Seven-Year clinical outcomes after implantation of Eyecryl posterior chamber phakic intraocular lenses for high myopia

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Abstract

Purpose: To evaluate the long-term clinical outcomes, safety and efficacy of Eyecryl posterior-chamber phakic intraocular lens implantation (pIOL) implantation in patients with high myopia.

Methods: Patients with myopia between −6.00 and −20.00 dioptres and with endothelial cell density (ECD) was ≥2300 cells/mm^2 were included. Preoperative and postoperative first, fourth, and seventh years of refraction, uncorrected/corrected distance visual acuity (UDVA/CDVA), ECD, central vault were detected.

Results: Thirty-six eyes were analyzed. The mean UDVA and CDVA in postoperative seventh years were 0.25 ± 0.31 and 0.13 ± 0.24 logMAR, respectively. The safety and efficacy indices were 1.55 ± 0.54 and 1.24 ± 0.53, respectively. The mean cumulative ECD loss was 6.96% ($p < 0.001$). The central vault at the 1st and the 7th year were 0.52 ± 0.14 and 0.49 ± 0.14 mm, respectively ($p = 0.25$).

Conclusions: These findings supported the long-term stability, efficacy, safety of the Eyecryl pIOL for high myopia. Eyecryl posterior chamber pIOL is one of the effective refractive options in correcting high myopia.

Keywords

IOLs < LENS / CATARACT, refractive phakic IOLs < REFRACTIVE SURGERY, postoperative posterior segment / vitreous problems < LENS / CATARACT, specular microscopy < LENS / CATARACT, complications of refractive surgery < REFRACTIVE SURGERY

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Introduction

Refractive surgical options for individuals with a high refractive error or thin cornea are limited; in these cases, phakic intraocular lens implantation (pIOL) is frequently the preferred choice.[1] One of the reasons pIOL implantation is preferred, especially in young patients, is the preservation of the crystalline lens, accommodation, and corneal dynamics.[1]

Today, there are many pIOL options in different models. Due to concerns about the gradual loss of endothelial cells in anterior chamber pIOLs, posterior chamber pIOLs have risen in favour.[2–4] As this surgery is typically done on young patients, it is important to monitor the long-term efficacy and safety. There are several studies reporting long-term clinical results with posterior chamber pIOLs such as implantable collamer lenses (ICL, Staar Surgical, Monrovia, CA) and phakic refractive lens (PRL, IOLTech/Carl Zeiss Meditec, AG).[1,5,6]

One of the relatively new models, Eyecryl posterior chamber pIOL (BioTech Healthcare GmbH, Lucerne, Switzerland) is a foldable, hydrophilic acrylic, plate-haptic, one-piece, injectable lens with a hole in the middle structure of the optic that allows the passage of aqueous humour.

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Among the studies reporting the clinical results of Eyecryl spherical pIOL for myopia, the longest has a five-year follow-up.[7] The aim of the study was to evaluate the long-term (7 years) clinical outcomes, safety and efficacy of Eyecryl posterior chamber pIOL implantation in patients with high myopia.

Methods

This retrospective study was approved by the University of Health Sciences ethics committee with decision number 26/5 dated December 2, 2022. The Declaration of Helsinki principles were respected in all procedures. Prior to the pIOL implantation, each patient provided full written informed consent for the surgery.

Patients with at least 7 years of follow-up, with high myopia between −6.00 and −20.00 dioptres (D), with astigmatism ≤2.5 D, with stable refraction for at least 2 years preoperatively, with anterior chamber depth (ACD) ≥ 3 mm, and with endothelial cell density (ECD) was ≥2300 cells/mm^2 were included. Patients under the age of 21, with any ocular or systemic disease or pregnancy, with a history of previous ocular surgery, and who did not attend their follow-up regularly were excluded from the study.

