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REFRACTIVE SURGERY

# Initial clinical outcomes of two different phakic posterior chamber IOLs for the correction of myopia and myopic astigmatism

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## Abstract

**Purpose** The purpose of this study is to document clinical outcomes of 2 posterior chamber phakic intraocular lenses with a central hole, the implantable contact lens (IPCL V2.0) and the Visian implantable collamer lens V4c (ICL), in myopic and myopic-astigmatic patients.

**Methods** Retrospective study comprising 111 IPCL (60 toric) and 106 ICL implantations (59 toric) with a follow-up of 3 months to 2 years. Primary outcome was uncorrected distance visual acuity (UDVA) improvement; secondary outcomes were changes in corrected distance visual acuity (CDVA), and complications.

**Results** At 3 months postoperatively, 76% of plano targeted eyes in the IPCL group and 83% of eyes in the ICL group had a UDVA of 20/20 or better. Ninety-six percent of IPCL implanted eyes and 94% of ICL implanted eyes had a postoperative UDVA within 1 line of preoperative CDVA. One eye lost one line of CDVA after IPCL implantation, and no lines were lost after ICL implantation; 33.7% of IPCL eyes and 40.6% of ICL eyes gained at least 1 line of CDVA. Cataract extraction (none because of anterior subcapsular opacification) was performed after 4 ICL implantations, none after IPCL implantation. Endothelial cell loss was mild with both pIOLs. Mean IOP was not clinically significantly affected at 3 months or thereafter.

**Conclusions** We observed equally excellent (statistically not different) results with the IPCL and ICL for the correction of myopia and myopic astigmatism, at least up to 2 years post implantation. Longer follow-up is needed to determine the stability of these results especially with the IPCL.

**Keywords** Implantable contact lens · IPCL · Visian implantable collamer lens · ICL

**Key messages**

**What is known:**

- The implantable collamer lens (ICL) is a safe and effective option to correct moderate and high myopia and astigmatism.

**What is new:**

- The Implantable phakic contact lens (IPCL) yielded equally excellent initial results in terms of safety, efficacy, and adverse events. The IPCL may become an alternative option to the ICL.

## Introduction

Phakic intraocular lenses (IOLs) are a popular treatment modality for the correction of refractive errors, especially when laser vision correction may not be a preferrable option. More than 30 years after their introduction, posterior chamber phakic IOLs have shown reasonable safety

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and efficacy [1, 2]. Advantages of posterior chamber phakic IOLs over keratorefractive methods include a wider range of dioptric correction [3] and their removability. The main advantage over refractive lens exchange is the continued use of accommodative capacity in younger patients [4]. Potential complications of phakic IOLs include damage to the endothelium or crystalline lens, acute or chronic rise of intraocular pressure, and (though overall rare) endophthalmitis [5, 6].

The Visian implantable collamer lens (ICL; Staar surgical, Nidau, Switzerland) has virtually become synonymous with posterior chamber phakic IOL because of its worldwide predominant use; in the USA, it is the only available phakic IOL at present. The ICL was introduced in 1993 and is currently available in dioptric powers from + 10 diopters (D) to − 20 D together with a torus of up to 6 D. The current version (V4c) has a hole in the center of myopic optics to facilitate aqueous humor circulation, thus obviating the need to perform iridotomies or iridectomies in order to prevent pupillary blocks with the exception of rare case reports [7, 8]. In Europe, a new variant of the ICL gained CE-certification for the surgical correction of presbyopia in 2020. Among the patient groups in which the ICL was successfully implanted were myopic children with special needs [9] and individuals who previously had undergone one of the earliest keratorefractive procedures, radial keratometry [10]. The study that led to the FDA approval of the ICL demonstrated after 3 years an UDVA of 20/20 or better in 40.8% and of 20/80 or better in 81% of eyes. [2] After 4 years of follow-up, a UDVA of 20/20 or better was reported in 73% of eyes by Igarashi et al. [11]; another study by Alfonso et al. with a 5-year follow-up demonstrated UDVA of 20/40 or better in 68% of eyes [12].

In recent years, however, some other phakic IOLs have demonstrated promising results [13–15].

One of these newer phakic IOLs is the implantable phakic contact lens (ICPL, Caregroup Sight Solution, Baroda, India). This hydrophilic hybrid acrylic IOL has been introduced in 2012 with refractive powers between + 15 D and − 30 D in sphere and up to 12 D in cylinder. The IPCL in its current version V2.0 is distributed mainly in Asian and European countries. Similar to the ICL, the IPCL has a hole in the center in minus powers and up to + 3.5 D in plus lenses (in addition, also two holes in the superior part of the optic that are covered by the upper lid). A presbyopia correcting version is also available [16, 17].

