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REVIEW

Intraocular Implantable Collamer Lens with a Central Hole Implantation: Safety, Efficacy, and Patient Outcomes

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Abstract: This review summarizes the available literature and provides updates on the efficacy, safety, and patient outcomes of phakic intraocular lens implantation using implantable collamer lens (ICL), with a focus on newer models with a central port (EVO/EVO+ Visian Implantable Collamer Lens, STAAR Surgical Inc.). All studies included in this review were identified from the PubMed database and were reviewed for relevancy of their topic. Data on hole-ICL implantation performed between October 2018 and October 2022 in 3399 eyes showed a weighted average efficacy index of 1.03 and a weighted average safety index of 1.19 within an average follow-up of 24.7 months. The incidence of complications such as elevated intraocular pressure, cataract, and corneal endothelial cell loss was low. Moreover, both quality of vision and quality of life improved after ICL implantation, confirming the benefits of this procedure. In conclusion, ICL implantation is a promising refractive surgery alternative to laser vision correction with excellent efficacy, safety, and patient outcomes.

Keywords: posterior chamber lens, phakic intraocular lens, Visian ICL, phakic refractive lens, refractive surgery

Introduction

A phakic intraocular lens (pIOL) is a supplementary intraocular lens implanted between the cornea and crystalline lens for correcting refractive error. In patients with moderate-to-high ametropia whose corneas are not suitable or are contraindicated for corneal refractive procedures [eg photorefractive keratectomy, laser-assisted in situ keratomileusis (LASIK), and small incision lenticule extraction (SMILE)], pIOL implantation could be a promising alternative because it involves minimal alteration to the corneal tissue via a clear corneal incision.[1,2] These lenses can be fixed at any angle, enclaved to the iris with a claw, or placed in the posterior chamber at the ciliary sulcus. The main advantage is the preservation of the crystalline lens, thereby ensuring that the natural lens functions are retained. Moreover, these procedures avoid vitreoretinal side effects that occur after clear lens extraction.[1] Earlier models including angle-fixated lenses and iris-supported lenses were subsequently phased out because of associated complications including corneal decompensation, uveitis-glaucoma-hyphema syndrome, and progressive erosion of the iris stroma.[1] Accordingly, pIOL implantation was developed. With this procedure, in the posterior chamber, the distance between the IOL and corneal endothelium is greater; thus, this type of pIOL could cause less corneal endothelial damage than the earlier models.[3]

Visian implantable collamer lens (ICL) (STAAR Surgical, Nidau, Switzerland), a posterior chamber pIOL, is used for the correction of myopia, hyperopia, and astigmatism. It is made of collamer, a proprietary hydroxyethyl methacrylate/porcine collagen polymer material containing an ultraviolet chromophore.[4,5] This collagen copolymer exhibited good biocompatibility as its postoperative inflammatory activity was minimal.[6,7] Moreover, its lower

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refractive index of 1.45 than those of other posterior chamber pIOL materials could contribute to reduced post-operative dysphotopsia.[8–11] The lens is specifically designed to be placed behind the iris in front of the crystalline lens with its haptics resting on the ciliary sulcus. ICL implantation has several advantages, including shorter visual recovery time than surface ablation techniques; comparable or better refractive outcome and stability over PRK,[12] LASIK,[13–17] and SMILE;[17–19] and potential reversibility as the lenses can be explanted if necessary. However, ICL implantation usually requires operations in two sittings, one for each eye, to decrease the risk of postoperative complications such as endophthalmitis, whereas LASIK is usually performed on both eyes in a single day.[20,21] Patients should be informed regarding possible risks including intraocular pressure (IOP) elevation, pigment dispersion, crystalline lens opacity, and corneal endothelial cell loss.[20] Some of these might lead to irreversible damage and require ICL explantation.[22]

