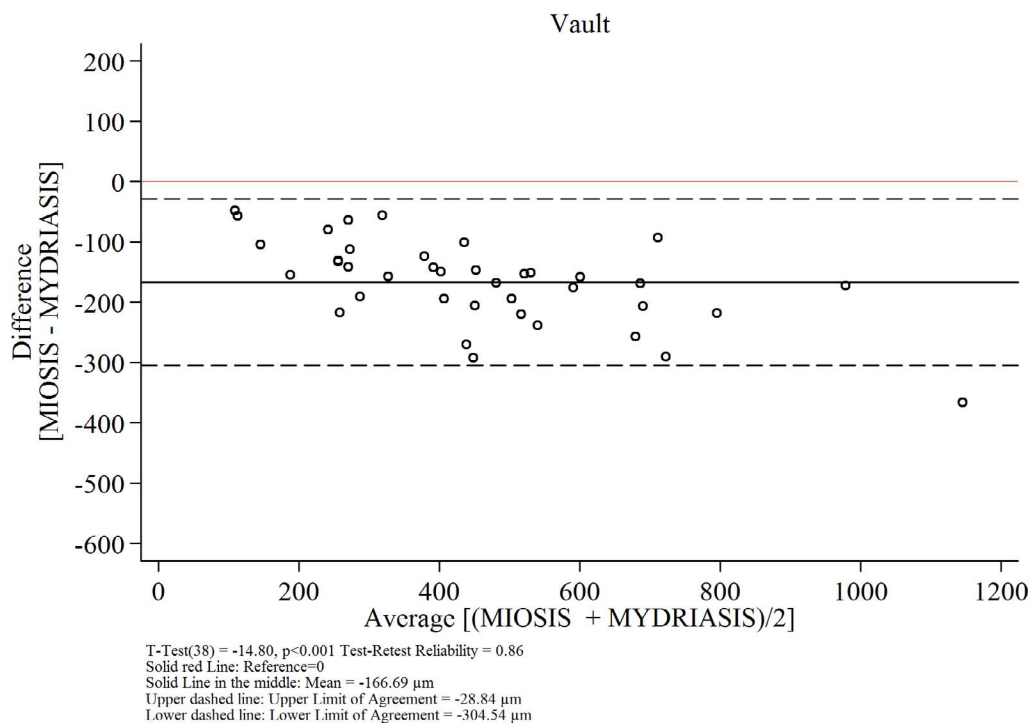
**Figure 2.** Bland–Altman plot showing the differences in vault between miosis and mydriasis (vault range) of the eyes analyzed.

Table 2. Comparison of Vault Range Between Subgroups

Characteristic	Mean Vault Change Scotopic–Photopic (v)	P (Independent Test)		
pIOL power <10 D	-171 ± 70	0.854 ^a		
pIOL power ≥10 D	-161 ± 73			
CLR (miosis) ≤150 μm	-183 ± 71	0.074 ^b		
CLR (miosis) >150 μm	-141 ± 63			
ACD (miosis) <3.3 mm	-161 ± 64	0.669 ^b		
ACD (miosis) ≥3.3 mm	-171 ± 76			
Vault (miosis) <250 μm (p1)	-122 ± 52	p1 vs. p2 0.090 ^b	p1 vs. p3 0.006 ^b	p2 vs. p3 0.515 ^b
Vault (miosis) 250–499 μm (p2)	-175 ± 61			
Vault (miosis) ≥500 μm (p3)	-211 ± 77			
pIOL size 12.1 and 12.6	-110 ± 93	0.157 ^b		
pIOL size 13.2 and 13.7	-245 ± 35			
pIOL model EVO +	-170 ± 64	0.910 ^a		
pIOL model V4c	-164 ± 76			

Values expressed as mean ± SD. When vault groups were compared, all *P* values were adjusted using Bonferroni correction.

^a Mann-Whitney *U* test.

^b Independent *t*-test.

defined according to CLR in miosis, ACD in miosis, vault in miosis, and the power, size, and model of the pIOL implanted. We only found statistically significant differences ($P = 0.006$) when comparing the low-vault subgroup (<250 μm in miosis) with the high-vault subgroup (≥500 μm in miosis), where VR was higher. Table 2 shows the comparison of vault between the subgroups.