However, studies comparing the IPCL to the ICL in the same clinical setting are warranted [18].

We started to implant the ICL in 2011 as soon as the new design with a central port became available and the IPCL in 2017 because of its wider range of powers. The aim of this study was to document clinical outcomes of the current versions of both posterior chamber phakic IOLs in myopic and myopic-astigmatic patients.

## Patients and methods

This retrospective, consecutive case series was conducted at the Center for Refractive Surgery, Eye Department at St. Francis Hospital Münster, Germany. All implantations of posterior chamber IOLs with a central hole into phakic eyes performed by a single surgeon (S.T.) since 2011 were reviewed, excluding presbyopia correcting versions of these IOLs and eyes with a shorter follow-up than 3 months.

The local Ethics Committee ruled that formal approval was not required because the study protocol used only retrospective and anonymized patient data. The study adhered to the tenets of the Declaration of Helsinki. A written informed consent was obtained from all patients for the surgical procedure and the potential use of anonymized data for scientific purposes. At the time of surgery, both IOLs were only approved for use in patients between 21 and 45 years of age. If a patient was outside of this range, a specific consent was obtained (meanwhile, the ICL and the presbyopia correcting version of the IPCL have been approved for ages of up to 59 years).

This study comprises 111 IPCL implantations (60 of which were toric) and 106 ICL implantations (59 of which were toric) for the correction of myopia or myopic astigmatism. Patient demographics are shown in Table 1.

Exclusion criteria for phakic IOL implantation were patients with disease progression, internal anterior chamber depth less than 2.8 mm, no visual acuity improvement with refraction or pinhole, endothelial cell count less than 2000 cells/mm$^2$, visually significant cataract, retinal or neuro-ophthalmic diseases and ocular inflammation, pregnant, or breast-feeding patients. For surgical planning, we measured the horizontal white-to-white distance, keratometry, and anterior chamber depth using the Orbscan IIz (Bausch & Lomb Technolas, Munich, Germany) and/or the Pentacam AXL (Oculus, Wetzlar, Germany). The Pentacam was used after 2016, before a IOL-Master 500 (Carl Zeiss Meditec, Jena, Germany) was used.

Lens calculation was done by the IOL company with white-to-white measurements from 2 different devices, and the surgeon generally selected the recommended lens size together with the closest available residual refractive outcome to emmetropia. In patients older than 45 years, the closest available myopic outcome was preferred. If residual myopia was targeted, then these eyes were included in the analysis of best corrected visual acuity, refractive outcomes, and complications but excluded from analysis of uncorrected

**Table 1** Baseline Demographics of All Patients

| Phakic IOL model | IPCL | ICL | *P* value |
|---|---|---|---|
| Number of eyes (patients) | $n=111$, $N=59$ | $n=106$, $N=55$ | |
| Gender (female/male) | 37/22 | 37/18 | |
| Median age (years) | 32 (range: 21 to 56) | 31.5 (range: 18 to 53) | .614 |
| CDVA (decimal scale) | 1.04 (range: 0.25 to 1.6) | 0.97 (range: 0.5 to 2.0) | .012 |
| Preoperative SE refraction (D) | $-10.65 \pm 3.15$ (range: $-4.5$ to $-19.25$) | $-10.92 \pm 3.12$ (range: $-3.25$ to $-22.75$) | .441 |
| Preoperative refractive astigmatism (D) | $-1.39 \pm 1.03$ (range: 0 to $-6$) | $-1.48 \pm 1.1$ (range: 0 to $-5.75$) | .654 |
| White to White (mm) | $11.67 \pm 0.44$ (range: 10.3 to 12.7) | $12.05 \pm 0.44$ (range: 10.9 to 12.9) | .0 |
| pIOL size (mm) | $12.61 \pm 0.49$ (range: 11.25 to 13.5) | $13.13 \pm 0.36$ (range: 12.1 to 13.75) | .0 |

*CDVA* corrected distance visual acuity, *SE* spherical equivalent, *D* diopters

visual acuity. Toric versions of the ICL or the IPCL were chosen when the spherical model would result in postoperative astigmatism > 1 D after taking into account the flattening effect of the tunnel incision ($0.25 \times 0°$).

All surgeries were performed under general anesthesia using the same standard technique. Prior to implantation of a toric ICL or IPCL, the horizontal axis was marked at a slit-lamp or using a pendular marker. A paracentesis was made superiorly and the main tunnel temporally at the limbus. Different ophthalmic viscosurgical devices were injected into the anterior chamber. All ICLs were inserted through a 3.2-mm incision and all IPCLs through a 2.8-mm incision, respectively. Then the IOLs were positioned into the ciliary sulcus carefully avoiding any endothelial and crystalline lens touch. A few toric ICLs had to be rotated between 0 and 10 degrees from the horizontal position according to a sketch provided with the implant by the manufacturer, whereas toric IPCLs were always positioned horizontally (0–180°) due to their custom-made toricity axis.

