Original Investigation

Clinical Outcomes and Cataract Formation Rates in Eyes 10 Years After Posterior Phakic Lens Implantation for Myopia

Ivo Guber, MD; Victoria Mouvet, MD; Ciara Bergin, PhD; Sylvie Perritaz, BScOptom; Philippe Othenin-Girard, MD; François Majo, MD, PhD

IMPORTANCE Intraocular collamer lenses (ICLs) are posterior chamber phakic lenses that provide a refractive surgery option for those with high myopia or astigmatism. The short-term and midterm results indicate good refraction stability, efficacy, and safety. Cataract has been suggested to be an important long-term complication of ICL implantation.

OBJECTIVE To report the rates of cataract development and refractive outcomes 10 years after ICL implantation.

DESIGN, SETTING, AND PARTICIPANTS The study included 133 eyes of 78 patients undergoing consecutive V4 model ICL implantations, which took place from January 1, 1998, through December 31, 2004, at Jules-Gonin Eye Hospital, Lausanne, Switzerland. Data analysis was performed from January 1, 2014, to May 31, 2014. The lenses implanted were as follows: 53 V4 model ICLs of −15.5 D or greater, 73 V4 model ICLs of less than −15.5 diopter (D), and 7 V4 model toric ICLs for myopia.

MAIN OUTCOMES AND MEASURES Rate of cataract surgery, lens opacity, ocular hypertension, refractive safety, predictability, and stability.

RESULTS A total of 133 eyes of 78 patients (34 men and 44 women, with a mean [SD] age of 38.8 [9.2] years at enrollment) met the inclusion criteria. The rate of lens opacity development was 40.9% (95% CI, 32.7%-48.8%) and 54.8% (95% CI, 44.7%-63.0%) at 5 and 10 years, respectively. Phacoemulsification was performed in 5 eyes (4.9%; 95% CI, 1.0%-8.7%) and 18 eyes (18.3%; 95% CI, 10.1%-25.8%) at 5 and 10 years after ICL implantation, respectively. The vault height (distance between the posterior ICL surface and anterior lens surface) measured a mean (SD) of 426 (344) µm immediately postoperatively, decreasing to 213 (169) µm at 10 years. A smaller vault height was associated with the development of lens opacity and phacoemulsification (P = .005 and .008, respectively). The intraocular pressure was 15 mm Hg postoperatively, and there was no significant increase in intraocular pressure observed until the 10-year follow-up (16 mm Hg, P = .02). At 10 years, 12 eyes (12.9%; 95% CI, 5.6%-19.6%) had developed ocular hypertension that required topical medication. At 10 years, the mean (SD) safety index was 1.25 (0.57), with a manifest spherical equivalent of −0.5 D at 1-year postoperatively vs −0.7 D at 10 years postoperatively in eyes aimed at emmetropia.

CONCLUSIONS AND RELEVANCE This retrospective single center study indicates that ICL implantation provides good long-term safety and stability of refraction in patients with high myopia compared with similar short-term studies. However, the rates of cataract formation and ocular hypertension at 10 years have important clinical implications, and as such this information should be part of the available patient information before ICL implantation.

Invited Commentary page 494

Supplemental content at jamaophthalmology.com

Author Affiliations: Department of Ophthalmology, University of Lausanne, Jules-Gonin Eye Hospital, Fondation Asile des Aveugles, Lausanne, Switzerland.

Corresponding Author: François Majo MD, PhD, Jules-Gonin Eye Hospital, University of Lausanne, Avenue de France 15, 1000 Lausanne 7, Vaud, Switzerland (fmajo@bluewin.ch).

JAMA Ophthalmol. 2016;134(5):487-494. doi:10.1001/jamaophthalmol.2016.0078
Published online March 3, 2016.

For patients with high ametropia or thin cornea, refractive surgery options are limited; in this case, implantation of artificial intraocular phakic lenses is often a preferred option.[1-5] In younger patients, implantation of artificial intraocular phakic lenses allows the retention of the crystalline lens and accommodation, without altering the corneal biostructure.[4] Three types of phakic intraocular lenses exist: anterior chamber angle-fixated lens, anterior chamber iris-fixated lens, and posterior chamber sulcus-fixated lens.

Alió et al[6] reported high rates of cataract (64%), endothelial cell loss (24%), and pupil ovalization (10%) with angle-supported phakic intraocular lenses. The detrimental effects on the endothelium with this lens type ultimately result in penetrating endothelial keratoplasty. Anterior chamber iris-fixated lenses have had greater success in terms of astigmatism correction, where the iris claw prevents rotation. A meta-analysis[7] comparing this model type with the posterior implantable collamer lens (ICL; Staar Surgical AG) revealed similar efficacy and better predictability but more cataract development with the posterior ICL, particularly in the V2 and V3 models; however, iris claw lenses have been associated with continuous endothelial cell loss.

The V4 model ICL was introduced in 1998 and is the sole sulcus-supported model approved by the US Food and Drug Administration. The short-term and midterm outcomes after V4 model ICL implantation in myopic eyes have revealed good safety, efficacy (of attaining desired manifest refraction), predictability (of lens strength required postoperatively), and refraction stability over time.[2,8-19] However, to our knowledge, there are only 2 reports[20,21] on outcomes after 5 years. Schmidinger et al[20] reported outcomes on cataract and vault height (distance between the posterior ICL surface and anterior lens surface) at a mean of 96 months after ICL implantation; in this report,[20] 17% of cases required phacoemulsification during follow-up, and an additional 28% presented with lens opacity. Igarashi et al[21] reported that, at 8 years after ICL implantation, 5% of cases required phacoemulsification and an additional 20% presented with lens opacity. These reports, among others,[20-25] indicate that cataract is an important long-term complication of ICL implantation, especially in eyes with limited vaulting.[20,23,26]

The aims of this study are to report the rate of complications, particularly with cataract (lens opacity and phacoemulsification), and investigate the association with vaulting. In addition, we aimed to report the safety, efficacy, predictability, and stability at set postoperative time points (1, 2, 5, and 10 years) in a large cohort of patients with myopia who have undergone ICL implantation (V4 model) and to compare these results with those available in the literature.

