Comparison of Dynamic Vault Changes Following Implantation of Two Different Models of Phakic Intraocular Lenses

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ABSTRACT

PURPOSE: To compare the dynamic vault range (the difference in the central vault height from scotopic to photopic light condition) after implantation of the ICL/TICL (STAAR Surgical) and Eyecryl phakic/Eyecryl phakic toric intraocular lens (IOL) (Biotech Healthcare).

METHODS: This retrospective study included patients with myopia or myopic astigmatism eligible for phakic IOL implantation with either the ICL/TICL or Eyecryl phakic/Eyecryl phakic toric IOL. Vault changes in varying light conditions (scotopic, mesopic, and photopic) were assessed using an anterior segment optical coherence tomography–based tomographer and dynamic vault range (DVR) was compared between the two groups.

RESULTS: A total of 60 eyes from 36 patients (30 eyes in each group) with a mean age of 28.63 ± 6.36 years were included. The mean postoperative follow-up at the time of assessment was 9.4 ± 5.3 and 8.9 ± 5.28 months (P = .75) in the ICL and Eyecryl groups, respectively. The mean values of scotopic, mesopic, and photopic vault were 490.56 ± 238.64, 453.56 ± 224.30, and 373.96 ± 200.24 µm in the ICL group and 515.46 ± 174.34, 490.26 ± 184.04, 450.43 ± 173.92 µm in the Eyecryl group (P = .32, .24, and .05, respectively). The DVR was 116.6 ± 59.29 µm in the ICL group versus 65.03 ± 31.78 µm in the Eyecryl group (P < .001).

CONCLUSIONS: The Eyecryl phakic IOL showed significantly fewer light-induced changes in the central vault height (DVR) compared to the ICL, which may be attributed to the difference in the material of the two phakic IOL models. This may be clinically significant in eyes with low postoperative vaults with respect to their follow-up and risk assessment of cataractogenesis in the long term.

[*J Refract Surg.* 2023;39(8):546-554.] VIDEO

Posterior chamber phakic intraocular lenses (IOLs) have now been accepted as a viable, safe, and effective surgical option for the correction of moderate to high myopia and myopic astigmatism.[1-5] However, achieving a safe and accurate vault postoperatively remains a challenge. One of the long-term complications of phakic IOLs that has been reported is development of anterior subcapsular cataract due to low postoperative vaulting (< 250 µm).[6-8] It was emphasized earlier that the conventional method of "static" vault measurement (ie, vault is measured in a fixed light condition) may not represent the real and physiological state of the phakic IOL implant in the eye because it may be affected by certain physiological and anatomical factors, such as accommodation and varying light conditions.[9] Hence, a dynamic measurement may be a better way of assessing positional changes in the vault in response to different light stimuli.

With respect to the phakic Implantable Collamer Lens (ICL) (STAAR Surgical), a study by Gonzalez-Lopez et al[10] showed a dynamic vault range (DVR) (the difference in the central vault value from scotopic to photopic light condition) of 167 ± 70 µm. The two currently available models of phakic IOLs, the Visian Implantable Collamer Lens (STAAR Surgical) and the Eyecryl phakic IOL (Biotech Healthcare),

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differ in their material properties. The ICL is made of Collamer (STAAR Surgical), a hydroxyethyl methacrylate (HEMA)/porcine-collagen based biocompatible polymer material, whereas the Eyecryl phakic IOL is made of a hydrophilic acrylic CQ ultraviolet-absorbing material.[11]

It was hypothesized that these differences in the material properties may influence the DVR range differently. The ICL is expected to mold more due to its comparatively softer and flexible nature. The current study was thus designed to evaluate the dynamic changes in the anterior segment in response to varying light conditions and their effect on the postoperative vault height following implantation of the above two phakic IOL models.