The ophthalmic viscosurgical device was then removed by manual irrigation. Postoperative care comprised unpreserved ofloxacin and dexamethasone eyedrops $4 \times$ daily each for 5 days without tapering. Additional non-steroidal anti-inflammatory eyedrops were prescribed $3 \times$ daily for 6 weeks. Oral acetazolamide 250 mg or more was given according to the intraocular pressure (IOP) 2 h after implantation. If the IOP was > 35 mmHg, then the anterior chamber was tapped. Routine follow-up visits at our institution were scheduled on the next day, after 1 week, 3 months, 12 months, and yearly after that. Patients were instructed to consult with their referring doctor in-between these visits. Vaulting of the IOL was initially evaluated at the slit-lamp only, the expected range being (0.5 to $1.5 \times$ corneal thickness). In 2013, anterior chamber optical coherence tomography was additionally used to document vaulting more accurately.

Patients' clinical characteristics, pre- and post-uncorrected (UDVA) and best corrected (CDVA) distance visual acuities, perioperative complications, and previous treatments were recorded and analyzed. Variables were collected in an Excel sheet (Microsoft Corp., Redmond, CA, USA), and the standard graphs for reporting outcomes in refractive surgery were used. Data are expressed as arithmetic mean ± standard deviation (*SD*), except of visual acuity, which is expressed as geometric *mean* ± *SD*.

The primary outcome was UDVA improvement. Secondary outcomes were changes in CDVA, surgical, and postoperative complications. For changes in mean, we used paired Wilcoxon test for numerical data and Fisher's exact test for categorical variables. For all statistical analysis, we considered significant a $P$ value < 0.05.

## Results

The two study groups were similar with no clinically significant difference in the gender and age distribution, spherical equivalent refraction, and refractive astigmatism. Only preoperative CDVA was statistically but not clinically different between both groups. Visual and refractive outcomes at 3 months of eyes with plano as target refraction are shown in Figs. 1 and 2.

### Efficacy

At 3 months postoperatively, 76% of plano targeted eyes in the IPCL group and 83% of eyes in the ICL group had a UDVA of 20/20 or better (Figs. 1A and 2A, $P$ value, 0.534). Figures 1B and 2B show that 96% of IPCL implanted eyes and 94% of ICL implanted eyes had a postoperative UDVA within 1 line of preoperative CDVA.