Key Points

Question: What are the long-term outcomes of patients with myopia and posterior phakic intraocular collamer lens (ICL) in situ?

Findings: In a retrospective review of consecutive patients with an ICL, the observed rate of phacoemulsification increased from 4.9% at 5 years to 18.3% at 10 years after ICL implantation and 13% of eyes developed ocular hypertension that required topical therapy at 10 years.

Meaning: The elevated risk of ocular hypertension and lens opacity after ICL implantation dictates that regular follow up of these patients is mandatory.

Methods

This retrospective study was approved by the Cantonal Committee for Ethics and Human Research, Vaud, Lausanne, and adhered to the tenets of the Declaration of Helsinki.[27] All (n = 133) V4 model ICL implantations performed at Jules-Gonin Eye Hospital in Lausanne, Switzerland, from January 1, 1998, through December 31, 2004, were reviewed. Data analysis was performed from January 1, 2014, to May 31, 2014. Patients had stable refraction for more than 1 year, an anterior chamber depth greater than 2.8 mm measured from the endothelium, high endothelial cell density (ECD) (>2000 cells/mm^2), no previous intraocular surgery or history of ocular hypertension or uveitis or preexisting ocular disease (eg, glaucoma), and no history of diabetes mellitus. The surgical technique has been previously described.[1]

A large proportion of eyes (n = 73) were operated on before the introduction of the V4 model toric ICLs and sufficiently strong ICL powers; therefore, the inserted lens was not aimed at achieving emmetropia in a proportion of these eyes. A subgroup analysis was performed on those eyes (n = 60) intended for emmetropia.

Preoperative examination, including slitlamp examination with intraocular pressure (IOP) assessment, corrected distance visual acuity (CDVA), uncorrected distance visual acuity (UDVA), manifest refraction, biometry (IOLMaster, Carl Zeiss Meditec Inc), and ECD assessment with the noncontact specular microscope, was performed with 2 devices (from 1998 until 2007, EM-3000, Tomey; and from 2007 on, Seaeagle, Rhine-Tec GmbH).

Lens Calculation

The calculation of the power of the lenses was made by Staar Surgical AG based on the measurements of manifest refraction and refraction after cycloplegy, keratometry (ARK-700 A [Nidek Co Ltd] or IOLMaster), pachymetry, and anterior chamber depth (Haag-Streit depth-measuring system 720 0018 [Haag-Streit] or IOLMaster). The length of the implanted ICL was determined by Staar Surgical AG, depending on the white to white distance, measured with the use of callipers on digital images taken with a Scheimpflug camera (Nidek Co Ltd).

Postoperative Follow-up

All available data from postoperative visits performed at 6 months and 1, 2, 5, and 10 years postoperatively were collated. Follow-up examinations included a full slitlamp examination with IOP, CDVA, UDVA, and manifest refraction. During follow-up, the crystalline lens and the ICL were periodically photographed with the Scheimpflug camera, with dilated pupils, allowing full visualization of the crystalline lens. The central vault height was measured on photographs taken by the

Table 1. Baseline Characteristics

Characteristic	Mean (SD)	Median (IQR)
Age, y	38.8 (9.2)	39.1 (31.5 to 45.8)
Distance visual acuity		
Uncorrected	<.05	<0.05 (<0.05 to 0.1)
Corrected	0.76 (0.24)	0.8 (0.6 to 1.0)
Manifest refraction, D		
Sphere	12 (2.9)	−12 (−13.8 to −9.5)
Cylinder	0.24 (1.6)	−0.5 (−1.25 to 0.8)
Spherical equivalent	11.4 (2.9)	−11.25 (−13.2 to −9.1)
ACD, mm	3.58 (0.31)	3.57 (3.34 to 3.80)
Pachymetry, µm	525 (34)	512 (500 to 552)
IOP, mm Hg	15.0 (2.3)	15 (14 to 16)
Corneal diameter, mm	12.0 (0.4)	12 (11.75 to 12.25)
ICL optical power	16.4 (2.9)	16.5 (14.0 to 18.5)

Abbreviations: ACD, anterior chamber depth; D, diopter; ICL, implantable collamer lens; IOP, intraocular pressure; IQR, interquartile range.

Scheimpflug camera or on digital photographs taken in the 180° axis using the EAS-1000 software program, version 1.23E, for Windows (Nidek EAS-1000, Nidek Co Ltd).

Statistical Analysis

At the study center, visual acuity was recorded in decimal format; therefore, the visual acuity was converted to logMAR to calculate mean values and subsequently reconverted into decimal format. All available visit data were collected and grouped with respect to the closest time point. If more than 1 visit was available within a given grouping, then the visit data closest to the given time point were used in the analysis. Baseline and follow-up data at each time point for the cohort were compared using analysis of variance (ANOVA). The patient identification number and eye were entered into the model to account for intereye correlations. For lens opacity survival analysis, the time from ICL implantation until lens opacity was first noted was calculated; if no lens opacity was noted, the data were censored at the last available visit. For phacoemulsification survival analysis, the time from ICL implantation until phacoemulsification was calculated; if no phacoemulsification was performed for those eyes with less than 10 years of follow-up data available, the data were censored at the last available visit.