The patients were evaluated pre- and postoperatively on the 1st day, 1st week, 1st, 6th, and 12th months, and with annual follow-ups thereafter. An automated phoropter and Snellen charts was used to assess both uncorrected and corrected distance visual acuity (UDVA and CDVA, respectively). Via an auto-refractometer (RM-8800 Autorefractor, Topcon, Japan), keratometry and objective refraction values were determined. The optical biometry (EchoScan-US 1800, Nidek Co., Ltd.) was used to measure the axial length (AL). Corneal topography and pachymetry were assessed using the Scheimpflug camera with a Placido disc topographer (Sirius, Costruzioni Strumenti, Oftalmici, Italy). The horizontal white-to-white (WTW) distances and ACD was assessed via the same topographer. ECD, coefficient of variation of cell area, and hexagonality were analyzed using a specular microscope (CEM 530, NIDEK, Japan). The intraocular pressure (IOP) was measured via the Goldmann applanation tonometer. The central vault (distance between the front apex of the crystalline lens and the midpoint of the pIOL's optic's back surface) height was measured by an anterior segment optical coherence tomography (OCT) (Visante OCT, Carl Zeiss AG, Germany). Having undergone cataract surgery or having a lens opacity resulting in the loss of 2 or more Snellen lines on CDVA was considered a cataract. The safety index was defined as the ratio of postoperative CDVA to preoperative CDVA, and the efficacy index was defined as the ratio of postoperative UDVA to preoperative CDVA.

The Eyecryl is an injectable, foldable, hydrophilic acrylic, plate-haptic, posterior chamber lens that is intended to be inserted into the sulcus of phakic eyes with myopia between −3.00 and −23.00 D. It has an aspheric optic with zero aberration. The optic is between 4.65 and 5.50 mm in diameter. A 360 µm hole at the centre of the optic prevents pupillary blockage. The power for the pIOL was established by targeting emmetropia using Biotech Vision Care proprietary calculator available on manufacturer's website. With a choice of three total lengths (12.0, 12.5, and 13.0 mm) available, the size of the lens is selected based on the horizontal WTW distance of the eye.

pIOL implantation procedure. @ All eyes were operated on by the same surgeon (AA) after subtenon anesthesia, and mydriasis was provided with preoperative topical cyclopentolate and phenylephrine. In all cases, a 2.8 mm temporal corneal incision was made with a slit blade. The anterior chamber was filled with 1% sodium hyaluronate (Provisc; Alcon Inc., Ft. Worth, TX, USA) following adrenaline injection. Using the injector cartridge system, the pIOL was placed in the anterior chamber in a horizontal manner. Using a push-pull maneuver, each haptic was individually placed in the ciliary sulcus. The viscosurgical material in the anterior chamber was washed using a buffered saline solution. Irrigation/aspiration cap was not used in any of the operations. Following the drainage of the viscosurgical material in the anterior chamber, miotic substance (carbachol) was introduced into the anterior chamber and the incision was hydrated.

The Statistical Package for the Social Sciences was used to conduct the statistical analysis (SPSS, v.20, Chicago, IL, USA). According to the Shapiro-Wilk test, all of the data were normally distributed. Snellen visual acuity was transformed to the logarithm of the minimal angle of resolution (logMAR). Repeated measures analysis of variance (ANOVA) was used to assess the differences in parameters between preoperative and follow-up visits. Bonferroni correction was used for pairwise comparisons. Statistical significance was set at $p < 0.05$. Microsoft Excel templates (2013, Microsoft Corporation, USA) made by London Vision Clinic (London, UK) were used to create the related graphics.

Results

Thirty-six eyes of 18 patients (8 men, 10 women) were analyzed in the study. The characteristics of patients are summarized in Table 1.

Uncorrected visual acuity:

The UDVA at preoperative, at the 1st year, at the 4rd year, at the 7th year visits were 1.54 ± 0.26, 0.22 ± 0.17, 0.28 ± 0.22, and 0.25 ± 0.31 logMAR, respectively ($p < 0.001$). Seven eyes (19%) had 20/20 or better, and 31 eyes

Table 1. Preoperative characteristics of patients.