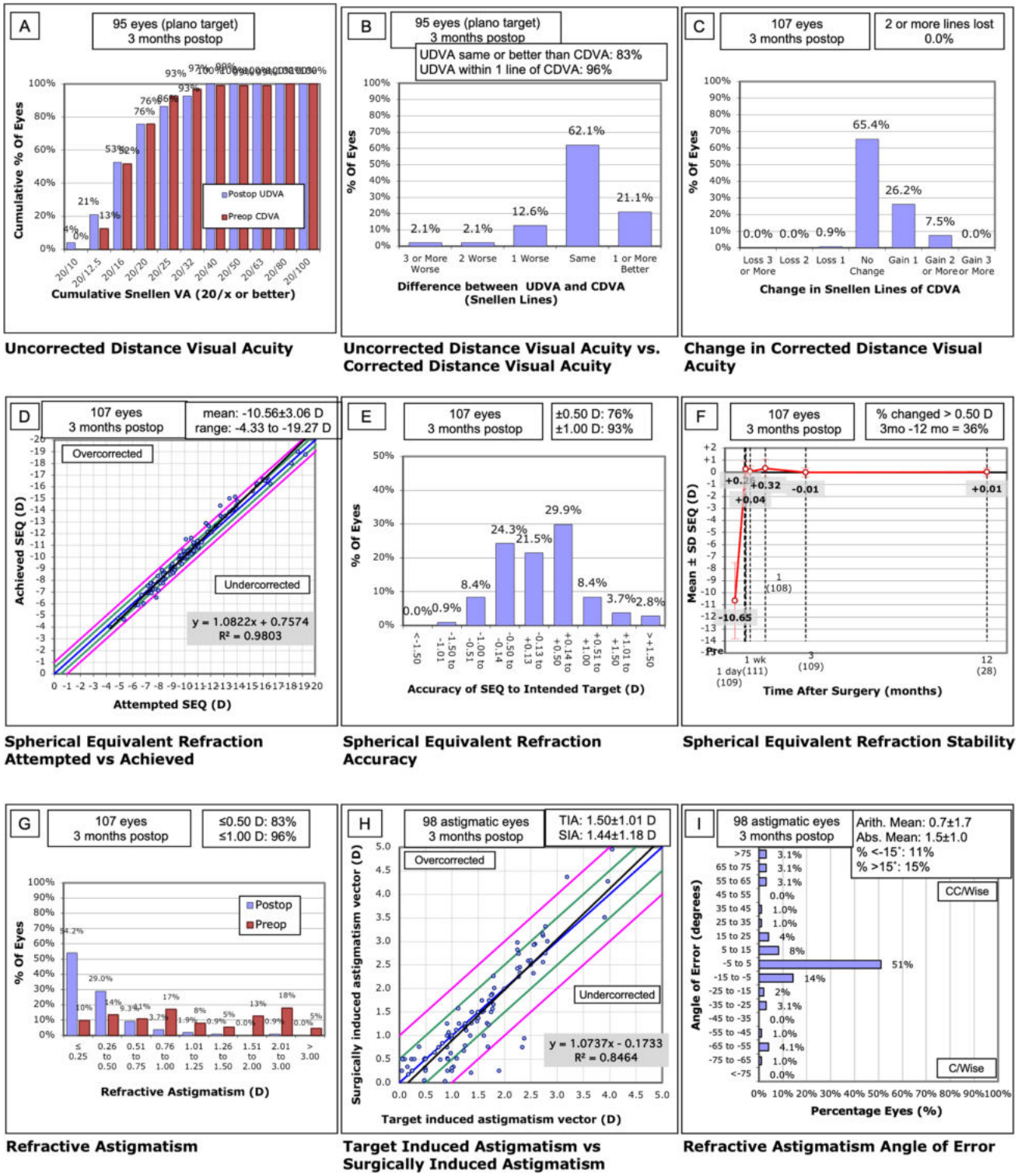


**Fig. 1** Standard graphs depicting visual and refractive results 3 months after IPCL implantation: (**A**) uncorrected distance visual acuity (**B**) uncorrected distance visual acuity versus corrected distance visual acuity, (**C**) change in corrected distance visual acuity, (**D**) spherical equivalent refraction attempted versus achieved, (**E**) spherical equivalent refraction accuracy, (**F**) spherical equivalent refraction stability, (**G**) refractive astigmatism, (**H**) target-induced astigmatism versus surgically induced astigmatism, and (**I**) refractive astigmatism angle of error. If residual myopia was targeted, then these eyes were included in the analysis of corrected distance visual acuity (CDVA) and refractive outcomes but excluded from analysis of uncorrected distance visual acuity (UDVA). SEQ = spherical equivalent refraction, TIA = target induced astigmatism, SIA = surgically induced astigmatism