Results

A total of 133 eyes of 78 patients (34 men and 44 women) met the inclusion criteria; the baseline characteristics are provided in **Table 1**. Seventy-five eyes (56.4%) from 45 patients were examined at the 10-year follow-up appointment, an additional 15 eyes (11.3%) had undergone phacoemulsification, and 43 eyes (32.3%) were lost to follow-up at 10 years. In the eTable in the Supplement, eyes with and without 10 years of follow-up were compared. Of age, IOP, ECD, and spherical equivalent, only spherical equivalent revealed a significant difference in baseline characteristics. The implanted ICL models were 53 V4 model ICLs of −15.5 diopter (D) or greater, 73 V4 model ICLs of less than −15.5 D, and 7 V4 model toric ICLs for myopia. Sixty eyes were aimed at emmetropia; these are referred to as the emmetropic group.

Safety Outcome (All Eyes)

Decimal CDVAs are provided in **Table 2**. The mean (SD) safety indexes (mean postoperative CDVA divided by mean preoperative CDVA) were 1.42 (0.51), 1.46 (0.61), 1.43 (0.52), 1.42 (0.57), and 1.25 (0.57) at 6 months and 1, 2, 5, and 10 years, respectively. Ten years postoperatively, 1 eye had lost 3 lines, 3 eyes had lost 2 lines, 7 had eyes lost 1 line, and the rest of the eyes were equal or better than preoperative measurements. These findings are summarized for all time points in **Figure 1**. The mean logMAR CDVAs were 0.04, 0.01, 0.01, 0.04 and 0.05 at 6 months and 1, 2, 5 and 10 years, respectively.

Efficacy Outcome (Emmetropic Group Only)

Decimal UDVAs are provided in Table 2 for all time points. In the emmetropic subgroup analysis, the mean (SD) efficacy indexes (mean postoperative UDVA divided by mean preoperative CDVA) were 1.03 (0.3), 0.95 (0.4), 1.00 (0.3), 0.92 (0.4), and 0.76 (0.4) at 6 months and 1, 2, 5, and 10 years, respectively.

Predictability (Emmetropic Group Only)

In the emmetropic subgroup analysis, at 6 months and 1, 2, 5, and 10 years, 31 (55.4%) of 56, 21 (51.2%) of 41, 17 (37.0%) of 46, 12 (27.9%) of 43, and 17 (48.6%) of 35 eyes, respectively were within ±0.5 D of the intended correction, and 46 (82.1%) of 56, 34 (73.9%) of 46, 31 (75.6%) of 41, 25 (58.1%) of 43, and 23 (65.7%) of 35 eyes, respectively, were within ±1.0 D of the intended correction.

Stability (All Eyes)

The spherical equivalent was stable throughout follow-up. At 6 months and 1, 2, 5, and 10 years after surgery, the mean manifest spherical equivalent was −0.4, −0.5, −0.7, −0.8, and −0.7 D, respectively, in the group aimed at achieving emmetropia, and the manifest spherical equivalent was −0.3, −0.5, −0.8, −0.9, and −1.1, respectively, in the whole group. Although there were significant changes in spherical equivalent during the first year (P = .007, ANOVA), there was no change in the spherical equivalent observed with longer follow-up.

Complications

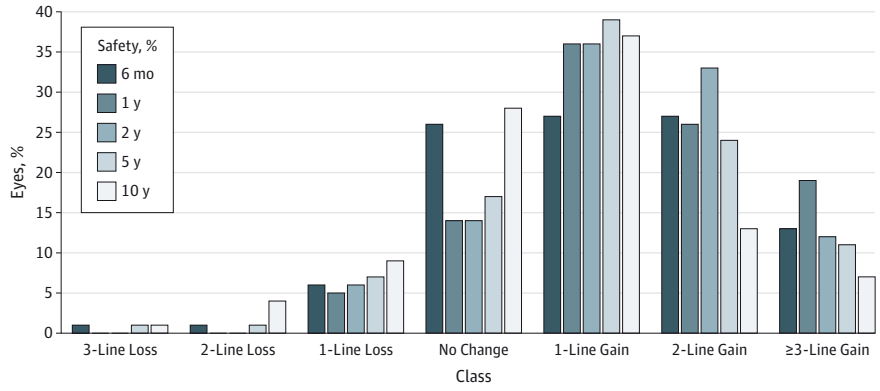
Eighteen eyes were observed to have an early complication (<1 year) after ICL implantation, 10 eyes had transient elevated IOP postoperatively, and 1 eye had excessive anterior chamber inflammation (suspected toxic anterior segment syndrome). Four eyes had peripheral contact between the ICL and lens; 1 eye developed myopic choroidal neovascularization. One patient had excessive glare, but this resolved after surgical reduction of the iridectomy. In the late postoperative phase (>1 year), 20 complications were observed in 19 eyes. Two eyes of 2 patients developed myopic choroidal neovascularization 1.6 and 11.2 years after ICL implantation. One eye of 1 patient developed central atrophy of the pigment epithelium 2.8 years after surgery, and 1 eye of 1 patient developed a retinal hole