Parameter	Mean ± SD (Range)
Age (year)	30.61 ± 7.17 (21–46)
UDVA (logMAR)	1.54 ± 0.26 (1–1.8)
CDVA (logMAR)	0.27 ± 0.17 (0–0.7)
SE (D)	−12.75 ± 3.11 (−7.00–−20.00)
Sphere (D)	−12.27 ± 3.14 (6.50–−19.75)
Cylinder (D)	−0.97 ± 0.68 (0–−2.50)
ACD (mm)	3.66 ± 0.31 (3.14–4.04)
IOP (mmHg)	14.13 ± 2.70 (10–21)
CCT (mm)	530.02 ± 35.60 (452–595)
AL (mm)	28.01 ± 1.49 (24.65–31.20)
Horizontal WTW distance (mm)	11.83 ± 0.29 (10.82–12.10)
ECD (cells/mm^2)	2673.77 ± 314.54 (2362–3189)

SD, standard deviation; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; logMAR, logarithm of the minimal angle of resolution; SE, spherical equivalent; D, dioptres; ACD, anterior chamber depth; IOP, intraocular pressure; CCT, central corneal thickness; AL, axial length; WTW, white-to-white; ECD, endothelial cell density.

(86%) had 20/40 or better UDVA at the 7th year visit. (Figure 1A). The efficacy index was 1.20 ± 0.42, 1.10 ± 0.44, 1.24 ± 0.53 at the 1st, the 4th and the 7th year visits, respectively ($p = 0.07$).

Safety

The CDVA at preoperative, at the 1st year, at the 4rd year, at the 7th year visits were 0.27 ± 0.17, 0.13 ± 0.10, 0.12 ± 0.14, and 0.13 ± 0.24 logMAR, respectively ($p < 0.001$). At the 7th year visit, 1 (2.8%) eye lost 3 or more lines, 1 (2.8%) eye lost 2 lines, 1 (3%) eye lost 1 line, 6 (17%) eyes showed no change, 8 (22%) eyes gained 1 line, 12 (33%) eyes gained 2 lines, 7 (19%) eyes gained 3 or more lines (Figure 1B). The safety index was 1.46 ± 0.45, 1.53 ± 0.53, 1.55 ± 0.54 at the 1st, the 4th and the 7th year visits, respectively ($p = 0.22$).

Predictability

A scatter plot of the attempted versus achieved correction of 36 eyes for spherical equivalent (SE) is shown in Figure 1C. At the 7th year visit, 33% and 67% of the eyes were within ±0.50 D and ±1.00 D of attempted SE, respectively. (Figure 1D). At the 7th year visit, 33% and 52% of the eyes had astigmatism ≤0.50 D and ≤1.00 D, respectively (Figure 1E).

Stability

The achieved SE is shown in Table 2 and Figure 1F. Table 2 summarizes the changes in refractive spherical error during the course of the follow-up. Postoperative SE nearly achieved emmetropia after the 1st year and remained steady throughout the follow-up period with a mild myopic shift ($p = 0.04$). Mean refractive cylindrical errors were similar preoperatively and at the 7th year visit (Figure 1E and Table 2).

Axial length

The AL at preoperative, at the 1st year, at the 4rd year, at the 7th year visits were 28.01 ± 1.49, 28.24 ± 1.48, 28.41 ± 1.36, and 28.51 ± 1.50 mm, respectively ($p < 0.001$). There was a significant increase in AL at the 1st visit compared to its preoperative value ($p < 0.001$). No significant change was observed at subsequent visits compared to the 1st year ($p > 0.05$).

Intraocular pressure

The IOP at preoperative, at the 1st year, at the 4rd year, at the 7th year visits were 14.13 ± 2.70, 12.33 ± 2.37, 14.64 ± 2.39, and 16.47 ± 2.95 mmHg, respectively ($p = 0.10$).

Endothelial cell parameters

The changes in the endothelial cell parameters during follow-up are listed in Table 3. At the 4th and 7th year visits, a significant decrease was observed in ECD compared to the preoperative period ($p = 0.03$ and $p = 0.001$, respectively).

Central vault height

The central vault height at the 1st year, at the 4rd year, at the 7th year visits were 0.52 ± 0.14, 0.49 ± 0.13, and 0.49 ± 0.14 mm, respectively ($p = 0.25$).

Complications

A minor complication was observed in one eye (2.8%) during the surgery, which developed as iris trauma and pigment distribution and regressed spontaneously in the 2nd week. No major complication was observed during the surgery.