PATIENTS AND METHODS

This hospital-based, retrospective, comparative study was approved by the institutional review board of Nethradhama Superspeciality Eye Hospital in Bengaluru, India, and adhered to the tenets of the Declaration of Helsinki. All patients who had previously undergone bilateral/unilateral phakic IOL surgery with either the ICL/TICL (STAAR Surgical) or the Eyecryl phakic or Eyecryl phakic toric IOL (EPTIOL) (Biotech Healthcare) from January 2016 to June 2022 were included for DVR assessment. All of these eyes satisfied the standard eligibility criteria mandate for phakic IOL implantation.[11]

Inclusion criteria were patients aged between 21 and 45 years who had surgery for correction of myopia for spherical error between -0.50 and -21.00 diopters (D) and astigmatism up to -6.00 D with either of the above phakic IOLs, and minimum postoperative follow-up of 3 months. Patients who had surgery for hyperopic refractive errors, ectatic corneal disorders, and a minimum follow-up of less than 3 months were excluded from the study.

Preoperative measurements were performed using digital calipers for the white-to-white distance (WTW) and Pentacam HR (Oculus Optikgeräte GmbH) for the anterior chamber depth and keratometry. Three readings were obtained with each device and the mean of these readings was used as the final value for input into the calculator. Implant size and power selection was done using the online calculators recommended by their respective companies.

In both groups, surgical procedures were performed using a standard operating technique by a single experienced surgeon (SG).[12] A markerless system (Callisto Eye; Carl Zeiss Meditec AG) was used to place the main corneal entry incision temporally at 0 degrees for the left eye and at 180 degrees for the right eye. A 2.8-mm keratome was used to create a clear corneal temporal incision for the Eyecryl phakic IOL. For the ICL, the incision was extended to 3.2 mm. This was followed by injection of preservative-free intracameral xylocaine (1%) and hyaluronic acid (1%). The phakic IOL was then inserted into the anterior chamber and its four haptics gently manipulated using a Vukich manipulator (ASICO) and tucked under the dilated pupil. The phakic IOL was then gently rotated and aligned with the target axis under the guidance of the markerless system and as per the rotation diagram provided by the manufacturer. This was followed by evacuation of the ophthalmic viscosurgical device using a coaxial irrigation/aspiration cannula and hydration of the wound.

Apart from the routine postoperative clinical examination that included assessment of the uncorrected and corrected distance visual acuity with the Early Treatment of Diabetic Retinopathy Study chart at 4 m, slit-lamp examination, non-contact tonometry, and specular examination, postoperative dynamic vault evaluation was performed using an anterior segment optical coherence tomography (AS-OCT)–based tomographer (MS-39; Costruzione Strumenti Oftalmici). The MS-39 is a combination of Placido disk topography and high-resolution OCT-based tomography. It has high specifications for capturing images, wherein the image field is 16 mm × 8 mm, the axial resolution of images is 3.6 µm in tissue, and the transverse resolution is 35 µm in air, together with a high-speed scanning of 30,000 A-scans per second.[13]

Dynamic vault evaluation was performed with an undilated pupil in three different light conditions (scotopic, mesopic, and photopic) at the light intensities of 0.04 lux (scotopic), 4 lux (mesopic), and 50 lux (photopic) by a single, trained optometrist who was well versed with the method of scan acquisition with the MS-39. First, three serial AS-OCT images were captured by manually selecting the light mode in the sequence of scotopic, mesopic, and photopic; followed by capturing of a "video" showing these changes dynamically in the same sequence. **Figures 1A-1B** show the evaluation of the vault in scotopic, mesopic, and photopic light conditions for the ICL group and Eyecryl group, respectively, at 6 months of follow-up. **Videos A-B** (available in the online version of this article) show the video recordings of dynamic vault changes for the same eyes. After these captures were taken, another independent observer, a trained fellow (SW) who was blinded to the model of the implant, performed the following measurements on the AS-OCT images captured in the three light conditions:

1. Measurement of pupil size (mm): to assess the degree of pupillary constriction in scotopic, mesopic, and photopic light intensities (**Figure 2A**).