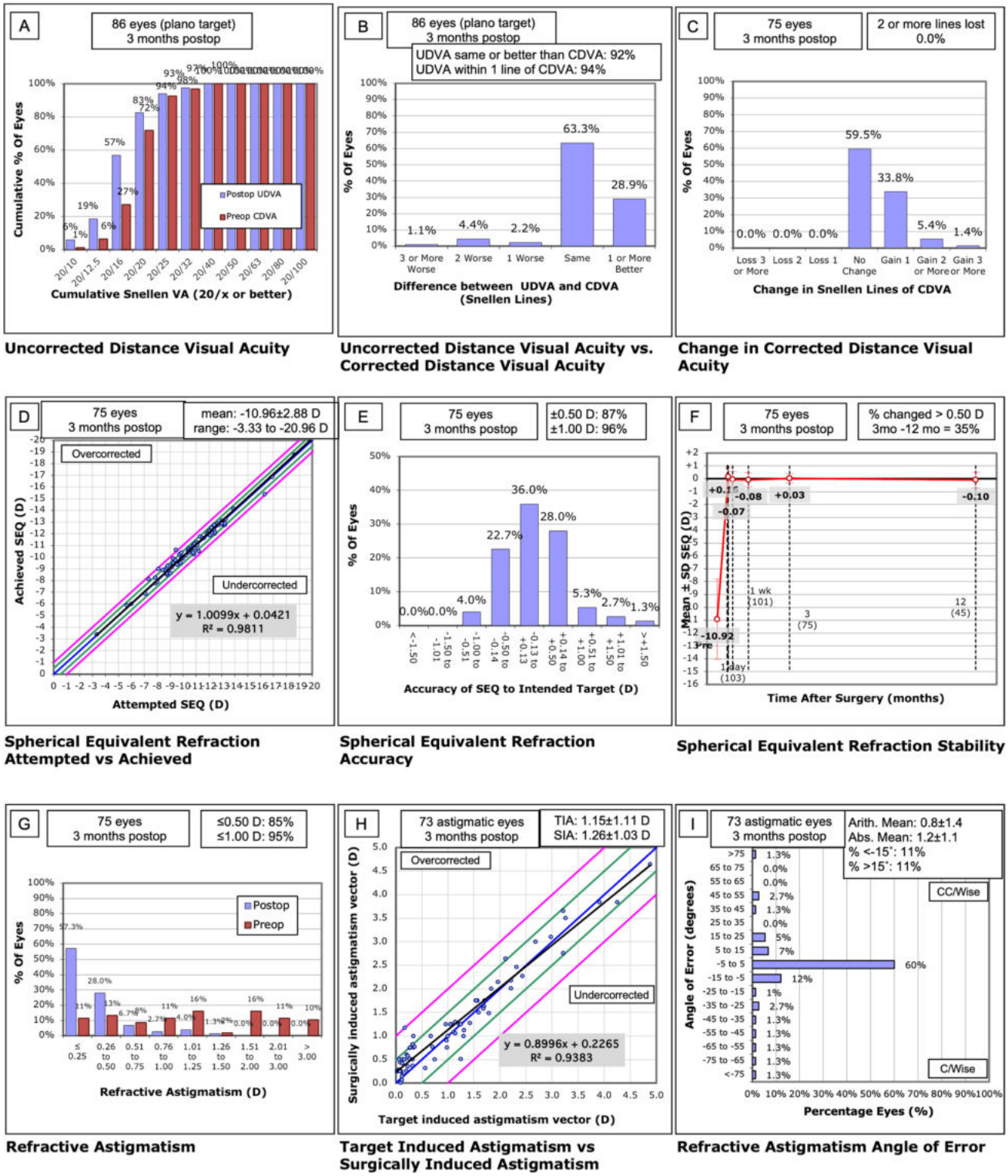


**Fig. 2** Standard graphs depicting visual and refractive results 3 months after ICL implantation: (**A**) uncorrected distance visual acuity, (**B**) uncorrected distance visual acuity versus corrected distance visual acuity, (**C**) change in corrected distance visual acuity, (**D**) spherical equivalent refraction attempted versus achieved, (**E**) spherical equivalent refraction accuracy, (**F**) spherical equivalent refraction stability, (**G**) refractive astigmatism, (**H**) target-induced astigmatism versus surgically induced astigmatism, and (**I**) refractive astigmatism angle of error. If residual myopia was targeted, then these eyes were included in the analysis of corrected distance visual acuity (CDVA), and refractive outcomes but excluded from analysis of uncorrected distance visual acuity (UDVA). SEQ = spherical equivalent refraction, TIA = target induced astigmatism, SIA = surgically induced astigmatism

### Safety

Figures 1C and 2C show that only 1 eye lost 1 line of CDVA after IPCL implantation and no eye lost any lines after ICL implantation; 33.7% of IPCL eyes and 40.6% of ICL eyes gained at least 1 line of CDVA.

### Predictability

With both IOLs, the correlation of intended to achieved spherical equivalent was reasonable, the IPCL displaying some overcorrections between − 10 D and − 15 D and the ICL displaying a tendency towards undercorrection in higher corrections (Figs. 1D and 2D). The accuracy was also similar with both IOLs, 76% of IPCL eyes and 87% of ICL eyes being within ± 0.5 D of the intended target spherical equivalent (Figs. 1E and 2E).

### Stability

Mean spherical equivalent refraction did not change significantly between 3 and 12 months after implantation of IPCL or ICL (Figs. 1F and 2F).

### Astigmatism

Comparing all eyes with plano target at 3 months, 83% of IPCL and 85% of ICL implanted eyes had a residual refractive astigmatism of ≤ 0.5 D (Fig. 1G and 2G). When comparing target induced astigmatism vs surgically induced astigmatism in astigmatic eyes only, the IPCL showed a tendency towards overcorrection and the ICL towards undercorrection; however, some outliers after IPCL implantation were seen (Figs. 1H and 2H). In these astigmatic eyes, the distribution of the postoperative refractive astigmatism angle of error was comparable; 51% were within ± 5° of the target axis after IPCL implantation and 60% after ICL implantation (Figs. 1I and 2I).

### Safety

There was no serious complication during surgery and no postoperative case of pupillary block nor inflammation. Table 2 shows a compilation of all adverse events in the last 10 years necessitating secondary surgical intervention to date.

Of note, the follow-up period was longer for the ICL due to the earlier implantations. The percentage of affected eyes was similar with both IOLs. However, there was a more frequent need for revision after an IPCL had rotated than for a rotated ICL; 4 IPCLs were surgically re-rotated, one twice; after repeat rotation, one patient opted for exchange of a toric IPCL to a spherical one. A single ICL was re-rotated (another was scheduled for re-rotation but the patient did not show up). Femto-LASIK was performed in 2 eyes in each group because a rotation would not have corrected the residual refraction fully. Advanced surface ablation was performed in 1 IPCL eye due to residual refractive error.