Postoperative complications are summarized in Table 4. The pupillary block was not developed in any eyes. In the first three months after surgery, only two eyes had mild IOP elevation (27 mmHg), which could be controlled with antiglaucomatous medication. No eyes suffered from glaucoma or corneal endothelial decompensation. No eyes needed a replacement pIOL because of size problems or an explanation for any severe adverse effects.

Four years after the pIOL was implanted, an asymptomatic anterior subcapsular opacity appeared in 1 (2.8%) of the eyes. One Snellen line of CDVA was lost in this eye.

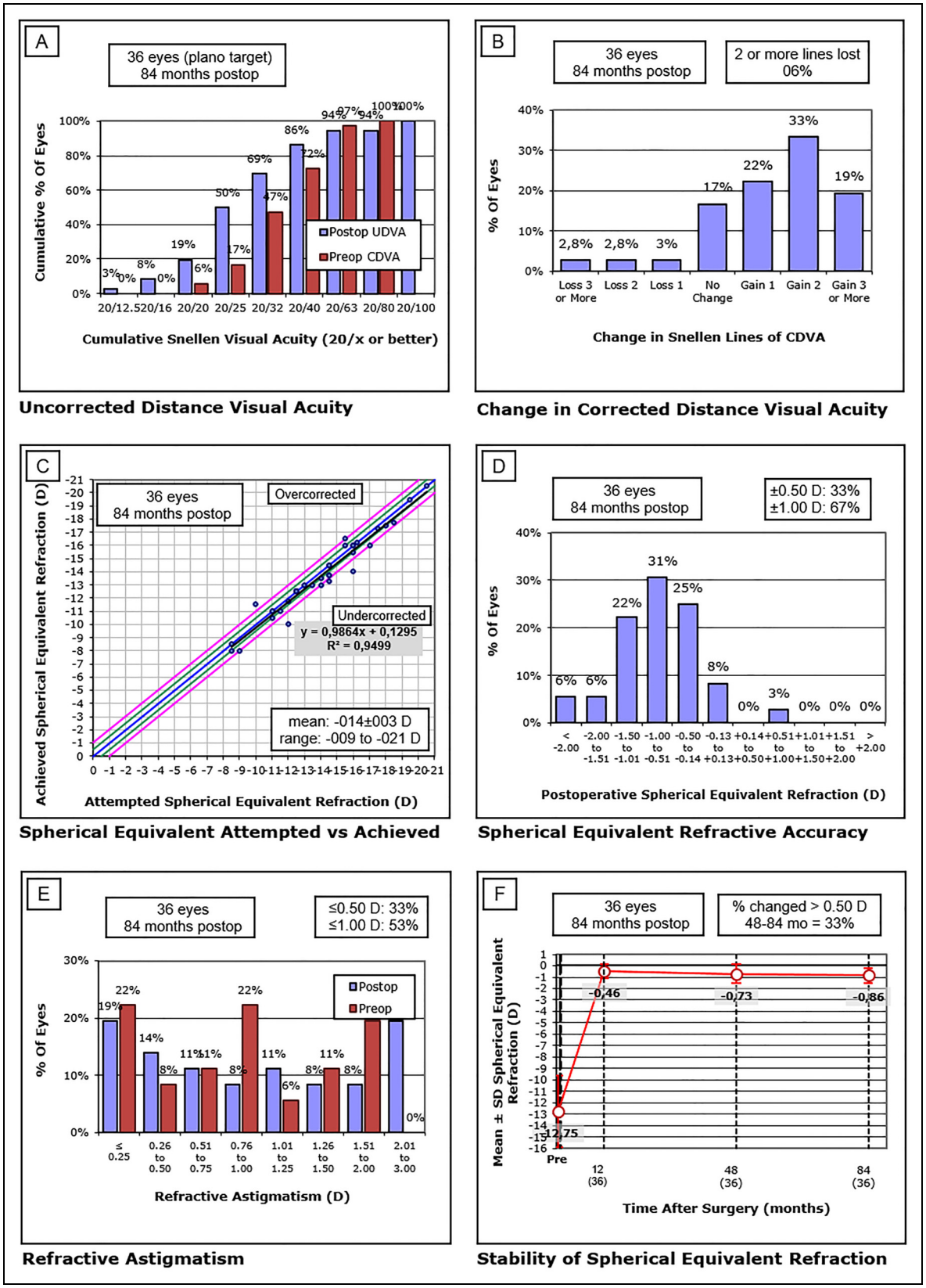

Figure 1. Analysis of the pre-and postoperative data of the eyes that underwent Eyecryl posterior chamber pIOL implantation. pIOL: Phakic intraocular lens (A) The cumulative Snellen visual acuity in 7 years. CDVA: corrected distance visual acuity, UDVA: uncorrected distance visual acuity. (B) Change in lines of corrected distance visual acuity in 7 years postoperatively. CDVA: corrected distance visual acuity. (C) Attempted versus achieved spherical equivalent refraction 7 years postoperatively. (D) Accuracy of the spherical equivalent refraction 7 years postoperatively. (E) Change in refractive astigmatism from preoperatively and 7 years postoperatively. (F) Change in spherical equivalent from preoperatively and 7 years postoperatively.

Table 2. Spherical equivalent, refractive spherical and cylindrical values of subjective manifest refraction during follow-up.

Parameters	Preoperative (mean ± SD)	1 year (mean ± SD)	4 years (mean ± SD)	7 years (mean ± SD)	p[a]
Spherical equivalent	−12.75 ± 3.11	−0.46 ± 0.59	−0.73 ± 0.82	−0.86 ± 0.66	<0.001*
Refractive spherical values	−12.27 ± 3.14	−0.09 ± 0.47	−0.26 ± 0.74	−0.32 ± 0.68	<0.001*
Refractive cylindrical values	−0.97 ± 0.68	−0.77 ± 0.74	−0.94 ± 0.82	−1.08 ± 0.79	0.03*

SD, standard deviation.