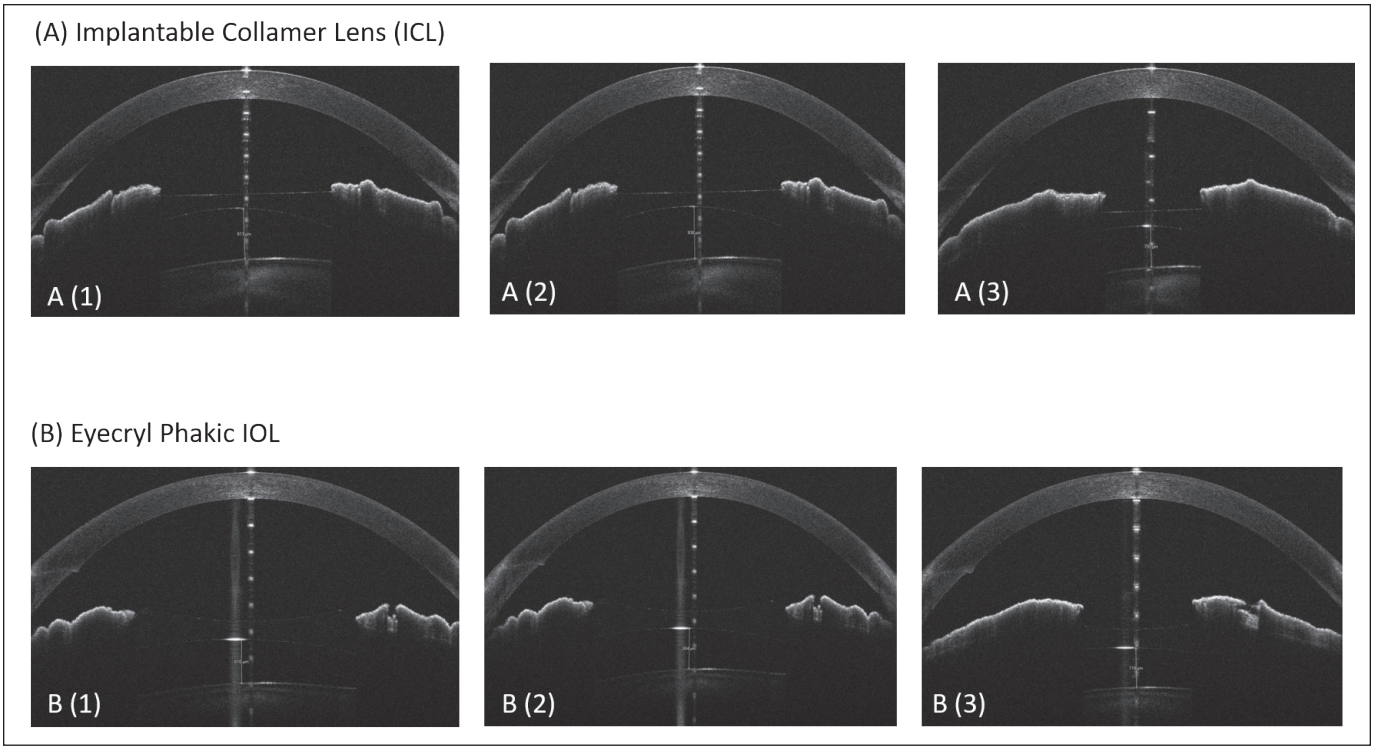

Figure 1. Evaluation of the vault in different light conditions using the anterior segment optical coherence tomography–based tomographer for an eye implanted with an ICL for (A1) scotopic, (A2) mesopic, and (A3) photopic in a 23-year-old woman, right eye preoperative spherical equivalent to -6.00 diopters sphere and an Eyecryl phakic intraocular lens (Biotech Healthcare) for (A1) scotopic, (A2) mesopic, and (A3) photopic in a 21-year-old woman, right eye preoperative spherical equivalent of -6.00 diopters sphere/-1.00 diopters cylinder at 6 months of follow-up.