Table 2. Postoperative Measures at Each of the Postoperative Time Points

Measure	Median (IQR) Baseline	6 mo	1 y	2 y	5 y	10 y
No. of eyes	133	133	100	104	106	75
Distance visual acuity						
Uncorrected	<.05	0.8 (0.5 to 1.0)	0.7 (0.5 to 1.0)	0.8 (0.5 to 1.0)	0.7 (0.45 to 1.0)	0.6 (0.3 to 1.0)
Corrected	0.8 (0.6 to 1.0)	1.0 (0.8 to 1.2)	1.0 (0.8 to 1.25)	1.0 (0.8 to 1.25)	1.0 (0.8 to 1.2)	1.0 (0.8 to 1.2)
Manifest refraction for distance vision, D						
Sphere	−12.00 (−13.8 to −9.5)	0.00 (−0.25 to 0.50)	0.00 (−0.75 to 0.50)	−0.25 (−0.75 to 0.25)	−0.25 (−1.00 to 0.25)	−0.25 (−1.00 to 0.25)
Cylinder	−0.5 (−1.25 to 0.8)	−1.00 (−1.50 to −0.25)	−1.00 (−1.50 to −0.50)	−1.00 (−1.50 to −0.50)	−1.00 (−1.50 to −0.50)	−0.75 (−1.25 to −0.50)
Spherical equivalent	−11.25 (−13.2 to −9.1)	−0.38 (−1.00 to 0.00)	−0.50 (−1.30 to −0.25)	−0.63 (−1.66 to −0.13)	−0.75 (−1.65 to −0.13)	−0.63 (−1.63 to −0.13)
IOP, mm Hg	15 (14 to 16)	14 (13 to 16)	14.5 (13 to 16)	14 (13 to 16)	15 (13 to 16.75)	16 (14 to 18)
ECD, cells/mm^2	2300	2275	2300	2242	2200	2393
Emmetropic aimed group						
No. of eyes	58	56	41	46	43	35
Distance visual acuity						
Uncorrected	<0.05	0.9 (0.6 to 1.2)	0.8 (0.5 to 1.0)	0.8 (0.6 to 1.0)	0.8 (0.5 to 1.0)	0.8 (0.3 to 1.0)
Corrected	0.8 (0.8 to 1.0)	1.0 (0.8 to 1.3)	1.0 (0.9 to 1.3)	1.0 (0.9 to 1.3)	1.0 (0.9 to 1.3)	1.0 (0.8 to 1.2)
Spherical equivalent	−10.5 (−12.5 to −8.7)	−0.3 (−0.0 to −0.9)	−0.4 (−0.3 to 0.8)	−0.6 (−0.1 to 1.0)	−0.8 (0.0 to −1.3)	−0.4 (0.1 to −1.3)

Abbreviations: D, diopter; ECD, endothelial cell density; IOP, intraocular pressure; IQR, interquartile range.

Figure 1. Safety Profile at Each Time Point



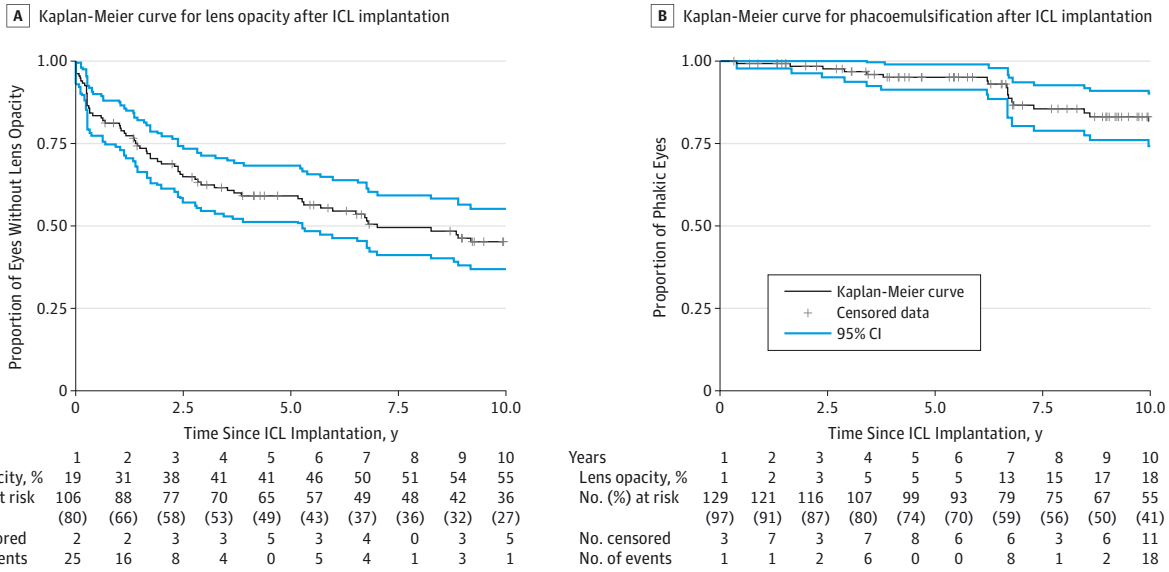
Safety, %							
6 mo	1	1	6	26	27	27	13
1 y	0	0	5	14	36	26	19
2 y	0	0	6	14	36	33	12
5 y	1	1	7	17	39	24	11
10 y	1	4	9	28	37	13	7

5.6 years after surgery. There were 16 cases of ocular hypertension controlled with IOP-lowering treatment, developing a mean of 7.3 years (range, 1.4-12 years) after implantation; at 10 years, this corresponds to a rate of 13% (95% CI, 6%-20%). The survival curve and risk table summarizing these occurrence rates at each year are given in eFigure 1 in the Supplement. In these eyes, excessive vault heights were not observed (403 µm on a mean of 190-740 µm), but pigmentation was observed in the iridocorneal angle. The IOP at each time point is provided in Table 2. Comparing the postoperative IOP and the preoperative measures, only IOPs at 10 years had a significant increase from baseline (P = .02, ANOVA).