[a]Repeated measures of analysis, p value for all visits. Post-hoc analysis for spherical equivalent: Significant difference was observed between the preoperative visit and the 1-year visit ($p < 0.001$), between the 1-year visit and the 4-year visit ($p = 0.04$), and between the 1-year visit and the 7-year visit ($p = 0.04$). There was no significant difference between the 4-year visit and the 7-year visit ($p = 1.0$). Post-hoc analysis for refractive spherical values: Significant difference was observed between the preoperative visit and the 1-year visit ($p < 0.001$), there was no significant difference between the 1-year visit and the 4-year visit ($p = 0.34$), and between the 4-year visit and the 7-year visit ($p = 1.0$). Post-hoc analysis for refractive cylindrical values: Significant difference was observed between the 1-year visit and the 7-year visit ($p = 0.02$), there was no significant difference between the preoperative and the 1-year visit ($p = 0.29$), between the 1-year visit and the 4-year visit ($p = 0.31$), and between the 4-year visit and the 7-year visit ($p = 0.97$).

Table 3. The changes in the endothelial cell parameters during follow-up.

Parameters	Preoperative	1 year	4 years	7 years	p[a]
Central ECD (cells/mm2) (mean ± SD) (% of cumulative ECD loss)	2673.77 ± 314.54	2631.47 ± 322.92 (1.57)	2544.37 ± 288.87 (4.83)	2487.83 ± 320.22 (6.96)	<0.001*
Coefficient of variation of cell area (%)	32.58 ± 9.00	29.80 ± 7.82	27.52 ± 3.44	28.12 ± 4.12	0.08
Hexagonal cells (%)	67.44 ± 9.57	66.27 ± 7.74	66.73 ± 4.81	68.19 ± 5.53	0.45

ECD, endothelial cell density; SD, standard deviation.

[a]Repeated measures analysis of variance, p value for all visits. Post-hoc analysis: There was no significant difference between preoperative and the 1-year visit ($p = 1.0$). Significant difference was observed between the preoperative visit and the 4-year visit ($p = 0.03$). And there was a significant difference between the preoperative visit and the 7-year visit ($p = 0.001$).

Table 4. Postoperative complications.