The interest in ICL began in 1993 when the first ICL prototypes were implanted.[1] Later, the lens underwent several design modifications in optic and haptic footplates, posterior lens design, and total diameter. Unlike newer versions, the conventional ICL models (before the V4c model) had two major problems: the requirement of preoperative laser peripheral iridotomy or intraoperative iridectomy to avoid pupillary block and the risk of cataract progression due to poor circulation of aqueous humor.[23] The introduction of an aperture in the lens optic was shown to improve aqueous circulation around the crystalline lens in in vitro experiments and pre-clinical studies in animal models.[24–27] Compared with multiple peripheral holes, one central hole in the optics may better improve fluid dynamics in an eye implanted with a posterior chamber pIOL.[27] Moreover, the addition of a central hole did not cause any significant differences in terms of optical and visual quality compared with those in the models without a central port.[28,29] Thus, in the recent ICL models (V4c and later), a central hole measuring 0.36 mm (the KS-Aquaport) is incorporated to allow the circulation of the aqueous fluid through the lens, improving the safety of the procedure.[25] Shimizu et al demonstrated that the ICL with a central hole was comparable to the conventional ICL with respect to higher-order aberrations (HOAs), contrast sensitivity change, and long-term refractive outcomes.[30,31]

The latest ICL models include EVO/EVO+ Visian Implantable Collamer Lens (EVO ICL™) and EVO/EVO+ Visian Toric Implantable Collamer Lens. The optic diameter varies with the dioptric power, from 4.9 mm to 5.8 mm and from 5.0 mm to 6.1 mm for the EVO and EVO+ models, respectively. The EVO+ ICL features a larger optic diameter for patients with larger pupils including younger patients. EVO and EVO+ lenses, introduced in 2011 and 2015, respectively, have been reported to be effective and safe. In March 2022, the United States Food and Drug Administration (US-FDA) approved the EVO/EVO+ Sphere and Toric ICL lenses.[32] These lenses are indicated for patients aged 21–45 years for the correction/reduction of myopia in patients with spherical equivalent (SE) ranging from −3.0 D to −20.0 D at the spectacle plane and for the correction/reduction of myopic astigmatism in patients, with SE ranging from −3.0 D to −20.0 D with a cylinder of 1.0 D to 4.0 D at the spectacle plane. A minimum true anterior chamber depth (ACD), measured from the corneal endothelium to the anterior surface of the crystalline lens, of 2.80 to 3.00 mm and a minimum age-appropriate endothelial cell density (ECD) are required for patients to be suitable for lens placement in the ciliary sulcus.[33–35] This review summarizes the available literature and provides updates on the efficacy, safety, and patient outcomes of ICL implantation, with a focus on the newer hole-ICL models currently in the market.

Literature Review

All studies included in this narrative review were identified through a PubMed database search using the search terms “implantable collamer lens” and “phakic intraocular lens.” All publications available in English full text were reviewed for relevancy of their topic regarding the efficacy, safety, and patient outcomes of ICL implantation. The exclusion criteria were as follows: studies on pIOL other than Visian ICL (eg Artisan pIOL or Artiflex anterior chamber IOL); studies on former ICL models without a central port, treatment of keratoconus, treatment of amblyopia, treatment of presbyopia, treatment of ametropia following corneal surgery or lenticular surgery; and studies on concomitant refractive procedures. The remaining studies were reviewed in detail. Reference studies cited in selected articles were also reviewed for potential inclusion.

Results

Efficacy

Refractive Outcomes

ICL implantation has been shown to be effective in the correction of myopic astigmatism in wide ranges of SE, including low myopia[36–38] and moderate-to-severe myopia.[30,31,39–41] Previous studies on toric ICLs have shown comparable efficacy in refractive error correction between toric and non-toric ICLs.[42,43] In patients with astigmatism, toric ICLs yielded promising results in correcting astigmatic component and were even more effective in eyes with high astigmatism (≥2 D and ≤4 D) than in those with low astigmatism (≥0.75 D and <2 D).[44,45] In a review of data from 1905 eyes by Packer in 2018, the weighted average efficacy index was 1.04 (range, 0.90–1.35) and weighted average postoperative uncorrected distance visual acuity (UDVA) was 20/19 (logMAR −0.02) (range, 20/12–20/27 (logMAR −0.20 to 0.14)), confirming the good refractive outcomes of the ICL.[46] In a recent US-FDA clinical trial evaluating 629 eyes of 327 participants, EVO ICL lenses achieved high levels of UDVA (−0.059 ± 0.10 logMAR), with an efficacy index of 1.06.[32]