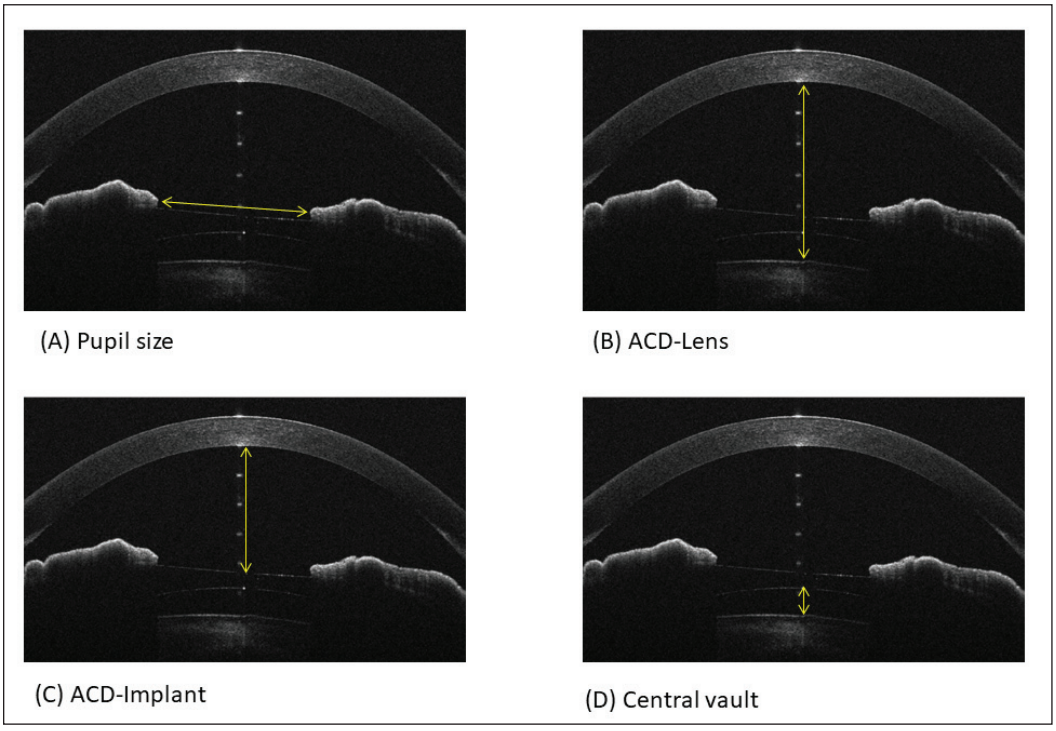

Figure 2. Various anterior segment optical coherence tomography (AS-OCT) parameters measured postoperatively (denoted by yellow line): (A) pupil size, (B) ACD-Lens, (C) ACD-Implant, (D) central vault. ACD = anterior chamber lens

2. ACD-Lens (µm): distance from the endothelium to the anterior surface of the crystalline lens (**Figure 2B**). The difference between ACD-Lens scotopic and ACD-Lens photopic would denote

TABLE 1
Preoperative Baseline Demographic Data

Parameter	ICL	Eycryl	*P*
Age (years)	29.66 ± 6.91	27.56 ± 5.85	.18
M:F ratio	7:11	7:11	
Sphere (D)	-9.26 ± 3.37	-9.63 ± 5.15	.76
Cylinder (D)	-1.15 ± 0.90	-1.52 ± 1.19	.17
SE (D)	-9.84 ± 3.46	-10.39 ± 5.26	.63
ACD (mm)	3.16 ± 0.27	3.3 ± 0.24	.02
Mean K (D)	44.02 ± 1.36	44.56 ± 0.93	.03
CCT (µm)	506.23 ± 23.02	497.26 ± 21.65	.06
WTW (mm)	11.82 ± 0.4	11.91 ± 0.4	.13
STS (mm)	11.64 ± 0.38	11.58 ± 0.47	.28
Lens rise (mm)	0.03 ± 0.16	0.09 ± 0.1	.02
Implant power (D)			
Sphere	-10.86 ± 3.0	-10.93 ± 7.34	.96
Cylinder	0.75 ± 1.09	1.30 ± 1.27	.07
Implant size (mm)	12.7 ± 0.37	12.55 ± 0.35	.11

ACD = anterior chamber depth; CCT = central corneal thickness; D = diopters; K = keratometry; SE = spherical equivalent; STS = sulcus to sulcus distance; WTW = white to white distance
The ICL is manufactured by STAAR Surgical and the Eycryl is manufactured by Biotech Healthcare.

the degree of forward movement of the crystalline lens during the dynamic vault assessment.