ECD Estimates

The median ECD estimates are provided in Table 2. Changes in ECD between 6 months and 1, 2, and 5 years of 25, 100, and 75 cells/mm^2, respectively, were observed, but these changes were not statistically significant (paired t test, P = .49, .14, and

Figure 2. Kaplan-Meier Curves for the Rate of Lens Opacity and the Rate of Cataract Extraction Over Time



Years	1	2	3	4	5	6	7	8	9	10
Lens opacity, %	19	31	38	41	41	46	50	51	54	55
No. (%) at risk	106 (80)	88 (66)	77 (58)	70 (53)	65 (49)	57 (43)	49 (37)	48 (36)	42 (32)	36 (27)
No. censored	2	2	3	3	5	3	4	0	3	5
No. of events	25	16	8	4	0	5	4	1	3	1

Years	1	2	3	4	5	6	7	8	9	10
Lens opacity, %	1	2	3	5	5	5	13	15	17	18
No. (%) at risk	129 (97)	121 (91)	116 (87)	107 (80)	99 (74)	93 (70)	79 (59)	75 (56)	67 (50)	55 (41)
No. censored	3	7	3	7	8	6	6	3	6	11
No. of events	1	1	2	6	0	0	8	1	2	18

.23, respectively). There was an increase of 114 cells/mm^2 in the ECD observed at 10 years, although this was an anomaly, the probable cause of which is discussed later in this article.

Vaulting, Lens Opacity, and Phacoemulsification (All Eyes)

Vaulting was a mean (SD) of 426 (344) µm at 2 years postoperatively. This height decreased significantly to 213 (169) µm at 10 years (P = .01, ANOVA; eFigure 2 in the Supplement). In those eyes that required phacoemulsification during follow-up, a mean (SD) reduction in vaulting from 307 (237) µm to 82 (111) µm before phacoemulsification and ICL extraction occurred. In those eyes with lens opacity observed at the slit-lamp examination, the mean (SD) vaulting was 378 (314) µm, decreasing to 184 (131) µm at 10 years postoperatively. In the clear lens group, mean (SD) vaulting was 548 (366) µm after implantation, decreasing to a mean (SD) of 229 (177) µm at 10 years postoperatively.

The rate of lens opacity development was 40.9% (95% CI, 32.7%-48.8%) and 54.8% (95% CI, 44.7%-63.0%) at 5 and 10 years, respectively. Phacoemulsification was performed in 6 eyes (4.9%; 95% CI, 1.0%-8.7%) and 18 eyes (18.3%; 95% CI, 10.1%-25.8%) at 5 and 10 years after ICL implantation. **Figure 2** shows the Kaplan-Meier curves of development of lens opacity and cataract surgery over time, with the corresponding at-risk table given below each. One eye of 1 patient developed cataract within the first postoperative year. In this case, the ICL fit had been unsatisfactory and required a corrective surgery; however, during correction there was capsular touch, which resulted in early postoperative cataract and phacoemulsification. No other intraoperative complications were observed. After the correlation between eyes had been accounted for (ANOVA), the relationship between vaulting and lens opacity (P = .008) and phacoemulsification (P = .005) was significant.

Discussion

This study reports the outcomes and complications 10 years after ICL implantation. A significant proportion of eyes developed lens opacity, resulting in approximately one-fifth of eyes undergoing cataract and ICL extraction during the first 10 years after ICL implantation. The rates of lens opacity and phacoemulsification increased with time. This trend coincides with trends reported in the literature on lens opacification: 3% of eyes at 1 year,[11] 4% to 11% at 2 years,[2,10,13,14] 7% to 13% at 5 years,[25,26] 20% at 8 years,[21] and 28% at 10 years.[20] The higher rate of lens opacity reported in this study may be owing to the wider view under full dilation and detection of peripheral lens opacity (eFigure 3 in the Supplement). The rates of phacoemulsification are more similar to those previously reported: 2% to 4% at 2 years,[2,10] 2% at 5 years,[25] 5% at 8 years,[21] and 17% at 10 years.[20] Study results indicate that cataract formation is a frequent complication of ICL implantation, continuing to develop up to 10 years after ICL implantation.

This is a retrospective study, with associated limitation with respect to potential sources of bias; for example, this cohort of consecutive cases dates from 1998 and, as such, includes some highly myopic and astigmatic eyes for which sufficiently powered or toric ICLs were not available, limiting the possible correction. We tried to control for these confounders by selecting the emmetropically aimed eyes. However, during the past 15 years, lens power calculations have improved, and it is acceptable that our study reports a lower efficacy and predictability compared with publications that report the outcomes of more recently performed operations (with shorter follow-up). Of importance, good stability of refraction and high safety rates were observed during the long-term follow-up; however, this limitation remains a possible source of bias. In

Table 3. Literature Review of Refractive Outcomes After ICL Implantation of Previously Published Articles at the Available Time Points