In several studies comparing eyes with a similar degree of preoperative myopia, ICL implantation yielded similar or superior efficacy to corneal laser refractive surgery.[6,7,26] Ganesh et al compared three modalities for the correction of low-to-moderate myopic astigmatism and found insignificant differences in postoperative UDVA among toric ICL, femto-LASIK, and SMILE, although the efficacy index was slightly higher in the toric ICL group (1.12, 1.02, and 1.06, respectively).[17] Siedlecki et al reported that ICL implantation had superior efficacy index to SMILE in a matched comparative study, although baseline corrected distance visual acuity (CDVA) was worse in the ICL group.[18] We have summarized the literature reporting efficacy data of hole-ICL implantation between October 2018 and October 2022 in Table 1. The weighted average efficacy index was 1.03 and the mean postoperative UDVA was −0.01, which were comparable to previously reported data.[46]

Refractive Predictability

Both ICL implantation and laser refractive surgery provided good and comparable predictability outcomes.[16,47,48] In one matched comparative study, Siedlecki et al demonstrated that ICL implantation yielded a significantly higher proportion of eyes with ±0.50 D of plano than SMILE (90% vs 73%, P = 0.045) within a mean postoperative follow-up of 27 months, although there was no difference in astigmatic accuracy.[18] The predictability of the astigmatism correction was also comparable between toric ICL, femto-LASIK, and SMILE, as demonstrated in 1-year results reported by Ganesh et al.[17] Regarding the preoperative degree of myopia, ICL implantation yielded excellent refractive predictability for the correction of both low and moderate-to-high myopia.[36,37,49,50] Compared with non-toric ICLs, toric ICLs had comparable predictability results with respect to postoperative SE.[42]

However, compared with patients with high astigmatism (≥2 D and ≤4 D), patients with low astigmatism (≥0.75 D and <2 D) showed slightly lower SE and percentage of eyes having cylinder rotation within 5°.[44] The literature published between October 2018 and October 2022 reporting predictability of refractive correction expressed as percentages within 0.5 D and 1.0 D of target is summarized in Table 2. The pooled data of over 3000 eyes are also shown in the table. A previous review in 2018 reported 90.8% and 98.7% of eyes achieving SE within 0.50 D and 1.00 D, respectively, within a mean follow-up time of 12.5 months.[46] Meanwhile, the current review found lower weighted averaged percentage of 84.2% and 95.4%, respectively, within a mean follow-up time of 25.2 months.

Refractive Stability

ICL implantation has good refractive stability outcomes and is more stable than laser refractive surgery.[14,16,18] The long-term stability of ICL and toric ICL has been demonstrated in several studies with data of >5 years of follow-up.[41,50–52] Papa-Vettorazzi et al reported the postoperative outcomes within a mean follow-up time of 11.35 ± 1.30 years; SE at 1 month and at the final follow-up was −0.49 ± 0.75 D and −1.24 ± 1.51 D, respectively, indicating a total myopic progression of −0.75 ± 1.20 D (p = 0.01).[52] There were comparable mean SE changes between patients with low myopia (≤6 D) and those with high myopia (>6 D) within a 1-year period.[37,38] However, eyes with superhigh myopia (>12 D) might have poorer refractive stability after ICL implantation, with data indicating continuous myopia progression and

Table 1 Literature Reporting on Efficacy and Safety of Hole-ICL Implantation Between October 2018 and October 2022