Complication type	Eye (n)	Time	Treatment	Visual acuity
Intraocular pressure elevation	2 eyes	In the first three months	Topical antiglaucomatous medication	No change
Anterior subcapsular opacity	1 eye	4th year	No treatment	1 Snellen line loss
Posterior subcapsular opacity	2 eyes	7th year	No treatment	No change
Rhegmatogenous retinal detachment	1 eye	3rd year	Pneumatic retinopexy	No change
Myopic choroidal neovascular membrane	2 eyes	3rd and 6th years	Intravitreal anti-VEGF injection	3 and 2 Snellen lines loss

VEGF, vascular endothelial growth factor.

Two (5.6%) eyes acquired asymptomatic posterior subcapsular opacity at the 7th year visit (Figure 2A). Both of them showed no change in the Snellen line.

Retinal complications were observed in three eyes (8.3%). Rhegmatogenous retinal detachment (RRD) occurred in one eye (2.8%) 3 years after surgery. Pneumatic retinopexy was performed by perfluoropropane to treat this eye. Within three days, laser photocoagulation was used to treat the retinal break. After seven years of follow-up, there was no change in the Snellen line in this patient. In one eye (2.8%) after the third year and in one eye (2.8%) 6 years after surgery (Figure 2B, 2C and 2D), myopic choroidal neovascular membrane (CNVM) appeared. An intravitreal anti-vascular endothelial growth factor (VEGF) injection was done to these 2 eyes. However, these eyes lost 3 and 2 Snellen lines, respectively. At the 7th year visit, the CDVAs were 1 logMAR in both of them (Figure 2).

Discussion

This study reports the long-term clinical outcomes, efficacy, and safety of Eyecryl posterior chamber spherical pIOL for correction of high myopia. To the best of our knowledge, there is no study presenting such long-term follow-up of Eyecryl spherical pIOLs in the literature. Our results demonstrated that Eyecryl pIOL implantation provided mostly favourable outcomes in all