Cataract extraction (none because of anterior subcapsular opacification) was performed after 4 ICL implantations. There was no contact of the phakic IOL and the crystalline lens in any of the complicated cases. Other eyes with a low vault of the phakic IOL are monitored on a more frequent basis than routinely.

Endothelial cell loss was mild (as shown in Fig. 3) and did not differ between both pIOLs at least during the first 2 years after implantation. Similarly, the intraocular pressure (IOP) showed a peak on the day of surgery (at the routine measurement 2 h after implantation), followed by swift normalization and stable values over the entire follow-up (Fig. 4). Mean IOP was not clinically significantly affected by phakic IOL implantation at 3 months or thereafter.

Vaulting of the lens after 3 months was similar in both groups: No ICL had a vaulting below 250 µm and 5 ICLs (11.4%) above 750 µm. Four (5.9%) IPCLs had a vaulting below 250 µm and 10 (14.7%) above 750 µm. Only one rotated pIOL (IPCL) displayed a low vaulting (237 µm) the others had a vault > 400 µm (Fig. 5).

**Table 2** Secondary surgical interventions after all implantations

| Phakic IOL model (date of surgery) | IPCL (2017–2020) | ICL (2011–2019) |
|---|---|---|
| Total implants | 111 (60 toric) | 106 (59 toric) |
| Number of secondary surgical interventions | 9 (8.2%) in 6 (5.5%) eyes | 7 (6.6%) in 7 (6.6%) eyes |
| 1st Re-rotation | 4 (3.6%) | 1 (0.9%) |
| 2nd Re-rotation | 1 (0.9%) | 0 |
| Femto-LASIK | 2 (1.8%) | 2 (1.9%) |
| Advanced surface ablation | 1 (0.9%) | 0 |
| Explantation + cataract surgery | 0 | 4 (3.8%) |
| Phakic IOL-exchange (toric to non-toric) | 1 (0.9%) | 0 |