Authors	Year	Eyes (N)	Follow-Up (Months)	Efficacy Index	Mean UDVA (LogMAR)	Safety Index
Igarashi et al[81]	2022	73	26	0.87	−0.07 ± 0.10	1.08
Alonso-Juárez et al[49]	2022	82	12	1.07	N/A	1.09
Papa-Vettorazzi et al[52]	2022	45	120	0.79	N/A	1.12
Zhao et al[19]	2022	32	6	1.29	N/A	1.34
Chen et al[53]	2022	116	12	1.08	0.00 ± 0.30	1.24
Kamiya et al[36]	2022	172	12	0.91	−0.10 ± 0.17	1.06
Packer[32]	2022	629	6	1.06	−0.059 ± 0.10	1.24
Chen et al[72]	2022	78	60	0.90	0.20 ± 0.26	1.25
Pinto et al[37]	2021	106	12	1.05	0.02 ± 0.17	1.13
		232	12	1.17	0.04 ± 0.20	1.26
Zhao et al[45]	2022	63	12	1.17	−0.08 ± 0.07	1.26
		55	12	1.2	−0.07 ± 0.07	1.29
Cano-Ortiz et al[44]	2021	126	6	1.06	0.01 ± 0.08	1.11
Kamiya et al[51]	2021	177	96	0.89	−0.07 ± 0.17	1.18
Fernández-Vega-Cueto et al[41]	2021	84	84	0.80	0.17 ± 0.23	1.05
Chen et al[50]	2021	43	60	0.83	0.08 ± 0.15	1.03
		40	60	0.86	0.22 ± 0.15	1.32
Wei et al[42]	2021	42	6	1.14	N/A	1.20
		46	6	1.17	N/A	1.20
Aruma et al[48]	2021	32	12	1.11	−0.10 ± 0.07	1.26
Ye et al[95]	2021	104	42	0.91	0.18 ± 0.25	1.26
Martínez-Plaza et al[91]	2021	36	6	1.15	−0.10 ± 0.09	1.20
Jiang et al[14]	2021	48	12	1.28	N/A	1.33
Yang et al[96]	2021	42	51	1.03	0.01 ± 0.09	1.22
Yang et al[73]	2021	48	52	1.04	0.02 ± 0.09	1.23
Zhao et al[97]	2021	65	52	1.03	0.01 ± 0.07	1.21
Yu et al[84]	2020	38	3	1.15	−0.04 ± 0.08	1.37
Wei et al[56]	2020	94	6	1.17	N/A	1.21
Chen et al[75]	2020	26	12	1.04	N/A	1.19
Kato et al[58]	2020	16	12	0.90	−0.10 ± 0.10	1.07
Niu et al[47]	2020	39	12	1.06	−0.10 ± 0.05	1.11
Wan et al[98]	2020	27	6	0.98	N/A	1.02
		29	6	0.96	N/A	1.02
		54	6	1.01	N/A	1.04
		27	6	1.03	N/A	1.23
Tañ´ a-Rivero et al[99]	2020	33	12	1	−0.09 ± 0.47	1.09
Siedlecki et al[18]	2020	40	26	1.28	−0.09 ± 0.10	1.31
Chaitanya et al[100]	2020	109	6	1.1	−0.08 ± 0.13	1.12
Zhao et al[76]	2019	37	18	0.95	0.03 ± 0.05	1.11
Alfonso et al[40]	2019	147	60	0.87	0.13 ± 0.18	1.09
Miao et al[86]	2018	67	3	1.14	−0.01 ± 0.09	1.33
Total of eyes reported		3399				
Weighted average			24.7	1.03	−0.01	1.19

Abbreviations: LogMAR, Logarithm of the Minimum Angle of Resolution; N/A, not available; UDVA, uncorrected distance visual acuity.

axial elongation in these eyes.[50,53] In terms of astigmatism, Bohac et al found that astigmatism changes after 4 years of toric ICL implantation were comparable to changes in untreated spectacle-wearer controls.[54] The mean SE and mean change in SE in recent studies are shown in Table 2.

