J Appl Biomed
DOI: 10.32725/jab.2026.004
journal homepage: http://jab.zsf.jcu.cz

Journal of Applied Biomedicine

Original research article

Five-year outcomes of posterior chamber phakic implantable collamer lens implantation in high myopia, keratoconus, and post-keratoplasty eyes

Iveta Němcová [1, 2] *, Jiří Pašta [1, 2], Kateřina Hladíková [1, 2], Martin Komarc [2, 3], Darina Pospíšilová [1], Jan Havlík [1], Jan Tesař [1, 2], Vladimír Krátký [2, 4], Martin Šín [1, 2]

[1] *Military University Hospital Prague, Department of Ophthalmology, Prague, Czech Republic*
[2] *Charles University, 1st Faculty of Medicine, Prague, Czech Republic*
[3] *Charles University, Faculty of Physical Education and Sport, Department of Methodology, Prague, Czech Republic*
[4] *Queen's University, Kingston Health Sciences Centre, Kingston, Canada*

Abstract
Purpose: To report on a 5-year follow-up of Implantable Collamer Lenses (ICL) implantation and compare it to previously published iris-fixated phakic intraocular lenses (IF pIOLs).
Methods: We describe the refractive results and adverse events of 30 eyes in 18 patients with high myopia, keratoconus, or status post-keratoplasty (PKP), at one, two and five years after surgery.
Results: Efficacy and safety index were 0.94 and 1.04, respectively, at 5 years after surgery. Intraocular pressure (IOP) was significantly higher postoperatively ($p = 0.005$). The endothelial cell loss (EC loss) caused by the ICL implantation was found to be 3.82%, 5.03%, and 11.41%, at one-, two-, and five-years post-surgery. During a 5-year follow-up, 92% of eyes lost a higher percentage of endothelial cells (EC) than the expected physiological loss. Among eyes with >25% EC loss, all affected eyes at 2 years, and 80% at 5 years, had either keratoconus or history of keratoplasty prior to ICL implantation.
Postoperative EC loss positively correlated with preoperative keratometry and negatively with preoperative pachymetry. Significant inverse relationship was found between baseline and postoperative anterior chamber angle (ACA) and EC loss. Postoperative vault (388 ± 159 μm) showed a negative correlation with endothelial cell density (ECD) in 5-year follow-up. There was no cataract formation at 5 years postoperatively.
Conclusion: Compared to the IF pIOLs, the V4c ICLs have similar frequency of postoperative cataract formation but appear to be safer for the endothelium. Therefore, they are likely more suitable for keratoconus and PKP patients. However, the risk of long term IOP elevation seems to be higher.

Keywords: Endothelial cell density; Implantable Collamer Lens; Intraocular pressure; Iris-fixated phakic intraocular lens; Keratometry; Pachymetry

Highlights:
- ICL implantation appears safe and effective for the correction of myopia.
- The procedure appears endothelial-safe and suitable in stable corneal pathology.
- ICL implantation appears more endothelial-friendly than iris-fixated pIOLs.
- Careful postoperative monitoring of intraocular pressure is required.
- Postoperative monitoring of the anterior chamber angle is mandatory.

Introduction

Phakic intraocular lens (pIOL) implantation has been a powerful solution for moderate and high myopia for more than 30 years, particularly in patients with contraindications to excimer laser refractive surgery. The most common long-term complications include corneal endothelial cell loss (EC loss), cataract formation, and secondary glaucoma, the incidence of which may be reduced by careful preoperative assessment.

Between 2005 and 2010, we implanted iris-fixated pIOLs (IF pIOLs) in 85 eyes. As previously reported (Nemcova et al., 2021), the 12-year follow-up showed increased EC loss, particularly in eyes with lower corneal pachymetry.

* **Corresponding author:** Iveta Němcová, Military University Hospital Prague, Department of Ophthalmology, U Vojenské nemocnice 1200, Prague 6, Czech Republic; e-mail: Iveta.nemcova@uvn.cz
http://doi.org/10.32725/jab.2026.004
Submitted: 2026-02-12 • Accepted: 2026-05-10 • Prepublished online: 2026-06-09
J Appl Biomed 24/2: 72–80 • EISSN 1214-0287 • ISSN 1214-021X

Since 2012, posterior chamber EVO Implantable Collamer Lenses (ICL model V4c; STAAR Surgical) have been used at our institution. The V4c ICL model is composed of a highly biocompatible Collamer material with long-standing clinical use in ICLs; a collagen-containing hydrophilic copolymer that provides excellent optical quality and long-term intraocular stability. Furthermore, the incorporation of a central port (KS-Aquaport) to V4c ICL model allows physiological aqueous humor circulation, eliminating the need for peripheral iridotomy, and potentially reducing the risk of anterior subcapsular cataract formation and intraocular pressure elevation observed with earlier ICL models.

The aim of the present study is to analyse the 5-year outcomes of V4c ICL implantation in eyes with high myopia, keratoconus, and after keratoplasty (PKP), with a focus on the influence of anterior segment parameters on EC loss, intraocular pressure (IOP), and cataract formation. In addition, our results are discussed in the context of previously published outcomes of IF pIOL implantation, providing a comprehensive overview of long-term pIOL safety.

Materials and methods

Study design

We describe the results of our cohort study that includes a group of 30 eyes in 18 myopic patients, 10 men (56%) and 8 women (44%). All patients underwent implantation of the V4c ICL pIOL (Staar) from January 2012 to December 2016. We tracked their refractive results and postoperative complications (e.g., EC loss, intraocular pressure, cataract formation) over 5 years. All surgeries and subsequent measurements of postoperative results were performed by a single surgeon (JP) at the Department of Ophthalmology, Military University Hospital, Prague (Czech Republic). The study was approved by the Medical Ethics Committee at University Medical Centre in accordance with tenets of the Declaration of Helsinki.