3. ACD-Implant (µm): distance from the endothelium to the anterior surface of the phakic IOL implant (**Figure 2C**). Difference between ACD-Implant scotopic and ACD-Implant would denote the degree of the posterior movement of the phakic IOL implant during the dynamic vault assessment.
4. Central vault (µm): measured from the posterior surface of the implant to the anterior surface of the crystalline lens (**Figure 2D**). Dynamic vault range was then calculated as the difference between the central vault scotopic and the central vault photopic in millimeters.

Statistical Analysis

Analyses was performed using the data analysis tool pack available in Microsoft Excel (Microsoft Corporation). Parametric or non-parametric tests were applied depending on the normality of data distribution. The relationship between DVR and different variables was evaluated by derivation of Pearson's correlations. A *P* value of less than .05 was considered statistically significant.

RESULTS

A total of 60 eyes from 36 eligible patients (30 eyes in each group) were analyzed. **Table 1** shows the preoperative demographic data of both study groups. The mean keratometry was significantly higher in the Eyecryl group, but other preoperative parameters were matched in both groups. Results were analyzed at a mean follow-up of 9.4 ± 5.3 months for the ICL group and 8.9 ± 5.28 months for the Eyecryl group. Of the total 30 eyes in each group, 22 and 24 eyes underwent implantation of toric models in the ICL and Eyecryl groups, respectively.

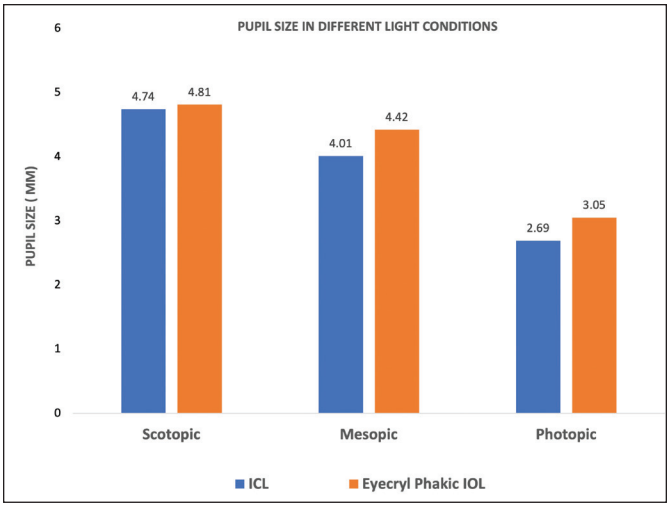

Figure 3. Mean pupil size in scotopic, mesopic, and photopic light conditions for the ICL (STAAR Surgical) and Eyecryl (Biotech Healthcare) phakic intraocular lens.

TABLE 2

Postoperative Comparison of Changes in Pupil Size, ACD-Lens, ACD-Implant, and Central Vault in Scotopic, Mesopic, and Photopic Light Conditions