Table 2 Literature Reporting on Predictability and Stability Data of Hole-ICL Implantation Between October 2018 and October 2022

Authors	Year	Eyes (N)	Follow-Up (Months)	± 0.5 D (%)	± 1 D (%)	SE at Last Visit (LogMAR)	Mean Change (LogMAR)
Igarashi et al[81]	2022	73	26	78	93	−0.61 ± 0.71	−0.20 ± 0.43
Papa-Vettorazzi et al[52]	2022	45	120	42	64	−1.24 ± 1.51	−0.75 ± 1.20
Packer[69]*	2022	119	96	72	95.5	−0.63	N/A
Zhao et al[19]	2022	32	6	100	100	−0.04	N/A
Chen et al[53]	2022	116	12	N/A	N/A	−0.48 ± 0.77	−0.15 ± 0.37
Kamiya et al[36]	2022	172	12	91	100	−0.14 ± 0.28	−0.07 ± 0.26
Packer[32]	2022	629	6	N/A	N/A	−0.08 ± 0.34	N/A
Chen et al[72]	2022	78	60	N/A	N/A	−1.65 ± 1.30	−0.94 ± 0.70
Pinto et al[37]	2021	106	12	86.8	94.3	−0.16 ± 0.47	−0.07 ± 0.25
		232	12	85.8	97.4	−0.10 ± 0.44	−0.07 ± 0.35
Zhao et al[45]	2022	63	12	100	N/A	−0.07 ± 0.22	N/A
		55	12	96	N/A	−0.11 ± 0.24	N/A
Cano-Ortiz et al[44]	2021	126	6	98	100	N/A	N/A
Kamiya et al[51]	2021	177	96	83	93	−0.28 ± 0.36	−0.13 ± 0.30
Fernández-Vega-Cueto et al[41]	2021	84	84	53.57	80.95	−0.62 ± 0.62	N/A
Chen et al[50]	2021	43	60	60.47	79.07	−0.67 ± 0.57	−0.72 ± 0.54
		40	60	22.5	47.5	−1.74 ± 1.19	−1.05 ± 0.61
Reinstein et al[101]	2021	42	12	74	98	−0.19 ± 0.36	−0.12
Wei et al[42]	2021	42	6	93	100	N/A	N/A
		46	6	91	100	N/A	N/A
Aruma et al[48]	2021	32	12	87	100	−0.38 ± 0.20	N/A
Ye et al[95]	2021	104	42	61	91	−0.99 ± 0.77	N/A
Martínez-Plaza et al[91]	2021	36	6	86.11	100	+0.11 ± 0.40	N/A
Jiang et al[14]	2021	48	12	97.92	100	N/A	−0.12 ± 0.37
Yang et al[96]	2021	42	51	79	100	−0.20 ± 0.32	N/A
Yang et al[73]	2021	48	52	79	100	−0.20 ± 0.32	N/A
Zhao et al[97]	2021	65	52	86	100	−0.37 ± 0.31	N/A
Yu et al[84]	2020	38	3	N/A	97.4	N/A	0.08 ± 0.6
Wei et al[56]	2020	94	6	95	100	−0.09 ± 0.25	N/A
Chen et al[75]	2020	26	12	N/A	N/A	−0.36 ± 0.98	N/A
Kato et al[58]	2020	16	12	96	100	N/A	−0.13 ± 0.26
Niu et al[47]	2020	39	12	90	100	0.07 ± 0.23	N/A
Wan et al[98]	2020	27	6	96	100	N/A	−0.01 ± 0.24
		29	6	100	100	N/A	−0.03 ± 0.24
		54	6	100	100	N/A	−0.03 ± 0.33
		27	6	81	96	N/A	−0.00 ± 0.44
Tañ´ a-Rivero et al[99]	2020	33	12	87.8	93.9	−0.09 ± 0.47	N/A
Siedlecki et al[18]	2020	40	26	90	100	−0.17 ± 0.33	N/A
Chaitanya et al[100]	2020	109	6	96.3	100	N/A	N/A
Zhao et al[76]	2019	37	18	66.7	100	−0.48 ± 0.23	N/A
Alfonso et al[40]	2019	147	60	67.4	90.1	−0.44 ± 0.47	N/A
Sachdev et al[102]	2019	203	12	94.09	96.06	N/A	N/A
Kamiya et al[38]	2018	57	12	93	98	N/A	−0.12 ± 0.34
		294	12	94	99	N/A	−0.18 ± 0.43
Miao et al[86]	2018	67	3	72	95	N/A	N/A
Total of eyes reported			4032	3145	3065	2849	1714
Weighted average			25.2	84.2	95.4	−0.33	−0.20

Note: *Data at the 8th year are used.
Abbreviations: LogMAR, Logarithm of the Minimum Angle of Resolution; N/A, not available; SE, spherical equivalent; UDVA, uncorrected distance visual acuity.