Inclusion and exclusion criteria

We strictly adhered to the inclusion criteria that we had used in our previous publication on IF pIOLs (Nemcova et al., 2021). All patients had to be older than 18 years of age and their refractive error had to be stable for at least 1 year. The V4c ICL implantation was carried out only in patients in whom excimer laser surgery was contraindicated for correcting existing ametropia. The eligibility criteria for the operated eye were as follows: endothelial cell density (ECD) >2300 cells/mm^2, anterior chamber depth (ACD, measured from the endothelium to the anterior lens surface) >2.9 mm, anterior chamber angle (ACA) ≥38°, absence of iris or pupillary abnormalities, and mesopic pupil size <6 mm. In eyes with keratoconus or prior PKP, a lower ECD threshold was accepted because of the expected visual benefit, provided endothelial cell morphology was preserved (Table 1). For 3 post-PKP eyes, an ACA ≥30° was considered acceptable, consistent with the criterion used for IF pIOLs. The study cohort consisted of three subgroups: high myopia (24 eyes, 80%; 13 patients), post-PKP (3 eyes, 10%; 3 patients), and stable keratoconus (3 eyes, 10%; 2 patients). Keratometry value >47 D was detected in 5 eyes (17%) of 5 patients. None of the eyes had a previous scleroplasty procedure. No prophylactic laser photocoagulation was carried out in any of the patients.

As for exclusion criteria, we excluded glaucoma and IOP >21 mm Hg, active disease of the anterior eye segment, recurrent or chronic uveitis, any form of cataract, pre-existing macular pathology or abnormal retinal condition, as well as any systemic disease (autoimmune disorders, connective tissue disease, atopy and diabetes mellitus).

Types of pIOLs, power calculation, and surgical technique

The model V4c ICL has been commercially available since 2011. This is a single-piece posterior chamber phakic intraocular lens designed with a central port that allows sufficient aqueous flow from the posterior chamber to the anterior chamber, thereby maintaining the normal physiology of the anterior segment of the eye (Packer, 2018). We evaluated the results of 23 (77%) V4c and 7 (23%) toric versions of model V4c in our study.

The pIOL power calculation was carried out before lens implantation. The commonly used ICL surgical calculator is provided by the STAAR company online. It is based on keratometry, ACD, corneal thickness (CT) and the best spectacle corrected distance visual acuity (CDVA), including axis of cylinder, and is independent of axial length. We used the most common sizing method, which is based on the horizontal corneal white-to-white (WTW) distance and ACD and is automatically generated by the calculator. The lens is available in four sizes, with an overall length of 12.1, 12.6, 13.2, and 13.7 mm for the V4c model. The proper sizing is crucial for the safe postoperative vault (the distance between the ICL and anterior central part of the human lens) and for a stable position of the pIOL in the posterior chamber.

Three days before the surgery, Maxitrol (neomycini sulfas, polymyxini B sulfas, dexamethasonum, Alcon Laboratories Inc.) eye drops were prescribed five times daily. After mydriatic agents and topical anaesthesia were administered, ophthalmic dispersive viscosurgical device (OVD) was injected to fill the anterior chamber. The V4c ICL was inserted through a 3 mm superotemporal sclerocorneal incision parallel to the iris plane and allowed to unfold. Then the footplate at each corner of ICL was positioned gently under the iris, in case of toric ICL we respected the planned axis. Finally, OVD was washed out of the anterior chamber with balanced salt solution, and the corneal incisions were hydrated. Maxitrol was instilled in the eye for 10 days after surgery.

Outcome measurements

Our data were collected preoperatively, and 1, 2, and 5 years after the V4 ICL implantation. All preoperative data are given in Table 1.

Firstly, we concentrated on the refractive outcomes following V4c ICL implantation. The objective refraction was measured using an autorefractokeratometer (Nidek) and subjective refraction and visual acuity using a Snellen projection chart (Nidek). We compared preoperative corrected distance visual acuity (CDVA) with postoperative CDVA and uncorrected distance visual acuity (UDVA). We evaluated spherical equivalent (D) and cylinder (D) postoperatively and calculated the Safety Index (SI; mean postoperative CDVA/mean preoperative CDVA) and Efficacy Index (EI; mean postoperative UDVA/mean preoperative CDVA).

Secondly, we concentrated on the most frequent pIOLs postoperative complications, such as EC loss (measured using a single type of endothelial microscope, CSO), IOP changes (measured by non-contact tonometer, Topcon), and cataract formation. We also followed traumatic or spontaneous luxation and subluxation, which were common complications of IF pIOLs (Nemcova et al., 2021). We checked for the presence of retinal detachment. Patients were also asked about subjective complaints of glare and halo phenomena.

Table 1. Baseline characteristics of patients

Parameters at baseline	Mean ± SD [range]
No. of eyes	30
No. of patients	18
Age	30 ± 7 [20; 42]
Gender (male/female), No.	10/8
Sphere (D)	–8.39 ± 2.22 [–12; –2.75]
Cylinder (D)	1.98 ± 2.60 [0; 10.25]
CDVA, Snellen decimal scale	0.94 ± 0.13 [0.5; 1.0]
IOP (mmHg)	14.7 ± 2.51 [10; 20]
ACD from endothelium (mm)	3.41 ± 0.35 [3.03; 4.63]
Mean keratometry (D)	45.7 ± 4.31 [41.6; 63.9]
Mean corneal pachymetry (μm)	515 ± 74 [207; 605]
Anterior chamber angle (°)	41.8 ± 5.26 [32; 55.3]
WTW (mm)	12.2 ± 0.41 [11.5; 13]
ECD (cells/mm^2)	2431 ± 442 [1028; 3014]
Type of implanted lens	**No.**
V4c ICL (Staar)	23
V4c Toric ICL (Staar)	7

Note: SD, standard deviation; No., number; D, dioptres; CDVA, corrected distance visual acuity; IOP, intraocular pressure; ACD, anterior chamber depth; ECD, endothelial cell density; WTW, white-to-white distance

Thirdly, we focused on baseline topometric parameters such as keratometry, corneal pachymetry measured by Pentacam (Oculus), and white-to-white (WTW) distance measured concurrently by Pentacam (Oculus), IOL Master 500 (Zeiss), and manually by caliper to verify accuracy. Next, we registered baseline ACD and ACA and compared them with postoperative values from Pentacam (Oculus). Finally, we measured the vault using Scheimpflug tomography in Pentacam (Oculus) 5 years after V4c ICL implantation. We concentrated on the correlation of all mentioned topometric anterior segment data and their influence on postoperative complications.