Parameter	ICL	Eyecryl	*P*
Pupil size (mm)			
Scotopic	4.74 ± 0.86	4.81 ± 1.27	.81
Mesopic	4.01 ± 0.66	4.42 ± 1.35	.14
Photopic	2.66 ± 0.46	3.05 ± 1.37	.17
Difference scotopic-photopic (degree of pupil constriction)	2.05 ± 0.77	1.75 ± 0.80	.15
P	< .001	< .001	
ACD-Lens (µm)			
Scotopic	3,124.33 ± 216.23	3,223.63 ± 216.68	.04
Mesopic	3,112.83 ± 214.66	3,205.57 ± 212.27	.04
Photopic	3,103.83 ± 214.58	3,204.53 ± 212.08	.03
Difference scotopic-photopic (degree of forward movement of the crystalline lens)	20.50 ± 15.71	19.10 ± 14.51	.36
P	.35	.36	
ACD-Implant (µm)			
Scotopic	2,316.37 ± 239.48	2,312.67 ± 174.12	.47
Mesopic	2,332.03 ± 239.94	2,331.47 ± 173.52	.49
Photopic	2,408.53 ± 226.49	2,361.93 ± 177.32	.18
Difference scotopic-photopic (µm) (degree of posterior movement of the pIOL)	92.16 ± 51.01	49.27 ± 27.23	< .001
P	.06	.14	
Central vault (µm)			
Scotopic	490.56 ± 238.64	515.46 ± 174.34	.32
Mesopic	453.56 ± 224.30	490.267 ± 184.04	.24
Photopic	373.96 ± 200.24	450.43 ± 173.93	.05
Difference scotopic-photopic (dynamic vault range)	116.6 ± 59.29	65.03 ± 31.78	< .001
P	.02	.07	
Mean follow-up (months)	9.4 ± 5.2 (3 to 24)	8.9 ± 5.28 (3 to 24)	.75

ACD = anterior chamber depth; pIOL = phakic intraocular lens
The ICL is manufactured by STAAR Surgical and the Eycryl is manufactured by Biotech Healthcare.

Pupillary Changes in Various Light Conditions

The baseline values of scotopic, mesopic, and photopic pupil sizes for both groups were comparable without any significant differences ($P < .05$ for all light conditions) (**Figure 3**). The degree of pupillary constriction (difference between scotopic and photopic pupil size) was 2.05 ± 0.77 mm in the ICL group versus 1.75 ± 0.80 mm in the Eyecryl group, and was not statistically significant ($P = .15$, **Table 2**).

ACD-Lens Changes in Various Light Conditions

There was no significant difference noted for the degree of forward movement of the crystalline lens (difference between scotopic and photopic ACD-Lens), which was 20.50 ± 15.71 µm for the ICL group and 19.10 ± 14.50 µm for the Eyecryl group, ($P = .36$; **Table 2**).

ACD Implant Changes in Various Light Conditions

The baseline values of scotopic, mesopic, and photopic ACD-Implant were comparable for both groups without any significant differences ($P > .05$ for all light conditions). However, the degree of posterior movement of the implant (difference between scotopic and photopic ACD-Implant) was significantly higher for the ICL group (92.16 ± 51.0 µm) versus the Eyecryl group (49.27 ± 27.23 µm) ($P < .001$; **Table 2**).

Vault Changes in Various Light Conditions

In both groups, a significant reduction in the central vault from scotopic to photopic light conditions was observed ($P < .001$. However, the mean DVR was significantly higher for the ICL group (116.6 ± 59.29 µm) when compared to the Eyecryl group (65.03 ± 31.78

TABLE 3
Correlations of Anatomical Parameters With the Dynamic Vault Range

	ICL		Eyecryl	
Parameter	R^2	*P*	R^2	*P*
Age (years)	0.148	.12	0.052	.39
Sphere (D)	-0.036	.42	-0.260	.08
Cylinder (D)	-0.059	.37	-0.103	.29
SE (D)	-0.043	.41	-0.266	.07
ACD (mm)	0.127	.25	0.086	.32
Mean K (D)	0.164	.19	-0.362	.12
CCT (µm)	0.212	.13	-0.154	.20
WTW (mm)	-0.186	.16	0.112	.27
STS (mm)	0.047	.40	0.167	.19
Lens rise (mm)	0.257	.08	0.190	.15
Pupil difference (mm)	0.60	.37	0.123	.25
Baseline mesopic vault (µm)	0.320	< .001	0.006	.68

ACD = anterior chamber depth; CCT = central corneal thickness; D = diopters; K = keratometry; SE = spherical equivalent; STS = sulcus to sulcus distance; WTW = white to white distance
The ICL is manufactured by STAAR Surgical and the Eycryl is manufactured by Biotech Healthcare.