Discussion

Vaulting in pIOL has primarily been related to a combination of the size of the lens, the vault intrinsic to the design of the lens, and the placement of the haptics in ciliary sulcus structures. Moreover, the classic approach to postoperative vault in clinical practice and in most published studies results in a static vault value, as vault is measured under specific ambient light conditions, that is, subjectively during the slit-lamp examination⁸ or objectively using high-frequency ultrasound biomicroscopy,⁹ Scheimpflug imaging,¹⁰ and AS-OCT.¹¹

The changes in vault under changing light conditions have been investigated by Petternel et al.¹ using partial coherence interferometry biometry. The ICLs studied included several models for the correction of myopia (11 eyes) and hyperopia (2 eyes), all without a central port. The authors found, applying our new dynamic concept approach, a mean VR of 73 ± 50

μm. More recently, Lindland et al.⁴ studied the dynamics of the myopic and toric ICL model V4 (without a central port). Using a Visante OCT (Carl Zeiss Meditec, Jena, Germany), the authors measured vault under photopic conditions (257 lux) and mesopic conditions (2 lux). They observed a significant mean decrease of 40 ± 60 μm in central vault under photopic conditions, which was again significantly lower than that found in our series, probably owing to differences in the pIOL models studied in the mentioned studies (all without central port) and the significant difference in the brightness of the penlight (18,500 lux) used in our study to induce miosis.

Recently, Lee et al.⁵ evaluated postoperative changes in vault under various lighting conditions in eyes implanted with ICLs with a central port. Static vault was assessed using a Visante OCT. The comparison of the V4c model with the V4 model revealed significant decreases in vault under photopic conditions in both groups. Moreover, changes in vault in eyes implanted with V4c ICLs were significantly larger than those recorded in eyes implanted with V4 ICLs, namely, a significant mean decrease in vault of 147 ± 59 μm in the V4c group (central port), whereas the decrease was only 88 ± 55 μm in the V4 group. These findings are consistent with our dynamic results, which show that the mean VR in lenses with a central port was very similar (167 ± 70 μm).

The findings from the above-mentioned studies

illustrate the essentially dynamic nature of ICL vaulting. The exploration by means of the AS-OCT technology allows us to verify the continuous movements of the pupil result in movement of the pIOL toward and away from the crystalline lens. Therefore, when defining the separation between the anterior surface of the lens and the back surface of the ICL, we need not maintain the classic static vault value as we have done to date, because it only offers data at a specific time and under specific ambient light conditions. In addition, there is a gap between the maximum value of the vault under scotopic light conditions (e.g., in a dark room) and the minimum vault value when environmental conditions are photopic (e.g., going outside on a sunny day). These observations support the role of VR and VI as a complement to classic vault value measurement.

Findings for the variations in AS induced by changes in brightness in our and other series are somewhat controversial. The interpretation of these variations is also open to debate. Dynamic AS-OCT provides clear in vivo images of the ICL and the anterior-segment movements. However, despite the accuracy of the measurements obtained using this technology, the sulcus structures remain inaccessible. Consequently, variations in the pIOL-sulcus complex cannot be measured properly, thus preventing us from explaining the discrepancies found. During penlight-induced miosis, the iris pushes the pIOL down and warps the ICL so it adapts to the posterior surface of the iris, thus decreasing central vault. This movement enables the flow of aqueous humor through both the lateral and the central holes.⁵ Similarly, we found no changes in ACD between photopic and scotopic conditions. However, we did find a significant increase in mean CLR ($60 \pm 66 \mu\text{m}$) during miosis as reported Lindland et al.,⁴ who emphasized the role of both the posterior movement of the ICL and the anterior movement of the crystalline lens in reducing vault under photopic conditions. Our findings contrast with those reported by Lin et al.¹² who observed that increasing light conditions shortened the ACD, while the ACD-ASpIOL remained mostly unchanged. In our series, the mean ACD-ASpIOL in miosis increased very significantly at $150 \pm 120 \mu\text{m}$. In addition, the ATA increased by a mean of $80 \pm 120 \mu\text{m}$ in miosis, while the chamber angles developed a mean opening of 4.4° temporally and 5.2° nasally. We think that in order to understand these anterior segment changes, they must be viewed in 3D. We theorize that in miosis, the iris pushes the lens down, the chamber angle opens, the ATA distance widens,

and the ACD increases. The CLR also increases and compensates for this change in the ACD; therefore, the final ACD does not vary significantly.

Statistically significant differences ($P < 0.05$) were found in VR when eyes with high vault were compared with eyes with low vault. The pIOL tends to move more under changing light conditions when vault is higher (VR $211 \pm 77 \mu\text{m}$) than when the pIOL is closer to the crystalline lens (VR $122 \pm 52 \mu\text{m}$). There were no statistically significant differences between the models with a central port, namely, V4c and EVO+. In our series, we found no cases of central contact between the ICL and the crystalline lens, even under photopic conditions, although the dynamism of the pIOL inside the eye could have led cases of low vaulting during miosis to have a potential impact on cataract formation. In addition, peripheral contacts, especially in high-power myopic pIOLs, could play a role in cataractogenesis. Future studies with larger series should determine the relevance of potential peripheral and central contacts. Furthermore, although clinical data indicate that the behavior of the port in the flow of the aqueous humor could reduce the incidence of cataractogenesis, the role of the port needs to be fully defined.