Statistical analysis

For our initial analysis of descriptive statistics, we used standard measures of central tendency such as the mean and median, along with measures of dispersion like variance, standard deviation, and percentiles, as well as data shape statistics including kurtosis and skewness. To evaluate the repeated measures of refractive outcomes, UDVA, CDVA, and intraocular pressure, we conducted a one-way repeated measures analysis of variance, complemented by the least-significance-difference (LSD) *post-hoc* tests. Longitudinal changes in EC loss were examined using a linear mixed-effects model, with repeated measures nested within each eye and an autoregressive covariance matrix accounting for relationships among observed variables. We then expanded this model by including time-invariant covariates such as age, degree of myopia, keratometry, ACD, and pachymetry to explore the impact of baseline "risk-factors" on longitudinal changes in ECD. Bivariate associations were evaluated through Pearson's correlation coefficient, and level of statistical significance was set to $\alpha = 0.05$. All statistical analyses were conducted using IBM SPSS version 25.0 (Chicago, IL).

Results

Refractive results

All refractive results are summarised in Table 2. One year after surgery, refractive outcomes were excellent and mean refractive spherical equivalent (MRSE) showed a mild hyperopic shift. The MRSE remained stable at 2 years, followed by a small but statistically significant shift toward emmetropia between 2 and 5 years postoperatively. No statistically significant change in refractive cylinder was observed after ICL implantation, and cylinder values remained stable throughout the follow-up period.

Visual outcomes assessed by UDVA and CDVA are summarised in Table 3. Mean UDVA at 1 year postoperatively did not differ significantly from preoperative CDVA, while postoperative CDVA showed a significant improvement compared with baseline. A small but statistically significant decrease in CDVA was observed at 2 years, with stability thereafter up to 5 years. Mean UDVA showed a mild but significant decline between 2 and 5 years postoperatively.

Table 2. Refractive results

Time after the ICL pIOL implantation	No. of eyes	MRSE (D) Mean ± SD [range]	*P*-value	Cylinder (D) Mean ± SD [range]	*P*-value
1 year	29	0.13 ± 0.76 [–2.5; 1.0]	0.000	1.03 ± 0.86 [0.25; 3]	0.062
2 years	26	0.20 ± 0.71 [–1.5; 1.0]	0.244	1.14 ± 1.08 [0.25; 4]	0.085
5 years	26	0.04 ± 0.84 [–2.5; 1.0]	0.029	1.16 ± 1.14 [0.25; 4]	0.779

Note: ICL pIOL, implantable contact lens phakic intraocular lens; MRSE, mean refractive spherical equivalent; *P*-value, probability for comparison with the previous time point; No., number; SD, standard deviation; D, dioptres

Table 3. Postoperative visual acuity results (Snellen decimal scale)

Time after ICL pIOL implantation	No. of eyes	UDVA Mean ± SD [range]	*P*- value	CDVA Mean ± SD [range]	*P*-value
1 year	29	0.93 ± 0.15 [0.50; 1.10]	0.000	1.01 ± 0.10 [0.60; 1.10]	0.000
2 years	26	0.91 ± 0.17 [0.50; 1.10]	0.100	0.97 ± 0.11 [0.65; 1.10]	0.033
5 years	26	0.88 ± 0.22 [0.40; 1.10]	0.040	0.98 ± 0.12 [0.65; 1.10]	0.103

Note: ICL pIOL, implantable contact lens phakic intraocular lens; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; *P*-value, probability for comparison with the previous time point; No., number; SD, standard deviation

There was no progression of myopia greater than –1.0 D 5 years after the surgery, even in eyes with keratoconus or post-PKP. One eye (3%) required a limbal relaxing incision (LRI) for the residual astigmatism 3 months after the surgery.

Efficacy was assessed using cumulative visual acuity outcomes. The pooled median proportion of eyes achieving UDVA ≥20/40 at 1, 2, and 5 years was 100%, 100%, and 92%, respectively, while UDVA 20/20 was achieved in 62%, 62%, and 58% of eyes (Fig. 1). The efficacy index (EI) was 0.98, 0.97, and 0.94 at 1, 2, and 5 years postoperatively, respectively.

Safety analysis showed that 100% of eyes maintained or gained CDVA throughout the follow-up period (Fig. 2). The safety index (SI) was 1.07, 1.03, and 1.04 at 1, 2, and 5 years, respectively.