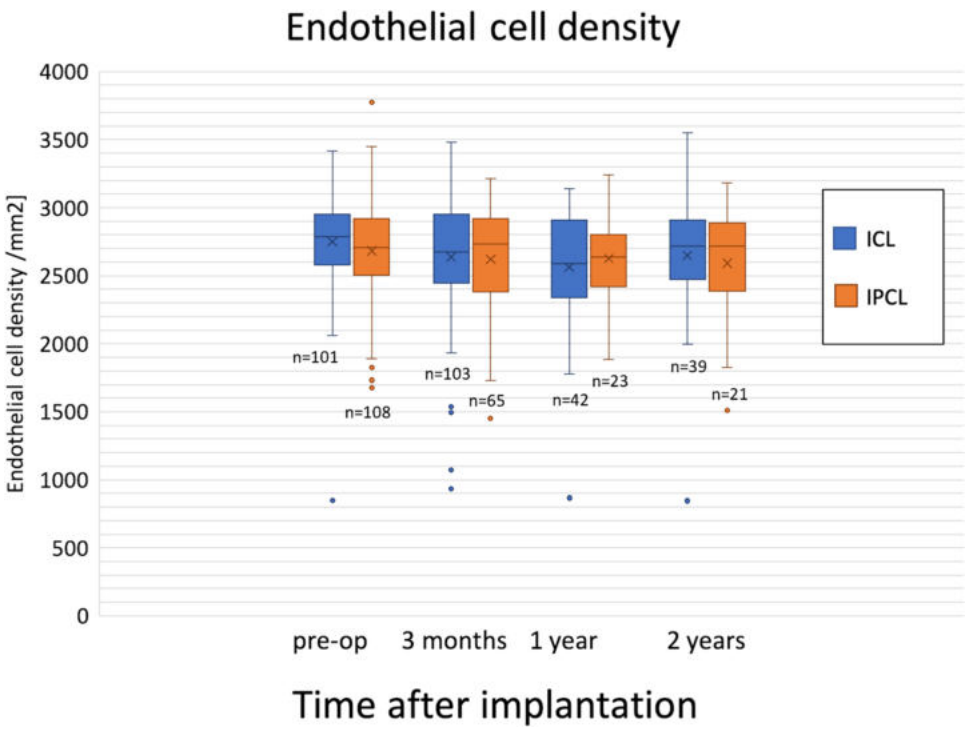


**Fig. 3** Endothelial cell density over time for both pIOL groups

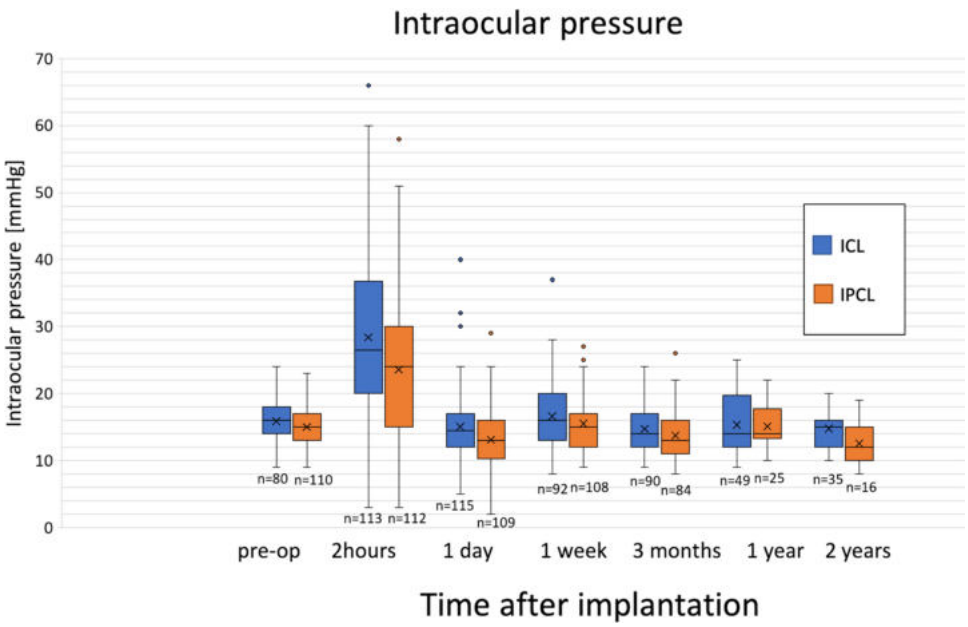


**Fig. 4** Intraocular pressure over time for both pIOL groups

## Discussion

This retrospective study comprises a similar number of IPCL and ICL with a comparable percentage of their respective toric versions for the correction of moderate to high myopia or myopic astigmatism. The current versions of both the IPCL and the ICL demonstrated to be safe and effective options. Refractive predictability and stability as well as the UDCV were excellent.

However, the impressive gain of lines may partly be explained optically by the obviated use of minifying minus lenses during refraction measurement in these highly myopic eyes.

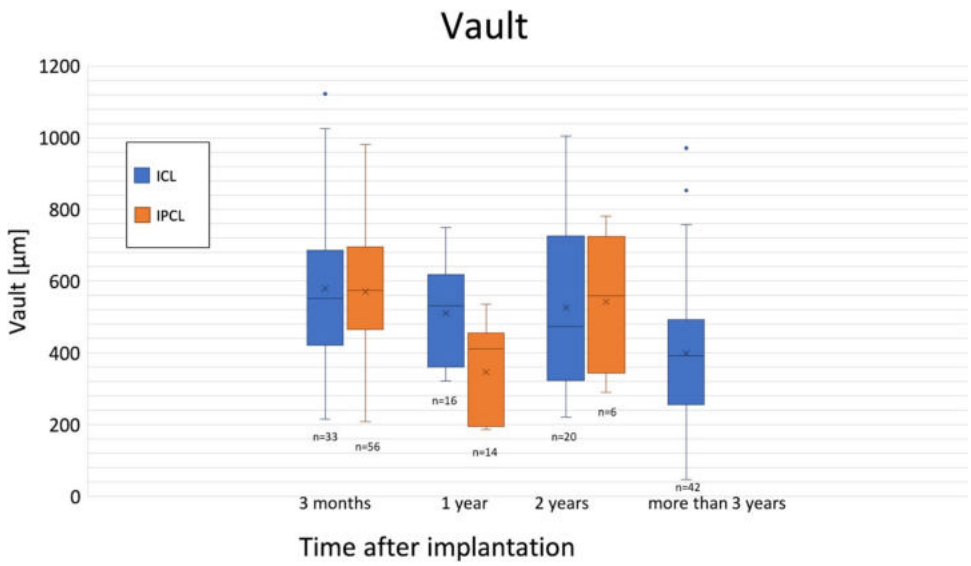


**Fig. 5** Vaulting over time for both pIOL groups

In terms of safety, no serious adverse event occurred during implantation nor in the follow-up period. Specifically, over 24 months, both the average loss of corneal endothelial cell density and the IOP were not different from findings after regular cataract surgery.