	Preoperative			Postoperative			Refractive Outcome Indexes	
Study	BCVA	UCVA	SE	BCVA	UCVA	SE	Safety	Efficacy
1-y Results								
Jiménez-Alfaro et al,[13] 2001	0.2	2.0	−14.1	0.1	0.3	−1.6	1.4	0.8
Sanders et al,[11] 2007	...	...	−9.4	...	...	...	...	...
Schallhorn et al,[12] 2007	0.0	...	−8.0	−0.2	...	0.3	1.3	...
Kamiya et al,[10] 2009	...	...	−10.0	...	...	0.0	...	...
Kamiya et al,[10] 2009	−0.2	1.5	−9.8	−0.2	0.0	0.0	1.1	0.7
Kamiya et al,[9] 2010	−0.1	1.5	−10.4	−0.2	−0.1	−0.1	1.1	1.0
Igarashi et al,[21] 2014	−0.1	1.5	−10.9	−0.2	−0.1	−0.2	1.2	0.9
2-y Results								
Arne and Lesueur,[2] 2000	0.2	2.0	−13.9	0.1	0.4	−1.2	1.2	0.7
Jiménez-Alfaro et al,[13] 2001	0.2	2.0	−14.1	0.1	0.3	−1.6	1.4	0.8
Chung et al,[14] 2009	0.1	1.3	−14.0	0.0	0.2	...	1.3	0.8
Kamiya et al,[10] 2009	−0.2	1.5	9.8	−0.2	−0.1	...	1.1	0.9
3-y Results								
Lackner et al,[16] 2004	0.4	1.3	−16.5	0.2	0.4	...	1.4	0.9
Alfonso et al,[15] 2010	...	...	−10.1	...	...	...	...	...
4-y Results								
Dejaco-Ruhswurm et al,[17] 2002	...	...	−16.5	...	...	...	...	...
Edelhauser et al,[18] 2004	...	...	−10.1	...	...	...	...	...
Kamiya et al,[10] 2009	−0.2	1.5	9.8	−0.2	0.0	...	1.1	0.8
Gomez-Bastar et al,[19]2014	0.2	1.7	−11.6	0.1	0.2	−0.5	1.2	1.0
Igarashi et al,[21] 2014	−0.1	1.5	−10.9	−0.2	−0.1	−0.3	1.2	0.8
5-y Results								
Sanders,[25] 2008	...	...	...	...	...	...	...	...
Lindland et al,[26] 2010	0.1	2.0	−8.9	0.0	0.2	...	1.3	0.7
Alfonso et al,[31] 2011	0.1	1.3	−11.2	0.1	0.2	−0.9	1.1	0.9
6-y Results								
Kamiya et al,[34] 2014	...	...	−10.6	...	...	...	...	...
8-y Results								
Igarashi et al,[21] 2014	−0.1	1.5	−10.9	−0.2	0.0	−0.4	1.1	0.8
10-y Results								
Schmidinger et al,[20] 2010	...	...	−15.7	...	...	...	...	...

Abbreviations: BCVA, best-corrected visual acuity; ellipses indicate data not available; ICL, intraocular collamer lenses; SE, spherical equivalence; UCVA, uncorrected visual acuity.

addition, a significant proportion of eyes that received ICL implants were lost to follow-up at 10 years (an approximately 5% dropout per year), and, as such, this is a potential source of bias with respect to the estimation of cataract or hypertension provided. Comparison of the baseline characteristics of those with and without 10 years of follow-up does not indicate bias. However, in eyes without 10 years of follow-up, more had received an ICL with an alternative geometry implanted (higher myopia >15.5 D; Isabel Argeles, PhD, Staar Surgical AG, oral communication, April 2015), and a greater proportion of these eyes had undergone phacoemulsification and therefore were not available for the 10-year follow-up. Data are insufficient to examine this in detail; however, the change in ICL geometry required for very high-powered lenses is a potential source of bias.

As previously reported, eyes that developed lens opacity or required cataract extraction had lower baseline vault heights than eyes that maintained a clear lens.[23] This finding was later confirmed by Schmidinger et al.[20] A reduction in vault height with time was observed in the study eyes, with the vault height decreasing by 26.8 µm per year. Likewise, Schmidinger et al[20] reported a reduction in vault height of 28 µm per year. Furthermore, a reduction in vault height over time was observed (subjectively) by Igarashi et al.[21] In eyes that maintained clear lens after ICL implantation, Lackner et al[16] reported a vault of 355 µm. Schmidinger et al[20] reported a mean vault height of greater than 300 µm at 10 years. Considering the reduction in vault height over time, to maintain an adequate vault height in the long term (>10 years), the immediate vault height after surgery should be greater than 550 µm.

The long-term safety of the ICL procedure reveals safety indexes greater than 1 throughout follow-up (**Table 3**). On the basis of a sample size of 133 eyes, we can be confident that complications will not occur more than 2.3% of the time.[28]

Efficacy appears to reduce slightly over time; for example, Igarashi et al[20] reported an efficacy of 0.94 at 1 year, decreasing to 0.83 at 8 years. In our cohort, a similar trend was observed, with a mild increase in myopia over time. This increased myopia may in part be owing to the development of nuclear cataract or myopia progression.[21]

In short-term to midterm follow-up, ECD loss of 7% to 12% was observed.[10,14,16-18,21] This reduction was observed immediately after surgery (1 month) and maintained during the postoperative follow-up and is similar to the effect of the surgical trauma associated with cataract surgery on ECD.[29,30] However, the ECD loss after cataract surgery stabilizes as early as 6 weeks postoperatively.[30] This stabilization coincides with the results of ICL implantation observed in previous reports.[10,14,21] To our knowledge, after the first year, no significant loss in ECD has been observed. In this cohort, an increase in ECD estimates was observed 10 years after surgery, which we believe to be related to a change in device that occurred during follow-up at our institution, but this outcome would at least suggest that a large loss in ECD is not present.

There were 10 cases of transient hypertension in the immediate postoperative phase that resolved during year 1, likely owing to remnants of viscoelastic devices and steroid responders. No cases of acute glaucoma owing to angle block were observed in this cohort. In alternative reports[9,10,14,21,31] with shorter follow-up, the incidence of chronic glaucoma ranged from 0% to 5%. No cases of chronic glaucoma were observed in this cohort. The mean IOP remains stable throughout follow-up.[10,14,21] With the longer follow-up reported in this study, a significant proportion of study eyes with pigmentation in the iridocorneal angle and ocular hypertension requiring IOP-lowering medication was observed. To our knowledge, to date, cases of ocular hypertension requiring treatment have not been discussed, making comparison impossible.[21]

Nonsurgical refractive correction in patients with high myopia remains the first treatment option. In cases of contact lens intolerance or poor visual quality, refractive surgery, such as ICL implantation, may provide a suitable solution. The amount of correction with phakic intraocular lenses is not limited by corneal thickness, and the biostructure is preserved.[32] Iris-fixated phakic intraocular lenses and posterior ICLs are preferable to clear lens extraction owing to premature loss of accommodation and increased probability of retinal detachment in this high-risk group.[33] Because the mean age was 38 years at implantation and 83% of cases retained their natural lens at 10 years postoperatively, most cases will have developed presbyopia before phacoemulsification is required.