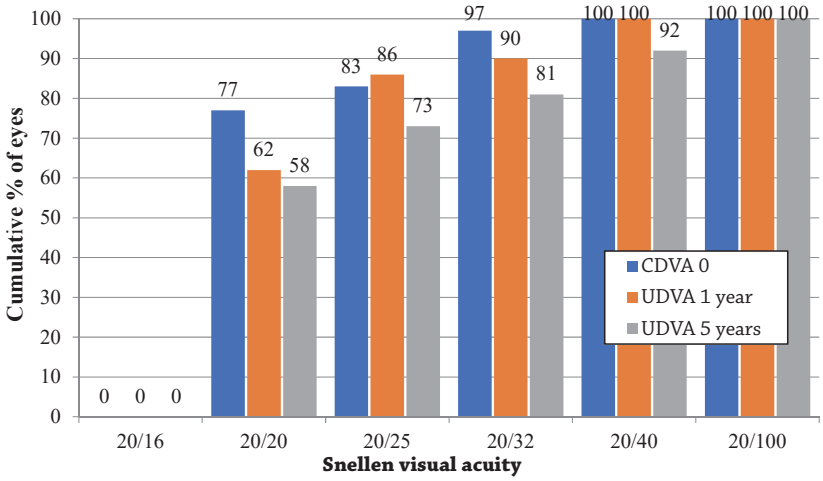

Fig. 1. Cumulative distance visual acuity

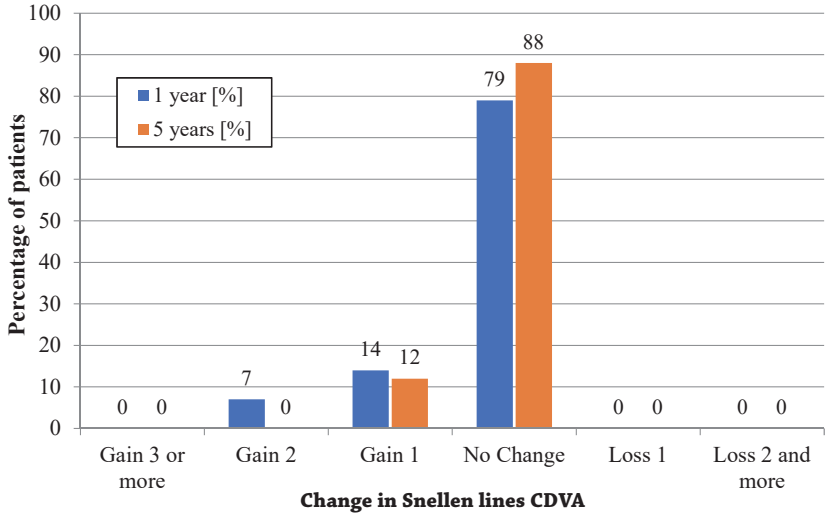

Fig. 2. Change in corrected distance visual acuity

Intraocular pressure

No cases of angle-closure glaucoma or pigment dispersion glaucoma were observed postoperatively in our cohort.

From the long-time perspective, a statistically significant increase in IOP was noted 5 years after V4c ICL implantation (Table 4). Baseline ACA and ACD had no significant effect on postoperative IOP (r = –0.133; p = 0.483 and r = 0.231; p = 0.202, respectively). Postoperative ACA and ACD values were significantly lower than preoperative ones (p < 0.01) (see Table 5), and the reduction in both parameters was positively correlated with postoperative IOP (r = 0.644; p < 0.0001 and r = 0.511; p = 0.004, respectively). The parameters of WTW and vault showed no significant effect on postoperative IOP (r = –0.031; p = 0.872 and r = –0.099; p = 0.604, respectively).

Adverse events

In our cohort, the incidence of cataract formation was 2 eyes (7%) of 1 patient. In this patient, cataract developed 10 years after the V4c ICL implantation (outside the scope of our follow-up period) and was treated by bilensectomy (consisting of explantation, phacoemulsification, and monofocal intraocular lens implantation) with an excellent result of UDVA 20/20. This patient had bilateral keratoconus and no other risk factors for cataract formation. Postoperative ACD was greater than 3 mm from the endothelium and the vault value was within normal range of 300–500 µm.

Another complication was incorrect positioning of the phakic intraocular lens. Overall, we had to perform implant repositioning in only 1 eye (3%), 3 months after toric V4c ICL

implantation due to incorrect lens axis alignment. There was no spontaneous or traumatic dislocation of the lens 5 years after the surgery.

High myopia is a known risk factor for peripheral retinal degeneration (PRD). In our cohort, no prophylactic retinal treatment was required, and no cases of PRD were observed during the 5-year follow-up.

Subjective satisfaction after V4c ICL implantation was high and there were only 2 eyes reporting bothersome phenomena such as glare or halo.

Table 4. Intraocular pressure

Time after the ICL pIOL implantation	No. of eyes	IOP, mm Hg Mean ± SD [range]	*P*-value
0 months	30	14.7 ± 2.51 [10; 20]	
1 year	30	15.23 ± 2.93 [7; 19]	0.279
5 years	26	16.31 ± 3.03 [10; 21.0]	0.005

Note: ICL pIOL, implantable contact lens phakic intraocular lens; No., number; IOP, intraocular pressure; SD, standard deviation; *P*-value, probability for comparison with the baseline values

Table 5. Anterior chamber angle

Time after the ICL pIOL implantation	No. of eyes	ACD (mm) Mean ± SD [range]	ACA (°) Mean ± SD [range]
0 months	30	3.41 ± 0.35 [3.03; 4.63]	41.8 ± 5.26 [32; 55.3]
5 years	26	3.23 ± 0.31 [2.64; 4.21]	29.3 ± 8.18 [15.6; 44.7]

Note: ICL pIOL, implantable contact lens phakic intraocular lens; No., number; ACD, anterior chamber depth from endothelium; ACA, anterior chamber angle; SD, standard deviation

Endothelial cell loss

Mean preoperative ECD value was 2431 ± 442 cells/mm^2. We recorded ECD at 1, 2, and 5 years after the implantation (Table 6, Fig. 3). We calculated total chronic EC loss and corrected it for a physiological EC loss 0.6% per year (0.6%, 1.2%, and 3% after 1, 2, and 5 years, respectively). All values of EC loss directly caused by V4c ICL presence were statistically significant ($p < 0.01$) – Table 6.

During the 2- and 5-year follow-up, 88% and 92% of eyes, respectively, showed EC loss exceeding the expected physiological decline.

The percentage of eyes with ≥25% endothelial cell loss was 8% at 2 years and 19% at 5 years after V4c ICL implantation. Among eyes with >25% EC loss, 2 eyes in 2 patients at 2 years (100%) and 4 eyes in 4 patients at 5 years (80%) had either keratoconus (1 eye and 2 eyes, respectively) or a history of keratoplasty (1 eye and 2 eyes, respectively) prior to ICL implantation.

At the 5-year follow-up, 5 eyes (19%) in 4 patients had an ECD <1500 cells/mm^2. All these cases were again associated with keratoconus (2 eyes in 1 patient) or previous keratoplasty (3 eyes in 3 patients). No patient with a preoperatively healthy cornea developed an ECD <1500 cells/mm^2.