µm) ($P < .001$). The baseline values of scotopic and mesopic central vault for both groups were comparable without any significant differences ($P > .05$). However, the photopic vault was significantly lower in the ICL group (373.96 ± 200.24 µm) versus the Eyecryl group (450.43 ± 173.92 µm) ($P = .05$; **Table 2**).

CORRELATIONS

None of the anatomical parameters correlated significantly with the DVR in either of the groups, but significant correlation of the baseline vault measured in mesopic condition was found with the DVR in the ICL group ($R^2 = 0.320$, $P = < .001$; **Table 3**).

COMPLICATIONS

No eye in either group had evidence of lenticular touch, cataract formation, pupillary block, secondary glaucoma, severe uveitis, or retinal detachment at the end of the follow-up period.

DISCUSSION

It has been shown in previously conducted studies that the vault of a phakic IOL is continuously affected during movements of the pupil induced by external luminance.[14,15] Using partial coherence interferometry, Petternel et al[16] observed a significant mean reduction of the distance between the ICL (without contraflow) and the crystalline lens by 28 µm (range: 16 to 188 µm), under photopic conditions, and postulated that this may possibly cause inadequate aqueous circulation in the pre-lenticular space, and subsequent subcapsular opacification in some of the eyes after ICL implantation. Lopez et al[10] assessed dynamic variations in the vault induced by changes in brightness in eyes implanted with a phakic IOL with a central port, using a non-invasive Fourier-domain swept-source AS-OCT system, to dynamically evaluate the shifts between the phakic IOL and anterior chamber structures under changing light conditions. They found a significant difference in vault values, wherein the mean vault range from scotopic (0.5 lux) to photopic (18,500 lux) light conditions was 167 ± 70 µm. The study identified quantifiable dynamic parameters vault range and vault interval obtained with AS-OCT that describe the position of the phakic IOL in the eye in a more accurate and real way than static vault measurements.

The current study aimed to evaluate light-induced changes in central vault height following two different models of phakic IOLs with different material properties used for myopia and myopic astigmatism correction.

Du et al[17] reported that the distance between the phakic IOL and the crystalline lens reduced as the phakic IOL moved posteriorly by the iris as a result of pupil constriction during pharmacologic accommodation with topical pilocarpine. Simultaneously, the anterior surface of the crystalline lens became more convex and moved anteriorly, further reducing the central vault of the phakic IOL.[17] Thus, the vault reduction in photopic light conditions could be attributed to both posterior movement of the phakic IOL due to constriction of the pupil and anterior movement of the crystal-

line lens. In the current study, there was no significant difference in the degree of crystalline lens movement between groups, which was approximately 20 µm for both phakic IOLs.

Posterior movement of the implant would be suggested by an increase in the value of the ACD Implant parameter (distance between the endothelium and the anterior surface of the phakic IOL), which in turn may be influenced by degree of pupillary constriction and the material properties of the implant. The change in ACD-Implant was significantly less for the Eyecryl lens in the current study. Because the degree of pupillary constriction was comparable between the groups, the significant differences in the ACD-Implant were thus mainly attributed to the differences in the material properties of the two phakic IOL models. The ICL is made from Collamer, a proprietary hydroxyethyl methacrylate/porcine-collagen–based biocompatible polymer material, which makes this implant soft and highly flexible in nature. These properties of the ICL may be responsible for its greater posterior movement and thus more changes in vault measurements under photopic conditions. The significant positive correlation of the DVR with the baseline mesopic vault in the ICL group also reinforces the same. On the other hand, the material of the Eyecryl phakic lens is hydrophilic acrylic, which is a relatively stiffer material and thus less susceptible to light- and pupil-induced changes in the vault position. Observations from our study may be clinically relevant in eyes with low postoperative vaults where a decision needs to be made about lens explantation and need for cataract surgery.