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Safety

CDVA and safety Index

Previous studies have reported no significant difference in mean postoperative CDVA between ICL and laser refractive surgery.[13,17,55] However, three studies reported a higher percentage of eyes gaining one or more lines of CDVA in the ICL group.[16–18] The preservation of CDVA is measured as a safety index; importantly, it is similar to or higher after ICL implantation than that after laser refractive surgeries[16–19,47,48,56] In our review of literature on the safety index of hole-ICL implantation published between October 2018 and October 2022, the weighted average safety index was 1.19 (Table 1), which was slightly higher than the safety index of 1.15 in a previous review by Packer in 2018.[46]

Lens Sizing and Vault

Vault (ie the distance between the posterior ICL surface and the anterior crystalline lens surface) can be measured using various methods of anterior segment imaging such as ultrasound biomicroscopy, optical coherence tomography (OCT), and Pentacam. In clinical settings, vault can be estimated by comparing it with the central corneal thickness using slit-lamp biomicroscopy.[3] Unlike former ICL models without a central hole, the addition of a central port in EVO/EVO+ models does not affect the vaulting of the lens, regardless of the sizing methodology used.[32,57] In general, the optimum vault is 250–750 µm or 0.5–1.5 times the corneal thickness.[58–60] Vaults exceeding 750 µm have been associated with significant angle closure, pupillary block, and pigment dispersion, and these may subsequently lead to ocular hypertension and glaucoma. By contrast, vaults measuring less than 250 µm are a risk factor for anterior subcapsular cataract development due to ICL-crystalline lens contact or due to interferences with lens nutrition.[59] Kato et al investigated the 1-year clinical results after hole-ICL implantation in low vault cases (<250 µm). They found no postoperative complications including cataracts, increased IOP, and decreased corneal endothelial cells.[58] Likewise, another study in low vault cases (<100 µm) and a control group with more than 4 years of follow-up reported that only one eye (4.17%) in the study group developed anterior subcapsular cataract and no significant differences in lens density were observed between two groups.[61] These indicated that hole-ICL yielded satisfactory results for at least the first few years postoperatively.[58] Vaults tend to decrease over time, prominently within the first 6 months after ICL implantation. Further, a significant correlation was observed between a larger change in vault and a higher initial vault value.[59] In a 7-year study, vaults were initially reduced and then stabilized after 5 years.[41] ICL size is an important determinant of the appropriate vaulting. The most popular sizing method is the measurement of the white-to-white horizontal diameter and ACD.[57] Alternative techniques include measurement of the sulcus-to-sulcus diameter, angle-to-angle diameter, or iris pigment end-to-pigment end diameter.[57] Recently, a study investigating ICL vaults in different light conditions found that these values were dynamic and positively correlated with pupil diameter.[62] Finally, crystalline lens rise was found to be another independent factor contributing to differences in postoperative vaulting and could possibly be used preoperatively for ICL size calculation.[63] These parameters may be helpful in ICL vault prediction and improving its sizing formula.[62,63]