Next, we focused on measurement of baseline and postoperative topometric parameters and their relationship to long-term postoperative EC loss using a mixed model analysis.

We found a significant inverse relationship between preoperative pachymetry and EC loss ($p = 0.045$), indicating that lower pachymetry leads to faster ECD decline. Conversely, a positive correlation was found between preoperative keratometry and postoperative EC loss ($p = 0.009$), suggesting more intensive EC loss in patients with steeper corneas. A significant inverse relationship was found between baseline and postoperative ACA and EC loss ($p = 0.019$), suggesting that lower ACA values before and after ICL implantation may contribute to higher EC loss. Baseline and postoperative ACD values were not found to be associated with postoperative EC loss ($p = 0.229$ and $p = 0.388$, respectively). The mean postoperative vault value was 388 ± 159 [160; 810] μm at the 5-year follow-up. It showed negative correlation with postoperative ECD ($r = –0.407$; $p = 0.039$), pointing to higher vault values as a potential contributor to EC loss.

The WTW parameter showed no significant effect on postoperative EC loss ($p = 0.825$).

Table 6. Endothelial cell density after the ICL pIOL implantation

Time after the ICL pIOL implantation	No. of eyes	ECD (cells/mm^2) Mean ± SD [range]	EC loss (%)	Corrected EC loss (%)*
1 year	30	2331 ± 425 [1370; 3010]	4.12	3.82
2 years	26	2264 ± 519 [963; 2986]	5.63	5.03
5 years	26	2051± 550 [706; 2986]	14.41	11.41

Note: ICL pIOL, implantable contact lens phakic intraocular lens; No., number; ECD, endothelial cell density; EC loss, endothelial cell loss;
* Endothelial cell loss corrected to physiological endothelial cell loss; SD, standard deviation

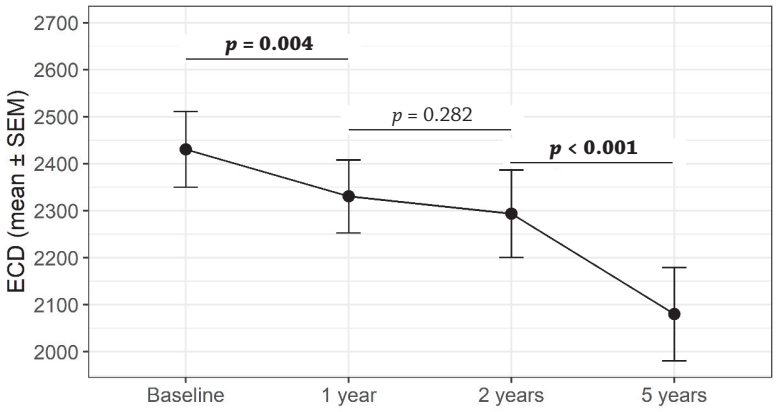

Fig. 3. Mean endothelial cell density (ECD, cells/mm^2) from the preoperative status to 5-year postoperative status in eyes implanted with ICL pIOLs

Discussion

Refractive results

Postoperative visual acuity demonstrated high predictability, with a slight myopic shift at 5 years following ICL implantation, in line with our previously reported IF pIOL outcomes (Nemcova et al., 2021). Postoperative toric measurements also showed high predictability and stable outcomes. This was supported by stable keratometry values in keratoconus and post-PKP eyes throughout the postoperative period. At 5 years postoperatively, EI was lower (0.94) than in our IF pIOL cohort (1.03). This was likely influenced by corneal pathologies (20% of eyes) in ICL group. However, the SI of the ICL group was very high (1.04) and comparable with the IF pIOL group (1.10). Alfonso et al. (2009) reported ICL implantation as a viable treatment for myopia and astigmatism after PKP. He recommended excluding eyes with ACD less than 3 mm. Despite a low mean preoperative ECD (1660 cells/mm^2), high predictability was demonstrated, with EI 1.02 and SI 1.58 at 24 months postoperatively. Regarding ICL implantation in eyes with keratoconus, Emerah et al. (2019) considered the procedure safe and predictable. Eligible patients were ≥21 years old, had stable refraction for at least 1 year after corneal cross-linking or intracorneal ring segment implantation, a clear central cornea, and demonstrated significant CDVA improvement with refraction. Because toric ICLs do not correct higher-order aberrations caused by irregular corneal shape, surgery was recommended only in early-stage keratoconus. Compared to our study, he reported similar effectivity (93%), but lower safety (93%). In contrast, Li et al. (2020) reported results on subclinical keratoconus and ICL implantation with very satisfactory outcomes for EI (1.19) and SI (1.24). In agreement with our findings, both authors emphasise that refractive outcomes depend on accurate manifest refraction and intraoperative axis alignment measurements, and that ICL calculation could be challenging in moderate and advanced keratoconus.

Intraocular pressure

In posterior chamber pIOL patients, IOP may rise in the first few hours after ICL implantation due to narrowing of the ACA caused by mydriasis (Hu et al., 2020). Steroid response, retained viscoelastic material, and pupillary block are the most common causes of intraocular pressure elevation in first postoperative days (Senthil et al., 2016). In our series, pupillary block was minimised by the presence of a central port in the V4c ICL model, which is considered safer than iridotomies required in older models (Senthil et al., 2016). There was no case of early IOP elevation in our group of V4c ICL patients.

Findings from published studies suggest that long-time elevated IOP is a relatively rare complication in patients with posterior chamber pIOLs (Naujokaitis et al., 2023). Guber et al. (2016) reported that 12.9% of eyes implanted with V4 ICLs without a central port required topical medication 10 years postoperatively. One possible explanation was pigment dispersion caused by friction between the ICL and the iris and excessive vaulting (normal vault range: 190–740 μm). Therefore, postoperative monitoring of the anterior chamber angle in patients with high vault is strongly recommended. However, the incidence of pigment dispersion glaucoma is quite rare in high volume studies. Sanders et al. (2004) reported 2 eyes out of 526 (0.4%) with increased IOL requiring treatment 3 years postoperatively. No pigment dispersion was observed in our V4c ICL group and the mean postoperative vault in our patients was close to normative values.