However, some rotated IOLs required revision in our series. This was to be expected because, in contrast to IOLs fixated by a shrinking capsule, these phakic IOLs placed into the ciliary sulcus are not fixated by shrinking tissue. In one extreme case, the IPCL toric was documented to be perfectly oriented before the patient noticed a sudden decline in vision without trauma 10.5 months after implantation and a rotation by 87° was seen at the slit-lamp. As the vault was normal, a decision was made to correct the orientation of the IPCL. However, 6 weeks after the second surgical intervention, the IPCL was again rotated by 87°. After some consideration, this patient opted then for exchange of his toric IPCL with a non-toric one. In our series, the IPCL rotated significantly more often than the ICL. At this point in time, we may only speculate whether this is caused by the different IOL designs or by anatomical features of the backsurface of the iris (e.g., cysts) or individual deviations from a circular sulcus. We have tried ultrasound-biomicroscopy in some patients before surgery but stopped when we realized that we could not obtain repeatable sulcus-to-sulcus measurements. Some surgeons advocate exchanging a rotated phakic IOL with one of the same power but larger diameter. We have not done that because all the rotated IOLs in our series had a normal (or borderline in 1 case) vault, and we did not want to risk potential problems with excessive vaulting like iris chafing, IOP rise, and chronic inflammation. Moreover, in the study that led to approval of the ICL by the FDA, phakic IOL exchange was identified to increase the risk of cataract formation [2]. Vaulting varied slightly more with the IPCL than with the ICL in spite of the fact that the IPCL is available in a broader size range with smaller steps (0.25 mm instead of 0.5 mm). However, we consider this difference clinically insignificant as we could not find a strong correlation between low vaulting and IOL rotation or cataract formation.

Cataract formation has been described as a potential complication of implanting an artificial lens right in front of the natural lens. We observed 4 eyes after ICL implantation that required explantation of the pIOL and phacoemulsification. Of note, the vaulting of all these phakic IOLs was normal and no anterior subcapsular opacification was seen. So, there was no indication that the phakic IOL might have contributed to cataract formation by touching the crystalline lens. All patients were presbyopic at the time of cataract extraction and highly myopic. Therefore, we think that in all cases the cataract formation was related to the patients' age and high myopia rather than to the pIOL. Recently, Gonzalez- Lopez et al. described an objective method of evaluating potential subcapsular opacification after phakic posterior IOL implantation with the Pentacam [19]. They found a long-term low risk of cataract formation even in the presence of low vaulting after implantation of an ICL with a central port. This is consistent with our own clinical impression so far and therefore we have been monitoring IPCLs and ICLs with a low vault but have not replaced them with a larger implant in order to avoid the risk of cataract induction by IOL replacement [2].

Our good refractive and visual results confirm earlier findings in a trial comparing these two pIOLs. Sachdev et al. found in young patients with a median age of 23 and 24 years in the respective groups an UDVA of 20/32 or better in 88.6% (ICL) and 86.5% (IPCL). Postoperative manifest SE was within ± 0.50 D of target refraction in 94% (ICL) and 90% (IPCL) of eyes, which are slightly better results than ours [18].

Safety and efficacy of the IPCL was evaluated by Vasavada et al. in 30 highly myopic eyes (more than − 8.0 D) with a follow-up of 3 years. In this cohort, mean *SE* decreased from − 16.5 D to − 0.89 D. Mean UDVA was 0.38 logMAR; mean CDVA was 0.24 logMAR. None of the eyes lost any line, while 49% gained one or more lines of CDVA [13]. Vasavada et al. observed a mean endothelial cell loss over 3 years of 9.73% which is higher in our cohort. A long-term study over 8 years reported an even milder endothelial cell loss of 6.2% after ICL implantation [11].

In Vasavada's study, there was one case of anterior subcapsular cataract formation after IPCL implantation. This caused no symptoms, and visual acuity was not affected in a significant way after 2 years [13]. In the larger cohort described by Sachdev et al. [18], the cataract incidence was equally low: 0.49% in the ICL and 2.52% in the IPCL group.

Limitations of our study include some missing data and the different maximum follow-up periods for the IPCL and the ICL. Therefore, we cannot rule out that long-term complications especially with the newer IOL (IPCL) may still occur. A longer follow-up is warranted, and we initiated a prospective multi-center trial over 3 years to better evaluate the IPCL.

In conclusion, our study confirmed the already established excellent outcomes achieved with the ICL for the correction of moderate to high myopia and myopic astigmatism. We observed equally excellent initial results with the IPCL. Longer follow-up is needed to determine the stability of these results, and we have initiated a prospective trial to this end.

So, refractive surgeons have more than one phakic posterior chamber IOL platform at their disposal which may become more important with the respective presbyopia correcting version of both the IPCL and the ICL.

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**Data availability** Not applicable.

**Code availability** Not applicable.

## Declarations

**Ethics approval** Ethical approval was waived by the local Ethics Committee of University of Münster in view of the retrospective nature of the study, and all the procedures performed were being part of the routine care.

**Consent to participate** Every patient signed informed consent for anonymized analysis of their data.

**Conflict of interest** Dr. Taneri received speaker´s honorarium from Polytech-Domilens and study support from Vision Ophthalmology Group.

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