Intraocular Pressure

Possible mechanisms underlying increased IOP include retained viscoelastic or intraoperative anterior chamber overfill, steroid response, pupillary block, pre-existing juvenile open-angle glaucoma, and malignant glaucoma.[64–66] Early IOP spikes following ICL implantation are most often transient and are usually managed conservatively; however, they may also lead to Urrett-Zavalia syndrome.[32,64,67] In the US-FDA clinical trial of EVO/EVO+ model in 629 eyes, 19.9% of eyes experienced a transient increase in IOP due to retained ophthalmic viscosurgical device within 1–6 h post-procedure.[32] These eyes were treated with ocular hypotensive medication and release of aqueous fluid from a previously constructed incision as needed. No eye with pupillary block and elevated IOP due to angle narrowing or pigment dispersion was identified. Hu et al found that early increase in IOP after V4c model implantation was associated with a narrowed anterior chamber angle and higher pupil diameter.[68] They recommended the use of intracameral miotics immediately after the operation to reduce the incidence of early postoperative increase in IOP. Persistent IOP elevation after ICL implantation in hole-ICL models is rare. Regarding long-term outcomes, previous studies found no significant increase in IOP, pigmentary glaucoma, and pupillary block during 8–[51] and 10-year[52] follow-up. Moreover, only 2/3105 eyes developed glaucoma after ICL surgery in a 11-year retrospective study.[69] In a previous review, although there were no data indicating increased IOP, the author found that pupillary block occurred in only 0.04% of the eyes.[46] In a recent series of 2283 V4c-model ICL procedures, only three eyes underwent ICL exchange/explantation due to uncontrolled ocular hypertension, supporting that persistent IOP elevation after hole-ICL implantation is rare.[22]

Corneal Endothelial Cell Loss

The number of corneal endothelial cells decreases following ICL implantation. Preoperative endothelial cell count (ECC) is a necessary measure of decline in corneal ECD. The US-FDA approval statement for ICL indicates that the age-specific recommendations on minimum ECD should be used, although the criteria were developed using data of a non-central port ICL model.[33] A study comparing conventional ICL and hole-ICL demonstrated that both models did not induce a significant change in ECD and eye morphology at the 2-year follow-up.[70] In the EVO/EVO+ FDA trial, ECC loss was 2.3% at 6 months.[32] Studies evaluating hole-ICL models reported ECC loss ranging 0.1–2.8% within 1 year postoperatively,[32,36,38,39,71] while it ranged from 0.43% to 21.8% decline in the final visit for studies with a follow-up of at least 4 years.[40,50–52,69,72,73] The number of corneal endothelial cells tended to deteriorate more rapidly during the first year after ICL implantation.[74] In the US-FDA trial, ECC loss ranged from 8.4% to 9.7% in the first 3 years postoperatively and stabilized thereafter.[4] Moreover, the rate of ECC loss was found to depend on the preoperative ECD and its decline over the first 2 years could be predictable on a case-by-case basis.[74] However, several reports also indicated no significant change in ECC during the study period.[75–79] Two mechanisms for ECC loss after phakic IOL implantation have been proposed: direct surgical trauma to peripheral ECC at the time of operation and ongoing loss due to iris vaulting with direct proximity to the peripheral corneal endothelium.[80] In the EVO/EVO+ FDA trial, 0.6% of eyes had extensive ECC decline (>30%) as an adverse event at 6 months postoperatively, but no eyes had ECD of <1500 cells/mm.[32]

Lens Opacity

In a previous review, Packer showed that asymptomatic anterior subcapsular cataract opacities and cataract formation occurred after ICL with central hole implantation in 0.49% and 0% of 617 eyes, respectively, within a weighted average follow-up of 13 months.[46] To demonstrate the long-term results of hole-ICL models, we summarized studies with more than 5 years of follow-up and that reported the incidence of cataract. The incidence rates for anterior subcapsular cataract (ASC) and nuclear cataract were 0.53% and 0.08%, respectively (Table 3). Nuclear cataracts mainly develop from age-related processes and pre-existing cataract, rather than from ICL. Meanwhile, ASCs are usually caused by ICL.[52,81] However, despite the low incidence of new lens opacity formation, progression of pre-existing cataract is still observed after hole-ICL implantation. Furthermore, it is the most common cause of ICL explantation, reported in 5/770 eyes in one series.[79] In that study, subsequent cataract surgery was performed at the time of ICL extraction using the same incision, and all surgeries were uneventful with visual acuity improvement. One study analyzed 1653 eyes and compared cataract-free survival between non-US-FDA cohorts and US-FDA cohorts. The results showed that age >45 years and ACD <3 mm, conditions outside the US-FDA guidelines, were associated with cataract formation.[82] ICL implantation in eyes with relatively shallow