We observed a statistically significant increase in IOP 5 years after V4c ICL implantation; however, all values remained within the normal range, and no patient required antiglaucoma treatment during follow-up. Consistent with Qian et al. (2023), postoperative IOP was associated with ACA. In contrast to their findings, we observed an association between postoperative ACD reduction and IOP. These results highlight the importance of long-term IOP monitoring, as progressive crystalline lens thickening may further decrease ACD and ACA over time and potentially influence IOP. From our perspective, V4c ICL implantation appears less safe with respect to long-term IOP outcomes compared with IF pIOL implantation, as no long-term IOP elevation has been reported for IF pIOLs in the literature. This is supported by our own previous dataset, where we observed no long-term statistically significant change in IOP, even 12 years after IF pIOL surgery (Nemcova et al., 2021).

Adverse events

Cataract formation

Early postoperative cataract formation may result from inadvertent surgical trauma. Igarashi et al. (2022) reported a 6.8% rate of anterior subcapsular cataract developing immediately after the surgery. We noted a focal type of subcapsular lens opacification just beneath the central port in one eye of

a patient, who was not included in our study due to a short follow-up period. In agreement with Igarashi's findings, the opacification did not progress and remains asymptomatic to date (i.e., 2 years after the surgery).

Long-term cataract development was associated with earlier V2 and V4 ICL models, which lacked a central port. Guber et al. (2016) found lens opacities in 40.9% of eyes at 5 years and in 54.8% of eyes at 10 years after the V4 ICL implantation. The proposed causes for these late-appearing lens opacities include alterations in aqueous humor circulation and intermittent lens touching. To improve aqueous humor flow, the manufacturer updated the design of the lens by including a central hole (Naujokaitis et al., 2023, Packer, 2018). This newer type of model, the ICL V4c, was implanted in our cohort, and so far, no cataract formation has been observed at 5 years postoperatively. One of our patients underwent successful both-eyes bilensectomy for cataract formation at 10 years after the implantation. Our findings are supported by other studies. Wannapanich et al. (2023) published a 0.6% rate of cataract formation at 5 years postoperatively using the hole-ICL model, reflecting the technical improvements in lens design. Finally, our current outcomes after V4c ICL implantation were comparable to our previously published results after IF pIOL implantation (Nemcova et al., 2021). In that cohort, cataract formation was observed in 0% of eyes at 5 years and 3.5% at 12 years, indicating similarly favourable outcomes.

The rotational stability of the V4c ICL is extremely high. Lee et al. (2018) posted an absolute rotational change of 2.81° immediately after the implantation, and 3.87° at 6 months postoperatively. Wei et al. (2023) demonstrated that the degree of ICL rotation is negatively correlated with postoperative vault and positively correlated with preoperative ACD. In our cohort, we adjusted the lens position in only one case, 3 months after implantation, with satisfactory result. In contrast, among eyes implanted with IF pIOLs, 28% required repositioning or re-enclavation, and 7% experienced lens luxation due to trauma. We observed no spontaneous or traumatic subluxation or luxation in the V4c ICL group.

The occurrence of bothersome visual phenomena such as glare and halos was rare in both of our groups: 7% in the V4c ICL group and 2.3% in the IF pIOL group (the latter related to the 5-mm optic diameter), with an additional 1.2% attributed to iridotomy effects (Nemcova et al., 2021). Niu et al. (2022) reported that small horizontal tilt and decentration of the ICL are positively correlated with subjective visual symptoms and may contribute to postoperative aberrations.

EC loss

Montés-Micó et al. (2021) compared long-time EC loss of new V4c ICL model with data from earlier designs lacking a central port and found that the newer model performed significantly better. Shimizu et al. (2016) reported 0.5% loss at 3 years and Alfonso et al. (2019) 0.5% at 5 years postoperatively. These authors suggested that most EC loss occurs immediately after implantation and is primarily attributable to surgical trauma rather than to long-term effects of the lens itself. On the other hand, a recently published meta-analysis by Kisiel and Gurumurthy (2024) included 18 studies and reported a higher average EC loss: 3.84% 2 years after V4c ICL implantation. Similarly, Yang et al. (2021) noted that a 4.03% EC loss, 4 years after V4c ICL implantation significantly correlated with vault height and postoperative changes in ACA and ACD value.

In our study, after subtracting the expected physiological EC loss, the remaining EC loss attributable to the V4c ICL was statistically significant and exceeded that reported in high-volume studies. This discrepancy can be explained by the fact that 100% and 80% of eyes with >25% EC loss at the 2- and 5-year follow-up, respectively, had keratoconus or had previously undergone PKP before ICL implantation.

Alhamzah et al. (2021) noted a tendency toward higher vault values particularly in keratoconus. Currently, the cornea in keratoconus exhibits altered biomechanical properties, making it softer and more susceptible to deformation (Li et al., 2020). Corneal biomechanics can now be assessed using Corneal Visualisation Scheimpflug Technology (CorVis ST, Oculus). In our V4c ICL cohort, steeper corneas and lower pachymetry values were significantly associated with a faster decline in ECD. We observed similar patterns after IF pIOLs implantation (Nemcova et al., 2021), suggesting that mechanical deformation related to eye rubbing may play a role. Corneas with lower pachymetry and steeper keratometry deform more readily, potentially causing transient anterior chamber shallowing and intermittent contact between the pIOL and the endothelium. In this context, Alfonso-Bartolozzi et al. (2022) reported very low EC loss (2.27%) at 3 years after V4c ICL implantation in deep anterior lamellar keratoplasty patients, in whom corneal biomechanics had been normalised.

Alfonso et al. (2009) evaluated ICL implantation in 15 post-PKP eyes and reported good outcomes, although the mean EC loss reached 8.1% at 24 months. Similarly, Alió et al. (2015) recommended pIOL implantation in post-PKP patients with regular astigmatism and clear crystalline lens. Both authors (Alfonso et al., 2009; Alió et al., 2015) emphasised the reversibility of the procedure. We took these findings into account during the patient selection process for ICL implantation in complex cases. Despite the high proportion of keratoconus and post-PKP in our V4c ICL group, EC loss results were better than those previously reported in our IF pIOL cohort, where EC loss reached 6.0%, 8.1%, 12.8%, at 1-, 2- and 5-years post-implantation, respectively (Nemcova et al., 2021).