Conclusions

This study confirms that ICL implantation provides good long-term safety and stability of refraction in patients with high myopia. There is a larger than expected rate of lens opacity and phacoemulsification, which continues to increase up to 10 years after surgery. The rates of ocular hypertension are greater than previously reported. These outcomes have important clinical implications, and, as such, this information should be part of the available patient information before ICL implantation.

ARTICLE INFORMATION

Submitted for Publication: May 27, 2015; final revision received January 6, 2016; accepted January 10, 2015.

Published Online: March 3, 2016. doi:10.1001/jamaophthalmol.2016.0078.

Author Contributions: Drs Bergin and Guber had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Drs Guber and Mouvet contributed equally to this work.
Study concept and design: Guber, Mouvet, Bergin, Othenin-Girard, Majo.
Acquisition, analysis, or interpretation of data: Guber, Mouvet, Bergin, Perritaz.
Drafting of the manuscript: Guber, Mouvet, Bergin, Perritaz, Othenin-Girard.
Critical revision of the manuscript for important intellectual content: Guber, Bergin, Majo.
Statistical analysis: Guber, Bergin.
Obtained funding: Majo.
Administrative, technical, or material support: Mouvet, Perritaz, Majo.
Study supervision: Othenin-Girard.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

REFERENCES

1. Gonvers M, Othenin-Girard P, Bornet C, Sickenberg M. Implantable contact lens for moderate to high myopia: short-term follow-up of 2 models. *J Cataract Refract Surg*. 2001;27(3):380-388.

2. Arne JL, Lesueur LC. Phakic posterior chamber lenses for high myopia: functional and anatomical outcomes. *J Cataract Refract Surg*. 2000;26(3):369-374.

3. Uusitalo RJ, Aine E, Sen NH, Laatikainen L. Implantable contact lens for high myopia. *J Cataract Refract Surg*. 2002;28(1):29-36.

4. Emarah AM, El-Helw MA, Yassin HM. Comparison of clear lens extraction and collamer lens implantation in high myopia. *Clin Ophthalmol*. 2010;4:447-454.

5. Sanders DR, Vukich JA. Comparison of implantable contact lens and laser assisted in situ keratomileusis for moderate to high myopia. *Cornea*. 2003;22(4):324-331.

6. Alió JL, Abdelrahman AM, Javaloy J, Iradier MT, Ortuño V. Angle-supported anterior chamber phakic intraocular lens explantation causes and outcome. *Ophthalmology*. 2006;113(12):2213-2220.

7. Liang G-L, Wu J, Shi J-T, Liu J, He F-Y, Xu W. Implantable collamer lens versus iris-fixed phakic intraocular lens implantation to correct myopia: a meta-analysis. *PLoS One*. 2014;9(8):e104649.

8. Boxer Wachler BS, Scruggs RT, Yuen LH, Jalali S. Comparison of the Visian ICL and Verisyse phakic intraocular lenses for myopia from 6.00 to 20.00 diopters. *J Refract Surg*. 2009;25(9):765-770.

9. Kamiya K, Shimizu K, Aizawa D, Igarashi A, Komatsu M, Nakamura A. One-year follow-up of posterior chamber toric phakic intraocular lens implantation for moderate to high myopic astigmatism. *Ophthalmology*. 2010;117(12):2287-2294.

10. Kamiya K, Shimizu K, Igarashi A, Hikita F, Komatsu M. Four-year follow-up of posterior chamber phakic intraocular lens implantation for moderate to high myopia. *Arch Ophthalmol*. 2009;127(7):845-850.

11. Sanders DR, Schneider D, Martin R, et al. Toric implantable collamer lens for moderate to high myopic astigmatism. *Ophthalmology*. 2007;114(1):54-61.

12. Schallhorn S, Tanzer D, Sanders DR, Sanders ML. Randomized prospective comparison of visian toric implantable collamer lens and conventional photorefractive keratectomy for moderate to high myopic astigmatism. *J Refract Surg*. 2007;23(9):853-867.

13. Jiménez-Alfaro I, Benítez del Castillo JM, García-Feijoó J, Gil de Bernabé JG, Serrano de La Iglesia JM. Safety of posterior chamber phakic intraocular lenses for the correction of high myopia: anterior segment changes after posterior chamber phakic intraocular lens implantation. *Ophthalmology*. 2001;108(1):90-99.

14. Chung T-Y, Park SC, Lee MO, Ahn K, Chung E-S. Changes in iridocorneal angle structure and trabecular pigmentation with STAAR implantable collamer lens during 2 years. *J Refract Surg*. 2009;25(3):251-258.

15. Alfonso JF, Lisa C, Abdelhamid A, Fernandes P, Jorge J, Montés-Micó R. Three-year follow-up of subjective vault following myopic implantable collamer lens implantation. *Graefes Arch Clin Exp Ophthalmol*. 2010;248(12):1827-1835.

16. Lackner B, Pieh S, Schmidinger G, et al. Long-term results of implantation of phakic posterior chamber intraocular lenses. *J Cataract Refract Surg*. 2004;30(11):2269-2276.

17. Dejaco-Ruhswurm I, Scholz U, Pieh S, et al. Long-term endothelial changes in phakic eyes with posterior chamber intraocular lenses. *J Cataract Refract Surg*. 2002;28(9):1589-1593.

18. Edelhauser HF, Sanders DR, Azar R, Lamielle H; ICL in Treatment of Myopia Study Group. Corneal endothelial assessment after ICL implantation. *J Cataract Refract Surg*. 2004;30(3):576-583.

19. Gomez-Bastar A, Jaimes M, Graue-Hernández EO, Ramirez-Luquin T, Ramirez-Miranda A, Navas A. Long-term refractive outcomes of posterior chamber phakic (spheric and toric implantable collamer lens) intraocular lens implantation. *Int Ophthalmol*. 2014;34(3):583-590.