Table 3 Studies on the Incidence of Cataract with More Than 5 Years of Follow-Up

Authors	Year	Eyes (N)	Follow-Up (Years)	ASC (%)	NS (%)
Papa-Vettorazzi et al[52]	2022	45	10	0	6.7
Packer et al[69]	2022	3105	11	0.45	0
Chen et al[72]	2022	78	5	3.85	0
Kamiya et al[51]	2021	177	8	1.7	0
Fernández-Vega-Cueto et al[41]	2021	84	7	0	0
Chen et al[50]	2021	83	5	0	0
Alfonso et al[40]	2019	147	5	0	0
Shimizu et al[31]	2016	32	5	0	0
Total		3751		0.53	0.08

Abbreviations: ASC, anterior subcapsular cataract; NS, nuclear sclerosis cataract.

anterior chamber could result in low vault and is a risk factor for the development of anterior lens opacity.[57] Therefore, a minimum vault of 150 μm is recommended to protect the lens from contact with the ICL.[82,83] However, it should be noted that there is still a lack of long-term studies regarding cataract incidence among young adults in the same age range, which is valuable to compare the rate of cataract formation associated with ICL implantation.

Patient Outcomes

Quality of Vision (QoV)

Myopia patients could benefit from ICL implantation with respect to better visual quality due to reduced intraocular light scattering.[84,85] Studies have demonstrated that total HOAs are lower in ICL implantation than in laser refractive surgery.[14,18,56] This finding might be explained by the fact that corneal refractive surgeries interfere with the central corneal shape, whereas ICL implantation procedures still maintain the prolate shape of the cornea.[86] While starbursts are the main subjective visual complaints after SMILE, halos are the main complaints after ICL.[48] Several studies demonstrated that the central hole has no optical effect on vision and that both ICL with and without a central hole produced similar optical quality.[87,88] By contrast, some studies found a difference in visual quality among the two ICL models. The newer V4c model achieves similar visual quality and low-order aberrations for high myopia than the older V4 model, but the V4c model tends to have higher spherical aberrations and overall HOAs.[89] Moreover, a visual disturbance described as "ring-shaped dysphotopsia" was reported, especially during the initial months after EVO implantation, and this is possibly related to light refraction at the central hole structure.[90–92] ICL toricity is also a potential risk factor for halos, with a high number of patients, with toric ICL developing such aberration postoperatively (85.7% for ICL and 100% for toric ICL).[42] However, these disturbances in visual quality stabilize as early as 3–6 months postoperatively.[84,86,91]

Patient-Reported Outcomes

QoV and quality of life (QoL) are mainly assessed using standardized questionnaires. In a matched comparative study, patients who had ICL implantation were less bothered by visual disturbances than patients who underwent SMILE.[18] Ieong et al reported that the overall QoL, particularly with respect to sports, self-confidence, and complications related to daily sight, significantly improved after ICL procedures. In their study, driving in glare conditions was the only task to have worsened postoperatively.[93] Similarly, the results of a study using the EVO+ model showed improvement in QoV and QoL despite transient difficulty to perform activities under mesopic conditions with glare during the initial weeks postoperatively.[91] The common responses from patients included "being satisfied or very satisfied with the visual outcome and self-images"[42,50,78] and "preference to undergo surgery in hindsight and to recommend the procedure to other patients."[42,78]

Conclusion

ICL implantation is becoming increasingly popular among patients with a wide range of refractive errors owing to its proven visual and refractive outcomes. More than 2,000,000 ICLs have been dispensed worldwide over 75 countries to date, with the recent market expansion to the US after gaining FDA approval.[94] It not only provides patients with visual freedom by reducing dependence on glasses or contact lenses but also assures them of better performance of daily tasks and self-confidence. In this review, we provide recent updates on ICL with a central hole and summarize the previous literature on conventional models. With the increasing rate of ICL implantation, further reviews regarding subsequent intraocular surgery in eyes with ICL implants, particularly for cataract surgery, will provide additional data that will be helpful for both surgeons and patients.

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author, NK, upon reasonable request.

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