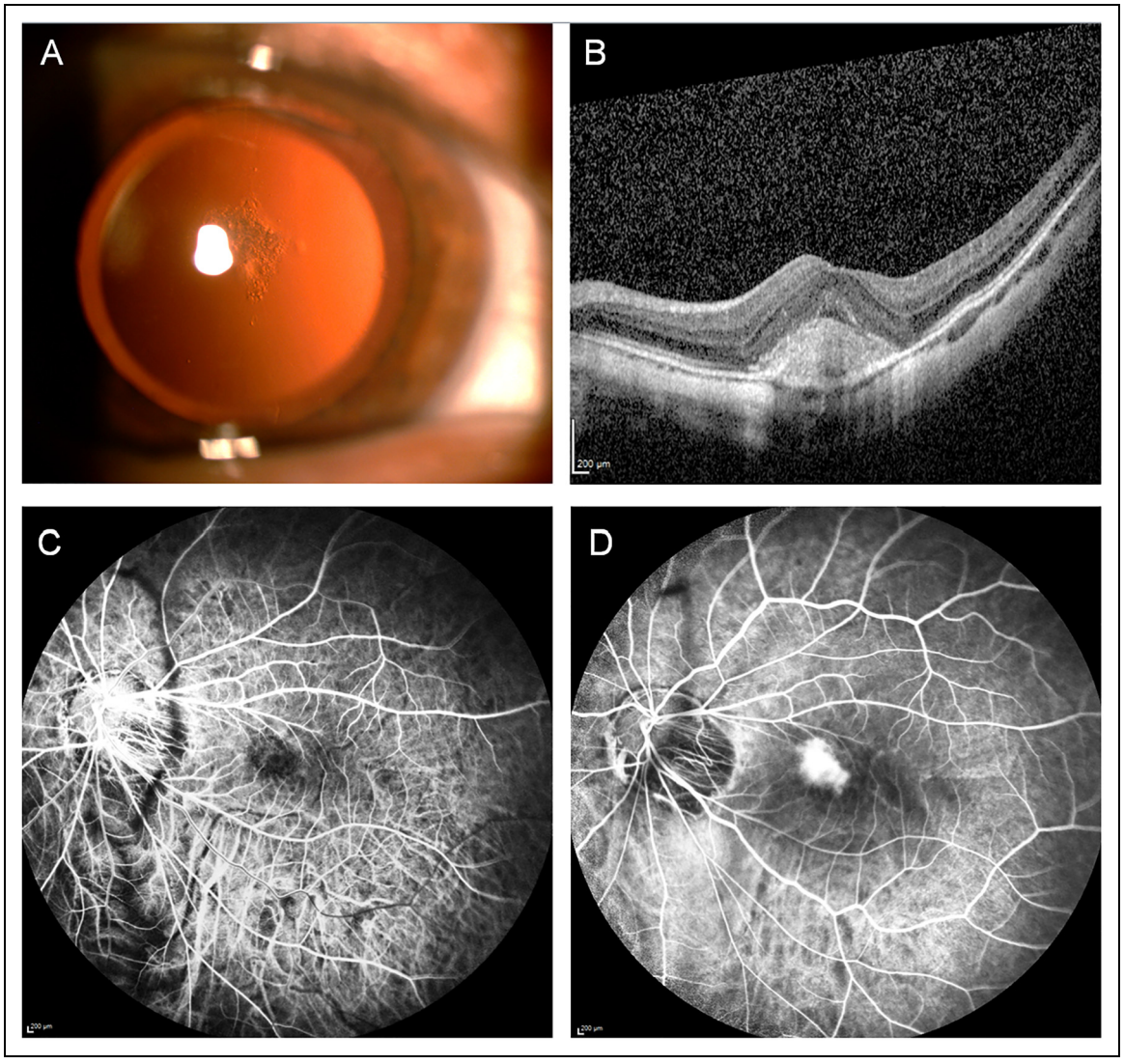

Figure 2. Examples of complicated cases. Anterior segment photograph of the case with posterior subcapsular opacity (A) Optical coherence tomography (B), early (C) and late phase (D) fundus fluorescein angiography of a case in which myopic choroidal neovascular membrane developed in the sixth postoperative year.

measures of safety, efficacy, predictability, and stability for the treatment of high myopia throughout the 7 years' follow-up.

Consistent with the literature and predictably, we found a significant improvement in UDVA at all visits after pIOL implantation.[1,4–6,8–17] The efficacy index was over 1 and similar at all visits, indicating that the postoperative UDVA was better than preoperative CDVA. At the 7th year visit, in 91% of the eyes, CDVA was preserved or improved. The safety index was >1 and similar at all visits, meaning that the postoperative CDVA was higher than preoperative CDVA. These results were in line with previous studies.[1,4,5,9,12,15,16]

The SE was significantly decreased after pIOL implantation as expected. However, significant myopic regression was noticed at the 4th year visit, although still lower than the preoperative period. The SE did not change significantly after this time point till the last visit in our study. Igarashi et al. noted significant myopic regression after ICL implantation in their 8-years follow-up study.[9] Similarly, Choi et al. detected a myopic shift 7 years after ICL implantation.[6] Nuclear sclerosis, corneal ectasia, compensatory epithelial hyperplasia, and AL elongation were thought to be among the possible causes of myopic regression after keratorefractive surgeries.[18] Saka et al. reported axial elongation in their study in which they followed 184 eyes with severe myopia for 8 years.[19] They added that there was a significant correlation between elongation in AL and ALs at baseline.[19] Although there was a significant increase in AL only at the first year visit compared to the previous one, we observed a sustained slight increase in AL at follow-up in our study. The myopic shift we observed in SE may

be due to AL elongation. Regarding the Eyecryl pIOL implantation's long-term predictability, 67% of the eyes were within 1.0 D of the attempted SE. Similar percentages were reported in previous studies.[1,12] The reason why 33% of eyes were outside the scope of 1.0 D of the attempted correction could be caused by the generation of myopic regression.[17]

In contrast to the typically used hydroxypropyl methylcellulose, 1% hyaluronic acid was utilized as the viscosurgical material in this study to prevent the IOP spikes.[20] The mean IOP was similar during 7 years' follow-up. Only two eyes had slight IOP elevation, which returned to normal within three months. The cause of early IOP elevation could be remnant ophthalmic viscosurgical device material or a response to steroid drops.[1] We did not observe pupillary block, and iridectomy was not required in the pre- or postoperative period. We think that the hole in the centre of Eyecryl pIOL allowing aqueous circulation has an effect on these outcomes.