20. Schmidinger G, Lackner B, Pieh S, Skorpik C. Long-term changes in posterior chamber phakic intraocular collamer lens vaulting in myopic patients. *Ophthalmology*. 2010;117(8):1506-1511.

21. Igarashi A, Shimizu K, Kamiya K. Eight-year follow-up of posterior chamber phakic intraocular lens implantation for moderate to high myopia. *Am J Ophthalmol*. 2014;157(3):532-9.e1.

22. Fernandes P, González-Méijome JM, Madrid-Costa D, Ferrer-Blasco T, Jorge J, Montés-Micó R. Implantable collamer posterior chamber intraocular lenses: a review of potential complications. *J Refract Surg*. 2011;27(10):765-776.

23. Gonvers M, Bornet C, Othenin-Girard P. Implantable contact lens for moderate to high myopia: relationship of vaulting to cataract formation. *J Cataract Refract Surg*. 2003;29(5):918-924.

24. Sánchez-Galeana CA, Smith RJ, Sanders DR, et al. Lens opacities after posterior chamber phakic intraocular lens implantation. *Ophthalmology*. 2003;110(4):781-785.

25. Sanders DR. Anterior subcapsular opacities and cataracts 5 years after surgery in the Visian implantable collamer lens FDA trial. *J Refract Surg*. 2008;24(6):566-570.

26. Lindland A, Heger H, Kugelberg M, Zetterström C. Vaulting of myopic and toric Implantable Collamer Lenses during accommodation measured with Visante optical coherence tomography. *Ophthalmology*. 2010;117(6):1245-1250.

27. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA*. 2013;310(20):2191-2194.

28. Hanley JA, Lippman-Hand A. If nothing goes wrong, is everything all right? interpreting zero numerators. *JAMA*. 1983;249(13):1743-1745.

29. Díaz-Valle D, Benítez del Castillo Sánchez JM, Castillo A, Sayagués O, Moriche M. Endothelial damage with cataract surgery techniques. *J Cataract Refract Surg*. 1998;24(7):951-955.

30. Bourne RR, Minassian DC, Dart JK, Rosen P, Kaushal S, Wingate N. Effect of cataract surgery on the corneal endothelium: modern phacoemulsification compared with extracapsular cataract surgery. *Ophthalmology*. 2004;111(4):679-685.

31. Alfonso JF, Baamonde B, Fernández-Vega L, Fernandes P, González-Méijome JM, Montés-Micó R. Posterior chamber collagen copolymer phakic intraocular lenses to correct myopia: five-year follow-up. *J Cataract Refract Surg*. 2011;37(5):873-880.

32. García M, González C, Pascual I, Fimia A. Magnification and visual acuity in highly myopic phakic eyes corrected with an anterior chamber intraocular lens versus by other methods. *J Cataract Refract Surg*. 1996;22(10):1416-1422.

33. Rodriguez A, Gutierrez E, Alvira G. Complications of clear lens extraction in axial myopia. *Arch Ophthalmol*. 1987;105(11):1522-1523.

34. Kamiya K, Shimizu K, Igarashi A, Kobashi H. Factors influencing long-term regression after posterior chamber phakic intraocular lens implantation for moderate to high myopia. *Am J Ophthalmol*. 2014;158(1):179-184.e1.

Invited Commentary

Long-term Clinical Outcomes and Cataract Formation Rates After Posterior Phakic Lens Implantation for Myopia

Stephen D. McLeod, MD

Phakic intraocular lenses (PILs) can provide optically superb correction of relatively high degrees of ametropia that lie well beyond the recommended range for keratorefractive procedures, such as laser in situ keratomileusis and photorefractive keratectomy. Although hundreds of thousands have been implanted, the predominant concern surrounding these devices remains that of long-term safety. Three lens types based on anatomical location have been developed—angle supported, iris fixated, and posterior chamber—each with its particular risk to benefit profile. Angle-supported implants can induce endothelial cell loss and corneal decompensation, as well as pupil ovalization, whereas iris-fixated implants pose risks of cataract, corneal decompensation, endothelial cell loss, and dislocation.[1] Posterior chamber PILs are intended to vault over the crystalline lens, but anterior subcapsular cataract was soon recognized as a relatively common occurrence with this design, especially with longer follow-up.

Related article page 487

On the basis of the assumption that cataract is a consequence of intermittent lens touch and chronic low-grade inflammation, as well as insufficient nutrition and impeded flow between the implant and the crystalline lens, early posterior chamber phakic lens designs were later modified to increase the vault gap (ie, the space between the posterior PIL surface and the anterior crystalline lens capsule). A retrospective comparative study[2] of these designs appears to confirm that the vault gap is inversely related to cataract risk. Now that this design iteration has been available for a number of years, it is important to reevaluate the cataract risk associated with posterior chamber PILs for myopic and hyperopic corrections.

Igarashi et al[3] reported the 8-year follow-up of the V4 model Visian implantable collamer lens (Staar Surgical AG) in 41 patients with myopia. Although refractive results were excellent, with a mean (SD) logMAR uncorrected distance acuity of 0.02 (0.33) at 8 years after surgery and 73% of eyes with uncorrected distance acuity of 20/20 or better, 17% of eyes that lost at least 1 line of best-corrected acuity, and 7% of eyes that lost 2 or more lines, 5% of eyes required cataract extraction during this 8-year period. Of note, a progressive reduction in vault gap was observed at 1 and 6 months and 1, 4, and 8 years after surgery, with a significant difference in the 1-month, 4-year, and 8-year estimates. In this cohort, intraocular pressure was monitored during the 8 years, but no increase was observed.