The incorporation of the central hole or the KS-Aquaport was a breakthrough in the ICL technology that significantly reduced the incidence of cataract after ICL implantation by improving the nutrition to the crystalline lens. A recent review on the ICL with a central port reported the incidence of anterior subcapsular cataract after ICL implantation as 0.6%, which was drastically less compared to its earlier models.[18] Visually significant cataract related to insufficient vault has not been reported in patients implanted with the EVO ICL. Overall, 11 publications including data on a total of 617 eyes with a weighted average follow-up of 13 months reported a 0.49% incidence of asymptomatic anterior subcapsular opacities. Karandikar et al[19] reported one visually insignificant anterior subcapsular opacity at 1 year. Fernández-Vigo et al[20] recorded mild anterior subcapsular cataract in 1 eye, but corrected distance visual acuity remained stable (0.1 logMAR) at 2 years so the lens was not explanted. Senthil et al[21] reported 1 eye that developed localized anterior subcapsular cataract following pupillary block treated with anterior chamber lavage. Five years following implantation, Shimizu et al[22] reported a zero incidence of anterior subcapsular opacity and cataract. These studies suggest the long-term safety of the ICL with CentraFLOW with respect to development of visually significant cataract. Regarding the safety of the Eyecryl phakic IOL, the longest-term study of 4 years of follow-up did not show any incidence of anterior subcapsular formation.[23] However, data with the latter implant model are limited compared to the ICL and hence further studies with longer follow-up periods are required to compare the long-term incidence of cataract formation following the implantation of the two lenses.

It is unclear at the moment if dynamic vault changes in varying light conditions truly result in increased risk of cataract formation. However, in the context of cataractogenesis, the peripheral vault, in addition to the central, was suggested to play a significant role because the crystalline lens touches the thickest part of the implant in the mid-periphery located at the optic–haptic junction. Hence, central vaulting does not necessarily mean separation between the crystalline lens and the implant. Because measurement of the peripheral vault is challenging using the AS-OCT due to inability to penetrate the iris pigment epithelium, ultrasound biomicroscopy was shown to be a useful tool in this situation.[17] Ultrasound biomicroscopy studies have demonstrated the values of the peripheral vault to be approximately 50% lower than those of the central vault.[17,24] Hence, dynamic change in the central vault is expected to affect the mid-peripheral vault proportionately, increasing the chances of friction between the implant and the crystalline lens in the mid-periphery. These changes may potentially result in constant or intermittent trauma to the crystalline lens, leading to lens epithelial metaplasia.[25]

The observations of our study were recorded at a photopic light illumination of 50 lux. However, it has been found that the intensity of light in various working areas (stairways, escalators, warehouse, easy office work, classrooms, study library, supermarkets, and operating rooms) and while performing some of the routine activities (reading, laptop work, and exercising) is much higher than that used in the study.[26] Thus, eyes with lower vaults, when combined with greater degrees of dynamic changes, would theoretically be at a higher risk of lens touch due to frequent exposure to higher light intensities. These results were recorded at a mean period of 9 months postoperatively. However, it is well known that the phakic IOL vault has a tendency to reduce over time due to an increase in crystalline lens thickness by an average of 20 µm/year

and decreased footplate support from zonular stretching.[25,27] One potential limitation of our study could be that the dynamic vault assessments were performed at variable follow-up times ranging from 3 to 24 months. A prospective study with larger sample size and longer follow-up comparing dynamic vault changes between the two implants at similar postoperative follow-up points may be indicated.

The Eyecryl phakic IOL showed significantly fewer light-induced changes in the central vault height (DVR) compared to the ICL, which may be attributed to the difference in the material of the two phakic IOL models. This may be clinically significant in eyes with low postoperative vaults with respect to their follow-up periods and risk assessment of cataractogenesis in the long term. Future prospective studies with more data are suggested to verify these preliminary results. To our knowledge, this is the first study comparing light induced changes in the vault following implantation of two different models of phakic IOLs for myopia and myopic astigmatism correction. The clinical significance of these results in assessing the long-term risk of cataractogenesis remains to be ascertained.

AUTHOR CONTRIBUTIONS

Study concept and design (SB); data collection (STW, SSS); analysis and interpretation of data (SB, SG); writing the manuscript (SB, STW); critical revision of the manuscript (SSS, SG); statistical expertise (STW); administrative, technical, or material support (SG); supervision (SG)

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