Postoperatively, the ECD had a tendency to decrease and by the 4th year visit, this decrease had become significant. The cumulative ECD loss was 6.96% at the 7th year visit. A 6.2% rate of ECD loss was reported 8 years following ICL implantation by Igarashi et al.[9] Torun et al found a 5.8% ECD loss average 7 years after PRL implantation.[5] The rate of ECD reduction in normal eyes has been presented as approximately 0.6% per year.[21] This suggests that aging, rather than the endothelial cell damage put on by the implantation of an Eyecryl pIOL, is the primary factor of endothelial cell loss over the long term.[6]

In the literature, there are studies reporting that the vault height decreases significantly over time as the crystalline lens thickens with age.[1,6,16] Although the height of the central vault decreased gradually during the follow-ups in our study, there was no significant difference between the measurements, as reported by Nakamura et al.[17] Previous studies have emphasized the development of anterior lens opacity and reduction in the vault height.[6,16] In addition to the reduction in vault height, it has been suggested that poor aqueous circulation may also lead to malnutrition of the crystalline lens, resulting in opacities.[22] Eyecryl pIOL has a central hole, so it does not interfere with the aqueous circulation. However, in our study, anterior subcapsular opacity developed in one eye, and we noticed that the central vault height of this eye decreased from 0.51 mm in the 1st year to 0.23 mm in the 7th year.

Posterior subcapsular opacity was noticed at the 7th year visit in two eyes. They had no Snellen line loss. We suppose that posterior subcapsular opacities are a condition unrelated to pIOL, developing due to aging and high myopia.[23,24]

It is known that the risk of RRD is increased in high myopia compared to emmetropic population.[23] Choi et al. found RRD in 1 eye at a 10-year follow-up after ICL implantation.[6] Torun et al. reported 2 eyes suffered from RRD on average 7 years of follow-up after PRL implantation.[5] Moya et al. declared 5 eyes developed RRD during 12 years of follow-up after ICL implantation.[16] Arrevola-Velasco et al declared that ICL implantation surgery for high myopia did not affect the prevalence of RRD in operated eyes over 10 years compared with similar nonoperated eyes.[25] In our study, RRD occurred 3 years after pIOL implantation in an eye with an AL of 28.69 mm and a SE of −12.25 D. There should be a higher rate of RRD following pIOL implantation in myopic eyes compared to the natural history of equivalent degrees of myopia for there to be a causative link between pIOL implantation and the occurrence of RRD.[26] Furthermore, if RRD results from pIOL implantation as opposed to myopia itself, one would anticipate the RRD to happen early (<6 months) after surgery.[26] Due to all of these factors, we believe that the RRD is caused by the pathophysiological alterations brought on by high myopia rather than a complication with the implantation of the posterior chamber pIOL.

Myopic CNVM is another problem, especially for high myopes.[23] Moya et al. reported 3 eyes developed CNVM 4, 8, and 10 years after ICL implantation.[16] Al-Abdullah et al detected CNVM in 1 eye, which occurred more than 3 years after uneventful Artisan lens implantation.[26] There were two eyes in which we detected myopic CNVM in one at the 3rd year and the other at the 6th year. Following pIOL implantation, the rate of CNVM is within the range predicted for eyes with similar degrees of myopia.[26] We suppose that high myopia-related pathophysiological alterations lead to the development of CNVM.

The current study has a few limitations. The main limitation is its retrospective methodology. Since the number of patients meeting the inclusion criteria was not enough, both eyes of the same patient were included in the assessment.

In conclusion, our findings supported the long-term (7 years) stability, efficacy, and safety of the Eyecryl spherical pIOL implantation for high myopia. ECD and vault height both tended to decrease over time. To ensure safe and effective long-term outcomes following the implantation of an Eyecryl spherical pIOL, routine exams that evaluate visual acuity, refraction, changes in vault height, the presence of lens opacity, and monitoring of endothelial cells are important. Additionally, further prospective randomized studies with longer follow-ups are required to evaluate these issues.

Declaration of conflicting interests

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