Our study showed that baseline and postoperative ACD values had no correlation with postoperative EC loss. Apart from IF pIOLs, the relationship between ACD and EC loss in posterior chamber pIOLs has not yet been clearly established in the literature (Naujokaitis et al., 2023). Niu et al. (2019) published outcomes of ICL implantation to eyes with preoperatively shallow ACD (<2.8 mm, measured from endothelium). Although they observed a relatively high EC loss of 8.38% at 15 months postoperatively, they found no correlation between ACD and changes in ECD.

In our V4c ICL cohort, there was a statistically significant decrease in ACA from baseline to the postoperative examination. Both preoperative and postoperative ACA were identified as risk factors for postoperative EC loss. Similar findings have been reported in several studies (Fernández-Vigo et al., 2016; Yang et al., 2021). Fernández-Vigo et al. (2016) demonstrated that ACA narrowing may be caused by contact between the haptics of the V4c ICL and the posterior iris surface.

Although vault values in our cohort remained within a relatively safe range, we found a negative correlation between vault height and postoperative ECD. Multiple regression analysis indicated that vault may play a major role in ECD changes (Fernandes et al., 2011). Several publications have recommended adhering to safe limits for preoperative ACD measurements, as the safety zone for vault appears to be narrower in eyes with shallow anterior chambers (Qian et al., 2023).

WTW, preoperative spherical error, and patient age showed no association with long-term endothelial cell loss, confirming

that refractive magnitude is irrelevant for corneal endothelial safety, consistent with previous IF pIOL studies (Nemcova et al., 2021).

Overall, our findings suggest that endothelial cell loss is primarily influenced by underlying corneal pathology, particularly in eyes with keratoconus or post-PKP, as well as by unfavourable corneal characteristics such as lower pachymetry and steeper keratometry, together with anterior segment configuration, including ACA and postoperative vault.

The relatively small and heterogeneous sample represents a limitation of this study and may affect the generalisability of the results. Findings in keratoconus (n = 3) and post-keratoplasty (n = 3) subgroups should be interpreted with caution.

Conclusion

V4c ICL implantation provides rapid and durable visual rehabilitation with favourable long-term safety and predictability. Compared with IF pIOLs, it demonstrates superior endothelial preservation with a comparable incidence of cataract formation and better long-term positional stability. V4c ICLs are an effective option for high myopia and for refractive correction in eyes with stable keratoconus or after penetrating keratoplasty, provided appropriate counselling and protective measures are in place. Careful patient selection, strict adherence to anterior segment safety parameters (ACA, ACD, vault), with particular attention to the anterior chamber angle and peripheral lens position, as well as long-term monitoring of both intraocular pressure and corneal endothelial status, are essential to ensure sustained safety. A major strength of this study is the long-term follow-up. Further studies with larger patient cohorts are warranted to confirm these findings.

Acknowledgement
The research was performed as a part of the authors' employment at Ophthalmology Department of Military University Hospital in Prague (Czech Republic).

Data availability
Data are available from the corresponding author upon reasonable request.

AI statement
No generative AI tools were used.

Ethical aspects and conflict of interest
The authors have no conflict of interest to declare.

References

Alfonso JF, Fernández-Vega-Cueto L, Alfonso-Bartolozzi B, Montés-Micó R, Fernández-Vega L (2019). Five-Year Follow-up of Correction of Myopia: Posterior Chamber Phakic Intraocular Lens with a Central Port Design. J Refract Surg 35(3): 169–176. DOI: 10.3928/1081597X-20190118-01.

Alfonso JF, Lisa C, Abdelhamid A, Montés-Micó R, Poo-López A, Ferrer-Blasco T (2009). Posterior chamber phakic intraocular lenses after penetrating keratoplasty. J Cataract Refract Surg 35(7): 1166–1173. DOI: 10.1016/j.jcrs.2009.02.027.

Alfonso-Bartolozzi B, Lisa C, Fernández-Vega-Cueto L, Baamonde B, Madrid-Costa D, Alfonso JF (2022). Three-year follow-up of posterior chamber phakic intraocular lens with a central port design after deep anterior lamellar keratoplasty. Eye Vis (Lond) 9(1): 34. DOI: 10.1186/s40662-022-00306-1.

Alhamzah A, Alharbi SS, Alfardan F, Aldebasi T, Almudhaiyan T (2021). Indications for exchange or explantation of phakic implantable collamer lens with central port in patients with and without keratoconus. Int J Ophthalmol 14(11): 1714–1720. DOI: 10.18240/ijo.2021.11.10.

Alió JL, Abdou AA, Abdelghany AA, Zein G (2015). Refractive surgery following corneal graft. Curr Opin Ophthalmol 26(4): 278–287. DOI: 10.1097/ICU.0000000000000161.

Emerah SH, Sabry MM, Saad HA, Ghobashy WA (2019). Visual and refractive outcomes of posterior chamber phakic IOL in stable keratoconus. Int J Ophthalmol 12(5): 840–843. DOI: 10.18240/ijo.2019.05.22.

Fernandes P, González-Méijome JM, Madrid-Costa D, Ferrer-Blasco T, Jorge J, Montés-Micó R (2011). Implantable collamer posterior chamber intraocular lenses: a review of potential complications. J Refract Surg 27(10): 765–776. DOI: 10.3928/1081597X-20110617-01.

Fernández-Vigo JI, Macarro-Merino A, Fernández-Vigo C, Fernández-Vigo JA, Martínez-de-la-Casa JM, Fernández-Pérez C, García-Feijóo J (2016). Effects of Implantable Collamer Lens V4c Placement on Iridocorneal Angle Measurements by Fourier-Domain Optical Coherence Tomography. Am J Ophthalmol 162: 43–52.e1. DOI: 10.1016/j.ajo.2015.11.010.