One limitation of the study is that the variation of the time span from the surgery was not considered in the analysis of the cases. The pIOL vault decreases with time and this circumstance could in some way affect the VR and VI. However, the main objective of this pilot study was to define the dynamism of the vault through these novel dynamic concepts, VR and VI, and to highlight its clinical importance. Future studies will evaluate if these parameters could be affected over time.

In conclusion, although pIOL vault has traditionally been considered a static parameter, our study strengthens the idea that it is actually fully dynamic, varying continuously with the natural movements of the iris throughout the day. Consequently, it should be supplemented by VR and VI, which are dynamic concepts that are able to better reflect the actual movements of the pIOL in relation to the anterior-segment structures. The security criteria so far accepted regarding the vault should now be reconsidered in terms of this dynamism, because all these values are based on a static measurement. This could have a significant clinical impact regarding not only the pIOL vault assessment of the operated eye, but also the lens-sizing calculation algorithm for the contralateral eye when binocular surgeries are scheduled; thereafter, this should now consider the VR and

VI obtained in the first eye. This and future studies using dynamic AS-OCT devices should help to redefine these new safety criteria in pIOLs.

Acknowledgments

The topic discussed in the present manuscript was presented by the main author at the XIII International EVO Visian ICL Experts Symposium, held on September 7–9, 2016 in Malmö, Sweden, where it was awarded with the votes of the attendance ophthalmologists as Best Free Paper Presentation of second daily session.

This material was presented as a Free Paper as well as a video (section Video Competition) at the XXXV Congress of the ESCRS, held on October 7–11, 2017 in Lisbon.

Disclosure: **F. Gonzalez-Lopez**, None; **B. Mompean**, None; **R. Bilbao-Calabuig**, None; **J. Vila-Arteaga**, None; **J. Beltran**, None; **J. Baviera**, None

References

- Petternel V, Köppl CM, Dejaco-Ruhswurm I, Findl O. Effect of accommodation and pupil size on the movement of a posterior chamber lens in the phakic eye. *Ophthalmology*. 2004;111:325–331.
- Lindland A, Heger H, Kugelberg M, Zetterstrom C. Vaulting of myopic and toric implantable collamer lenses during accommodation measured with Visante optical coherence tomography. *Ophthalmology*. 2010;117:1245–1250.
- Lege BA, Haigis W, Neuhann TF, Bauer MH. Age-related behavior of posterior chamber lenses in myopic phakic eyes during accommodation measured by anterior segment partial coherence interferometry. *J Cataract Refract Surg*. 2006;32:999–1006.
- Lindland A, Heger H, Kugelberg M, Zetterstrom C. Changes in vaulting of myopic and toric implantable collamer lenses in different lighting conditions. *Acta Ophthalmol*. 2012;90:788–791.
- Lee H, Kang SY, Seo KY, et al. Dynamic vaulting changes in V4c versus V4 posterior chamber phakic lenses under differing lighting conditions. *Am J Ophthalmol*. 2014;158:1199–1204.
- Mak H, Xu G, Leung C K-S. Imaging the iris with swept-source optical coherence tomography: relationship between iris volume and primary angle closure. *Ophthalmology*. 2013;120:2517–2524.
- Neri A, Ruggeri M, Protti A, Leaci R, Gandolfi SA, Macaluso C. Dynamic imaging of accommodation by swept-source anterior segment optical coherence tomography. *J Cataract Refract Surg*. 2015;41:501–510.
- Alfonso JF, Lisa C, Palacios A, Fernandes P, González-Méijome JM, Montés-Micó R. Objective vs subjective vault measurement after myopic implantable Collamer lens implantation. *Am J Ophthalmol*. 2009;147:978–983.
- García-Feijoo J, Jimenez-Alfaro J, Ricardo Cuiña-Sardiña R, Mendez-Hernandez C, Benitez Del Castillo JM, Garcia-Sanchez J. Ultrasound biomicroscopy examination of posterior chamber phakic intraocular lens position. *Ophthalmology*. 2003;110:163–172.
- Kamiya K, Shimizu K, Kawamorita T. Changes in vaulting and the effect on refraction after phakic posterior chamber intraocular lens implantation. *J Cataract Refract Surg*. 2009;35:1582–1586.
- Bechmann M, Ullrich S, Thiel MJ, Kenyon KR, Ludwig K. Imaging of posterior chamber phakic intraocular lens by optical coherence tomography. *J Cataract Refract Surg*. 2002;28:360–363.
- Lin H, Yan P, Yu K, Luo L, Jingjing Chen J, Lin Z, Chen W. Anterior segment variations after posterior chamber phakic intraocular lens implantation in myopic eyes. *J Cataract Refract Surg*. 2013;39:730–738.