Guber I, Mouvet V, Bergin C, Perritaz S, Othenin-Girard P, Majo F (2016). Clinical Outcomes and Cataract Formation Rates in Eyes 10 Years After Posterior Phakic Lens Implantation for Myopia. JAMA Ophthalmol 134(5): 487–494. DOI: 10.1001/jamaophthalmol.2016.0078.

Hu Z, Chen C, Sun M, Yuan R, Ye J (2020). The Relationship between Anterior Chamber Angle and Intraocular Pressure Early after V4c Implantable Collamer Lens Implantation. J Ophthalmol 2020: 4014512. DOI: 10.1155/2020/4014512.

Igarashi A, Kamiya K, Ichikawa K, Kitazawa Y, Kojima T, Nakamura T, Shimizu K (2022). Multicenter clinical outcomes of hole implantable collamer lens implantation in middle-aged patients. Sci Rep 12(1): 4236. DOI: 10.1038/s41598-022-08298-7.

Kisiel FB, Gurumurthy GJ (2024). Endothelial cell loss post-implantable collamer lens V4c: meta-analysis. J Cataract Refract Surg 50(4): 420–423. DOI: 10.1097/j.jcrs.0000000000001389.

Lee H, Kang DSY, Choi JY, Ha BJ, Kim EK, Seo KY, Kim TI (2018). Rotational Stability and Visual Outcomes of V4c Toric Phakic Intraocular Lenses. J Refract Surg 34(7): 489–496. DOI: 10.3928/1081597X-20180521-01.

Li K, Wang Z, Zhang D, Wang S, Song X, Li Y, Wang MX (2020). Visual outcomes and corneal biomechanics after V4c implantable collamer lens implantation in subclinical keratoconus. J Cataract Refract Surg 46(10): 1339–1345. DOI: 10.1097/j.jcrs.0000000000000262.

Montés-Micó R, Ruiz-Mesa R, Rodríguez-Prats JL, Tañá-Rivero P (2021). Posterior-chamber phakic implantable collamer lenses with a central port: a review. Acta Ophthalmol 99(3). DOI: 10.1111/aos.14599.

Naujokaitis T, Auffarth GU, Łabuz G, Kessler LJ, Khoramnia R (2023). Diagnostic Techniques to Increase the Safety of Phakic Intraocular Lenses. Diagnostics (Basel) 13(15): 2503. DOI: 10.3390/diagnostics13152503.

Nemcova I, Pasta J, Hladikova K, Komarc M, Pospisilova D, Nemec P, et al. (2021). Myopic Correction with Iris-Fixated Phakic Intraocular Lenses: Twelve-Year Results. J Ophthalmol 2021: 7027793. DOI: 10.1155/2021/7027793.

Niu L, Miao H, Han T, Ding L, Wang X, Zhou X (2019). Visual outcomes of Visian ICL implantation for high myopia in patients with shallow anterior chamber depth. BMC Ophthalmol 19(1): 121. DOI: 10.1186/s12886-019-1132-z.

Niu L, Zhang Z, Miao H, Zhao J, Li M, He JC, Yao P, Zhou X (2022). Effects of tilt and decentration of Visian Implantable Collamer Lens (ICL V4c) on visual quality: an observational study. BMC Ophthalmol 22(1): 294. DOI: 10.1186/s12886-022-02499-4.

Packer M (2018). The Implantable Collamer Lens with a central port: review of the literature. Clin Ophthalmol 12: 2427–2438. DOI: 10.2147/OPTH.S188785.

Qian T, Du J, Ren R, Zhou H, Li H, Zhang Z, Xu X (2023). Vault-Correlated Efficacy and Safety of Implantable Collamer Lens V4c Implantation for Myopia in Patients with Shallow Anterior Chamber Depth. Ophthalmic Res 66(1): 445–456. DOI: 10.1159/000528616.

Sanders DR, Doney K, Poco M; ICL in Treatment of Myopia Study Group (2004). United States Food and Drug Administration clinical trial of the Implantable Collamer Lens (ICL) for moderate to high myopia: three-year follow-up. Ophthalmology 111(9): 1683–1692. DOI: 10.1016/j.ophtha.2004.03.026.

Senthil S, Choudhari NS, Vaddavalli PK, Murthy S, Reddy JC, Garudadri CS (2016). Etiology and Management of Raised Intraocular Pressure following Posterior Chamber Phakic Intraocular Lens Implantation in Myopic Eyes. PLoS One 11(11): e0165469. DOI: 10.1371/journal.pone.0165469. Erratum in: PLoS One 2017 12(2): e0172929. DOI: 10.1371/journal.pone.0172929.

Shimizu K, Kamiya K, Igarashi A, Kobashi H (2016). Long-Term Comparison of Posterior Chamber Phakic Intraocular Lens With and Without a Central Hole (Hole ICL and Conventional ICL) Implantation for Moderate to High Myopia and Myopic Astigmatism: Consort-Compliant Article. Medicine (Baltimore) 95(14): e3270. DOI: 10.1097/MD.0000000000003270.

Wannapanich T, Kasetsuwan N, Reinprayoon U (2023). Intraocular Implantable Collamer Lens with a Central Hole Implantation: Safety, Efficacy, and Patient Outcomes. Clin Ophthalmol 17: 969–980. DOI: 10.2147/OPTH.S379856.

Wei PH, Li J, Jiao XL, Yu Z, Song H (2023). Short-term clinic observation of misalignment and rotational stability after implantable collamer lens implantation. Graefes Arch Clin Exp Ophthalmol 261(5): 1473–1481. DOI: 10.1007/s00417-022-05929-7.

Yang W, Zhao J, Sun L, Zhao J, Niu L, Wang X, Zhou X (2021). Four-year observation of the changes in corneal endothelium cell density and correlated factors after Implantable Collamer Lens V4c implantation. Br J Ophthalmol 105(5): 625–630. DOI: 10.1136/bjophthalmol-2020-316144.